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DECREE
of 22 January 2026,

**amending Decree No 422/2016 on radiation
protection and security of radionuclide sources**

Pursuant to § 236 of Act No 263/2016 , the Atomic Act, as amended by Act No 83/2025 , in order to implement § 9(2)(c) and (j), § 17(3)(a) and (b), § 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) and § 164(2), the State Office for Nuclear Safety lays down the following:

Article I

Decree No 422/2016 on radiation protection and security of radionuclide sources is amended as follows:

1. In the introductory sentence, the words ‘and point (k)’ are inserted after ‘(i)’, ‘§ 84(6)’ is deleted, the number ‘4’ is replaced by the number ‘5’ and the words ‘, § 159a(5)’ are inserted after ‘9’.
2. § 2(q) reads as follows:

‘q) conversion factor for radionuclide intake means a coefficient indicating the committed effective dose per unit intake of a radionuclide; the conventional values of conversion factors for radionuclide intake are set out in Annex 3 to this Decree;’.

3. In § 2(v), the semicolon at the end is replaced by the word ‘and’.
4. In § 2(w) the word ‘; and’ is replaced by a full stop.
5. § 2(x) is deleted.
6. In § 5(1), the words ‘or registrant’ are inserted after the words ‘permit’.
7. In the introductory part of § 6(4), the word ‘paragraph’ is replaced by the word ‘paragraphs’.
8. In the introductory part of § 6(4), the words ‘to 8’ are inserted after the number ‘6’.
9. In § 6, paragraphs (5) and (6) read as follows:

‘(5) For the calculation pursuant to paragraph (4), the conversion factor for the unidentified form and properties of a radionuclide shall be that specified in Annex 3 to this Decree for all unspecified forms of a radionuclide.’.

(6) The derived limit corresponding to a committed effective dose of 20 mSv for exposure to mixtures of long-lived alpha-emitting radionuclides of the uranium–radium series is an intake by inhalation of 1 600 Bq per calendar year.’.

10. In § 6, the following paragraphs (7) and (8) are added:

‘(7) The derived limit corresponding to a committed effective dose of 20 mSv from exposure to radon progeny is an intake of latent energy of

(a) 8 mJ per calendar year in underground workplaces with forced ventilation;

(b) 4 mJ per calendar year in underground workplaces with natural ventilation.’.

‘(8) If an exposed worker is simultaneously subjected to external and internal exposure to radon progeny and to mixtures of long-lived alpha-emitting radionuclides of the uranium-radium series, the limit for exposed workers shall be considered not to have been exceeded if the following conditions are met:

$$E_{\text{ext}} + E_{\text{int,Rn}} + E_{\text{int,d.l.alfa}} \leq 0,02 \text{ Sv,}$$

where

E_{ext} (Sv) is the effective dose from external gamma radiation exposure;

$E_{\text{int,Rn}}$ (Sv) is the committed effective dose from internal exposure to radon progeny;

$E_{\text{int,d.l.alfa}}$ (Sv) is the committed effective dose from internal exposure by inhalation of a mixture of long-lived alpha-emitting radionuclides of the uranium-radium series.’.

11. In § 8, the reference reads as follows:

‘[Regarding § 24(7) and § 66(6)(c) of the Atomic Act]’.

12. In the introductory part of § 8(5), the word ‘Documentation’ is replaced by the word ‘Procedures’.

13. In § 10(1), the words ‘used by a person’ are replaced by the word ‘that’ and the words ‘are handled’ are added at the end.

14. § 15(a) reads as follows:

‘(a) a radiation generator intended for medical exposure, except for X-ray bone densitometers, intraoral dental X-ray equipment and panoramic dental X-ray equipment;’.

15. In § 15(b), the words ‘with energy above 1 MeV’ are added at the end.

16. In § 15(e), the word ‘objects’ is replaced by the words ‘tissue, blood and objects’.

17. In § 15(f), the word ‘or’ is deleted.

18. In § 15(g), the full stop at the end is replaced by the word ‘; or’.

19. The following § 15(h) is added:

‘(h) a radiation generator used in veterinary radiotherapy for treatment purposes.’.

20. In § 18(1), the words ‘radioactive sources are collected’ are replaced by the words ‘where more than one radionuclide source is present at the same time’.
21. In § 19(1)(a), the words ‘of a type not approved by the Office,’ are deleted.
22. In § 19(1)(c), the words ‘with veterinary or’ are replaced by the word ‘with’.
23. In § 19(1)(e), the word ‘and’ is deleted.
24. In § 19(1)(f), the full stop at the end is replaced by the word ‘; and’.
25. In § 19(1), the following subparagraph (g) is added:

‘(g) workplaces with X-ray equipment used in veterinary medicine, except for radiotherapy for treatment purposes.’.

26. In § 19(2), subparagraph (b) reads as follows:

‘(b) workplaces with X-ray equipment intended for medical exposure in radiodiagnostics or radiotherapy, with the exception of

1. bone densitometers; or
2. dental X-ray equipment;’.

27. In § 19(2)(f), the word ‘and’ is deleted.
28. In § 19(2)(g), the words ‘and tissue’ are inserted after the word ‘blood’.
29. In § 19(2)(g), the full stop at the end is replaced by the word ‘and’.
30. The following § 19(2)(h) is added:

‘(h) a workplace with X-ray equipment used in veterinary radiotherapy for treatment purposes.’.

31. In § 19(3)(a), the words ‘with energy above 1 MeV’ are added at the end.
32. In § 21(2)(d), the words ‘, including software and artificial intelligence tools’ are inserted after the word ‘accessories’.
33. In § 21(2)(d), the word ‘has’ is replaced by the word ‘have’.
34. In § 21(2)(l), the words ‘preventive medical’ are replaced by the words ‘occupational medical’.
35. § 26 reads as follows:

‘§ 26

Acceptance test

[Regarding § 68(2)(a) and (k) and § 69(2)(c) and (g) of the Atomic Act]

- (1) An acceptance test must be carried out after installation of a source of ionising radiation, prior to commencement of its use
 - (a) for a newly manufactured source of ionising radiation;
 - (b) after a significant change in most of the properties of the source of ionising radiation or its accessories,
 - (c) after relocation of a stationary source of ionising radiation;
 - (d) after relocation of a mobile source of ionising radiation to another address;
 - (e) after a change in the holder of the permit for its use and, at the same time, the address of the workplace in the case of a portable radiation generator used for medical exposure or in veterinary medicine; or
 - (f) after any other change that may significantly affect the functionality of the source of ionising radiation.
- (2) The acceptance test must be carried out when the source of ionising radiation and the site where it is located are fit for performing the test.
- (3) The acceptance test must include the tests specified in Annex 12 to this Decree.
- (4) Restricted operation in the event of unsatisfactory acceptance test results may only be imposed in the case of a source of ionising radiation used by a holder of a permit for medical exposure, if the unsatisfactory results relate to a specific restricted regime of use of the source of ionising radiation, provided that there is another restricted operating regime that is fully adequate and free of defects for the specific purpose of its use. In such a case:
 - (a) the person in charge of the acceptance test, in cooperation with the clinical medical physics expert at the site where the source is used, may declare the acceptance test successful for this specific restricted regime and, at the same time, lay down an operating restriction corresponding to the established facts;
 - (b) the person conducting the acceptance test, together with the clinical medical physics expert, shall record the operating restriction and the reasons for it in writing and shall immediately forward this record to the permit holder or registrant who will be using the source of ionising radiation; and
 - (c) the person conducting the acceptance test shall state the reasons for the operating restriction in the acceptance test report.
- (5) The operating restriction may be modified or removed after the cause of the unsatisfactory results has been eliminated and on the basis of the results of a subsequent successful partial acceptance test.
- (6) The person who carries out the acceptance test must adapt the scope of the test to the specific purpose of use and to the specific characteristics of the source of ionising radiation and its accessories that have an impact on radiation protection.
- (7) The permit holder who performed the acceptance test is obliged to submit the acceptance test report to the permit holder or registrant who uses the source of ionising radiation within one month of the date on which the test was performed.’.

36. In § 27(1)(f), the word ‘and’ is deleted.

37. In § 27(1)(g), the full stop at the end is replaced by the words ‘, except for minor defects with no impact on radiation protection, for which it was stated in the report of the long-term stability test in which the defect was first identified that its rectification can be confirmed by an operational stability test;’.

38. In § 27(1), the following subparagraphs (h) and (i) are added:

‘(h) if the reason for restricted operation pursuant to § 30(3) is eliminated and’.

‘(i) if there is a significant change in the manner of use of the source of ionising radiation that affects the parameters tested in the long-term stability test.’.

39. § 28(1) reads as follows:

‘(1) The content of the long-term stability test is laid down in Annex 12 to this Decree.’.

40. In § 29(1)(e), the words ‘protection, and’ are replaced by the word ‘protection,’.

41. § 29(1)(f) reads as follows:

‘f) § 27(1)(g), it has been verified whether

1. the defect found in the previous long-term stability test has been rectified;
and
2. no other defect has arisen as a result of the rectification of that defect;’.

42. In § 29(1), the following subparagraphs (g) and (h) are added:

‘(g) § 27(1)(h), it has been verified that the reason for restricted operation pursuant to § 30 has been eliminated; and

(h) § 27(1)(i), it has been verified that the equipment also meets the requirements of the long-term stability test within the scope of the newly introduced manner of use.’.

43. § 30 reads as follows:

‘§ 30

**Evaluation of the long-term stability test and the
elimination of defects**

[Regarding § 68(2)(g) and § 69(2)(g) of the Atomic Act]

- (1) The rules for the categorisation of very serious and minor defects detected during the long-term stability test are set out in Annex 12 to this Decree.
- (2) The long-term stability test report must be submitted by the permit holder who performed the test to the permit holder or registrant who uses the source of ionising radiation within one month of the date on which the test was performed.

- (3) Restricted operation in the event of unsatisfactory results in the long-term stability test may only be imposed in the case of a source of ionising radiation used by a permit holder for medical exposure, if the unsatisfactory results relate only to the specific restricted regime of use of the source of ionising radiation, provided that another restricted operating regime exists that is fully adequate and free of defects for the specific purpose of its use. In this case, the person conducting the long-term stability test, in cooperation with the clinical medical physics expert at the workplace where the source is used, may declare the long-term stability test successful for that specific restricted regime and, at the same time, lay down an operating restriction corresponding to the established facts.
- (4) The operating restriction and the reasons for it must be recorded in writing by the person directing the long-term stability test together with the clinical medical physics expert and this record must be transmitted without delay to the permit holder or registrant using the source of ionising radiation. The operating restriction and its reasons must also be stated in the long-term stability test report.
- (5) If the partial long-term stability test pursuant to § 29(1)(g) proves that the reason for the restricted operation has been eliminated, the operating restriction shall be lifted.
- (6) If a very serious defect is detected during the long-term stability test, the permit holder conducting the test must immediately notify in writing the permit holder or registrant who uses the source of ionising radiation and their clinical medical physics expert, if the availability of that expert is required by other legislation, and must include this information in the long-term stability test report.
- (7) As regards the time limit for eliminating a minor defect and the operating restrictions resulting from this defect, the permit holder conducting the long-term stability test must,
 - (a) immediately upon becoming aware of the defect, notify the permit holder or registrant who uses the source of ionising radiation and their clinical medical physics expert, if the availability of that expert is required under other legislation; and
 - (b) indicate them in the long-term stability test report.
- (8) When setting the time limit for the elimination of a minor defect pursuant to paragraph (7), which must not exceed 3 months and shall run from the date of the long-term stability test in which the defect was first detected, account must be taken of the nature of the minor defect detected and of the manner of normal use of the source of ionising radiation and its accessories that has an impact on radiation protection.’.

44. The following § 30a is inserted after § 30:

‘§ 30a

**Scope and method of performing the activities of persons
directing and carrying out the evaluation of the properties
of a source of ionising radiation**

[Regarding § 69(2)(f) of the Atomic Act]

- (1) The person directing the evaluation of the properties of a source of ionising radiation
 - (a) provides methodological guidance to persons evaluating the properties of a source of ionising radiation, or persons assisting them, and ensures their initial and ongoing professional training in this field;
 - (b) ensures the maintenance of good practice in the evaluation of the properties of a source of ionising radiation, particularly with regard to the current state of scientific knowledge and technological development;
 - (c) establishes and updates the methodologies, model protocols and concept for ensuring the measurement of quantities and keeps them in accordance with the requirements of good practice, the actual conduct of the activity and the requirements of the Atomic Act;
 - (d) is responsible for the metrological assurance of the activity carried out and for the availability and suitability of measuring instruments;
 - (e) in the event of the occurrence or suspected occurrence of defects in a source of ionising radiation not used in radiodiagnostics, interventional radiology or non-medical exposure, classifies them into a category, sets the time limits for their elimination, and, where applicable, imposes operating restrictions resulting from a minor defect;
 - (f) in the event of the occurrence or suspected occurrence of very serious defects or atypical minor defects in a source of ionising radiation used in radiodiagnostics, interventional radiology or non-medical exposure, classifies them into a category, sets the time limits for their elimination, and, where applicable, imposes operating restrictions resulting from a minor defect;
 - (g) determines on the test procedure in the case of an atypical source of ionising radiation or its accessories, or in the case of atypical findings during the test;
 - (h) in the case of an acceptance test, or in the case of a long-term stability test in which the unsuitability of the current scope or frequency of operational stability tests has been identified, draws up a proposal for their amendment or a new proposal;
 - (i) assesses whether the workplace and the source of ionising radiation are technically suitable for commencing the test;
 - (j) if necessary, personally participates in the test and evaluates the properties of the source of ionising radiation, including the evaluation of the results;
 - (k) in the case of the evaluation of the properties of a source of ionising radiation not used in radiodiagnostics, interventional radiology or non-medical exposure, evaluates the test results;
 - (l) in cooperation with the clinical medical physics expert at the workplace that uses the source of ionising radiation, lays down operating restrictions pursuant to § 26(4) and § 30(3).

- (2) The person performing the evaluation of the properties of a source of ionising radiation
- (a) evaluates the properties of the source of ionising radiation under standard conditions and records the measured values;
 - (b) in the case of the evaluation of the properties of a source of ionising radiation used in radiodiagnostics, interventional radiology or non-medical exposure, evaluates the test results;
 - (c) in the case of an acceptance test or a long-term stability test during which the unsuitability of the current scope or frequency of operational stability tests has been detected, provides to the person directing the evaluation of the properties of the source of ionising radiation the supporting materials for drawing up a proposal for the amendment or for a new proposal;
 - (d) in the event of the occurrence or suspected occurrence of common minor defects in a source of ionising radiation used in radiodiagnostics, interventional radiology or non-medical exposure, classifies them into a category, sets the time limits for their elimination and, where applicable, imposes operating restrictions resulting from the minor defect; in other cases, the person shall request guidance from the person directing the evaluation of the properties of the source of ionising radiation;
 - (e) in the case of an atypical source of ionising radiation or its accessories, or atypical findings during the test, shall request methodological guidance from the person directing the evaluation of the properties of the source of ionising radiation at the site of measurement.’.

45. In § 31(2)(b)(4), the word ‘and’ is deleted.

46. In § 31(2)(c)(4), the full stop at the end is replaced by the word ‘and’.

47. The following § 31(2) is added:

‘(d) in the case of a source of ionising radiation used in radiography or mammography, analysis of repeated images every 12 months.’.

48. In § 32, the reference reads as follows:

‘[Regarding § 68(2)(c) to (f) of the Atomic Act]’.

49. In § 32(1)(a), point 2 reads as follows:

‘2. a health professional who uses a source of ionising radiation in clinical practice, or, if required by operating conditions, a medical physics expert or radiological technician, in the case of an operational stability test of a computed tomography scanner, including a computed tomography scanner used in nuclear medicine and radiotherapy;’.

50. In the introductory part of § 32(2), the words ‘obliged to ensure the verification of the properties of a source of ionising radiation by means of’ are replaced by the word ‘directing’,

and the words ‘, the continuous evaluation of the results of this test and, in the case of unsatisfactory results, the implementation of corrective action’ are deleted.

51. § 32(3) is deleted.

Paragraphs (4) and (5) become paragraphs (3) and (4).

52. After § 32(2), the following new paragraph (3) is inserted:

‘(3) A person directing operational stability tests

- (a) is responsible for the operation of the operational stability test system, the training of personnel carrying out operational stability tests and identification of the equipment needed to conduct them;
- (b) is responsible for the system for transmitting information on the results and corrective actions pursuant to paragraphs (4) and (5);
- (c) chooses a suitable method for their implementation and recording; and
- (d) stipulates the scope and frequency of operational stability tests for a permit holder.’.

Paragraphs (3) and (4) become paragraphs (4) and (5).

53. In § 32(4)(b), the word ‘and’ is replaced by a semicolon.

54. § 32(4)(c) reads as follows:

‘(c) be available to the person directing the operational stability tests and’.

55. The following § 32(4)(d) is added:

‘(d) immediately forwarded to the person in charge of operational stability tests, if the results are unsatisfactory.’

56. In § 32(5), the word ‘immediately’ is inserted after the word ‘measures’.

57. In the introductory part of § 33(3), the words ‘or voluntarily assist a natural person undergoing medical exposure in a controlled area’ are deleted.

58. In § 33(3)(c), the words ‘or another unique identifier;’ are added at the end.

59. In § 33(5), the words ‘Personal doses’ are replaced by the words ‘Data on personal doses’.

60. In § 33(7), the words ‘according to its requirements’ are inserted after the word ‘format’ and the words ‘, through the holder of a permit to perform personal dosimetry’ are added at the end.

61. In § 35(4), the word ‘Model’ is replaced by ‘Content particulars’.

62. In § 38(2)(k), the words ‘the Atomic Act’ are replaced by the words ‘this Decree’.

63. § 38(3) reads as follows:

‘(3) The protocol from the acceptance test and the record of the operating restriction pursuant to § 26(4) must be kept by the permit holder or the registrant using the source of ionising radiation for as long as the source of ionising radiation is used.’.

64. In § 38(4), the words ‘must be kept’ are replaced by the words ‘the permit holder or registrant using the source of ionising radiation must keep’, the words ‘long-term stability shall be kept on file’ are replaced by the words ‘long-term stability shall be kept on file by the permit holder or the registrant using the source of ionising radiation’ and the words ‘. The record of the operating restriction pursuant to § 30(3) must be kept by the permit holder or registrant using the source of ionising radiation for the entire duration of this restriction’ are added at the end.
65. In § 39, the reference reads as follows:

‘[Regarding § 25(1)(h) and (2)(d) of the Atomic Act]’.

66. In § 39(3), the words ‘and the registrant’ are replaced by the words ‘, the holder of a permit to add a radioactive substance to a consumer product during its manufacture or preparation, or to import and export such a consumer product and the registrant’.
67. In § 43(3)(l), the words ‘the test’ are replaced by the words ‘directing the test’.
68. In § 43, the following paragraphs (4) and (5) are added:

- ‘(4) The number of workplaces under continuous supervision by a supervisor is considered excessive for the purpose of effectively ensuring radiation protection if, in total, these workplaces contain more than 75 generators and devices with sealed radionuclide sources, or if they are workplaces of more than 25 permit holders. This restriction shall not apply to the provision of continuous supervision by a supervisor for permit holders pursuant to § 9(2)(f), point 6, and (i) of the Atomic Act.
- (5) A supervisor shall cooperate with the clinical medical physics expert if other legislation requires availability of the expert.’.

69. § 46(7) reads as follows:

- ‘(7) In a controlled area, only a category A exposed worker may perform work related to the radiation activity for which the controlled area has been designated. Another natural person may enter the controlled area only in justified cases and carry out the necessary or incidental activity there for the time strictly necessary and under the supervision of a category A exposed worker designated by the operator of the controlled area, or, in the case of a category B exposed worker, activity consisting in providing assistance to a natural person undergoing medical exposure.’.

70. In § 46(8), the words ‘for the purposes of carrying out administrative and supervision activities’ are added at the end.
71. In § 47(e), the words ‘, except for persons undergoing medical exposure or non-medical exposure’ are inserted after the words ‘may be entered’ and the word ‘the controlled area’ are inserted after the word ‘leaving’.
72. In § 47(h), the words ‘area, the controlled-area operator shall’ are replaced by the words ‘area, except for persons undergoing medical exposure or non-medical exposure, the controlled-area operator shall’.
73. In § 48, the reference reads as follows:

‘(Regarding § 24(7) and § 73(3) of the Atomic Act)’.

74. In the introductory part of § 48(1), the words ‘licensed activity that is’ are deleted and the comma is replaced by the words ‘when carrying out a licensed activity’.
75. In § 48(2)(a), the words ‘and conditions’ are inserted after the word ‘instructions’ and the words ‘and the conditions for entry into the controlled area’ are deleted.
76. § 49(3)(b) reads as follows:

‘(b) for a natural person who is not an exposed worker, who enters a supervised area, is not undergoing medical or non-medical exposure in the area and whose presence in the supervised area could result in exceeding the dose optimisation limit for members of the public, the operator of the supervised area must set operational levels in the monitoring programme to ensure that this limit is not exceeded;’.

77. In § 49(3)(c), the words ‘radiation; and’ are replaced by the word ‘radiation;’.
78. In § 49(3)(d), the full stop at the end is replaced by the word ‘; and’.
79. The following § 49(3)(e) is added:

‘(e) the regime in the supervised area of a workplace with an open radionuclide source must be organised so as to limit the spread of radioactive substances, in accordance with the optimisation procedures pursuant to § 66 of the Atomic Act.’.

80. § 50(5) reads as follows:

‘(5) The permit holder must verify the exposed worker’s knowledge and competence to perform radiation activities safely prior to the commencement of work and, in addition, on a regular basis, at least once per calendar year, by means of a test, for which a record must be made. If the exposed worker fails the test, the permit holder must establish corrective actions to remedy this undesirable situation.’.

81. § 50(7) reads as follows:

‘(7) Verification pursuant to paragraph (5) is not required for an exposed worker who performs the function of a supervisor for the relevant permit holder.’.

82. In § 52(a), point 4, the words ‘reliability; and’ are replaced by the word ‘reliability;’.
83. In § 52(a), point 5, the semicolon at the end is replaced by the word ‘and’.
84. In § 52(a), the following point 6 is added:

‘6. a description of the monitoring of servicing interventions on the source of ionising radiation and its accessories that have an impact on radiation protection;’.

85. In § 52(c), point 2, the words ‘assignment; and’ are replaced by the word ‘assignment;’.
86. In § 52(g), point 3, the words ‘assignment; and’ are replaced by the word ‘assignment;’.
87. In § 52(h), point 3, the full stop at the end is replaced by the word ‘and’.
88. The following § 52(i) is added:

- ‘(i) installation, repair and servicing of a source of ionising radiation
1. a description of how the user of the source of ionising radiation will be familiarised with the documentation for the licensed activity;
 2. a description of how the permit holder or the registrant using the source of ionising radiation will be informed of any servicing interventions carried out on the source that have an impact on radiation protection;
 3. a description of how the personnel performing the activities will be trained in the manufacturer’s servicing procedures for the source of ionising radiation;
 4. a description of the assessment of the readiness of the source of ionising radiation and the workplace where it is located for further operation after completion of the installation, repair or servicing of a source of ionising radiation intended for radiotherapy treatment;
 5. work procedures for monitoring the workplace or measuring secondary radiation in the case of the installation of a source of ionising radiation intended for radiotherapy treatment;
 6. a list of equipment used for measurement purposes during the installation of a source of ionising radiation intended for radiotherapy treatment;
 7. a description of how the provision of occupational health services to exposed workers is ensured; and
 8. principles for the use of personal protective equipment and devices, their characteristics and a description of the system for their allocation.’.

89. § 53 reads as follows:

‘§ 53

Other documentation
[Regarding § 24(7) of the Atomic Act]

- (1) The specification of the source of ionising radiation to be handled, its type and accessories, and the activities to be performed with it, must include information on whether the source of ionising radiation will be used for medical or non-medical exposure, or in veterinary medicine.
- (2) The content of other selected documentation is laid down in Annex 19 to this Decree.’.

90. § 54(1)(i) reads as follows:

- ‘(i) statistics on radiological incidents and potential radiological incidents;’.

91. In § 54(1)(j), the words ‘overview of revisions of local’ are replaced by the words ‘typical values of quantities used to assess optimisation by means of’.

92. In § 56(7), the number ‘2’ is replaced by ‘2.2’.

93. In § 63(c), the words ‘for the use of sources of ionising radiation’ are added at the end.
94. In § 63(e), the words ‘operational stability tests of sources of ionising radiation and participation in them’ are replaced by the words ‘transmission of information to persons who perform them’.
95. In § 63(f), the words ‘for the safe handling of a source’ are replaced by the words ‘to ensure radiation protection by the registrant when using a source’.
96. In § 63(g), the words ‘thereto; and’ are replaced by the word ‘thereto;’.
97. In § 63(h), the full stop at the end is replaced by the word ‘; and’.
98. The following § 63(i) is added:

‘(I) directing operational stability tests of a source of ionising radiation.’

99. In the heading of § 65, the words ‘for the use of a source of ionising radiation’ are added at the end.
100. In the introductory part of § 65(1), the words ‘for the use of a source of ionising radiation’ are inserted after the word ‘activity’.
101. After § 65(1), the following new paragraph (2) is inserted:

- ‘(2) Documentation for the registered activity for the use of a source of ionising radiation also includes
- (a) in the case of the use of portable intraoral X-ray equipment for medical exposure, justification of the clinical need for its use and a description of the monitoring of exposed workers; and
 - (b) in the case of the use of a bone densitometer for non-medical exposure, justification of the intended purpose of use.’

The existing paragraph (2) becomes paragraph (3).

102. In § 66(2)(i), the word ‘and’ is deleted.
103. In § 66(2)(j), the full stop at the end is replaced by the word ‘and’.
104. The following § 66(2)(k) is added:

‘(k) a list of specified measuring instruments for the verification of which the permit holder is responsible and their classification under the items on the list of types of specified measuring instruments in accordance with the Decree laying down measuring instruments subject to mandatory verification and measuring instruments subject to type-approval.’

105. The following § 66(4) is added:

‘(4) The monitoring programme for a Category IV workplace that includes a nuclear reactor must contain an overview of intervention levels, exceedance of which indicates an operational occurrence, including the classification of the operational occurrence in the appropriate category.’

106. § 67(1) reads as follows:

‘(1) Where the intake activities of radionuclides are converted to committed effective dose, conversion factors must be used. In the case of unidentified radionuclides and chemical forms or properties of the inhaled aerosol, the conversion factor specified in Annex 3 to this Decree for all unspecified forms of a radionuclide shall be used for exposed workers, and for members of the public, the highest conversion factor specified in Annex 3 to this Decree for inhalation intake by an individual of the given age category.’.

107. In § 67(5), the word ‘average’ is replaced by the words ‘exposure of a member of the public’, the word ‘activities’ is replaced by the word ‘activity’ and the words ‘dispersed in the atmosphere’ are replaced by the words ‘in the air’.

108. § 68(2) is deleted.

Paragraphs (3) to (6) become paragraphs (2) to (5).

109. After § 68(1), the following new paragraph (2) is inserted:

‘(2) The recording levels must be set at the level of the smallest detectable value of the measured quantity.’.

Paragraphs (2) to (5) become paragraphs (3) to (6).

110. In the introductory part of § 68(3), the words ‘so as to serve to detect possible deviations from the normal state, usually’ are inserted after the word ‘stipulated’.

111. § 70(2) reads as follows:

‘(2) Personal monitoring of external exposure and, where provided for by law, of internal exposure of a category A exposed worker must be ensured using a personal dosimeter, the evaluation period for which is one calendar month.’.

112. In § 70(5), the following words are inserted at the end of the first sentence: ‘otherwise, the permit holder or registrant for the relevant dosimeter must have an approved and validated method of deriving doses for another type of radiation’.

113. § 70(6) reads as follows:

‘(6) An exposed worker who performs an activity that is carried out and controlled by means of a source of ionising radiation, and who is physically present near that source of ionising radiation in circumstances where their exposure could, under normal working procedures, exceed 10 mSv effective dose per year, and who is equipped with a protective shielding apron in accordance with the monitoring programme, must be assigned two personal dosimeters, one to be worn on the apron and the other underneath it. The supervisor must determine the attenuation coefficient of the protective shielding apron used and the effective dose received by the exposed worker, taking into account the exposure of unshielded parts of the body.’.

114. In § 72, the reference reads as follows:

[Re § 78(3)(a) and (f) of the Atomic Act]

115. In § 73(2)(a), the words ‘released during the stipulated period’ are inserted after the word ‘radionuclides’ and the words ‘, released during the stipulated period’ are deleted..

116. In § 74(3), the words ‘, unless otherwise provided by this Decree’ are added at the end.

117. In § 74, the following paragraphs (5) to (7) are added:

- ‘(5) If liquid radioactive substances are released from the workplace into surface waters, monitoring of the area surrounding the workplace must include both surface waters unaffected by the discharge and surface waters affected, or potentially affected, by the discharge. Surface water sampling points shall be determined
 - (a) in waters unaffected by the discharge, in the watercourse upstream of the discharge point; in the case of discharge into a water reservoir, in the watercourse upstream of the impounded water level of the reservoir;
 - (b) in waters affected, or potentially affected, by the discharge
 - 1. in locations where sufficient mixing of the discharge in the watercourse can be expected; in the case of discharge into a reservoir, usually downstream of the outlet from the reservoir;
 - 2. in the case of a discharge from a workplace with a nuclear power installation, also within the water source protection zone at each point of abstraction of water for drinking water treatment, if such a point is situated within 30 river kilometres downstream of the discharge, or at the nearest downstream point of abstraction of water for drinking water treatment.’.
- (6) Monitoring of surface waters into which radioactive substances are released must include all released radionuclides that contribute significantly to the exposure of the population, namely
 - (a) in the case of a discharge from a workplace with a nuclear power installation
 - 1. in waters unaffected by discharges in the watercourse upstream of the discharge point, at least tritium and radionuclides emitting gamma radiation with quarterly frequency;
 - 2. in waters affected, or potentially affected, by discharges, at least tritium and gamma-emitting radionuclides with monthly frequency, in the case of ⁹⁰Sr with annual frequency;
 - (b) in the case of a discharge from a workplace with a nuclear power installation;
 - (c) in the case of a discharge from another workplace, at least once a year at the time of discharge or at most 24 hours after the end of the discharge.
- (7) The investigation level in waters affected, or potentially affected, by discharges must be determined according to the radionuclides being discharged
 - (a) in the case of discharge from a workplace with a nuclear power installation, at the point of abstraction of water for drinking water treatment

1. for tritium at 100 Bq/l; if this is exceeded, it must be assessed whether discharge procedures have been breached and whether the investigation level for ^{137}Cs has been exceeded;
 2. for ^{137}Cs at 0.5 Bq/l; if this is exceeded, the operator abstracting water for the treatment of drinking water must be informed of the results of the determination of the activity concentration of artificial radionuclides;
- (b) in the case of a discharge from a workplace associated with the extraction of radioactive minerals, 0.3 mg/l for U_{nat} and 0.4 Bq/l for ^{226}Ra ; if the investigation level is exceeded, the causes must be investigated and, where appropriate, preventive action must be established;
- (c) in the case of a discharge from another workplace, one tenth of the release level pursuant to § 104(1)(b); if the investigation level is exceeded, the cause must be investigated and, where appropriate, preventive measures must be established. The intervention level in waters affected, or potentially affected, by discharges from a workplace with a nuclear power installation must be set at 1 000 Bq/l for tritium; if that level is exceeded, it must be assessed whether discharge procedures have been breached and, where appropriate, corrective or preventive action must be established in order not to exceed the annual average tritium activity concentration of 1 000 Bq/l and a maximum permissible tritium activity concentration of 3 500 Bq/l.’

118. § 75(1)(c)(2) reads as follows:

‘2. ‘localisation device for displaying the irradiated area;’.

119. § 75(4) reads as follows:

- ‘(4) Workplaces with a source of ionising radiation intended for medical exposure must be equipped with aids for conducting operational stability tests as follows:
- (a) radiotherapy facilities with closed radionuclide sources or particle accelerators, nuclear medicine facilities and registrants’ facilities with aids for conducting all operational stability tests;
 - (b) other facilities with aids for conducting operational stability tests at least once a month.’.

120. § 76 and § 77 read as follows:

‘§ 76

[Regarding § 86(3)(a) of the Atomic Act]

A source of ionising radiation used in medical exposure

- (a) intended for the purposes of planning, management and verification in radiotherapy installed after 1 January 2017 must be equipped with an apparatus or

equivalent means to provide quantitative information on patient exposure; where technically feasible, this information must be automatically transferred to the patient's examination record;

- (b) a source of ionising radiation used in interventional radiology must
 - 1. indicate the kerma–area product and the cumulative reference kerma at the patient entrance reference point, if it is radiographic-fluoroscopic or fluoroscopic; this information must be automatically transferred to the patient examination record;
 - 2. provide structured radiation dose reports that are automatically transferred to the patient's examination record; and
- (c) a source of ionising radiation that is a computed tomography scanner, including a computed tomography scanner used for imaging in radiotherapy and nuclear medicine, must
 - 1. be equipped with automatic current modulation if it is a stationary source of ionising radiation;
 - 2. have examination protocols that are adapted to the examination of children, where it is used to image children;
 - 3. provide information on the kerma–length product ; this information must be automatically transferred to the patient's examination record;
 - 4. provide information on the volumetric kerma index for computed tomography; this information must be automatically transferred to the patient's examination record; and

§ 77

[Regarding § 86(3)(a) of the Atomic Act]

- (1) A source of ionising radiation used in medical exposure
 - (a) that is radiographic
 - 1. must not allow imaging from the shield;
 - 2. that is stationary with a digital image receptor, with the exception of equipment intended exclusively for imaging limbs, must be equipped with automatic exposure control;
 - (b) that is fluoroscopic
 - 1. must not permit direct fluoroscopic imaging;
 - 2. must be equipped with automatic regulation of the dose rate;
 - 3. must automatically adjust the size of the X-ray beam according to the selected magnification;
 - 4. must be equipped with an audible signal after 5 minutes of cumulative fluoroscopic time;
 - 5. must be equipped with a function that holds the last image on the monitor after the end of exposure;

6. installed after 1 February 2026, must provide structured radiation dose reports; and
- (c) that is mammographic
1. must be equipped with automatic exposure control;
 2. must not be equipped with an image film receptor or indirect digitalisation;
 3. must provide information on the compression force and the post-compression thickness;
 4. that is equipped with multiple filters, must be equipped with an automatic filter replacement function depending on the post-compression thickness;
 5. must allow for the creation of an image with dimensions of at least 23 cm x 29 cm, unless it is intended solely for stereotaxy;
 6. installed after 1 February 2026, must block exposure in clinical operation in the absence of collimation;
 7. installed after 1 February 2026, must block exposure in clinical operation where collimation is incorrect in relation to the size of the compression paddle used;
 8. must provide quantitative information about the patient's exposure, which must be automatically transferred to the patient's examination record;
 9. must provide images from which the signal-to-noise ratio and the contrast-to-noise ratio can be determined from linearised data; and
 10. must block exposure in clinical operation if the image is not being stored;
- (d) that is intraoral dental
1. must have a nominal voltage of at least 60 kV;
 2. must have a distance from the focal spot to the end of the cone of at least 20 cm;
 3. must not be equipped with radiographic films of speed class D or lower; and
 4. installed after 1 January 2017, must provide quantitative information on patient exposure, or must have values specified in the documentation for the source of ionising radiation from which this information can be calculated for all exposure settings;
- (e) dental panoramic
2. installed after 1 January 2017, must provide quantitative information on patient exposure, or must have values specified in the documentation for the source of ionising radiation from which this information can be calculated for all exposure settings.

- (2) A source of ionising radiation used in medical exposure that is a dental computed tomography scanner or bone densitometer installed after 1 January 2017 must provide quantitative information on the patient's exposure.'
128. In § 78(3), the words 'and, in the event of such contamination, decontaminated or disposed of as radioactive waste' are deleted.
129. In § 78(6), the words 'before performing medical exposure' are inserted after the word 'report'.
130. In § 78(6), the words 'breastfeeding prior to the execution of medical exposure' are replaced by the word 'breastfeeding'.
131. § 79 reads as follows:

‘§ 79

**Contents of the notification of the submission of an
application for authorisation of a clinical trial of
radiopharmaceuticals
[Regarding § 85(5) of the Atomic Act]**

The notification of the submission of an application for authorisation of a clinical trial of radiopharmaceuticals contains information relating to that trial that is important from the point of view of radiation protection, in particular

- (a) a summary of the clinical trial protocol;
 - (b) the specification of the radiopharmaceutical;
 - (c) information for the patient, including instructions on protecting other person;
 - (d) the patient's informed consent form;
 - (e) information for persons living in the same household as the clinical trial participant; and
 - (f) a list of facilities at which the clinical trial will be conducted.'
132. § 80(1) reads as follows:

- ‘(1) Patient exposure that is considered to be erroneous for the purposes of defining a radiological incident is
- (a) exposure arising from
 - 1. unintended medical exposure events involving human error or instrument failure; or
 - 2. other events during medical exposure, the consequences of which cannot be disregarded from the point of view of radiation protection;
 - (b) in radiotherapy
 - 1. exposure of the wrong patient;
 - 2. therapeutic exposure of a tissue or organ other than that planned;

3. application of a total dose or fractional dose that differs significantly from the indicated dose;
 4. application of an incorrectly prescribed dose;
 5. irradiation that causes the radiobiological effect of the treatment to differ from that originally planned, due to an interruption or premature termination of the planned treatment that is not caused by the patient's state of health; or
 6. unintentional exposure of the embryo or foetus during a procedure performed on a pregnant woman;
- (c) in nuclear medicine
1. administration of a radiopharmaceutical other than planned;
 2. application of activity significantly different from the prescribed activity;
 3. exposure of the wrong patient;
 4. administration of an activity or radiopharmaceutical that was incorrectly prescribed;
 5. unintentional exposure of the embryo or foetus during a procedure performed on a pregnant woman; or
 6. unintentional exposure of the child during a procedure performed on a breastfeeding woman;
- (d) in radiodiagnostics
1. exposure that is multiple times greater than necessary;
 2. exposure of the wrong patient;
 3. irradiation of an organ or tissue other than that planned; or
 4. unintentional exposure of the embryo or foetus during a procedure performed on a pregnant woman to a direct beam; and
- (e) in interventional radiology
1. exposure that is multiple times greater than necessary;
 2. exposure of the wrong patient;
 3. irradiation of an organ or tissue other than that planned;
 4. unintentional exposure of the embryo or foetus during a procedure performed on a pregnant woman to a direct beam; or
 5. a case where a tissue reaction occurs due to incorrect performance of the procedure.'.

133. § 81 reads as follows:

‘§ 81

Radiological incidents
[Regarding § 87(5) of the Atomic Act]

- (1) A Category A radiological incident is a serious radiological incident.
- (2) Annex 23 to this Decree lays down
 - (a) the criteria for classifying a radiological incident as category A, B or C;
 - (b) the procedure to be followed in the event of a radiological incident or a potential radiological incident;
 - (c) the content and retention period of the records of the investigation of a radiological incident or of a potential radiological incident; and
 - (d) the scope and time limits for the provision of information on a serious radiological incident and potential radiological incident.’.

134. In the heading of § 83 and in the introductory part of § 83, the word ‘medical’ is deleted.

135. In the heading of § 83 and in the introductory part of § 83, the word ‘equipment’ is replaced by the word ‘device’.

136. In § 83(e), the word ‘performed’ is replaced by the words ‘performed; and’.

137. § 83(f) is deleted.

Subparagraph (g) becomes subparagraph (f).

138. In the heading of § 87, the reference reads as follows:

‘[Regarding § 93(5)(a) of the Atomic Act]’.

139. In § 87(p), the words ‘release level’ are replaced by the words ‘one of the release levels set out in § 105’.

140. In § 87(q), the words ‘underground’ are added at the end.

141. § 88 reads as follows:

‘§ 88

**Determination of personal doses of workers in workplaces
with potentially increased exposure from a natural
radiation source**

[Regarding § 93(5)(b) of the Atomic Act]

- (1) Measurement method for determining personal doses
 - (a) of a worker handling material containing elevated concentrations of natural radionuclides at workplaces with material containing elevated concentrations of natural radionuclides must include
 1. measurement of ambient dose equivalent rate;
 2. measurement of the average activity concentration of radionuclides in air;
 3. measurement of surface contamination at the workplace; and
 4. a record of occupancy time; or

- (b) a worker who is an aircraft crew member on board an aircraft flying at an altitude above 8 km must include the determination of
 - 1. the extent of the worker's participation in individual flights,
 - 2. the flight characteristics; and
 - 3. parameters important for the calculation of the effective dose, assessed repeatedly for each calendar year.
 - (2) At workplaces with materials containing elevated concentrations of natural radionuclides, measurements must be taken to assess whether the following levels have been exceeded:
 - (a) 300 Bq/m³ for the average activity concentration of radon in air during work; or
 - (b) 1 mSv per year for the effective dose, which does not include doses from exposure to natural background radiation and from radon and its progeny.
 - '(3) At facilities with material containing elevated concentrations of natural radionuclides where the level pursuant to paragraph (2) has not been found to have been exceeded, employees' personal doses do not need to be determined unless there is a change in working conditions, production processes or raw materials.
 - '(4) At workplaces with material containing elevated concentrations of natural radionuclides, where it has been established that the level pursuant to paragraph (2) has been exceeded, optimisation of radiation protection must be carried out and, after optimisation, measurements must be made in order to determine the personal dose of the worker during their presence in the workplace.
 - '(5) If, following the optimisation of radiation protection, a worker's exposure at the workplace may exceed an effective dose of 6 mSv per year, the worker's personal dose at the workplace must be determined repeatedly in each calendar year.
 - '(6) The determination of a worker's personal doses does not need to be repeated in each calendar year at a workplace with material containing elevated concentrations of natural radionuclides, provided that there has been no a change in working conditions, production processes or raw materials and provided that the measurements pursuant to paragraph (4) have not identified the possibility of exceeding
 - (a) 6 mSv per year for the effective dose; or
 - (b) one third of the limits for a calendar year set out in § 4(1)(a) to (d).
 - (7) In the case of work at multiple workplaces with material containing elevated concentrations of natural radionuclides, the worker's effective doses must be aggregated.
 - (8) The dose conversion factors for determining the effective dose are set out in Annex 30 to this Decree.'
142. In the heading of § 89, the reference reads as follows:

‘[Regarding § 93(5)(b) and (c) of the Atomic Act]’.

143. In § 89(2), the number ‘4’ is replaced by ‘5’.
144. In § 89(2), the words ‘, through the permit holder pursuant to § 9(2)(h), point 2 of the Atomic Act’ are added at the end.
145. In the heading of § 90, the reference reads as follows:

‘[Regarding § 66(6)(c) and § 93(5)(d) of the Atomic Act]’.

146. In § 90(1), the following words are added at the end: ‘As part of optimisation, an optimisation analysis containing alternative solutions must be prepared and the most appropriate alternative must be selected and implemented to reduce exposure from a natural radiation source.’.
147. After § 91(2), the following new paragraph (3) is inserted:

‘(3) If the measurement results do not exceed the release levels set out in § 105 in five consecutive years, or if there is a change that could affect the radionuclide content in the radioactive substance, the measurement and evaluation referred to in paragraph (1) must continue to be carried out at least every five years.’.

Paragraphs (3) to (5) become paragraphs (4) to (6).

148. In § 91(5), the word ‘their’ is inserted after the word ‘from’ and the words ‘directly or through a permit holder pursuant to § 9(2)(h), point 7 of the Atomic Act’ are deleted.
149. § 93(1) reads as follows:

‘(1) At workplaces with potentially increased exposure from radon, measurements must be carried out to assess whether the reference level of 300 Bq/m³ for the average radon activity concentration during the worker’s presence at the workplace is exceeded.’.

150. § 93(2) reads as follows:

‘(2) At workplaces with potentially increased exposure from radon, where it has been established that the reference level pursuant to paragraph (1) has been exceeded, radiation protection optimisation and, after optimisation, measurement must be carried out in order to determine the worker’s effective dose.’.

151. In the introductory part of § 93(3), the words ‘during repeated measurement’ are replaced by the words ‘by measurement after optimisation’.
152. In § 93(4), the words ‘upon repeated measurement’ are replaced by the words ‘by measurement after optimisation’ and the word ‘repeatedly’ is inserted after the word ‘performed’.
153. The following § 93(5) is added:

‘(5) The dose conversion factors for determining a worker’s effective dose are set out in Annex 30 to this Decree.’.

154. In § 94(2), the words ‘, through the permit holder pursuant to § 9(2)(h), point 2 of the Atomic Act’ are added at the end.

155. § 95(1) reads as follows:

‘(1) Optimisation of radiation protection at workplaces with potentially increased exposure from radon must be carried out when the reference level pursuant to § 93(1) has been exceeded. As part of the optimisation of radiation protection, an optimisation analysis containing alternative solutions must be prepared and the most suitable option for reducing the activity concentration of radon must be selected and applied, which must meet the following requirements:

- ‘(a) its implementation can ensure a reduction in the activity concentration of radon;
- ‘(b) it can be implemented at the workplace; and
- ‘(c) it cannot impair the structural and technical condition of the workplace.’.

156. § 95(2) reads as follows:

‘(2) The measures for implementing the optimisation of radiation protection pursuant to paragraph (1) are, in particular,

- (a) structural and technical measures;
- (b) increased air exchange; and
- (c) a change in the organisation or arrangement of work.’.

157. In the heading above § 98, the word ‘natural’ is deleted.

158. In § 98(1), the words ‘and tritium’ are inserted after the word ‘radon’.

159. In § 98(2), § 98(3), in the introductory part of § 98(4), § 98(5), § 98(6), in the introductory part of § 99(6), in the introductory part of § 100(1) and in the introductory part of § 100(2), the word ‘natural’ is deleted.

160. In § 98, the following new paragraph (5) is inserted after paragraph (4):

‘(5) Systematic measurement and evaluation of the content of artificial radionuclides in water must be carried out when water from a surface or groundwater source affected by a discharge from a workplace with an energy nuclear power installation has been used for the production of drinking water.’.

Paragraphs (5) to (7) become paragraphs (6) to (8).

161. In § 98(7), the words ‘, investigation levels of ¹³⁷Cs activity concentration’ are inserted after the word ‘alpha activity concentration’.

162. In § 98(8), the number ‘6’ is replaced by the number ‘7’.

163. In § 98(8), the words ‘in the case of natural radionuclides’ are inserted after the word ‘be’.

164. In § 99(1), the number ‘6’ is replaced by the number ‘7’.

165. In the introductory part of § 99(5), the words ‘Compliance with the values pursuant to § 98(1) and (2)’ are replaced by the words ‘Systematic measurement’.

166. In the introductory part of § 99(5), the number '6' is replaced by the words 'evaluation of radionuclide content in drinking water'.
167. In the introductory part of § 99(5), the word 'assessed' is replaced by 'performed'.
168. The following § 99(7) is added:

'(7) If it is established that the indicator of tritium activity concentration in water exceeds 100 Bq/l, the activity concentration of gamma-emitting radionuclides must be measured.'

169. In the heading of § 100, the word 'natural' is deleted.
170. In § 100(1)(c), the words 'and the operational records identification number' are added at the end.
171. § 100(4)(b) reads as follows:

'(b) for each change in recorded data.'

172. § 100(5) is deleted.

Paragraph (6) becomes paragraph (5).

173. In § 101(b), the word 'natural' is deleted and word 'or' is deleted.
174. In § 101(c), the full stop at the end is replaced by the word '; or'.
175. The following § 101(d) is added:

'(d) mixing water from several sources.'

176. In the final part of § 102(3), the text '²²⁸Th' is replaced by '²³²Th'.
177. In § 102(6), the text '²²⁸Th' is replaced by '²³²Th'.
178. In the introductory part of § 103(3), the text '(a) to (f)' is inserted after '(1)'.
179. § 103(3)(b) reads as follows:

'(b) for each change in recorded data.'

180. § 103(4) is deleted.

Paragraph (5) becomes paragraph (4).

181. In § 104(1)(c), the following words are added at the end: '; in the case of continuous discharge, the average daily activity concentration and, in the case of one-off discharge, the average activity concentration relative to the total discharged volume, are assessed'.
182. In the introductory part of § 105(3) and in the introductory part of § 105(5), the words 'waters and mining' are inserted after the word 'waste'.
183. in § 105(6), the word 'or' is replaced by the word 'and';
184. § 107(3) reads as follows:

'(3) A justified urgent protective action means:

- (a) sheltering, if the averted effective dose exceeds 10 mSv within a period of not more than two days;
- (b) iodine prophylaxis, if
 1. there is a risk of internal contamination with radioactive iodine; and
 2. the averted committed equivalent dose to the thyroid from radioiodine exceeds 100 mSv;
- (c) evacuation, if the sum of the effective dose already received in the emergency exposure situation, taking into account the effects of protective actions already implemented, and the effective dose that could be averted by evacuation over 7 days exceeds 100 mSv;
- (d) a ban on the consumption and distribution of locally produced or unprotected food in areas affected by a radiological accident, for the period strictly necessary to determine the specific conditions for its consumption and distribution in the given accident situation; or
- (e) a ban on the distribution and placing on the market of products located in the areas affected by a radiological accident for the period strictly necessary to determine the specific conditions for their distribution and placing on the market in a given accident situation.’.

185. In § 107(4)(a), after the word ‘mSv’, the following words shall be inserted: ‘, provided that, if the areas affected by the radiological accident in which, based on an assessment of the radiological situation, individuals may continue to reside under specified conditions can be supplied with uncontaminated food, water and feed, that option shall be given priority’.

186. The following § 114a is inserted after § 114:

‘§ 114a

**Scope and method of ensuring, continuously developing,
maintaining and regularly evaluating the security culture
of a radionuclide source**

[Regarding § 159a of the Atomic Act]

As part of the security culture of the radionuclide source, the permit holder must ensure that

- (a) responsibility for compliance with established safety principles and practices has been assigned;
- (b) the documentation related to the security of the radionuclide source is clear and unambiguous for all responsible and affected persons;
- (c) a systematic approach is implemented for the training and qualification of responsible and affected persons from the perspective of security of the radionuclide source;
- (d) responsible and affected persons are informed about threats and the importance of securing the radionuclide source;

- (e) the effectiveness of the radionuclide source security system is regularly verified and evaluated;
- (f) the current results of the verification of the effectiveness of the radionuclide source security system are provided to the responsible and affected persons and, if the verification of the effectiveness of security does not fully meet the objectives, corrective actions are taken to remedy this situation;
- (g) the integrity of the security system is not compromised and pre-planned procedures are followed in the event of foreseeable events;
- (h) compensatory measures are applied during regular maintenance and inspection of the radionuclide source security system, where this could compromise its effectiveness;
- (i) a self-assessment process is in place to confirm that the level of the radionuclide source security culture is appropriate;
- (j) communication and involvement of responsible and affected persons, as well as other persons, in the risk assessment process and in identifying shortcomings in the radionuclide source security, including the submission of proposals for its improvement, are supported;
- (k) the security culture is supported and encouraged, with a focus on teamwork, openness and trust between responsible and affected persons.’.

187. In § 116, paragraphs (2) and (3) are deleted.

Paragraphs (4) and (5) become paragraphs (2) and (3).

188. In Annex 2, in row 3, column 2 of the table, the word ‘-2.2’ is replaced by ‘-2.2’.

189. In the table in Annex 2, row 4 reads as follows: ‘

greater than 100	$\frac{300}{\sqrt{L}}$
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’.

190. Annex 3 reads as follows:

‘Annex 3 to Decree No 422/2016 .

Conversion factors

Conversion factors for calculating the effective dose rate for a member of the public due to immersion in a cloud of artificial radioactive noble gases

Nuklid	T _{1/2}	Konverzní faktor (nSv·h ⁻¹ ·Bq ⁻¹ ·m ³)					
		novorozenec	1 rok	5 let	10 let	15 let	dospělý
Ne-19	17,22 s	1,94E-01	1,84E-01	1,77E-01	1,67E-01	1,60E-01	1,56E-01
Ne-24	3,38 min	1,04E-01	9,88E-02	9,52E-02	8,99E-02	8,64E-02	8,38E-02
Ar-37	35,04 d	0,00E+00	0,00E+00	0,00E+00	0,00E+00	0,00E+00	0,00E+00
Ar-39	269 r	3,43E-04	3,55E-04	3,53E-04	3,54E-04	3,57E-04	3,56E-04
Ar-41	109,61 min	2,61E-01	2,47E-01	2,41E-01	2,31E-01	2,30E-01	2,19E-01
Ar-42	32,9 r	3,78E-04	3,88E-04	3,87E-04	3,89E-04	3,92E-04	3,93E-04
Ar-43	5,37 min	3,29E-01	3,10E-01	3,00E-01	2,87E-01	2,81E-01	2,70E-01
Ar-44	11,87 min	3,94E-01	3,74E-01	3,66E-01	3,52E-01	3,50E-01	3,35E-01
Kr-74	11,50 min	1,93E-01	1,84E-01	1,78E-01	1,67E-01	1,61E-01	1,56E-01
Kr-75	4,29 min	2,56E-01	2,41E-01	2,29E-01	2,17E-01	2,05E-01	1,99E-01
Kr-76	14,8 h	7,48E-02	7,15E-02	6,98E-02	6,55E-02	6,33E-02	6,03E-02
Kr-77	74,4 min	1,90E-01	1,81E-01	1,75E-01	1,64E-01	1,58E-01	1,53E-01
Kr-79	35,04 h	4,55E-02	4,35E-02	4,23E-02	3,99E-02	3,86E-02	3,71E-02
Kr-81	2,29E+5 r	1,85E-04	1,82E-04	1,56E-04	1,45E-04	1,40E-04	1,34E-04
Kr-81m	13,10 s	2,22E-02	2,11E-02	2,06E-02	1,93E-02	1,87E-02	1,75E-02
Kr-83m	1,83 h	1,54E-05	9,96E-06	8,18E-06	7,14E-06	6,73E-06	6,69E-06
Kr-85	10,756 r	8,40E-04	8,24E-04	8,11E-04	7,94E-04	7,83E-04	7,78E-04
Kr-85m	4,480 h	2,70E-02	2,57E-02	2,49E-02	2,35E-02	2,26E-02	2,13E-02
Kr-87	76,3 min	1,76E-01	1,65E-01	1,59E-01	1,52E-01	1,47E-01	1,42E-01
Kr-88	2,84 h	4,01E-01	3,82E-01	3,76E-01	3,61E-01	3,59E-01	3,45E-01
Kr-89	3,15 min	4,08E-01	3,86E-01	3,76E-01	3,60E-01	3,53E-01	3,40E-01
Xe-120	40 min	6,91E-02	6,55E-02	6,32E-02	5,95E-02	5,80E-02	5,56E-02
Xe-121	40,1 min	2,89E-01	2,75E-01	2,68E-01	2,55E-01	2,50E-01	2,41E-01
Xe-122	20,1 h	9,48E-03	8,76E-03	8,49E-03	7,84E-03	7,50E-03	7,09E-03
Xe-123	2,08 h	1,18E-01	1,12E-01	1,09E-01	1,03E-01	1,01E-01	9,68E-02
Xe-125	16,9 h	4,46E-02	4,22E-02	4,10E-02	3,84E-02	3,71E-02	3,50E-02
Xe-127	36,4 d	4,59E-02	4,35E-02	4,24E-02	3,96E-02	3,82E-02	3,60E-02
Xe-127m	69,2 s	2,61E-02	2,46E-02	2,35E-02	2,20E-02	2,09E-02	1,97E-02
Xe-129m	8,88 d	4,91E-03	4,07E-03	3,86E-03	3,36E-03	3,12E-03	2,84E-03
Xe-131m	11,84 d	1,90E-03	1,56E-03	1,47E-03	1,28E-03	1,19E-03	1,07E-03
Xe-133	5,243 d	5,90E-03	5,53E-03	5,11E-03	4,60E-03	4,38E-03	4,03E-03
Xe-133m	2,19 d	5,61E-03	5,12E-03	4,98E-03	4,56E-03	4,37E-03	4,08E-03
Xe-135	9,14 h	4,44E-02	4,24E-02	4,16E-02	3,90E-02	3,78E-02	3,57E-02
Xe-135m	15,29 min	7,73E-02	7,39E-02	7,17E-02	6,76E-02	6,52E-02	6,32E-02
Xe-137	3,818 min	6,36E-02	5,66E-02	4,98E-02	4,81E-02	4,09E-02	4,01E-02
Xe-138	14,08 min	2,29E-01	2,17E-01	2,12E-01	2,03E-01	2,01E-01	1,93E-01

Vysvětlivky:

T_{1/2}: Poločas radioaktivní přeměny

Conversion factors for calculating the 50-year committed effective dose for intake by ingestion, inhalation and direct entry into the blood for an exposed worker

Nuklid	$T_{1/2}$	Cesta příjmu	Forma	Typ	Sloučenina	f_a	AMAD (μm)	$e(50)$ ($\text{Sv}\cdot\text{Bq}^{-1}$)
H-3	12,32 r	přímý vstup do krve						2,00E-11
		požití			biogenní formy	0,99		5,10E-11
		požití			relativně nerozpustné formy	0,1		2,00E-12
		požití			rozpustné formy	0,99		1,90E-11
		vdechnutí	aerosol	F	tritium ve slitinách s lanthanem, niklem a hliníkem	0,99	1	8,60E-12
		vdechnutí	aerosol	F	tritium ve slitinách s lanthanem, niklem a hliníkem	0,99	5	1,30E-11
		vdechnutí	aerosol	M	všechny nespecifikované sloučeniny, úlomky skla, svítilic barvy, tritid titanu, tritid zirkonu	0,2	1	4,30E-11
		vdechnutí	aerosol	M	všechny nespecifikované sloučeniny, úlomky skla, svítilic barvy, tritid titanu, tritid zirkonu	0,2	5	2,40E-11
		vdechnutí	aerosol	S	tritiováný uhlík, tritid hafnia	1E-2	1	5,20E-10
		vdechnutí	aerosol	S	tritiováný uhlík, tritid hafnia	1E-2	5	2,60E-10
		vdechnutí	aerosol		biogenní organické sloučeniny	0,99	1	2,30E-11
		vdechnutí	aerosol		biogenní organické sloučeniny	0,99	5	3,50E-11
		vdechnutí	plyny a páry	V	tritiováný methan			5,90E-14
		vdechnutí	plyny a páry	V	tritiová voda (HTO)			2,00E-11
		vdechnutí	plyny a páry	V	elementární tritium (HT)			2,00E-15
vdechnutí	plyny a páry	F	nespecifikované plyny a páry	0,99		2,00E-11		
Be-7	53,22 d	přímý vstup do krve						2,10E-10
		požití			všechny sloučeniny	5E-3		2,10E-11
		vdechnutí	aerosol	F		5E-3	1	4,90E-11
		vdechnutí	aerosol	F		5E-3	5	5,70E-11
		vdechnutí	aerosol	M		1E-3	1	6,60E-11
		vdechnutí	aerosol	M		1E-3	5	4,30E-11
		vdechnutí	aerosol	S		5E-5	1	8,70E-11
		vdechnutí	aerosol	S		5E-5	5	5,30E-11
C-14	5,70E+3 r	přímý vstup do krve						1,60E-10
		požití			všechny chemické formy	0,99		1,60E-10
		vdechnutí	aerosol	F		0,99	1	7,30E-11
		vdechnutí	aerosol	F		0,99	5	1,10E-10

Conversion factors for calculating the committed effective dose for radionuclide intake by ingestion and inhalation by a member of the public

Nuklid	T _{1/2}	Cesta příjmu	Forma	Typ	Stoučenina	f _a věk 3 měsíce	h	f _a ≥ 1 rok	h 1 rok	h 5 let	h 10 let	h 15 let	h dospělý	Poznámka	
H-3	12,32 r	požití			tritiová voda a ostatní rozpustné formy (pro vdechnutí přiřazené typu F)	1	1,1E-10	1	7,2E-11	3,6E-11	2,7E-11	2,0E-11	1,9E-11		
					relativně nerozpustné formy (typy M a S)	0,2	2,2E-11	1E-01	7,2E-12	3,6E-12	2,7E-12	2,1E-12	2,0E-12		
					biogenní organické sloučeniny (OBT)	1	1,9E-10	1	1,5E-10	7,8E-11	5,8E-11	5,1E-11	5,1E-11		
		vdechnutí	plyny nebo páry			tritiová voda (HTO)		1,1E-10		7,2E-11	3,6E-11	2,7E-11	2,1E-11	2,0E-11	
						elementární tritium (HT)		1,1E-14		7,2E-15	3,6E-15	2,7E-15	2,1E-15	2,0E-15	
						tritiový methan (CH ₄ -T ₂)		3,3E-13		2,2E-13	1,1E-13	8,2E-14	6,2E-14	5,9E-14	
						nespecifikované plyny a páry (včetně nespecifikovaných organických par)		1,1E-10		7,2E-11	3,6E-11	2,7E-11	2,1E-11	2,0E-11	
						biogenní organické sloučeniny (OBT)		9,6E-11		8,0E-11	3,6E-11	2,7E-11	2,1E-11	2,2E-11	
						tritid ve slitnách s lanthanem, niklem a hliníkem (LaNi ₅ Al _{0,75})		5,5E-11		3,7E-11	1,6E-11	1,2E-11	8,3E-12	8,2E-12	
						úlomky skla, svítilny barvy, tritid titanu, tritid zirkonu, všechny nespecifikované sloučeniny		2,6E-10		2,2E-10	1,2E-10	7,1E-11	5,0E-11	4,6E-11	
vdechnutí	plyny nebo páry			tritiový uhlík, tritid hafnia		1,4E-09		1,4E-09	9,0E-10	6,1E-10	5,4E-10	5,6E-10			
C-14	5,70E+3 r	požití			všechny chemické formy	1	5,1E-10	1	4,7E-10	2,5E-10	1,8E-10	1,6E-10	1,6E-10		
					hydrogenuhlíčan		4,8E-11	1	4,8E-11	2,3E-11	1,5E-11	1,5E-11	1,3E-11		
		vdechnutí	plyny nebo páry			oxid uhelnatý (CO)		1,9E-11		1,2E-11	5,8E-12	3,5E-12	2,1E-12	1,8E-12	
						oxid uhličitý (CO ₂)		4,6E-11		4,6E-11	2,1E-11	1,4E-11	1,5E-11	1,3E-11	
						methan (CH ₄)		4,6E-13		3,1E-13	1,6E-13	9,8E-14	5,9E-14	5,1E-14	
						nespecifikované plyny a páry		5,4E-10		5,0E-10	2,6E-10	1,9E-10	1,7E-10	1,7E-10	
						uhlíčan barnatý (model CO ₂)		4,2E-11		3,8E-11	1,6E-11	1,0E-11	8,9E-12	8,0E-12	

191. In Annex 5, point 4, a comma is inserted after the word ‘persons’.
192. In Annex 5, in the introductory part of point 6, a full stop is inserted at the end of the first sentence.
193. In Annex 10, point 1.4, the full stop at the end is replaced by the words ‘or another test directly verifying the leak-tightness of the sealed source housing; or’.
194. In Annex 10, the following point 1.5 is added:
- ‘1.5 measuring the decrease in radionuclide activity in the case of equipment with a sealed radionuclide source containing radionuclide only in gaseous form.’
195. In Annex 10, point 2, the words ‘performed pursuant to § 26(2)(d), point 5 or § 28(1)(b), point 5’ are deleted.
196. In Annex 10, point 2, the words ‘by measuring the decrease in radionuclide activity in the case of equipment with a sealed radionuclide source containing radionuclide only in gaseous form; or’ are inserted after the word ‘performed’.
197. In Annex 10, point 2, the words ‘in the case of other equipment with a sealed radionuclide source’ are added at the end.
198. In Annex 10, in the introductory part of point 3, the word ‘exceeded’ is replaced by the words ‘were detected’ and the words ‘limit values for test media activity’ are replaced by the word ‘facts’.

199. In Annex 10, point 3.1, the words ‘, the test media activity exceeded’ are inserted after the words ‘liquid immersion test’.
200. In Annex 10, point 3.2, the words ‘, the test media activity exceeded’ are inserted after the word ‘source’.
201. In Annex 10, point 3.3, the words ‘, the test media activity exceeded’ are inserted after the word ‘surface’ and the word ‘or’ is deleted.
202. In Annex 10, point 3.4, the words ‘the test media activity exceeded’ are inserted after the word ‘test,’ and the full stop at the end is replaced by a semicolon.
203. In Annex 10, the following point 3.5 is added:

‘3.5. when measuring the decline in radionuclide activity, the deviation from the natural radioactive decay curve exceeded 20 %.’.

204. In the introductory part of Annex 11, in row 6, column 1 of the table, the words ‘emitting gamma radiation with lower activity’ are deleted.
205. In the introductory part of Annex 11, in row 6, column 2 of the table, the number ‘15’ is replaced by ‘10’.
206. In the introductory part of Annex 11, in row 6, column 3 of the table, the number ‘10’ is replaced by ‘5’.
207. In the introductory part of Annex 11, in row 6, column 4 of the table, the number ‘36’ is replaced by ‘24’.
208. In the introductory part of Annex 11, row 8 of the table is deleted.
209. Annex 12 reads as follows:

‘Annex 12 to Decree No 422/2016 .

Content of the acceptance test, the long-term stability test and the categorisation of defects identified during the long-term stability test

1. The acceptance test and the long-term stability test must include:
 - 1.1. a visual inspection of
 - 1.1.1. the integrity and intactness of the source of ionising radiation;
 - 1.1.2. the marking of the controls;
 - 1.1.3. the visibility of the light field, if the source of ionising radiation is equipped with one;
 - 1.2. functional tests of control, operating, safety, signalling, indication and adjustment elements;
 - 1.3. verification that the measured values correspond to typical values and, if they do not, verification that this is not due to a defect;
 - 1.4. in the case of a source of ionising radiation subject to type approval, tests within the scope specified in the product type-approval decision;
 - 1.5. in the case of a sealed radionuclide source:

- 1.5.1. verification of the information stated in the certificate of the sealed radionuclide source;
- 1.5.2. a leak-tightness test pursuant to Annex 10;
- 1.6. in the case of equipment with a sealed radionuclide source and in the case of a radiation generator:
 - 1.6.1. verification of the functionality of the source of ionising radiation;
 - 1.6.2. verification of the operating parameters and properties of the source of ionising radiation;
 - 1.6.3. determination of dosimetric quantities relevant to the purpose of use of the source of ionising radiation;
- 1.7. in the case of equipment with a sealed radionuclide source, a leak-tightness test of the sealed radionuclide source pursuant to Annex 10;
- 1.8. evaluation of whether the source of ionising radiation used for medical exposure meets the requirements of § 76 and § 77;
- 1.9. in the case of a source of ionising radiation used in radiotherapy for treatment purposes:
 - 1.9.1. verification of imaging systems that do not use ionising radiation or that use ionising radiation originating from the source of ionising radiation used for treatment;
 - 1.9.2. determination of the combined measurement uncertainty for quantities relevant to the purpose of use of the source of ionising radiation, namely:
 - 1.9.2.1. air-kerma strength in brachytherapy;
 - 1.9.2.2. absorbed doses under reference conditions, or dose rate for other radiotherapy modalities;
 - 1.9.3. selected tests of the planning system;
 - 1.9.4. selected tests of the recording and verification system;
- 1.10. for X-ray equipment used in radiodiagnosics, interventional radiology or radiotherapy for imaging purposes:
 - 1.10.1. verification of imaging systems;
 - 1.10.2. checking for artefacts in the image;
- 1.11. for mammography X-ray equipment:
 - 1.11.1. a spatial resolution test;
 - 1.11.2. digital tomosynthesis tests;
- 1.12. for radiographic x-ray equipment:
 - 1.12.1. a kerma reproducibility check, including exposure with a short exposure time;
 - 1.12.2. a spatial resolution test;
 - 1.12.3. short exposure time check;
- 1.13. for fluoroscopic X-ray equipment used for medical exposure in radiodiagnosics and interventional radiology:
 - 1.13.1. checking that the dimensions of the image receptor and the X-ray field correspond at the base of magnification;
 - 1.13.2. a spatial resolution test;

- 1.14. for intraoral dental X-ray equipment:
 - 1.14.1. where an image film receptor is used, checking the condition of the processing chemicals and films, the suitability of their combination and checking the documentation on their replacement;
 - 1.14.2. checking the condition of all imaging plates used for indirect digitisation;
 - 1.15. for X-ray equipment used in veterinary medicine, checking the condition of the protective shielding aids;
 - 1.16. for X-ray equipment used for medical exposure in radiodiagnostics, interventional radiology or radiotherapy for imaging purposes that provides quantitative information on patient exposure, verification of the accuracy of that information.
2. The acceptance test must also include
 - 2.1. verification of the data from the manufacturer relevant from the point of view of radiation protection to the possible use of the source of ionising radiation and its accessories, or, if this verification cannot be performed during the test, verification that it was performed by the person who installed the source of ionising radiation;
 - 2.2. for a radiotherapy X-ray irradiator, preparation of the irradiation table;
 - 2.3. for intraoral dental X-ray equipment, optimisation of the imaging process;
 - 2.4. an estimate of secondary radiation in the vicinity of intraoral dental or panoramic dental X-ray equipment and, in the event of an unsatisfactory measurement result;
 - 2.5. measurement of secondary radiation in the vicinity of X-ray equipment used in medical exposure for imaging purposes other than those specified in point 2.4;
 - 2.6. checking that an initial verification of the planning system and of the recording and verification system in radiotherapy has been carried out.
 3. The long-term stability test must also include
 - 3.1. verification of the stability of the operating parameters and properties of radiation generators and equipment with sealed radionuclide sources, and assessment of whether any instability constitutes a defect;
 - 3.2. verification of the stability of dosimetric quantities relevant to the purpose of use of the radiation generator and equipment with a closed radionuclide source, and assessment of whether any instability constitutes a defect;
 - 3.3. verification of data from the manufacturer relevant from the point of view of radiation protection to the method of use of the source of ionising radiation and its accessories, if this verification can be performed during the test;
 - 3.4. for radiotherapy X-ray equipment, verification of the irradiation table;
 - 3.5. an estimate of secondary radiation around intraoral dental or panoramic dental X-ray equipment, if there has been a change in its use that could have affected the values given in the last estimate of secondary radiation, or if no estimate or measurement of secondary radiation has been performed on the equipment since installation, or the results are no longer available;

- 3.6. measurement of secondary radiation in the vicinity of X-ray equipment used in medical exposure for imaging purposes other than those specified in point 3.5, if there has been a change in its use that could have affected the values specified in the last measurement of secondary radiation, or if no measurement of secondary radiation has been performed on the equipment since installation, or the results are no longer available, as well as in the case of an unsatisfactory result of the estimate of secondary radiation pursuant to point 3.5;
 - 3.7. in the case of a long-term stability test following the replacement of accessories to a source of ionising radiation that has an impact on radiation protection, verification of the accuracy of the data given in the technical documentation of those accessories that are relevant from the point of view of radiation protection to the normal use of the source of ionising radiation or its accessories;
 - 3.8. in the case of a long-term stability test at the registrant's premises, checking the operational stability tests and the availability of equipment required to perform them,
 - 3.9. in the case of intraoral dental X-ray equipment, verification of the optimisation of the imaging process and, if the result is unsatisfactory, carrying out that optimisation.
4. For a source of ionising radiation used for medical radiation exposure in radiotherapy, the following are classified as
 - 4.1. very serious defects:
 - 4.1.1. leakage of a sealed radionuclide source;
 - 4.1.2. a defect of a serious nature or a serious combination of defects that may endanger the health of a patient or worker, or that seriously breaches the principles of radiation protection; and
 - 4.2. minor defects:
 - 4.2.1. visible damage to a sealed radionuclide source that could lead to leakage in the near future and which is not a very serious defect;
 - 4.2.2. other defects detected during the long-term stability test.
 5. For a source of ionising radiation used for medical exposure in radiodiagnostics, interventional radiology or in radiotherapy for imaging purposes, the following are classified as
 - 5.1. very serious defects:
 - 5.1.1. a defect of a serious nature or a serious combination of defects that may endanger the health of a patient or worker, or that seriously breaches the principles of radiation protection; and
 - 5.1.2. the occurrence of significant artefacts completely precluding the diagnostic interpretation of the image;
 - 5.1.3. on radiographic and fluoroscopic X-ray equipment, the first half-value layer at 80 kV is less than 2.3 mm Al;
 - 5.1.4. on radiographic X-ray equipment:
 - 5.1.4.1. a voltage deviation from the nominal value greater than 20 %;

- 5.1.4.2. with a film image receptor, reproducibility of the automatic exposure control greater than 40 %; or
- 5.1.4.3. spatial resolution of less than 1.6 lp/mm;
- 5.1.5. on fluoroscopic X-ray equipment:
 - 5.1.5.1. a sum of deviations between the edges of the X-ray field and the image receptor on all sides greater than 10 % of the focus-to-image receptor distance;
 - 5.1.5.2. low-contrast detectability greater than 4 %; or
 - 5.1.5.3. a spatial resolution less than 0.8 lp/mm;
 - 5.1.5.4. direct fluoroscopy is enabled;
 - 5.1.5.5. the automatic dose rate control is not functional;
- 5.1.6. on computed tomography devices, a decrease in the computed tomography kerma index by 70 % or more relative to the baseline value under the same exposure parameters;
- 5.2. minor defects:
 - 5.2.1. non-compliance with a requirement under § 76 or § 77 that does not constitute a very serious defect;
 - 5.2.2. for mammography X-ray equipment, a signal-to-noise ratio from linearised data of less than 40;
 - 5.2.3. for radiographic X-ray equipment used for imaging children under 3 years of age:
 - 5.2.3.1. a coefficient of variation of the transmitted kerma for exposure times up to 10 ms greater than 5 %;
 - 5.2.3.2. a spatial resolution of less than 3 lp/mm;
 - 5.2.3.3. inability to produce a usable image at 50-70 kV with an exposure time of less than 10 ms;
 - 5.2.4. for fluoroscopic X-ray equipment used for medical exposure:
 - 5.2.4.1. for devices where the shape of the image receptor and the shape of the X-ray field differ, the absolute value of the difference between the size of the areas of the image receptor and the X-ray field at basic magnification is greater than 10 % of the active area of the image receptor;
 - 5.2.4.2. a discrepancy between the indicated and measured values of the dose quantity greater than 35 % of the measured value;
 - 5.2.4.3. used for imaging children under 3 years of age, a spatial resolution of less than 1.4 lp/mm;
 - 5.2.5. for intraoral dental X-ray equipment used for medical exposure:
 - 5.2.5.1. a discrepancy between the indicated and measured values of the dose quantity greater than 50 % of the measured value;
 - 5.2.5.2. with a film image receptor, the unsatisfactory condition of the processing chemicals or films, or an inappropriate combination of them;
 - 5.2.5.3. the inability to find an optimised setting of the exposure parameters;

- 5.2.6. for X-ray equipment used for medical exposure in radiodiagnostics, interventional radiology or radiotherapy for imaging purposes, the presence of artefacts that interfere with the diagnostic interpretation of the image;
 - 5.2.7. other defects detected during the long-term stability test.
6. Defects identified for sources of ionising radiation used in defectoscopy and core logging are
- 6.1. very serious defects, namely
 - 6.1.1. leakage of a sealed radionuclide source;
 - 6.1.2. a defect of a serious nature or a serious combination of defects that may endanger the health of the worker or another person, or that seriously breaches the principles of radiation protection;
 - 6.2. minor defects, namely other defects identified during the long-term stability test.
7. Defects identified for other source of ionizing radiation are
- 7.1. very serious defects, namely
 - 7.1.1. leakage of a sealed radionuclide source;
 - 7.1.2. a defect of a serious nature or a serious combination of minor defects that may endanger the health of the worker or another person, or that seriously breaches the principles of radiation protection;
 - 7.2. minor defects, namely
 - 7.2.1. visible damage to a sealed radionuclide source that could lead to leakage in the near future and which is not a very serious defect;
 - 7.2.2. damage to the protective aids for veterinary x-ray equipment that significantly impairs their protective function; or
 - 7.2.3. another defect identified during the long-term stability test.’.
210. In Annex 13, in the introductory part of point 1, the words ‘used for medical exposure’ are added at the end.
211. In Annex 13, point 2 reads as follows:
- ‘2. for dental panoramic X-ray equipment:
 - 2.1. a jaw phantom imaging test according to the instructions of the manufacturer of the equipment, or, if the manufacturer did not provide such instructions, according to the instructions of the person who carried out the long-term stability test or acceptance test
 - 2.1.1. once every 6 months;
 - 2.1.2. whenever there is a suspected malfunction of the source of ionising radiation or the imaging process;
 - 2.1.3. in the event of a change significant from the point of view of radiation protection;
 - 2.1.4. after downtime of more than 6 months; and
 - 2.1.5. in the event of non-compliance being identified within the scope of points 2.1.1 to 2.1.4 after corrective action has been taken;

- 2.2. visual verification of the cleanliness of the monitor used for clinical diagnosis;
 - 2.2.1. once per month; and
 - 2.2.2. if the monitor is found to be contaminated within the scope of point 2.2.1 after corrective action;
- 2.3. ongoing verification of the quality of standard cephalometric images;’.

212. In Annex 13, in the introductory part of point 3, the words ‘or 2’ are deleted.

213. In Annex 13, point 5.1.2, the word ‘and’ is replaced by a semicolon.

214. In Annex 13, new points 5.1.3 and 5.1.4 are inserted after point 5.1.2, which read as follows:

‘5.1.3. whenever damage to protective aids is suspected;

5.1.4. after downtime of more than one year; and’.

Point 5.1.3 becomes point 5.1.5.

215. In Annex 13, point 5.2.2, the word ‘and’ is replaced by a semicolon.

216. In Annex 13, new points 5.2.3 and 5.2.4 are inserted after point 5.2.2, which read as follows:

‘5.2.3. whenever miscollimation of the X-ray beam is suspected;

5.2.4. after downtime of more than 6 months; and’.

Point 5.2.3 becomes point 5.2.5.

217. In Annex 13, point 5.2.5, the words ‘and 5.2.2’ are replaced by ‘to 5.2.4’.

218. In Annex 13, points 5.3 and 5.4 are deleted.

219. In Annex 14, point 1, the words ‘, identification number’ are inserted after the word ‘name’.

220. In Annex 14, point 2, the word ‘surname’ is inserted after the word ‘name,’ and the words ‘surname at birth’ are inserted after the word ‘and’.

221. In Annex 14, point 5, the words ‘personal identification number, if assigned, or the number of the permit for’ are replaced by the words ‘permanent address’ and the words ‘for foreign nationals’ are replaced by the words ‘and the nationality of the radiation worker’.

222. In Annex 14, point 8, the words ‘and total time working with sources of ionising radiation’ are deleted.

223. In Annex 14, point 9, the word ‘and’ is replaced by the word ‘or’.

224. In Annex 14, point 10, the words ‘the date personal monitoring of the radiation worker commenced’ are replaced by the words ‘measured/monitored quantities’.

225. In Annex 14, points 11 to 15 are deleted.

Points 16 to 21 become points 11 to 16.

226. In Annex 14, point 13, the semicolon at the end is replaced by a full stop.

227. In Annex 14, points 14 to 16 are deleted.

228. Annex 15 reads as follows:

‘Annex 15 to Decree No 422/2016

Content requirements for a personal radiation card

Part A of the personal radiation card contains:

1. the registration number of the personal radiation card assigned by the Office;
2. name(s), surname and title;
3. gender;
4. date of birth;
5. the personal code of the exposed worker assigned by the Office;
6. nationality;
7. identity card number of a citizen of the Czech Republic, or the passport number of a foreign national;
8. an identity card photograph in accordance with the legislation governing the particulars of identity cards;
9. date of issue;
10. annual effective doses [mSv] in the previous four years, with the date of entry and the name and signature of the supervisor:
 - (a) personal dose equivalent at a depth of 10 mm – $H_{P(10)}$;
 - (b) committed effective dose – E_{50} ;
 - (c) effective dose – E ;
 - (d) equivalent dose – H_T (including specification of the organ or tissue for which the equivalent dose has been determined);
11. details of the permit holder responsible for the radiation protection of an external worker:
 - (a) name;
 - (b) address;
 - (c) the registration number assigned by the Office (only for holders of permits issued in the Czech Republic);
 - (d) permit number;
 - (e) the start and end of work with sources of ionising radiation for the indicated permit holder;
12. results of preventive medical check-ups:
 - (a) date;
 - (b) result of the check-up (fit/fit under stipulated conditions – a report specifying the conditions under which the work may be performed must be provided/unfit);
 - (c) name and signature of the authorised person.
13. records of completion of radiation protection training:
 - (a) the date of completion of the training;

- (b) name and signature of the authorised person.

Part B of a personal radiation card contains:

1. the registration number of the personal radiation card assigned by the Office;
 2. name(s), surname and title;
 3. the personal code of the exposed worker assigned by the Office provided in Part A;
 4. the registration number of the holder of a permit assigned by the Office provided in Part A
 5. date of assignment of this part to the worker;
 6. personal doses for each monitoring period in a specific year (if a worker works at more than one workplace during one monitoring period, their monitoring and, where appropriate, the summation of doses from multiple dosimeters in that period, must be ensured in accordance with the monitoring programme);
 7. signature of the supervisor;
 8. the results of the personal monitoring of an external worker at the premises of an operator of a controlled area, namely:
 - (a) the name of the operator of the controlled area;
 - (b) the registration number of the controlled area operator assigned by the Office;
 - (c) identification of the controlled area operator's workplace to which the monitoring results relate;
 - (d) start and end of work in the controlled area;
 - (e) signature of the supervisor;
 - (f) effective doses expressed in mSv for a specific period, no more than one month:
 - (i) Personal dose equivalent at a tissue depth of 10 mm – $H_{P(10)}$;
 - (ii) Committed effective dose – E_{50} ;
 - (iii) Effective dose – E ;
 - (iv) Equivalent dose – H_T (including specification of the organ or tissue for which the equivalent dose has been determined);
229. In Annex 16, point 1.7, the words 'of security of the radionuclide' are inserted after the word 'category' and the words 'ionising radiation (insignificant, minor, simple, significant, very significant)' are deleted.
230. In Annex 17, in the introductory part of point 3, the words 'handed over' are replaced by the words 'being handed over'.
231. In Annex 17, in the introductory part of point 4, the words 'handed over' are replaced by the words 'being handed over'.
232. In Annex 17, point 6.3, the full stop at the end is replaced by a semicolon.
233. In Annex 17, the following point 7 is added:

- '7. in the case of a manufactured radiation generator

- 7.1. type name;
- 7.2. type approval information (yes/no, type of document and number); and
- 7.3. serial number.’.

234. In Annex 17, the following paragraph is added at the end:

‘The holder of a permit to add a radioactive substance to a consumer product during its manufacture or preparation, or to import and export such a consumer product, must send the Office the following data on the consumer products manufactured, imported and exported:

1. type of consumer product;
2. type approval information (yes/no, type and number of document);
3. specification of the radionuclide;
4. the activity of the radionuclide and the date on which it was determined; and
5. the number of consumer products of that type.’.

235. In the introductory part of Annex 18, in row 2, column 1 of the table, the words ‘and monitored’ are inserted after the word ‘controlled’.

236. In the introductory part of Annex 18, in row 2, column 3 of the table, the number ‘4’ is replaced by ‘10’.

237. In the introductory part of Annex 18, in row 3, column 3 of the table, the number ‘0.4’ is replaced by ‘1’.

238. In the introductory part of Annex 18, in row 4, column 1 of the table, the words ‘and monitored’ are inserted after the word ‘controlled’.

239. In Annex 18, point 2, the words ‘and monitored’ are inserted after the word ‘controlled’.

240. In Annex 19, point 1 reads as follows:

‘1. The documentation for the evaluation of the properties of a source of ionising radiation must contain

1.1. in the case of methodologies,

1.1.1. the identification data of the holder of the permit for the assessment of the properties of the source of ionising radiation;

1.1.2. the name(s) and surname of the person who drawn up the methodology and the date when it was drawn up;

1.1.3. the type of test for which the document has been drawn up;

1.1.4. the type, modality or type of source of ionising radiation for which the methodology has been drawn up, or, where appropriate, a description of the manner in which it is normally used;

1.1.5. the method of assessment and the criteria to determine whether the workplace and the source of ionising radiation are technically fit to initiate the test;

1.1.6. instructions that in cases where a requirement of the manufacturer for a parameter is stated in the methodology and the model report, the manufacturer’s specific requirement must be stated in the test report;

- 1.1.7. a clear specification of technical terms, quantities, units or abbreviations used in the methodology or in the model protocol where their interpretation could be ambiguous;
- 1.1.8. the procedure for conducting the individual parts of the test, including
 - 1.1.8.1. the characteristics of the measured parameter;
 - 1.1.8.2. the type of measuring instruments and aids used;
 - 1.1.8.3. the measurement procedure and the method for obtaining the measurement results, in particular a description of the measurement, a diagram of the geometric arrangement of the measurement, the settings of the source of ionising radiation and of the measuring instrument, the quantities and units used, and a description of how they are interpreted;
 - 1.1.8.4. the calculations, algorithms and description of how they are interpreted;
 - 1.1.8.5. if the measured values are compared with baseline initial values, a description of how those baseline values were determined;
 - 1.1.8.6. a description of the determination of the combined measurement uncertainties in the case of radiotherapy for dosimetric quantities relevant to the purpose of use of the source of ionising radiation pursuant to Annex 12;
 - 1.1.8.7. the tolerances for the measured parameters and the recommended values;
 - 1.1.8.8. the method for the final evaluation of the test;
- 1.2. in the case of a model protocol, the following information completed with actual measurement data:
 - 1.2.1. identification details of the permit holder who conducted the test;
 - 1.2.2. the report number;
 - 1.2.3. information as to which type of test is involved;
 - 1.2.4. in the case of a partial long-term stability test, the reason why it was performed;
 - 1.2.5. identification details of the natural person who conducted the test and of the natural person who directed the test;
 - 1.2.6. in the case of radiotherapy, the identification details of the natural person who represented the operator of the source of ionising radiation during the test and information on their function;
 - 1.2.7. the date and time of the start and end of the test; the end of the test is considered to be the end of the measurements at the workplace; subsequent measurements are not counted in the original test;
 - 1.2.8. the date by which the next periodic long-term stability test must be performed on the source of ionising radiation;
 - 1.2.9. the type, modality and method of use of the tested source of ionising radiation;

- 1.2.10. identification details of the permit holder or registrant using the source of ionising radiation;
- 1.2.11. information on the location of the source of ionising radiation;
- 1.2.12. identification details of the tested source of ionising radiation, including
 - 1.2.12.1. the type name and serial number of the source of ionising radiation;
 - 1.2.12.2. the type name and serial number of the sealed radionuclide source;
 - 1.2.12.3. the type name and serial number of the radiation generator;
 - 1.2.12.4. the type name and serial number of the X-ray tube and its housing;
 - 1.2.12.5. the type name and serial number of the image receptor that is an integral part of the source of ionising radiation used in radiodiagnostics or interventional radiology;
 - 1.2.12.6. the year of manufacture and the year of installation of the source of ionising radiation;
 - 1.2.12.7. the specification of the focal spot and filtration for a source of ionising radiation used in radiodiagnostics or interventional radiology;
 - 1.2.12.8. the specification of other important components of the source of ionising radiation, including modalities and additional systems in radiotherapy;
 - 1.2.12.9. the specification of the radionuclide contained in the sealed radionuclide source, including its activity;
- 1.2.13. the protocol number, the date of measurement and the identification of the permit holder who performed the acceptance test;
- 1.2.14. the protocol number, the date of measurement and the identification of the permit holder who performed the previous long-term stability test;
- 1.2.15. information on whether the source of ionising radiation used in radiodiagnostics, interventional radiology and veterinary imaging uses an image receptor
 - 1.2.15.1. with direct digitisation;
 - 1.2.15.2. with indirect digitisation; or
 - 1.2.15.3. film-based;
- 1.2.16. an indication of whether the source of ionising radiation used in radiodiagnostics, interventional radiology or veterinary imaging is equipped with
 - 1.2.16.1. automatic exposure control;
 - 1.2.16.2. tomography or digital tomosynthesis;
 - 1.2.16.3. digital subtraction angiography;
 - 1.2.16.4. cephalostat;

- 1.2.17. information as to whether
 - 1.2.17.1. the mammography device permits stereotaxy;
 - 1.2.17.2. an X-ray device is used in radiotherapy, including information on the method of that use;
 - 1.2.17.3. the computer tomography device allows a fluoroscopic imaging mode;
- 1.2.18. information on whether the source of ionising radiation is
 - 1.2.18.1. stationary;
 - 1.2.18.2. mobile;
 - 1.2.18.3. portable,
- 1.2.19. identification data of the accessories of a source of ionising radiation that have an impact on radiation protection, in particular
 - 1.2.19.1. the examination tools used in radiodiagnostics or interventional radiology;
 - 1.2.19.2. the developer processor or the indirect digitisation reader used in radiodiagnostics, or interventional radiology;
 - 1.2.19.3. the cassettes, indirect digitisation plates, X-ray films and intensifying screens used, including their sensitivity and an indication of whether they are a green or blue system or high-sensitivity screens, in radiodiagnostics;
 - 1.2.19.4. the diagnostic monitor which, as part of the test, is inspected or used for the evaluation of tests, in radiodiagnostics or interventional radiology;
 - 1.2.19.5. the planning system in radiotherapy;
 - 1.2.19.6. the recording and verification system in radiotherapy;
 - 1.2.19.7. the system for the transmission of data from the source of ionising radiation to the planning system and to the recording and verification system in radiotherapy;
 - 1.2.19.8. the applicators used for sealed radionuclide sources;
- 1.2.20. an assessment of the availability at the workplace of documentation for the source of ionising radiation that is necessary to carry out the test, namely:
 - 1.2.20.1. the instructions for use; and
 - 1.2.20.2. the type-approval decisions in the case of an acceptance test performed on a source of ionising radiation subject to type approval;
- 1.2.21. information on
 - 1.2.21.1. technical changes which have occurred since the previous test, affecting the source of ionising radiation and its accessories and having an impact on radiation protection, that may affect how the test is performed;
 - 1.2.21.2. any limitation of the scope of the test to be performed and the reason for that limitation;

- 1.2.21.3. any changes to the test procedures that occurred during the test, including their justification;
- 1.2.21.4. the operating conditions affecting the test being performed;
- 1.2.22. details of the instruments and aids used, including the date of the last verification of specified measuring instruments;
- 1.2.23. in the case of an acceptance test on an intraoral dental X-ray device with image digitisation, a copy of the user-adjustable software settings that may affect the image at the initial display of the image without post-processing;
- 1.2.24. records of the tests performed as part of the testing, including records of any tests that were performed as part of the testing beyond the scope of the methodology, containing
 - 1.2.24.1. information on the measurement conditions that affect the parameters tested;
 - 1.2.24.2. a record of the observed data and measured values and of the parameters derived from them;
 - 1.2.24.3. the calibration coefficients and correction factors used in radiotherapy;
 - 1.2.24.4. the formulae of the calculations used, or the completed actual measured values, from which the correctness of the formulae in the model protocol can be verified;
 - 1.2.24.5. the baseline values, including the date on which they were determined, if the measured values are compared to them;
 - 1.2.24.6. in the case of radiotherapy, the combined measurement uncertainty for dosimetric quantities relevant to the purpose of use of the source of ionising radiation pursuant to Annex 12;
 - 1.2.24.7. an evaluation of the test results;
 - 1.2.24.8. the tolerances and recommended values of the parameters to be verified;
 - 1.2.24.9. in the event of non-compliance with the tolerances or the recommended values of the parameters being verified, where insufficient stability of a key quantity describing the properties of the source of ionising radiation is identified, or in the case of borderline results, a written comment describing the non-compliance or borderline results, including a recommended solution;
 - 1.2.24.10. in the event of a deviation from the methodology, a record and a more detailed description of the deviation and its justification;
- 1.2.25. in the case of radiotherapy, a calculation file containing the calculations, algorithms and a description of how they are to be interpreted for the calculation of dosimetric quantities relevant to the purpose of use of the source of ionising radiation; if a script is used for these calculation, its description forms part of the model protocol;

- 1.2.26. a summary overview of the results of the individual tests, which includes
 - 1.2.26.1. a table containing the numbers and titles of the tests performed together with their evaluation;
 - 1.2.26.2. written comments on all tests in which a defect, borderline or atypical results, or non-compliance with recommendations were detected;
 - 1.2.26.3. time limits for rectifying minor defects and, if an operating restriction resulting from such a defect has been imposed, its description;
 - 1.2.26.4. specification of any very serious defects together with a warning that, due to the very serious defect identified, the source of ionising radiation must not be used until that defect has been demonstrably eliminated;
 - 1.2.26.5. for radiographic and fluoroscopic X-ray equipment used for medical exposure, a specification as to whether the equipment is suitable for imaging children under 3 years of age;
 - 1.2.26.6. for a sealed radionuclide source and for equipment with a sealed radionuclide source, a description of any visible damage to the radionuclide source, in particular cracks, notches, corrosion or wear;
- 1.2.27. in the case of an acceptance test or a long-term stability test which has revealed that the current scope or frequency of operational stability tests is unsuitable, a proposed scope and frequency of the operational stability tests;
- 1.2.28. if incorrect performance of tests of operational stability has been identified, appropriate instructions;
- 1.2.29. the proposed scope of long-term stability tests, if that scope is atypical;
- 1.2.30. in the case of an acceptance test or a long-term stability test performed on X-ray equipment used for medical exposure for imaging purposes after servicing that could have affected secondary radiation, or after significant changes in normal operation that could have affected the personal doses of exposed workers or members of the public, a record of the measurements or an estimate of secondary radiation in the vicinity of the source of ionising radiation that includes
 - 1.2.30.1. in the case of measurements, the measured values at workplaces near the source of ionising radiation and at locations where persons are present;
 - 1.2.30.2. the exposure parameters and the positions of the source of ionising radiation used during the measurements, corresponding to the standard exposure parameters;
 - 1.2.30.3. estimates of the number and duration of exposures for one calendar year;

- 1.2.30.4. calculated estimates of the dose quantities at workplaces and at locations where other persons are present, from all modes of use of the source, for one calendar year;
- 1.2.30.5. a description and diagram of the surroundings of the source of ionising radiation, including a description of the shielding barriers, the distances between workplaces and locations where other persons are present and the source of ionising radiation and the heights of the measurement points above the floor;
- 1.2.30.6. instructions for the user of the source arising from the measurements or the estimate of secondary radiation;
- 1.2.30.7. in the case of portable veterinary and industrial sources of ionising radiation, information on the distance from the source of ionising radiation at which the warning tape is to be placed during normal use;
- 1.2.31. if a detected defect is remedied before the test report is issued,
 - 1.2.31.1. the results of the tests carried out before the defect was remedied;
 - 1.2.31.2. a description of the actions taken after the defect was detected and how it was remedied;
 - 1.2.31.3. the results of the tests after the defect was remedied;
- 1.3. in the case of a scheme for ensuring the measurement of quantities
 - 1.3.1. information on evidence of the specific professional competence of the persons directing and performing the evaluation of the properties of sources of ionising radiation;
 - 1.3.2. the designation of the person overseeing the management of the evaluation of the properties of the source of ionising radiation for each modality separately;
 - 1.3.3. a list of the specified measuring instruments used during the tests, including their type and serial number;
 - 1.3.4. a list of the working measuring instruments used during the tests, including their type and serial number;
 - 1.3.5. the concept for metrological assurance of specified and working measuring instruments;
 - 1.3.6. a list of the aids used during the tests;
 - 1.3.7. the specification of, and method for ensuring access to measuring aid and measuring instruments used in the tests that are not owned by the permit holder.’.

241. In Annex 19, point 2.1.6, the words ‘and specifications of the conversion factors used, if not set out in Annex 3 to this Decree,’ are added at the end.

242. In Annex 19, point 3.1.7, the word ‘(b)’ is deleted.

243. In Annex 19, point 3.1.12.1, the word ‘number’ is replaced by the words ‘unique report identifier’.

244. In Annex 19, point 3.1.12.6, the words ‘the registration number of the workplace assigned by the Authority’ are added at the end.
245. In Annex 19, point 4.1.5.1, the word ‘number’ is replaced by the words ‘unique report identifier’.
246. In Annex 19, point 4.1.5.5, the word ‘execution’ is replaced by the words ‘commencement and completion’.
247. In Annex 19, point 4.1.5.6, the words ‘(workplace, residential building, school, educational establishment), plot number and cadastral area,’ are added at the end.
248. In Annex 19, point 4.1.5.8, the words ‘(measurement of a new building before use, reconstruction of a building, informative measurement)’ are added at the end.
249. In Annex 19, point 4.1.5.9, the words ‘description of building ventilation,’ are added at the end of.
250. In Annex 19, point 4.1.5.13, the words ‘with a proposal for further action’ are deleted.
251. In Annex 19, point 5.1.2.1, the word ‘number’ is replaced by the words ‘unique report identifier’.
252. In Annex 19, point 5.1.2.5, the words ‘plot number and cadastral area’ are added at the end.
253. In Annex 19, point 5.1.2.7, the word ‘execution’ is replaced by the words ‘and the time of commencement and completion’.
254. In Annex 19, point 5.1.2.16, the words ‘with information on further action’ are deleted.
255. In Annex 19, point 6.1.5, the words ‘Th-228’ are replaced by ‘Th-232’.
256. In Annex 19, point 6.1.7, the number ‘105’ is replaced by ‘102’.
257. In Annex 19, point 6.1.8.1, the word ‘number’ is replaced by the words ‘unique report identifier’.
258. In Annex 19, point 7.2.1, the word ‘number’ is replaced by the words ‘unique report identifier’.
259. In Annex 19, point 7.2.9, the words ‘and the address’ are added at the end.
260. In Annex 19, point 8.2.1, the word ‘number’ is replaced by the words ‘unique report identifier’.
261. In Annex 19, point 8.2.5, the words ‘(registration number assigned by the Office, address)’ are added at the end.
262. In Annex 19, point 8.2.10, the words ‘(plot number and cadastral area)’ are added at the end.
263. In Annex 20, the following point 1.4 is added:
 - ‘1.4. The registrant must ensure the optimisation of radiation protection for exposed workers and the public by complying with the instructions on protection against secondary radiation specified in the acceptance test or long-term stability test report during normal imaging, including appropriate structural modifications or the use of protective equipment.’.
264. In Annex 20, point 2.1.2., the words ‘retain it for a period of five years from the date of its acquisition’ are added at the end.
265. In Annex 20, point 2.1.3 is deleted.
266. In Annex 20, points 2.2 to 2.4 are deleted.

Points 2.5 to 2.5.4 become points 2.2 to 2.2.4.

- 267. In Annex 20, point 2.2.1, the word 'standard' is replaced by word 'standard'.
- 268. In Annex 20, point 3.1.2., the words 'retain it for a period of five years' are added at the end.
- 269. In Annex 20, point 3.1.3 is deleted.
- 270. In Annex 20, point 3.2 is deleted.

Points 3.3 to 3.3.4 become points 3.2 to 3.2.4.

- 271. In Annex 20, point 3.2 reads as follows:
 - '3.2. If a non-conformity is detected during the operational stability test carried out pursuant to Annex 13 to this Decree
 - 3.2.1. in the cases referred to under points 2.1., 2.2. or 4.1, the registrant shall ensure corrective servicing;
 - 3.2.2. in the cases referred to under points 2.2 or 4.2, the registrant shall clean the monitor used to perform clinical diagnosis.'

- 272. In Annex 20, point 4 reads as follows:

- '4. Requirements for the use of veterinary X-ray equipment
 - 4.1. The registrant must ensure the optimisation of the radiation protection of exposed workers and the public by
 - 4.1.1. ensuring that only individuals whose presence is necessary during the examination are present in the examination room within a distance of up to 2 m from the X-ray beam; for this person, the registrant shall ensure
 - 4.1.1.1. the correct use of a protective shielding apron and collar providing shielding equivalent to lead with a thickness of at least 0.25 mm Pb;
 - 4.1.1.2. if the individual's hands are present in the vicinity of the X-ray beam during exposure, the use of protective shielding gloves of at least 0.25 mm Pb equivalent;
 - 4.1.1.3. instructing them on the correct method of assisting with the examination with regard to the edges of the X-ray field and the results of measurements of secondary radiation;
 - 4.1.1.4. adjusting the size and position of the X-ray field by means of a light field so that the hands of this natural person are not in the X-ray beam;
 - 4.1.1.5. based on their records, that they do not exceed the dose optimisation limit for a member of the public of 0.25 mSv effective dose per year;
 - 4.1.2. ensuring collimation of the X-ray beam so that the size of the X-ray field is as small as possible, taking into account the needs of the examination;

- 4.1.3. administering sedatives to the animal before the examination, if possible;
- 4.1.4. selecting the collimation of the X-ray beam and the size of the image receptor so that the X-ray beam does not exceed the image receptor during radiographic examination.
- 4.2. When performing imaging and during normal operation, the registrant must
 - 4.2.1. use the source of ionising radiation in accordance with the manufacturer's instructions;
 - 4.2.2. for persons pursuant to point 4.1.1,
 - 4.2.2.1. ensure that the individual is over 15 years of age;
 - 4.2.2.2. inform this individual about the potential risks of ionising radiation associated with assisting in the examination;
 - 4.2.2.3. request their written consent to assist with the examination and retain it for 5 years;
 - 4.2.2.4. keep records of these persons and retain the data therein for a period of 5 years.
- 4.3. During a radiographic examination at a temporary workplace, the registrant must
 - 4.3.1. preferably use a space that is enclosed by natural barriers, in particular by a wall or fence;
 - 4.3.2. if the use of a space pursuant to point 4.3.1 is not possible and the examination is carried out in an open area, ensure that no individual is present in the space in the direction of the primary beam during exposure;
 - 4.3.3. mark off the area where the animals are imaged with warning tape placed at a distance specified in the report from the acceptance test or the long-term stability test;
 - 4.3.4. preferably place the image receptor in a holder so that it does not need to be held during exposure; if this is not possible, use means to ensure that the hands of the individual holding the image receptor are not in the immediate vicinity of the X-ray beam; in this case, the registrant must ensure that the individual holding the image receptor wears protective gloves;
 - 4.3.5. choose the direction of the X-ray beam so that it is absorbed by the terrain as soon as possible;
 - 4.3.6. define the size of the X-ray beam field with a light field and, if lighting conditions do not allow for good visibility, use means that ensure that the edges of the X-ray beam field are correctly focused;
 - 4.3.7. ensure that the exposed worker performing the imaging clearly warns aloud all persons potentially present in the vicinity of the irradiation site immediately before irradiation that ionising radiation will be used.
- 4.4. In the event of a discrepancy being found during the operational stability test carried out in accordance with Annex 13 to this Decree,

- 4.4.1. point 5.1, the registrant must remove the non-compliant protective aid from service; and
- 4.4.2. point 5.2 to this Decree, the registrant shall ensure corrective servicing.’.

- 273. In Annex 20, point 5.1.2., the words ‘retain it for a period of five years’ are added at the end.
- 274. In Annex 20, point 5.1.3, the words ‘keep the record pursuant to point 5.1.2 for ten years’ are replaced by the words ‘during exposure by maintaining a distance of at least 2.5 m from the bone densitometer or by placing a protective shielding barrier with an equivalent of at least 0.25 mm lead between these persons and the bone densitometer’.
- 275. Annex 21 reads as follows:

‘Annex 21 to Decree No 422/2016.

REGISTRATION FORM – REGISTRATION APPLICATION

Záznamy SÚJB

REGISTRAČNÍ FORMULÁŘ
Žádost o registraci
podle § 10 zákona č. 263/2016 Sb.

A. Identifikace žadatele

1. Výběr typu osoby:

fyzická osoba

právnická osoba

2a. Fyzická osoba:

Titul před	Jméno	Příjmení	Titul za
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Adresa trvalého bydliště

Ulice	Číslo popisné	Číslo orientační
<input type="text"/>	<input type="text"/>	<input type="text"/>
PSČ	Obec	Stát
<input type="text"/>	<input type="text"/>	<input type="text"/>

Mám zřízenou datovou schránku

2b. Právnická osoba:

Název	Právní forma
<input type="text"/>	<input type="text"/>

Adresa sídla

Ulice	Číslo popisné	Číslo orientační
<input type="text"/>	<input type="text"/>	<input type="text"/>
PSČ	Obec	Stát
<input type="text"/>	<input type="text"/>	<input type="text"/>

REGISTRATION FORM – CONFIRMATION OF REGISTRATION



STÁTNÍ ÚŘAD PRO JADERNOU BEZPEČNOST

Dne:
 Č. j.:
 Spis. značka:
 Útvar:

Vyřizuje:
 Tel.:

REGISTRAČNÍ FORMULÁŘ - POTVRZENÍ REGISTRACE

Státní úřad pro jadernou bezpečnost, jako správní úřad příslušný podle § 10 zákona č. 263/2016 Sb., atomový zákon, potvrzuje registraci:

- dovozu generátoru záření kromě dovozu pro vlastní potřebu
- vývozu generátoru záření kromě vývozu pro vlastní potřebu a vývozu generátoru záření, který je nevýznamným nebo drobným zdrojem ionizujícího záření
- distribuci generátoru záření
- používání zubního rentgenového zařízení pro lékařské ozáření
- používání rentgenového kostního denzitometru pro lékařské ozáření
- používání rentgenového kostního denzitometru pro lékařské nebo nelékařské ozáření
- používání skiagrafického nebo intraorálního rentgenového zařízení ve veterinární medicíně

pro osobu: *Název právnické osoby nebo jméno, popřípadě jména, a příjmení fyzické osoby*

adresa: *Adresa místa pobytu fyzické osoby nebo sídla právnické osoby*

IČ:

Evidenční číslo SÚJB:

Za Státní úřad pro jadernou bezpečnost:

Rozdělovník:

- SÚJB, příslušný útvar, adresa
- Název a adresa registrovaného subjektu

277. Annex 23 reads as follows:

‘Annex 23 to Decree No 422/2016.

Criteria for the classification of a radiological incident, procedures to follow in the event of a radiological incident or potential radiological incident, the content and retention period of records from the investigation of a radiological incident or potential radiological incident, and the scope of, and time limits for, the provision of information on the radiological incident

1. Criteria for classification of an unrepeated radiological incident involving a single patient

When classifying a radiological incident involving a single patient, the permit holder and the registrant shall proceed as follows:

1. In radiotherapy and in the therapeutic application of radionuclides, a radiological incident is classified
 - 1.1. in category A, if the patient experiences or is expected to experience a serious clinical manifestation that may lead to permanent health damage or premature death, or if there is an increased likelihood of late effects of ionising radiation associated with excessive exposure of healthy tissue;
 - 1.2. in category B, if the patient experiences or is expected to experience a significant clinical manifestation that does not pose a threat to life but increases the likelihood of an undesirable outcome, in particular treatment complications or inadequate tumour control;
 - 1.3. in category C, if there is a low likelihood of clinical manifestation.
2. In diagnostic nuclear medicine, radiodiagnostics or interventional radiology, a radiological incident is classified
 - 2.1. in category A, if the patient may experience tissue reactions that could lead to permanent damage to health and quality of life, or premature death;
 - 2.2. in category B, if the patient may experience tissue reactions that cannot lead to permanent damage to health and quality of life, or premature death;
 - 2.3. in category C, in the case of other radiological incidents, in particular
 - 2.3.1. examination of the wrong patient; or
 - 2.3.2. examination of the wrong anatomical region.

2. Criteria for classification of repeated radiological incidents concerning a single patient

If more than one radiological incident occurs in a single patient, the permit holder must consider the total radiation exposure of the patient and the severity of errors in those radiological incidents. If that overall exposure level or error severity is associated with a level of health risk or error severity corresponding to another category of radiological incident, the permit holder shall re-evaluate these events as a single radiological incident of the corresponding category.

3. Criteria for classifying repeated radiological incidents involving multiple patients

In the event of a repetition of a radiological incident of the same nature due to the same error or set of errors in various patients, the permit holder or registrant is obliged to consider the level of severity of this repetition. In the event that the number of such repeated radiological incidents indicates a serious systemic error, the permit holder must reclassify all such repeated radiological incidents into a higher category, depending on the severity of the error.

4. Time limits for reporting radiological incidents and potential radiological incidents

1. The Office must be informed in the event of
 - 1.1. a category A radiological incident
 - 1.1.1. immediately after it is ascertained that a radiological incident has occurred, of all known facts concerning it;
 - 1.1.2. immediately after all other facts have been ascertained within the framework of the investigation of the radiological incident, in particular after ascertaining the facts set out in Part 5, of those facts;
 - 1.1.3. immediately after all actions have been taken to minimise the consequences of the radiological incident, of the actions taken;
 - 1.1.4. immediately after the adoption of all actions to prevent the occurrence of a similar radiological incident in the future, of the actions taken; and
 - 1.1.5. in full, pursuant to Part 5, no later than one month after ascertaining that a category A radiological incident in radiotherapy has occurred;
 - 1.2. a category B radiological incident, no later than three months after ascertaining that a radiological incident has occurred;
 - 1.3. a potential radiological incident that could have serious systemic implications, in full, pursuant to Part 5, no later than one month after ascertaining that a potential radiological incident has occurred.
2. The patient or their legal representative, the prescribing physician and the treating specialist must be informed if tissue reactions caused by incorrect irradiation may adversely affect the patient's health or if changes to their treatment regimen are necessary due to a radiological incident, in the event of

- 2.1. a category A radiological incident
 - 2.1.1. immediately after it is ascertained that this radiological incident has occurred, of all known facts concerning it;
 - 2.1.2. immediately after all other facts set out in Part 5 have been ascertained during the investigation of the event, of those facts;
 - 2.1.3. immediately after all actions have been taken to minimise the consequences of the radiological incident, of the actions taken;
 - 2.1.4. immediately after taking all actions to prevent the occurrence of a similar radiological incident in the future, of the actions taken; the patient or their legal representative need not be informed of these actions , and
 - 2.1.5. in full, pursuant to Part 5, no later than one month after ascertaining that a category A radiological incident has occurred in radiotherapy or nuclear medicine;
- 2.2. a category B radiological incident, in full, pursuant to Part 5, no later than three months after ascertaining that a radiological incident has occurred.

5. Scope of the provision of information on serious radiological incidents

1. The Office must be informed, within the time limits set out in Part 4, to the following extent:
 - 1.1. in the event of a category A radiological incident
 - 1.1.1. the date and time when the radiological incident was detected and when it occurred, if known;
 - 1.1.2. the nature, extent and severity of the radiological incident;
 - 1.1.3. the potential impact of the radiological incident;
 - 1.1.4. the actions taken to minimise the consequences of the radiological incident;
 - 1.1.5. other facts ascertained in the course of investigating the radiological incident that affect its nature, extent, impact and severity;
 - 1.1.6. the next planned steps to be taken in investigating the radiological incident; and
 - 1.1.7. the actions taken to prevent the occurrence of a similar radiological incident in the future;
 - 1.2. in the event of a category B radiological incident
 - 1.2.1. the date when the radiological incident was detected and when it occurred , if known;
 - 1.2.2. the nature, extent and severity of the radiological incident;
 - 1.2.3. the potential impact of the radiological incident;
 - 1.2.4. the actions taken to minimise the consequences of the radiological incident;

- 1.2.5. other facts ascertained in the course of investigating the radiological incident that affect its nature, extent, impact and severity; and
 - 1.2.6. the actions taken to prevent the occurrence of a similar radiological incident in the future;
 - 1.3. in the event of a potential radiological incident that could have led to a category A radiological incident
 - 1.3.1. the date and time when the potential radiological incident was detected;
 - 1.3.2. the date and time when the potential radiological incident occurred, if known;
 - 1.3.3. the nature, extent and severity of the potential radiological incident;
 - 1.3.4. the possible impact of the radiological incident that could have occurred;
 - 1.3.5. any other facts identified in the course of investigating the potential radiological incident that affect its nature, extent, impact and severity;
 - 1.3.6. all actions taken to prevent the occurrence of a similar radiological incident in the future.
 2. The patient or their legal representative, the referring physician and the administering specialist must be informed, within the time limits set out in Part 4, to the following extent:
 - 2.1. in the event of a category A radiological incident
 - 2.1.1. information that an erroneous exposure has occurred;
 - 2.1.2. the date and time when the radiological incident was detected and when it occurred, if known;
 - 2.1.3. the nature, extent and severity of the radiological incident;
 - 2.1.4. the potential impact of the radiological incident;
 - 2.1.5. the actions taken to minimise the consequences of the radiological incident;
 - 2.1.6. other facts ascertained in the course of investigating the radiological incident that affect the patient's health and treatment; and
 - 2.1.7. the next planned steps in addressing the radiological incident;
 - 2.2. in the event of a category B radiological incident
 - 2.2.1. information that an erroneous exposure has occurred;
 - 2.2.2. the date when the radiological incident was detected and when it occurred , if known;
 - 2.2.3. the nature, extent and severity of the radiological incident;
 - 2.2.4. the potential impact of the radiological incident;
 - 2.2.5. the actions taken to minimise the consequences of the radiological incident; and
 - 2.2.6. other facts ascertained in the course of investigating the radiological incident that affect the patient's health and treatment.

3. Summary information on the radiological incident and on the potential radiological incident in radiotherapy, of which the Office is informed in accordance with points 1.1.5, 1.2.1, 2.1.5 and 2.2 of Part 4 and which the permit holder prepares and retains in accordance with points 1.1.6, 1.1.7, 1.4.5 and 1.4.6 of Part 7, must include
 - 3.1. the date and time when the radiological incident or potential radiological incident occurred, its duration, and the date and time when it was detected;
 - 3.2. a description of the radiological incident or potential radiological incident, its extent, severity and category;
 - 3.3. the causes of the radiological incident or potential radiological incident and other facts ascertained in the course of investigating it that affect its nature, extent, impact and severity;
 - 3.4. clinical manifestations resulting from the radiological incident;
 - 3.5. the estimated potential long-term consequences of the radiological incident;
 - 3.6. actions to limit the clinical consequences of the radiological incident;
 - 3.7. immediate measures to prevent recurrence of the radiological incident or potential radiological incident; these measures need not be included in the information provided to the patient or their legal representative; and
 - 3.8. preventive systemic measures to prevent the recurrence of the radiological incident or potential radiological incident; these measures need not be included in the information provided to the patient or their legal representative.

6. Content and retention period of records on radiological incidents and potential radiological incidents

1. Records of a radiological incident and potential radiological incident must be retained, in the case of
 - 1.1. a category A radiological incident, for a period of 30 years from its detection;
 - 1.2. a category B radiological incident, for a period of 10 years from its detection;
 - 1.3. a category C radiological incident, for a period of 10 years from its detection; and
 - 1.4. a potential radiological incident, for a period of 5 years from its detection.
2. These records must contain all information on the radiological incident or potential radiological incident identified during the investigation, as well as information on the actions taken.

7. Procedures in the event of a radiological incident or potential radiological incident

1. In radiotherapy, in the event of
 - 1.1. a category A or B radiological incident,
 - 1.1.1. a dosimetric and clinical evaluation of the event must be commenced without delay, involving, at a minimum, a radiation oncologist and a clinical medical physics expert;
 - 1.1.2. measures must be taken to limit the clinical consequences of the event for the affected patient, in particular interruption of treatment according to the original treatment plan and recalculation of the treatment plan and related activities, including the preparation of a new treatment plan, simulation and verification of the plan if it is necessary to modify the original plan or prepare an entirely new one;
 - 1.1.3. immediate measures must be taken to ensure radiation protection for other patients, including verification that the same cause of the radiological incident is not occurring in other cases;
 - 1.1.4. as part of the investigation of the radiological incident, investigation teams must be established, the problem defined and analysed, and an analysis of the root causes, course and consequences of the radiological incident must be carried out;
 - 1.1.5. preventive systemic measures must be implemented;
 - 1.1.6. a summary of the information on the radiological incident pursuant to Part 5, point 3 must be prepared and sent to the Office within one month of detection of the event; and
 - 1.1.7. a summary of the radiological incident information, to the extent pursuant to Part 5, point 3, must be retained for the period specified in Part 6 and in the patient's medical records;
 - 1.2. a category A radiological incident, if tissue reactions caused by erroneous exposure may negatively affect the patient's health, or if changes in the patient's treatment are necessary due to the radiological incident, the patient or their legal representative, the administering specialist and the referring physician must all be informed within one month after detection of the radiological incident, to the extent pursuant to Part 5, point 2.1;
 - 1.3. a category B radiological incident, if tissue reactions caused by erroneous exposure may negatively affect the patient's health, or if significant changes in the patient's treatment are necessary due to the radiological incident, the patient or their legal representative, the administering specialist and the referring physician must all be informed within three months after detection of the radiological incident, to the extent pursuant to Part 5, point 2.2;
 - 1.4. a category C radiological incident,
 - 1.4.1. as part of the investigation of the radiological incident, an investigation team must be established, the problem defined and analysed, and an analysis of the root causes, course and consequences of the radiological incident carried out, together with a dosimetric and clinical evaluation of the radiological incident;
 - 1.4.2. measures must be taken to limit the clinical consequences of the event for the affected patient;

- 1.4.3. if necessary, the treatment plan must be amended;
 - 1.4.4. preventive systemic measures must be implemented;
 - 1.4.5. a summary of the radiological incident information must be prepared within one month of detection of the radiological incident to the extent specified in Part 5, point 3; and
 - 1.4.6. a summary of the radiological incident information, to the extent pursuant to Part 5, point 3, must be retained;
 - 1.5. a potential radiological incident,
 - 1.5.1. immediately after it is established that a radiological incident may occur, measures must be taken to prevent it from occurring;
 - 1.5.2. an investigation must be conducted and root causes and contributing factors found;
 - 1.5.3. a record of the case must be created and filed; and
 - 1.5.4. preventive measures must be taken to prevent similar cases from occurring in the future.
 2. In nuclear medicine, interventional radiology or radiodiagnostics, in the case of
 - 2.1. a radiological incident in a manner and with timing appropriate to the severity of the radiological incident and its possible consequences,
 - 2.1.1. immediately after ascertaining that a radiological incident has occurred, measures must be taken to avoid increasing the undesirable dose for the patient and to prevent the radiological incident from recurring in another patient;
 - 2.1.2. all available data on the radiological incident must then be collected;
 - 2.1.3. timely actions must be taken to mitigate the consequences of the radiological incident, if possible;
 - 2.1.4. the causes of the radiological incident must be identified and procedures changed to prevent the event from recurring;
 - 2.1.5. the Office, the patient or their legal representative, the administering specialist and the referring physician must be informed of the radiological incident pursuant to Parts 4 and 5; and
 - 2.1.6. records of the radiological incident, its investigation and the measures taken in accordance with Part 6 must be retained;
 - 2.2. a potential radiological incident,
 - 2.2.1. immediately after it is established that a radiological incident may occur, measures must be taken to prevent it from occurring;
 - 2.2.2. the causes of the potential radiological incident must be subsequently ascertained, it must be verified whether the existing standard procedures ensure prevention of the radiological incident, and if not, those procedures must be changed so that a radiological incident cannot occur in the future;
 - 2.2.3. all records of these cases, their investigations and of the measures taken must be retained.’.
278. In Annex 24, point 1 is deleted.

Points 2 to 2.2.10 become points 1 to 1.2.10.

279. In Annex 24, point 1.1.4, the words ‘identification of the health insurance company,’ are added at the end.
280. In Annex 24, point 1.1.5, the word ‘district’ is replaced by the words ‘district code’ and the words ‘according to the currently valid version of the code list of the Czech Statistical Office,’ are added at the end.
281. In Annex 24, point 1.1.7, the words ‘year of birth’ are replaced by the word ‘age’.
282. In Annex 24, point 1.1.8. reads as follows:

1.1.8. the unique patient identifier for all provided data created by the health insurance company, identification of the health insurance company;’.

283. In Annex 24, the following points 1.1.9 and 1.1.10 are added:

‘1.1.9. the date of examination; and
1.1.10. the number of examinations.’.

284. In Annex 24, point 1.2.3, the words ‘identification of the health insurance company,’ are added at the end.
285. In Annex 24, point 1.2.4, the word ‘district’ is replaced by the words ‘district code’ and the words ‘according to the currently valid version of the code list of the Czech Statistical Office,’ are added at the end.
286. In Annex 24, point 1.2.6, the words ‘year of birth’ are replaced by the word ‘age’.
287. In Annex 24, point 1.2.8, the words ‘identification of the health insurance company,’ are added at the end.
288. In Annex 25, point A, point 1.1 is deleted.

Points 1.2 to 1.5 become points 1.1 to 1.4.

289. In Annex 25, point A, point 3, in row 8, column 3 of the table, the word ‘JÍLOVIŠTĚ’ is inserted after the word ‘ČÍČOVICE’.
290. In Annex 25, point A, point 3, in row 21, column 3 of the table, the word ‘ČIŽICE’ is inserted at the beginning.
291. In Annex 25, point A, point 3, in row 30, column 3 of the table, the word ‘, TEPLICE’ is inserted at the end.
292. In Annex 25, point A, point 3, in row 31, column 3 of the table, the words ‘, JABLONEC NAD NISOU’ are inserted after the word ‘DESNÁ’.
293. In Annex 25, point A, point 3, in row 31, column 3 of the table, the word ‘, PULEČNÝ’ is inserted after the word ‘NISOU’.
294. In Annex 25, point A, point 3, in row 31, column 3 of the table, the word ‘, TANVALD’ is inserted at the end.
295. In Annex 25, point A, point 3, in row 32, column 3 of the table, the word ‘, MNÍŠEK’ is inserted after the word ‘LIBEREC’.
296. In Annex 25, point A, point 3, in row 43, column 3 of the table, the words ‘, JAKUBOV U MORAVSKÝCH BUĎĚJOVIC, JAROMĚŘICE NAD ROKYTNOU’ are inserted after the word ‘HROZNATÍN’.

297. In Annex 25, point A, point 3, in row 44, column 3 of the table, the word ‘, SVRATKA’ is inserted after the word ‘ZHOR’.
298. In Annex 25, point A, point 3, in row 47, column 3 of the table, the word ‘KRÁSENSKO’ is inserted at the beginning.
299. In Annex 25, point A, point 3, in row 47, column 3 of the table, the word ‘, VYŠKOV’ is inserted at the end.
300. In Annex 25, point A, point 3, in row 50, column 3 of the table, the word ‘, BYSTROVANY’ is inserted after the word ‘BOUZOV’.
301. Annex 27 reads as follows:

‘Annex 27 to Decree No 422/2016 .

Activity concentration of radionuclides in drinking water for public consumption and for placing bottled water on the market

Maximum permissible value of the activity concentration of radon and tritium

	Maximum permissible value
Activity concentration of Rn-222	300 Bq/l
Activity concentration of H-3	3500 Bq/l

Reference levels for radionuclide content

	Reference level
Activity concentration of Rn-222	100 Bq/l
Activity concentration of H-3	1000 Bq/l
Indicative dose	0,1 mSv/rok

Investigation levels of radionuclide activity concentrations

	Investigation levels
Total alpha activity concentration	0,2 Bq/l
Total beta activity concentration	0,5 Bq/l
Activity concentration of Cs-137	0,5 Bq/l

The method and scope of systematic measurement and evaluation of natural radionuclide content in water

1. Basic analysis

- (a) activity concentration of Rn-222, in the case of water from a groundwater source;
- (b) total alpha activity concentration;
- (c) total beta activity concentration.

2. Supplementary analysis

Analysis of the presence of individual natural radionuclides in water in which an investigation level has been exceeded, according to the following procedure:

- (a) uranium content, if the total alpha activity concentration exceeds the investigation level;
- (b) Ra-226 activity concentration, if the total alpha activity concentration, after deduction of the uranium contribution, exceeds the investigation level;
- (c) Ra-228 activity concentration, if the Ra-226 activity concentration exceeds the investigation level for total alpha activity;
- (d) determination of other alpha-emitting radionuclides, if the total alpha activity concentration, after deduction of the Ra-226 and uranium contribution, exceeds the investigation level;
- (e) potassium content, if the total beta activity concentration exceeds the investigation level;
- (f) determination of other beta-emitting radionuclides, if the total beta activity concentration, after deduction of the K-40 contribution, exceeds the investigation level.

The method and scope of systematic measurement and evaluation of artificial radionuclide content in water

- (a) tritium activity concentration;
- (b) activity concentration of gamma-emitting radionuclides when the tritium activity concentration exceeds the indicator value of 100 Bq/l;

(c) the indicative dose if the Cs-137 activity concentration exceeds the investigation level.’.

302. In the heading of Annex 28, the words ‘Building materials’ are replaced by the words ‘List of building materials’.

303. In Annex 28, point 5, the number ‘92’ is replaced by ‘93’.

304. In Annex 28, point 5, the words ‘and (c)’ are deleted.

305. The following Annex 30 is added:

‘Annex 30 to Decree No 422/2016.

Dose conversion factors for determining the effective dose from radon inhalation

Table 1: Dose conversion factors

	Dose conversion factor	
	radon decay products, ^{222}Rn	radon ^{222}Rn
Nature of the workplace	mSv/(mJ·h·m⁻³)	mSv/(Bq·h·m⁻³)
underground workplaces with natural ventilation	6	$13 \cdot 10^{-6}$
workplaces in buildings, including underground levels; underground workplaces with forced ventilation	3	$6,7 \cdot 10^{-6}$

Table 2: Derived values for workplaces in buildings including underground levels, and underground workplaces with forced ventilation, corresponding to an effective dose of 20 mSv assuming a working time of 2 000 hours, a breathing rate of 1.2 m³/h and an equilibrium factor F = 0.4

Quantity	Value	Unit
Exposure to ^{222}Rn	$3 \cdot 10^6$	Bq·h·m⁻³
Exposure from radon progeny	$1,2 \cdot 10^6$	Bq·h·m⁻³

Annual latent energy intake	8	mJ
Annual intake of radon progeny	$1,4 \cdot 10^6$	Bq
Average equivalent radon activity concentration	600	$\text{Bq}\cdot\text{m}^{-3}$
Average latent energy concentration	3,3	$\mu\text{J}\cdot\text{m}^{-3}$
Average radon ^{222}Rn activity concentration	1500	$\text{Bq}\cdot\text{m}^{-3}$

Table 3: Derived values for underground workplaces with natural ventilation, corresponding to an effective dose of 20 mSv assuming a working time of 2 000 hours, a breathing rate of 1.2 m³/h and an equilibrium factor F = 0.4

Quantity	Value	Unit
Exposure to ^{222}Rn	$1,5 \cdot 10^6$	$\text{Bq}\cdot\text{h}\cdot\text{m}^{-3}$
Exposure from radon progeny	$0,6 \cdot 10^6$	$\text{Bq}\cdot\text{h}\cdot\text{m}^{-3}$
Annual latent energy intake	4	mJ
Annual intake of radon progeny	$0,7 \cdot 10^6$	Bq
Average equivalent radon activity concentration	300	$\text{Bq}\cdot\text{m}^{-3}$
Average latent energy concentration	1,6	$\mu\text{J}\cdot\text{m}^{-3}$
Average radon ^{222}Rn activity concentration	750	$\text{Bq}\cdot\text{m}^{-3}$

’.

Article II

Effective date

This Decree comes into effect on 1 February 2026, except for

- (a) the provisions of Article I, point 123, Article I, point 124, Article I, point 125, Article I, point 126 and Article I, point 127, which shall come into effect on 1 January 2028;
- (b) the provisions of Article I, point 121, and Article I, point 122, which shall come into effect on 1 January 2030.

Chairperson:

represented by Ing. Merxbauer, Ph.D., m.p.

Director of the Management and Technical Support Section