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DECREE
of …

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

Pursuant to § 236 of Act No. 263/2016, the Atomic Act, the State Office for Nuclear Safety lays down the following for the implementation of § 24(7), § 56(2), § 57(3), § 58(9) and§ 59(4):

Article I

Decree No 358/2016 on requirements for quality assurance and technical safety and assessment and verification of conformity of selected equipment is amended as follows:

1. In the introductory sentence, the reference ‘§ 58(7)’ is replaced by the reference ‘§ 58(9)’.
2. In § 1(j) the word ‘and’ is replaced by a semicolon.
3. In § 1(k), the full stop at the end is replaced by the word ‘; and’.
4. The following § 1(l) is added:

‘l) the prerequisites for the assessment of technical safety that must be fulfilled for the Office to issue a binding opinion pursuant to § 58(3) of the Act.’.

5. In § 2(b)(4), the full stop at the end is replaced by a semicolon.
6. The following § 2(c) is added:

‘c) repair of selected equipment means an activity carried out on operated selected equipment that rectifies its non-conforming condition or the impact of ageing, during which the selected equipment may be re-installed in order to comply with the requirements set out in the technical specification of the selected equipment; and’.

7. The following § 2(d) is added:

‘d) maintenance of selected equipment means an activity carried out on operated selected equipment or part thereof in order to maintain the safe and operational condition of that equipment or an activity involving the replacement of a part of the selected equipment in a detachable manner, unless it is a repair.’.

8. In § 4(4)(b), the words ‘for monitoring and evaluation of viability’ are replaced by the words ‘parameters monitored in the ageing management process’.
9. § 4(4)(e) reads as follows:

‘e) a list of the parts of selected equipment; and’.

10. In § 5(1), the words ‘of selected equipment and parts’ are inserted after the word ‘installation’.
11. In § 5(2)(d), the words ‘of selected equipment and parts’ are inserted after the word ‘installation’.
12. In § 5(2)(d), the word ‘its’ is deleted.
13. In § 5(2)(g), the words ‘, unless it is selected equipment pursuant to § 12(3)(e),’ are inserted after the word ‘it’.
14. In § 5(3)(b), the word ‘and’ is replaced by the word ‘or’.
15. The title of § 6 reads as follows:

‘Scope and method of quality assurance in the procurement process of selected equipment and parts of selected equipment’.

16. In the introductory part of § 6(1), the words ‘of selected equipment and parts’ are inserted after the word ‘procurement’.
17. In § 6(1)(a), the words ‘parts of selected equipment and’ are added at the end.
18. In the introductory part of § 6(2), the words ‘of selected equipment and parts’ are inserted after the word ‘procurement’.
19. In § 6(2)(b), the words ‘of selected equipment and parts’ are inserted after the word ‘quality’.
20. In § 6(2)(d), the words ‘of selected equipment and parts’ are inserted after the word ‘quality’.
21. § 7(f), the word ‘re-operating’ is replaced by the word ‘pre-operating’.
22. In § 7(g), the word ‘and’ is replaced by a semicolon.
23. In § 7(h), the full stop at the end is replaced by the word ‘; and’.
24. The following § 7(i) is added:

‘i) an assessment of the conformity of the modification of selected equipment resulting in the modification of the design of the selected equipment is carried out.’.

25. The existing text of § 7 becomes Paragraph 1 and the following Paragraph 2 is added:

‘(2) The requirements of Paragraph 1 do not apply to selected equipment referred to in § 12(3)(e).’.

26. In § 8(1)(c), the words ‘in the case of pressure equipment classified in safety class 1 or 2’ are deleted.
27. In § 8(1)(d), the words ‘in the case of pressure equipment classified in safety class 1 or 2’ are deleted.
28. In § 11(1), the word ‘and’ is replaced by a semicolon.
29. In § 11(1), the words ‘and changes’ are inserted after the word ‘installation’.
30. In § 12(3)(c), the word ‘and’ is replaced by a semicolon.
31. In § 12(3)(d), the words ‘Paragraph 2.’ are replaced by the words ‘Paragraph 2, and’.
32. The following (e) is added to § 12(3):

‘e) selected equipment that is fuel element cladding and the fuel assembly structure.’.

33. § 12(4) reads as follows:

‘(4) The conformity assessment of the selected equipment referred to in Paragraph 2(c) may be carried out by an accredited entity if the conformity assessment is carried out in accordance with the procedure pursuant to § 15(1)(e)(1).’.

34. In § 12(6), the word ‘designed’ is deleted.
35. In § 12(6), the words ‘referred to in Paragraph 3’ are replaced by the words ‘classified in safety class 2 or 3’.
36. In § 12(6), the word ‘designed’ is deleted.
37. In § 12(6), the words ‘The conformity assessment of a part of the selected equipment referred to in Paragraph 2(b) may also be carried out by the operator of the selected equipment if it is’ are added at the end.
38. The following § 12(6)(a) is added:

‘a) conformity assessment carried out in accordance with the procedure pursuant to § 15(2)(b)(1); and’.

39. The following § 12(6)(b) is added:

‘b) the operator of selected equipment must assess compliance only for the part of the selected equipment intended solely for its own use.’.

40. In § 12(8), the word ‘authorised’ is deleted.
41. In § 12(8), the words ‘, an accredited entity, the manufacturer or the importer of the selected equipment’ are replaced by the words ‘performing conformity assessment’.
42. The following § 12(9) is added:

‘(9) Conformity assessment of pressure equipment safety accessories must be carried out at least at the same level as the conformity assessment of the selected equipment these accessories protect.’.

43. The following § 12(10) is added:

‘(10) The procedure for conformity assessment procedure by an authorised entity, an accredited entity and an operator of selected equipment must meet the requirements of

a) technical standards relating to the competence, consistent activity and impartiality of authorities performing certification of products, processes and services as regards the conformity assessment procedures set out in Parts 3 to 11 of Annex 7 to this Decree;

b) technical standards containing general criteria for the competence of authorities carrying out inspection and for the impartiality and consistency of their inspection activities as regards:

1. the approval of the procedures referred to in Point 6.5 of Part A of Annex 2 to this Decree;
2. the activities referred to in Points 8.3, 13.6, 13.9.1 and 13.11 of Part A of Annex 2 to this Decree;
3. the conformity assessment procedure referred to in Part 2 of Annex 7 to this Decree;
4. the procedure for the assessment of the conformity of a part of selected equipment by the operator set out in Part 12 of Annex 7 to this Decree.’.

44. The following § 12(11) is added:

‘(11) Compliance with the requirements of the conformity assessment procedure pursuant to Paragraph 10 must be demonstrated by accreditation under the Act on Technical Product Requirements.’.

45. The following § 12(12) is added:

‘(12) A prerequisite for the assessment of technical safety by an authorised entity, which must be fulfilled for the Office to issue a binding opinion pursuant to § 58(3) of the Act, is the fulfilment of the requirements pursuant to Paragraphs 10 and 11.’.

46. In § 13(1), the words ‘of selected equipment or parts of selected equipment’ are inserted after the word ‘importer’.
47. In § 13(1), the words ‘of selected equipment or parts’ are inserted after the word ‘marking’.
48. In § 13(2), the words ‘of selected equipment or parts’ are inserted after the word ‘compliance’.
49. In the first sentence of § 13(3), the words ‘equipment or part of selected’ are inserted after the word ‘selected’.
50. In § 13(3), the words ‘of selected equipment or parts’ are inserted after the word ‘documentation’.
51. In § 13(3), the words ‘if it does not allow’ are replaced by the words ‘if they do not allow’.
52. In § 13(3), the words ‘by its’ is replaced by ‘or part of selected equipment by their’.
53. In the second sentence of § 13(3), the words ‘equipment or part of selected’ are inserted after the word ‘selected’.
54. In § 14(2)(b), the word ‘authorised’ is deleted.

55. In § 14(2)(b), the words ‘by an accredited entity, manufacturer or importer of selected equipment’ are replaced by the words ‘carrying out conformity assessment’.
56. In the introductory part of § 15(2)(a), the words ‘and (b)’ are deleted.
57. In § 15(2)(a)(3), the word ‘G’ is replaced by the word ‘F1’.
58. In the introductory part of § 15(2)(b), the reference ‘§ 12(2)(c)’ is replaced by the word ‘§ 12(2)(b)’.
59. In § 15(2)(b)(1), the word ‘A1’ is replaced by the words ‘parts of selected equipment by the operator’.
60. In § 15(2)(b)(2), the word ‘procedures’ is replaced by the word ‘procedure’.
61. In § 15(2)(b)(2), the words ‘D1, or’ are replaced by the words ‘set out in (a) and’.
62. § 15(2)(d)(3) is deleted.
63. In § 15(2)(c), the words ‘§ 12(2)(c) or’ are inserted after the word ‘in’.
64. In § 16(2), the words ‘in a preventive maintenance programme’ are inserted after the word ‘and’.
65. In § 16(6), the word ‘verified’ is replaced by 'ensured'.
66. In § 16(6), the words ‘complies with technical requirements. The verification of part of selected equipment must be carried out’ is replaced by ‘has been assessed’.
67. In § 16(6), the word ‘F1’ is deleted.
68. In § 16(6), the words ‘Annex 8 to this Decree’ are replaced by the words ‘§ 15(2)’.
69. Annex 1 reads as follows:

‘Annex 1 to Decree No 358/2016

Technical requirements for selected equipment and parts of selected equipment

A. Technical requirements for pressure equipment and certain other selected equipment and packaging for the transport, storage and disposal of spent nuclear fuel

1. General requirements

1.1. The technical requirements set out in this Annex apply to all pressure equipment and pressure equipment assemblies and parts thereof.

1.2. Technical requirements set out in

1.2.1. Points 1.3 to 1.8, 1.13, 1.14, 2 to 5 and 11 to 14 apply to packaging for the transport, storage and disposal of spent nuclear fuel; and

1.2.2. Points 1.3 to 1.10, 1.12 to 1.14, 2 to 5, 7, 8 and 11 to 15 apply to selected equipment set out in § 12(3)(a) and (d).

1.3. Pressure equipment must be designed in accordance with the requirements stipulated

1.3.1. in its technical specifications pursuant to the Decree on the requirements for nuclear installation design and

1.3.2. by this Decree.

1.4. Pressure equipment must be designed in such a way that
1.4.1. there can be no sudden failure under all test and operating conditions, including impermissible release of media;
1.4.2. all necessary scheduled and unscheduled checks or diagnostics of the equipment can be carried out safely during its operation; and
1.4.3. repairs and maintenance can be carried out safely.
1.5. Pressure equipment must be so designed as to withstand the hazards arising from the site characteristics of the location of the nuclear installation, external influences and internal influences.
1.6. Pressure equipment must be capable of performing the required function under all operating conditions of the nuclear installation and under the emergency conditions for which it is intended.
1.7. Materials used for the manufacture of pressure equipment and parts thereof ensuring the hermeticity of the protective envelope are subject to the requirements for materials for pressure equipment set out in Points 12 and 13 of Part A of Annex 2 to this Decree.
1.8. Pressure equipment must be designed so as to enable its decontamination and, where possible, subsequent passivation of the inner surfaces.
1.9. Pressure equipment design must be based on stipulated
1.9.1. design, operational and test loads and their limits;
1.9.2. the operating conditions for the pressure equipment in question;
1.9.3. the limiting parameters for the serviceability of pressure equipment in the operation of which mechanical movement occurs;
1.9.4. the operating modes with regard to classification of the pressure equipment in a safety class;
1.9.5. the chemical and physical parameters of the media used in the pressure equipment;
1.9.6. the corrosive effects of the media used on the material of the pressure equipment during the required lifetime of the equipment; and
1.9.7. requirements for the resistance of pressure equipment to seismic effects or to cyclic loads.
1.10. Pressure equipment must be so designed as to eliminate or minimise the risk of substantial loss of resistance to pressure due to a failure leading to a breach of the integrity of the pressure equipment and the release of radioactive substances. In cases where this risk cannot be ruled out, the maintenance of a sufficient level of media in the pressure equipment and the removal of residual heat through downstream supply and heat removal systems must be ensured during operation of the pressure equipment and after shutdown by appropriate means of protection to maintain the operating parameters.

1.11. Pressure equipment constituting the protective envelope system, including those affecting the hermeticity of the protective envelope, must be so designed that it is possible to determine tightness at the designed calculation pressure after the installation of all hermetic bushings, hermetic doors and inlets.

1.12. Piping that is pressure equipment must be designed so that the risk of overloading due to inadmissible free movement or excessive forces arising in particular from flanges, connections, and bellows is minimised, in particular by using supports, reinforcements, anchoring, position alignment and pre-stressing of suspension elements.

1.13. Pressure equipment must be designed for loading under all operating conditions of the nuclear installation and under the emergency conditions for which it is intended. It is necessary to take the different loads that may act together into account, considering the probability of their simultaneous occurrence.

1.14. Design of pressure equipment ensuring appropriate strength must be based on the calculation method pursuant to Point 2, supplemented where necessary by an experimental method. Only verified calculation programs may be used in the calculation.

2. Calculation method

2.1. The calculation method used must apply a conservative approach and limit the risks to persons and property to the lowest reasonably achievable level in accordance with the requirements set out in the technical regulations and technical specifications for

2.1.1. performing strength calculations;

2.1.2. the mechanical properties of the basic and additional materials used;

2.1.3. fixed joints;

2.1.4. carrying out inspections of pressure equipment; and

2.1.5. monitoring and evaluating the ageing of pressure equipment.

Resistance to internal pressure and other aspects of loading

2.2. The permissible stresses for pressure equipment must be limited by reference to the types of failures foreseeable to occur under operating conditions and modes of operation. Safety coefficients must be used that make it possible to completely eliminate any uncertainties arising from production, actual operating conditions, stresses, calculation models and material characteristics and behaviour.

Strength

2.3. Appropriate strength calculations including appropriate design, service and test loads must be used to ensure the strength of the pressure equipment.

2.4. In particular, the following loads must be taken into account in the calculation of the strength of the pressure equipment:

2.4.1. internal and external pressure;

2.4.2. the effect of the inherent weight of the device and its charge;

2.4.3. additional loads, including the effect of the weight of connected equipment, insulation and pipes;
2.4.4. forces induced by supports and pipes;
2.4.5. temperature effects, including temperature shocks;
2.4.6. vibration load;
2.4.7. seismic effects and environmental conditions during extreme atmospheric events;
2.4.8. processes causing material degradation, including the effect of radioactivity;
2.4.9. hydraulic resistances and pressure shocks;
2.4.10. the fall of an aircraft; and
2.4.11. other loads arising from the risk analysis pursuant to Point 3.1 of Part A of Annex 2 to this Decree.

Calculated loads

2.5. The calculated pressure must be greater than the maximum allowable pressure and must take into account:
2.5.1. pressure shocks;
2.5.2. control system errors and measurement uncertainties; and
2.5.3. system configuration effects.

2.6. For parts of the pressure equipment loaded simultaneously with internal and external pressures, the calculated pressure is stipulated as the difference in these pressures at which the greatest wall thickness is reached.

2.7. The calculated temperature must not be less than the expected maximum mean temperature after the thickness of the part under consideration to which the limits for normal and abnormal operating conditions apply. If equipment or pipelines are heated by heat transfer from sources such as induction spirals, sheathing or internal heat sources, their influence must be taken into account when determining the calculated temperature.

2.8. Additional calculated loads must be selected in such a way that, in combination with the influences of the calculated pressure to which the limits for normal operating conditions apply, the maximum wall thickness of the equipment is determined.

2.9. Pressure equipment must be so designed that the maximum stress values and strain concentrations corresponding to the calculated load are kept within safe limits.

Operating load

2.10. When calculating the strength of pressure equipment, account must be taken of all loads that may occur in all operational states of the nuclear installation and under emergency conditions that it is intended to manage. In particular, it is necessary to consider the loads causing stresses and deformations in the material from which the equipment is made, arising during manufacture, transport, assembly and pressure testing, including residual stresses, and their effect on the ultimate

strength limit states must be assessed individually according to their significance.

Test load

2.11. When calculating strength for pressure equipment, the expected test loads to which the pressure equipment is subjected during the pressure test during the final assessment must be taken into account.

2.12. The test pressure must be determined in relation to the design pressure or, where applicable, the maximum permissible pressure, taking into account the assessment of the geometrical and material properties and the test conditions during manufacture and operation in accordance with the requirements specified in the technical regulations or technical specifications for the manufacture of the pressure equipment.

Strength calculations, design of basic dimensions and check calculations

2.13. Strength calculations for pressure equipment must be carried out for the following limit states:

2.13.1. sudden breach of integrity by a ductile or brittle fracture;

2.13.2. elastic deformation over the whole cross-section of the part of the pressure equipment;

2.13.3. unidirectional growth of the elastic component of relative deformation under cyclic loading leading to an impermissible change in dimensions or to a violation of integrity;

2.13.4. the formation of cracks under cyclic loading; and

2.13.5. loss of stability.

2.14. In the calculation of the strength for the limit states set out in Point 2.13, the values to be used must be those corresponding to the material, strength, ductile and brittle fracture characteristics and resistance to deformation specified for the given materials in technical regulations or experimentally determined by an accredited testing laboratory. For the purposes of this strength calculation, values specified in technical standards may be used.

2.15. In the case of permanent joints, suitable coefficients of permanent joints must be selected for the material properties depending on the type of materials connected, the type of non-destructive inspections used and the function of the selected equipment in all operational states of the nuclear installation and under emergency conditions that it is intended to manage.

2.16. Foreseeable degradation mechanisms, in particular the effects of radioactivity, corrosion and material fatigue, must be taken into account in the design of the pressure equipment, as appropriate to the intended use of the pressure equipment and its planned lifetime.

2.17. When calculating the strength of a pressure device, the following must be carried out:

2.17.1. a calculation for the design of the basic dimensions of the equipment (hereinafter 'basic dimensions design'); and

2.17.2. a check calculation of the pressure equipment (hereinafter a ‘check calculation’).

2.18. During basic dimensions design, the permissible stresses must be calculated from the tensile strength and the contractual yield strength permitted for the manufacture of the pressure equipment. The relevant safety coefficients must be taken into account when calculating permissible strains.

2.19. When designing the basic dimensions it is necessary to consider the limit states of

2.19.1. damage to the integrity of a tough fracture;

2.19.2. elastic deformation over the entire cross-section of a part of the pressure equipment; and

2.19.3. loss of stability.

2.20. After the basic dimensions design of the pressure equipment, a check calculation must be carried out to demonstrate

2.20.1. strength under static load;

2.20.2. strength under cyclic load;

2.20.3. resistance to sudden breach;

2.20.4. strength in the presence of vibrations;

2.20.5. resistance to loss of stability; and

2.20.6. resistance to seismic effects.

2.21. All loads, including temperature effects, and all operating conditions set out in the technical specifications must be taken into account in the check calculation. In particular, the degradation of material properties during operation, surface quality, the influence of the stress gradient and the influence of the corrosion environment must be taken into account.

3. Experimental method for the design of pressure equipment

3.1. The accuracy of the design of the pressure equipment or parts thereof must be verified by appropriate checks carried out on a representative sample of the pressure equipment in accordance with an inspection programme established for the purposes of the experimental design method. This programme of checks must be approved by the authorised entity carrying out the design conformity assessment.

3.2. The test conditions and acceptance criteria must be defined in the inspection programme. Before the individual checks are carried out, the actual values of the basic dimensions and properties of the materials of which the pressure equipment is composed must be measured.

4. Design of safe handling and operation of pressure equipment

4.1. The prescribed method of handling and operation of pressure equipment must eliminate the risks arising from the risk analysis pursuant to Point 3.1 of Part A of Annex 2 to this Decree. Special attention must be given to:

4.4.1. closures and openings;

4.4.2. dangerous discharges from safety valves; and

4.4.3. elements that prevent physical access into the equipment when there is pressure or vacuum in the equipment.

5. Means of examination
   5.1. The pressure equipment must be designed in such a way that all necessary checks can be carried out to ensure technical safety.
   5.2. If the pressure equipment cannot be designed in such a way that it is possible to carry out checks of this equipment within the required scope during operation,
      5.2.1. other checks ensuring the same level of technical safety, including indirect controls, must be stipulated; or
      5.2.2. approved calculation methods must be used

      and safety margins established by the conservative approach and adequate safety measures must be used to avoid possible unexpected failure of the pressure equipment.
6. Means of draining and venting
   6.1. The design of the pressure equipment must, throughout the lifetime of the pressure equipment and during its inspection by the use of appropriate means of draining and venting the pressure equipment,
      6.1.1. prevent water hammer, collapse of pressure equipment due to vacuum or corrosion and uncontrolled chemical reaction and other adverse effects; and
      6.1.2. allow for the safe decontamination, cleaning, checking and maintenance of pressure equipment.
7. Corrosion and other chemical effects
   7.1. Where a risk of corrosion or other chemical effects has been identified in the risk analysis referred to in Point 3.1 of Part A of Annex 2 to this Decree, taking into account the intended use of the pressure equipment, these effects must be minimised in the design of the pressure equipment by the use of:
      7.1.1. other corrosion-resistant material;
      7.1.2. increasing wall thickness by a corrosion allowance; or
      7.1.3. protection against corrosion or other chemical effects.
8. Wear and tear
   8.1. Where a risk of erosion or abrasion has been identified in the risk analysis referred to in Point 3.1 of Part A of Annex 2 to this Decree, taking into account the intended use of the pressure equipment, these effects must be minimised in the design of the pressure equipment by:
      8.1.1. using other material resistant to erosion or abrasion;
      8.1.2. increasing wall thickness by a wear allowance;
      8.1.3. using lining or re-plating to allow replacement of the most afflicted parts; or
      8.1.4. other measures minimising the effects of wear and tear.
9. Pressure equipment assemblies
   9.1. Pressure equipment assemblies must be designed in such a way as to ensure:

9.1.1. the parts of the pressure equipment assembly being assembled are suitable and reliable for the given use;
9.1.2. all parts of the pressure equipment assembly are properly integrated and assembled in an appropriate manner; and
9.1.3. parts have been included in the pressure equipment assembly
9.1.3.1. on the basis of the pre-predictable risks identified in the risk analysis referred to in Point 3.1 of Part A of Annex 2 to this Decree;
9.1.3.2. with regard to the suitability and reliability of assembly; and
9.1.3.3. on the basis of the correct breakdown of the parts of the pressure equipment assembly being assembled.

9.2. The method used to protect a pressure equipment assembly against exceeding operating limits and checks of the safety accessories of the assembly must be designed taking into account the most significant safety class in which any selected equipment that is parts of the pressure equipment assembly is classified.

10. Filling and emptying

10.1. In the design of pressure equipment, a suitable structure, pressure equipment accessories or use of the provisions for its installation must ensure safe filling and discharge of the pressure equipment and sampling of the working medium, taking into account in particular the risks
10.1.1. during its filling, which are:
10.1.1.1. overfilling or exceeding pressure, in particular with regard to the filling ratio and the vapour pressure at the corresponding temperature; and
10.1.1.2. instability of pressure equipment
10.1.2. during discharge, which is uncontrolled leakage of the medium under pressure; and
10.1.3. during filling or discharge, which are hazardous connections and breaches of connections.

11. Protection against exceeding permissible limits

11.1. If permissible limits could be exceeded during the operation of the pressure equipment, the design of the pressure equipment must
11.1.1. include added protective device preventing these limits from being exceeded, or a combination of such protective devices; or
11.1.2. use appropriate precautions for its installation.

11.2. The protective device or combination of protective devices must be designed taking into account the specific characteristics of the pressure equipment or pressure equipment assembly to be protected by them.

11.3. Protective devices or a combination of protective devices are
11.3.1. safety accessories; or
11.3.2. monitoring devices, such as indicators or warning devices, that allow appropriate intervention to be carried out

automatically or manually to maintain the operation of the pressure equipment within the permitted limits.

12. Safety accessories
    12.1. Safety accessories must
        12.1.1. be designed to ensure appropriate and reliable protection for the pressure equipment;
        12.1.2. be designed taking into account the maintenance and inspection requirements of this equipment;
        12.1.3. be designed in such a way as to ensure, in particular
            12.1.3.1. failure protection;
            12.1.3.2. backup of safety accessories;
            12.1.3.3. diversity of safety accessory design and build; and
            12.1.3.4. automatic self-diagnosis;
        12.1.4. ensure, where necessary for its proper functioning, in addition to the protection of the machinery parts of the pressure equipment, the protection of the power supply, control, measurement and regulation and related control systems of the nuclear installation; and
        12.1.5. be assessed as part of the conformity assessment of the pressure equipment or pressure equipment assembly.
    12.2. Safety accessories must not be intended to perform other functions unrelated to the protection of the pressure equipment, except where the performance of its protective function cannot be affected by these other functions.
    12.3. Equipment limiting the pressure, level or flow of the medium must be so designed that the maximum permissible pressure, level or flow of the medium is not exceeded; a short-term increase in pressure due to the action of the safety accessories is permissible provided that it does not exceed 10% of the maximum permissible pressure under all operating conditions of the nuclear installation and under the emergency conditions it is designed to handle.
    12.4. Temperature control devices must have a suitable delay time in accordance with the measuring function.
13. Electrical equipment
    13.1. Electrical equipment must be designed
        13.1.1. together with the pressure equipment; and
        13.1.2. in such a way as to permit reliable performance of the safety function of the pressure equipment.
14. Protection against external fire
    14.1. Pressure equipment, having regard to the purpose of its use, must be fitted with suitable accessories or provisions must be taken for its installation in such a way as to meet the requirements for limiting damage in the event of an external fire.
15. Hydraulic and pneumatic devices that provide control, regulation, signalling and measurement

15.1. The general requirements specified in Points 1.1 to 1.8, 1.13 and 1.14 and the technical requirements for pressure equipment specified in Points 2, 3, 5 to 8 and 13 must apply to hydraulic and pneumatic devices that provide control, regulation, signalling and measurement.
15.2. Each fast-acting valve of the safety system of a nuclear installation must be controlled by its own air distributor.
15.3. Pneumatic actuators and air distributors must allow repeated pressurisation with air or other gas.
15.4. Pneumatic actuators must be designed in such a way that
15.4.1. the formation of sediments, corrosion products, dust and other impurities is minimised; and
15.4.2. the external and internal treatment of their surfaces allows, as far as possible, the removal of sediments, corrosion products, dust and other impurities.

B. Technical requirements for selected control equipment

1. Selected control equipment must be designed in accordance with the requirements set out
1.1. in its technical specifications pursuant to the Decree on the requirements for nuclear installation design and
1.2. by this Decree.
2. Selected control equipment must bear the identification of the manufacturer of the equipment or, where the identification of the manufacturer cannot be provided directly on the equipment, the identification must be provided on the packaging. The manufacturer must always be identified in the accompanying technical documentation of this equipment.
3. The basic technical characteristics of selected control equipment that the equipment must comply with during operation in order for the equipment to be used safely and in the conditions for which it was manufactured must be marked on the selected equipment and listed in its accompanying technical documentation or, if this information cannot be provided directly on that equipment, must be listed in its accompanying technical documentation.
4. Selected control equipment must be designed to ensure that
4.1. natural persons are adequately protected against injury or other hazards that could be caused by electric current when coming into contact with live and non-live parts;
4.2. natural persons and property are protected against non-electrical hazards that may be caused by the selected control equipment;
4.3. there is no dangerous temperature increase, electrical arc or radiation;
4.4. the proposed isolation of the selected control equipment is appropriate for all operating conditions of the nuclear installation and the emergency conditions it is intended to handle;
4.5. it will withstand the hazards arising from the characteristics of the area where the nuclear installation will be situated, external influences and internal influences;

4.6. it will be capable of performing the required function in all operational states of the nuclear installation and under emergency conditions that it is intended to handle;
4.7. activities can be carried out safely during operation or planned shutdown, in particular the separability and disconnectability of the equipment must be ensured; and
4.8. diagnostic devices can be used efficiently.

5. Cables that are selected control equipment or that are part of selected control equipment must be
5.1. designed so that they can be installed in the environment for which they are intended by their characteristics in a manner preventing their damage; and
5.2. laid in trays in a predetermined arrangement in layers and gaps prescribed in the laying plan to ensure separation of cables of the secured power supply system from the other sets of cables.

C. Technical requirements for selected construction equipment

1. Selected construction equipment must be designed in accordance with the requirements stipulated
1.1. in its technical specifications pursuant to the Decree on the requirements for nuclear installation design and
1.2. by this Decree.
2. Selected construction equipment must be designed so that it meets the requirements pursuant to Point 1 in all operational states of the nuclear installation and under emergency conditions that it is intended to handle.
3. Selected construction equipment must be designed to withstand the hazards arising from the site characteristics of the location of the nuclear installation, external influences and internal influences.
4. Selected construction equipment must be capable of performing the required function under all operating conditions of the nuclear installation and under emergency conditions that it is intended to handle.
5. The design of the selected construction equipment must be supported by calculations, models or, if necessary, supplemented by experimental verification. Only verified calculation programs may be used in the calculation.
6. Selected construction equipment must be designed so that the effects of the load, the characteristics of the site of the nuclear installation, the external influences and the internal influences specified by the design of the nuclear installation cannot cause:
6.1. the collapse of the building;
6.2. impermissible transformation of the building;
6.3. disturbance of the stability of the building;
6.4. reduction of the mechanical resistance of the building;
6.5. impermissible oscillation of the structure;
6.6. a threat to the functioning of selected equipment located within the building or in its vicinity; or

6.7. damage to the building to an extent disproportionate to the original cause.

7. Selected construction equipment must be designed to ensure that, in the case of fire,
   7.1. the integrity and load-bearing capacity of the building structure is maintained for a specified period of time;
   7.2. its spread within the building is limited by the spatial design and hermetic elements;
   7.3. its spread to neighbouring buildings is restricted; and
   7.4. natural persons can leave the building by means of escape routes.

D. Technical requirements for selected equipment that is fuel element cladding and the fuel assembly structure

1. Fuel element cladding and the fuel assembly structure must be designed in accordance with the requirements laid down in its technical specifications in accordance with the Decree on nuclear installation design requirements.
2. The design of fuel element cladding and the fuel assembly structure must be based on requirements for
   2.1. the mechanical characteristics of the permanent joints as per Point 6.3 of Part A of Annex 2 to this Decree, and
   2.2. the materials used for their manufacture pursuant to Points 12 and 13.1 to 13.5 of Part A of Annex 2 to this Decree.’.

70. Annex 2 reads as follows:

‘Annex 2 to Decree No 358/2016

Requirements for the method of ensuring the conformity of selected equipment and parts of selected equipment

A. Requirements for the method of ensuring conformity in the design, manufacture and installation of pressure equipment and certain other selected equipment and parts thereof and packages for the transport, storage and disposal of spent nuclear fuel

1. Selected equipment and parts of selected equipment must be
   1.1. designed, manufactured and assembled in such a way as to ensure their technical safety when put into service;
   1.2. manufactured in accordance with technical documentation for the given type of packaging approved pursuant to the Decree on the type approval of certain products in the field of peaceful use of nuclear energy and ionising radiation and the carriage of radioactive or fissile material, in the case of packaging for the transport, storage and disposal of spent nuclear fuel; and
   1.3. manufactured in accordance with the technical documentation for the type of fuel assembly approved under the operating permit of the nuclear installation or nuclear fuel modification, in the case of fuel element cladding and fuel assembly structures.
2. Requirements for the method used to ensure conformity in the design, manufacture and installation of selected equipment set out in
   2.1. Points 1 and 3 to 17 apply to packaging for the transport, storage and disposal of spent nuclear fuel;
   2.2. Points 1, 3 to 5, 6.1 to 6.4, 6.5(1), 6.6, 6.8, 7.1, 7.2, 8.1, 8.2, 9, 10, 11, 12, 13.1 to 13.5, 13.7, 13.8, 13.9.3 and 14 to 17 apply to the selected equipment set out in § 12(3)(a) and (d); and
   2.3. Points 1, 3.4, 4, 5, 6.1 to 6.4, 6.6.1, 6.8, 7.1, 7.2, 8.1, 8.2, 9.1, 10.1, 10.2, 11, 12, 13.8, 13.9.3 and 14 apply to the selected equipment set out in § 12(3)(e).

Design of pressure equipment

3. When designing pressure equipment,
   3.1. a risk analysis from the point of view of technical safety must be carried out in order to identify and evaluate the risks involved; to evaluate these safety effects by means of a risk analysis, the required conditions in which the pressure equipment is to perform its function must be stipulated;
   3.2. the technical design of the pressure equipment must be carried out taking into account the result of the risk analysis pursuant to Point 3.1;
   3.3. when choosing the most appropriate technical solution for the pressure equipment,

3.3.1. any foreseeable risk must be eliminated to a reasonably achievable extent; or
3.3.2. appropriate safeguards must be applied to limit the impacts of a risk that cannot be ruled out; and

3.4. the design of the selected equipment must be reviewed for suitability and adequacy of the specification of the technical requirements, verified for compliance with the technical requirements and validated for compliance with the technical requirements and its intended use.

Manufacture of pressure equipment

4. Manufacturing processes
   4.1. Pressure equipment must be manufactured in accordance with the technical documentation of the equipment in question. The methods and manufacturing processes must be designed so that all the prescribed checks can be carried out. The technical requirements adopted in the design process must be applied during manufacturing.
5. Manufacture of parts
   5.1. Defects and cracks or changes in mechanical properties that could jeopardise the technical safety of the pressure equipment must not be allowed to occur during the manufacture of pressure equipment parts.
6. Permanent joints
   6.1. The requirements for permanent joints apply to the following types of joints in particular:
      6.6.1. fusion welding and metal smelting;
      6.6.2. soldering;
      6.6.3. spraying and weld deposits; and
      6.6.4. gluing.
   6.2. Permanent joints and their adjacent areas must be executed so that they are free from any surface or internal defects that could jeopardise the technical safety of the pressure equipment.
   6.3. The basic mechanical properties of permanent joints must correspond at least to those of the basic materials that are being joined, unless values corresponding to other mechanical properties of the material have been deliberately taken into account in the strength calculation.
   6.4. Technical, inspection and technological activities relating to permanent joints on selected equipment may only be carried out by special process supervisors qualified in the field of making and testing permanent joints.
   6.5. Permanent joints of parts of selected equipment that contribute to the resistance of the equipment to internal pressure and elements that are directly connected to it must be executed by personnel qualified according to the requirements of the applied technical regulations, technical standards or technical specifications, using qualified technological procedures. The qualification of the personnel must be verified in the conformity assessment, unless the permanent joints set out in Paragraph 6.1.4 are involved. Technological procedures must be approved

6.5.1. by an authorised entity, in the case of a permanent joint on selected equipment set out in § 12(2); or

6.5.2. by an accredited entity, in the case of a permanent joint on selected equipment set out in § 12(2)(c).

6.6. In the context of qualification of technological processes,

6.6.1. checks must be carried out to verify that the proposed technological procedure for executing a permanent joint complies with the technical requirements for permanent joints, including the requirements of technical regulations, technical standards or technical specifications for carrying out checks on permanent joints,

6.6.2. the procedure for making a permanent joint must be qualified using a test joint according to the requirements of the applicable technical regulations, technical standards or technical specifications, if it involves selected equipment of safety class 1 or 2.

6.7. Surveillance of activities pursuant to Point 6.6, including their evaluation and transfer of markings, must be carried out

6.7.1. by an authorised entity, in the case of a permanent joint on selected equipment set out in § 12(2); or

6.7.2. by an accredited entity, in the case of a permanent joint on selected equipment set out in § 12(2)(c).

6.8. The technical documentation of selected equipment concerning permanent joints must demonstrate compliance with the requirements for the:

6.8.1. qualification of technological procedures for the execution of permanent joints;

6.8.2. necessary qualifications of the personnel making the permanent joints;

6.8.3. necessary qualifications of the personnel designing, verifying and evaluating the permanent joints; and

6.8.4. eligibility of the equipment used in making permanent joints.

7. Non-destructive checks

7.1. Non-destructive checks of permanent joints must preferably be carried out by personnel certified by an entity accredited by an accreditation body in accordance with the relevant technical standards concerning the qualification and certification of personnel performing non-destructive checks of permanent joints.

7.2. Personnel carrying out non-destructive checks of permanent joints in a manner for which certification under Paragraph 7.1 is not available must have certification at a comparable level.

7.3. The comparability of the level of certification of personnel pursuant to Point 7.2 must be verified in the conformity assessment if the permanent joint is on selected equipment set out in § 12(2)(a) or (b).

8. Heat treatment

8.1. If there is a risk that the manufacturing process of selected equipment or part of selected equipment will alter the properties of the material used to an extent that could jeopardise the technical safety of the pressure equipment, adequate heat treatment must be carried out at an appropriate stage of manufacture of selected equipment or part of selected equipment.

8.2. The heat treatment of parts of selected pressure equipment must be carried out by qualified personnel.

8.3. The actual heat treatment of parts of selected pressure equipment set out in § 12(2)(a) must be carried out under the supervision of an authorised entity.

9. Identifiability

9.1. Procedures must be in place and followed to ensure the identification of

9.9.1. materials;

9.9.2. parts of pressure equipment; and

9.9.3. checks of materials and parts of pressure equipment.

9.2. Identifiability must be ensured from initial checks of received material or parts of pressure equipment until the final assessment of the pressure equipment.

10. Marking and labelling

10.1. The pressure equipment must be labelled or otherwise marked. The label or other marking method must indicate the following:

10.10.1. identification of the manufacturer or of the entity carrying out installation, such as first name, surname and business address for a natural person, or the business name and registered office for a corporate entity;

10.10.2. year of manufacture;

10.10.3. identification of the pressure equipment according to its nature, such as type, series or production run and serial number;

10.10.4. basic upper and lower working limits; and

10.10.5. identification of the entity that carried out the conformity assessment of the pressure equipment, in the case of equipment set out in § 12(2).

10.2. The required information must be provided on the pressure equipment or on a label permanently affixed to it, except in cases where

10.2.1. appropriate documentation is used, where applicable, to avoid repeat marking of individual parts intended for the same pressure equipment assembly, such as pipe sections; or

10.2.2. the pressure equipment is too small and the information is provided on a separate tag attached to the pressure equipment.

11. Instructions for use

11.1. If pressure equipment is commissioned, it must be accompanied, where appropriate, by instructions or other relevant operating

documentation containing all necessary information relating to technical safety and relating to its:

11.1.1. installation or installation of its parts;

11.1.2. commissioning;

11.1.3. operation, including identification of its parts, working conditions and how it is used, and

11.1.4. maintenance, including checks carried out during operation.

11.2. The instructions must contain the information set out in Point 11.1 and, where necessary for a full understanding of the instructions, must be accompanied by additional technical documentation, drawings and diagrams.

12. Pressure equipment materials

12.1. Only approved basic and ancillary materials included in the list of materials accepted for this use may be used for the manufacture, repair or modification of pressure equipment. The list of materials must be prepared in relation to the safety class classification of the pressure equipment.

12.2. The basic and ancillary materials used must be suitable for the application throughout the expected lifetime of the pressure equipment.

12.3. Welding materials must comply with the requirements set out in Points 12 and 13, both separately and in conjunction with the structure.

13. Materials of parts of pressure equipment subjected to pressure

13.1. The basic materials affecting the technical safety of the pressure equipment must, both alone and in the design in conjunction with suitable ancillary material, meet the requirements of the technical specifications of the pressure equipment, in particular the requirements for suitable properties under all operating conditions under which the pressure equipment is to perform its function.

13.2. The parts of the selected equipment subjected to pressure are always considered to be parts of a pressure interface. Within the scope of the boundary of selected equipment, the material used for a permanent joint to parts of this selected equipment must be documented in accordance with the requirements of Points 13.9 or 13.11.

13.3. When selecting a material for the manufacture, assembly, repair or modification of pressure equipment, its chemical composition, physical and mechanical properties, weldability and suitability for operation in the operating conditions in which the pressure equipment is intended to perform its function must be taken into account.

13.4. Material used for the manufacture, assembly, maintenance, repair or modification of part of the pressure equipment must be

13.4.1. identical to the material of the original part specified in the technical specification of the pressure equipment;

13.4.2. included in the list of materials admissible for the use in question; or

13.4.3. other material, if the material pursuant to Point 13.4.1 or 13.4.2 cannot be used.

13.5. If a material pursuant to Point 13.4 of Point 13.4.2 is used that has characteristics other than those of the original material, it must be demonstrated that its characteristics are appropriate for the use in question, taking into account the operating conditions and the safety class in which the pressure equipment is classified.

13.6. If the proposed material is not included in the list of materials admissible for the given use, a specific evaluation of the proposed material must be carried out for pressure equipment set out in § 12(2) (a) or (b). The performance of the specific evaluation of the proposed material must be assessed by an authorised entity.

13.7. Suitable precautions must be taken during manufacture, assembly, repair or modification to ensure that the material used complies with the requirements of the technical specifications of the pressure equipment. In particular, documentation confirming the conformity of the materials used with the technical specifications of the material must be available for all basic and ancillary materials used.

13.8. Only material for which an assessment of conformity with the technical requirements for the material has been carried out may be used for the manufacture, assembly, repair or modification of pressure equipment.

13.9. The assessment of the material with regard to its conformity with the technical specification of the material must be documented by:

13.9.1. a material certificate issued by the manufacturer of the material, which, after supervision by an authorised entity and evaluation of material tests, is confirmed by an authorised entity in the case of material for pressure equipment set out in § 12(2)(a) or (b);

13.9.2. a material certificate issued by the manufacturer of the material, if the material is for pressure equipment set out in § 12(2)(c), and

13.9.3. a material certificate issued by the manufacturer of the material, in the case of material for pressure equipment set out in § 12(3).

13.10. Material for which a material certificate has been issued in accordance with Points 13.9.2 and 13.9.3 may be used for pressure equipment set out in § 12(2)(a) and (b) if additional material tests have been carried out to the extent specified by the manufacturer of the selected equipment or part of the selected equipment or the assembler on the basis of the results of the risk analysis so as to demonstrate that the material is suitable for use in this pressure equipment. The additional material tests referred to in this Point are in addition to the material certificate referred to in Points 13.9.2 and 13.9.3 and their results do not justify an increase in the permissible design strain above the values specified for the basic material.

13.11. The stipulation of the scope of the additional tests and their performance must be under the supervision of an authorised entity. The conformity of the results of the additional tests with the

technical specifications of the material must be assessed by an authorised entity. If the results of the checks coincide with the values specified in the technical specifications of the material, the authorised entity must issue an inspection report or certificate proving compliance with the conditions for the use of the material for pressure equipment set out in § 12(2)(a) or (b).

14. Material quality control
    14.1. Material quality control must be carried out to the extent and by the methods specified in the technical regulations, technical standards or technical specifications for materials.
    14.2. Semi-finished products for the manufacture of pressure equipment, in particular sheet metal, forgings, extrusions, castings, rolled steel for fasteners and semi-finished products for the manufacture of seals, must be manufactured in accordance with the requirements laid down in the design of the pressure equipment, technical standards or technical specifications that specify the scope and methods of inspection to verify their quality.
    14.3. For semi-finished products made of austenitic steels for the manufacture of pressure equipment in contact with the primary circuit medium, limit values for the cobalt content of the steel must be established.

Installation of pressure equipment

15. The installation of the pressure equipment must be carried out in accordance with a technological installation procedure comprising methods and installation procedures in such a way that all the required checks can be carried out. The technical requirements adopted in the design process apply during installation.
16. The specific processes used in the installation of the selected equipment or pressure equipment assembly must be carried out in accordance with the requirements for permanent joints, non-destructive checks and heat treatment set out in Points 6 to 8.
17. The quality of the installation must be verified on the basis of the plan or programme of checks according to which the installation is carried out.

B. Requirements for the method of ensuring conformity in the design, manufacture and installation of selected control equipment and parts thereof

1. Selected equipment and parts of selected equipment must be designed, manufactured and installed in such a way as to ensure technical safety when commissioned.

Design of selected control equipment

2. When designing selected control equipment,
    2.1. a risk analysis must be drawn up from the perspective of technical safety in order to identify and evaluate the risks involved; in order to evaluate these safety effects by means of a risk analysis, the required states in which the control equipment selected is to perform its function must be determined;

2.2. the technical solution of selected control equipment must take into account the result of the risk analysis according to Point 2.1;
2.3. when selecting the most suitable technical solution for the selected control equipment,
2.3.1. any foreseeable risk must be eliminated to a reasonably achievable extent; or
2.3.2. appropriate safeguards must be applied to limit the impacts of a risk that cannot be ruled out; and
2.4. the design of the selected equipment must be reviewed for suitability and adequacy of the specification of the technical requirements, verified for compliance with the technical requirements and validated for compliance with the technical requirements and its intended use.

Manufacture of selected control equipment

3. Selected control equipment must be manufactured in accordance with the technical documentation of the equipment, including the appropriate methods and the corresponding manufacturing procedures, so that all the prescribed checks can be carried out. The technical requirements adopted in the design process must be applied during manufacturing.
4. For the production of selected control equipment, procedures must be in place and followed to ensure identification of this equipment during its production.
5. During the manufacture of selected control equipment, checks must be carried out in accordance with the requirements set out in its technical documentation.

Installation of selected control equipment

6. Installation of selected control equipment must be carried out in accordance with a technological installation procedure comprising methods and installation procedures so that all the required checks can be carried out. The technical requirements adopted in the design process apply during installation.
7. The specific processes used in the installation of selected control equipment must be carried out in accordance with the requirements for permanent joints, non-destructive checks and heat treatment in Part A, Points 6 to 8, and the requirements for software development.
8. The quality of the installation must be verified on the basis of the inspection programme according to which the installation is carried out.

C. Requirements for the manner of ensuring conformity in the design, manufacture and installation of selected construction equipment and parts thereof

1. Selected equipment and parts of selected equipment must be designed, manufactured and installed in such a way as to ensure technical safety when commissioned.

Design of selected construction equipment

2. When designing selected construction equipment, its design must be examined from the point of view of the suitability and adequacy of stipulation of technical requirements, verified from the point of view of conformity with the technical requirements, and validated from the point of view of the conformity of the technical requirements and its intended use.

Manufacture and installation of selected construction equipment

3. Selected construction equipment must be designed, manufactured and assembled in accordance with technical documentation in such a way that all prescribed checks to ensure technical safety can be carried out. Technical requirements adopted in the design process must be applied in the construction process.
4. Production of concrete must take place in accordance with the prescribed production processes that guarantee, during the solidification process, the prescribed strength values and other properties set out in the design of the selected equipment. The production procedures must provide for checks on the prescribed values of strength and other properties specified in the design of the selected equipment.
5. The specific processes used for the installation of selected construction equipment must be carried out in accordance with the requirements for permanent joints, non-destructive checks and heat treatment set out in Points 6 to 8 of Part A.
6. Only metal and construction materials specified in the design of the selected equipment may be used for the manufacture and installation of selected construction equipment.

D. Requirements for the manner of ensuring conformity when commissioning selected equipment and parts thereof

1. Selected equipment, or parts thereof, must be manufactured and supplied in such a way as to ensure its safe and correct installation and connection.
2. After the completion of installation of technology and construction of a nuclear installation that includes selected equipment, it must be verified that the technical specifications and the unambiguous identification of the location of the selected equipment are in accordance with the nuclear installation as built, and that this selected equipment has the corresponding accompanying technical documentation supplied by the manufacturer of the selected equipment or part thereof and by the contractor performing installation and construction within the scope of Annex 4 to this Decree, and that it contains as-built information regarding deliveries and works, specifically
   2.1. before the initial loading of nuclear fuel into the nuclear reactor or, for a nuclear installation without a nuclear reactor, in the period immediately after the completion of the supply or works; and
   2.2. before the selected equipment is accepted by the operator of the nuclear installation and used for the purpose for which it was constructed.
3. During the commissioning of a nuclear installation, selected equipment must be tested individually in sequence in accordance with a pre-prepared
   3.1. programme of operational checks;
   3.2. pre-operational ageing management programme for the first physical start-up; and
   3.3. operational ageing management programme for first power start-up and trial operation

in such a way as to verify their compliance with the technical requirements pursuant to Annex 1 to this Decree that apply during operation, to enable functional verification of the entire nuclear installation before the start of trial operation.

4. Prior to the start of each stage of commissioning of selected equipment, the following must be documented:
   4.1. training of operators and managers with a list of their names and functions;
   4.2. the competence of staff to manage and carry out checks of selected equipment;
   4.3. the readiness of selected equipment in the relevant stage; and
   4.4. fulfilment of further requirements established by the Office on the basis of an evaluation of the previous stage of commissioning.
5. The requirements of Points 1 to 4 do not apply to selected equipment set out in § 12(3)(e).

E. Requirements for the method of ensuring conformity during the operation of selected equipment and parts thereof

1. Selected equipment must be operated in such a way as to maintain its technical safety during operation.
2. During operation, the accompanying technical documentation of selected equipment must be supplemented by further evidence of the repair, maintenance or modification of this equipment. A system must be in place to maintain the accompanying technical documentation in such a way that compliance with the technical requirements for the selected equipment can be verified.
3. Selected equipment can only be assembled and disassembled under predetermined safe conditions and in accordance with the regulations for assembly, disassembly and recommissioning.
4. Selected equipment must be operated in accordance with the requirements of internal regulations and other documentation for the operation of the nuclear installation. The technical requirements and recommendations of the manufacturer of the selected equipment must be included in the regulations for the maintenance and operation of the selected equipment.
5. Selected equipment may be operated and used only for the purposes and under the conditions for which it is intended and in accordance with the design of the nuclear installation. Technical and organisational measures must be taken to ensure that selected equipment is operated in the conditions for which it was designed, does not endanger human health and does not pose an unacceptable risk of damage to property.
6. During operation of selected equipment, a system must be in place to monitor and document deviations from normal operation that could lead to malfunctions and a reduction in the level of technical safety of the selected equipment.
7. During the operation of selected equipment, as part of the established process of ageing management of selected equipment, continuous monitoring of its condition and identification of the evolution of the effects of ageing and the

application of degradation mechanisms that could lead to a reduction in the level of technical safety of the selected equipment must be carried out.

8. During the operation of selected equipment, a system of maintenance and a system of checks carried out during the operation of the selected equipment must be put in place, which must:
   8.1. be implemented taking into account the operating conditions affecting the technical safety of the equipment; and
   8.2. establish technical and organisational measures to ensure compliance.
9. Maintenance, repair or modification of selected equipment in operation must be carried out in accordance with the requirements for the method of ensuring conformity in the design, manufacture, installation and commissioning of selected equipment set out in Parts A to D; where specific processes are carried out in the maintenance, repair or modification of selected equipment in operation, they must be carried out in accordance with the requirements for permanent joints, non-destructive checks and heat treatment set out in Part A, Points 6 to 8.
10. During maintenance, repair and modification of selected equipment, oversight must be carried out over the contractor, verifying that the maintenance, repair or modification activities carried out on the selected equipment are carried out in accordance with documentation relating to the preparation and performance of repairs, maintenance or modification of selected equipment.
11. Activities on selected control equipment may be carried out only by personnel qualified in accordance with Government Regulation No 194/2022 on requirements for professional competence to perform activities on electrical equipment and for professional competence in electrical technology.
12. The requirements of Points 1 to 11 do not apply to selected equipment set out in § 12(3)(e).’.

71. Annex 3 reads as follows:

‘Annex 3 to Decree No 358/2016

Requirements for technical documentation of selected equipment

The technical documentation of selected equipment must be clearly drawn up in such a way as to enable conformity assessment to be carried out to the extent laid down in this Decree.

A. Technical documentation for the design, manufacture and installation of pressure equipment and certain other selected equipment and packaging for the transport, storage and disposal of spent nuclear fuel

Technical documentation for the design, manufacture and installation of pressure equipment and other selected equipment set out in § 12(3)(d) and packaging for the transport, storage and disposal of spent nuclear fuel must include

1. the name of the selected equipment, its identification and description;
2. identification of the manufacturer;
3. the design of the selected equipment;
4. connection schematics;
5. manufacturing drawings and schematics and drawings of assemblies and sub-assemblies containing
   - 5.1. indication of the prescribed quality and condition of the metallurgical blanks or other parts of the selected equipment;
   - 5.2. indication of the prescribed quality of ancillary materials;
   - 5.3. the dimensions and thickness of the walls and the data necessary for their dimensioning;
   - 5.4. the location, type, dimensions and values of the factors of welded joints and their classification level;
   - 5.5. the type of checks, test media and their parameters and the acceptance criteria for the checks;
   - 5.6. the descriptions and explanations necessary for the understanding of drawings, schematics and functions of selected equipment; and
   - 5.7. the maximum allowable pressure, the calculated temperature and the test pressure in the case of pressure equipment;
6. technical data on pressure accessories, including their technical documentation if they are separate selected equipment;
7. technical details of safety accessories and accessories that ensure the functionality of the pressure equipment;
8. a list of the technical regulations, technical standards and technical specifications that were or will be used;
9. proof of suitability of the solutions used in the design of the selected equipment;
10. the results of strength calculations, service life calculations, including the conditions of their validity, seismic resistance calculations and other important technical data prepared in accordance with applicable technical standards,

technical specifications or new information in the area of science and technology;

11. degradation mechanisms or impacts of ageing included in lifetime calculations;
12. the results of the technical safety risk analysis performed during the design of the selected equipment;
13. documents attesting the conformity of the material with the technical specifications for the basic and ancillary materials used in the manufacture of the selected equipment or parts thereof;
14. technical specifications for the manufacture and installation of the selected equipment or similar documents containing
    14.1. the technical specifications for basic and ancillary materials or semi-finished products;
    14.2. specific requirements for material treatment technology, in particular requirements for the heat treatment process and internal crystalline structure and homogeneity;
    14.3. a description of the expected operating conditions;
    14.4. data relevant to reliability and durability and other data relevant to technical safety;
    14.5. a description of the conduct of the input, inter-operational and output checks, the criteria for the acceptability of the checks, the media used for these checks and their parameters;
    14.6. the method and scope of verification of the technical condition of the selected equipment during its operation; and
    14.7. a description of the scope of the accompanying technical documentation of the selected equipment;
15. inspection plans and programmes for the design, manufacture and installation of selected equipment;
16. a preliminary ageing management programme;
17. a list of the parts of selected equipment and the technical requirements for these parts;
18. a description of the manufacturing or installation technological processes, including a description of the technical and organisational measures;
19. regulations for the installation, commissioning or operation of the selected equipment;
20. a list of special process supervisors and of the personnel responsible for checking and evaluating permanent joints, including their authorisation and their name, surname and date of birth, if permanent joints are made during manufacture or installation;
21. a list of the persons carrying out special processes, including the type and validity of their authorisation and their name, surname and date of birth, if a specific process is carried out during manufacture or installation; and
22. specimens of records, including certificates and inspection reports, used in the manufacture or installation of the selected equipment.

B. Technical documentation for the design, manufacture and installation of selected control equipment

Technical documentation for the design, manufacture and installation of selected control equipment must include

1. the name of the selected equipment, its identification and description;
2. the design of the selected equipment;
3. identification of the manufacturer;
4. drawings and diagrams of components and circuits containing
   4.1. an indication of the prescribed quality of the parts of the selected equipment; and
   4.2. the descriptions and explanations necessary for the understanding of drawings, schematics and functions of the selected equipment; and
5. a list of the technical regulations, technical standards and technical specifications that were or will be used;
6. the results of the technical safety risk analysis performed during the design of the selected equipment;
7. instructions for use;
8. the results of design calculations;
9. the results of service life calculations, including the conditions of their validity, seismic resistance calculations and other important technical data prepared in accordance with applicable technical standards, technical specifications or new information in the area of science and technology;
10. degradation mechanisms or impacts of ageing included in lifetime calculations;
11. inspection plans and programmes for the design, manufacture and installation of selected equipment;
12. a preliminary ageing management programme;
13. reports of type tests carried out with the results of assessments by independent testing laboratories, including accredited testing laboratories of individual manufacturers;
14. a list of the parts of selected equipment and the technical requirements for these parts;
15. requirements for inspections of selected equipment and parts thereof;
16. a list of special process supervisors and of the personnel responsible for checking and evaluating permanent joints, including their authorisation and their name, surname and date of birth, if permanent joints are made during manufacture or installation;
17. a list of the persons carrying out special processes, including the type and validity of their authorisation and their name, surname and date of birth, if a specific process is carried out during manufacture or installation;
18. a description of the scope of the accompanying technical documentation of the selected equipment; and
19. regulations for the installation. commissioning and operation of the selected equipment.

C. Technical documentation for the design, production and installation of selected construction equipment

Technical documentation for the design, manufacture and installation of selected construction equipment must include

1. the name of the selected equipment, its identification and description;
2. the design of the selected equipment;
3. a description of the building component into which it will be incorporated;
4. identification of how it will be incorporated or used in the building component;
5. identification of the manufacturer;
6. a list of the technical regulations, technical standards and technical specifications that were or will be used;
7. complete static calculations and dynamic calculations, if such have been performed;
8. manufacturing drawings and drawings of the building component into which the selected equipment will be incorporated, containing
   8.1. an indication of the prescribed quality of the parts of the selected equipment;
   8.2. an indication of the prescribed quality of the materials used; and
   8.3. the descriptions and explanations necessary for the understanding of drawings and functions of the selected equipment;
9. procedures for the manufacture, installation and use of the selected equipment, including requirements for
   9.1. pouring concrete and the execution of concrete reinforcement;
   9.2. the execution of bushings, hermetic doors, hatches and closures;
   9.3. surface treatment of building structures;
   9.4. performance of individual outlets for individual leak checks of individual parts of pressure equipment that is part of the protective envelope system; and
   9.5. the execution of building electrical wiring;
10. data on the properties of construction or metal materials;
11. the results of service life calculations, including the conditions of their validity, seismic resistance calculations and other important technical data prepared in accordance with applicable technical standards, technical specifications or new information in the area of science and technology;
12. degradation mechanisms or impacts of ageing included in lifetime calculations;
13. plans and programme of checks for the design, manufacture and installation of selected equipment;
14. a preliminary ageing management programme;
15. a list of special process supervisors and of the personnel responsible for checking and evaluating permanent joints, including their authorisation and their name, surname and date of birth, if permanent joints are made during manufacture or installation;
16. a list of the persons carrying out special processes, including the type and validity of their authorisation and their name, surname and date of birth, if a specific process is carried out during manufacture or installation;

17. records with the results of the design and construction calculations and tests carried out, or certificates if they were issued prior to the conformity assessment; and
18. a description of the scope of the accompanying technical documentation of selected equipment.

D. Technical documentation for the design and manufacture of selected equipment that is fuel element cladding and the fuel assembly structure

The technical documentation for selected equipment set out in § 12(3)(e) must include

1. the name of the selected equipment, its identification and description;
2. identification of the manufacturer;
3. the design of the selected equipment;
4. manufacturing drawings and schematics and drawings of assemblies and sub-assemblies containing
   4.1. indication of the prescribed quality and condition of the metallurgical blanks or other parts of the selected equipment;
   4.2. indication of the prescribed quality of ancillary materials;
   4.3. the dimensions and thickness of the walls and the data necessary for their dimensioning;
   4.4. the location, type, dimensions and values of the factors of welded joints and their classification level;
   4.5. the type of checks, test media and their parameters and the acceptance criteria for the checks;
   4.6. the descriptions and explanations necessary for the understanding of drawings, schematics and functions of selected equipment; and
5. a list of the technical regulations, technical standards and technical specifications that were or will be used;
6. documents attesting the conformity of the material with the technical specifications for the basic and ancillary materials used in the manufacture of the selected equipment or parts thereof;
7. a description of the scope of the accompanying technical documentation of the selected equipment;
8. a description of the manufacturing or installation technological processes, including a description of the technical and organisational measures; and
9. specimens of records, including certificates and inspection reports, used in the manufacture or installation of the selected equipment.’.

72. Annex 4 reads as follows:

‘Annex 4 to Decree No 358/2016

Requirements for accompanying technical documentation of selected equipment

The accompanying technical documentation of selected equipment must be drawn up clearly to document, to the extent necessary, the results of compliance assurance and verification for the entire duration of the operation of this equipment.

A. Accompanying technical documentation for pressure equipment and certain other selected equipment and packaging for the transport, storage and disposal of spent nuclear fuel

Accompanying technical documentation for pressure equipment and other selected equipment set out in § 12(3)(d) and packaging for the transport, storage and disposal of spent nuclear fuel must include

1. a passport prepared by the manufacturer containing
   1.1. the name of the selected equipment, its identification and description;
   1.2. a declaration of conformity;
   1.3. a plan and programme for checks during the design, manufacture and installation of the selected equipment, evaluated in terms of the fulfilment of the requirements contained therein;
   1.4. material certificates;
   1.5. records of checks carried out and their evaluation;
   1.6. records of heat treatment; and
   1.7. records from the final assessment;
2. the results of strength calculations, service life calculations, including the conditions of their validity, seismic resistance calculations and other technical data prepared in accordance with applicable technical standards, technical specifications and new information in the area of science and technology;
3. a preliminary ageing management programme;
4. drawings of the selected equipment containing:
   4.1. a drawing of the assembly with the main connection dimensions;
   4.2. drawings of the individual parts of the selected equipment;
   4.3. a drawing for the expected extent of repairs, if part of the instructions;
   4.4. axonometric diagrams with identification of individual welds, hinges, fixed points and supports, in the case of piping routes; and
   4.5. drawings identifying individual welds, bushings, manholes, hatches, hermetic doors or other devices ensuring the hermeticity of the protective envelope, in the case of pressure equipment forming the protective envelope system;
5. evidence of qualification of the procedure for creating permanent joints;
6. a list of personnel creating permanent joints, including the type and validity of their licenses and their name, surname and date of birth;

7. a list of special process supervisors and of the personnel responsible for checking and evaluating permanent joints, including their authorisation and their name, surname and date of birth;
8. technical data on pressure accessories, including their technical documentation if they are separate selected equipment;
9. technical details of safety accessories and accessories that ensure the functionality of the pressure equipment;
10. details of repairs carried out during manufacture or installation;
11. documentation containing information relating to technical safety during the operation of selected equipment, in particular operating instructions and instructions for installation, commissioning and operation, including instructions for repair and maintenance;
12. documentation containing information relating to the ageing management of the selected equipment during its commissioning and operation, in particular the monitored parameters and their limit values for monitoring and evaluating the ageing of the selected equipment and measures when the limit values of the monitored parameters are reached;
13. records of repairs and maintenance carried out on the selected equipment, including records of the results of inspections carried out after repair, maintenance or re-installation following repair and/or maintenance of the selected equipment, or references to where these records are kept and stored; and
14. records of changes made to the selected equipment, including records of the results of checks carried out after the reassembly of that equipment, or references where such records are kept and stored.

B. Accompanying technical documentation of selected control equipment

The accompanying technical documentation for selected control equipment must include:

1. the name of the selected equipment, its identification and description;
2. a declaration of conformity;
3. a plan and programme for checks during the design, manufacture and installation of the selected equipment, evaluated in terms of the fulfilment of the requirements contained therein;
4. a preliminary ageing management programme;
5. records of checks and inspection reports and their evaluation;
6. documentation containing information relating to technical safety during the operation of selected equipment, in particular operating instructions and instructions for installation, commissioning and operation, including instructions for repair and maintenance;
7. a list of personnel creating permanent joints, including the type and validity of their licenses and their name, surname and date of birth;
8. a list of special process supervisors and of the personnel responsible for checking and evaluating permanent joints, including their authorisation and their name, surname and date of birth;

9. laying plans, including evidence of fire protection measures in cable ducts and areas where cables are located;
10. drawings of the selected equipment, including the internal schematics of the switchboard;
11. evidence of qualification of the procedure for creating permanent joints;
12. records of repairs and maintenance carried out on the selected equipment, including records of the results of checks carried out after repair, maintenance or re-installation following repair and/or maintenance of the selected equipment, or references to where these records are kept and stored;
13. documentation containing information relating to the ageing management of the selected equipment during its commissioning and operation, in particular the monitored parameters and their limit values for monitoring and evaluating the ageing of the selected equipment and measures when the limit values of the monitored parameters are reached;
14. records of changes made to the selected equipment, including records of the results of checks carried out after the reassembly of that equipment, or references where such records are kept and stored.

C. Accompanying technical documentation for selected construction equipment

The accompanying technical documentation for selected construction equipment must include:

1. the name of the selected equipment, its identification and description;
2. a declaration of conformity;
3. a plan and programme for checks during the design, manufacture and installation of the selected equipment, evaluated in terms of the fulfilment of the requirements contained therein;
4. a preliminary ageing management programme;
5. the results of strength calculations, service life calculations, including the conditions of their validity, seismic resistance calculations and other technical data prepared in accordance with applicable technical standards, technical specifications and new information in the area of science and technology;
6. records of checks and their evaluation, including records of checks of properties of concrete;
7. drawings of selected equipment and drawings of the building component into which the selected equipment will be incorporated;
8. documentation containing information on the properties of the selected equipment;
9. a list of personnel creating permanent joints, including the type and validity of their licenses and their name, surname and date of birth;
10. a list of special process supervisors and of the personnel responsible for checking and evaluating permanent joints, including their authorisation and their name, surname and date of birth;
11. identification of how it will be incorporated or used in the building component;

12. documentation containing information relating to technical safety during the operation of selected equipment, in particular instructions for commissioning and operation, including instructions for repair and maintenance; and
13. documentation containing information relating to the ageing management of the selected equipment during its commissioning and operation, in particular the monitored parameters and their limit values for monitoring and evaluating the ageing of the selected equipment and measures when the limit values of the monitored parameters are reached.

D. Accompanying technical documentation for selected equipment that is fuel element cladding and the fuel assembly structure

Accompanying technical documentation for selected equipment that is fuel element cladding and the fuel assembly structure must include:

1. a document produced by the manufacturer containing:

1.2. the name of the selected equipment, its identification and description;

1.3. a declaration of conformity;

1.4. material certificates;

2. handling records’.

73. In Annex 6, Point A, Point 3, the word ‘procedures’ is replaced by the words ‘in advance’.
74. In Annex 6, Point A, Point 3, the words ‘in programme of checks of’ are replaced by the word ‘procedures’.
75. In Annex 6, Point B, Point 1.5.4.3, the word ‘welding’ is deleted.
76. In Annex 6, Point B, Point 1.5.4.3, the words ‘of special processes’ are inserted after the word ‘supervision’.
77. In Annex 6, Point B, Point 1.10, the words ‘Decree No 18/1979 specifying selected pressure equipment and laying down some requirements to ensure its safety, as amended’ are replaced by the words ‘Government Regulation No 192/2022 on selected pressure equipment and requirements to ensure its safety’.
78. In Annex 6, Point B, the following Point 1.11 is inserted after Point 1.10:

‘1.11. The final post-manufacture assessment of selected equipment set out in § 12(3)(e) consists only of a final test, which must include
1.11.1. checking that the selected equipment is complete; and
1.11.2. checking that the quality records of the selected equipment are complete, including records on the quality of fuel element cladding ensuring its hermeticity.’.

Points 1.11 to 1.13.2 become Points 1.12 to 1.14.2.

79. Annex 7 reads as follows:

‘Annex 7 to Decree No 358/2016

Conformity assessment procedures

1. CONFORMITY ASSESSMENT PROCEDURE A (INTERNAL PRODUCTION MANAGEMENT)
    1. The manufacturer, importer or assembler of selected equipment after manufacture carrying out the conformity assessment in accordance with this procedure must ensure that the selected equipment complies with the requirements of this Decree and issue a declaration of conformity.
    2. The manufacturer, importer or assembler of selected equipment after manufacture must ensure that an initial test of a sample of the selected equipment to be manufactured (hereinafter the ‘production type’) is carried out and assess whether the production type complies with technical regulations, stipulated technical standards or technical specifications in the case of selected construction equipment pursuant to § 12(3)(c).
    3. The manufacturer, importer or assembler of selected equipment after manufacture must take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the selected equipment with the requirements of this Decree.
    4. The manufacturer, importer or assembler of selected equipment after manufacture must ensure that a final assessment of the selected equipment is carried out.
    5. If selected equipment meets the requirements of this Decree, the manufacturer, importer or assembler of selected equipment after manufacture must mark it with a conformity mark together with its identification and must issue a declaration of conformity; in the case of selected construction equipment pursuant to § 12(3)(c), the declaration of conformity may be issued only if the selected equipment is in conformity with the production type assessed pursuant to Point 2.
2. CONFORMITY ASSESSMENT PROCEDURE A1 (INTERNAL PRODUCTION CONTROL WITH SURVEILLANCE OF FINAL ASSESSMENT)
    1. The manufacturer, importer or assembler of selected equipment after manufacture carrying out the conformity assessment by this procedure must, in accordance with this procedure and conformity assessment procedure A and under the surveillance of an accredited or authorised entity for the final assessment, ensure that the selected equipment complies with the requirements of this Decree and issue a declaration of conformity.
    2. The accredited or authorised entity must oversee the final assessment in the form of unannounced inspections in which
        2.1. it verifies that the final assessment of the selected equipment is carried out in accordance with the requirements for the final assessment in Annex 6 to this Decree; and
        2.2. it takes samples of the selected equipment from production or storage areas for inspection.

3. The accredited or authorised entity determines the quantity of selected equipment in the sample for which it will participate in the final assessment.
4. In cases where one or more pieces of selected equipment are non-compliant, the accredited or authorised entity must specify the appropriate measures to rectify the non-compliance.
5. The accredited or authorised entity must issue an inspection report based on the results of the surveillance of the final assessment.
6. If the performance of the final assessment meets the requirements of this Decree, the accredited or authorised entity must mark the selected equipment for which it has supervised the final assessment with its identification; the marking of the selected equipment with the identification of the accredited or authorised entity may be carried out by the manufacturer or importer on the basis of a mandate from the accredited or authorised entity.

3. CONFORMITY ASSESSMENT PROCEDURE B (PRODUCTION TYPE EXAMINATION)
   1. The manufacturer or importer must ensure that the production type meets the requirements of this Decree in accordance with this procedure.
   2. A production type may include more than one modification of the selected equipment provided that the differences between the modifications do not affect the level of technical safety.
   3. The manufacturer or importer must submit a conformity assessment application to the selected authorised entity. The application must contain:
      3.1. identification of the manufacturer or importer, namely:
         3.1.1. the name(s), surname, residential or business address and identification number, if assigned, in the case of a natural person; or
         3.1.2. the business name, registered office and identification number in the case of a corporate entity;
      3.2. a written declaration that a conformity assessment contract has not been concluded with another authorised entity;
      3.3. the technical documentation for the selected equipment;
      3.4. the production type; and
      3.5. other information on the selected equipment necessary for the conformity assessment, in particular the safety class in which it has been placed.
   4. The authorised entity will request additional samples if necessary for the performance of the test programme.
   5. The authorised entity must
      5.1. review the technical documentation of the selected equipment, including an assessment of whether it meets the requirements set out in Annex 3 to this Decree;
      5.2. assess the materials used, including assessment of the material certificates pursuant to Points 13.9 or 13.11 of Part A of Annex 2 to this Decree, unless they have previously been assessed by another authorised entity;
      5.3. check technological procedures for the execution of permanent joints in accordance with Point 6.5 of Part A of Annex 2 to this Decree and

approve these procedures, unless they have already been approved by another authorised entity;

5.4. verify that personnel performing special processes comply with the requirements of Points 6.5 and 7 of Part A of Annex 2 to this Decree;

5.5. perform or arrange the performance of the necessary checks to ascertain whether technical standards or technical specifications have been correctly applied;

5.6. agree with the manufacturer, importer or assembler of selected equipment after manufacture on the place where verification will be carried out whether the manufacturing type has been manufactured in accordance with the reviewed technical documentation;

5.7. verify that the production type complies with the requirements of this Decree, including carrying out the necessary related checks; and

5.8. prepare a report on the evaluation of the activities pursuant to Points 5.1 to 5.7 and their results.

6. If the manufacturing type complies with the requirements of this Decree, the authorised entity must issue a type examination certificate to the manufacturer, importer or assembler of the selected equipment after manufacture. The certificate must contain:

6.1. the name of the selected equipment, its identification and basic description;

6.2. the identification data of the manufacturer or importer, namely

6.2.1. the name(s), surname, residential or business address and identification number, if assigned, in the case of a natural person; or

6.2.2. the business name, registered office and identification number in the case of a corporate entity;

6.3. the conclusions of the production type examination;

6.4. the period of validity of the certificate, which must not exceed 10 years; and

6.5. other documents necessary to demonstrate the conformity of the production type with the requirements of this Decree.

7. The manufacturer or importer must inform the authorised entity that issued the type examination certificate of any changes to the production type described in the type examination certificate. If a change in the production type may affect the conformity of the selected equipment with the technical requirements, the authorised entity must examine the change in accordance with the procedure set out in Point 5 and, if the change meets the requirements of this Decree, issue an addendum to the original type examination certificate.

8. The authorised entity must keep a copy of the type examination certificate and the activity evaluation report.

9. The authorised entity must inform the Office of any issued, withdrawn, suspended or otherwise restricted type examination certificates or additions thereto and make them available to the Office upon request.

10. The authorised entity must inform other authorised entities performing conformity assessment of revoked, suspended or otherwise restricted type examination certificates or additions thereto.

4. CONFORMITY ASSESSMENT PROCEDURE B1 (DESIGN EXAMINATION OF SELECTED EQUIPMENT)
    1. The manufacturer or importer must ensure, in accordance with this procedure, that the design of the selected equipment complies with the requirements of this Decree.
    2. This conformity assessment procedure cannot be used for the experimental design method.
    3. The manufacturer or importer must submit a conformity assessment application to the selected authorised entity. The application must contain:
        3.1. identification of the manufacturer or importer, namely:
            3.1.1. the name(s), surname, residential or business address and identification number, if assigned, in the case of a natural person; or
            3.1.2. the business name, registered office and identification number in the case of a corporate entity;
        3.2. a written declaration that a conformity assessment contract has not been concluded with another authorised entity;
        3.3. the technical documentation for the selected equipment;
        3.4. the design of the selected equipment; and
        3.5. other information on the selected equipment necessary for the conformity assessment, in particular the safety class in which it has been placed.
    4. The design of the selected equipment may include several modifications of the designed selected equipment, provided that the differences between the modifications do not affect its level of technical safety.
    5. The authorised entity must
        5.1. review the technical documentation of the selected equipment, including an assessment of whether it meets the requirements set out in Annex 3 to this Decree;
        5.2. assess the materials used, including assessment of the material certificates pursuant to Points 13.9 or 13.11 of Part A of Annex 2 to this Decree, unless they have previously been assessed by another authorised entity;
        5.3. check technological procedures for the execution of permanent joints in accordance with Point 6.5 of Part A of Annex 2 to this Decree and approve these procedures, unless they have already been approved by another authorised entity;
        5.4. verify that personnel performing special processes comply with the requirements of Points 6.5 and 7 of Part A of Annex 2 to this Decree;
        5.5. perform or arrange the performance of the necessary checks to ascertain whether technical standards or technical specifications have been correctly applied;
        5.6. verify that the design of the selected equipment complies with the requirements of this Decree; and
        5.7. prepare a report on the evaluation of the activities set out in Points 5.1 to 5.6 and their results.

6. If the design of the selected equipment complies with the requirements of this Decree, the authorised entity must issue a design examination certificate to the manufacturer or importer. The certificate must contain:
    6.1. the name of the selected equipment, its identification and basic description;
    6.2. the identification data of the manufacturer or importer; namely
        6.2.1. the name(s), surname, residential or business address and identification number, if assigned, in the case of a natural person; or
        6.2.2. the business name, registered office and identification number in the case of a corporate entity;
    6.3. the conclusions of the examination of the design of the selected equipment;
    6.4. the period of validity of the certificate, which must not exceed 10 years; and
    6.5. other documents necessary to demonstrate the conformity of the design of the selected equipment with the requirements of this Decree.
7. The manufacturer or importer must inform the authorised entity that issued the design examination certificate of any changes to the design of the selected equipment described in the design examination certificate. If a change in the design of the selected equipment may affect the conformity of the selected equipment with the technical requirements, the authorised entity must examine the change in accordance with the procedure set out in Point 5 and, if the change meets the requirements of this Decree, issue an addendum to the original design examination certificate.
8. The authorised entity must keep a copy of the design examination certificate and the activity evaluation report.
9. The authorised entity must inform the Office of issued, withdrawn, suspended or otherwise restricted design examination certificates or additions thereto and make them available to the Office upon request.
10. The authorised entity must inform other authorised entities performing conformity assessment of revoked, suspended or otherwise restricted design examination certificates or additions thereto.

5. CONFORMITY ASSESSMENT PROCEDURE D (CONFORMITY BASED ON MANUFACTURING QUALITY ASSURANCE)
    1. The manufacturer, importer or assembler of the selected equipment after manufacture must, in accordance with this procedure and under the supervision of an authorised entity, ensure that the selected equipment is in conformity with:
        1.1. the production type as described in the type examination certificate under conformity assessment procedure B; or
        1.2. the design of the selected equipment as described in the design examination certificate under conformity assessment procedure B1
        and meets the requirements of this Decree, and issue a declaration of conformity.

2. The manufacturer or entity installing the selected equipment after manufacture must have a quality system in place for manufacture or installation, in accordance with an established management system. The importer must have a system of checks in place for selected equipment.
3. The manufacturer, importer or assembler of selected equipment after manufacture must ensure that a final assessment of the selected equipment is carried out.
4. The manufacturer, importer or assembler of selected equipment after manufacture must submit a conformity assessment application to the selected authorised person. The application must contain:
    4.1. identification of the manufacturer, importer or assembler after manufacture of the selected equipment, namely
        4.1.1. the name(s), surname, residential or business address and identification number, if assigned, in the case of a natural person; or
        4.1.2. the business name, registered office and identification number in the case of a corporate entity;
    4.2. a written declaration that a conformity assessment contract has not been concluded with another authorised entity;
    4.3. documentation relating to the method of ensuring the quality of manufacture or installation, or the documentation of the inspection system, in the case of an application submitted by the importer;
    4.4. the number of the EC-type examination certificate or the EC design examination certificate;
    4.5. the technical documentation of the selected equipment; and
    4.6. other information on the selected equipment necessary for the conformity assessment, in particular the safety class to which it is assigned.
5. The authorised entity must assess the quality system of the manufacturer or assembler of the selected equipment after manufacture and verify that
    5.1. the method of quality assurance ensures the conformity of the selected equipment with the production type described in the type examination certificate or the design of the selected equipment described in the design examination certificate, including conformity with the technical documentation of the selected equipment, and with the requirements of this Decree; and
    5.2. the documentation for the quality system contains
        5.1.1. a description of the quality objectives and the organisational structure, including the rights and obligations of the persons who plan and direct the manufacture or assembly of the selected equipment;
        5.1.2. a description of the manufacturing processes, the method of management and quality assurance of the processes and other systematic measures to be used, in particular those ensuring compliance with the essential requirements to ensure technical safety;

5.1.3. a description of the checks to be carried out before, during and after manufacture or assembly, indicating the frequency with which they are to be carried out and the acceptance criteria applied to these checks;
5.1.4. quality assurance records for the selected equipment; and
5.1.5. a description of the means of monitoring the achievement of the prescribed level of quality of the selected equipment and of assessing the effectiveness of the management system in ensuring its quality.

6. The quality system must be assessed by an authorised entity in the operating premises of the manufacturer or assembler of the selected equipment after manufacture. The assessment must be attended by an employee of the authorised entity who has experience in the assessment of the management system and knowledge of the requirements of this Decree. The authorised entity must notify the manufacturer, the importer or the assembler of the selected equipment after manufacture of the results of the assessment of the quality system, including the requirements to rectify any non-conformities.
7. The importer must ensure assessment of a foreign manufacturer's quality system pursuant to Points 5 and 6. The authorised entity must assess the importer's inspection system and verify that the inspections it carries out on the selected equipment ensure conformity of the selected equipment with the production type described in the type examination certificate or the design of the selected equipment described in the design examination certificate, including conformity with the technical documentation of the selected equipment, and with the requirements of this Decree.
8. If the quality assurance method complies with the requirements set out in Point 5, the authorised entity must issue a document of approval of the quality system to the manufacturer, importer or assembler of the selected equipment after manufacture.
9. The manufacturer, importer or assembler of the selected equipment after manufacture must comply with the requirements set out in the quality system as approved by the authorised entity and ensure that it remains substantially correct and effective.
10. The manufacturer, importer or assembler of selected equipment after manufacture must provide the authorised entity that has approved the quality system with information about planned changes to the quality system described in the quality system approval document. The authorised entity must assess the proposed change and decide whether the modified quality system complies with the requirements set out in Point 5. The authorised entity must communicate its assessment findings, including the reasons for them, to the manufacturer, importer or assembler of the selected equipment after manufacture and, if the change to the quality system complies with the requirements referred to in Point 5, must issue an addendum to the original quality system approval document.
11. Surveillance by an authorised entity

11.1. Surveillance must ensure that the manufacturer, importer or assembler of selected equipment after manufacture duly fulfils the requirements resulting from the approved quality system.

11.2. The manufacturer, importer or assembler of the selected equipment after manufacture must allow the authorised entity access to the manufacturing, inspection and testing premises and warehouses for purposes of exercising surveillance and provide it with all necessary information.

11.3. For surveillance purposes, the authorised entity must have a system of checks in place that stipulates the type and frequency of checks to be carried out on the manufacturer, importer or assembler of the selected equipment after manufacture.

11.4. The authorised entity must carry out regular checks to ensure that the manufacturer, importer or assembler of selected equipment after manufacture maintains and applies a quality system as approved. The frequency of periodic checks must be such that a new full verification is carried out at least once every 12 months.

11.5. Within the scope surveillance, the authorised entity must perform unannounced checks of the manufacturer, importer or assembler of selected equipment after manufacture. The type and frequency of unannounced checks must be stipulated by the authorised entity, taking the following into account in particular:

11.5.1. the safety class to which the selected equipment is assigned;

11.5.2. the results of previous inspections checks out as part of surveillance;

11.5.3. the need to monitor compliance with measures to rectify non-conformity; and

11.5.4. significant changes in manufacturing organisation, concept or technology.

11.6. During these checks, the authorised entity may carry out, or have carried out, checks to verify that the quality system is functioning correctly.

11.7. The authorised entity must draw up reports on the results of the surveillance on the basis of the checks carried out and forward them to the manufacturer, importer or assembler of the selected equipment after manufacture.

12. If the selected equipment conforms to the requirements of this Decree and is in conformity with the production type as described in the type examination certificate or the design of the selected equipment as described in the design examination certificate, the manufacturer, importer or assembler of the selected equipment after manufacture must affix the conformity mark together with their identification and that of the authorised entity and issue a declaration of conformity.

13. The authorised entity must keep a copy of the quality system approval document and the surveillance results report.

14. The authorised entity must inform the Office of any issued, withdrawn, suspended or otherwise restricted management system approval documents or addenda thereto and make them available to the Office on request.
15. The authorised entity must inform other conformity assessment entities of withdrawn, suspended or otherwise restricted quality system approval documents or addenda thereto.

6. CONFORMITY ASSESSMENT PROCEDURE D1 (MANUFACTURING QUALITY ASSURANCE)
    1. The manufacturer, importer or assembler of selected equipment after manufacture must, in accordance with this procedure and under the surveillance of the authorised entity, ensure that the selected equipment meets the requirements of this Decree and issue a declaration of conformity.
    2. The manufacturer or assembler of the selected equipment after manufacture must have a production quality system in place, in accordance with the established management system. The importer must have a system of checks in place for selected equipment.
    3. The manufacturer, importer or assembler of selected equipment after manufacture must ensure that a final assessment of the selected equipment is carried out.
    4. The manufacturer, importer or assembler of selected equipment after manufacture must submit a conformity assessment application to the selected authorised person. The application must contain:
        4.1. identification of the manufacturer, importer or assembler after manufacture of the selected equipment, namely
            4.1.1. the name(s), surname, residential or business address and identification number, if assigned, in the case of a natural person; or
            4.1.2. the business name, registered office and identification number in the case of a corporate entity;
        4.2. a written declaration that a conformity assessment contract has not been concluded with another authorised entity;
        4.3. documentation relating to manufacturing quality assurance or documentation for a system of checks, in the case of an application submitted by an importer;
        4.4. the technical documentation of the selected equipment; and
        4.5. other information on the selected equipment necessary for the conformity assessment, in particular the safety class to which it is assigned.
    5. The authorised entity must assess the quality system of the manufacturer or assembler of the selected equipment after manufacture, including the manufacturing quality assurance method, and verify that
        5.1. the quality assurance method ensures compliance of the selected equipment with the technical documentation of the selected equipment and with the requirements of this Decree; and
        5.2. the documentation for the quality system contains

5.2.1. a description of the quality objectives and the organisational structure, including the rights and obligations of the persons who plan and direct the manufacture or assembly of the selected equipment;
5.2.2. a description of the manufacturing processes, the method of management and quality assurance of the processes and other systematic measures to be used, in particular those ensuring compliance with the essential requirements to ensure technical safety;
5.2.3. a description of the checks to be carried out before, during and after manufacture or assembly, indicating the frequency with which they are to be carried out and the acceptance criteria applied to these checks;
5.2.4. quality assurance records for the selected equipment; and
5.2.5. a description of the means of monitoring the achievement of the prescribed level of quality of the selected equipment and of assessing the effectiveness of the management system in ensuring its quality.

6. The quality system must be assessed by an authorised entity in the operating premises of the manufacturer or assembler of the selected equipment after manufacture. The assessment must be attended by an employee of the authorised entity who has experience in the assessment of the management system and knowledge of the requirements of this Decree. The authorised entity must notify the manufacturer, the importer or the assembler of the selected equipment after manufacture of the results of the assessment of the quality system, including the requirements to rectify any non-conformities.
7. An importer must ensure assessment of a foreign manufacturer’s quality system pursuant to Points 5 and 6. An authorised entity must assess the importer's system of controls and verify that the controls carried out by the importer on selected equipment ensure that the selected equipment complies with the requirements of this Decree.
8. If the quality system complies with the requirements referred to in Point 5, the authorised entity must issue a document of approval of the quality system to the manufacturer, importer or assembler of the selected equipment after manufacture.
9. The manufacturer, importer or assembler of the selected equipment after manufacture must comply with the requirements set out in the quality system as approved by the authorised entity and ensure that it remains substantially correct and effective.
10. The manufacturer, importer or assembler of selected equipment after manufacture must provide the authorised entity that has approved the quality system with information about planned changes to the quality system described in the quality system approval document. The authorised entity must assess the proposed change and decide whether the modified quality system complies with the requirements set out in Point 5. The authorised entity must communicate its assessment findings, including the reasons for them, to the manufacturer, importer or assembler of the selected equipment

after manufacture and, if the change to the quality system complies with the requirements referred to in Point 5, must issue an addendum to the original quality system approval document.

11. Surveillance by an authorised entity
    - 11.1. Surveillance must ensure that the manufacturer, importer or assembler of selected equipment after manufacture duly fulfils the requirements resulting from the approved quality system.
    - 11.2. The manufacturer, importer or assembler of the selected equipment after manufacture must allow the authorised entity access to the manufacturing, inspection and testing premises and warehouses for purposes of exercising surveillance and provide it with all necessary information.
    - 11.3. For surveillance purposes, the authorised entity must have a system of checks in place that stipulates the type and frequency of checks to be carried out on the manufacturer, importer or assembler of the selected equipment after manufacture.
    - 11.4. The authorised entity must carry out regular checks to ensure that the manufacturer, importer or assembler of selected equipment after manufacture maintains and applies a quality system as approved. The frequency of periodic checks must be such that a full verification is carried out at least once every 12 months.
    - 11.5. Within the scope surveillance, the authorised entity must perform unannounced checks of the manufacturer, importer or assembler of selected equipment after manufacture. The type and frequency of unannounced checks must be stipulated by the authorised entity, taking the following into account in particular:
        - 11.5.1. the safety class to which the selected equipment is assigned;
        - 11.5.2. the results of previous inspections checks out as part of surveillance;
        - 11.5.3. the need to monitor compliance with measures to rectify non-conformity; and
        - 11.5.4. significant changes in manufacturing organisation, concept or technology.
    - 11.6. During these checks, the authorised entity may carry out, or have carried out, checks to verify that the quality system is functioning correctly.
    - 11.7. The authorised entity must draw up reports on the results of the surveillance on the basis of the checks carried out and forward them to the manufacturer, importer or assembler of the selected equipment after manufacture.
12. If the selected equipment conforms to the requirements of this Decree, the manufacturer, importer or assembler of the selected equipment after manufacture must affix the conformity mark together with their identification and that of the authorised entity and issue a declaration of conformity.
13. The authorised entity must keep a copy of the quality system approval document and the surveillance results report.

14. The authorised entity must inform the Office of any issued, withdrawn, suspended or otherwise restricted management system approval documents or addenda thereto and make them available to the Office on request.
15. The authorised entity must inform other conformity assessment entities of withdrawn, suspended or otherwise restricted quality system approval documents or addenda thereto.

7. CONFORMITY ASSESSMENT PROCEDURE E (QUALITY ASSURANCE OF SELECTED EQUIPMENT)
    1. The manufacturer, importer or assembler of the selected equipment after manufacture must, in accordance with this procedure and under the supervision of an authorised entity, ensure that the selected equipment is in conformity with:
        1.1. the production type as described in the type examination certificate under conformity assessment procedure B; or
        1.2. the design of the selected equipment as described in the design examination certificate under conformity assessment procedure B1
        and meets the requirements of this Decree, and issue a declaration of conformity.
    2. The manufacturer or assembler of the selected equipment after manufacture must have a production quality system in place, in accordance with the established management system. The importer must have a system of checks in place for selected equipment.
    3. The manufacturer, importer or assembler of selected equipment after manufacture must ensure that a final assessment of the selected equipment is carried out.
    4. The manufacturer, importer or assembler of selected equipment after manufacture must submit a conformity assessment application to the selected authorised person. The application must contain:
        4.1. identification of the manufacturer, importer or assembler after manufacture of the selected equipment, namely
            4.1.1. the name(s), surname, residential or business address and identification number, if assigned, in the case of a natural person; or
            4.1.2. the business name, registered office and identification number in the case of a corporate entity;
        4.2. a written declaration that a conformity assessment contract has not been concluded with another authorised entity;
        4.3. manufacturing quality system documentation or documentation for a system of checks, in the case of an application submitted by an importer;
        4.4. the number of the EC-type examination certificate or the EC design examination certificate;
        4.5. the technical documentation of the selected equipment; and
        4.6. other information on the selected equipment necessary for the conformity assessment, in particular the safety class to which it is assigned.

5. The authorised entity must assess the quality system of the manufacturer or assembler of the selected equipment after manufacture and verify that
   5.1. the method of quality assurance ensures the conformity of the selected equipment with the production type described in the type examination certificate or the design of the selected equipment described in the design examination certificate, including conformity with the technical documentation of the selected equipment, and with the requirements of this Decree; and
   5.2. manufacturing quality system documentation must include
      5.2.1. a description of the quality objectives and the organisational structure, including the rights and obligations of the persons who plan and direct the manufacture or assembly of the selected equipment;
      5.2.2. a description of the manufacturing processes, the method of management and quality assurance of the processes and other systematic measures to be used, in particular those ensuring compliance with the essential requirements to ensure technical safety;
      5.2.3. a description of the checks that will be carried out after the end of manufacture or installation, indicating the frequency with which they will be carried out and the acceptance criteria applied during those checks;
      5.2.4. quality assurance records for the selected equipment; and
      5.2.5. a description of the means of monitoring the achievement of the prescribed level of quality of the selected equipment and of assessing the effectiveness of the management system in ensuring its quality.
6. The quality system must be assessed by an authorised entity in the operating premises of the manufacturer or assembler of the selected equipment after manufacture. The assessment must be attended by an employee of the authorised entity who has experience in the assessment of the management system and knowledge of the requirements of this Decree. The authorised entity must notify the manufacturer, the importer or the assembler of the selected equipment after manufacture of the results of the assessment of the quality system, including the requirements to rectify any non-conformities.
7. An importer must ensure assessment of a foreign manufacturer’s quality system pursuant to Points 5 and 6. The authorised entity must assess the importer’s inspection system and verify that the inspections it carries out on the selected equipment ensure conformity of the selected equipment with the production type described in the type examination certificate or the design of the selected equipment described in the design examination certificate, including conformity with the technical documentation of the selected equipment, and with the requirements of this Decree.
8. The manufacturer or assembler of selected equipment after manufacture must examine the selected equipment after completion of manufacture or installation. An importer must examine selected equipment during importation. As part of the examination, the checks set out in the technical

documentation of the selected equipment must be carried out in such a way as to ensure conformity of the selected equipment with the production type described in the type examination certificate or the design of the selected equipment described in the design examination certificate and with the requirements of this Decree.

9. If the quality system complies with the requirements referred to in Point 5, the authorised entity must issue a document of approval of the quality system to the manufacturer, importer or assembler of the selected equipment after manufacture.
10. The manufacturer, importer or assembler of the selected equipment after manufacture must comply with the requirements set out in the quality system as approved by the authorised entity and ensure that it remains substantially correct and effective.
11. The manufacturer, importer or assembler of selected equipment after manufacture must provide the authorised entity that has approved the quality system with information about planned changes to the quality system described in the quality system approval document. The authorised entity must assess the proposed change and decide whether the modified quality system complies with the requirements set out in Point 5. The authorised entity must communicate its assessment findings, including the reasons for them, to the manufacturer, importer or assembler of the selected equipment after manufacture and, if the change to the quality system complies with the requirements referred to in Point 5, must issue an addendum to the original quality system approval document.
12. Surveillance by an authorised entity
    12.1. Surveillance must ensure that the manufacturer, importer or assembler of selected equipment after manufacture duly fulfils the requirements resulting from the approved quality system.
    12.2. The manufacturer, importer or assembler of the selected equipment after manufacture must allow the authorised entity access to the manufacturing, inspection and testing premises and warehouses for purposes of exercising surveillance and provide it with all necessary information.
    12.3. For surveillance purposes, the authorised entity must have a system of checks in place that stipulates the type and frequency of checks to be carried out on the manufacturer, importer or assembler of the selected equipment after manufacture.
    12.4. The authorised entity must carry out regular checks to ensure that the manufacturer, importer or assembler of selected equipment after manufacture maintains and applies a quality system as approved. The frequency of periodic checks must be such that a full verification is carried out at least once every 12 months.
    12.5. Within the scope surveillance, the authorised entity must perform unannounced checks of the manufacturer, importer or assembler of selected equipment after manufacture. The type and frequency of unannounced checks must be stipulated by the authorised entity, taking the following into account in particular:

12.5.1. the safety class to which the selected equipment is assigned;
12.5.2. the results of previous inspections checks out as part of surveillance;
12.5.3. the need to monitor compliance with measures to rectify non-conformity; and
12.5.4. significant changes in manufacturing organisation, concept or technology.

12.6. During these checks, the authorised entity may carry out, or have carried out, checks to verify that the quality system is functioning correctly.

12.7. The authorised entity must draw up reports on the results of the surveillance on the basis of the checks carried out and forward them to the manufacturer, importer or assembler of the selected equipment after manufacture.

13. If the selected equipment conforms to the requirements of this Decree and is in conformity with the production type as described in the type examination certificate or the design of the selected equipment as described in the design examination certificate, the manufacturer, importer or assembler of the selected equipment after manufacture must affix the conformity mark together with their identification and that of the authorised entity and issue a declaration of conformity.
14. The authorised entity must keep a copy of the quality system approval document and the surveillance results report.
15. The authorised entity must inform the Office of any issued, withdrawn, suspended or otherwise restricted quality system approval documents or addenda thereto and make them available to the Office on request.
16. The authorised entity must inform other conformity assessment entities of withdrawn, suspended or otherwise restricted quality system approval documents or addenda thereto.

8. CONFORMITY ASSESSMENT PROCEDURE E1 (QUALITY ASSURANCE OF SELECTED EQUIPMENT CHECKS)
1. The manufacturer, importer or assembler of selected equipment after manufacture must, in accordance with this procedure and under the surveillance of the authorised entity, ensure that the selected equipment meets the requirements of this Decree and issue a declaration of conformity.
2. The manufacturer or assembler of the selected equipment after manufacture must have a production quality system in place, in accordance with the established management system. The importer must have a system of checks in place for selected equipment.
3. The manufacturer, importer or assembler of selected equipment after manufacture must ensure that a final assessment of each piece of selected equipment is carried out.
4. The manufacturer, importer or assembler of selected equipment after manufacture must submit a conformity assessment application to the selected authorised person. The application must contain:

4.1. identification of the manufacturer, importer or assembler after manufacture of the selected equipment, namely
4.1.1. the name(s), surname, residential or business address and identification number, if assigned, in the case of a natural person; or
4.1.2. the business name, registered office and identification number in the case of a corporate entity;
4.2. a written declaration that a conformity assessment contract has not been concluded with another authorised entity;
4.3. management system documentation relating to manufacturing quality assurance or documentation for a system of checks, in the case of an application submitted by an importer;
4.4. the technical documentation of the selected equipment; and
4.5. other information on the selected equipment necessary for the conformity assessment, in particular the safety class to which it is assigned.

5. The authorised entity must assess the quality system of the manufacturer or assembler of the selected equipment after manufacture and verify that
5.1. the quality assurance method ensures compliance of the selected equipment with the technical documentation of the selected equipment and with the requirements of this Decree; and
5.2. manufacturing quality system documentation must include
5.2.1. a description of the quality objectives and the organisational structure, including the rights and obligations of the persons who plan and direct the manufacture or assembly of the selected equipment;
5.2.2. a description of the manufacturing processes, the method of management and quality assurance of the processes and other systematic measures to be used, in particular those ensuring compliance with the essential requirements to ensure technical safety;
5.2.3. a description of the checks that will be carried out after the end of manufacture or installation, indicating the frequency with which they will be carried out and the acceptance criteria applied during those checks;
5.2.4. quality assurance records for the selected equipment; and
5.2.5. a description of the means of monitoring the achievement of the prescribed level of quality of the selected equipment and of assessing the effectiveness of the management system in ensuring its quality.

6. The quality system must be assessed by an authorised entity in the operating premises of the manufacturer or assembler of the selected equipment after manufacture. The assessment must be attended by an employee of the authorised entity who has experience in the assessment of the management system and knowledge of the requirements of this Decree. The authorised entity must notify the manufacturer, the importer or the assembler of the

selected equipment after manufacture of the results of the assessment of the quality system, including the requirements to rectify any non-conformities.

7. An importer must ensure assessment of a foreign manufacturer’s quality system pursuant to Points 5 and 6. An authorised entity must assess the importer's system of controls and verify that the controls carried out by the importer on selected equipment ensure that the selected equipment complies with the requirements of this Decree.
8. The manufacturer or assembler of selected equipment after manufacture must examine the selected equipment after completion of manufacture or installation. An importer must examine selected equipment during importation. In the examination, the checks specified in the technical documentation of the selected equipment must be carried out to ensure that the selected equipment complies with the requirements of this Decree.
9. If the quality system complies with the requirements referred to in Point 5, the authorised entity must issue a document of approval of the quality system to the manufacturer, importer or assembler of the selected equipment after manufacture.
10. The manufacturer, importer or assembler of the selected equipment after manufacture must comply with the requirements set out in the quality system as approved by the authorised entity and ensure that it remains substantially correct and effective.
11. The manufacturer, importer or assembler of selected equipment after manufacture must provide the authorised entity that has approved the quality system with information about planned changes to the quality system described in the quality system approval document. The authorised entity must assess the proposed change and decide whether the modified quality system complies with the requirements set out in Point 5. The authorised entity must communicate its assessment findings, including the reasons for them, to the manufacturer, importer or assembler of the selected equipment after manufacture and, if the change to the quality system complies with the requirements referred to in Point 5, must issue an addendum to the original quality system approval document.
12. Surveillance by an authorised entity
    12.1. Surveillance must ensure that the manufacturer, importer or assembler of selected equipment after manufacture duly fulfils the requirements resulting from the approved quality system.
    12.2. The manufacturer, importer or assembler of the selected equipment after manufacture must allow the authorised entity access to the manufacturing, inspection and testing premises and warehouses for purposes of exercising surveillance and provide it with all necessary information.
    12.3. For surveillance purposes, the authorised entity must have a system of checks in place that stipulates the type and frequency of checks to be carried out on the manufacturer, importer or assembler of the selected equipment after manufacture.
    12.4. The authorised entity must carry out regular checks to ensure that the manufacturer, importer or assembler of selected equipment after

manufacture maintains and applies a quality system as approved. The frequency of periodic checks must be such that a full verification is carried out at least once every 12 months.

12.5. Within the scope surveillance, the authorised entity must perform unannounced checks of the manufacturer, importer or assembler of selected equipment after manufacture. The type and frequency of unannounced checks must be stipulated by the authorised entity, taking the following into account in particular:

12.5.1. the safety class to which the selected equipment is assigned;

12.5.2. the results of previous inspections checks out as part of surveillance;

12.5.3. the need to monitor compliance with measures to rectify non-conformity; and

12.5.4. significant changes in manufacturing organisation, concept or technology.

12.6. During these checks, the authorised entity may carry out, or have carried out, checks to verify that the quality system is functioning correctly.

12.7. The authorised entity must draw up reports on the results of the surveillance on the basis of the checks carried out and forward them to the manufacturer, importer or assembler of the selected equipment after manufacture.

13. If the selected equipment conforms to the requirements of this Decree, the manufacturer, importer or assembler of the selected equipment after manufacture must affix the conformity mark together with their identification and that of the authorised entity and issue a declaration of conformity.

14. The authorised entity must keep a copy of the quality system approval document and the surveillance results report.

15. The authorised entity must inform the Office of any issued, withdrawn, suspended or otherwise restricted quality system approval documents or addenda thereto and make them available to the Office on request.

16. The authorised entity must inform other conformity assessment entities of withdrawn, suspended or otherwise restricted quality system approval documents or addenda thereto.

9. CONFORMITY ASSESSMENT PROCEDURE F (VERIFICATION OF SELECTED EQUIPMENT)

1. The manufacturer, importer or assembler of the selected equipment after manufacture must, in accordance with this procedure, ensure that the selected equipment is in conformity with:

1.1. the production type described in the type-examination certificate in accordance with conformity assessment procedure B;

1.2. the design of the selected equipment as described in the design examination certificate under conformity assessment procedure B1; or

1.3. the product type approved pursuant to § 137(1)(a) of the Atomic Act, in the case of selected equipment set out in § 12(2)(b)(5);

and meets the requirements of this Decree, and issue a declaration of conformity.

2. The manufacturer, importer or assembler of selected equipment after manufacture must take the necessary measures to ensure that the manufacturing or assembly process and its checks ensure conformity of the selected equipment with the production type described in the type examination certificate, the design of the selected equipment described in the design examination certificate, or with product type approved pursuant to § 137(1)(a) of the Atomic Act and with the requirements of this Decree.
3. The manufacturer, importer or assembler of selected equipment after manufacture must ensure that a final assessment of the selected equipment is carried out.
4. The manufacturer or assembler of selected equipment after manufacture must examine the selected equipment after completion of manufacture or installation. An importer must examine selected equipment during importation. As part of the examination, the checks set out in the technical documentation of the selected equipment must be carried out in such a way as to ensure conformity of the selected equipment with the production type described in the type examination certificate, the design of the selected equipment described in the design examination certificate or the product type approved pursuant to § 137(1)(a) of the Atomic Act and with the requirements of this implementing decree.
5. The manufacturer, importer or assembler of selected equipment after manufacture must submit a conformity assessment application to the selected authorised person. The application must contain:
    5.1. identification of the manufacturer, importer or assembler after manufacture of the selected equipment, namely
        5.1.1. the name(s), surname, residential or business address and identification number, if assigned, in the case of a natural person; or
        5.1.2. the business name, registered office and identification number in the case of a corporate entity;
    5.2. a written declaration that a conformity assessment contract has not been concluded with another authorised entity;
    5.3. the technical documentation for the selected equipment;
    5.4. a copy of the type examination certificate, the design examination certificate or the product type approval decision pursuant to § 137(1)(a) of the Atomic Act; and
    5.5. other information on the selected equipment necessary for the conformity assessment, in particular the safety class to which it is assigned.
6. The authorised entity must
    6.1. assess the materials used, including assessment of the material certificates pursuant to Points 13.9 or 13.11 of Part A of Annex 2 to this Decree, unless they have previously been assessed by another authorised entity;
    6.2. check technological procedures for the execution of permanent joints in accordance with Point 6.5 of Part A of Annex 2 to this Decree and

approve these procedures, unless they have already been approved by another authorised entity;

6.3. verify that personnel performing special processes comply with the requirements of Points 6.5 and 7 of Part A of Annex 2 to this Decree;

6.4. perform surveillance of final assessment;

6.5. verify that the selected equipment is in conformity with the production type described in the type examination certificate, the design of the selected equipment described in the design examination certificate or with the product type approved pursuant to § 137(1)(a) of the Atomic Act and complies with the requirements of this Decree, including performing the necessary related checks; and

6.6. prepare a report on the evaluation of the activities set out in Points 6.1 to 6.5 and their results.

7. If the selected equipment meets the requirements of this Decree and is in conformity with the production type described in the type examination certificate, the design of the selected equipment described in the design examination certificate or with the product type approved pursuant to § 137(1)(a) of the Atomic Act, the authorised entity must issue a certificate of verification of the selected equipment to the manufacturer, importer or assembler of the selected equipment after manufacture. The certificate must contain:

7.1. the name of the selected equipment, its identification and basic description;

7.2. identification of the manufacturer, importer or assembler of the selected equipment after manufacture, namely

7.2.1. the name(s), surname, residential or business address and identification number, if assigned, in the case of a natural person; or

7.2.2. the business name, registered office and identification number in the case of a corporate entity;

7.3. the conclusions of the verification of the selected equipment; and

7.4. other documents necessary to demonstrate the conformity of the selected equipment with the production type described in the type examination certificate, the design of the selected equipment described in the design examination certificate or with the product type approved pursuant to § 137(1)(a) of the Atomic Act and with the requirements of this Decree.

8. If the selected equipment conforms to the requirements of this Decree and is in conformity with the production type as described in the type-examination certificate or the design of the selected equipment as described in the design examination certificate or with the product type approved pursuant to § 137(1)(a) of the Atomic Act, the manufacturer, importer or assembler of the selected equipment after manufacture must affix the conformity mark together with their identification and that of the authorised entity and issue a declaration of conformity.

9. The authorised entity must keep a copy of the design examination certificate and the activity evaluation report.

10. The authorised entity must inform the Office of any issued, withdrawn, suspended or otherwise restricted selected equipment verification certificates and make them available to the Office on request.
11. The authorised entity must inform other authorised entities performing conformity assessment about certificates of verification of selected equipment that have been withdrawn, suspended or otherwise restricted.

10. CONFORMITY ASSESSMENT PROCEDURE F1 (VERIFICATION OF PART OF SELECTED EQUIPMENT)
    1. The manufacturer, importer or assembler of a part of selected equipment after manufacture must, in accordance with this procedure, ensure that the part of selected equipment complies with the requirements of this Decree and issue a declaration of conformity.
    2. The manufacturer, importer or assembler of a part of selected equipment after manufacture must take measures necessary so that the manufacturing or installation process and its checks ensure conformity of the part of selected equipment with the requirements of this Decree.
    3. The manufacturer, importer or assembler of a part of selected equipment after manufacture must ensure that a final assessment of each part of selected equipment is carried out.
    4. The manufacturer or assembler of a part of selected equipment after manufacture must examine each part of selected equipment after completion of manufacture or installation. An importer must examine each part of selected equipment as part of import. As part of the examination, the checks specified in the part of the technical documentation of the selected equipment relating to the assessed part of selected equipment must be carried out to ensure that the part of selected equipment complies with the requirements of this Decree.
    5. The manufacturer, importer or assembler of a part of selected equipment after manufacture must submit a conformity assessment application to the selected authorised person. The application must contain:
        5.1. identification data of the manufacturer, importer or assembler if the part of the selected equipment after manufacture, namely
            5.1.1. the name(s), surname, residential or business address and identification number, if assigned, in the case of a natural person; or
            5.1.2. the business name, registered office and identification number in the case of a corporate entity;
        5.2. a written declaration that a conformity assessment contract has not been concluded with another authorised entity;
        5.3. the part of the technical documentation of the selected equipment relating to the part of the selected equipment under assessment; and
        5.4. other information on the selected equipment and the part of the selected equipment necessary for the conformity assessment, in particular the safety class to which it is assigned.
    6. The authorised entity must
        6.1. assess the materials used, including assessment of the material certificates pursuant to Points 13.9 or 13.11 of Part A of Annex 2 to

this Decree, unless they have previously been assessed by another authorised entity;

6.2. check technological procedures for the execution of permanent joints in accordance with Point 6.5 of Part A of Annex 2 to this Decree and approve these procedures, unless they have already been approved by another authorised entity;

6.3. verify that personnel performing special processes comply with the requirements of Points 6.5 and 7 of Part A of Annex 2 to this Decree;

6.4. perform surveillance of the final assessment; and

6.5. verify that the part of the selected equipment complies with the requirements of this Decree, including carrying out the necessary related checks.

6.6. prepare a report on the evaluation of the activities set out in Points 6.1 to 6.5 and their results.

7. If the part of selected equipment complies with the requirements of this Decree, the authorised entity must issue a certificate of verification of the part of selected equipment to the manufacturer, importer or assembler of the part of selected equipment after manufacture. The certificate must contain:

7.1. the name of the part of the selected equipment, its identification and basic description;

7.2. identification of the manufacturer, importer or assembler after manufacture of the part of selected equipment after manufacture, namely

7.2.1. the name(s), surname, residential or business address and identification number, if assigned, in the case of a natural person; or

7.2.2. the business name, registered office and identification number in the case of a corporate entity; and

7.3. the conclusions of the verification of the part of selected equipment.

8. If the part of selected equipment conforms to the requirements of this Decree, the manufacturer, importer or assembler of the selected equipment after manufacture must affix the conformity mark together with their identification and that of the authorised entity and issue a declaration of conformity.

9. The authorised entity must keep a copy of the certificate of verification of the part of selected equipment.

11. CONFORMITY ASSESSMENT PROCEDURE G (OVERALL VERIFICATION)

1. The manufacturer, importer or assembler of selected equipment after manufacture must, in accordance with this procedure, ensure that the selected equipment complies with the requirements of this Decree and issue a declaration of conformity.

2. The manufacturer, importer or assembler of selected equipment after manufacture must submit a conformity assessment application to the selected authorised person. The application must contain:

2.1. identification of the manufacturer, importer or assembler after manufacture of the selected equipment, namely

2.1.1. the name(s), surname, residential or business address and identification number, if assigned, in the case of a natural person; or

2.1.2. the business name, registered office and identification number in the case of a corporate entity;

2.2. a written declaration that a conformity assessment contract has not been concluded with another authorised entity;

2.3. the technical documentation for the selected equipment;

2.4. the design of the selected equipment; and

2.5. other information on the selected equipment necessary for the conformity assessment, in particular the safety class to which it is assigned.

3. The manufacturer, importer or assembler of selected equipment after manufacture must ensure that a final assessment of each piece of selected equipment is carried out.

4. The manufacturer or assembler of selected equipment after manufacture must examine the selected equipment after completion of manufacture or installation. An importer must examine selected equipment during importation. In the examination, the checks specified in the technical documentation of the selected equipment must be carried out to ensure that the selected equipment complies with the requirements of this Decree.

5. The authorised entity must

5.1. review the technical documentation of the selected equipment, including an assessment of whether it meets the requirements set out in Annex 3 to this Decree;

5.2. assess the materials used, including assessment of the material certificates pursuant to Points 13.9 or 13.11 of Part A of Annex 2 to this Decree, unless they have previously been assessed by another authorised entity;

5.3. check technological procedures for the execution of permanent joints in accordance with Point 6.5 of Part A of Annex 2 to this Decree and approve these procedures, unless they have already been approved by another authorised entity;

5.4. verify that personnel performing special processes comply with the requirements of Points 6.5 and 7 of Part A of Annex 2 to this Decree;

5.5. perform or arrange verification of the necessary checks to ascertain whether technical standards or technical specifications have been correctly applied;

5.6. verify that the design of the selected equipment complies with the requirements of this Decree;

5.7. perform surveillance of final assessment;

5.8. verify that the selected equipment conforms to the design of the selected equipment and meets the requirements of this Decree, including the performance of the necessary related inspections; and

5.9. prepare a report on the evaluation of the activities set out in Points 5.1 to 5.8 and their results.

6. If the selected equipment complies with the requirements of this Decree, the authorised entity must issue an overall certification certificate to the manufacturer, importer or assembler of the selected equipment after manufacture. The certificate must contain:
    6.1. the name of the selected equipment, its identification and basic description;
    6.2. identification of the manufacturer, importer or assembler of the selected equipment after manufacture, namely
        6.2.1. the name(s), surname, residential or business address and identification number, if assigned, in the case of a natural person; or
        6.2.2. the business name, registered office and identification number in the case of a corporate entity;
    6.3. the conclusions of the overall verification; and
    6.4. other documents necessary to demonstrate the conformity of the design of the selected equipment and the selected equipment with the requirements of this Decree.
7. If the selected equipment conforms to the requirements of this Decree, the manufacturer, importer or assembler of the selected equipment after manufacture must affix the conformity mark together with their identification and that of the authorised entity and issue a declaration of conformity.
8. The authorised entity must keep a copy of the overall verification certificate and the activity evaluation report.
9. The authorised entity must inform the Office about issued, withdrawn, suspended or otherwise restricted certificates of overall verification and must make them available to the Office upon request.
10. The authorised entity must inform any other authorised entities performing conformity assessments about overall verification certificates that have been withdrawn, suspended or otherwise restricted.

12. PROCEDURE FOR THE CONFORMITY ASSESSMENT OF A PART OF SELECTED EQUIPMENT BY THE OPERATOR

1. The manufacturer, importer or assembler of a part of selected equipment after manufacture must, in accordance with this procedure and under the surveillance of the operator of the selected equipment, ensure that the part of selected equipment meets the requirements of this Decree and issue a declaration of conformity.
2. The operator of the selected facility must:
    2.1. check the materials used, including their identification and compliance with the requirements of Paragraphs 13.9 or 13.11 of Part A of Annex 2 to this Decree;
    2.2. check that suitable technological procedures complying with the requirements set out in Point 6.5 of Part A of Annex 2 have been used for the implementation of permanent joints;

2.3. verify that the personnel carrying out special processes comply with the requirements of Points 6.5 and 7 of Part A of Annex 2 to this Decree;
2.4. verify compliance with the inspection plan for the manufacture or assembly of the part of selected equipment;
2.5. oversee the final assessment; and
2.6. verify that the part of the selected equipment complies with the requirements of this Decree, including carrying out the necessary related checks.

3. Based on the results of the surveillance, the operator of the selected equipment must issue an inspection report.
4. If the part of selected equipment conforms to the requirements of this Decree, the manufacturer, importer or assembler of the selected equipment after manufacture must affix the conformity mark together with their identification and issue a declaration of conformity.'.

80. Annex 8 reads as follows:

'Annex 8 to Decree No 358/2016

Conformity verification requirements

1. The general requirements for checks carried out in the context of verifying the conformity of selected equipment with technical requirements is subject to the general requirements for checks pursuant to Part A of Annex 6 to this Decree.
2. All selected equipment in operation must be inspected in accordance with
   2.1. internal regulations;
   2.2. a programme of operational checks of the selected equipment; and
   2.3. documentation concerning repairs, maintenance or changes to the selected equipment.
3. When stipulating requirements for the scope, type, method and periodicity of checks of selected equipment in operation and the acceptance criteria used for such checks, especially the following must be taken into account:
   3.1. properties of the selected equipment;
   3.2. stipulated conditions for safe operation;
   3.3. the requirements of internal regulations for the operation of the nuclear installation; and
   3.4. knowledge and experience with the current operation of the selected equipment and the nuclear installation.
4. The plans for operational checks must be provided to the personnel performing the checks before the start of the operational checks.'.

Article II

Transitional provisions

1. Entities intending to assess conformity that are not accreditation holders on the effective date of this Decree must obtain accreditation pursuant to this Decree within 18 months of the effective date of this Decree.
2. Conformity assessments of selected equipment and parts of selected equipment commenced before the effective date of this Decree shall be completed in accordance with existing legislation and are deemed to be a conformity assessments pursuant to this Decree.

Article III

Common provisions

3. This Decree was notified in accordance with Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services.

Article IV

Effective date

This Decree comes into effect on 1 February 2026.