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DECREE
of ... 2016,

on requirements for assurance of quality and technical safety and assessment and verification of conformity of selected equipment

Pursuant to § 236 of Act No .../..., the Atomic Act (hereinafter the 'Act'), the State Office for Nuclear Safety lays down the following to implement § 24(7), § 56(2)(a) and (b), § 57(3)(a) to (c), § 137(6), § 58(7)(a) to (c), and § 59(4)(a) and (b) of the Act:

§ 1

Subject matter

This Decree regulates:

a) the content of the selected equipment list;
b) the quality assurance scope and method for the design, manufacturing, assembly, procurement, commissioning, and operation of selected equipment;
c) the types of quality assurance records for selected equipment, and how they are kept;
d) technical requirements for selected equipment and parts of selected equipment;
e) requirements for ensuring compliance of selected equipment and parts of selected equipment with technical requirements;
f) requirements for documentation on ensuring compliance of selected equipment and parts of selected equipment with technical requirements;
g) the scope of and procedures for assessing conformity of selected equipment with technical requirements;
h) requirements for documenting the assessment of conformity of selected equipment with technical requirements;
i) specific procedures that may be applied to assess the conformity of selected equipment with technical requirements;
j) the scope of and method for verifying conformity of selected equipment in use with technical requirements; and
k) the method for documenting verification of conformity of selected equipment in use with technical requirements and the content of this documentation.

§ 2

Definitions

The following definitions apply for the purposes of this Decree:

l) pressure equipment is defined as selected equipment under stress from pressure exerted by a process medium with maximum operating pressure in excess of 0.05 MPa, including elements connected to parts exposed to pressure, safety and pressure equipment and other equipment that ensures its functionality;
m) a pressure equipment system is a set of several parts, at least one of which is pressure equipment that

1. are connected and constructed to be mutually compatible;
2. only perform their stipulated safety function if all of the parts in the set are present;
3. are installed by one contractor; and
4. serve for joint use as a whole.

§ 3

Content of the selected equipment list

(1) The text portion of the selected equipment list must clearly specify individual pieces of selected equipment and state the safety class in which they are classified.

(2) The drawing portion of the selected equipment list must:

a) schematically depict process systems and structural parts of the nuclear installation that contain selected equipment;
b) mark the safety classes of individual pieces of selected equipment different ways, and highlight the boundary between selected equipment and other equipment or other parts of the nuclear installation building; and
c) provide identification of selected equipment and other information from which its function and location within the scope of the nuclear installation is unmistakably clear.

(3) The selected equipment list must contain rules for

a) specifying the borders between systems, equipment, or parts of the nuclear installation building ensuring safety and other systems, equipment or parts of the nuclear installation building; and
b) specifying the borders between individual safety classes of selected equipment.

(4) The selected equipment list must indicate selected equipment for which pursuant to § 12(2) its conformity with technical requirements (hereinafter 'conformity assessment') is performed by an authorised or accredited person.

§ 4

Scope and manner of quality assurance during the design process for selected equipment

(1) During the design of selected equipment, which includes its development, engineering, and planning (hereinafter the 'design process'), final documentation for the design process must be created (hereinafter the 'selected equipment design').

(2) The design process and the selected equipment design must comply with technical requirements for the selected equipment and part of the selected equipment specified in § 9.

(3) The design process must be verified by

a) the persons who implemented the design process; and
b) independent persons.

(4) The selected equipment design must stipulate the following:

a) acceptability criteria for monitoring and assessing reliability;
b) acceptability criteria for monitoring and assessing service life;
c) use and operating conditions;
d) acceptability criteria related to performance of safety functions;
e) acceptability criteria for quality assurance; and

f) technical regulations, technical standards, or technical specifications that are to be used.

§ 5

Scope and manner of quality assurance during the manufacture and installation process for selected equipment

(1) Prior to commencing the manufacture and installation process for selected equipment, all documentation needed to implement this process must be available.

(2) During the manufacture and installation of selected equipment,

a) the selected equipment design must be followed;
b) technical specifications for the selected equipment and any changes thereto must be available;
c) checks, tests, and inspections (hereinafter 'checks') must be performed to verify the compliance of the selected equipment with technical requirements;
d) the manufacturing and installation method and process for the specified equipment must be documented, including checks thereof, in accordance with requirements stipulated in the selected equipment design;
e) the manner and extent to which the selected equipment will be reviewed, verified, and validated;
f) the selected equipment must be identified in a unique manner and this identification must be maintained;
g) information on the current or past condition of the selected equipment, its location and use, or the manner in which it is being or has been treated must be available; and
h) any part of the selected equipment that is delivered separately must be in a condition that permits verification of the manufacturing and installation process for this part.

(3) Once the manufacture and installation of selected equipment has been completed,

a) the selected equipment must be checked to verify its conformity with technical requirements; and
b) a final assessment must be performed to verify the conformity of the selected equipment with requirements in the selected equipment design and in its manufacturing and installation documentation; a final assessment of pressure equipment in accordance with the first sentence must take place after the pressure equipment system has been installed as a whole.

(4) Requirements for checks pursuant to (3), including final assessment requirements, are specified in Annex 6 to this Regulation.

§ 6

Scope and manner of quality assurance during the selected equipment procurement process

(1) The selected equipment design must stipulate the following:

a) the procurement documentation must specify the requirements for the selected equipment; and
b) the selection method and evaluation criteria for the vendor of the product or service (hereinafter the 'vendor') must be specified.

(2) During selected equipment procurement,

a) the vendor must be evaluated and selected in accordance with the stipulated method and evaluation criteria;
b) the vendor's quality assurance documentation for the selected equipment must be reviewed to determine whether it is correct and complete;
c) requirements for the method and extent to which the vendor will be notified of discrepancies and how they will be addressed must be specified; and
d) the vendor must be supervised.

§ 7

Scope and manner of quality assurance during the commissioning and operation of selected equipment

During the commissioning and operation of selected equipment,

a) identification of the selected equipment and the use of spare parts of the selected equipment must be documented;
b) information on the current and past condition of the selected equipment, its location and use, or the manner in which it is being and has been treated must be available;
c) plans and programmes for commission and operation of the selected equipment must be drawn up, implemented, and maintained;
d) identification of the selected equipment assigned during manufacturing and installation must be maintained;
e) activities must be performed in accordance with commissioning programmes for the selected equipment;
f) activities must be planned and performed in accordance with internal rules and other operating documentation, including plans and programmes for operating checks of selected equipment, the pre-operational and operational managed ageing programme, and plans and programmes for checks during maintenance, repairs, or changes to selected equipment, and with technical requirements specified by this Decree;
g) repairs, maintenance, or changes to selected equipment must be performed in accordance with requirements specified in repair, maintenance, or change documentation for the selected equipment; and
h) it must be ensured that selected equipment is handled and stored in a manner that prevents damage, incorrect use, or destruction of the selected equipment or part thereof.

§ 8

Types of quality assurance records for selected equipment, and how they are kept

(1) Quality assurance for selected equipment must be documented by the following in particular:

a) special process records;
b) discrepancy assessment and evaluation records, in the case of selected equipment classified in safety class 1 to 3;
c) records documenting fulfilment of quality requirements for the selected equipment, including qualification requirements for personnel performing checks and verification of the selected equipment design, the quality of its parts and materials used in its manufacture, in the case of pressure equipment classified in safety class 1 or 2; and
d) records documenting the elimination of found faults in selected equipment and the manner in which they were repaired, and records regarding faults that have not been

eliminated and the method for their managed monitoring and evaluation, in the case of pressure equipment classified in safety class 1 or 2.

(2) Quality assurance records for selected equipment are permanent or temporary.

(3) The following are permanent quality assurance records for selected equipment:

a) the selected equipment design;
b) a record that a selected equipment vendor's quality assurance documentation has been reviewed for correctness and completeness;
c) a record of the current technical condition of selected equipment upon completion of its manufacture;
d) a record of the current technical condition of selected equipment after its installation and checks;
e) a record that selected equipment is operated, maintained, or subjected to checks in accordance with technical requirements, technical specifications, an operating check programme, a managed ageing operating programme, a maintenance programme, maintenance procedures, or legislative requirements;
f) a record that documents that a person who plans, manages, or evaluates processes applicable to the design, manufacture, installation, procurement, commissioning, or operation of selected equipment or part thereof meets qualification requirements;
g) a record that documents planning and performance of maintenance, repairs, or changes to the selected equipment, including quality certificates of spare parts used;
h) a record that documents that he quality of originally in-built selected equipment, repaired or replaced selected equipment, or selected equipment that has been changed, complies with technical requirements and technical specifications of the selected equipment; and
i) a record that documents that a discrepancy has been corrected and preventive measures have been implemented to prevent these discrepancies.

(4) A temporary quality assurance record for selected equipment is any quality assurance record for selected equipment that is not a permanent quality assurance records for selected equipment.

(5) A permanent quality assurance records for selected equipment must be archived from the time of selected equipment design for its entire service life.

(6) Quality assurance records for selected equipment must be kept to an extent and in a manner to ensure that it is possible to assess whether the condition of the selected equipment or parts thereof comply with relevant technical requirements at any time.

(7) Records from the manufacture, installation, and procurement of selected equipment must be created prior to the commencement of the selected equipment's commissioning phase.

(8) Records from selected equipment's commissioning phase must be created prior to the selected equipment being placed into operation.

(9) Operating records must also contain how repairs, maintenance, or changes to selected equipment were performed.

§ 9

Technical requirements for selected equipment and parts of selected equipment

The technical requirements for selected equipment and parts of selected equipment that are applied during its design, manufacture, installation, commissioning, and operation are stipulated by Annex 1 to this Decree.

§ 10

Requirements for ensuring compliance of selected equipment and parts of selected equipment with technical requirements

(1) Ensuring compliance of selected equipment and parts of selected equipment with technical requirements (hereinafter "compliance assurance") must be performed and documented in a manner that ensures that documentation and proof required to ensure technical safety are secured.

(2) Anyone who designs, manufactures, installs, commissions, or repairs selected equipment or parts of selected equipment or maintains it, and a permit holder pursuant to § 9f(1)(b) to (h) of the Act must provide the vendor information regarding the selected equipment or parts thereof, including requirements as to type, amount, terms and dates of delivery, the quality of the selected equipment or parts thereof according to its safety classification.

(3) During compliance assurance, a permit holder must ensure the following within the scope of the contractual relationship with a vendor:

a) there is a vendor system with the required sources and external and internal communication, including a system of mutual independent checks;
b) that quality assurance and managed ageing programme records are be kept for selected equipment, and are available for review;
c) control mechanisms and mutual communication methods in the supply chain for the given selected equipment or part thereof;
d) implementation of a system of checks and tests of the selected equipment or part thereof corresponding to the life cycle phase of the selected equipment that is used to verify compliance with prescribed procedures and inspection records;
e) checks of progress of activities on selected equipment corresponding to the life cycle of the selected equipment or parts thereof within the scope of a system of independent checks by the permit holder and a system of independent checks by the vendor;
f) performance of a final assessment of the selected equipment with technical requirements stipulated in manufacturing, installation, or repair procedures for the selected equipment;
g) documentation of the final assessment of selected equipment pursuant to f);
h) verification of fulfilment of technical requirements stipulated in procedures for maintenance of selected equipment by a vendor who maintains selected equipment;
i) documentation of fulfilment of technical requirements pursuant to f);
j) availability of documentation applicable to selected equipment or part thereof corresponding to its as-built condition to a predetermined extent.

(4) Verification of the quality of materials used and the correctness and completeness of technical documentation, repair and maintenance documentation, and attendant technical documentation for selected equipment, including verification of final assessment procedures,

must be performed for selected equipment stipulated in § 12(2) or part thereof by individuals who

a) have achieved a university or higher technical education with successful completion of an accredited educational programme in the area of mechanical engineering, electrical engineering, civil engineering or a related field that has provided them with theoretical technical skills necessary for performance of these activities, or a high school education with a leaving exam in the field of mechanical engineering, electrical engineering, civil engineering or a related field that has provided them with theoretical technical skills necessary to perform these tasks; and
b) have at least five years' experience in the relevant field, in the case of individuals with a high school education with a leaving exam, at least three years' experience in the relevant field, in the case of individuals with a higher technical education, or at least two years' experience in the relevant field in the case of individuals with a university education.

(5) Requirements for compliance assurance

a) during the manufacture and installation of selected equipment and parts of selected equipment;
b) during the commissioning of selected equipment and parts of selected equipment; and
c) during operation of selected equipment and parts of selected equipment are specified in Annex 2 to this Decree.

§ 11

Requirements for documentation on ensuring compliance of selected equipment and parts of selected equipment with technical requirements

(1) The manner in which selected equipment and parts of selected equipment are designed, manufactured, and installed must be documented in a way that permits conformity assessment.

(2) Conformity assessment must be documented in conformity assessment documentation pursuant to requirements stipulated

a) in Annex 3 to this Decree, in the case of technical documentation for selected equipment; and
b) in Annex 4 to this Decree, in the case of accompanying technical documentation for selected equipment.

(3) Conformity assessment documentation must be archived for the entire service life of the selected equipment.

§ 12

Scope of and procedures for assessing conformity of selected equipment with technical requirements

(1) Conformity assessment must take place prior to the use of selected equipment in a nuclear installation.

(2) An authorised person performs conformity assessment for

a) selected equipment in safety class 1, which is on the nuclear reactor coolant pressure circuit boundary, specifically

1. pressure vessels, tanks, and chillers, including the nuclear reactor pressure vessel and steam generators, working with radioactive substances with a greatest operating pressure in excess of 0.05 MPa and volume in excess of 10 l; and
2. pumps, piping, and armatures, working with radioactive substances with a greatest operating pressure in excess of 0.05 MPa and nominal diameter greater than DN 70;

b) selected equipment in safety class 2, specifically
1. pressure vessels, tanks, and chillers providing nuclear reactor cooling, volume compensation, hermetic area cooling, emergency filling, primary circuit after-cooling, and cleaning of the pressure circuit process media, working with radioactive substances with a greatest operating pressure in excess of 0.05 MPa and volume in excess of 10 l;
2. pumps, piping, and armatures providing nuclear reactor cooling, volume compensation, hermetic area cooling, emergency filling, primary circuit after-cooling, and cleaning of the pressure circuit process media, working with radioactive substances with a greatest operating pressure in excess of 0.05 MPa and nominal diameter greater than DN 70;
3. pressure equipment making up a protective envelope system, including equipment ensuring that the protective envelope is hermetically sealed during a basic design accident;
4. secondary circuit pressure equipment where the greatest operating pressure of the process media at an operating pressure greater than 100 °C exceeds 4 MPa, and with a nominal diameter greater than DN 200;
5. packaging for carriage, storage, and disposal of spent nuclear fuel; and
6. reinforced concrete structures of the nuclear reactor building, including the profile of the nuclear reactor building's installation cover, and steel liners defining the hermetic area; and

c) selected equipment in safety class 3, specifically
1. pressure vessels, tanks, and chillers ensuring normal filling, boron regulation, and cooling of spent nuclear fuel facilities working with radioactive substances with a greatest operating pressure in excess of 0.05 MPa and volume in excess of 10 l;
2. pumps, piping, and armatures ensuring normal filling, boron regulation, and cooling of spent nuclear fuel facilities working with radioactive substances with a greatest operating pressure in excess of 0.05 MPa and nominal diameter greater than DN 70; and
3. secondary circuit pressure equipment where the greatest operating pressure of the process media at an operating pressure greater than 100 °C exceeds 4 MPa, and with a nominal diameter greater than DN 200.

(3) A manufacturer or importer performs conformity assessment for

a) selected equipment with parameters lower than or equal to those stipulated in (2);
b) electrical selected equipment and selected equipment belonging to automated process control systems, including software (hereinafter 'selected control equipment');
c) selected equipment that is part of the structural part of a nuclear installation (hereinafter 'selected structural equipment') in safety class 3; and
d) other selected equipment in safety class 2 or 3 other than selected equipment specified in (2).

(4) An accredited person performs a conformity assessment on selected equipment specified in (2)(c) if the conformity assessment is performed as specified pursuant to § 15(1)(e) Point 1.

(5) In the case of a conformity assessment of a pressure equipment assembly, this assembly must be assessed as a whole. For conformity assessment of a pressure equipment assembly, the results of conformity assessments of individual pieces of selected equipment that are part of the assembly are used. The conformity assessment of a pressure equipment assembly must be performed with regards to the highest safety class pieces of selected equipment that are part of the assembly.

(6) For individual parts of selected equipment that are independently designed, manufactured, or installed after manufacture, conformity assessment must take place to the extent corresponding to this part of the selected equipment; this does not apply to parts of selected equipment specified in (3), for which conformity assessment to the extent corresponding to this part of selected equipment is not prescribed in the selected equipment design. The results of conformity assessments of individual pieces of selected equipment that are independently designed, manufactured, or installed after manufacture are used for the conformity assessment of selected equipment.

(7) Conformity assessment is performed inclusive of conformity assessment of raw materials and intermediate products with technical requirements for these materials and intermediate products.

(8) In any case, an individual conformity assessment procedure may be performed only by an authorised person, an accredited person, the manufacturer, or an importer of selected equipment. If a combination of conformity assessment procedures is prescribed, individual conformity assessment procedures may be performed by various persons.

§ 13

Conformity mark

(1) A person pursuant to § 58(2) of the Act performing conformity assessment must mark the selected equipment with a conformity mark along with his identification; if the conformity assessment procedure stipulates participation of an authorised or accredited person, this person must also be identified.

(2) Marking with a conformity mark confirms the conformity of selected equipment with technical requirements and adherence to the chosen conformity assessment procedure stipulated by this Decree.

(3) The conformity mark must be placed on the selected equipment in an indelible and legible manner, and must not be smaller than 5 mm. The conformity mark may be placed in the accompanying technical documentation of selected equipment if it is impossible to place on the selected equipment due to its design or size, or if this selected equipment will not be accessible after installation.

(4) The graphic appearance of the conformity mark is specified in Annex 9 to this Decree.

§ 14

Requirements for documenting the assessment of conformity of selected equipment with technical requirements

(1) Documentation used for conformity assessment is as follows:

a) technical documentation for selected equipment specified in Annex 3 to this Decree; and
b) documentation concerning the management system of the manufacturer or person performing installation, and quality assurance documentation for selected equipment of the manufacturer or person performing installation, if the conformity assessment procedure includes an assessment of the management system of the manufacturer or person performing installation.

(2) Conformity assessment must be documented via

a) documents regarding the conformity assessment procedure used; and
b) documents issued during conformity assessment by an authorised person, an accredited person, a manufacturer, or an importer of selected equipment to the extent specified in individual conformity assessment procedures.

(3) For each piece of selected equipment for which a conformity assessment has been performed, a written declaration of conformity must be issued by whomever performs design, manufacture, or post-manufacture installation of this equipment. The essentials of a declaration of conformity are stipulated in Annex 5 to this Decree.

(4) A declaration of conformity is part of the accompanying technical documentation for selected equipment.

(5) If an authorised or accredited person refuses to issue a conformity assessment certificate, the grounds for this decision are part of the conformity assessment documentation.

(6) The documentation pursuant to (2) must be archived for the entire service life of the selected equipment.

§ 15

Specific procedures that may be applied to assess the conformity of selected equipment with technical requirements

(1) Individual conformity assessment procedures are as follows:

a) for selected equipment specified in § 12(2)(a):
    1. conformity assessment procedures B and D;
    2. conformity assessment procedures B and F; or
    3. conformity assessment procedure G;
b) for selected equipment specified in § 12(2)(b) Points 1 to 4:
    1. conformity assessment procedures B1 and D;
    2. conformity assessment procedures B1 and F;
    3. conformity assessment procedures B and E; or
    4. conformity assessment procedure G;
c) for selected equipment specified in § 12(2)(b) Point 5, conformity assessment procedure F;
d) for selected equipment specified in § 12(2)(b) Point 6:
    1. conformity assessment procedures B and E;

2. conformity assessment procedures B and D; or
3. conformity assessment procedure G;

e) for selected equipment specified in § 12(2)(c):
   1. conformity assessment procedure A1;
   2. conformity assessment procedure D1;
   3. conformity assessment procedure E1; or
   4. the conformity assessment procedure or a combination of conformity assessment procedure, if prescribed, specified in a) or b); and

f) for selected equipment specified in § 12(2)(b) Point 3, conformity assessment procedure A.

(2) Individual conformity assessment procedures within the scope of parts of selected equipment pursuant to § 12(6) are as follows:

a) for selected equipment specified in § 12(2)(a) and (b):
   1. conformity assessment procedure D1;
   2. conformity assessment procedure E1; or
   3. conformity assessment procedure G;

b) for selected equipment specified in § 12(2)(c):
   1. conformity assessment procedure A1;
   2. conformity assessment procedure D1; or
   3. conformity assessment procedure E1; and

c) for selected equipment specified in § 12(3), conformity assessment procedure A.

(3) Individual conformity assessment procedures are specified in Annex 7 to this Decree.

§ 16

Scope of and method for verifying conformity of selected equipment with technical requirements

(1) Verification of conformity of selected equipment in operation with technical requirements (hereinafter 'verification of conformity') must be performed in a manner and within the scope stipulated in Annex 8 to this Decree and in compliance with verification of conformity documentation pursuant to § 17(2).

(2) Regular verification of conformity must be planned and performed at intervals and in the manner stipulated in a programme of operating checks and in compliance with the technical specifications of individual pieces of selected equipment.

(3) Within the scope of regular verification of conformity, checks of selected equipment stipulated in a programme of operating checks must be performed. Requirements for these checks are stipulated in Annex 6 to this Decree.

(4) The results of checks must be assessed in terms of the technical safety of selected equipment within the scope of regular verification of conformity.

(5) The results of checks stipulated in repair or maintenance documentation must be assessed in terms of the technical safety of this equipment within the scope of verification of conformity following repairs, maintenance, or re-installation following repairs or maintenance of selected equipment.

(6) Within the scope of verification of conformity following repairs, maintenance, or re-installation following repairs or maintenance of selected equipment, it is necessary to verify that the part of the selected equipment specified in § 12(2) used during repair or maintenance

of selected equipment complies with technical requirements. Verification of parts of selected equipment is performed via procedure F1 pursuant to Annex 8 to this Decree.

(7) A final assessment pursuant to Annex 6 to this Decree must be performed within the scope of verification of conformity following repairs or post-repair re-installation and following changes to selected equipment.

§ 17

Method for documenting verification of conformity of selected equipment in use with technical requirements and the content of this documentation.

(1) Requirements for verification of conformity documentation are stipulated by Annex 8 to this Decree.

(2) Verification of conformity documentation contains:

a) work orders and guidelines for verification of conformity;
b) internal rules, if they contain information regarding checks of selected equipment;
c) plans for operating checks;
d) an operating check programme;
e) a managed ageing operating programme;
f) accompanying technical documentation for selected equipment pursuant to Annex 4 to this Decree;
g) documentation applicable to the preparation and performance of repairs and maintenance of selected equipment; and
h) records of operating checks and checks performed during repairs, maintenance, or changes to selected equipment.

(3) An operating check programme contains:

a) lists of individual pieces of selected equipment broken down by selected equipment type;
b) operating check programmes of individual pieces of selected equipment containing:
    1. checkpoints on selected equipment;
    2. check methods applied on checkpoints on selected equipment;
    3. acceptability criteria for assessing check methods;
    4. how often checks are performed during operation; and
c) an overview of changes made to the operating check programme during the commissioning and operation of selected equipment.

§ 18

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.

§ 19

Transitional provisions

(4) Conformity assessment of selected equipment that is specially designed for nuclear installation with technical requirements for ensuring technical safety pursuant to Decree No 309/2005, on provision of technical safety for selected equipment, as amended effective prior

to the effective date of this Decree, is considered to be conformity assessment of selected equipment or part thereof pursuant to this Decree, and verification pursuant to § 16(6) of this Decree, and it is assumed that this selected equipment meets the requirements of this Decree.

(5) Selected equipment which is not specially designed equipment for nuclear installations pursuant to Decree No 309/2005, on provision of technical safety for selected equipment, as amended, which was in effect before this Decree enters into legal effect, and which meets the requirements of Decree No 132/2008, on a quality assurance system in carrying out activities connected with use of nuclear energy and radiation protection and on quality assurance of selected equipment with regard to its safety classification, as amended effective prior to the effective date of this Decree, is considered selected equipment or part thereof that has undergone a conformity assessment pursuant to this Decree, and it is assumed that it meets the requirements of this Decree.

Chair:

Annex 1 to Decree No ……

Technical requirements for selected equipment and parts of selected equipment

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

1. General requirements

1.1. The technical requirements specified in this annex apply to all pressure equipment and pressure equipment assemblies and parts thereof.

1.2. Technical requirements specified 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 specified in § 12(3)(a) and (d).

1.3. Pressure equipment must be designed in compliance with requirements stipulated

1.3.1. in its technical specifications pursuant to the decree on nuclear installation design requirements; and

1.3.2. this decree.

1.4. Pressure equipment must be designed so that

1.4.1. a sudden breach cannot occur during all test and operating states, including impermissible media leaks;

1.4.2. all necessary planned and unplanned checks or diagnostics of this equipment can be safely performed during its operation; and

1.4.3. it can be safely repaired and maintained.

1.5. Pressure equipment must be designed to resist hazards that follow from the properties of the area where the nuclear installation is located, external effects, and internal effects.

1.6. Pressure equipment must be capable of performing its required function in all nuclear installation operating states and accident conditions for which it is intended.

1.7. Materials used in the manufacture of pressure equipment and parts thereof which ensure that the protective envelope is hermetically sealed are subject to requirements for materials for pressure equipment pursuant to Point 12 and 13 of part A of Annex 2 to this Decree.

1.8. Pressure equipment must be designed so that it can be decontaminated, and if possible, so that its internal surfaces can then be passivated.

1.9. Selected equipment design must be based on stipulated

1.9.1. calculated, operating, and test loads and their limits;

1.9.2. operating conditions for the given pressure equipment;

1.9.3. limit parameters for operability of pressure equipment whose function involves mechanical motion;

1.9.4. operating modes with respect to classification of pressure equipment in the appropriate safety class;

1.9.5. chemical and physical parameters of media used in pressure equipment;

1.9.6. corrosion effects of media on pressure equipment material for the duration of this equipment's required service life; and

1.9.7. requirements for the resistance of pressure equipment to seismic effects or to cyclic loading.

1.10. Pressure equipment must be designed to rule out or minimise the risk of a substantial loss of resistance to pressure due to defects leading to a breach of the pressure equipment's integrity and leakage of radioactive substances. In cases where this risk cannot be ruled out, suitable means of maintaining operating parameters must be used during operation of pressure equipment and its shut-down to maintain sufficient medial levels in the pressure equipment and to eliminate excess heat, by connected feed systems and heat elimination systems.

1.11. Pressure equipment making up the protective envelope system, including equipment affecting the hermetic seal of the protective envelope, must be designed so that it is possible to stipulate impermeability at calculated design pressure after the installation of all hermetic bushings, hermetic doors, and inputs.

1.12. Pipes that are pressure equipment must be designed so that the risk of overloading due to impermissible tolerances or excessive forces occurring especially at flanges, connections, and bellows are minimised, in particular through the use of supports, reinforcements, anchors, position levelling, and pre-stressing of hangers.

1.13. Pressure equipment must be designed for loading during nuclear installation operating states and accident conditions for which it is intended. It is necessary to take into account various loads that can act in concert, taking into account the likelihood of their simultaneous occurrence.

1.14. The design of pressure equipment ensuring suitable strength must be based on the calculation method pursuant to Point 2, supplemented by an experimental method if necessary. Only tested calculation programs may be used for calculations.

2. Calculation method

2.1. The calculation method used must apply a conservative approach and limit risks to persons and property to the lowest reasonably achievable degree in accordance with requirements stipulated in technical requirements and technical specifications

2.1.1. for strength calculations;
2.1.2. for mechanical properties of basic and auxiliary materials used;
2.1.3. for permanent joints;
2.1.4. for performance of checks and tests of selected equipment; and
2.1.5. for monitoring and assessing ageing of selected equipment.

Resistance to internal pressure and other stress perspectives

2.2. Permitted loads on pressure equipment must be limited with regards to the types of defects whose occurrence under operating conditions and operating modes can be predicted. Safety factors must be used that make it possible to entirely rule out any uncertainties that follow from manufacturing, real-life operating conditions, loads, calculation models, and material properties and behaviour.

Strength

2.3. To ensure the strength of pressure equipment, suitable strength calculations that include relevant calculated, operating, and test loads must be used.

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

2.4.1. internal and external pressure;

2.4.2. the effect of the equipment's own weight and its contents;
2.4.3. additional loads, including the effects of the weight of connected equipment, insulation, and piping;
2.4.4. forces elicited by supports and piping;
2.4.5. thermal effects, including thermal shocks;
2.4.6. vibration loads;
2.4.7. seismic effects and environmental conditions during extreme weather conditions;
2.4.8. processes leading to material degradation, including the effects of radioactivity;
2.4.9. hydraulic resistance and pressure shocks;
2.4.10. plane crashes; and
2.4.11. other loads that follow from a risk analysis pursuant to Point 3.1 of Part A of Annex 2 to this Decree.

Calculated loads

2.5. Calculated pressure must be higher than the highest permitted 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 pressure equipment simultaneously subjected to internal and external pressure, the calculation pressure is stipulated as the difference between these pressures for which the greatest wall thickness is achieved.

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

2.8. Other calculated loads must be selected so that in combination with the effects of calculated pressure to which limits for normal operating conditions apply, they specify the maximum wall thickness for equipment.

2.9. Pressure equipment must be designed so that the greatest stress and tension concentration values corresponding to calculated loads are kept within safe limits.

Operating loads

2.10. When calculating the strength of pressure equipment, all loads that can occur during normal operation and during accident conditions under which this equipment needs to perform its function must be taken into account. It is especially important to take into account loads causing strain and deformation in materials from which the equipment is made that occur during manufacture, transport, installation, and pressure tests, including residual strains, the effect of which on strength limit conditions must be assessed individually according to their significance.

Test loads

2.11. During strength calculations for pressure equipment, it is necessary to take into account test loads to which the pressure equipment will be subjected during the pressure test in the course of the final assessment.

2.12. The test pressure must be stipulated in relation to the calculated or highest permitted pressure, taking into account evaluation of geometric and material properties and test

conditions during manufacturing and operation in accordance with requirements specified in technical regulations or technical specifications for the manufacture of pressure equipment.

Strength calculation, design of basic dimensions, and check calculation

2.13. A strength calculation for pressure equipment must be performed for the following limit conditions:
  2.13.1. a sudden breach of integrity due to a ductile or brittle fracture;
  2.13.2. plastic deformation across the entire cross-section of the pressure equipment;
  2.13.3. unidirectional growth of the plastic component of relative deformation during cyclic loading leading to impermissible changes in dimensions or breach of integrity;
  2.13.4. creation of fractures during cyclic loading; and
  2.13.5. loss of stability.

2.14. Strength calculations for limit states listed in Point 2.13 must use values that correspond to material, strength, plastic, and brittle fracture characteristics and resistance to deformation stipulated for the given materials in technical regulations or experimentally stipulated by an accredited test facility. For purposes of this strength calculation, values stipulated in technical standards may be used.

2.15. In the case of permanent joints, suitable permanent joint coefficients must be chosen for material properties depending on the type of materials being joined, the type of non-destructive tests used, and expected operating conditions.

2.16. Pressure equipment design must, in a suitable manner corresponding to its intended use and its planned service life, take into account foreseeable degradation mechanisms, in particular the effect of radioactivity, corrosion, and material fatigue.

2.17. During the calculation of strength of pressure equipment, the following must be performed:
  2.17.1. a calculation for the design of basic equipment dimensions (hereinafter the 'basic dimensions design'); and
  2.17.2. a check calculation for the equipment (hereinafter the 'check calculation').

2.18. During the design of basic dimensions, permitted strains are calculated from tensile strength and from the proof stresses permissible for manufacture of pressure equipment. During the calculation of permitted strains, appropriate safety factors must be taken into account.

2.19. During the design of basic dimensions, limit states must be considered for
  2.19.1. breach of integrity due to a ductile fracture;
  2.19.2. plastic deformation across the entire cross-section of the pressure equipment; and
  2.19.3. loss of stability.

2.20. Following the design of basic equipment dimensions, a check calculation must be performed that must demonstrate:
  2.20.1. strength during static loading;
  2.20.2. strength during cyclic loading;
  2.20.3. resistance to a sudden breach;
  2.20.4. strength during vibration;
  2.20.5. resistance to loss of stability; and
  2.20.6. resistance to seismic effects.

2.21. The pressure equipment check calculation must take into account all loading, including thermal effects, and all operating states specified in technical specifications. Degradation of material properties during operation, surface quality, the effect of strain gradient, and the effect of a corrosive environment must be taken into account in particular.

3. Experimental design method for pressure equipment design

3.1. Correct design of pressure equipment or part thereof must be verified through suitable checks made on representative samples of pressure equipment in accordance with a check programme established for purposes of the experimental design method. This checks programme must be approved by an authorised person responsible for the design conformity assessment procedure.

3.2. The checks and testing programme must define test conditions and acceptability criteria. Prior to the performance of individual checks and tests, true values of basic dimensions and the properties of which the pressure equipment is made must be measured.

4. Design of safe handling and operation of pressure equipment

4.1. The prescribed manner of handling and operation of pressure equipment must rule out risks that follow from a risk analysis pursuant to Point 3.1 of Part A of Annex 2 to this Decree. Special attention must be given to

4.1.1. closures and openings;

4.1.2. hazardous blow-off from relief fittings; and

4.1.3. elements that prevent physical entry to the system, if the equipment is pressurised or contains a vacuum.

5. Test equipment

5.1. Pressure equipment must be designed so that all checks necessary to ensure technical safety can be performed.

5.2. If pressure equipment cannot be designed so that it can be checked to the required extent during operation,

5.2.1. other checks ensuring the same degree of technical safety, including indirect checks, must be stipulated; or

5.2.2. approved calculation methods must be used;

and safety margins must be stipulated in a conservative manner and reasonable safety measures must be taken to rule out possible unexpected pressure equipment failure.

6. Means for purging water and air

6.1. The pressure equipment design must, for its entire service life and during its testing, through the use of suitable means for purging water and air from the pressure equipment

6.1.1. prevent water shocks, destruction of the pressure equipment due to vacuum or corrosion and uncontrolled chemical reactions and other negative effects; and

6.1.2. permit the safe decontamination, cleaning, checking, and maintenance of pressure equipment.

7. Corrosion and other chemical effects

7.1. If the risk analysis pursuant to Point 3.1 of part A of Annex 2 to this Decree identified a risk of corrosion or other chemical effects, these effects must be minimised, taking

into account the intended use of the pressure equipment in the pressure equipment design, by

7.1.1. using other corrosion-resistant material;

7.1.2. increasing wall thickness by an additional corrosion factor; or

7.1.3. protecting against corrosion or other chemical effects.

8. Wear and tear

8.1. If the risk analysis pursuant to Point 3.1 of part A of Annex 2 to this Decree identified a risk of erosion or wear, these effects must be minimised, taking into account the intended use of the pressure equipment in the pressure equipment design, by

8.1.1. using other material resistant to erosion or wear;

8.1.2. increasing wall thickness by an additional wear factor; or

8.1.3. using liners or plating that allow the replacement of parts that are most affected; or

8.1.4. other measures minimising the effects of wear and tear.

9. Selected equipment assembly

9.1. A pressure equipment assembly must be designed so that

9.1.1. the parts being assembled are suitable and reliable for the given purpose;

9.1.2. all parts of the pressure equipment assembly are properly incorporated and assembled; and

9.1.3. parts are included in the pressure equipment assembly

9.1.3.1. based on foreseeable risks identified in the risk analysis pursuant to 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;

9.1.3.3. based on correct layout of jointly assembled parts of the pressure equipment assembly; and

9.1.3.4. with regards to the safety class into which the pressure equipment assembly is placed.

9.2. The manner in which the pressure equipment assembly is protected from exceeding operating limits and safety equipment checks must be designed with respect to the safety class into which the pressure equipment assembly is placed.

9.3. A pressure equipment assembly must be placed in the safety class that matches the highest safety class of at least one of its parts.

10. Filling and emptying

10.1. The pressure equipment design must use suitable construction, pressure equipment accessories, or the use of measures for its installation to ensure safe filling and emptying of the pressure equipment and sampling of process media, in particular keeping in mind risks

10.1.1. during its filling, which are

10.1.1.1. overfilling or exceeding pressure, in particular with respect to the filling ratio and to vapour pressures at the relevant temperature; and

10.1.1.2. pressure equipment instability;

10.1.2. during emptying that involves uncontrolled release of media under pressure; and

10.1.3. during filling or emptying that involves dangerous connections and interruption of connections.

11. Protection from exceeding permitted limits

11.1. If during the operation of pressure equipment permitted limits could be exceeded, the pressure equipment design must

11.1.1. include protective equipment to prevent these limits from being exceeded, or a combination of several pieces of such protective equipment; or

11.1.2. have suitable measures in place for its installation.

11.2. Protective equipment or a combination of several pieces of such protective equipment must be designed with regards to the specific properties of the pressure equipment or pressure equipment assembly that it is to protect.

11.3. Protective equipment or a combination of several pieces of such protective equipment is defined as

11.3.1. safety equipment; or

11.3.2. monitoring equipment such as indicators or warning devices that allow suitable automatic or manual intervention in order to maintain pressure equipment operation within permitted limits.

12. Safety equipment

12.1. Safety equipment

12.1.1. must be designed to ensure suitable and reliable protection of the given pressure equipment;

12.1.2. must be designed with regards to maintenance and supervision of this equipment;

12.1.3. must be designed to primarily ensure

12.1.3.1. protection from faults;

12.1.3.2. safety equipment redundancy;

12.1.3.3. various designs; and

12.1.3.4. automatic self-diagnostics;

12.1.4. must also protect, if required for its correct functionality, aside from the mechanical parts of the pressure equipment, power, control, measurement, and regulation systems and related nuclear installation control systems; and

12.1.5. must be assessed within the scope of conformity assessment of the pressure equipment or pressure equipment assembly.

12.2. Safety equipment must not be assigned any other functions unrelated to protection of pressure equipment, except for cases where these other functions cannot affect its protective functionality.

12.3. Equipment limiting media pressure, level, or flow must be designed so that the greatest permitted media pressure, level, or flow is not exceeded; a short-term pressure increase caused by safety equipment is permitted if it does not exceed 10 % of the greatest permitted pressure value.

12.4. Temperature measurement devices must have a suitable delay period in accordance with their measurement functions.

13. Electrical equipment

13.1. Electrical equipment must be designed

13.1.1. together with pressure equipment; and

13.1.2. in a manner that permits the reliable performance of the safety function of pressure equipment.

14. External fire protection

14.1. Taking into account its intended use, pressure equipment must be equipped with suitable accessories or measures must be put into place for its installation to meet requirements for damage control in the case of external fire.

15. Hydraulic and pneumatic equipment ensuring control, regulation, signalling, and measurement

15.1. The general requirements in Points 1.1 to 1.8, 1.13, and 1.1.4 and technical requirements for pressure equipment specified in Points 2, 3, 5 to 8, and 13 apply to hydraulic and pneumatic equipment providing control, regulation, signalling, and measurement.

15.2. Every quick-acting armature in a nuclear installation's safety system must be controlled by its own air line.

15.3. Pneumatic drives and air distribution lines must permit repeated application of pressure using air or another gas.

15.4. Pneumatic drives must be designed

15.4.1. to minimise creation of deposits, corrosion products, dust, and other impurities; and

15.4.2. so that its inner and outer surfaces make it as easy as possible to remove deposits, corrosion products, dust, and other impurities.

B. Technical requirements for selected control equipment

1. Selected control equipment must be designed in compliance with requirements stipulated
   1.1. in its technical specifications pursuant to the decree on nuclear installation design requirements; and
   1.2. in this Decree.
2. Selected control equipment must bear the name of its manufacturer, or if the manufacturer cannot be marked directly on the equipment, this identification must be marked on the package. The manufacturer must always be identified in accompanying technical documentation for this equipment.
3. Basic technical characteristics of selected control equipment that need to be adhered to during the operation of this equipment in order for its safe use in conditions for which it was made must be marked on the selected equipment and stated in its accompanying technical documentation, or if this information cannot be marked directly on this selected equipment, it must be stated in its accompanying technical documentation.
4. Pressure equipment must be designed to ensure that
   4.1. individuals are protected to a reasonable degree from injury or other hazards that could result from electrical current upon contact with live or non-live parts;
   4.2. individuals and property are protected from non-electrical hazards that the selected control equipment could cause;
   4.3. dangerous temperature increases, electrical arcs, or radiation do not occur;
   4.4. selected control equipment insulation design corresponds to all nuclear installation operating states and accident conditions for which this equipment is intended;
   4.5. it will resist hazards that follow from the properties of the area where the nuclear installation is located, external effects, and internal effects;
   4.6. it is capable of performing its required function in all nuclear installation operating states and accident conditions for which it is intended;

4.7. during operation or planned shutdown, it can be worked on safely, in particular regarding its separability ability to be disassembled; and
4.8. diagnostic equipment can be used effectively.

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 a manner that prevents their damage in an environment for which their characteristics were intended; and
5.2. placed on racks in a pre-specified arrangement in layers and gaps prescribed in the laying plan in order to ensure uninterruptible power system cables are separate from other cable sets.

C. Technical requirements for selected structural equipment

1. Selected structural equipment must be designed in compliance with requirements stipulated
1.1. in its technical specifications pursuant to the decree on nuclear installation design requirements; and
1.2. with requirements stipulated by this Decree.

2. Selected structural equipment must be designed so that it meets requirements pursuant to (1) during nuclear installation operating states and accident conditions for which it is intended.

3. Selected structural equipment must be designed to resist hazards that follow from the properties of the area where the nuclear installation is located, external effects, and internal effects.

4. Selected structural equipment must be capable of performing its required function in all nuclear installation operating states and accident conditions for which it is intended.

5. The design of selected structural equipment must be supported by calculations, models, or supplemented with experimental verification if required. Only tested calculation programs may be used for calculations.

6. Selected structural equipment must be designed so that the effects of loading and properties of the area where the nuclear installation is located, external effects, and internal effects stipulated by the nuclear installation's design cannot cause
6.1. structural collapse;
6.2. impermissible structural deformation;
6.3. interference with structural stability;
6.4. reduction of the structure's mechanical resistance;
6.5. impermissible structural vibration;
6.6. a threat to the functionality of selected equipment located inside the structure or in its vicinity; or
6.7. structural damage incommensurate to the root cause.

7. Selected structural equipment must be designed so that in case of fire
7.1. the integrity and load-bearing capability of the structure is preserved for a specified period;
7.2. spatial design and hermetic elements limit its propagation within the structure;
7.3. its propagation to adjacent structures is limited; and
7.4. individuals can exit the structure via escape routes.

Annex 2 to Decree No ……

Requirements for ensuring compliance of selected equipment and parts of selected equipment

A. Requirements for ensuring compliance during the design, manufacture, and installation of pressure equipment and some other selected equipment and parts thereof, and packaging for the transport, storage, and disposal of spent nuclear fuel

1. Selected equipment and parts thereof must be

   1.1. designed, manufactured, and installed in a manner that their technical safety is ensured during their commissioning; and

   1.2. manufactured in accordance with the technical documentation for the given type of packaging approved pursuant to the decree on type approval of certain products in the area of the peaceful use of nuclear energy and ionising radiation that transport of radioactive or fissile material, in the case of packaging for the transport, storage, and disposal of spent nuclear fuel.

2. Requirements for ensuring compliance during the design, manufacture, and installation of selected equipment specified in

   2.1. Points 1 and 3 to 17 apply to packaging for the transport, storage, and disposal of spent nuclear fuel; and

   2.2. Points 1, 3 to 5, 6.1 to 6.4, 6.5 sentence one, 6.6, 6.8, 7.1, 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 selected equipment specified in § 12(3)(a) and (d).

Pressure equipment design

3. During pressure equipment design,
   3.1. a risk analysis must be performed from the perspective of safety in order to identify and assess its possible risks; in order to assess these safety influences through a risk analysis, required states must be stipulated under which the pressure equipment must perform its function;
   3.2. the technical design of the pressure equipment must be performed taking into account the results of the risk analysis pursuant to Point 3.1;
   3.3. during the selection of the most suitable technical design of pressure equipment
      3.3.1. every foreseeable risk must be ruled out to an achievable degree; or
      3.3.2. suitable protective measures must be implemented to limit the effects of risks that cannot be ruled out; and
   3.4. the selected equipment design must be reviewed in terms of suitability and adequacy of stipulation of technical requirements, verified in terms of compliance with technical requirements, and validated in terms of technical requirements and its intended use.

Pressure equipment manufacture

4. **Manufacturing procedures**

   4.1. Pressure equipment must be manufactured in compliance with its technical documentation. Manufacturing methods and procedures must be designed so that all prescribed checks can be performed. During manufacturing, technical requirements that were adopted during the design process are applied.

5. **Parts manufacturing**

5.1. During the manufacture of pressure equipment, defects and cracks or changes in mechanical properties that could threaten its technical safety must not occur.

6. **Permanent joints**

6.1. Requirements for permanent joints apply primarily to the following joint types:
- 6.1.1. welded metal joints;
- 6.1.2. soldering; and
- 6.1.3. sprayed-on and welded-on materials.

6.2. Permanent joints and their adjacent areas must be performed so that they are free of any surface or internal defects that could threaten the technical safety of pressure equipment.

6.3. The basic mechanical properties of permanent joints must at least correspond to the properties of the basic materials that are being joined, unless values corresponding to other mechanical properties of the material were intentionally taken into account during strength calculations.

6.4. Technical, checking, and technological activities applicable to permanent joints on selected equipment may only be performed by welding supervisors certified by a national authorised body for the area of the creation and testing of permanent joints.

6.5. Permanent joints of parts of selected equipment specified in § 12(2) that contribute to the ability to equipment to resist internal pressure, and directly connected elements, must be made by appropriately qualified personnel using suitable work procedures. These work procedures and qualified personnel making permanent joints and welding supervisors must be approved by an authorised person, except for permanent joints on selected equipment specified in § 12(3).

6.6. Within the scope of conformity assessment of selected equipment,
- 6.6.1. checks must be performed to verify that the proposed technical procedure for creating a permanent joint is in compliance with technical requirements for permanent joints, including requirements of technical standards for checking permanent joints; or
- 6.6.2. a test weld joint must be made for selected equipment specified in § 12(2)(a) or (b).

6.7. An authorised person supervises performance of checks pursuant to 6.6.1 and of the test weld joint, including supervision of performance of relevant checks to assess this joint and transfer of markings.

6.8. Technical documentation for selected equipment dealing with welding must certify fulfilment of requirements for
- 6.8.1. the creation, assessment, and approval of work procedures for creation of permanent joints;
- 6.8.2. the required qualifications of personnel making permanent joints;
- 6.8.3. the required qualifications of personnel designing, verifying, and evaluating the welding process; and
- 6.8.4. the fitness of the welding and checking equipment.

7. **Non-destructive checks**

7.1. Non-destructive checks of permanent joints must be performed by personnel certified by a subject accredited by an accreditation authority pursuant to relevant technical

standards regarding qualification and certification of personnel performing non-destructive checks of welded joints.

7.2. Personnel performing non-destructive checks of permanent joints must be approved by an authorised person, except for permanent joints on selected equipment specified in § 12(3).

8. **Heat treatment**

8.1. If there is a risk that a manufacturing procedure will change material properties to an extent that could threaten the technical safety of pressure equipment, adequate heat treatment must be applied at a suitable stage of the manufacturing process.

8.2. Heat treatment of parts of pressure equipment must be performed by qualified personnel.

8.3. The heat treatment of parts of selected equipment specified in § 12(2)(a) must be performed under the supervision of an authorised person.

8.4. Personnel performing heat treatment of parts of pressure equipment specified in § 12(2)(a) must be approved by an authorised person.

9. **Identifiability**

9.1. Procedures must be implemented and follow to ensure the identifiability of
9.1.1. materials;
9.1.2. parts of pressure equipment; and
9.1.3. checks of materials and parts of pressure equipment.

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

10. **Marking and affixing labels**

10.1. Pressure equipment must be marked with a label, or in another manner. The label or other manner of marking must include
10.1.1. the name of the manufacturer or person performing installation; for example name, surname, and place of business in the case of a natural person, or the company name and registered offices, in the case of a legal entity;
10.1.2. the year of manufacture;
10.1.3. identification of pressure equipment according to its nature, for example type, series, or identification of production batch and serial number;
10.1.4. basic highest and lowest operating limits; and
10.1.5. designation of the person who performed a conformity assessment of pressure equipment, in the case of equipment specified in § 12(2).

10.2. The required information must be provided on the pressure equipment or on a label permanently affixed to it, except for cases when
10.2.1. suitable documentation us used, if possible, to prevent the repeated marking of individual parts intended for the same assembly, for example pipe sections; or
10.2.2. the pressure equipment is too small and information is provided on a separate label affixed to the pressure equipment.

11. **Instruction manuals**

11.1. If pressure equipment is being commissioned, if possible it must be accompanied by an instruction manual or other appropriate operating documentation containing all required information concerning technical safety concerning its

11.1.1. installation, or installation of a part thereof;
11.1.2. commissioning;
11.1.3. operation, including identification of its parts, operating conditions, and manner of its use; and
11.1.4. maintenance, including in-service checks.

11.2. The manual must contain information specified in Point 1.1, and if necessary for complete comprehension of the manual, must contain technical documentation, drawings, and schematics.

12. **Pressure equipment materials**

12.1. Only approved basic and auxiliary materials on the list of materials permitted for this use may be used to manufacture, repair, or modify pressure equipment. The list of materials must be drawn up with respect to classification of pressure equipment in the appropriate safety class.

12.2. Basic and auxiliary materials used must be suitable for the given use for the entire expected service life of the pressure equipment.

12.3. Auxiliary welding materials must meet requirements specified in Points 12 and 13, both alone and when incorporated within a structure.

13. **Materials of parts of pressure equipment exposed to pressure**

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

13.2. Parts of selected equipment exposed to pressure are always considered to be those parts that make up a pressure interface or that are joined to these parts in a permanent manner.

13.3. In choosing material for manufacture, installation, repair, or modification of pressure equipment, it is necessary to take into account its chemical composition, physical and mechanical properties, weldability and ability to operate under operating conditions in which the pressure equipment is to perform its function.

13.4. The material used in the manufacture, installation, repair, or modification of pressure equipment must be
13.4.1. the same as the material of the original part listed in the technical specifications of the pressure equipment;
13.4.2. on the list of materials permitted for the given use; or
13.4.3. another material, if material pursuant to Point 13.4.1 or 13.4.2 cannot be used.

13.5. If material pursuant to Point 13.4.2 is used that has properties different from the original material, it is necessary to prove that its properties are suitable for the given use with respect to operating conditions and the safety class of the given pressure equipment.

13.6. If the proposed material is not on the list of materials permitted for the given use, a specific assessment of the proposed material must take place; for pressure equipment specified in § 12(2), an authorised person must arrange the specific assessment of the proposed material.

13.7. Suitable measures must be implemented during manufacture, installation, repair, or modification to ensure that the material used complies with the requirements of the technical specifications for the pressure equipment. In particular, there must be documentation for all basic and auxiliary materials used available confirming the compliance of the materials used with the material's technical specifications.

13.8. Only material that has undergone an assessment of its conformity with technical requirements for material may be used to manufacture, repair, or modify pressure equipment.

13.9. The material assessment must be certified in terms of its compliance with technical material specifications,

13.9.1. by a material certificate issued by the manufacturer, confirmed by an authorised person, in the case of material for pressure equipment specified in § 12(2)(a) or (b);

13.9.2. by a material certificate issued by the manufacturer, in the case of material for pressure equipment specified in § 12(2)(c); and

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

13.10. For pressure equipment specified in § 12(2)(a) or (b), material for which a material certificate was issued pursuant to Point 13.9.2 and 13.9.3 may be used only if additional checks were performed with the participation of an authorised person in order to prove that this material is suitable for use in this pressure equipment. If the results of checks agree with the values specified in the original material certificate, the authorised person shall issue an inspection report or certificate proving compliance with conditions for use of the material in pressure equipment specified in § 12(2)(a) or (b).

14. **Material quality control**

14.1. Material quality control must be performed to the extent and using methods specified in technical regulations, technical standards, or technical specifications for materials.

14.2. Intermediate products for the manufacture of pressure equipment, in particular sheet metal, forged pieces, pressed pieces, cast pieces, rolled steel for joint parts, and intermediate products for the manufacture of seals, must be manufactured in compliance with requirements stipulated by the pressure equipment design, technical standards, or other technical specifications that determine the extent and methods of checks used to verify their quality.

14.3. Limit values for the steel's cobalt content must be stipulated for intermediate parts made of austenitic steels for the manufacture of pressure equipment that come into contact with primary circuit media.

Pressure equipment installation

15. Pressure equipment must be installed in compliance with a technical installation procedure that includes installation methods and procedures that make it possible to perform all prescribed checks. Technical requirements that were adopted during the design process are applied during installation.

16. Special processes used during installation of selected equipment or selected equipment assemblies must be performed in accordance with requirements for permanent joints, non-destructive checks, and thermal treatment specified in Points 6 to 8.

17. Installation quality must be verified based on a plan or programme of checks according to which the installation is performed.

B. Requirements for ensuring compliance during 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 a manner that during their commissioning their technical safety is ensured.

Selected control equipment design

2. During the design of selected control equipment,
   2.1. a risk analysis must be performed from the perspective of safety in order to identify and assess its possible risks; in order to assess these safety influences through a risk analysis, required states must be stipulated under which the selected control equipment must perform its function;
   2.2. the technical design of the selected control equipment must be performed taking into account the results of the risk analysis pursuant to Point 2.1;
   2.3. during the selection of the most suitable technical design of selected control equipment
      2.3.1. every foreseeable risk must be ruled out to an achievable degree; or
      2.3.2. suitable protective measures must be implemented to limit the effects of risks that cannot be ruled out; and
   2.4. the selected equipment design must be reviewed in terms of suitability and adequacy of stipulation of technical requirements, verified in terms of compliance with technical requirements, and validated in terms of technical requirements and its intended use.

Selected control equipment manufacture

3. Selected control equipment must be manufactured in compliance with a technical documentation for this equipment that includes suitable methods and appropriate manufacturing procedures that make it possible to perform all prescribed checks. During manufacturing, technical requirements that were adopted during the design process are applied.
4. For the manufacture of selected control equipment, it is necessary to implement and adhere to procedures ensuring the identification of this equipment during its manufacture.
5. During the manufacture of selected control equipment, checks must be performed in accordance with requirements stipulated in its technical documentation.

Selected control equipment installation

6. Selected control equipment must be installed in compliance with a technical installation procedure that includes installation methods and procedures that make it possible to perform all prescribed checks. During installation, technical requirements that were adopted during the design process are applied.
7. Special processes used during installation of selected control equipment must be performed in accordance with requirements for permanent joints, non-destructive checks, and thermal treatment specified in Part A Points 6 to 8 and software development requirements.
8. Installation quality must be verified based on a programme of checks according to which the installation is performed.

C. Requirements for ensuring compliance during the design, manufacture, and installation of selected structural equipment and parts thereof

1. Selected equipment and parts of selected equipment must be designed, manufactured, and installed in a manner that during their commissioning their technical safety is ensured.

Selected structural equipment design

2. Selected equipment design must be reviewed in terms of suitability and adequacy of stipulation of technical requirements, verified in terms of compliance with technical requirements, and validated in terms of technical requirements and its intended use.

Selected structural equipment manufacture and installation

3. Selected structural equipment must be designed, manufactured, and installed in accordance with technical documentation so that all prescribed checks necessary to ensure technical safety can be performed. During construction, technical requirements that were adopted during the design process are applied.
4. Concrete must be produced in compliance with prescribed production procedures that during hardening guarantee prescribed strength values and other properties stipulated in the selected equipment design. Prescribed strength values and other properties stipulated in the selected equipment design must be stipulated within the scope of production procedures.
5. Special processes used during installation of selected structural equipment must be performed in accordance with requirements for permanent joints, non-destructive checks, and thermal treatment specified in Part A Points 6 to 8.
6. Only metal and construction materials stipulated in this selected equipment design may be used for its manufacture and installation.

D. Requirements for ensuring compliance when commissioning selected equipment and parts thereof

1. Selected equipment or part thereof must be manufactured and supplied to ensure their safe and correct installation and connection.
2. Once installation of technologies and construction of the nuclear installation they are part of have completed, it must be verified whether technical specifications and unique identification of the placement of selected equipment is in compliance with the as-built status of the nuclear installation and whether they have appropriate accompanying technical documentation supplied by the manufacturer of the selected equipment or parts thereof and the installation and construction contractor to the extent of Annex 4 to this Decree, and it has been marked with the actual deliveries and work performed, specifically
   2.1. prior to the first insertion of nuclear fuel into a nuclear reactor or a nuclear installation without a nuclear reactor in the period immediately after deliveries or work have been completed;
   2.2. prior to the acceptance of the equipment by the operator of the nuclear installation and its use for the purpose for which it was made.
3. When commissioning a nuclear installation, individual selected equipment must be gradually tested in compliance with a predetermined
   3.1. operating check programme;
   3.2. pre-operational managed ageing programme for first physical startup; and

3.3. an operational managed ageing programme for first power startup and test operation in order to verify their compliance with technical requirements pursuant to Annex 1 to this Decree that are applied during operation, in order to facilitate the functional verification of the entire nuclear installation prior to the commencement of test operation.

4. Before commencing each phase of commissioning of selected equipment, the following must be certified:
   4.1. the training of operators and managers, with a list of names and job positions;
   4.2. the ability of personnel to manage and perform checks of selected equipment;
   4.3. the readiness of selected equipment in the relevant phase; and
   4.4. fulfilment of other requirements stipulated by the Office based on an assessment of the previous phase of commissioning.

E. Requirements for ensuring compliance when operating selected equipment and parts thereof

1. Selected equipment must be operated so that its technical safety is maintained during operation.
2. During operation, accompanying technical documentation of the selected equipment must be supplemented with additional documents regarding the performance of repairs, maintenance, or modifications to this equipment. A system of maintaining accompanying technical documentation must be implemented to make it possible to verify the fulfilment of technical requirements for selected equipment.
3. Selected equipment can be installed and de-installed only under predetermined safe conditions and in compliance with rules for installation, de-installation, and re-commissioning.
4. Selected equipment must be operated in compliance with the requirements of internal rules and other documentation for the operation of a nuclear facility. Rules for the maintenance and operation of selected equipment must include technical requirements and recommendations of the manufacturer of the selected equipment.
5. The selected equipment may be operated and used only for purposes and under conditions for which it is intended, and in compliance with the nuclear installation's design. Technical and organisational measures must be put in place that shall ensure that selected equipment is operated under conditions for which it has been designed, and does not threaten human health or present an inadmissible risk of damage to property.
6. During the operation of selected equipment, a system of tracking and documenting discrepancies from normal operation that could lead to defects and a reduction of the safety level of the selected equipment must be implemented.
7. During the operation of selected equipment, within the scope of an implemented managed ageing process for selected equipment, its condition must be tracked systematically, the impact of ageing and the effect of degradation mechanisms that could lead to defects and a reduction of the safety level of the selected equipment must be determined.
8. During the operation of selected equipment, a maintenance system and a system of checks performed during the operation of selected equipment must be put into place, which must
   8.1. be implemented with respect to operating conditions affecting the technical safety of this equipment; and
   8.2. stipulate technical and organisational measures for conformity assurance.

9. Maintenance, repairs, or modifications of selected equipment that is in operation must be performed in compliance with compliance assurance requirements for design, manufacturing, installation, and commissioning of selected equipment specified in Part A to D; if special processes are performed during maintenance, repairs, or modifications of selected equipment that is in operation, they must be performed in compliance with requirements for permanent joints, non-destructive checks, and thermal treatment specified in Part A Points 6 to 8.
10. During maintenance, repairs, or modifications of selected equipment, contractor supervision must take place involving verification that activities occurring during maintenance, repairs, or modifications of selected equipment are performed in compliance with documentation applicable to the preparation and performance of maintenance, repairs, or modifications of selected equipment.
11. Activities taking place on selected control equipment may be performed only by personnel qualified pursuant to Decree No 50/1978, on professional electrical engineering qualifications, as amended.

Annex 3 to Decree No

Requirements for technical documentation for selected equipment

Technical documentation for selected equipment must be drawn up in a well-organised manner to make it possible to assess conformity to the extent prescribed by this Decree.

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

Technical documentation for design, manufacture, and installation of pressure equipment, selected equipment specified in § 12(3)(a) and (d), and packaging for the transport, storage, and disposal of spent nuclear fuel contains

1. the name of the selected equipment, its identification, and description;
2. identification of the manufacturer;
3. the selected equipment design;
4. connection schematics;
5. manufacturing drawings and schematics of assemblies and sub-assemblies containing
   - 5.1. a description of the prescribed quality and condition of forged intermediate products or other selected equipment parts;
   - 5.2. a description of the prescribed quality of auxiliary materials;
   - 5.3. the dimensions and thickness of walls and information needed for their dimensioning;
   - 5.4. the placement, type, dimensions, values of coefficients of welded joints, and their class;
   - 5.5. types of checks, test media and their parameters, and acceptability criteria;
   - 5.6. descriptions and legends needed to understand drawings, schematics, and functions of selected equipment; and
   - 5.7. the greatest permitted pressure, calculated temperature, and test pressure, in the case of pressure equipment;
6. technical information regarding pressure gear, including its technical documentation if it is stand-alone selected equipment;
7. technical information regarding safety equipment and equipment ensuring the functionality of pressure equipment;
8. a list of technical regulations, technical standards, and technical specifications that were or should be used;
9. certificates of suitability for solutions used in designing selected equipment;
10. results of strength calculations, service life calculations, including conditions for their applicability, seismic resistance calculations, and other important technical information drawn up according to technical standards and technical specifications used, or new scientific and technical developments;
11. degradation mechanisms or impacts of ageing used in service life calculations;
12. results of risk analyses in terms of technical safety performed during selected equipment design;
13. certificates confirming compliance of material with technical specifications for basic and auxiliary materials used in the manufacture of selected equipment or parts thereof;
14. technical specifications for the manufacture and installation of selected equipment or similar documents that contain
    - 14.1. technical specifications for basic and auxiliary materials or intermediate products;
    - 14.2. specific requirements for materials processing technology, in particular requirements for the thermal treatment process and internal crystalline structure and homogeneity;
    - 14.3. a description of expected service conditions;

14.4. information important to reliability, service life, and other information important to technical safety;
14.5. a description of initial, intra-operational, and final checks, acceptability criteria, media used during these checks, and their parameters;
14.6. the method and scope for verifying the technical condition of selected equipment during its operation; and
14.7. a description of the scope of accompanying technical documentation for selected equipment;
15. check plans and programmes for the design, manufacture, and installation of selected equipment;
16. a preliminary managed ageing programme;
17. a list of parts of selected equipment and technical requirements for these parts of selected equipment;
18. a description of technological procedures for manufacturing or installation, including a description of technical and organisational measures;
19. regulations for the commissioning or operation of selected equipment;
20. a list of welding supervisors and personnel checking and assessing permanent joints, including their authorisation and their name, surname, and date of birth, if a permanent joint is created during manufacturing or installation;
21. a list of personnel performing special processes, including the type and validity of their authorisation and their name, surname, and date of birth, if a special process is performed during manufacturing or installation; and
22. sample record forms, including test attestation and certificates, used during manufacturing or installation of 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 contains
1. the name of the selected equipment, its identification, and description;
2. the selected equipment design;
3. identification of the manufacturer;
4. drawings and schematics of parts and circuits containing
   4.1. a description of the prescribed quality of parts of selected equipment; and
   4.2. descriptions and legends needed to understand drawings, schematics, and functions of selected equipment;
5. a list of technical regulations, technical standards, and technical specifications that were or should be used;
6. results of risk analyses from the perspective of technical safety performed during selected equipment design;
7. instruction manuals;
8. the results of design calculations;
9. results of service life calculations, including conditions for their applicability, seismic resistance calculations, and other important technical information drawn up according to technical standards and technical specifications used, or new scientific and technical developments;
10. degradation mechanisms or impacts of ageing used in service life calculations;
11. check plans and programmes for the design, manufacture, and installation of selected equipment;
12. a preliminary managed ageing programme;

13. test certificates from type examinations and results of assessments by independent test facilities;
14. a list of parts of selected equipment and technical requirements for these parts of selected equipment;
15. requirements for checking selected equipment and parts thereof;
16. a list of welding supervisors and personnel checking and assessing permanent joints, including their authorisation and their name, surname, and date of birth, if a permanent joint is created during manufacturing or installation;
17. a list of personnel performing special processes, including the type and validity of their authorisation and their name, surname, and date of birth, if a special process is performed during manufacturing or installation;
18. a description of the scope of accompanying technical documentation for selected equipment; and
19. regulations for the installation, commissioning, and operation of selected equipment.

C. Technical documentation for the design, manufacture, and installation of selected structural equipment

Technical documentation for the design, manufacture, and installation of selected structural equipment contains

1. the name of the selected equipment, its identification, and description;
2. the selected equipment design;
3. a description of the structural part into which it will be incorporated;
4. identification of how it will be incorporated into or used in the structural part;
5. identification of the manufacturer;
6. a list of technical regulations, technical standards, and technical specifications that were or should be used;
7. complete static calculations and dynamic calculations, if performed;
8. manufacturing drawings and drawings of the structural part into which the selected equipment will be incorporated, containing
   8.1. a description of the prescribed quality of parts of selected equipment;
   8.2. a description of the prescribed quality of materials used; and
   8.3. descriptions and legends needed to understand drawings and functions of selected equipment;
9. manufacturing, installation, and usage procedures for selected equipment, including requirements for
   9.1. pouring concrete and installing rebar;
   9.2. implementation of bushings, hermetic doors, hatches, and closures;
   9.3. implementation of surface treatments of structures;
   9.4. implementation of individual terminals used for individual leak checks of individual parts of pressure equipment that is part of the protective envelope system; and
   9.5. implementation of structural electrical wiring;
10. information regarding the properties of structural or metal materials;
11. results of service life calculations, including conditions for their applicability, seismic resistance calculations, and other important technical information drawn up according to technical standards and technical specifications used, or new scientific and technical developments;
12. degradation mechanisms or impacts of ageing used in service life calculations;
13. check plans and programmes for the design, manufacture, and installation of selected equipment;
14. a preliminary managed ageing programme;

15. a list of welding supervisors and personnel checking and assessing permanent joints, including their authorisation and their name, surname, and date of birth, if a permanent joint is created during manufacturing or installation;
16. a list of personnel performing special processes, including the type and validity of their authorisation and their name, surname, and date of birth, if a special process is performed during manufacturing or installation;
17. records with the results of design and engineering calculations and tests, as well as certificates, if these were issued prior to conformity assessment; and
18. a description of the scope of accompanying technical documentation for selected equipment.

Annex 4 to Decree No

Requirements for accompanying technical documentation for selected equipment

Accompanying technical documentation for selected equipment must be drawn up in a well-organised manner in order to document the results of conformity assurance and verification to the necessary degree for the entire duration of this equipment's operation.

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

Accompanying technical documentation for pressure equipment specified in § 12(3)(a) and (d), and packaging for the transport, storage, and disposal of spent nuclear fuel contains

1. a technical passport made out 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 check plan and programme for the design, manufacture, and installation of selected equipment in terms of fulfilment of the requirements they contain;
   1.4. material certificates;
   1.5. records of checks performed and their evaluation;
   1.6. thermal treatment records; and
   1.7. final assessment records;
2. results of strength calculations, service life calculations, including conditions for their applicability, seismic resistance calculations, and other important technical information drawn up according to technical standards and technical specifications used, and new scientific and technical developments;
3. a preliminary managed ageing programme;
4. drawings for selected equipment containing
   4.1. an assembly drawing with the main connection dimensions;
   4.2. a drawing of individual parts of selected equipment;
   4.3. a drawing for the expected scope of repairs specified in the manual;
   4.4. axonometric schematics indicating individual welds, suspension points, fixed points, and supports, in the case of pipes, or
   4.5. drawings indicating individual welds, bushings, access holes, hatches, hermetic doors, or other equipment ensuring the protective envelope is hermetically sealed, in the case of pressure equipment making up the protective envelope system;
5. attestation certificates for welding technologies used;
6. a list of personnel performing special processes, including the type and validity of their authorisation and their name, surname, and date of birth;
7. a list of welding supervisors and personnel checking and assessing permanent joints, including their authorisation and their name, surname, and date of birth;
8. technical information regarding pressure gear, including its technical documentation if it is stand-alone selected equipment;
9. technical information regarding safety equipment and equipment ensuring the functionality of pressure equipment;
10. information regarding repairs performed during manufacturing or installation;
11. documentation containing information concerning technical safety during operation of selected equipment, in particular an instruction manual and installation, commissioning, and operating instructions, including repair and maintenance instructions;
12. documentation containing information concerning managed ageing of selected equipment during its commissioning and operation, in particular monitored parameters and their limit

values for monitoring and evaluation of the ageing of selected equipment and measures to be taken when the limit values of monitored parameters are reached;
13. records of repairs and maintenance performed on selected equipment, including records of the results of checks performed after repair, maintenance, or re-installation following repair or maintenance of selected equipment, or information as to where these records are kept and archived; and
14. records of modifications to selected equipment, including records of the results of checks performed after this equipment has been re-installed, or information as to where these records are kept and archived.

B. Accompanying technical documentation for selected control equipment

Accompanying technical documentation for selected control equipment contains
1. the name of the selected equipment, its identification, and description;
2. a declaration of conformity;
3. a check plan and programme for the design, manufacture, and installation of selected equipment assessed in terms of fulfilment of the requirements they contain;
4. a preliminary managed ageing programme;
5. records of checks performed and inspection reports and their evaluation;
6. documentation containing information concerning technical safety during operation of selected equipment, in particular an instruction manual and installation, commissioning, and operating instructions, including repair and maintenance instructions;
7. a list of personnel performing special processes, including the type and validity of their authorisation and their name, surname, and date of birth;
8. a list of welding supervisors and personnel checking and assessing permanent joints, including their authorisation and their name, surname, and date of birth;
9. cable laying plans, including documentation regarding fire prevention measures in cable channels and areas where cables are located;
10. selected equipment design, including internal schematics for switchgear;
11. attestation certificates for welding technologies used;
12. records of repairs and maintenance performed on selected equipment, including records of the results of checks performed after repair, maintenance, or re-installation following repair or maintenance of selected equipment, or information as to where these records are kept and archived;
13. documentation containing information concerning managed ageing of selected equipment during its commissioning and operation, in particular monitored parameters and their limit values for monitoring and evaluation of the ageing of selected equipment and measures to be taken when the limit values of monitored parameters are reached; and
14. records of modifications to selected equipment, including records of the results of checks performed after re-installation of this equipment, or information as to where these records are kept and archived.

C. Accompanying technical documentation for selected structural equipment

Accompanying technical documentation for selected structural equipment contains
1. the name of the selected equipment, its identification, and description;
2. a declaration of conformity;
3. a check plan and programme for the design, manufacture, and installation of selected equipment assessed in terms of fulfilment of the requirements they contain;
4. a preliminary managed ageing programme;
5. results of strength calculations, service life calculations, including conditions for their applicability, seismic resistance calculations, and other important technical information

drawn up according to technical standards and technical specifications used, and new scientific and technical developments;

6. records of checks performed and their evaluation, including records from concrete property checks;
7. selected equipment drawings and drawings of the structural part into which the selected equipment will be incorporated;
8. documentation containing information regarding properties of selected equipment;
9. a list of personnel performing special processes, including the type and validity of their authorisation and their name, surname, and date of birth;
10. a list of welding supervisors and personnel checking and assessing permanent joints, including their authorisation and their name, surname, and date of birth;
11. identification of how it will be incorporated into or used in the structural part;
12. documentation containing information concerning technical safety during operation of selected equipment, in particular commissioning and operating instructions, including repair and maintenance instructions; and
13. documentation containing information concerning managed ageing of selected equipment during its commissioning and operation, in particular monitored parameters and their limit values for monitoring and evaluation of the ageing of selected equipment and measures to be taken when the limit values of monitored parameters are reached.

Annex 5 to Decree No

Essentials of a declaration of conformity

A declaration of conformity for selected equipment contains

1. identification of the declaration of conformity;
2. identification information of the person issuing the declaration of conformity;
3. the name of the selected equipment, its identification, and basic description;
4. identification of the structural part into which the selected equipment is to be incorporated, in the case of selected structural equipment;
5. identification information of the manufacturer;
6. identification information of the person performing the conformity assessment of selected equipment;
7. references to technical requirements and technical specifications of selected equipment;
8. information regarding the conformity assessment procedure or combination of conformity assessment procedures used;
9. references to documents issued during conformity assessment by the person performing the conformity assessment to the extent specified in individual conformity assessment procedures;
10. references to legislation, technical regulations, technical standards, or technical specifications used;
11. a declaration that the selected equipment meets the requirements of this Decree from the manufacturer, importer, or installer of the selected equipment;
12. the date the declaration of conformity was issued; and
13. the name and function of the person authorised to sign the declaration of conformity for the person issuing the declaration of conformity.

Identification information is the name(s), surname, residential or business address and ID number, if assigned, in the case of a natural person, or the company name, registered offices, and ID number in the case of a legal entity.

Annex 6 to Decree No

Requirements for performance of selected equipment checks

A. General checking requirements

1. Basic requirements for the scope, type, and manner in which checks are performed during the design, manufacture, installation, commissioning, and operation of selected equipment and acceptability criteria used during these checks must be stipulated in
   1.1. technical documentation for selected equipment;
   1.2. documentation regarding repairs, maintenance, or modifications to selected equipment; or
   1.3. operating check programmes for selected equipment:
2. The scope, type, and manner in which checks are performed on selected equipment and acceptability criteria used during these checks must be chosen in a manner that proves that the selected equipment meets technical requirements.
3. Selected equipment must be checked in accordance with procedures stipulated in the checks programme. Technical, organisational, and safety measures must be implemented to meet requirements for the scope, type, and manner in which checks are performed.
4. Selected equipment may only be checked by personnel qualified to check selected equipment and authorised to perform this activity by a person is obliged to perform conformity assurance that pursuant to § 57 of the Act; only personnel authorised by a nuclear installation operating permit holder may check selected equipment that is in operation.
5. All measuring instruments used during checks must at the time of the checks are performed have valid metrological calibration or verification in accordance with requirements for ensuring metrological uniformity and correctness of measuring instruments and measurements pursuant to the Metrology Act. Metrological continuity of measuring instruments used must be documented.
6. The results of checks must be documented by a check performance record. A check performance records contains
   6.1. information regarding the subject of the check;
   6.2. a description of the scope of the check;
   6.3. a description of the procedure used during the check or the checking activity methodology;
   6.4. a list of measuring instruments and other devices used during the check; and
   6.5. an evaluation of the results of the check in terms of acceptability criteria used during the check.
7. The list of checks performed must be confirmed by the signature and assigned mark of those performing them.

B. Requirements for checks of selected equipment upon completion of manufacturing and installation, and checks of selected equipment performed within the scope of conformity assessment after repair, maintenance, or re-installation after repair or maintenance of selected equipment

1. Final assessment

1.1. Prior to commencing final assessment of selected equipment, authorised personnel performing supervision during the manufacture, installation, or repair of selected equipment must have at their disposal all documentation and information needed to perform the final assessment, including in particular:

1.1.1. final assessment procedures, including final test, pressure test, tightness test, or other equivalent test procedures; and
1.1.2. accompanying technical documentation for selected equipment.

1.2. The conformity assessment is issued contingent on a positive final assessment.

Final assessment of pressure equipment

1.3. Final assessment of pressure equipment includes
1.3.1. a final test;
1.3.2. a pressure test, a tightness test, or other equivalent test; and
1.3.3. a check of safety equipment and equipment ensuring the functionality of pressure equipment;

1.4. A pressure test, a tightness test, or other equivalent test
1.4.1. During a pressure test or tightness test, it must be verified that during test pressure the pressure equipment does not exhibit significant deformation or leakage exceeding stipulated acceptability criteria.
1.4.2. If a pressure test or tightness test is unsuitable for or impossible to perform on the given pressure equipment, other equivalent tests must be performed that can be used to verify the strength and tightness of the pressure equipment.
1.4.3. A pressure test and tightness test is performed using hydraulic pressure prescribed in technical specifications for the given pressure equipment. The test hydraulic pressure must be stipulated pursuant to Point 2.12 of Part A of Annex 1 to this Decree;

1.5. Final test
1.5.1. During the final test, a visual inspection of the pressure equipment and a check of the accompanying technical documentation for the selected equipment must be performed to assess whether the selected equipment and related quality assurance records are in mutual accord and comply with all requirements stipulated in technical documentation or compliance verification documentation.
1.5.2. Tests performed during the manufacturing of the pressure equipment can also be taken into account in performing the final test.
1.5.3. During the final test, every part of the pressure equipment must be visually inspected internally as well as externally in terms of technical safety, if necessary. If this inspection cannot be arranged during the final test, especially in cases where the nature of the pressure equipment makes inspection of its individual parts impossible without the need for disassembly, this inspection can be performed during checking operations preceding the final test, and the final test will simply involve a check of the accompanying technical documentation.

1.5.4. The final test must primarily verify the following:
1.5.4.1. identification markings on the pressure equipment, including information on equipment labels and information embossed on pressure parts and markings on materials, castings, and intermediate products;
1.5.4.2. the main dimensions of the equipment, the location of orifices, access holes, gear, feet, supports, and the assembly of individual parts according to drawings;
1.5.4.3. the results of checks of welded joints via an external or internal inspection, including the results of prescribed checks during the

performance of special processes, welders' marks, welding supervision records, thermal treatment records, and materials certification of materials and intermediate products used; and

1.5.4.4. compliance with welders' marks placed on selected equipment with lists of welders, identifying their qualifications.

1.6. Check of safety equipment and equipment ensuring the functionality of pressure equipment;

1.6.1. A check of safety equipment and equipment ensuring the functionality of pressure equipment must be made to verify fulfilment of requirements stipulated

1.6.1.1. for safety equipment in Point 12 of Part A of Annex 1 to this Decree;

1.6.1.2. for electrical equipment in Point 13 of Part A of Annex 1 to this Decree; and

1.6.1.3. for hydraulic and pneumatic equipment providing control, regulation, signalling, and measurement during operation in Point 15 of Part A of Annex 1 to this Decree.

1.7. Final assessment after repair or modifications to selected equipment specified in § 12(2)(a) or (b) must always be performed under the supervision of an authorised representative of a permit holder.

1.8. A final assessment for pressure equipment that makes up the protective envelope system, equipment ensuring the protective envelope is hermetically sealed during a maximum design accident, including selected structural equipment, consists only of a final test that includes:

1.8.1. a check that the structure and relevant equipment are complete once construction and installation work has been completed;

1.8.2. a check that quality records for individual selected equipment are complete, including quality records for equipment ensuring they are hermetically sealed;

1.8.3. individual tightness checks of individual parts of pressure equipment that is part of the protective envelope system, dimensioned for internal overpressure; and

1.8.4. A pressure test and tightness test is performed using hydraulic pressure prescribed in technical specifications for the given pressure equipment.

1.9. Successful performance of the final test is required for commencement of pressure tests, tightness tests, and other equivalent tests.

1.10. A final test and a pressure test, tightness test, or other equivalent test performed within the scope of conformity verification following repair or re-installation following repair must be performed by a technical inspector pursuant to Decree No 18/1979, which specifies certain pressure equipment subject to specific obligations and provides for certain conditions to ensure the safety thereof, as amended.

<u>Final assessment of selected control equipment</u>

1.11. A final assessment of selected control equipment only includes a final test, during which a visual inspection and a check of the accompanying technical documentation for the selected equipment must be performed to assess whether the selected equipment and related quality assurance records are in mutual accord and comply with all requirements stipulated in technical documentation or compliance verification documentation.

1.12. In performing the final test, tests performed during the manufacture of the selected control equipment can also be taken into account.

1.13. The final test of selected control equipment must primarily verify the following:
1.13.1. identification of the selected equipment;
1.13.2. that checks stipulated in technical documentation or repair documentation for selected equipment were performed completely.

2. Other checks after the completion of manufacture and installation of selected equipment

2.1. Once the installation of pressure equipment has been completed, an individual test of the pressure equipment must be performed, if one has been stipulated in the design for this selected equipment, to verify that the equipment is complete and functional, and that it has been properly installed.

2.2. Once the installation of selected control equipment that ensures the activity of emergency systems and primary circuit after-cooling systems has been completed, in particular of their power, control, regulation, protection, signalling, and measurement, their correct functionality must be verified.

C. Requirements for checking selected equipment within the scope of regular conformity verification

1. Checks performed as part of regular conformity verification must verify whether the technical condition of selected equipment has not deteriorated and whether it is suitable for continued operation.

2. During conformity verification, it must be ensured that the following are performed:
2.1. periodical operating checks;
2.2. checks pursuant to the managed ageing operating programme;
2.3. a final assessment following repair or modification;
2.4. periodic strength and tightness checks of the primary and secondary circuit of the nuclear installation;
2.5. periodic strength and tightness checks of hermetic areas of the protective envelop system; and
2.6. other checks prescribed by internal rules for the operation of the nuclear installation.

3. Within the scope of conformity verification of selected equipment, it must be ensured that the following are performed:
3.1. periodical operating checks;
3.2. checks pursuant to the managed ageing operating programme;
3.3. a final assessment following repair or modification; and
3.4. other checks prescribed by internal rules for the operation of the nuclear installation.

Annex 7 to Decree No

Conformity assessment procedures

1. CONFORMITY ASSESSMENT PROCEDURE A (INTERNAL MANUFACTURING CONTROL)

1. A manufacturer, importer, or person installing selected equipment after manufacture performing conformity assessment through this procedure must, in compliance with this procedure, ensure that the selected equipment meets the requirements of this Decree, and issue a declaration of conformity.
2. A manufacturer, importer, or person installing selected equipment after manufacture must ensure the performance of an initial selected equipment type examination on a sample and assess whether the selected equipment type meets technical requirements, technical standards, or technical specifications, in the case of selected structural equipment pursuant to § 12(3)(c).
3. A manufacturer, importer, or person installing selected equipment after manufacture must take all necessary measures to ensure the manufacturing process and its supervision ensures compliance of the selected equipment with the requirements of this Decree.
4. A manufacturer, importer, or person installing selected equipment after manufacture must ensure that a final assessment is performed on every piece of selected equipment.
5. If the selected equipment meets the requirements of this Decree, the manufacturer, importer, or person installing the selected equipment after manufacture shall mark it with a conformity mark along with his identification, and issue a declaration of conformity; in the case of selected structural equipment pursuant to § 12(3)(c), a declaration of conformity can only be issued if the selected equipment is the same as the type assessed pursuant to Point 2.

2. CONFORMITY ASSESSMENT PROCEDURE A1 (INTERNAL MANUFACTURING CONTROL WITH SUPVERVISION OF FINAL ASSESSMENT)

1. A manufacturer, importer, or person installing selected equipment after manufacture performing conformity assessment through this procedure must, in compliance with this procedure and conformity assessment procedure A and under the supervision of an accredited or authorised person of the final assessment, ensure that the selected equipment meets the requirements of this Decree, and issue a declaration of conformity.
2. An accredited or authorised person performs supervision of the final assessment by performing unannounced checks, within the scope of which
   2.1. he checks that the final assessment of the selected equipment is performed in compliance with final assessment requirements in Annex 6 to this Decree; and
   2.2. takes samples of selected equipment from manufacturing or storage areas for checking.
3. The accredited or authorised person determines the number of pieces of selected equipment in the sample for which he shall include in conducting in the final assessment.
4. In cases in which one or more pieces of selected equipment is not satisfactory, the accredited or authorised person shall specify suitable measures to eliminate the discrepancy.

5. Based on the results of supervision of the final assessment, the accredited or authorised person must issue a report on the check.

6. If the performance of the final assessment complies with the requirements of this Decree, the accredited or authorised person shall mark the selected equipment for which he performed the supervision of final assessment with his identification; selected equipment may be marked with the identification of the accredited or authorised person by the manufacturer or importer based on authorisation by the accredited or authorised person.

3. CONFORMITY ASSESSMENT PROCEDURE B (TYPE EXAMINATION)

1. The manufacturer or importer must ensure, in compliance with this procedure, that the sample of selected equipment that is to be manufactured (hereinafter the 'type') meets the requirements of this Decree.

2. The type may include multiple modifications to selected equipment, assuming that differences between individual modifications do not affect its degree of technical safety.

3. The manufacturer or importer must submit a request for a conformity assessment to the chosen authorised person. The request contains
   3.1. identification information of the manufacturer or importer, as follows:
      3.1.1. the name(s), surname, residential or business address and ID number, if assigned, in the case of a natural person; or
      3.1.2. the company name, registered offices, and ID number in the case of a legal entity;
   3.2. a written declaration that a conformity assessment contract has not been concluded with a different authorised person;
   3.3. technical documentation for the selected equipment;
   3.4. its type; and
   3.5. other information on the selected equipment necessary for the conformity assessment, in particular its safety class.

4. The authorised person will ask for additional types if this is necessary for the performance of the test programme.

5. An authorised person
   5.1. reviews technical documentation for the selected equipment, including an assessment of whether it meets requirements stipulated in Annex 3 to this Decree;
   5.2. assesses materials used, including assessment of material certificates pursuant to Point 13.9 of Part A of Annex 2 to this Decree, if they were not already assessed by a different authorised person;
   5.3. checks technological procedures for the creation of permanent joints pursuant to Point 6.6 of Part A of Annex 2 to this Decree and approves these procedures, if they were not already approved by a different authorised person;
   5.4. checks that personnel performing special processes and welding supervisors have valid qualification certificates, and approves these personnel pursuant to Point 6.6, 7.2, and 8.3 of part A of Annex 2 to this Decree;
   5.5. performs checks or has them performed in order to determine whether technical standards or technical specifications have been used properly;
   5.6. reaches an agreement with the manufacturer, importer, or person installing selected equipment after manufacture regarding the location where verification of whether the type was manufactured in compliance with reviewed technical documentation will take place;

5.7. verifies whether the type is in compliance with the requirements of this Decree, including performing necessary related checks; and
5.8. creates an inspection report on the assessment of activities specified in Points 5.1 to 5.7 and their results.

6. If the type complies with the requirements of this Decree, the authorised person shall issue the manufacturer, importer, or person installing selected equipment after manufacture a type examination certificate. The certificate contains
6.1. the name of the selected equipment, its identification, and basic description;
6.2. identification information of the manufacturer or importer, as follows:
6.2.1. the name(s), surname, residential or business address and ID number, if assigned, in the case of a natural person; or
6.2.2. the company name, registered offices, and ID number in the case of a legal entity;
6.3. the conclusions of the type examination;
6.4. the expiry date of the certificate; and
6.5. other documents needed to prove the type's compliance with the requirements of the Decree.

7. The manufacturer or importer must inform the authorised person that issued the type examination certificate regarding all changes to the type described in the type examination certificate. If the type change could affect the selected equipment’s compliance with technical requirements, the authorised person verifies this change by proceeding in accordance with Point 5, and if this change corresponds to the requirements of this Decree, issued an addendum to the original type examination certificate.

8. The authorised person keeps a copy of the type examination certificate and the inspection report on file.

9. The authorised person informs the Office of type examination certificates or their addenda that have been issued, rescinded, suspended, or otherwise restricted, and makes them available to the Office upon request.

10. The authorised person informs other authorised persons performing conformity assessment of type examination certificates or their addenda that have been issued, rescinded, suspended, or otherwise restricted.

4. CONFORMITY ASSESSMENT PROCEDURE B1 (DESIGN EXAMINATION)

1. The manufacturer or importer must ensure, in compliance with this procedure, that the selected equipment design meets 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 request for a conformity assessment to the chosen authorised person. The request contains
3.1. identification information of the manufacturer or importer, as follows:
3.1.1. the name(s), surname, residential or business address and ID number, if assigned, in the case of a natural person; or
3.1.2. the company name, registered offices, and ID number in the case of a legal entity;
3.2. a written declaration that a conformity assessment contract has not been concluded with a different authorised person;
3.3. technical documentation for the selected equipment;

3.4. the selected equipment design; and
3.5. other information on the selected equipment necessary for the conformity assessment, in particular its safety class.

4. The design may include multiple modifications to selected equipment being designed, assuming that differences between individual modifications do not affect its degree of technical safety.

5. An authorised person
5.1. reviews technical documentation for the selected equipment, including an assessment of whether it meets requirements stipulated in Annex 3 to this Decree;
5.2. assesses materials used, including assessment of material certificates pursuant to Point 13.9 of Part A of Annex 2 to this Decree, if they were not already assessed by a different authorised person;
5.3. checks technological procedures for the creation of permanent joints pursuant to Point 6.6 of Part A of Annex 2 to this Decree and approves these procedures, if they were not already approved by a different authorised person;
5.4. checks that personnel performing special processes and welding supervisors have valid qualification certificates, and approves these personnel pursuant to Point 6.6, 7.2, and 8.3 of part A of Annex 2 to this Decree;
5.5. performs checks or has them performed in order to determine whether technical standards or technical specifications have been used properly;
5.6. checks that the selected equipment design is in compliance with the requirements of this Decree; and
5.7. creates an inspection report on the assessment of activities specified in Points 5.1 to 5.6 and their results.

6. If the selected equipment design complies with the requirements of this Decree, the authorised person shall issue the manufacturer, or importer a design examination certificate. The certificate contains
6.1. the name of the selected equipment, its identification, and basic description;
6.2. identification information of the manufacturer or importer, as follows:
6.2.1. the name(s), surname, residential or business address and ID number, if assigned, in the case of a natural person; or
6.2.2. the company name, registered offices, and ID number in the case of a legal entity;
6.3. the conclusions of the selected equipment design examination;
6.4. the expiry date of the certificate; and
6.5. other documents needed to prove the compliance of the selected equipment design with the requirements of the Decree.

7. The manufacturer or importer must inform the authorised person that issued the design examination certificate regarding all changes to the design described in the design examination certificate. If the design change could affect the selected equipment's compliance with technical requirements, the authorised person verifies this change by proceeding pursuant to Point 5, and if this change corresponds to the requirements of this Decree, issued an addendum to the original selected equipment design examination certificate.

8. The authorised person keeps a copy of the design examination certificate and the inspection report on file.

9. The authorised person informs the Office of selected equipment design examination certificates or their addenda that have been issued, rescinded, suspended, or otherwise restricted, and makes them available to the Office upon request.

10. The authorised person informs other authorised persons performing conformity assessment of selected equipment design examination certificates or their addenda that have been issued, rescinded, suspended, or otherwise restricted.

5. CONFORMITY ASSESSMENT PROCEDURE D (TYPE CONFORMITY BASED ON MANUFACTURING QUALITY ASSURANCE)

1. A manufacturer, importer, or person installing selected equipment after manufacture must, in compliance with this procedure and under the supervision of an authorised person, ensure that the selected equipment conforms to
   1.1. the type described in the type examination certificate pursuant to conformity assessment procedure B; or
   1.2. the selected equipment design described in the design examination certificate pursuant to conformity assessment procedure B1

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

2. A manufacturer or person installing selected equipment after manufacture must have implemented a management system, including a manufacturing quality assurance method, in accordance with the requirements of the decree on management system requirements. An importer must have implemented a system of selected equipment checks.

3. A manufacturer, importer, or person installing selected equipment after manufacture must ensure that a final assessment is performed on every piece of selected equipment.

4. A manufacturer, importer, or person installing selected equipment after manufacture must submit a request for a conformity assessment to the chosen authorised person. The request contains
   4.1. the identification information of the manufacturer, importer, or person installing selected equipment after manufacture, as follows:
      4.1.1. the name(s), surname, residential or business address and ID number, if assigned, in the case of a natural person; or
      4.1.2. the company name, registered offices, and ID number in the case of a legal entity;
   4.2. a written declaration that a conformity assessment contract has not been concluded with a different authorised person;
   4.3. management system documentation applicable to the quality assurance method used for manufacturing or installation, or documentation regarding a system of checks in the case of a request submitted by an importer;
   4.4. a copy of the type examination certificate or of the design examination certificate;
   4.5. technical documentation for the selected equipment; and
   4.6. other information on the selected equipment necessary for the conformity assessment, in particular its safety class.

5. The authorised person assesses the management system of the manufacturer or person installing selected equipment after manufacture, including the manufacturing quality assessment method; and verifies that
   5.1. the management system ensures conformity of the selected equipment with the type described in the type examination certificate or the design of the selected equipment with the design examination certificate, including conformity with technical

documentation for the selected equipment, and with the requirements of this Decree; and

5.2. management system documentation contains:

5.2.1. a description of the objectives of the quality and organisational structure, including the rights and obligations of persons who plan and manage manufacturing or installation of selected equipment;

5.2.2. a description of manufacturing procedures, process quality management and assurance methods, and other systematic measures that will be used, in particular procedures ensuring the fulfilment of basic requirements for ensuring technical safety;

5.2.3. a description of checks that will be performed prior to commencement, during, and upon completion of manufacturing or installation, stating their frequency and acceptability criteria applied during these checks;

5.2.4. quality assurance records for selected equipment; and

5.2.5. a description of means permitting supervision of achievement of the prescribed quality level for selected equipment and assessing the efficacy of the management system in the area of assuring its quality.

6. The management system must be assessed by an authorised person on the premises of the manufacturer or of the person installing selected equipment after manufacturing. At least one employee of the authorised person with experience in assessing the manufacturing process for the selected equipment and who is familiar with the requirements of this Decree shall participate in the assessment. The authorised person must inform the manufacturer, importer, or person installing selected equipment after manufacture of the results of the management system assessment, including requirements for elimination of any discrepancies.

7. The importer must ensure that foreign manufacturers' management systems are assessed in accordance with Point 5 and 6. The authorised person assesses an importer's system of checks and ensures that the checks he performs on selected equipment ensure conformity of the selected equipment with the type described in the type examination certificate or the design of the selected equipment with the design examination certificate, including conformity with technical documentation for the selected equipment, and with the requirements of this Decree.

8. If the management system complies with the requirements specified in Point 5, the authorised person shall issue the manufacturer, importer, or person installing selected equipment after manufacture a management system approval certificate.

9. A manufacturer, importer, or person installing selected equipment after manufacture must comply with requirements stipulated in the management system as approved by the authorised person, and ensure that it continues to be factually correct and effective.

10. A manufacturer, importer, or person installing selected equipment after manufacture must provide the authorised person who approved the management system information regarding planned changes to the management system described in the management system approval certificate. The authorised person shall assess the proposed change and decide whether the modified system complies with requirements pursuant to Point 5. The authorised person conveys the conclusions of the assessment, including justification, to the manufacturer, importer, or person installing selected equipment after manufacture, and if the change to the management system complies with requirements pursuant to Point 5, issues an addendum to the original management system approval certificate.

11. Supervision by an authorised person
    11.1. Supervision must ensure that a manufacturer, importer, or person installing selected equipment duly complies with requirements that follow from the examined management system, including manufacturing quality assurance requirements.
    11.2. A manufacturer, importer, or person installing selected equipment after manufacture must grant the authorised person access to manufacturing, inspection, test, and storage areas in order to perform supervision, and provide him with all needed information.
    11.3. For purposes of supervision, an authorised person has implemented a system of checks that specifies the type and frequency of checks performed on the premises of the manufacturer, importer, or person installing selected equipment after manufacture.
    11.4. Within the scope of supervision, an authorised person performs regular checks to make sure that the manufacturer, importer, or person installing selected equipment after manufacture maintains and applies the management system as it was approved. He chooses the frequency of regular checks so that a new complete audit takes place at least once every 12 months.
    11.5. Within the scope of supervision, an authorised person performs unannounced checks on the premises of a manufacturer, importer, or person installing selected equipment after manufacture. The authorised person stipulates the type and frequency of unannounced checks primarily taking into account
        11.5.1. the safety class of the selected equipment;
        11.5.2. the results of previous checks performed as part of supervision;
        11.5.3. the need to monitor adherence to corrective measures; and
        11.5.4. significant changes in the organisation of manufacturing or manufacturing concept or technology.
    11.6. During these checks, the authorised person may perform checks (or have them performed) to verify whether the management system is working correctly.
    11.7. Based on performed checks, an authorised person creates reports on the results of supervision and gives them to the manufacturer, importer, or person installing selected equipment after manufacture.

12. If the selected equipment complies with the requirements of this Decree and if it complies with the type described in the type examination certificate or the design described in the design examination certificate, the manufacturer, importer, or person installing selected equipment after manufacture affixes a conformity mark along with his identification, and under the responsibility of the authorised person, as well as his identification, and issues a declaration of conformity.

13. The authorised person keeps a copy of the management system approval certificate and of the supervision results report on file.

14. The authorised person informs the Office of management system approval certificates or their addenda that have been issued, rescinded, suspended, or otherwise restricted, and makes them available to the Office upon request.

15. The authorised person informs other authorised persons performing conformity assessment of management system approval certificates or their addenda that have been issued, rescinded, suspended, or otherwise restricted.

6. CONFORMITY ASSESSMENT PROCEDURE D1 (MANUFACTURING QUALITY ASSURANCE)

1. A manufacturer, importer, or person installing selected equipment after manufacture must ensure that the selected equipment conforms to the requirements of this Decree, and issue a declaration of conformity in compliance with this procedure and under the supervision of an authorised person.

2. A manufacturer or person installing selected equipment after manufacture must have implemented a management system, including a manufacturing quality assurance method, in accordance with the requirements of the decree on management system requirements. An importer must have implemented a system of selected equipment checks.

3. A manufacturer, importer, or person installing selected equipment after manufacture must ensure that a final assessment is performed on every piece of selected equipment.

4. A manufacturer, importer, or person installing selected equipment after manufacture must submit a request for a conformity assessment to the chosen authorised person. The request contains
   - 4.1. the identification information of the manufacturer, importer, or person installing selected equipment after manufacture, as follows:
     - 4.1.1. the name(s), surname, residential or business address and ID number, if assigned, in the case of a natural person; or
     - 4.1.2. the company name, registered offices, and ID number in the case of a legal entity;
   - 4.2. a written declaration that a conformity assessment contract has not been concluded with a different authorised person;
   - 4.3. management system documentation applicable to the manufacturing quality assurance method, or documentation regarding a system of checks in the case of a request submitted by an importer;
   - 4.4. technical documentation for the selected equipment; and
   - 4.5. other information on the selected equipment necessary for the conformity assessment, in particular its safety class.

5. The authorised person assesses the management system of the manufacturer or person installing selected equipment after manufacture, including the manufacturing quality assessment method; and verifies that
   - 5.1. the management system ensures compliance of selected equipment with technical documentation for selected equipment and the requirements of this Decree; and
   - 5.2. management system documentation contains:
     - 5.2.1. a description of the objectives of the quality and organisational structure, including the rights and obligations of persons who plan and manage manufacturing or installation of selected equipment;
     - 5.2.2. a description of manufacturing procedures, process quality management and assurance methods, and other systematic measures that will be used, in particular procedures ensuring the fulfilment of basic requirements for ensuring technical safety;
     - 5.2.3. a description of checks that will be performed prior to commencing, during, and upon completion of manufacturing or installation, stating their frequency and acceptability criteria applied during these checks;
     - 5.2.4. quality assurance records for selected equipment; and

5.2.5. a description of means permitting supervision of achievement of the prescribed quality level for selected equipment and assessing the efficacy of the management system in the area of assuring its quality.

6. The management system must be assessed by an authorised person on the premises of the manufacturer or of the person installing selected equipment after manufacturing. At least one employee of the authorised person with experience in assessing the manufacturing process for the selected equipment and who is familiar with the requirements of this Decree shall participate in the assessment. The authorised person must inform the manufacturer, importer, or person installing selected equipment after manufacture of the results of the management system assessment, including requirements for elimination of any discrepancies.

7. The importer must ensure assessment of a foreign manufacturer's management system pursuant to Point 5 and 6. The authorised person assesses an importer's system of checks and ensures that the checks he performs on selected equipment ensure conformity of the selected equipment with the requirements of this Decree.

8. If the management system complies with the requirements specified in Point 5, the authorised person shall issue the manufacturer, importer, or person installing selected equipment after manufacture a management system approval certificate.

9. A manufacturer, importer, or person installing selected equipment after manufacture must comply with requirements stipulated in the management system as approved by the authorised person, and ensure that it continues to be factually correct and effective.

10. A manufacturer, importer, or person installing selected equipment after manufacture must provide the authorised person who approved the management system information regarding planned changes to the management system described in the management system approval certificate. The authorised person shall assess the proposed change and decide whether the modified system complies with requirements pursuant to Point 5. The authorised person conveys the conclusions of the assessment, including justification, to the manufacturer, importer, or person installing selected equipment after manufacture, and if the change to the management system complies with requirements pursuant to Point 5, issues an addendum to the original management system approval certificate.

11. Supervision by an authorised person
    11.1. Supervision must ensure that a manufacturer, importer, or person installing selected equipment duly complies with requirements that follow from the examined management system, including manufacturing or installation quality assurance requirements.
    11.2. A manufacturer, importer, or person installing selected equipment after manufacture must grant the authorised person access to manufacturing, inspection, test, and storage areas in order to perform supervision, and provide him with all needed information.
    11.3. For purposes of supervision, an authorised person has implemented a system of checks that specifies the type and frequency of checks performed on the premises of the manufacturer, importer, or person installing selected equipment after manufacture.
    11.4. Within the scope of supervision, an authorised person performs regular checks to make sure that the manufacturer, importer, or person installing selected equipment after manufacture maintains and applies the management system as it was approved. He chooses the frequency of regular checks so that a new complete audit takes place at least once every 12 months.

11.5. Within the scope of supervision, an authorised person performs unannounced checks on the premises of a manufacturer, importer, or person installing selected equipment after manufacture. The authorised person stipulates the type and frequency of unannounced checks primarily taking into account
11.5.1. the safety class of the selected equipment;
11.5.2. the results of previous checks performed as part of supervision;
11.5.3. the need to monitor adherence to corrective measures; and
11.5.4. significant changes in the organisation of manufacturing or manufacturing concept or technology.
11.6. During these checks, the authorised person may perform checks (or have them performed) to verify whether the management system is working correctly.
11.7. Based on performed checks, an authorised person creates reports on the results of supervision and gives them to the manufacturer, importer, or person installing selected equipment after manufacture.

12. If the selected equipment complies with the requirements of this Decree, the manufacturer, importer, or person installing selected equipment after manufacture affixes a conformity mark along with his identification, and under the responsibility of the authorised person, as well as his identification, and issues a declaration of conformity.

13. The authorised person keeps a copy of the management system approval certificate and of the supervision results report on file.

14. The authorised person informs the Office of management system approval certificates or their addenda that have been issued, rescinded, suspended, or otherwise restricted, and makes them available to the Office upon request.

15. The authorised person informs other authorised persons performing conformity assessment of management system approval certificates or their addenda that have been issued, rescinded, suspended, or otherwise restricted.

7. CONFORMITY ASSESSMENT PROCEDURE E (QUALITY ASSURANCE FOR SELECTED EQUIPMENT)

1. A manufacturer, importer, or person installing selected equipment after manufacture must, in compliance with this procedure and under the supervision of an authorised person, ensure that the selected equipment conforms to
1.1. the type described in the type examination certificate pursuant to conformity assessment procedure B; or
1.2. the selected equipment design described in the design examination certificate pursuant to conformity assessment procedure B1
and meets the requirements of this Decree, and issue a declaration of conformity.

2. A manufacturer or person installing selected equipment after manufacture must have implemented a management system, including a manufacturing quality assurance method, in accordance with the requirements of the decree on management system requirements. An importer must have implemented a system of selected equipment checks.

3. A manufacturer, importer, or person installing selected equipment after manufacture must ensure that a final assessment is performed on every piece of selected equipment.

4. A manufacturer, importer, or person installing selected equipment after manufacture must submit a request for a conformity assessment to the chosen authorised person. The request contains

4.1. the identification information of the manufacturer, importer, or person installing selected equipment after manufacture, as follows:
   4.1.1. the name(s), surname, residential or business address and ID number, if assigned, in the case of a natural person; or
   4.1.2. the company name, registered offices, and ID number in the case of a legal entity;
4.2. a written declaration that a conformity assessment contract has not been concluded with a different authorised person;
4.3. management system documentation applicable to the manufacturing quality assurance method, or documentation regarding a system of checks in the case of a request submitted by an importer;
4.4. a copy of the type examination certificate or of the design examination certificate;
4.5. technical documentation for the selected equipment; and
4.6. other information on the selected equipment necessary for the conformity assessment, in particular its safety class.

5. The authorised person assesses the management system of the manufacturer or person installing selected equipment after manufacture, including the manufacturing quality assessment method; and verifies that
   5.1. the management system ensures conformity of the selected equipment with the type described in the type examination certificate or the design of the selected equipment with the design examination certificate, including conformity with technical documentation for the selected equipment, and with the requirements of this Decree; and
   5.2. management system documentation for manufacturing contains:
      5.2.1. a description of the objectives of the quality and organisational structure, including the rights and obligations of persons who plan and manage manufacturing or installation of selected equipment;
      5.2.2. a description of manufacturing procedures, process quality management and assurance methods, and other systematic measures that will be used, in particular procedures ensuring the fulfilment of basic requirements for ensuring technical safety;
      5.2.3. a description of checks that will be performed upon completion of manufacturing or installation, stating their frequency and acceptability criteria applied during these checks;
      5.2.4. quality assurance records for selected equipment; and
      5.2.5. a description of means permitting supervision of achievement of the prescribed quality level for selected equipment and assessing the efficacy of the management system in the area of assuring its quality.

6. The management system must be assessed by an authorised person on the premises of the manufacturer or of the person installing selected equipment after manufacturing. At least one employee of the authorised person with experience in assessing the manufacturing process for the selected equipment and who is familiar with the requirements of this Decree shall participate in the assessment. The authorised person must inform the manufacturer, importer, or person installing selected equipment after manufacture of the results of the management system assessment, including requirements for elimination of any discrepancies.

7. The importer must ensure assessment of a foreign manufacturer's management system pursuant to Point 5 and 6. The authorised person assesses an importer's system of checks and ensures that the checks he performs on selected equipment ensure conformity of the

selected equipment with the type described in the type examination certificate or the design of the selected equipment with the design examination certificate, including conformity with technical documentation for the selected equipment, and with the requirements of this Decree.

8. A manufacturer or person installing selected equipment after manufacture must examine each piece of selected equipment upon completion of manufacture or installation. An importer must examine each piece of selected equipment within the scope of import. Within the scope of examination, checks specified in technical documentation for selected equipment must be performed in order to ensure conformity of the selected equipment with the type described in the type examination certificate or the design of the selected equipment with the design examination certificate, and with the requirements of this Decree.
9. If the management system complies with the requirements specified in Point 5, the authorised person shall issue the manufacturer, importer, or person installing selected equipment after manufacture a management system approval certificate.
10. A manufacturer, importer, or person installing selected equipment after manufacture must comply with requirements stipulated in the management system as approved by the authorised person, and ensure that it continues to be factually correct and effective.
11. A manufacturer, importer, or person installing selected equipment after manufacture must provide the authorised person who approved the management system information regarding planned changes to the management system described in the management system approval certificate. The authorised person shall assess the proposed change and decide whether the modified system complies with requirements pursuant to Point 5. The authorised person conveys the conclusions of the assessment, including justification, to the manufacturer, importer, or person installing selected equipment after manufacture, and if the change to the management system complies with requirements pursuant to Point 5, issues an addendum to the original management system approval certificate.
12. Supervision by an authorised person
    - 12.1. Supervision must ensure that a manufacturer, importer, or person installing selected equipment duly complies with requirements that follow from the examined management system, including quality assurance requirements for the selected equipment.
    - 12.2. A manufacturer, importer, or person installing selected equipment after manufacture must grant the authorised person access to manufacturing, inspection, test, and storage areas in order to perform supervision, and provide him with all needed information.
    - 12.3. For purposes of supervision, an authorised person has implemented a system of checks that specifies the type and frequency of checks performed on the premises of the manufacturer, importer, or person installing selected equipment after manufacture.
    - 12.4. Within the scope of supervision, an authorised person performs regular checks to make sure that the manufacturer, importer, or person installing selected equipment after manufacture maintains and applies the management system as it was approved. He chooses the frequency of regular checks so that a new complete audit takes place at least once every 12 months.
    - 12.5. Within the scope of supervision, an authorised person performs unannounced checks on the premises of a manufacturer, importer, or person installing selected

equipment after manufacture. The authorised person stipulates the type and frequency of unannounced checks primarily taking into account

12.5.1. the safety class of the selected equipment;

12.5.2. the results of previous checks performed as part of supervision;

12.5.3. the need to monitor adherence to corrective measures; and

12.5.4. significant changes in the organisation of manufacturing or manufacturing concept or technology.

12.6. During these checks, the authorised person may perform checks (or have them performed) to verify whether the management system is working correctly.

12.7. Based on performed checks, an authorised person creates reports on the results of supervision and gives them to the manufacturer, importer, or person installing selected equipment after manufacture.

13. If the selected equipment complies with the requirements of this Decree and if it complies with the type described in the type examination certificate or the design described in the design examination certificate, the manufacturer, importer, or person installing selected equipment after manufacture affixes a conformity mark along with his identification, and under the responsibility of the authorised person, as well as his identification, and issues a declaration of conformity.

14. The authorised person keeps a copy of the management system approval certificate and of the supervision results report on file.

15. The authorised person informs the Office of management system approval certificates or their addenda that have been issued, rescinded, suspended, or otherwise restricted, and makes them available to the Office upon request.

16. The authorised person informs other authorised persons performing conformity assessment of management system approval certificates or their addenda that have been issued, rescinded, suspended, or otherwise restricted.

8. CONFORMITY ASSESSMENT PROCEDURE E1 (QUALITY ASSURANCE FOR SELECTED EQUIPMENT CHECKS AND TESTS)

1. A manufacturer, importer, or person installing selected equipment after manufacture must, in compliance with this procedure and under the supervision of an authorised person, ensure that the selected equipment conforms to the requirements of this Decree, and issue a declaration of conformity.

2. A manufacturer or person installing selected equipment after manufacture must have implemented a management system, including a manufacturing quality assurance method, in accordance with the requirements of the decree on management system requirements. An importer must have implemented a system of selected equipment checks.

3. A manufacturer, importer, or person installing selected equipment after manufacture must ensure that a final assessment is performed on every piece of selected equipment.

4. A manufacturer, importer, or person installing selected equipment after manufacture must submit a request for a conformity assessment to the chosen authorised person. The request contains

4.1. the identification information of the manufacturer, importer, or person installing selected equipment after manufacture, as follows:

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

4.1.2. the company name, registered offices, and ID number in the case of a legal entity;

4.2. a written declaration that a conformity assessment contract has not been concluded with a different authorised person;

4.3. management system documentation applicable to the manufacturing quality assurance method, or documentation regarding a system of checks in the case of a request submitted by an importer;

4.4. technical documentation for the selected equipment; and

4.5. other information on the selected equipment necessary for the conformity assessment, in particular its safety class.

5. The authorised person assesses the management system of the manufacturer or person installing selected equipment after manufacture, including the manufacturing quality assessment method; and verifies that

5.1. the management system ensures compliance of selected equipment with technical documentation for selected equipment and the requirements of this Decree; and

5.2. management system documentation for manufacturing contains:

5.2.1. a description of the objectives of the quality and organisational structure, including the rights and obligations of persons who plan and manage manufacturing or installation of selected equipment;

5.2.2. a description of manufacturing procedures, process quality management and assurance methods, and other systematic measures that will be used, in particular procedures ensuring the fulfilment of basic requirements for ensuring technical safety;

5.2.3. a description of checks that will be performed upon completion of manufacturing or installation, stating their frequency and acceptability criteria applied during these checks;

5.2.4. quality assurance records for selected equipment; and

5.2.5. a description of means permitting supervision of achievement of the prescribed quality level for selected equipment and assessing the efficacy of the management system in the area of assuring its quality.

6. The management system must be assessed by an authorised person on the premises of the manufacturer or of the person installing selected equipment after manufacturing. At least one employee of the authorised person with experience in assessing the manufacturing process for the selected equipment and who is familiar with the requirements of this Decree shall participate in the assessment. The authorised person must inform the manufacturer, importer, or person installing selected equipment after manufacture of the results of the management system assessment, including requirements for elimination of any discrepancies.

7. The importer must ensure assessment of a foreign manufacturer's management system pursuant to Point 5 and 6. The authorised person assesses an importer's system of checks and ensures that the checks he performs on selected equipment ensure conformity of the selected equipment with the requirements of this Decree.

8. A manufacturer or person installing selected equipment after manufacture must examine each piece of selected equipment upon completion of manufacture or installation. An importer must examine each piece of selected equipment within the scope of import. Within the scope of examination, checks specified in technical documentation for selected equipment must be performed in order to ensure conformity of the selected equipment with the requirements of this Decree.

9. If the management system complies with the requirements specified in Point 5, the authorised person shall issue the manufacturer, importer, or person installing selected equipment after manufacture a management system approval certificate.

10. A manufacturer, importer, or person installing selected equipment after manufacture must comply with requirements stipulated in the management system as approved by the authorised person, and ensure that it continues to be factually correct and effective.

11. A manufacturer, importer, or person installing selected equipment after manufacture must provide the authorised person who approved the management system with information regarding planned changes to the management system described in the management system approval certificate. The authorised person shall assess the proposed change and decide whether the modified system complies with requirements pursuant to Point 5. The authorised person conveys the conclusions of the assessment, including justification, to the manufacturer, importer, or person installing selected equipment after manufacture, and if the change to the management system complies with requirements pursuant to Point 5, issues an addendum to the original management system approval certificate.

12. Supervision by an authorised person
    12.1. Supervision must ensure that a manufacturer, importer, or person installing selected equipment duly complies with requirements that follow from the examined management system, including quality assurance requirements for the selected equipment.
    12.2. A manufacturer, importer, or person installing selected equipment after manufacture must grant the authorised person access to manufacturing, inspection, test, and storage areas in order to perform supervision, and provide him with all needed information.
    12.3. For purposes of supervision, an authorised person has implemented a system of checks that specifies the type and frequency of checks performed on the premises of the manufacturer, importer, or person installing selected equipment after manufacture.
    12.4. Within the scope of supervision, an authorised person performs regular checks to make sure that the manufacturer, importer, or person installing selected equipment after manufacture maintains and applies the management system as it was approved. He chooses the frequency of regular checks so that a new complete audit takes place at least once every 12 months.
    12.5. Within the scope of supervision, an authorised person performs unannounced checks on the premises of a manufacturer, importer, or person installing selected equipment after manufacture. The authorised person stipulates the type and frequency of unannounced checks primarily taking into account
        12.5.1. the safety class of the selected equipment;
        12.5.2. the results of previous checks performed as part of supervision;
        12.5.3. the need to monitor adherence to corrective measures; and
        12.5.4. significant changes in the organisation of manufacturing or manufacturing concept or technology.
    12.6. During these checks, the authorised person may perform checks (or have them performed) to verify whether the management system is working correctly.
    12.7. Based on performed checks, an authorised person creates reports on the results of supervision and gives them to the manufacturer, importer, or person installing selected equipment after manufacture.

13. If the selected equipment complies with the requirements of this Decree, the manufacturer, importer, or person installing selected equipment after manufacture affixes

a conformity mark along with his identification, and under the responsibility of the authorised person, as well as his identification, and issues a declaration of conformity.

14. The authorised person keeps a copy of the management system approval certificate and of the supervision results report on file.

15. The authorised person informs the Office of management system approval certificates or their addenda that have been issued, rescinded, suspended, or otherwise restricted, and makes them available to the Office upon request.

16. The authorised person informs other authorised persons performing conformity assessment of management system approval certificates or their addenda that have been issued, rescinded, suspended, or otherwise restricted.

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

1. A manufacturer, importer, or person installing selected equipment after manufacture must, in compliance with this procedure, ensure that the selected equipment conforms to
   1.1. the type described in the type examination certificate pursuant to conformity assessment procedure B;
   1.2. the selected equipment design described in the design examination certificate pursuant to conformity assessment procedure B1; or
   1.3. a type approved pursuant to § 138 of the Act, in the case of selected equipment specified in § 12(2)(b) Point 5;

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

2. A manufacturer, importer, or person installing selected equipment after manufacture must implement all necessary measures so that the manufacturing or installation process and its checking ensures conformity of the selected equipment with the type described in the type examination certificate, the design of the selected equipment with the design examination certificate, or with the type approved pursuant to § 138 of the Act and with the requirements of this Decree.

3. A manufacturer, importer, or person installing selected equipment after manufacture must ensure that a final assessment is performed on every piece of selected equipment.

4. A manufacturer or person installing selected equipment after manufacture must examine each piece of selected equipment upon completion of manufacture or installation. An importer must examine each piece of selected equipment within the scope of import. Within the scope of examination, checks specified in technical documentation for selected equipment must be performed in order to ensure conformity of the selected equipment with the type described in the type examination certificate, the design of the selected equipment with the design examination certificate, or with the type approved pursuant to § 138 of the Act and with the requirements of this Decree.

5. A manufacturer, importer, or person installing selected equipment after manufacture must submit a request for a conformity assessment to the chosen authorised person. The request contains
   5.1. the identification information of the manufacturer, importer, or person installing selected equipment after manufacture, as follows:
      5.1.1. the name(s), surname, residential or business address and ID number, if assigned, in the case of a natural person; or
      5.1.2. the company name, registered offices, and ID number in the case of a legal entity;

5.2. a written declaration that a conformity assessment contract has not been concluded with a different authorised person;
5.3. technical documentation for the selected equipment;
5.4. a copy of the type examination certificate, of the design examination certificate, or of the type approval decision pursuant to § 138 of the Act; and
5.5. other information on the selected equipment necessary for the conformity assessment, in particular its safety class.

6. An authorised person
6.1. assesses materials used, including assessment of material certificates pursuant to Point 13.9 of Part A of Annex 2 to this Decree, if they were not already assessed by a different authorised person;
6.2. checks technological procedures for the creation of permanent joints pursuant to Point 6.6 of Part A of Annex 2 to this Decree and approves these procedures, if they were not already approved by a different authorised person;
6.3. checks that personnel performing special processes and welding supervisors have valid qualification certificates, and approves these personnel pursuant to Point 6.6, 7.2, and 8.3 of part A of Annex 2 to this Decree;
6.4. supervises final assessment;
6.5. verifies that each piece of selected equipment conforms to the type described in the type examination certificate, the design of the selected equipment with the design examination certificate, or with the type approved pursuant to § 138 of the Act, and meets the requirements of this Decree, including the performance of necessary related checks; and
6.6. creates an inspection report on the assessment of activities specified in Points 6.1 to 6.5 and their results.

7. If the selected equipment complies with the requirements of this Decree and if it conforms to the type described in the type examination certificate, the design described in the design examination certificate, or with the type approved pursuant to § 138 of the Act, the authorised person issues the manufacturer, importer, or person installing selected equipment after manufacture a selected equipment verification certificate for each piece of selected equipment. The certificate contains
7.1. the name of the selected equipment, its identification, and basic description;
7.2. the identification information of the manufacturer, importer, or person installing selected equipment after manufacture, specifically
7.2.1. the name(s), surname, residential or business address and ID number, if assigned, in the case of a natural person; or
7.2.2. the company name, registered offices, and ID number in the case of a legal entity;
7.3. the conclusions of the verification of the selected equipment; and
7.4. other documentation required to prove conformity of the selected equipment with the type described in the type examination certificate, the design of the selected equipment with the design examination certificate, or the type approval decision pursuant to § 138 of the Act, and with the requirements of this Decree.

8. If the selected equipment complies with the requirements of this Decree and if it complies with the type described in the type examination certificate, the design of the selected equipment with the design examination certificate, or the type approval decision pursuant to § 138 of the Act, the manufacturer, importer, or person installing selected equipment after manufacture affixes a conformity mark along with his identification, and under the

responsibility of the authorised person, as well as his identification, and issues a declaration of conformity.

9. The authorised person keeps a copy of the selected equipment verification certificate and the inspection report on file.

10. The authorised person informs the Office of selected equipment verification certificates that have been issued, rescinded, suspended, or otherwise restricted, and makes them available to the Office upon request.

11. The authorised person informs other authorised persons performing conformity assessment of selected equipment verification certificates or their addenda that have been issued, rescinded, suspended, or otherwise restricted.

10. CONFORMITY ASSESSMENT PROCEDURE G (VERIFICATION OF A COMPLEX)

1. A manufacturer, importer, or person installing selected equipment after manufacture must, in compliance with this procedure, ensure that the selected equipment conforms to the requirements of this Decree, and issue a declaration of conformity.

2. A manufacturer, importer, or person installing selected equipment after manufacture must submit a request for a conformity assessment to the chosen authorised person. The request contains
   2.1. the identification information of the manufacturer, importer, or person installing selected equipment after manufacture, as follows:
      2.1.1. the name(s), surname, residential or business address and ID number, if assigned, in the case of a natural person; or
      2.1.2. the company name, registered offices, and ID number in the case of a legal entity;
   2.2. a written declaration that a conformity assessment contract has not been concluded with a different authorised person;
   2.3. technical documentation for the selected equipment;
   2.4. the selected equipment design; and
   2.5. other information on the selected equipment necessary for the conformity assessment, in particular its safety class.

3. A manufacturer, importer, or person installing selected equipment after manufacture must ensure that a final assessment is performed on every piece of selected equipment.

4. A manufacturer or person installing selected equipment after manufacture must examine each piece of selected equipment upon completion of manufacture or installation. An importer must examine each piece of selected equipment within the scope of import. Within the scope of examination, checks specified in technical documentation for selected equipment must be performed in order to ensure conformity of the selected equipment with the requirements of this Decree.

5. An authorised person
   5.1. reviews technical documentation for the selected equipment, including an assessment of whether it meets requirements stipulated in Annex 3 to this Decree;
   5.2. assesses materials used, including assessment of material certificates pursuant to Point 13.9 of Part A of Annex 2 to this Decree, if they were not already assessed by a different authorised person;

5.3. checks technological procedures for the creation of permanent joints pursuant to Point 6.6 of Part A of Annex 2 to this Decree and approves these procedures, if they were not already approved by a different authorised person;
5.4. checks that personnel performing special processes and welding supervisors have valid qualification certificates, and approves these personnel pursuant to Point 6.6, 7.2, and 8.3 of part A of Annex 2 to this Decree;
5.5. performs verification and needed checks or has them performed in order to determine whether technical standards or technical specifications have been used properly;
5.6. checks that the selected equipment design is in compliance with the requirements of this Decree;
5.7. supervises final assessment;
5.8. verifies whether each piece of selected equipment is in compliance with the requirements of this Decree, including performing necessary related checks; and
5.9. creates an inspection report on the assessment of activities specified in Points 5.1 to 5.8 and their results.

6. If the selected equipment complies with the requirements of this Decree, the authorised person shall issue the manufacturer, importer, or person installing selected equipment after manufacture a verification certificate for the complex. The certificate contains
6.1. the name of the selected equipment, its identification, and basic description;
6.2. the identification information of the manufacturer, importer, or person installing selected equipment after manufacture, specifically
6.2.1. the name(s), surname, residential or business address and ID number, if assigned, in the case of a natural person; or
6.2.2. the company name, registered offices, and ID number in the case of a legal entity;
6.3. the conclusions of the verification of the complex; and
6.4. other documents needed to prove the compliance of the selected equipment design and the selected equipment with the requirements of the Decree.

7. If the selected equipment complies with the requirements of this Decree, the manufacturer, importer, or person installing selected equipment after manufacture affixes a conformity mark along with his identification, and under the responsibility of the authorised person, as well as his identification, and issues a declaration of conformity.

8. The authorised person keeps a copy of the complex verification certificate and the inspection report on file.

9. The authorised person informs the Office of complex verification certificates that have been issued, rescinded, suspended, or otherwise restricted, and makes them available to the Office upon request.

10. The authorised person informs other authorised persons performing conformity assessment of complex verification certificates that have been issued, rescinded, suspended, or otherwise restricted.

Annex 8 to Decree No

Requirements for compliance verification

VERIFICATION OF PART OF SELECTED EQUIPMENT (PROCEDURE F1)

1. A manufacturer, importer, or person installing selected equipment after manufacture must, in compliance with this procedure, ensure that the part of selected equipment conforms to the requirements of this Decree, and issue a declaration of conformity.
2. A manufacturer, importer, or person installing selected equipment after manufacture must take all necessary measures to ensure the manufacturing process and its supervision ensure compliance of the part of selected equipment with the requirements of this Decree.
3. A manufacturer, importer, or person installing selected equipment after manufacture must ensure that a final assessment is performed on every part of selected equipment.
4. A manufacturer or person installing selected equipment after manufacture must examine each part of selected equipment upon completion of manufacture or installation. An importer must examine each part of selected equipment within the scope of import. Within the scope of examination, checks specified in technical documentation for selected equipment applicable to the assessed part of the selected equipment must be performed in order to ensure conformity of the part of selected equipment with the requirements of this Decree.
5. A manufacturer, importer, or person performing installation of a part selected equipment after manufacture must submit a request for a conformity assessment to the chosen authorised person. The request contains
   5.1. the identification information of the manufacturer, importer, or person performing installation of part of selected equipment after manufacture, as follows:
      5.1.1. the name(s), surname, residential or business address and ID number, if assigned, in the case of a natural person; or
      5.1.2. the company name, registered offices, and ID number in the case of a legal entity;
   5.2. a written declaration that a conformity assessment contract has not been concluded with a different authorised person;
   5.3. the part of technical documentation for selected equipment applicable to the assessed part of the selected equipment; and
   5.4. other information on the selected equipment and part of the selected equipment necessary for the conformity assessment, in particular its safety class.
6. An authorised person
   6.1. assesses materials used, including assessment of material certificates pursuant to Point 13.9 of Part A of Annex 2 to this Decree, if they were not already assessed by a different authorised person;
   6.2. checks technological procedures for the creation of permanent joints pursuant to Point 6.6 of Part A of Annex 2 to this Decree and approves these procedures, if they were not already approved by a different authorised person;
   6.3. checks that personnel performing special processes and welding supervisors have valid qualification certificates, and approves these personnel pursuant to Point 6.6, 7.2, and 8.3 of part A of Annex 2 to this Decree;
   6.4. supervises final assessment; and
   6.5. verifies whether each part of selected equipment is in compliance with the requirements of this Decree, including performing necessary related checks.

7. If the part of selected equipment complies with the requirements of this Decree, the authorised person shall issue the manufacturer, importer, or person installing selected equipment after manufacture a verification certificate for the part of selected equipment. The certificate contains
   7.1. the name of the part of selected equipment, its identification, and basic description;
   7.2. the identification information of the manufacturer, importer, or person performing installation of the part of selected equipment after manufacture, specifically
      7.2.1. the name(s), surname, residential or business address and ID number, if assigned, in the case of a natural person; or
      7.2.2. the company name, registered offices, and ID number in the case of a legal entity; and
   7.3. the conclusions of the selected equipment verification.
8. If the part of selected equipment complies with the requirements of this Decree, the manufacturer, importer, or person installing selected equipment after manufacture affixes a conformity mark along with his identification, and under the responsibility of the authorised person, as well as his identification, and issues a declaration of conformity.
9. The authorised person keeps a copy of the part of selected equipment verification certificate and the inspection report on file.

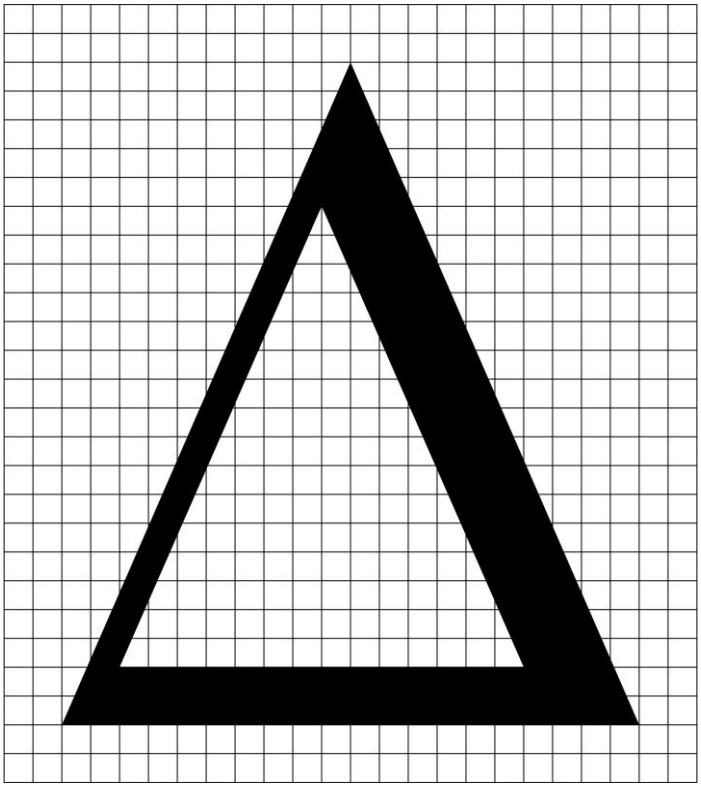
Requirements for the scope of and method for verifying conformity of selected equipment in operation with technical requirements

1. Checks performed within the scope of conformity assessment of selected equipment with technical requirements are subject to general requirements for checks pursuant to Part A of Annex 6 to this Decree.
2. Every piece of selected equipment in operation must be checked in compliance with
   2.1. internal rules;
   2.2. an operating check programme; and
   2.3. documentation regarding repairs, maintenance, or modifications to selected equipment.
3. When stipulating requirements for the scope, type, manner, and periodicity with which checks of selected equipment in operation are performed and acceptability criteria used during these checks, in particular the following must be taken into account:
   3.1. the properties of the selected equipment;
   3.2. stipulated conditions for safe operation;
   3.3. requirements of internal rules for the operation of the nuclear installation; and
   3.4. existing skills and experience with the operation of selected equipment and nuclear installations.
4. Personnel performing checks must be informed of plans for operating checks prior to their commencement.

Annex 9 to Decree No

Conformity mark

1. The conformity mark is the capital Greek letter delta in this shape:



2. If the conformity mark is reduced or enlarged, its proportions given by the grid in the figure shown in Point 1 must be preserved.
3. The conformity mark must be at least 5 mm wide.
4. The sample conformity mark is displayed on an auxiliary grid that is not part of the mark and is used for its proportional enlargement or reduction in size.