STATUTORY INSTRUMENTS

2016 No. 1105

The Pressure Equipment (Safety) Regulations 2016

PART 3

Conformity assessment

Presumption of conformity

40.—(1) Pressure equipment or an assembly which is in conformity with a harmonised standard (or part of such a standard) the reference to which has been published in the Official Journal is to be presumed to be in conformity with the essential safety requirements covered by that standard (or that part of that standard).

(2) The materials used for the manufacture of pressure equipment or an assembly which are in conformity with a European approval for materials, the reference to which has been published in the Official Journal, are to be presumed to be in conformity with the essential safety requirements applicable to that European approval for materials.

(3) The presumptions in paragraph (1) and (2) are rebuttable.

Conformity assessment procedures

41. For the assessment of conformity of pressure equipment falling within regulation 6, the manufacturer must determine the applicable category in accordance with the procedure set out in Schedule 3.

42.—(1) The manufacturer must follow one of the following conformity assessment procedures referred to in Annex III to the Directive (as amended from time to time) according to the category in which the equipment is classified—

(a) Category I: Module A;

(b) Category II: Module A2; or, at the choice of the manufacturer, Module D1; or Module E1;

(c) Category III: Modules B (design type) + D; or, at the choice of the manufacturer, Modules B (design type) + F; or Modules B (production type) + E; or Modules B (production type) + C2; or Module H;

(d) Category IV: Modules B (production type) + D; or, at the choice of the manufacturer, Modules B (production type) + F; or Module G; or Module H1.

(2) The manufacturer may also choose to apply one of the procedures which apply to a higher category, if available.

43.—(1) The notified body or user inspectorate must, when performing unexpected visits in the framework of quality assurance procedures for pressure equipment in categories III and IV in regulation 6(a)(i), 6(a)(ii)(aa) or 6(b), take a sample of equipment from the manufacturing or storage premises in order to perform, or have performed, the final assessment as referred to in paragraph 25 of Schedule 2.

(2) The manufacturer must inform the notified body or user inspectorate of the intended schedule of production.

(3) The notified body or user inspectorate must carry out at least two visits during the first year of manufacturing.

(4) The notified body or user inspectorate must determine the frequency of subsequent visits on the basis of the criteria set out in point 4.4. of modules D, E and H and point 5.4 of module H1 in Annex III to the Directive (as amended from time to time).

44. In the case of one-off production of vessels and pressure equipment in category III referred to in regulation 6(b) under the module H procedure, the notified body or user inspectorate must perform or have performed the final assessment, as referred to in paragraph 25 of Schedule 2, for each unit.

45. For the assessment of conformity of assemblies referred to in regulation 7, the manufacturer must apply a global conformity assessment procedure comprising—

(a) the assessment (the procedure for which is to be determined by the category of each item) of each item of pressure equipment making up the assembly and referred to in regulation 6 which has not been previously subjected to a conformity assessment procedure and to a separate CE marking;

(b) the assessment of the integration of the components of the assembly as referred to in paragraphs 7, 12 and 13 of Schedule 2 which must be determined by the highest category applicable to the equipment concerned other than that applicable to any safety accessories; and

(c) the assessment of the protection of an assembly against exceeding the permissible operating limits as referred to in paragraph 14 and 28 of Schedule 2 which must be conducted against the highest category applicable to individual items of equipment included in the assembly.

46. Regulations 41 to 45 do not apply to pressure equipment items and assemblies which are made available on the market or put into service solely in the interests of experimentation.

47. The records and correspondence relating to conformity assessment must be in an official language of the Member State where the body responsible for carrying out such conformity assessment procedures is established, or in a language accepted by that body.

EU declaration of conformity

48. The EU declaration of conformity in respect of pressure equipment or an assembly must—

(a) state that the fulfilment of the essential safety requirements has been demonstrated in respect of pressure equipment;

(b) contain the elements specified in Annex III to the Directive (as amended from time to time) for the relevant conformity assessment procedure followed in respect of the pressure equipment or assembly; and

(c) have the model structure set out in Schedule 11.

CE marking

49.—(1) Before placing on the market, the CE marking must be affixed visibly, legibly and indelibly to the following:

(a) any item of pressure equipment referred to in regulation 6 or its dataplate; and

(b) any assembly referred to in regulation 7 or its dataplate.

(2) The requirement in paragraph (1) does not apply in cases where—

(a) the conformity assessment procedure followed in accordance with regulation 42 is either module A2, C2, F or G; and

(b) the conformity assessment procedure has been carried out by a user inspectorate.

(3) Where it is not possible or warranted, on account of the nature of the equipment or assembly, to affix the CE marking in accordance with paragraph (1), the CE marking must be affixed to—

(a) the packaging; and

(b) the accompanying documents.

(4) At the time the CE marking is affixed, the item or assembly referred to in subparagraph (1)(a) or (b) must be—

(a) complete; or

(b) in a state permitting final assessment as described in paragraph 25 (Final assessment) of Schedule 2.

(5) Individual items of pressure equipment already bearing the CE marking when incorporated into an assembly must continue to bear that marking, but the CE marking need not be affixed to each additional item of pressure equipment making up an assembly.

(6) The CE marking must be followed by the identification number of the notified body which carried out the relevant conformity assessment procedure for the pressure equipment or assembly, where that body is involved in the production control phase.

(7) The identification number of the notified body must be affixed—

(a) by the notified body itself; or

(b) under the instructions of the notified body, by the manufacturer or his authorised representative.

(8) The CE marking and, where applicable, the identification number of the notified body may be followed by any other mark indicating a special risk or use.

European approval for materials

50.—(1) For the purpose of this regulation, an issuing body is a body which has been notified under regulation 55 (notification) specifically in relation to the activity of issuing European approval for materials.

(2) European approval for materials must be issued, at the request of one or more manufacturers of materials or equipment, by an issuing body.

(3) The issuing body must determine and perform, or arrange for the performance of, the appropriate inspections and tests to certify the conformity of the types of material with the corresponding requirements of these Regulations.

(4) In the case of materials recognised as being safe to use before 29 November 1999, the issuing body must take account of the existing data when certifying such conformity.

(5) Prior to issuing a European approval for materials, the issuing body must inform the other member States and the Commission by sending them the appropriate information.

(6) Where, within three months of being informed by the issuing body, a member State or the Commission provides comments with reasons, the issuing body must take those comments into account before issuing the European approval for materials.

(7) A copy of the European approval for materials must be sent to the member States, the bodies notified under regulation 55 and the Commission.

(8) The issuing body must withdraw its approval if it finds that it should not have been issued or that the type of materials is covered by a harmonised standard.

(9) If an issuing body withdraws approval for materials under paragraph 8, it must immediately inform the other member States and the bodies notified under regulation 55 of that withdrawal.