STATUTORY INSTRUMENTS

2016 No. 1153

The Measuring Instruments Regulations 2016

PART 4

CONFORMITY OF MEASURING INSTRUMENTS

CHAPTER 1

ESTABLISHING COMPLIANCE WITH THE ESSENTIAL REQUIREMENTS

Introductory

36. This chapter applies for the purposes of establishing whether a measuring instrument (whether it is a regulated measuring instrument or a non-prescribed measuring instrument) complies with the essential requirements.

Methods of establishing conformity with the essential requirements

37. Conformity with the essential requirements may be established in relation to a measuring instrument—

(a) through conformity with harmonised standards (or parts of those standards) covering the essential requirements where the harmonised standards have been published in the Official Journal of the European Union;

(b) through conformity with parts of normative documents which cover the essential requirements where the parts of the normative documents have been included in a list published in the Official Journal of the European Union; or

(c) through the use by the manufacturer of any other technical solution that complies with the essential requirements.

Presumptions of conformity of measuring instruments

38.—(1) Measuring instruments which are in conformity with harmonised standards (or parts of those standards) of a kind mentioned in regulation 37(a), are to be presumed to be in conformity with the essential requirements covered by those standards (or parts of those standards).

(2) Measuring instruments which are in conformity with parts of normative documents of a kind mentioned in regulation 37(b), are to be presumed to be in conformity with the essential requirements covered by those parts of normative documents.

(3) To benefit from a presumption of conformity under paragraphs (1) or (2), the manufacturer must correctly apply solutions mentioned in the relevant harmonised standards or in the normative documents.

(4) Compliance with the appropriate tests mentioned in regulation 45(1)(i) is to be presumed if the corresponding test programme has been performed in accordance with the documents mentioned in paragraphs (1) and (2) and if the test results ensure compliance with the essential requirements.

Conformity assessment procedures

39.—(1) Conformity assessment of a measuring instrument with the essential requirements must be established by the application at the choice of the manufacturer, of one of the conformity assessment procedures listed as applicable in relation to the measuring instrument in Schedule 1.

(2) A notified body must carry out the conformity assessment procedure selected by the manufacturer in accordance with the requirements of Schedule 4.

(3) The documents and correspondence relating to the conformity assessment procedures referred to in this regulation which are carried out in the United Kingdom must be drawn up in English.

Capacity serving measures - accredited in house bodies

40.—(1) This regulation applies to the conformity assessment of capacity serving measures.

(2) An accredited in-house body may be used to carry out conformity assessment activities for the undertaking of which it forms part for the purposes of implementing the procedures set out in Module A2 of Annex II to the Directive.

(3) The body must constitute a separate and distinct part of the undertaking and must not participate in the design, production, supply, installation, use or maintenance of the measuring instrument it assesses.

(4) An accredited in-house body must meet the following requirements—

(a) it must be accredited in accordance with RAMS;

(b) the body and its personnel must be organisationally identifiable and have reporting methods within the undertaking of which they form a part which ensure their impartiality and demonstrate it to the relevant national accreditation body;

(c) neither the body, nor its personnel shall be responsible for the design, manufacture, supply, installation, operation or maintenance of the measuring instruments they assess nor shall they engage in any activity that might conflict with their independence of judgment or integrity in relation to their assessment activities; and

(d) it must supply its services exclusively to the undertaking of which it forms a part.

(5) An accredited in-house body need not be notified to the notifying authority or the Commission, but information concerning its accreditation must be given by the undertaking of which it forms part to the notifying authority at the request of that authority.

Subsidiaries and contractors

41.—(1) Where a notified body subcontracts specific conformity assessment activities, or has such activities carried out by a subsidiary, the activities are only to be treated as having been carried out by a notified body for the purposes of regulation 39 (conformity assessment procedures) where the conditions in paragraphs (2) and (3) are met.

(2) The notified body must—

(a) ensure that the subcontractor or subsidiary meets the notified body requirements; and

(b) inform the Secretary of State accordingly.

(3) The notified body must have obtained the agreement of the client to the use of a subcontractor or subsidiary.

(4) Where a notified body subcontracts specific conformity assessment activities, or has such activities carried out by a subsidiary, the notified body must for a period of at least 10 years beginning on the day on which the activities are carried out, keep at the disposal of the Secretary of State the documentation concerning—

(a) the assessment of the qualifications of the subcontractor or the subsidiary; and

(b) the conformity assessment activities carried out by the subcontractor or subsidiary.

(5) When monitoring a notified body in accordance with regulation 58 (monitoring), the Secretary of State must treat the notified body as responsible for the tasks performed by a subcontractor or subsidiary, wherever the subcontractor or subsidiary is established.

Fees

42.—(1) A United Kingdom notified body may charge fees in connection with, or incidental to, the carrying out of conformity assessment procedures or specific tasks as it may determine.

(2) The fees referred to in paragraph (1) must not exceed the following—

(a) the costs incurred or to be incurred by the United Kingdom notified body in performing the relevant function; and

(b) an amount on account of profit which is reasonable in the circumstances having regard to—

(i) the character and extent of the work done or to be done by that notified body on behalf of the applicant; and

(ii) the commercial rate normally charged on account of profit for that work or similar work.

(3) The power in paragraph (1) includes the power to require payment of fees or a reasonable estimate of such fees in advance of carrying out the work requested by the applicant.

(4) Where any fees payable to a United Kingdom notified body pursuant to this regulation remain unpaid 28 days after either the work has been requested or payment of the fees has been requested in writing, whichever is the later, the notified body may by 14 days' notice in writing provide that, unless the fees are paid before the expiry of the notice, the certificate or notification appropriate to the relevant conformity assessment procedure may be suspended until payment of the fees has been received.

(5) This regulation does not apply to the Secretary of State.

CHAPTER 2

REQUIREMENTS AS TO THE TECHNICAL DOCUMENTATION REQUIRED FOR THE PURPOSES OF CONFORMITY ASSESSMENT

Application of this Chapter

43. The technical documentation required for the purposes of conformity assessment under these Regulations must satisfy the requirements of this Chapter.

General requirements to be met by technical documentation

44.—(1) The technical documentation must—

(a) render the design, manufacture and operation of the measuring instrument intelligible; and

(b) permit an assessment of its conformity with the applicable requirements of the Directive.

(2) The technical documentation must be sufficiently detailed to ensure compliance with the following requirements—

(a) the definition of the metrological characteristics;

(b) the reproducibility of the metrological performances of produced measuring instruments when properly adjusted using appropriate intended means; and

(c) the integrity of the measuring instrument.

Specific information to be included in technical documentation

45.—(1) The technical documentation must, insofar as relevant for assessment and identification of either the measuring instrument or its type (or both), include the following information—

(a) a general description of the measuring instrument;

(b) the conceptual design and manufacturing drawings and plans of components, sub-assemblies, circuits etc.;

(c) manufacturing procedures to ensure consistent production;

(d) if applicable, a description of the electronic devices with drawings, diagrams, flow diagrams of the logic and general software information explaining their characteristics and operation;

(e) descriptions and explanations necessary for the understanding of the information referred to in sub-paragraphs (b) to (d);

(f) a list of any harmonised standards and normative documents which have been applied in full or in part, the references of which have been published in the Official Journal of the European Union;

(g) descriptions of the solutions adopted to meet the essential requirements where harmonised standards or normative documents have not been applied, including a list of other relevant technical specifications applied;

(h) results of design calculations, examinations etc.;

(i) the appropriate test results, where necessary to demonstrate that the type or measuring instruments or both comply with the following—

(i) the requirements of the Directive under declared rated operating conditions and under specified environmental disturbances; and

(ii) the durability specifications for gas, water and thermal-energy meters as well as for liquids other than water; and

(j) the EU-type examination certificates or EU design examinations certificates in respect of measuring instruments containing parts identical to those in the design.

(2) The manufacturer must specify where seals and markings have been applied.

(3) The manufacturer must indicate the conditions for compatibility with interfaces and sub-assemblies where relevant.

CHAPTER 3

REQUIREMENTS RELATING TO EU DECLARATIONS OF CONFORMITY

Application of Chapter

46. This Chapter applies in relation to EU declarations of conformity made in relation to a measuring instrument for the purposes of these Regulations.

Form and contents of EU declaration of conformity etc.

47.—(1) The EU declaration of conformity must—

(a) state that the fulfilment of the essential requirements has been demonstrated in relation to the measuring instrument;

(b) contain the elements specified in the relevant conformity assessment modules set out in Annex II to the Directive and be updated when appropriate;

(c) have the model structure set out in Annex XIII to the Directive.

(2) Where a regulated measuring instrument is placed or made available on the market in the United Kingdom, the EU declaration of conformity in relation to the instrument must be in English.

Measuring instruments that require more than one declaration of conformity

48.—(1) This regulation applies where a measuring instrument is subject to a requirement of European Union legislation for an EU declaration of conformity otherwise than by virtue of these Regulations.

(2) Where this regulation applies, a single EU declaration of conformity must be drawn up covering all applicable requirements which identifies the Union acts concerned including their publication references.

Responsibility of manufacturer that draws up declaration of conformity

49. A manufacturer, who draws up an EU declaration of conformity in relation to a measuring instrument, is responsible for compliance of the measuring instrument with the requirements of these Regulations.

CHAPTER 4

CONFORMITY MARKING

Conformity with Directive requirements to be indicated by the CE marking

50. The conformity of a measuring instrument with the requirements of these Regulations must be indicated by the presence on it of the CE marking and the M marking.

General principles relating to the M marking

51. The general principles set out in article 30 of RAMS apply to the M marking with such modifications as are necessary in the circumstances.

Rules and conditions for affixing the CE marking and the M marking

52.—(1) The CE marking and the M marking ("the markings") must be affixed to a measuring instrument in accordance with the provisions of this regulation.

(2) The markings must be affixed visibly, legibly and indelibly to the measuring instrument or its data plate.

(3) Paragraph (2) does not apply where it is not possible or not warranted on account of the nature of the measuring instrument, in which case the markings must be affixed to the documents which accompany the measuring instrument and any packaging.

(4) When a measuring instrument consists of a series of devices, not being sub-assemblies, operating together, the markings must be affixed on the instrument's main device.

(5) The markings must be affixed before the measuring instrument is placed on the market.

(6) The markings may be affixed to the measuring instrument during the fabrication process, if justified.

(7) The M marking must immediately follow the CE marking.

(8) The markings must immediately be followed by the identification number of the notified body where that body is involved in the production control phase as set out in Annex II to the Directive.

(9) The identification number of the notified body referred to in paragraph (8) must—

(a) be affixed by the body itself, or under its instructions by the manufacturer or his authorised representative; and

(b) be indelible or self-destructive upon removal.

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