STATUTORY INSTRUMENTS

1995 No. 1907

The Non-automatic Weighing Instruments (EEC Requirements) Regulations 1995

PART II

APPROVAL AND CERTIFICATION OF NON-AUTOMATIC WEIGHING INSTRUMENTS

Examination and Supervision

EC type-examination

10.—(1) An application for EC type-examination shall be made in writing to the Secretary of State by the manufacturer or by his authorised representative and shall include—

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address;

(b) a declaration that no other application for EC type-examination in respect of the instrument has been made to the Secretary of State or to any approved body; and

(c) the design documentation,

and the person making the application shall, when requested by the Secretary of State, provide an instrument which is representative of the production envisaged (in this regulation referred to as "the type").

(2) On an application made to him under paragraph (1) above the Secretary of State shall—

(a) examine the design documentation and check that the type has been manufactured in conformity with that documentation;

(b) agree with the applicant the places where the examinations and tests shall be carried out;

(c) carry out, or have carried out, examinations and tests to check—

(i) where the manufacturer has chosen to apply the relevant national standards, whether the instrument has been manufactured wholly in conformity with those standards in such a manner that it satisfies the essential requirements; or

(ii) if it has not been so manufactured, whether the instrument nevertheless satisfies the essential requirements.

(3) Where the Secretary of State, after carrying out his functions under paragraph (2) above, is satisfied that the type complies with the provisions of the Directive which apply to it, he shall grant to the applicant an EC type-approval certificate in respect of that type.

(4) Subject to any restrictions imposed under paragraph(S) below, an EC type-approval certificate issued under paragraph (3) above shall be valid for a period of ten years and its validity may be extended for successive periods of ten years:

Provided that its validity shall not be extended after the date of the entry into force of any amendment to the Directive if it could not have been granted on the basis of the Directive as so amended.

(5) Where new techniques are employed or other fundamental changes are made to the design of an approved type, a further application may be made under paragraph (1) above and a further EC type-approval certificate may be issued in respect of the type for a specified period; and—

(a) the initial period for which a certificate is issued under this paragraph shall be restricted to a period of two years; and

(b) only one extension of that period, for a period of three years, may be issued:

Provided that its validity shall not be extended after the date of the entry into force of any amendment to the Directive if it could not have been granted on the basis of the Directive as so amended.

(6) Any EC type-approval certificate shall—

(a) state the conclusions of the EC type-examination carried out by the Secretary of State;

(b) indicate any conditions subject to which the certificate is granted; and

(c) be accompanied by the data and descriptions necessary for identification of the approved type,

and there shall be annexed to the certificate all relevant drawings and layouts.

(7) Where the Secretary of State, after carrying out his functions under paragraph (2) above, refuses to issue an EC type-approval certificate or to extend its period of validity, he shall in writing inform the applicant of his decision and the grounds for his decision.

(8) Where—

(a) an EC type-approval certificate granted under this regulation is in force in respect of an approved type; and

(b) it is proposed that any modifications or additions should be made to the approved type,

the manufacturer or his authorised representative (instead of making an application under paragraph (1) above for an EC type-approval certificate) shall in writing notify the Secretary of State of all such proposed modifications or additions to the approved type.

(9) On receipt of a notification under paragraph (8) above, the Secretary of State shall consider whether the proposed modifications or additions might influence the conformity of the approved type with the essential requirements or with any conditions for use indicated in the EC type-approval certificate, and if it appears to him that those modifications or additions might have that effect, he shall conduct an examination of the approved type with those modifications or additions; and, in a case where—

(a) he is satisfied that the approved type with those modifications or additions complies with the provisions of the Directive that apply to it, the Secretary of State shall—

(i) subject to the provisions of this regulation, approve the modifications or additions; and

(ii) issue an addition to the original EC type-approval certificate in respect thereof; or

(b) he is not so satisfied, the Secretary of State shall notify the person who gave the notification of his decision and of the grounds for it.

(10) No person shall make an application under this regulation if—

(a) he has previously made an application; or

(b) he has reasonable cause to believe that an application has previously been made by any other person,

in respect of the same type under this regulation or under corresponding provisions of the law of a member State other than the United Kingdom.

(11) The Secretary of State shall not consider an application which appears to him to contravene paragraph (10) above.

(12) The Secretary of State shall periodically send to the other member States a list of—

(a) applications received by him for EC type-examination;

(b) EC type-approval certificates issued by him;

(c) refusals by him to issue EC type-approval certificates; and

(d) additions and amendments relating to documents already issued,

and, on request, shall send to other member States a copy of any EC type-approval certificates that he has issued.

EC verification

11.—(1) All necessary measures shall be taken to secure that the manufacturing process for instruments intended for EC verification shall ensure conformity with the approved type, where appropriate, and with the requirements of the Directive which apply to them.

(2) The manufacxturer or his authorised representative shall—

(a) affic the CE marking and the sticker to each instrument (by way of confirmation that the instruments may be used for a Schedule 3 application) in accordance with regulation 18; and

(b) draw up a written declaration of conformity that the instrument conforms with the requirements of the Directive which apply to it.

(3) Subject to paragraphs (6) and (7) below, an application for the carrying out of the appropriate examinations and tests with a view to EC verification shall be made to an approved body by the manufacturer or his authorised representative; and each application shall, if the approved body so requests, be accompanied—

(a) in the case of instruments manufactured in conformity with an approved type, by a copy of the EC type-approval certificate in respect of that approved type; or

(b) in the xase of an instrument which does not use electronic devices and of which the load measuring device does not use one or more springs to balance the load, by the design documentation relating to those instruments.

(4) Where the approved body is satisfied, on application made to it under paragraph (3) above and after carrying out, or having had carried out, the appropriate examinations and tests, that the instruments (if properly installed and used for the purposes for which they are intended)—

(a) where appropriate, have been manufactured in conformity with the approved type; and

(b) satisfy the provisions of the Directive which apply to them,

the approved body shall affix or cause to be affixed to each instrument the identification number of the approved body in accordance with regulation 18, and shall provide to the manufacturer or his authorised representative a written certificate of conformity relating to the tests carried out; and the manufacturer or his authorised representative shall ensure that he is able to provide the certificate to any person entitled to see it.

(5) Where the approved body is not satisfied, it shall decline to affix its identification number to the instrument and to provide to the manufacturer or his authorised representative a written certificate of conformity under paragraph (4) above; and it shall in writing inform the applicant of its decision and of the grounds for its decision.

(6) In the case of an instrument—

(a) to which the CE marking, identification number and sticker have been affixed; and

(b) to which a disqualification sticker has been affixed under regulation 24, 25 or 27 or under any corresponding provision in the law of a member State other than the United Kingdom,

the foregoing provisions of this regulation shall have effect as modified under paragraph (7) below.

(7) In a case to which paragraph (6) above applies an application under paragraph (3) above may be made by any person established in the Community and—

(a) in paragraph (3) above, the words after the first semi-colon shall not have effect; and

(b) in paragraph (4) above, for the words "approved body shall affix" to the end there shall be substituted the words "the approved body shall affix or cause to be affixed to each instrument the identification number of the approved body and the re-qualification sticker in accordance with regulation 18.".

EC unit verification

12.—(1) All necessary measures shall be taken to secure that the manufacturing process for instruments intended for EC unit verification shall ensure conformity with the requirements of the Directive which apply to them.

(2) after the procedures set out in paragraphs (4) and (5) below have been completed the manufacturer or his authorised representative shall—

(a) affix the CE marking and the sticker to the instrument (by way of confirmation that it may be used for a Schedule 3 application) in accordance with regulation 18; and

(b) draw up a written declaration of conformity that the instrument conforms with the requirements of the Directive which apply to it.

(3) Subject to paragraphs (6) and (7) below, an application for the carrying out of the appropriate examinations and tests with a view to EC unit verification shall be made in writing to the Secretary of State by the manufacturer or his authorised representative; and each application shall be accompanied by the design documentation relating to the instrument.

(4) Where the Secretary of State is satisfied, on application made to him under paragraph (3) above and after carrying out, or after having carried out, the appropriate examinations and tests, that the instrument (if properly installed and used for the purposes for which it is intended) satisfies the provisions of the Directive that apply to it—

(a) the Secretary of State shall in accordance with regulation 18—

(i) affix, or cause to be affixed, his identification number to the instrument, and

(ii) provide to the manufacturer or his authorised representative a written certificate of conformity relating to the tests carried out; and

(b) the manufacturer or his authorised representative shall ensure that he is able to provide the certificate to any person entitled to see it.

(5) Where the Secretary of State is not si satisfied, he shall decline to affix his identification number to the instrument and to provide to the manufacturer or his authorised representative a written certificate of conformity under paragraph (4) above; and he shall in writing inform the applicant of his decision and of the grounds for his decision.

(6) In the case of an instrument—

(a) to which the identification number, CE marking and sticker have been affixed; and

(b) to which a disqualification sticker has been affixed under regulation 24, 25 or 27 or under any corresponding provision in the law of a member State other than the United Kingdom,

the foregoing provisions of this regulation shall have effect as modified under paragraph (7) below.

(7) In a case to which paragraph (6) above applies an application under paragraph (3) above may be made by any person established in the Community and—

(a) in paragraph (3) above, the words after the semi-colon shall not have effect; and

(b) in paragraph (4) above, for sub-paragraphs (a) and (b) there shall be substituted the words "the Secretary of State shall in accordance with regulation 18 affix, or cause to be affixed, to the instrument his identification number and the re-qualification sticker.".

Quality system approval and EC declaration of type conformity

13.—(1) An application for approval of a quality system as provided in paragraph 2.3 of Annex II of the Directive shall be made in writing to an approved body; and each application shall be accompanied by an undertaking by the manufacturer—

(a) to carry out the obligations arising fro the approved quality system; and

(b) to maintain the approved quality system to ensure its continuing suitability and effectiveness.

(2) The manufacturer shall make available to the approved body all relevant information including in particular—

(a) the documentation of the quality system presented in a systematic and orderly manner in the form of written rules, rocedures and instructions with a view to ensuring a proper understanding of the quality programmes, plans, manuals and records; and

(b) the design documentation of the instruments.

(3) On application made to it under paragraph (1) above, the approved body shall evaluate the quality system to determine whether it satisfies the requirements referred to in paragraph 2.3.2 of Annex II of the Directive and, if it conforms with the relevant national standard, it shall be taken to conform to those requirements.

(4) Where the approved body is satisfied, on application made to it under paragraph (1) above and after examining and evaluating the quality system, that the system satisfies the requirements referred to in paragraph 2.3.2 of Snnex II of the Directive it shall grant to the manufacturer an approval of the quality system; and accordingly the manufacturer shall have authority to make EC declarations of type conformity in accordance with paragraph (7) below.

(5) The approved body shall—

(a) include in the approval the conclusions of the examination and evaluation carried out by it; and

(b) shall inform the Secretary of State of the granting of the approval with a view to his notifying the other member States.

(6) Where the approved body, after carrying out its duties under paragraph (3) above, refuses to grant an approval of the quality system it shall in writing inform the manufacturer and the Secretary of State of its decision and the grounds for its decision.

(7) Where the manufacturer makes an EC declaration of type conformity, that is to say—

(a) he has adequately implemented an approved quality system;

(b) he has carried out the appropriate examinations and tests; and

(c) he is satisfied that the instruments concerned, where appropriate, have been manufactured in conformity with the approved type and satisfy the provisions of the Directive that apply to them,

the manufacturer or his authorised representative shall, in accordance with regulation 18, affix to each such instrument—

(i) the CE marking;

(ii) the inscriptions;

(iii) the sticker by way of confirmation that the instrument may be used for a Schedule 3 application; and

(iv) the identification number of the approved body which approved the manufacturer's quality system,

and shall draw up a written declaration of conformity.

(8) In the case of an instrument—

(a) to which the CE marking, identification number and sticker have been affixed; and

(b) to which a disqualification sticker has been affixed under regulation 24, 25 or 27 or any corresponding provision in the law of a member State other than the United Kingdom,

the foregoing provisions of this regulation shall have effect as modified under paragraph (9) below.

(9) In a case to which paragraph (8) above applies, in paragraph (7) above for the words "the manufacturer or his authorised representative shall affix" to the end there shall be substituted the words

"the manufacturer or his authorised representative shall affix to each such instrument—

(a) the re-qualification sticker;

(b) the identification number of the approved body which approved the manufacturer's quality system if that number is different from the number already affixed to the instrument.".

Provisions supplemental to regulations 11, 12 and 13

14.—(1) Subject to paragraphs (2) and (3) below, the procedures referred to in regulations 11(4), 12(4) and 13(7) ("the procedures") shall be carried out at the place of use of the instrument unless—

(a) the instrument does not have to be dismantled for transport or any such dismantling is not likely to affect its performance; or

(b) before the instrument is taken into service, no work is required which is likely to affect its performance,

in which case they may be carried out at any place.

(2) In the case of an instrument whose performance is sensitive to differences in gravity, either—

(a) any difference between the gravity at the place where the procedures mentioned in paragraph (1) above are carried out and that at the place where the instrument is to be used shall be taken into account in carrying out the procedures; or

(b) the procedures shall be carried out in two stages in accordance with paragraph (4) below.

(3) In the case of an instrument whose performance is not sensitive to differences in gravity and if the manufacturer so desires, the procedures shall be carried out in two stages in accordance with paragraph (4) below.

(4) The two stages referred to in paragraphs (2) and (3) above are—

(a) a first stage ("the first stage") which shall comprise all examinations and tests not within the second stage and which may be carried out at any place; and

(b) a second stage ("the second stage")—

(i) which, in the case of an instrument whose performance is sensitive to differences in gravity, shall comprise all examinations and tests of which the outcome is gravity dependent and which shall be carried out at the place of use of the instrument or, if

gravity zones(**1**) have been established, elsewhere within the gravity zone in which that place is situated; and

(ii) which, in the case of any other instrument, may be carried out at any place.

(5) Where the manufacturer has made an EC declaration of type conformity under regulation 13 in relation to an instrument and the procedures in the first stage are carried out under that regulation, those carried out in the second stage shall be those specified in regulation 11 or in regulation 13.

(6) Where an approved body carries out the procedures in the first stage under regulation 11, that body or another approved body may carry out the procedures in the second stage.

(7) Where in pursuance of paragraph (5) or (6) above, the procedures in the first stage are carried out by the manufacturer or an approved body ("the first party") and the procedures in the second stage are carried out by a different manufacturer (being a manufacturer having the authority to make the relevant EC declaration of type conformity) or by an approved body ("the second party")—

(a) the first party shall issue a certificate to the second party identifying the instrument in question and specifying the procedures it has carried out and shall affix, or cause to be affixed, its identification number, and

(b) the second party—

(i) shall carry out the examinations and tests not carried out by the first party; and

(ii) shall be responsible for completion of whichever of the procedures is appropriate.

(8) For the purposes of regulations 11(4), 12(4) and 13(7), the appropriate examinations and tests shall include those specified in the relevant national standard or equivalent tests.

EC surveillance

15.—(1) Where a manufacturer has made an EC declaration of type conformity under regulation 13, the approved body to which the manufacturer made an application for approval of the quality system shall carry out EC surveillance and in particular—

(a) shall periodically carry out audits in order to ensure that the manufacturer is maintaining and applying the quality system and provide the manufacturer with an audit report; and

(b) shall, from time to time, carry out visits at the places of manufacture, inspection, testing and storage and—

(i) check whether the manufacturer is maintaining and applying the quality system, and

(ii) at its direction, carry out full or partial audits,

and shall provide the manufacturer with a report on each such visit and on any such audit.

(2) For the purpose of assisting the approved body to carry out the audits and checks specified in paragraph (1) above the manufacturer shall, in respect of each instrument, keep available for inspection by the approved body all necessary information, including—

(a) the documentation of the quality system;

(b) the design documentation of the instrument; and

(c) all related quality records,

and shall inform the approved body of any changes in its quality system.

Suspension of EC declaration of type conformity

16.—(1) If it appears to an authorised person that there are, on any prmises of a manufacturer, instruments to which CE markings or stickers have been, or are being, affixed otherwise than

(**1**) The United Kingdom has not established gravity zones within its territory.

in conformity with these Regulations, he may give to the manufacturer a notice suspending the manufacturer's authority to make the EC declaration of type conformity in question for a period not exceeding twenty-eight days.

(2) Where an authorised person gives a notice under paragraph (1) above, he shall forthwith—

(a) inform the approved body which approved the quality system of the effect of the notice;

(b) second a copy of the notice to the Secretary of State; and

(c) inform the manufacturer of his right to apply for a review of the decision under regulation 21.

(3) If the manufacturer contravenes a notice under paragraph (1) above—

(a) he shall be guilty of an offence; and

(b) all instruments to which the offence relates shall be liable to be forfeited.

Withdrawal of approval of quality system

17.—(1) If it appears to an approved body, in relation to any quality system approved by it, that—

(a) an undertaking given pursuant to regulation 13(1) has not been complied with; or

(b) by reason of the refusal or neglect of the manufacturer, it is not able to carry out its functions under regulation 15(1); or

(c) regulation 15(2) has not been complied with; or

(d) the Secretary of State has informed the approved body under regulation 20(6)(a) that he is of the opinion that consideration should be given to withdrawal of any relevant quality system approval,

it may, after giving the manufacturer the opportunity of making representations as to why it should not be withdrawn, by notice given to the manufacturer withdraw approval of the quality system.

(2) A notice under paragraph (1) above shall be in writing and shall—

(a) specify the date on which it is to take effect; and

(b) specify the grounds for the decision.

(3) The approved body shall send to the Secretary of State a copy of any notice given by it under paragraph (2) above with a view to his notifying the other member States.

(4) A manufacturer who fails to comply with a notice given to him under paragraph (2) above shall be guilty of an offence.

Affixing of CE marking etc

18.—(1) The CE marking and each sticker, inscription or identification number mentioned in paragraph (3) below shall be affixed on—

(a) each instrument to which it relates; or

(b) on a data plate attached to the instrument in such a way that the plate—

(i) cannot be removed without being destroyed, or

(ii) is capable of being sealed with a control mark,

and shall satisfy the requirements of paragraph (2) below and, as the case may require, of paragraph (3) below.

(2) The requirement of this paragraph is that each CE marking, identification number, sticker or inscription shall be clearly visible, easily legible and indelible.

(3) The requirements of this paragraph, in the case of—

(a) the CE marking, are those specified in heads (a), (c) and (d) of paragraph (4) below;

(b) the identification number, are those specified in head (a) of paragraph (4) below;

(c) all inscriptions referred to in paragraph 1.1(c) of Annex IV of the Directive, are those specified in heads (c) and (d) of paragraph (4) below; and

(d) the inscriptions "Max", "Min", "e" and "d" referred to in paragraph 1.4 of Annex IV of the Directive, are those specified in heads (b), (c) and (d) of paragraph (4) below.

(4) The requirements referred to in paragraph (3) above in relation to the CE marking, identification number or inscription in question are—

(a) a requirement that it be grouped together with all other such information;

(b) a requirement that it be placed near the display of the result of the operation of the instrument;

(c) a requirement that it be impossible to remove without damaging the marking or inscription;

(d) a requirement that it be clearly visible when the instrument is in its regular operating position.

(5) The CE marking consists of the symbol "CE" of which a form is shown for purposes of illustration in Schedule 4.

(6) Each load measuring device which is connected, or can be connected, to one or more load receptors shall also bear the inscriptions which apply to each such load receptor.

(7) Where the manufacturer or his authorised representative affixes a CE marking and sticker under paragraph (1) above to an instrument which—

(a) is used for a Schedule 3 application; and

(b) includes or is connected to any device exempted from the essential requirements by virtue of the Preliminary observations in Annex I of the Directive which is set out in Schedule 2,

each such device shall bear the restrictive use symbol referred to in paragraph 3 of Annex IV of the Directive.

(8) Any person who—

(a) gives information in connection with an instrument, by means of a misleading mark or inscription or otherwise, which is likely to be confused with the CE marking; or

(b) affixes any other mark to the instrument which obscures the visibility or legibility of the EC marking,

shall be guilty of an offence.

Conformity with other directives

19.—(1) Subject to paragraph (2) below, where a CE marking is affixed to an instrument, the affixing of that marking shall indicate that the instrument conforms also with any other directive other than the Directive which provides for the affixing of the CE marking.

(2) Where, during a relevant transitional period specified in any such directive a manufacturer chooses not to apply provisions adopted pursuant to the directive in question, paragraph (1) above shall not apply if that fact and particulars of that directive as published in the Official Journal of the European Communities are stated in the documents, notices or instructions required to accompany the instrument.

Wrongful use of CE marking

20.—(1) If an authorised person is satisfied that a CE marking has been placed on an instrument save as required by, and in conformity with, the requirements of these Regulations, he shall give

notice to the manufacturer or his authorised representative specifying the respects in which those requirements have not been satisfied.

(2) The matters to be specified in a notice given under paragraph (1) above pursuant to this paragraph are that, unless steps are taken which ensure—

(a) that the instrument or any instrument of the same type does so conform or comply, or

(b) that the manufacturer or his authorised representative does so act, as the case may require—

(i) any EC type-approval certificate granted under regulation 10(3), or

(ii) any approval of a quality system granted under regulation 13(4),

may be withdrawn.

(3) A notice under paragraph (1) above shall be in writing and shall—

(a) specify the date on which it is to take effect;

(b) specify the grounds for the decision; and

(c) inform the manufacturer of his right to apply for a review of the decision under regulation 21.

(4) Where an authorised person gives a notice under paragraph (1) above, he shall forthwith send a copy of the notice to the Secretary of State.

(5) If the Secretary of State—

(a) in the case of an EC type-approval certificate which he has granted, after giving the manufacturer the opportunity of making representations as to why it should not be withdrawn, decides that the EC type-approval certificate should be withdrawn, he shall immediately—

(i) give notice of the decision to the manufacturer, and

(ii) inform the other member States of the decision; and

(b) in the case of an EC type-approval certificate granted under the law of another member State, is of the opinion that consideration ought to be given to whether the EC type-approval certificate should be withdrawn he shall immediately inform the relevant competent authority of that fact.

(6) If the Secretary of State is of the opinion that consideration should be given to withdrawal of any relevant quality system approval—

(a) in the case of an approval granted by an approved body under these Regulations, he shall inform the approved body of that fact; and

(b) in the case of an approval granted under the law of another member State, he shall immediately inform the relevant competent authority of that fact.

(7) The Secretary of State shall publish, in such manner as he may consider appropriate, particulars of any notice under paragraph (5) above withdrawing an EC type-approval certificate.