STATUTORY INSTRUMENTS

1995 No. 1629

The Gas Appliances (Safety) Regulations 1995

Certification and attestation

EC type-examination

- **10.**—(1) Where an application to a notified body for EC type-examination is made under these Regulations by the manufacturer or by his authorised representative established in the Community ("the applicant"), the application shall be in writing 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 an application for EC type-examination in respect of the appliance or fitting has not been made to any other notified body; and
 - (c) the design documentation.
 - (2) The applicant shall supply to the notified body—
 - (a) an appliance or fitting which, so far as concerns its characteristics relevant to any type of risk relevant to the essential requirements, is representative of the production envisaged ("the type"); and
 - (b) such further appliances or fittings as the notified body may reasonably require for the purposes of this regulation,

and shall undertake to pay the appropriate fee to the notified body.

- (3) On an application made to it under paragraph (1) above the notified body shall—
 - (a) examine the design documentation and check that the type has been manufactured in conformity with that documentation; and
 - (b) carry out, or have carried out, examinations and tests to check whether the type satisfies the essential requirements.
- (4) Where the notified body, after carrying out its duties under paragraph (3) above, is satisfied that the type complies with the essential requirements which apply to it, the notified body shall, on payment of the appropriate fee, issue to the applicant an EC type-examination certificate in respect of that type.
 - (5) An EC type-examination certificate shall identify the type to which it relates and—
 - (a) shall state the conclusions of the EC type-examination carried out by the notified body;
 - (b) shall indicate any conditions to be satisfied for its continued validity;
 - (c) shall be accompanied by the data and descriptions necessary for identification of the approved appliance or fitting; and
 - (d) if relevant to its compliance with the essential requirements, shall be accompanied by a description of its functioning,

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

(6) The notified body shall forthwith inform all other notified bodies of—

- (a) each EC type-examination certificate issued by it; and
- (b) particulars of additions and amendments relating to documents already issued,

and, on request made by it, shall send to any other notified body a copy of any EC type-examination certificate that it has issued and, if any other notified body satisfies the notified body that there is good reason why they should be made available to it, copies of the annexes to the certificate and reports on the examinations and tests which the notified body has carried out.

- (7) Where—
 - (a) an EC type-examination certificate issued under this regulation is in force in respect of an approved type; and
 - (b) the manufacturer or his authorised representative established in the Community proposes to make modifications or additions to the approved type which affect its conformity with the essential requirements or with the prescribed conditions for use of the appliance,

the manufacturer or such representative (instead of making an application under paragraph (1) above) may make an application in writing to the notified body which issued the certificate for approval of modifications or additions to the approved type; and the foregoing provisions of this regulation shall have effect in relation to such an application as they have effect in relation to an application for an EC type-examination.

Application to be made to a single notified body

- 11.—(1) No person shall make an application for EC type-examination under regulation 10 in respect of a type at any time when there is pending in respect of that type an application for EC type-examination made by any person to any other notified body.
 - (2) Where—
 - (a) an application for EC type-examination is made to a notified body under regulation 10 in respect of a type; and
 - (b) to the knowledge of the notified body, an application to another notified body for an EC type-examination certificate in respect of that type is pending,

the notified body shall not consider, or shall not further consider, the application until the other application has been determined or withdrawn.

Refusal of EC type-examination certificate

- **12.**—(1) If a notified body is minded to refuse to issue an EC type-examination certificate under regulation 10, it shall give the applicant the opportunity, within a reasonable period, of making representations as to why it should not be refused.
- (2) Where the notified body, after considering any representations made in accordance with paragraph (1) above, refuises to issue an EC type-examination certificate or to extend its period of validity, it shall in writing—
 - (a) inform the applicant and the Secretary of State of its decision and the grounds for its decision; and
 - (b) inform all other notified bodies of the decision.

Withdrawal of EC type-examination certificate

- 13.—(1) If it appears to a notified body—
 - (a) that—

- (i) there has been a breach of any condition subject to which the body issued an EC type-examination certificate, and
- (ii) the person to whomit was issued is unable or unwilling to effect a sufficient remedy; or
- (b) that appliances or fittings which conform with the type in respect of which an EC type-examination certificate has been issued do not satisfy the essential requirements,

the notified body may withdraw the certificate after giving the person to whom it was issued the opportunity of making representations within a reasonable period as to why it should not be withdrawn.

- (2) Where a notified body, having considered any representations made under paragraph (1) above, withdraws an EC type-examination certificate, it shall, in writing,—
 - (a) inform the person to whom it was issued and the Secretary of State of the withdrawal of the certificate and of its reasons for the withdrawal; and
 - (b) inform all other notified bodies of its withdrawal.

Quality system approval

- **14.**—(1) Where an application for approval of—
 - (a) a quality system relating to production quality; or
 - (b) a quality system relating to product quality,

is made to a notified body (whether the relevant EC type-examination certificate was issued by it or by another notified body), the application shall be made in writing and shall be accompanied by an undertaking by the manufacturer—

- (i) to carry out the obligations arising from the approved quality system;
- (ii) to maintain the approved quality system to ensure its continuing suitability and effectiveness; and
- (iii) to pay the appropriate fee,

and such systems shall be designed to secure that appliances and fittings comply with the essential requirements which apply to them.

- (2) The manufacturer shall make available to the notified body—
 - (a) a copy of the EC type-examination certificate;
 - (b) all relevant information including in particular the documentation of the quality system; and
 - (c) the design documentation of the appliances or fittings.
- (3) The documentation of the quality system shall be systematic and shall permit a clear interpretation to be made of the manufacturer's quality programme, plans, manuals and records and shall include, in particular, descriptions of—
 - (a) the manufacturer's quality objectives relating to production of the appliances or fittings;
 - (b) the manufacturer's management structures and the responsibilities of managers within that structure which are relevant to the quality of production;
 - (c) in the case of an application under paragraph (1)(a) above,—
 - (i) the manufacturing process, quality control and quality assurance techniques and systems employed in production of the appliances or fittings, and
 - (ii) the nature and frequency of examinations and tests carried out before, during and after the manufacture of appliances or fittings;

- (d) in the case of an application under paragraph (1)(b) above, the nature of examinations and tests carried out after the manufacture of each appliance or fitting;
- (e) the method employed to monitor attainment of the quality objectives referred to in subparagraph (a) above; and
- (f) the method employed to monitor the effectiveness of the examinations and tests referred to in subparagraph (d) above.
- (4) On an application made to it under paragraph (1) above the notified body shall take all necessary steps to examine and evaluate the quality system.
 - (a) (5) (a) if the notified body is minded to refuse to approve the quality system, it shall give the applicant the opportunity, within a reasonable period, of making representations as to why it should not be refused.
 - (b) Where the notified body, after considering any representations made to it in accordance with paragraph (a) above, refuses to approve a quality system, it shall in writing—
 - (i) inform the Secretary of State of its decision and the grounds for its decision; and
 - (ii) inform all other notified bodies of the decision.
 - (6) The notified body shall, in writing,—
 - (a) inform the manufacturer of—
 - (i) the results of the examination, and
 - (ii) the reasons for the decision;
 - (b) if it is satis|fi|ed that the quality system satis|fi|es the relevant provisions of Annex II of the Directive, on payment of the appropriate fee,—
 - (i) notify the applicant of its approval of the quality system; and
 - (ii) inform all other notified bodies of its decision.
 - (7) Where—
 - (a) an approval of a quality system under this regulation is in force; and
 - (b) the manufacturer proposes to make modifications or additions to the approved quality system,

the manufacturer (instead of making an application under paragraph (1) above) may make an application in writing to the notified body which gave the approval for approval of modifications or additions to the quality system; and the foregoing provisions of this regulation shall have effect in relation to such an application as they have effect in relation to an application for approval of a quality system.

Withdrawal of quality system approval

- **15.**—(1) If it appears to a notified body which approved a quality system under regulation 14 that the person to whom it was issued—
 - (a) has failed to implement the approved system; and
 - (b) is unable or unwilling to effect a sufficient remedy,

the notified body may withdraw the approval after giving the person to whom it was issued the opportunity of making representations within a reasonable period as to why it should not be withdrawn.

(2) Where the notified body, having considered any representations made under paragraph (1) above, withdraws a quality system approval, it shall, in writing,—

- (a) inform the person to whom it was issued and the Secretary of State of the withdrawal of the approval and of its reasons for the withdrawal; and
- (b) inform all other notified bodies of its withdrawal.

EC declaration of conformity (guarantee of product or production quality)

- **16.** Where a manufacturer has implemented a quality system which has been approved under regulation 14 or under a corresponding provision of the law of another member State and the manufacturer or his authorised representative established in the Community is satisfied that an appliance or a fitting has been manufactured in conformity with an approved type,
 - (a) in the case of an appliance,
 - (i) he may issue and if he does so shall retain a declaration that the appliance conforms with the relevant EC type-examination certificate and satisfies the relevant essential requirements (an "EC declaration of conformity (guarantee of product or production quality)"), and
 - (ii) if he does so, shall affix the CE Marking in accordance with regulation 25; and
 - (b) in the case of a fitting, shall supply a fitting certificate.

EC declaration of conformity (EC verification)

- 17.—(1) Where an EC type-examination certificate has been issued in respect of a type and the manufacturer or his authorised representative established in the Community is satisfied that an appliance or fitting has been manufactured in accordance with an approved type and that the requirements of the Directive that apply to it are satisfied in relation to an appliance or fitting,—
 - (a) in the case of an appliance,
 - (i) he may issue an EC declaration of conformity to type (EC verification), and
 - (ii) if he does so, shall affix the CE Marking in accordance with regulation 25;
- (b) in the case of a fitting, shall supply a fitting certificate, but subject to regulation 19 or 20.
- (2) An EC declaration of conformity to type (EC verification) may relate to more than one appliance and shall be retained by the manufacturer, or as the case may be his authorised representative established in the Community.

EC declaration of conformity (EC unit verification)

- **18.**—(1) Where a manufacturer of an appliance or his authorised representative established in the Community is satisfied that the requirements of the Directive that apply to it are satisfied in relation to the appliance he may issue and if he does so shall retain an EC declaration of conformity (EC unit verification).
- (2) If the manufacturer or his authorised representative established in the Community issues an EC declaration of conformity to type (EC Unit verification), he shall affix the CE Marking in accordance with regulation 25 but subject to regulation 21.

EC verification (individual appliances and fittings)

19.—(1) Where a manufacturer or his authorised representative established in the Community submits an appliance or fitting to a notified body for verification under this regulation together with an undertaking to pay the appropriate fee, the notified body shall examine the appliance or fitting

and carry out tests to establish whether it satisfies the provisions of these Regulations which apply to it and in the case of an appliance, it conforms with the relevant EC type-examination certificate.

(2) If having carried out the examination, the notified body is satisfied that an EC certificate of conformity should be issued, it shall, on payment of the appropriate fee, issue an EC certificate of conformity (which may relate to one or more appliance or fitting and shall be retained by the manufacturer or his authorised agent established in the Community) and in the case of an appliance shall affix or cause to be affixed its identification number on each appliance.

EC verification by batch (statistical method)

- **20.**—(1) Where a manufacturer or his authorised representative established in the Community submits a batch of appliances or fittings to a notified body for verification under this regulation together with an undertaking to pay the appropriate fee, the approved body shall carry out an examination and tests of appliances or fittings in the batch in accordance with paragraph (2) below to establish whether items in the batch—
 - (a) conform with the relevant EC type-examination certificate; and
 - (b) in the case of an appliance satisfy the provisions of these Regulations which apply to it.
- (2) The notified body shall examine and carry out tests on appliances or fittings in the batch by reference to a sampling plan designed to ensure—
 - (a) a standard quality level corresponding to a 95% probability of acceptance with a range of non-conformity between 0.5% and 1.5%; and
 - (b) a limit quality corresponding to a 5% probability of acceptance with a percentage of non-conformity between 5% and 10%.
- (3) If, having carried out the examination, the notified body is satisfied that an EC certificate of conformity should be issued it shall, on payment of the appropriate fee, issue an EC certificate of conformity which—
 - (a) shall identify any appliance or fitting in the batch with which the notified body is not satisfied having regard to the foregoing provisions of this regulation; and
 - (b) shall be retained by the manufacturer or his authorised representative established in the Community;
 - (c) in the case of an appliance, affix or cause to be affixed its identification number.
- (4) In order to comply with the provision of paragraph (3)(c) above a notified body may authorise a manufacturer to affix its identification number during the manufacturing process.
- (5) Where the notified body issues an EC certificate of conformity in respect of a batch, the manufacturer or his authorised agent established in the Community—
 - (a) may supply any appliance or fitting in the batch other than one within subparagraph (b) below; and
 - (b) shall not supply any appliance or fitting which is identified in the EC certificate of conformity as one with which the notified body was not satisfied.
- (6) Where the notified body declines to issue an EC certificate of conformity in respect of a batch,—
 - (a) the notified body shall take all reasonable steps to ensure that no appliance or fitting in the batch is supplied by any person; and
 - (b) no person shall supply any appliance or fitting which was comprised in the batch.
- (7) If, having regard to the objectives of the Directive, it appears to the notified body that the number of batches of appliances or fittings to which an EC type-examination certificate applies and in respect of which it has declined to issue an EC certificate of conformity is unsatisfactory, it may

suspend verification under this regulation in respect of appliances or fittings to which that EC type-examination certificate applies.

(8) In this regulation, "batch" means a number of appliances or fittings all of which are of the same model, have the same design characteristics; and have been manufactured under the same conditions.

EC unit verification

- **21.**—(1) Where a manufacturer or his authorised representative established in the Community desires that an EC certificate of conformity shall be issued by a notified body under this regulation, he shall—
 - (a) inform the notified body of his desire;
 - (b) provide the design documentation to the notified body; and
 - (c) either—
 - (i) submit the appliance to the notified body, or
 - (ii) if the notified body so decides, make provision for the notified body to carry out its functions under this regulation at the place where the appliance is installed,

and shall undertake to pay the appropriate fee to the notified body.

- (2) The notified body shall examine the appliance and carry out tests to establish whether it satisfies the essential requirements and the provisions of these Regulations which apply to it.
- (3) If, having carried out the examination and tests, the notified body is satisfied that an EC certificate of conformity should be issued, it shall, on payment of the appropriate fee,—
 - (a) issue an EC certificate of conformity, which shall be retained by the manufacturer or his authorised representative established in the Community; and
 - (b) affix or cause to be affixed its identification number to the approved appliance.

Refusal to issue certificate of conformity

- **22.**—(1) If a notified body is minded to refuse to issue an EC certificate of conformity under any of regulations 19, 20 and 21, it shall give the applicant the opportunity of making representations within a reasonable period as to why it should not be refused.
- (2) Where a notified body, having considered any representations made in accordance with paragraph (1) above, refuses an EC certificate of conformity, it shall, in writing, inform the applicant of its decision and the grounds for its decision.

EC declaration of conformity to type (type-examination)

- **23.**—(1) Where an EC type-examination certificate has been issued in respect of a type and the manufacturer or his authorised representative established in the Community is satisfied—
 - (a) that an appliance or a fitting has been manufactured in conformity with that certificate; and
- (b) that the requirements of regulation 7 are satisfied in relation to the appliance or fitting, subject to regulation 24, he may—
 - (i) in the case of an appliance, issue an EC declaration of conformity to type; and
 - (ii) in the case of a fitting, supply a fitting certificate.
- (2) An EC declaration of conformity to type may relate to more than one appliance or fitting and shall be retained by the manufacturer or his authorised representative established in the Community.

(3) If the manufacturer or his authorised representative established in the Community issues an EC declaration of conformity to type he shall, in the case of an appliance, affix the CE Marking in accordance with regulation 25.

Surveillance by notified bodies

- **24.**—(1) Subject to the following provisions of this regulation where a manufacturer or his authorised representative established in the Community issues an EC declaration of conformity to type or a fitting certificate under regulation 23, he shall—
 - (a) appoint a notified body for the purposes of EC surveillance under the Directive, and
 - (b) undertake to pay from time to time the appropriate fee for work done by a notified body under this regulation;

and the notified body shall carry out checks under this paragraph.

- (2) Where a quality system was approved under regulation 14, the notified body which approved the quality system shall be the body to carry out EC surveillance under this paragraph.
 - (3) In carrying out EC surveillance under this regulation, the notified body,—
 - (a) in the case of surveillance under paragraph (1) above, shall, at intervals of not more than one year, carry out suf|fi|cient random examinations and checks in order to ensure that appliances or fittings manufactured by the manufacturer conform to the relevant EC type-examination certificate and the relevant essential requirements; and
 - (b) in the case of surveillance under paragraph (2) above,—
 - (i) shall, at intervals of not more than two years, carry out checks in order to ensure that the manufacturer is maintaining and applying the quality system; and
 - (ii) may, from time to time as it thinks fit, carry out visits at the places of manufacture, inspection, testing and storage and carry out, or have carried out, tests on appliances or fittings to check whether the manufacturer is maintaining and applying the quality system,

and shall, in each case, provide the manufacturer with a report on its findings.

- (4) A manufacturer shall, upon request made by it (if it is not the notified body which made the report) provide to the notified body which issues the EC type-examination certificate a copy of any report made to him under paragraph (3) above and shall permit inspection of the original thereof.
- (5) For the purpose of assisting the notified body to carry out EC surveillance under paragraph (2) above, the manufacturer shall, in respect of each appliance or fitting keep available for inspection by the notified body all necessary information, including—
 - (a) the documentation of the quality system;
 - (b) the design documentation of the appliance or fitting; and
 - (c) the quality records.
- (6) For the purposes of the foregoing provisions of this regulation, a duly authorised officer of the notified body responsible for EC surveillance may, on production if requested of his credentials, at all reasonable times enter any premises used for the purpose of manufacture CE, inspection, testing or storage of any appliance or fitting by or on behalf of the manufacturer.
- (7) If the notified body is not satisfied that the appliances or fittings tested by it satisfy the requirements of the relevant EC type-examination certificate or of these Regulations, it shall give to the manufacturer a report advising him of the steps necessary to remedy the non-compliance and,—
 - (a) if—
 - (i) it is the notified body which issued the EC type-examination certificate, consider whether it should exercise its powers under regulation 13, or

- (ii) it is not the notified body which issued the EC type-examination certificate, notify the notified body which issued it; or
- (b) if—
 - (i) it is the notified body which approved the quality system, consider whether it should exercise its powers under regulation 15, or
 - (ii) it is not the notified body which approved the quality system, notify the notified body which issued it.
- (8) Upon receipt of a notification under paragraph (7) above, it shall be the duty of a notified body to consider whether it should exercise its powers under regulation 13 or 15.
- (9) A manufacturer shall, on demand, pay to the notified body the appropriate fee for work done by it under this regulation.