1996 No. 192

The Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 1996

PART III

GENERAL REQUIREMENTS

General duty relating to the placing on the market of equipment, protective systems or devices by a responsible person

6.—(1) Subject to regulation 9 below, no person who is a responsible person shall place on the market any equipment, protective system or device to which these Regulations apply unless the requirements of paragraph (2) below have been complied with in relation thereto.

(2) The requirements of this paragraph, in respect of any equipment, protective system or device, are that—

- (a) it satisfies the relevant essential health and safety requirements and, for the purpose of satisfying those requirements,
 - (i) where a transposed harmonized standard covers one or more of the essential health and safety requirements, any equipment, protective system or device constructed in accordance with that transposed harmonized standard shall be presumed to comply with that or, as the case may be, those essential health and safety requirements; and
 - (ii) a certificate of conformity to the harmonized standards specified in the Electrical Equipment for Explosive Atmospheres (Certification) Regulations 1990(1) ("the 1990 Regulations") and obtained in accordance with the procedures for obtaining such certificates in the 1990 Regulations shall continue to be valid for the purposes of these Regulations until 30th June 2003 (unless it expires before that date) in respect of any electrical equipment, as defined in the 1990 Regulations, which conforms to the type covered by the said certificate;
- (b) the appropriate conformity assessment procedure, in accordance with regulation 10(1) below, has been carried out—
 - (i) by the manufacturer; or
 - (ii) where permitted by that procedure, wholly or partly as the case may be, by the manufacturer's authorized representative established in the Community,
 - save that,
 - (aa) where the procedure in Annex III, VI or VIII of the ATEX Directive (which are respectively set out in Schedules 6, 9 and 11 hereto) is part of or, as the case may be, is the appropriate conformity assessment procedure; and

(1) S.I. 1990/13; relevant amending instruments are S.I. 1990/2377, 1991/2826, 1995/1186.

(bb) the person placing the equipment, protective system or device on the market is neither the manufacturer nor his authorized representative established in the Community,

the obligation to retain the technical documentation, required as part of that appropriate conformity assessment procedure, shall be fulfilled by the person who places that equipment, protective system or device on the market;

- (c) the CE marking has been affixed to it by the manufacturer or his authorized representative established in the Community in accordance with Schedule 2 hereto and Schedule 2 shall have effect for that purpose; and
- (d) it is in fact safe.

General duty relating to the supply of equipment, protective systems or devices by a person other than the responsible person

7.—(1) Subject to paragraph (2) below, it shall be the duty of any person who supplies any equipment, protective system or device to which these Regulations apply, but who is not a person to whom regulation 6 above applies, to ensure that that equipment, protective system or device is safe.

(2) Without prejudice to any other safety requirement which may apply in respect of such equipment, protective system or device, this regulation does not apply to—

- (a) equipment, a protective system or device which has been placed on the market in the Community before 1st March 1996; or
- (b) the supply of any equipment, protective system or device which has previously been put into service in the Community.

General duty relating to the placing on the market of components by a responsible person

8.—(1) Subject to regulation 9(a) below, no person who is a responsible person shall place on the market any component to which these Regulations apply unless the requirements of paragraph (2) below have been complied with in relation thereto.

(2) The requirements of this paragraph, in respect of any component, are that-

- (a) the appropriate conformity assessment procedure, in accordance with regulation 10(2) below, has been carried out by the person specified in regulation 6(2)(b) above; and
- (b) it is accompanied by a certificate which has been issued by the manufacturer or his authorized representative established in the Community and which—
 - (i) declares the conformity of the component with the provisions of the ATEX Directive which apply to it; and
 - (ii) states its characteristics and how it must be incorporated into equipment or protective systems to assist compliance with the essential requirements applicable to finished equipment or protective systems.

Exceptions to placing on the market in respect of certain equipment, protective systems, devices and components

9. For the purposes of regulation 6 or 8 above, equipment, a protective system, device or, in the case of paragraph (a) below, a component shall not be regarded as being placed on the market—

(a) where that equipment, protective system, device or component

- (i) will be put into service in a country outside the Community; or
- (ii) is imported into the Community for re-export to a country outside the Community,

save that this paragraph shall not apply if the CE marking, or any inscription liable to be confused therewith, is affixed thereto; or

- (b) by the exhibition at trade fairs and exhibitions of that equipment, protective system or device, provided that where the provisions of these Regulations are not satisfied—
 - (i) a notice is displayed in relation to the equipment, protective system or device in question to the effect—
 - (aa) that it does not satisfy those provisions; and
 - (bb) that it may not lawfully be placed on the market until the responsible person has ensured that those provisions are satisfied; and
 - (ii) adequate safety measures are taken to ensure the safety of persons.

Conformity assessment procedures

10.—(1) Subject to paragraphs (4) and (5) below, for the purposes of regulation 6(2)(b) above, the appropriate conformity assessment procedure shall—

- (a) in the case of equipment and, where necessary, a device, be determined in accordance with paragraph (3) below by reference to the equipment-group and equipment-category of that particular equipment or, as the case may be, device; and
- (b) in the case of an autonomous protective system, be the procedure set out in paragraph (3)(a) or (d) below.

(2) For the purposes of regulation 8(2)(a) above, in the case of a component the appropriate conformity assessment procedure shall be the procedure set out in paragraph (3) below, which relates to the equipment or protective system into which that component is to be incorporated, with the exception of the affixing of the CE marking.

(3) The procedures referred to in paragraphs (1) and (2) above are as follows:

- (a) without prejudice to sub-paragraph (d) below, in the case of equipment-group I and II, equipment-category M 1 and 1, the manufacturer or his authorized representative established in the Community must, in order to affix the CE marking, follow the EC type-examination procedure (referred to in Annex III of the ATEX Directive, which is set out in Schedule 6 hereto), in conjunction with:
 - (i) the procedure relating to production quality assurance (referred to in Annex IV of the ATEX Directive, which is set out in Schedule 7 hereto); or
 - (ii) the procedure relating to product verification (referred to in Annex V of the ATEX Directive, which is set out in Schedule 8 hereto);
- (b) without prejudice to sub-paragraph (d) below, in the case of equipment-group I and II, equipment-category M 2 and 2,
 - (i) in the case of internal combustion engines and electrical equipment in these groups and categories, the manufacturer or his authorized representative established in the Community shall, in order to affix the CE marking, follow the EC-type examination procedure (referred to in Annex III of the ATEX Directive, which is set out in Schedule 6 hereto), in conjunction with:
 - (aa) the procedure relating to conformity to type referred to in Annex VI of the ATEX Directive (which is set out in Schedule 9 hereto); or
 - (bb) the procedure relating to product quality assurance referred to in Annex VII of the ATEX Directive (which is set out in Schedule 10 hereto); and
 - (ii) in the case of other equipment in these groups and categories, the manufacturer or his authorized representative established in the Community must, in order to affix

the CE mark, follow the procedure relating to internal control of production (referred to in Annex VIII of the ATEX Directive, which is set out in Schedule 11 hereto) and communicate the dossier, provided for in paragraph 3 of Annex VIII, to a notified body, which shall acknowledge receipt of it as soon as possible and shall retain it;

- (c) without prejudice to sub-paragraph (d) below, in the case of equipment-group II, equipment-category 3, the manufacturer or his authorized representative established in the Community must, in order to affix the CE marking, follow the procedure relating to internal control of production referred to in Annex VIII of the ATEX Directive (which is set out in Schedule 11 hereto); or
- (d) in the case of equipment-groups I and II, as an alternative to the procedures referred to in sub-paragraphs (a), (b) and (c) above, the manufacturer or his authorized representative established in the Community may, in order to affix the CE marking, follow the procedure relating to CE unit verification (referred to in Annex IX of the ATEX Directive, which is set out in Schedule 12 hereto).

(4) In the case of equipment, protective systems or devices, the manufacturer or his authorized representative established in the Community may, in order to affix the CE marking, follow the procedure relating to internal control of production (referred to in Annex VIII of the ATEX Directive, which is set out in Schedule 11 hereto) with regard to the safety aspects referred to in point 1.2.7 of Annex II of the ATEX Directive (which is set out in Schedule 3 hereto).

(5) Notwithstanding the previous paragraphs of this regulation, the Secretary of State may, on a duly justified request, authorize the placing on the market and putting into service of equipment, protective systems and individual devices referred to in Article 1(2) in respect of which the procedures referred to in the previous paragraphs have not been applied and the use of which is in the interests of protection.

(6) Documents and correspondence relating to the procedures referred to in the above-men tioned paragraphs shall be drawn up in one of the official languages of the member States in which those procedures are being applied or in a language accepted by the notified body to which an application is made pursuant to one of those procedures.

Notified bodies

11. For the purposes of these Regulations, a notified body is a body which has been appointed to carry out one or more of the conformity assessment procedures specified in Article 8 of the ATEX Directive and referred to in regulation 10 above which has been—

- (a) appointed as a notified body in Great Britain pursuant to regulation 12 below;
- (b) appointed as a notified body in Northern Ireland; or
- (c) appointed by a member State other than the United Kingdom,

and in the case of (a), (b) and (c) above has been notified by the member State concerned to the Commission and the other member States pursuant to Article 9(1) of the ATEX Directive.

Notified bodies appointed by the Secretary of State

12.—(1) The Secretary of State may from time to time appoint such qualified persons as he thinks fit to be notified bodies for the purposes of these Regulations.

- (2) An appointment—
 - (a) may relate to all descriptions of equipment, protective systems, devices or components or such descriptions (which may be framed by reference to any circumstances whatsoever) of equipment, protective systems, devices or components as the Secretary of State may from time to time determine;

- (b) may be made subject to such conditions as the Secretary of State may from time to time determine, and such conditions may include conditions which are to apply upon or following termination of the appointment;
- (c) shall, without prejudice to the generality of sub-paragraph (b) above, require that body, subject to paragraph (4) below, to carry out the procedures and specific tasks for which it has been appointed including (where so provided as part of those procedures) surveillance to ensure that the manufacturer duly fulfils the obligations arising out of the relevant quality assurance procedure;
- (d) shall be terminated—
 - (i) if it appears to the Secretary of State that the notified body is no longer a qualified person; or
 - (ii) upon 90 days' notice in writing to the Secretary of State, at the request of the notified body; and
- (e) may be terminated if it appears to the Secretary of State that any of the conditions of the appointment are not complied with.

(3) Subject to paragraph (2)(d) and (e) above, an appointment under this regulation may be for the time being or for such period as may be specified in the appointment.

(4) A notified body appointed by the Secretary of State shall not be required to carry out the functions referred to in paragraph (2)(c) above if—

- (a) the documents submitted to it in relation to carrying out such functions are not in English or another language acceptable to that body;
- (b) the person making the application has not submitted with its application the amount of the fee which the body requires to be submitted with the application pursuant to regulation 13 below; or
- (c) the body reasonably believes that, having regard to the number of applications made to it in relation to its appointment under these Regulations which are outstanding, it will be unable to commence the required work within 3 months of receiving the application.

(5) If for any reason the appointment of a notified body is terminated under this regulation, the Secretary of State may authorise another notified body to take over its functions in respect of such cases as he may specify.

(6) A notified body which is responsible, as part of any of the conformity assessment procedures referred to in regulation 10 above, for the assessment of the conformity of electrical equipment placed on the market before 1st July 2003, shall take account of the results of tests and verifications already carried out in respect of the harmonized standards which are applicable under—

- (a) Council Directive 76/117/EEC(2) and Council Directive 79/196/EEC(3); or
- (b) Council Directive 82/130/EEC(4).

(7) If a notified body, to which an application has been made for an EC type-examination certificate pursuant to the EC type-examination procedure (referred to in Annex III of the ATEX Directive and set out in Schedule 6 hereto), is not satisfied that the requirements for such a certificate are met and is minded to refuse to issue an EC type-examination certificate, it shall—

⁽²⁾ OJNo. L24, 30.1.76, p. 45.

⁽³⁾ OJ No. L43, 20.2.79, p. 20. Council Directive 79/196/EEC was adapted to technical progress by Commission Directives 84/47/EEC (OJ No. L31, 2.2.84, p. 19), 88/571/EEC (OJ No. L311, 17.11.88, p. 46) and 94/26/EC (OJ No. L157, 24.6.94, p. 33) and was amended by Council Directives 88/665/EEC (OJ No. L382, 31.12.88, p. 42) and 90/487/EEC (OJ No. L270, 2.10.90, p. 23).

⁽⁴⁾ OJ No. L59, 2.3.82, p. 10. Council Directive 82/130/EEC was adapted to technical progress by Commission Directives 88/35/ EEC (OJ No. L20, 26.1.88, p. 28), 91/269/EEC (OJ No. L134, 29.5.91, p. 51) and 94/44/EC (OJ No. L248, 23.9.94, p. 22).

- (a) inform the applicant in writing of the reasons why it proposes to refuse to issue an EC type-examination certificate;
- (b) give the applicant the opportunity, within a reasonable period, of making representations as to why it should not be refused; and
- (c) if, after considering any representations made pursuant to sub-paragraph (b) above, it remains unsatisfied in respect of those requirements, it shall—
 - (i) notify its decision in writing to the applicant stating the grounds on which the refusal is based; and
 - (ii) inform the applicant in writing of the procedure which it has established whereby an appeal may be made against that decision.
- (8) In this regulation—

"qualified person" means a person (which may include the Secretary of State) who meets the minimum criteria; and

"minimum criteria" means the criteria set out in Annex XI of the ATEX Directive (minimum criteria to be taken into account by member States for the notification of bodies)(5).

Fees

13.—(1) Without prejudice to the power of the Secretary of State, where he is a notified body, to charge fees pursuant to regulations made under section 56 of the Finance Act 1973(6) and subject to paragraph (2) below, a notified body appointed by the Secretary of State, other than the Secretary of State, may charge such fees in connection with, or incidental to, carrying out its duties in relation to the functions referred to in regulation 12(2)(c) above as it may determine; provided that such fees shall not exceed the sum of the following—

- (a) the costs incurred or to be incurred by the 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 the body on behalf of the applicant; and
 - (ii) the commercial rate normally charged on account of profit for that work or similar work.

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

⁽⁵⁾ Notified bodies meeting the assessment criteria laid down in the relevant harmonized standards are presumed to meet the minimum criteria.

^{(6) 1973} c. 51.