S.I. No. 83/1999 - European Communities (Equipment and Protective Systems Intended For Use in Potentially Explosive Atmospheres) Regulations, 1999.

I, MARY HARNEY, Minister for Enterprise, Trade and Employment, in exercise of the powers conferred on me by section 3 of the European Communities Act, 1972 (No. 27 of 1972), and for the purpose of giving effect to Council Directive 94/9/EC of 23 March, 1994,[1] hereby make the following regulations:

1. (1) These Regulations may be cited as the European Communities (Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres) Regulations, 1999.

(2) These Regulations shall come into operation on the 30th day of March, 1999.

2. (1) In these Regulations, except where the context otherwise requires—

"the Authority" means the National Authority for Occupational Safety and Health established under section 15 (1) of the Safety, Health and Welfare at Work Act, 1989 (No. 7 of 1989);

"authorised officer" means a person authorised in accordance with Regulation 13;

"CE conformity marking" shall be construed in accordance with Regulation 8;

"certificate of conformity" shall be construed in accordance with Regulation 6;

"conformity assessment procedures" shall be construed in accordance with Regulation 7;

"the Council Directive" means Council Directive 94/9/EC of 23 March, 1994;

"EC declaration of conformity" means a declaration set out in the form specified in the First Schedule;

"essential health and safety requirem" means the requirements specified in the Second Schedule;

"manufacturer" means the manufacturer of the equipment, a protective system, a device or a component;

"manufacturer's representative" means the authorised representative of a manufacturer established within the European Community;

"Member State" means a Member of the European Communities and a reference to a Member State includes a reference to an EEA State;

"the Minister" means the Minister for Enterprise, Trade and Employment;

“notified body” means a body appointed in accordance with Regulation 9;

“place on the market” means supply, sell, offer for sale, expose for sale or have in possession for sale; place on the market under a rental agreement, lease agreement, hire purchase agreement or any other type of agreement and cognate words shall be construed accordingly;

“the Regulations of 1981” means the European Communities (Electrical Equipment for Use in Potentially Explosive Atmospheres) Regulations, 1981 (S.I. No. 61 of 1981);

“the Regulations of 1986” means the European Communities (Electrical Equipment for Use in Potentially Explosive Atmospheres) (Amendment) Regulations, 1986 (S.I. No. 244 of 1986);

“the Regulations of 1991” means the European Communities (Electrical Equipment for Use in Potentially Explosive Atmospheres) (Amendment) Regulations, 1991 (S.I. No. 289 of 1991);

“the Regulations of 1998” means the European Communities (Electrical Equipment for Use in Potentially Explosive Atmospheres) (Amendment) Regulations, 1998 (S.I. No. 355 of 1998);

“responsible person” has the meaning assigned to it by Regulation 11 (7).

(2) A word or expression that is used in these Regulations and is also used in the Council Directive has, unless the context otherwise requires, the same meaning in these Regulations as it has in the Council Directive.

(3) In these Regulations—

(*a*) A reference to a Regulation or a Schedule is a reference to a Regulation of or Schedule to these Regulations unless it is indicated that reference to some other Regulations is intended, and

(*b*) A reference to a paragraph or a subparagraph, is a reference to the paragraph or the subparagraph of the provision in which the reference occurs unless it is indicated that reference to some other provision is intended.

3. (1) Subject to Regulation 4 these Regulations shall apply to—

(*a*) equipment and protective systems intended for use in potentially explosive atmospheres, and

(*b*) devices and components,

which are placed on the market on or after 1st day of March, 1996.

(2) These Regulations shall not apply to—

(*a*) medical devices intended for use in a medical environment,

(*b*) equipment and protective systems where the explosion hazard results exclusively from the presence of explosive substances or unstable chemical substances,

(*c*) equipment intended for use in domestic and non-commercial environments where potentially explosive atmospheres may only rarely be created, solely as a result of the accidental leakage of fuel gas.

(*d*) personal protective equipment covered by the Safety, Health and Welfare at Work (General Application) Regulations, 1993 (S.I. No. 44 of 1993), apply,

(*e*) seagoing vessels and mobile offshore units together with equipment on board such vessels or units,

(*f*) means of transport including vehicles and their trailers intended solely for transporting passengers by air or by road, rail or water networks, as well as means of transport in so far as such means are designed for transporting goods by air, by public road or rail networks or by water, but vehicles intended for use in a potentially explosive atmosphere are not excluded,

(*g*) the equipment covered by Article 223 (1) (*b*) of the Treaty establishing the European Community, and

(*h*) equipment, protective systems, or devices shown at trade fairs, exhibitions or demonstrations which do not conform with the provisions of these Regulations if a notice clearly specified that such equipment, protective system or device does not so conform and is not for sale until it has been brought into such conformity and that for the time that it is on show adequate safety measures are taken.

4. (1) These Regulations shall not apply to equipment or a protective system—

(*a*) placed on the market in the European Community on or before 30th day of June, 2003, and

(*b*) that complies with any health and safety provisions required for such equipment or protective systems placed on the market in the State on the 23rd day of March, 1994.

(2) Paragraph (1) above does not apply in the case of equipment or a protective system which—

(*a*) unless required to bear the CE marking pursuant to any other Community obligation, bears the CE marking or an inscription liable to be confused therewith, or

(*b*) bears or is accompanied by any other indication, howsoever expressed, that it complies with the Council Directive.

(3) In these Regulations, "health and safety provisions" means any requirement imposed by an enactment which has the same, or substantially the same, effect as any of the essential health and safety requirements specified in these Regulations and which would, but for the provisions of this Regulation, be applicable to that equipment or protective system for the purposes of complying with these Regulations.

5. (1) A person shall not place on the market or put into service any equipment, protective system or a device unless such equipment, protective system or device—

(*a*) complies with the relevant essential health and safety requirements specified for such equipment, protective system or device concerned having regard to its intended use,

(*b*) has been examined in accordance with the appropriate conformity assessment procedure for such equipment, protective system, or device specified in Regulation 7,

(*c*) has the CE marking affixed to such equipment, protective system, or device in accordance with Regulation 8 and the First Schedule, and

(*d*) has an EC declaration of conformity issued in respect of the equipment, protective system, or device.

(2) Equipment, a protective system or device shall not be placed on the market and put into service unless when it—

(*a*) is properly installed and maintained,

(*b*) is used for its intended purpose

it does not endanger the health and safety of persons and, where appropriate, domestic animals or property.

(3) Without prejudice to paragraph (1), any equipment, protective system, device or component to which these Regulations apply that has been constructed in accordance with a national standard that—

(*a*) transposes a harmonised standard, and a reference for such transposition has been published in the Official Journal of the European Communities, and

(*b*) concerns one or more of the essential health and safety requirements,

shall be presumed, unless the contrary is shown, to comply with the relevant essential health and safety requirements concerned for such equipment, protective system, device or component having regard to its intended use.

(4) A certificate of conformity to the harmonised standards specified in the Regulations of 1981, and obtained in accordance with the procedures to obtaining such certificates shall continue to be used for the purposes of these Regulations until the 30th day of June 2003, unless such certificate expires before that date, in respect of electrical equipment to which the Regulations of 1981 apply, that conforms to the type of electrical equipment to which the certificate applies.

(5) Where—

(*a*) in relation to equipment, a protective system or a device—

(i) an EC declaration of conformity has been issued by the manufacturer or such manufacturer's representative containing the matters specified in the First Schedule, and

(ii) the CE conformity marking is affixed,

such equipment, protective system or device shall be presumed, unless the contrary is shown, to comply with these Regulations,

(*b*) in relation to a component, a certificate of conformity has been issued in accordance with these Regulations, such component shall be presumed, unless the contrary is shown, to comply with these Regulations.

(6) A person shall not place on the market, or, where appropriate, withdraw from the market, or shall not put into service or use any equipment or protective system in respect of which an authorised officer is of the opinion that such equipment or protective system—

(*a*) bears the conformity marking, and

(*b*) is used in accordance with its intended use, and

(*c*) is likely to endanger the safety of persons and, where appropriate domestic animals or property.

(7) A person who fails to comply with a provision of this Regulation shall be guilty of an offence.

6. (1) A person shall not place any component on the market unless—

(*a*) the appropriate conformity assessment procedure in accordance with Regulation 7 has been carried out, and

(*b*) a certificate (in these Regulations referred to as a "certificate of conformity") has been issued by the manufacturer or such manufacturer's representative that—

(i) declares the conformity of the component with the provisions of these Regulations, and

(ii) states the characteristics of the component concerned and the manner in which it is to be incorporated into equipment or protective systems to assist compliance with the essential requirements, applicable to finished equipment or protective systems.

(2) A person who fails to comply with a provision of this Regulation shall be guilty of an offence.

7. (1) The appropriate conformity assessment procedure for—

(*a*) equipment and, where appropriate, a device, shall be determined in accordance with paragraph (3) by reference to the equipment-group and equipment-category of the type of equipment or, device concerned, and

(*b*) an autonomous protective system, is the procedure specified in paragraph 3 (*a*) or (*d*), whichever is appropriate.

(2) The appropriate conformity assessment procedure for a component shall be the procedure set out in paragraph (3) for 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 conformity assessment procedure—

(*a*) without prejudice to subparagraph (*d*), for equipment — Group I and II, equipment category MI and I, the manufacturer or such manufacturer's representative shall, in order to offer the affix the CE marking, apply the EC type examination procedure referred to in the Third Schedule together with—

(i) the procedure relating to production quality assurance referred to in the Fourth Schedule, or

(ii) the procedure relating to product verification referred to in the Fifth Schedule,

(*b*) without prejudice to subparagraph (*d*) for equipment — Group I and II, equipment category M2 and 2—

(i) internal combustion engines and electrical equipment in such groups and such equipment categories, the manufactuer or his or her authorised representative established in the Community

shall, in order to offer the CE marking, apply the EC type examination procedure referred to in the Third Schedule together with—

(I) the procedure relating to conformity to type referred to in the Sixth Schedule, or

(II) the procedure relating to product quality assurance referred to in the Seventh Schedule, and

(ii) equipment, other than that specified in subparagraph (*b*) (i), in such groups and equipment categories, the manufacturer or manufacturer's representative shall, in order to affix the CE marking, apply the procedure relating to internal control of production referred to in the Eighth Schedule and send the dossier referred in paragraph 3 of the Eighth Schedule to a notified body,

(*c*) without prejudice to subparagraph (*d*) for equipment — group II, equipment — category 3, the manufacturer or such manufacturer's representative shall, in order to affix the CE marking, apply the procedure relating to internal control of production referred to in the Eighth Schedule, or

(*d*) for equipment — groups I and II, as an alternative to the procedures specified in subparagraphs (*a*), (*b*) and (*c*), the manufacturer or such manufacturer's representative may, in order to affix the CE marking, apply the procedure relating to CE unit verification referred to in the Ninth Schedule.

(4) A manufacturer or such manufacturer's representative may, for the purposes of affixing the CE marking on equipment, a protective system or device, apply the procedures relating to internal control of production referred to in the Eighth Schedule concerning the safety aspects referred to in paragraph 1.2.7 of the Second Schedule.

(5) The Minister may, following a request to do so, authorise the placing on the market and putting into service of equipment, a protective system and device notwithstanding that the procedures referred to in this Regulation for the equipment, protective system or device concerned have not been applied and the use of which is in the interests of protection.

(6) The manufacturer or such manufacturer's representative shall ensure that all documents and correspondence relating to the procedures specified in this Regulation for the equipment, protective system or device concerned are written in one of the official languages of the Member States in which these procedures are being applied or in a language acceptable by the notified body to which an application is made pursuant to one of those procedures.

8. (1) The CE conformity marking shall consist of the letters “CE” in the form specified in the First Schedule and the First Schedule shall apply to the affixing of such conformity marking and the EC declaration of conformity.

(2) The manufacturer or such manufacturer's representative shall ensure that the CE conformity marking—

(*a*) is affixed distinctly, visibly, legibly and indelibly to equipment and protective systems that have conformed to the conformity assessment procedure specified, including where appropriate, devices, and

(*b*) bears, where appropriate, the identification number of a notified body involved in the production control stage.

(3) In affixing the CE conformity marking, the manufacturer or such manufacturer's representative shall ensure that marking, other than that referred to on paragraph (1), does not reduce the visibility or legibility of the

CE marking.

(4) A manufacturer or such manufacturer's representative shall ensure that CE conformity marking on equipment, a protective system or, where appropriate, a device, clearly describes the meaning and form of the CE marking.

(5) Where an authorised officer establishes that a CE conformity marking has been incorrectly affixed to equipment, a protective system, or where appropriate, a device, the manufacturer or such manufacturer's representative, shall take all necessary steps, as soon as may be, to make equipment, protective system, or where appropriate, a device conform to the provisions of these Regulations.

(6) Where in relation to the incorrect affixing of the CE conformity marking refered to in paragraph (4), a manufacturer or such manufacturer's representative has failed to take all necessary steps to ensure that such equipment, protective system or device, conforms to these Regulations, the manufacturer or such manufacturer's representative shall withdraw as soon as possible such equipment, protective system or device from the market.

(7) A person shall not affix markings on equipment or a protective system in respect of the meaning and form of the CE conformity marking if such markings, other than the CE conformity markings, are likely to deceive third parties as to the meaning and form of the CE conformity marking.

(8) A person who fails to comply with a provision of this Regulation shall be guilty of an offence.

9. (1) The Minister may, subject to such conditions as he or she thinks fit, appoint a body (referred to in these Regulations as a "notified body")—

(*a*) to carry out one or more of the conformity assessment procedures specified in these Regulations, and

(*b*) to carry out any matter for the purpose of these Regulations.

(2) A notified body shall take account of the results of tests and verifications that have been carried out in respect of the harmonised standards applicable under these Regulations, and, subject to Regulation 17, the Regulations of 1981, the Regulations of 1986, the Regulations of 1991 and the Regulations of 1998.

(3) Where a notified body has, in accordance with Regulation 7, received a dossier it shall acknowledge receipt of such dossier to the manufacturer or such manufacturer's representative concerned.

10. (1) Requests to a notified body to carry out one or more of the conformity assessment procedures specified in Regulation 7 shall be made in writing and shall be accompanied by the prescribed fee.

(2) Where a notified body is satisfied, following the carrying out of the conformity assessment procedures in respect of which the application was made, that the results of any of the tests or examination conducted by it do not satisfy the requirements of these Regulations it shall inform the applicant in writing stating the reasons and of the right to apply for a review of the decision under Regulation 12.

11. (1) An authorised officer may from time to time carry out an inspection on—

(*a*) equipment, protective system or device on which the CE marking has been placed or in respect of which an EC declaration of conformity has been issued, or

(*b*) a component in respect of which a declaration of conformity with these Regulations has been issued, in

accordance with these Regulations, or where appropriate, the law of a Member State,

for the purposes of ascertaining if such equipment, protective system, device or component has been manufactured to conform in all aspects with the requirement of these Regulations.

(2) A responsible person shall, for the purpose of assisting an authorised officer to carry out an inspection in respect of—

(*a*) equipment, a protective system or a device referred to in paragraph (1),

or

(*b*) a component referred to in paragraph (1)

retain, from the date of issue of an EC declaration of conformity for equipment, a protective system or a device referred to in subparagraph (*a*) or a certificate of conformity for a component referred to in subparagraph (*b*) proper records, including documentation specifying the conformity assessment procedures carried out, on the equipment, protective system, device or component concerned and that the conformity assessment procedures have been complied with, and shall when requested to do so by the authorised officer produce them to the authorised officer.

(3) Where an authorised officer is of the opinion that the equipment, protective system, device or component has not been manufactured in conformity with the requirements of these Regulations or that proper records have not been kept in accordance with paragraph (2), he or she shall notify in writing the responsible person of such opinion in accordance with paragraph (5).

(4) If an authorised officer is notified that—

(*a*) equipment, a protective system or a device—

(i) bearing the CE markings, or

(ii) in respect of which an EC declaration of conformity or an EC type examination certificate has been issued, or

(*b*) a component for which a declaration of conformity with these Regulations has been issued, or in respect of which an EC type examination certificate has been issued,

has not been manufactured in conformity with the requirement of these Regulations or that proper records have not been kept in accordance with paragraph (2), the authorised officer may notify in writing the responsible person in accordance with paragraph (5).

(5) An authorised officer shall, when issuing a notification under paragraph (3) or (4) state—

(*a*) the manner in which the equipment, protective system, device or component does not conform with these Regulations, or in which proper records have not been kept.

(*b*) the procedure specified in these Regulations for the purpose of ensuring that—

(i) the equipment, protective system, device or component or any equipment, protective systems,

devices or components of the same type, conform, or

(ii) proper records are kept within a specified period and a declaration that if the appropriate procedure is not completed the equipment, protective system, device or component shall not be marketed, or as the case may be, shall be withdrawn from the market,

(*c*) that the equipment, protective system, device or component concerned shall not be put into service nor transported to another Member State, except in order to bring the equipment, protective system, device or component into compliance with these Regulations, and, if appropriate, any EC type examination certificate issued in respect of the equipment, protective system, device or component of the same type will be suspended or withdrawn, and

(*d*) where appropriate, the date on which it is to take effect.

(6) Where an authorised officer decides that equipment, a protective system, device or component—

(*a*) shall not be marketed, shall be withdrawn from the market or shall be prohibited from being put into service, or

(*b*) shall be prohibited from being transported to another Member State,

except in order to bring the equipment, protective system, device or component concerned into compliance with the Regulation, the authorised officer shall give immediate notice in writing to the responsible person specifying the grounds on which such decision has been made in addition to the matters specified in paragraph (5).

(7) In these Regulations "responsible person" means—

(*a*) the manufacturer of equipment, a protective system, a device or a component concerned,

(*b*) the manufacturer's representative, or

(*c*) where the manufacturer is not established in the European Community and—

(i) has not appointed an authorised representative who is also established in the European Community, or

(ii) the representative established in the European Community is not the person who places that equipment, protective system, device or component on the market.

the person who places it on the market in the Community.

12. (1) Any person aggrieved by a decision of a notified body under Regulation 10 may, by notice in writing given to the Authority not later than 14 days after the receipt of notice of that decision, appeal to the Authority against the decision and the Authority, having considered any submissions made to him or her by that person, and any other interested parties and the report of any enquiry held under paragraph (2) in relation to the appeal or of any assessor appointed under paragraph (3) in relation thereto, may uphold, vary or reverse the decision of a notified body.

(2) The Authority may appoint an officer to hold an enquiry in connection with an appeal under this Regulation and to make a report to the Authority on the findings and the result of the enquiry.

(3) The Authority may appoint an assessor to assist and to make a report to the Authority in relation to an appeal under this Regulation or to assist an officer of the Authority in relation to an appeal under this Regulation or to assist an officer of the Authority in relation to an enquiry being held under paragraph (2) of this Regulation.

13. (1) The Minister or the Authority may authorise such and so many officers of the Minister, as the Minister or the Authority thinks fit, to be authorised officers for the purpose of these Regulations.

(2) A person appointed under paragraph (1) shall, on such appointment, be furnished by the Minister or the Authority, as may be appropriate, with a certificate of authorisation of his or her authorisation and when exercising power conferred by these Regulations shall, if requested by any person thereby affected, produce such certificate or an authenticated copy of it to that person for inspection.

(3) An authorised officer for the purpose of these Regulations, may—

(*a*) enter, inspect, examine, and search at all times any structure, premises or other land which he or she has reasonable grounds for believing is being used for or in connection with the manufacture, storage, packing or placing on the market of any equipment, protective systems, components or device,

(*b*) at such structure, premises or other land inspect and take copies of, or extracts from, any books, records in other documents which he or she finds in the course of an inspection, examination or search,

(*c*) require any person whom the authorised officer considers to be in charge of or employed in or on any structure, premises or other land entered by the authorised officer under these Regulations, to—

(i) produce any equipment, protective system, component or device which is in the possession or under the control of such person,

(ii) produce any books, records or other documents which relate to transactions concerning any equipment, protective systems, components or device and which are in the possession or under the control of such person, and

(iii) require any person whom the authorised officer finds on any structure, premises or other land, to furnish such information as the authorised officer may reasonably require for the purposes of these Regulations,

(*d*) make such examination and inquiry as may be necessary to ascertain whether the provisions of these Regulations are being complied with,

(*e*) take possession of and remove from the premises for examination and checking, any equipment, protective systems, component or device, and

(*f*) carry out or cause to have carried out any test which the authorised officer considers to be appropriate in order to establish conformity of equipment, a protective system, device or a component if an EC declaration of conformity has been issued in respect of any equipment, protective systems, or device or a declaration of conformity has been issued in respect of a component and there are reasonable grounds for believing that such equipment, protective system, device or component does not comply with the essential handling and safety requirements.

(4) A person who obstructs or interferes with an authorised officer in the course of exercising a power conferred on such authorised officer by these Regulations or impedes the exercise by the authorised officer of such power or fails or refuses to comply with a request made by, or to answer a question asked by, an authorised

officer purport to these Regulations or in purported compliance with such request or in answer to such question gives information to any authorised officer that he or she knows to be false or misleading in a material respect, shall be guilty of an offence.

14. Proceedings for an offence under these Regulations may be brought and be prosecuted by the Minister or the Authority.

15. (1) A person guilty of an offence under these Regulations shall be liable on summary conviction of a fine not exceeding £1,500.

(2) Where an offence under this Act is committed by a body corporate and is proved to have been so committed with the consent, connivance or approval of or to be attributable to any neglect on the part of the person being a director, manager, secretary or other officer of the body corporate, or any other person who was acting or purporting to act in any such capacity, that person as well as the body corporate shall be guilty of an offence and be liable to be proceeded against and punished as if he or she were guilty of the first-mentioned offence.

(3) If the contravention in respect of which a person is convicted of an offence under these Regulations is continued after the conviction, the person shall be guilty of a further offence on every day on which the contravention continues and for each such offence the person shall be liable, on summary conviction, to a find not exceeding £200.

16. (1) All the parties involved in the application of these Regulations shall, subject to paragraph (2), observe confidentiality in respect of all information obtained in the performance of carrying out their tasks under these Regulations.

(2) Paragraph (1) does not affect the obligations of the State and of the notified bodies regarding reciprocal information and the dissemination of warnings.

17. As and from the 1st day of July, 2003—

(*a*) the Regulations of 1981

(*b*) the Regulations of 1986

(*c*) the Regulations of 1991, and

(*d*) the Regulations of 1998

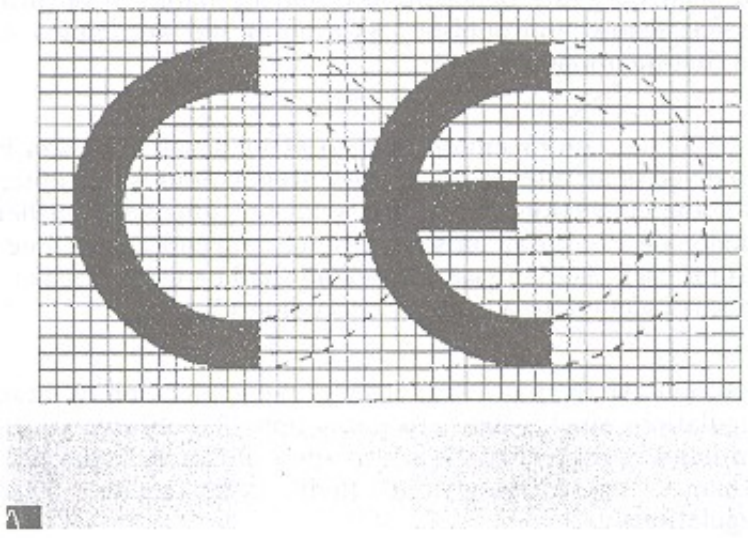
are hereby revoked.

FIRST SCHEDULE

Regulation 2

CE Marking and Other Inscriptions

1. The CE conformity marking shall consist of the initials CE taking the following form.



2. If the marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.

3. The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm. This minimum dimension may be waived for small-scale equipment, protective systems or devices referred to in these Regulations.

4. The CE marking shall be followed by the identification number of the notified body where such body is involved in the production control stage.

5. The CE marking shall be affixed distinctly, visibly, legible and indelibly to equipment and protective systems, supplementary to the provisions of paragraph 1.0.5 of the Second Schedule.

6. Subject to paragraph 7, where equipment, a protective system or device is the subject of other Community Directives which also provide for the affixing of the CE marking, such marking shall indicate that the equipment, protective system or device in question is also presumed to comply with the provisions of those other Directives.

7. Where one or more of the other Directives referred to in paragraph 6, allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate conformity only with the Directives applied by the manufacturer. In this case, particulars of the said Directives, as published in the Official Journal of the European Communities, must be given in the documents, notices or instructions required by the Directives and accompanying such equipment protective systems of device.

8. The affixing of markings on the equipment or protective systems which are likely to deceive third parties as to the meaning and form of the CE marking shall be prohibited. Any other marking may be affixed to the equipment or protective systems, provided that the visibility and legibility of the CE marking is not thereby reduced.

Content of the EC declaration of conformity

The EC declaration of conformity must contain the following elements:

(*a*) the name or identification mark and the address of the manufacturer or his authorised representative established within the Community;

(*b*) a description of the equipment, protective system, or device;

(*c*) all relevant provisions fulfilled by the equipment, protective system, or device;

(*d*) where appropriate, the name, identification number and address of the notified body and the number of the EC-type-examination certificate;

(*e*) where appropriate, reference to the harmonised standards;

(*f*) where appropriate, the standards and technical specifications which have been used;

(*g*) where appropriate, references to other Community Directives which have been applied;

(*h*) identification of the signatory who has been empowered to enter into commitments on behalf of the manufacturer or his authorised representative established within the Community.

SECOND SCHEDULE

Regulation 2

Essential health and safety requirements relating to the design and construction of equipment and protective systems intended for use in potentially explosive atmospheres

Preliminary observations

A. Technological knowledge, which can change rapidly, must be taken into account as far as possible and be utilised immediately.

B. For devices the essential requirements shall apply only in so far as they are necessary for the safe and reliable functioning and operation of those devices with respect to the risks of explosion.

1. Common requirements for equipment and protective systems

1.0. General requirements

1.0.1. Principles of integrated explosion safety

Equipment and protective systems intended for use in potentially explosive atmospheres must be designed from the point of view of integrated explosion safety.

In this connection, the manufacturer must take measures:

— above all, if possible, to prevent the formation of explosive atmospheres which may be produced or released by equipment and by protective systems themselves,

— to prevent the ignition of explosive atmospheres, taking into account the nature of every electrical and non-electrical source of ignition,

— should an explosion nevertheless occur which could directly or indirectly endanger persons and, as the case may be, domestic animals or property, to halt it immediately and to limit the range of explosion flames and explosion pressures to a sufficient level of safety or both

1.0.2. Equipment and protective systems must be designed and manufactured after due analysis of possible operating faults in order as far as possible to preclude dangerous situations. Any misuse which can reasonably be anticipated must be taken into account.

1.0.3. Special checking and maintenance conditions

Equipment and protective systems subject to special checking and maintenance conditions must be designed and constructed with such conditions in mind.

1.0.4. Surrounding area conditions

Equipment and protective systems must be so designed and constructed as to be capable of coping with actual or foreseeable surrounding area conditions.

1.0.5. Marking

All equipment and protective systems must be marked legibly and indelibly with the following minimum particulars:

— name and address of the manufacturer,

— CE marking,

— designation of series or type,

— serial number, if any,

— year of construction,

— the specific marking of explosion protection Ex followed by the symbol of the equipment group and category,

— for equipment-group II, the letter “G” (concerning explosive atmospheres caused by gases, vapours or mists),

and

the letter “D” (concerning explosive atmospheres caused by dust), or both such letters.

Furthermore, where necessary, they must also be marked with all information essential to their safe use.

1.0.6. Instructions

(*a*) All equipment and protective systems must be accompanied by instructions, including at least the following particulars:

— a recapitulation of the information with which the equipment or protective sysem is marked, except for the serial number referred to in paragraph 1.0.5. together with any appropriate additional information to facilitate maintenance and should include the address of the importer, repairer;

— instructions for safe:

— putting into service,

— use,

— assembling and dismantling,

— maintenance (servicing and emergency repair),

— installation,

— adjustment;

— where necessary, an indication of the danger areas in front of pressure-relief devices;

— where necessary, training instructions;

— details which allow a decision to be taken beyond any doubt as to whether an item of equipment in a specific category or a protective system can be used safely in the intended area under the expected operating conditions;

— electrical and pressure parameters, maximum surface temperatures and other limit values;

— where necessary, special conditions of use, including particulars of possible misuse which experience has shown might occur;

— where necessary, the essential characteristics of tools which may be fitted to the equipment or protective system.

(*b*) The instructions shall be drawn up in one of the Community languages by the manufacturer or his or her authorised representative established in the Community.

On being put into service, all equipment and protective systems must be accompanied by a translation of the instructions in the language or languages of the country in which the equipment or protective system is to be used and by the instructions in the original language.

This translation must be made by either the manufacturer or his or her authorised representative established in the Community or the person introducing the equipment or protective system into the language area in question.

By way of derogation from this requirement, the maintenance instructions for use by the specialist personnel employed by the manufacturer or his or her authorised reprasentative established in the Community may be drawn up in a single Community language underestood by that personnel.

(*c*) The instructions must contain the drawings and diagrams necessary for the putting into service, maintenance, inspection, checking of correct operation and, where appropriate, repair of the equipment or protective system, together with all useful instructions, in particular with regard to safety.

(*d*) Literature describing the equipment or protective system must not contradict the instructions with regard to safety aspects.

1.1. Selection of materials

1.1.1. The materials used for the construction of equipment and protective systems must not trigger off an explosion, taking into account foreseeable operational stresses.

1.1.2. Within the limits of the operating conditions laid down by the manufacturer, it must not be possible for a reaction to take place between the materials used and the constituents of the potentially explosive atmosphere which could impair explosion protection.

1.1.3. Materials must be so selected that predictable changes in their characteristics and their compatibility in combination with other materials will not lead to a reduction in the protection afforded; in particular, due account must be taken of the material's corrosion and wear resistance, electrical conductivity, impact strength, ageing resistance and the effects of temperature variations.

1.2. Design and Construction

1.2.1. Equipment and protective systems must be designed and constructed with due regard to technological knowledge of explosion protection so that they can be safely operated throughout their foreseeable lifetime.

1.2.2. Components to be incorporated into or used as replacements in equipment and protective systems must be so designed and constructed that they function safely for their intended purpose of explosion protection when they are installed in accordance with the manufacturer's instructions.

1.2.3. Enclosed structure and prevention of leaks

Equipment which may release flammable gases or dusts must wherever possible employ enclosed structures only. If equipment contains openings or non-tight joints, these must as far as possible be designed in such a way that developing gases or dusts cannot give rise to explosive atmospheres outside the equipment. Points where materials are introduced or drawn off must, as far as possible, be designed and equipped so as to limit escapes of flammable materials during filling or draining.

1.2.4. Dust deposits

Equipment and protective systems which are intended to be used in areas exposed to dust must be so designed that deposit dust on their surfaces is not ignited. In general, dust deposits must be limited where possible. Equipment and protective systems must be easily cleanable. The surface temperatures of equipment parts must be kept well below the glow temperature of the deposit dust. The thickness of deposit dust must be taken into consideration and, if appropriate, means must be taken to limit the temperature in order to prevent a heat build up.

1.2.5. Additional means of protection

Equipment and protective systems which may be exposed to certain types of external stresses must be equipped, where necessary, with additional means of protection. Equipment must withstand relevant stresses, without adverse effect on explosion protection.

1.2.6. Safe opening

If equipment and protective systems are in a housing or a locked container forming part of the explosion protection itself, it must be possible to open such housing or container only with a special tool or by means of appropriate protection measures.

1.2.7. Protection against other hazards

Equipment and protective systems must be so designed and manufactured as to:

(*a*) avoid physical injury or other harm which might be caused by direct or indirect contact;

(*b*) assure that surface temperatures of accessible parts of radiation which would cause a danger, are not produced;

(*c*) eliminate non-electrical dangers which are revealed by experience;

(*d*) assure that foreseeable conditions of overload shall not give rise to dangerous situations.

Where, for equipment and protective systems, the risks referred to in this paragraph are wholly or partly covered by other Community Directives, these Regulations shall not apply or shall cease to apply in the case of such equipment and protective systems and of such risks upon application of those specific Directives or these Regulations where appropriate.

1.2.8. Overloading of equipment

Dangerous overloading of equipment must be prevented at the design stage by means of integrated measurement, regulation and control devices, such as over-current cut-off switches, temperature limiters, differential pressure switches, flowmeters, time-lag relays, overspeed monitors and similar types of monitoring devices or both such switches, limiters, flowmeters, relays and monitors.

1.2.9. Flameproof enclosure systems

If parts which can ignite an explosive atmosphere are placed in an enclosure, measures must be taken to ensure that the enclosure withstands the pressure developed during an internal explosion of an explosive mixture and prevents the transmission of the explosion to the explosive atmosphere surrounding the enclosure.

1.3. Potential ignition sources

1.3.1. Hazards arising from different ignition sources

Potential ignition sources such as sparks, flames, electric arcs, high surface temperatures, acoustic energy, optical radiation, electro-magnetic waves and other ignition sources must not occur.

1.3.2. Hazards arising from static electricity

Electrostatic charges capable of resulting in dangerous discharges must be prevented by means of appropriate measures.

1.3.3. Hazards arising from stray electric and leakage currents

Stray electric and leakage currents in conductive equipment parts which could result in, for example, the occurrence of dangerous corrosion, overheating of surfaces or sparks capable of provoking an ignition must be prevented.

1.3.4. Hazards arising from overheating

Overheating caused by friction or impacts occurring, for example, between materials and parts in contact with each other while rotating or through the intrusion of foreign bodies must, as far as possible, be prevented at the design stage.

1.3.5. Hazards arising from pressure compensation operations

Equipment and protective systems must be so designed or fitted with integrated measuring, control and regulation devices that pressure compensations arising from them do not generate shock waves or compressions which may cause ignition.

1.4. Hazards arising from external effects

1.4.1. Equipment and protective systems must be so designed and constructed as to be capable of performing their intended function in full safety, even in changing environmental conditions and in the presence of extraneous voltages, humidity, vibrations, contamination and other external effects, taking into account the limits of the operating conditions established by the manufacturer.

1.4.2. Equipment parts used must be appropriate to the intended mechanical and thermal stresses and capable of withstanding attack by existing or foreseeable aggressive substances.

1.5. Requirements in respect of safety-related devices

1.5.1. Safety devices must function independently of any measurement or control devices required for operation. As far as possible, failure of a safety device must be detected sufficiently rapidly by appropriate technical means to ensure that there is only very little likelihood that dangerous situations will occur. For electrical circuits the fail-safe principle is to be applied in general. Safety-related switching must in general directly actuate the relevant control devices without intermediate software command.

1.5.2. In the event of a safety device failure, equipment and protective systems shall, wherever possible, be secured.

1.5.3. Emergency stop controls of safety devices must, as far as possible, be fitted with restart lockouts. A new start command may take effect on normal operation only after the restart lockouts have been intentionally reset.

1.5.4. Control and display units

Where control and display units are used, they must be designed in accordance with ergonomic principles in order to achieve the highest possible level of operating safety with regard to the risk of explosion.

1.5.5. Requirements in respect of devices with a measuring function for explosion protection

In so far as they relate to equipment used in explosive atmospheres, devices with a measuring function

must be designed and constructed so that they can cope with foreseeable operating requirements and special conditions of use.

1.5.6. Where necessary, it must be possible to check the reading accuracy and serviceability of devices with a measuring function.

1.5.7. The design of devices with a measuring function must incorporate a safety factor which ensures that the alarm threshold lies far enough outside the explosion and ignition limits or either of them of the atmospheres to be registered, taking into account, in particular, the operating conditions of the installation and possible aberrations in the measuring system.

1.5.8. Risks arising from software

In the design of software-controlled equipment, protective systems and safety devices, special account must be taken of the risks arising from faults in the programme.

1.6. Integration of safety requirements relating to the system

1.6.1. Manual override must be possible in order to shut down the equipment and protective systems incorporated within automatic processes which deviate from the intended operating conditions, provided that this does not compromise safety.

1.6.2. When the emergency shutdown system is actuated, accumulated energy must be dispersed as quickly and as safely as possible or isolated so that it no longer constitutes a hazard. This does not apply to electrochemically-stored energy.

1.6.3. Hazards arising from power failure

Where equipment and protective systems can give rise to a spread of additional risks in the event of a power failure, it must be possible to maintain them in a safe state of operation independently of the rest of the installation.

1.6.4. Hazards arising from connections

Equipment and protective systems must be fitted with suitable cable and conduit entries. When equipment and protective systems are intended for use in combination with other equipment and protective systems, the interface must be safe.

1.6.5. Placing of warning devices as parts of equipment

Where equipment or protective systems are fitted with detection or alarm devices for monitoring the occurrence of explosive atmospheres, the necessary instructions must be provided to enable them to be provided at the appropriate places.

2. Supplementary requirements in respect of equipment

2.0. Requirements applicable to equipment in category M of equipment-group I.

2.0.1. Requirements applicable to equipment in category M 1 of equipment-group I.

2.0.1.1. Equipment must be so designed and constructed that sources of ignition do not become active, even in the event of rare incidents relating to equipment.

Equipment must be equipped with means of protection such that:

— either, in the event of failure of one means of protection, at least an independent second means provides the requisite level of protection,

— or, the requisite level of protection is ensured in the event of two faults occurring independently of each other.

Where necessary, this equipment must be equipped with additional special means of protection. It must remain functional with an explosive atmosphere present.

2.0.1.2. Where necessary, equipment must be so constructed that no dust can penetrate it.

2.0.1.3. The surface temperatures of equipment parts must be kept clearly below the ignition temperature of the foreseeable air/dust mixtures in order to prevent the ignition of suspended dust.

2.0.1.4. Equipment must be so designed that the opening of equipment parts which may be sources of ignition is possible only under non-active or intrinsically safe conditions. Where it is not possible to render equipment non-active, the manufacturer must affix a warning label to the opening part of the equipment. If necessary, equipment must be fitted with appropriate additional interlocking systems.

2.0.2. Requirements applicable to equipment in category M 2 of equipment-group I.

2.0.2.1. Equipment must be equipped with means of protection ensuring that sources of ignition do not become active during normal operation, even under more severe operating conditions, in particular those arising from rough handling and changing environmental conditions. The equipment is intended to be de-energised in the event of an explosive atmosphere.

2.0.2.2. Equipment must be so designed that the opening of equipment parts which may be sources of ignition is possible only under non-active conditions or via appropriate interlocking systems. Where it is not possible to render equipment non-active, the manufacturer must affix a warning label to the opening part of the equipment.

2.0.2.3. The requirements regarding explosion hazards arising from dust applicable to category M 1 must be applied.

2.1. Requirements applicable to equipment in category 1 of equipment-group II.

2.1.1. Explosive atmospheres caused by gases, vapours or hazes.

2.1.1.1. Equipment must be so designed and constructed that sources of ignition do not become active, even in event of rare incidents relating to equipment. It must be equipped with means of protection such that:

— either, in the event of failure of one means of protection, at least an independent second means provides the requisite level of protection,

— or, the requisite level of protection is ensured in the event of two faults occurring independently of each other.

2.1.1.2. For equipment with surfaces which may heat up, measures must be taken to ensure that the stated maximum surface temperatures are not exceeded even in the most unfavourable circumstances.

Temperature rises caused by heat build-ups and chemical reactions must also be taken into account.

2.1.1.3. Equipment must be so designed that the opening of equipment parts which might be sources of ignition is possible only under non-active or intrinsically safe conditions. Where it is not possible to render equipment non-active, the manufacturer must affix a warning label to the opening part of the equipment. If necessary, equipment must be fitted with appropriate additional interlocking systems.

2.1.2. Explosive atmospheres caused by air/dust mixtures.

2.1.2.1. Equipment must be so designed and constructed that ignition of air/dust mixtures does not occur even in the event of rate incidents relating to equipment. It must be equipped with means of protection such that

— either, in the event of failure of one means of protection, at least an independent second means provides the requisite level of protection,

— or, the requisite level of protection is ensured in the event of two faults occurring independently of each other.

2.1.2.2. Where necessary, equipment must be so designed that dust can enter or escape from the equipment only at specifically designated points. This requirement must also be met by cable entries and connecting pieces.

2.1.2.3. The surface temperatures of equipment parts must be kept well below the ignition temperature of the foreseeable air/dust mixtures in order to prevent the ignition of suspended dust.

2.1.2.4. With regard to the safe opening of equipment parts, requirement 2.1.1.3 applies.

2.2. Requirements for category 2 of equipment-group II.

2.2.1. Explosive atmospheres caused by gases, vapours or mists.

2.2.1.1. Equipment must be so designed and constructed as to prevent ignition sources arising, even in the event of frequently occurring disturbances or equipment operating faults, which normally have to be taken into account.

2.2.1.2. Equipment parts must be so designed and constructed that their stated surface temperatures are not exceeded, even in the case of risks arising from abnormal situations anticipated by the manufacturer.

2.2.1.3. Equipment must be so designed that the opening of equipment parts which might be sources of ignition is possible only under non-active conditions or via appropriate interlocking systems. Where it is not possible to render equipment non-active, the manufacturer must affix a warning label to the opening part of the equipment.

2.2.2. Explosive atmospheres caused by air/dust mixtures.

2.2.2.1. Equipment must be designed and constructed so that ignition of air/dust mixtures is prevented, even in the event of frequently occurring disturbances or equipment operating faults which normally have to be taken into account.

2.2.2.2. With regard to surface temperatures, requirement 2.1.2.3 applies.

2.2.2.3. With regard to protection against dust, requirement 2.1.2.2 applies.

2.2.2.4. With regard to the safe opening of equipment parts, requirement 2.2.1.3 applies.

2.3. Requirements applicable to equipment in category 3 of equipment-group II.

2.3.1. Explosive atmospheres caused by gases, vapours or mists.

2.3.1.1. Equipment must be so designed and constructed as to prevent foreseeable ignition sources which can occur during normal operation.

2.3.1.2. Surface temperatures must not exceed the stated maximum surface temperatures under intended operating conditions. Higher temperatures in exceptional circumstances may be allowed only if the manufacturer adopts special additional protective measures.

2.3.2. Explosive atmospheres caused by air/dust mixtures.

2.3.2.1. Equipment must be so designed and constructed that air/dust mixtures cannot be ignited by foreseeable ignition sources likely to exist during normal operation.

2.3.2.2. With regard to surface temperatures, requirement 2.1.2.3 applies.

2.3.2.3. Equipment, including cable entries and connecting pieces, must be so constructed that, taking into account the size of its particles, dust can neither develop explosive mixtures with air nor form dangerous accumulation inside the equipment.

3. Supplementary requirements in respect of protective systems

3.0. General requirements.

3.0.1. Protective systems must be dimensioned in such a way as to reduce the effects of an explosion to a sufficient level of safety.

3.0.2. Protective systems must be designed and capable of being positional in such a way that explosions are prevented from spreading through dangerous chain reactions or flashover and incipient explosions do not become detonations.

3.0.3. In the event of a power failure, protective systems must retain their capacity to function for a period sufficient to avoid a dangerous situation.

3.0.4. Protective systems must not fail due to outside interference.

3.1. Planning and design.

3.1.1. Characteristics of materials

With regard to the characteristics of materials, the maximum pressure and temperature to be taken into consideration at the planning stage are the expected pressure during an explosion occurring under extreme operating conditions and the anticipated heating effect of the flame.

3.1.2. Protective systems designed to resist or contain explosions must be capable of withstanding the shock wave produced without losing system integrity.

3.1.3. Accessories connected to protective systems must be capable of withstanding the expected maximum explosion pressure without losing their capacity to function.

3.1.4. The reactions caused by pressure in peripheral equipment and connected pipe-work must be taken into consideration in the planning and design of protective systems.

3.1.5. Pressure relief systems.

If it is likely that stresses on protective systems will exceed their structural strength, provision must be made in the design for suitable pressure-relief devices which do not endanger persons in the vicinity.

3.1.6. Explosion suppression systems.

Explosion suppression systems must be so planned and designed that they react to an incipient explosion at the earliest possible stage in the event of an incident and counteract it to best effect, with due regard to the maximum rate of pressure increase and the maximum explosion pressure.

3.1.7. Explosion decoupling systems.

Decoupling systems intended to disconnect specific equipment as swiftly as possibly in the event of incipient explosions by means of appropriate devices must be planned and designed so as to remain proof against the transmission of internal ignition and to retain their mechanical strength under operating conditions.

3.1.8. Protective systems must be capable of being integrated into a circuit with a suitable alarm threshold so that, if necessary, there is cessation of product feed and output and shutdown of equipment parts which can no longer function safely.

4. Minimum criteria to be taken into account by Member States for the notification of bodies

1. The body, its director and the staff responsible for carrying out the verification tests shall not be the designer, manufacturer, supplier or installer of equipment, protective systems, or devices which they inspect, nor the authorised representative of any of these parties. They shall become involved neither directly nor as authorised representatives in the design, construction, marketing or maintenance of the equipment, protective systems or devices in question. This does not preclude the possibility of exchanges of technical information between the manufacturer and the body.

2. The body and its inspection staff shall carry out the verification tests with the highest degree of professional integrity and technical competence and shall be free from all pressures and inducements, particularly financial, which may influence their judgement or the results of the inspection, especially from persons or groups of persons with an interest in the result of verifications.

3. The body shall have at its disposal the necessary staff and possess the necessary facilities to enable it to perform properly the administrative and technical tasks connected with verification; it shall also have access to the equipment required for special verification.

4. The staff responsible for inspection shall have:

— sound technical and professional training,

— satisfactory knowledge of the requirements of the tests which they carry out and adequate experience of such tests;

— the ability to draw up the certificates, records and reports required to authenticate the performance of the tests.

5. The impartiality of inspection staff shall be guaranteed. Their remuneration shall not depend on the number of tests carried out or on the results of such tests.

6. The body shall take out liability insurance unless its liability is assumed by the State in accordance with national law or the Member State itelf is directly responsible for the tests.

7. The staff of the body shall be bound to observe professional secrecy with regard to all information gained in carrying out its tasks (except vis-à-vis the competent administrative authorities of the State in which its activities are carried out) under these Regulations or any provision of national law giving effect to it.

THIRD SCHEDULE

Regulation 7

Module EC-Type Examination

1. This module describes that part of the procedure by which a notified body ascertains and attests that a specimen representative of the production envisaged meets the relevant applicable provisions of these Regulations.

2. The application for the EC-type examination shall be lodged by the manufacturer or his authorised representative established within the Community with a notified body of his choice.

The application shall include:

— the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address in addition;

— a written declaration that the same application has not been lodged with any other notified body;

— the technical documentation, as described in paragraph 3.

The applicant shall place at the disposal of the notified body a specimen representative of the production envisaged and hereinafter called `type'. The notified body may request further specimens if needed for carrying out the test programme.

3. The technical documentation shall enable the conformity of the product with the requirements of these Regulations to be assessed. It shall, to the extent necessary for such assessment, cover the design, manufacture and operation of the product and shall to that extent contain:

— a general type-description;

— design and manufacturing drawings and layouts of components, sub-assemblies, circuits, etc.;

— descriptions and explanations necessary for the understanding of said drawings and layouts and the operation of the product;

— a list of the standards referred to in these Regulations, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of these Regulations where the standards referred to have not been applied;

— results of design calculations made, examinations carried out, etc.;

— test reports.

4. The notified body shall:

4.1. examine the technical documentation, verify that the type has been manufactured in conformity with the technical documentation and identify the elements which have been designed in accordance with the relevant provisions of the standards referred to in Regulation 5(2), 6 and 8, as well as the components which have been designed without applying the relevant provisions of those standards;

4.2. perform or have performed the appropriate examinations and necessary tests to check whether the solutions adopted by the manufacturer meet the essential requirements of these Regulations where the standards referred to have not been applied;

4.3 perform or have performed the appropriate examinations and necessary tests to check whether these have actually been applied, where the manufacturer has chosen to apply the relevant standards;

4.4 agree with the applicant the location where the examinations and necessary tests shall be carried out.

5. Where the type meets the provisions of these Regulations, the notified body shall issue an EC-type-examination certificate to the applicant. The certificate shall contain the name and address of the manufacturer, conclusions of the examination and the necessary data for identification of the approved type. A list of the relevant parts of the technical documentation shall be annexed to the certificate and a copy kept by the notified body. If the manufacturer or his authorised representative established in the Community is denied a type certification, the notified body shall provide detailed reasons for such denial. Provision shall be made for an appeals procedure.

6. The applicant shall inform the notified body which holds the technical documentation concerning the EC-type-examination certificate of all modifications to the approved equipment or protective system which must receive further approval where such changes may effect conformity with the essential requirements or with the prescribed conditions for use of the product. This further approval is given in the form of an addition to the original EC-type-examination certificate.

7. Each notified body shall communicate to the other notified bodies the relevant information concerning the EC-type-examination certificates and additions issued and withdrawn.

8. The other notified bodies may receive copies of the EC-type-examination certificates and their additions or both. The annexes to the certificates shall be kept at the disposal of the other notified bodies.

9. The manufacturer or his authorised representative established in the Community shall keep with the technical documentation copies of EC-type-examination certificates and their additions for a period ending at least 10 years after the last equipment or protective system was manufactured. Where neither the manufacturer nor his authorised representative is established within the Community, the obligation to keep the technical documentation available shall be the responsibility of the person who places the product on the Community market.

FOURTH SCHEDULE

Regulation 7

Module: Production Quality Assurance

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of paragraph 2 ensures and declares that the products concerned are in conformity with the type as described in the EC-type-examination certificate and satisfy the requirements of these Regulations which apply to them. The manufacturer, or his authorised representative established in the Community, shall affix the CE marking to each piece of equipment and draw up a written declaration of conformity. The CE marking shall be accompanied by the identification number of the notified body responsible for EC monitoring, as specified in paragraph 4.

2. The manufacturer shall operate an approved quality system for production, final equipment inspection and testing as specified in paragraph 3 and shall be subject to monitoring as specified in paragraph 4.

3. Quality system.

3.1 The manufacturer shall lodge an application for assessment of his quality system with a notified body of his choice, for the equipment concerned.

The application shall include:

— all relevant information for the product category envisaged;

— the documentation concerning the quality system;

— technical documentation on the approved type and a copy of the EC-type-examination certificate.

3.2 The quality system shall ensure compliance of the equipment with the type as described in the EC-type-examination certificate and with the requirements of these Regulations which apply to them. All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation must permit a consistent interpretation of quality programmes, plans, manuals and records. It shall contain, in particular, an adequate description of — the quality objectives and the organisational structure, responsibilities and powers of the management with regard to equipment quality;

— the manufacturing, quality control and quality assurance techniques, processes and systematic actions which will be used;

— the examinations and tests which will be carried out before, during and after manufacture and the frequency with which they will be carried out;

— the quality records, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned, etc.;

— the means to monitor the achievement of the required equipment quality and the effective operation of the quality system.

3.3 The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in paragraph 3.2. It shall presume conformity with these requirements in respect of quality systems which implement the relevant harmonised standard. The auditing team shall have at least one member with experience of evaluation in the equipment technology concerned. The evaluation procedure shall include an inspection visit to the manufacturer's premises. The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

3.4 The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to uphold the system so that it remains adequate and efficient. The manufacturer or his authorised representative shall inform the notified body which has approved the quality system of any intended updating of the quality system. The notified body shall evaluate the modifications proposed and decide whether the amended quality system will still satisfy the requirements referred to in paragraph 3.2 or whether a reassessment is required. It shall notify its decision to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

4. Surveillance under the responsibility of the notified body

4.1 The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2 The manufacturer shall, for inspection purposes, allow the notified body access to the manufacture, inspection, testing and storage premises and shall provide it with all necessary information, in particular — the quality system documentation — the quality records, such as inspection reports and text data, calibration data, reports on the qualifications of the personnel concerned, etc.

4.3 The notified body shall periodically carry out audits to ensure that the manufacturer maintains and applies the quality system and shall provide an audit report to the manufacturer.

4.4 Furthermore, the notified body may pay unexpected visits to the manufacturer. During such visits, the notified body may carry out tests, or arrange for tests to be carried out, to check that the quality system is functioning correctly, if necessary. The notified body shall provide the manufacturer with a visit report and, if a test has taken place with a test report.

5. The manufacturer shall, for a period ending at least 10 years after the last piece of equipment was manufactured, keep at the disposal of the national authorities:

— the documentation referred to in the second of paragraph 3.1;

— the updating referred to in the second subparagraph of paragraph 3.4;

— the decisions and reports from the notified body which are referred to in paragraph 3.4, last subparagrph, paragraph 4.3 and paragraph 4.4.

6. Each notified body shall apprise the other notified bodies of the relevant information concerning the quality system approvals issued and withdrawn.

FIFTH SCHEDULE

Regulation 7

Module: Product Verification

1. This module describes the procedure whereby a manufacturer or his authorised representative established within the Community checks and attests that the equipment subject to the provisions of paragraph 3 are in conformity with the type as described in the EC-type-examination certificate and satisfy the relevant requirements of these Regulations.

2. The manufacturer shall take all measures necessary to ensure that the manufacturing process guarantees conformity of the equipment with the type as described in the EC-type-examination certificate and with the requirements of these Regulations which apply to them. The manufacturer or his authorised representative established in the Community shall affix the CE marking to each piece of equipment and shall draw up a declaration of conformity.

3. The notified body shall carry out the appropriate examinations and tests in order to check the conformity of the equipment, protective system or device, with the relevant requirements of these Regulations, by examining and testing every product as specified in paragraph 4.

The manufacturer or his authorised representative shall keep a copy of the declaration of conformity for a period ending at least 10 years after the last piece of equipment was manufactured.

4. Verification by examination and testing of each piece of equipment.

4.1 All equipment shall be individually examined and appropriate tests as set out in the relevant standard referred to in these Regulations or equipment tests shall be carried out in order to verify their conformity with the type as described in the EC-type-examination certificate and the relevant requirements of these Regulations.

4.2 The notified body shall affix or have affixed its identification number to each approved item of equipment and shall draw up a written certificate of conformity relating to the the tests carried out.

4.3 The manufacturer or his authorised representative shall ensure that he is able to supply the notified body's certificates of conformity on request.

SIXTH SCHEDULE

Regulation 7

Module: Conformity to Type

1. This module describes that part of the procedure whereby the manufacturer or his authorised representative established within the Community ensures and declares that the equipment in question is in conformity with the type as described in the EC-type-examination certificate and satisfy the requirements of these Regulations applicable to them. The manufacturer or his authorised representative established within the Community shall affix the CE marking to each piece of equipment and draw up a written declaration of conformity.

2. The manufacturer shall take all measures necessary to ensure that the manufacturing process assures compliance of the manufactured equipment or protective systems with the type as described in the EC-type-examination certificate and with the relevant requirements of these Regulations.

3. The manufacturer or his authorised representative shall keep a copy of the declaration of conformity for a period ending at least 10 years after the last piece of equipment was manufactured. Where neither the manufacturer nor his authorised representative is established within the Community, the obligation to keep the technical documentation available shall be the responsibility of the person who places the equipment or protective system on the Community market.

For each piece of equipment manufactured, tests relating to the anti-explosive protection aspects of the product shall be carried out by the manufacturer or on his behalf. The tests shall be carried out under the responsibility of a notified body, chosen by the manufacturer. On the responsibility of the notified body, the manufacturer shall affix the forger's identification number during the manufacturing process.

SEVENTH SCHEDULE

Regulation 7

Module: Product Quality Assurance

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of paragraph 2 ensures and declares that the equipment is in conformity with the type as described in the EC-type-examination certificate. The manufacturer or his authorised representative established within the Community shall affix the CE marking to each product and draw up a written declaration of conformity. The CE marking shall be accompanied by the identification number of the notified body responsible for surveillance as specified in paragraph 4.

2. The manufacturer shall operate an approved quality system for the final inspection and testing of equipment as specified in paragraph 3 below and shall be subject to surveillance as specified in paragraph 4 below.

3. Quality system.

3.1. The manufacturer shall lodge an application for assessment of his quality system for the equipment and protective systems, with a notified body of his choice.

The application shall include:

— all relevant information for the product category envisaged;

— documentation on the quality system;

— technical documentation on the approved type and a copy of the EC-type-examination certificate.

3.2. Under the quality system, each piece of equipment shall be examined and appropriate tests as set out in the relevant standard referred to in these Regulations or equivalent tests shall be carried out in order to ensure its conformity with the relevant requirements of these Regulations.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instruments. This quality system documentation must permit a consistent intepretation of the quality programmes, plans, manuals and records.

It shall contain, in particular, an adequate description of:

— the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;

— the examinations and tests which will be carried out after manufacture;

— the means to monitor the effective operation of the quality system;

— quality records, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned, etc.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in paragraph 3.2. It shall presume conformity with these requirements in respect of quality systems which implement the relevant harmonised standard.

The auditing team shall have at least one member experienced as an assessor in the product technology concerned. The assessment procedure shall include an assessment visit to the manufacturer's premises.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

3.4. The manufacturer shall undertake to discharge the obligations arising from the quality system as approved and to maintain it in an appropriate and efficient manner.

The manufacturer or his authorised representative shall inform the notified body which has approved the quality system of any intended updating of the quality system.

The notified body shall evaluate the modifications proposed and decide whether the modified quality system will still satisfy the requirements referred to in paragraph 3.2 or whether a reassessment is required.

It shall notify its decision to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

4. Surveillance under the responsibility of the notified body.

4.1. The purpose of surveillance is to ensure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2. The manufacturer shall for inspection purposes allow the notified body access to the inspection, testing and storage premises and shall provide it with all necessary information, in particular:

— quality system documentation;

— technical documentation;

— quality records, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned, etc.

4.3. The notified body shall periodically carry out audits to ensure that the manufacturer maintains and applies the quality system and shall provide an audit report to the manufacturer.

4.4. Furthermore, the notified body may pay unexpected visits to the manufacturer. At the time of such visits, the notified body may carry out tests or arrange for tests to be carried out in order to check the proper functioning of the quality system, where necessary; it shall provide the manufacturer with a visit report and, if a test has been carried out, with a test report.

5. The manufacturer shall, for a period ending at least 10 years after the last piece of equipment was manufactured, keep at the disposal of the national authorities:

— the documentation referred to in the third indent of paragraph 3.1;

— the updating referred to in the second paragraph of paragraph 3.4;

— the decisions and reports from the notified body which are referred to in paragraph 3.4, last subparagraph, paragraph 4.3 and paragraph 4.4.

6. Each notified body shall forward to the other notified bodies the relevant information concerning the quality system approvals issued and withdrawn.

EIGHTH SCHEDULE

Regulation 7

Module: Internal Control of Production

1. This module describes the procedure whereby the manufacturer or his authorised representative established within the Community, who carries out the obligations laid down in paragraph 2, ensures and declares that the equipment satisfy the requirements of these Regulations applicable to it. The manufacturer or his authorised representative established within the Community shall affix the CE marking to each piece of equipment and draw up a written declaration of conformity.

2. The manufacturer shall establish the technical documentation described in paragraph 3 and he or his authorised representative established within the Community shall keep it at the disposal of the relevant national authorities for inspection purposes for a period ending at least 10 years after the last piece of equipment was manufactured.

Where neither the manufacturer nor his authorised representative is established within the Community, the obligation to keep the technical documentation available shall be the responsibility of the person who places the equipment on the Community market.

3. Technical documentation shall enable the conformity of the equipment with the relevant requirements of these Regulations to be assessed. It shall, to the extent necessary for such assessment, cover the design, manufacture and operation of the product. It shall contain:

— a general description of the equipment;

— conceptual design and manufacturing drawings and schemes of components, sub-ssemblies, circuits, etc.;

— descriptions and explanations necessary for the understanding of said drawings and schemes and the operation

of the equipment;

— a list of the standards applied in full or in part, and descriptions of the solutions adopted to meet the safety aspects of these Regulations where the standards have not been applied;

— results of design calculations made, examinations carried out, etc.;

— test reports.

4. The manufacturer or his authorised representative shall keep a copy of the declaration of conformity with the technical documentation.

5. The manufacturer shall take all measures necessary to ensure that the manufacturing process guarantees compliance of the manufactured equipment with the technical documentation referred to in paragraph 2 and with the requirements of these Regulations applicable to such equipment.

NINTH SCHEDULE

Regulation 7

Module: Unit Verification

1. This module describes the procedure whereby the manufacturer ensures and declares that the equipment or protective system which has been issued with the certificate referred to in paragraph 2 conforms to the requirements of these Regulations which are applicable to it. The manufacturer or his authorised representative in the Community shall affix the CE marking to the equipment or protective system and draw up a declaration of conformity.

2. The notified body shall examine the individual equipment or protective system and carry out the appropriate tests as set out in the relevant standard referred to in these Regulations, or equivalent tests, to ensure its conformity with the relevant requirements.

The notified body shall affix, or cause to be affixed, its identification number on the approved equipment or protective system and shall draw up a certificate of conformity concerning the tests carried out.

3. The aim of the technical documentation is to enable conformity with the requirements of these Regulations to be assessed and the design, manufacture and operation of the equipment or protective system to be understood.

The documentation shall contain:

— a general description of the product;

— conceptual design and manufacturing drawings and layouts of components, sub-assemblies, circuits, etc.;

— descriptions and explanations necessary for the understanding of said drawings and layouts and the operation of the equipment or protective system;

— a list of the standards referred to in these Regulations, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of these Regulations where the standards referred to have not been applied;

— results of design calculations made, examinations carried out, etc.;

— test reports.

GIVEN under my Official Seal, this 30th day of March, 1999.

MARY HARNEY,

Minister for Enterprise, Trade and Employment.

EXPLANATORY NOTE.

(This note is not part of the Instrument and does not purport to be a legal interpretation.)

These Regulations implement Council Directive 94/9/EC on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres. They apply to equipment, protective systems, devices and components intended for use in potentially explosive atmospheres and going on the market for the first time after the 1st March 1996. The Regulations require compliance with the essential health and safety requirents (Schedule 2) and the affixing of the CE marking. The CE marking can only be affixed if the equipment has undergone the appropriate conformity assessment procedure (Regulation 7) and in respect of which an EC declaration of Conformity has been drawn up.

The aim of the Directive is to remove barriers to trade in the area of equipment and protective systems which are intended for use in potentially explosive atmospheres.

There is a transitional period up to the 30th June 2003 whereby the Regulations do not apply to equipment or a protective system which complies with the health and safety provisions, in respect of it, which were in force in Ireland on 23rd of March 1994. Also, electrical equipment which complies with Directives 76/117/EEC and 79/196/EEC may continue to be marketed until the 30th June 2003.

[1] OJ No. L100, 19.4.94. p.1.