

Health and Safety Executive  
for Northern Ireland

Proposals for New Equipment and  
Protective Systems Intended for Use in  
Potentially Explosive Atmospheres  
Regulations (Northern Ireland) 2016 to  
Implement Directive 2014/34/ EU (the  
ATEX Directive)

Consultative Document

March 2016

**Proposals for New Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations (Northern Ireland) 2016 to Implement Directive 2014/34/ EU (the ATEX Directive)**

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This Consultative Document follows closely the Consultative Document “*Alignment of Nine EU Single Market Directives with the New Legislative Framework: Consultation on UK Implementation*” issued by the Department for Business

Innovation & Skills and the Health and Safety Executive in Great Britain, whose assistance is gratefully acknowledged.

**If you would prefer a printed version, it can be obtained on request. Furthermore, if you require a more accessible format, executive summaries are available in Braille or large print, on disc or audio-cassette, or in Irish, Ulster Scots and other languages of the minority ethnic communities in Northern Ireland. To obtain a summary in one of these formats, please contact Robert Greer at the address shown at paragraph 43.**

# PROPOSALS FOR NEW EQUIPMENT AND PROTECTIVE SYSTEMS INTENDED FOR USE IN POTENTIALLY EXPLOSIVE ATMOSPHERES REGULATIONS (NORTHERN IRELAND) 2016 TO IMPLEMENT DIRECTIVE 2014/34/ EU (THE ATEX DIRECTIVE)

## INTRODUCTION

1. This consultative document (CD) seeks views on proposals by the Health and Safety Executive for Northern Ireland (HSENI) to introduce new Regulations entitled “The Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations (Northern Ireland) 2016”. The Regulations will implement, in Northern Ireland, Council Directive 2014/34/EU (the ATEX Directive)<sup>1</sup> relating to equipment and protective systems intended for use in potentially explosive atmospheres. A copy of the proposed Regulations is shown at **Annex A**.

## BACKGROUND TO THE PROPOSALS

### **New Legislative Framework**

2. In 2006, the European Commission conducted a review into the functioning of the internal market for goods. It concluded that the EU harmonised legislation was not as effective as it should be. In particular three main deficiencies were highlighted:
  - the high number of products that were on the EU market that did not comply with product safety legislation;
  - the unsatisfactory performance of some conformity assessment bodies; and
  - the difficulties that many stakeholders faced in understanding and using the EU legislation.
3. By way of response the New Legislative Framework (NLF) was created. It was adopted as an EU Regulation and an EU Decision in July 2008. The core principles of the NLF are that:
  - legislation governing products should be clear and more consistent across sectors;
  - the obligations of all economic operators in the supply chain should be set out in more detail;
  - provision should be made to ensure that products are more traceable;

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<sup>1</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014L0034&from=EN>

- those bodies which carry out conformity assessments should have certain attributes (e.g. independence and capability) and certain operational obligations; and
  - each Member State should have robust, but proportionate, market surveillance and enforcement mechanisms in place based on a set of common requirements at EU level.
4. In order to bring existing product harmonisation legislation into line with the Decision, an “Alignment Package” was introduced to align nine European Directives (which would not otherwise have been revised in the near future) to the NLF. The Alignment Package was fully published in March 2014. Other EU product legislation will also be aligned to the NLF when it undergoes formal review.
  5. The NLF Directives revoke and replace existing Directives and impose new obligations on manufacturers, importers and distributors. They also make detailed provisions concerning the bodies which are entitled to carry out conformity assessments and the market surveillance regime.
  6. The UK has an obligation under EU law to implement the Directives. More information can be found in the consultation document issued by the Department for Business, Innovation & Skills (BIS) and the Health and Safety Executive (HSE)<sup>2</sup>.
  7. Of the nine Directives, five are of interest to HSENI. However, current legislation relating to four of the five is made on a UK-wide basis, and it is proposed that new implementing Regulations will also be made on that basis.

### **The ATEX Directive**

8. In the case of the ATEX Directive the current Regulations have been made separately by Great Britain and Northern Ireland (i.e. the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 1996 (“GB 1996 Regulations”)<sup>3</sup> and the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations (Northern Ireland) 1996 (“NI 1996 Regulations”)<sup>4</sup>. It is therefore proposed that the new Regulations will also be made separately to replace the respective GB and NI 1996 Regulations.

### **THE PROPOSALS**

9. The current ATEX Directive (94/9/EC) will be revoked and replaced by the new ATEX Directive (2014/34/EU). Although this will mean some changes, many things will remain the same.

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<sup>2</sup> <https://www.gov.uk/government/consultations/eu-single-market-directives-alignment-with-new-legislation>

<sup>3</sup> <http://www.legislation.gov.uk/ukxi/1996/192/contents/made>

<sup>4</sup> <http://www.legislation.gov.uk/nisr/1996/247/contents/made>

10. This consultation document highlights the key respects in which the law in relation to ATEX in Northern Ireland will change or, where the provisions below already exist, be reaffirmed.

## **What will the changes mean for stakeholders?**

### ***Obligations of manufacturers***

11. Manufacturers will need to provide instructions and safety information with a product in a language which is easily understood by consumers and end-users.
12. They will also need to ensure that products bear the CE marking (which demonstrates conformity with the essential requirements of the Directive) and that they are accompanied by the required documents.
13. Manufacturers will also need to ensure that the name and address of the manufacturer is indicated on the product or its packaging.
14. They should also carry out sample testing on products which they have supplied, when this is appropriate in the light of the risks presented by a product to the health and safety of consumers. If necessary, they must also keep a register of complaints, non-conforming products and product recalls and keep distributors informed about such monitoring.

### ***Obligations of Importers***

15. Importers will need to keep a copy of the EU declaration of conformity and ensure that the technical documentation can be obtained when it is requested by authorities.
16. They will be obliged to check that the manufacturer outside the EU has applied the correct conformity assessment procedure.
17. In addition, they should check that products bear the CE marking and are accompanied by the required documents.
18. Furthermore importers should ensure that the name and address of both the manufacturer and importer is indicated on the products or the packaging.
19. They should also carry out sample testing and product monitoring as it applies to manufacturers.

### ***Obligations of all Economic Operators (EOs): Manufacturers, Importers and Distributors***

20. Introduction of traceability requirements: to ensure traceability of products throughout the whole distribution chain, manufacturers and importers must put their contact details on the product or, where this is not possible, on the packaging or an accompanying document.

21. Furthermore every economic operator must be able to inform the authorities of the economic operator from whom he purchased a product and to whom he supplied it.
22. Reorganisation/streamlining of safeguard clause procedure (i.e. the procedure followed when a product is non-compliant and poses a risk): the new procedure ensures that the relevant enforcement authorities are informed about products which pose a risk and that similar action is taken against that product in all Member States.
23. What has changed: EOs are already required to retain some information however the requirement will be broadened. In some cases the products concerned will have a life span of less than 10 years.
24. Manufacturers and importers are already obliged to include identifying information on products but the amount required will increase.
25. In relation to post marketing obligations (sample testing, keeping a register of complaints etc.) some bodies already have these systems in place. However those who do not will need to establish them.

### ***Conformity Assessment and Notified Bodies***

26. Conformity assessment: The technical complexity of industry and business means that it is becoming increasingly important to be able to demonstrate that what is being supplied actually meets the requirements specified or claimed. Such a demonstration is called “conformity assessment” and put simply means a demonstration that specified requirements relating to a product, process, system, person or body are fulfilled. A “conformity assessment body” is a body that performs conformity assessment activities, including calibration, testing, certification and inspection.
27. Notified Bodies: Some conformity assessment procedures require the involvement of third party conformity assessment bodies. These third party bodies, once assessed for their competence and appointed by a Member State, are then notified to the European Commission and become “Notified Bodies”. Their role is to verify that the designer/manufacturer has produced a safe and compliant product.

### ***Measures intended to ensure the quality of the work performed by Notified Bodies (NBs)***

28. Reinforcement of the notification requirements for NBs: To be authorised to carry out conformity assessment activities under the Directive, NBs must satisfy certain requirements. All NBs must follow the work of notified body coordination groups and apply guidance developed by them. They must have procedures in place for risk-based assessments which take due account of the size of the enterprise and the degree of the complexity of the product

assessed. Subcontractors and subsidiaries, which carry out parts of the conformity assessment, must also fulfil the notification criteria.

29. Revised notification process: Member States notifying an organisation as a NB must include information on the valuation of competence of that body. Other Member States may object to the notification within a certain period. Where competence is demonstrated by an accreditation certificate, a facilitated procedure applies. Where Member States have not used accreditation to evaluate the body's competence, documentary evidence must be provided and the objection period is longer (at 2 months).
30. Requirements for notifying authorities (i.e. the national authorities in charge of the assessment, notification and monitoring of NBs): Specific requirements and obligations for notifying authorities are introduced according to which they must be organised and operated so as to safeguard objectivity, impartiality and competence in carrying out their activity. Notifying authorities must de-notify bodies which no longer meet the notification requirements or fail to fulfil their obligations.
31. Information and other obligations for NBs: NBs must inform notifying authorities about refusals, restrictions, suspensions and withdrawals of certificates and other NBs about negative conformity assessment results. They must perform conformity assessment in a proportionate manner taking due account of the size of an enterprise, the structure of a sector, the complexity of the product technology etc.
32. What has changed: NBs are already required to exchange information, however the obligation has been widened and so exchanges will need to be more frequent.

### ***Measures intended to ensure more consistency between the NLF Directives***

33. Alignment of commonly used definitions and terminology: Definitions of common terms like "manufacturer", "importer", "placing on the market" are introduced into the Directive concerned and replicated in the new Regulations. Existing conflicting definitions are removed.
34. Alignment of the texts and certain elements of the conformity assessment procedures: The existing text of the modules in the Directives is aligned with the standard modules set out in Annex II to the NLF Decision.

### **Offences and Penalties**

35. The proposed changes are largely presentational and their impact will extend or clarify the scope of current offences rather than creating completely new offences from scratch.
36. It should be noted that in 2008 the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres (Amendment)



Regulations (Northern Ireland) 2008<sup>5</sup> amended the penalty provisions in the NI 1996 Regulations. This had the effect of aligning the penalty provisions with those that already applied in the GB 1996 Regulations and other UK-wide product safety legislation. The proposed Regulations will maintain this position.

## **RELATIONSHIP WITH GREAT BRITAIN**

37. The proposals set out in this CD refer only to ATEX but they do not differ in any significant way from the over arching proposals contained in the GB consultation document on the alignment package which also includes proposals in relation to ATEX (see acknowledgement on page 1). Such differences as do occur relate only to Northern Ireland legislation and institutions and to the omission of references specific to the other Directives which are not relevant to ATEX. As the GB and Northern Ireland proposals, taken together, are intended to implement the ATEX Directive it is essential that the same legal requirements apply throughout the UK.

## **INITIAL IMPACT ASSESSMENT**

38. A copy of the initial impact assessment (IA) prepared for the proposals is set out at **Annex B**. This shows that due to the nature of ATEX, it has not been possible to determine the size of the sector and therefore the overall cost of implementing the proposals in Northern Ireland. However, it is estimated that the overall costs and benefits will be modest given that this is an alignment of existing legislation rather than the introduction of many new requirements; the benefits are harder to quantify than the costs which are in part one-off costs arising from the need to adapt to the new requirements.

39. Comments on the conclusions reached in the IA would be welcome. In particular: -

(a) Do you expect any benefits from the proposed changes? If so, what would they be; what evidence do you have for them; and how great would they be?; and

(b) (i) Do you consider that the proposed Regulations are effective and proportionate? If not, please explain why you think this is the case. (ii) Do the proposed Regulations impose requirements which go beyond the requirements set out in the ATEX Directive and which you consider to be disproportionate or unnecessary? If so, please explain why you think this is the case.

(c) Does the IA (Annex B) adequately reflect the effect of the ATEX Directive?

(d) Do you agree with our estimate of the number of businesses affected? Can you provide additional evidence?

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<sup>5</sup> <http://www.legislation.gov.uk/nisr/2008/422/contents/made>

- (e) Are you able to provide any evidence (quantified or otherwise) of the likely costs of the changes for the main affected groups i.e. manufacturers, importers or distributors? If so, what is this based on?
- (f) If you are able to be more specific, can you give an estimate of the costs to business for (i) Familiarising themselves with the proposed Regulations; (ii) Holding the additional data; (iii) Obtaining new conformity assessment documentation; (iv) Post-marketing obligations?

## **EQUALITY IMPACT**

40. The proposals have been screened for any possible impact on equality of opportunity affecting the groups listed in section 75 of the Northern Ireland Act 1998 and no adverse or differential aspects were identified. The proposed introduction of the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations (Northern Ireland) 2016 will apply equally to all relevant businesses and there is no evidence to suggest that this will impact disproportionately upon any particular group. A copy of the screening document is attached at **Annex C**.

## **HUMAN RIGHTS**

41. The Department of Enterprise, Trade and Investment has considered the matter of Convention rights and is satisfied that there are no matters of concern.

## **INVITATION TO COMMENT**

42. HSENI would welcome your comments on the proposals in this CD. In particular, comment is invited on the assumption relating to costs relevant to Northern Ireland and the conclusion that the proposals would have no adverse effect on any section 75 groups.

43. Comments, in whatever format you choose to use, should be sent to: -

Robert Greer  
Health and Safety Executive for Northern Ireland  
83 Ladas Drive  
Belfast, BT6 9FR  
Tel: (028) 90 546 817; Fax: (028) 90 235 383;  
Textphone: (028) 90 546 896  
E-mail: robert.greer@hseni.gov.uk

so as to arrive no later than **noon on Monday 16 May 2016**.

44. HSENI tries to make its consultation procedures as thorough and open as possible. Responses to this consultation will be kept at the office of HSENI at the above address after the close of this consultation period, where they can be inspected by members of the public or be copied to them. HSENI can only refuse to disclose information in exceptional circumstances. Before you

submit your response, please read the paragraphs below on the confidentiality of information given by you in response to this consultation.

45. The Freedom of Information Act 2000 gives the public a right of access to any information held by a public authority, namely, HSENI in this case. This right of access to information includes information provided in response to a consultation. HSENI cannot automatically consider as confidential information supplied to it in response to a consultation. However, it does have the responsibility to decide whether any information provided by you in response to this consultation, including information about your identity, should be made public or be treated as confidential. If you do not wish information about your identity to be made public, please include an explanation in your response.
46. This means that information provided by you in response to the consultation is unlikely to be treated as confidential, except in very particular circumstances.

March 2016

Health and Safety Executive for Northern Ireland

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 STATUTORY RULES OF NORTHERN IRELAND
 

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**2016 No. 000**

**HEALTH AND SAFETY**

**The Equipment and Protective Systems Intended for Use in  
Potentially Explosive Atmospheres Regulations (Northern  
Ireland) 2016**

*Made* - - - - *00th xxx 2016*

*Coming into operation* - *00th xxx 2016*

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The Department of Enterprise, Trade and Investment(**a**) makes the following Regulations in exercise of the powers conferred by section 2(2) of, and paragraph 1A(**b**) of Schedule 2 to, the European Communities Act 1972 (“the 1972 Act”)(**c**).

The Department is designated(**d**) for the purposes of section 2(2) of the 1972 Act in relation to measures relating to equipment and protective systems intended for use in potentially explosive atmospheres.

The Regulations make provision for a purpose mentioned in section 2(2) of the 1972 Act and it appears to the Department that it is expedient for certain references to provisions of EU instruments to be construed as references to those provisions as amended from time to time.

## PART 1

### PRELIMINARY

#### Citation and commencement

1. These Regulations may be cited as the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations (Northern Ireland) 2016 and shall come into operation on 00th xxx 2016 (“the commencement date”).

#### Interpretation

2.—(1) In these Regulations—

“the 1978 Order” means the Health and Safety at Work (Northern Ireland) Order 1978(**e**);

“the 1994 Directive” means Directive 94/9/EC of the European Parliament and the Council on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres(**f**);

“the 1996 Regulations” means the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations (Northern Ireland) 1996(**g**);

“accreditation” has the meaning set out in point 10 of Article 2 of RAMS (as amended from time to time);

“accreditation certificate” means a certificate, issued by the United Kingdom Accreditation Service or a national accreditation body in another Member State or Great Britain, attesting that a conformity assessment body meets the notified body requirements;

“ATEX Directive” means Directive 2014/34/EU of the European Parliament and of the Council on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (recast)(**h**);

“attestation of conformity” means a declaration of conformity required to be drawn up in accordance with regulation 7(3) (EU declaration of conformity and CE marking);

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(a) Formerly the Department of Economic Development; *see* S.I. 1999/283 (N.I. 1), Article 3(5); that Department was formerly the Department of Manpower Services, *see* S.I. 1982/846 (N.I. 11), Article 3

(b) Paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006 (c. 51) and amended by Part 1 of the Schedule to the European Union (Amendment) Act 2008 (c. 7)

(c) 1972 c. 68; the enabling powers conferred by section 2(2) were extended by virtue of section 1 of the European Economic Area Act 1993 (c. 51). Section 2(2) was further amended by section 27(1) of the Legislative and Regulatory Reform Act 2006 (c. 51) and by Part 1 of the Schedule to the European Union (Amendment) Act 2008 (c. 7)

(d) S.I. 1995/751

(e) S.I. 1978/1039 (N.I. 9)

(f) O.J. L 100, 19.4.1994, p. 1

(g) S.R. 1996 No. 247, amended by S.R. 1998 No. 77, S.R. 1999 No. 125 and S.R. 2008 No. 422

(h) O.J. L 96, 29.3.2014, p. 309

“authorised representative” means a person established in the EU appointed in accordance with regulation 17(1);

“CE marking” means a marking which takes the form set out in Annex II of RAMS (as amended from time to time);

“competent national authority” means an authority having responsibility for enforcing the law of a Member State which implements the Directive;

“components” means any item essential to the safe functioning of equipment and protective systems but with no autonomous function;

“conformity assessment” means the process demonstrating whether the essential safety requirements relating to a product have been fulfilled;

“conformity assessment body” means a body that performs conformity assessment activities, including calibration, testing, certification and inspection;

“distributor” means any person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market;

“economic operator” means a manufacturer, authorised representative, importer or distributor;

“enforcing authority” means any person enforcing these Regulations under regulation 52 (Enforcement);

“equipment” means machines, apparatus, fixed or mobile devices, control components and instrumentation thereof and detection or prevention systems which, separately or jointly, are intended for the generation, transfer, storage, measurement, control and conversion of energy and/or the processing of material, which are capable of causing an explosion through their own potential sources of ignition;

“equipment-category” means the classification of equipment, within each equipment group specified in Annex I of the ATEX Directive (as amended from time to time), determining the requisite level of protection to be ensured;

“equipment-group I” means equipment intended for use in underground parts of mines, and in those parts of surface installations of such mines, liable to be endangered by firedamp and/or combustible dust, comprising equipment categories M 1 and M 2 as set out in Annex I of the ATEX Directive (as amended from time to time);

“equipment-group II” means equipment intended for use in other places liable to be endangered by explosive atmospheres, comprising categories 1, 2 and 3 as set out in Annex I of the ATEX Directive (as amended from time to time);

“essential safety requirements” means the requirements set out in Schedule 1 (Essential safety requirements);

“EU declaration of conformity” means a declaration of conformity required to be drawn up in accordance with regulation 7(1)(a) (EU declaration of conformity and CE marking);

“European Commission” means the Commission of the European Union;

“the Executive” means the Health and Safety Executive for Northern Ireland;

“explosive atmosphere” means a mixture with air, under which atmospheric conditions of flammable substances in the form of gases, vapours, mists or dusts in which, after ignition has occurred, combustion spreads to the entire unburned mixture;

“harmonised standard” has the meaning given by Article 2(1)(c) of Regulation (EU) 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation<sup>(a)</sup> (as amended from time to time);

“importer” means any person who—

(a) is established within the EU; and

(b) places a product from a third country on the EU market;

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(a) O.J. L 316, 14.11.2012, p.12



“intended use” means the use of a product prescribed by the manufacturer by assigning the equipment to a particular equipment-group and category or by providing all the information which is required for the safe functioning of a protective system, device or component;

“make available on the market” means any supply for distribution, consumption or use on the EU market in the course of a commercial activity, whether in return for payment or free of charge;

“manufacturer” means a person who—

- (a) manufactures a product, or has such a product designed or manufactured; and
- (b) markets that product—
  - (i) under that person’s name or trade mark; or
  - (ii) uses such product for that person’s own purposes;

“market surveillance authority” has the meaning set out in regulation 51 (Designation of market surveillance authority);

“national accreditation body” has the meaning set out in point 11 of Article 2 of RAMS (as amended from time to time);

“notified body requirements” means the requirements set out in Schedule 2 (Notified body requirements);

“place on the market” means the first making available on the EU market;

“potentially explosive atmosphere” means an atmosphere which could become explosive due to local and operational conditions;

“protective systems” means devices other than components of equipment which are intended to halt incipient explosions immediately and/or to limit the effective range of an explosion and which are separately made available on the market for use as autonomous systems;

“RAMS” means Regulation (EC) 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93(a);

“recall” means taking any measure aimed at achieving the return of a product that has already been made available to the end-user;

“relevant conformity assessment procedure” means a conformity assessment procedure referred to in regulation 39 (Conformity assessment procedures);

“relevant economic operator” means, in relation to a product, an economic operator with obligations in respect of that product under Part 2;

“technical documentation” has the meaning given in regulation 6 (Technical documentation and conformity assessment);

“technical specification” means a document that prescribes technical requirements to be fulfilled by a product; and

“withdraw”, when used in relation to a product, means taking any measure aimed at preventing a product in the supply chain from being made available on the market.

(2) In these Regulations, a reference to a product being “in conformity with Part 2” means that—

- (a) the product is in conformity with the essential safety requirements; and
- (b) each relevant economic operator has complied with the obligations imposed on them under Part 2 which shall be satisfied at or before the time at which they make the product available on the market.

(3) In these Regulations (except in Part 4 (Notification of conformity assessment bodies) and Schedules 2 (Notified body requirements) and 3 (Operational obligations of notified bodies)), “notified body” means—

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(a) O.J. L 218, 13.8.2008, p.30

- (a) a notified body within the meaning set out in regulation 42 (Notified bodies); or
  - (b) a notified body under the laws of any other Member State which implement the Directive.
- (4) In regulations 10(1) and 24(1) (Monitoring) and Schedule 1 (Essential safety requirements), “risk” means a risk which could arise from lawful and readily predictable human behaviour.
- (5) In the other provisions of these Regulations, “risk” means a risk—
- (a) which could arise from lawful and readily predictable human behaviour; and
  - (b) which may result in harm to any of the following interests—
    - (i) human health;
    - (ii) domestic animals; or
    - (iii) property.
- (6) In these Regulations, a reference to a Member State shall be read as a reference to an EEA State and references to the EU shall be read as references to the EEA.
- (7) The Interpretation Act (Northern Ireland) 1954<sup>(a)</sup> shall apply to these Regulations as it applies to an Act of the Assembly.

### Scope

- 3.—**(1) Subject to paragraph (3), these Regulations apply to products.
- (2) For the purposes of these Regulations a “product” shall mean—
- (a) equipment and protective systems intended for use in potentially explosive atmospheres;
  - (b) safety devices, controlling devices and regulating devices intended for use outside potentially explosive atmospheres but required for or contributing to the safe functioning of equipment and protective systems with respect to the risks of explosion;
  - (c) components intended to be incorporated into equipment and protective systems referred to in paragraph (a).
- (3) These Regulations do 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 gas;
  - (d) personal protective equipment covered by Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment<sup>(b)</sup>;
  - (e) seagoing vessels and mobile offshore units together with equipment on board such vessels or units;
  - (f) means of transport, i.e. 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. Vehicles intended for use in a potentially explosive atmosphere shall not be excluded from the scope of this Regulation;
  - (g) the equipment covered by Article 346(1)(b) of the Treaty on the Functioning of the European Union<sup>(c)</sup>.

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<sup>(a)</sup> 1954 c. 33 (N.I.), as amended by S.I. 1999/663, Schedule 1 paragraph 9

<sup>(b)</sup> O.J. L 399, 30.12.1989, p. 18

<sup>(c)</sup> O.J. C 326, 26.10.2012, p. 47

**Exceptions for trade fairs, exhibitions and demonstrations**

4. The provisions of Part 2 (and of Part 5, so far as applying in relation to obligations under Part 2) do not apply to the showing of a product at a trade fair exhibition or demonstration, provided that a visible sign clearly indicates—

- (a) the product is not in conformity with Part 2; and
- (b) that the product is not available for sale until brought into conformity with Part 2.

**PART 2****CHAPTER 1****MANUFACTURERS****Design and manufacture in accordance with essential safety requirements**

5. Before placing a product on the market or using a product for their own purposes, a manufacturer shall ensure that it has been designed and manufactured in accordance with the essential safety requirements.

**Technical documentation and conformity assessment**

6. Before placing a product on the market or using it for their own purposes, a manufacturer shall—

- (a) carry out the relevant conformity assessment procedure or have a relevant conformity assessment procedure carried out; and
- (b) draw up the technical documentation referred to—
  - (i) for a product in respect of which the conformity assessment procedure in regulation 39(a) is being carried out, in point 3(c) of Module B of Annex III to the ATEX Directive (as amended from time to time);
  - (ii) for a product in respect of which the conformity assessment procedure in regulation 39(b) is being carried out, in point 3(c) of Module B of Annex III to the ATEX Directive (as amended from time to time);
  - (iii) for a product in respect of which the conformity assessment procedure in regulation 39(c) is being carried out, in point 2 of Module A of Annex VIII to the ATEX Directive (as amended from time to time);
  - (iv) for a product in respect of which the conformity assessment procedure in regulation 39(d) is being carried out, in point 2 of Module G of Annex IX to the ATEX Directive (as amended from time to time);

**EU declaration of conformity and CE marking**

7.—(1) Save for where a product is a component, where the conformity of a product with the essential safety requirements has been demonstrated by a relevant conformity assessment procedure, the manufacturer shall, before placing the product on the market—

- (a) draw up a declaration of conformity in accordance with regulation 40 (EU declaration of conformity); and
- (b) affix the CE marking in accordance with regulation 41 (CE marking).

(2) The manufacturer shall keep the EU declaration of conformity up-to-date.

(3) Where the conformity of a component with the essential safety requirements has been demonstrated by a relevant conformity assessment procedure, the manufacturer shall, before placing the component on the market, draw up a written attestation of conformity in accordance with regulation 39(3) (Conformity assessment procedures).

(4) Subject to paragraph (5), before placing a product on the market, the manufacturer shall ensure that each product is accompanied by a copy of the EU declaration of conformity or attestation of conformity as appropriate.

(5) Where a large batch of products is delivered to a single user, the batch or consignment may be accompanied by a single copy of the EU declaration or attestation of conformity as appropriate.

(6) Where a product is subject to more than one EU instrument requiring a declaration of conformity to be drawn up, the manufacturer shall draw up a single declaration of conformity, which—

- (a) identifies the EU instruments; and
- (b) includes references to the publication of those EU instruments in the Official Journal.

### **Retention of technical documentation and EU declaration of conformity**

**8.** A manufacturer shall keep the technical documentation and the EU declaration of conformity or where applicable, the attestation of conformity drawn up in respect of a product for a period of 10 years beginning on the day on which the product was placed on the market.

### **Compliance procedures for series production**

**9.—(1)** A manufacturer shall ensure, before placing a product on the market, that procedures are in place to ensure that series production remains in conformity with Part 2.

(2) In doing so, the manufacturer shall take adequate account of—

- (a) any change in the product design or characteristics; and
- (b) any change in a harmonised standard or in another technical specification by reference to which the EU declaration of conformity or attestation of conformity was drawn up.

### **Monitoring**

**10.—(1)** When appropriate, with regard to the risks to the health and safety of end-users presented by a product, a manufacturer shall—

- (a) carry out sample testing of a product manufactured by it made available on the market;
- (b) investigate complaints that a product manufactured by it is not in conformity with Part 2; and
- (c) keep distributors informed of any actions carried out under sub-paragraphs (a) and (b).

(2) A manufacturer shall keep a register and shall promptly make entries in that register of any—

- (a) complaints that a product is not in conformity with Part 2;
- (b) products which are found not to be in conformity with Part 2; and
- (c) product recalls.

### **Labelling and packaging of products**

**11.—(1)** Before placing a product on the market, a manufacturer shall ensure that it bears a type, batch or serial number allowing its identification.

(2) If the size or nature of the product does not provide sufficient space for the labelling requirements in paragraph (1), the manufacturer shall ensure that the information is provided on the packaging or in a document accompanying the product.

### Labelling and packaging of products, other than components

12. Save for where a product is a component, before placing a product, on the market a manufacturer shall ensure that it—

- (a) bears the specific marking of explosion protection as referred to at paragraph 5(f) of Schedule 1; and
- (b) where applicable, the other markings and information referred to at paragraph 5 of Schedule 1.

### Information identifying manufacturer

13.—(1) Before placing a product on the market, a manufacturer shall indicate on the product—

- (a) the name, registered trade name or registered trade mark of the manufacturer; and
- (b) a postal address at which the manufacturer can be contacted.

(2) Where it is not possible to indicate the information specified in paragraph (1) on the product, the manufacturer shall indicate that information—

- (a) on the product packaging; or
- (b) in a document accompanying the product.

(3) The information specified in paragraph (1) shall be in a language which can be easily understood by end-users and the competent national authority in the Member State in which it is to be made available to such end-users.

### Instructions and safety information

14.—(1) When placing a product on the market, a manufacturer shall ensure that it is accompanied by instructions and safety information in a language which can be easily understood by end-users in the Member State in which it is to be made available on the market.

(2) The instructions and safety information referred to in paragraph (1) and any labelling shall be clear and understandable.

(3) Where the product is being made available to end-users in the United Kingdom the language which can be easily understood by end-users is English.

### Duty to take action in respect of a product placed on the market which is considered not to be in conformity

15.—(1) A manufacturer who considers, or has reason to believe, that a product which the manufacturer has placed on the market is not in conformity with Part 2 shall immediately take the corrective measures necessary to—

- (a) bring the product into conformity;
- (b) withdraw the product; or
- (c) recall the product.

(2) Where the product presents a risk, the manufacturer shall immediately inform the market surveillance authority, and the competent national authorities of any other Member State in which the manufacturer made the product available on the market, of the risk, giving details of—

- (a) the respect in which the product is considered not to be in conformity with Part 2; and
- (b) any corrective measures taken.

### Provision of information and cooperation

16.—(1) A manufacturer shall, further to a reasoned request from an enforcing authority, and within such period as the enforcing authority may specify, provide the authority with all the

information and documentation necessary to demonstrate that the product is in conformity with Part 2—

- (a) in paper or electronic form; and
- (b) in a language which can be easily understood by the enforcing authority.

(2) A manufacturer shall, at the request of the enforcing authority, cooperate with the authority on any action taken to—

- (a) evaluate a product in accordance with regulation 55 (Evaluation of a product presenting a risk); or
- (b) eliminate the risks posed by a product which the manufacturer has placed on the market.

### **Authorised representatives**

**17.**—(1) A manufacturer may, by written mandate, appoint a person as their authorised representative to perform specified tasks on the manufacturers behalf.

(2) A manufacturer who has appointed an authorised representative to perform, on the manufacturer's behalf, a task under these Regulations remains responsible for the proper performance of that task.

(3) The obligations laid down in regulation 5 (Design and manufacture in accordance with essential safety requirements) or regulation 6(b) (Technical documentation and conformity assessment) shall not form part of an authorised representative's mandate.

(4) The mandate shall allow the authorised representative to do at least the following in relation to a product covered by the mandate—

- (a) perform the manufacturer's obligations under regulation 8 (Retention of technical documentation and EU declaration of conformity); and
- (b) perform the manufacturer's obligations under regulation 16 (Provision of information and cooperation);

(5) An authorised representative shall comply with all duties imposed on the manufacturer in relation to each obligation under these Regulations that the authorised representative is appointed by the mandate to perform and, accordingly—

- (a) as far as those duties are concerned, a reference in these Regulations to the manufacturer (except in this regulation) is to be taken as including a reference to the authorised representative; and
- (b) if the authorised representative contravenes or fails to comply with any of those duties, the authorised representative may be proceeded against as though the authorised representative were the manufacturer.

## **CHAPTER 2**

### **IMPORTERS**

#### **Prohibition on placing on the market products which are not in conformity**

**18.** An importer shall not place a product on the market unless it is in conformity with the essential safety requirements.

#### **Requirements which shall be satisfied before an importer places a product on the market**

**19.**—(1) Before placing a product on the market, an importer shall ensure that—

- (a) a relevant conformity assessment procedure has been carried out by the manufacturer;
- (b) the manufacturer has drawn up the technical documentation;
- (c) the product—
  - (i) bears the CE marking where applicable;

- (ii) is accompanied by the EU declaration of conformity or the attestation of conformity as appropriate;
  - (iii) and is accompanied by the required documents; and
  - (d) the manufacturer has complied with the requirements set out in regulation 11 (Labelling and packaging of products), regulation 12 (Labelling and packaging of products, other than components) and regulation 13 (Information identifying manufacturer).
- (2) In paragraph (1)(c)(iii), “required documents” means any documents that are required to be provided with a product pursuant to—
- (a) regulation 11(2) (Labelling and packaging of products);
  - (b) regulation 13(2) (Information identifying manufacturer); and
  - (c) regulation 14(1) (Instructions and safety information).

**Prohibition on placing on the market products considered not to be in conformity with the essential safety requirements**

**20.**—(1) Where an importer considers, or has reason to believe, that a product is not in conformity with the essential safety requirements, the importer shall not place the product on the market.

(2) Where the product presents a risk, the importer shall inform the manufacturer and the market surveillance authority of that risk.

**Information identifying importer**

**21.**—(1) Before placing a product on the market, an importer shall indicate on the product—

- (a) the name, registered trade name or registered trade mark of the importer; and
- (b) a postal address at which the importer can be contacted.

(2) The information specified in paragraph (1) shall be in a language which can be easily understood by end-users and the competent national authority in the Member State in which it is to be made available to end-users.

(3) Where it is not possible to indicate the information specified in paragraph (1) on the product, the importer shall indicate that information—

- (a) on the packaging; or
- (b) in a document accompanying the product.

**Instructions and safety information**

**22.**—(1) When placing a product on the market, an importer shall ensure that it is accompanied by instructions and safety information in a language which can be easily understood by end-users in the Member State in which the product is to be made available to such end-users.

(2) Where the instructions and safety information are made available to end-users in the United Kingdom the language which can be easily understood by end-users is English.

**Storage and transport**

**23.** Where an importer has responsibility for a product, the importer shall ensure that the conditions under which the product is stored or transported do not jeopardise its conformity with the essential safety requirements.

**Monitoring**

**24.**—(1) When deemed appropriate, with regard to the risks to the health and safety of end-users presented by a product, an importer shall—

- (a) carry out sample testing of a product made available by the importer on the market;
  - (b) investigate complaints that a product made available on the market by the importer is not in conformity with Part 2; and
  - (c) keep distributors informed of actions carried out under sub-paragraphs (a) and (b).
- (2) An importer shall keep a register and shall promptly make entries in that register of any—
- (a) complaints that a product is not in conformity with Part 2;
  - (b) products which are found not to be in conformity with Part 2; and
  - (c) product recalls.
- (3) An importer shall keep an entry made in the register for a period of at least 10 years beginning on the day on which the obligation to make the entry arose.

#### **Duty to take action in respect of a product placed on the market which is considered not to be in conformity**

**25.**—(1) An importer who considers, or has reason to believe, that a product which the importer has placed on the market is not in conformity with Part 2 shall immediately take the corrective measures necessary to—

- (a) bring the product into conformity;
- (b) withdraw the product; or
- (c) recall the product.

(2) Where the product presents a risk, the importer shall immediately inform the market surveillance authority, and the competent national authorities of any Member State in which the importer made the product available on the market, of the risk, giving details of—

- (a) the respect in which the product is considered not to be in conformity with Part 2; and
- (b) any corrective measures taken.

#### **Provision of information and cooperation**

**26.**—(1) An importer shall, further to a reasoned request from an enforcing authority and within such period as the enforcing authority may specify, provide the authority with the information and documentation necessary to demonstrate that the product is in conformity with Part 2—

- (a) in paper or electronic form; and
- (b) in a language which can be easily understood by the enforcing authority.

(2) An importer shall, at the request of the enforcing authority, cooperate with the authority on any action taken to—

- (a) evaluate a product in accordance with regulation 55 (Evaluation of a product presenting a risk);
- (b) eliminate the risks posed by the product which the importer has placed on the market.

#### **Retention of technical documentation and EU declaration of conformity**

**27.** An importer shall for a period of ten years beginning on the day on which the product was placed on the market—

- (a) keep a copy of the EU declaration of conformity (as referred to in regulation 40) or, where applicable, the attestation of conformity at the disposal of enforcing authorities; and
- (b) ensure that the technical documentation can be made available to enforcing authorities, upon request.



CHAPTER 3  
DISTRIBUTORS

**Duty to act with due care**

**28.** When making a product available on the market, a distributor shall act with due care to ensure that it is in conformity with Part 2.

**Requirements which shall be satisfied before a distributor makes a product available on the market**

**29.**—(1) Before making a product available on the market, the distributor shall verify that—

- (a) the product—
  - (i) bears the CE marking where appropriate;
  - (ii) is accompanied by the EU declaration of conformity or the attestation of conformity;
  - (iii) is accompanied by the required documents;
  - (iv) is accompanied by instructions and safety information in a language which can be easily understood by end-users in the Member State in which the product is to be made available on the market;
- (b) the manufacturer has complied with the requirements set out in regulation 11 (Labelling and packaging of products), regulation 12 (Labelling and packaging of products, other than components) and regulation 13 (Information identifying manufacturer); and
- (c) the importer has complied with the requirements set out in regulation 21 (Information identifying importer).

(2) In paragraph (1)(a)(iii), “required documents” means the documents that the manufacturer or importer is required to provide with the product pursuant to—

- (a) regulation 11(2) (Labelling and packaging of products);
- (b) regulation 13(2)(b) (Information identifying manufacturer);
- (c) regulation 21(3)(b) (Information identifying importer).

**Storage and transport**

**30.** Where a distributor has responsibility for a product, the distributor shall ensure that the conditions under which it is stored or transported do not jeopardise its conformity with the essential safety requirements.

**Prohibition on making available on the market where product not considered to be in conformity with safety objectives**

**31.**—(1) Where a distributor considers, or has reason to believe, that a product is not in conformity with the essential safety requirements, the distributor shall not make the product available on the market.

(2) Where the product presents a risk, the distributor shall inform the following persons of the risk—

- (a) the manufacturer or the importer; and
- (b) the market surveillance authority.

**Duty to take action in respect of products made available on the market which are not in conformity**

**32.**—(1) A distributor who considers, or has reason to believe, that a product which the distributor has made available on the market is not in conformity with Part 2 shall make sure that the necessary corrective measures are taken to—

- (a) bring that product into conformity;
- (b) withdraw the product; or
- (c) recall the product.

(2) Where the product presents a risk, the distributor shall immediately inform the market surveillance authority, and the competent national authorities of the other Member States in which the distributor has made the product available on the market, of that risk, giving details of—

- (a) the respect in which the product is considered not to be in conformity with Part 2; and
- (b) any corrective measures taken.

**Provision of information and cooperation**

**33.**—(1) A distributor shall, further to a reasoned request from an enforcing authority and within such period as the authority may specify, provide the authority with the information and documentation, in paper or electronic form, necessary to demonstrate that the product is in conformity with Part 2.

(2) A distributor shall, at the request of the enforcing authority, cooperate with the authority on any action taken to—

- (a) evaluate the product in accordance with regulation 55 (Evaluation of a product presenting a risk);
- (b) eliminate the risks posed by the product which the distributor has made available on the market.

## CHAPTER 4

## IMPORTERS AND DISTRIBUTORS

**Cases in which obligations of manufacturers apply to importers and distributors**

**34.** An economic operator (“A”) who would, but for this regulation, be considered an importer or distributor, is to be considered a manufacturer for the purposes of these Regulations and is subject to the obligations of the manufacturer under this Part, where A—

- (a) places a product on the market under A’s own name or trademark; or
- (b) modifies a product already placed on the market in such a way that it may affect whether the product is in conformity with Part 2.

## CHAPTER 5

## ALL ECONOMIC OPERATORS

**Identification of economic operators**

**35.**—(1) An economic operator (“E”) who receives a request from the market surveillance authority before the end of the relevant period, shall, within such period as the authority may specify, identify to the authority—

- (a) any economic operator who has supplied E with a product; and
- (b) any economic operator to whom E has supplied a product.

(2) The relevant period is—

- (a) for information under paragraph (1)(a), a period of 10 years beginning on the day on which E was supplied with the product;
- (b) for information under paragraph (1)(b), a period of 10 years beginning on the day on which E supplied the product.

**Prohibition on improper use of CE marking**

**36.**—(1) An economic operator shall not affix the CE marking to a product unless—

- (a) that economic operator is the manufacturer; and
- (b) the conformity of the product with the essential safety requirements has been demonstrated by a relevant conformity assessment procedure.

(2) An economic operator shall not affix to a product a marking (other than the CE marking) which purports to attest that the product is in conformity with the essential safety requirements.

(3) An economic operator shall not affix to a product a marking, sign or inscription which is likely to mislead any other person as to the meaning or form of the CE marking.

(4) An economic operator shall not affix to a product any other marking if the visibility, legibility and meaning of the CE marking would be impaired as a result.

**Translation of declaration of conformity**

**37.**—(1) Before making a product available on the market, an economic operator shall ensure that the EU declaration of conformity is prepared in, or translated into, the language required by the Member State in which it is to be made available on the market.

(2) Where the product is to be made available on the market in the United Kingdom, the language required is English.

**PART 3**

**CONFORMITY ASSESSMENT**

**Presumption of conformity**

**38.**—(1) A product which is in conformity with a harmonised standard (or part of such a standard) the reference to which has been published in the Official Journal is presumed to be in conformity with the essential safety requirements covered by that standard (or that part of that standard).

(2) The presumption in paragraph (1) is rebuttable.

**Conformity assessment procedures**

**39.**—(1) For the assessment of conformity of equipment, and where necessary those devices referred to at regulation 3(2)(b), the manufacturer shall follow one of the following procedures—

- (a) for equipment-groups I and II, equipment-categories M 1 and 1, the manufacturer shall follow the EU-type examination set out in Annex III to the ATEX Directive (as amended from time to time), in conjunction with—
  - (i) conformity to type based on quality assurance of the production process as set out in Annex IV to the ATEX Directive (as amended from time to time); or
  - (ii) conformity to type based on product verification as set out in Annex V to the ATEX Directive (as amended from time to time);
- (b) for equipment-groups I and II, equipment-categories M 2 and 2, the manufacturer shall follow—

- (i) for internal combustion engines and electrical equipment in these groups and categories, the EU-type examination referred to in Annex III to the ATEX Directive (as amended from time to time) in conjunction with—
    - (aa) conformity to type based on internal production control plus supervised product testing as referred to in Annex VI to the ATEX Directive (as amended from time to time); or
    - (bb) conformity to type based on product quality assurance as set out in Annex VII to the ATEX Directive (as amended from time to time).
  - (ii) for other equipment in these groups and categories—
    - (aa) the procedure relating to internal production control referred to in Annex VIII to the ATEX Directive (as amended from time to time); and
    - (bb) the manufacturer shall provide a notified body with the technical documentation provided for in paragraph 2 of Annex VIII to the Directive (as amended from time to time);
  - (c) for equipment-group II, equipment category 3, the procedure relating to internal production control referred to in Annex VIII to the ATEX Directive (as amended from time to time);
  - (d) for equipment-groups I and II, in addition to the procedures referred to in paragraphs (1)(a), (b) and (c) the manufacturer may also follow conformity based on unit verification referred to in Annex IX to the ATEX Directive (as amended from time to time).
- (2) The procedure referred to in paragraph (1)(a) or (d) shall be used for the conformity assessment of protective systems.
- (3) For the assessment of conformity of components, the manufacturer shall—
- (a) follow the procedures referred to in paragraph (1), with the exception of—
    - (i) affixing of the CE marking; and
    - (ii) drawing up of the EU declaration of conformity;
  - (b) issue a written attestation of conformity. The attestation of conformity shall—
    - (i) confirm conformity of the component with Part 3 of these Regulations;
    - (ii) state the characteristics of the component; and
    - (iii) explain how the component shall be incorporated into equipment or protective systems to comply with the essential safety requirements.
- (4) With regard to the safety aspects referred to at paragraph 13 of Schedule 1, in addition to the conformity assessment procedures referred to in paragraphs (1) and (2), the manufacturer may also follow the procedure referred to in Annex VIII to the ATEX Directive (as amended from time to time).
- (5) Where the procedures referred to in paragraphs (1), (2) and (4) have not been applied, the competent national authority, may authorise the placing on the market and the putting into service, of a product, other than a component, in the Member State concerned where—
- (a) the competent national authority is in receipt of a duly justified request from a manufacturer requesting the placing on the market and the putting into service of a product, other than a component where paragraphs (1), (2) and (4) have not been applied; and
  - (b) the use of the product, other than a component is in the interests of protection.

#### **EU declaration of conformity**

- 40.** The EU declaration of conformity for a product shall—
- (a) state that the fulfilment of the essential safety requirements have been demonstrated in respect of the product;
  - (b) have the model structure set out in Schedule 6;

- (c) contain the elements specified in Annexes III to IX to the ATEX Directive (as amended from time to time) for the relevant conformity assessment procedures followed in respect of the product.

**CE marking**

**41.**—(1) The CE marking shall be affixed visibly, legibly and indelibly to the product or the product's data plate.

(2) Where it is not possible or warranted, on account of the nature of the product, to affix the CE marking in accordance with paragraph (1), the CE marking shall be affixed to—

- (a) the packaging; and
- (b) the accompanying documents.

(3) The CE marking shall be followed by the identification number of the notified body which carried out the relevant conformity assessment procedure for the product, where that body is involved in the production control phase.

(4) The identification number of the notified body shall be affixed—

- (a) by the notified body itself; or
- (b) under the instructions of the notified body, by the manufacturer.

(5) The CE marking and, where applicable, the identification number of the notified body shall be followed by—

- (a) the specific marking of explosion protection as referred to in Schedule 1, paragraph 5(f);
- (b) the symbols of the equipment-group and category; and
- (c) where applicable, the other markings and information referred to in Schedule 1, paragraph 5.

(6) The CE marking and the markings, symbols and information referred to in paragraph (5), and, where applicable, the identification number of the notified body, may be followed by any other mark indicating a special risk or use.

(7) Products designed for a particular explosive atmosphere shall be marked accordingly.

**PART 4****NOTIFICATION OF CONFORMITY ASSESSMENT BODIES****Notified bodies**

**42.**—(1) For the purposes of this Part, a notified body is a conformity assessment body—

- (a) which has been notified by the Executive to the European Commission, Great Britain and to the other Member States—
  - (i) under regulation 44 (Notification); or
  - (ii) before the commencement date, in accordance with Article 17 of the ATEX Directive; and
- (b) in respect of which no objections are raised by the European Commission or the other Member States—
  - (i) within two weeks of the date of notification, where the notification is accompanied by an accreditation certificate; or
  - (ii) within two months of the date of notification, where the notification is not accompanied by an accreditation certificate.

(2) Paragraph (1) has effect subject to regulation 48 (Changes to notifications).

### Presumption of conformity of notified bodies

43.—(1) Where a conformity assessment body demonstrates its conformity with the criteria laid down in a harmonised standard (or part of such a standard), the reference of which has been published in the Official Journal, the Executive is to presume that the conformity assessment body meets the notified body requirements covered by that standard (or part of that standard).

(2) The presumption in paragraph (1) is rebuttable.

### Notification

44.—(1) The Executive may notify to the European Commission, Great Britain and the other Member States only those conformity assessment bodies established within Northern Ireland that qualify for notification.

(2) A conformity assessment body qualifies for notification if the first and second conditions below are met.

(3) The first condition is that the conformity assessment body has applied to the Executive to become a notified body and the application is accompanied by—

- (a) a description of—
  - (i) the conformity assessment activities that the conformity body intends to carry out;
  - (ii) the conformity assessment module for which the conformity assessment body claims to be competent; and
  - (iii) the product for which the conformity assessment body claims to be competent; and either
- (b) an accreditation certificate; or
- (c) the documentary evidence necessary for the Executive to verify, recognise and regularly monitor the conformity assessment body's compliance with the notified body requirements.

(4) The second condition is that the Executive is satisfied that the conformity assessment body meets the notified body requirements.

(5) For the purposes of paragraph (4), the Executive may accept an accreditation certificate, provided in accordance with paragraph (3)(b), as sufficient evidence that the conformity assessment body fulfils the notified body requirements.

(6) When deciding whether to notify a conformity assessment body that qualifies for notification to the European Commission, Great Britain and the other Member States, the Executive may—

- (a) have regard to any other matter which appears to the Executive to be relevant; and
- (b) set conditions that the conformity assessment body shall meet.

(7) The Executive shall inform the European Commission of Northern Ireland's procedures for the assessment and notification of conformity assessment bodies and any such changes to those procedures.

### Contents of notification

45. A notification under regulation 44 (Notification) shall include—

- (a) details of—
  - (i) the conformity assessment activities in respect of which the conformity assessment body has made its application for notification;
  - (ii) the conformity assessment module in respect of which the conformity assessment body has made its application for notification; and

- (iii) the product in respect of which the conformity assessment body has made its application for notification; and either
- (b) an accreditation certificate; or
- (c) documentary evidence which attests to—
  - (i) the conformity assessment body's competence; and
  - (ii) the arrangements in place to ensure that the conformity assessment body will be monitored regularly and will continue to meet the notified body requirements.

### **Monitoring**

**46.**—(1) The Executive shall monitor each notified body with a view to verifying that the notified body—

- (a) continues to meet the notified body requirements;
- (b) meets any conditions set in accordance with regulation 44(6)(b); and
- (c) carries out its functions in accordance with these Regulations.

(2) The Executive shall inform the European Commission of the United Kingdom's procedures for the monitoring of notified bodies, and any changes to those procedures.

### **United Kingdom Accreditation Service**

**47.** The Executive may seek, and have regard to, the advice of the United Kingdom Accreditation Service when—

- (a) assessing whether a conformity assessment body meets the notified body requirements; and
- (b) monitoring notified bodies in accordance with regulation 46.

### **Changes to notifications**

**48.**—(1) Where the Executive determines that a notified body no longer meets a notified body requirement, or is failing to fulfil its obligations under these Regulations, other than conditions set in accordance with regulation 44(6)(b), the Executive shall restrict, suspend or withdraw the body's status as a notified body under regulation 42.

(2) With the consent of a notified body, or where the Executive determines that a notified body no longer meets a condition set in accordance with regulation 44(6)(b), the Executive may restrict, suspend or withdraw the body's status as a notified body under regulation 42.

(3) In deciding what action is required under paragraph (1) or (2), the Executive shall have regard to the seriousness of the non-compliance.

(4) Where the Executive takes action under paragraph (1) or (2), the Executive shall immediately inform the European Commission, Great Britain and the other Member States.

(5) Where the Executive has taken action in respect of a notified body under paragraphs (1) or (2), or where the notified body has ceased its activity, the notified body shall, at the request of the Executive—

- (a) transfer its files relating to the activities it has undertaken as a notified body to another notified body or to the Executive; or
- (b) keep its files relating to the activities it has undertaken as a notified body available for the Executive for a period of 10 years from the date they were created.

### **Operational obligations of notified bodies**

**49.** When a notified body carries out a relevant conformity assessment procedure, Schedule 3 (Operational obligations of notified bodies) has effect.

**Subsidiaries and contractors**

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

(2) The notified body shall—

- (a) ensure that the subcontractor or subsidiary meets the notified body requirements; and
- (b) inform the Executive accordingly.

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

(4) Where a notified body subcontracts specific conformity assessment activities, or has such activities carried out by a subsidiary, the notified body shall for a period of 10 years beginning on the day on which the activities are carried out, keep available for inspection by the Executive the documentation concerning—

- (a) the assessment of the qualifications of the subcontractor or the subsidiary; and
- (b) the conformity assessment activities carried out by the subcontractor or subsidiary.

(5) When monitoring a notified body in accordance with regulation 46, the Executive shall treat the notified body as responsible for the tasks performed by a subcontractor or subsidiary, wherever the subcontractor or subsidiary is established.

**PART 5****MARKET SURVEILLANCE AND ENFORCEMENT****Designation of market surveillance authority**

**51.** In Northern Ireland, the market surveillance authority for a product is the Executive.

**Enforcement**

**52.** The market surveillance authority shall enforce these Regulations and RAMS (in its application to a product) or ensure that they are enforced.

**Enforcement powers**

**53.**—(1) Schedule 4 (Enforcement powers of the Executive under the 1978 Order) is to have effect.

(2) In addition to the powers available to the market surveillance authority under paragraph (1) or (2), the authority may use the powers set out in Schedule 5 (Compliance, withdrawal and recall notices).

**Exercise of enforcement powers**

**54.** When enforcing these Regulations, the market surveillance authority shall exercise its powers in a manner which is consistent with—

- (a) regulation 55 (Evaluation of a product presenting a risk);
- (b) regulation 56 (Enforcement action in respect of products which are not in conformity and which present a risk);
- (c) regulation 57 (EU safeguard procedure);
- (d) regulation 58 (Enforcement action in respect of products which are in conformity, but present a risk);



- (e) regulation 59 (Enforcement action in respect of formal non-compliance);
- (f) regulation 60 (Restrictive measures).

### **Evaluation of a product presenting a risk**

**55.** Where the market surveillance authority has sufficient reason to believe that a product presents a risk, the market surveillance authority shall carry out an evaluation in relation to the product covering the relevant requirements of Part 2 applying in respect of that product.

### **Enforcement action in respect of products which are not in conformity and which present a risk**

**56.**—(1) Where, in the course of the evaluation referred to in regulation 55, the market surveillance authority finds that the product is not in conformity with Part 2, it shall, without delay, require a relevant economic operator to—

- (a) take appropriate corrective actions to bring the product into conformity with those requirements within a prescribed period;
- (b) withdraw the product within a prescribed period; or
- (c) recall the product within a prescribed period.

(2) The market surveillance authority shall inform the notified body which carried out the conformity assessment procedure in respect of the product of—

- (a) the respect in which the product is not in conformity with Part 2; and
- (b) the actions which the market surveillance authority is requiring the relevant economic operator to take.

(3) Where the Executive considers that the lack of conformity referred to in paragraph (1) is not restricted to the United Kingdom, the Executive shall inform the European Commission and the other Member States of—

- (a) the results of the evaluation; and
- (b) the actions which the market surveillance authority has required the economic operator to take.

(4) Where the relevant economic operator does not take adequate corrective action within the prescribed period, the market surveillance authority shall take appropriate measures to—

- (a) prohibit or restrict the product being made available on the market in the United Kingdom;
- (b) withdraw the product from the United Kingdom market; or
- (c) recall the product.

(5) Where the market surveillance authority takes measures under paragraph (4), the Executive shall notify the European Commission and the other Member States of those measures without delay.

(6) The notice in paragraph (5) shall include details about the product and, in particular—

- (a) the data necessary for the identification of the product which is not in conformity with Part 2;
- (b) the origin of the product;
- (c) the nature of the lack of conformity alleged and the risk involved;
- (d) the nature and duration of the measures taken;
- (e) the arguments put forward by the relevant economic operator;
- (f) whether the lack of conformity is due to either of the following—
  - (i) failure of the product to meet requirements relating to a risk;

- (ii) shortcomings in the harmonised standards referred to in regulation 38 (Presumption of conformity) conferring a presumption of conformity.
- (7) In this regulation, “prescribed period” means a period which is—
- (a) prescribed by the market surveillance authority; and
  - (b) reasonable and commensurate with the nature of the risk presented by the product.

### **EU safeguard procedure**

**57.**—(1) Where another Member State has initiated the procedure under Article 35 of the ATEX Directive (as amended from time to time), the Executive shall, without delay, inform the European Commission and the other Member States of—

- (a) any measures taken by the market surveillance authority in respect of the product;
- (b) any additional information which the market surveillance authority has at its disposal relating to the lack of conformity of the product; and
- (c) any objections that the Executive may have to the measure taken by the Member State initiating the procedure.

(2) Where a measure taken by another Member State in respect of a product is considered justified under Article 35(7) of the ATEX Directive (as amended from time to time), the market surveillance authority shall ensure that appropriate measures, such as withdrawal, are taken in respect of the product without delay.

(3) Where a measure taken by another Member State in respect of a product is considered justified by the European Commission under Article 36(1) of the ATEX Directive (as amended from time to time), the market surveillance authority shall take the necessary measures to ensure that the product is withdrawn from the United Kingdom market.

(4) Where the market surveillance authority has taken action under paragraphs (2) and (3), the Executive shall inform the European Commission of the action taken.

(5) If a measure taken by the market surveillance authority pursuant to regulation 56 is considered unjustified by the European Commission under Article 36(1) of the ATEX Directive (as amended from time to time), the market surveillance authority shall withdraw that measure.

### **Enforcement action in respect of products which are in conformity, but present a risk**

**58.**—(1) Where, having carried out an evaluation under regulation 55, the market surveillance authority finds that although a product is in conformity with Part 2, it presents a risk, the market surveillance authority shall require a relevant economic operator to take appropriate measures to—

- (a) ensure that the product concerned, when placed on the market, no longer presents a risk;
- (b) withdraw the product within a prescribed period; or
- (c) recall the product within a prescribed period.

(2) Where the market surveillance authority takes measures under paragraph (1), the Executive shall notify the European Commission and the other Member States immediately.

(3) The notice referred to in paragraph (2) shall include details about the product and, in particular—

- (a) the data necessary for the identification of the product concerned;
- (b) the origin and the supply chain of the product;
- (c) the nature of the risk involved; and
- (d) the nature and duration of the measures taken by the enforcing authority.

(4) In this regulation, “prescribed period” means a period which is—

- (a) prescribed by the market surveillance authority; and
- (b) reasonable and commensurate with the nature of the risk presented by the product.

**Enforcement action in respect of formal non-compliance**

**59.**—(1) Where an enforcing authority makes one of the following findings relating to a product, it shall require a relevant economic operator to remedy the non-compliance concerned within a specified period—

- (a) the CE marking—
  - (i) where required, has not been affixed; or
  - (ii) has been affixed otherwise than in accordance with regulations 36 (Prohibition on improper use of CE marking) and 41 (CE marking);
- (b) where a notified body is involved in the production control phase for the product, the identification number of the notified body—
  - (i) has not been affixed; or
  - (ii) has been affixed otherwise than in accordance with regulation 41;
- (c) the EU declaration of conformity or the attestation of conformity as appropriate—
  - (i) does not accompany the product; or
  - (ii) has been drawn up otherwise than in accordance with regulations 7 (EU declaration of conformity and CE marking) and 40 (EU declaration of conformity);
- (d) the technical documentation is either not available or not complete;
- (e) the following product information has been affixed otherwise than in accordance with paragraph 5 of Schedule 1—
  - (i) specific marking of explosion protection in accordance with paragraph 5(f) of Schedule 1;
  - (ii) the symbols of the equipment-group and category in accordance with paragraphs 5(g) and 5(h) of Schedule 1; and
  - (iii) where applicable, the other markings and information required by paragraph 5 of Schedule 1.
- (f) the product information at paragraph (1)(e) has not been affixed;
- (g) the following information that is required to be included in the labelling of the product is absent, false or incomplete—
  - (i) the information specified in regulation 13 (Information identifying manufacturer);
  - (ii) the information specified in regulation 21 (Information identifying importer); or
- (h) any other administrative requirement imposed on the manufacturer or importer under Part 2 has not been fulfilled.

(2) The enforcing authority shall not take any enforcement action against the relevant economic operator under these Regulations in respect of the non-compliance concerned until the period referred to in paragraph (1) has elapsed.

(3) Where the non-compliance referred to in paragraph (1) persists, the enforcing authority shall take appropriate measures to—

- (a) restrict or prohibit the product being made available on the market;
- (b) ensure that the product is withdrawn; or
- (c) ensure that the product is recalled.

(4) This regulation does not apply where a product presents a risk.

**Restrictive measures**

**60.** When enforcing these Regulations, the market surveillance authority shall comply with the requirements of Article 21 of RAMS (as amended from time to time) in relation to any measure to—

- (a) prohibit or restrict a product being made available on the market;

- (b) withdraw a product; or
- (c) recall a product.

### Offences

**61.**—(1) It is an offence for any person to contravene or fail to comply with any requirement of regulations 5 to 33.

(2) It is an offence for any person to contravene or fail to comply with any requirement of a notice, other than a compliance notice, served on that person by an enforcing authority under these Regulations.

(3) It is an offence for any person—

- (a) intentionally to obstruct—
  - (i) an enforcing authority (or officer of such authority) acting in pursuance of its powers and duties under these Regulations or Article 19 of RAMS (as amended from time to time);
  - (ii) a customs officer facilitating the action of an enforcing authority under these Regulations; or
- (b) knowingly or recklessly to provide any statement, information, document or record which is false or misleading in a material respect in purported compliance with any requirement of these Regulations or Article 19 of RAMS (as amended from time to time).

(4) It is an offence for any person who is not authorised to act on behalf of an enforcing authority to purport to exercise any of the powers of the enforcing authority under these Regulations or RAMS.

(5) It is an offence for a conformity assessment body to fail to comply with regulation 48 (Changes to notifications).

### Penalties

**62.** A person guilty of an offence under regulation 61 is liable—

- (a) on summary conviction, to a fine not exceeding the statutory maximum or to imprisonment for a term not exceeding three months or to both; and
- (b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or to both.

### Defence of due diligence

**63.**—(1) Subject to paragraphs (2), (4) and (6), in proceedings for an offence under regulation 61, it is a defence for a person (“P”) to show that P took all reasonable steps and exercised all due diligence to avoid committing the offence.

(2) P may not rely on a defence under paragraph (1) which involves a third party allegation unless P has—

- (a) served a notice in accordance with paragraph (3); or
- (b) obtained the leave of the court.

(3) The notice shall—

- (a) give any information in P’s possession which identifies or assists in identifying the person who—
  - (i) committed the act or default; or
  - (ii) supplied the information on which P relied.
- (b) be served on the person bringing the proceedings not less than seven clear days before the hearing of the proceedings.

(4) P may not rely on a defence under paragraph (1) which involves an allegation that the commission of the offence was due to reliance on information supplied by another person unless it was reasonable for P to have relied upon the information, having regard in particular—

- (a) to the steps that P took, and those which might reasonably have been taken, for the purpose of verifying the information; and
- (b) to whether P had any reason to disbelieve the information.

(5) In this regulation, “third party allegation” means an allegation that the commission of the offence was due—

- (a) to the act or default of another person; or
- (b) to reliance on information supplied by another person.

(6) This regulation does not apply in respect of proceedings for offences under regulation 61(6).

### **Liability of persons other than principal offender**

**64.**—(1) Where the commission of an offence by one person (“A”) under regulation 61 is due to anything which another person (“B”) did or failed to do in the course of business, B is guilty of the offence and may be proceeded against and punished, whether or not proceedings are taken against A.

(2) Where a body corporate commits an offence, a relevant person is also guilty of the offence where the body corporate’s offence was committed—

- (a) with the consent or connivance of the relevant person; or
- (b) as a result of the negligence of the relevant person.

(3) In paragraph (2), “relevant person” means—

- (a) a director, manager, secretary or other similar officer of the body corporate;
- (b) in relation to a body corporate managed by its members, a member of that body corporate performing managerial functions; or
- (c) a person purporting to act as a person described in subparagraphs (a) or (b).

### **Time limit for prosecution of offences**

**65.**—(1) Subject to paragraph (2), information relating to an offence under regulation 61 that is triable by a magistrates’ court may be so tried if it is laid within twelve months after the date on which evidence sufficient in the opinion of the prosecutor to justify the proceedings comes to the knowledge of the prosecutor.

(2) No proceedings may be brought more than three years after the commission of the offence.

(3) For the purposes of this regulation a certificate of the prosecutor as to the date on which the evidence referred to paragraph (1) came to light, is conclusive evidence.

(4) This regulation has effect subject to paragraphs 1(n) and 2(l) of Schedule 4 (Enforcement powers of the Executive under the 1978 Order).

### **Service of documents**

**66.**—(1) Any document required or authorised by these Regulations to be served on a person may be served by—

- (a) delivering it to that person in person;
- (b) leaving it at that person’s proper address; or
- (c) sending it by post or electronic means to that person’s proper address.

(2) In the case of a body corporate, a document may be served on a director of that body.

(3) In the case of a partnership, a document may be served on a partner or a person having control or management of the partnership business.

(4) For the purposes of this regulation, “proper address” means—

- (a) in the case of a body corporate or its director—
  - (i) the registered or principal office of that body; or
  - (ii) the email address of the secretary or clerk of that body;
- (b) in the case of a partnership, a partner or person having control or management of the partnership business—
  - (i) the principal office of the partnership; or
  - (ii) the email address of a partner or person having that control or management;
- (c) in any other case, a person’s last known address, which includes an email address.

(5) If a person to be served with a document has specified an address in the United Kingdom (other than that person’s proper address) at which that person or someone on that person’s behalf will accept service, that address shall also be treated as that person’s proper address.

### Recovery of expenses of enforcement

**67.**—(1) This regulation applies where a person commits an offence under regulation 61.

(2) The court may (in addition to any other order it may make as to costs or expenses) order the person to reimburse the enforcing authority for any expenditure which the enforcing authority has incurred in investigating the offence.

### Action by enforcing authority

**68.**—(1) An enforcing authority may itself take action which an economic operator could have been required to take by a notice served under these Regulations where the conditions for serving such a notice are met and either—

- (a) the enforcing authority has been unable to identify any economic operator on whom to serve such a notice; or
- (b) the economic operator on whom such a notice has been served has failed to comply with it.

(2) If the enforcing authority has taken action as a result of the condition in paragraph (1)(b) being met, the authority may recover from the economic operator, as a civil debt, any costs or expenses reasonably incurred by the enforcing authority in taking the action.

(3) A civil debt recoverable under paragraph (2) may be recovered summarily in proceedings under Article 62 of the Magistrates’ Courts (Northern Ireland) Order 1981(a).

### Appeals against notices

**69.**—(1) An application for an order to vary or set aside the terms of a notice served under these Regulations may be made—

- (a) by the economic operator on whom the notice has been served; and
- (b) in the case of a notice other than a recall notice, by a person having an interest in the product in respect of which the notice has been served.

(2) An application shall be made before the end of the period of 21 days beginning with the day on which the notice was served.

(3) The appropriate court may only make an order setting aside a notice served under these Regulations if satisfied—

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(a) S.I. 1981/1675 (N.I. 26)

- (a) that the product to which the notice relates is in conformity with Part 2; or
  - (b) that the enforcing authority failed to comply with regulation 54 (Exercise of enforcement powers) when serving of the notice.
- (4) On an application to vary the terms of a notice served under these Regulations, the appropriate court may vary the terms of the notice as it considers appropriate.
- (5) In this regulation—
- (a) the “appropriate court” is to be determined in accordance with regulation 70 (Appropriate court for appeals against notices); and
  - (b) “notice” means any of the following—
    - (i) a notice to warn served in accordance with Schedule 4 (Enforcement powers of the Executive under the 1978 Order);
    - (ii) a suspension notice served in accordance with Schedule 4;
    - (iii) a compliance notice served in accordance with Schedule 5 (Compliance, withdrawal and recall notices);
    - (iv) a withdrawal notice served in accordance with Schedule 5;
    - (v) a recall notice served in accordance with Schedule 5.

#### **Appropriate court for appeals against notices**

**70.**—(1) The appropriate court for the purposes of regulation 69 is—

- (a) the court in which proceedings have been brought in relation to the product for an offence under regulation 61 (Offences);
- (b) an industrial tribunal seized of appeal proceedings against a notice which relates to the product and which has been served under or by virtue of paragraph 1 of Schedule 4 (Enforcement powers of the Executive under the 1978 Order); or
- (c) in any other case, a magistrates’ court.

(2) A person aggrieved by an order made by a magistrates’ court pursuant to an application under regulation 69, or by a decision of such a court not to make such an order, may appeal against that order or decision to the county court.

## **PART 6**

### **MISCELLANEOUS**

#### **Transitional provisions**

**71.** A certificate issued, or approval granted, by a notified body under Schedule 6 to the 1996 Regulations, or any enactment of another Member State which implemented the 1994 Directive, is to be treated as a certificate issued or approval granted under these Regulations.

#### **Consequential amendments, revocations and savings**

**72.**—(1) The statutory provisions referred to in column 1 of Schedule 7 shall be amended to the extent specified in column 3 of that Schedule.

(2) The statutory provisions referred to in column 1 of Schedule 8 shall be revoked to the extent specified in column 3 of that Schedule.

(3) The 1996 Regulations, the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres (Amendment) Regulations (Northern Ireland) 1999<sup>(a)</sup> and

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(a) S.R. 1999 No. 125

the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres (Amendment) Regulations (Northern Ireland) 2005<sup>(a)</sup> continue to apply, as if they had not been revoked, to a product placed on the market before the commencement date.

Sealed with the Official Seal of the Department of Enterprise, Trade and Investment on xxth xxx  
2016



*Jackie Kerr*

A senior officer of the Department of Enterprise, Trade and Investment

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<sup>(a)</sup> S. R. 2008 No. 422



## SCHEDULE 1

Regulation 2(1)

## ESSENTIAL SAFETY REQUIREMENTS

ESSENTIAL HEALTH AND SAFETY REQUIREMENTS RELATING TO THE DESIGN AND CONSTRUCTION OF EQUIPMENT AND PROTECTIVE SYSTEMS INTENDED FOR USE IN POTENTIALLY EXPLOSIVE ATMOSPHERES (Annex II of the ATEX Directive)

**Preliminary observations**

1.—(1) Technological knowledge, which can change rapidly, shall be taken into account as far as possible and be utilised immediately.

(2) For the devices referred to in regulation 3(2)(b), the essential health and safety 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.

**Common requirements for Equipment and protective systems****General requirements****Principles of integrated explosion safety**

2.—(1) Equipment and protective systems intended for use in potentially explosive atmospheres shall be designed from the point of view of integrated explosion safety.

(2) In this connection, the manufacturer shall take measures:

- (a) above all, if possible, to prevent the formation of explosive atmospheres which may be produced or released by equipment and by protective systems themselves;
- (b) to prevent the ignition of explosive atmospheres, taking into account the nature of every electrical and non-electrical source of ignition; and
- (c) 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/or to limit the range of explosion flames and explosion pressures to a sufficient level of safety.

(3) Equipment and protective systems shall be designed and manufactured after due analysis of possible operating faults in order as far as possible to preclude dangerous situations.

(4) Any misuse which can reasonably be anticipated shall be taken into account.

**Special checking and maintenance conditions**

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

**Surrounding area conditions**

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

**Marking**

5.—(1) All equipment and protective systems shall be marked legibly and indelibly with the following minimum particulars—

- (a) name, registered trade name or registered trade mark, and address of the manufacturer;

- (b) CE marking (see Annex II to Regulation EC No 765/2008);
- (c) designation of series or type;
- (d) batch or serial number, if any;
- (e) year of construction;
- (f) the specific marking of explosion protection



followed by the symbol of the equipment-group and category;

- (g) for equipment-group II, the letter 'G' (concerning explosive atmospheres caused by gases, vapours or mists); and/or
- (h) the letter 'D' (concerning explosive atmospheres caused by dust).

(2) Furthermore, where necessary, they shall also be marked with all information essential to their safe use.

### Instructions

6.—(1) All equipment and protective systems shall be accompanied by instructions, including at least the following particulars—

- (a) a recapitulation of the information with which the equipment or protective system is marked, except for the batch or serial number (see paragraphs 5(1) and (2)), together with any appropriate additional information to facilitate maintenance (e.g. address of the importer, repairer, etc.);
- (b) instructions for safe—
  - (i) putting into service;
  - (ii) use;
  - (iii) assembling and dismantling;
  - (iv) maintenance (servicing and emergency repair);
  - (v) installation;
  - (vi) adjustment;
- (c) where necessary, an indication of the danger areas in front of pressure-relief devices;
- (d) where necessary, training instructions;
- (e) 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;
- (f) electrical and pressure parameters, maximum surface temperatures and other limit values;
- (g) where necessary, special conditions of use, including particulars of possible misuse which experience has shown might occur;
- (h) where necessary, the essential characteristics of tools which may be fitted to the equipment or protective system.

(2) The instructions shall 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.

(3) Literature describing the equipment or protective system shall not contradict the instructions with regard to safety aspects.

**Selection of materials**

7.—(1) The materials used for the construction of equipment and protective systems shall not trigger off an explosion, taking into account foreseeable operational stresses.

(2) Within the limits of the operating conditions laid down by the manufacturer, it shall 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.

(3) Materials shall 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 shall be taken of the material's corrosion and wear resistance, electrical conductivity, mechanical strength, ageing resistance and the effects of temperature variations.

**Design and construction**

8.—(1) Equipment and protective systems shall be designed and constructed with due regard to technological knowledge of explosion protection so that they can be safely operated throughout their foreseeable lifetime.

(2) Components to be incorporated into or used as replacements in equipment and protective systems shall 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.

**Enclosed structures and prevention of leaks**

9.—(1) Equipment which may release flammable gases or dusts shall wherever possible employ enclosed structures only.

(2) If equipment contains openings or non-tight joints, these shall as far as possible be designed in such a way that releases of gases or dusts cannot give rise to explosive atmospheres outside the equipment.

(3) Points where materials are introduced or drawn off shall, as far as possible, be designed and equipped so as to limit releases of flammable materials during filling or draining.

**Dust deposits**

10.—(1) Equipment and protective systems which are intended to be used in areas exposed to dust shall be so designed that deposit dust on their surfaces is not ignited.

(2) In general, dust deposits shall be limited where possible. Equipment and protective systems shall be easily cleanable.

(3) The surface temperatures of equipment parts shall be kept well below the glow temperature of the deposit dust.

(4) The thickness of deposit dust shall be taken into consideration and, if appropriate, means shall be taken to limit the temperature in order to prevent a heat build up.

**Additional means of protection**

11.—(1) Equipment and protective systems which may be exposed to certain types of external stresses shall be equipped, where necessary, with additional means of protection.

(2) Equipment shall withstand relevant stresses, without adverse effect on explosion protection.

**Safe opening**

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

**Protection against other hazards**

- 13.**—(1) Equipment and protective systems shall 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 or 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 do not give rise to dangerous situations.

(2) Where, for equipment and protective systems, the risks referred to in this paragraph are wholly or partly covered by other European Union legislation, this paragraph shall not apply or shall cease to apply in the case of such equipment and protective systems and of such risks upon application of that specific European Union legislation.

**Overloading of equipment**

**14.** Dangerous overloading of equipment shall 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/or similar types of monitoring devices.

**Flameproof enclosure systems**

**15.** If parts which can ignite an explosive atmosphere are placed in an enclosure, measures shall 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.

**Potential ignition sources****Hazards arising from different ignition sources**

**16.** Potential ignition sources such as sparks, flames, electric arcs, high surface temperatures, acoustic energy, optical radiation, electromagnetic waves and other ignition sources shall not occur.

**Hazards arising from static electricity**

**17.** Electrostatic charges capable of resulting in dangerous discharges shall be prevented by means of appropriate measures.

**Hazards arising from stray electric and leakage currents**

**18.** 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 shall be prevented.

**Hazards arising from overheating**

**19.** 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 shall, as far as possible, be prevented at the design stage.

**Hazards arising from pressure compensation operations**

20. Equipment and protective systems shall 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.

**Hazards arising from external effects**

21.—(1) Equipment and protective systems shall 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.

(2) Equipment parts used shall be appropriate to the intended mechanical and thermal stresses and capable of withstanding attack by existing or foreseeable aggressive substances.

**Requirements in respect of safety-related devices**

22.—(1) Safety devices shall function independently of any measurement or control devices or both measurement and control devices required for operation.

(2) As far as possible, failure of a safety device shall be detected sufficiently rapidly by appropriate technical means to ensure that there is only very little likelihood that dangerous situations will occur.

(3) The fail-safe principle is to be applied in general.

(4) Safety-related switching shall in general directly actuate the relevant control devices without intermediate software command.

(5) In the event of a safety device failure, equipment and/or protective systems shall, wherever possible, be secured.

(6) Emergency stop controls of safety devices shall, 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.

**Control and display units**

23. Where control and display units are used, they shall 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.

**Requirements in respect devices with a measuring function for explosion protection**

24.—(1) In so far as they relate to equipment used in explosive atmospheres, devices with a measuring function shall be designed and constructed so that they can cope with foreseeable operating requirements and special conditions of use.

(2) Where necessary, it shall be possible to check the reading accuracy and serviceability of devices with a measuring function.

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

**Risks arising from software**

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

**Integration of safety requirements relating to the system**

26.—(1) Manual override shall 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.

(2) When the emergency shutdown system is actuated, accumulated energy shall be dispersed as quickly and as safely as possible or isolated so that it no longer constitutes a hazard.

(3) This does not apply to electrochemically-stored energy.

**Hazards arising from power failure**

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

**Hazards arising from connections**

28.—(1) Equipment and protective systems shall be fitted with suitable cable and conduit entries.

(2) When equipment and protective systems are intended for use in combination with other equipment and protective systems, the interface shall be safe.

**Placing of warning devices as parts of equipment**

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

**Supplementary requirements in respect of equipment****Requirements applicable to equipment in equipment-group I****Requirements applicable to equipment in category M 1 of equipment-group I**

30.—(1) Equipment shall be so designed and constructed that sources of ignition do not become active, even in the event of rare incidents relating to equipment.

(2) Equipment shall be equipped with means of protection such that—

(a) either, in the event of failure of one means of protection, at least an independent second means provides the requisite level of protection; or

(b) the requisite level of protection is ensured in the event of two faults occurring independently of each other.

(3) Where necessary, equipment shall be equipped with additional special means of protection.

(4) It shall remain functional with an explosive atmosphere present.

(5) Where necessary, equipment shall be so constructed that no dust can penetrate it.

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

(7) Equipment shall 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 shall affix a warning label to the opening part of the equipment.

(8) If necessary, equipment shall be fitted with appropriate additional interlocking systems.

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

**31.**—(1) Equipment shall 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.

(2) The equipment is intended to be de-energised in the event of an explosive atmosphere.

(3) Equipment shall 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 shall affix a warning label to the opening part of the equipment.

(4) The requirements regarding explosion hazards arising from dust applicable to category M 1 shall be applied.

**Requirements applicable to equipment in category 1 of equipment-group II****Explosive atmospheres caused by gases, vapours or mists**

**32.**—(1) Equipment shall be so designed and constructed that sources of ignition do not become active, even in event of rare incidents relating to equipment.

(2) It shall be equipped with means of protection such that—

- (a) either, in the event of failure of one means of protection, at least an independent second means provides the requisite level of protection; or
- (b) the requisite level of protection is ensured in the event of two faults occurring independently of each other.

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

(4) Temperature rises caused by heat build-ups and chemical reactions shall also be taken into account.

(5) Equipment shall 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 shall affix a warning label to the opening part of the equipment.

(6) If necessary, equipment shall be fitted with appropriate additional interlocking systems.

**Explosive atmospheres caused by air/dust mixtures**

**33.**—(1) Equipment shall be so designed and constructed that ignition of air/dust mixtures does not occur even in the event of rare incidents relating to equipment.

(2) It shall be equipped with means of protection such that—

- (a) either, in the event of failure of one means of protection, at least an independent second means provides the requisite level of protection; or
- (b) the requisite level of protection is ensured in the event of two faults occurring independently of each other.

(3) Where necessary, equipment shall be so designed that dust can enter or escape from the equipment only at specifically designated points.

(4) This requirement shall also be met by cable entries and connecting pieces.

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

(6) With regard to the safe opening of equipment parts, paragraph 32(5) applies.

## Requirements applicable to equipment in category 2 of equipment-group II

### Explosive atmospheres caused by gases, vapours or mists

34.—(1) Equipment shall 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) Equipment parts shall 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.

(3) Equipment shall 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 shall affix a warning label to the opening part of the equipment.

### Explosive atmospheres caused by air/dust mixtures

35.—(1) Equipment shall 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) With regard to surface temperatures, paragraph 33(5) applies.

36. With regard to protection against dust, paragraph 33(3) applies.

37. With regard to the safe opening of equipment parts, paragraph 34(3) applies.

## Requirements applicable to equipment in category 3 of equipment-group II

### Explosive atmospheres caused by gases, vapours or mists

38.—(1) Equipment shall be so designed and constructed as to prevent foreseeable ignition sources which can occur during normal operation.

(2) Surface temperatures shall 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.

### Explosive atmospheres caused by air/dust mixtures

39.—(1) Equipment shall be so designed and constructed that air/dust mixtures cannot be ignited by foreseeable ignition sources likely to exist during normal operation.

(2) With regard to surface temperatures, paragraph 33(5) applies.

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

## Supplementary requirements in respect of protective systems

### General requirements

40.—(1) Protective systems shall be dimensioned in such a way as to reduce the effects of an explosion to a sufficient level of safety.

(2) Protective systems shall be designed and capable of being positioned in such a way that explosions are prevented from spreading through dangerous chain reactions or flashover and incipient explosions do not become detonations.

(3) In the event of a power failure, protective systems shall retain their capacity to function for a period sufficient to avoid a dangerous situation.



(4) Protective systems shall not fail due to outside interference.

**Planning and design**

**Characteristics of materials**

41.—(1) 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.

(2) Protective systems designed to resist or contain explosions shall be capable of withstanding the shock wave produced without losing system integrity.

(3) Accessories connected to protective systems shall be capable of withstanding the expected maximum explosion pressure without losing their capacity to function.

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

**Pressure-relief systems**

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

**Explosion suppression systems**

43. Explosion suppression systems shall 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.

**Explosion decoupling systems**

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

45. Protective systems shall 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.

## SCHEDULE 2

Regulation 2(1)

## NOTIFIED BODY REQUIREMENTS

1. A conformity assessment body shall be established in Northern Ireland and have legal personality.

2. A conformity assessment body shall be a third party body independent of the organisation or the product it assesses.

3. A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of products it assesses is a conformity assessment body for the purposes of regulation 44 (Notification) provided that such body can demonstrate—

- (a) its independence from such business association or professional federation; and
- (b) the absence of any conflict of interest.

4.—(1) A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment activities shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the products, nor the representative of any of those parties.

(2) Sub-paragraph (1) does not preclude the use of assessed products that are necessary for the operations of the conformity assessment body or the use of products for personal purposes.

5. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment activities shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of the products, or represent the parties engaged in those activities.

6. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment activities shall not engage in activity that may conflict with their independence of judgment or integrity in relation to conformity assessment activities for which they are notified (including consultancy services).

7. A conformity assessment body shall ensure that the activities of its subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

8. A conformity assessment body and its personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgment or the results of their conformity assessment activities, especially as regards persons or groups of persons who have an interest in those activities.

9. A conformity assessment body shall be capable of carrying out all of the conformity assessment activities in relation to for which it has been, or is to be, notified, whether those activities are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

10. A conformity assessment body shall have—

- (a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment activities;
- (b) descriptions of procedures in accordance with which conformity assessment activities are to be carried out, ensuring the transparency of and the ability to reproduce those procedures, and have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;

- (c) procedures for the performance of conformity assessment activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the process.

**11.** A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to the necessary equipment or facilities to enable it to perform those activities.

**12.** The personnel responsible for carrying out conformity assessment activities shall have—

- (a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;
- (b) satisfactory knowledge of the requirements of the assessments which the personnel carry out and adequate authority to carry out those assessments;
- (c) appropriate knowledge and understanding of the essential safety requirements, of the applicable harmonised standards and of the ATEX Directive and of these Regulations;
- (d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

**13.** A conformity assessment body shall be able to guarantee the impartiality of its top level management and the personnel responsible for carrying out the conformity assessment activities.

**14.** The remuneration of the top level management and the personnel responsible for carrying out the conformity assessment activities shall not depend on the number of assessments carried out or on the results of those assessments.

**15.** A conformity assessment body shall have, and shall satisfy the Executive that it has, adequate civil liability insurance in respect of its activities.

**16.** A conformity assessment body shall ensure that its personnel observe professional secrecy with regard to all information obtained in carrying out their tasks in accordance with these Regulations and that proprietary rights are protected.

**17.** Paragraph 16 does not prevent the personnel from providing information to the Executive or an enforcing authority pursuant to these Regulations or under any enactment.

**18.** A conformity assessment body shall participate in, or ensure that its personnel who are responsible for carrying out the conformity assessment activities are informed of, the relevant standardisation activities and the activities of any notified body coordination group established under the ATEX Directive and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

## SCHEDULE 3

Regulation 49

## OPERATIONAL OBLIGATIONS OF NOTIFIED BODIES

1. A notified body shall carry out conformity assessments in accordance with the relevant conformity assessment procedures.

2. A notified body shall carry out conformity assessments in a proportionate manner, avoiding unnecessary burdens on economic operators.

3. A notified body shall perform its activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

4. A notified body shall respect the degree of rigour and the level of protection required to ensure that the product is in conformity with the requirements of these Regulations.

5. Where a notified body finds that essential safety requirements or corresponding harmonised standards or other technical specifications have not been met by a manufacturer, it shall require the manufacturer to take appropriate corrective measures and shall not issue a certificate of conformity or grant an approval.

6. Where, in the course of the monitoring of conformity following the issue of a certificate or grant of an approval, a notified body finds that a product is no longer in conformity with the essential safety requirements, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate of conformity or approval (if necessary).

7. Where the notified body has required a manufacturer to take corrective measures and the manufacturer has failed to take such measures, or those measures have not had the required effect, the notified body shall restrict, suspend or withdraw any certificate of conformity or approval.

8. Paragraph 9 applies where a notified body is minded to—

- (a) refuse to issue a certificate of conformity or grant an approval;
- (b) restrict, suspend or withdraw a certificate of conformity or approval.

9. Where this paragraph applies, the notified body shall—

- (a) give the person applying for the certificate or approval, or the person to whom the certificate or approval was given, a notice in writing giving reasons and specifying the date on which the refusal, restriction, suspension or withdrawal is intended to take effect;
- (b) give the person applying for the certificate or approval, or the person to whom the certificate or approval was given, an opportunity to make representations within a reasonable period from the date of the notice; and
- (c) take account of any such representations before taking its decision.

10. A notified body shall inform the Executive of—

- (a) any refusal, restriction, suspension or withdrawal of a certificate of conformity or approval;
- (b) any circumstances affecting the scope of, or conditions for, notification under regulation 44 (Notification);
- (c) any request for information which it has received from an enforcing authority regarding conformity assessment activities; and

- (d) on request, any conformity assessment activities performed within the scope of its notification under regulation 44 and any other activity performed, including cross-border activities and subcontracting.

**11.** A notified body shall make provision in its contracts with its clients enabling such clients to appeal against a decision—

- (a) to refuse to issue a certificate of conformity or grant an approval; or
- (b) to restrict, suspend or withdraw a certificate of conformity or approval.

**12.** A notified body shall provide other bodies notified under the ATEX Directive carrying out similar conformity assessment activities covering the same products with relevant information on issues relating to negative and, on request, positive conformity assessment results.

**13.** A notified body shall participate in the work of any notified body coordination group established under the ATEX Directive, directly or by means of its designated representatives.

**14.** A notified body shall—

- (a) acknowledge receipt of the technical documentation provided by the manufacturer in accordance with regulation 39(b)(ii)(bb) (Conformity assessment procedures) as soon as possible; and
- (b) retain the technical documentation in sub-paragraph (a).

## SCHEDULE 4

Regulation 53(1)

## ENFORCEMENT POWERS OF THE EXECUTIVE UNDER THE 1978 ORDER

**Enforcement powers under the 1978 Order**

1. For the purposes of enforcing these Regulations, the following Articles of the 1978 Order apply subject to the modifications in paragraph 2—

- (a) Article 21 (Appointment of inspectors);
- (b) Article 22 (Powers of inspectors);
- (c) Article 23 (Improvement notices);
- (d) Article 24 (Prohibition notices);
- (e) Article 25 (Provisions supplementary to Articles 23 and 24);
- (f) Article 26 (Appeal against improvement or prohibition notice);
- (g) Article 27 (Power to deal with cause of imminent danger);
- (h) Article 27A (Power of customs officer to detain articles and substances);
- (i) Article 28 (Power of enforcing authorities to indemnify inspectors);
- (j) Article 29 (Obtaining of information);
- (k) Article 29A (Information communicated by Commissioners for Revenue and Customs);
- (l) Article 30 (Restrictions on disclosure of information);
- (m) Article 31 (Offences);
- (n) Article 32 (Extension of time for bringing summary proceedings);
- (o) Article 33 (Venue);
- (p) Article 36 (Prosecution by inspectors);
- (q) Article 38 (Evidence); and
- (r) Article 39 (Power of court to order cause of offence to be remedied and, in certain cases, forfeiture).

**Modifications to the 1978 Order**

2. The Articles of the 1978 Order referred to in paragraph 1 are to apply as if—

- (a) references to “relevant statutory provisions” were references to—
  - (i) the provisions of the 1978 Order set out in paragraph 1, as modified by this paragraph; and
  - (ii) these Regulations;
- (b) references to “risk” where references to risk within the meaning of regulation 2(6);
- (c) in Article 21—
  - (i) in paragraph (1), for “Every enforcing authority” there were substituted “the Health and Safety Executive for Northern Ireland”;
  - (ii) in paragraph (1), “within its field of responsibility” were omitted;
  - (iii) in paragraph (2), sub-paragraph (b) were omitted;
  - (iv) in paragraph (3), for “enforcing authority which appointed him” there were substituted “Health and Safety Executive for Northern Ireland”;
- (d) in Article 22—

- (i) in paragraph (1), “within the field of responsibility of the enforcing authority which appointed him” were omitted;
- (ii) in paragraph (2)(c)(i), for “his (the inspector’s) enforcing authority” there were substituted “the Health and Safety Executive for Northern Ireland”;
- (iii) in paragraph 2(h), for “him to have caused or likely to cause danger to health or safety”, there were substituted “contravene the relevant statutory provisions or present a risk”; and
- (iv) paragraph (3) were omitted;
- (e) in Article 23—
  - (i) before paragraph (a), there were inserted—
    - “(za) is making available on the market a product which presents a risk;”;
    - (ii) after “specifying the”, there were inserted “risk, or”; and
    - (iii) after “requiring that person to”, there were inserted “address the risk or”;
- (f) for Article 24(2) there were substituted—
  - “(2) An inspector may serve a notice (in this Part referred to as “a prohibition notice”) on a person if, as regards any activities to which this paragraph applies, the inspector is of the opinion that, as carried on or likely to be carried on by or under the control of the person in question, the activities involve or, as the case may be, will involve—
    - (a) a risk; or
    - (b) a contravention of a relevant statutory provision.”
- (g) in Article 25, paragraphs (3), (4) and (5) were omitted
- (h) in Article 27A(1)—
  - (i) for “any enforcing authority or inspector”, there were substituted “the Health and Safety Executive for Northern Ireland”; and
  - (ii) for the “authority”, there were substituted “the Health and Safety Executive for Northern Ireland”;
- (i) for the title to Article 28, there were substituted “Power to indemnify its inspectors”;
- (j) in Article 28, for each of the following references there were substituted “the Health and Safety Executive for Northern Ireland”
  - (i) “the enforcing authority which appointed him”;
  - (ii) “that authority”; and
  - (iii) “the authority”;
- (k) in Article 29, paragraph (1)—
  - (i) sub-paragraph (b) were omitted; and
  - (ii) “or, as the case may be, to the enforcing authority in question” were omitted;
- (l) for Article 29A(2) substitute—
  - “(2) This paragraph applies to the Health and Safety Executive for Northern Ireland and to an inspector”;
- (m) in Article 30—
  - (i) in paragraph (3)(a), “or any enforcing authority” were omitted;
  - (ii) in paragraph (4)—
    - (aa) “or an enforcing authority” were omitted; and
    - (bb) “(including, in the case of an enforcing authority, any inspector appointed by it)” were omitted;
  - (iii) in paragraph (5)(a), “or the purposes of the enforcing authority in question in connection with the relevant statutory provisions” were omitted; and

- (iv) in paragraph 6—
  - (aa) “16(4)(a) or” were omitted; and
  - (bb) for paragraph (b), there were substituted—
    - “(b) for the purposes of any legal proceedings or for the purposes of a report of any such proceedings;”;
- (n) in Article 31—
  - (i) in paragraph (1), sub-paragraphs (a) to (i) and (k) to (m) were omitted;
  - (ii) for paragraph (2), there were substituted—
    - “(2) A person guilty of an offence under this Article is liable—
      - (a) on summary conviction, to a fine not exceeding the statutory maximum or to imprisonment for a term not exceeding three months or to both; and
      - (b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or to both.”;
  - (iii) paragraph (3) were omitted;
- (o) in Article 32—
  - (i) in paragraph (1)—
    - (aa) , sub-paragraphs (a) and (b) were omitted; and
    - (bb) for the words from “and it appears” to the end, there were substituted—
      - “and it appears from the investigation or from the proceedings at the inquest, that any of the relevant statutory provisions was contravened at a time which is material in relation to the subject-matter of the investigation, summary proceedings against any person liable to be proceeded against in respect of the contravention may be commenced at any time within three months of the conclusion of the investigation”; and
  - (ii) paragraphs (3) and (4) were omitted;
- (p) in Article 33, for “any enforcing authority”, there were substituted “the Health and Safety Executive for Northern Ireland”;
- (q) in Article 36, for “enforcing authority which appointed him” there were substituted “Health and Safety Executive for Northern Ireland”; and
- (r) in Article 39, paragraphs (3A), (4) and (5) were omitted.



## SCHEDULE 5

Regulation 53(2)

## COMPLIANCE, WITHDRAWAL AND RECALL NOTICES

**Compliance notice**

1.—(1) An enforcing authority may serve a compliance notice on a relevant economic operator in respect of a product if the authority has reasonable grounds for believing that there is non-compliance.

(2) A compliance notice shall—

(a) require the relevant economic operator on which it is served to—

(i) end the non-compliance within such period as may be specified in the notice; or

(ii) provide evidence, within such period as may be specified in the notice, demonstrating to the satisfaction of the enforcing authority that the non-compliance has not in fact occurred; and

(b) warn the economic operator that, if the non-compliance persists or if satisfactory evidence has not been produced under sub-paragraph (a) within the period specified in the notice, further action may be taken in respect of the product or any product of the same type made available on the market by that relevant economic operator.

(3) A compliance notice may include directions as to the measures to be taken by the economic operator to secure compliance, including different ways of securing compliance.

(4) Subject to sub-paragraph (5), an enforcing authority may revoke or vary a compliance notice by serving a notification on the economic operator.

(5) An enforcing authority may not vary a compliance notice so as to make it more restrictive for the economic operator or more onerous for the economic operator to comply.

**Withdrawal notice**

2.—(1) An enforcing authority may serve a withdrawal notice on a relevant economic operator in respect of a product if the authority has reasonable grounds for believing that—

(a) the product has been made available on the market; and

(b) there is non-compliance.

(2) A withdrawal notice shall prohibit the relevant economic operator from making the product available on the market without the consent of the enforcing authority.

(3) A withdrawal notice may require the relevant economic operator to take action to alert end-users to any risk presented by the product.

(4) A withdrawal notice may require the relevant economic operator to keep the enforcing authority informed of the whereabouts of any product referred to in the notice.

(5) A consent given by the enforcing authority pursuant to a withdrawal notice, may impose such conditions on the making available on the market as the enforcing authority considers appropriate.

(6) Subject to sub-paragraph (7), an enforcing authority may revoke or vary a withdrawal notice by serving a notification on the economic operator.

(7) An enforcing authority may not vary a withdrawal notice so as to make it more restrictive for the economic operator or more onerous for the economic operator to comply.

(8) A withdrawal notice has effect throughout the United Kingdom.

**Recall notice**

3.—(1) The enforcing authority may serve a recall notice on a relevant economic operator in respect of a product if the authority has reasonable grounds for believing that—

- (a) the product has been made available to end-users; and
- (b) there is non-compliance.

(2) A recall notice shall require the relevant economic operator to use reasonable endeavours to organise the return of the product from end-users to the relevant economic operator or another person specified in the notice.

(3) A recall notice may—

- (a) require the recall to be effected in accordance with a code of practice;
- (b) require the relevant economic operator to—
  - (i) contact end-users in order to inform them of the recall, to the extent that it is practicable to do so;
  - (ii) publish a notice in such form and such manner as is likely to bring to the attention of end-users any risk the product poses and the fact of the recall; or
  - (iii) make arrangements for the collection or return of the product from end-users or its disposal; or
- (c) impose such additional requirements on the relevant economic operator as are reasonable and practicable with a view to achieving the return of the product.

(4) In determining what requirements to include in a recall notice, the enforcing authority shall take into consideration the need to encourage distributors and end-users to contribute to its implementation.

(5) A recall notice may only be issued by the enforcing authority where—

- (a) other action which it may require under these Regulations would not suffice to address the non-compliance;
- (b) the action being undertaken by the relevant economic operator is unsatisfactory or insufficient to address the non-compliance;
- (c) the enforcing authority has given not less than 10 days' notice to the relevant economic operator of its intention to serve such a notice; and
- (d) the enforcing authority has taken account of any advice obtained under sub-paragraph (6).

(6) A relevant economic operator which has received notice from the enforcing authority of an intention to serve a recall notice may at any time prior to the service of the recall notice require the authority to seek the advice of such person as the Institute determines on the questions of—

- (a) whether there is non-compliance; and
- (b) whether the issue of a recall notice would be proportionate.

(7) Sub-paragraphs (5)(b), (c) and (d) do not apply in the case of a product presenting a serious risk requiring, in the view of the enforcing authority, urgent action.

(8) Where a relevant economic operator requires the enforcing authority to seek advice under sub-paragraph (6), that relevant economic operator is to be responsible for the fees, costs and expenses of the Institute and of the person appointed by the Institute to advise the enforcing authority.

(9) In this regulation, “Institute” means the charitable organisation with registered number 803725 and known as the Chartered Institute of Arbitrators.

(10) A recall notice served by the enforcing authority may require the relevant economic operator to keep the authority informed of the whereabouts of a product to which the recall notice relates, so far as the relevant economic operator is able to do so.

(11) Subject to sub-paragraph 12, an enforcing authority may revoke or vary a recall notice by serving notification on the economic operator.

(12) An enforcing authority may not vary a recall notice so as to make it more restrictive for the economic operator or more onerous for the economic operator to comply.

(13) A recall notice has effect throughout the United Kingdom.

**Interpretation**

4. In this Schedule, “non-compliance” means that the product—

- (a) presents a risk; or
- (b) is not in conformity with Part 2 or RAMS in its application to a product.

**SCHEDULE 6**

Regulation 40(b)

**EU DECLARATION OF CONFORMITY (No. XXXX)**

- 1.** Product model/product (product, type, batch or serial number):
- 2.** Name and address of manufacturer and, where applicable, his authorised representative:
- 3.** This declaration of conformity is issued under the sole responsibility of the manufacturer.
- 4.** Object of the declaration (identification of product allowing traceability; it may, where necessary for the identification of the product, include an image):
- 5.** The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:
- 6.** References to the relevant harmonised standards used or references to the other technical specifications in relation to which conformity is declared:
- 7.** Where applicable, the notified body...(name, number) performed...(description of intervention) and issued the certificate:
- 8.** Additional information:
  - Signed for on behalf of:
  
  - (place and date of issue):
  
  - (name, function) (signature):

SCHEDULE 7  
AMENDMENTS

Regulation 72(1)

<i>Column 1</i> <i>Title</i>	<i>Column 2</i> <i>Reference</i>	<i>Column 3</i> <i>Extent of amendment</i>
Electricity at Work Regulations (Northern Ireland) 1991	S.R. 1991 No. 13(a)	In regulation 19(2) for sub-paragraph (d) substitute— “(d) [ <b>wording to be drafted</b> ]”
Provision of Use at Work Equipment Regulations (Northern Ireland) 1999	S.R. 1999 No. 305(b)	In column (1) of Schedule 2 for “Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations (Northern Ireland) 1996” substitute “Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations (Northern Ireland) 2016”; and  In column (2) of Schedule 2 for “S.R. 1996 No. 247, amended by S.R. 1998 No. 77, S.R. 1999 No. 125 and S.R. 2008 No. 422” substitute “S.R. 2016 No. <b>XX</b> ”
Dangerous Substances and Explosive Atmospheres Regulations (Northern Ireland) 2003	S.R. 2003 No. 152(c)	In paragraph 1 of Schedule 3 for “Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations (Northern Ireland) 1996” substitute “Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations (Northern Ireland) 2016”

(a) S.R. 1991 No. 13, as amended by S.R. 1996 No. 247, S.R. 1998 No. 47, S.R. 1999 No. 150, S.R. 2000 No. 85 and S.R. 2006 No. 205

(b) S.R. 1999 No. 305, as amended by S.I. 1999/2001; S.R. 2000 No. 87; S.I. 2001/1701; S.R. 2003 No. 423; S.I. 2004/129; S.R. 2005 No. 279; S.R. 2005 No. 397; S.R. 2006 No. 1; S.R. 2007 No. 31; S.R. 2007 No. 291; S.R. 2008 No. 422; S.I. 2011/2157; S.R. 2012 No. 179; revoked in part by S.R. 2007 No. 291; S.R. 2015 No. 223

(c) S.R. 2003 No. 152, as amended by S.R. 2006 No. 173, S.R. 2010 No. 160, S.R. 2012 No. 177 and S.R. 2015 No. 265

**SCHEDULE 8**  
**REVOCATIONS**

Regulation 72(2)

<i>Column 1</i> <i>Title</i>	<i>Column 2</i> <i>Reference</i>	<i>Column 3</i> <i>Extent of revocation</i>
Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations (Northern Ireland) 1996	S.R. 1996 No. 247(a)	The whole Regulations
Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres (Amendment) Regulations (Northern Ireland) 1999	S.R. 1999 No. 125(b)	The whole Regulations
Electrical Equipment for Explosive Atmospheres (Certification) (Amendment) Regulations (Northern Ireland) 2000	S.R. 2000 No. 85(c)	The whole Regulations
Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres (Amendment) Regulations (Northern Ireland) 2008	S.R. 2008 No. 422(d)	The whole Regulations

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(a) S.R. 1996 No. 247, amended by S.R. 1998 No. 77, S.R. 1999 No. 125 and S.R. 2008 No. 422

(b) S.R. 1999 No. 125

(c) S.R. 2000 No. 85, revoked in part by S.R. 2008 No. 422

(d) S.R. 2008 No. 422

**EXPLANATORY NOTE**

*(This note is not part of the Regulations)*

**1.** These Regulations transpose Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (recast) (OJ L 96, 29.03.2014, p.309) (the Directive).

**2.** The Directive repeals and replaces Directive 1994/9/EC of the European Parliament and the Council of 23 March 1994 on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres (OJ L 100, 19.04.1994, p.1) which was implemented in the United Kingdom by the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations (Northern Ireland) 1996 (S.R. 1996 No. 247) (as amended) (“the 1996 Regulations”). These Regulations revoke and replace the 1996 Regulations.

**3.** Regulation 3 defines a “product” for use within potentially explosive atmospheres or for incorporation into equipment and protective systems. Regulation 4 provides an exception, allowing the use of a product which is not in conformity with Part 2, for the purposes of trade fairs, exhibitions and demonstrations.

**4.** Part 2 sets out the obligations of economic operators. Regulations 5 to 17 set out the obligations specific to manufacturers. These obligations include ensuring that a product has been designed and manufactured in accordance with the essential safety requirements set out in Schedule 1, taking action where products are not in conformity, having a relevant conformity assessment procedure carried out, affixing the CE marking, obligations to retain technical documentation, appointment of authorised representatives and product requirements.

**5.** Regulations 18 to 27 set out the obligations that are specific to importers. These obligations include ensuring that importers are not placing on the market products which are not in conformity with the essential safety requirements and taking action where they are not, checking that the manufacturer has carried out a relevant conformity assessment procedure and labelled the products correctly, ensuring storage and transport conditions do not jeopardise conformity with essential safety requirements and product monitoring obligations.

**6.** Regulations 28 to 33 set out the obligations that are specific to distributors. These obligations include acting with due care to ensure that the product is in conformity with Part 2 and taking action where it is not, checking that the product bears the CE marking, ensuring storage and transport conditions do not jeopardise conformity with essential safety requirements and checking that the products are labelled correctly.

**7.** Regulations 35 to 37 set out the obligations that manufacturers, importers and distributors have. These obligations include prohibitions on the improper use of the CE marking and a requirement to translate the declaration of conformity into the language required by the Member States within which it is made available.

**8.** Part 3 sets out provisions concerning the conformity assessment procedure, declarations of conformity and CE marking.

**9.** Part 4 sets out provisions concerning the bodies which carry out conformity assessment procedures.

**10.** Part 5 sets out provisions for market surveillance and enforcement. Regulation 51 identifies the market surveillance authority which has an obligation to enforce the Regulations in respect of the products. Regulation 53 and Schedules 4 and 5 provide for the enforcement powers which the enforcing authorities are to have. Regulation 61 provides for the contravention of provisions to be an offence. Regulation 62 sets out the penalties that are to apply for offences.

**11.** Part 6 sets out transitional provisions and consequential amendments. The 1996 Regulations will continue to apply to any products which are in conformity and placed on the market prior to the xx xxxxx 2016.

**12.** A transposition note and assessment of the impact that these Regulations will have on the costs to business is available from the Health and Safety Executive for Northern Ireland, 83 Ladas Drive, Belfast, BT6 9FR and are also published with the Explanatory Memorandum which is available alongside these Regulations at [www.legislation.gov.uk](http://www.legislation.gov.uk).

**13.** In Great Britain the corresponding Regulations are the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 2016 (S.I. 2016/??).



## INITIAL IMPACT ASSESSMENT FOR THE PROPOSALS FOR NEW EQUIPMENT AND PROTECTIVE SYSTEMS INTENDED FOR USE IN POTENTIALLY EXPLOSIVE ATMOSPHERES REGULATIONS (NORTHERN IRELAND) 2016 TO IMPLEMENT DIRECTIVE 2014/34/EU (THE ATEX DIRECTIVE)

1. This Impact Assessment (IA) draws on the contents of the IA published with the Consultative Document “*Alignment of Nine EU Single Market Directives with the New Legislative Framework: Consultation on UK Implementation*” issued by the Department for Business Innovation & Skills and the Health and Safety Executive in Great Britain, whose assistance is gratefully acknowledged.
2. That Great Britain IA<sup>1</sup> considers seven of the nine Directives under “overarching” headings. Much of this assessment, including the summaries of benefits and costs, refers to the overarching consideration of the effects of implementing these Directives in the alignment package, but HSENI is content that all of this consideration is directly applicable to the transposition of the ATEX Directive as part of that package.

### Problem under consideration

3. In 2006 the European Commission conducted a review of the way that the internal market for goods was working. The Commission found that harmonised legislation was not working effectively across and within EU Member States. They identified three main problems including (i) the number of products that were on the EU market that did not comply with product safety legislation; (ii) the unsatisfactory performance of some Notified Bodies (NBs - the bodies which determine whether a product meets the essential requirements of the legislation) and (iii) difficulties in using and understanding the current legislation. The Commission proposed a Decision in an attempt to improve this.
4. The New Legislative Framework (NLF) which resulted is a common set of principles which aims to make legislation on the Single Market for Goods clearer, more consistent and more understandable. It was adopted as an EU Regulation and an EU Decision in July 2008. Subsequently an “Alignment Package” was introduced to align nine existing European Union Directives to the NLF. These are:
  - Civil Explosives 2014/28 EU
  - Simple Pressure Vessels 2014/29 EU
  - Electromagnetic Compatibility 2014/30 EU
  - Non Automatic Weighing Instruments 2014/31 EU
  - Measuring Instruments 2014/32 EU
  - Lifts and their Safety Components 2014/33 EU
  - **Equipment for Use in Explosive Atmospheres (“ATEX”) 2014/34 EU**
  - Low Voltage 2014/35 EU

<sup>1</sup> [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/450592/BIS-15-469-IA-alignment-of-nine-EU-single-market-directives-with-the-new-legislative-framework.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/450592/BIS-15-469-IA-alignment-of-nine-EU-single-market-directives-with-the-new-legislative-framework.pdf)

- Pressure Equipment 2014/68/EU.
5. Of the nine Directives, five are of interest to HSENI – simple pressure vessels, lifts and their safety components, ATEX, low voltage and pressure equipment. However, current legislation relating to four of the five is made on a UK-wide basis, and it is proposed that new implementing Regulations will also be made on that basis.
  6. In the case of the ATEX Directive, current legislation is made separately by Great Britain and Northern Ireland and it is proposed that the new implementing Regulations will also be made separately.

### **Obligations imposed through the whole Alignment Package**

7. The details below set out the obligations imposed through the Alignment Package, however some of these obligations are not new. The table below is more explicit about existing obligations that are confirmed in the Alignment Package and obligations that are entirely new.

#### **Manufacturers**

- To provide instructions and safety information with a product in a language easily understood by consumers and end-users.
- To ensure that products bear the CE marking (which demonstrates conformity with the essential requirements of the Directive) and are accompanied by the required documents.
- To ensure that the name and address of the manufacturer is indicated on the product or its packaging.
- To carry out sample testing on products which they have supplied, when this is appropriate in the light of the risks presented by a product to the health and safety of consumers. If necessary, they must also keep a register of complaints, non-conforming products and product recalls and keep distributors informed about such monitoring.

#### **Importers**

- To keep a copy of the EU declaration of conformity and ensure that the technical documentation can be obtained when it is requested by authorities.
- To check that the manufacturer outside the EU has applied the correct conformity assessment procedure.
- To check that products bear the CE marking and are accompanied by the required documents.
- To ensure that the name and address of both the manufacturer and importer is indicated on the products or the packaging.
- To carry out sample testing and product monitoring as it applies to manufacturers.

### All Economic Operators (EOs): Manufacturers, Importers, Distributors

- Introduction of traceability requirements: ensure traceability of products throughout the whole distribution chain. Manufacturers and importers must put their contact details on the product or, where this is not possible, on the packaging or an accompanying document.
- Furthermore every economic operator must be able to inform the authorities of the economic operator from whom he purchased a product and to whom he supplied it.
- Reorganisation/streamlining of safeguard clause procedure (i.e. the procedure followed when a product is non-compliant and poses a risk): the new procedure ensures that the relevant enforcement authorities are informed about products which pose a risk and that similar action is taken against that product in all Member States.

### Measures intended to ensure the quality of the work performed by Notified Bodies (NBs)

- Reinforcement of the notification requirements for NBs: To be authorised to carry out conformity assessment activities under the Directives, NBs must satisfy certain requirements. All NBs must follow the work of notified body coordination groups and apply guidance developed by them. They must have procedures in place for risk-based assessments which take due account of the size of the enterprise and the degree of the complexity of the product assessed. Subcontractors and subsidiaries, which carry out parts of the conformity assessment, must also fulfil the notification criteria.
- Revised notification process: Member States notifying an organisation as a NB must include information on the valuation of competence of that body. Other Member States may object to the notification within a certain period. Where competence is demonstrated by an accreditation certificate, a facilitated procedure applies. Where Member States have not used accreditation to evaluate the body's competence, documentary evidence must be provided and the objection period is longer (at 2 months).
- Requirements for notifying authorities (i.e. the national authorities in charge of the assessment, notification and monitoring of NBs): Specific requirements and obligations for notifying authorities are introduced according to which they must be organised and operated so as to safeguard objectivity, impartiality and competence in carrying out their activity. Notifying authorities must de-notify bodies which no longer meet the notification requirements or fail to fulfil their obligations.
- Information and other obligations for NBs: NBs must inform notifying authorities about refusals, restrictions, suspensions and withdrawals of certificates and other NBs about negative conformity assessment results. They must perform conformity assessment in a proportionate manner taking due account of the size of an enterprise, the structure of a sector, the complexity of the product technology etc.

Measures intended to ensure more consistency among the Directives:

- Alignment of commonly used definitions and terminology: Definitions of common terms like “manufacturer”, “importer”, “placing on the market” are introduced into the Directive concerned. Existing conflicting definitions are removed.
- Alignment of the texts and certain elements of the conformity assessment procedures: The existing text of the modules in the Directives is aligned with the standard modules set out in Annex II to the NLF Decision.

**Rationale for intervention**

8. The purpose of the alignment is to make products in the EU safer, and to make the Single Market function more effectively, by making the relevant legislation easier for users to understand and apply. In order to meet our EU law obligations the Directive must be transposed into national law by April 2016.
9. This assessment relates solely to implementation of the ATEX Directive. We propose to transpose the requirements of that Directive by revoking and replacing the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations (Northern Ireland) 1996.

**Policy Objective**

10. The objective is to transpose the requirements of the ATEX Directive into Northern Ireland law. This will (i) ensure that the safety and economic benefits of clearer legislation, and improved traceability, reach NI consumers and workers; and (ii) ensure that products first placed on the market are compliant.

**Description of options**

11. We considered two possible options. It is not possible to do nothing as the UK has treaty obligations to implement the Directives; not transposing them would expose the UK to a high risk of infraction.

**Option 1 – make legislation to implement the Directive – PREFERRED**

12. We propose to implement the legislation by revoking and replacing the existing Regulations. This option would ensure that the Northern Ireland Regulations reflect the updated obligations and requirements.

**Option 2 – non-regulatory approach**

13. We considered a non-legislative approach and rejected it. This is because it would not meet the UK’s EU law obligations to implement Directives by binding measures of national law which provide for legal certainty.

## Monetised and non-monetised costs and benefits of options

### Option 1 – make legislation to implement the Directive

#### Benefits

Table: Short Summary of Key Benefits and Estimated Impact:

Change	Is this a new requirement?	Bodies affected	Estimated level of awareness of the change (High/Medium/Low)	Description of the benefit
Retention of information about other EOs in the supply chain – need to keep information for 10 years	<u>Partially.</u> EOs are already required to retain some information however the requirement will be broadened. In some cases the products concerned will have a life span of less than 10 years.	EOs Market Surveillance Authorities	<u>Medium.</u> Trade Associations, for example, will have made their members aware of the changes but there will inevitably be some who are unaware of their new obligations.	This should facilitate a more effective Market Surveillance regime as market surveillance authorities will have greater access to information about products. This should lead to a greater proportion of safe products on the market.  It should be noted, however, that where products have a life span of less than 10 years there is potential that EOs will be expected to retain information about products which are no longer on the market.
Reinforcement of notification requirements and exchange of information	<u>Partially.</u> NBs are already required to exchange information, however the obligation has been widened and so exchanges will need to be more frequent.	NBs	<u>Medium.</u> There is high awareness among UK NBs of the new Directive, however some may be less familiar with the detail than others.	Facilitated exchanges between NBs should make it easier to find information about conformity assessments and conformity assessed products. This should lead to a greater proportion of safe products on the market and may facilitate more effective competition in the Single Market.
Traceability requirements	<u>Partially.</u> Manufacturers and importers are already obliged to include identifying information on products but the amount required will increase	Manufacturers Importers Market Surveillance Authority	<u>Medium.</u> Trade Associations, for example, will have made their members aware of the changes but there will inevitably be some who are unaware of their new obligations.	Market Surveillance Authorities will find it easier to trace a product's origins and this will help them to determine whether or not a product is safe. It might also enable market surveillance activity to be more targeted and proportionate.
Post	<u>Partially.</u>	Manufacturers	<u>Medium.</u> Trade	Market Surveillance

marketing obligations (sample testing, keeping a register of complaints etc.)	Some bodies already have these systems in place however those who do not will need to establish them.	Importers Market Surveillance Authorities	Associations, for example, will have made their members aware of the changes but there will inevitably be some who are unaware of their new obligations.	Authorities will find it easier to trace a product's origins and this will help them to determine whether or not a product is safe. This will also assist with post-market surveillance
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### *Harmonised Legislative Environment*

14. The legislative environment in the EU is complex and inconsistent, with products often being regulated by several legal instruments with different objectives. They therefore often use different terminology. Manufacturers must currently comply with all of these requirements which means that they incur additional costs. The introduction of a set of common requirements will make it easier for all EOs to understand their obligations as these will not vary between Directives. Harmonising of duties of those in the supply chain across the Union will facilitate movement of goods in the internal market and level the playing field between manufacturers. This will have positive implications for competition.

### *Increased responsibility of importers*

15. Consumers will be better protected, as importers will have an increased role in ensuring that only safe products are placed on the market. Currently some importers rely on a general statement from the manufacturer that they have complied with their obligations. In future, importers will have a clearer list of the things that they need to check (e.g. that the product has been conformity assessed, bears the CE marking and is accompanied by the required documents) and will have some additional obligations (e.g. indicating their name and contact details on the product). This will make it easier for importers to know what they need to do and easier for market surveillance authorities to check compliance.

### *Declarations of Conformity*

16. Additional requirements in the Declaration of Conformity will lead to more effective enforcement, because they require an economic operator to provide more information about the product, which should in turn facilitate more effective market surveillance of products.

### *Notification process*

17. There could be marginal benefits to organisations wishing to become NBs as a result of a clearer explanation of the notification process that they will need to follow. This could, for example, decrease the administrative costs involved in the notification process.

*Enforcement*

18. Because fewer non-compliant products will be available on the market and because it will be easier for enforcers to identify and take action in respect of these products, it is likely that customers will be less likely to encounter products which are unsafe or potentially unsafe. This should reduce the number of complaints made to enforcers.
19. There are also indications that industry stakeholders anticipate the changes being beneficial by levelling the playing field between manufacturers (and especially with those importing from outside the EU) and between manufacturers and retailers of own-brand goods who would now also be covered by the legislation.

*Increased business and financial savings for NBs*

20. There may be financial savings and additional business for some NBs in the short term. Where products are certified by conformity assessment bodies, the requirements on those bodies will increase. This may generate a greater income for accreditation bodies in the short term, since there will be a significant number of new inspections/notifications to process. This gain is likely to be offset by the loss to companies of having to pay the fees.

*Traceability*

21. Clearer duties on operators throughout the supply chain (i.e. not just manufacturer/importer) may also bring some minor benefits in that the enforcement authority will be able to target more directly those infringing the requirements, and remove dangerous goods quickly and efficiently from the market.
22. There may be some financial savings in enforcement costs; improved traceability requirements and increased co-operation between NBs for articles placed on the market may reduce the amount of time that it takes to enforce the legislation.

Costs*Retention of information*

23. There will be a duty for all EOs to keep for 10 years information in relation to who supplied them with a product and to whom they have supplied a product. Some of the products may have a lifespan of less than ten years. The additional data collection and storage cost is expected to be marginal for many EOs given that much of it will be now stored electronically and many firms will already keep some records.

*Change of Directive number*

24. A new Directive number might lead to minor logistical difficulties and costs being incurred for manufacturers and NBs necessitating the re-drafting and re-issue of documents and manuals to include the revised number. Those involved in writing standards will also be involved in discussions on how the standards should cross-refer to legislation. There will be a transitional period before these requirements will come into operation hence any alterations could be incorporated more broadly into periodic updating. We do not expect the additional cost associated with the redrafting and reissue to be significant.

*Notification process*

25. NBs could be affected due to reinforcement of the notification requirements and information obligations – strengthened obligations on information sharing among NBs would lead to some increase in on-going costs – there are already some occasions when NBs are required to exchange information, but the obligation has been widened and so such exchanges will need to be more frequent. To date we have no indication that this will impose significant costs.

*Familiarisation costs*

26. Enforcers, industry and government will need to ensure that importers, manufacturers and distributors are aware of changes to legislation (for example in relation to withdrawal/recall, and the associated procedures) and this could lead to some one-off costs.

Table: Summary of key costs and estimated impact

<b>Change</b>	<b>Is this a new requirement?</b>	<b>Bodies affected</b>	<b>Estimated level of awareness of the change (High/Medium/Low)</b>	<b>Description of the cost</b>
Retention of information – need to keep information for 10 years	Partially. EOs are already required to retain some information however the requirement will be broadened. In some cases the products concerned will have a life span of less than 10 years.	EOs Market Surveillance Authorities	Medium. Trade Associations, for example, will have made their members aware of the changes but there will inevitably be some who are unaware of their new obligations.	The cost with collecting and retaining additional data is expected to be marginal.
Change of Directive number	<u>Yes</u>	All	High. The majority of bodies who this will affect have been aware of the forthcoming changes for some time, although there will be some bodies who are unaware of the change.	There will be low one-off costs in changing the Directive number on official documents.



Reinforcement of notification requirements and exchange of information	<u>Partially.</u> NBs are already required to exchange information, however the obligation has been widened and so exchanges will need to be more frequent.	NBs	<u>Medium.</u> There is high awareness among UK NBs of the new Directive, however some may be less familiar with the detail than others.	We do not expect this to be a significant cost. Exchanges between NBs already occur, although these will increase.
Traceability requirements	<u>Partially</u> Manufacturers and importers are already obliged to include identifying information on products but the amount required will increase	Manufacturers Importers Market Surveillance Authority	<u>Medium.</u> Trade Associations, for example, will have made their members aware of the changes but there will inevitably be some who are unaware of their new obligations.	We anticipate that the one-off costs of including this information might be high, however the cost in the longer term will be lower.
Post marketing obligations (sample testing, keeping a register of complaints etc.)	<u>Partially.</u> Some bodies already have these systems in place however those who don't will need to establish them.	Manufacturers Importers Market Surveillance Authorities	<u>Medium.</u> Trade Associations, for example, will have made their members aware of the changes but there will inevitably be some who are unaware of their new obligations.	42% of EOs and 23% of SMEs attribute no/no significant cost increase. 30% of EOs and 18% SMEs attribute a significant cost increase <sup>2</sup> .

### Comment

27. Many of the changes associated with the new Directive present both costs and benefits. For example, new traceability requirements and the need to retain documents for 10 years will inevitably lead to increased costs for specifically for manufacturers and also for other EOs in the supply chain. However, this should also lead to a more effective market surveillance regime, with market surveillance authorities being able to more efficiently check products. This should in turn lead to a greater proportion of safe products on the market.

### **Option 2 – non-regulatory approach**

#### Benefits

28. Nil.

#### Costs

29. This option would ignore the legal requirement for Member States to implement as set out in the Directive.

<sup>2</sup> European Commission Impact Assessment

## Risks and assumptions

30. We have assumed that industry is already keeping a certain amount of the new data required, e.g. site of manufacture of imported articles, and that they have efficient data retrieval systems. Industry has been aware of the alignment package for a number of years and so we expect the majority of them to have prepared for the changes. However, this is less likely to be the case for small or micro businesses so costs could be more than anticipated.

## Affected groups and size of industry

31. The Directive extends responsibilities to include all EOs in the supply chain.

32. NBs offer certification and approval services to their clients. They also vary widely in terms of their size. A Notified Body's capacity to respond to the changes presented by the new Directive can therefore vary widely.

33. NBs will be affected due to the reinforcement of the notification requirements, revised notification process, requirements for notifying authorities and information obligations. UK-wide 7 NBs will be affected by the ATEX Directive and colleagues in GB have advised that none of these are in Northern Ireland.

34. It is not possible to estimate the size of the ATEX sector as it isn't captured in official data – it will, for example, cover the adaptation of existing machinery for use in explosive atmospheres rather than the original machinery. The EU IA for the NLF estimated the industry's turnover, and, if apportioned on the basis of the UK population as a proportion of EU population turnover in the UK could be around £0.3 billion. If a similar apportionment is carried out for NI's population relative to that in the UK<sup>3</sup>, this would equate to an estimated figure of £8.4 million. It is estimated in the EU IA that approximately 90% of the companies in this sector are SMEs.

## Direct costs to business

35. Many of the direct costs to industry will arise from new labelling and data retention requirements. Rather than seeking to itemise these separately for each potential costs element, we have given an indication of costs and impact according to different elements of the supply chain.

36. New traceability requirements could increase operating costs and/or administrative burdens for manufacturers and importers as manufacturers' names, addresses as well as the products' identifying batches/serial numbers are required to be included on products. In addition an EO must keep records of the EO from whom he purchases a product and to whom he supplies a product. However, manufacturers are already obliged to include their name under the existing Directive. Some will already include identifying serial numbers of products also. Similar traceability requirements also exist in

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<sup>3</sup> Office for National Statistics overview of the UK population shows that Northern Ireland's population is 2.8% of the UK total.

respect of products that are also consumer products within scope of the General Product Safety Directive. The EU IA survey results suggest that 55% of general EOs believe that this will result in a moderate impact on costs, and that 1 – 5% expect a significant costs increase. These will mostly be one-off costs (the data retention costs and some traceability requirements will be on-going).

37. Post marketing obligations (e.g. sample testing, keeping register of complaints and defective products) will, if appropriate, need to be established if not already in place.
38. 42% of general EOs and 23% of SMEs attribute no/no significant cost increase to these elements whilst 30% of EOs and 18% of SME a significant increase. These will mostly be one-off costs<sup>4</sup>.
39. Of the EOs and SMEs who provided estimates of magnitude of increased costs, most EOs estimated the increase in cost up to 5% of current operating costs and SMEs estimated a 6 – 10% increase.<sup>5</sup>
40. A new Directive number might lead to costs being incurred for manufacturers and NBs necessitating the re-drafting and re-issue of documents to include the revised number. These costs will be one-off although for some companies a large number of documents might need to be updated.
41. We expect that strengthened obligations on information sharing among NBs (e.g. on withdrawn certificates etc.) will lead to some increase in on-going costs – there are already some occasions when NBs are required to exchange information, but the obligation has been widened and so such exchanges will need to be more frequent.
42. Enhanced traceability should enable enforcement authorities to identify the party at fault and thus avoid the costs above falling on others in the supply chain who were acting in good faith on information given by those responsible.

Table: Sector Definition and Industry Size

<b>Directive</b>	ATEX
<b>Examples of products</b>	Mechanical, electrical and telecommunication equipment, protective systems and devices, to be used in potentially explosive atmospheres
<b>Size of industry (EU market output)<sup>6</sup></b>	€2.2 billion
<b>Size of industry (UK) (GVA)</b>	£0.3 billion (estimate) <sup>7</sup> (around £8.4 million in Northern Ireland (estimate))
<b>Industry Structure in UK</b>	<i>A large number of SME and micro enterprises, around 90% of which are based in France, Germany and the UK</i>

<sup>4</sup> European Commission Impact Assessment

<sup>5</sup> European Commission Impact Assessment

<sup>6</sup> EU New Legislative Framework (NLF) Alignment Package Impact Assessment, 2011

<sup>7</sup> ABI (ONS, Annual Business Inquiry), 2009

<b>No. UK Businesses<sup>8</sup></b>	Not obtainable
<b>No. UK employees<sup>9</sup></b>	Not obtainable
<b>No. NBs (EU)<sup>10</sup></b>	55
<b>No. of NBs (UK)</b>	7

### Direct impacts on NBs

43. There could be marginal benefits to organisations wishing to become NBs from a clearer indication of the notification process. NBs that wish to become accredited to make conformity assessments under the new Directive will be charged a fee by the UK Accreditation Service (UKAS). There are 7 NBs for ATEX in the UK. We are not aware of any NBs in Northern Ireland.
44. If we assume that assessment under the new Directive is a simple process (as we anticipate, given that this is a simplification of legislation rather than legislation introducing many new requirements), an indicative cost to NBs might be calculated as follows (figures obtained from the United Kingdom Accreditation Service (UKAS)):
- Head Office visit = 2 days (1 day x 2 people) x £820 (standard assessment day rate) = £1640
  - Witnessed Assessment and cost of follow up = 1 day x £820 (standard assessment day rate) = £820
  - Total = £2460 per Notified Body
45. This figure does not include the cost of accreditation which would not be an extraordinary cost. The figure above is indicative as the number of Head Office visits, assessments and follow up work may vary. Bodies which wish to become accredited for the first time may be charged additional and optional fees for pre-assessment documentation reviews, at approximately £1080.
46. NBs may elect to recuperate the cost of accreditation through their charges to business.

### Direct benefits to business

47. There could be marginal benefits to organisations wishing to become NBs because the notification process will be easier to understand. Additionally some benefits are expected from clarifications and harmonisation of definitions across Member States, though it is not possible to quantify these.
48. Specifically addressing the duties of those in the supply chain across the European Union will facilitate market surveillance of goods in the internal market, with potential positive implications on competition for safe products as all in the supply chain will have duties of due diligence and responsibility for ensuring the product is in conformity.

<sup>8</sup> ABI, 2009

<sup>9</sup> ABI, 2009

<sup>10</sup> EU New Legislative Framework (NLF) Alignment Package Impact Assessment, 2011

49. Enhanced traceability should enable enforcement authorities to identify the party at fault and thus avoid these costs falling on others in the supply chain who were acting in good faith on information given by those responsible.
50. We expect that there will be some benefit from clarification and harmonisation of definitions and duties for business across Member States.

### Impact on enforcement bodies

51. The traceability obligations of the Directive will facilitate the identification of EOs having marketed non-compliant products. This may reduce the cost of investigations for enforcement bodies and we will seek to gain more information about this through the consultation.
52. Clearer duties on operators throughout the supply chain may also bring some minor cost benefits in that enforcement agencies will be able to target more directly those infringing the requirements.
53. Enforcement will be assisted by the obligation in most cases to use authorised NBs (NBs) to demonstrate compliance. Existing manufacturers that do not meet the new requirements will not be notified and will no longer be able to operate – this would mitigate against unfair competition.
54. There would be a moderate (temporary) increase in administrative burdens arising from the need to request new notifications and to produce updated evidence to show compliance with the new requirements (e.g. accreditation and/or other certificates showing professional qualifications). Accreditation is not mandatory but many NBs are already accredited.
55. Stronger cross-border co-operation will mean there will be information obligations (e.g. transmitting information from NBs on refusals, restrictions, suspensions and withdrawals of certificates, negative conformity assessment results). The strengthening of NB requirements is not expected to lead to any additional operating costs and/or administrative burdens on NBs that act in accordance with recognised professional standards.
56. There may be costs associated with updating the training of enforcement agency inspectors, although this would probably be included as part of a routine update, thus minimising costs.

### Wider impacts

57. Economic impacts: better functioning of the internal market, competitiveness of EU firms, and simplification of the existing regulatory environment. There are also potential cost savings from avoiding the cost of gathering information on the reliability of products supplied by importers/distributors and the cost of insurance to cover risks due to non-compliant products.

58. Social impacts: benefit to the health and safety of consumers and workers through reducing the number of non-compliant products on the market (via clear obligations for importers and distributors/market surveillance/traceability requirements).
59. Environmental impacts: reduction in the risk of environmentally unfriendly goods and prevention of accidents leading to environmental risks.

### Summary and preferred option

60. In summary we recommend Option 1: to make legislation to implement the Directives. This should help to make products safer by making the relevant legislation easier for users to understand and apply. It should make it easier to trace products throughout the supply chain and thereby improve market surveillance.
61. We anticipate that the overall costs and benefits will be modest given that this is an alignment of existing legislation rather than the introduction of many new requirements; the benefits are harder to quantify than the costs which are in part one-off costs arising from the need to adapt to the new requirements. However there is cautious optimism that the Directive will succeed in achieving the long term aim of improving the internal market in products through more effective market surveillance, better regulation of NBs and more effective legislative harmonisation.
62. We would implement by bringing in secondary legislation to revoke and replace the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations (Northern Ireland) 1996.
63. This would bring the clarity of a fresh set of easy to understand Regulations rather than introducing confusing amendments into the existing legislation. We believe that Industry is already aware of the requirements of the legislation and so should be prepared for implementation by 2016. Copy out will be used in transposing the Directive where possible, however it is anticipated that there may be cases where it will have to be departed from for reasons of legal certainty.
64. Comments on the conclusions reached in this assessment will be sought during the associated consultation exercise.

Health and Safety Executive for Northern Ireland  
March 2016

## DETI EQUALITY SCREENING FORM

### Part 1. Policy scoping

The first stage of the screening process involves scoping the policy under consideration. The purpose of policy scoping is to help prepare the background and context and set out the aims and objectives for the policy, being screened. At this stage, scoping the policy will help identify potential constraints as well as opportunities and will help the policy maker work through the screening process on a step by step basis.

Public authorities should remember that the Section 75 statutory duties apply to internal policies (relating to people who work for the authority), as well as external policies (relating to those who are, or could be, served by the authority).

### Information about the policy

Name of the policy

Proposals for New Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations (Northern Ireland) 2016 to Implement Directive 2014/34/EU (the ATEX Directive)

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Is this an existing, revised or a new policy?

Revised. The proposed Regulations revoke and replace the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations (Northern Ireland) 1996. Being the result of an alignment and a recast, the main changes in the new Directive (2014/34/EU) with respect to the previous Directive (94/9/EC) are quite limited, and do not concern the most substantial characteristics that remain the same.

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What is it trying to achieve? (intended aims/outcomes)

The objective is to transpose the requirements of the ATEX Directive into Northern Ireland law. This will (i) ensure that the safety and economic benefits of clearer legislation, and improved traceability, reach NI consumers and workers; and (ii) ensure that products first placed on the market are compliant.

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Are there any Section 75 categories which might be expected to benefit from the intended policy?

If so, explain how.

No. The provisions of the proposed Regulations will apply universally and are expected to benefit all Section 75 groups equally.

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Who initiated or wrote the policy?

European Directive 2014/34/EU provides for the policy changes to be made by all member states. HSENI is responsible for devising and delivering the proposals for the NI implementing legislation to DETI. If DETI accepts the proposals, it is responsible for enacting the legislation.

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Who owns and who implements the policy?

HSENI owns the policy and is responsible for the enforcement of the proposed Regulations in Northern Ireland.

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### **Implementation factors**

Are there any factors which could contribute to/detract from the intended aim/outcome of the policy/decision?

If yes, are they

- financial
- legislative
- other, please specify \_\_\_\_\_



## Main stakeholders affected

Who are the internal and external stakeholders (actual or potential) that the policy will impact upon?

- staff
- service users
- other public sector organisations
- voluntary/community/trade unions
- other, please specify – the proposed Regulations will apply to all equipment intended for use in potentially explosive atmospheres, whether electrical or mechanical, and also to protective systems. Economic operators (manufacturers, importers and distributors) in this sector will be affected. Notified bodies will also be affected due to reinforcement of the notification requirements, revised notification process, requirements for notifying authorities and information obligations.

## Other policies with a bearing on this policy

- what are they?

The European measures known as the New Legislative Framework (NLF) are due to be implemented throughout the UK.

- who owns them?

Department for Business Innovation & Skills

## Available evidence

Evidence to help inform the screening process may take many forms. Public authorities should ensure that their screening decision is informed by relevant data.

What evidence/information (both qualitative and quantitative) have you gathered to inform this policy? Specify details for each of the Section 75 categories.

<b>Section 75 category</b>	<b>Details of evidence/information</b>
Religious belief	It is not possible to estimate the size of the ATEX sector as it is not captured in official data. However, account has been taken of the 2006 European Commission review into the functioning of the internal market for goods and the European Union impact assessment for the NLF.
Political opinion	As above.
Racial group	As above.
Age	As above.
Marital status	As above.
Sexual orientation	As above.
Men and women generally	As above.
Disability	As above.
Dependants	As above.

## Needs, experiences and priorities

Taking into account the information referred to above, what are the different needs, experiences and priorities of each of the following categories, in relation to the particular policy/decision? Specify details for each of the Section 75 categories

Section 75 category	Details of needs/experiences/priorities
Religious belief	Not applicable. The proposals are specifically designed to implement the ATEX Directive in NI and will apply equally to all Section 75 categories.
Political opinion	As above.
Racial group	As above.
Age	As above.
Marital status	As above.
Sexual orientation	As above.
Men and women generally	As above.
Disability	As above.
Dependants	As above.

## Part 2. Screening questions

### Introduction

In making a decision as to whether or not there is a need to carry out an equality impact assessment, the public authority should consider its answers to the questions 1-4 detailed below.

If the public authority's conclusion is **none** in respect of all of the Section 75 equality of opportunity and/or good relations categories, then the public authority may decide to screen the policy out. If a policy is 'screened out' as having no relevance to equality of opportunity or good relations, a public authority should give details of the reasons for the decision taken.

If the public authority's conclusion is **major** in respect of one or more of the Section 75 equality of opportunity and/or good relations categories, then consideration should be given to subjecting the policy to the equality impact assessment procedure.

If the public authority's conclusion is **minor** in respect of one or more of the Section 75 equality categories and/or good relations categories, then consideration should still be given to proceeding with an equality impact assessment, or to:

- measures to mitigate the adverse impact; or
- the introduction of an alternative policy to better promote equality of opportunity and/or good relations.

### In favour of a 'major' impact

- a) The policy is significant in terms of its strategic importance;
- b) Potential equality impacts are unknown, because, for example, there is insufficient data upon which to make an assessment or because they are complex, and it would be appropriate to conduct an equality impact assessment in order to better assess them;
- c) Potential equality and/or good relations impacts are likely to be adverse or are likely to be experienced disproportionately by groups of people including those who are marginalised or disadvantaged;

- d) Further assessment offers a valuable way to examine the evidence and develop recommendations in respect of a policy about which there are concerns amongst affected individuals and representative groups, for example in respect of multiple identities;
- e) The policy is likely to be challenged by way of judicial review;
- f) The policy is significant in terms of expenditure.

### **In favour of 'minor' impact**

- a) The policy is not unlawfully discriminatory and any residual potential impacts on people are judged to be negligible;
- b) The policy, or certain proposals within it, are potentially unlawfully discriminatory, but this possibility can readily and easily be eliminated by making appropriate changes to the policy or by adopting appropriate mitigating measures;
- c) Any asymmetrical equality impacts caused by the policy are intentional because they are specifically designed to promote equality of opportunity for particular groups of disadvantaged people;
- d) By amending the policy there are better opportunities to better promote equality of opportunity and/or good relations.

### **In favour of none**

- a) The policy has no relevance to equality of opportunity or good relations.
- b) The policy is purely technical in nature and will have no bearing in terms of its likely impact on equality of opportunity or good relations for people within the equality and good relations categories.

Taking into account the evidence presented above, consider and comment on the likely impact on equality of opportunity and good relations for those affected by this policy, in any way, for each of the equality and good relations categories, by applying the screening questions detailed below and indicate the level of impact on the group i.e. minor, major or none.

## Screening questions

1 What is the likely impact on equality of opportunity for those affected by this policy, for each of the Section 75 equality categories? minor/major/none		
Section 75 category	Details of policy impact	Level of impact? minor/major/none
Religious belief	No impact on equality of opportunity. The proposals are specifically designed to implement the ATEX Directive in Northern Ireland and will apply equally to all Section 75 categories.	None
Political opinion	As above.	None
Racial group	As above.	None
Age	As above.	None
Marital status	As above.	None
Sexual orientation	As above.	None
Men and women generally	As above.	None
Disability	As above.	None
Dependants	As above.	None

2 Are there opportunities to better promote equality of opportunity for people within the Section 75 equalities categories?		
Section 75 category	If <b>Yes</b> , provide details	If <b>No</b> , provide reasons
Religious belief		Implementation of the ATEX Directive will apply equally to all categories and consequently there is no opportunity to promote equality of opportunity.
Political opinion		As above.
Racial group		As above.
Age		As above.
Marital status		As above.
Sexual orientation		As above.
Men and women generally		As above.
Disability		As above.
Dependants		As above.

3 To what extent is the policy likely to impact on good relations between people of different religious belief, political opinion or racial group?		
Section 75 category	Details of policy impact	Level of impact minor/major/none
Religious belief	The proposals are specifically designed to implement the ATEX Directive in Northern Ireland and will not impact on good relations.	None
Political opinion	As above.	None
Racial group	As above.	None



4 Are there opportunities to better promote good relations between people of different religious belief, political opinion or racial group?		
Good relations category	If <b>Yes</b> , provide details	If <b>No</b> , provide reasons The implementation of the ATEX Directive will apply equally to all categories and consequently the changes will not contribute to or detract from the promotion of good relations.
Religious belief		As above.
Political opinion		As above.
Racial group		As above.

### Additional considerations

#### Multiple identity

Generally speaking, people can fall into more than one Section 75 category. Taking this into consideration, are there any potential impacts of the policy/decision on people with multiple identities? *(For example; disabled minority ethnic people; disabled women; young Protestant men; and young lesbians, gay and bisexual people).*

Provide details of data on the impact of the policy on people with multiple identities. Specify relevant Section 75 categories concerned.

The policy has been designed to implement a European Directive into Northern Ireland law. This will (i) ensure that the safety and economic benefits of clearer legislation, and improved traceability, reach NI consumers and workers; and (ii) ensure that products first placed on the market are compliant.

It will apply equally to all of the Section 75 Groups and there is no evidence to suggest that people with multiple identities will be adversely affected.

### Part 3. Screening decision

If the decision is not to conduct an equality impact assessment, please provide details of the reasons.

The policy change is necessary to transpose a European Directive into Northern Ireland law. It will apply equally to all businesses to which the proposed Regulations apply. There is no evidence to suggest that any Section 75 group will be adversely affected by the proposals.

If the decision is not to conduct an equality impact assessment the public authority should consider if the policy should be mitigated or an alternative policy be introduced.

An alternative policy is not available as Northern Ireland is obliged to meet European obligations.

If the decision is to subject the policy to an equality impact assessment, please provide details of the reasons.

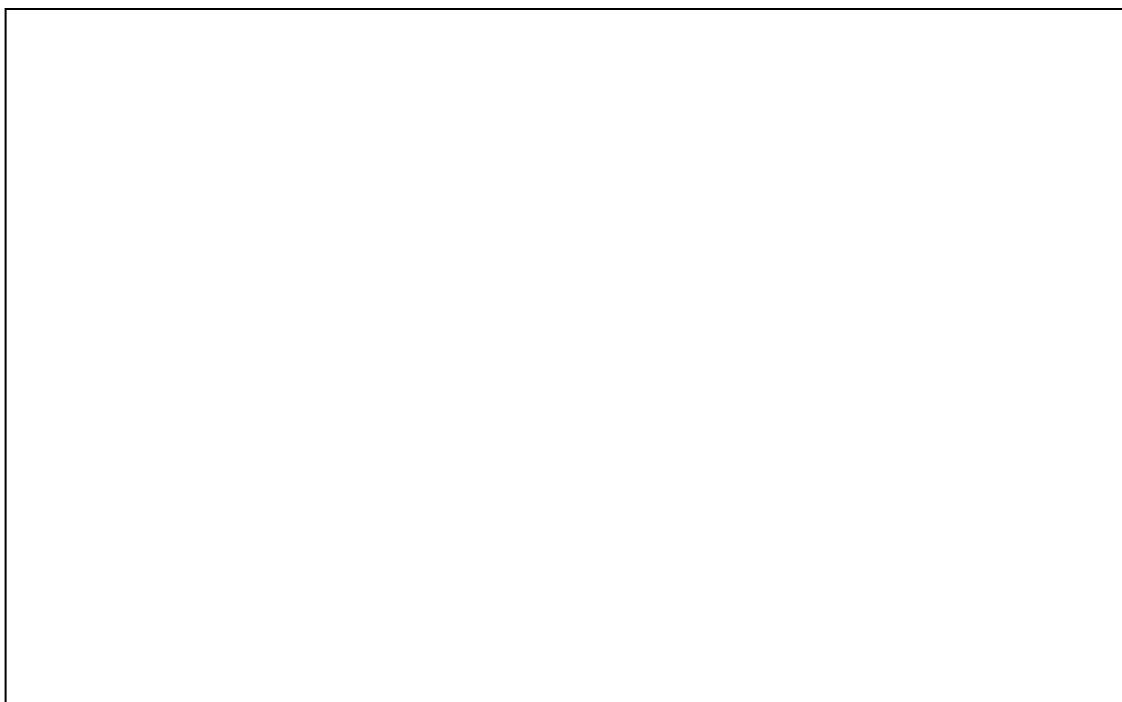
All public authorities' equality schemes must state the authority's arrangements for assessing and consulting on the likely impact of policies adopted or proposed to be adopted by the authority on the promotion of equality of opportunity. The Commission recommends screening and equality impact assessment as the tools to be utilised for such assessments. Further advice on equality impact assessment may be found in a separate Commission publication: Practical Guidance on Equality Impact Assessment.

## Mitigation

When the public authority concludes that the likely impact is 'minor' and an equality impact assessment is not to be conducted, the public authority may consider mitigation to lessen the severity of any equality impact, or the introduction of an alternative policy to better promote equality of opportunity or good relations.

Can the policy/decision be amended or changed or an alternative policy introduced to better promote equality of opportunity and/or good relations?

If so, give the **reasons** to support your decision, together with the proposed changes/amendments or alternative policy.

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## Timetabling and prioritising

Factors to be considered in timetabling and prioritising policies for equality impact assessment.

If the policy has been '**screened in**' for equality impact assessment, then please answer the following questions to determine its priority for timetabling the equality impact assessment.

On a scale of 1-3, with 1 being the lowest priority and 3 being the highest, assess the policy in terms of its priority for equality impact assessment.

Priority criterion	Rating (1-3)
Effect on equality of opportunity and good relations	
Social need	
Effect on people's daily lives	
Relevance to a public authority's functions	

Note: The Total Rating Score should be used to prioritise the policy in rank order with other policies screened in for equality impact assessment. This list of priorities will assist the public authority in timetabling. Details of the Public Authority's Equality Impact Assessment Timetable should be included in the quarterly Screening Report.

Is the policy affected by timetables established by other relevant public authorities?

If yes, please provide details

## Part 4. Monitoring

Public authorities should consider the guidance contained in the Commission's Monitoring Guidance for Use by Public Authorities (July 2007).

The Commission recommends that where the policy has been amended or an alternative policy introduced, the public authority should monitor more broadly than for adverse impact (See Benefits, P.9-10, paras 2.13 – 2.20 of the Monitoring Guidance).

Effective monitoring will help the public authority identify any future adverse impact arising from the policy which may lead the public authority to conduct an equality impact assessment, as well as help with future planning and policy development.

## Part 5. Disability Duties

Under the Disability Discrimination Act 1995 (as amended by the Disability Discrimination (Northern Ireland) Order 2006), public authorities, when exercising their functions, are required to have due regard to the need:

- **to promote positive attitudes towards disabled people; and**
- **to encourage participation by disabled people in public life.**

5. Does this policy/legislation have any potential to contribute towards promoting positive attitudes towards disabled people or towards encouraging participation by disabled people in public life? If yes, please give brief details.

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**Name of Consultees**

Action on Hearing Loss  
 Advice NI  
 AES  
 Age NI  
 Age Sector Platform  
 Agency for the Legal Deposit Libraries  
 Alliance Party  
 Allpipe Engineering Ltd.  
 An Munia Tober  
 Archbishop of Armagh and Primate of all Ireland  
 Ards Business Centre Ltd.  
 Argyle Business Centre Ltd.  
 Armagh Business Centre Ltd.  
 Aspergers Network  
 Attorney General (NI)  
 Autism Northern Ireland  
 Ballymena Business Centre Ltd.  
 Banbridge Enterprise Centre  
 Bar Council  
 Belfast Centre for the Unemployed  
 Belfast City Centre Management  
 Belfast Harbour Commissioners  
 Belfast Health and Social Care Trust  
 Belfast Hebrew Congregation  
 Belfast Islamic Centre  
 Belfast Solicitors Association  
 Bishop of Down and Connor  
 Board of Deputies of British Jews  
 BOC  
 Bombardier  
 British Deaf Association  
 British Library – Legal Deposit Office  
 Bryson House  
 BSC and Electric Ireland  
 Buildhealth NI  
 Business in the Community  
 Calor Gas (NI) Ltd.  
 Cancer Focus Northern Ireland  
 Cara-Friend  
 Carers NI  
 Carrickfergus Enterprise Agency Ltd.  
 Catholic Bishops of Northern Ireland  
 Causeway Enterprise Agency Ltd.  
 Cedar Foundation  
 Central Services Agency  
 Chartered Institute of Environmental Health NI  
 Chemical Business Association  
 Chief Constable Police Service of Northern Ireland

Children in Northern Ireland  
Children's Law Centre  
Chinese Chamber of Commerce  
Chinese Welfare Association  
Civil Law Reform Division  
Civil Service Occupational Health Service  
Commission for Victims and Survivors  
Commissioner for Older People Northern Ireland  
Committee on the Administration of Justice  
Communication Access  
Community Foundation for Northern Ireland  
Community Relations Council  
Construction Employers' Federation  
Construction Industry Training Board NI  
Cookstown Enterprise Centre Ltd.  
Co-Operation Ireland  
Council for Catholic Maintained Schools  
Countryside Services Ltd.  
Courts and Tribunal Service  
Creggan Enterprises Ltd.  
Democratic Unionist Party  
Disability Action  
District Councils  
Driver and Vehicle Testing Agency  
Du Pont (UK) Industrial Ltd.  
Dungannon Enterprise Centre Ltd.  
East Belfast Community Development Agency  
East Belfast Enterprise Park Ltd.  
East Belfast Partnership Board  
Eastern Group Environmental Health Committee  
Education Authority  
Employers For Disability NI  
Engineering Employers' Federation NI (EEF)  
Equality Coalition  
Equality Commission  
Executive Council of the Inn of Court of NI  
Falls Community Council  
Federation of Small Businesses  
Fermanagh Enterprise Ltd.  
Fire Brigades Union  
Food Standards Agency Northern Ireland  
Forensic Science Agency of Northern Ireland  
Foyle Women's Information Network  
Freight Transport Association  
General Consumer Council for Northern Ireland  
Gingerbread Northern Ireland  
GMB  
Gray & Adams (Ireland) Ltd  
Greater Shankill Partnership



Green Party  
Harland and Wolff Heavy Industries Ltd.  
Health and Safety Executive  
Health and Social Care Board HQ  
Heron Brothers Ltd.  
HM Council of County Court Judges  
HM Revenue and Customers  
Home Retail Group  
Inclusive Mobility and Transport Advisory Committee (IMTAC)  
INCORE Conflict Resolutions Ltd.  
Indian Community Centre  
Independent Political Parties  
Information Commissioner's Office  
Institute of Directors  
Institute of Directors (NI Division)  
Invest NI  
Irish National Teachers' Organisation (INTO)  
Judge G Conner  
Justice for Asbestos Victims  
Kesh Development Association Charitable Trust  
Labour Party  
Labour Relations Agency  
Larne Development Forum  
Law Centre (NI)  
Law Society of Northern Ireland  
Lonmin (NI) Ltd  
Lord Chief Justice Office  
Mallusk Enterprise Park  
Maritime and Coastguard Agency  
McAlorum Construction Ltd.  
McClay Library, QUB  
MENCAP  
Methodist Church in Ireland  
Mindwise  
Ministry of Defence  
MPs & MEPs (NI)  
Mr Sam McKane  
Musicians Union  
Mutual Energy Ltd.  
National Collection of NI Publications  
National Library of Ireland  
Newry and Mourne Enterprise Agency  
NI21  
North Belfast Partnership  
North City Business Centre Ltd.  
North Down Development Organisation Ltd.  
North / South Ministerial Council  
North West Community Network  
Northern Group  
Northern Health and Social Care Trust

Northern Ireland Assembly Library  
Northern Ireland Assembly Members  
Northern Ireland Assembly – The Speaker  
Northern Ireland Association for Mental Health  
Northern Ireland Association for the Care and Resettlement of Offenders  
Northern Ireland Audit Office  
Northern Ireland Authority for Utility Regulation  
Northern Ireland Association of Citizens Advice Bureaux  
Northern Ireland Centre for Competitiveness  
Northern Ireland Chamber of Commerce  
Northern Ireland Chamber of Trade  
Northern Ireland Commissioner for Children and Young People  
Northern Ireland Committee/Irish Congress of Trade Unions  
Northern Ireland Conservative Association  
Northern Ireland Council for Ethnic Minorities  
Northern Ireland Council for Voluntary Action  
Northern Ireland Court Service  
Northern Ireland Electricity  
Northern Ireland Environment Link  
Northern Ireland Fire and Rescue Service  
Northern Ireland Gay Rights Association  
Northern Ireland Housing Executive  
Northern Ireland Human Rights Commission  
Northern Ireland Judicial Appointments Commission  
Northern Ireland Law Commission  
Northern Ireland Local Government Association (NILGA)  
Northern Ireland Prison Service  
Northern Ireland Public Service Alliance (NIPSA)  
Northern Ireland Public Services Ombudsperson’s Office (NIPSO)  
Northern Ireland Safety Group (NISG)  
Northern Ireland Statistics and Research Agency (NISRA)  
Northern Ireland Tourist Board  
Northern Ireland Women's European Platform  
NSPCC, Northern Ireland Regional Office  
NUS/USI  
NW Community Network  
Occupational Health Service  
Office of Industrial Tribunals  
Omagh Enterprise Co. Ltd.  
Ormeau Enterprises Ltd.  
Participation the Practice of Rights Project  
Pharmaceutical Society of Northern Ireland  
POBAL  
Police Federation for Northern Ireland  
Police Service of Northern Ireland  
Presbyterian Church in Ireland  
Prince's Trust  
Progressive Unionist Party  
Prospect  
Quarry Products Association NI

Queen's University  
 Roads Service  
 Roman Catholic Church  
 Roy Coulter Consulting Ltd.  
 Royal College of Midwives  
 Royal Institution of Chartered Surveyors (RICS)  
 Royal National Institute for the Blind (NI)  
 Rural Community Network  
 Rural Development Council  
 St. John Ambulance NI  
 Scotia Gas Networks (SGN)  
 SDLP  
 Seagate Technology (Ireland)  
 Sense NI  
 Services Industrial Professional Technical Union (SIPTU)  
 Sinn Fein  
 Social Security Agency  
 Society of Local Authority Chief Executives  
 South Belfast Partnership Board  
 South Eastern Health and Social Care Trust  
 South West Fermanagh Development Organisation Ltd.  
 Southern Group Environmental Health Committee  
 Southern Health and Social Care Trust  
 SSE Airtricity Energy Supply (NI) Ltd  
 Strabane Industrial Properties Ltd.  
 Tennants Textile Colours Ltd.  
 Townsend Enterprise Park Ltd.  
 Traditional Unionist Voice  
 Training for Women Network Ltd.  
 Translink  
 Transport Salaried Staff Association  
 UK Independence Party  
 UK National Committee of UN Women  
 Ulster Farmers' Union  
 Ulster Scots Community Network  
 Ulster Teachers' Union  
 Ulster Unionist Party  
 Union of Construction, Allied Trades and Technicians (UCATT)  
 Union of Shop, Distributive and Allied Workers (USDAW)  
 UNISON (Northern Ireland)  
 Unite the Union  
 University of Ulster  
 Volunteer Centre  
 Volunteer Now  
 Visual Access NI (Braille, Audio and DAISY)  
 Water Service  
 West Belfast Development Trust Ltd.  
 West Belfast Partnership Board  
 Western Group Environmental Service  
 Western Health and Social Care Trust

Westlink Enterprise Ltd.  
William Keown Trust  
Women's Forum NI  
Women's Information NI  
Women's Resource and Development Agency  
Women's Support Network  
Women's Training, Enterprise and Childcare  
Workers' Party  
Workspace