STATUTORY INSTRUMENTS

2016 No. 1107

The Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 2016

PART 5

Market surveillance and enforcement

Designation of market surveillance authority

- **51.**—(1) Save where paragraph (2) applies, the market surveillance authority in Great Britain for a product is the Health and Safety Executive.
- (2) The market surveillance authority in Great Britain for a product is the Office for Nuclear Regulation, in so far as these Regulations apply to—
 - (a) any person who places on the market or supplies a product intended exclusively or primarily for use on a GB nuclear site;
 - (b) any person who puts into service a product on a relevant nuclear site.
 - (3) In paragraph (2), "relevant nuclear site" means a site which is—
 - (a) a GB nuclear site;
 - (b) an authorised defence site (within the meaning given in regulation 2(1) of the Health and Safety (Enforcing Authority) Regulations 1998);
 - (c) a new nuclear build site (within the meaning given in regulation 2A of the Health and Safety (Enforcing Authority) Regulations 1998).
- (4) In paragraphs (2) and (3), "GB nuclear site" means a nuclear site in Great Britain (within the meaning given in section 68 of the Energy Act 2013(1)).

Enforcement

- **52.**—(1) The market surveillance authority must enforce these Regulations and RAMS in its application to a product.
 - (2) In Scotland, only the Lord Advocate may prosecute an offence under these Regulations.

Enforcement powers

- **53.**—(1) Schedule 4 (enforcement powers of the Health and Safety Executive and the Office for Nuclear Regulation under the 1974 Act) is to have effect.
- (2) In addition to the powers available to the market surveillance authority under paragraph (1), 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 must 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 must carry out an evaluation in relation to the product covering the relevant requirements of Part 2.

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 must, without delay, require a relevant economic operator to—
 - (a) take appropriate corrective action 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 must 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 market surveillance authority considers that the lack of conformity referred to in paragraph (1) is not restricted to Great Britain, it must notify the Secretary of State of—
 - (a) the results of the evaluation, and
 - (b) the actions which it has required the economic operator to take.
- (4) Where the Secretary of State receives a notice under paragraph (3), or otherwise considers that the lack of conformity referred to in paragraph (1) is not restricted to Great Britain, the Secretary of State must inform the European Commission, Northern Ireland 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.
- (5) Where the relevant economic operator does not take adequate corrective action within the prescribed period, the market surveillance authority must take appropriate measures to—
 - (a) prohibit or restrict the product being made available on the market in Great Britain,

- (b) withdraw the product from the market in Great Britain, or
- (c) recall the product.
- (6) Where the market surveillance authority takes measures under paragraph (5), it must notify the Secretary of State of those measures without delay.
- (7) Where the Secretary of State receives a notice under paragraph (6), the Secretary of State must notify the European Commission, Northern Ireland and the other Member States of those measures without delay.
- (8) The notices in paragraphs (6) and (7) must 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.
 - (9) In this regulation, "prescribed period" means a period which is—
 - (a) prescribed by the market surveillance authority;
 - (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 market surveillance authority must, without delay, inform the Secretary of State 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.
- (2) Where another Member State has initiated the procedure under Article 35 of the ATEX Directive (as amended from time to time), the Secretary of State must, 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;
 - (c) any objections that the Secretary of State may have to the measure taken by the Member State initiating the procedure.
- (3) 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 must ensure that appropriate measures, such as withdrawal, are taken in respect of the product without delay.
- (4) 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 must take the necessary measures to ensure that the product is withdrawn from the market in Great Britain.

- (5) Where the market surveillance authority has taken action under paragraphs (3) or (4), it must inform the Secretary of State.
- (6) Where the Secretary of State receives a notice under paragraph (5), the Secretary of State must inform the European Commission of the action taken.
- (7) 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 must 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 must 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), it must notify the Secretary of State immediately.
- (3) Where the Secretary of State receives a notice under paragraph (2), the Secretary of State must notify the European Commission and the other Member States immediately.
- (4) The notices referred to in paragraphs (2) and (3) must 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;
 - (d) the nature and duration of the measures taken by the market surveillance authority.
 - (5) In this regulation, "prescribed period" means a period which is—
 - (a) prescribed by the market surveillance authority;
 - (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 the market surveillance authority makes one of the following findings relating to a product, it must 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;
 - (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;
 - (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;
 - (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 not been affixed or has been affixed otherwise than in accordance with paragraph 5 of Schedule 1—
 - (i) specific marking of explosion protection in accordance with paragraph 5(1)(f) of Schedule 1;
 - (ii) the symbols of the equipment-group and category in accordance with paragraph 5(1) (g) of Schedule 1;
 - (iii) where applicable, the other markings and information required by paragraph 5(1) of Schedule 1;
- (f) 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);
- (g) any other administrative requirement imposed on the manufacturer or importer under Part 2 has not been fulfilled.
- (2) The market surveillance authority must 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 market surveillance authority must 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 must 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 a person to contravene or fail to comply with any requirement of regulations 5 to 15, 16(2), 18 to 25, 26(2), 27 to 32, 33(2), 35 or 36.
- (2) It is an offence for any person to contravene or fail to comply with any requirement of a withdrawal or recall notice served on that person by the market surveillance authority under these Regulations.

Penalties

- **62.** A person guilty of an offence under regulation 61 is liable—
 - (a) on summary conviction—
 - (i) in England and Wales, to a fine or imprisonment for a term not exceeding 3 months or to both;
 - (ii) in Scotland, to a fine not exceeding the statutory maximum or imprisonment for a term not exceeding 3 months, or to both;
 - (b) on conviction on indictment, to a fine or imprisonment for a term not exceeding 2 years or to both.

Defence of due diligence

- **63.**—(1) Subject to paragraphs (2) and (4), 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 must—
 - (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 7 clear days before—
 - (i) in England and Wales, the hearing of the proceedings;
 - (ii) in Scotland, the trial diet.
- (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 to—
 - (a) the steps that P took, and those which might reasonably have been taken, for the purpose of verifying the information, and
 - (b) 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.

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 any of the following—
 - (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;
 - (c) in relation to a Scottish partnership, a partner;
 - (d) a person purporting to act as a person described in sub-paragraphs (a), (b) or (c).

Time limit for prosecution of offences

- **65.**—(1) Subject to paragraph (3), in England and Wales, information relating to an offence under regulation 61 that is triable by a magistrates' court may be so tried if it is laid within 12 months after the date on which evidence which is sufficient in the opinion of the prosecutor to justify the proceedings comes to the knowledge of the prosecutor.
 - (2) Subject to paragraph (3), in Scotland—
 - (a) summary proceedings for an offence under regulation 61 may be commenced before the end of 12 months after the date on which evidence which is sufficient in the Lord Advocate's opinion to justify the proceedings came to the Lord Advocate's knowledge;
 - (b) section 136(3) of the Criminal Procedure (Scotland) Act 1995 (time limit for certain offences) applies for the purpose of this paragraph as it applies for the purpose of that section.
 - (3) No proceedings may be brought more than 3 years after the commission of the offence.
- (4) For the purposes of this regulation a certificate of the prosecutor (or in Scotland, the Lord Advocate) as to the date on which the evidence referred to paragraphs (1) and (2) came to light, is conclusive evidence.
- (5) This regulation has effect subject to paragraphs 1(n) and 2(o) of Schedule 4 (enforcement powers of the Health and Safety Executive and the Office for Nuclear Regulation under the 1974 Act).

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;
 - (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;
- (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 must also be treated as that person's proper address.
 - (6) In this regulation, "partnership" includes a Scottish partnership.

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 market surveillance authority for any expenditure which the market surveillance authority has incurred in investigating the offence.

Action by the market surveillance authority

- **68.**—(1) The market surveillance 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 market surveillance 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 market surveillance 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 market surveillance authority in taking the action.
- (3) A civil debt recoverable under paragraph (2) may be recovered summarily in England and Wales by way of a complaint pursuant to section 58 of the Magistrates' Courts Act 1980(2).

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;
 - (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 must 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—
 - (a) that the product to which the notice relates is in conformity with Part 2 and does not present a risk;, or
 - (b) that the market surveillance authority failed to comply with regulation 54 (exercise of enforcement powers) when serving 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);
 - (b) "notice" means any of the following—
 - (i) a notice to warn served in accordance with Schedule 4 (enforcement powers of the Health and Safety Executive and the Office for Nuclear Regulation under the 1974 Act):
 - (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) In England and Wales, 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 employment 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 Health and Safety Executive and the Office for Nuclear Regulation under the 1974 Act), or
 - (c) in any other case, a magistrates' court.
- (2) In Scotland, the appropriate court for the purposes of regulation 69 is—
 - (a) the sheriff of a sheriffdom in which the person making the appeal resides or has a registered or principal office, or
 - (b) an employment 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 Health and Safety Executive and the Office for Nuclear Regulation under the 1974 Act).
- (3) A person aggrieved by an order made by a magistrates' court in England and Wales 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 in England and Wales, to the Crown Court.