

2016 No.

HEALTH AND SAFETY

**The Explosives Regulations 2014 (Amendments) Regulations
2016**

(Notified Body Provisions Only)

<i>Made</i>	- - - -	***
<i>Laid before Parliament</i>		***
<i>Coming into force</i>	- -	20th April 2016

The Secretary of State makes these Regulations in exercise of powers conferred by the Health and Safety at Work etc Act 1974 and the European Communities Act 1972

Citation, commencement and extent

1. These Regulations may be cited as the Explosives Regulations 2014 (Amendments) Regulations 2016.

Amendments to the Explosives Regulations

2.—(1) The Explosives Regulations 2014 are amended as follows;

(2) In Regulation 2(1), after the definition of “the Commission” insert—

““conformity assessment” means the process of demonstrating whether the essential safety requirements relating to an explosive have been fulfilled;

“conformity assessment body” means a person that performs conformity assessment activities;

“the Directive” means Directive 2014/28/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 the making available on the market and supervision of explosives for civil uses (recast);

“essential safety requirements” means the requirements set out in Schedule 2 (essential safety requirements);

“harmonised standard” has the meaning set out in point 1(c) of Article 2 of Regulation (EU) 1025/2012 of the European Parliament and of the Council on European standardisation (as amended from time to time);

“notified body requirements” means the requirements set out in Schedule 15 (notified body requirements);

“relevant conformity assessment procedure” means a conformity assessment procedure referred to in regulation 40 (conformity assessment procedures);”

(3) For Regulation 41 of the Explosives Regulations 2014 substitute—

“Notified bodies

41. (1) For the purposes of this Part, a notified body is a conformity assessment body which –

- (a) has been notified to the European Commission and to the other member States under regulation 43, and where
- (b) no objections are raised by the European Commission or the other member States—
 - (i) within two weeks of a notification, where an accreditation certificate is used; or
 - (ii) within two months of a notification, where accreditation is not used.

(2) Paragraph (1) has effect subject to regulation 47 (changes to notifications).

Presumption of conformity of notified bodies

42. (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 of the European Union, the Secretary of State 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

43.—(1) The Secretary of State must notify to the European Commission and the other member States only those conformity assessment bodies 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 makes an application to the Secretary of State for notification and that the application is accompanied by -

- (a) a description of—
 - (i) the conformity assessment activities;
 - (ii) the conformity assessment modules for which the conformity assessment body claims to be competent; and
 - (iii) the explosives for which the conformity assessment body claims to be competent; and either
- (b) an accreditation certificate issued by the United Kingdom Accreditation Service attesting that the conformity assessment body fulfils the notified body requirements; or
- (c) the documentary evidence necessary for the Secretary of State to verify, recognise and regularly monitor the conformity assessment body’s compliance with the notified body requirements.

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

(5) For the purposes of meeting the second condition, the Secretary of State may accept an accreditation certificate under 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 Commission and the other member States, the Secretary of State may—

(a) have regard to any other matter which appears to the Secretary of State to be relevant; and

(b) set conditions that the conformity assessment body must meet.

(7) The Secretary of State must notify to the Commission its procedures for the assessment and notification of conformity assessment bodies, and any such changes to those procedures which from time to time the Secretary of State considers appropriate.

Contents of notification

44.—(1) A notification under regulation 43 must include—

(a) details of—

(i) the conformity assessment activities of the conformity assessment body; and

(ii) the conformity assessment module or modules and the explosive or explosives in respect of which the conformity assessment body's application for notification is based; and either

(b) an accreditation certificate issued by the United Kingdom Accreditation Service attesting that the conformity assessment body fulfils the notified body requirements; 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 satisfy the notified body requirements.

Monitoring

45.—(1) The Secretary of State must 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 43(6)(b); and

(c) carries out its functions in accordance with these Regulations.

(2) The Secretary of State must notify to the Commission its procedures for the monitoring of notified bodies, and any such changes to those procedures which from time to time it considers appropriate.

Delegation to the United Kingdom Accreditation Service

46. The Secretary of State may authorise the United Kingdom Accreditation Service to carry out the following activities on behalf of the Secretary of State—

(a) assessing applications for designation as an authorised body; and

(b) monitoring notified bodies.

Changes to notifications

47.—(1) Where the Secretary of State determines that a notified body no longer meets the notified body requirements, or that it is failing to fulfil its obligations under these Regulations, the Secretary of State must restrict, suspend or withdraw the body's status as a notified body under regulation 41.

(2) With the consent of a notified body, or where the Secretary of State determines that a notified body no longer meets a condition set in accordance with regulation 43(6)(b), the Secretary of State may restrict, suspend or withdraw the body's status as a notified body under regulation 41.

(3) In deciding what action is required under paragraph (1) or (2), the Secretary of State must have regard to the seriousness of the failure to meet the notified body requirements or to fulfil the obligations under these Regulations.

(4) Before taking action under paragraph (1) or (2), the Secretary of State must—

- (a) give notice in writing that it intends to take such action and the reasons for taking such action; and
- (b) give the notified body an opportunity to make representations within a reasonable period from the date of that notice and consider any such representations.

(5) Where the Secretary of State takes action under paragraph (1) or (2), the Secretary of State must immediately inform the Commission and the other member States.

(6) Where the Secretary of State has taken action under paragraph (1) or (2), or where the notified body has ceased its activity, the notified body must—

- (a) on the request of the Secretary of State, transfer its files (including the register which it maintains under paragraph 5 of Schedule 16 (operational obligations of notified bodies)) to another notified body or to the Secretary of State; or
- (b) ensure that its files are kept available for the Secretary of State and enforcing authorities for a period equal to that specified in paragraphs 5 and 6 of Schedule 16.

Operational obligations of notified bodies

48. When a notified body carries out a relevant conformity assessment procedure, it must do so in accordance with Schedule 16 (operational obligations of notified bodies).

Subsidiaries and contractors

49.—(1) Where a notified body subcontracts specific tasks connected with conformity assessment, or has such tasks carried out by a subsidiary, the tasks are only to be treated as having been carried out by a notified body for the purposes of regulation 48 (operational obligations of notified bodies) where the conditions in paragraphs (2) and (3) are satisfied.

(2) The notified body must—

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

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

(4) Where a notified body subcontracts specific tasks connected with conformity assessment, or has such tasks carried out by a subsidiary, the notified body must for a period of 10 years beginning on the day on which the tasks are carried out, keep at the disposal of the Secretary of State 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 45, the Secretary of State is to treat the notified body as responsible for the tasks performed by a subcontractor or subsidiary, wherever the subcontractor or subsidiary is established.”

(4) After Schedule 14 add:

Notified body requirements

1. A conformity assessment body must be established in the United Kingdom and have legal personality.

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

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

(2) Subparagraph (1) does not preclude the use of explosives that are necessary for the operations of the conformity assessment body or the use of explosives for personal purposes.

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

5. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment activities must 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).

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

7. A conformity assessment body and its personnel must carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and must 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 with an interest in those activities.

8. A conformity assessment body must be capable of carrying out all of the conformity assessment activities for which it has been designated, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

9. A conformity assessment body must have at its disposal—

- (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 is carried out, ensuring the transparency and the ability of reproduction of 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 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.

10. A conformity assessment body must have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and must have access to the necessary equipment or facilities.

11.The personnel responsible for carrying out conformity assessment activities must 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 Directive and of these Regulations;
- (d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

12.A conformity assessment body must be able to demonstrate the impartiality of its top level management and the personnel responsible for carrying out the conformity assessment activities.

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

14.A conformity assessment body must have, and must satisfy the Secretary of State that it has, adequate civil liability insurance in respect of its activities.

15.A conformity assessment body must 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.

16.Paragraph 15 does not prevent the personnel from providing information to the Secretary of State.

17.A conformity assessment body must 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 Directive and must apply as general guidance the administrative decisions and documents produced as a result of the work of that group

SCHEDULE 16

Operational obligations of notified bodies

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

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

3.A notified body must 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 must respect the degree of rigour and the level of protection required to ensure that the explosive is in conformity with the requirements of these Regulations.

5.A notified body carrying out a conformity assessments must—

- (a) assign a registration number in the form specified in Article 1 of Commission Implementing Directive 2014/58/EU setting up a system for the traceability of explosives (as amended from time to time), which identifies the explosives which have been subject to a conformity assessment and their manufacturers; and

- (b) maintain a register with the registration number of the explosives in respect of which it has issued a certificate of conformity or granted an approval for a period of 10 years beginning on the day on which the certificate of conformity was issued or the approval was granted.

6.After 16th October 2016—

- (a) an entry made in the register referred to in paragraph 5(b) must contain at least the information set out in the Annex to Commission Implementing Directive 2014/58/EU (as amended from time to time);
- (b) the notified body must—
 - (i) keep the information referred to in subparagraph (a) in respect of an explosive for a period of 10 years beginning on the day on which the certificate of conformity was issued or the approval was granted;
 - (ii) update the register referred to paragraph 5(b) and make it publicly available on the internet.

7.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 must require the manufacturer to take appropriate corrective measures and must not issue a certificate of conformity or grant an approval.

8.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 an explosive is no longer in conformity with the essential safety requirements, it must require the manufacturer to take appropriate corrective measures and must suspend or withdraw the certificate of conformity or approval (if necessary).

9.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 must restrict, suspend or withdraw any certificate of conformity or approval.

10.Paragraph 11 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.

11.Where this paragraph applies, the notified body must—

- (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.

12.A notified body must inform the Secretary of State 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;
- (c) any request for information which it has received from an enforcing authority regarding conformity assessment activities; and
- (d) on request, conformity assessment activities performed within the scope of its designation and any other activity performed, including cross-border activities and subcontracting.

13.A notified body must 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.

14.A notified body must provide other bodies notified under the Directive carrying out similar conformity assessment activities covering the same explosives with relevant information on issues relating to negative and, on request, positive conformity assessment results.

15.A notified body must participate in the work of any notified body coordination group established under the Directive, directly or by means of its designated representatives.”

EXPLANATORY NOTE

(This note is not part of the Order)

The Secretary of State is designated as the Notifying Authority for the purposes of Art 25.

It is assumed that the requirements relating to Notifying Authorities in Article 26 are inherent in the nature of the office of the Secretary of State.