Department for Business Innovation & Skills

THE PYROTECHNIC ARTICLES (SAFETY) REGULATIONS 2010

Guidelines on the appointment of UK Notified Bodies to undertake Conformity Assessment

NOVEMBER 2012

Contents

1. Introduction

1.1 These guidelines describe the requirements applying in the United Kingdom for the assessment and appointment of Notified Bodies under the Pyrotechnic Articles (Safety) Regulations 2010 (S.I. 2010/1554) ("the 2010 Regulations"), which implement the provisions of the EC Pyrotechnics Directive (2007/23/EC) in UK law. Notified Bodies are appointed under and operate according to the law which transposes the provisions of the Directive. The text of the Directive was adopted by the European Parliament and the Council on 23 May 2007 and published in the Official Journal No. L 154/1 of 14 June 2007. The Directive applies in the European Economic Area (EEA).

1.2 The 2010 Regulations apply to 'pyrotechnic articles' which fall within the definition set out in regulation 2(1). All products within this definition will require third party conformity assessment as described in Regulation 11 and, in the case of category 4 fireworks and theatrical and other pyrotechnic articles, Regulation 28.

1.3 Third party conformity assessment requires the involvement of Notified Bodies in the type examination process, unit verification or assessment of the manufacturer's quality system as described in Annex II to the Directive (reproduced here at Appendix 2). Article 9 of the Directive indicates that there is a choice for conformity assessment for Category 1 to 3 pyrotechnic articles of:

a) Module B and in addition any one of Module C, D, or E; OR

b) Module G on its own; OR

c) Module H on its own.

1.4 Category 4 fireworks conformity assessment can only be performed under Module H on its own.

1.5 Subject to paragraph 7 (below), these third party bodies are appointed by member/EEA States. In the United Kingdom, they are appointed under Regulations 43 to 44 of the Pyrotechnic Articles (Safety) Regulations 2010. These third party bodies, once assessed for their competence and appointed by the Secretary of State, are then notified to the European Commission and become "Notified Bodies". The scope of products within Schedule 1 to the Regulations which a Notified Body (NB) is authorised to assess will be published and will also be specified in the letter of appointment. The Secretary of State for the Department for Business at present has the responsibility for appointing Notified Bodies in the United Kingdom to carry out the functions referred to above and for notifying the appointments to the European Commission and other member/EEA States.

2. Criteria, Application and Appointment

2.1 An organisation wishing to be appointed as a UK notified body will need to be able to undertake tasks and comply with duties in accordance with the relevant provisions of the 2010 Regulations (which implement Article 10 and Annex II of the Directive and reproduced here at **Appendix 2**) and meet the minimum criteria set out in Annex III of the Directive (reproduced here at **Appendix 3** to these Guidelines). It should, however, be noted that

meeting the minimum criteria for appointment will not automatically lead to such an appointment as this remains at the discretion of the Secretary of State. The requirements set out in paragraph 2.5 below must also be fulfilled and a successful NB will need to provide for the appeal mechanism as required by Regulation 44. Finally reference should also be made to paragraph 3.11 regarding insurance arrangements.

2.2 Applicants will be required in the first instance, to make an application for accreditation to the United Kingdom Accreditation Service (UKAS) which will undertake an assessment of the applicant against the relevant harmonised standard(s) (see para 3.4 below) to ensure that the applicant complies with the requirements. Applications should be submitted using the relevant UKAS form (AC1 to AC4 - available to download from the UKAS website at www.ukas.com) dependent upon the standard against which accreditation is required. The scope of accreditation will be defined by reference to the specific products set out in the Regulations and applicants should indicate the particular product(s) (if not all) in respect of which they wish to be appointed. UKAS will quote and charge applicants against its standard scales of charges for its accreditation activities under the provisions of these guidelines. UKAS has established procedures to handle complaints or appeals associated with its assessment activities.

2.3 At the same time as it submits its application for accreditation to UKAS, the applicant will be required to send a copy to the Department. This will provide the Secretary of State with advance notice of the intention to apply for appointment.

2.4 Once UKAS has completed its accreditation, it will issue an accreditation certificate and schedule to the CAB. The CAB should then submit an application for appointment to the Department. The application should describe the conformity assessment activities and the products for which the CAB wishes to be appointed and should be accompanied by the accreditation certificate and schedule issued by UKAS and evidence of the applicant's insurance cover (see para 3.12). The Secretary of State will then make a decision on appointment on the basis of all of the evidence. If satisfied that the applicant is fit for appointment under the Regulations, the Secretary of State will issue a letter of appointment.

2.5 The precise terms of appointment will be set out in the individual letters of appointment, but they will include conditions that the applicant agrees:

- to take part in co-ordination activities at both UK and European level;
- to surveillance annually or at whatever intervals are thought appropriate by the Department (newly appointed Notified Bodies may be required to undergo an initial surveillance after 6 months);
- to a full reassessment every four years or at whatever intervals are thought appropriate by the Department.

2.6 Once acceptance of the conditions of the letter of appointment has been received, the Department will notify the European Commission and the other member/EEA States of the appointment. The appointment will become effective two weeks after the notification provided that no objections are raised by the European Commission or member/EEA states and will be confirmed at that point.

2.7 Reassessment and surveillance will be carried out on behalf of the Secretary of State, by UKAS in line with usual accreditation practice and para 2.5 above. A report on the reassessment and surveillance will be sent to the Secretary of State. Reassessment and surveillance may also be carried out by the Secretary of State. UKAS will advise the Department of the outcome of annual surveillance, four yearly re-assessment and any other necessary monitoring in intervening periods in order for the Department to take any necessary decisions about the continuation of the appointment. The information provided by UKAS to the Department will include supporting documentation such as a copy of the assessor's visit report, details of identified deficiencies and any agreed remedial action.

2.8 To be eligible for appointment as a United Kingdom Notified Body for the purposes of the Regulations, an applicant must be a legal entity in the United Kingdom. An applicant must exercise management control of the process, have technical capability and carry out its final assessment functions within the jurisdiction of the United Kingdom. It may conduct technical activities, or have technical activities conducted on its behalf, outside the jurisdiction of the United Kingdom.

2.9 Notified Bodies should ensure that they do not unreasonably restrict the access of manufacturers of products within the scope of the Regulations to their services. They must not place undue financial or other conditions upon such manufacturers. The procedures under which a Notified Body operates must be administered in a non-discriminatory manner.

3. Meeting the criteria

Accreditation

3.1 Applicants are required to demonstrate conformity with the requirements set out in the Regulations by being accredited to the appropriate scope of one, or more, of the relevant EN 45000 and ISO 17000 series of standards, which contain requirements for bodies issuing certificates, performing inspections or conducting tests.

3.2 All applicants, as part of the accreditation process, will need to meet any additional requirements set out in these guidelines which may change from time to time.

3.3 As indicated in paragraph 2.2 and 2.4 (above), applicants will need to state for which products specified in the Regulations they wish to be appointed. The scope of accreditation and subsequent appointment will be determined by reference to the categories of product specified.

3.4 Accreditation will be carried out against the most relevant standard for the organisation concerned, taking into account the requirements of other relevant standards depending on the modules for which the applicant wishes to be appointed. The relevant standards, mapped against the modules, are as set out in **Appendix 1**.

In all cases, the standards will be applied in accordance with EA 2/17 – Guidance on the horizontal requirements for the accreditation of conformity assessment bodies for notification purposes[1].

Note that consideration is being given at both national and European level to the use of the various EN 45000 and ISO/IEC 17000 standards for the accreditation of conformity assessment bodies for notification purposes. The standards against which accreditation may be carried out for the purposes of appointment in accordance with these guidelines may change depending on the outcome of this work.

3.5 All applicants will need to be able to demonstrate their professional ability and a necessary level of understanding of the Pyrotechnic Articles Directive and of the implementing Regulations to be able to determine whether products offered for assessment satisfy the Essential Safety Requirements (ESR) and the other relevant provisions.

3.6 Applicant companies must also be able to demonstrate that the company has sufficient resources to deliver the necessary level of professional knowledge and experience. Compliance with the nominated deputy provisions of EN ISO 17020 would be a satisfactory method of achieving this requirement and ensuring the company can provide an effective and continuous service.

Harmonised Standards

3.7 The Directive also defines the role of harmonised standards, which are produced in response to a mandate from the European Commission to the European standards organisations, the Comité Européan de Normalisation (CEN) and the European Committee for Electrotechnical Standardization (CENELEC) and listed in the Official Journal of the European Union. Products within the scope of the Directive produced in accordance with such standards will enjoy a presumption of conformity with the relevant ESRs (set out in Schedule 2 to the Regulations). Under the appropriate conformity assessment procedures, applicants will need to be able to examine or inspect against the ESRs and other relevant provisions directly. They will also need to be able to inspect against the CEN and CENELEC standards.

Quality System

3.8 All applicants will need to have a Quality System, usually specified in a Quality Manual and associated documented operational procedures, appropriate to the conformity assessment modules and types of product which it wishes to certify. The Quality System will need to ensure that all of the relevant requirements of the appropriate standards in the EN 17000 and 45000 series are met plus any further requirements for appointment and operation as a Notified Body.

Sub-contracting

3.9 Where an applicant wishes to sub-contract testing, the Quality Manual of the applicant will need to describe the procedures to be followed by the applicant to ensure compliance by the sub-contractors with the relevant requirements and to demonstrate that the sub-

[1] Available from the EA website at www.european-accreditation.org/n1/doc/EA-2_17.pdf

contractor is competent to carry out the task for which it has been engaged. Such competence will include, but is not limited to, the ability fully to conform to the requirements that are placed on the applicant itself in respect of the task contained within the subcontract. The applicant will need to maintain documented procedures for the assessment and monitoring of sub-contractors, and a list of sub-contractors and the facilities used by them to carry out work packages on behalf of the applicant. The list will need to form part of the Register specified in the next paragraph.

3.10 An applicant will need to have fully documented agreements with its sub-contractors. A Register of all sub-contractors which may be used by the applicant will need to be maintained; the Quality Manual will either contain the Register or will state where the Register is to be found. The agreements and the Register will need to be available for scrutiny at any reasonable time on request by the Secretary of State or such other person as may be appointed on behalf of the Secretary of State for that purpose.

3.11 A Notified Body will at all times be responsible for ensuring that the conformity assessment is carried out in accordance with the requirements of the implementing Regulations.

Insurance

3.12 All applicants will be required to demonstrate that they have adequate public liability and professional indemnity insurance for the activities they wish to carry out. Evidence of this should be submitted to UKAS and to BIS at the point at which a body makes an application to be appointed as a Notified Body. Thereafter, the Notified Body should make available to UKAS evidence of insurance at each annual surveillance undertaken by UKAS. Such cover should extend to the whole of the Community, the European Economic Area (EEA), or, if the applicant intends to carry out work under the Directive outside these areas; world-wide. The Secretary of State will not in relation to any case or circumstance cover a Notified Body's liability.

4. Duties of Notified Bodies

4.1 It will be the duty of a Notified Body to assess the conformity of the products or quality systems, which fall within the scope of its appointment, against the requirements of the 2010 Regulations. A Notified Body will have to carry out the functions of such a body referred to in regulation 44 of the 2010 Regulations which refers to various duties set out in Annex II of the Directive, these include various on-going duties including monitoring and periodic audits of clients and providing information to other Notified Bodies in the UK and elsewhere. When a Notified Body assesses products as being in conformity with the 2010 Regulations, it will be required to issue the appropriate conformity assessment documentation as specified in the Regulations. This would include a type examination or quality assurance certificate stating that the product or quality system concerned complies with the terms of the Directive which apply to it and has been assessed as such.

4.2 An applicant will be required to have documented procedures covering all aspects of its work relating to the conformity assessment activities for which it seeks approval. As part of the accreditation process, an assessment will be made of the adequacy of the internal organisation and the procedures adopted to give confidence in the quality of the applicant's services. Where judgements or interpretation of a standard or requirement are implicit or

explicit in a decision to grant or withhold certification, the applicant will be required to have procedures for achieving consistency. Guidance for achieving wider national and European agreement on interpretation and application of the Pyrotechnic Articles Directive and the implementing 2010 Regulations can be sought from the Department, or through the national and European fora already in place for the exchange of views and discussion of interpretative issues in which prospective applicants are expected to fully participate.

4.3 A Notified Body will be required to maintain an up to date record of any certification which it has issued, and to whom it has been issued. The records will need to be made available on request to the Secretary of State or such other person as may be authorised by the Secretary of State.

4.4 A Notified Body will be required to inform the Secretary of State and UKAS immediately of any changes within itself which, in any way, affect its ability to carry out the duties within the authorised scope to the declared procedures. This includes any change in its status, ownership, location, key personnel, technical competence, facilities etc.

5. Misuse of Certificates and Conformity Numbers

5.1 The Quality Manual should state the Notified Body's policy and procedure for controlling the use of its certificates and conformity numbers. Incorrect references to the certification system or misleading use of information found in advertisements, catalogues etc. will be dealt with by suitable means including corrective action, publication of the transgression and, if necessary, legal action.

5.2 A Notified Body will need to have documented procedures for the control and use of its identification number complete with guidelines on action to be taken in cases of misuse. The procedures will need to be contained or referenced within the Quality Manual.

6. Use of UKAS Symbols

6.1 Notified Bodies may make reference to UKAS Accreditation or include the relevant National Accreditation Symbol on certificates issued where the conformity assessment work reported is included within the scope of accreditation of the Notified Body.

6.2 Certificates bearing an accreditation symbol must comply with the requirements of the relevant conformity assessment body standard against which accreditation is held (e.g. EN 45011, ISO/IEC 17020 etc), with the requirements for notification and with the requirements in BIS publication 09/1090 'Conditions' document and any other requirements specified by UKAS.

7. Mutual Recognition Agreements

7.1 Applicants should note that the European Community aims to reach Mutual Recognition Agreements (MRAs) with key trading partners. Under these agreements, EC Notified Bodies may be eligible to perform conformity assessments as required by the third country's laws and, similarly, those trading partners' equivalents to Notified Bodies may be eligible for appointment to perform conformity assessments under EC Directives. If an applicant organisation wishes to be considered for appointment under MRAs, it should inform the Department.

8. Contact Points

8.1 Contact addresses are:

Christine Knox
Department for Business
Product Regulation Directorate
Orchard 1 Level 4
1 Victoria Street
LONDON SW1H 0ET

Tel: 020 7215 3465
Email: christine.knox@bis.gsi.gov.uk

Kevin Belson (or your usual accreditation manager)
United Kingdom Accreditation Service
21 - 47 High Street
FELTHAM
Middlesex TW13 4UN

Tel: 020 8 917 8400
Fax: 020 8917 8500
Email: kevin.belson@ukas.com

9. Sources of relevant documents

9.1 Copies of the Pyrotechnics Directive (2007/23/EC) Directive are available from the Europa website at www.europa.eu

9.2 Copies of the Pyrotechnic Articles (Safety) Regulations 2010 may be obtained from the Office of Public Sector Information web-site at www.opsi.gov.uk or from:

The Stationery Office Ltd
PO Box 29
Norwich, NR3 IGN

Tel: 0870 600 5522
Fax: 0870 600 5533
Email: customer.services@tso.co.uk
Textphone 0870 240 3701

9.3 Information on the EN 17000 and EN 45000 series of standards and the harmonised standards is available from:

BSI British Standards
389 Chiswick High Road
London, W4 4AL

Tel: 0208-996 9001
Fax: 0208-996 7001
Web: http://www.bsi.group.com

Appendix I: Table of Modules and applicable standards[2]

Module	EN Standard(s) applicable
AI, A2	EN ISO/IEC 17025 (+ability to decide on conformity), or EN ISO/IEC 17020 (EN ISO/IEC 17025 to be taken into account for testing required), or EN ISO/IEC 45011 (EN ISO/IEC 17025 to be taken into account for testing required)
B	EN ISO/IEC 17020 (EN ISO/IEC 17025 to be taken into account for testing required), or EN ISO/IEC 45011 (EN 17025 to be taken into account for testing required)
CI, C2	EN ISO/IEC 17025 (+ability to decide on conformity), or EN ISO/IEC 17020 (EN ISO/IEC 17025 to be taken into account for testing required), or EN ISO/IEC 45011 (EN ISO/IEC 17025 to be taken into account for testing required)
D, DI	EN ISO/IEC 17021 (+product related knowledge)
E, EI	EN ISO/IEC 17021(+product related knowledge)
F, F1	EN ISO/IEC 17025 (+ability to decide on conformity), or EN ISO/IEC 17020 (EN 17025 to be taken into account for testing required), or EN ISO/IEC 45011 (EN 17025 to be taken into account for testing required)
G	EN ISO/IEC 17020 (EN 17025 to be taken into account for testing required), or EN ISO/IEC 45011 (EN 17025 to be taken into account for testing required)
H	EN 1SO/IEC 17021 (+product related knowledge)
H1	EN ISO/EIC 17021 (+product related knowledge) + EN ISO/IEC 17020 (EN ISO/IEC 17025 to be taken into account for testing required), or EN ISO/IEC 17021 (+product related knowledge) + EN ISO/IEC 45011 (EN ISO/IEC 17025 to be taken into account for testing required)

[2] Reproduced from the European Commission working paper Certif 2009/8: “Using standards to assess the competence of conformity assessment bodies in the context of the New Legislative Framework.”.

Appendix 2: Extract from the Pyrotechnics Directive - Conformity Assessment Procedures

ANNEX II Conformity assessment procedures

1. MODULE B: EC type-examination

1. This module describes that part of the procedure by which a notified body ascertains and attests that a sample, representative of the production envisaged, meets the relevant provisions of Directive 2007/23/EC (hereinafter referred to as this Directive).

2. The application for EC type-examination must be lodged by the manufacturer with the notified body of his choice. The application must include:

(a) the name and address of the manufacturer,
(b) a written declaration that the same application has not been lodged with any other notified body,
(c) the technical documents, as described in point 3.

The applicant must place at the disposal of the notified body a sample representative of the production envisaged, hereinafter called 'type'. The notified body may request further samples if needed for carrying out the test programme.

3. The technical documents must enable the conformity of the article with the requirements of this Directive to be assessed. They must, as far as is relevant for such assessment, cover the design, manufacture and operation of the article and contain where relevant for the assessment:

(a) a general type-description,
(b) conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.
(c) descriptions and explanations necessary for the understanding of the drawings and diagrams and the operation of the article,
(d) a list of the harmonised standards referred to in Article 8 of this Directive, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where the harmonised standards referred to in Article 8 of this Directive have not been applied,
(e) results of design calculations made, examinations carried out, etc.,
(f) test reports.

4. The notified body must:

(a) examine the technical documents, verify that the type has been manufactured in conformity with those documents and identify the elements which have been designed in accordance with the relevant provisions of the harmonised standards referred to in Article 8 of this Directive as well as the components which have been designed without applying the relevant provisions of those harmonised standards,
(b) perform or have performed the appropriate examinations and necessary tests to check whether, where the harmonised standards referred to in Article 8 of this Directive have not been applied, the solutions adopted by the manufacturer meet the essential safety requirements of this Directive,
(c) perform or have performed the appropriate examinations and necessary tests to check whether, where the manufacturer has chosen to apply the relevant harmonised standards, these have been applied,
(d) agree with the applicant the location where the examinations and necessary tests are to be carried out.

5. Where the type meets the relevant provisions of this Directive, the notified body must issue an EC type examination certificate to the applicant. The certificate must contain the name and address of the manufacturer, the results of the examination and the data necessary for the identification of the approved type.

A list of the relevant parts of the technical documents must be annexed to the certificate and a copy thereof kept by the notified body.

Where the manufacturer is refused a type certificate, the notified body must provide detailed reasons for such refusal.

Provision must be made for an appeals procedure.

6. The applicant must inform the notified body that holds the technical documents concerning the EC type examination certificate of all modifications to the approved article which must receive additional approval where such changes may affect the conformity with the essential requirements or the prescribed conditions for use of the article. This additional approval must be given in the form of an addition to the original EC type examination certificate.

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

8. The other notified bodies may receive copies of the EC type-examination certificates and/or any additions thereto. The annexes to the certificates must be kept at the disposal of the other notified bodies.

9. The manufacturer must keep with the technical documents copies of EC type-examination certificates and any additions thereto for a period of at least 10 years after the last date of manufacture of the article concerned.

Where the manufacturer is not established within the Community, the obligation to keep the technical documents available is the responsibility of the person who places the product on the market.

2. MODULE C: Conformity to type

1. This module describes that part of the procedure whereby the manufacturer ensures and declares that the pyrotechnic articles concerned are in conformity with the type as described in the EC type-examination certificate and satisfy the requirements of this Directive that apply to them. The manufacturer must affix the CE marking to each pyrotechnic article and draw up a written declaration of conformity.

2. The manufacturer must take all measures necessary to ensure that the manufacturing process ensures the conformity of the manufactured product with the type as described in the EC type-examination certificate and with the essential safety requirements of this Directive.

3. The manufacturer must keep a copy of the declaration of conformity for a period of at least 10 years after the last date of manufacture of the article concerned.
Where the manufacturer is not established within the Community, the obligation to keep the technical documents available is the responsibility of the person who places the product on the market.

4. A notified body chosen by the manufacturer must perform or cause to be performed examinations of the article at random intervals. A suitable sample of the finished articles, taken on the spot by the notified body, must be examined and appropriate tests, defined in the applicable harmonised standard referred to in Article 8 of this Directive or equivalent, carried out to check the conformity of the article with the requirements of this Directive. In the event of one or more samples of the articles examined not conforming, the notified body must take appropriate measures.

Under the responsibility of the notified body the manufacturer must affix the identification number of that body during the manufacturing process.

3. MODULE D: Production quality assurance

1. This module describes the procedure whereby a manufacturer who satisfies the obligations set out in point 2 ensures and declares that the pyrotechnic articles concerned are in conformity with the type as described in the EC type-examination certificate and satisfy the requirements of this

Directive. The manufacturer must affix the CE marking to each article and draw up a written declaration of conformity. The CE marking must be accompanied by the identification number of the notified body responsible for the monitoring referred to in point 4.

2. The manufacturer must operate an approved quality system for production, final product inspection and testing as specified in point 3. He must be subject to the monitoring referred to in point 4.

3. *Quality system*

3.1. The manufacturer must lodge an application for assessment of his quality system with the notified body of his choice in relation to the pyrotechnic articles concerned.

The application must include:

(a) all relevant information for the pyrotechnic article category envisaged,
(b) the documents concerning the quality system,
(c) the technical documents pertaining to the approved type and a copy of the EC type- examination certificate.

3.2. The quality system must ensure the conformity of pyrotechnic articles with the type as described in the EC type-examination certificate and with the requirements of this Directive that apply to them.
All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documents must permit a consistent interpretation of the quality programmes, plans, manuals and quality records.

They must contain in particular an adequate description of:

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to the quality of the pyrotechnic articles,
(b) the manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,
(c) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,
(d) the quality records, such as inspection reports and test data, calibration data, and qualification reports of the personnel concerned,
(e) the means of monitoring the achievement of the required quality of the pyrotechnic articles and the effective operation of the quality system.

3.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It must presume conformity with those requirements in respect of quality systems that implement the relevant harmonised standard. The auditing team must have at least one member with experience of assessing the relevant product technology. The assessment procedure must include an inspection visit to the manufacturer's premises.

A duly substantiated assessment decision must be notified to the manufacturer. It must contain the results of the examination.

3.4. The manufacturer must undertake to fulfil the obligations arising out of the quality system as approved and maintain it at an adequate and efficient level.

The manufacturer must keep the notified body that has approved the quality system informed of any proposed change to the quality system.

The notified body must assess the changes proposed and decide whether the altered quality system will still satisfy the requirements referred to in point 3.2 or whether reassessment is required.

A duly substantiated assessment decision must be notified to the manufacturer. It must contain the results of the examination.

4. *Monitoring under the responsibility of the notified body*

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

4.2. The manufacturer must allow the notified body access for inspection purposes to the manufacturing, inspection, testing and storage premises and provide it with all necessary information, in particular:
(a) the quality system documents,
(b) the quality records, such as inspection reports and test data, calibration data, and qualification reports of the personnel concerned.

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

4.4. Additionally the notified body may pay unannounced visits to the manufacturer. During such visits the notified body may, if necessary, carry out tests or have them carried out to verify that the quality system is functioning correctly. The notified body must provide the manufacturer with a visit report and, if a test has taken place, with a test report.

5. The manufacturer must, for a period of at least 10 years after the last date of manufacture of the article, keep at the disposal of the national authorities:

(a) the documents referred to in point 3.1.(b),
(b) documents relating to the updating referred to in second subparagraph of point 3.4,
(c) the decisions and reports of the notified body referred to in the fourth subparagraph of point 3.4, and in points 4.3 and 4.4.

6. Each notified body must give the other notified bodies the relevant information concerning quality system approvals issued or withdrawn.

4. MODULE E: Product quality assurance

1. This module describes the procedure whereby a manufacturer who satisfies the obligations set out in point 2 ensures and declares that the pyrotechnic articles are in conformity with the type as described in the EC type examination certificate. The manufacturer must affix the CE marking to each article and draw up a written declaration of conformity. The CE marking must be accompanied by the identification number of the notified body responsible for the monitoring referred to in point 4.

2. The manufacturer must operate an approved quality system for final pyrotechnic article inspection and testing as specified in point 3. He must be subject to the monitoring referred to in point 4.

3. *Quality system*

3.1. The manufacturer must lodge an application with the notified body of his choice for the assessment of the quality system in relation to his pyrotechnic articles. The application must include:

(a) all relevant information for the pyrotechnic category envisaged,
(b) the quality system documents,
(c) the technical documents pertaining to the approved type and a copy of the EC type- examination certificate.

3.2. Under the quality system, each pyrotechnic article must be examined and appropriate tests, as defined in the relevant harmonised standard(s) referred to in Article 8 of this Directive or equivalent, carried out in order to verify the conformity of the article with the relevant requirements of this Directive.

All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documents must permit a consistent interpretation of the quality programmes, plans, manuals and quality records.

They must in particular contain an adequate description of:

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality,
(b) the examination and tests that will be carried out after manufacture,
(c) the means of monitoring the effective operation of the quality system,
(d) quality records, such as inspection reports and test data, calibration data, and qualification reports of the personnel concerned.

3.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It must presume conformity with these requirements in respect of quality systems that implement the relevant harmonised standard.
The auditing team must have at least one member with experience of assessing the relevant product technology. The assessment procedure must include an inspection visit to the manufacturer's premises.

A duly substantiated assessment decision must be notified to the manufacturer. It must contain the results of the examination.

3.4. The manufacturer must undertake to fulfil the obligations arising out of the quality system as approved and maintain it at an adequate and efficient level.

The manufacturer must keep the notified body which has approved the quality system informed of any proposed change to the quality system.
The notified body must assess the changes proposed and decide whether the altered quality system will still satisfy the requirements referred to in point 3.2 or whether a reassessment is required.
A duly substantiated assessment decision must be notified to the manufacturer. It must contain the results of the examination.

4. *Monitoring under the responsibility of the notified body*

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

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

(a) the quality system documents,
(b) the technical documents,
(c) the quality records, such as inspection reports and test data, calibration data and qualification reports of the personnel concerned.

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

4.4. Additionally, the notified body may pay unannounced visits to the manufacturer. During such visits the notified body may, if necessary, carry out tests or have them carried out to verify that the quality system is functioning correctly. The notified body must provide the manufacturer with a visit report and, if a test has been carried out, with a test report.

5. The manufacturer must for a period of at least 10 years after the last date of manufacture of the article keep at the disposal of the national authorities:

(a) the documents referred to in point 3.1.(b),

(b) documents relating to the updating referred to in the second subparagraph of point 3.4,
(c) the decisions and reports of the notified body referred to in the fourth subparagraph of point 3.4, and in points 4.3 and 4.4.

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

5. MODULE G: Unit verification

1. This module describes the procedure whereby the manufacturer ensures and declares that the pyrotechnic article which has been issued with the certificate referred to in point 2 conforms with the relevant requirements of this Directive. The manufacturer must affix the CE marking to the article and draw up a declaration of conformity.

2. The notified body must examine the pyrotechnic article and carry out the appropriate tests as set out in the relevant harmonised standard(s) referred to in Article 8 of this Directive, or equivalent tests, to ensure the conformity of the article with the relevant requirements of this Directive.
The notified body must affix, or cause to be affixed, its identification number to the approved pyrotechnic article and draw up a certificate of conformity concerning the tests carried out.

3. The aim of the technical documents is to enable conformity with the requirements of this Directive to be assessed and the design, manufacture and operation of the pyrotechnic article to be understood.

Where necessary for the assessment, the documents must contain:

(a) a general description of the type,
(b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies and circuits,
(c) the descriptions and explanations necessary for the understanding of the conceptual design and manufacturing drawings, the schemes of components, sub-assemblies and circuits and the operation of the pyrotechnic article,
(d) a list of the harmonised standards referred to in Article 8 of this Directive, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where the harmonised standards referred to in Article 8 of this Directive have not been applied,
(e) results of design calculations made and examinations carried out,
(f) test reports.

6. MODULE H: Full quality assurance

1. This module describes the procedure whereby the manufacturer who satisfies the obligations set out in point 2 ensures and declares that the articles concerned meet the requirements of this Directive. The manufacturer or his importer must affix the CE marking to each article and draw up a written declaration of conformity. The CE marking must be accompanied by the identification number of the notified body responsible for the monitoring referred to in point 4.

2. The manufacturer must operate an approved quality system for the design, production, final product inspection and testing as specified in point 3 and must be subject to the monitoring referred to in point 4.

3. *Quality system*

3.1. The manufacturer must lodge an application for assessment of his quality system with a notified body.

The application must include:
(a) all relevant information for the pyrotechnic article category envisaged,
(b) the documents concerning the quality system.

3.2. The quality system must ensure the conformity of the article with the requirements of this Directive.

All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documents must permit a consistent interpretation of the quality programmes, plans, manuals and quality records.

They must contain in particular an adequate description of:

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product design and quality,
(b) technical construction specifications including the standards applicable and, if the standards referred to in Article 8 of this Directive have not been fully applied, the means of ensuring that the relevant basic requirements of this Directive have been met,
(c) techniques to control and assess the development results, processes and systematic actions that will be used to develop products belonging to the product category in question,
(d) the manufacturing, quality control and quality assurance techniques and the processes and systematic actions applied,
(e) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,
(f) the quality records, such as inspection reports and test data, calibration data, and qualification reports of the personnel concerned,
(g) the means of monitoring the achievement of the required design and quality of the product and the effective operation of the quality system.

3.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It must presume conformity with those requirements in respect of quality systems that implement the relevant harmonised standard.
The auditing team must have at least one member with experience of assessing the relevant product technology. The assessment procedure shall include an inspection visit to the manufacturer's premises.

A duly substantiated assessment decision must be notified to the manufacturer. It must contain the results of the examination.

3.4. The manufacturer must undertake to fulfil the obligations arising out of the quality system as approved and maintain it at an adequate and efficient level.
The manufacturer must keep the notified body that has approved the quality system constantly informed of any proposed update of the quality system.
The notified body must assess the changes proposed and decide whether the altered quality system will still satisfy the requirements referred to in point 3.2 or whether reassessment is required.
A duly substantiated assessment decision must be notified to the manufacturer. It must contain the results of the examination.

4. *EC monitoring under the responsibility of the notified body*

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

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

(a) the quality system documents,
(b) the quality records required under the quality system for the development field such as the results of analyses, calculations and tests,
(c) the quality records required under the quality system for the manufacturing field such as inspection reports and test data, calibration data, and qualification reports of the personnel concerned.

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

4.4. Additionally the notified body may pay unannounced visits to the manufacturer. During such visits the notified body may, if necessary, carry out tests or have them carried out to verify that the quality system is functioning correctly. The notified body must provide the manufacturer with a visit report and, if a test has taken place, with a test report.

5. The manufacturer must, for a period of at least 10 years after the last date of manufacture of the article, keep at the disposal of the national authorities:

(a) the documents referred to in point 3.1.(b),
(b) documents relating to the updating referred to in second subparagraph of point 3.4,
(c) the decisions and reports of the notified body referred to in the fourth subparagraph of point 3.4, and in points 4.3 and 4.4.

6. Each notified body must give the other notified bodies the relevant information concerning quality system approvals issued or withdrawn.

Appendix 3: Extract from the Pyrotechnics Directive – Minimum Criteria

ANNEX III Minimum criteria to be taken into account by Member States for the bodies responsible for conformity assessments

1. The body, its director and the staff responsible for carrying out the verification tests must not be the designer, manufacturer, supplier, installer or importer of pyrotechnic articles which they inspect, nor the authorised representative of any of these parties. They must not become involved either directly or as authorised representative in the design, construction, marketing, maintenance or importation of such articles. This does not preclude the possibility of exchanges of technical information between the manufacturer and the body.

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

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

4. The staff responsible for inspection must have:

(a) sound technical and professional training,

(b) satisfactory knowledge of the requirements of the tests they carry out and adequate experience of such tests,

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

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

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

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

Appendix 4: Extract from the Pyrotechnics Directive – Categorisation

Article 3 Categorisation

Categorisation

1. Pyrotechnic articles shall be categorised by the manufacturer according to their type of use, or their purpose and level of hazard, including their noise level. The notified bodies referred to in Article 10 shall confirm the categorisation as part of the conformity assessment procedures in accordance with Article 9.

Categorisation shall be as follows:

(a) *Fireworks*

Category 1: fireworks which present a very low hazard and negligible noise level and which are intended for use in confined areas, including fireworks which are intended for use inside domestic buildings;

Category 2: fireworks which present a low hazard and low noise level and which are intended for outdoor use in confined areas;

Category 3: fireworks which present a medium hazard, which are intended for outdoor use in large open areas and whose noise level is not harmful to human health;

Category 4: fireworks which present a high hazard, which are intended for use only by persons with specialist knowledge (commonly known as fireworks for professional use) and whose noise level is not harmful to human health.

(b) *Theatrical pyrotechnic articles*

Category T1: pyrotechnic articles for stage use which present a low hazard;

Category T2: pyrotechnic articles for stage use which are intended for use only by persons with specialist knowledge.

(c) *Other pyrotechnic articles*

Category P1: pyrotechnic articles other than fireworks and theatrical pyrotechnic articles which present a low hazard;

Category P2: pyrotechnic articles other than fireworks and theatrical pyrotechnic articles which are intended for handling or use only by persons with specialist knowledge.

2. Member States shall inform the Commission of the procedures whereby they identify and authorise persons with specialist knowledge.

This publication is also available on our website at www.bis.gov.uk

Any enquiries regarding this publication should be sent to:

Department for Business, Innovation and Skills
1 Victoria Street
London SW1H 0ET
Tel: 020 7215 5000

If you require this publication in an alternative format, email enquiries@bis.gsi.gov.uk, or call 020 7215 5000.

URN 12/556