

SCHEDULE 19

Amendment of the Pyrotechnic Articles (Safety) Regulations 2015

Insertion of Schedule 2A

39. After Schedule 2 insert—

“SCHEDULE 2A
Regulations 2(3), 8, 40(a), 41(b),
48(3)(a)

Conformity Assessment Procedures (Annex II to the Directive)

PART 1

Module B: Type Examination

1. Type examination is the part of a conformity assessment procedure in which an approved body examines the technical design of a pyrotechnic article and verifies and attests that the technical design of the pyrotechnic article meets the requirements of these Regulations that apply to it.

2. Type examination shall be carried out as an assessment of the adequacy of the technical design of the pyrotechnic article through examination of the technical documentation and supporting evidence referred to in point 3, plus examination of a specimen, representative of the production envisaged, of the complete product (combination of production type and design type).

3. The manufacturer shall lodge an application for a Type examination with a single approved body of his choice.

The application shall include:

- (a) the name and address of the manufacturer;
- (b) a written declaration that the same application has not been lodged with any other approved body;
- (c) the technical documentation. The technical documentation shall make it possible to assess the pyrotechnic article's conformity with the applicable requirements of these Regulations and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the pyrotechnic article. The technical documentation shall contain, wherever applicable, at least the following elements:
 - (i) a general description of the pyrotechnic article;
 - (ii) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;
 - (iii) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the pyrotechnic article;
 - (iv) a list of the designated standards applied in full or in part and, where those designated standards have not been applied, descriptions of the solutions adopted to meet the essential safety requirements of these Regulations including a list of other relevant technical specifications applied. In the case of partly applied designated standards, the technical documentation shall specify the parts which have been applied;

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- (v) results of design calculations made, examinations carried out, etc.;
- (vi) test reports;
- (d) the specimens representative of the production envisaged. The approved body may request further specimens if needed for carrying out the test programme;
- (e) the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant designated standards have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

4. The approved body shall:

For the pyrotechnic article:

4.1. Examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the pyrotechnic article.

For the specimen(s):

4.2. Verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant designated standards, as well as the elements which have been designed in accordance with other relevant technical specifications;

4.3. Carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant designated standards, these have been applied correctly;

4.4. Carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant designated standards have not been applied, the solutions adopted by the manufacturer, including those in other relevant technical specifications applied, meet the corresponding essential safety requirements of these Regulations;

4.5. Agree with the manufacturer on a location where the examinations and tests will be carried out.

5. The approved body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à-vis the Secretary of State, the approved body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

6. Where the type meets the requirements of these Regulations that apply to the pyrotechnic article concerned, the approved body shall issue a Type examination certificate to the manufacturer. That certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The Type examination certificate may have one or more annexes attached.

The Type examination certificate and its annexes shall contain all relevant information to allow the conformity of manufactured pyrotechnic articles with the examined type to be evaluated and to allow for in-service control.

Where the type does not satisfy the applicable requirements of these Regulations, the approved body shall refuse to issue a Type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

7. The approved body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of these Regulations, and shall determine whether such changes require further investigation. If so, the approved body shall inform the manufacturer accordingly.

The manufacturer shall inform the approved body that holds the technical documentation relating to the Type examination certificate of all modifications to the approved type that may affect the conformity of the pyrotechnic article with the essential safety requirements of these Regulations or the conditions for validity of that certificate. Such modifications shall require additional approval in the form of an addition to the original Type examination certificate.

8. Each approved body shall inform the Secretary of State concerning the Type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to the Secretary of State the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each approved body shall inform the other approved bodies concerning the Type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning such certificates and/or additions thereto which it has issued.

The Secretary of State and other approved bodies may, on request, obtain a copy of the Type examination certificates and/or additions thereto. On request the Secretary of State may obtain a copy of the technical documentation and the results of the examinations carried out by the approved body. The approved body shall keep a copy of the Type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of that certificate.

9. The manufacturer shall keep a copy of the Type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the pyrotechnic article has been placed on the market.

PART 2

Module C2: Conformity to type based on internal production control plus supervised product checks at random intervals

1. Conformity to type based on internal production control plus supervised product checks at random intervals is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the pyrotechnic articles concerned are in conformity with the type described in the Type examination certificate and satisfy the requirements of these Regulations that apply to them.

2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured pyrotechnic articles with the type described in the Type examination certificate and with the requirements of these Regulations that apply to them.

3. Product checks

An approved body, chosen by the manufacturer, shall carry out product checks or have them carried out at random intervals determined by the body, in order to verify the quality of the internal checks on the pyrotechnic article, taking into account, inter alia, the technological

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complexity of the pyrotechnic articles and the quantity of production. An adequate sample of the final products, taken on site by the approved body before the placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the designated standards and/or equivalent tests set out in other relevant technical specifications, shall be carried out to check the conformity of the pyrotechnic article with the type described in the Type examination certificate and with the relevant requirements of these Regulations. Where a sample does not conform to the acceptable quality level, the body shall take appropriate measures.

The acceptance sampling procedure to be applied is intended to determine whether the manufacturing process of the pyrotechnic article performs within acceptable limits, with a view to ensuring conformity of the pyrotechnic article.

The manufacturer shall, under the responsibility of the approved body, affix the approved body's identification number during the manufacturing process.

4. UK marking and declaration of conformity

4.1. The manufacturer shall affix the UK marking to each individual pyrotechnic article that is in conformity with the type described in the Type examination certificate and satisfies the applicable requirements of these Regulations.

4.2. The manufacturer shall draw up a written declaration of conformity for each product model and keep it at the disposal of the national authorities for 10 years after the pyrotechnic article has been placed on the market. The declaration of conformity shall identify the pyrotechnic article for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

PART 3

Module D: Conformity to type based on quality assurance of the production process

1. Conformity to type based on quality assurance of the production process is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the pyrotechnic articles concerned are in conformity with the type described in the Type examination certificate and satisfy the requirements of these Regulations that apply to them.

2. Manufacturing

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the pyrotechnic articles concerned as specified in point 3 and shall be subject to surveillance as specified in point 4.

3. Quality system

3.1. The manufacturer shall lodge an application for assessment of his quality system with the approved body of his choice for the pyrotechnic articles concerned.

The application shall include:

- (a) the name and address of the manufacturer;
- (b) a written declaration that the same application has not been lodged with any other approved body;
- (c) all relevant information for the pyrotechnic article category envisaged;
- (d) the documentation concerning the quality system;

- (e) the technical documentation of the approved type and a copy of the Type examination certificate.

3.2. The quality system shall ensure that the pyrotechnic articles are in conformity with the type described in the Type examination certificate and comply with the requirements of these Regulations that apply to them.

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

It shall, 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 corresponding 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, qualification reports on the personnel concerned, etc.; and
- (e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

3.3. The approved body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant designated standard.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant product field and product technology concerned, and knowledge of the applicable requirements of these Regulations. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1(e) to verify the manufacturer's ability to identify the relevant requirements of these Regulations and to carry out the necessary examinations with a view to ensuring compliance of the pyrotechnic article with those requirements.

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

3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

3.5. The manufacturer shall keep the approved body that has approved the quality system informed of any intended change to the quality system.

The approved body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

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

4. Surveillance under the responsibility of the approved body

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

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

- (a) the quality system documentation;
- (b) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

4.3. The approved body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

4.4. In addition, the approved body may pay unexpected visits to the manufacturer. During such visits the approved body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The approved body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

5. UK marking and declaration of conformity

5.1. The manufacturer shall affix the UK marking, and, under the responsibility of the approved body referred to in point 3.1, the latter's identification number to each individual pyrotechnic article that is in conformity with the type described in the Type examination certificate and satisfies the applicable requirements of these Regulations.

5.2. The manufacturer shall draw up a written declaration of conformity for each product model and keep it at the disposal of the national authorities for 10 years after the pyrotechnic article has been placed on the market. The declaration of conformity shall identify the pyrotechnic article for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

6. The manufacturer shall, for a period ending 10 years after the pyrotechnic article has been placed on the market, keep at the disposal of the national authorities:

- (a) the documentation referred to in point 3.1;
- (b) the information relating to the change referred to in point 3.5, as approved;
- (c) the decisions and reports of the approved body referred to in points 3.5, 4.3 and 4.4.

7. Each approved body shall inform the Secretary of State of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to the Secretary of State the list of quality system approvals refused, suspended or otherwise restricted.

Each approved body shall inform the other approved bodies of quality system approvals which it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of quality system approvals which it has issued.

PART 4

Module E: Conformity to type based on product quality assurance

1. Conformity to type based on product quality assurance is that part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the pyrotechnic articles concerned are in conformity with the type described in the Type examination certificate and satisfy the requirements of these Regulations that apply to them.

2. Manufacturing

The manufacturer shall operate an approved quality system for final product inspection and testing of the pyrotechnic articles concerned as specified in point 3 and shall be subject to surveillance as specified in point 4.

3. Quality system

3.1. The manufacturer shall lodge an application for assessment of his quality system with the approved body of his choice for the pyrotechnic articles concerned.

The application shall include the following information:

- (a) the name and address of the manufacturer;
- (b) a written declaration that the same application has not been lodged with any other approved body;
- (c) all relevant information for the pyrotechnic article category envisaged;
- (d) the documentation concerning the quality system;
- (e) the technical documentation of the approved type and a copy of the Type examination certificate.

3.2. The quality system shall ensure compliance of the pyrotechnic articles with the type described in the Type examination certificate and with the applicable requirements of these Regulations.

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

It shall, 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 examinations and tests that will be carried out after manufacture;
- (c) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.;
- (d) the means of monitoring the effective operation of the quality system.

3.3. The approved body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant designated standard.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant product field and product technology concerned, and knowledge of the applicable requirements of these Regulations. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1(e), in order to verify the manufacturer's ability to identify the relevant requirements of these Regulations and to carry out the necessary examinations with a view to ensuring compliance of the pyrotechnic article with those requirements.

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

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3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

3.5. The manufacturer shall keep the approved body that has approved the quality system informed of any intended change to the quality system.

The approved body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

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

4. Surveillance under the responsibility of the approved body

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

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

- (a) the quality system documentation;
- (b) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

4.3. The approved body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

4.4. In addition, the approved body may pay unexpected visits to the manufacturer. During such visits the approved body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The approved body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

5. UK marking and declaration of conformity

5.1. The manufacturer shall affix the UK marking, and, under the responsibility of the approved body referred to in point 3.1, the latter's identification number to each individual pyrotechnic article that is in conformity with the type described in the Type examination certificate and satisfies the applicable requirements of these Regulations.

5.2. The manufacturer shall draw up a written declaration of conformity for each product model and keep it at the disposal of the national authorities for 10 years after the pyrotechnic article has been placed on the market. The declaration of conformity shall identify the pyrotechnic article for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

6. The manufacturer shall, for a period ending 10 years after the pyrotechnic article has been placed on the market, keep at the disposal of the national authorities:

- (a) the documentation referred to in point 3.1;
- (b) the information relating to the change referred to in point 3.5, as approved;
- (c) the decisions and reports of the approved body referred to in points 3.5, 4.3 and 4.4.

7. Each approved body shall inform the Secretary of State of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to the Secretary of State the list of quality system approvals refused, suspended or otherwise restricted.

Each approved body shall inform the other approved bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.

PART 5

Module G: Conformity based on unit verification

1. Conformity based on unit verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 5, and ensures and declares on his sole responsibility that the pyrotechnic article concerned, which has been subject to the provisions of point 4, is in conformity with the requirements of these Regulations that apply to it.

2. Technical documentation

The manufacturer shall establish the technical documentation and make it available to the approved body referred to in point 4. The documentation shall make it possible to assess the pyrotechnic article's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the pyrotechnic article. The technical documentation shall, wherever applicable, contain at least the following elements:

- (a) a general description of the pyrotechnic article;
- (b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;
- (c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the pyrotechnic article;
- (d) a list of the designated standards applied in full or in part and, where those designated standards have not been applied, descriptions of the solutions adopted to meet the essential safety requirements of these Regulations, including a list of other relevant technical specifications applied. In the case of partly applied designated standards, the technical documentation shall specify the parts which have been applied;
- (e) results of design calculations made, examinations carried out, etc.;
- (f) test reports.

The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the pyrotechnic article has been placed on the market.

3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured pyrotechnic article with the applicable requirements of these Regulations.

4. Verification

An approved body chosen by the manufacturer shall carry out appropriate examinations and tests, set out in the relevant designated standards and/or equivalent tests set out in other relevant technical specifications, to check the conformity of the pyrotechnic article with the applicable requirements of these Regulations, or have them carried out. In the absence of such a designated standard the approved body concerned shall decide on the appropriate tests to be carried out.

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The approved body shall issue a certificate of conformity in respect of the examinations and tests carried out and shall affix its identification number to the approved pyrotechnic article, or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for 10 years after the pyrotechnic article has been placed on the market.

5. UK marking and declaration of conformity

5.1. The manufacturer shall affix the UK marking and, under the responsibility of the approved body referred to in point 4, the latter's identification number to each pyrotechnic article that satisfies the applicable requirements of these Regulations.

5.2. The manufacturer shall draw up a written declaration of conformity and keep it at the disposal of the national authorities for 10 years after the pyrotechnic article has been placed on the market. The declaration of conformity shall identify the pyrotechnic article for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

PART 6

Module H: Conformity based on full quality assurance

1. Conformity based on full quality assurance is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the pyrotechnic articles concerned satisfy the requirements of these Regulations that apply to them.

2. Manufacturing

The manufacturer shall operate an approved quality system for design, manufacture and final product inspection and testing of the pyrotechnic articles concerned as specified in point 3 and shall be subject to surveillance as specified in point 4.

3. Quality system

3.1. The manufacturer shall lodge an application for assessment of his quality system with the approved body of his choice for the pyrotechnic articles concerned.

The application shall include:

- (a) the name and address of the manufacturer;
- (b) the technical documentation for one model of each pyrotechnic article category intended to be manufactured. The technical documentation shall, wherever applicable, contain at least the following elements:
 - a general description of the pyrotechnic article;
 - conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;
 - descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the pyrotechnic article;
 - a list of the designated standards applied in full or in part and, where those designated standards have not been applied, descriptions of the solutions adopted to meet the essential safety requirements of these Regulations, including a list of other relevant technical specifications applied. In the event of partly

applied designated standards, the technical documentation shall specify the parts which have been applied;

- results of design calculations made, examinations carried out, etc.;
- test reports;
- (c) the documentation concerning the quality system;
- (d) a written declaration that the same application has not been lodged with any other approved body.

3.2. The quality system shall ensure compliance of the pyrotechnic articles with the applicable requirements of these Regulations.

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

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

- (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality;
- (b) the technical design specifications, including standards that will be applied and, where the relevant designated standards will not be applied in full, the means that will be used to ensure that the essential safety requirements of these Regulations will be met;
- (c) the design control and design verification techniques, processes and systematic actions that will be used when designing the pyrotechnic articles pertaining to the pyrotechnic article category covered;
- (d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;
- (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, qualification reports on the personnel concerned, etc.;
- (g) the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.

3.3. The approved body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant designated standard.

In addition to experience in quality management systems, the auditing team shall have at least one member experienced as an assessor in the relevant product field and product technology concerned, and knowledge of the applicable requirements of these Regulations. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1(b) to verify the manufacturer's ability to identify the applicable requirements of these Regulations and to carry out the necessary examinations with a view to ensuring compliance of the pyrotechnic article with those requirements.

The manufacturer shall be notified of the decision.

The notification shall contain the conclusions of the audit and the reasoned assessment decision.

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3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

3.5. The manufacturer shall keep the approved body that has approved the quality system informed of any intended change to the quality system.

The approved body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

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

4. Surveillance under the responsibility of the approved body

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

4.2. The manufacturer shall, for assessment purposes, allow the approved body access to the design, manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:

- (a) the quality system documentation;
- (b) the quality records as provided for by the design part of the quality system such as the results of analyses, calculations, tests, etc.;
- (c) the quality records as provided for by the manufacturing part of the quality system such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

4.3. The approved body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

4.4. In addition, the approved body may pay unexpected visits to the manufacturer. During such visits, the approved body may, if necessary, carry out product tests, or have them carried out, in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

5. UK marking and declaration of conformity

5.1. The manufacturer shall affix the UK marking and, under the responsibility of the approved body referred to in point 3.1, the latter's identification number to each individual pyrotechnic article that satisfies the applicable requirements of these Regulations.

5.2. The manufacturer shall draw up a written declaration of conformity for each product model and keep it at the disposal of the national authorities for 10 years after the pyrotechnic article has been placed on the market. The declaration of conformity shall identify the pyrotechnic article for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

6. The manufacturer shall, for a period ending 10 years after the pyrotechnic article has been placed on the market, keep at the disposal of the national authorities:

- (a) the technical documentation referred to in point 3.1;
- (b) the documentation concerning the quality system referred to in point 3.1;
- (c) the information relating to the change referred to in point 3.5, as approved;
- (d) the decisions and reports of the approved body referred to in points 3.5, 4.3 and 4.4.

7. Each approved body shall inform the Secretary of State of quality system approvals issued or withdrawn and shall, periodically or upon request, make available to the Secretary of State the list of quality system approvals refused, suspended or otherwise restricted.

Each approved body shall inform the other approved bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.”.