[F1SCHEDULE 15 Regulations 42, 44 to 47, 50 to 52 and 54

Conformity assessment procedures

Textual Amendments

F1 Sch. 15 inserted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 28 para. 54** (with Sch. 28 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

MODULE A

Internal production control

Internal production control

1. Internal production control is the conformity assessment procedure whereby the manufacturer—

(a) fulfils the obligations set out in paragraphs 2 to 4; and

(b) ensures and declares on the manufacturer's sole responsibility that the product concerned meets the essential requirements that apply to it.

Technical documentation

2.—(1) The manufacturer must draw up the technical documentation.

(2) The technical documentation must—

(a) make it possible to assess the product's conformity with the essential requirements that apply to it;

(b) include an adequate analysis and assessment of any risks;

(c) specify the essential requirements that apply to the product; and

(d) cover, as far as relevant for the assessment, the design, manufacture and operation of the product.

(3) The technical documentation must contain, where applicable, at least the following—

(a) a general description of the product;

(b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies and circuits;

(c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product;

(d) a list of the designated standards and other relevant technical specifications applied in full or in part (and where designated standards have been applied in part, the technical documentation must specify the parts which have been applied);

(e) where designated standards have not been applied, descriptions of the solutions adopted to meet the essential requirements;

(f) results of design calculations made and examinations carried out;

(g) test reports.

Manufacturing

3. The manufacturer must take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured product with—

(a) the technical documentation referred to in paragraph 2; and

(b) the essential requirements that apply to it.

UK marking and declaration of conformity

4.—(1) The manufacturer must affix the UK marking to each individual product that meets the essential requirements that apply to it.

(2) The manufacturer must draw up a declaration of conformity for each product model and keep it together with the technical documentation at the disposal of the enforcing authority for 10 years after the product has been placed on the market. The declaration of conformity must identify the product model for which it has been drawn up.

(3) The manufacturer must make a copy of the declaration of conformity available to the enforcing authority upon request.

MODULE A1

Internal production control plus supervised product testing

Internal production control plus supervised product testing

1. Internal production control plus supervised product testing is the conformity assessment procedure whereby the manufacturer—

(a) fulfils the obligations set out in paragraphs 2 to 5; and

(b) ensures and declares on the manufacturer's sole responsibility that the product concerned meets the essential requirements that apply to it.

Technical documentation

2.—(1) The manufacturer must draw up the technical documentation.

(2) The technical documentation must—

(a) make it possible to assess the product's conformity with the essential requirements that apply to it;

(b) include an adequate analysis and assessment of any risks;

(c) specify the essential requirements that apply to the product; and

(d) cover, as far as relevant for the assessment, the design, manufacture and operation of the product.

(3) The technical documentation must contain, where applicable, at least the following—

(a) a general description of the product;

(b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies and circuits;

(c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product;

(d) a list of the designated standards and other relevant technical specifications applied in full or in part (and where designated standards have been applied in part, the technical documentation must specify the parts which have been applied);

(e) where designated standards have not been applied, descriptions of the solutions adopted to meet the essential requirements;

(e) results of design calculations made and examinations carried out;

(f) test reports.

Manufacturing

3. The manufacturer must take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured product with—

(a) the technical documentation referred to in paragraph 2; and

(b) the essential requirements that apply to it.

Product checks

4.—(1) For each individual product manufactured, one or more tests on one or more specific aspects of the product must be carried out on the manufacturer's behalf in order to verify the product's conformity with the essential requirements that apply to it.

(2) The tests must be carried out under the responsibility of an approved body chosen by the manufacturer.

(3) The manufacturer must, under the responsibility of the approved body, affix the approved body's identification number to the product during the manufacturing process.

UK marking and declaration of conformity

5.—(1) The manufacturer must affix the UK marking to each individual product that meets the essential requirements that apply to it.

(2) The manufacturer must draw up a declaration of conformity for each product model and keep it together with the technical documentation at the disposal of the enforcing authority for 10 years after the product has been placed on the market. The declaration of conformity must identify the product model for which it has been drawn up.

(3) The manufacturer must make a copy of the declaration of conformity available to the enforcing authority upon request.

MODULE B

Type examination

Type examination

1. Type examination is the part of a conformity assessment procedure in which an approved body—

(a) examines the technical design of a product; and

(b) verifies and attests that the technical design of the product meets the essential requirements that apply to it.

How type examination must be carried out, etc.

2.—(1) The conformity assessment procedure must include an assessment of the adequacy of the technical design of the product through examination of the technical documentation and supporting evidence referred to in paragraph 3, plus examination of specimens, representative of the production envisaged, of one or more critical parts of the product (combination of production type and design type).

(2) The assessment referred to in sub-paragraph (1) may cover several versions of the product if—

(a) the differences between the versions of the product do not affect the level of safety and the other requirements concerning the performance of the product; and

(b) the different versions of the product are referred to in the corresponding type examination certificate, if necessary by means of amendments to the original certificate.

Application for type examination

3.—(1) The manufacturer must lodge an application for type examination with a single approved body of the manufacturer's choice.

(2) The application must include—

(a) the name and address of the manufacturer and, if the application is lodged by an authorised representative, the name and address of the authorised representative;

(b) a declaration that the same application has not been lodged with any other approved body;

(c) the technical documentation;

(d) the specimens representative of the production envisaged; and

(e) the supporting evidence for the adequacy of the technical design solution.

(3) The manufacturer must, if requested by the approved body, provide further specimens if needed for carrying out the test programme.

(4) The technical documentation referred to in sub-paragraph (2)(c) must—

(a) make it possible to assess the product's conformity with the essential requirements that apply to it;

(b) include an adequate analysis and assessment of any risks;

(c) specify the essential requirements that apply to the product; and

(d) cover, as far as relevant for the assessment, the design, manufacture and operation of the product.

(5) The technical documentation referred to in sub-paragraph (2)(c) must contain, where applicable, at least the following—

(a) a general description of the product;

(b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies and circuits;

(c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product;

(d) a list of the designated standards and other relevant technical specifications applied in full or in part (and where designated standards have been applied in part, the technical documentation must specify the parts which have been applied);

(e) where designated standards have not been applied, descriptions of the solutions adopted to meet the essential requirements;

(f) results of design calculations made and examinations carried out;

(g) test reports.

(5) The supporting evidence for the adequacy of the technical design solution referred to in sub-paragraph (2)(e) must—

(a) mention any documents that have been used, in particular where the relevant designated standards or technical specifications have not been applied in full; and

(b) include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer, or by another testing laboratory on the manufacturer's behalf and under the manufacturer's responsibility.

Examination, etc. by approved body

4.—(1) The approved body must examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the product.

(2) The approved body must—

(a) verify that the specimen has 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 or technical specifications, as well as the elements which have been designed without applying the relevant provisions of those standards or specifications;

(b) 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 or technical specifications, these have been applied correctly;

(c) carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant designated standards or technical specifications have not been applied, the solutions adopted by the manufacturer meet the essential requirements covered by the standards or specifications; and

(d) agree with the manufacturer on a location where the examinations and tests will be carried out.

Evaluation report

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

Type examination certificate

6.—(1) Where the type meets the essential requirements that apply to the product concerned, the approved body must issue a type examination certificate to the manufacturer.

(2) The certificate (which may have one or more annexes attached) must contain—

(a) the name and address of the manufacturer;

(b) the conclusions of the examination;

(c) the conditions (if any) for its validity;

(d) the necessary data for identification of the approved type; and

(e) all relevant information to allow the conformity of manufactured products with the examined type to be evaluated and to allow for in-service control.

(3) Where the type does not meet the essential requirements that apply to the product concerned, the approved body must refuse to issue a type examination certificate and must inform the applicant accordingly, giving detailed reasons for its refusal.

Changes

7.—(1) The approved body must 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 essential requirements that apply to the product concerned and must determine whether such changes require further investigation. If so, the approved body must inform the manufacturer accordingly.

(2) The manufacturer must 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 product with the essential requirements that apply to it or the conditions for validity of the certificate. Such modifications require additional approval in the form of an addition to the original type examination certificate.

Approved body's duties in respect of type examination certificates

8.—(1) The approved body must inform the Secretary of State about the type examination certificates and any additions thereto which it has issued or withdrawn and must, periodically or upon request, make available to the Secretary of State a list of certificates and any additions thereto refused, suspended or otherwise restricted.

(2) The approved body must inform the other approved bodies about the type examination certificates and any additions thereto which it has refused, withdrawn, suspended or otherwise restricted and, upon request, about such certificates and additions thereto which it has issued.

(3) The approved body must, on request, provide the Secretary of State and other approved bodies with a copy of the type examination certificates and additions thereto which it has issued.

(4) The approved body must, on request, provide the Secretary of State with a copy of the technical documentation and the results of the examinations carried out by the approved body.

(5) The approved body must 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 the certificate.

Manufacturer's duties in respect of type examination certificates

9. The manufacturer must keep a copy of the type examination certificate, its annexes and additions together with the technical documentation at the disposal of the enforcing authority for 10 years after the product has been placed on the market.

MODULE C

Conformity to type based on internal production control

Conformity to type based on internal production control

1. Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer—

(a) fulfils the obligations set out in paragraphs 2 and 3; and

(b) ensures and declares that the product concerned is in conformity with the type described in the type examination certificate and meets the essential requirements that apply to it.

Manufacturing

2. The manufacturer must take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured product with—

(a) the approved type described in the type examination certificate; and

(b) the essential requirements that apply to it.

UK marking and declaration of conformity

3.—(1) The manufacturer must affix the UK marking to each individual product thatis in conformity with the type described in the type examination certificate and meets the essential requirements that apply to it.

(2) The manufacturer must draw up a declaration of conformity for each product model and keep it at the disposal of the enforcing authority for 10 years after the product has been placed on the market. The declaration of conformity must identify the product model for which it has been drawn up.

(3) The manufacturer must make a copy of the declaration of conformity available to the enforcing authority upon request.

MODULE C1

Conformity to type based on internal production control plus supervised product testing

Conformity to type based on internal production control plus supervised product testing

1. Conformity to type based on internal production control plus supervised product testing is the part of a conformity assessment procedure whereby the manufacturer—

(a) fulfils the obligations set out in paragraphs 2 to 4; and

(b) ensures and declares on the manufacturer's sole responsibility that the product concerned—

(i) is in conformity with the type described in the type examination certificate; and

(ii) meets the essential requirements that apply to it.

Manufacturing

2. The manufacturer must take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured product with—

(a) the type described in the type examination certificate; and

(b) the essential requirements that apply to it.

Product checks

3.—(1) For each individual product manufactured, one or more tests on one or more specific aspects of the product must be carried out on the manufacturer's behalf in order to verify the product's conformity with the essential requirements that apply to it.

(2) The tests must be carried out under the responsibility of an approved body chosen by the manufacturer.

(3) The manufacturer must, under the responsibility of the approved body, affix the approved body's identification number to the product during the manufacturing process.

UK marking and declaration of conformity

4.—(1) The manufacturer must affix the UK marking to each individual product thatis in conformity with the type described in the type examination certificate and meets the essential requirements that apply to it.

(2) The manufacturer must draw up a declaration of conformity for each product model and keep it at the disposal of the enforcing authority for 10 years after the product has been placed on the market. The declaration of conformity must identify the product model for which it has been drawn up.

(3) The manufacturer must make a copy of the declaration of conformity available to the enforcing authority upon request.

MODULE D

Conformity to type based on quality assurance of the production process

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—

(a) fulfils the obligations set out in paragraphs 2 and 5; and

(b) ensures and declares on the manufacturer's sole responsibility that the product concerned—

(i) is in conformity with the type described in the type examination certificate; and

(ii) meets the essential requirements that apply to it.

Manufacturing

2. The manufacturer—

(a) must operate an approved quality system for production, final product inspection and testing of the products concerned as specified in paragraph 3; and

(b) is subject to surveillance as specified in paragraph 4.

Quality system

3.—(1) The manufacturer must lodge an application for assessment of the manufacturer's quality system with the approved body of the manufacturer's choice for the products concerned.

(2) The application must include—

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, the name and address of the authorised representative;

(b) a declaration that the same application has not been lodged with any other approved body;

(c) all relevant information for the product 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) The quality system must ensure that the products—

(a) are in conformity with the type described in the type examination certificate; and

(b) meet the essential requirements that apply to them.

(4) 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.

(5) The quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records and 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 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 and qualification reports on the personnel concerned; and

(e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

(6) The approved body must assess the quality system to determine whether it satisfies the requirements referred to in sub-paragraph (3). The approved body must 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 or technical specification.

(7) For the purpose of the assessment referred to in sub-paragraph (6), the approved body must ensure that—

(a) in addition to experience in quality management systems, the auditing team has at least one member with experience of evaluation in the relevant product field and product technology concerned and knowledge of the essential requirements that apply to the products;

(b) the audit includes an assessment visit to the manufacturer's premises; and

(c) the auditing team reviews the technical documentation referred to in sub-paragraph (2)(e) to verify the manufacturer's ability to identify the essential requirements that apply to the products and to carry out the necessary examinations with a view to ensuring compliance of the products with those requirements.

(8) The approved body must notify its decision on whether the quality system satisfies the requirements referred to in sub-paragraph (3) to the manufacturer. The notification must contain the conclusions of the audit and the approved body's reasoned assessment.

(9) The manufacturer must undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

(10) The manufacturer must keep the approved body that approved the quality system informed of any intended change to the quality system, and if so informed, the approved body must evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in sub-paragraph (3) or whether a reassessment is necessary.

(11) The approved body must notify the manufacturer of its decision. The notification must contain the conclusions of the examination and the approved body's reasoned assessment.

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.

(2) The manufacturer must, for assessment purposes, allow the approved body access to the manufacture, inspection, testing and storage sites and must 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, and qualification reports on the personnel concerned.

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

(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 must provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

UK marking and declaration of conformity

5.—(1) The manufacturer must affix the UK marking and, under the responsibility of the approved body referred to in paragraph 3(1), the approved body's identification number to each individual product that is in conformity with the type described in the type examination certificate and meets the essential requirements that apply to it.

(2) The manufacturer must draw up a declaration of conformity for each product model and keep it at the disposal of the enforcing authority for 10 years after the product has been placed on the market. The declaration of conformity must identify the product model for which it has been drawn up.

(3) The manufacturer must make a copy of the declaration of conformity available to the enforcing authority upon request.

Manufacturer's duty to keep application, etc.

6. The manufacturer must, for a period ending at least 10 years after the product has been placed on the market, keep at the disposal of the enforcing authority—

(a) a copy of the application referred to in paragraph 3(1) including the information and documentation referred to in paragraph 3(2);

(b) documents relating to any change to the quality system referred to in paragraph 3(10), as approved by the approved body;

(c) the decisions and reports of the approved body referred to in paragraphs 3(11) and 4(3) and (4).

Approved body's duties in respect of quality system approvals

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

(2) Each approved body must 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.

MODULE E

Conformity to type based on product quality assurance

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—

(a) fulfils the obligations set out in paragraphs 2 and 5; and

(b) ensures and declares on the manufacturer's sole responsibility that the product concerned—

(i) is in conformity with the type described in the type examination certificate; and

(ii) meets the essential requirements that apply to it.

Manufacturing

2. The manufacturer—

(a) must operate an approved quality system for final product inspection and testing of the products concerned as specified in paragraph 3; and

(b) is subject to surveillance as specified in paragraph 4.

Quality system

3.—(1) The manufacturer must lodge an application for assessment of the manufacturer's quality system with the approved body of the manufacturer's choice for the products concerned.

(2) The application must include—

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, the authorised representative's name and address;

(b) a declaration that the same application has not been lodged with any other approved body;

(c) all relevant information for the product category envisaged;

(d) the documentation concerning the quality system; and

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

(3) The quality system must ensure that the products—

(a) are in conformity with the type described in the type examination certificate; and

(b) meet the essential requirements that apply to them.

(4) 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.

(5) The quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records and 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 examinations and tests that will be carried out after manufacture;

(c) the quality records, such as inspection reports and test data, calibration data and qualification reports on the personnel concerned; and

(d) the means of monitoring the effective operation of the quality system.

(6) The approved body must assess the quality system to determine whether it satisfies the requirements referred to in sub-paragraph (3). The approved body must 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 or technical specification.

(7) For the purpose of the assessment referred to in sub-paragraph (6), the approved body must ensure that—

(a) in addition to experience in quality management systems, the auditing team has at least one member with experience of evaluation in the relevant product field and product technology concerned and knowledge of the essential requirements that apply to the products;

(b) the audit includes an assessment visit to the manufacturer's premises; and

(c) the auditing team reviews the technical documentation referred to in sub-paragraph (2)(e) to verify the manufacturer's ability to identify the essential requirements that apply to the products and to carry out the necessary examinations with a view to ensuring compliance of the products with those requirements.

(8) The approved body must notify its decision on whether the quality system satisfies the requirements referred to in sub-paragraph (3) to the manufacturer. The notification must contain the conclusions of the audit and the approved body's reasoned assessment.

(9) The manufacturer must undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

(10) The manufacturer must keep the approved body that approved the quality system informed of any intended change to the quality system, and if so informed, the approved body must evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in sub-paragraph (3) or whether a reassessment is necessary.

(11) The approved body must notify the manufacturer of its decision. The notification must contain the conclusions of the examination and the approved body's reasoned assessment.

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.

(2) The manufacturer must, for assessment purposes, allow the approved body access to the manufacture, inspection, testing and storage sites and must 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 and qualification reports on the personnel concerned.

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

(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 must provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

UK marking and declaration of conformity

5.—(1) The manufacturer must affix the UK marking and, under the responsibility of the approved body referred to in paragraph 3(1), the approved body's identification number to each

individual product that is in conformity with the type described in the type examination certificate and meets the essential requirements that apply to it.

(2) The manufacturer must draw up a declaration of conformity for each product model and keep it at the disposal of the enforcing authority for 10 years after the product has been placed on the market. The declaration of conformity must identify the product model for which it has been drawn up.

(3) The manufacturer must make a copy of the declaration of conformity available to the enforcing authority upon request.

Manufacturer's duty to keep application, etc.

6. The manufacturer must, for a period ending at least 10 years after the product has been placed on the market, keep at the disposal of the enforcing authority—

(a) a copy of the application referred to in paragraph 3(1) including the information and documentation referred to in paragraph 3(2);

(b) documents relating to any change to the quality system referred to in paragraph 3(10), as approved by the approved body;

(c) the decisions and reports of the approved body referred to in paragraphs 3(11) and 4(3) and (4).

Approved body's duties in respect of quality system approvals

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

(2) Each approved body must 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.

MODULE F

Conformity to type based on product verification

Conformity to type based on product verification

1. Conformity to type based on product verification is the part of a conformity assessment procedure whereby the manufacturer—

(a) fulfils the obligations set out in paragraphs 2, 5(1) and 6; and

(b) ensures and declares on the manufacturer's sole responsibility that the product concerned, which has been subject to the provisions of paragraph 3—

(i) is in conformity with the type described in the type examination certificate; and

(ii) meets the essential requirements that apply to it.

Manufacturing

2. The manufacturer must take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured product with—

(a) the approved type described in the type examination certificate; and

(b) the essential requirements that apply to it.

Verification

3.—(1) An approved body chosen by the manufacturer must carry out appropriate examinations and tests in order to check the conformity of the product with—

(a) the approved type described in the type examination certificate; and

(b) the essential requirements that apply to it.

(2) The examinations and tests to check the conformity of the products with the essential requirements that apply to it must be carried out, at the choice of the manufacturer, either by—

(a) examination and testing of every product as specified in paragraph 4; or

(b) examination and testing of the products on a statistical basis as specified in paragraph 5.

Verification of conformity by examination and testing of every product

4.—(1) All products must be individually examined, and appropriate tests set out in the relevant designated standard or technical specifications or equivalent tests must be carried out in order to verify conformity with the approved type described in the type examination certificate and with the essential requirements that apply to it. In the absence of such a designated standard, the approved body concerned must decide on the appropriate tests to be carried out.

(2) The approved body must issue a certificate of conformity in respect of the examinations and tests carried out and must affix its identification number to each approved product or have it affixed under its responsibility.

(3) The manufacturer must keep the certificates of conformity at the disposal of the enforcing authority for 10 years after the product has been placed on the market.

Statistical verification of conformity

5.—(1) The manufacturer must take all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of each lot produced and must present the manufacturer's products for verification in the form of homogeneous lots.

(2) A random sample must be taken from each lot by the approved body. All products in a sample must be individually examined, and appropriate tests set out in the relevant designated standard or technical specification or equivalent tests must be carried out in order to ensure their conformity with the essential requirements that apply to them and to determine whether the lot is to be accepted or rejected. In the absence of such a designated standard, the approved body concerned must decide on the appropriate tests to be carried out.

(3) If a lot is accepted, all products of the lot must be considered approved, except for those products from the sample that have been found not to satisfy the tests.

(4) The approved body must issue a certificate of conformity in respect of the examinations and tests carried out and must affix its identification number to each approved product or have it affixed under its responsibility.

(5) The manufacturer must keep the certificates of conformity at the disposal of the enforcing authority for 10 years after the product has been placed on the market.

(6) If a lot is rejected, the approved body or, if the approved body fails to do so, the Secretary of State must take appropriate measures to prevent that lot being placed on the market. In the event of the frequent rejection of lots, the approved body may suspend the statistical verification and take appropriate measures.

UK marking and declaration of conformity

6.—(1) The manufacturer must affix the UK marking and, under the responsibility of the approved body referred to in paragraph 3, the approved body's identification number to each individual product that is in conformity with the approved type described in the type examination certificate and meets the essential requirements that apply to it.

(2) The manufacturer must draw up a declaration of conformity for each product model and keep it at the disposal of the enforcing authority for 10 years after the product has been placed on the market. The declaration of conformity must identify the product model for which it has been drawn up.

(3) The manufacturer must make a copy of the declaration of conformity available to the enforcing authority upon request.

(4) If the approved body referred to in paragraph 3 agrees and under its responsibility, the manufacturer may also affix the approved body's identification number to the product.

Affixing of approved body's identification number during manufacturing process

7. If the approved body agrees and under its responsibility, the manufacturer may affix the approved body's identification number to the product during the manufacturing process.

Authorised representative

8. Where the manufacturer appoints an authorised representative (see regulation 39), the obligations in paragraphs 2 and 5(1) must not form part of the authorised representative's mandate.

MODULE G

Conformity based on unit verification

Conformity based on unit verification

1. Conformity based on unit verification is the conformity assessment procedure whereby the manufacturer—

(a) fulfils the obligations set out in paragraphs 2, 3 and 5; and

(b) ensures and declares on the manufacturer's sole responsibility that the product concerned, which has been subject to the provisions of paragraph 4, meets the essential requirements that apply to it.

Technical documentation

2.—(1) The manufacturer must draw up the technical documentation and make it available to the approved body referred to in paragraph 4.

(2) The technical documentation must—

(a) make it possible to assess the product's conformity with the essential requirements that apply to it;

(b) include an adequate analysis and assessment of the risks;

(c) specify the essential requirements that apply to the product; and

(d) cover, as far as relevant for the assessment, the design, manufacture and operation of the product.

(3) The technical documentation must contain, where applicable, at least the following—

(a) a general description of the product;

(b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies and circuits;

(c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product;

(d) a list of the designated standards and other relevant technical specifications, applied in full or in part (and where designated standards have been applied in part, the technical documentation must specify the parts which have been applied);

(e) where designated standards have not been applied, descriptions of the solutions adopted to meet the essential requirements;

(f) results of design calculations made and examinations carried out;

(g) test reports.

(4) The manufacturer must keep the technical documentation at the disposal of the enforcing authority for 10 years after the product has been placed on the market.

Manufacturing

3. The manufacturer must take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured product with the essential requirements that apply to it.

Verification

4.—(1) An approved body chosen by the manufacturer must carry out appropriate examinations and tests, set out in the relevant designated standard or technical specification or equivalent tests, to check the conformity of the product with the essential requirements that apply to it or have them carried out. In the absence of such a designated standard or technical specification the approved body concerned must decide on the appropriate tests to be carried out.

(2) The approved body must issue a certificate of conformity in respect of the examinations and tests carried out and must affix its identification number to the approved product or have it affixed under its responsibility.

(3) The manufacturer must keep the certificates of conformity at the disposal of the enforcing authority for 10 years after the product has been placed on the market.

UK marking and declaration of conformity

5.—(1) The manufacturer must affix the UK marking and, under the responsibility of the approved body referred to in paragraph 4, the approved body's identification number to each product that meets the essential requirements that apply to it.

(2) The manufacturer must draw up a declaration of conformity and keep it at the disposal of the enforcing authority for 10 years after the product has been placed on the market. The declaration of conformity must identify the product for which it has been drawn up.

(3) The manufacturer must make a copy of the declaration of conformity available to the enforcing authority upon request.

MODULE H

Conformity based on full quality assurance

Conformity based on full quality assurance

1. Conformity based on full quality assurance is the conformity assessment procedure whereby the manufacturer—

(a) fulfils the obligations set out in paragraphs 2 and 5; and

(b) ensures and declares on the manufacturer's sole responsibility that the product concerned meets the essential requirements that apply to it.

Manufacturing

2. The manufacturer—

(a) must operate an approved quality system for design, manufacture and final product inspection and testing of the product concerned as specified in paragraph 3; and

(b) is subject to surveillance as specified in paragraph 4.

Quality system

3.—(1) The manufacturer must lodge an application for assessment of the manufacturer's quality system with the approved body of the manufacturer's choice for the product concerned.

(2) The application must include—

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, the name and address of the authorised representative;

(b) the technical documentation for one model of each category of products intended to be manufactured, which must contain, where applicable, at least the following—

(i) a general description of the product;

(ii) conceptual design and manufacturing drawings and schemes of components, sub-assemblies and circuits;

(iii) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product;

(iv) a list of the designated standards and other relevant technical specifications applied in full or in part (and where designated standards have been applied in part, the technical documentation must specify the parts which have been applied);

(v) where designated standards have not been applied, descriptions of the solutions adopted to meet the essential requirements;

(vi) results of design calculations made and examinations carried out;

(vii) test reports;

(c) the documentation concerning the quality system; and

(d) a declaration that the same application has not been lodged with any other approved body.

(3) The quality system must ensure that the products meet the essential requirements that apply to them.

(4) 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.

(5) The quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records and 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 design and product quality;

(b) the technical design specifications, including standards, that will be applied and, where the relevant designated standards or technical specifications will not be applied in full, the means that will be used to ensure that the essential requirements that apply to the products will be met;

(c) the design control and design verification techniques, processes and systematic actions that will be used when designing the products pertaining to the product 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 and qualification reports on the personnel concerned;

(g) the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.

(6) The approved body must assess the quality system to determine whether it satisfies the requirements referred to in sub-paragraph (3). The approved body must 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 or technical specification.

(7) For the purpose of the assessment referred to in sub-paragraph (6), the approved body must ensure that—

(a) in addition to experience in quality management systems, the auditing team has at least one member experienced as an assessor in the relevant product field and product technology concerned, and knowledge of the essential requirements that apply to the products;

(b) the audit includes an assessment visit to the manufacturer's premises; and

(c) the auditing team reviews the technical documentation referred to sub-paragraph (2)(b) to verify the manufacturer's ability to identify the essential requirements that apply to the products and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.

(8) The approved body must notify the manufacturer or the manufacturer's authorised representative of its decision on whether the quality system satisfies the requirements referred to in sub-paragraph (3). The notification must contain the conclusions of the audit and the approved body's reasoned assessment.

(9) The manufacturer must undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

(10) The manufacturer must keep the approved body that approved the quality system informed of any intended change to the quality system, and if so informed, the approved body must evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in sub-paragraph (3) or whether a reassessment is necessary.

(11) The approved body must notify the manufacturer of its decision. The notification must contain the conclusions of the examination and the approved body's reasoned assessment.

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.

(2) The manufacturer must, for assessment purposes, allow the approved body access to the design, manufacture, inspection, testing and storage sites and must 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 results of analyses, calculations and tests; and

(c) the quality records as provided for by the manufacturing part of the quality system, such as inspection reports and test data, calibration data and qualification reports on the personnel concerned.

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

(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 must provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

UK marking and declaration of conformity

5.—(1) The manufacturer must affix the UK marking and, under the responsibility of the approved body referred to in paragraph 3(1), the approved body's identification number to each individual product that meets the essential requirements that apply to it.

(2) The manufacturer must draw up a declaration of conformity for each product model and keep it at the disposal of the enforcing authority for 10 years after the product has been placed on the market. The declaration of conformity must identify the product model for which it has been drawn up.

(3) The manufacturer must make a copy of the declaration of conformity available to the enforcing authority upon request.

Manufacturer's duty to keep application, etc.

6. The manufacturer must, for a period ending at least 10 years after the product has been placed on the market, keep at the disposal of the enforcing authority—

(a) the technical documentation referred to in paragraph 3(2)(b);

(b) the documentation concerning the quality system referred to in paragraph 3(2)(c);

(c) documents relating to any change to the quality system referred to in paragraph 3(10), as approved by the approved body;

(d) the decisions and reports of the approved body referred to in paragraphs 3(11) and 4(3) and (4).

Approved body's duties in respect of quality system approvals

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

(2) Each approved body must 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.**]**

Changes to legislation:
There are currently no known outstanding effects for the The Recreational Craft Regulations 2017, SCHEDULE 15.