SCHEDULE 28

Amendment of the Recreational Craft Regulations 2017 and related amendment

PART 1

Amendment to the Recreational Craft Regulations 2017

Introduction

1. The Recreational Craft Regulations 2017 are amended in accordance with paragraphs 2 to 54.

Amendment to regulation 2

2.—(1) Regulation 2 (interpretation) is amended as follows.

(2) In paragraph (1)—

(a) omit the definition of "accreditation";

(b) omit the definition of "accreditation certificate";

(c) after the definition of "adaptor" insert—

""approved body" has the meaning given to it in regulation 55 (approved bodies);";

(d) for the definition of "authorised representative" substitute—

""authorised representative" means—

(a) a person who—

(i) immediately before exit day was established in the United Kingdom or an EEA state and was appointed by a manufacturer by written mandate to perform specified tasks for that manufacturer, in accordance with regulation 39, as it had effect immediately before exit day; and

(ii) on or after exit day continues to be so established and appointed by the manufacturer to perform those tasks; or

(b) a person who, on or after exit day, is appointed in accordance with regulation 39;";

(e) omit the definition of "CE marking";

(f) omit the definition of "competent national authority";

(g) in the definition of "components" omit "EU";

(h) after the definition of "conformity assessment body" insert—

""declaration of conformity" means the declaration required to be drawn up in accordance with regulation 10;

"designated standard" has the meaning given to it in regulation 2A;";

(i) omit the definition of "Decision 768/2008";

(j) in the definition of the "Directive" at the end insert "(as it had effect immediately before exit day)";

(k) omit the definition of "EU declaration of conformity";

(l) omit the definition of "harmonised standard";

(m) in the definition of "hull length" for "harmonised" substitute "designated";

(n) for the definition of "importer" substitute—

""importer" means a person who—

(a) is established in the United Kingdom; and

(b) places a product from a country outside of the United Kingdom on the market;";

(o) in the definition of "making available on the market" for "EU" substitute "United Kingdom";

(p) omit the definition of "national accreditation body";

(q) omit the definition of "notified body requirements";

(r) in the definition of "placing on the market" for "EU" substitute "United Kingdom";

(s) for the definition of "private importer" substitute—

""private importer" means a person who—

(a) is established in the United Kingdom; and

(b) imports in the course of a non-commercial activity a watercraft from a country outside of the United Kingdom into the United Kingdom with the intention of putting it into service for the person's own use;";

(t) in the definition of "putting into service" for "EU" substitute "United Kingdom";

(u) after the definition of "technical documentation" insert—

""technical specification" means a document that prescribes technical requirements to be fulfilled by a product;

"UK marking" means the marking in the form set out in Annex 2 of RAMS;

"UK national accreditation body" means the body appointed by the Secretary of State in accordance with Article 4 of RAMS;".

(3) Omit paragraphs (4) and (5).

Insertion of regulation 2A

3. After regulation 2 insert—

"**Designated standard**

2A.—(1) Subject to paragraphs (6) and (7), in these Regulations, a "designated standard" means a technical specification which is—

(a) adopted by a recognised standardisation body, for repeated or continuous application, with which compliance is not compulsory; and

(b) designated by the Secretary of State by publishing the reference to the standard and maintaining that publication in a manner the Secretary of State considers appropriate.

(2) For the purposes of paragraph (1), a "technical specification" means a document that prescribes technical requirements to be fulfilled by a product, process, service or system and which lays down one or more of the following—

(a) the characteristics required of a product, including—

(i) levels of quality, performance, interoperability, environmental protection, health, safety or dimensions, and

(ii) the requirements applicable to the product as regards the name under which the product is sold, terminology, symbols, testing and test methods, packaging, marking or labelling and conformity assessment procedures; and

(b) production methods and processes relating to the product, where these have an effect on the characteristics of the product.

(3) For the purposes of this regulation, a "recognised standardisation body" means any one of the following organisations—

(a) the European Committee for Standardisation (CEN);

(b) the European Committee for Electrotechnical Standardisation (Cenelec);

(c) the European Telecommunications Standards Institute (ETSI);

(d) the British Standards Institution (BSI).

(4) When considering whether the manner of publication of a reference is appropriate in accordance with paragraph (1)(b), the Secretary of State must have regard to whether the publication will draw the standard to the attention of any person who may have an interest in the standard.

(5) Before publishing the reference to a technical specification adopted by the British Standards Institution, the Secretary of State must have regard to whether the technical specification is consistent with technical specifications adopted by the other recognised standardisation bodies.

(6) The Secretary of State may remove from publication the reference to a standard which has been published in accordance with paragraph (1)(b).

(7) Where the Secretary of State removes the reference to a standard from publication, that standard is no longer a designated standard.

(8) The Secretary of State may by regulations amend paragraph (3) to reflect any changes in the name or structure of the recognised standardisation bodies.

(9) Regulations made under paragraph (8) are to be made by statutory instrument.

(10) A statutory instrument containing regulations made under paragraph (8) is subject to annulment in pursuance of a resolution of either House of Parliament.".

Amendment to regulation 4

4. In regulation 4 (exclusions), in paragraph (1)(g), for "EU" substitute "United Kingdom".

Amendment to regulation 7

5. In regulation 7 (making available and putting into service)—

(a) omit paragraph (1)(c)(ii);

(b) in paragraph (2)—

(i) in sub-paragraph (a) omit "either Directive 97/68/EC or";

(ii) in sub-paragraph (b) omit "either the Directive or".

Substitution of regulation 10

6. For regulation 10 (EU declaration of conformity and CE marking) substitute—

"**Declaration of conformity and UK marking**

10.—(1) Where the conformity of a product with the essential requirements has been demonstrated by a relevant conformity assessment procedure, the manufacturer must, before placing the product on the market—

(a) draw up a declaration of conformity in accordance with regulation 53; and

(b) affix the UK marking to the product in accordance with regulation 54.

(2) The declaration of conformity must follow the format set out in Schedule 4.

(3) But where a declaration of conformity relates to a partly-completed watercraft, the declaration must follow the format set out in Schedule 3.

(4) The manufacturer must keep the declaration of conformity up to date.

(5) Where a product is subject to more than one enactment requiring the drawing up of a declaration of conformity, the manufacturer must draw up a single declaration of conformity which identifies each enactment by its title.".

Amendment to regulation 11

7. In regulation 11 (duty of manufacturers to retain technical documentation and EU declaration of conformity) and in the heading to that regulation omit "EU".

Amendment to regulation 12

8. In regulation 12 (compliance procedures for series production), in paragraph (2)(b)—

(a) for "harmonised" substitute "designated";

(b) omit "EU".

Amendment to regulation 15

9. In regulation 15 (instructions and safety information)—

(a) in paragraph (1) for "a language which can be easily understood by consumers and other end-users in the Member State in which the product is to be made available" substitute "English";

(b) omit paragraph (2).

Amendment to regulation 16

10. In regulation 16 (duty to take action in respect of product placed on the market which is considered not to be in conformity), in paragraph (2) omit "and the competent national authorities in any Member State in which the manufacturer has made the product available on the market".

Amendment to regulation 19

11. In regulation 19 (requirements that must be satisfied before an importer places a product on the market)—

(a) in paragraph (1)—

(i) in sub-paragraph (a) after "assessment" insert "procedure";

(ii) in sub-paragraph (c)(i) for "CE" substitute "UK";

(b) in paragraph (2)(a) omit "EU".

Amendment to regulation 21

12. In regulation 21, for paragraph (2) substitute—

"(2) Paragraph (1) does not apply where—

(a) either—

(i) in the case of a component, it is not possible to indicate the information specified in paragraph (1) on the component, or

(ii) the importer has imported the product from an EEA state and places it on the market within the period of 18 months beginning with exit day, and

(b) before placing the product on the market, the importer indicates the information specified in paragraph (1)—

(i) in the case of component, in a document accompanying the product or on the packaging; or

(ii) in all other cases, in a document accompanying the product.".

Amendment to regulation 22

13. In regulation 22 (instructions and safety information)—

(a) in paragraph (1) for "a language which can be easily understood by consumers and other end-users in the Member State in which the product is to be made available" substitute "English";

(b) omit paragraph (2).

Amendment to regulation 24

14. In regulation 24 (duty to take action in respect of product placed on the market which is considered not to be in conformity), in paragraph (2) omit "and the competent national authorities of any other Member State in which the importer has made the product available on the market".

Amendment to regulation 25

15. In regulation 25 (duty of importers to retain technical documentation and EU declaration of conformity) and in the heading to that regulation omit "EU".

Amendment to regulation 28

16. In regulation 28 (making available on the market), in paragraph (1)(a)—

(a) in paragraph (i) for "CE" substitute "UK";

(b) in paragraph (iii) for "a language that can be easily understood by consumers and other end-users in the Member State in which the product is to be made available on the market" substitute "English".

Amendment to regulation 29

17. In regulation 29 (duty not to make available a product on the market where a distributor suspects that it is not in conformity), in paragraph (2) omit "and the competent national authorities of other Member States in which the distributor has made the product available on the market".

Amendment to regulation 31

18. In regulation 31 (duty to take action in respect of watercraft placed on the market which is considered not to be in conformity), in paragraph (2) omit "and the competent national authorities of any other Member State in which the distributor has made the product available on the market".

Omission of regulation 35

19. Omit regulation 35 (translation of EU declaration of conformity).

Amendment to regulation 36

20. In regulation 36 (private importers)—

(a) in paragraph (1)(b)—

(i) in paragraph (ii) for "(EU declaration of conformity and CE marking)" substitute "(declaration of conformity and UK marking)";

(ii) in paragraph (iii) omit "EU";

(b) in paragraph (4) for "notified" substitute "approved".

Amendment to regulation 39

21. In regulation 39 (authorised representatives)—

(a) in paragraph (1) for "EU" substitute "United Kingdom";

(b) in paragraph (3)(a)—

(i) in paragraph (i) omit "EU";

(ii) omit "and competent national authorities";

(c) in paragraph (3)(c) for "competent national authorities" substitute "enforcing authority".

Amendment to regulation 40

22. In regulation 40 (prohibition on improper use of CE marking) in each place in which it occurs, and in the heading to that regulation, for "CE" substitute "UK".

Insertion of regulations 40A and 40B

23. After regulation 40 insert—

"**Obligations that are met by complying with obligations in the Directive**

40A.—(1) In this regulation—

(a) any reference to an Article or an Annex is a reference to an Article of or Annex to the Directive;

(b) "CE marking" has the meaning given in Article 3(28);

(c) "harmonised standard" has the meaning given in Article 3(20).

(2) For the purposes of this regulation, references to the requirements set out in Article 4(1) and Annex I are to be read as if they include a requirement that the owner's manuals referred to in point 2.5 of Part A of Annex I and point 4 of Part B of that Annex must be in English (instead of in a language or languages which can be easily understood by consumers and other end-users, as determined by the member State concerned).

(3) Where a product meets the requirements set out in Article 4(1) and Annex I—

(a) the requirements of regulation 6(a) and (b) are to be treated as being satisfied;

(b) regulation 2(2)(a) applies subject to the modification set out in paragraph (15)(c).

(4) Subject to paragraphs (8) and (9), paragraph (5) applies where, before placing a product on the market, the manufacturer—

(a) ensures that the product has been designed and manufactured in accordance with the requirements set out in Article 4(1) and Annex I;

(b) draws up the technical documentation in accordance with Article 25;

(c) carries out the conformity assessment procedure applicable to the product in accordance with Articles 19 to 22 and 24 or has it carried out;

(d) ensures that the technical documentation and any other records and correspondence relating to the conformity assessment procedures are prepared in or translated into English;

(e) affixes a CE marking to the product in accordance with Articles 16 to 18;

(f) draws up an EU declaration of conformity in accordance with Article 15; and

(g) ensures that the EU declaration of conformity is prepared in or translated into English.

(5) Where this paragraph applies—

(a) the requirements of regulations 8, 9 and 10(1), (2), (3) and (5) are to be treated as being satisfied;

(b) regulations 10(4), 11, 12(2), 39(3) and 40 apply subject to the modifications set out in paragraph (15);

(c) Part 3 (except for regulations 43(2) and (3) and 48) does not apply;

(d) regulation 71 does not apply.

(6) Subject to paragraphs (8) and (9), paragraph (7) applies where, before placing a product on the market, the importer ensures that—

(a) the conformity assessment procedure applicable to the product in accordance with Articles 19 to 22 and 24 has been carried out;

(b) the manufacturer has drawn up the technical documentation in accordance with Article 25; and

(c) the product bears the CE marking in accordance with Articles 16 to 18.

(7) Where this paragraph applies—

(a) the requirements of regulation 19(1)(a), (b) and (c)(i) are to be treated as being satisfied;

(b) regulations 18, 19(2), 20, 23 and 25 apply subject to the modifications set out in paragraph (15).

(8) This paragraph applies where there is no designated standard or part of a designated standard that corresponds exactly to a harmonised standard or part of a harmonised standard referred to in Article 14.

(9) Where paragraph (8) applies, paragraphs (4)(c) and (6)(a) of this regulation are to be read as requiring—

(a) in respect of products referred to in Article 20(1)(b)(i), one of the conformity assessment procedures (combination of procedures) referred to in the second indent of Article 20(1)(b)(i);

(b) in respect of exhaust emissions for products referred to in points (d) and (e) of Article 2(1), one of the conformity assessment procedures (or combinations of procedures) referred to in Article 21(b);

(c) in respect of noise emissions for products referred to in Article 22(1)—

(i) the conformity assessment procedure referred to in Article 22(1)(b); or

(ii) where applicable in accordance with Article 22(1)(c), one of the conformity assessment procedures referred to in Article 22(1)(c);

(d) in respect of noise emissions for products referred to in Article 22(2), the conformity assessment procedure referred to in Article 22(2)(b).

(10) Paragraph (11) applies where, before making a product available on the market, the distributor ensures that the product bears the CE marking in accordance with Articles 16 to 18.

(11) Where this paragraph applies—

(a) the requirement of regulation 28(1)(a)(i) is to be treated as being satisfied;

(b) regulations 19(2) (which contains the definition of "required documents" for the purposes of regulation 28), 29 and 30 apply subject to the modifications set out in paragraph (15).

(12) Paragraph (13) applies where the private importer—

(a) ensures before putting a product into service that the product has been designed and manufactured in accordance with the requirements set out in Article 4(1) and Annex I; and

(b) ensures that the name and postal address of the notified body that carried out the conformity assessment procedure applicable to the product in accordance with Articles 19 to 22 and 24 is marked on the product.

(13) Where this paragraph applies, the requirements of regulation 36(1)(a) and 36(4) are to be treated as being satisfied.

(14) Where, before placing a product on the market or putting a product into service, a person applies the procedure referred to in Article 23 to the product, the requirements of regulation 43 are to be treated as being satisfied.

(15) The modifications referred to in paragraphs (3)(b), (5)(b), (7)(b) and (11)(b) are that—

(a) any reference to "declaration of conformity" is to be read as a reference to the EU declaration of conformity;

(b) any reference to "designated standard" is to be read as a reference to a harmonised standard;

(c) any reference to "essential requirements" is to be read as a reference to the requirements set out in Article 4(1) and Annex I (as modified by paragraph (2));

(d) any reference to "UK marking" is to be read as a reference to the CE marking;

(e) any reference to "relevant conformity assessment procedure" is to be read as a reference to the conformity assessment procedures that apply to the product in accordance with Articles 19 to 22 and 24;

(f) any reference to "technical documentation" is a reference to the technical documentation referred to in Article 25.

Conformity assessment procedure obligation which is met by complying with the Directive

40B.—(1) In this regulation any reference to an Article or an Annex is a reference to an Article of or Annex to the Directive.

(2) Paragraph (3) applies where—

(a) Articles 20 or 21 provide that the conformity assessment procedure referred to as Module B in those Articles may be carried out in relation to a product; and

(b) prior to the manufacture of a product, the manufacturer ensures that—

(i) the product has been designed in accordance with the essential requirements set out in Annex I to the Directive;

(ii) the conformity assessment procedure referred to as Module B in Articles 20 and 21 has been carried out in relation to that product, in accordance with those Articles and with Article 24(1).

(3) Where this paragraph applies—

(a) the requirement in regulation 42 to apply the conformity assessment procedure referred to in regulations 44 and 45 as Module B is to be treated as being satisfied in relation to that product;

(b) any reference to "relevant conformity assessment procedure" in regulations 9, 10(1), 19(1)(a), 36(4), 40(1)(b) and 53(b) is to be read as including the conformity assessment procedure referred to in Articles 20, 21 and 24 as Module B; and

(c) any reference to "technical documentation" in regulations 9(b), 11, 19(1)(b), 25(b) and 36(3) is to be read as including the technical documentation relating to the design of the product referred to in Article 25 of the Directive;

(d) the reference to "approved body" in regulation 36(4) is to be read as the body that undertook the conformity assessment procedure referred to as Module B in Articles 20 or 21.".

Amendment to regulation 41

24. In regulation 41 (presumption of conformity), in paragraph (1)—

(a) for "harmonised" substitute "designated";

(b) omit "the reference to which has been published in the Official Journal of the European Union".

Amendment to regulation 42

25. In regulation 42 (applicable conformity assessment procedures), for "Annex II of Decision 768/2008" substitute "Schedule 15".

Amendment to regulation 44

26.—(1) Regulation 44 (design and construction) is amended as follows.

(2) In paragraph (1)—

(a) for "Annex II to Decision 768/2008/EC" substitute "Schedule 15";

(b) in sub-paragraph (a) for "(EU-type examination)" in both places in which it occurs substitute "(type examination)";

(c) in sub-paragraph (b)—

(i) for "EU type-examination" in each place in which it occurs substitute "type examination";

(ii) for "harmonised" in both places in which it occurs substitute "designated";

(d) in sub-paragraph (c)(iii) for "EU- type examination" substitute "type examination".

(3) In paragraphs (2) and (3) for "Annex II to Decision 768/2008/EC" substitute "Schedule 15".

(4) In paragraph (2)(c) for "EU type-examination" substitute "type examination".

(5) In paragraph (3)(a) for "(EU type-examination)" substitute "(type examination)".

Amendment to regulation 45

27. Regulation 45 (exhaust emissions) is amended as follows—

(a) for "Annex II to Decision 768/2008/EC" substitute "Schedule 15";

(b) in paragraphs (a) and (b) for "harmonised" substitute "designated";

(c) in paragraph (a)(i) for "(EU-type examination)" substitute "(type examination)";

(d) in paragraph (b)(i) for "(the EU-type examination)" substitute "(type examination)".

Amendment to regulation 46

28. In regulation 46 (noise emissions: recreational craft)—

(a) in paragraph (1) for "Annex II to Decision 768/2008/EC" substitute "Schedule 15";

(b) in paragraphs (2) and (3) for "harmonised" substitute "designated".

Amendment to regulation 47

29. In regulation 47 (noise emissions: personal watercraft)—

(a) in paragraph (1) for "Annex II to Decision 768/2008/EC" substitute "Schedule 15";

(b) in paragraphs (2) and (3) for "harmonised" substitute "designated".

Omission of regulation 49

30. Omit regulation 49 (conformity assessments carried out under Module B (EU-type examination)).

Amendment to regulation 50

31. In regulation 50 (conformity assessments carried out under Module A1 (internal production control plus supervised product testing))—

(a) in paragraph (1) for "of Annex II to Decision 768/2008/EC" substitute "as set out in Schedule 15";

(b) omit paragraph (2).

Amendment to regulation 51

32. In regulation 51 (conformity assessments carried out under Module F (conformity to type based on product verification)), for "of Annex II to Decision 768/2008/EC" substitute "as set out in Schedule 15".

Amendment to regulation 52

33. In regulation 52 (conformity assessments carried out under Module C (conformity to type based on internal production control))—

(a) in paragraph (1)—

(i) in sub-paragraph (a) for "of Annex II of Decision 768/2008/EC" substitute "set out in Schedule 15";

(ii) in sub-paragraph (c) for "of Annex II to Decision 768/2008/EC" substitute "set out in Schedule 15";

(b) in paragraph (2)—

(i) for "A notified" substitute "An approved";

(ii) for "the notified" substitute "the approved".

Amendment to regulation 53

34. In regulation 53 (EU declaration of conformity)—

(a) in the heading, for "EU declaration" substitute "Declaration";

(b) omit "EU";

(c) in paragraph (b) after "assessment" insert "procedure".

Amendment to regulation 54

35. In regulation 54 (CE marking)—

(a) for the heading substitute "UK marking";

(b) for "CE" in each place in which it occurs substitute "UK";

(c) in paragraph (4)(a) for "Annex II of Decision 768/2008" substitute "Schedule 15";

(d) in paragraph (5) for "notified" in each place in which it occurs substitute "approved".

Substitution of Part 4

36. For Part 4 substitute—

"PART 4

APPROVAL OF CONFORMITY ASSESSMENT BODIES

Approved bodies

55.—(1) An approved body is a conformity assessment body which—

(a) has been approved by the Secretary of State pursuant to the procedure set out in regulation 56 (approval of conformity assessment bodies); or

(b) immediately before exit day was a notified body in respect of which the Secretary of State had taken no action under regulation 61(1) or (2) as they had effect immediately before exit day to suspend or withdraw the body's status as a notified body.

(2) Paragraph (1) has effect subject to regulation 59 (restriction, suspension or withdrawal of approval).

(3) In this Part—

"notified body" means a body—

(a) which the Secretary of State had before exit day notified to the European Commission and the member States of the European Union in accordance with Article 26 of the Directive; and

(b) in respect of which no objections had been raised, as referred to in regulation 55(b), as it had effect immediately before exit day;

"approved body requirements" means the requirements set out in Schedule 11.

Approval of conformity assessment bodies

56.—(1) The Secretary of State may approve only those conformity assessment bodies that qualify for approval.

(2) A conformity assessment body qualifies for approval if the first and second conditions below are met.

(3) The first condition is that the conformity assessment body has applied to the Secretary of State to become an approved body and the application is accompanied by—

(a) a description of—

(i) the conformity assessment activities that the conformity assessment body intends to carry out;

(ii) the relevant conformity assessment procedure in respect of which the conformity assessment body claims to be competent;

(iii) the product in respect of which the conformity assessment body claims to be competent; and

(b) either—

(i) an accreditation certificate; or

(ii) the documentary evidence necessary for the Secretary of State to verify, recognise and regularly monitor the conformity assessment body's compliance with the approved body requirements.

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

(5) For the purposes of paragraph (4), the Secretary of State may accept an accreditation certificate provided in accordance with paragraph (3)(b), as sufficient evidence that the conformity assessment body meets the approved body requirements.

(6) When deciding whether to approve a conformity assessment body that qualifies for approval, the Secretary of State may—

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

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

(8) For the purposes of this regulation, "accreditation certificate" means a certificate, issued by the UK national accreditation body, attesting that a conformity assessment body meets the approved body requirements.

Presumption of conformity of approved bodies

57.—(1) Where a conformity assessment body demonstrates its conformity with the criteria set out in a designated standard (or part of such standard), the Secretary of State

is to presume that the conformity assessment body meets the approved body requirements covered by that standard (or that part of the standard).

(2) The presumption in paragraph (1) is rebuttable.

Monitoring of approved bodies

58. The Secretary of State must monitor each approved body with a view to verifying that the body—

(a) continues to meet the approved body requirements;

(b) meets any condition set—

(i) in accordance with regulation 56(6)(b); or

(ii) in the case of an approved body that was a notified body immediately before exit day, in accordance with regulation 56(6)(b) as it applied immediately before exit day; and

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

Restriction, suspension or withdrawal of approval

59.—(1) Where the Secretary of State determines that an approved body—

(a) no longer meets an approved body requirement; or

(b) is failing to fulfil its obligations under these Regulations, other than a condition referred to in regulation 58(b),

the Secretary of State must restrict, suspend or withdraw the body's status as an approved body under regulation 55 (approved bodies).

(2) With the consent of the approved body or where the Secretary of State determines that an approved body no longer meets a condition referred to in regulation 58(b), the Secretary of State may restrict, suspend or withdraw the body's status as an approved body under regulation 55.

(3) In deciding what action is required under paragraph (1) or (2), the Secretary of State must have regard to the seriousness of the non-compliance.

(4) Where the Secretary of State has taken action in respect of an approved body under paragraph (1) or (2), or where an approved body has ceased its activities, the approved body must—

(a) at the request of the Secretary of State, transfer its files relating to the activities it has undertaken as an approved body to another approved body or to the Secretary of State; or

(b) in the absence of a request under sub-paragraph (a), keep its files relating to the activities it has undertaken as an approved body available for inspection by the Secretary of State and the market surveillance authorities for a period of 10 years from the date they were created.

(5) The activities undertaken as an approved body referred to in paragraph (4) include any activities that the body has undertaken as a notified body.

Notice of proposed restriction, suspension or withdrawal of approval

60.—(1) Where the Secretary of State proposes to restrict, suspend or withdraw a body's status as an approved body in accordance with regulation 59 (restriction, suspension or

withdrawal of approval), the Secretary of State must give notice in writing to the approved body that its approval will be restricted, suspended or withdrawn.

(2) A notice provided in accordance with paragraph (1) must—

(a) state the date on which the notice is issued;

(b) state the reasons why the approval is being restricted, suspended or withdrawn;

(c) state the date on which the restriction, suspension or withdrawal of the approval is to take effect;

(d) where an approval is being restricted or suspended, state what the effect of that restriction or suspension is on the approved body;

(e) inform the approved body of its right to make written representations to the Secretary of State against the proposal within 14 days of the date of the notice.

(3) Where an approved body submits written representations to the Secretary of State within 14 days of the notice in accordance with paragraph (2)(e), the Secretary of State must respond to the representations within 21 days of the date on which the representations are received, stating whether, having considered the representations, the notice issued under paragraph (1) will be modified or withdrawn.

Operational requirements of approved bodies

61. When an approved body carries out a relevant conformity assessment procedure, Schedule 12 (operational requirements of approved bodies) has effect.

Subsidiaries and contractors

62.—(1) Where an approved body subcontracts specific tasks connected with conformity assessment, or has such tasks carried out by a subsidiary, the tasks are to be treated as having been carried out by an approved body for the purposes of regulations 44 to 47 only where the conditions in paragraphs (2) and (3) are satisfied.

(2) The approved body must—

(a) ensure that the subcontractor or subsidiary meets the approved body requirements; and

(b) inform the Secretary of State accordingly.

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

(4) Where an approved body subcontracts specific tasks connected with conformity assessment, or has such tasks carried out by a subsidiary, the approved body must, for a period of 10 years beginning on the day on which the tasks are carried out, keep at the disposal of the Secretary of State the documentation concerning—

(a) the assessment of the qualifications of the subcontractor or subsidiary; and

(b) the conformity assessment activities carried out by the subcontractor or subsidiary.

(5) When monitoring an approved body in accordance with regulation 58 (monitoring of approved bodies), the Secretary of State must treat the approved body as responsible for the tasks performed by a subcontractor or subsidiary, wherever the subcontractor or subsidiary is established.

(6) In this regulation "subsidiary" has the meaning given to it in section 1159 of the Companies Act 2006(**1**).

Register of approved bodies

63.—(1) The Secretary of State must—

(a) assign an approved body identification number to each approved body; and

(b) compile and maintain a register of—

(i) approved bodies;

(ii) their approved body identification numbers;

(iii) the activities for which they have been approved; and

(iv) any restrictions on those activities.

(2) The register referred to in paragraph (1) must be made publicly available.

Authorisation of UK national accreditation body

64. The Secretary of State may authorise the UK national accreditation body to carry out the following activities on behalf of the Secretary of State—

(a) assessing whether a conformity assessment body meets the approved body requirements;

(b) monitoring approved bodies in accordance with regulation 58;

(c) compiling and maintaining the register of approved bodies in accordance with regulation 63.".

Amendment to regulation 69

37. In regulation 69 (enforcement action in respect of products that are not in conformity and which present a risk)—

(a) in paragraph (2) for "the notified" substitute "any approved";

(b) omit paragraphs (4) and (7);

(c) in paragraph (8)—

(i) for "notices referred to in paragraphs (6) and (7)" substitute "notice referred to in paragraph (6)";

(ii) in sub-paragraph (f)(ii) for "a harmonised standards referred to in regulation 41 (presumption of conformity) which confer" substitute "a designated standard referred to in regulation 41 (presumption of conformity) which confers".

Omission of regulation 70

38. Omit regulation 70 (EU safeguard procedure).

Amendment to regulation 71

39. In regulation 71 (enforcement action in respect of formal non-compliance), in paragraph (1)—

(a) in sub-paragraph (a), for "CE" substitute "UK" in each place in which it occurs;

(**1**) 2006 c.46.

(b) in sub-paragraph (b) omit "EU".

Insertion of Part 5A

40. After regulation 83 insert—

"PART 5A

POWERS OF THE SECRETARY OF STATE

Power to amend Schedules

83A.—(1) The Secretary of State may by regulations amend any of the provisions specified in paragraph (2) where the Secretary of State considers it necessary to do so in order to take into account technical progress and new scientific evidence.

(2) The provisions referred to in paragraph (1) are—

(a) in Schedule 1—

(i) points 2.3, 2.4, 2.5 and Section 3 of Part B;

(ii) Section 3 of Part C;

(b) Schedule 7;

(c) Schedule 9.

(3) The Secretary of State may by regulations amend Schedule 5 where the Secretary of State considers it necessary to do so in order to take into account technical progress, the adequacy of ensuring equivalent conformity and new scientific evidence.

(4) Regulations made under this regulation may—

(a) make different provisions for different cases; and

(b) make such supplemental, consequential and transitional provisions as the Secretary of State considers appropriate.

(5) Regulations made under this regulation are to be made by statutory instrument subject to annulment in pursuance of a resolution of either House of Parliament.

Power to make provision for application of conformity assessments and of Schedule 1

83B.—(1) Where one or both of the conditions in paragraph (2) is met, the Secretary of State may by regulations make provision about—

(a) detailed procedures for the operation of regulations 50 to 52 and paragraph 2 of Module B (as set out in Schedule 15), taking into account the specific conformity assessment needs of the products covered by these Regulations;

(b) the application of the watercraft design categories set out in point 1 of Part A of Schedule 1, including on the use of weather terminology and measurement scales used in those categories;

(c) the information on the builder's plate set out in point 2.2 of Part A of Schedule 1;

(d) the application of the Regulations on navigation lights set out in point 5.7 of Part A of Schedule 1;

(e) arrangements for discharge prevention, in particular as regards operation of holding tanks, set out in point 5.8 of Part A of Schedule 1;

(f) the installation and testing of gas appliances and permanently installed gas systems on watercraft, as referenced in point 5.5 of Part A of Schedule 1.

(2) The conditions referred to in paragraph (1) are that the Secretary of State considers it necessary to make such provision in order to—

(a) take into account the progress of technical knowledge; and

(b) ensure that these Regulations are applied in a uniform manner.

(3) Before making regulations under this regulation, the Secretary of State must consult such persons as the Secretary of State considers appropriate.

(4) Regulations made under this regulation may—

(a) make different provisions for different cases; and

(b) make such supplemental, consequential and transitional provisions as the Secretary of State considers appropriate.

(5) Regulations made under this regulation are to be made by statutory instrument subject to annulment in pursuance of a resolution of either House of Parliament.".

Transitional provision in relation to EU Exit

41. After regulation 89 insert—

"**Transitional provisions in relation to EU Exit**

89A.—(1) In this regulation, "pre-exit period" means the period beginning on the commencement date and ending immediately before exit day.

(2) Subject to paragraph (3), where a product was made available on the market or put into service during the pre-exit period, despite the amendments made by Schedule 28 to the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019(**2**), any obligation to which a person was subject under these Regulations as they had effect immediately before exit day, continues to have effect as it did immediately before exit day, in relation to that product.

(3) Paragraph (2) does not apply to—

(a) any obligation of any enforcing authority to inform the European Commission or a member State of any matter; or

(b) any obligation to take action outside of the market in respect of the product.

(4) Where during the pre-exit period—

(a) a product has not been placed on the market; and

(b) the manufacturer has taken any action under regulation 42 or a person has taken action under regulation 43(2) or (3), as those provisions had effect immediately before exit day in relation to that product,

that action has effect as if it had been done under regulation 42 or 43 as they have effect on and after exit day.

(5) Where during the pre-exit period—

(a) a product has not been placed on the market or put into service; and

(b) the private importer or a person to whom regulation 43(2) applies, has taken any action under Schedule 5 as it had effect immediately before exit day in relation to that product,

(**2**) S.I. 2019/696.

that action has effect as if it had been done under Schedule 5 as it has effect on and after exit day.".

Amendment to regulation 90

42.—(1) Regulation 90 (revocations and savings) is amended as follows.

(2) After paragraph (1) insert—

"(1A) For the purposes of paragraph (1), the Recreational Craft Regulations 1996(**3**) have effect with the following modifications—

(a) any reference to "the Community" is to be read as including the United Kingdom;

(b) any reference to a "member State" is to be read as including the United Kingdom;

(c) in Schedule 7 (EC type-examination (module B))—

(i) in paragraph 7 omit "and withdrawn";

(ii) omit paragraph 8;

(d) in Schedules 9 (production quality assurance (module D)) and 12 (full quality assurance (module H))—

(i) in paragraph 5, for "national" substitute "enforcement"; and

(ii) in paragraph 6 omit "and withdrawn";

(e) in Schedule 15 (enforcement), in paragraph 2 omit "with a view to this information being passed by the Secretary of State to the Commission".".

(3) After paragraph (2) insert—

"(3) "For the purposes of paragraph (2), the Recreational Craft Regulations 2004(**4**) have effect with the following modifications—

(a) any reference to "the Community" or "the European Union" is to be read as including the United Kingdom;

(b) any reference to a "member State" is to be read as including the United Kingdom;

(c) in Schedule 7 (EC type-examination)—

(i) in paragraph 7 omit "and withdrawn";

(ii) omit paragraph 8;

(d) in Schedules 9 (production quality assurance), 12 (full quality assurance) and 15 (product quality assurance (module E))—

(i) in paragraph 5, for "national" substitute "enforcement"; and

(ii) in paragraph 6 omit "and withdrawn;

(e) in Schedule 17 (enforcement), in paragraph 2 omit "with a view to this information being passed by the Secretary of State to the Commission".".

Amendment to Schedule 1

43.—(1) Schedule 1 (essential requirements) is amended as follows.

(2) In Part A (essential requirements for the design and construction of products referred to in Article 2(1))—

(**3**) S.I. 1996/1353, amended by S.I. 1998/116 and S.I. 2004/693. The Regulations were revoked with savings by S.I. 2004/1464.
(**4**) S.I. 2004/1464, amended by S.I. 2004/3201 and 2011/1043. The Regulations were revoked with savings by S.I. 2017/737.

(a) in the Explanatory Notes to Section 1 (Watercraft Design Categories), in the final paragraph, for "Annex" substitute "Schedule";

(b) in paragraph 2.1—

(i) in paragraph (2) for "the national authority of the Member State" substitute "or on behalf of the Secretary of State";

(ii) for "harmonised" substitute "designated";

(c) for paragraph 2.2—

(i) for paragraph (b) substitute—

"(b) UK marking, as provided for in regulation 54;";

(ii) for "notified" substitute "approved";

(d) in paragraph 2.5 for "in accordance with Article 7(7) and Article 9(4)" substitute "including the instructions and safety information referred to in regulations 15 and 22".

(3) In Part B (essential requirements for exhaust emissions from propulsion engines)—

(a) for paragraph 1.1(d) substitute—

"(d) UK marking, as provided for in regulation 54.";

(b) in paragraphs 2.3 and 2.5—

(i) for "Notified" substitute "Approved";

(ii) for "harmonised" substitute "designated";

(c) in paragraph 4—

(i) for "a language or languages which can be easily understood by consumers and other end-users, as determined by the Member State in which the engine is to be marketed" substitute "English";

(ii) in sub-paragraph (b) for "harmonised" substitute "designated".

Amendment to Schedule 3

44. Schedule 3 (declaration by the manufacturer or the importer of the partly completed watercraft (Article 6(2)) is amended as follows—

(a) for "established in the Union referred to in Article 6(2)" substitute "established in the United Kingdom referred to in regulation 7(1)(b)";

(b) in paragraph (b) for "established in the Union" substitute "established in the United Kingdom";

(c) in paragraph (d)—

(i) for "harmonised" substitute "designated";

(ii) for "this Directive" substitute "these Regulations".

Amendment to Schedule 4

45. Schedule 4 (EU declaration of conformity No xxxxx) is amended as follows—

(a) in the heading omit "EU";

(b) in paragraph 3 for "Article 19(3) or (4) of Directive 2013/53/EU" substitute "regulation 43(2) or (3) of the Recreational Craft Regulations 2017 (S.I. 2017/737, "the Regulations")";

(c) in paragraph 5 for "Union harmonisation legislation" substitute "statutory requirements";

(d) in paragraph 6 for "harmonised" substitute "designated";

(e) in paragraph 7 for "notified" substitute "approved";

(f) in paragraph 9—

(i) omit "EU" in both places in which it occurs;

(ii) for "points (b) and (c) of Article 6(4)" substitute "regulation 7(1)(c)(iii)";

(iii) for "this Directive" substitute "the Regulations" in both places in which it occurs;

(iv) omit sub-paragraph (a)(ii);

(v) for "Article 55(2)" substitute "regulation 89(2)".

Amendment to Schedule 5

46.—(1) Schedule 5 (equivalent conformity based on post-construction assessment (module PCA)) is amended as follows.

(2) For "this Directive" substitute "these Regulations" in each place in which it occurs.

(3) In paragraph 1, for "Article 19(2), (3) or (4) substitute "regulation 43(1), (2) or (3)".

(4) In paragraph 2—

(a) for "a notified" substitute "an approved";

(b) for "the notified" in both places in which it occurs substitute "the approved";

(c) for "relevant national authorities" substitute "enforcing authority".

(5) In paragraph 3—

(a) for "notified" in each place in which it occurs substitute "approved";

(b) for "national authorities" substitute "enforcing authority";

(c) for "CE" substitute "UK";

(d) for "Annex I" substitute "Schedule 1";

(e) for "the national authority of the Member State" substitute "or on behalf of the Secretary of State".

(6) In paragraph 4—

(a) for the heading substitute "UK marking and declaration of conformity";

(b) in sub-paragraph 1—

(i) for "CE" substitute "UK";

(ii) for "notified" in both places in which it occurs substitute "approved";

(c) in sub-paragraph 2—

(i) for "an EU" substitute "a";

(ii) for "national authorities" substitute "enforcing authority";

(iii) for "the EU" substitute "the";

(iv) for "relevant authorities" substitute "enforcing authority";

(d) in sub-paragraph 3, for "Annex I" in both places in which it occurs substitute "Schedule 1".

(7) In paragraph 5 for "notified" substitute "approved".

Amendment to Schedule 6

47. Schedule 6 (supplementary requirements when internal production control plus supervised production tests set out in module A1 is used (Article 24(2))) is amended as follows—

(a) for “Annex I” substitute “Schedule 1” in each place in which it occurs;

(b) for “a notified” in both places in which it occurs substitute “an approved”;

(c) for “Annex VII” substitute “Schedule 7”.

Amendment to Schedule 7

48. In Schedule 7 (conformity of production assessment for exhaust and noise emissions) in paragraph 1, for “notified” substitute “approved”.

Amendment to Schedule 8

49. Schedule 8 (supplementary procedure to be applied under conformity to type based on internal production control (module C)) is amended as follows—

(a) for “Article 24(5)” substitute “regulation 52”;

(b) for “Annex I” in both places in which it occurs substitute “Schedule 1”;

(c) for “this Directive” substitute “these Regulations”;

(d) for “Annex VII” substitute “Schedule 7”.

Amendment to Schedule 9

50. Schedule 9 is amended as follows—

(a) omit “referred to in Article 7(2) and Article 25”;

(b) for “Article 14” in both places in which it occurs substitute “regulation 41”;

(c) for “Annex I” in each place in which it occurs substitute “Schedule 1”.

Amendment to Schedule 10

51. Schedule 10 (EU-type examination) is omitted.

Amendment to Schedule 11

52. Schedule 11 (requirements of notified bodies) is amended as follows—

(a) for the heading substitute “Requirements of approved bodies”;

(b) in paragraph 11(c) for “a notified” substitute “an approved”;

(c) in each place in which it occurs (other than that referred to in sub-paragraph (b)), for “notified” substitute “approved”.

Amendment to Schedule 12

53. Schedule 12 (operational requirements of notified bodies) is amended as follows—

(a) for the heading substitute “Operational requirements of approved bodies”;

(b) in paragraph 1 for “Notified” substitute “Approved”;

(c) in paragraph 3 for “the Directive” substitute “these Regulations”;

(d) in paragraphs 4 and 5 for “a notified” substitute “an approved”;

(e) in paragraph 4 for “harmonised” substitute “designated”;

(f) in paragraphs 6 and 9 for “notified” substitute “approved”;

(g) in paragraphs 7(1), 7(2), 8, 9 and 10 for “A notified” substitute “An approved”;

(h) in paragraph 7—

(i) for "notification" in both places in which it occurs substitute "approval";

(ii) for "the notified" substitute "the approved";

(i) in paragraph 10 for "any notified body coordination group established under the Directive" substitute "any approved body coordination group established by the Secretary of State".

Insertion of Schedule 15

54. After Schedule 14 insert—

"SCHEDULE 15 Regulations 42, 44 to 47, 50 to 52 and 54

Conformity assessment procedures

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(**5**).

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.

(**5**) Regulation 50 and Schedule 6 make further provision where an economic operator has a conformity assessment carried out on a product under this Module.

(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(**6**).

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

(**6**) Regulation 52 and Schedule 8 make further provision in certain circumstances where an economic operator has a conformity assessment carried out on a product under this Module.

(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(**7**).

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.

(**7**) Regulation 51 and Schedule 7 make further provision where an economic operator has a conformity assessment carried out on a product under this Module.

(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.".