SCHEDULE 4 Regulation 4

Modules for conformity assessment

PART 1

General

CHAPTER 1

Miscellaneous

1. A notified body referred to in this Schedule means a notified body appointed by agreement between that body and one or more of the following—

(a) the manufacturer of a listed product;

(b) an authorised representative;

(c) an importer of a listed product.

2. In the remaining provisions of this Schedule, references to a manufacturer include—

(a) an authorised representative; or

(b) an importer of a listed product,

where such person undertakes some or all of a conformity assessment procedure.

3. "Equivalent standards" means standards equivalent to the harmonised standards, including national standards notified by the Commission pursuant to Article 5 of Annex II.B to the Council Resolution of 7 May 1985(**1**).

4. A notified body must carry out tests or examinations—

(a) at such place as the manufacturer and notified body agree; and

(b) so far as appropriate, in accordance with—

(i) the harmonised standards; or

(ii) equivalent standards.

5. A notified body must, under module B—

(a) determine the elements of the listed product, or the design for such a product, which have been made or designed in accordance with a harmonised standard or equivalent standard; and

(b) in respect of elements not made or designed in accordance with a harmonised standard or equivalent standard, determine how those elements conform to the product requirements.

6. A notified body must ensure that—

(a) in module D, at least one member of the team which carries out the determination of the application has experience of the product technology in question;

(b) in module E, at least one member of the team which carries out the determination of the application has experience as an assessor in the product technology in question; and

(c) in modules D and E, it makes at least one inspection visit to the premises of the manufacturer.

(**1**) O.J. No. C136, 4.6.1985, p. 1.

7. Expressions used in this Schedule which are used in Council Decision 93/465/EEC concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonisation directives(**2**), have the same meaning as they do in that Decision.

CHAPTER 2

General technical documentation

8. The general technical documentation means the documentation necessary to enable an assessment of the conformity of a listed product to the product requirements, including as appropriate documentation concerning—

(a) the design, manufacture and operation of the product;

(b) the harmonised standards or equivalent standards applied, or to be applied, to the product.

9. The provision of the documentation under paragraph 8 may be satisfied by the supply of equivalent documentation required under Community legislation other than the implementing measure relating to a listed product.

CHAPTER 3

Testing and checking process

10. The testing and checking process means the notified body carries out product checks—

(a) at random intervals; and

(b) on an adequate sample taken on site by the notified body.

11. If the testing and checking process demonstrates that a listed product conforms to the product requirements, the notified body must permit the manufacturer to affix the identification number or symbol of the notified body to the listed product during the manufacturing process.

CHAPTER 4

Notified bodies and non-conformity

12. Where a notified body determines that a listed product does not conform, or will not conform, to the product requirements, it must, subject to paragraph 13, request the manufacturer to provide such further information or to take such additional steps that it believes are necessary to demonstrate conformity.

13. If—

(a) no such further information or steps are possible; or

(b) such information or steps do not demonstrate conformity,

the notified body must give the manufacturer a non-conformity notice.

14. "A non-conformity notice" means a written notice that—

(a) states that the notified body is not satisfied that a listed product conforms, or will conform, to the product requirements; and

(b) gives details of the non-conformity.

15. Where a notified body has given a non-conformity notice and prior to that notice has given to the manufacturer —

(a) an EC type-examination certificate or an EC design examination certificate; or

(b) an approval to a quality assurance procedure under modules D or E,

(**2**) O.J. No. L220, 30.8.1993, p. 23.

the notified body must state in the non-conformity notice if, and the extent to which, the giving of the notice withdraws a certificate or approval, including any additions or modifications to a certificate or approval.

PART 2

Module A (internal production control)

1. The manufacturer must establish the general technical documentation.

2. The general technical documentation must be kept with the declaration of conformity.

3. The manufacturer must take all necessary measures to ensure that the manufacturing process of a listed product ensures that the product complies with the general technical documentation.

PART 3

Module B (EC type-examination)

1. The manufacturer must make a written application to a notified body for that body to provide an EC type-examination certificate.

2. The application must include—

(a) the name and address of the manufacturer and, if appropriate, the authorised representative of the manufacturer;

(b) a declaration that an application has not been made to another notified body; and

(c) the general technical documentation.

3. The notified body must—

(a) examine the general technical documentation;

(b) determine if the type has been manufactured in accordance with that documentation;

(c) carry out tests and examinations to determine whether—

(i) elements designed in accordance with—

(aa) the harmonised standards; or

(bb) equivalent standards,

meet those standards;

and

(ii) elements not so designed conform to the product requirements.

4. If a notified body is satisfied that the type conforms to the product requirements, it must—

(a) give to the manufacturer an EC type-examination certificate;

(b) annex to that certificate a list of the general technical documentation; and

(c) keep a copy of the certificate and the annexed list of general technical documentation.

5. An EC type-examination certificate must be in writing and include—

(a) the name and address of the manufacturer;

(b) the conclusions of the tests and examinations referred to in paragraph 3;

(c) any conditions of validity of the certificate; and

(d) the data necessary to identify the approved type.

6. If a manufacturer makes modifications to a listed product that affect its conformity to the product requirements, the manufacturer must make an application to the notified body that granted the EC type-examination certificate for an additional approval to that certificate.

7. Where an application is made for an additional approval to a EC type-examination certificate—

(a) the manufacturer must make that application, so far as appropriate, in accordance with paragraph 2; and

(b) the notified body must—

(i) comply with paragraph 3; and

(ii) if it is satisfied that the type continues to conform to the product requirements, comply with paragraph 4 as if reference to an EC type-examination certificate were a reference to an additional approval to that certificate.

8. Relevant documentation under regulation 10 includes—

(a) the EC type-examination certificate; and

(b) any additional approval.

PART 4

Module C (conformity to type)

1. The manufacturer must take all necessary measures to ensure that the manufacturing process of a listed product ensures that the product—

(a) complies with the type as described in the EC type-examination certificate; and

(b) conforms to the product requirements.

PART 5

Module D (production quality assurance)

1. The manufacturer must operate an approved quality system in respect of—

(a) the production of the product; and

(b) the final product inspection and testing.

2. A quality system is approved if it is approved by a notified body and it meets the following criteria—

(a) it must ensure compliance of a listed product with the type as described in the EC type-examination certificate and that it conforms to the product requirements;

(b) 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; and

(c) the quality system documentation must—

(i) permit a consistent interpretation of the quality programmes, plan, manual and records; and

(ii) include the matters contained in paragraph 3.

3. The matters referred to in paragraph 2(c)(ii) are that the quality system documentation 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 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, including inspection reports and test data, calibration data and qualification reports of the personnel concerned; and

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

4. A manufacturer must apply for approval of his quality system to a notified body and must include in that application—

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

(b) the documentation concerning the quality system; and

(c) if applicable—

(i) the general technical documentation of the approved type; and

(ii) a copy of the EC type-examination certificate.

5. Where a notified body receives an application in accordance with paragraph 4, the it must—

(a) determine the application; and

(b) if it is satisfied that the quality system meets the criteria contained or referred to in paragraph 2, the notified body must provide its approval to the manufacturer.

6. An approval under paragraph 5 must be in writing and include—

(a) the reasons for the decision; and

(b) the conclusions of the examinations and tests.

7. If a manufacturer intends to modify the approved quality system—

(a) he must inform in writing the notified body that approved the quality system; and

(b) the notified body must determine whether or not the proposed modification requires a re-assessment of the quality system.

8. If the notified body determines that a re-assessment is required, the procedures in paragraphs 4 to 6 apply in respect of an application for assessment of the quality system as proposed to be modified.

9. A notified body must carry out—

(a) periodic audits of the quality system of the manufacturer; and

(b) periodic unannounced visits to the premises of the manufacturer,

whose quality system it has approved in order to determine that the manufacturer is maintaining and applying the quality system.

10. A notified body must inform the manufacturer of the results of the audit and visit by providing written audit and visit reports.

11. In relation to paragraph 9, a manufacturer must—

(a) allow the notified body access to the locations of manufacture, inspection and testing, and storage;

(b) provide all necessary documentation to the notified body, including—

(i) the documentation concerning the quality system; and

(ii) the quality records, including inspection reports and test data, calibration data and qualification reports of the personnel concerned;

and

(c) in respect of visits by the notified body, carry out or allow the notified body to carry out tests necessary to determine that the quality system is functioning correctly.

12. Relevant documentation under regulation 10 includes—

(a) the documentation concerning the quality system submitted with an application for approval;

(b) approvals in relation to the quality system;

(c) details of the modifications to the quality system; and

(d) audit and visit reports.

PART 6

Module E (product quality assurance)

1. The manufacturer must operate an approved quality system in respect of the final product inspection and testing.

2. Paragraphs 2 to 12 of module D (production quality assurance) apply save that the following are omitted—

(a) paragraph 3(b); and

(b) in paragraph 11(a), the word “manufacture”.