

## <sup>F1</sup>ANNEX I

### Textual Amendments

- F1** Deleted by [Commission Regulation \(EU\) No 813/2013 of 2 August 2013 implementing Directive 2009/125/EC of the European Parliament and of the Council with regard to ecodesign requirements for space heaters and combination heaters \(Text with EEA relevance\).](#)

## <sup>F2</sup>ANNEX II

### [<sup>F2</sup>AWARD OF ENERGY-PERFORMANCE LABELS]

### Textual Amendments

- F2** Deleted by [Directive 2005/32/EC of the European Parliament and of the Council of 6 July 2005 establishing a framework for the setting of ecodesign requirements for energy-using products and amending Council Directive 92/42/EEC and Directives 96/57/EC and 2000/55/EC of the European Parliament and of the Council.](#)

[<sup>F2</sup>]

## ANNEX III

### Module B: EC type-examination

1. This module describes that part of the procedure by which a notified body ascertains and attests that an example, representative of the production envisaged, meets the relevant provisions of the Directive.
2. The application for EC type-examination is lodged by the manufacturer or his authorized representative established within the Community with a notified body of his choice.

The application must include:

- the name and address of the manufacturer and, if the application is lodged by the authorized representative, the name and address in addition,
- a written declaration that the same application has not been lodged with any other notified body,
- the technical documents, as described in section 3.

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

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3. The technical documents must enable the conformity of the appliance with the requirements of the Directive to be assessed. They must, as far as is relevant for such assessment, cover the design, manufacture and operation of the appliance and contain as far as is relevant for assessment:
  - a general type-description,
  - conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,
  - descriptions and explanations necessary for the understanding of the drawings and diagrams and the operation of the product,
  - a list of the standards referred to in Article 5 (2), applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the Directive where the standards referred to in Article 5 have not been applied,
  - results of design calculations made, examinations carried out, etc.,
  - test reports.
4. The notified body must:
  - 4.1. examine the technical documents, verify that the type has been manufactured in conformity with those documents and identify the elements which have been designed in accordance with the relevant provisions of the standards referred to in Article 5 (2) as well as the components which have been designed without applying the relevant provisions of those standards;
  - 4.2. perform or have performed the appropriate examinations and necessary tests to check whether, where the standards referred to in Article 5 (2) have not been applied, the solutions adopted by the manufacturer meet the essential requirements of the Directive;
  - 4.3. perform or have performed the appropriate examinations and necessary tests to check whether, where the manufacturer has chosen to apply the relevant standards, these have actually been applied;
  - 4.4. agree with the applicant the location where the examinations and necessary tests are to be carried out.
5. Where the type meets the relevant provisions of this Directive, the notified body issues an EC type-examination certificate to the applicant. The certificate contains the name and address of the manufacturer, the conclusion of the examination and necessary data for identification of the approved type.

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

If the manufacturer or his authorized representative established in the Community is refused a type certificate, the notified body must provide detailed reasons for such refusal.

Provision must be made for an appeals procedure.

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

7. Each notified body must communicate to the other notified bodies the relevant information concerning the EC type-examination certificates and additions issued and withdrawn.
8. The other notified bodies may receive copies of the EC type-examination certificates and/or their additions. The Annexes to the certificates must be kept at the disposal of the other notified bodies.
9. The manufacturer or his authorized representative established within the Community must keep with the technical documents copies of EC type-examination certificates and their additions for a period of at least 10 years after the last date of manufacture of the product concerned.

Where neither the manufacturer nor his authorized representative is established within the Community, the obligation to keep the technical documents available is the responsibility of the person who places the product on the Community market.

## ANNEX IV

### Module C: Conformity to type

1. This module describes that part of the procedure whereby the manufacturer or his authorized representative established within the Community ensures and declares that the appliances concerned are in conformity with the type as described in the EC type-examination certificate and satisfy the requirements of this Directive that apply to them. <sup>F3</sup>The manufacturer or his authorized representative established within the Community shall affix the CE marking to each appliance and draw up a written declaration of conformity.]

#### Textual Amendments

**F3** Substituted by Council Directive 93/68/EEC of 22 July 1993 amending Directives 87/404/EEC (simple pressure vessels), 88/378/EEC (safety of toys), 89/106/EEC (construction products), 89/336/EEC (electromagnetic compatibility), 89/392/EEC (machinery), 89/686/EEC (personal protective equipment), 90/384/EEC (non-automatic weighing instruments), 90/385/EEC (active implantable medicinal devices), 90/396/EEC (appliances burning gaseous fuels), 91/263/EEC (telecommunications terminal equipment), 92/42/EEC (new hot-water boilers fired with liquid or gaseous fuels) and 73/23/EEC (electrical equipment designed for use within certain voltage limits).

2. The manufacturer must take all measures necessary to ensure that the manufacturing process assures the conformity of the manufactured appliances with the type as described in the EC type-examination certificate and with the efficiency requirements of the Directive.
3. The manufacturer or his authorized representative must keep a copy of the declaration of conformity for a period of at least 10 years after the last date of manufacture of the product concerned.

Where neither the manufacturer nor his authorized representative is established within the Community, the obligation to keep the technical documents available is the responsibility of the person who places the product on the Community market.

4. A notified body chosen by the manufacturer must perform or have performed examinations of the product at random intervals. A suitable sample of the finished products, taken on the spot by the notified body, is examined and appropriate tests, defined in the applicable standard or standards referred to in Article 5 (2) or equivalent tests are carried out to check the conformity of the product with the requirements of the corresponding Directive. In the event of one or more samples of the products examined not conforming, the notified body must take the appropriate measures.

#### Module D: Production quality assurance

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of section 2 ensures and declares that the appliances concerned are in conformity with the type as described in the EC type-examination certificate and satisfy the requirements of this Directive. [F<sup>3</sup>The manufacturer or his authorized representative established within the Community shall affix the CE marking to each appliance and draw up a written declaration of conformity. The CE marking is accompanied by the identification number of the notified body responsible for the checks referred to in section 4.]
2. The manufacturer must operate an approved quality system for production, final appliance inspection and testing as specified in section 3. He is subject to the checks referred to in section 4.
3. Quality system
  - 3.1. The manufacturer lodges an application for assessment of his quality system with a notified body of his choice, for the appliances concerned.

The application must include:

- all relevant information for the appliance category envisaged,
  - the documents concerning the quality system,
  - the technical documents pertaining to the approved type and a copy of the EC type-examination certificate.
- 3.2. The quality system must ensure conformity of appliances with the type as described in the EC type-examination certificate and with the requirements of this Directive that apply to them.

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

It must contain in particular an adequate description of:

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to appliance quality,
- the manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,
- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,
- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.,

— the means of monitoring the achievement of the required appliance quality and the effective operation of the quality system.

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

The decision is notified to the manufacturer. The notification must contain the conclusions of the examination and the duly substantiated assessment decision.

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

The manufacturer or his authorized representative must keep the notified body that has approved the quality system informed of any proposed change in the quality system.

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

It must notify the manufacturer of its decision. The notification must contain the conclusions of the examination and the substantiated assessment decision.

4. Monitoring under the responsibility of the notified body

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

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

- the quality system documents,
- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc..

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

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

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

- the document referred to in the second indent of 3.1,
- the updating referred to in the second paragraph of 3.4,
- the decisions and reports from the notified body which are referred to in the final paragraph of 3.4, and in 4.3 and 4.4.

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

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## Module E: Product quality assurance

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of section 2 ensures and declares that the boilers and appliances are in conformity with the type as described in the EC type-examination certificate. [<sup>F3</sup>The manufacturer or his authorized representative established within the Community shall affix the CE marking to each boiler and appliance and draw up a written declaration of conformity. The CE marking must be accompanied by the identification number of the notified body responsible for the checks referred to in section 4.]
2. The manufacturer must operate an approved quality system for final boiler and appliance inspection and testing as specified in section 3. He must be subject to the checks referred to in section 4.
3. Quality system
  - 3.1. The manufacturer lodges an application with a notified body of this choice for the assessment of the quality system for his boilers and appliances.

The application must include:

- all relevant information for the boiler or appliance category envisaged,
  - the quality system's documentation,
  - the technical documents pertaining to the approved type and a copy of the EC type-examination certificate.
- 3.2. Under the quality system, each boiler or appliance is examined and appropriate tests as defined in the relevant standard(s) referred to in Article 5 or equivalent tests are carried out in order to verify its conformity with the relevant requirements of the Directive. All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation must enable the quality programmes, plans, manuals and records to be interpreted in a uniform manner.

It must in particular contain an adequate description of:

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to product quality,
  - the examination and tests that will be carried out after manufacture,
  - the means of monitoring the effective operation of the quality system,
  - quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.
- 3.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in 3.2. It must presume conformity with these requirements in respect of quality systems that implement the relevant harmonized standard.

The auditing team must have at least one member with experience of assessing the relevant product technology. The assessment procedure must include an inspection visit to the manufacturer's premises.

The manufacturer must be notified of the decision. The notification must contain the conclusions of the examination and the substantiated assessment decision.

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

The manufacturer or his authorized representative must keep the notified body which has approved the quality system informed of any proposed change in the quality system.

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

It must notify the manufacturer of its decision. The notification must contain the conclusions of the examination and the substantiated assessment decision.

4. Monitoring under the responsibility of the notified body
  - 4.1. The purpose of monitoring is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
  - 4.2. The manufacturer must allow the notified body access for inspection purposes to the inspection, testing and storage premises and provide it with all necessary information, in particular:
    - the quality system documentation,
    - the technical documents,
    - the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.
  - 4.3. The notified body must periodically carry out audits to ensure that the manufacturer maintains and applies the quality system and must provide an audit report to the manufacturer.
  - 4.4. Additionally, the notified body may pay unannounced visits to the manufacturer. During such visits the notified body may carry out tests or have them carried out to verify that the quality system is functioning correctly; if necessary, the notified body must provide the manufacturer with a visit report and, if a test has been carried out, with a test report.
5. The manufacturer must, for a period of at least 10 years after the last date of manufacture of the boiler or appliance, keep at the disposal of the national authorities:
  - the documents referred to in the third indent of 3.1,
  - the changes referred to in the second paragraph of 3.4,
  - the decisions and reports from the notified body which are referred to in the final paragraph of 3.4, and in 4.3 and 4.4.
6. Each notified body must forward to the other notified bodies the relevant information concerning the quality system approvals issued and withdrawn.

## ANNEX V

Minimum criteria to be taken into account by Member States for the notification of bodies

1. The body, its director and the staff responsible for carrying out the verification tests may not be the designer, manufacturer, supplier or installer of appliances which they inspect, nor the authorized representative of any of those parties. They may not become either involved directly or as authorized representatives in the design, construction, marketing or maintenance of such boilers and appliances. This does not preclude the possibility of exchanges of technical information between the manufacturer and the body.

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2. The body and its staff must carry out the verification tests with the highest degree of professional integrity and technical competence and must be free from all pressures and inducements, particularly financial, which might influence their judgment of the results of the inspection, especially from persons or groups of persons with an interest in the result of verifications.
3. The body must have at its disposal the necessary staff and possess the necessary facilities to enable it to perform properly the administrative and technical tasks connected with verification; it must also have access to the equipment required for special verification.
4. The staff responsible for inspection must have:
  - sound technical and professional training,
  - satisfactory knowledge of the requirements of the tests they carry out and adequate experience of such tests,
  - the ability to draw up the certificates, records and reports required to authenticate the performance of the tests.
5. The impartiality of inspection staff must be guaranteed. Their remuneration must not depend on the number of tests carried out or on the results of such tests.
6. The body must take out liability insurance unless its liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the tests.
7. The staff of the body must be bound to observe professional secrecy (except *vis-à-vis* the competent administrative authorities of the State in which its activities are carried out) under this Directive or any provision of national law giving effect to it.