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**COUNCIL DIRECTIVE 92/42/EEC**

**of 21 May 1992**

**on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels**

(OJ L 167, 22.6.1992, p. 17)

Amended by:

		Official Journal		
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► <b><u>M1</u></b>	Council Directive 93/68/EEC of 22 July 1993	L 220	1	30.8.1993
► <b><u>M2</u></b>	Directive 2004/8/EC of the European Parliament and of the Council of 11 February 2004	L 52	50	21.2.2004
► <b><u>M3</u></b>	Directive 2005/32/EC of the European Parliament and of the Council of 6 July 2005	L 191	29	22.7.2005
► <b><u>M4</u></b>	Directive 2008/28/EC of the European Parliament and of the Council of 11 March 2008	L 81	48	20.3.2008

**COUNCIL DIRECTIVE 92/42/EEC****of 21 May 1992****on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels**

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission <sup>(1)</sup>,

In cooperation with the European Parliament <sup>(2)</sup>,

Having regard to the opinion of the Economic and Social Committee <sup>(3)</sup>,

Whereas Decision 91/565/EEC <sup>(4)</sup> provides for the promotion of energy efficiency in the Community under the SAVE programme;

Whereas it is important to promote measures aimed at the progressive establishment of the internal market in the period up to 31 December 1992; whereas the internal market encompasses an area without internal frontiers, in which the free circulation of goods, persons, services and capital is assured;

Whereas the Council resolution of 15 January 1985 on the improvement of energy-saving programmes in the Member States <sup>(5)</sup> invites Member States to pursue and where necessary increase their efforts to promote the more rational use of energy by the further development of integrated energy-saving policies;

Whereas the Council resolution of 16 September 1986 concerns new Community energy-policy objectives for 1995 and convergence of the policies of the Member States <sup>(6)</sup>, and in particular the objective of improving the efficiency of final energy demand by at least 20 %;

Whereas Article 130r of the Treaty provides that action by the Community relating to the environment shall have the objective of ensuring a prudent and rational utilization of natural resources;

Whereas it is appropriate to take as a base a high level of protection in proposals for the approximation of the provisions laid down by law, regulation or administrative action in Member States and concerning health, safety, environmental protection and consumer protection;

Whereas the Council resolution of 21 June 1989 declares 'that the Community should take proper account of potential climatic change linked to the greenhouse effect' <sup>(7)</sup> and the Council's conclusions of 29 October 1990 state that CO<sub>2</sub> emissions in the year 2000 should be stabilized throughout the Community at their 1990 level;

Whereas the importance of the domestic and tertiary sector, which absorbs a major proportion of the final consumption of energy in the Community, is considerable;

Whereas this sector will become even more important through trends towards more central heating and a general increase in thermal comfort;

Whereas better boiler efficiency is in the consumer's interest; whereas energy saving will be reflected in fewer imports of hydrocarbons; whereas reduction in the Community's energy dependence will have a positive impact on its trade balance;

<sup>(1)</sup> OJ No C 292, 22.11.1990, p. 8.

<sup>(2)</sup> OJ No C 129, 20.5.1991, p. 97 and OJ No C 94, 13.4.1992.

<sup>(3)</sup> OJ No C 102, 18.4.1991, p. 46.

<sup>(4)</sup> OJ No L 307, 8.11.1991, p. 34.

<sup>(5)</sup> OJ No C 20, 22.1.1985, p. 1.

<sup>(6)</sup> OJ No C 241, 25.9.1986, p. 1.

<sup>(7)</sup> OJ No C 183, 20.7.1989, p. 4.

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Whereas Council Directive 78/170/EEC of 13 February 1978 on the performance of heat generators for space heating and the production of hot water in new or existing non-industrial buildings and on the insulation of heat and domestic hot-water distribution in new non-industrial buildings<sup>(1)</sup>, has given rise to the establishment of substantially different efficiency levels between one Member State and another;

Whereas the requirement of high efficiency for hot-water boilers will reduce the range of technical properties of equipment placed on the market, thus facilitating series production and making for economies of scale; whereas the absence of a measure laying down energy requirements at a sufficiently high level may result, with the completion of the internal market, in a significant drop in the efficiency levels of heating installations through the spread on the market of low-efficiency boilers;

Whereas local climatic conditions and the energy and occupancy characteristics of buildings differ greatly within the Community; whereas Member States must take this diversity into account when determining the conditions for putting boilers into service in implementation of this Directive; whereas these circumstances justify the fact that Member States where back-boilers and boilers designed to be installed in the living space are widely installed at the date of the adoption of this Directive should continue to authorize, within specific limits, the placing on their markets and the putting into service of such boilers; whereas these arrangements should be subject to particular surveillance by the Commission;

Whereas this Directive, which is aimed at eliminating technical barriers with regard to boiler efficiency, must follow the new approach established by the Council resolution of 7 May 1985<sup>(2)</sup> which specifically lays down that legislative harmonization is limited to the adoption, by means of directives based on Article 100 of the EEC Treaty, of the essential requirements with which products put on the market must conform and that 'these essential requirements shall be worded precisely enough in order to create legally binding obligations which can be enforced and to enable the certification bodies to certify products as being in conformity, having regard to those requirements in the absence of standards';

Having regard to Directive 83/189/EEC<sup>(3)</sup> laying down a procedure for the provision of information in the field of technical standards and regulations;

Having regard to Decision 90/683/EEC<sup>(4)</sup> concerning the modules for the various phases of the conformity assessment procedures which are intended to be used in the technical harmonization directives;

Whereas boilers complying with the efficiency requirements should bear the CE mark and, where appropriate, signs in order to enable them to move freely and to be put into service in accordance with their intended purpose within the Community;

Having regard to Directive 89/106/EEC<sup>(5)</sup> on the approximation of laws, regulations and administrative provisions of the Member States relating to construction products;

Whereas efficiency requirements to encourage the rational use of energy as laid down in Council Directive 90/396/EEC of 29 June 1990 on the approximation of the laws of the Member States relating to appliances

<sup>(1)</sup> OJ No L 52, 23.2.1978, p. 32. Directive amended by Directive 82/885/EEC (OJ No L 378, 31.12.1982, p. 19).

<sup>(2)</sup> OJ No C 136, 4.6.1985, p. 1.

<sup>(3)</sup> OJ No L 109, 26.4.1983, p. 8; Directive last amended by Decision 90/230/EEC (OJ No L 128, 18.5.1990, p. 15).

<sup>(4)</sup> OJ No L 380, 31.12.1990, p. 13.

<sup>(5)</sup> OJ No L 40, 11.2.1989, p. 12.

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burning gaseous fuels <sup>(1)</sup> should be established for the gas boilers referred to in this Directive,

HAS ADOPTED THIS DIRECTIVE:

*Article 1*

This Directive, which comes under the SAVE programme concerning the promotion of energy efficiency in the Community, determines the efficiency requirements applicable to new hot-water boilers fired by liquid or gaseous fuels with a rated output of no less than 4 kW and no more than 400 kW, hereinafter called 'boilers'.

*Article 2*

For the purposes of this Directive:

- *boiler*: the combined boiler body-burner unit, designed to transmit to water the heat released from burning,
- *appliance*:
  - the boiler body designed to have a burner fitted,
  - the burner designed to be fitted to a boiler body,
- *effective rated output (expressed in kW)*: the maximum calorific output laid down and guaranteed by the manufacturer as being deliverable during continuous operation while complying with the useful efficiency indicated by the manufacturer,
- *useful efficiency (expressed in %)*: the ratio between the heat output transmitted to the boiler water and the product of the net calorific value at constant fuel pressure and the consumption expressed as a quantity of fuel per unit time,
- *part load (expressed in %)*: the ratio between the effective output of a boiler operating intermittently or at an output lower than the effective rated output and the same effective rated output;
- *average temperature of the boiler water*: the average of the water temperatures at the entry and exit of the boiler,
- *standard boiler*: a boiler for which the average water temperature can be restricted by design,
- *back-boiler*: a boiler designed to supply a central-heating system and to be installed in a fireplace recess as part of a back boiler/gas fire combination,
- *low-temperature boiler*: a boiler which can work continuously with a water supply temperature of 35 to 40 °C, possibly producing condensation in certain circumstances, including condensing boilers using liquid fuel,
- *gas condensing boiler*: a boiler designed to condense permanently a large part of the water vapour contained in the combustion gases,
- *boiler to be installed in the living space*: a boiler with an effective rated output of less than 37 kW, designed to provide heat to the part of the living space in which it is installed by means of the emission of heat from the casing having an open expansion chamber, supplying hot water using gravity circulation; such boilers shall bear on their casings the explicit indication that they must be installed in living space.

*Article 3*

1. The following shall be excluded from this Directive:

- hot-water boilers capable of being fired by different fuels including solid fuels,
- equipment for the instantaneous preparation of hot water,

<sup>(1)</sup> OJ No L 196, 26.7.1990, p. 15.

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- boilers designed to be fired by fuels the properties of which differ appreciably from the properties of the liquid and gaseous fuels commonly marketed (industrial waste gas, biogas, etc),
- cookers and appliances designed mainly to heat the premises in which they are installed and, as a subsidiary function, to supply hot water for central heating and sanitary hot water,
- appliances with rated outputs of less than 6 kW using gravity circulation and designed solely for the production of stored sanitary hot water,
- boilers manufactured on a one-off basis,

**▼ M2**

- cogeneration units as defined in Directive 2004/8/EC of the European Parliament and of the Council of 11 February 2004 on the promotion of cogeneration based on useful heat demand in the internal energy market <sup>(1)</sup>.

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2. In the case of boilers with a dual function, that of heating premises and also providing sanitary hot water, the efficiency requirements referred to in Article 5 (1) concern the heating function only.

*Article 4***▼ M1**

1. Member States may not prohibit, restrict or impede the placing on the market or entry into service within their territories of appliances and boilers which comply with the provisions of this Directive and which bear the CE marking provided for in Article 7 attesting to the conformity to all the provisions of this Directive, including the conformity assessment procedures laid down in Articles 7 and 8, save as otherwise laid down in the Treaty or other Directives or Community provisions.

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2. Member States shall take all necessary measures to ensure that boilers cannot be put into service unless they satisfy the efficiency requirements set out in Article 5 (1) and the conditions for entry into service which the Member States lay down on the basis of local climatic conditions and the energy and occupancy characteristics of the buildings.
3. However, Member States where back-boilers and/or boilers that are to be installed in the living space, are widely installed at the date of the adoption of the present Directive, shall continue to authorize their entry into service, provided that their efficiency both at rated output and at 30 % part load is not more than 4 % below the requirements laid down in Article 5 (1) for standard boilers.
4. The effects of the provisions in paragraphs 2 and 3 shall be constantly monitored by the Commission and analysed in the report to be submitted under Article 10. To this end the Member States shall forward to the Commission any information it requires to submit to the Council the proposed amendments, provided for in that Article, designed to ensure at all events the energy efficiency and free movement of boilers in the Community.

**▼ M1**

- 5 (a) Where the boilers are subject to other Directives concerning other aspects which also provide for the affixing of the CE marking, the latter shall indicate that the boilers in question are also presumed to conform to the provisions of those other Directives.

<sup>(1)</sup> OJ L 52, 21.2.2004, p. 50.

**▼M1**

- (b) However, where one or more of these Directives allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate conformity to the provisions only of those Directives applied by the manufacturer. In this case, particulars of the Directives applied, as published in the *Official Journal of the European Communities*, must be given in the documents, notices or instructions required by the Directives and accompanying the boilers.

**▼B***Article 5*

1. Boilers must comply with the following useful efficiency requirements:

- at rated output, i.e. operating at rated output  $P_n$  expressed in kW, at an average boiler-water temperature of 70 °C, and
- a part load, i.e. operating at 30 % part load, at an average boiler-water temperature which varies according to the type of the boiler.

The useful efficiency requirements to be complied with are set out in the following table:

Type of boiler	Range of power output	Efficiency at rated output		Efficiency at partload	
		Average boiler-water temperature (in °C)	Efficiency requirement expressed (in %)	Average boiler-water temperature (in °C)	Efficiency requirement expressed (in %)
Standard boilers	4 to 400	70	$\geq 84 + 2 \log P_n$	$\geq 50$	$\geq 80 + 3 \log P_n$
Low-temperature boilers (*)	4 to 400	70	$\geq 87,5 + 1,5 \log P_n$	40	$\geq 87,5 + 1,5 \log P_n$
Gas condensing boilers	4 to 400	70	$\geq 91 + 1 \log P_n$	30 (**)	$\geq 97 + 1 \log P_n$

(\*) Including condensing boilers using liquid fuels.

(\*\*) Temperature of boiler water-supply.

2. The harmonized standards relating to the requirements of this Directive drawn up under mandate from the Commission in accordance with Directive 83/189/EEC and 88/182/EEC <sup>(1)</sup> shall determine, *inter alia*, the verification methods valid for production and measurements. Appropriate tolerances must be incorporated in the efficiency levels.

**▼M3****▼B***Article 7*

1. Member States shall deem that boilers which comply with the harmonized standards, the reference numbers of which have been published in the *Official Journal of the European Communities* and for which the Member States have published the reference numbers of the national standards transposing those harmonized standards, to be in conformity with the essential efficiency requirements stipulated in Article 5 (1). Such boilers must bear the ►**M1** CE marking ◀ referred to in Annex I, section 1, and be accompanied by the EC declaration of conformity.

<sup>(1)</sup> OJ No L 81, 26.3.1988, p. 75.

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2. The conformity of series-produced boilers shall be certified by:
- examination of the efficiency of a boiler type in accordance with module B as described in Annex III,
  - a declaration of conformity to the approved type in accordance with module C, D or E as described in Annex IV.

For boilers burning gaseous fuels, the procedures for assessing the conformity of their efficiency shall be those used to assess conformity to the safety requirements laid down in Directive 90/396/EEC on the approximation of the laws of the Member States relating to appliances burning gaseous fuels.

3. When appliances marketed separately are placed on the market, they must bear the ►**M1** CE marking ◀ and be accompanied by the EC declaration of conformity, which defines the parameters enabling them after assembly to achieve the useful efficiency levels laid down in Article 5 (1).

**▼M1**

4. The CE mark of conformity to the requirements of this Directive and to the other provisions concerning the granting of the CE marking, and also the inscriptions specified in Annex I, shall be affixed on boilers in a visible, easily legible and indelible manner. The affixing on such products of any markings likely to deceive third parties as to the meaning and form of the CE marking shall be prohibited. Any other marking may be affixed to the boilers and appliances provided that the visibility and legibility of the CE marking is not thereby reduced.
5. (a) Where a Member State or a notified body establishes that the CE marking has been affixed unduly, the manufacturer or his agent established within the Community shall be obliged to make the boiler comply as regards the provisions concerning the CE marking and to end the infringement under conditions imposed by the Member State;
- (b) where non-compliance continues, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market, and shall inform the Commission and the other Member States accordingly.

**▼B***Article 8***▼M1**

1. Member States shall inform the Commission and the other Member States of the bodies which they have appointed to carry out the procedures referred to in Article 7, together with specific tasks which these bodies have been appointed to carry out and the identification numbers assigned to them beforehand by the Commission.

The Commission shall publish in the *Official Journal of the European Communities* a list of the notified bodies with their identification numbers and the tasks for which they have been notified. The Commission shall ensure that this list is kept up to date.

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2. Member States shall implement the minimum criteria laid down in Annex V for the appointment of such bodies. Bodies which satisfy the criteria laid down in the corresponding harmonized standards shall be deemed to comply with the criteria laid down in that Annex.
3. A Member State which has notified a particular body must withdraw that notification if it finds that the body concerned no longer satisfies the criteria referred to in paragraph 2. It shall immediately inform the other Member States and the Commission accordingly and shall withdraw the notification.

**▼ B***Article 9*

1. By 1 January 1993, Member States shall adopt and publish the provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof.

They shall apply those provisions from 1 January 1994.

When Member States adopt those provisions, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

2. Until 31 December 1997, Member States shall permit the placing on the market and putting into service of appliances complying with the national rules and schemes in force within their territories on the date of the adoption of this Directive.

*Article 10*

Three years after the implementation of this Directive the Commission shall submit a report to the European Parliament and to the Council on the results achieved. That report shall be accompanied by proposals for any changes to be made to this Directive in the light of those results and of advances in technology.

**▼ M3***Article 10a*

This Directive constitutes an implementing measure within the meaning of Article 15 of 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 <sup>(1)</sup>, with regard to energy efficiency during use, in accordance with that Directive, and may be amended or repealed ► **M4** in accordance with Article 19(3) of Directive 2005/32/EC ◀.

**▼ B***Article 11*

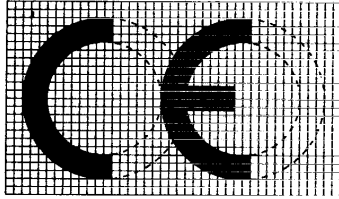
This Directive is addressed to the Member States.

<sup>(1)</sup> OJ L 191, 22.7.2005, p. 29.



**▼M1***ANNEX I***CE CONFORMITY MARKING AND ADDITIONAL SPECIFIC MARKINGS****1. CE conformity marking**

- The CE conformity marking shall consist of the initials 'CE' taking the following form:



- If the CE marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.
- The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm.

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*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.

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.

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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. ► **M1** 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. ◀
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. ► **M1** 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:

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- 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.

**▼B****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. ► **M1** 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.

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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.
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.