

L.N. 62 of 2002**PRODUCT SAFETY ACT
(ACT NO. V OF 2001)****Efficiency Requirements for New Hot-Water Boilers Fired with
Liquid or Gaseous Fuels Regulations, 2002**

IN exercise of the powers conferred by articles 38 to 40 of the Product Safety Act, 2001, the Minister for Economic Services, on the advice of the Malta Standards Authority, has made the following regulations:-

1.1. The title of these regulations is the Efficiency Requirements for New Hot-Water Boilers Fired with Liquid or Gaseous Fuels Regulations, 2002.

Citation and
commencement

1.2. These regulations shall become operative on the 1st January, 2003:

Provided that the requirement to provide information to the European Commission referred to in regulation 7.5 of these regulations shall come into force on such date as the Minister responsible for consumer affairs, after consultation with the Malta Standards Authority, may prescribe.

2.1. The following shall be excluded from the scope of these regulations:

Scope

2.1.1. hot-water boilers capable of being fired by different fuels including solid fuels,

2.1.2. equipment for the instantaneous preparation of hot water,

2.1.3. 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),

2.1.4. 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,

2.1.5. appliances with rated outputs of less than 6 kW using gravity circulation and designed solely for the production of stored sanitary hot water,

2.1.6. boilers manufactured on a one-off basis.

2.2. 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) of the Directive, which is set out in Schedule VI section 1 hereto, concern the heating function only.

Definitions

3.1. For the purposes of these regulations, the following definitions shall apply:

3.1.1. "The Directive" means Council Directive 92/42/EEC¹ of the European Parliament and of the Council of 21st May, 1992 on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels.

3.1.2. "Boiler": the combined boiler body-burner unit, designed to transmit to water the heat released from burning,

3.1.3. "Appliance":

- the boiler body designed to have a burner fitted,
- the burner designed to be fitted to a boiler body,

3.1.4. "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,

3.1.5. "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,

3.1.6. "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;

3.1.7. "Average temperature of the boiler water": the average of the water temperatures at the entry and exit of the boiler,

3.1.8. "Standard boiler": a boiler for which the average water temperature can be restricted by design,

¹ OJ No. L 167, 22.06.92, P. 17.

3.1.9. "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,

3.1.10. "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,

3.1.11. "Gas condensing boiler": a boiler designed to condense permanently a large part of the water vapour contained in the combustion gases,

3.1.12. "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.

3.1.13. Any word or expression used, but not defined, in these regulations which is also used in the Directive has, in these regulations, the meaning it has in the Directive.

3.1.14. In these regulations, unless the context otherwise requires –

3.1.14.1. any reference to a numbered regulation or Schedule is a reference to the regulation or Schedule in these regulations which bears that number, and

3.1.14.2. any reference in a regulation or Schedule to a numbered paragraph is a reference to the paragraph which bears that number in that regulation or Schedule.

3.1.15. "Harmonised Standard" means a technical specification adopted by the European Committee for Standardisation (CEN) or the European Committee for Electrotechnical Standardisation (CENELEC) or the European Telecommunications Standards Institute (ETSI), upon a remit from the European Commission in accordance with Directive 98/34/EC² of the European Parliament and of the Council laying down a procedure for the provision of information in the field of technical standards and regulations as amended by Directive 98/48/EC³ of the European Parliament and of the Council.

² OJ No. L 204, 21.07.98, P. 37.

³ OJ No. L 217, 05.08.98, P. 18.

3.1.16. "National Standard transposing the Harmonised Standard" means a Standard issued by one of the members of CEN/CENELEC/ETSI which is declared and noted to be technically equivalent to the Harmonised Standard originally issued by CEN/CENELEC/ETSI.

3.1.17. "OJ" means the Official Journal of the European Communities.

3.1.18. "Community" means the European Community.

3.1.19. "Notified body" means a body responsible for carrying out functions relating to the conformity assessment procedures outlined in Annexes III and IV of the Directive, which are set out in Schedules III and IV hereto, which has been notified by the Member State concerned to the Commission and the other Member States pursuant to Article 8 of the Directive;

3.1.20. "CE marking" means the CE conformity marking consisting of the symbol "CE" as set out in Schedule I to these regulations;

3.1.21. "Manufacturer" means the person:

3.1.21.1. who is primarily responsible for the design and construction of the boiler so that it complies with the requirements of these regulations;

3.1.21.2. who is responsible for "re-building" or modifying an existing boiler, and who in so doing is creating an "as-new" boiler;

3.1.21.3. who takes responsibility for the appraisal of the design, construction and any necessary modification of used imported boilers.

3.1.22. "Local authorised representative" means any person (or organisation) established in Malta who has been appointed by the manufacturer to act on his behalf in carrying out certain tasks required by these regulations;

3.1.23. "Importer" means any person who places a boiler from a foreign country on to the Maltese market so that he supplies such a boiler on the first occasion that it is supplied in Malta;

3.1.24. "Person who supplies boilers" means wholesalers, distributors, retailers etc.

3.1.25. "Supply" includes offering to supply, agreeing to supply, exposing for supply and possessing for supply, and cognate expressions shall be construed accordingly:

Provided that "supply" does not include exhibition at trade fairs and exhibitions of boilers in respect of which the provisions of these regulations are not satisfied if a notice is displayed in relation to the boiler in question to the effect:-

3.1.25.1. that it does not satisfy those provisions; and

3.1.25.2. that it may not lawfully be supplied until the responsible person has ensured that those provisions are satisfied;

3.1.26. "Responsible person" in relation to boilers means:

3.1.26.1. the manufacturer thereof

3.1.26.2. the manufacturer's local authorised representative;
or

3.1.26.3. where the manufacturer is not established in Malta and he has not appointed a local authorised representative, the person who places the boilers on the local market.

3.1.27. "Placing on the market" means importation, wholesale, retail, sale and distribution free of charge.

4.1. These regulations, implementing the 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". Applicability

4.2. The provisions of these regulations are applicable to all imported boilers as well as to those manufactured for the local market.

4.2.1. No person may construct, import, place on the market or put into service any boiler which does not comply with the provisions of these regulations.

5.1. The placing on the market or putting into service of appliances and boilers which comply with the provisions of these regulations and which bear the CE marking provided for in regulation 8 of these regulations attesting to the conformity to all the provisions of Free movement

these regulations, including the conformity assessment procedures laid down in regulation 6 of these regulations and Article 8 of the Directive, save as otherwise laid down in the Treaty or other Directives or Community provisions, may not be prohibited, restricted or impeded.

Conformity
assessment
procedures

6.1. 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 of the Directive, which is set out in Schedule III hereto,
- a declaration of conformity to the approved type in accordance with module C, D or E as described in Annex IV of the Directive, which is set out in Schedule IV hereto.

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/EEC⁴ on the approximation of the laws of the Member States relating to appliances burning gaseous fuels.

Withdrawal and
prohibition from
market

7.1. The Director of Consumer Affairs 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) of the Directive, which is set out in Schedule VI section 1 hereto, and the conditions for entry into service laid down on the basis of local climatic conditions and the energy and the occupancy characteristics of the buildings.

7.2. However, 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 regulations, 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) of the Directive, which is set out in Schedule VI section 1 hereto, for standard boilers.

7.3. Where a non-complying boiler, referred to in regulation 3.1.2 of these regulations bears the CE marking and inscriptions, the Director of Consumer Affairs shall take appropriate action against whom so ever has affixed the marking or drawn up the declaration and shall so inform the Consumer and Industrial Goods Directorate⁵ of the Malta Standards Authority.

7.4. Any decision taken pursuant to these regulations, which contains a restriction on the placing on the market of boilers, shall state the precise grounds on which it is based.

⁴ L.N. 52 of 1996: Appliances Burning Gaseous Fuels, implementing Directive 90/396/EEC (OJ No. L 196, 26.07.90, P. 15-29).

⁵ L.N. 213 of 2000 – Malta Standards Authority (Establishment of Directorates) Order, 2000, published in the Government Gazette No. 17,002 of 20th October, 2000.

7.4.1. The party concerned shall be notified without delay of the decision and shall be informed at the same time of the possibilities and time limits regarding the legal remedies available to it under the laws in force in Malta and of the time limits to which such remedies are subject.

7.5. The Consumer and Industrial Goods Directorate of the Malta Standards Authority shall immediately inform the Commission of any measures taken in pursuance of regulation 7.3 of these regulations.

7.6. All appropriate measures shall be taken to encourage the local authorities responsible for implementing these regulations to cooperate with each other and provide each other with information in order to assist the functioning of these regulations.

8.1. Boilers which comply with the harmonised standards, the reference numbers of which have been published in the *Official Journal of the European Communities* and for which the reference numbers of the national standards transposing those harmonised standards have been published, shall be deemed to be in conformity with the essential efficiency requirements stipulated in Article 5 (1) of the Directive, which is set out in Schedule VI section 1 hereto. Such boilers must bear the CE marking referred to in Annex I, section 1 of the Directive, which is set out in Schedule I hereto, and be accompanied by the EC declaration of conformity. CE Marking

8.2. When appliances marketed separately are placed on the market, they must bear the 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) of the Directive, which is set out in Schedule VI section 1 hereto.

8.3. The CE mark of conformity to the requirements of these regulations and to the other provisions concerning the granting of the CE marking, and also the inscriptions specified in Annex I of the Directive, which is set out in Schedule I hereto, shall be affixed on boilers in a visible, easily legible and indelible manner.

8.3.1. 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.

8.4. Where it is established that the CE marking has been affixed unduly, the manufacturer or his agent shall be obliged to make the boiler comply as regards the provisions concerning the CE marking and to

end the infringement under conditions laid down by the Director of Consumer Affairs;

8.4.1. Where non-compliance continues, the Director of Consumer Affairs 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, in accordance with the procedures laid down in regulation 7 of these regulations.

8.5. 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.

8.5.1. Where one or more of the Directives referred to in regulation 8.5 above, 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.

Schedule I

Based on Annex I of the Directive

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:



For the avoidance of doubt, it is hereby declared that the grid providing the background in the above graduated drawing is not part of the CE marking.

- 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.

2. Additional specific markings

- The last two digits of the year in which the CE marking was affixed.

- The energy performance label awarded under Article 6 of the Directive, which is set out in Schedule II of these regulations, consists of the following symbol:



Schedule II

Based on Annex II of the Directive

AWARD OF ENERGY-PERFORMANCE LABELS

Efficiency requirements to be met both at nominal output and at part-load of 0.3 Pn

<i>Label</i>	<i>Efficiency requirement at nominal output Pn and at an average boiler-water temperature of 70°C%</i>	<i>Efficiency requirement at part load of 0.3 Pn and at an average boiler-water temperature of 50°C%</i>
*	$\geq 84 + 2 \log P_n$	$\geq 80 + 3 \log P_n$
**	$\geq 87 + 2 \log P_n$	$\geq 83 + 3 \log P_n$
***	$\geq 90 + 2 \log P_n$	$\geq 86 + 3 \log P_n$
****	$\geq 93 + 2 \log P_n$	$\geq 89 + 3 \log P_n$

1. Under the procedures laid down in Article 7 of the Directive, which is transposed in regulations 6.1, 8.1 and 8.2 of these regulations, it may be decided to apply a specific system of labels enabling the energy performance of boilers to be clearly ascertained. This system shall apply to boilers the efficiency of which is superior to the requirements for standard boilers set out in Article 5 (1) of the Directive, which is set out in Schedule VI section 1 hereto.

If its efficiency at rated output and its efficiency at part load are equal to or greater than the relevant values for standard boilers, a boiler shall be awarded an '★' as set out in Annex I, section 2 of the Directive, which is set out in Schedule I hereto.

If its efficiency at rated output and its efficiency at part load are three or more points higher than the relevant values for standard boilers a boiler shall be awarded '★★'.

Every extra step of efficiency of three points at rated output and at part load will allow the attribution of an extra '★' as set out in Annex II of the Directive, which is set out in Schedule II hereto.

2. No other label which is likely to be confused with those referred to in paragraph 1 of this Schedule may be authorised.

Schedule III

Based on Annex III of the Directive

EC-TYPE EXAMINATION

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 these regulations.

2. The application for EC type-examination is lodged by the manufacturer or his authorized representative 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 of this Module.

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 these regulations 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) of the Directive, which is set out in Schedule VI paragraph 2 hereto, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of these regulations

where the standards referred to in Annex VI of the Directive, which is set out in Schedule VI hereto, 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 Annex VI, paragraph 2 of the Directive, which is set out in Schedule VI hereto, 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 Annex VI, paragraph 2 of the Directive, which is set out in Schedule VI hereto have not been applied, the solutions adopted by the manufacturer meet the essential requirements of these regulations;

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 these regulations, 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 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 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 in Malta, the obligation to keep the technical documents available is the responsibility of the person who places the product on the market.

Schedule IV

Based on Annex IV of the Directive

CONFORMITY TO TYPE AND QUALITY ASSURANCE

Module C: Conformity to type

1. This module describes that part of the procedure whereby the manufacturer or his authorized representative 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 these regulations that apply to them. The manufacturer or his authorized representative 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 regulations.

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 in Malta, the obligation to keep the technical documents available is the responsibility of the person who places the product on the 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) of the Directive, which is set out in Schedule VI paragraph 2 hereto, 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 of this Module, 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 these regulations. The manufacturer or his authorized representative 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 of this Module.

2. The manufacturer must operate an approved quality system for production, final appliance inspection and testing as specified in section 3 of this Module. He is subject to the checks referred to in section 4 of this Module.

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 these regulations 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 point 3.2 of this Module. 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 point 3.2 of this Module 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.

- 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 annex VI of the directive, which is set out in Schedule VI hereto, or equivalent tests are carried out in order to verify its conformity with the relevant requirements of these regulations. 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 point 3.2 of this Module. 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 point 3.2 of this Module 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 point 3.1 of this Module,
- the changes referred to in the second paragraph of point 3.4 of this Module,
- the decisions and reports from the notified body which are referred to in the final paragraph of point 3.4, and in point 4.3 and point 4.4 of this Module.

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

Schedule V

Based on Annex V of the Directive

MINIMUM CRITERIA TO BE TAKEN INTO ACCOUNT 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 these regulations or any provision of national law giving effect to it.

Schedule VI

Based on Article 5 of the Directive

THE EFFICIENCY REQUIREMENTS

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

- at 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	$\geq 84 + 2 \log P_n$	≥ 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 these regulations drawn up under mandate from the Commission in accordance with Directive 83/189/EEC⁶ and 88/182/EEC⁷ shall determine, *inter alia*, the verification methods valid for production and measurements.

Appropriate tolerances must be incorporated in the efficiency levels.

⁶ OJ No. L 109, 26.04.83, P. 08-12.

⁷ OJ No. L 81, 26.03.88, P. 75.