

**GENERAL AGREEMENT ON
TARIFFS AND TRADE**

RESTRICTED

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18 March 1985

Committee on Technical Barriers to Trade

Original: Spanish

ROYAL DECREE 2584/1981 ON STANDARDIZATION
AND TYPE APPROVAL

The following communication, dated 22 February 1985, has been received from the delegation of Spain.

In accordance with the recommendation made by the Committee at its meeting in September 1984, as reproduced in document TBT/M/Spec/4, paragraph 7, I have pleasure in forwarding herewith the notification regarding Royal Decree 2584/81 of 18 September (Official Gazette of 3 November) as well as a copy of that Royal Decree.

At the same time, my authorities have advised me that new provisions amending articles of that Royal Decree are to be issued shortly, and will be communicated to you as soon as published.

Committee on Technical Barriers to Trade

NOTIFICATION

The following notification is being circulated in accordance with Article 10.4.

1. Party to Agreement notifying: <u>SPAIN</u>
2. Agency responsible: Ministry of Industry and Energy
3. Notified under Article 2.5.2 <input type="checkbox"/> , 2.6.1 <input checked="" type="checkbox"/> , 7.3.2 <input type="checkbox"/> , 7.4.1 <input type="checkbox"/> , Others:
4. Products covered (CCCN where applicable, otherwise national tariff heading):
5. Title: Royal Decree 2584/1981, of 18 September
6. Description of content: Proceedings of the Ministry of Industry and Energy in the field of standardization and type approval.
7. Objective and rationale: Protection of consumer interests. General framework regarding product standards and type approval. Accreditation of laboratories.
8. Relevant documents: Official Gazette No. 263 of 1981
9. Proposed dates of adoption and entry into force: Twenty working days following publication in the Official Gazette
10. Final date for comments: Amendments to R.D. 2584/1981 will be published in the near future.
11. Texts available from: National enquiry point <input type="checkbox"/> or address of other body:

MINISTRY OF INDUSTRY AND ENERGY

25549 Royal Decree 2584/1981 of 18 September, approving the General Regulations for Proceedings of the Ministry of Industry and Energy in the field of standardization and type approval

The Ministry of Industry and Energy, acting under its authority, has drawn up provisions designed to protect users against risks deriving from utilization of industrial apparatus and products, establishing appropriate technical specifications to that end.

Likewise, other provisions have been considered to regulate production of certain components, with a view to protecting the economic interests of consumers, by stipulating dimensions, minimum yield and other aspects, to which end the corresponding technical specifications have also been established.

Furthermore, where necessary, provisions regarding type approval are being established in many cases to facilitate attainment of the above-mentioned objectives.

A certain and sometimes excessive degree of variation has resulted in the legal and administrative treatment of these matters; it is therefore necessary to have an instrument establishing adequate uniformity in regard to standardization and type approval.

In other countries, the provisions on standardization and type approval in the industrial field are much more numerous, and it is foreseeable that the Ministry of Industry and Energy will have to meet existing requirements in regard to these matters by aligning its legislation mainly with that of the countries of the European Economic Community.

The present instrument apportions responsibilities and indicates the general framework within which the Ministry of Industry and Energy can establish provisions regarding product standards and type approval.

It stipulates the procedure for accreditation of the laboratories that will be needed for type approval of products and verification that manufactured series continue to correspond to the approved model or type; provision is made for the use of co-operating entities, having regard to the large number of proceedings to be carried out in future, and to the need to take account of quality marks of a private character.

A list of the terms used in standardization and type approval is being drawn up by the Interministerial Commission on Standardization and Type Approval, and the final version thereof will be considered to be a supplement to the present instrument.

Accordingly, acting on a proposal by the Minister for Industry and Energy and after consideration by the Council of Ministers on 18 September 1981,

I HEREBY DECREE AS FOLLOWS:

Article 1 - The General Regulations for Proceedings of the Ministry of Industry and Energy in the field of standardization and type approval are hereby approved.

Article 2 - The Ministry of Industry and Energy is hereby authorized to establish the necessary implementing provisions for the present Regulations.

TRANSITIONAL PROVISIONS

1. Type approvals and registration already in force shall be maintained in their present form until the end of their period of validity, at which time and for any subsequent prolongation they must be adapted to these new provisions.
2. Type-approval applications that are awaiting a decision shall be adapted to the provisions of these Regulations in respect of any formalities not yet carried out at the time of their entry into force.
3. Testing laboratories officially recognized under existing regulations shall, throughout the period of validity of their recognition, be deemed to be accredited laboratories in terms of the present instrument.

Laboratories in respect of which no period of validity has been specified shall comply with the provisions of these Regulations within a period of not more than two years.

4. Except where the Consumer Law determines the form of participation of consumers or users in public administration bodies, intervention by them as foreseen in the present Regulations shall be determined subject to a report by the National Consumer Institute.

REVOCATION

Upon entry into force of the present Royal Decree, the following shall be revoked in respect of testing laboratories and the type approval of prototypes, types and models: Royal Decree 891/1980 of 14 April on type approval of solar panels (Articles 3, 4, 5, 6 and 7); Royal Decree 788/1980 of 28 March approving the Regulations on Electrical

Household Appliances (Articles 5 and 10); Order of the Ministry of Industry and Energy of 21 December 1979 on type approval of electronic apparatus and equipment and components thereof (Articles 3, 4 and 5); Order of the Ministry of Industry of 10 December 1975 approving the Regulations on type approval of liquid-fuel burners in fixed installations (Articles 2, 7 and 8 of the Regulations); Decree 1651/1974 of 7 March approving the Regulations on appliances that use gaseous fuels (Articles 5 and 10 of the Regulations); the provisions thus revoked shall be replaced by those of the present Regulations. Any provisions of equal or inferior rank not consistent with the provisions of the present Royal Decree are likewise revoked.

Done at Madrid on 18 September 1981.

JUAN CARLOS R.

The Minister for Industry and Energy
Ignacio Bayon Marine

GENERAL REGULATIONS FOR PROCEEDINGS OF THE MINISTRY OF INDUSTRY AND ENERGY
IN THE FIELD OF STANDARDIZATION AND TYPE APPROVAL

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Chapter 1. Competent Bodies within the Department

Section 1. Ministerial Commission on Standardization, Type Approval
and Safety

1.1.1. The Ministerial Commission on Standardization, Type Approval and Safety shall have responsibility for co-ordination and prior investigation of all proceedings of the Ministry of Industry and Energy in the field of standardization and type approval, in particular, proposals relating to:

- (a) provisions establishing regulations, standards and supplementary technical instructions;
- (b) decisions on case files regarding type approval of prototypes, types and models;
- (c) accreditation of testing laboratories and establishment of co-operation agreements for development of such laboratories;
- (d) registration of co-operating entities and recognition of quality-mark administering entities;
- (e) decisions on penalization case files.

1.1.2. The Commission, whose Chairman shall be the Under-Secretary, shall comprise the Directors-General and the Technical Secretary-General of the Department.

1.1.3. The Commission shall be assisted by a working party comprising officials of the Department who are most closely concerned with standardization, type approval and industrial or mining safety.

Section 2. Directorates-General

1.2.1. The following criteria shall be observed in apportioning responsibilities as between the various Directorates-General in the field of standardization and type approval:

- (a) Each sectoral Directorate-General shall carry out standardization and type-approval proceedings in respect of manufactured or imported products falling within its sphere of competence.
- (b) The Directorate-General for Industrial Innovation and Technology shall carry out activities of a horizontal nature such as those in regard to testing laboratories, co-operating entities in the field of standardization and type approval, and quality-mark administering entities.
- (c) Standardization and type approval for exclusive reasons of safety, and likewise verification of the safety status of products and equipment, shall be the responsibility of the body with specific competence in regard to industrial or mining safety.

Section 3. Supervision and Certification Commission

1.3.1. A Supervision and Certification Commission is hereby established in the Ministry of Industry and Energy to be responsible for supervising and monitoring type approval in order to ensure full compliance with the

provisions in force. It shall likewise carry out advisory functions for the various Directorates-General and shall issue conformity certificates and labels for products subject to type approval.

1.3.2. The Supervision and Certification Commission shall have as its Chairman and Under-Secretary for Industry and Energy; its Vice-Chairman shall be the Director-General for Industrial Innovation and Technology. Its members shall include representatives of the Directorates-General and the Technical General Secretariat and likewise representatives of the Ministerial Departments concerned, manufacturers and consumers together with such persons whose inclusion is considered appropriate by the Directorates-General of the Department by reason of their experience and knowledge.

1.3.3. For carrying out these tasks, specific committees may be established by product category or category grouping.

Chapter 2. Testing Laboratories

Section 1. Accreditation of Industrial Testing Laboratories

2.1.1. Accreditation of a testing laboratory shall imply that the latter is capable of carrying out tests and analyses deemed valid by the Ministry of Industry and Energy, when required for type approval of prototypes, types or models or for verification of product conformity with standards.

Accreditation shall be granted only for one or more tests or types of tests, without this implying at any time that the laboratory must cease to engage in other activities for which it is not accredited.

Regardless of the geographical location of a laboratory, accreditation obtained by it shall be valid throughout the entire national territory.

2.1.2. The Directorate-General for Industrial Innovation and Technology is the component body of the Ministry of Industry and Energy for granting accreditation to laboratories that so request and for supervising and monitoring their activities; it may likewise grant accreditation to laboratories belonging to public entities that furnish services of interest for industry, subject to prior agreement with the entity concerned.

2.1.3. Laboratories wishing to obtain accreditation for one or more tests must submit their application to the Directorate-General for Industrial Innovation and Technology together with the following documentary information in triplicate:

- (a) Legal status of the undertaking with tax identification number, or non-profit-making foundation or such other status as corresponds to the applicant laboratory.
- (b) Name of the responsible official of the laboratory and of the person or persons who, being empowered to do so, will be the signatories of, and accordingly responsible for, the accuracy of analyses and tests in respect of which the laboratory wishes to be accredited.

- (c) Period of time during which the laboratory has been carrying out its activities.
- (d) List of persons employed in the laboratory with an indication of their relevant qualifications and aptitudes, and of the estimated number of hours that they devote to testing activities.
- (e) Statement to the effect that members of the staff do not maintain with undertakings or organizations interested in test results, any special links that could affect the independence and neutrality of their work.
- (f) Detailed description of the limits and necessities of the tests for which the laboratory is requesting accreditation.
- (g) Overall capacity of the laboratory to carry out the corresponding tests with sufficient accuracy and repetition, in a rational, organized and economic manner.
- (h) Previous experience of the testing laboratory in the same field of activity. Time-schedule for improvements to be introduced to the laboratory to maintain the technical and professional level, having regard to development trends in the testing area concerned.
- (i) Internal organization of the laboratory, working methods, registers, accounting, and all aspects relevant to the establishment and maintenance of documentary records of tests.

2.1.4. The Directorate-General for Industrial Innovation and Technology shall establish general and specific criteria for granting accreditation in respect of each specific test category.

2.1.5. Accreditation shall be valid for not more than three years; within six months prior to expiry of that period the party concerned may request extension thereof.

2.1.6. The Ministerial Commission on Standardization, Type Approval and Safety must examine the matter prior to any decision on the accreditation file of a testing laboratory.

It shall be communicated to the Advisory Group and to the applicant laboratory and shall be published in the Official Gazette.

2.1.7. Refusal of accreditation may be the subject of an appeal to the Ministry of Industry and Energy under the terms and procedures laid down in the Law on Administrative Procedures.

Section 2. Advisory Groups

2.2.1. The Directorate-General for Industrial Innovation and Technology may establish, for each test category or each homogenous set of products,

an Advisory Group comprising persons from public and private entities competent in the matter, as deemed appropriate in each case by the aforementioned Directorate-General.

2.2.2. These Advisory Groups shall have the following functions:

- (a) To advise the Directorate-General for Industrial Innovation and Technology as to whether or not it is appropriate to grant the accreditation requested by each laboratory falling within the purview of the Advisory Group. The Advisory Group may inspect the installations of the applicant laboratory, its equipment and work processes. It may likewise carry out inspections of tests made in recent years in the relevant field, on the basis of records kept in the laboratory's archives.
- (b) To ensure that during the period of validity of the accreditation granted there is no deterioration in the technical level of the laboratory nor in the testing capacity it had at the time of accreditation. Any adverse changes that could be liable to penalization in pursuance of Chapter 9 of these Regulations shall be reported by them to the Directorate-General for Industrial Innovation and Technology.
- (c) To propose to the Directorate-General for Industrial Innovation and Technology any specific criteria, additional to the basic criteria already mentioned, which in their opinion should be applied to laboratory accreditation in respect of the test category or product grouping concerned.
- (d) To make such proposals and suggestions as they consider relevant for proper operation of the accreditation process.

Section 3. National Network of Industrial Testing Laboratories

2.3.1 Accredited laboratories shall together make up the National Network of Industrial Testing Laboratories whose field of activities shall cover the entire territory.

Any laboratory that becomes part of the Network by virtue of accreditation shall remain independent in respect of its management without the fact of being accredited for one or more types of test affecting in any way the rest of the laboratory's activities.

2.3.2. The Directorate-General for Industrial Innovation and Technology, in its capacity as the body responsible for granting accreditation to industrial testing laboratories, shall publish from time to time any additions to or deletions from the list of laboratories that make up the Networks and the testing services offered by the up-dated National Network, and shall supervise and monitor its activities.

2.3.3. The Ministry of Industry and Energy shall lay down provisions determining the manner in which laboratories are to present the results of the work for which they have been accredited, and the form in which they may publicize the fact of having been accredited.

Section 4. Calibration

2.4.1. In order to meet the special need on the part of both manufacturers and accredited laboratories for the measurements used to be kept within admissible margins of variation, the Ministry of Industry and Energy, within its sphere of competence, may establish a system of industrial calibration to facilitate this basic task.

2.4.2. This system will be linked to national models, to the extent that its availabilities allow, and its services can be at the disposal not only of manufacturers of type-approved products, but also of all domestic manufacturers and professional persons.

2.4.3. In addition to the Advisory Groups by test category or product grouping as referred to in Section 2, the Directorate-General for Industrial Innovation and Technology shall establish an Advisory Group of a horizontal character whose activities shall focus on various aspects relating to the calibration system established by laboratories for equipment used in industrial testing.

Section 5. Co-operation Agreements

2.5.1. The Ministry of Industry and Energy may conclude co-operation agreements with public or private entities under the conditions and modalities stipulated in this Chapter in order to increase the supply of analysis and testing services, whether by developing any new testing methods that may be needed or by improving existing facilities whose capacity or geographical distribution is inadequate.

The Interministerial Commission on Standardization and Type Approval shall be advised of such co-operation agreements.

2.5.2. Any such agreement shall cover the programme of investments needed for the relevant tests, specifying the various component parts and personnel resources by employment category, as well as budget estimate for operating the new laboratory or expanding an existing one.

Where appropriate, the Ministry of Industry and Energy may make equipment and instruments available to laboratories covered by a co-operation agreement. The laboratory that receives and uses the said equipment and instruments shall undertake to take proper care thereof.

Under the Agreement, the Ministry of Industry and Energy may form part of the governing body of the laboratory that is to be established or

expanded, but its intervention shall not extend to management of the entity that owns the laboratory, which shall continue to be governed by its constitution and regulations.

2.5.3. Appropriate arrangements shall be made by the Directorate-General for Industrial Innovation and Technology for the monitoring and supervision of co-operation agreements.

Chapter 3. Entities Co-operating in the Field of Standardization and Type Approval

Section 1. Procedures and Requirements

3.1.1. For the purpose of carrying out the functions entrusted to it by regulations in the field of standardization and type approval, the Ministry of Industry and Energy may require the undertakings concerned to present documentary evidence that verifications and inspections have been carried out by a co-operating entity duly registered in accordance with Royal Decree 735/1979 of 20 February and with the provisions of this Chapter.

Co-operating entities in the field of standardization and type approval which meet the requirements set forth below may request their inclusion in a section of the special register to be opened in pursuance of Royal Decree 735/1979 in the Directorate-General for Industrial Innovation and Technology.

The tasks of such co-operating entities shall include the following:

- (a) Verification of the quality-control system integrated in the manufacturing process, covering all production phases from reception from suppliers to analysis of the end-product.
- (b) Selection by sampling, on the basis of techniques guaranteeing statistical representativity, of manufactured products subject to inspection.

3.1.2. In addition to the general conditions established in Royal Decree 735/1979, co-operating entities must fulfil the following requirements:

- (a) Spanish companies, associations or foundations whose principal objective is the study and development of quality-control techniques throughout the national territory may be co-operating entities in the field of standardization and type approval;
- (b) Co-operating entities in the field of standardization and type approval must have at least fifty staff members with accredited competence in the field of industrial quality;

- (c) They must keep record books, numbered and stamped by the Provincial Delegation of the Ministry corresponding to their business address, in which must be recorded the services and inspections carried out, the reports, findings and certifications issued and likewise the services entrusted to them by bodies of the Ministry.

The files and detailed data shall be held available for consultation for not less than five years.

Section 2. Registration

3.2.1. Application for registration as a co-operating entity in the field of standardization and type approval must be submitted by the entity concerned to the Provincial Delegation of the Ministry of Industry and Energy corresponding to its business headquarters, addressed in the first place to the Director-General for Industrial Innovation and Technology of the Ministry of Industry and Energy, accompanied by the following documentation in triplicate:

- (a) A sworn declaration that it is not liable to any of the incompatibilities mentioned in Article 3:2(a) of Royal Decree 735/1979;
- (b) The text of the constitution and statutes establishing the entity.

In the case of a company with foreign capital participation, certification in writing that such participation does not represent more than 25 per cent of the total registered capital. In the case of a stock company, evidence that the shares are registered.

- (c) A memorandum giving the following information:
 - (1) Activities to be carried out by the entity as a co-operator in regard to standardization and type approval;
 - (2) Personnel of the entity, indicating professional qualifications and place of residence;
 - (3) Intended tariffs for services furnished, where not fixed officially by the Administration;
 - (4) Where applicable, information on technical links or arrangements with similar specialized undertakings or entities.

3.2.2. The Provincial Delegation of the Ministry of Industry and Energy shall examine the documentation presented and after making any verifications it considers appropriate shall, within one month at the latest, send two copies of the said documentation to the Directorate-General for Industrial Innovation and Technology together with its report and proposal in which the information furnished in the memorandum shall be appraised.

The Directorate-General for Industrial Innovation and Technology shall request any supplementary reports that it considers appropriate, and in any case a report by the Ministerial Commission on Standardization, Type Approval and Safety and, where appropriate and within not more than two months, shall decide that the co-operating entity is to be included in the special register opened for that purpose; it shall communicate its decision to the relevant Provincial Delegation and to the applicant and have it published in the Official Gazette.

3.2.3. Co-operating entities shall be required to maintain the minimum conditions of capacity recorded in the register in their regard.

In the event that a co-operating entity is found to have failed to comply with its obligations or to have infringed administrative standards applicable to it, the matter shall be investigated by the competent local Provincial Delegation.

3.2.4. For the purpose of application of the provisions of point 3.2.3. the Provincial Delegations of the Ministry of Industry and Energy shall inspect periodically, and at least once a year, the proceedings of co-operating entities, examine their record books and verify that they still have the capacity to exercise their activities.

The Provincial Delegations shall report to the Directorate-General for Industrial Innovation and Technology on their inspections of co-operating entities.

3.2.5. Co-operating entities shall be responsible for their own opinions and actions, notwithstanding their having been recognized by the Administration.

Chapter 4. Technical Regulations and Standards and Supplementary Technical Instructions

Section I. General Aspects

4.1.1. Having regard to the growing complexity of industrial legislation in respect of standardization and type approval and for reasons of efficiency and administrative economy, the said legislation must use the reference to standards whenever possible.

The reference to standards may be general, concrete or not, or in whatever form is considered most appropriate having regard to the characteristics of the instrument. The said reference, when not considered sufficient, may be accompanied by requirements on instructions for correct use, maintenance, after-sales service, possible accidents, and any others that might be considered necessary.

4.1.2. As regards the field of application of regulations, standards and supplementary technical instructions, the following two cases must be considered:

- (a) Their application is compulsory in the case of all products covered by the instrument regardless of their origin, their sale or installation being considered unlawful throughout the national territory if they fail to comply with the requirements established as compulsory in respect of the use for which they are intended;
- (b) Application may be required in certain specified situations when preference is given to manufacturing undertakings which voluntarily observe the standards when advantages are granted to consumers or users who acquire the products.

4.1.3. For a standard to be declared compulsory in a specified field of application, or for its application to be exigible for the grant of a preference or benefit, the need therefor shall be justified, the existence of any of the following reasons being considered sufficient for such purpose:

- (a) Safety, health and hygiene of users or consumers, or of third parties and their property, including protection of the environment;
- (b) Defence of the economic interests of the user or consumer, and prevention of deceptive practices;
- (c) Conservation of energy and consumption of scarce resources;
- (d) National security and defence of climatic factors or other basic geographical factors;
- (e) Fundamental technological problems;
- (f) Requirements of an international agreement.

4.1.4. Where it is difficult for users or consumers to verify that a standard is being applied to a product, the instrument may make type approval compulsory in respect of the corresponding model, type or prototype of the product; such type approval shall be carried out in accordance with Chapter 5.

In addition, verification, whether total or by sampling, may be required that production and not solely the model is in conformity with the standard, in accordance with Chapter 6.

Similarly the instrument shall establish, in general, that analyses and tests required under the standard shall be carried out in laboratories accredited in pursuance of Chapter 2.

Section 2. Formulation of the Necessary Provisions and Formalities

4.2.1. The sectoral Directorate-General whose field of competence covers the activities of manufacturers covered by the instrument shall draw up regulations and provisions which contain references to standards or include standards and supplementary technical instructions.

The Directorate-General shall seek the co-operation of the industrial sector concerned, and likewise of consumers or users, and may establish joint co-operation and advisory committees to study the effects of the new standards and assemble the documentation needed.

The Directorates-General concerned shall be responsible for drawing up regulations and provisions in regard to industrial or mining safety.

4.2.2. The Directorate-General for Industrial Innovation and Technology, having general competence in regard to the services and capacity of the testing laboratories needed for application of the instrument, shall communicate its report for the purpose of complying with the relevant formalities.

If the Directorate-General for Industrial Innovation and Technology finds that there are not sufficient laboratories for future compliance with the standard, its report shall be binding and shall have the effect of suspending the process until such time as the necessary increase has been made in the National Network of Industrial Testing Laboratories.

4.2.3. The proposed instrument shall be brought to the knowledge of the Ministerial Commission on Standardization, Type Approval and Safety and, where appropriate, the Inter-Ministerial Commission on Standardization and Type Approval; it shall be sent to the Technical General Secretariat so that the latter may issue the mandatory report required under Article 130.1 of the Law on Administrative Procedures.

Chapter 5. Type Approval of Prototypes, Types and Models

Section 1. General Aspects

5.1.1. Type approval of a prototype, type or model of production shall imply official recognition that it complies with a regulation, standard or supplementary technical instruction, the observance of which is required under an existing instrument.

This procedure which is compulsory for the administration does not relieve the manufacturer or importer from responsibility if the rest of his production does not conform to the type-approved model.

5.1.2. The model on the basis of which type approval was granted shall be held on the manufacturer's premises, duly sealed or stamped by the Provincial Delegation.

In the case of destructive tests, another example of the model shall be held in safe-keeping.

5.1.3. In the case of a group of products with common parts on which depend the characteristics that are tested, type approval may be granted for the entire group of products.

5.1.4. In the case of one-off constructions or manufactures with special characteristics in respect of which the Administration has to approve plans and grant type approval of prototypes on the basis of monitoring reports by a specially assigned co-operating entity, the corresponding instrument must be observed in that regard.

Section 2. Application

5.2.1. Application for type approval of a prototype, type or model must be made to the Director-General whose field of competence covers the product concerned.

The application, together with the documentation mentioned below, shall be presented in triplicate directly to the Directorate-General or to the Provincial Delegation corresponding to the address of the manufacturing undertaking or, where applicable, the importer, by reason of his business address.

5.2.2. The application must give the following particulars:

- (a) Identity of the applicant. If a domestic manufacturer, the registration number in the Industrial Registry; if an importer, his tax identification number, particulars concerning the manufacturer, and the latter's representative in Spain;
- (b) The annual production volume of the product to be approved, and the share of the national market covered, or which is covered by like products existing on the market;
- (c) The percentage of national content of the product and the origin of its technology.

5.2.3. The documentation that must accompany the application is of two kinds:

- (a) Technical report from one of the laboratories accredited for the required tests, recording the results of the analyses and tests to which the prototype or model has been subjected;
- (b) Verification report as to the adequacy of its means of production and quality control system integrated in the manufacturing process, established by an entity co-operating in the field of standardization or type approval;

This verification report must include a report on the way in which the undertaking carries out calibration in respect of all its measuring components and equipment;

- (c) Documentation, in Spanish, explaining the functions and characteristics of the equipment or apparatus.

Section 3. Decision

5.3.1. For the purpose of deciding on the application, the Directorate-General may request co-operation from the industrial sector concerned and from consumers or users as well as from bodies or entities concerned with research and technological development. In all cases a report shall be requested from the Supervision and Certification Commission.

If additional tests are considered necessary, such decision shall be notified to the applicant so as to formalize acceptance of the new tests.

5.3.2. The decision shall specify the identification particulars that it is considered necessary to include in products corresponding to the type-approved model, as well as the period of validity of the type approval which may be renewed for successive periods on request by the interested party.

5.3.3. The decision, which must first be communicated to the Ministerial Commission on Standardization, Type Approval and Safety shall be communicated to the applicant undertaking and published in the Official Gazette; the type approval granted shall be given a number.

5.3.4. Refusal of type approval may be the subject of an appeal to the Ministry of Industry and Energy under the terms and procedures of the Law on Administrative Procedures.

Section 4. Modifications

5.4.1. Any modification that the manufacturer or importer wishes to introduce in the production corresponding to a type-approved model must be the subject of a request to the Directorate-General which granted the type approval.

5.4.2. The request must be accompanied by a memorandum indicating the changes proposed together with a report by an accredited laboratory on the extent to which the modification affect compliance with the standard.

5.4.3. The Directorate-General shall either authorize the modification, retaining the same type-approval number, or shall refuse the request.

Chapter 6. Production-Conformity Certificate and Mark

Section 1. Production-Conformity Certificate

6.1.1. When on the occasion of type approval it has been decided that production is to be monitored to ensure continuing compliance with the conditions on which the type approval was based, the manufacturers of the products concerned shall present the following documentation to the Supervision and Certification Commission with the frequency or at the intervals specified in the type-approval decision.

- (a) A statement that manufacture of the said products has continued;
- (b) A certificate by an entity co-operating in the field of standardization and type approval regarding the continued adequacy of the production means and quality control used, and regarding identification of the sample selected for testing;
- (c) A technical report by an accredited laboratory on the results of the analyses and tests to which the sample selected by the co-operating entity has been subjected.

The Supervision and Certification Commission may order a repetition of the sampling and testing procedures if it deems appropriate.

When the type-approved model subject to monitoring corresponds to an imported product, selection of the sample to be sent to an accredited laboratory shall be made by the co-operating entity for each lot to be imported.

Where the instrument establishing type approval does not stipulate the sampling methodology to be used, the UNE standards published to date shall be applied.

6.1.2. If the documentation submitted is found satisfactory by the Supervision and Certification Commission, it shall issue a certificate stating that the production conforms to the type-approved model. In the contrary case, it shall report to the Directorate-General which granted type approval so that the latter may make the necessary investigation with a view to penalization.

6.1.3. Where the above-mentioned conformity certificate has been granted, the products concerned must bear a mark or label distributed by the Supervision and Certification Commission, the content of which is described in Section 2.

6.1.4. The Supervision and Certification Commission, either directly or through the intermediary of a co-operating entity, may at any time verify whether manufacturers and importers are fulfilling the obligations incumbent on them in regard to production-conformity; to this end, full facilities shall be given to its inspectors for examining documentation and verifying products, taking samples and, where necessary, removing them for testing.

6.1.5. Similarly, the Ministry of Industry and Energy may inspect the activities of co-operating entities to ensure proper execution of their inspection operations.

Section 2. Production-Conformity Mark

6.2.1. The production-conformity mark shall be the same for all industrial products and shall include the following particulars:

- (a) Name of the product;
- (b) Wording indicating that production of the item concerned has undergone the verification indicated in the relevant provisions.

6.2.2. The Ministry of Industry and Energy shall register in its name a reproduction of the mark to be affixed on all products in respect of which there is such an obligation and right, in the form and conditions stipulated above.

Chapter 7. Quality-Mark Administering Entities

7.1. Upon request from the interested party, the Ministry of Industry and Energy shall accord recognition to entities that either grant their own quality marks or are licensees of foreign or international marks if they fulfil the following conditions:

- (a) Both the entity and its directors must be independent of the interests of undertakings to whose products they grant marks;
- (b) The entity must have technical staff with adequate qualifications and in sufficient number to carry out inspections;
- (c) The entity must have the necessary technical resources and facilities to determine product quality;
- (d) The entity must apply standards and regulations with adequately defined quality requirements at a higher level than those fixed in any existing mandatory standards.

7.2. Entities wishing to obtain recognition from the Ministry for Industry and Energy shall address their request to the Directorate-General for Industrial Innovation and Technology, together with the following documents:

- (a) A descriptive memorandum indicating the entity's activities as well as its personnel and technical resources, technical facilities and the organizational system it uses, and likewise the products to which it grants or intends to grant its marks;
- (b) A certified copy of the entity's statutes;
- (c) A list of the entity's responsible officers and Board of Directors or similar organ;
- (d) A copy of the regulations and other documentation governing the grant and issue of the marks;
- (e) A copy of the marks, dies, labels, etc. displaying the marks that the entity grants;
- (f) A sworn statement that it has no participation in the undertakings to which it grants its marks;
- (g) Where relevant, a reference to undertakings that constitute its prior experience in this field of activity.

7.3. After requesting from the Provincial Delegation of the Ministry or other bodies any clarifications and reports it may consider appropriate, the Directorate-General for Industrial Innovation and Technology shall forward its proposal for a decision to the Ministerial Commission on Standardization, Type Approval and Safety.

If approved by the Commission, the decision shall be communicated to the requesting entity and to the appropriate Provincial Delegation.

7.4. Recognized entities must record in their published procedures the fact that they have been recognized by the Ministry of Industry and Energy.

From time to time the Directorate-General for Industrial Innovation and Technology shall publish an updated list of recognized entities.

7.5. The Ministry of Industry and Energy may inspect from time to time the procedures of these entities and verify that the conditions that justified their recognition still exist.

If as a result of inspection it is found that the initial conditions are not being fulfilled or that marks are being applied improperly, penalizing action may be taken as provided in Chapter 9.

Chapter 8. Determination of Prices of Services furnished
by Accredited Laboratories and Co-operating Entities

8.1. Any party requesting a test with a view to type approval or conformity with standards shall have the right to require that the fee charged by the accredited laboratory for the test to be carried out is consistent with the tariff communicated to the Ministry of Industry and Energy.

8.2. Every six months, each accredited laboratory shall send to the Directorate-General for Industrial Innovation and Technology, in an authentic form, a list of hourly rates for the various personnel categories, with a breakdown indicating labour costs, social costs and overhead costs.

Where a laboratory is accredited to carry out various kinds of tests, it shall present its tariff for each type of test.

8.3. The Directorate-General for Industrial Innovation and Technology may inform users of the tariffs in force for a certain type of test in the various laboratories accredited to carry it out.

8.4. The services of co-operating entities shall be furnished in accordance with tariffs communicated to the Ministry of Industry and Energy which may be adjusted only at six-monthly intervals, for which purpose the relevant list of hourly rates for the various personnel categories, with the breakdown stipulated in 8.2, shall be sent to the Directorate-General for Industrial Innovation and Technology.

Chapter 9. Infringements and Penalties

Section 1. Infringements

9.1.1. Minor administrative infringements shall be deemed to be any actions or omissions that can be remedied easily and do not affect compliance by products with the technical requirements stipulated in standards that are compulsory or exigible or contained in the basic provisions in regard to product-conformity or quality marks.

9.1.2. Serious administrative infringements shall in general be deemed to be those that affect compliance with the technical requirements mentioned in the preceding paragraph but where non-compliance does not cause any danger for persons or objects, and likewise recurrence of more than two minor infringements in the course of a single year.

In particular, any of the following infringements shall be deemed serious:

- (a) For accredited laboratories, deterioration of the laboratory's technical level or of the testing capacity it had at the time of accreditation and likewise the issuance of reports without the corresponding tests having been duly carried out;

- (b) For co-operating entities, deterioration of capacity to carry out their activities, and likewise the issuance of reports that have no reasonable basis or are not consistent with the principles of proper practice, and shortcomings in regard to professional ethics in random sampling;
- (c) For importing manufacturers:
 - (1) the sale on national territory of products that do not fulfil the requirements of compulsory standards or type approval;
 - (2) the fraudulent affixing of marks or labels and the issuance of certificates provided for in these regulations in respect of products that do not comply with the requirements of the relevant provisions;
 - (3) the omission or inadequacy of instructions in correct Spanish when this is required in the provision establishing compulsory standards or type approval, in respect of the operation and, where applicable, the maintenance, assembly or installation of products;
 - (4) the omission of product identification marks;
 - (5) refusal to make available to inspectors the data they need for supervising compliance with exigible requirements in respect of products covered by standardization or type-approval provisions;
 - (6) unwarranted and recurring disregard of recommendations made by the Ministry of Industry and Energy or its inspectors regarding measures to ensure compliance by their products with exigible requirements;
- (d) For quality-mark administering entities:
 - (1) non-compliance with the conditions that were the basis for their recognition;
 - (2) infringements of their own statutes and regulations when this results in non-compliance with exigible quality levels of the products for which they have responsibility.

9.1.3. Very serious infringements shall be deemed to be those mentioned as being serious which involve possible risk to persons or objects, and likewise recurrence of serious infringements mentioned in 9.1.2.

Section 2. Penalties

9.2.1. Administrative penalties for minor infringements shall consist of written censure of the party responsible. Serious infringements shall be recorded in the file of the undertaking or entity, and can result in temporary suspension of the activities concerned, for a period of not more than six months, or subject to remedy of the infringements found to exist.

Very serious infringements shall be penalized by suspension for more than six months and can result in total and definitive stoppage of the activity concerned.

In cases of proven non-compliance with exigible requirements, the products concerned may not be sold in the national territory.

9.2.2. In all cases, the procedure established by the Law on Administrative Procedures of 17 July 1958 shall be applied, and infringements and penalties shall be reported to the Ministerial Commission on Standardization, Type Approval and Safety.