

Committee on Technical Barriers to Trade

Original: Spanish

COMMITTEE INVESTIGATION UNDER ARTICLE 14:4 CONCERNING TYPE
APPROVAL OF HEATING RADIATORS AND ELECTRICAL
MEDICAL EQUIPMENT

Addendum

Pursuant to its communication of 28 May 1984, the delegation of Spain has transmitted the following additional information on 26 June 1984.

ADMINISTRATIVE PROCEDURE FOR TYPE APPROVAL OF
ELECTRICAL MEDICAL EQUIPMENT

In the context of consumer safety and protection policy, the Spanish administration draws up technical regulations providing for a series of actions in regard to technical and administrative requirements to be met by importers and domestic manufacturers. In most cases, and specifically for the type approval of apparatus for monitoring intensive care of patients, the technical requirements are practically identical to those applied in the majority of OECD countries.

As regards the basic documents to be furnished, the administrative procedure is as described below.

The interested party (manufacturer or importer) presents to the competent administrative body as determined by law the application for type approval together with the required technical documentation. Together with this application, the administration requires certain particulars identifying the applicant.

The application must be accompanied by:

1. A certificate from the laboratory where the tests were carried out. To date there are 4 laboratories authorized to test monitoring equipment: the Industrial Automation Institute, the Spanish Electrotechnical Association (ASINEL), INTA and the Central Electrotechnical Laboratory.
2. A report from a co-operating entity. In Spain there are 4 entities authorized for these tasks and they are well-known to manufacturers and importers. The report must confirm that the producing factory has established an adequate quality-control system.

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3. A file including the relevant documentation or technical papers explaining and defining the functions and characteristics of the equipment presented for type approval.

When the above documentation is complete, it is examined by the Electronics and Computer Technology Committee and the Supervision and Certification Commission, which makes the corresponding proposal to the Commission for Standardization, Type Approval and Security. The Chairman of this Committee is the Director-General for Electronics and Computer Technology of the Ministry of Industry and Energy, and its membership includes two representatives of the Ministry of Economic and Financial Affairs, one representative of the Ministry of Health and Consumer Affairs, one representative of the National Consumer Institute, one representative of the Ministry of Education and two representatives of the Ministry of Industry and Energy. One representative of the technical association of the sector concerned also sits in the Committee with technical observer status. The Commission on Standardization, Type Approval and Security is chaired by the Under-Secretary of the Ministry of Industry and Energy; its membership comprises all Directors-General of the Department and the Technical Secretary General of the latter. All proposals for type approval provisions are put before the Commission which can comment on the texts submitted to it.