

A Primer on Regulations and Standards

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It is all too easy to become entangled in the complicated structure of the rulemaking and standards-writing world, with its maze of private, public, and semi-public organizations, committees, subcommittees, working groups, secretariats, reviews, votes, public comments, and revisions. Better understanding of this sometimes complex world can ease the anxiety and burden of compliance and help manufacturers and their agents avoid having an antagonistic, adversarial relationship with the regulators.

Today's products must conform to a host of regulations and standards derived from the joint actions of government regulatory agencies and private standards organizations. The regulations set the overall rules, while the detailed technical standards needed to implement the rules are frequently derived from private standards, such as those of the International Electrotechnical Commission (IEC). Thus, standards that were originally designed to be voluntary become mandatory and gain the force of law. Manufacturers need to be aware of the activities of both government agencies and private standards groups.

Government Bodies

Naturally, manufacturers are concerned primarily with the mandatory regulations imposed by governments.

The United States

In the United States, the power of government is divided among the executive, judiciary, and legislative branches. The legislative branch, Congress, creates the statutes governing the country. Congress's power is not unlimited; its scope is defined by the Constitution. The power to regulate commerce and to mandate product compliance is granted by the Constitution's Commerce Clause, which authorizes Congress to "regulate commerce with the foreign nations and among the several states."

The Commerce clause also authorizes Congress to create agencies to handle the detailed implementation of congressional statutes. These agencies, which are rulemaking bodies in their own right, supply the manpower and technical expertise necessary to flesh out the statutes.

The shifting of rulemaking authority from the popularly elected Congress to the appointed administrative agencies has allowed for greater efficiency in government but has also created the potential for arbitrary or capricious rulemaking. For this rea-

son, Congress passed the Administrative Procedure Act (APA) to limit federal agencies' ability to make and enforce regulations.

The APA requires that all agency rulemakings be subject to a "notice and comment" procedure. Notice of proposed rules must be published in the Federal Register (which is published daily by the U.S. government) and must state the terms of the proposed regulations and cite the authority allowing the agency to propose them. At least 30 days must pass before agency regulations can become effective, and the agency must respond to any written comments concerning the proposed rules. The public right to notice and comment does not, however, apply to two kinds of rules, those that 1) regulate the internal procedures of an agency, or 2) interpret existing law rather than creating new law ("interpretive" rules).

Individuals not only have the right to comment on proposed regulations, but may also petition the agencies to initiate new rules or to amend or appeal existing ones.

Where technical standards are required, federal agencies can either adopt those used in the private sector or write their own. OMB Circular No. A-119 urges federal agencies to work with private standards organizations and to incorporate privately developed standards in their rules. Such adoptions are still subject to the notice-and-comment procedure.

Hand in hand with the right to issue regulations goes the right to enforce them. Included among the agencies' enforcement powers are the rights to issue fines and to control the issuance of licenses. Where severe penalties are concerned, the agency must first provide advance notice and the opportunity for a hearing. The hearing may vary from a statement by the violator to a full-blown trial. The courts have laid down complicated outlines governing the proper hearing format for different regulatory problems.

Under the APA the revocation of a license, such as an FCC registration or certification grant, must also follow a notice and hearing process.

Federal agencies generally do not have the authority to seize equipment or arrest lawbreakers. Criminal actions must be undertaken by the executive branch, usually by the Justice Department at the request of a federal agency. One notable exception to this rule concerns Customs, which is empowered to seize imported goods.

Once an agency has issued its final judgment, the aggrieved party may choose to follow a detailed and intricate appeals proce-

sure. It is important that the plaintiff exhaust all remedies within the agency before appealing to the federal court system, as failure to follow proper agency appeal procedures can preclude further appeal.

The European Communities / European Union

One difference between United States law and the law of Western European nations is the role played by the European Communities (EC, or EU in more recent jargon). The United States, a sovereign power all by itself, writes its own laws. EU members, in this sense, are not completely sovereign. They are members of the Common Market and are bound by Common Market treaties. High on the list of the EU's priorities is the abrogation of technical standards that would act as trade barriers. EU directives are effectively binding on all EU members.

The EU's lawmaking process begins with the European Commission, a body composed of appointed administrators who are, in theory, beholden only to the Community at large and not to the member states they are individually from. Their proposals pass first to the European Parliament and then to the final deciding body, the Council of Ministers. The Parliament is popularly elected and acts as a legislature, but its powers are limited. The ultimate power instead lies with the council, representing the member states.

These proceedings eventually result in regulations and directives. Regulations, which are directly binding on the member states without their having to take any individual action, apply mainly to the controversial area of agriculture. Directives do not

create new law directly but simply instruct member states to amend their national codes within a prescribed period.

At first, the EU was slow to exert its full power over its members. However, in the past ten years, consensus has been reached that free trade is essential to the economic wellbeing of Europe, and the widely publicized push for an open European market has led to the passage of hundreds of directives. This acceleration was made possible by the Single European Act, which allows directives to be passed by weighted majority in the Council of Ministers rather than by the unanimous vote previously required.

Judicial oversight is the function primarily of the European Court of Justice.

GATT

The General Agreement on Tariff and Trade (GATT) is a multilateral agreement to which more than a hundred governments subscribe. In areas of international trade, it represents a means by which the United States can redress grievances. Its primary goal is the creation of a barrier-free world through the reduction of tariffs and the elimination of nontariff barriers to trade. The treaty, initially created in 1948, has evolved over the seven rounds of Multilateral Trade Negotiations (MTN). The Uruguay Round of negotiations was completed in 1994.

The provisions of the Standards Code were designed to eliminate the use of standards and certification systems as barriers to trade. It regulates how standards and certification systems can be developed and applied but does not actually specify the standards themselves.

Key provisions of the Standards Code stipulate that each country must treat imported products no less favorably than it treats domestic ones. The Standards Code mandates that tests should not cost more or take longer for foreign than for domestic suppliers. Information on test results must be made available to foreign manufacturers, and furthermore, the location of the tests themselves should cause them no undue inconvenience.

Along with these provisions, GATT also sets up notification schemes according to which each country receives notice of regulations that may affect exports. The National Institute of Standards & Technology (NIST) acts as a clearinghouse for pending changes in foreign standards.

CCITT

The International Telegraph and Telephone Consultative Committee (CCITT) is one of two committees operating under the auspices of the International Telecommunications Union (ITU). Its aim is to foster international cooperation in telegraphy and telephony, operating in tandem with its sister radio organization, the CCIR.

The ITU was first formed in 1865, but since 1974 it has been a specialized agency of the U.N., headquartered in Geneva and consisting of 157 member countries.

The CCITT makes worldwide operational and tariff recommendations for its members, meeting every four years for a plenary session. In this session, issues to be studied and standardized, known as "study questions," are approved and taken up by one of 15 study groups. The work of the CCITT is codified every four years in a set of books named by color (the 1984 set was the "Red" book, the 1988 "Blue," etc.).

While private organizations and standards groups can be members of the CCITT, each national committee is headed by a government body. The United States, for example, is represented by the State Department. Study groups are made up of technical experts who subdivide their tasks, delegating them to working parties that meet several times a year.

Private Standards Organizations

Private standards organizations, such as the IEC, ANSI, and CISPR, are not part of any government body. Nonetheless, they have great influence on the standards that governments adopt. Frequently, especially in European countries, standards produced by these organizations are taken up by governments and given the force of law. The work of these standards organizations is therefore of more than passing interest to manufacturers.

There are more than a thousand of these organizations worldwide. A few of the most influential are described below.

The ISO and the IEC

The International Electrotechnical Commission (IEC) is the largest and perhaps the most influential of all the private standards organizations. It was formed in 1906 and now consists of national committees representing 80% of the world's population.

Countries participate in the IEC through their national committees, which are usually sponsored by prominent standards organizations within each country. In the United States, the American National Standards Institute (ANSI) serves as the national committee to the IEC. Each national committee is allotted one vote on IEC standards.

The technical work of the IEC is done through Technical Committees (TC). In turn, these Technical Committees delegate functions to subcommittees and working groups. Once agreement has been reached within a Technical Committee, a draft is circulated to all national committees. The IEC currently has more than eighty such Technical Committees.

Each Technical Committee is headed by a Secretariat (usually one of the national committees) whose job it is to take the lead in standards development. Each country is represented on the Technical Committee by a Technical Advisor chosen by each national committee. The Technical Advisors in turn appoint the members of the Technical Advisory Group (TAG) that will advise them on what the national committee's position should be.

The IEC's sister organization, the International Standards Organization (ISO), was founded in 1947. By agreement with the IEC, it focuses its standards activities on nonelectrical subjects.

CENELEC

The European Committee for Electrotechnical Standardization (CENELEC) has become a pervasive and effective force in standardizing requirements throughout Western Europe and, indirectly, much of the rest of the world. Its 18 member countries include all 12 Common Market members. CENELEC is not a government body, but a private organization serving a regional rather than a national standardization function.

CENELEC's aim is to remove any technical barriers to trade that result from conflicting requirements in the technical content of the national electrotechnical standards of its members. In order to avoid creating new general trade barriers at the European level against countries outside Europe, such as the United States, it bases most of its standards on those of the IEC.

CENELEC documents come in the form either of European Standards (EN) or of Harmonization Documents (HD). While national modifications are permitted in the Harmonization Documents, such deviations are not allowed in European Standards. Most of the documents issued by CENELEC are European Standards.

A separate Marks Committee within CENELEC deals with the recognition of national marks of conformity in individual countries, including a special HAR scheme for cables and cords.

In 1982, the CENELEC Certification Agreement came into effect. This agreement speeds the right to use the national mark of any CENELEC member based on test data of another member. For instance, products tested by VDE can qualify for the use of a BSI mark without further testing by the British Standards Institute, so long as the procedures in the CENELEC Certification Agreement (Memorandum No. 13) are followed. CENELEC's sister organization, CEN, covers the nonelectrotechnical field.

EOTC

The European Organization for Testing and Certification (EOTC) was created in 1990 through a joint agreement among the European Community, the European Free Trade Association (EFTA, consisting of Norway, Sweden, Finland, Iceland, Switzerland, Austria, and Liechtenstein), and CEN/CENELEC. Its main goal is to foster the development of pan-European certification systems and mutual-recognition agreements in areas where the EC does not regulate by directive (i.e., where voluntary standards are in effect), though its efforts will affect certification systems under mandatory regulations as well.

The EOTC is governed by a council and divided into functional (or "specialized") and "sectoral" committees. Sectoral committees are set up for different industries, including information technology, steel, medical, and so on, while specialized committees are established along functional lines (focusing on testing, certification, quality system registration, etc.). Each committee fosters mutual recognition agreements through its Agreement Groups.

ETSI

Telecommunications is such a complex and specialized field that a new European organization had to be created to develop appropri-

ate technical specifications for it. This organization is the European Telecommunications Standards Institute (ETSI), founded in 1988.

ETSI, headquartered outside Nice, France, is run by a Technical Assembly. Reporting to the Technical Assembly are committees on Intellectual Property and Strategic Planning and, most important, Technical Committees.

These Technical Committees write European standards for telecommunications. Some of these standards will be given the force of law through the adoption by the European Community of directives such as 91/263/EEC; for example, ETSI standards on X.21 and X.25 devices have already displaced country-specific regulations for these devices. Most significant are the standards for terminal equipment, which will become a pan-European version of the FCC's Part 68 rules (albeit with significant differences).

CISPR

The International Special Committee on Radio Interference (CISPR) was organized under the auspices of the IEC and is run by a Plenary Assembly consisting of delegates from all the member bodies, including the United States. It meets at least every three years to elect a chairman and a vice chairman. The Plenary Assembly also selects subcommittee chairmen and secretariats (managing nations) for each of the CISPR subcommittees. Most of the day-to-day work is performed not by the Plenary Assembly itself, but by a kind of executive subgroup known as the Steering Committee.

The subcommittees meet every few months. Of broad interest to many *Compliance Engineering* readers will be Subcommittee B, which covers interference from ISM devices, and Subcommittee G, which works on interference problems associated with Information Technology Equipment.

ANSI

The premier private standards organization in the United States is the American National Standards Institute (ANSI). ANSI operates as the United States' national committee to the IEC. ANSI itself does not write standards but only acts as a "national clearinghouse." It works with other groups such as IEEE and EIA to write standards that it then reviews for technical accuracy and adherence to due process. If a standard is approved, it becomes an American National Standard. Today there are about ten thousand such approved American National Standards.

ANSI becomes active as a national clearinghouse if and when input from industry or consumer groups indicates that a standard is needed. If a need can be established, an "accredited committee" is created, chaired by an organization that serves as secretariat. In the alternative, an accredited organization can develop its own standards under ANSI auspices. Finally, standards can also be set by canvassing public opinion. This "canvass" method is frequently used by UL.

The guiding principle behind ANSI is standardization by consensus. Consensus implies "much more than the concept of simple majority, but not necessarily unanimity." In order to ensure "due process," the basic standard of fairness required by ANSI, "The Procedures for Development and Coordination of American National Standards" specify that "everyone with a direct or material interest has a right to express a viewpoint and, if dissatisfied, to appeal." Due process also requires balanced representation and the

opportunity for all to speak “without dominance by any single interest.”

Once a standards organization has finished its work, further review by the public is prescribed. The proposed standard is sent to the Board of Standards Review (BSR), which publishes a notice of the proposed standard in the ANSI publication Standards Action. There is a 30- to 60-day period of comment. If comments are forthcoming, a “concerted effort to resolve all objections must be made.” Once adopted, standards are reviewed every five years.

International Certification and Approvals Schemes

In an effort to promote international trade, a number of certification and approvals schemes have been set up to allow any member country’s tests to be recognized worldwide.

CB Scheme

The IECEE Scheme for Recognition of Results of Testing to Standards for Safety of Electrical Equipment, or CB Scheme, is administered by the CCB Committee of the IECEE, under the auspices of the IEC. The committee operates under rules set out in IEC publications IECEE 01 and 02 and publishes a *CB Bulletin*.

Each national member of the CB Scheme agrees to accept test data from other participants for the purpose of issuing its national mark. For example, under the scheme, Germany’s VDE will issue its safety mark based on a CB Certificate issued by Sweden’s SEMKO if the tests were performed to the VDE’s published specifications. Each national member publishes its specs, which must be IEC-harmonized with any national deviations called out in the *CB Bulletin*.

The scheme currently covers many types of electrical equipment, from household appliances (IEC 65) to office machines (IEC 950). Components (cables and appliance couplers) are also covered.

The United States joined this scheme in 1992. U.S.-based product safety certifiers DS&G, ETL, MET, and UL can now issue CB Certificates.

CENELEC Certification Agreement

The CENELEC Certification Agreement allows for mutual recognition of electrical safety tests among the European CENELEC countries. The scheme requires the principal test house in each CENELEC member country to recognize test data from its counterparts in other CENELEC countries as a basis for the issuance of its national safety mark. The standards used are those falling within the EU Low-Voltage Directive and the IECEE CB Scheme.

The United States, not being a CENELEC member, does not participate in the CENELEC Certification Agreement.

CENELEC HAR Agreement

The CENELEC HAR Agreement is specifically designed for cords and cables. Cords and cables that bear the HAR marking or a CENELEC-recognized common marking thread must be accepted by participating organizations without further testing. Any national testing organization that agrees to abide by the scheme may test manufacturers’ cables and cords for conformity and issue the right to use the HAR mark or thread-marking. There are 12 participants in the scheme, including France, Germany, and the U.K. The United States does not participate.