

# **Standards Developer's Drive for International Harmonization**

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## **SAFETY STANDARDS AND PRODUCT CERTIFICATION IN A GLOBAL MARKET**

### **INTRODUCTION**

Industry's interest in global market access for its products is the primary driver for harmonization. Manufacturers want to comply with one standard and have their products accepted globally. The Standards development process must facilitate, rather than impede, trade while reflecting time-to-market sensitivities of technology-driven sectors and producing Standards that are globally relevant and technically sound. The process and principles used to develop standards must meet the WTO TBT definition of an "international standard", "...to ensure transparency, openness, impartiality and consensus, effectiveness and relevance, coherence..."

The process of standards development and product certification are intertwined. This paper explores current initiatives in standards harmonization and the resultant initiatives in product certification.

### **THE SPECTRUM OF HARMONIZATION**

The term "harmonization" refers to a process by which the technical requirements of various standards have been made equivalent or identical. Although the actual words comprising harmonized standards may be different, the performance requirements or safety issues have been addressed equally. By using a harmonized standard, manufacturers and certification agencies can be assured that any product tested to one standard will meet the requirements of another standard.

Confusion exists over the meaning of the term "harmonization." Some in the standards community believe that "harmonization" equals "identical"; others believe a standard is harmonized if the requirements are technically compatible. Additionally, harmonization with international standards is discussed quite often, although it is virtually impossible to publish a standard that is identical to an IEC Standard, particularly in the US or Canada.

Differences are usually necessary. Though a quantifiable description of harmonization would be desirable, it would require detailed analysis and interpretation of requirements to arrive at such a description, and the degree of harmonization would probably remain debatable. We can define the levels of harmonization as:

- A) Identical standards,
- B) Technically compatible standards, or
- C) Standards adopted with differences

Further harmonization may occur through technical equivalency. Many times, requirements are different, (i.e., different methods used to conduct a test to evaluate the same property, but they both may establish a “level of safety” that is acceptability equivalent. Requirements that are technically equivalent are also technically compatible. For example, one standard may require an appliance to be subjected to a drop test and a corresponding standard may require an appliance to be subjected to an impact test. In each of these tests, the appliance is subject to impact. Different methods are used, but the end result of the tests could be considered technically equivalent in that the product has been tested for the property of impact resistance.

## **A MODEL FOR HARMONIZATION**

The affected industries must encourage and support harmonization. As such, the particular industry is heavily involved in identifying the need for harmonization, including the level of harmonization desired. For example, while a standards developer, such as UL, may support international harmonization with IEC or ISO standards, some industries are not ready for that level of harmonization. They may desire a more Regional approach towards harmonization, such as through harmonizing requirements within North America. A national standards body or standards developer must take a very active and committed role with harmonization; however, they can't do it alone. Therefore, with each new harmonization effort, representatives from industry must be identified who will participate in the harmonization effort. Once the players have been identified, they will need to determine the phases and schedule for harmonization.

To comply with the intent or actual terms of the World Trade Organization Technical Barriers to Trade Agreement (WTO-TBT), accredited national standards bodies must adopt policies that have a strong international thrust.

First, participation in ISO and IEC standards activities to develop new internationally accepted standards is essential. This is particularly relevant when no national, regional, or international standard exists. Such participation may also include increased participation in the applicable national standards systems.

Second, when a need for a new standard has been identified, primary consideration should be given to adopting an existing international standard if the requirements fully address the level of safety expected by the public. Alternatively, if the International Standard is not fully sufficient, it may form the basis for a new standard, modified to include National Differences to address the level of safety expected by the national safety systems.

Third, when no ISO or IEC standard exists, yet a national standard exists, the accredited national standards body should promote the adoption of the existing national standard as an international standard without

differences if the requirements of the national standard addresses the levels of safety expected by the various national safety systems.

Lastly, for those situations where both a national standard and an IEC or ISO standard exists, and where the scopes of the standards are generally aligned, the preference is to harmonize the national standard with the ISO or IEC Standard (or the ISO or IEC standard with the UL Standard) with as few national differences as possible.

## **STANDARDS ADOPTED WITH DIFFERENCES**

Manufacturers trying to sell their products in global markets want to avoid delays and costs associated with compliance to multiple standards and gaining product approval or certification in each country.

As you all know, the development of international standards is proceeding in two leading international organizations, the International Electrotechnical Commission (IEC) and the International Organization for Standardization (ISO). It's not a rapid process. Even slower is the adoption of such standards by most countries. Many industries are not ready to move to international standards.

Industry and user needs are the key to harmonization with international standards. Harmonization with international standards may well require the involved industries to modify specific products, modifications that may require considerable investment of time and money. It becomes difficult for manufacturers to make changes that are costly, and add little or nothing to the safety of the products involved, simply for the sake of harmonization. And, yet, as the motivation to seek global markets grows, conformity to international standards becomes a prerequisite. Typically when a country adopts an international standard, the standard is adopted with differences. These differences may be labeled either as "national conditions" or "national differences".

Justification for identified National Differences may include:

1. Documented national legislation, providing cause for a difference.
2. Documented national legal precedent, or
3. Documented technical prerequisites of the national safety system or the national installation code or practice

National differences can and should be minimized by:

1. Introducing technically and experience-supported national basic safety requirements into the current ISO or IEC standard (or into the general ISO or IEC standards system); or
2. Negotiating alternative or harmonized “safety-equivalent” evaluation criteria that will not have the result of a possible source of barriers to trade. This particular approach should be used when no other possibility exists for eliminating the National Differences.

## **NATIONAL SAFETY SYSTEMS**

The national safety system in place in any country is a product of its culture. Most safety systems are a unique mix of voluntary and mandatory components, with roles for a variety of interested parties. Three elements that generally work together in any country are: product standards, installation codes and regulations. While these elements are separate, they have two things in common: they identify the requirements to be met and they contain mechanisms to demonstrate compliance to those requirements. Product standards contain requirements for the safety and performance of products. Generally, standards are developed in the by a variety of groups. Codes address the safe installation, application and placement of products and materials. Significantly, these codes are generally adopted word-for-word or with minor modifications by local governments as law. The third element, regulations, mandates safety requirements covering employers, employees and consumers.

## **THIRD PARTY CERTIFICATION**

For the manufacturer, the end means of harmonization is to minimize the cost of product testing while gaining acceptance of their product in multiple markets. Product certification plays an integral role in that process. One such means of product certification is third party. There are a number of reasons why a manufacturer may decide to pursue third party certification. In general, the chief reason is that market forces require evidence that products comply with standards, codes and laws. .

As in any transaction, the seller wants to sell a product to a buyer. A buyer will only purchase the product if they have confidence that the product will fulfill a need. Along with usability, quality, service, etc., buyers need confidence that the product complies with standards, codes and laws. Third party certification can provide the bridge of confidence that a product complies with standards, codes and laws.

Now, there is a new term, "Globalization." Globalization has gained tremendous momentum in recent years.

There is hardly an industry meeting that does not include seminars, meetings and discussions relating to the expansion of foreign markets, concerns about barriers to trade, impact of fluctuations in the value of currency, and competitive pressures brought on by strides in technology. The concept of a single world market and its challenges is equivalent in impact with other pressing problems facing governments, such as the deficit, imbalance of trade and threat to leadership in technology. Both IEC and ISO are actively involved in crafting policies and practices focusing on creating globally relevant standards to meet the needs of the global market.

## BILATERAL RECIPROCAL ARRANGEMENTS

A related imperative to standard harmonization must be treated - namely, some form of reciprocity of test data or certification among product approval systems in various countries. In this case, the process becomes even more complicated than harmonizing standards. There are major differences in product approval or certification requirements in different countries, ranging from practically no approval requirements in the emerging countries, to some legislated requirements in many countries, to the fairly sophisticated national, state and local enforcement system used in the United States and the national and provincial system in place in Canada.

In recognition and support of the objective of manufacturers to reduce the cost and delays in achieving product safety certifications in different countries, test laboratories have established bilateral reciprocal arrangements. These arrangements have been methodically established for specific products, with cross training, round robin testing, mutual witnessing of tests and other measures to assure duplication of results.

Establishing bilateral reciprocal arrangements is expensive and is undertaken only for industries that can demonstrate and document the need for such reciprocal arrangements. These bilateral reciprocal arrangements may be altered in the future. Decisions being made, and which will be made at the national government level, may well change the approach.

As in all international negotiations, there is a quid pro quo; that is, gaining acceptance of test results on products of U.S. manufacturers in other countries means a willingness to accept test results from laboratories in other countries on products from their manufacturers.

Until 10 or 15 years ago conformity assessment was carried out by official organizations, in the majority of cases only one organization per country, often directly authorized by the state, sometime operating in a regulatory context which made certification compulsory. In any case such organizations operated in a consensus environment and all relevant interests at the national level were represented in the certification organization. Furthermore each certification organization granted its own mark of conformity or a national

mark owned by the state. The meaning of such a mark was conformity to the national standards.

In recent years this situation has changed: compulsory certification, where existing, was eliminated in most countries and certification is more and more seen as a service required by the market (by manufacturers, by consumers and sometimes by authorities) and, as such, as a service to be granted under free competition rules. Until 20 years ago each country had its own set of standards that differed from each other.

A product to be marketed in various countries had to meet all the different standards of each country. The increase of international trade made it necessary to harmonize these varying standards that were otherwise considered a technical barrier to trade.

The consequence of the harmonization process on conformity assessment is that the meaning of all marks of conformity tends to be the same, i.e., conformity to the international standards. This is a great change in that all the different marks, even with different shape, mean the same. This fact cannot be ignored and from a commercial point of view may have some consequences.

When a product is marketed in various countries, it has the need that the requirements to comply with are the same (need of harmonization of standards) and then has the need not to repeat unnecessary tests in the various countries. As a consequence, these issues have given use to various agreements among certification organizations within economically homogeneous areas. Due to the IECEE/CB Scheme mutual recognition of test results is growing. The great development of the CB Scheme demonstrates the effectiveness of this mechanism as a response to the real trade issues of manufacturers. Previously, when manufacturers made use of mutual recognition agreements on test results or the CB Scheme, the final certification granted was always one or more marks of conformity owned by each certification organization involved. With these agreements, certification is represented by one mark of conformity having a regional or wider recognition. The same mark may be granted by any one of the organizations participating to the relevant agreement. Examples of this are some European marks. A foreseeable next step could be an international mark having a worldwide acceptance.

Four main conditions must exist for implementation of an international mark of conformity:

- The Standards used for assessment must be equal in all countries participating in the scheme;
- The participating countries must be economically homogeneous,
- The program must have the support of the relevant affected industries and;
- Participating certification organizations must cooperate.

Furthermore all certification organizations participating in the scheme must have a well-established certification scheme in their own country and must be committed to recognizing the common mark as equivalent to their own mark. A consequence of this trend from nationally recognized marks to an international mark means better service for industry, but also a further reduction of business for certification organizations, since not only type test and initial assessment will be conducted by a single organization as well as certification and follow-up inspections. The advantage for industry is that they deal with a single certification organization for certification recognized in several countries.

## **SUMMARY**

The drive for standards harmonization is but one element, albeit an essential element, of the overall trend for manufacturers to seek global market access for their products. As you can see, many methods subsequent to harmonization are used to achieve the goal of test once, certify once, and accepted globally. Standards developers, testing organization and government bodies all need to adjust their policies and practices to respond to the global market.