



*Worldwide Standards Systems  
Part 1: Europe and the USA*



## Introduction

To help standards users, IFAN has written this guide to the different standards systems round the world.

Though the International Standards Organization [ISO] and the International Electrotechnical Committee [IEC] are recognised and used in most countries there are a variety of national and regional systems that are different.

This part of Guide 6 focuses on the European regional system and the national system in the United States of America [USA]

IFAN welcome feedback on all of its guides.

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## The European Standards System

The purpose of the European standardization system is to help create new markets, support trade between countries and balance thoroughness and cost of compliance.

There are three European Standards Organizations (ESO):

CEN - the European Committee for Standardization.

CENELEC - the European Committee for Electrotechnical Standardization.

ETSI - the European Telecommunications Standards Institute.

The ESOs are officially recognised by the EU as the providers of European standards. They develop standards to be used throughout the European internal market. ESO standards and other content are made available by the member National Standards Bodies in their countries. Additionally the three ESOs supply a small number of national and worldwide distributors, and ETSI also sells directly from its website.

Using and complying with a European standard could be for these reasons:

- o Voluntary use. Users and organisations choose to use it where a benefit or benefits are understood.
- o Harmonised use. The standard is harmonised with a European Directive or a Technical Specification for Interoperability. Using the standard indicates conformity with EU regulations implemented in member states and Northern Ireland, and includes obligations for product and document labelling. The UK has an equivalent for its regulations.
- o Mandatory use. Complying with the standard is required in another document, often a standard from an industry organisation, or a contract.

### **National Standards Bodies.**

There are 34 members of ESO. They are made up of all of the EU member states national standards bodies, plus the national standards bodies of Iceland, Norway and Switzerland through membership of EFTA, and four additional non-EU states - North Macedonia, Serbia, Turkey and UK.

National Standards Bodies sell and publish standards on behalf of CEN/CENELEC and ETSI. They also have provide the specialists needed to create and manage this content.

### **European standards authoring and publishing.**

Proposals for standards come from public and commercial organizations, the European Commission for harmonized ENs, and in the UK the Office for Product Safety and Standards UKCA designated standards. Harmonized ENs are listed on the [EC Europa website](#). UK designated standards are listed on the [Office of Product Safety and Standards website](#). The actual development of agreed upon standards is by subject matter specialists through individual Technical Committees established by each of the three ESOs.

European standards can also be based on standards and other technical specifications already published by a National Standards Body. Once a CEN or CENELEC standard is published, National Standards Bodies must then publish them in their countries, amending the CEN /CENELEC identifier by adding their national identifier.

At the same time they must withdraw existing national standards that would be in conflict, This is known as the single standard model, and is designed to support the smooth working of the EU single market. Through agreements with the International Standards Organization (ISO) (Vienna Agreement) and the International Electrotechnical Commission (IEC) (Frankfurt Agreement), these European norms frequently become templates from which their ISO/IEC counterparts are then developed.

The ESOs and European National Standards bodies prefer standards to be published by the international standards organizations ISO and IEC, and then adopt them as ENs.

The process of authoring a European standard is explained in [IFAN Guide 5:2020](#). Introduction of the world of European standards for users. Each standard is managed by a Technical Committee made up of specialists and stakeholders from member National Standards Bodies. In turn, the National Standards Bodies have mirror committees from their country, carrying out analysis, national consultation, technical and organizational commentary to the European standard's Technical Committee.

### **Northern Ireland national standards**

The position on the use of national standards has not changed following the UK's withdrawal from the EU. BSI remains the national standards body. BSI is a non-EEA member of CEN and CENELEC until 31 December 2021.

### **Northern Ireland - Products requiring conformity assessment to designated standards.**

The UK has set up a product harmonisation system - UK Conformity Assessment (UKCA). There is a version for Northern Ireland, NI Conformity Assessment (UKNI). UKNI is only used by UK Approved Bodies carrying out mandatory conformity assessment and is not recognised in Europe. In Northern Ireland UKNI marking must always be accompanied by EU conformity marking.

- o Relevant products placed on the market in Northern Ireland before 31 December 2021 must have CE marking.
- o All relevant products placed on the market in Northern Ireland from 1 January 2022 must have both CE and UKNI marking if an Approved Body is used, or CE marking if an EU Notified Body is used.
- o Relevant products made in Northern Ireland to be sold in GB (the rest of the UK) in 2021 require UKNI or CE marking. From 2022 these products require UKNI marking.
- o Products available in Northern Ireland that are not under a Customs Procedure or in temporary storage in Northern Ireland awaiting shipment to Great Britain, are qualifying goods allowed Unfettered Access to GB. Qualifying goods may be marked either CE or CE and UKNI.
- o Products being made in Northern Ireland to be sold in the EU require EU marking. These products must not be marked with the UKNI mark.

There are exceptions for certain product sectors. These are explained on the UK government website. You should check this site to verify the information in this Introduction.

### **Northern Ireland - supplier's declaration of conformity**

These products will not require additional CE and UKNI marking. They must comply with EU and UK regulatory requirements.

## **The United States Standards System**

The purpose of the United States standards system is to provide a framework for safety, compatibility, fitness for purpose, and consistency in the US marketplace. It is a hybrid of government documents, related to procurement and regulation, and industry standards used in trade. Government standards are mandatory as part of the regulatory framework or by the use of them in procurement documents. Industry standards are predominately voluntary. Because industry standardization developed as self-regulation within trade associations, there is an abundance of standards developing organizations (SDO's) here in the US. Some remain national in scope, while others create documents used around the world.

This national system is quite different than many other jurisdictions. For one, the US national standards body, ANSI (the American National Standards Institute) does not author any standards. It is an umbrella organization which can adopt existing documents as US National Standards and represents the US in international activities. Also, within our executive branch of government, some regulations and procurement documents are labeled as standards which is not the case elsewhere.

### **Government Standards:**

The National Institute of Standards and Technology (NIST) is the branch of the US National government tasked with overseeing the government use of standards, as well as interacting with industry standardization efforts here in the US. But most government standards are developed in other departments.

The majority of government documents used by industry are generated by the US Department of Defense. At one time, these Mil Specs and Standards were widely adopted here in the US. However, in the mid 1990's many were withdrawn in favor of industry documents. Use now centers on procurement of items used only by the military.

Some government standards can be found within the Code of Federal Regulations (CFR's). An example would be the Federal Motor Vehicle Safety Standards (FMVSS's). They are issued by the National Highway Transportation Safety Administration (NHTSA). They cover all US National regulations for cars, trucks, buses and so on.

Some industry standards are embedded into government regulation. This comes with some challenges. The process for government to adopt an industry standard is cumbersome. It is called incorporation by reference (IBR) and is a lengthy endeavour. This leads to regulations requiring adherence to obsolete industry standards in some cases. So in theory, adoption should be encouraged. But in practice, it is not used as much as industry would prefer.

### **Industry Standards:**

At last count in 1996, Bob Toth writing in NIST special publication 806 estimated that there are more than 700 SDO's in the US. Again, the umbrella organization for these activities is ANSI, the American National Standards Institute. While ANSI does not write standards, it does represent the US standards system in international forums and may at times direct standards activities of other organizations. It also certifies that member SDO's follow good standardization practices. As of this writing (2021), there are 430 SDO's in the "ANSI" federation. An unknown number of additional US standards developers are outside this system.

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Toth divides non-government standards into four broad categories:

### **Scientific and professional**

An example of this is the US Pharmacopeial Convention (USP). Their standards cover drug substances, doses, inactive ingredients, and so on. USP standards have been adopted by the US FDA (Food and Drug Administration), as well as other jurisdictions around the world.

### **Trade associations**

One such organization is AWS, the American Welding Association. It was founded to advance the science and technology of welding. Currently, AWS standards are used both for application and for certification. As with many US SDO's, AWS does represent the US at the international level by participating in IEC (International Electrotechnical Commission) committees.

### **Standards developing organizations**

ASTM International typifies a US SDO with international reach. It produces standards focusing on testing and materials. Membership is predominately US companies, but there is strong international participation as well.

### **Developers of informal standards (consortia)**

Fleeting in nature, these organizations are created to solve a specific issue by the use of a rapidly developed document(s). While originally cropping up in areas with fast changing technologies, now areas of interest have expanded. An example is the Smart Card Alliance, which promotes the widespread acceptance of multiple application smart card technology.

### **US standards authoring**

US Standards are authored by each organization based on its own internal rules. Most rules regarding authoring have procedures for proposing new standards as well as for withdrawing obsolete ones. Should the organization be ANSI accredited, it will have to abide by ANSI's criteria. This includes such things as review of existing standards once every 5 years to confirm validity and so on. Adoption as a US National standard used to be highly regarded. Currently, organizations prefer not to do this so that their value as the authoring organization is highlighted rather than giving credit to ANSI.

### **Procuring US Standards**

For government standards, many can be found within the US CFR's. Each federal executive branch has a specific volume of the code, with its regulations then divided up by chapters and parts. For example, 49 CFR Part 595 is the NHTSA section containing the FMVSS on air bag deactivation.

Some government standards may also be procured directly from the issuing body. The US Department of Defense (DoD) has provided free copies of the Mil Specs and Standards for years, with availability now online at DoD Quicksearch.

For industry standards, each authoring SDO normally has a webstore or other direct channel for purchase of their copyright documents.

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Additionally, third party vendors like IHS Global, Techstreet and Document Center Inc. provide aggregated collections for resale. Occasionally US SDO's will make their standards available at no charge. This is particularly true for standards reference in US regulations which may be available in read only format on the web. But many US SDO's rely on the sale of standards as part or all of their revenue stream to support authoring activities.

Consortia standards on the other hand may require membership in the organization in order to receive copies of any consortia publications. This is in contrast to the availability of most other standards. Only classified government documents and many company standards are similarly restricted.

To learn more about how US Standards ought to be written, organized and numbered, see SES 1:2017, Recommended Practice for Designation and Organization of Standards and SES 2:2011, Model Procedure for the Development of Standards.

## **IFAN Publications**

**Guide 2:2019** Second edition of Guidance for establishing a National Standards Users Group

Guidance for establishing a National Standards Users Group. The brochure includes, inter alia, information on the objectives, membership, benefits of membership, structure, etc. of the National Standards Users' Society. It is designed to facilitate the creation of national standards users' societies.

**Guide 3:2018** Guidelines to assist members of standards committees in preparing user-friendly European standards

Guidelines that provide a checklist which contains requirements for European Standards in order to assist standards committee experts in preparing user-friendly standards.

**Guide 4:2018** Education and Training about Standardization (Updated 2018 and corrected by corrigenda 1)

Different needs for different roles.

**Guide 5:2020** Introduction to the world of European standards for standards users

An introduction for beginners in the standardization department of organizations

All IFAN Guides are free-of-charge and can be downloaded at: [www.ifan.org/ifan-publications](http://www.ifan.org/ifan-publications)