

Get wise to Understanding Standards

An introduction to understanding standards

We all come across items in our daily lives that are regulated by standards, even if we do not know it. Meeting standards leads to increased safety, better compatibility between items, and better practice. In this article, we cover the hierarchy of standards across the world as they benefit us in the UK, and reflect on their importance with particular reference to medical devices, and ultimately the safety of our customers, clients, and patients.

Most of us will have come across the BSI Kitemark™. The BSI Kitemark originated as the British Standards Mark in 1903 for use on tramway rails when standardization reduced the number of rail sizes from 75 to five. Today the BSI Kitemark can be seen on hundreds of products from manhole covers to condoms, from security locks to fire extinguishers and riding helmets.



Having a BSI Kitemark associated with a product or service confirms that it conforms to a particular standard: each BSI Kitemark scheme involves a determination of conformity to the relevant standard or specification of the product and an assessment of the management system operated by the supplier. This symbol is one that is trusted across the UK, and indeed across the world.

So what are these standards that are being referred to?



What is a standard?

A standard is an agreed way of doing something. It could be about making a product, managing a process, delivering a service, or supplying materials – standards can cover a huge range of activities undertaken by organizations and used by their customers.

Standards are the distilled wisdom of people with expertise in their subject matter and who know the needs of the organizations they represent – such as manufacturers, sellers, buyers, customers, trade associations, users, or regulators.

BSI, in its role as the UK National Standards Body, has a portfolio that extends to more than 30,000 current standards. They are designed for voluntary use so it's up to you – you're not forced to follow a set of rules that make life harder for you, you're offered ways to do your work better.

Standards are knowledge. They are powerful tools that can help drive innovation and increase productivity.

They can make organizations more successful and people’s everyday lives easier, safer, and healthier. As a result, standards share good ideas and solutions, technological know-how, and best management practices. They identify safety issues of products and services, and make products compatible so that they fit and work well with each other. An example of the latter are the HDMI or USB ports on your computer.

Who issues these standards?



There is a generally accepted hierarchy of standards, starting with the International Organization for Standardization (ISO*) being adopted worldwide, the European Committee for Standardization (CEN)’s EN standards being adopted across Europe, and national standards being created and adopted by individual countries (e.g. BS standards in Britain, under the auspices of the BSI (British Standards Institute)). Some International standards will have been adopted (and ‘harmonised’) across the EU, and also adopted in, say, the UK, and as a result will have the letters BS, as well as EN and ISO, in front of them. The added bit of fun is that at each level, the adopting body can add its own foreword to make minor alterations to the standard, for their local jurisdiction.

An infographic titled 'We are ISO, the International Organization for Standardization'. It lists several key facts: ISO is an independent, non-governmental organization; it is a global network of national standards bodies with one member per country; its job is to make International Standards; it is coordinated by a Central Secretariat in Geneva, Switzerland; it is not for profit, selling standards to finance development in a neutral environment; and it provides a platform for developing practical tools through common understanding and cooperation with all stakeholders. On the right side, statistics are listed: 164* members, 22500* International Standards, 100 new standards each month, and 249* technical committees. A small note at the bottom right says '* August 2019'.

*Notice that ISO’s acronym doesn’t match ISO’s name? It’s not meant to. “ISO” is derived from the Greek word isos (equal), so that it’s the same in all languages.



Who creates the standards?

Standards are prepared by **Technical Committees** (TCs – e.g. ISO TC173 Assistive Products or CEN TC 293 Assistive Products and Accessibility). Each TC has its own field of operation (scope) within which a work programme of identified standards is developed and executed. TCs work on the basis of national participation by the ISO or CEN Members, where delegates represent their respective national points of view. This principle allows the TCs to take balanced decisions that reflect a wide consensus.

A **Subcommittee** (SC) can be established within a TC, in the case of large programmes of work. The real standards development is undertaken by **Working Groups** (WGs) where experts, nominated and appointed by the ISO or CEN country members, but speaking in a personal capacity, come together and develop a draft that will become the future standard. This reflects an embedded principle of ‘direct participation’ in the standardization activities. The aim of the WGs is to have a balance across potential stakeholders, from commercial providers, public sector, etc, through to end user.

Individual countries opt to be participating members of any committee, or observers (where in this case they do not have a vote), or decide not to participate at all. Each country that participates tends to have its own national ‘mirror’ group, which feeds back each country’s comments and votes to the TCs and thereby the WGs.

The kinds of standards

In addition to 'normative' (i.e. prescriptive) standards, some will be called Technical Reports (TR) or Technical Specifications (TS), and these are informative.

A number of these informative standards become updated to become normative standards, as the material in them has been shown to stand the test of time. In the UK, BSI also produces Publicly Available Specifications (PAS), which, with time, can move onto being BS (British Standard) versions.

Standards go through an iterative process on the road to final acceptance and publication. ISO tends to have more steps than CEN or BSI. The ISO steps are generally as follows, though often the Working Groups get permission to skip a step or two. The earliest stage is when a perceived need for a new standard, or revision of a standard, has been identified, and this goes out to international vote, at which stage it is called a NWIP (New Work Item Proposal).

When approved by a minimum of 5 countries (who also have to put forward experts to work on the project), it becomes an AWI (Approved Work Item).

The document itself it may start as a WD (Working Draft) or as a CD (Committee Draft), which is put out for international comments and vote. The Working Group then works through the comments, and if the

feeling is that these have been addressed, the next stage is a DIS (Draft International Standard – the European equivalent is prEN) (or else it goes back for another round of CD comments and voting).

At the DIS stage any technical concerns should have been addressed, so when this draft goes out for voting, any comments coming back should really be editorial, unless some technical issues had been overlooked. If everyone agrees technically with the DIS, then it can be agreed to go straight to publication (with any editorial corrections addressed), or else it goes for one more round of voting as an FDIS (Final Draft International Standard – the European equivalent is FprEN), after which with majority approval it can be published. The drafts from DIS onwards can be referenced and worked with in the public domain.

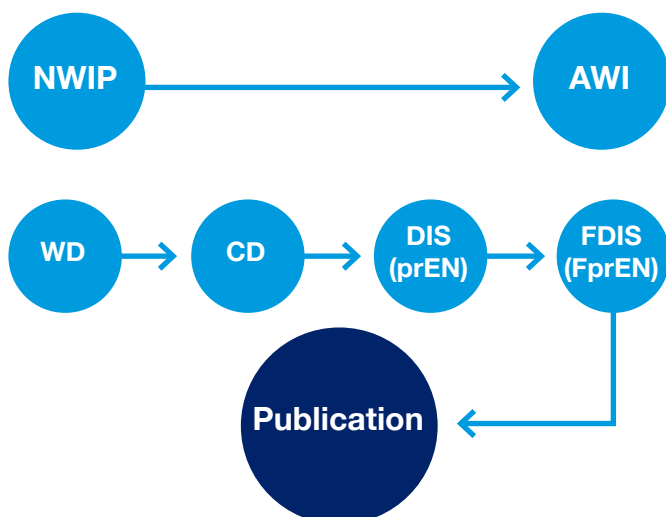
Most standards have to be purchased, and are available through the BSI shop. For the ISO standards, it is possible to download the Introduction, Scope, and Terms and Definitions, for each standard for free from the platform: <https://www.iso.org/obp/ui>

Where and how do standards affect me?

Medical devices are placed on the market with specific clinically-related claims. The manufacturer has to justify these claims, and also show that the product is safe and fit for purpose. Testing to, and passing, recognised standards is part of this process. If the manufacturer claims that their product is a medical device, they have to have it CE/UKCA marked in the EU and Great Britain respectively. The placement of a CE or UKCA mark, and the MD symbol, on the product and its packaging, indicate that the product has been assessed against these criteria, and registered in the relevant market places.

Testing to ISO standards is voluntary, but if a manufacturer chooses to take another route, they need to have strong justifications not to use a recognised published standard. Where a product is sold in the EU or Northern Ireland, and there is a harmonised EN standard, then it is appropriate that the standard be followed.

The journey to a published standard





Outside the regulatory framework above, as a prescriber you are following better practice for client safety and product assurance if you select an item that has been tested to, and passed, one or more of these recognised standards, than if the product is selected on, say, purely price grounds. The price may be slightly higher, but you will have the peace of mind that the manufacturer has picked up the costs of product testing, and thereby that your client is protected.

While some standards cover product testing, others provide guidance to best clinical practice, as well. Over and above the latter standards, there are also other sources of guidelines, such as the BHTA range of Get Wise Leaflets and guidance publications, the Posture and Mobility Group Best Practice Guidelines, and RESNA's position papers, all of which are free to download from these respective organisations.

Get involved

BSI, and the Working Groups, welcome all applications to become a standards maker: you only need to have relevant knowledge and experience, or to represent a relevant group of stakeholders such as BHTA.

Please get in contact with BSI via standardsmakers@bsigroup.com

Standards committees relating to Assistive Technology



ISO
Technical Committee: TC173 Assistive Products*

Sub-committees:

TC173 SC1 Wheelchairs, which has four active Working Groups

- TC173 SC1 WG1 Wheelchair test methods
- TC173 SC1 WG6 Wheelchair transportation
- TC173 SC1 WG10 Wheelchair electrical/electronic safety
- TC173 SC1 WG11 Wheelchair Seating

TC173 SC2 Classification and terminology

TC173 SC3 Aids for Ostomy and Incontinence

TC173 SC7 Assistive products for persons with impaired sensory functions

TC173 also has the following individual Working Groups:

- TC173 WG1 Assistive products for walking
- TC173 WG9 Assistive products for personal hygiene
- TC173 WG10 Assistive products for cognitive disabilities
- TC173 WG11 Assistive products for tissue integrity
- TC173 WG12 General requirements
- TC173 WG13 Hoists for transfer of persons



CEN
Technical committee: TC293 Assistive Products and Accessibility, which has a number of working groups:

- TC293 WG1 Walking aids
- TC293 WG2 Wheelchairs, scooters, microcars
- TC293 WG3 Hoists for the transfer of disabled persons
- TC293 WG4 Adjustable beds
- TC293 WG5 Prostheses and orthoses
- TC293 WG8 Remote control systems
- TC293 WG9 Wheelchairs – revision of EN 12183 and EN 12184
- TC293 WG12 Accessibility
- TC293 WG13 Tactile lettering

Working Groups are disbanded when the standard they have been working on has been published, and they have nothing else currently on their work programme. TC293 Working Groups WG2, WG3, WG4, and WG8 are currently inactive for this reason.



BSI
 CH 173 – ISO TC173 and TC293 Mirror Group
 CH 173/1 – ISO TC173 SC1 and TC293 WG9 Mirror Group

*ISO TC173 has a website from which it is possible to link with some of the TC173 activities, and access documents which are in the public domain: <https://committee.iso.org/home/tc173>

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The BHTA is a trade association with members in healthcare and assistive technology, all of whom commit to the **BHTA Code of Practice, the only one in this industry to be approved by The Chartered Trading Standards Institute. BHTA member companies operate to higher standards of customer protection than the law requires.**



Better health, better care, better value