Let's Get It Clear No.26
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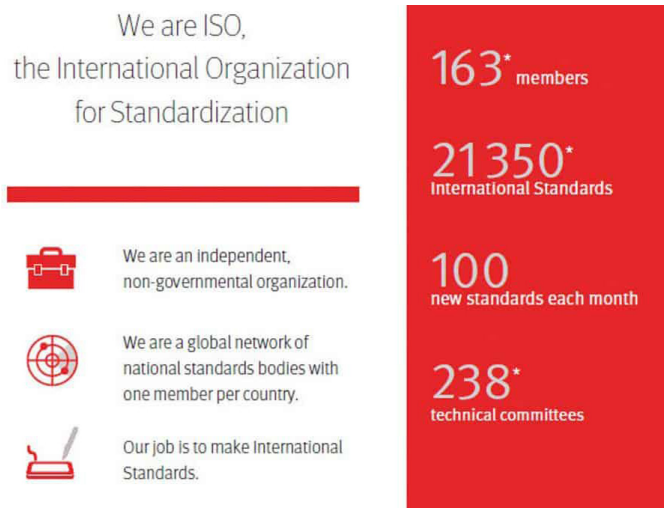
Understanding standards in relation to medical devices

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 a document containing practical information and best practice that has been brought together by a group of experts, and then put out to broader scrutiny and acceptance before final publication (see below).

A standard is often an agreed way of doing something, or providing a unified solution to a broad problem. 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 EN 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.

Who creates the standards?

Standards are prepared by Technical Committees (TCs – e.g. ISO TC173 Assistive Technology or CEN TC 293 Technical Aids for Disabled Persons). 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 (e.g. ISO TC173 SC1 Wheelchairs).

The real standards development is undertaken by Working Groups (WGs) (e.g. ISO TC 173 SC1 WG1 Wheelchair test methods or ISO TC173 WG11 Assistive products for tissue integrity) 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. 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).

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.

The journey to a published standard

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. 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 have used 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 required that the standard be followed.

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 passing product tests, 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[1] 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

References

1. For example, the material in this article, and a bit more, can be found in Get Wise to Understanding Standards, accessible from https://www.bhta.com/get-wise/ where other Get Wise leaflets are also posted