Developers guidance

Understanding technical standards for digital technology in health and social care

This is best practice guidance

Although not legally required, it's an essential activity.

This Guide covers:

- Great Britain (England, Scotland, Wales)

From:

- AI and Digital Regulations Service

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To increase trust and confidence in your digital technology, you should show compliance with technical standards.

The importance of technical standards

Meeting technical standards is an efficient way to demonstrate the reliability and quality of a digital technology. This increases trust and confidence with regulators and adopters.

A standard is a document that provides uniform rules or guidelines for:

- specific technologies or services
- production methods
- management systems processes

Your organisation can produce these formal documents for internal guidance. However, specific standards produced by recognised standards organisations can provide a common set of rules and guidelines across a sector, nationally and internationally.

Standards are developed by panels of experts who work together to find an agreed set of rules or guidelines. Some standards are referenced against specific regulations, such as medical device regulations. These are referred to as designated standards.

Standards are recognised by a:

- prefix that identifies the geographical region it aligns with
- title
- unique number, and
- publication year

It is important to make sure you are following the most recent version of a standard and that it is recognised in the region you operate. For example, the term ISO indicates that the standard has been assessed and recognised by the global harmonisation body International Organization for Standardization.

Examples of these include:

- ISO 13485
- ISO 14971

Designated standards

Following digital technology technical standards is best practice and all standards are voluntary. However, a ‘designated’ standard is recognised by government in part or in full. Designated standards enable developers and service providers to claim ‘presumption of conformity’. Combined with associated evidence, this shows you have met the related legal requirements. Showing compliance with designated standards will help you access the market.

You can meet the legal requirements without following specific standards. However, you would need to provide evidence that your alternative method is robust, appropriate, and not inferior to the standardised approach. And it may be challenging to find an approved body willing to assess a technology against a non-typical set of criteria.

Following general standards

Think about your organisational goals. There are general standards that may be applicable to your company’s ethos and vision. Demonstrating compliance with these standards increases customers’ trust in your organisation. For example:

- quality management
- sustainability
- social responsibility

Following technical standards

Identify the technical standards you wish to comply with at an early stage. This helps you manage your risks and development processes as well as operation of the technology or service. It also allows you to interact with regulators and supporting services early on, to plan the most efficient and safe access to market.

You also need to select standards that are specific to the technology or service you are developing. This could be standards for:

- medical devices
- product quality
- customer satisfaction

- meeting state of the art

Speak to your industry association or national standards organisations to help you identify the most relevant standards. If you plan to develop for the international market, then it will be important to consider international standards. These are developed by organisations such as ISO, IEC, IEEE or other national organisations such as AAMI (US). Usually, these standards have been aligned with national standards.

It is useful to research the standards your competitors are using and that customers prefer, and the reasons why.

Also consider the standards that are used throughout the supply chain to make sure your technology or service is fully compatible for the health sector.

Purchasing a standard

Standards are not open access, so you will need to buy them. The cost should be factored into your budgeting. The cost of not following recognised standards can be greater because of:

- inefficient development
- poor risk management
- poor evidence gathering
- not demonstrating compliance with regulation

Not using the standards can put you at a competitive disadvantage and result in lack of confidence or trust of customers.

Applying a standard

It is worth purchasing accompanying guidance documents to help you apply the selected standards. Engaging with innovation services, our team at the AI and Digital Regulations Service and the regulators will also help you because they can offer expertise and guidance. If a skills gap is identified in your organisation, you can employ consultants to advise on standards.

Changing technical standards

Standards are reviewed every few years and updated versions are published, with amendments or appendices. This is particularly the case in AI because the technology and its use are continually developing. You will see which version is the most recent because it will include the year of the update.

This information is not intended to replace formal statutory guidance regarding legal requirements. For an authoritative view of what regulations require beyond this digest, please see the relevant gov.uk web pages pertaining to the MHRA.

