

4.1.1 Identifying applicable rules and regulations

Practical guidance – healthcare

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Introduction

[BSI's Standards Landscape Report](#) [1] gives a quantitative analysis of current and relevant standards in health software, particularly those that relate to AI and ML. This standards roadmap that will support the safe application of AI and machine learning in healthcare.

The need for the standards landscape

Recent advances mean that AI and ML is now being used for a [whole host of new applications](#), from condition monitoring that enables early intervention, to streamlined drug discovery that cuts time to market and costs. However, the technology also raises issues around patient safety, AI performance, and system security. This is especially true in the health sector where multiple organisations are responsible for regulation.

A safety assurance framework for AI and ML in healthcare will support the industry and healthcare services to meet regulatory and patient safety obligations. Consensus standards will play a central role by setting an agreed specification that should be met and offering examples of best practice and guidance to help organisations meet the requirements.

The [Standards Landscape Report](#) [1] provides a comprehensive overview of the standards landscape in the UK, Europe and internationally. The aim is to make it easy to identify the standards that exist from the perspective of medical device software, health IT and AI/ML. The report is an important step in developing the much-needed safety assurance framework.

How was the report developed?

The report's methodology defined two initial stages.

Stage one established six areas of focus:

- Medical device safety and performance
- Medical device software
- Generic AI
- Medical device/health AI specific
- Generic (non-health) IT
- Health IT

In stage two, BSI research experts conducted keyword searches to find matching and relevant standards to the areas of focus. Results were refined with input from technical experts.

What does the report reveal about the current standards landscape?

The report identified 236 standards that were relevant to the area of focus. Most standards were in IT (103 out of 236), 68 related to generic (non-health IT), 26 to generic AI, 21 to

medical device software, 18 to medical device safety and performance and zero related to medical device/health specific to AI (however, there is one BSI standard being developed in this area).

Unsurprisingly, the number of standards in development has increased over the past five years, with 25% of the identified standards published in 2020 alone.

The UK's standards catalogue contains 128 standards relevant to AI and ML in healthcare. Of these, 125 were developed by international standards development organisations (SDOs) and the remaining three were developed by BSI. All have been adopted by the UK through BSI.

What new standards can we expect to see in the future?

Over 50% of current standards were developed by international SDOs. Committees within ISO, IEC, CEN, CENELEC and ETSI (along with their BSI shadow committee equivalents) all have a significant number of standards in development. These will be essential for meeting regulatory and patient safety obligations as the application of AI and ML in healthcare continues to accelerate.

ISO technical committees have 48 standards on health informatics in development; elsewhere an IEC subcommittee is currently developing a further 33 standards on electromedical equipment.

The first standard related to the search 'Medical Device/Health specific to AI' is currently being developed by BSI: AAMI 34971. The report also lists private standards such as those developed by the Data Alliance Partnership Board – NHS Digital, which fall outside the formal standards landscape but may be relevant.

References

[1] BSI, SAFR - AI and Machine Learning in the healthcare domain Standards Landscape Report, June 2021, available at:

<https://infogram.com/1pdzwwn950np1vbm6z0k93n6xakmy3y16y?live>