Hardian Health

Innovate UK

Health Innovation Network South London

Module 5: What standards apply to medical devices?

Outline

This talk will cover:

- What are ISO (International Standards Organisation) and IEC (International Electrotechnical Commission) standards?
- Why do medical devices and healthcare software need ISO and IEC standards?
- What ISO and IEC standards do software and AI medical devices need to follow?
- Where can you find ISO and IEC standards?

What are ISO and IEC standards?

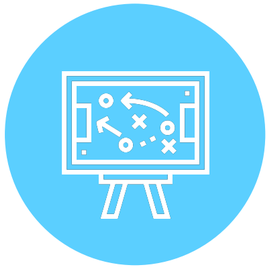
ISO and IEC standards are designed to help businesses ensure that their products and services meet a certain level of quality, safety, and effectiveness.

Normative	Informative
• Requirements that an organisation must meet in order to achieve certification or compliance with the standard. • They are mandatory. • Use the terms “shall”, “should”, or “may” to indicate the level of requirement.	• Guidance on how to meet the requirements of the standard. • They are not mandatory and are intended to help organisations understand the concepts and principles underlying the standard. • Informative elements may include examples, best practices, and case studies.

Why do medical devices need ISO and IEC standards?

Consistency

Quality



Commitment

Continuous improvement

Transparency

ISO 13485:2016: Medical Devices - Quality Management Systems - Requirements For Regulatory Purposes

A company-level structured system of procedures and processes covering all aspects of Design, Manufacturing, Supply, Risk Management, Management Responsibility, Customer Related Processes and CAPAs.

A QMS is legally required for all medical device software and IVD manufacturers in the EU and the US and a QMS should **be built, not bought.**

ISO 13485 typically requires formal audit and certification that must be maintained.

ISO 14155:2020: Clinical Investigation Of Medical Devices For Human Subjects - Good Clinical Practice

ISO 14155 describes good clinical practice for the design, conduct, recording and reporting of clinical investigations carried out in human subjects to assess the clinical performance or effectiveness and safety of medical devices.

ISO 14155 aims to:

- Protect the rights, safety and well-being of human subjects,
- Ensure the scientific conduct of the clinical investigation and the credibility of the clinical investigation results,
- Define the responsibilities of the sponsor and principal investigator, and
- assist sponsors, investigators, ethics committees, regulatory authorities and other bodies involved in the conformity assessment of medical devices.

ISO 14971:2019: Application of risk management to medical devices

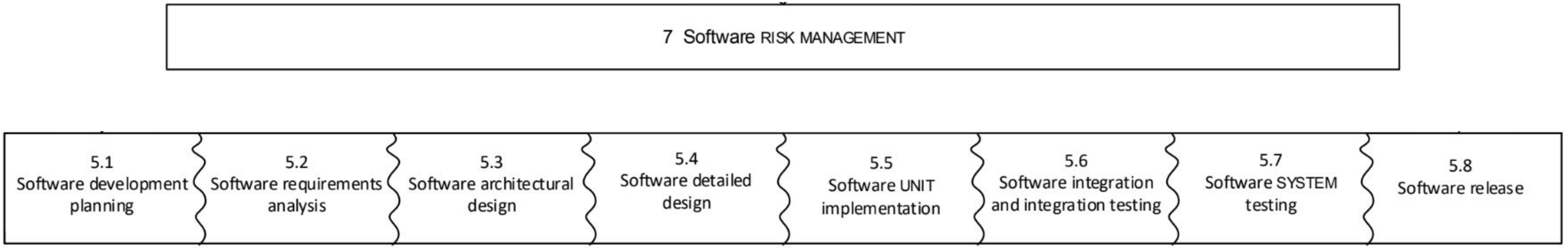
ISO 14971 details how to classify the risk of medical devices, consider the potential harm resulting from foreseeable events when a patient or user interacts with a medical device and how to mitigate these risks.

It also takes into account the hazards that arise from this situation and how they can impact the safety of the device. ISO 14971 provides guidance on managing the risks associated with medical devices to ensure their safe and effective use.

ISO 14971 does not require formal audit and certification, but is a key standard for medical device manufacturers.

IEC 62304:2006+A1:2015: Medical Device Software - Software Life Cycle Processes

IEC 62304 ensures that there are ways to verify and test each part of the software to make sure it will integrate properly into existing systems.



IEC 82304-1:2016 and ISO/TS 82304-2:2021 - Health software

- IEC 82304-1 is applicable to health apps, which are a special form of health software. It covers the entire lifecycle including design, development, validation, installation, maintenance, and disposal of health software products.

- ISO/TS 82304-2 can be used voluntarily by developers of mobile health and wellness apps, including Software as a Medical Device (SaMD), as a useful checklist of compliance against the various key indicators of app quality.

- Currently there is no formal accreditation scheme in existence for ISO/TS 82304-2, however this may change in the future.

ISO/IEC 27001:2022 Information Security, Cybersecurity And Privacy Protection - Information Security Management Systems

ISO/IEC 27001 is the most common standard for information security management systems (ISMS). It defines requirements an ISMS must meet.

An ISMS implemented according to this standard is a tool for companies to provide risk management, cyber-resilience and operational excellence. However, just because you comply with this standard doesn't mean you're done and dusted. Healthcare systems like the NHS, have their own information security standards that you need to conform to, as well as GDPR.

ISO 27001 requires formal audit and certification that must be maintained.

IEC 62366-1:2015: Medical Devices - Part 1: Application Of Usability Engineering To Medical Devices

IEC 62366 (British version: BS EN 62366) outlines the best practices for building safe and usable medical devices (including software). The focus of IEC 62366 is on minimizing risk from lack of usability.

The usability engineering process found in IEC 62366 consists of a series of steps to ensure that the UI of a medical device has been rigorously evaluated for user and patient safety, including:

- Define intended users, use environments, and user interface,
- Identify use-related hazards,
- Identify and categorise critical tasks,
- Develop and implement risk mitigation/control measures,
- Validate user safety and effectiveness,
- Document your evaluation process.

Where can I find these standards?

British Standards Institution

https://knowledge.bsigroup.com/

What you must not do:

- Don’t distribute standards online,
- Don’t reproduce or otherwise share standards,
- Don’t translate or modify standards in any way,
- Don’t sell standards without authorization,
- Don’t use someone else’s copy - you must buy your own. Auditors will check!

Summary

Key points discussed

a. Medical device standards promote consistency, quality, transparency and accountability within product development and medical devices,
b. Standards such as ISO 13485:2016 are mandatory for medical device approvals,
c. Several of the key medical device standards require formal auditing and certification,
d. Standards must be purchased, and licensed to the manufacturer.

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