



ISO 7101:2023 as a Valuable tool for Healthcare Organisations

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Opportunities and
Advantages of
Implementation

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Quality Management Standards for Healthcare Organisations

EN ISO 9001 Quality management systems. Requirements

EN15224 Health care services - Quality management systems
- Requirements based on EN ISO 9001:2015

ISO 7101 Management systems for quality in healthcare
organizations – Requirements

Accreditation standards for hospitals and other healthcare
providers by independent organisations (ISQua)

ISO 9001 Quality management systems. Requirements (Currently under review)

- ▶ Benefits:
 - ▶ Widely known standard across the world
 - ▶ A mark of quality
 - ▶ Often required for contracts
 - ▶ Required in the UK for Radiotherapy Services
 - ▶ Can be applied in any type of organisation

ISO 9001 Quality management systems. Requirements (Currently under review)

- ▶ Downside:
 - ▶ Difficult to understand in the healthcare context
 - ▶ Very generic
 - ▶ Not meaningful to healthcare professionals
 - ▶ Have to interpret the clauses in order to improve quality
 - ▶ Reliant on auditors to have an in depth understanding and competence to audit correctly
 - ▶ Often thought to be a ‘paper exercise’ all about ‘documentation’

EN15224 Health care services - Quality management systems - Requirements based on EN ISO 9001:2015



A multi-national working party CEN TC362 was set up



The initial draft before publication was healthcare focussed



The first publication in 2012 was edited to meet the rules for ISO Harmonized structure of standards (can't add many requirements)



The 2012 edition included an annex which gave more detail, but this was not included in the later version published 2016



The main benefit was that it included additional clauses and notes related to healthcare but still generic

Some examples showing additions in EN15224

5 Leadership

5.1 Leadership and commitment

5.1.1 General

d) promoting the use of the process approach and risk-based thinking; *i.e. ensuring that clinical risk management is an integrated part of the quality management system;*

8 Operation

8.3 Design and development of products and services

8.3.2 Design and development planning

- ▶ In determining the stages and controls for design and development, the organization shall consider:
- ▶ *c) approaches for risk assessment in each stage of the clinical processes;*


EN15224

- ▶ Not widely used
- ▶ Few countries implemented it
- ▶ Unsure if it will be updated
- ▶ Still very generic and still requires interpretation



Why is ISO 7101 different

Clause 8 Operation

- ▶ Contingency planning
 - ▶ Waste management (waste management plan required for all types of waste)
 - ▶ Environmental responsibility
 - ▶ Emerging technologies and AI
 - ▶ People-centred care
 - Service user experience
 - Compassionate care
 - Inclusivity and diversity
 - Health literacy
 - Co-production
 - Workforce wellbeing
 - ▶ Ethics
 - ▶ Patient safety
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Opportunities and advantages with ISO 7101

- ▶ Less requirement needed for interpretation
 - ▶ Will need some interpretation based on the type of care delivered
 - ▶ Less guessing on what is needed
 - ▶ More specificity on documents
 - ▶ Clearer requirements for departments and services
- ▶ Links to current issues such as climate change, workforce burn out and AI
 - ▶ Having these areas in the standards ensures they are considered
- ▶ Requires organisations to look at national and international health indicators - makes you measure your performance
- ▶ Requires review of patient safety, risk mitigation etc

Advantages

- ▶ Written in consultation with healthcare and quality professionals
- ▶ Does not contain any clauses or requirements that healthcare organisations should not be doing or working towards
- ▶ Will be assessed by professionals who have the competence and understanding of how healthcare is delivered in the local context

Challenges

However, it will take:

- ▶ Commitment
- ▶ Time and effort
- ▶ Resources
- ▶ Importance of leadership
- ▶ It will take time and need to be planned
- ▶ Project team - not just one person's job

Why implement ISO 7101

- ▶ Shows that the organisation is committed to quality improvement
- ▶ May give confidence to those who can choose where to be treated
- ▶ For those who offer health tourism a recognised quality mark
- ▶ May link to insurance
- ▶ Potential cost savings through waste reduction from improved processes
- ▶ In a world where litigation is growing having a quality system will help with internal investigations

Finally



AS HEALTHCARE PROVIDERS WE
OWE IT TO OUR PATIENTS AND
STAFF TO PROVIDE THE BEST
AND SAFEST CARE POSSIBLE



IMPLEMENTING A SET OF
STANDARDS TO IMPROVE
QUALITY CAN ONLY BE A GOOD
THING

Thank you

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