David Ricketts
Consultancy Limited

Applying ISO standards to improve quality

Part 1 – what are ISO standards

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Consultancy Limited

Learning outcomes

Understand the background to ISO standards

Understand what we are trying to achieve

Understand the purpose behind the design of ISO standards

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Consultancy Limited

ISO is very process driven

It is an international standard therefore must be written for a wide community and in easy terms, we cannot just think first world service delivery

It will be translated into French as well as English

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Who writes the standards

The standards are written by the international community

There are two classes of member, P and O

P members are participating members who have a vote, whilst O members have observer status

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The options for standard writing

ISO has two types of standard it is used to delivering

Management system standards (MSS)

Conformity assessment

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Management system standards (MSS)

If this standard is deemed to be developing a Quality Management system requirement then it needs to comply with 6.8.2 of the ISO/IEC Directives, Part 2

As with all MSS, it must follow the rules outlined in Annex SL of the Dir Pt 1 + Supplement notably, in the first instance, a justification study must be submitted to the TMB MSS Task Force

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Stages of an MSS

Project stage
Associated document
Name Abbreviation
Preliminary stage Preliminary work item PWI
Proposal stage New work item proposal a NP
Preparatory stage Working draft(s) a WD
Committee stage Committee draft(s) a CD
Enquiry stage Enquiry draft b ISO/DIS
IEC/CDV
Approval stage final draft International Standard c FDIS
Publication stage International Standard ISO, IEC or
ISO/IEC

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6.8.2 what is it

This links any MSS to ISO9001

Any terms and definitions for a QMS must be taken verbatim from ISO9000 or be referenced

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Conformity assessment

QMS standards are not suitable to be used for technical competence to be assessed

These documents are conformity assessment documents

ISO15189 sits in between both documents

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Words

- Requirements: Shall, shall not
- Recommendations: Should, should not
- Permission: may, need not
- Possibility and capability: can, cannot

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Normative reference

- These are documents which are indispensable for the application of the standards

- ISO9001 is normative to ISO17025
- ISO17025 is normative to ISO15189
- ISO15189 is normative to ISO22870

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ISO standards purpose

They are designed as a framework that can be used to develop local systems and processes

They tell you what the outcome should look like, not how to get there

They are not designed to be used as an accreditation tool, but can be used for that purpose

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Scope

The scope of the document is key for understanding the purpose of what is intended

When writing a document, it cannot proceed until the scope is written, agreed and voted on

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How do we write the standards

Each standard requires a project lead who facilitates the process

They write the first draft

A team of volunteers from the working group then input into the draft

This then goes to the whole working group

Agreement is based on the lack of sustained objection

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POCT accreditation

It is possible to accredit POCT to ISO15189(2012)

ISO22870 has been remapped to the new ISO15189(2012) standard and this is due for release imminently

It is for the applicant to define what is and what is not in scope

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POCT and quality

The purpose of ISO22870 is to provide guidance to what you should look to put in place for a POCT service

It looks to expand on the requirements for ISO15189(2012) and make them more specific for the POCT service

David Ricketts
Consultancy Limited

Thank you