ISO22870 – Requirements for Quality and Competence

WEQAS Annual Conference

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Learning outcomes

Understand the background to ISO standards

Understand what we are trying to achieve

Understand quality and quality management concepts

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POCT and ISO standards

ISO 15189 (2012) was released and was a significant change from the 2007 version

ISO 22870 was an annex of the old ISO 15189.

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Background

Initially it was felt that the new version of ISO22870 should be a stand alone standard

There is a recognised need to try and improve quality in delivering POCT

There are two distinct challenges globally to good quality POCT, the service that fall under direct laboratory control and those unable or unwilling to engage with local laboratory services

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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 and Russian as well as English

This requires the standard writers to understand local sensitivity in terms of both language used and local regulation

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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

This becomes relevant when looking at new versions as a change in style of a normative reference will influence the writing of a new standard. ISO17025 is currently undergoing a major overhaul

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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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Words- requirement

Shall :	is to
	is required to
	it is required that
	has to
	only … is permitted
	it is necessary
	needs to

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Requirement

Shall not:	is not allowed [permitted] [acceptable] [permissible]
	is required to be not
	is required that … be not
	is not to be
	need not
	do not

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Recommendation

Should:	it is recommended that
	ought to
Should not	it is not recommended that
	ought not to

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The politics

ISO has two types of standard it is used to delivering:

Management system standards (MSS)

Conformity assessment

This has been a long source of debate which has finally been resolved

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Why ISO22870(2016)

ISO22870(2006) was a companion document to ISO15189(2003)

When ISO15189(2003) was revised in 2007 there was minimal change

ISO15189(2012) had significant change in terms of both scope and content

The POCT document extensively cross referenced to the 2003 and then the 2007 versions of ISO15189, these were no longer valid with ISO15189(2012)

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Revision of ISO22870

Initially a stand alone standard was developed

This was not without issue as it attempted to cover both laboratory supported POCT and non laboratory supported POCT

This was also a hybrid of MSS and CA

This ran into issues with the international community as well as the standards central secretariat

A compromise of a remapping to the new ISO15189(2012) was reached and a separate work stream was started for ISO/NP/TS22583 for non laboratory supported POCT

Scope of ISO22870(2016)

This remains identical to the old ISO22870(2006)

The standard requires it to be used in conjunction with ISO15189(2012)

It applies to hospitals, clinics and healthcare organisations providing ambulatory care

It applies to transcutaneous measurements, the analysis of expired air and in vivo monitoring of physiological parameters

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Management of POCT

4.1.1 b)

The need to establish processes and documents, and provide resources specific to POCT

An ISO standard does not tell you how to do something but what is expected

Proper resourcing of POCT support is one of the main challenges to quality

Almost all of the results are generated by non laboratory staff and usually do not appear in any laboratory KPI, therefore is seen as an overhead

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POCT and the core laboratory

Good POCT has a significant impact on both the patient pathway and how the core laboratory operates

I have yet to met a POCT department who feels they have adequate manpower and are often seen as an overhead, yet the impact on the patient pathway is significant

ISO22870(2106) being an annex of ISO15189(2012) suggests we already have the systems in place to support this along with the necessary skills

The temptation is to divorce the two and run parallel systems, competing for resource

POCT manager

This title suggests the POCT expert has managerial control over the users of the service, such as direct accountability for the area in which POCT is performed

This role requires diplomacy as a required skill as well as technical competence and a good understanding of both the clinical and scientific challenges of delivering high quality POCT

This is often akin to herding cats, whilst maintaining quality

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Multidisciplinary group

The standard requires a management group which is multidisciplinary, to take responsibility for the service

The challenge is to get good engagement from the users and the senior management of the organisation, for something they assume gives the correct result

The standard also requires staff are free from undue pressures to prevent them from doing their work, I would argue insufficient resources would count as an undue pressure

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Appoint a quality manager

4.2.2.1 g)

Appoint a person with appropriate training and experience, as a quality manager responsible for POCT quality, etc

With the systems in place to cover ISO15189(2012) do not reinvent the wheel but share resource and even look at shared documentation

UKAS is a good place to look for advice with this

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Identification and control of nonconformities

4.3 and 4.9.4 which asks for data analysis

When setting up systems is there a good mechanism for capturing data?

Manual systems are incredible labour intensive and hard to maintain

When you are procuring systems make sure you allow for data capture in your POCT solution

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Review of benefits

4.12.2 this is a key driver in the decision to maintain a POCT service

This is a good opportunity to link this to the patient pathway and access the value of POCT

This is not an exercise in the ability to audit

POCT needs to add value to the patient pathway to be effective

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Technical requirements

5.1.1 The organisation shall determine and provide human resources needed to:

a) Implement and maintain the POCT quality management system and continually improve its effectiveness

Note this is a shall statement

This continuous improvement ideally should be defined in terms of patient outcomes rather than in terms of better paperwork

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5.1.1 b)

This sub clause is to ensure that the training is provided to personnel performing POCT from all services, programmes and departments

This can be a challenge with areas not under the management of the laboratory

This is best included in any contract with POCT IVD suppliers as the key word is ensure, not do

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5.1.1 c)

This sub clause is to enhance healthcare provider/ patient / client satisfaction by meeting customer requirements

Getting feedback from patients is key for this standard to positively impact pathways. The temptation is to survey the ‘users’

Be imaginative with the questions asked, a good survey can include a confounding question to ensure some thought has gone into the answers

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15189

We have hit the review period

There is a thought that adding POCT to the text of the next version should be looked at!!

What do you think, this is your chance to input your views

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Thank you

Questions?

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