



# Applying ISO standards to improve quality

Part 2 – improving quality



# Learning outcomes

Understand how to use these standards to improve quality

Understand what to put in scope

Understand how to develop your QMS



# ISO15189(2012) and ISO22870

ISO15189(2012) details the requirements for quality and competence in the medical laboratory

ISO22870 details the requirements for quality and competence in POCT

You cannot use ISO22870 without understanding ISO15189(2012)



# The scope

ISO22870 states in its scope it is to be used with ISO15189

It is designed to support POCT carried out in hospital, clinics and by healthcare organisations providing ambulatory care

Patient self testing is excluded



# Supporting quality

The document guides you through the requirements the international experts have deemed as essential to develop a safe high quality service

The document should be viewed as a road map



# Organization and management

These have shall statements, i.e. compulsory

There needs to be a planned service with appropriate documentation

It covers Record keeping, validation, verification, selection of equipment

There is a requirement for someone to be responsible and accountable



# Involve others

There is a requirement for a POCT committee to ensure the users of the service are involved in the governance of POCT and take ownership of the testing they help to deliver



# Quality management

- There is a requirement for a quality policy and quality objectives to be set which meet the needs of the users
- There must be a quality management system designed with a quality manual describing this
- This requirement of the standard is to encourage the service to understand what it is for and how it is to achieve its objectives





# Using the standard to support quality

The standard, when used in conjunction with ISO15189, is detailed in the type and breath of documentation you should look to produce to evidence the quality of the service you provide

It also advises on how you control these documents to ensure you have a system to identity that current documentation is in place



# Complaints and non conformance

These are viewed as opportunities to improve the service therefore careful documentation and understanding of them is part of the standard

In order for these to be effective in improving quality it is important to carry out a full root cause analysis





# Corrective action

Following a complaint is it important to document and implement corrective action

The standard requires you to fix problems and learn from them

As well as corrective actions there should be preventative action to stop error occurring in the first place



# Continued improvement

This can be monitored by auditing the service and carrying improvements based on the outcomes

Setting key performance indicators also helps to monitor performance and improve on the quality

Collect staff ideas and input and use this to improve the service



# AMR

The Annual Management Review is a document designed to get you to reflect on the previous year and see if you met your targets and plan ahead for the next year. It should set the scene for your service and allow those who are interested to understand what you are achieving and how you intend to develop.



# Personnel

This never tells you how many staff to have but helps to develop fit for purpose training, job descriptions, competence, development and record keeping

This training is not just equipment related but there needs to be an understanding of the concept of quality management for all staff involved in POCT



# Accommodation and environment

This part of the standard covers storage of reagents, the temperature of this storage as well as the area in which the sample is collected

There needs to be good working conditions

This links into national and local legislation



# Equipment

There is detail on traceability of the equipment

Recording of calibration and controls as well as what to do when the equipment fails





# Pre examination

The standard provides information on pre examination consideration

This includes patient information and information for those doing the POCT



# Post examination

How do you report the results

What to do with a critical abnormal

When to ask for help

How do you ensure the right people get to see the result  
you have produced



Thank you