

Point-of-Care testing and ISO 15189 – What’s the “point”?

Daniel Boyland

Senior Training Manager – UKAS Academy

WEQAS Conference 2023



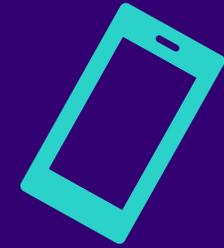
What's in this whistlestop tour?

- + Why is there a Standard?
- + What is POCT (officially)?
- + Change in POCT for 15189
- + Supporting documents
- + Applying for POCT accreditation
- + What does this all mean!?
- + Ongoing support.



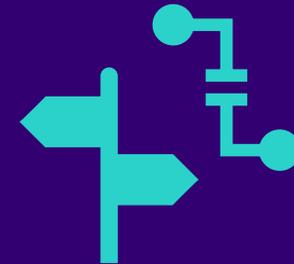
Have your mobiles ready

- + That way you can join in
- + Also, you can take images, and share on “the socials”
 - + And if I’m boring, you can check out with impunity 😊
- + **Take these questions back...**



Why is there a POCT Standard?

- + “Proximity” risk
- + Inconsistency and for ISO 15189
- + Recent impacts?



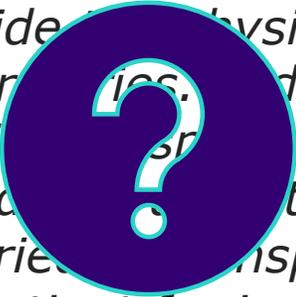
Why is there a POCT Standard?

“The latest revision of ISO15189 published in 2022 brings POCT into this widely adopted standard and it is expected that laboratory services will extend their accreditation to include POCT as ISO 22870 is withdrawn.”

Point of Care Testing – National Strategic Guidance for at
Point of Need Testing

Is POCT well defined?

..analytical patient testing activities provided within the institution (responsibility of the accredited entity) but performed outside the physical facilities of the clinical laboratories. It does not require permanent dedicated space but instead includes kits and reagents, which are either hand-carried or transported to the vicinity of the patient for immediate testing at that site...



- + Background – College of American Pathologist (CAP)

- + Definition in ISO 15189:2022

3.22

Point-of-care testing

POCT

Examination performed near or at the site of a patient...

- + Source: ISO 22583

BUT...is it understood?

Main changes of 15189– Big hitters or Soft impacts, that’s up to you

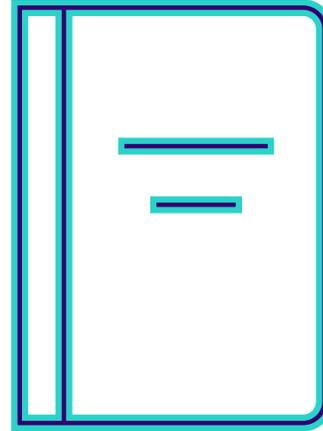
- + The alignment to other ISO Standards (17025)
- + Incorporation of ISO 22870
- + Out-of-date

- + The importance of Risk **management...**
- + The emphasis on **patient care**
- + Less “**prescriptive**” – More **risk-based**

- + **It’s up to you how you design and apply the framework – So treat everyone like they don’t know ANYTHING!**

“Folded” into ISO 15189

- + POCT is now an integral part of ISO15189.
- + Explicit clauses...
 - + Service agreements between the laboratory and other parts of the organization using laboratory supported POCT, shall ensure that respective responsibilities and authorities are specified and communicated. [6.7.2]
- + Implicit references...
 - + All personnel of the laboratory, either internal or external, that could influence the laboratory activities shall act impartially, ethically, be competent and work in accordance with the laboratory’s management system. [6.2.1]
- + AND Annex A which is specific to POCT
 - + And other documents that I’ll refer to shortly



ISO/TS 22583:2019

Guidance for supervisors and operators of point-of-care testing (POCT) devices

- + Despite its concise title, this is not a “full” standard but a technical specification
- + What does that mean?
 - + Support
 - + Guidance
 - + Signposting
- + Key components and considerations of the risk in delivering POCT particularly where there may be standalone provision of these services
- + It aims to make it applicable and relevant to those responsible for POCT

Other “Companion” documents

Written by the same peer groups

- + Risk Management – ISO 22367
- + Measurement (Un)certainty – 20914
- + Safety – 15190
- + Support Only – Not assessed!
- + (Sadly) UKAS doesn't own or control these
...or get royalties



A person in a dark suit and light blue shirt is sitting at a wooden desk, reading a large document. The document is open, and the person's hands are visible, holding the pages. A large, solid purple rectangle is overlaid on the left side of the image, partially covering the document. The text "Annex A" is written in white, sans-serif font on this purple rectangle. The background is slightly blurred, showing the person's torso and the desk surface.

Annex A

Annex A – Overview

+ General [A.1]

- + ...additional requirements for the laboratory for POCT that are **distinct**.
- + Specify responsibilities for devices, training, quality, and management review.

+ Governance [A.2]

- + Ultimate responsibility (**Who**) for accuracy and quality?
- + Agreements and their approval.
 - + Shall be communicated...

+ Quality Assurance Programme [A.3]

- + shall have appropriate **training and experience** to be responsible for POCT quality.
- + ...which includes a review of and conformity with the requirements of ISO 15189 for POCT.

+ Training Programme [A.4]

- + shall have appropriate **training and experience** shall be appointed to manage training and competency...
- + The “trainer” shall **develop, implement, and maintain** a...training programme for all POCT personnel.



Applying → Assessment planning

- + New or Existing – required for impartiality and objective review
- + Assigned an Assessment Manager who will:
 - + Engage to understand what the requirements are – does anything need more detail?
 - + Not offer answers, but will offer support, signposting and context
- + The scope of what you apply for is up to you.
 - + May want to start small, perhaps one group of devices/tests or one “area”
- + **Apply when you intend to become accredited not when ready!**
 - + But you don't have to “do it all”





Hints and tips for building a framework and applying

A world of confidence

Framework considerations

- + Legal Entity
- + Director
 - + Clinical input, advice, involvement
- + What do you “provide”?
 - + Risk
 - + How do you “provide”?
 - + LIMS and IMS
- + Quality
- + Can you “provide” alone
 - + ...UKAS/International publications

Who is legally accountable?

Is this defined and documented?

Who is responsible? What do they do (and delegate)?
DO THEY KNOW?

What do you do and how do you do it? **WHY** do you do it?

Are agreements required to provide these services?

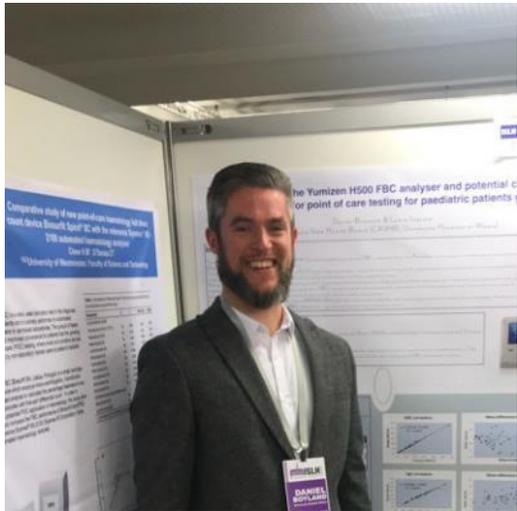
“That’s lovely Dan, but so what?!”

- + POCT is on the agenda
 - + National expectations from all stakeholders are developing
- + 15189:2022 is the minimum framework recognised to deliver POCT services
 - + SHOULD be more accessible
- + There are sources to support this framework
- + How you apply the framework is less prescriptive BUT...
 - + **Define it**
 - + **Document it**
 - + **Do it**





Support Signposting Self-direction



- + UKAS Training Academy
 - + Trainer-led courses
 - + Self-directed eLearning
- + Contacting UKAS
 - + Applications sales@ukas.com
 - + Training training@ukas.com
- + The various references (including a bundle discount – you are welcome to share that)
- + Linking to us via social media – That’s me
- + **And Finally, what can UKAS do?**



Thanks and Any Questions

