UKAS
A world of confidence

ISO 15189:2022 – Transition Update

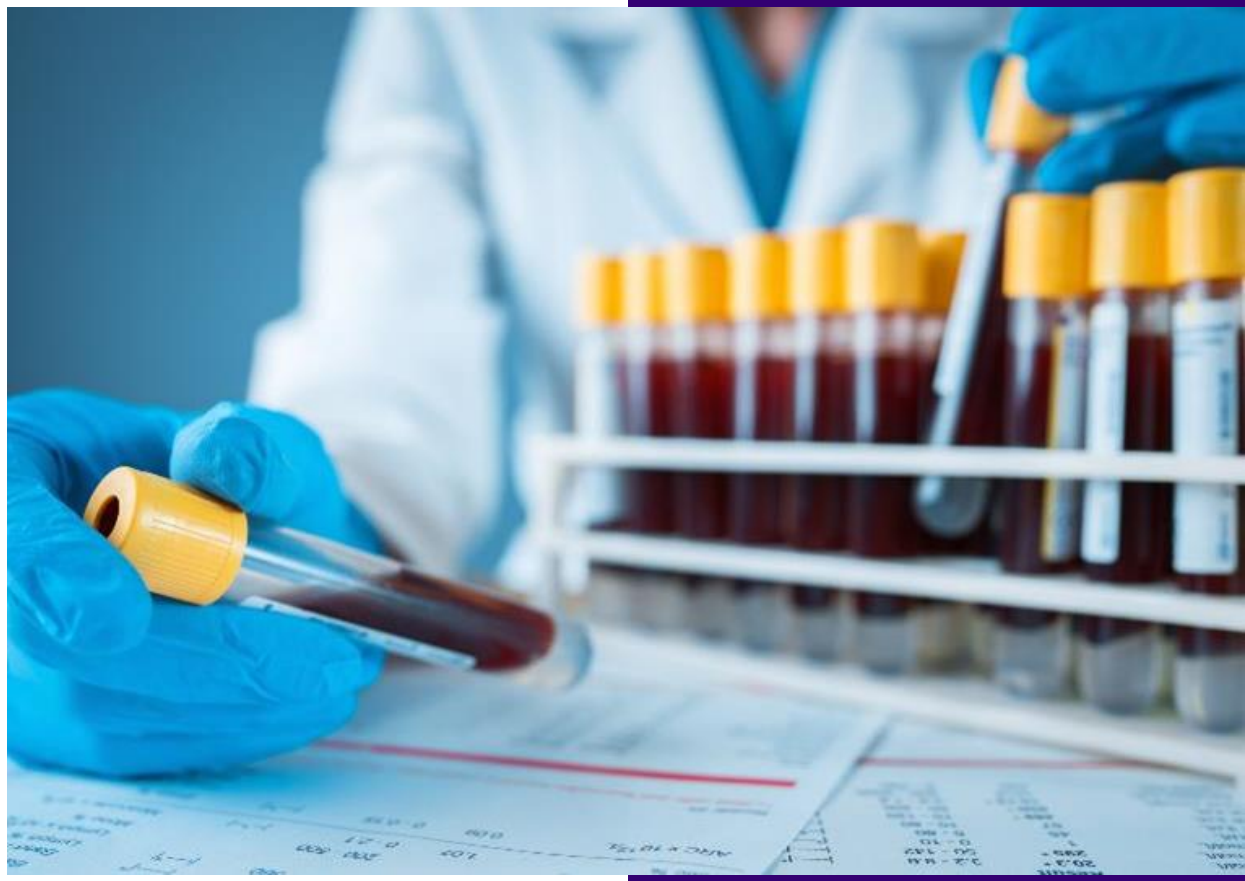
Joint UK NEQAS BTLP and BBTS Blood Bank Technology SIG Annual Meeting

– November 2024

John Ringrow – Senior Assessment Manager, Healthcare

Agenda

- ISO 15189:2022 background, UKAS process and transition progress
- Gap analysis
- Trends from transition assessments
- Take home messages so far…



ISO 15189:2022 Transition: background

- Hopefully everyone is aware of this, but just in case:

  - ISO 15189 has been revised and was republished in December 2022.
  - Revision process was led by ISO committee TC 212
  - UK input to the revision was both by direct membership of ISO TC 212 and via the UK BSI mirror committee
  - Major changes relate to bigger focus on clinical risk and patient impact, plus the inclusion of POCT
  - Publication of ISO 15189:2022 kicked off a 3-year worldwide transition process, managed in the UK by UKAS
  - UKAS has developed a Transition project:
    - Year 1 (2023): UKAS gap analysis. Assessor training. Customer education and awareness, in collaboration with professional bodies
    - Year 2 (2024): Transition assessments
    - Year 3 (2025): Grant of any remaining transitions, completion of admin work, buffer zone for any labs needing as second transition assessment.

ISO 15189 key changes summary

- **Patient Focused**

  "The objective of this document is to *promote the welfare of patients* and satisfaction of laboratory users through confidence in the quality and competence of medical laboratories."

- **Risk based**

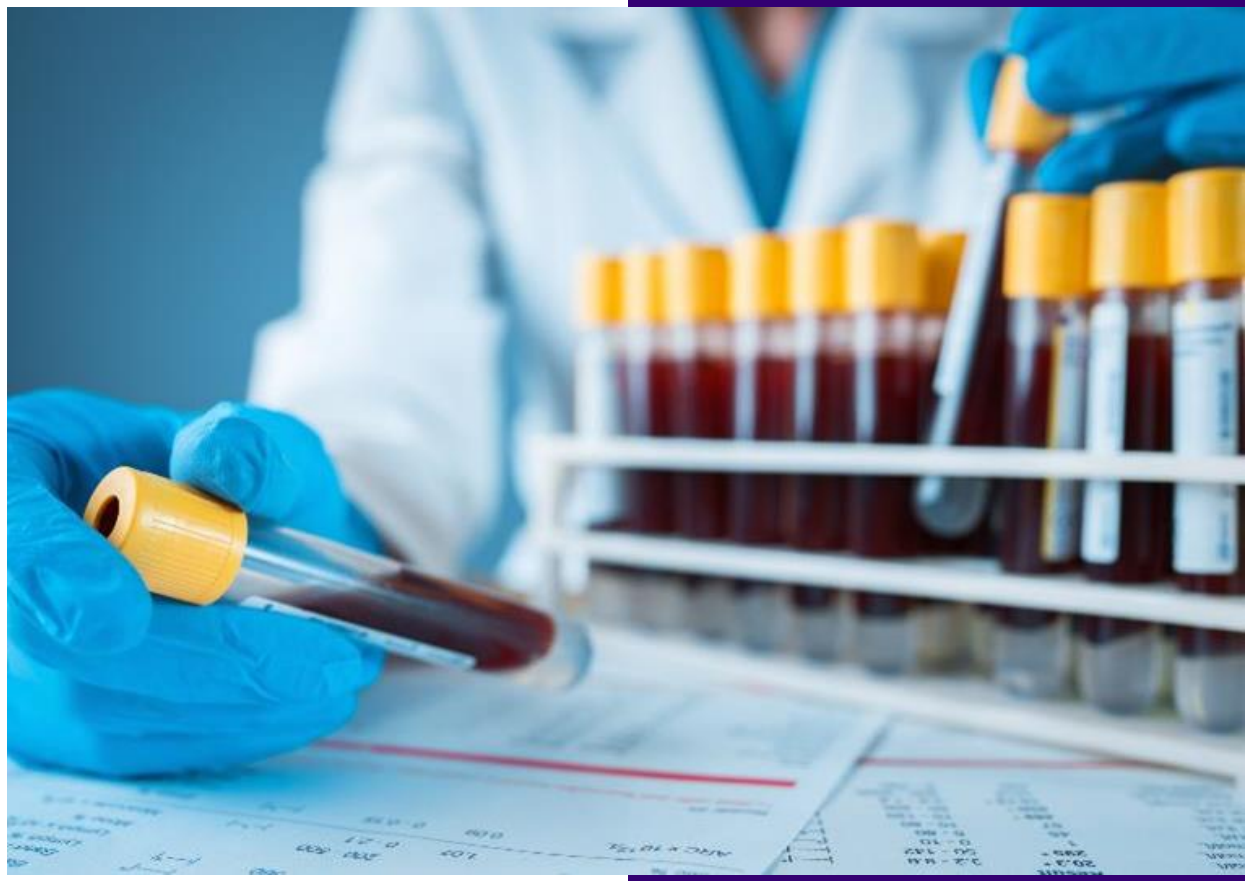
  ISO 22367:2020 Medical Laboratories - Application of risk management to medical laboratories

  ISO 35001:2019 - Biorisk management for laboratories and other related organisations

- **ISO 22870 (PoCT), is incorporated into ISO 15189**

Metrics of the Transition

- Approx 700 Laboratories to transition
- Approx 170 assessors and decision makers have been trained and authorised (Healthcare staff & Technical Assessors)
- 36 Months to complete it all



ULTIMATE DEADLINE

6th December 2025

(3 years transition period ends)

After this date, accreditation to

ISO 15189:2012 and ISO 22870:2016

will cease to be valid

ISO 15189:2022 Transition: process summary

- Hopefully everyone is aware of this, but just in case:
  - Follow the process as detailed in the UKAS technical bulletins sent to all labs and published on the UKAS website
  - Labs complete gap analysis (more later!) and submit it to UKAS
  - UKAS assesses the gap analysis, and follows-up queries on site
  - Findings are raised, findings are cleared, lab is granted accreditation to ISO 15189:2022
  - Usual UKAS PD/FD (decision making) process is followed. When all transition findings are closed and FD completed, customer is granted accreditation to ISO 15189:2022
  - Four-year accreditation cycle and accreditation expiry date are unchanged

ISO 15189:2022 Transition: progress

+ Nearly 60 customers have been granted accreditation to ISO 15189:2022 to date, number increasing weekly.
+ Many more are in the decision-making process.
+ Over 80% of the Transition assessments are booked or have been performed.
+ Transition assessments have generally gone well so far.
+ However:-
    - Some lab services are still unaware that a transition is taking place…….
    - Some labs services have not read the UKAS process timelines, and think they can postpone their transition assessment until Dec 2025…
    - Some lab services have not understood that UKAS is assessing *implementation* of ISO 15189:2022, not *intention* to implement…

Gap Analysis

ISO 15189:2022 Transition: gap analysis (1)

- UKAS accreditation is based on assessment of objective evidence, to demonstrate that an organisation is competent and complies with the requirements of the relevant standard
- Technical bulletin, Jan 2023:
  - "The first step is for each accredited customer to… identify any gaps between the policies and processes currently in place compared to the requirements of ISO 15189:2022, and develop an action plan for **implementing** any new requirements"
  - "customers shall provide UKAS with a completed gap analysis detailing identified gaps and **actions taken.** As part of the gap analysis, customers shall provide evidence (for example, updated documents/policies/records) to demonstrate the actions they have taken to **comply** with ISO 15189:2022"
- UKAS gap analysis template:
  - "It is the responsibility of the Laboratory to identify the changes between the standards, determine the impact of these on its systems, and then make and **implement** any required alterations as necessary"
  - "The submission of the [gap analysis] template should be supported by documentation demonstrating how **new or changed** requirements **are met**."
  - "Effective **implementation** will be assessed at the site visit."

ISO 15189:2022 Transition: gap analysis (2)

- Technical bulletin, Jan 2024:
  - "One month before the transition assessment takes place, customers shall provide UKAS with a completed gap analysis detailing identified gaps and **actions taken**"
  - "UKAS expects laboratories to have updated **relevant** policies, procedures, SOPs and processes by the time of their transition assessment to demonstrate that the new version of the ISO 15189 has been understood. There shall be evidence of **implementation** of the new requirements, with particular **focus on the major** changes between ISO 15189:2012 and ISO 15189:2022 identified via each laboratory's gap analysis"

ISO 15189:2022 Transition: gap analysis (3)

4.9	Identification and control of NCNs	7.5	Nonconforming work	Major	**To Do:** CRxxx added to SOP1: • process for risk assessing audits/audit schedule . • Discuss inclusion of Impact & Extent stage as risk assessment to CA/PA records. **Complete:** • CRxx added to SOP2 : • inclusion of responsibilities, authorities, and clinical significance. • link to SOP xxx • update authority for resumption of work.

+ SOP 1 was the audit SOP. Also mentioned against 4.14.5/8.8.3 (audit clause).Not provided as evidence with the gap analysis. Finding raised as “major” gap and no evidence of implementation
+ SOP 2 was the SOP for identification and management of NCs. Policy was provided as evidence with the gap analysis. No finding raised as policy had been updated

ISO 15189:2022 Transition: gap analysis (4)

		6.2.3	Personnel: Authorization	Major	**No gap** Lab listed a number of policies including: Validation/verification policy Equipment management policy Several policies relating to their LIMS

- No policies or other evidence provided
- UKAS assessor raised a finding as this is a “major” gap none of the policies (assessed on site) demonstrated compliance with the ISO 15189:2022 requirements relating to authorization of personnel for activities such as signing off verification reports, or releasing results

ISO 15189:2022 Transition: gap analysis (5)

5.5.3	Documentation of examination procedures	7.3.6	Examination processes: Documentation of examination procedures	Minor	**No gap** Lab listed a number of policies relating to document control and SOP templates

- No policies or other evidence provided
- “Minor” gap and no change to lab processes, so no specific transition assessment needed. UKAS assessor commented on structure and content of SOPs, as compliance with ISO 15189:2022 was seen

UKAS
A world of confidence

Trends from Transition assessments so far…

Trends from transition assessments – Q1

Trends in findings

High-level trends

Clause	No. of NCs	Clause header
7.3	255	Examination processes
6.2	113	Personnel
7.8	56	Continuity and emergency preparedness
8.8	48	Evaluations
7.2	43	Pre-examination processes
7.4	43	Post-examination processes
6.6	42	Reagents and consumables
7.5	42	Nonconforming work

Trends from transition assessments

7.3 Breakdown

Clause	No. of NCs	Clause header	Summary of findings
7.3.7	128	Ensuring the validity of results	No "trend within a trend". Findings raised against lots of different aspects of this clause inc. lack of IQC at clinical decision limits, lack of documented justification of suitability of EQA schemes, lack of consideration of use of 3rd party controls
7.3.2	34	Verification of examination methods	Lack of clinical sign off/authorisation, lack of competency assessment/authorisation for performing verification, lack of consideration of pertinent clinical decision making in verification reports/SOP

Trends from transition assessments

6.2 breakdown

Clause	No. of NCs	Clause header	Summary of findings
6.2.3	62	Authorisation	Lack of evidence of staff being trained, competency assessed and authorised to perform specific lab activities
6.2.2	25	Competence requirements	

7.8 breakdown

Clause	No. of NCs	Clause header	Summary of findings
7.8	56	Continuity and emergency preparedness	Lack of evidence of testing of Business Continuity Plans

Trends from transition assessments

8.8 breakdown

Clause	No. of NCs	Clause header	Summary of findings
8.8.3	47	Internal audits	Lack of evidence of a risk-based approach to auditing. Both lack of documented policy and lack of risk-based audit schedule.

Trends from transition assessments – Q2 (as of October 2024)

Trends in findings

Quick review of findings –

Top ten clauses that have findings raised against them

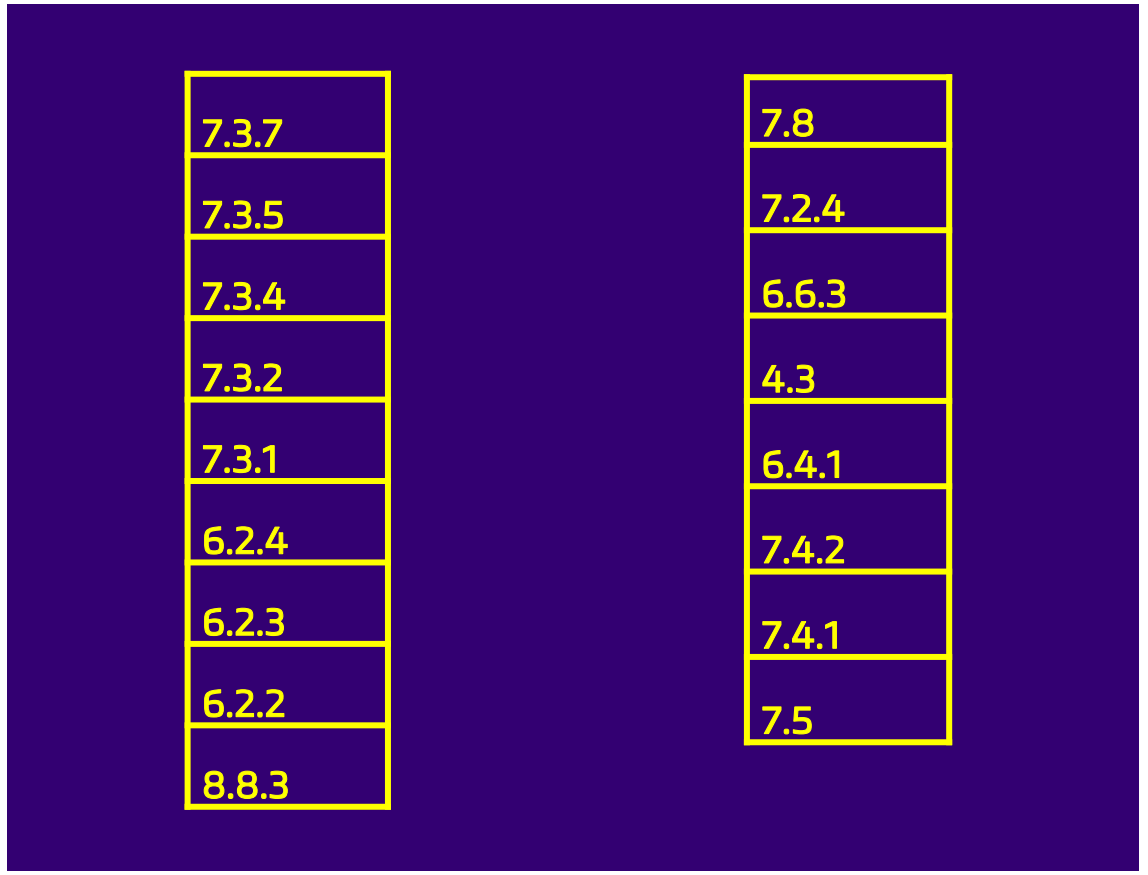
7.3	1
6.2	2
8.8	3
7.8	4
7.2	5
6.6	6
4.3	7
6.4	8
7.4	9
7.5	10

Trends from transition assessments – Q2 (as of October 2024)

Trends in findings

Quick review of findings –

Within 7.3 (as it is a big clause with many sub-sections), analysis of this section show subclauses of the 7.3, with highest number of findings. Some are still x.x rather than x.x.x as they don't have a subclause.



POCT and 15189:2022

- To accredit to ISO 22870:2016, compliance to ISO15189:2012 was required
- Now - POCT is now and integral part of ISO15189 and as such **all of the requirements apply**.
- There is a normative Annex, Annex A that is specific to POCT.
- A normative Annex means that if POCT is included in the scope then the requirements of that Annex apply.

Why Annex A (previously 22870)?

Annex A - General

- …additional requirements for the laboratory for POCT that are **distinct.**
- These requirements specify the laboratory's responsibilities…regarding:
  - Devices,
  - Training of personnel,
  - Quality assurance,
  - …management review of the complete POCT process.
  - Governance

Patient self-testing is excluded, but elements of this document may be applicable.

ISO/TS 22583 – Guidance for supervisors and operators of point-of-care testing (POCT) devices

Take home messages

• The Transition from 15189:2012 to 2022 is live and happening…

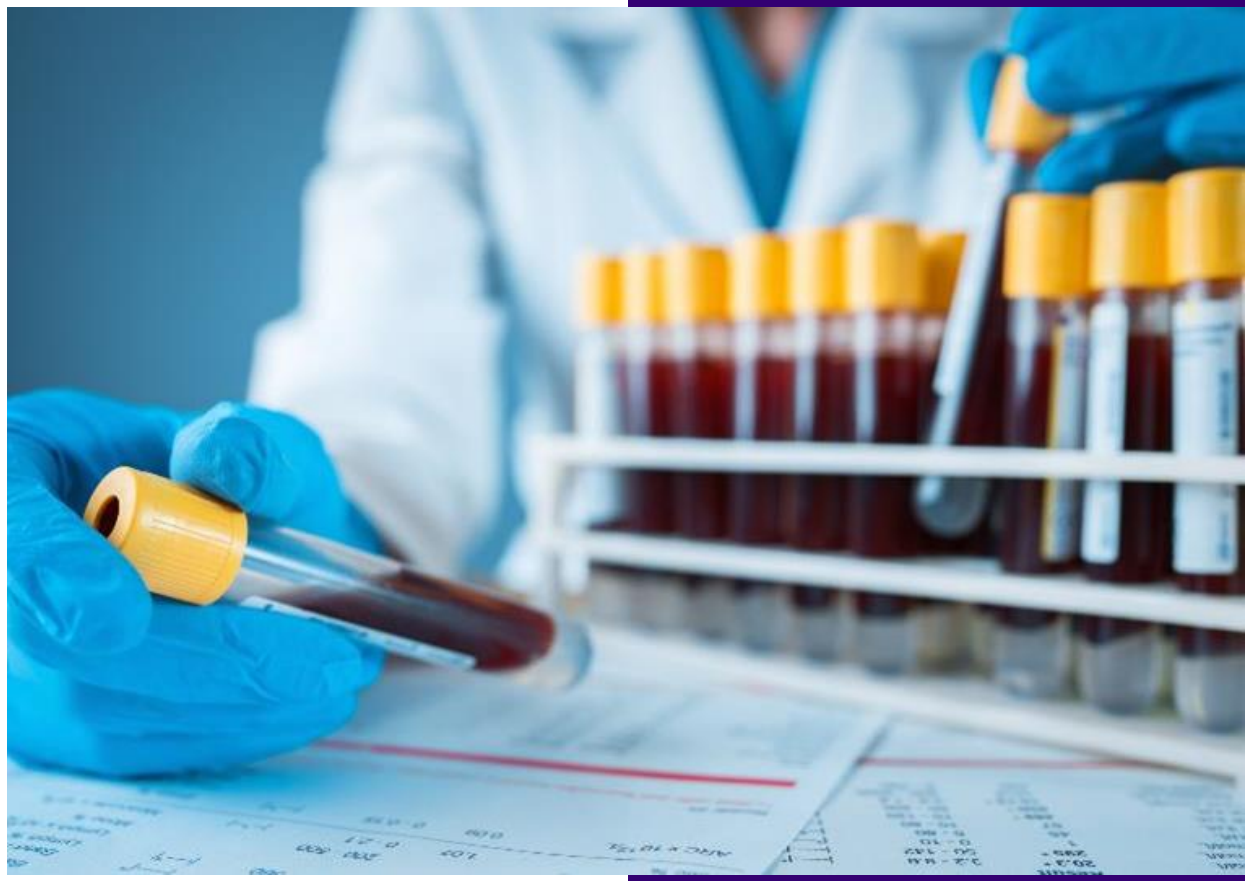
•Read the Standard

•Read the information available on the UKAS website

•Complete your Gap Analysis – and remember that supporting evidence of implementation is needed, not statements of intent.

•UKAS cannot carry out your gap analysis whilst on site – we will review your submitted form and evidence prior to your next annual assessment and will likely note any questions to ask when we are on site for that assessment.

•Remember the deadline - 6th December 2025



UKAS

A world of confidence