UKAS
A world of confidence

What does UKAS expect from quality assurance?

……and it wouldn't be a UKAS presentation without mentioning the ISO 15189:2022 transition

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What does UKAS expect from quality assurance?

ISO 15189 definitions

3.10
external quality assessment
EQA
evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons

3.12
interlaboratory comparison
organization, performance and evaluation of measurements or *examinations* (3.8) on the same or similar materials by two or more independent laboratories in accordance with pre-determined conditions

3.13
internal quality control
IQC
quality control
QC
internal procedure which monitors the testing process to verify the system is working correctly and gives confidence that the results are reliable enough to be released

But I also Googled it

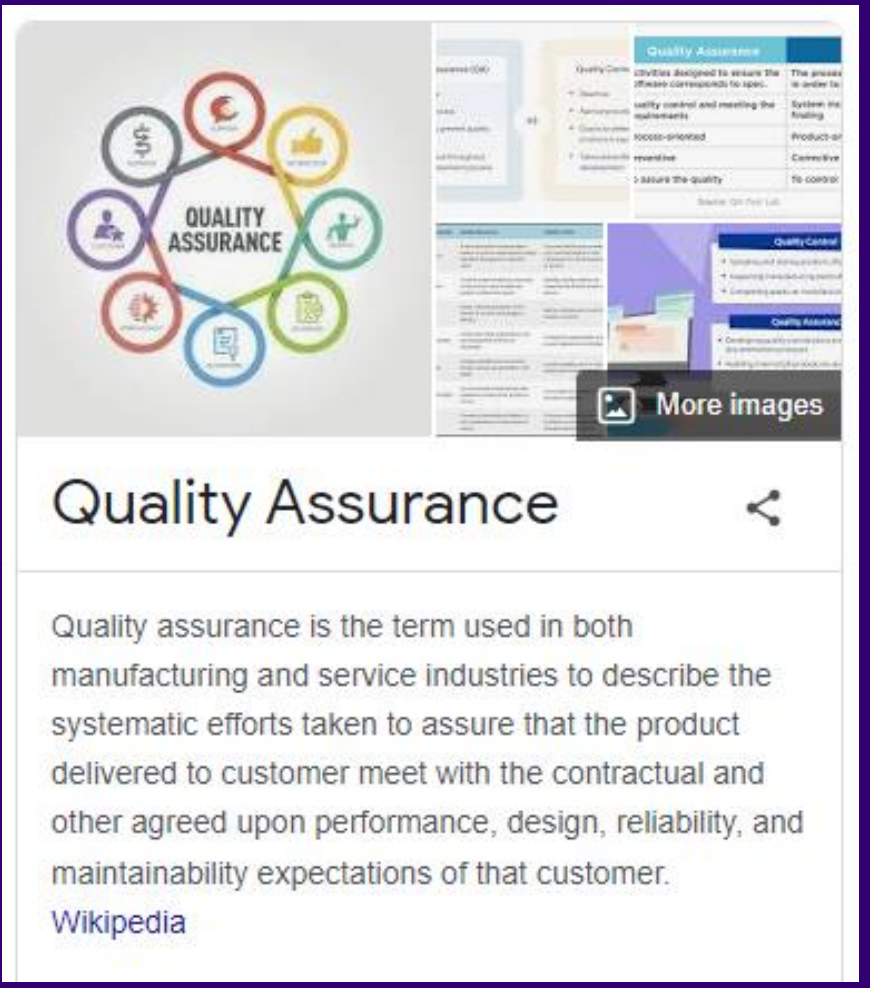
Dictionary

Definitions from Oxford Languages · Learn more

quality assurance

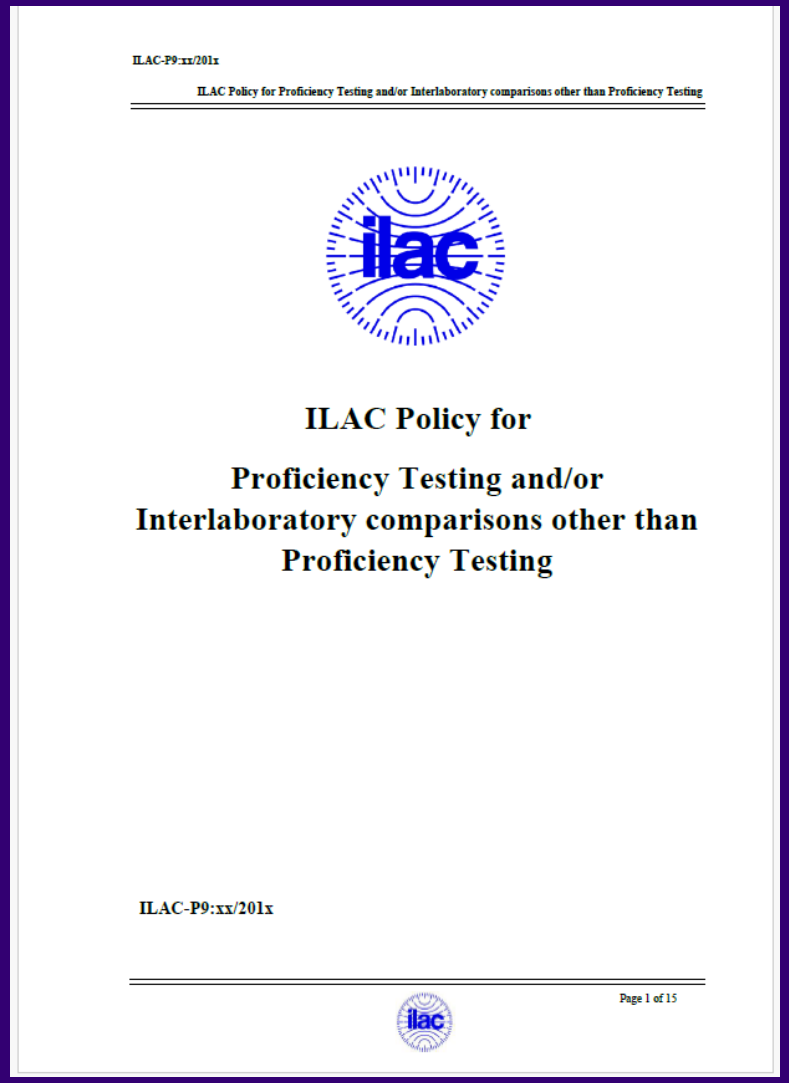
noun

the maintenance of a desired level of quality in a service or product, especially by means of attention to every stage of the process of delivery or production.



Google & Wikipedia's contributions to this presentation are acknowledged

ILAC (International Laboratory Accreditation Cooperation) requirements



ILAC-P9:xx/201x

ILAC Policy for Proficiency Testing and/or Interlaboratory comparisons other than Proficiency Testing

ILAC Policy for

Proficiency Testing and/or Interlaboratory comparisons other than Proficiency Testing

ILAC-P9:xx/201x

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106 This policy sets out the requirements for, and gives guidance to, accreditation bodies (ABs) on the use
107 and assessment of PT and/or ILCs other than PT in the accreditation process for all CABs performing
108 testing or calibration activities – i.e., testing, calibration and medical laboratories, inspection bodies,
109 biobanks, PT providers and reference material producers.

78 - For ISO/IEC 17043: 2023 [4], no specific requirements for PT and/or other ILCs than PT are
79 mentioned in the standard, however, the requirements for ISO/IEC 17025:2017 [1] and ISO 15189
80 [2] are to be met when considering testing or calibration activities.

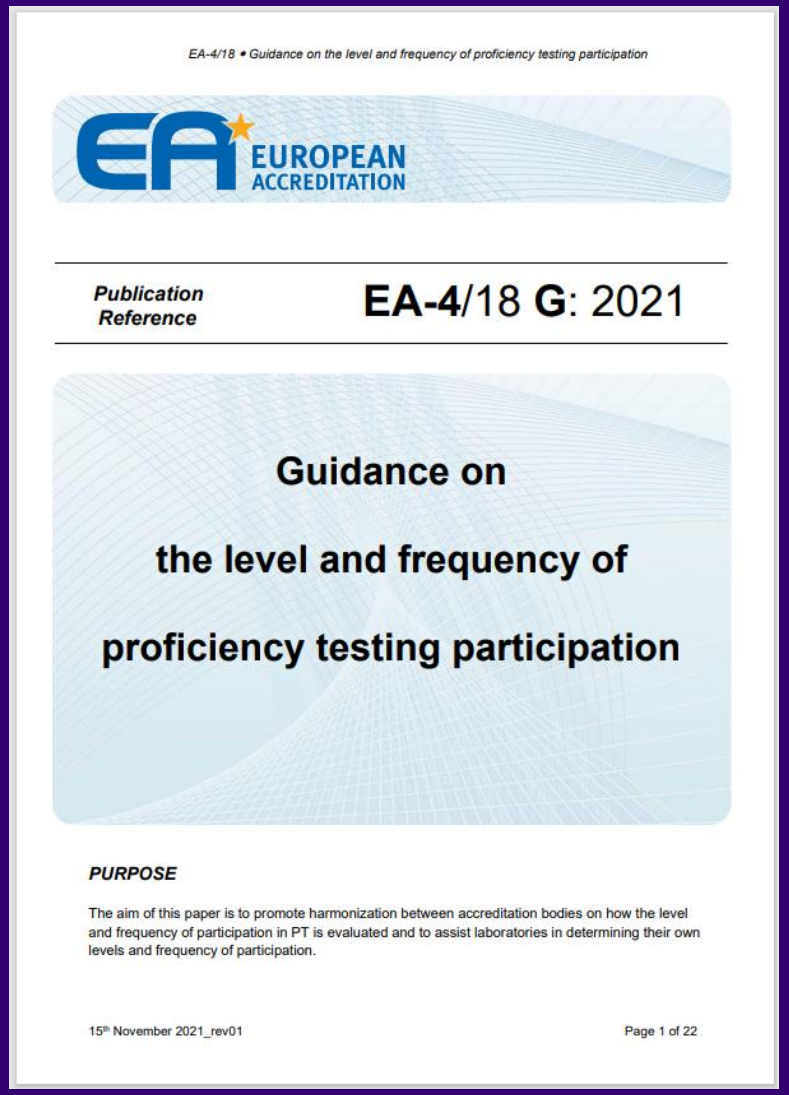
142 1) Participation in PT and/or ILCs other than PT is considered mandatory where PTs are available
143 and appropriate.

144 2) Mandatory participation is applicable not only to laboratories, but also to other accredited
145 CABs performing testing or calibration activities.

152 6) Where satisfactory performance is not achieved, ABs shall request their applicant and
153 accredited CABs to implement appropriate corrective actions.

ILAC's contribution to this presentation is acknowledged

EA (European Cooperation for Accreditation) requirements



EA-4/18 • Guidance on the level and frequency of proficiency testing participation

EUROPEAN ACCREDITATION

Publication Reference **EA-4/18 G: 2021**

Guidance on

the level and frequency of

proficiency testing participation

PURPOSE

The aim of this paper is to promote harmonization between accreditation bodies on how the level and frequency of participation in PT is evaluated and to assist laboratories in determining their own levels and frequency of participation.

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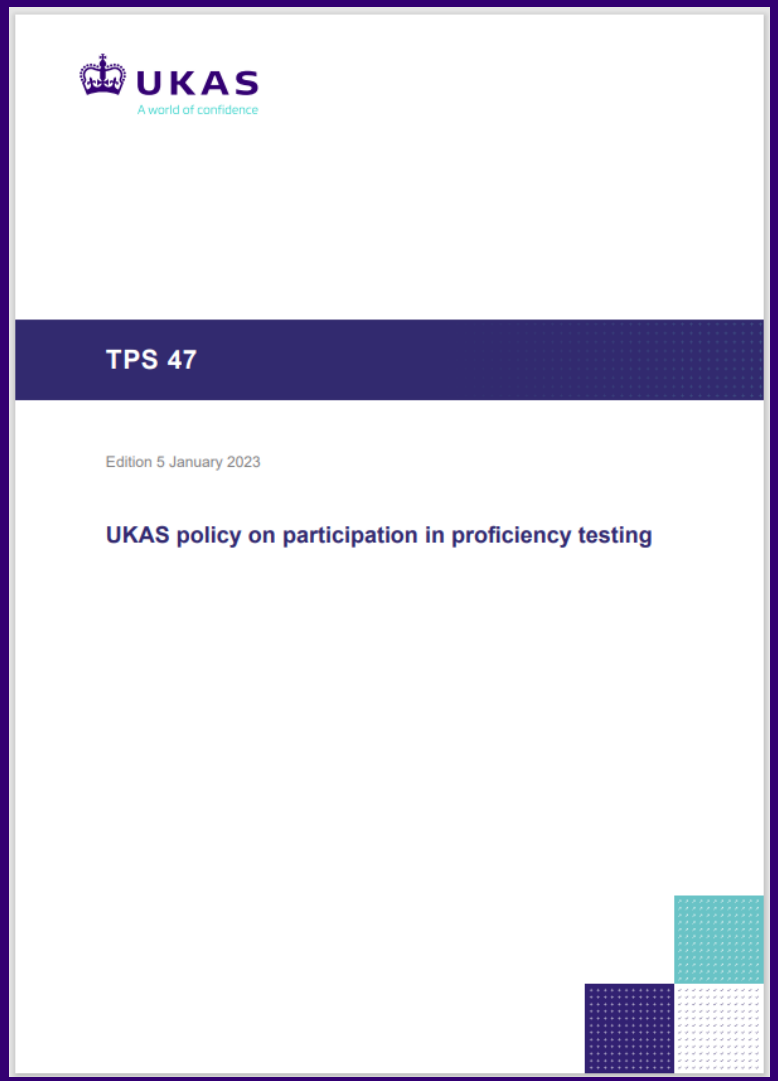
(1) The laboratory should define the level and frequency of its participation after careful analysis of its other quality assurance (QA) measures to ensure the validity of the results (especially those that are able to disclose, quantify and follow the development of bias of a stated magnitude). The level and frequency of participation should be made dependent on the extent to which other measures have been taken into account. QA measures can include, but are not limited to:

- Regular use of certified reference materials and/or reference materials.
- Comparison of analysis by independent techniques.
- Participation in ILCs for method development/validation and/or reference material characterisation studies.
- Use of internal quality control (IQC) measures.

- Other inter/intra – laboratory comparisons e.g. analysis on blind samples within the laboratory.
- Robustness of the metrological traceability chain. (Are instruments calibrated under the same conditions as routinely used versus assumptions on e.g. influence factors or secondary parameters)

EA's contribution to this presentation is acknowledged

UKAS requirements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TPS 47

Edition 5 January 2023

UKAS policy on participation in proficiency testing

4. Policy

4.1 It is UKAS policy that all accredited laboratories shall participate in PT/ILCs where such schemes are available and relevant to their scope of accreditation. Where applicable, this also holds for accredited inspection bodies.

4.2 Laboratories and inspection bodies are required to investigate PT/ILC scheme availability and also determine the appropriateness of the available scheme(s).

4.6 Laboratories and inspection bodies preparing for initial accreditation or wishing to extend their scope of accreditation are required to participate in PT/ILCs where such schemes are available and relevant to their scope of application. Satisfactory performance, and/or appropriate corrective actions to eliminate the cause of unsatisfactory performance, must be demonstrated before accreditation can be granted.

4.7 Where no appropriate PT/ILCs are available, or where no distributions/rounds of appropriate PT/ILC are available, laboratories and inspection bodies are required to demonstrate the ongoing validity of their tests by other means *(use of reference materials, replicate testing, etc.)*.

UKAS requirements

4.4 Laboratories and inspection bodies must be prepared to justify their policy and approach to both frequency of participation and any non-participation in readily available PT schemes that are appropriate.

4.5 Laboratories and inspection bodies should define the level and frequency of participation after careful analysis of risk factors that could affect the results produced. The participation should be dependent on the level of quality assurance activities; historic performance could also be used to justify changes in participation levels. QA activities include but are not limited to:

- Regular use of reference materials;
- Comparison of analysis by independent techniques;
- Participation in method development/validation and/or reference material characterisation studies;
- Use of internal quality control measures;
- Other inter/intra - laboratory comparisons e.g., analysis of blind samples within the laboratory.

UKAS requirements

Comment *(justification for change)*	**Proposed change**	**UKAS observations** on each comment submitted
EQA sets the participation level for all participants	It is the choice of the laboratory to participate or not. However, this could mean the non- participation in the full EQA cycle, will lead to a laboratory receiving a poor performance record.	Not accepted. Requirement of EA-4/18 G: 2021. This does not mean that participants can vary the level of participation stipulated in any particular scheme protocols and if they did this would normally result in poor performance in the scheme due to non-participation. In some instances, participation in 1 scheme may not allow sufficiently frequent participation, in which case participation in more than 1 scheme may be required.

- Evaluation of the appropriateness of a scheme includes the frequency of distribution and number of samples per distribution meeting the lab's needs
- Labs are expected participate at the frequency decided by the EQA scheme provider

Frequency of participation

- SARS-CoV-2 PCR
  - 50 samples/day (
  - Participate in EQA
- SARS-CoV-2 PCR t
  - 50,000 samples/d
  - Participate in EQA
  - Also participate in
  - And EQA scheme 1
  - Plus other quality

mples per year

amples per year
5 samples per year
r year

ISO 15189 requirements

5.6 Ensuring quality of examination results 5.6.1 General	7.3.7 Ensuring the validity of examination results 7.3.7.1 General
5.6.2 Quality control 5.6.2.1 General 5.6.2.2 Quality control materials 5.6.2.3 Quality control data	7.3.7.2 Internal quality control (IQC)
5.6.3 Interlaboratory comparisons 5.6.3.1 Participation 5.6.3.2 Alternative approaches 5.6.3.3 Analysis of interlaboratory comparison samples 5.6.3.4 Evaluation of laboratory performance	7.3.7.3 External quality assessment (EQA)
5.6.4 Comparability of examination results	7.3.7.4 Comparability of examination results

ISO verbs

Shall: indicates a requirement (329 in 2022)

Should: indicates a recommendation (justification if not)

May: indicates a permission

Can: indicates a possibility or capability

ISO 15189 requirements

7.3.7 Ensuring the validity of examination results

7.3.7.1 General

The laboratory shall have a procedure for monitoring the validity of results. The resulting data shall be recorded in such a way that trends and shifts are detectable and, where practicable, statistical techniques shall be applied to review the results. This monitoring shall be planned and reviewed.

7.3.7.2 Internal quality control (IQC)

a) The laboratory shall have an IQC procedure for monitoring the ongoing validity of examination results, according to specified criteria, that verifies the attainment of the intended quality and ensures validity pertinent to clinical decision making.

ISO 15189 requirements

7.3.7.3 External quality assessment (EQA)

a) The laboratory shall monitor its performance of examination methods, by comparison with results of other laboratories. This includes participation in EQA programmes appropriate to the examinations and interpretation of examination results, including POCT examination methods.

b) The laboratory shall establish a procedure for EQA enrollment, participation and performance for examination methods used, where such programmes are available.

c) EQA samples shall be processed by personnel who routinely perform pre-examination, examination, and post-examination procedures.

d) The EQA programme(s) selected by the laboratory shall, to the extent possible:

1) have the effect of checking pre-examination, examination, and post-examination processes;

2) provide samples that mimic patient samples for clinically relevant challenges;

3) fulfill ISO/IEC 17043 requirements.

ISO 15189 requirements

g) EQA data shall be reviewed at regular intervals with specified acceptability criteria, in a time frame which allows for a meaningful indication of current performance.

h) Where EQA results fall outside specified acceptability criteria, appropriate action shall be taken (see 8.7), including an assessment of whether the non-conformance is clinically significant as it relates to patient samples.

i) Where it is determined that the impact is clinically significant, a review of patient results that could have been affected and the need for amendment shall be considered and users advised as appropriate.

To answer the question….

What does UKAS expect from quality assurance?

- Laboratories / other CABs understand the relevant requirements
- Suitable procedures form monitoring the validity of results are established and implemented on a continual basis
- Appropriate actions are taken to address any identified QA issues
- Evidence of this is retained & made available at assessments

ISO 15189:2022

ISO 15189:2022 transition

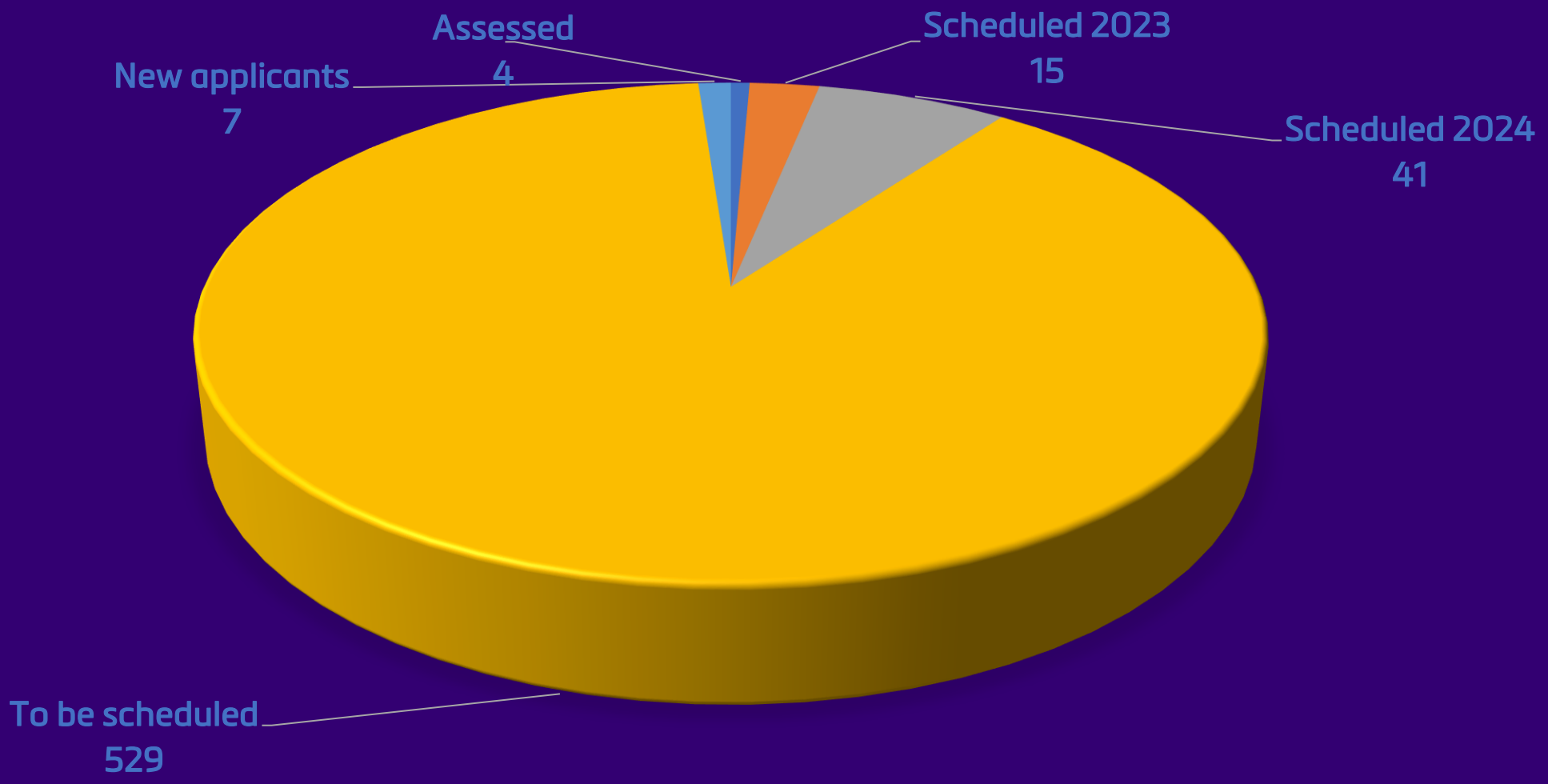
Date	Milestone/Activity
6 December 2022	ISO 15189: 2022 issued
December 2022 to March 2023	UKAS preparation
1 April 2023	UKAS ready to start assessing to ISO 15189: 2022
1 April 2023 to 31 Dec 2023	Optional Stage: Labs can choose to be assessed to the 2022 version or remain with the 2012 version. In any case reports may highlight major deviations from the new standard
01 July 2023 onwards	Only applications to ISO 15189: 2022 accepted*
1 January 2024 onwards	All initial assessments will be to ISO 15189: 2022
1 January 2024 onwards (assessment visits should be completed by 31 May 2025)	Mandatory Stage: All surveillance/reassessments will be to ISO 15189: 2022
6 December 2025	Accreditations to ISO 15189: 2012 cease to be valid. Laboratories that have not transitioned to the 2022 version by this date will no longer be able to claim accreditation for their laboratory activities.

*Excluding extensions to scope, these can only be assessed against the Standard version a laboratory is accredited to

ISO 15189:2022 transition

- Technical bulletins (www.ukas.com/accreditation/iso-15189-transition):
  - 23 December 2022
  - 16 January 2023
- Gap analysis template available February 2023
- Training of UKAS personnel and contracted Technical Assessors completed:
  - 50 UKAS personnel
  - 192 contracted Technical Assessors
- Test of Understanding:
  - All UKAS personnel passed & competent to assess to 2022
  - 106 contracted Technical Assessors passed & competent
  - 86 contracted Technical Assessors still to pass

589 ISO 15189 accredited medical laboratories



ISO 15189:2022 transition assessments

- Usually carried out with the scheduled annual surveillance/reassessment
  - No application needed
  - 2023: Onus is on the lab to request early transition
  - 2024: UKAS will arrange transition assessment
  - Additional office time charged
- Gap analysis template must be completed and returned to UKAS at least 1 month before the assessment
  - Lab's own evaluation of readiness to transition
  - To include supporting documentation of how any gaps have been addressed
- On-site assessment to verify the effectiveness of changes made
  - Findings raised where non-conformity is found
  - 1 month deadline for evidence submission
- Once all mandatory findings are cleared, impartial decision to transition to 2022

ISO 15189:2022 Gap analysis

Key - Extent of Change:

- **Structural** – Requirement remains the same but is under a new clause number
- **Minor** – Wording of the requirement has changed but overall intent is consistent
- **Major** – Changes will require the CAB to implement new or change existing practice
- **New** – New requirement(s)/concept(s) not in previous version of the standard

4.6	External services and supplies	6.8	Externally provided products and services	Structural		
		7.6.5	Control of data and information management: Offsite management	Structural		
4.7	Advisory services	5.3.3	Advisory activities	Minor		
4.8	Resolution of complaints	7.7	Complaints	Minor		
4.9	Identification and control of NCNs	7.5	Nonconforming work	Major		
4.10	Corrective action	8.7	Nonconformities and corrective actions	Major		

ISO 15189:2022 key changes

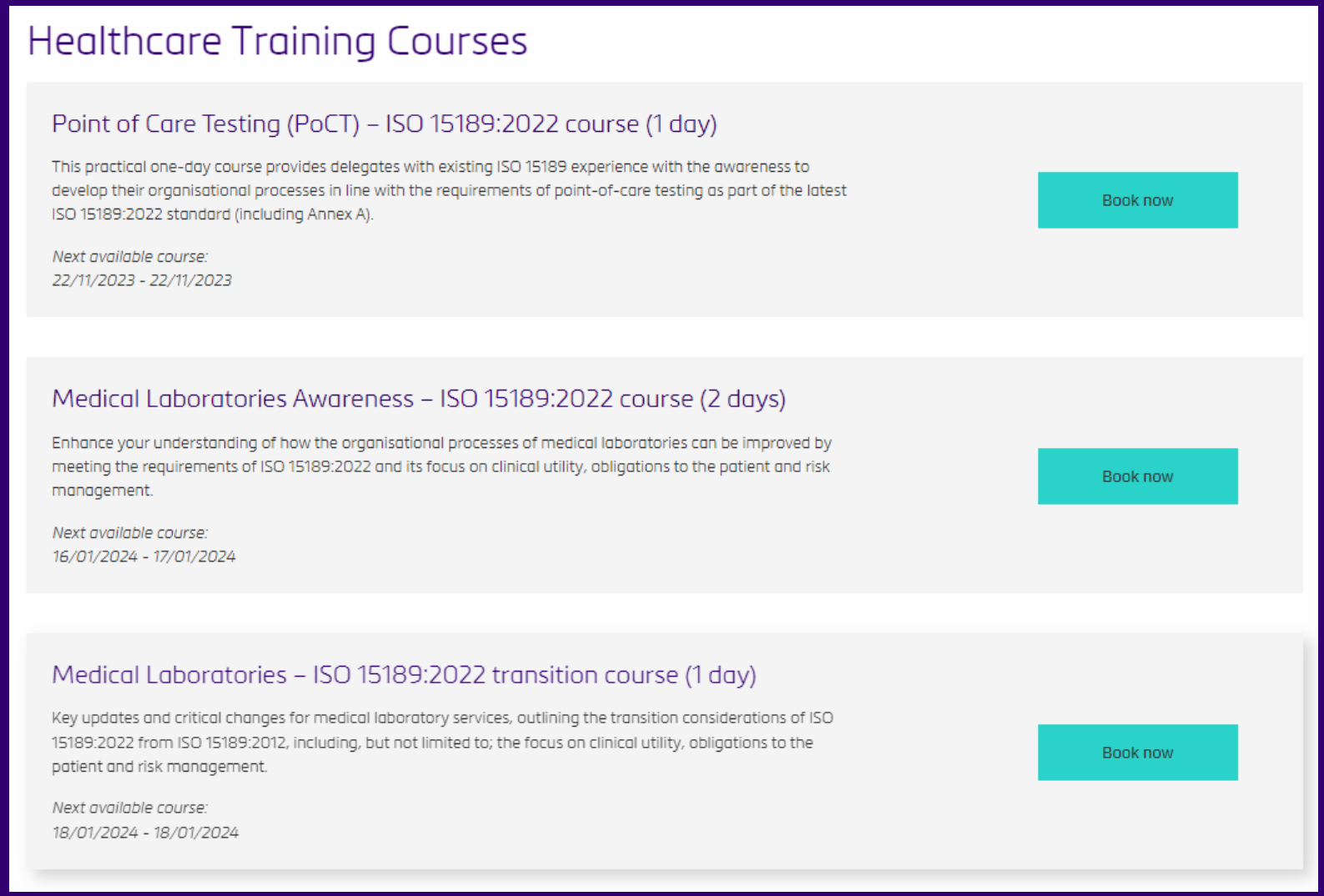
- Structural change to bring ISO 15189 in line with ISO 17025
- ISO 22870 (PoCT), is incorporated into ISO 15189
- **Bigger focus on clinical outcomes and risk to patient. First sentence of introduction:**

  *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.*

	2012	2022/23
Patient(s)	97	141
Clinical / clinically	67	52
Risk(s)	24	83

- Other: e.g., less prescriptive specimen labelling/request form requirements, SOPs, report content, verification must be clinically relevant and appropriate staff shall be authorised to perform and review verification.
- Risk management and laboratory safety requirements are aligned with ISO 22367 and 15190

ISO 15189:2022 UKAS resources



Healthcare Training Courses

Point of Care Testing (PoCT) – ISO 15189:2022 course (1 day)

This practical one-day course provides delegates with existing ISO 15189 experience with the awareness to develop their organisational processes in line with the requirements of point-of-care testing as part of the latest ISO 15189:2022 standard (including Annex A).

Next available course:
22/11/2023 - 22/11/2023

Book now

Medical Laboratories Awareness – ISO 15189:2022 course (2 days)

Enhance your understanding of how the organisational processes of medical laboratories can be improved by meeting the requirements of ISO 15189:2022 and its focus on clinical utility, obligations to the patient and risk management.

Next available course:
16/01/2024 - 17/01/2024

Book now

Medical Laboratories – ISO 15189:2022 transition course (1 day)

Key updates and critical changes for medical laboratory services, outlining the transition considerations of ISO 15189:2022 from ISO 15189:2012, including, but not limited to; the focus on clinical utility, obligations to the patient and risk management.

Next available course:
18/01/2024 - 18/01/2024

Book now

www.ukas.com/training-and-advisory/training/healthcare/

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Thank you

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