ISO/IEC 17025:2017

UKAS Transition Process Webinar

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Webinar Agenda

- Webinar Aims
- Transition Metrics
- Timeframes and Deadlines
- UKAS Transition Process
- Transition Template Guidance
- Training and Support
- Questions

Webinar Aims

- To provide clarity to customers on:
  - Transition process
  - Timeframes and deadlines
  - Actions needed by the laboratory
  - What a laboratory can do to aid their transition

- Webinar is being recorded and a version will be published on UKAS website along with FAQs

Questions

- Use the GoTo Webinar ‘Questions’ function to ask questions
  - Ask at the end or as we go through the webinar
  - Questions will be answered at the end
  - We will be keeping questions anonymous
- However:
  - Will not be addressing laboratory specific questions
  - Will not be answering questions on interpretation of 17025 clauses

Metrics of the Transition

- 1596 Laboratories to transition
- Over 3000 independent review points
- 298 Assessors and decision makers to train and authorise
- 36 Months to complete it all

Largest transition UKAS has ever conducted

Timeframes and Deadlines

ULTIMATE DEADLINE

30th NOVEMBER 2020

After this date, accreditation to ISO/IEC 17025:2005 will cease to be valid

Timeframes and Deadlines

DATE	MILESTONE/ACTIVITY
30 November 2017	ISO/IEC 17025: 2017 published.
December 2017 to February 2018	UKAS training and preparation.
1 March 2018 to 31 December 2018	Laboratories advised to have transition assessment in 2019 but could choose to be assessed to the 2017 version early.
1 July 2018 onwards	New applications must be to ISO/IEC 17025:2017.
1 January 2019 to 31 December 2019	To facilitate ease of transition it is mandatory that all annual UKAS ISO/IEC 17025 assessments are to ISO/IEC 17025:2017
30 November 2020	After this date Accreditations to ISO/IEC 17025: 2005 cease to be valid.

FAQ – Why is Assessment Mandatory in 2019?

- Given the scale of the transition UKAS needs to:
  - Ensure customers, assessors, decision makers and administrators have adequate time to conduct necessary actions
  - Spread out transitions to make best use of resources
  - Provide a contingency for unforeseen circumstances
- Average time from assessment to transition is 4-6 Months
- Previous transitions have shown that when given choice, a majority of customers leave their transition until the last 6 months.

UKAS Transition Process

- No need to submit an application form – transition will be assessed during scheduled annual UKAS assessment in 2019.
- Additional chargeable time required for UKAS to conduct the review and transition – depends upon size / complexity of laboratory.
  - Approx. 0.5 Day (Small Lab), 1.0 Day (Medium Lab), 1+ Days (Large Lab)
- UKAS will conduct a desktop review based on the ‘Transition Template’ submitted by the laboratory.
  - Purpose is to identify focus areas for on-site assessment (i.e. where the laboratory has made major changes or change does not appear compliant)

UKAS Transition Process

- ‘Transition Template’ will form the basis for the report on the transition assessment.
- Improvement actions specific to the transition will, where raised, need to be closed out prior to grant of transition.
- Following assessment an independent decision will be conducted to review and approve the assessment team’s recommendation.
- New accreditation certificate and schedule will be issued upon successful transition.
  - Accreditation number and initial date of accreditation will remain unchanged

The Transition Template

- Will be sent to customers several months in advance of annual assessment, but can also be downloaded from UKAS website.
- Needs to be returned to UKAS ***at least*** one month prior to assessment, ideally earlier.
  - Content will be discussed at the assessment
- Must describe the changes the laboratory has made for the new standard.
- Identifies what UKAS considers to be ‘New’ requirements and ‘Major’ and ‘Minor’ Changes

Transition Template – Important Points

- Provide details of the changes made, do not simply reference updated procedures or quality manual sections.
- Return the template ***at least*** one month; but ideally further, in advance of your assessment.
- Provide the completed template in Microsoft Word format; do not return it in protected formats (e.g. PDF) as the template will be amended or updated by the assessment team.
- Whilst there have been several changes to the standard, including a fundamental change to the structure of the standard, it is considered that many are not significant and therefore major changes to your systems and procedures should not be required.

Transition Template – Important Points

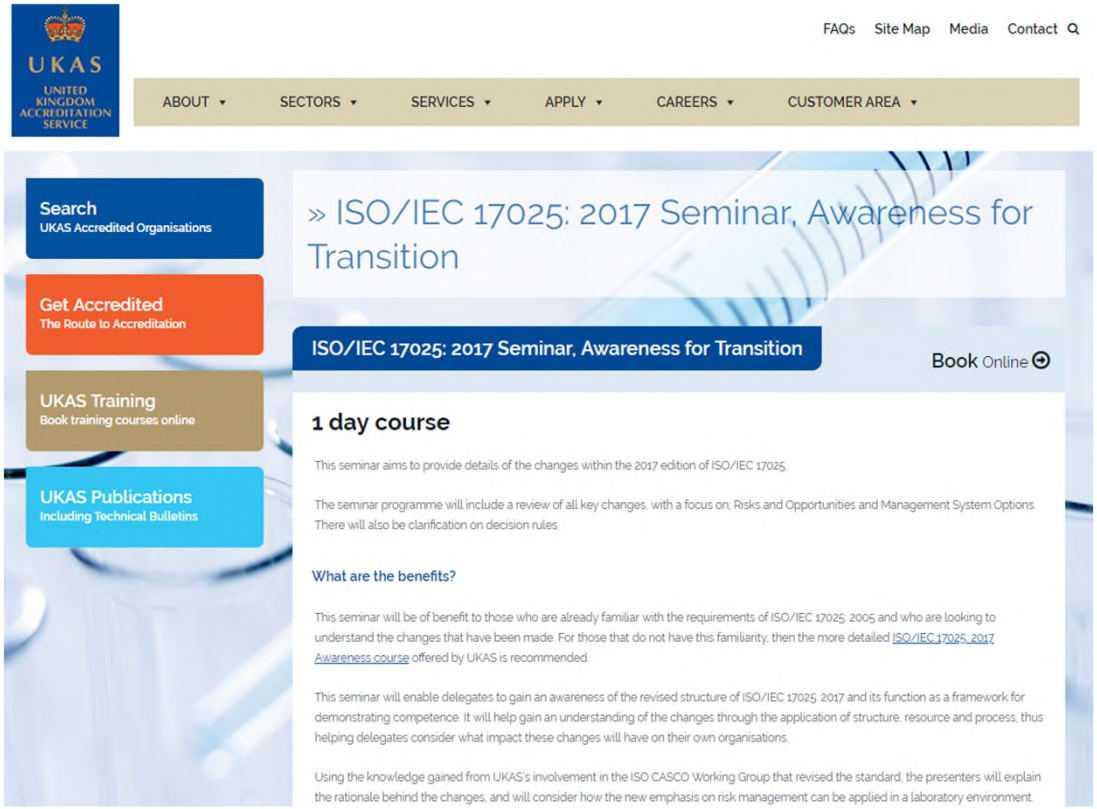
- Where the template submission does not satisfactorily address the previous points, the cost of the assessment may need to increase to cover additional time taken by our assessment teams to perform their review.
- The UKAS transition assessment is not a gap analysis for the laboratory. Where no attempt to prepare for transition has been made, the assessment will be cancelled, and an extra assessment conducted at a later date. This cancellation and additional assessment will be chargeable to the customer.

Support and Training

- Support with transitioning to ISO/IEC 17025:2017
  - BMTA (British Measurement and Testing Association) https://www.bmta.co.uk/
  - ISO (International Standards Organisation) https://www.iso.org/home/standards/popular-standards/isoiec-17025-testing-and-calibra.html
- General information on UKAS website:
  - https://www.ukas.com/news/revision-to-iso-iec-170252017-transition-timeline/
- Link to UKAS ISO/IEC 17025:2017 Transition Template:
  - https://www.ukas.com/download/publications/publications-relating-to-laboratory-accreditation/ISO-IEC-17025-2017-Transition-Template.docx

Support and Training

https://www.ukas.com/about/training-services/



Questions

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Example of Risk & Opportunity

The requirement for impartiality is a good example of where the risk and measures necessary do vary greatly between laboratories.

A privately owned independent lab, in the UK, with many customers, where the owner has no other activities or ownerships is unlikely to need extensive measures to protect impartiality.

Consider alternatively:

- A lab with only one customer
- A lab where the owner owns some customers
- A lab of a manufacturer also taking on third party work
- A lab with minimum wage-staff or in a culture known for corruption
- A lab whose ownership is complex and keeps changing as does that of related bodies

A Change of Approach

ISO/IEC 17025:2005 Standard Managed Risk Out goes	ISO/IEC 17025:2017 Risk and Opportunity Managed in comes
• Quality Manual • Policies • Most Procedures • Job Descriptions • Top Management • QM, TM	• Documented Information • Processes • Establishing Risk • Monitoring • Ongoing Review

Decision Rules

- A Laboratory must specify and apply an agreed decision rule when it is required to make a pass/fail statement
- If it is not in the Standard contracted and the customer does not ask, you are not required to make a decision
- Ignoring uncertainty in your decision rule is unlikely to be compliant