The latest developments at UKAS

Jon Murthy

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Updates at UKAS

- Standards under revision
- CPA / 15189 transition
- Common Issues
- Latest news

Standards Transitions – those underway

- ISO/IEC 17020:2012 Deadline is 1 March 2015
- ISO/IEC 17024:2012 Deadline is 1 July 2015
- ISO/IEC 17065:2012 Deadline is 1 Sept 2015
- ISO 15189:2012 Deadline is 1 Nov 2015
- ISO TS/22003:2013 Deadline in Dec 2016
- ISO 9001 – published in Sep 2015. 3 year transition
- ISO 14001 - published in Sep 2015. 3 year transition

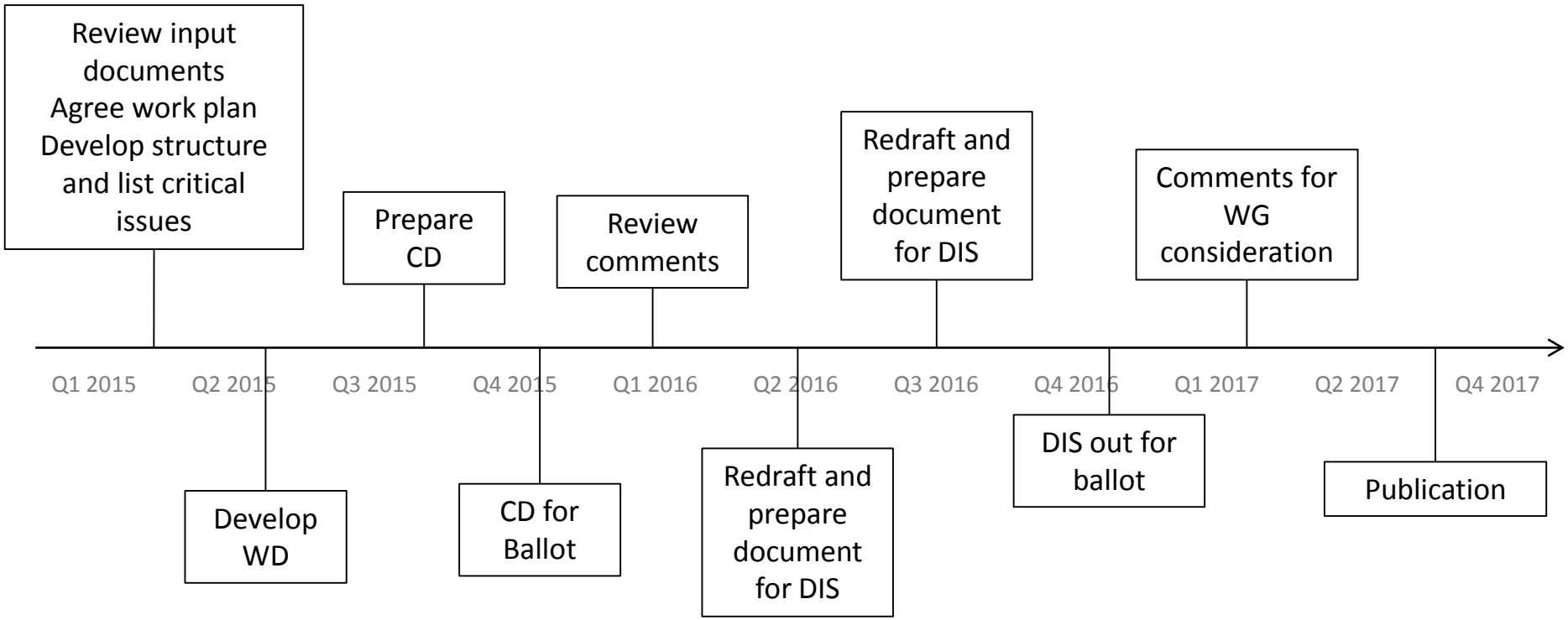
Standards transitions

- Revision of ISO/IEC 17025 – ISO CASCO WG 44
- Revision of ISO/IEC 17021:2011 – ISO CASCO WG21 There will be a 2-year transition period.
- Development of ISO Guide 34 into ISO 17034 – ISO CASCO WG43 - Expected publication approx 2 yrs
- Revision of ISO/IEC 17011 – publication in 2 years.
- ISO 45001 (replacing OHSAS 18001) expected 2016

ISO/IEC 17025

- Clarification rather than major revision
- Inclusion of the recommended ISO/CASCO structure
- Intention is to harmonise the 17000 standards with the developments of ISO 9001 (Option A/B). Inclusion of obligatory requirements on impartiality, confidentiality, complaints and appeals, and the management system into the document, Common Elements in CASCO Standards.
- Management and Technical Requirement sections have been expanded to include structural, resource, process and MS requirements.
- Reporting – common day practice

Revision of ISO/IEC 17025 (36 months)



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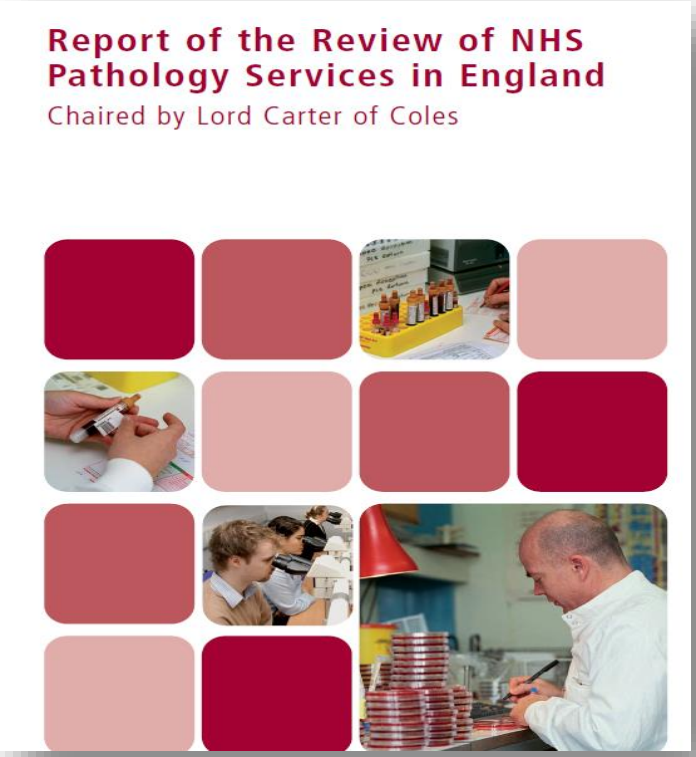
Medical Labs – transition to ISO 15189



- '….objective and measurable quality standards should be developed for pathology services from sample request to delivery of the interpreted result'
- Criticism of the low number of fully accredited laboratories.
- 'pathology service providers, in future, should be subject to mandatory accreditation by an organisation (UKAS) independent of the providers and the Profession.

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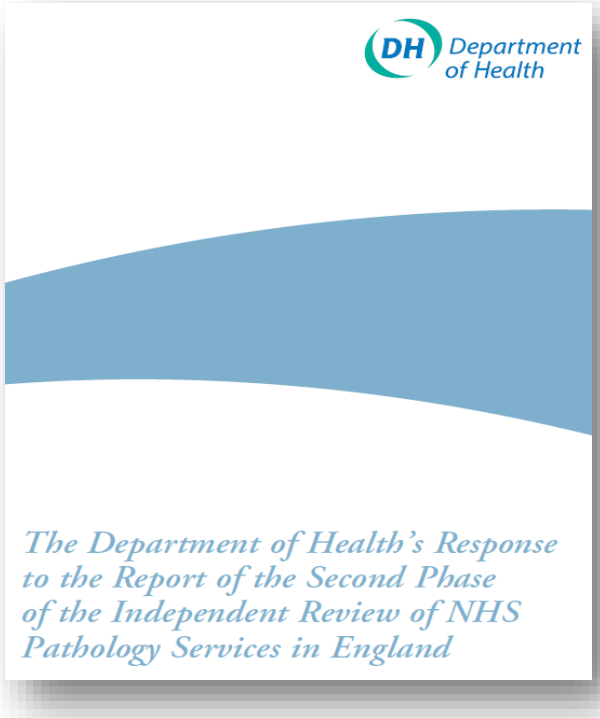
DoH response



- CPA to update its approach to accreditation, in the light of changes in the NHS and the need for transparent consistency in the application of standards.
- DoH supports any moves by CPA to merge with the UKAS.
- New European legislation in both the regulated and voluntary sectors.
- DH will continue to work closely with UKAS to ensure that accreditation supports high quality, safe diagnostic services for patients.

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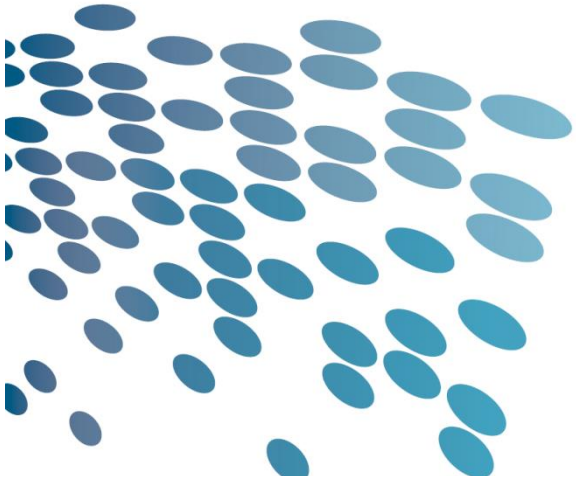
Pathology Quality Assurance Review

Pathology Quality Assurance Review



Chaired by Dr Ian Barnes

January 2014

- Accreditation to ISO15189 is strongly supported and “has increased emphasis on continuous improvement”
- Greater emphasis on EQA and also for UKAS accreditation of EQA schemes.
- UKAS recommended to undertake additional unannounced “spot checks” on medical laboratories focusing on the quality of output
- Key Assurance Indicators (“KAIs”) to be developed to evidence the quality and safety of services.

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Transition to ISO15189

- Approx. 900 CPA accredited med labs.
- To date: 250 labs assessed
- 60 accredited, more than 90 labs close to accreditation
- Many laboratories are now “joining up” individual labs for one single UKAS accreditation which covers a range of scopes.
- It is expected that this consolidation will lead to approximately 300-350 laboratory units being accredited in 2018 (March).

Key areas of difference

The main areas of difference and the areas where laboratories have experienced the greatest difficulty with implementing ISO 15189 are:-

- Validation and Verification
- Measurement of uncertainty
- Traceability
- Staff Competence

Purpose of UKAS Assessment

Can you demonstrate your competence?

- Has competence been maintained since the last assessment
  - Records, minutes, feedback, complaints
- Are you still competent now?
  - Witnessing, interviewing, questioning
- How will you maintain competence in the future?
  - Effective & compliant Quality Management System

In simple terms:-

- Providing confidence that a body can provide reliable, reproducible outcomes that are fit for purpose
- Expectation that one will get the 'right' result and a reliable outcome

Common issues

- Understanding of Mandatory Improvement Action not Requiring Evidence
- Insufficient depth / record of detail in system and technical audits
- Document control – uncontrolled documents, obsolete forms in circulation, uncontrolled issue of key documents, operatives not in possession of relevant current documents
- Organisation's understanding how to audit independence, impartiality and integrity
- Use of UKAS Accreditation Symbol – particularly on literature and web sites and especially where these are prepared by a third party

Leveraging your assessment visit

- Accreditation is based on an impartial and independent assessment of the laboratory.
- Therefore improvement actions can be useful, valid evidence of a weakness in a laboratory.
- Examples where accreditation has helped:- staff demographics: staffing levels; laboratory premises and conditions, equipment investment

- Customer area
- Subscribe to UKAS publications and technical bulletins
- Online ETS application forms
- Book training online
- ‘Browse’ search

- PR and media
- Calendar of events for customers, stakeholders, international partners, and staff

Contact details

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