ISO Standards and UKAS Inspection Question and Answer Session

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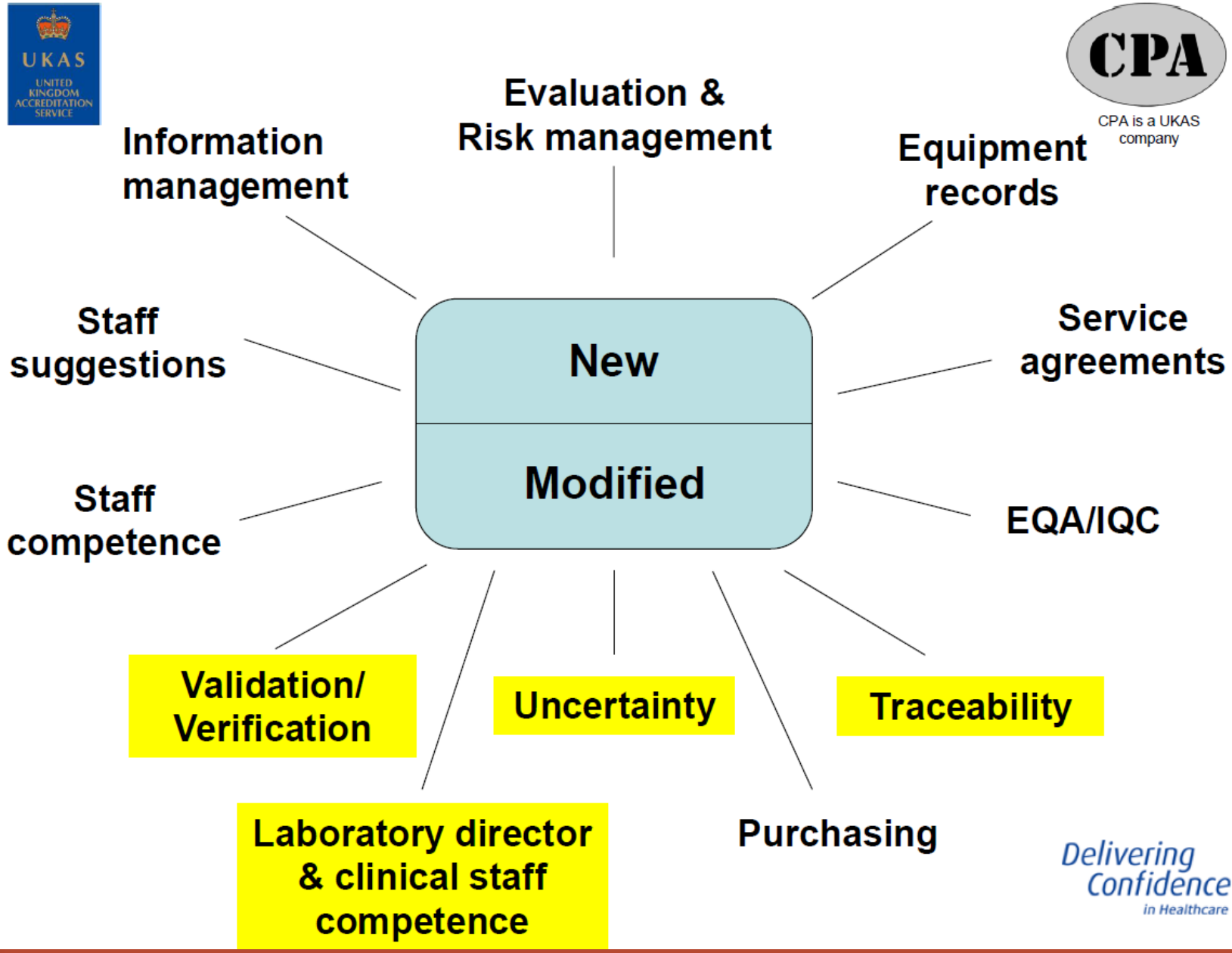
- Read the standards & perform a gap analysis
- Talk to others especially local departments
- Prepare your evidence and documentation, compliance must be demonstrated
- Ensure you are clear about which tests you want accredited
- Keep on track with the application and pre-visit documentation


UKAS
UNITED KINGDOM ACCREDITATION SERVICE
CPA
CPA is a UKAS company
Information management
Evaluation & Risk management
Equipment records
Staff suggestions
New
Modified
Service agreements
Staff competence
EQA/IQC
Validation/ Verification
Uncertainty
Traceability
Laboratory director & clinical staff competence
Purchasing
Delivering Confidence in Healthcare

Verification and Validation

- Laboratory is responsible for undertaking verification of all examinations
- There is no requirement to repeat the work done by the manufacturer but the laboratory must have confidence in the performance claims made
- Methods that have been in use for some time need to review current date to demonstrate clinically appropriate This could be a report on performance using, EQA, IQC, verification data etc. and should include a rationale/justification as to why it is fit for purpose
- Acceptance against defined criteria
- CE marking doesn't give you complete traceability of reagents and by itself does not confer fitness for purpose

Traceability of calibration

- Clause: 5.3.1.4
- When equipment directly or indirectly affects results
- Verification at defined intervals
- Records of metrological traceability of calibration standards
- Manufacturer data may or may not be sufficient
- Provenance of reference materials
- Where traceability not possible/relevant, other means of providing confidence in the results required

What needs to be traceable?

- Equipment; pipettes, balance spectrophotometer, temperature etc. (ISO 17025 or equivalent)
- Method calibrants; traceability to a reference material or method. (ISO 17511)

Assessor issues

- Labs fail to decide on what requires a traceable calibration and what doesn't.

  If there is a critical aspect to the use of the equipment then a traceable calibration is usually required. There is sometimes an insufficient awareness of what the calibration company is providing.

- There is sometimes a failure to review as acceptable calibration certificates, QC certificates etc.

  For example, pipette calibration certificates should be reviewed and accepted as ok by the lab based on the uncertainty stated. Does this meet the labs requirement?

- Traceability of calibrators not always established by the laboratory

Uncertainty of measurement

- Laboratories shall determine uncertainty of the result if the examination procedure is quantitative.
- The mechanism to quantify this should include all/any pre examination, examination and post examination aspects.
- If a result is not numeric i.e. qualitative, all aspects of the process will need to be reviewed to establish if there is a measurement step e.g. temperature, weights, volumes to determine the result.

  For example, was a limit of detection established in order to issue a ‘not detected’ result?

Uncertainty of measurement

- Includes intermediate precision and bias.
- Beware of using inappropriate formula! Calculation, table and time scale to update
- To use in a clinical context, uncertainty may be combined with intra-individual variation, but this is not a feature of the Standard

Assessment of competence

- Applies to all staff

  Laboratory Director, laboratory managers, technical, clinical advice
- Ultimately, the basis on which the laboratory feels an individual does have the competence to perform such tasks needs to be justified and how this meets requirements documented
- Defining an on-going competency assessment programme with defined acceptance criteria
- It would be expected that such an on-going programme is suitably robust to cover all of the staff member's scope of activity, at sufficient frequency.
- FRCPath status in isolation does not confer competency

Assessment of competence

- Consider why this is important and develop relevant competencies specific to the task

  Example - Duty Biochemist – Reading appropriate documents, attendance a DB clinical meetings, participation in cases for comment, undertaking a per-review of reports

- Review continuing education and effectiveness

- Produce evidence of the assessment, not a tick box

Suggested competency tools

- Qualification records, experience, knowledge and training
- EQA records (individual schemes)
- Appraisal records*
- Mechanisms to monitor on-going competency and associated records
- CPD relevant to the scope of practice
- Review of test reports
- Suitability of acceptance criteria

Other issues
Assessors perspective

Evidence

- Where does it say what you do?
- Why is it done that way?
- Do staff know what should be done and why?
- Where is this implemented?
- Where is the evidence that this is implemented?
- Is the evidence objective?
- What does the evidence tell you?
- Does it work?

Acceptance testing

- Responsible for reviewing and accepting as OK everything that goes on in the lab.
- May accept what a manufacturer will recommend without critically reviewing it and deciding that it meets their requirements
- Not clearly defining the approach to acceptance testing
- EG, establishing the timeframe for acceptance testing is up to the lab but-

  Need to consider risks of this and arrangements to mitigate them

Understanding the requirements of the standards

- Not fully understanding the requirements of the standard

  For example, lab internal auditors accepting verification of method evidence as satisfactory that does not meet the standard

Justifying your approach

- Whatever the lab decides, it needs to be able to justify its approach.

  If for example full metrological traceability is not possible

  What additional measures or steps have they taken to mitigate this and provide test assurance

  Examples - traceable 3rd party QC, enhanced surveillance/IQC/inter-lab comparison)

LIMS Verification

- LIMS and interface verification not documented.

  This has usually been done but not documented, evaluated or signed off

Suppliers

- Not including all key suppliers in their acceptance and review procedure
- Focusing on main equipment and consumables
- Accepting Trust systems for ordering without determining if the labs ISO requirements are met
- They have the required input to the process.

Internal Audit

- Not setting an audit cycle that covers the scope of testing and QMS sufficiently. (This is difficult if the scope of accreditation is large)
- The cycle for internal auditing should normally be completed in one year. It is not necessary that internal audits cover each year, in depth
- This may not mean auditing everything to the same degree but justifying what is done and how this provides confidence that systems are ok.
- Failure to document details of conformance sufficiently to indicate that the audit has been carried out to a satisfactory depth

Non-conformities

- The same problems continue to crop up as for the CPA assessments
- Only remedial action is taking to mitigate the effects on that one NC.
- Lack of consideration of root causes of the non-conformity
- Lack of subsequent effective corrective action to prevent re-occurrence is not well documented

Basic cycle of accreditation