Setting standards in food analysis

Confidence in food analysis through accreditation

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29th April 2010

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UKAS Overview

- **1 December 2009 – UK National Accreditation Body under Regulation (EC) 765/2008**
- **Operates under an MoU with Government (BIS)**
- **Accredits using internationally Standards (ISO/IEC 17025, ISO/IEC 17020 etc)**
- **Multi-lateral agreements in place with many National Accreditation Bodies**
- **Peer reviewed by international counterparts (ISO/IEC 17011)**

Drivers for accreditation

Mandatory accreditation

- **Food enforcement purposes**
- **Testing of animal by-products**
- **Testing under poultry orders and regulations**

Commercial and retail customers

Food related accreditation activities

- **ISO/IEC 17025: 119 food testing laboratories**
- **ISO/IEC 17043: 5 PT providers**
- **ISO Guide 34: 2 reference material producers**
- **ISO/IEC 17020: 11 inspection bodies**
- **EN 45011: 25 product certification bodies**
- **ISO/IEC 17021: 27 food safety management system certification bodies**

Agri-Food & Biosciences

- **Accreditation Manager**
- **2 SSAM**
- **7 Assessment Managers**
- **Assessors and technical experts drawn from industry and academic institutions**
- **750 Years of commercial testing and research experience**

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Assessors

- **A broad technical background**
- **Appreciation of emerging food related technologies & analytical techniques**
- **Up-to-date knowledge with food issues**
- **Ability to adapt to differing company cultures and practices**
- **Enquiring mind**
- **Good communication skills**

Fields of testing

- **Nutritional and labeling**
- **Adulteration**
- **Environmental and process contaminants**
- **Authenticity**
- **Microbiological (pathogens, spoilage organisms)**
- **Quantitative and qualitative…….**

Techniques

- **Atomic and molecular spectroscopic techniques**
- **Separation, mass spectrometric and isotopic techniques**
- **immunoassay**
- **Molecular techniques**
- **Radiochemical methods**
- **Sample preparation and decomposition methods……**

Method validation (1)

Proof that the intended method works

- **What is the purpose of the analysis?**
- **What are the results used for?**
- **how is the method validated (validation plan)**
- **What reference materials are used to assess trueness of results?**
- **Is the method specific (matrix effects, selectivity, specificity, interference studies)?**

Method validation (2)

- **Is there enough performance data to give confidence?**
- **Does the candidate method meet the performance criteria (precision, trueness, UoM, LoD, LoQ)?**
- **is there a validation report with a sign-off to confirm fitness for purpose?**
- **Is the SOP reviewed along with its validation regularly to ensure continued fitness for purpose, meeting the needs of the customers?**

Validation begins when all experimental conditions/

parameters for the analytical system have been optimised.

It is not done alongside method development.

Internal quality control

- **What is the system for quality control (CRM, IH, duplicate same or different analysts, blind samples, other means)?**
- **Is it satisfactory for method control and performance monitoring?**
- **Are QC data presented to enable trend analysis?**
- **What are the rules used for trend analysis**
- **Are the results repeatable and show statistical control?**
- **Are the action and warning limits set appropriately**
- **What is the basis for revising control limits?**
- **what actions are taken for outliers, reasonable?**
- **Are the data included in method review?**

External proficiency

- **What is the laboratory's policy?**
- **Is there a relevant scheme?**
- **Is participation level appropriate (frequency and distributions)?**
- **Are the results reviewed, anomalous results investigated to assess impact on reported results and validity of the method?**
- **What are the root causes of PT failures?**
- **Is the trend good or deteriorating?**
- **Does the lab evaluate the PT providers?**

Measurement uncertainty

- **A significant parameter that needs to be established at method validation stage**
- **Value need to reflect the capability required of the method and industry expectation**
- **It is a requirement to report uncertainty:**
    - **On request**
    - **If relevant to the interpretation of the result**
    - **If result is close to a specification/threshold value**

Organisation
Legal status
Resources
Impartiality & integrity

Accommodation Environment Facilities

Management
Internal audit
Review
Supervision
Documentation & control
Continuous improvement

Service to Customers
Contract review
Confidentiality

Equipment
Measurement traceability
Reference standards/materials

Result
Reporting
Uncertainty
Quality assurance
Opinions & Interpretations

Method
Fitness for purpose
Validation

The Test

Personnel
Training
On-going competence

Services & Supplies
Subcontracting
Purchasing

Handling of Test Item

Control of Non-conforming Work
Cause analysis
Corrective action
Preventative action
Complaints

Records
Technical
Management system

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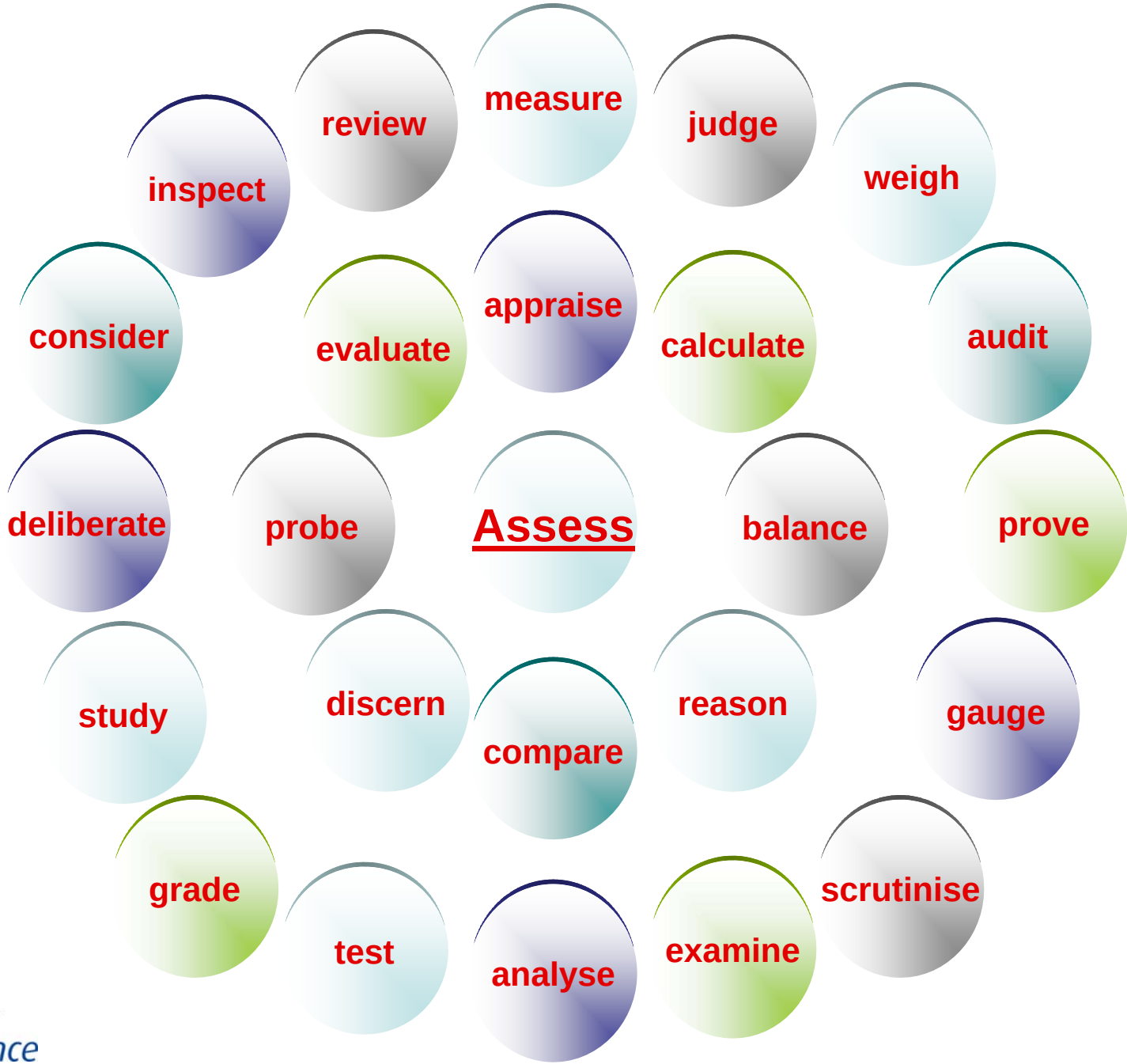

UKAS
UNITED KINGDOM ACCREDITATION SERVICE

Delivering Confidence

Confidence

To have belief in the output the input variables must be credible

- **Laboratories**
- **UKAS**
- **UKAS staff and assessors**
- **Resource**

Confidence (laboratories)

- **Conformance to ISO/IEC 17025**
- **CPD, knowledge management**
- **Use recognised and validated methods that demonstrate fitness for purpose**
- **Calibrated and maintained equipment**
- **Measurement traceable to national, international standards**
- **Effective monitoring systems (EQA, IQC, internal audits)**
- **Regular surveillance/reassessment, unannounced visits**

Confidence (UKAS)

- **Conformance to ISO/IEC 17011**
- **CPD, knowledge management**
- **Use effective assessment tools**
- **Peer evaluation by EA**
- **Efficiency review by BIS**
- **Effective monitoring systems (e.g., internal audits)**
- **MLAs**
- **Customer satisfaction surveys**

Confidence (UKAS staff and assessors)

- **AMs – monitored at least annually and evaluated at regular intervals**
- **Assessors - monitored at least annually and evaluated at three yearly intervals**
- **Smart technical competence criteria**
- **Feedback from laboratories**

Confidence (resource)

Sufficient income?

- **Enormous effort to establish and maintain an accredited System**
- **Worries about - Risk based approach, due diligence testing, best value, the means to drive down costs**
- **There is a limit to getting more for less**

Confidence

To have belief in the output the input variables must be credible

- **Laboratories**
- **UKAS**
- **UKAS staff and assessors**
- **Resource**

When we put these ingredients together, we can have the confidence in the quality of our cake

21st century assessing (UKAS)

- **Continually enhance service delivery and technical competence**
- **Responsive to customer and technological changes**
- **Communicate the importance of accreditation**
- **Work closely with stakeholders**
- **Continually enhance assessment tools and methods**
- **Provide value for money**

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21st century assessing- laboratories

- **Revision of ISO 17025**
- **Continued emphasis on fitness for purpose testing including customer requirements?**
- **Traceability for chemical measurements (IUPAC)?**
- **Development in accreditation for certified reference material producers and proficiency scheme providers?**
- **Alignment with BS EN ISO 9001:2008?**

21st century assessing (customers)

- **Contract on the basis of quality**
- **Help laboratories to clarify purpose**

ISO/IEC 17025 accreditation

Is :-

- **about confidence, assurance, integrity, technical competence, using up-to-date and explicit knowledge (relevant publications, regulations, best practice), informed decisions**
- **Integrated with business**
- **A focus for learning, sharing knowledge**

Not :-

- **about stifling creativity nor putting obstacles in place**

Definition

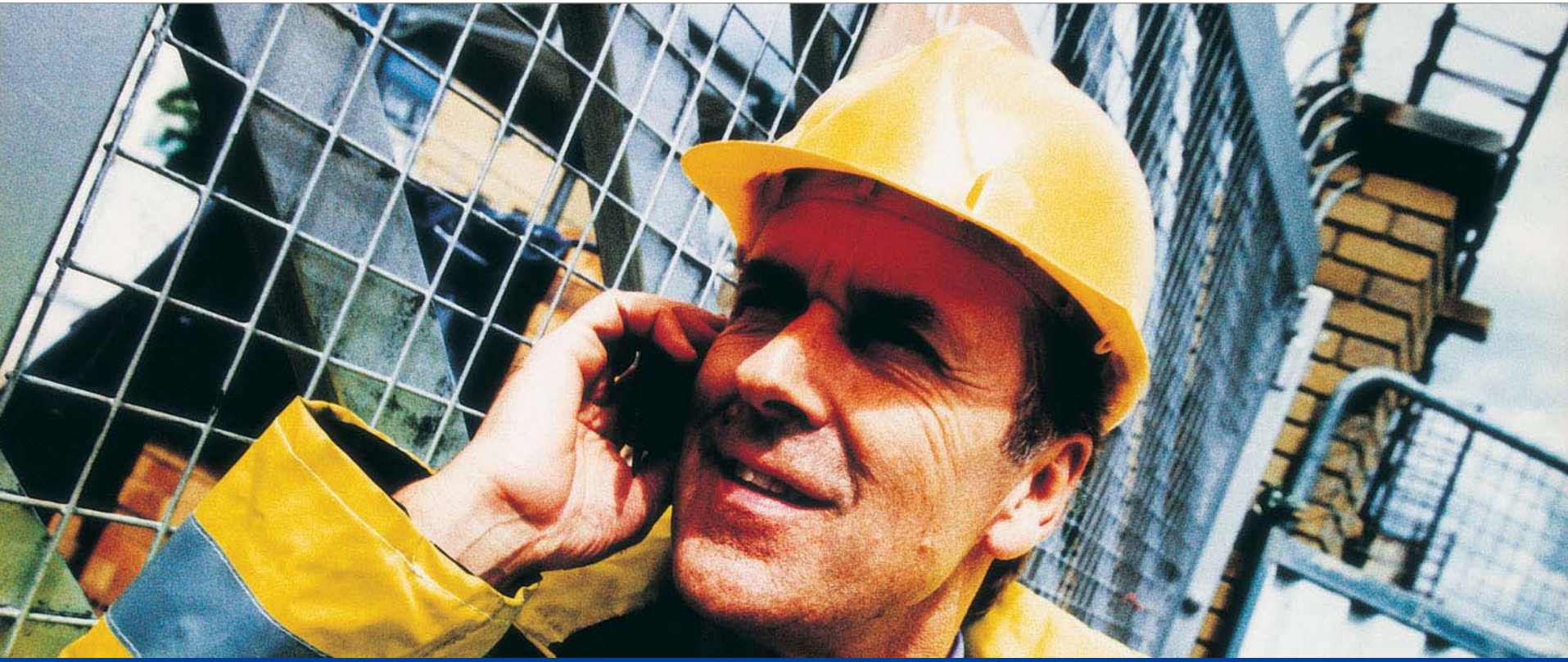
Accreditation to ISO/IEC 17025

- **Testing - recognition that a laboratory is competent to conduct the tests within their scope of accreditation**
- **Opinions and interpretation - recognition that a laboratory has the requisite knowledge and expertise to interpret results on a sound technical basis**

Certification to ISO 9001

- **Recognition that a laboratory's processes are under control and implemented in a consistent manner**

Slide title



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