



# Review of ISO/IEC 17043

An Accreditation Perspective

EURACHEM/CITAC/EQALM PT - Berlin Oct 14

*Delivering  
Confidence*



# Introduction

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Delia unfortunately not able to attend however she has developed a presentation which Ian Mann (SAS) will deliver

Any queries about the content can be sent to [delia.geary@ukas.com](mailto:delia.geary@ukas.com)



# Introduction

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## **Objectives of this presentation:**

Brief update on UKAS and accreditation of EQA/PT providers

Representation of accreditation i.e. accredited scope of different providers and presentation by accreditation bodies



# Introduction (ctd)

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- Objectives of schemes and role in assessment
- Some challenges faced during assessment



# UKAS and accredited providers

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- UKAS has 16 EQA (PT) providers accredited to ISO/IEC 17043 with approximately 19 applicants in progress
- Accredited providers come from a range of sectors
- Applicants are mainly from medical sector



# Scope of accreditation

## One type of UKAS representation

<b>Materials/Products</b>	<b>Scheme Name/Type of Test/Properties Measured</b>	<b>Scheme Protocols/Procedures/ Techniques Used</b>
Stack emissions gas simulator	Stack emissions gas measurements of: carbon monoxide nitrogen monoxide sulphur dioxide volatile organic compounds (propane) oxygen	Known value - details of the scheme are included in QPAS/B/551



# Scope of accreditation

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## Another type of UKAS representation

<b>Materials/Products</b>	<b>Scheme Name/Type of Test/Properties Measured</b>	<b>Scheme Protocols/Procedures</b>
WASTEWATERS AND EFFLUENTS - INORGANIC	AQUACHECK Chemical analysis	Details of the scheme including the specific analytes are documented in the Aquacheck scheme description



# Scope of accreditation

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DAkkS – free text on website

‘....physical and chemical analysis of water, sediments, soils and old neglected deposits of toxic waste as well as waste’ (translated)





# Scope of accreditation

## *American Association for Laboratory Accreditation*

<b>Lab Discipline</b>	<b>Survey Code</b>	<b>EQA Survey</b>	<b>Frequency per Year</b>
Microbiology	BACT	Bacteriology	3
	BACT CD	Bacteriology C.difficile	2



# Scope of accreditation

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COFRAC includes specific detail associated with the scope in an Annex (available on the COFRAC website) – resembling type one UKAS presentation



# Objectives of accreditation

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What are we accrediting when we accredit an EQA provider to ISO/IEC 17043? A generic reference to their ability to provide schemes for a particular purpose or a defined list of components?

Obviously we are assessing and looking for competence but how do we represent this?

Are there any benefits to the provider to accredit a 'fixed' and detailed scope?



# Objectives of accreditation

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Many providers need flexibility within the accreditation and its representation to develop and improve their schemes – sometimes at short notice



# Objectives of accreditation

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## **ISO 17011**

**‘7.2** Application for accreditation - c) a clearly defined, requested, scope of accreditation

**7.9.4 /7.9.5;** requirements for ‘certificates’ do not include EQA providers however more general requirements still apply such as defining the scope



# Objectives of accreditation

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## **ISO 17011**

### **8.2 Obligations of the accreditation body**

‘c) scopes of accreditation, condensed and/or in full. If only condensed scopes are provided, information shall be given on how to obtain full scopes.’



# Objectives of accreditation

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## **ILAC-G18:04/2010**

‘Guideline for the Formulation of Scopes of Accreditation for Laboratories’

General approach to accrediting fixed and flexible scopes of accreditation



# Objectives of accreditation

## EA 4-19 (DRAFT): Guidelines for ABs on the contents of the scopes of accreditation for PT providers

PT Scheme Identification	Technical field	Test Item level 1	Test Item level 2	Property level 1	Property level 2	Date of introduction to scope
PT Chem	Beverage Testing	Alcoholic beverages	Beer	Metals	Iron	01.11.2012

Four cases depending on what is included in the scope:  
Property level 1 and 2, test item level 1 and 2 in scope: Fixed scope  
Property level 1, test item level 1 and 2 in scope: Flexible scope  
Property level 1 and 2, test item level 1 in scope: Flexible scope  
Property level 1, test item level 1 in scope: Flexible scope





# Objectives of the EQA scheme

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## **ISO /IEC 17043:**

4.4.1.3 'The proficiency testing provider shall document a plan before commencement of the proficiency testing scheme that addresses the **objectives**, purpose....'

4.4.4.1 'Statistical designs shall be developed to meet the **objectives** of the scheme,....'



# Objectives of the EQA scheme

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EQA providers need to state the objective of the particular scheme and include in the scheme planning

Must be available to participants to enable an informed choice

Increasingly a focus of assessments as in 'fitness for purpose'



# Objectives of the EQA scheme

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Also a focus of ISO 15189 and ISO/IEC 17025 assessments to ensure that the lab has a system in place to evaluate their own performance in context

Laboratories under assessment to ISO/IEC 17025 or ISO 15189 will need to demonstrate that they review the potential impact of their performance on 'customers' results.



# Subcontracting

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## **5.5 Subcontracting services**

5.5.1 'When a proficiency testing provider subcontracts work, the proficiency testing provider shall demonstrate that the subcontractors' experience and technical competence are sufficient for their assigned tasks **and** that they comply with the relevant clauses of this International Standard and other appropriate standards.'



# Subcontracting?

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What about the situation of a provider having an 'in house' service provider e.g. a laboratory?

Generally these are unaccredited

Are they covered by the Quality management system of the provider i.e. do they have direct control over the 'service provider'?



# Subcontractors

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The assessment to ISO 17043 has to conclude that any subcontracted activities are being conducted appropriately and that the provider has suitably reviewed the labs competence based on relevant criteria

The AB may or may not visit the subcontractor (internal or external) – depends on what the provider has done to establish competence, and participant results



# Conclusion

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From a very small sample of ABs there are apparently varying degrees of flexibility in the assessment and the representation

If flexibility is applied in the scope then we need to be sure that the providers are assessed with this in mind

Objectives of accreditation and EQA providers are linked and providers should ensure that the objectives are clearly defined and fit for purpose



# Conclusion

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Participants' own evaluation of their performance will be based at least partly on information provided by the provider and linked to the established objectives

Subcontracted activities need to meet the needs of the provider and may or may not follow the procedures the subcontractor routinely uses. The provider will need to establish that the methods used are appropriate for their requirements. Competence and knowledge needs to be established.





# Thank you!!

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A very big thank you to Ian who has stepped in at the very last minute.

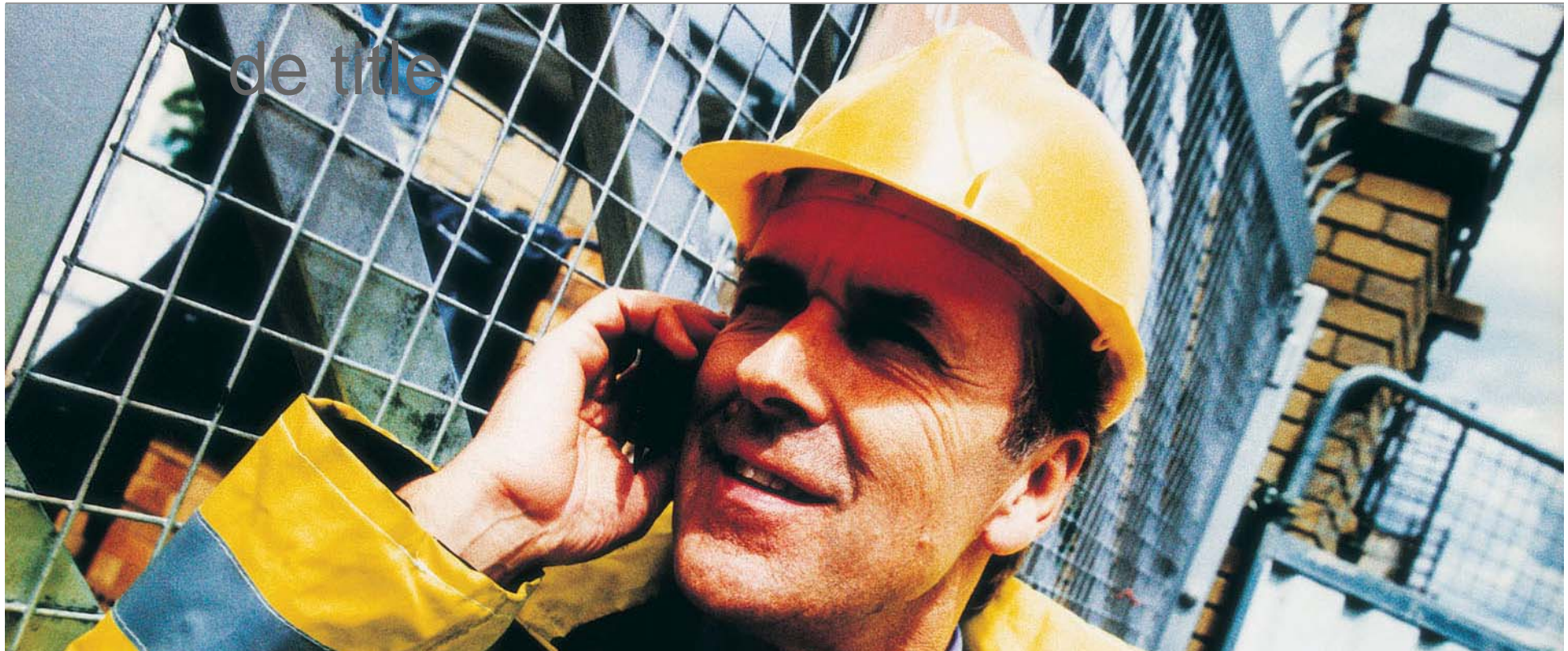
If you do have any queries please do contact me at [delia.geary@ukas.com](mailto:delia.geary@ukas.com). I would be happy to answer (if I can!) any questions posed about the content.



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