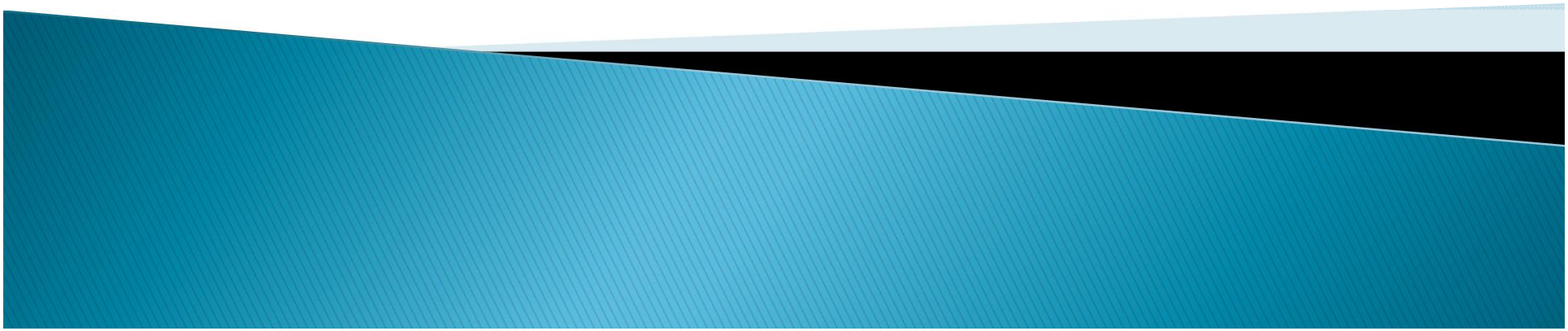
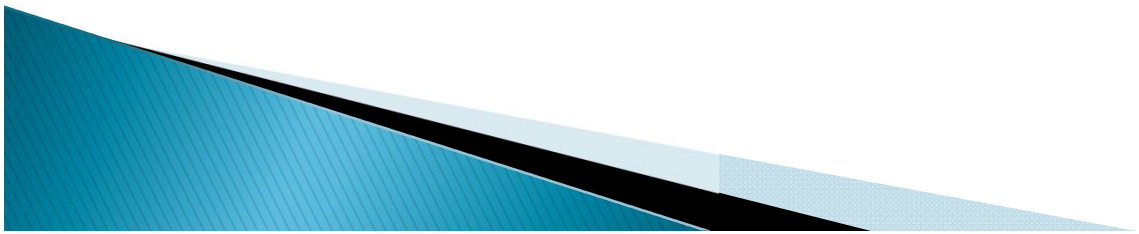
Do transfusion laboratories need to be accredited by UKAS when they are already regulated by MHRA?
Setting the scene

Richard Haggas
Blood Transfusion Quality Manager
Leeds Teaching Hospitals NHS Trust



Background

- MHRA
  - Oversees compliance with Blood safety and quality regulations
  - Annual compliance report submitted by each transfusion laboratory. Inspections if deemed necessary
  - Inspects QMS using EudraLex – Volume 4 Good manufacturing practice (GMP) Guidelines.
- UKAS
  - Only laboratory accreditation body in the UK
  - Checks for compliance with: Medical laboratories – Requirements for quality and competence (ISO 15189(2012)
  - Regular on-site assessments.



UKAS and ISO 15189

- ISO 15189 (2012) is intended to cover laboratories providing diagnostic test results to clinicians.
- UKAS only accredits tests performed on samples
  - Blood grouping, antibody screening and identification, crossmatching, Kleihauer…etc.
  - It does not accredit for other activities; thawing of components, issuing components…etc.
- Includes aspects not associated with the laboratory.
  - Clinical advice
  - Pre testing procedures e.g. phlebotomy
- Involves several assessors over several days.
  - Includes peer assessors

MHRA and BSQR

- BSQR covers blood transfusion laboratories only and is intended to ensure safe components are provided to patients.
- MHRA is not a accreditation body.
- Inspection includes all laboratory aspects of component provision
  - Thawing of components.
  - Issue of components.
- No regular inspections.
- Usually involves one inspector for one day

Standards

- Chapter 1 Quality System
- Chapter 2 Personnel
  - Organisational structure
  - Responsibility and authority
  - Training and competence
  - Hygiene
- Chapter 3 Premise and Equipment
  - Premises
  - Storage – cold chain
  - Equipment and Materials
  - Validation, Qualification and change control
  - Calibration
- Chapter 4 Documentation
  - Policies
  - Procedures
  - Forms
- Chapter 5 Production *(Testing)*
  - Calibration
  - Reagents and Materials
  - Testing
  - Preventative Maintenance
  - IT Systems
- Chapter 6 Quality Control
- Chapter 7 on Outsourced activities
  - Service level agreements
- Chapter 8 Complaints and Product Recall
- Chapter 9 Self Inspection

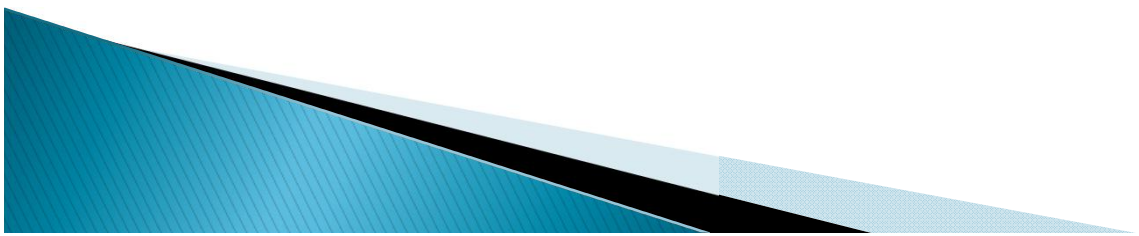
- Annex 15 Qualification and validation

EudraLex – Volume 4 Good manufacturing practice (GMP) Guidelines.

ISO 15189 (2012)

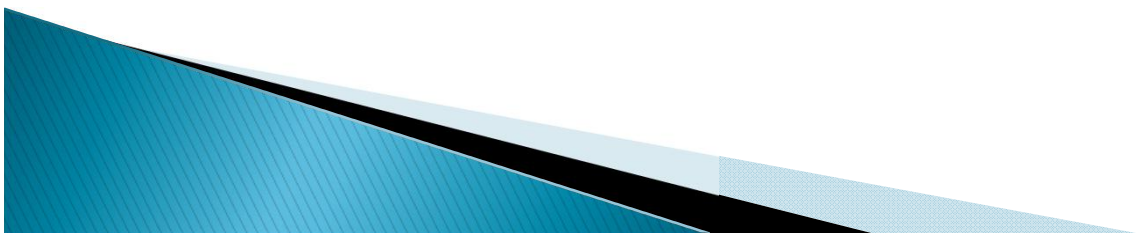
Common areas

- Quality management system
- Documentation
- Training and competence
- Testing
- Service level agreements
- Self inspection / audit
- Premises



Areas of difference / contention

- Validation / verification / qualification
- Corrective and preventive action
- Calibration
- Uncertainty of measurement



Nomenclature issues – Validation and CAPA

- Qualification (IQ and OQ)
- Qualification (PQ) and Validation

- Corrective action
- Preventive action

MHRA Terminology

- Validation

- Verification

- Remedial action
- Corrective action
- Preventive action

UKAS Terminology

Calibration

- Comparison of a measurement (e.g. weight, temperature, time) given by equipment to that of a known standard which is traceable to a recognised source.
- ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories.

Calibration

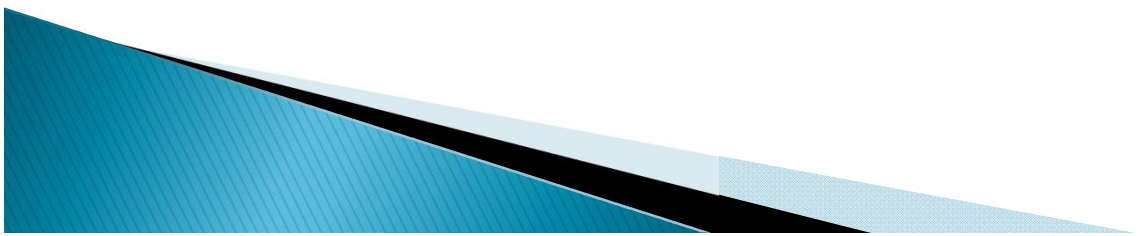
- Equipment used to perform a check is certified to ISO17025
- Does not require the piece of lab equipment to be certified itself

- Equipment is not calibrated unless the equipment is certified as calibrated to ISO17025

MHRA	UKAS

Uncertainty of measurement.

- Only required by UKAS.
- Really designed to give uncertainty of measurement for measured quantities (e.g. ±2 SD).
- Need to evaluate all possible sources of error including.
  - random and systematic effects from human operators
  - metrological characteristics of the equipment used.
- Very difficult to produce a value for uncertainty for most blood transfusion results.



The good(ish) news

- MHRA is working with UKAS to understand where there may be commonalities in approach which might lead to a reduction in burden for HBB.

- Early stages of discussion, and no timelines have been agreed.

Why we should have both

Mallika Sekhar

Royal Free Hospital

SHOT 2015

- **Headline: Laboratory errors have increased from 334 in 2014 to 455 in 2015**
- **Deaths related to transfusion reported in 2015 n=26**
- **Major morbidity (serious harm) reported in 2015 n=166**
- **Near miss incidents: Total 288 possible ABO-incompatible transfusions**

- MHRA/SHOT
- UKAS/ISO
- NICE
- BCSH

is displayed, click here to view it in a web browser.
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Kingdom Accreditation Service

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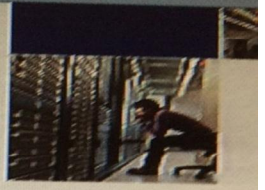
CELEBRATING 21 YEARS 1995–2016



A new development in healthcare accreditation

West Midlands Quality Review Service (WMQRS) celebrate their achievement of becoming the first peer review service to gain UKAS accreditation as an inspection body.

Read more

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CELEBRATING 21 YEARS 1995–2016

UKAS Customer Days 2016

UKAS will be holding a series of Customer Days as part of the programme of celebratory events for our anniversary year and dates have been arranged for December 2016.

Read more

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In this issue

The Chancellor opens new UKAS Headquarters

On Friday 16th September UKAS held an office opening ceremony with The Rt Hon Philip Hammond MP, Chancellor of the Exchequer in attendance.

Read more

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Assessor Opportun

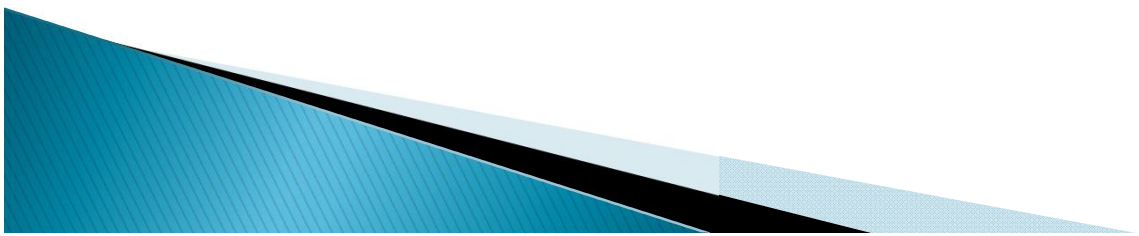
Training Courses »

Events »

Vacancies at UKAS

d email messages from this person.

Martin Maley
RCI Head of Laboratory
NHSBT Newcastle

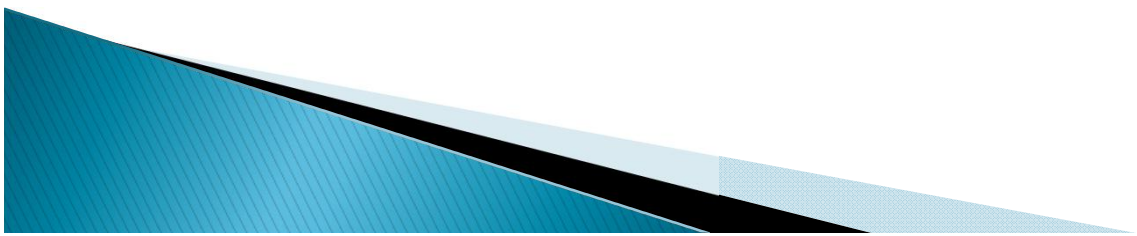


RCI (NHSBT) Perspective

- My own personal experiences
- Spoke to QA colleagues
- “You can’t say that”
- MHRA v UKAS in RCI
- Differences
- Value

Differences – Time

- Time allocated to RCI lab
- 2-3 hours for us and H+I
- Sticking to schedule
- Not covering all areas of NHSBT (MHRA)
- Thoroughness

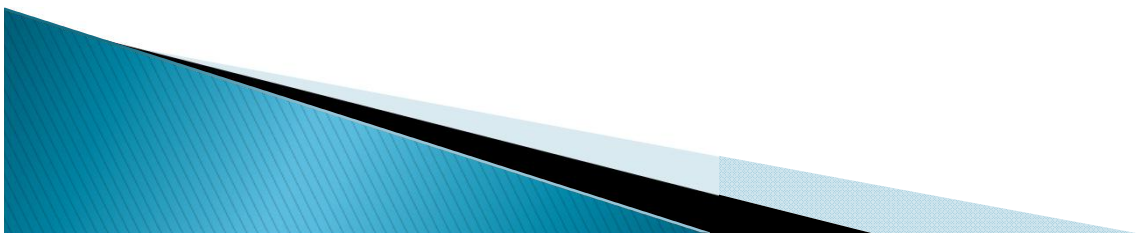


Differences – Assessors

- Areas inspected
- Assessor practices / specialities
- Same MHRA assessor = same areas audited
- “I’m not a serologist but…”
- Assessor continuity
- Links in with time

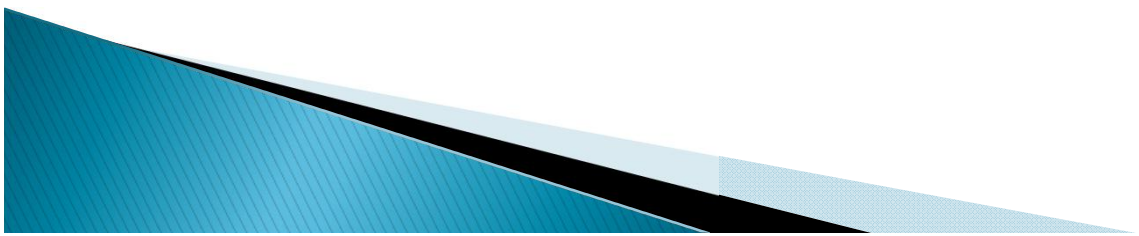
Differences – Discussion

- Discussion of NCs at the time they are found
- Discussion of NCs at the end of the session
- Closing meeting
- Responses to findings (time)



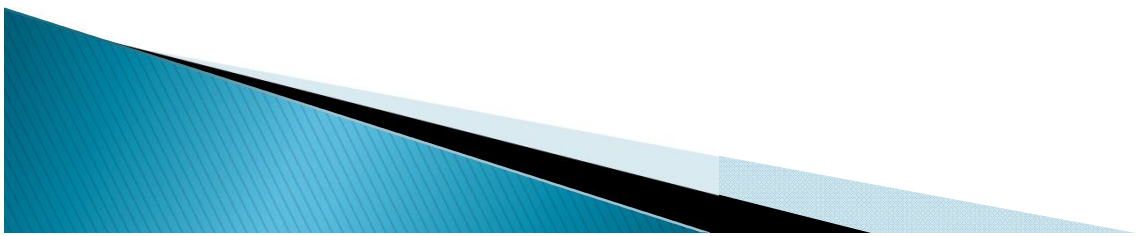
Differences – Findings

- Raise nationally (UKAS accreditation applied for nationally as a function)
- Findings ‘in the pocket’
- Findings should be constructive



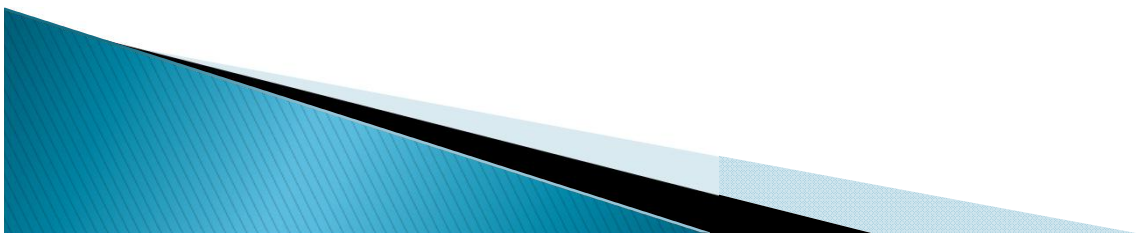
Differences – Value

- MHRA has not added value or even given a feeling that it will add value
- UKAS adds value, highlights non-compliance with ISO15189



Differences – Auditee

- Auditee confidence
- Feeling of contribution to continuous improvement culture
- Should be put at ease
- Creates culture of openness

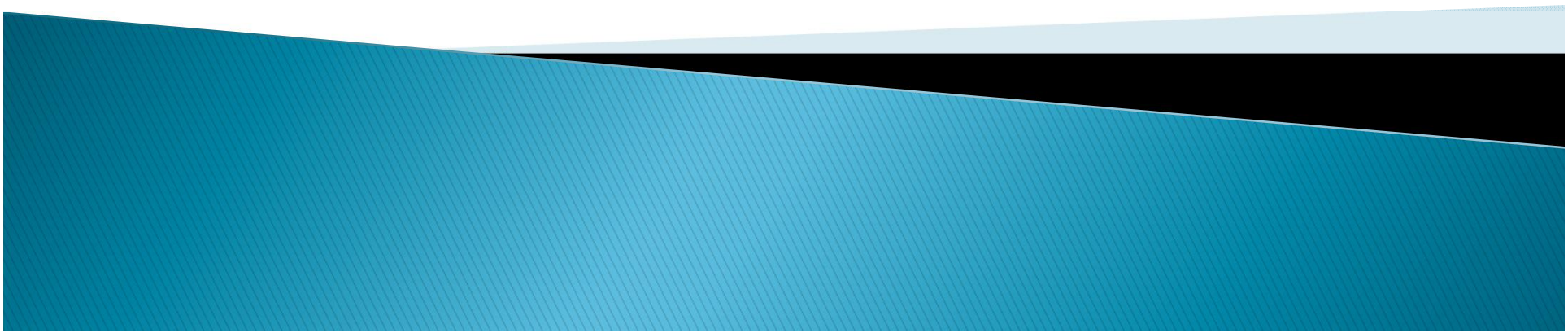


Conclusions

- MHRA and UKAS both have a huge role to play
- RCI – UKAS adds more value, is more thorough, feels part of the CI culture
- If UKAS cover all aspects of RCI that MHRA would want to assess, then MHRA can concentrate on other areas of NHSBT
- Discussions are at an early stage – but are happening

Why the MHRA is better than UKAS for Hospital Blood Banks

Richard Haggas
Blood Transfusion Quality Manager
Leeds Teaching Hospitals NHS Trust



What is the purpose of a hospital blood bank?

- Main role: To provide safe blood components and products for patients
  - This is the purpose of blood safety regulations
- Minor role: To provide diagnostic tests results
  - FMH estimation
  - DAT
  - Ante-natal blood grouping and antibody screening
- Hospital blood banks have more in common with a pharmacy than with other pathology laboratories.

ISO 15189 accreditation

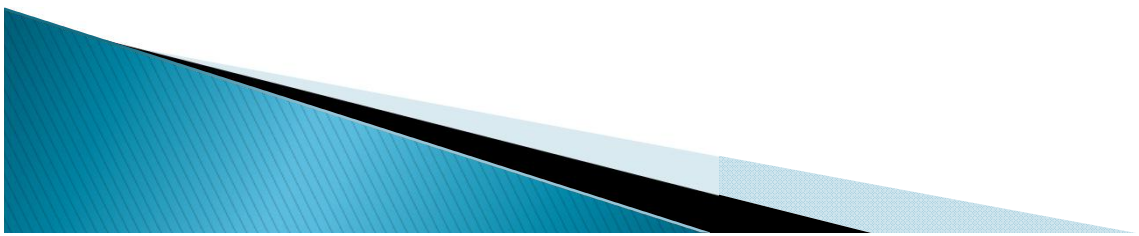
- Does UKAS accreditation add value over and above BSQR compliance and improve the Hospital Blood Bank?
- A lot of extra work to ensure compliance

Calibration

- UKAS: mapping of fridges should be done using17025 certified probes as the storage temperature is critical.
- Requirement for storage is 2 to 6ºC; generally accepted that checking should be with an accuracy of +/- 0.5ºC
  - At 2ºC ±0.5ºC is within 25%
  - At 6ºC ±0.5ºC is within 8%
- MHRA acceptance of probes checked with a 17025 calibrated probe would seem reasonable.

Uncertainty of measurement

- We should know what causes variation in our testing
- Do we need to quantify it?
  - We need to show that we are doing things to reduce its influence
- Are we doing things to check the accuracy of our results?
  - QC
  - EQA
  - Comparability checking

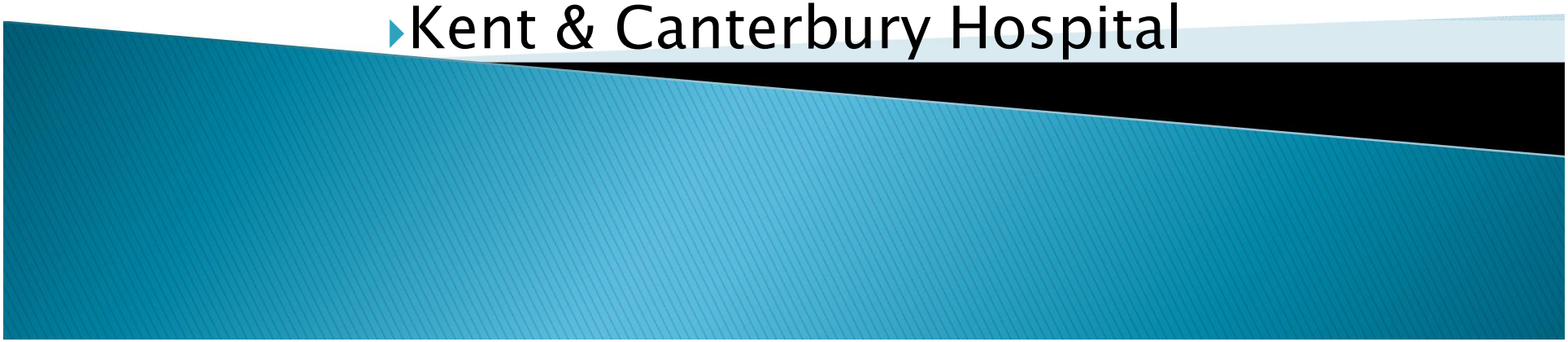


Pathology accreditation approach

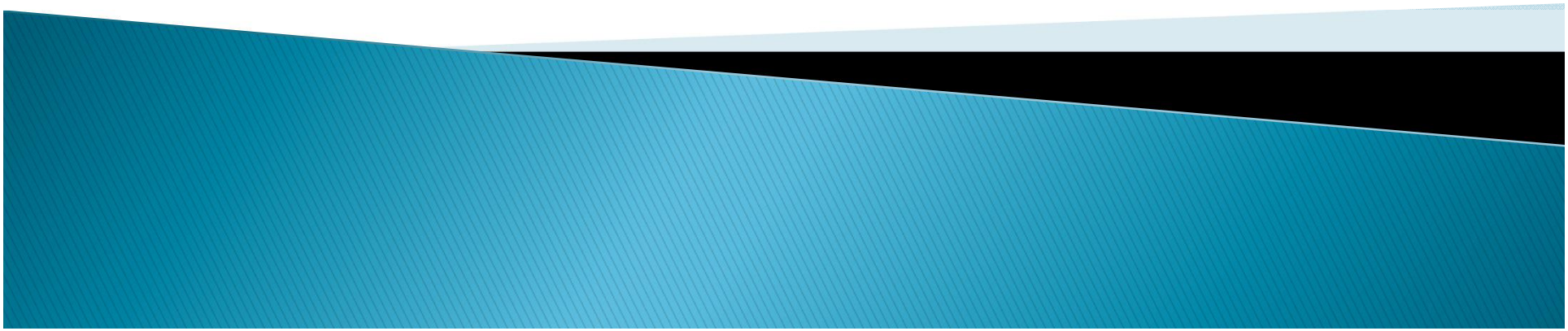
- The rest of the Pathology labs could remain accredited
- Don’t include blood bank tests in your UKAS application.

What *value* is this duplication of work adding?

- Catherine Lorenzen
- Chief Biomedical Scientist
- Kent & Canterbury Hospital

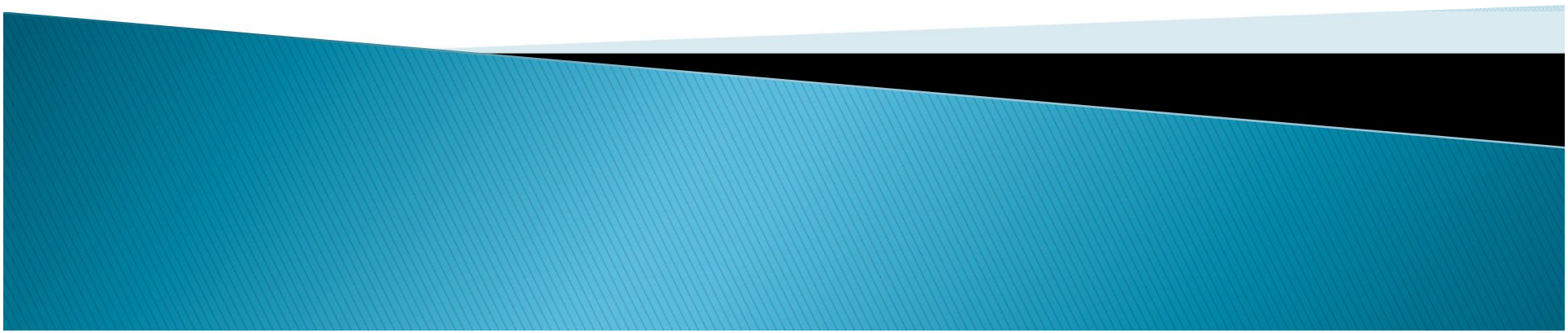


- *Multiple* inspections are a waste of resource!
  - We are supposed to be making our processes: more efficient, less costly, more effective, streamlined…. even profitable!



Multiple inspections cause frustration and could they cause a decrease in Quality?

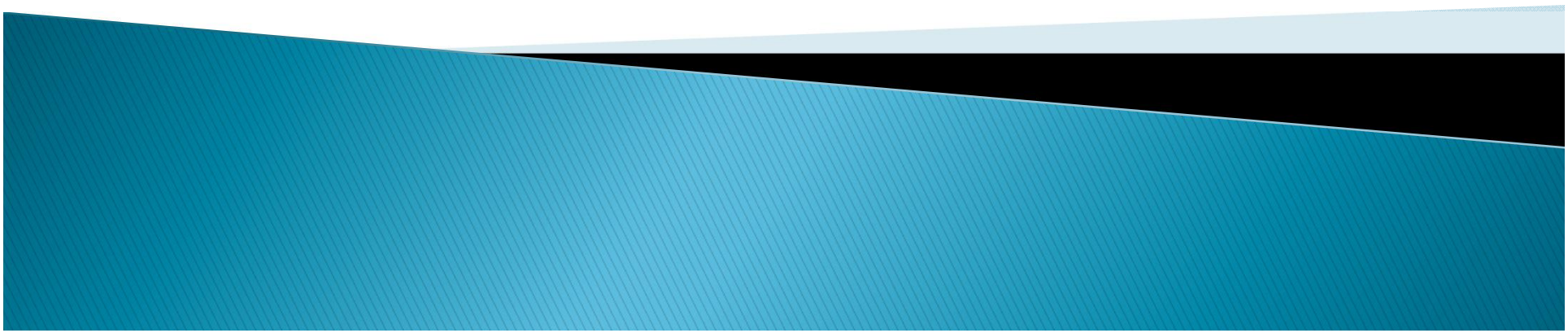
Are we spending so much time on proving how we do things that we no longer do them as efficiently as we could?



When we ask for a second 'check' sample in BT it's to prove we got the right one, first time

When we are inspected isn't it better to get it *right* first time?

We shouldn't need a second check by another technique…..



MHRA and UKAS need to work together for all of us to prevent unnecessary work and expense

Albert Einstein said ‘The definition of insanity is doing something over and over again and expecting a different outcome’