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ISO 15189:2012

MYTHS or are they?

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Myths

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Let’s examine them

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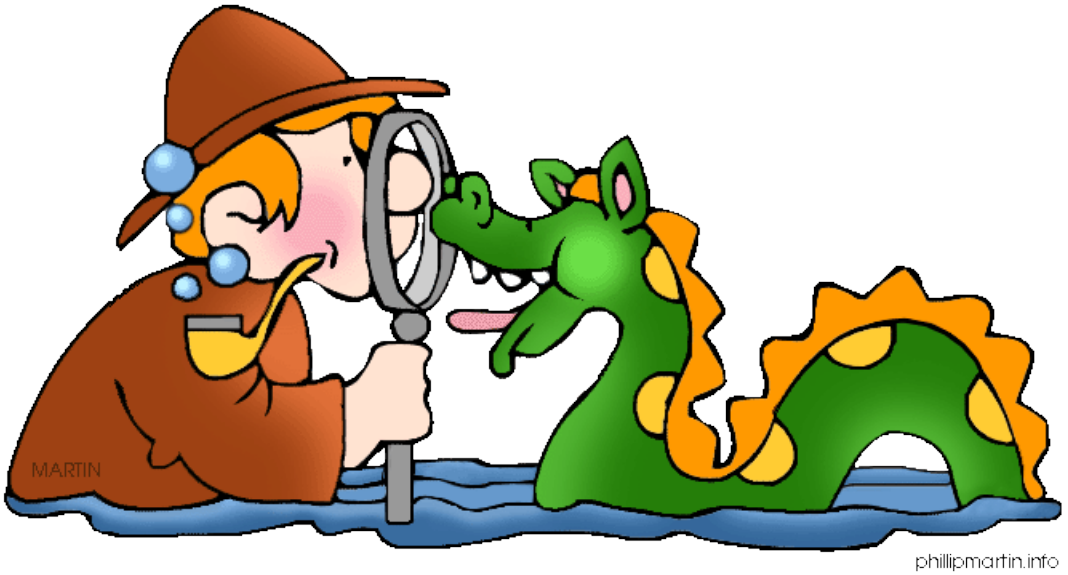

Content of presentation

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- How much of 15189 applies to BT?
- Evaluation of suppliers
- Metrological traceability
- Biological traceability
- Uncertainty of measurement
- Auto release of results
- SOPs
- Content of SOPs, U of M, PA and limitations of tests
- EQA ILC and Comparabilities
- Compliance with 15189 and do what you say you do
- Confidence and justification of processes

4.1.1.1

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MYTH-

Not all of the clauses in 15189 apply to BT

- Oh yes-
- “the lab shall meet requirements of this standard”

4.4, 4.5, 4.6 and 5.6.3

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MYTH

We need all our suppliers (EQA, Referral) to fill out questionnaires we send them.

- It is up to the lab to evaluate and monitor all their suppliers, for services and equipment / reagents, including EQA suppliers
- SLA s are required by the lab supplying/providing the services

5.3.1.4

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MYTH

We do not have anything that we measure, so we cannot, or do not need any traceability of calibration

- Metrological Traceability of **calibration** of critical parts of your process- BT analysers
- Temp at 37°C (waterbaths/ heating blocks/incubators)
- Temp at 2-8° (fridges)
- ? Centrifugal speed/force

5.3.1.4

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MYTH- there is no traceability of Fya controls, so it does not apply.

- Controls or calibrators?
- What is it you are detecting/measuring ?
- What does your analyser/ eye detect?
- How can you prove this measurement point ?
- ? Validation/ verification

5.3.1.4

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"Where not possible or relevant for metrological traceability- other means for providing confidence shall be applied"

- Certified reference materials
- Examination or calibration by another procedure (including comparabilities)
- Mutual consent standards or methods
- Use of 3rd party controls
- Evidence of absence of any non-conformances
- Evidence of absence of any poor performance in EQA/ILC

Pooled together in report/justification/providing confidence.

5.5.1.4

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Myth-Uncertainty of measurement cannot be worked out/does not exist for blood groups, it is only a + or-

- Manual- look at your process- there WILL be steps in there that involve temperature, dilution, cell %, time, volume etc.- work out what could go astray to give you a wrong result or a different result (e.g 2+ not 3+), and will give you an idea- this should be documented somewhere to show that you have considered these. Operator variability can play a big part- could ask staff to perform manual testing and compare results
- D,s could be fun!!

5.5.1.4

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Blood grouping / XM UoM

- Same applies to your process/procedure- you need to know the steps that could go wrong in this –
- Discrepancy boxes- how many can the analyser not read ?
- Compare same samples to other analysers

Query

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Text on the standards has limited definition but understanding is that UKAS are seeking greater confidence in uncertainty of measurement such as training of staff, external QA, calibration of pipettes. I have been asked that all additional things go towards extending the confidence but perhaps are not all required for uncertainty of measurement. I may be totally incorrect. And I have also been asked should all these details be on a report or made available to customers as a user guide or be presented when the customers seek this information

4.11

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- Preventative action includes all you put in place to ensure your processes give you the correct result- good one is Change Control.
- You put these in to prevent problems and erroneous processes, includes training
- Limitations of test are things you can mitigate
- Uncertainty is the inherent variation- can be mitigated as much as possible with critical measurement steps having traceable calibrated equipment.

5.5.1.4

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- Uncertainty is all about how much confidence you have on your test result being the right one and how would a different one impact on patients results for diagnosis /treatment.
- This info should be made available ON REQUEST by users.

5.5.2 and 5.9.2a

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MYTH

We need image analysis calculations (on BT analysers)

- 5.5.2-You define the reference intervals and clinical decision values- how are the grading's set?
- 5.9.2a-criteria for auto selection and reporting are defined …
- 5.6.4-Comparibility studies-
- 5.5.1.2-Verification by lab

5.5.3

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SOPs are becoming unwieldy and unusable

- SOPs should contain requirements of 5.5.3. if NA, then say its NA
- Use of laboratory instructions are fine as long as subject to labs document control procedure

5.6.3 and 5.6.4

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MYTH- UKAS require all platforms to be registered in an EQA scheme

No, we don't- as long as…

- EQA
- ILC
- Procedures giving like results require to be compared somehow- same comparability studies could do

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5.5.3 and 4.9

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- MYTH
- NC may be given because the lab is not doing what it says it is doing to meet a standard, rather than that they are not actually meeting the standard itself.
- Both- say what you do to comply with 15189 , and do what you say.
- Labs have confidence and justification in own processes.

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Thank you for your attention

Any Questions?