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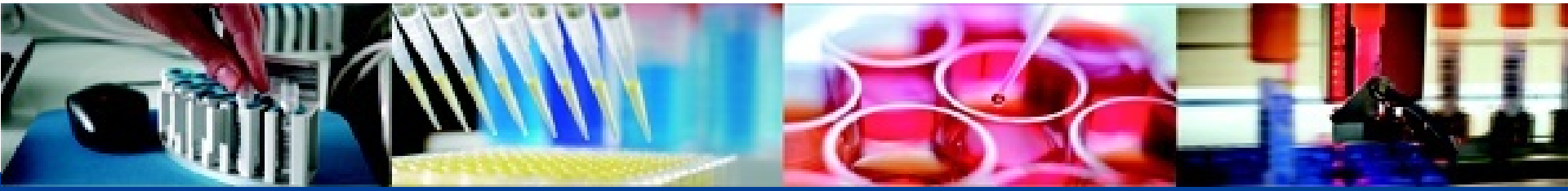

Martin Stearn, Senior Assessment Manager

New for old: Selection, validation & verification under ISO 15189:2012

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Objectives

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- Define what is meant by validation & verification
- Discuss this in relation to the ISO 15189:2012 Standard
  - 5.5.1 Selection, verification & validation of examination procedures
  - 5.5.1 also includes measurement uncertainty

- Not to tell you what you need to do or how to do it

Validation

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Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled.

The method achieves the intended outcome because;

- Evidence A
- Evidence B
- Evidence C

The method works

The zones of growth inhibition achieved by the AST method accurately demonstrate susceptibility or resistance for that organism

Verification

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Confirmation, through provision of objective evidence, that specified requirements have been fulfilled.

We (the laboratory) can achieve the intended outcome because;

- Evidence X
- Evidence Y
- Evidence Z

The method works in our hands

The zones of growth inhibition we achieve by the AST method accurately demonstrate the susceptibility or resistance of the isolates to which the method has been applied

ISO 15189:2012

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5.5.1 Selection, verification and validation of examination processes

5.5.1.1 General

The laboratory **shall** select examination procedures which have been validated for their intended use.

'Shall' = you must
'Should' = you shall unless you can justify not doing so

NOTE: Preferred procedures are those specified in the instructions for use of *in vitro* medical devices or those that have been **published in established/authoritative textbooks, peer-reviewed texts or journals, or in international consensus standards or guidelines, or national or regional regulations.** (Standard methods)

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Validation (again)

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Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled.

The method achieves the intended outcome because;

- Evidence A; published in established/authoritative textbooks, peer-reviewed texts or journals,
- Evidence B; international consensus standards or guidelines
- Evidence C; national or regional regulations.
- Evidence D: Records of who has validated the procedure

The method works

The zones of growth inhibition achieved by the AST method accurately demonstrate susceptibility or resistance for that organism

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Method selection

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Laboratories are free to use whatever method they select.

ISO 15189:2012 does not prescribe any particular method or the use of a ‘gold standard’ or the need to change to the latest method.

Neither do UKAS, we’ll assess your methods and your competence to use them.

ISO 15189:2012 does specify the need to select methods which have been validated and verified to achieve the right result.

ISO 15189:2012

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5.5.1 Selection, verification and validation of examination processes

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5.5.1 Selection, verification and validation of examination processes

5.5.1.3 Validation of examination procedures

The **laboratory shall validate** examination procedures derived from the following sources:

a) Non-standard methods
b) Laboratory designed or developed methods
c) Standard methods used outside their intended scope
- Applying breakpoint criteria to related or even unrelated organisms

a) Validated methods subsequently modified
- Alteration of the method in **any** way (e.g. incubation time/temperature, disc concentration)

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5.5.1 Selection, verification and validation of examination processes

5.5.1.2 Verification of examination procedures

The laboratory shall obtain information from the manufacturer/method developer for confirming the performance characteristics (expected zone diameters, MICs) of the procedure.

What are you aiming to achieve? What are the intended outcomes of the method being used?

Control strains (ATCC/NCTC) subject to the method should achieve the intended result (zone diameter, MIC) when we do the test.

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5.5.1 Selection, verification and validation of examination processes

5.5.1.2 Verification of examination procedures

Validated examination procedures used without modification shall be subject to independent verification **by the laboratory before being introduced into routine use.**

Generally acceptable for retrospective verification of historical methods (inc. BSAC), e.g. demonstrable ability to meet performance claims through quality assurance.

What evidence do you have to demonstrate new methods (inc. EUCAST) have been verified as fit for purpose **before** being applied to clinical isolates and informing clinical decisions.

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5.5.1 Selection, verification and validation of examination processes

5.5.1.2 Verification of examination procedures

The independent **verification by the laboratory** shall confirm, through obtaining objective evidence (in the form of performance characteristics) that the **performance claims for the examination procedure have been met**. The performance claims for the examination procedure confirmed during the verification process shall be those relevant to the intended use of the examination results.

How can you show the assessors that you can accurately determine the susceptibility of your isolates when using the validated AST method?

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ISO 15189:2012

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5.5.1 Selection, verification and validation of examination processes

5.5.1.2 Verification of examination procedures

The laboratory shall **document the procedure used for the verification** and record the results obtained.

Show us your procedure. Is the technical approach to verification sufficient and suitable for the intended use of the procedure?

Staff with the appropriate authority shall **review the verification results** and record the review.

Who has reviewed the data and signed off the verification? Are they competent to do so?

Verification (again)

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Confirmation, through provision of objective evidence, that specified requirements have been fulfilled.

We (the laboratory) can achieve the intended outcome because;

- Evidence X; performance characteristics (we can do) demonstrate the performance claims (what is expected) have been met in our lab
- Evidence Y; documented verification procedure
- Evidence Z; records of review & authorisation of the verification data

The method works in our hands

The zones of growth inhibition we achieve by the AST method accurately demonstrate the susceptibility or resistance of the isolates to which the method has been applied

5.5.1 Selection, verification and validation of examination processes

5.5.1.4 Measurement uncertainty of measured quantity values

The laboratory shall determine measurement uncertainty for each measurement procedure in the examination phase used to report measured quantity values on patients' samples.

The laboratory shall define the performance requirements for the measurement uncertainty of each measurement procedure and regularly review estimates of measurement uncertainty.

Documentation

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- Entirely up to you
- Not applicable
  - OK, how have you come to that conclusion?
- Often see overarching/standalone procedure on MU,
  - OK, how have you applied that to your AST method
- Need to consider influence on each measurement and document it somehow
- Upon request make MU available to users

Questions?

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