What is the Decision Rule all about??

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What is a decision rule

• Let’s start with what is a decision?
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- Let's start with what is a decision?
What is a decision rule

- Let's look at some metrology

Where will the next reading probably be?
What is a decision rule

- Let's look at some metrology
What is a decision rule

- Let’s look at some metrology

Not likely but possible
What is a decision rule

- Let's look at some metrology

Years

Are these readings in Specification?
What is a decision rule

- Let's look at some metrology

Before we decide, we need to know the limits (specification)

Are these readings in Specification?
What is a decision rule

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So are the readings in Specification?
What is a decision rule

- In the current version of ISO/IEC 17025 it states in clause 5.10.4.2 “When statements of conformance are made, the uncertainty of measurement shall be taken into account.”
- A statement of conformance is something like “The calibration of this instrument shows that all the readings are within the manufacturer’s specifications” or “This instrument complies with the requirements of the XYZ standard.”
What is a decision rule

• Let’s look at some metrology

On this graph, the uncertainty of measurement has not been taken into account.
What is a decision rule

• Let’s look at some metrology

Upper Limit

Nominal

The Uncertainty bars are now included

Lower Limit
What is a decision rule

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So are these readings in Specification?

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- Let’s look at some metrology
What is a decision rule

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Three different groups of readings.
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So are the readings in Specification?

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So does this meet the requirements of ISO/IEC 17025?
What is a decision rule

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The undecided could however lead to lots of arguments.
What is a decision rule

- Let's look at some metrology

Readings 1 to 4 are clearly “pass” and within Specification.
Reading 7 is clearly “fail” and outside of Specification.
It is readings 5 and 6 that cause the arguments.

The undecided could however lead to lots of arguments.

Upper Limit
Undecided
Lower Limit
Nominal

Pass

Fail

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The undecided could however lead to lots of arguments.

If you are the user, then the undecided are not acceptable but if you are the supplier you could argue that they are acceptable because of the uncertainty associated with the readings.
What is a decision rule

- Let's look at some metrology

The undecided could however lead to lots of arguments.

In this case we have a series of readings over a period of time so we have an understanding of how the artefact behaves and can reasonably predict what will happen in the future. This reduces the risk involved in a decision.
What is a decision rule

• Let's look at some metrology

Similarly – if we had several of the same instruments, such as a production run, and get the above results, we know a lot more about the behaviour of the products
What is a decision rule

- Let's look at some metrology

If we had only one (or one set) of readings, would we view it any differently?

Is this a pass or fail?

There may be a lot of money or risk resting on the decision.
What is a decision rule

Let’s look at some metrology

Many cal labs would not make a decision based on this information but would rather pass the information to the customer to decide for themselves.
So this would not be a statement of conformance but merely a calibration report.
What is a decision rule

• Let’s look at some metrology

If however the lab was tasked to give a statement of compliance, what would the decision be?

Clearly it depends who’s side you are on. Different labs could give different decisions.

So the customer needs to be told what “decision rule” you applied to the statement of compliance.
What is a decision rule

• The current wording of **17025:2005** leaves it very vague and open to a wide range of interpretation.

• The **ILAC G-8:2009** has tried to provide some clarity by writing this guideline on how to look at pass/fail conformity assessment.

• The **JCGM 106:2012** “Evaluation of Measurement Data- the Role of measurement uncertainty in conformance assessment is a further guideline on how to deal with the problem.
What is a decision rule

- In the current version of ISO/IEC 17025 it states in clause 5.10.4.2 “When statements of conformance are made, the uncertainty of measurement shall be taken into account”
What is a decision rule

- The ILAC G-8:2009 has tried to provide some clarity by writing this guideline on how to look at pass/fail conformity assessment.

- Compliance: If the specification limit is not breached by the measurement result plus the expanded uncertainty with a 95% coverage probability, then compliance with the specification can be stated (See Case 1 of Fig.1). This can be reported as “Compliance” or “Compliance – The measurement result is within (or below) the specification limit when the measurement uncertainty is taken into account”. In calibration this is often reported as “Pass”;
What is a decision rule

• The ILAC G-8:2009 has tried to provide some clarity by writing this guideline on how to look at pass/fail conformity assessment.

• Non-compliance: If the specification limit is exceeded by the measurement result minus the expanded uncertainty with a 95% coverage probability, then noncompliance with the specification can be stated. (See Case 4 of Fig.1) This can be reported as “Non-compliance” or “Non-compliance – The measurement result is outside (or above) the specification limit when the measurement uncertainty is taken into account”. In calibration this is often reported as “Fail”;
What is a decision rule

- The ILAC G-8:2009 has tried to provide some clarity by writing this guideline on how to look at pass/fail conformity assessment.
- If the measurement result plus/minus the expanded uncertainty with a 95 % coverage probability overlaps the limit, it is not possible to state compliance or non-compliance. The measurement result and the expanded uncertainty with a 95 % coverage probability should then be reported together with a statement indicating that neither compliance nor non-compliance was demonstrated.
- This is what most SANAS labs use today.
What is a decision rule

- The JCGM 106:2012 “Evaluation of Measurement Data - the Role of measurement uncertainty in conformance assessment” is a further guideline on how to deal with the problem.

- This document address a lot more detail and gives different ways of interpreting results

- This goes into the “knowledge of the measurand”, Bayes Theorem, conformance probabilities and much more”
What is a decision rule

• So the bottom line is that much more knowledge on the subject is required to enter into an educated discussion with the customer about the probability of “False accepts” when a product should fail and “False rejects” when a product should pass.

• It is suggested that a good study of JCGM 106:2012 is made.

• It is available free off the BIPM web site

• There is also a lot more information available on the Web related to this subject.
What is a decision rule

- So why all the fuss?
- Again, it depends if you are the user or the supplier and it boils down to the issue of the probability of “False Accept” or “False Reject”. What is the risk to both parties.
- Whilst the current 17025 and the ILAC G-8:2009 give direction it is not always enforced.
- Very few people know about the JCGM 106.
What is a decision rule

• So what is proposed in the new 17025?

Analysis of the results

7.7.1 Evaluation of conformance

When statement of conformity to a specification or standard for test or calibration is requested, the laboratory shall:

a) document the decision rules employed taking into account the level of risk associated with the decision rule employed (false accept and false reject and statistical assumptions associated with the decision rule employed);

b) apply the decision rule.

NOTE For further information see ISO/IEC Guide 98-4.
What is a decision rule

• So breaking this down further

When statement of conformity to a specification or standard for test or calibration is requested, the laboratory shall:

• The key here is “when it is requested” which implies it is requested by the customer.
• This means that “contract review” must take place and a clear definition agreed on BEFORE the job is started.
What is a decision rule

• During Contract review

The laboratory needs to be prepared to discuss what the decision rule options are regarding the compliance statement.

They also need to understand what the customer may require and where the risk of “false accept” or “false reject” lies so that they do not get drawn into legal battles or compensation claims.

As with all statistical analysis, it is open to different interpretations and care must be taken to ensure a correct agreement between parties.
What is a decision rule

• During Contract review
There are many models which may be applied and they will vary greatly depending on the application.
You may be testing a new prototype where no previous or group history is available or you may be checking a widely manufactured and accepted item against a manufacturer’s specification. The approach will be very different.
What is a decision rule

- Different approaches to each condition

One instrument over a long time

One batch of the same model instrument

One reading (or set of readings on a prototype)
What is a decision rule

- Different approaches to each condition

A knowledge of “Guardbands” and the way they are implemented is advisable.
What is a decision rule

- Different approaches to each condition

![Graph showing upper limit, guardband limit, nominal, and lower limit.]

Guardband Limit - upper
Nominal
Guardband Limit - lower
Upper Limit
Lower Limit
What is a decision rule

- Different approaches to each condition

- For example – if the **TAR method** is used and a 4:1 TAR is applicable then the rules are
  a) Both the UUT and STD must be working in normal operating specifications
  b) The STD must be calibrated and within the normal calibration interval
  c) The UUT reading must be < 70% of the normal specification limit of the UUT
     (This is a 30% guardband)
What is a decision rule

- Different approaches to each condition
- Similarly, if the guidance of the ILAC G8 is used, then it must be clearly understood and stated as such.
- The same will apply to the JCGM 106.
- There are also many ISO/SANS/Industry standards that define clearly what decision rule must be applied.
What is a decision rule

• During Contract review

Once agreed with the customer – the work can continue.
What is a decision rule

• In the Lab

... the laboratory shall:

a) document the decision rules employed taking into account the level of risk associated with the decision rule employed (false accept and false reject and statistical assumptions associated with the decision rule employed);

• Take the time to clearly document what has been agreed and ensure that lab procedures allow for the correct treatment of the readings and uncertainties.
What is a decision rule

• In the Lab

... the laboratory shall:

a) document the decision rules employed taking into account the level of risk associated with the decision rule employed (false accept and false reject and statistical assumptions associated with the decision rule employed);

• Might need to change test procedures to cater for the decision rule that will be applied. It has to be such that anybody in the lab will know what is required and what the limits are.
What is a decision rule

• In the report

... the laboratory shall:

a) document the decision rules employed taking into account the level of risk associated with the decision rule employed (false accept and false reject and statistical assumptions associated with the decision rule employed);

b) apply the decision rule.

• The report must contain either the decision rule used or a reference to a standard or agreed decision rule
What is a decision rule

• In the report

... the laboratory shall:

a) document the decision rules employed taking into account the level of risk associated with the decision rule employed (false accept and false reject and statistical assumptions associated with the decision rule employed);

b) apply the decision rule .

• The appropriate statement of conformity which has been requested or required by a standard.
What is a decision rule

• In the report
• There must be enough detail so that if another lab is tasked with taking the same measurements and using the same decision rule, that they will come to the same conclusion about a “pass” or “fail”
What is a decision rule

• **In general**

• This means that if a certificate or statement of conformance is required, a lot more detail is required to be addressed before the measurements are taken and then the Lab will need to be very clear about the criteria used and this must be defined on the test report, certificate of conformance or statement of compliance.
What is a decision rule

• **In general**
  • This is not so difficult if it is broken down in simple logical steps.

• **How do you eat an elephant?**
• **One bite at a time!**
Practical Example

• We have a calibrator such as the 5522A
• The specification is \Fluke Files\Fluke Products\5522A Calibrator\Model 5522A Extended Spec.pdf
• We have a 177 DMM that needs to be calibrated.
• The specification is \Fluke Files\Fluke Products\Industrial Products various\17X Calibration Manual.pdf
• Plan to take a measurement at 5.000 Vdc
• Calculate the Specification for both in Vdc
• What are the limits for the DMM in Vdc
• Calculate the TAR
• According to the rules, what is the guardbanded upper and lower limit if this method is used?
• If the reading on the DMM is 5.001 Vdc is it a Pass or Fail? And at 5.006 Vdc? And at 5.010 Vdc?
Practical Example

• Now if we applied the ILAC G8 approach what would we need to do?
• Assume the readings are as follows:-
  o 5.000, 5.001, 5.000, 5.000, 5.001 Vdc
• Then what ??
Practical Example

• Now if we looked at the manufacturers verification procedure, what would we find?
• How do we interpret the requirement?
• How does it compare to the two decision rules we have worked on?
• Do you need to validate the procedure?
• Why or why not?
What is a decision rule

- In Summary – it is the balance of risk

- FDA evaluates benefits/risks for the population

- Provider evaluates benefits/risks for a patient

- Patient evaluates benefits/risks in terms of personal values
What is a decision rule

It is all about communication between interested parties
What is a decision rule

“I fear the day that technology will surpass our human interaction. The world will have a generation of idiots.”

Albert Einstein
What is a decision rule