TEST IT LAB	RECORD		
	DECISION RULE AND REPORTING STATEMENT OF CONFORMITY		
	Compiler	Elsabe Botes	QM No. 7.8/R-02
	Reviewer	Francois le Roux	Rev 02
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1. SCOPE

This procedure describes the decision rule employed by the laboratory when reporting a statement of conformity i.e. how the laboratory decides whether a result passes or fails. In conformity assessment, a measurement result is used to decide if an item of interest conforms to a specified requirement.

The decision rule is a documented rule that describes how measurement uncertainty will be allocated with regard to the acceptance or rejection of a product according to its specification and the result of a measurement. This document is applicable to the decision rule used by the laboratory i.e. the "binary simple acceptance decision rule" for quantitative methods – Figure 1.

2. RESPONSIBILITIES

This procedure applies to Test It LAB Technical signatories

3. REFERENCE DOCUMENTS

ISO/IEC 17025:2017 Clause 7.8

ILAC-G8:09/2019: Guidelines on Decision Rules and Statements of Conformity

ISO/IEC Guide 98-4: Uncertainty of measurement

4. DEFINITIONS AND ABBREVIATIONS

Conformity assessment	Activity to determine whether specified requirements relating to a product, process, system, person or body are fulfilled
Decision rule	Rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement
Guard band (w)	Interval between a tolerance limit and a corresponding acceptance limit
Measurement uncertainty	The expression of the statistical dispersion of the values attributed to a measured quantity
Simple acceptance	Decision rule in which the acceptance limit (AL) is the same as the tolerance limit (TL), i.e. $AL=TL$
Tolerance / acceptance limit	Specified upper or lower bound of permissible values of a property

5. PROCEDURE

5.1. A conformity statement or a statement of conformity is an expression that clearly describes the state of compliance or non-compliance to a specification, standard, or requirement.

5.2. Because of uncertainty in measurements, there is always the risk of incorrectly deciding whether or not an item conforms to a specified requirement based on the measured value of a property of the item. Such incorrect decisions can lead to an item being accepted as conforming, but it may actually be non-conforming and an item being rejected as non-conforming may actually be conforming.

5.3. When the laboratory reports or when customers request a statement of conformity, the laboratory clearly defines or makes reference to the decision rules.

5.4. Reference to measurement uncertainty values and the decision rule are provided in test reports.

5.5. The customer acknowledges and agrees to the decision rule that is employed by the laboratory by signing the contracts or proposals. Should the customer propose a different decision rule to be used, the laboratory will document the details in the contract as well as the test report. The laboratory will not be responsible for statements of conformity and risks will not be determined.

5.6. The laboratory has implemented the decision rule as per guidelines documented in ILAC-G8:09/2019 and ISO/IEC Guide 98-4. It is therefore not necessary to further consider the level of risk as per the note given in ISO/IEC 17025:2017, Clause 7.8.6.1, however the decision rule employed can be seen as a shared risk with the customer.

5.7. A widely used decision rule is known as “simple acceptance” or “shared risk”. The laboratory and the customer agree to accept as conforming (and reject otherwise) an item whose property has a measured value within the tolerance limits. The laboratory and customer then share the consequences of incorrect decisions because the probability to be outside the tolerance limit may be as high as 50% in the case when a measurement result is exactly on the tolerance limit. To keep the chances of incorrect decisions to levels acceptable to both the laboratory and the customer, the requirement is that the measurement uncertainty has been judged to be acceptable for the intended purpose.

5.8. The laboratory has implemented the binary simple acceptance decision rule where the result is limited to two choices i.e. pass or fail where guard band (w) are not used (calculated).

5.9. Binary statement for simple acceptance rule (w=0).

5.10. Statements of conformity are reported as:

5.10.1. **Pass** - The measured value is below the acceptance limit

5.10.2. **Fail** - The measured value is above the acceptance limit

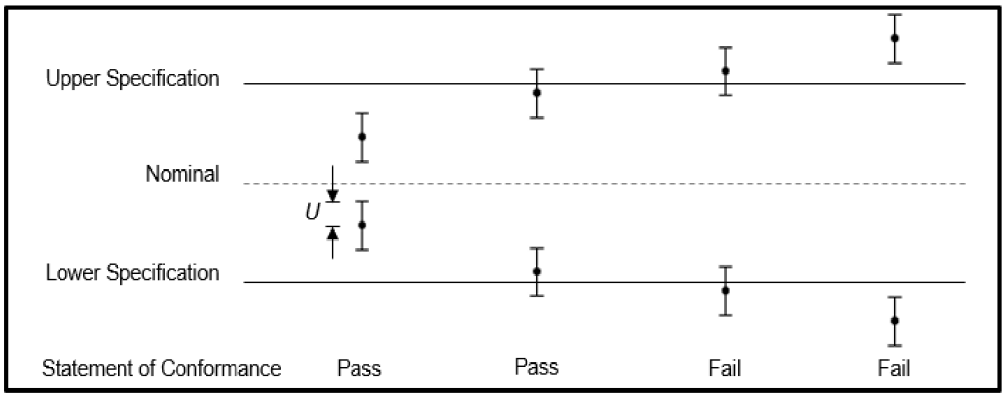

Figure 1: Example of decision rule employed by the laboratory

5.11. Risk to decision:

5.11.1. Case 1 = Low

5.11.2. Case 2 = Medium

5.11.3. Case 3 = High

5.11.4. Case 4 = Low

5.12. Test It LAB provides a statement of conformity by reporting results against a report Specification as and if applicable and / or required by the client

5.12.1. Exceedances are indicated with a symbol

5.12.2. If a client requires comparison to a different regulation, specification or normative document, this will be clearly indicated on the report

6. RECORDS

All records are kept as per QM No. 8.4/R-01

7. RISKS

List risks

8. AMENDMENT RECORD

Proposed by	Section	Change
Rev 01: EB	Header	Updated to new layout including Compiler, Reviewer and Approver
Rev 01: EB	7	Amendment record added
Rev 02: EB	5	Report specifications generalised Disclaimers section removed