

**PHCE Laboratory Sciences
Decision Rule Implementation Form**

Customer:	Date Initiated:
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1. Statements of Conformity

ISO/IEC 17025:2017 gives the following directives to PHCE, LS:

7.8.6 Reporting statements of conformity

7.8.6.1 When a statement of conformity to a specification or standard is provided, the laboratory shall document the decision rule employed, taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed and apply the decision rule.

NOTE: Where the decision rule is prescribed by the customer, regulations or normative documents, a further consideration of the level of risk is not necessary.

7.8.6.2 The laboratory shall report on the statement of conformity, such that the statement clearly identifies:

- a) to which results the statement of conformity applies;
- b) which specifications, standards or parts thereof are met or not met;
- c) the decision rule applied (unless it is inherent in the requested specification or standard)

2. Decision Rule

Statements of conformity to a specification or standard require the use of a decision rule to take into account the uncertainty associated with each method. Some decision rules are documented within compliance programs or standard methods. When the decision rule is not provided, the laboratory must document the decision rule and account for the level of risk associated with the decision rule used.

In this issue of conformity, LS must make an educated discussion with principals (customers or regulators) during the negotiation of a job contract or a contract review. It is a risk to both parties concerned, which must be duly assessed and decided upon when the reported measurement is found not within or below/above the regulatory limit. LS may also discuss with the principals regarding a "Guard Band" that will be comfortable to both parties, and ensure that its test procedures can meet the required limits. LS may also change or modify its test procedures (e.g., by lowering its method detection limit) in support of the agreed upon decision rule.

3. Reporting Statements of Conformity

Any statements of conformity reported on the LS Final Report clearly identify:

- A. The results the statement applies to;
- B. Which standards or regulations were met, or not met;
- C. The decision rule applied (unless it is defined in the specification or regulation).

Agreement between LS and Customer: The Customer understands LS requirements in Paragraphs 1 to 3 and agrees with LS on the Decision Rule below, which will remain in effect unless otherwise specified during Contract Review using LOD Form 1 – Request for Laboratory Services (RLS).

**PHCE Laboratory Sciences
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Decision Rule:

Review:

Customer Authorized Representative:

Comments

Signature

Date

Quality Assurance Officer or Executive Officer, LS:

Comments

Signature

Date

Scientific Director or Laboratory Director, LS:

Comments

Signature

Date