

## **1. Purpose**

This document provides information on the procedure for the evaluation of conformity of test results as well as on the decision rule applied within the scope of testing services. The description is provided in accordance with the requirements of DIN EN ISO/IEC 17025:2018 and the specifications of the German Accreditation Body (DAkkS). The objective is the transparent documentation of the procedures applied for conformity assessment and the associated decision rule.

## **2. Conformity Assessment**

Conformity assessment is a process used to determine whether a test or measurement result complies with the requirements of a defined specification, standard, or legal limit value. The basis for this assessment is formed by the applicable requirements, which may be defined by standards, technical regulations, or customer specifications.

Conformity assessment includes the systematic comparison of the determined result with the specified requirements. The aim is to provide a clear statement as to whether the tested object is to be classified as “conforming” (“compliant”) or “non-conforming” (“non-compliant”).

### **2.1 Pure Reporting of Measurement Results / As-Is Analysis**

In certain cases, tests or analyses are limited to the determination and communication of measurement results (actual values) to the customer, without any evaluation regarding compliance with specifications, standards, or limit values. In such cases, no conformity assessment and no application of a decision rule are carried out. The evaluation and interpretation of the measurement results remain the responsibility of the customer.

The requirements for the presentation and traceability of the measurement results continue to follow the provisions of DIN EN ISO/IEC 17025:2018, particularly with regard to the complete and transparent documentation of all relevant information (e.g., applied methods, measurement uncertainty, environmental conditions). The test report explicitly states that no conformity statement is made and that the evaluation is the responsibility of the customer.

## **3. Decision Rule**

The decision rule describes how measurement uncertainty is considered during conformity assessment. It defines the criteria according to which, taking measurement uncertainty into account, a result is judged to be conforming or non-conforming.

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The decision rule may be defined by standards, legal regulations, customer requirements, or by the laboratory itself. It is a key element for the transparent and traceable management of the risk of incorrect decisions (e.g., false acceptance or false rejection). The precise wording and application of the decision rule are essential for the traceability and comparability of conformity statements.

### 4. Handling of Decision Rules at CleanControlling

#### a) Decision Rules Specified by Specifications or Standards

If specific decision rules are defined in the applicable specifications or standards, only these rules shall be applied. Compliance with the respective requirements has the highest priority.

#### b) Customer-Specific Decision Rules According to ILAC G8

If the customer requests a specific handling of the decision rule (e.g., application of a specific guard band or a deviating risk consideration according to ILAC G8), this must be communicated to the laboratory explicitly and in writing in advance. The requested procedure will then be implemented accordingly after consultation and documented in the test report.

#### c) Standard Procedure – Simple Acceptance

If neither normative nor customer-specific decision rules have been agreed upon, conformity assessment shall be performed according to the principle of simple acceptance using a binary decision rule.

This means that a measurement result is assessed as “conforming” if, without consideration of the measurement uncertainty, it lies within the specified limit values. Although the measurement uncertainty is not used for conformity assessment, it is always determined and documented internally in accordance with ISO/IEC 17025 and ILAC G8, and is communicated to the customer upon request or directly stated in the report.

The application of this decision rule is illustrated in the following diagram.

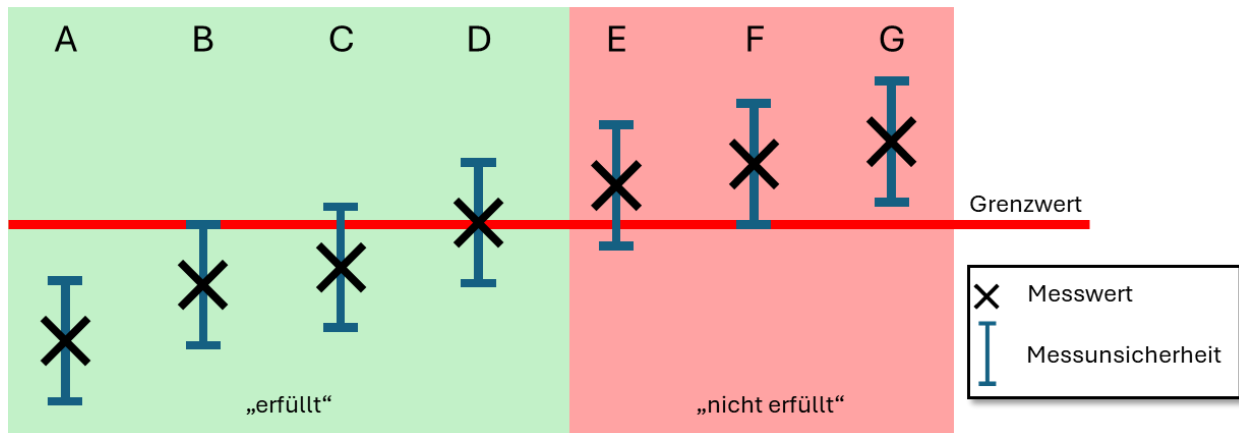


Figure 1 Application of Simple Acceptance (Example: Upper Limit)

**Case A**

**Situation:** The measured value lies significantly below the limit value, and the measurement uncertainty also does not reach the limit value.

**Assessment:** The result is assessed as “compliant” (conforming).

**Case B**

**Situation:** The measured value lies below the limit value, and the measurement uncertainty does not overlap the limit value.

**Assessment:** The result is assessed as “compliant” (conforming).

**Case C**

**Situation:** The measured value lies below the limit value, but the measurement uncertainty reaches or slightly exceeds the limit value.

**Assessment:** The result is assessed as “compliant” (conforming), since only the measured value is considered for the assessment.

**Case D**

**Situation:** The measured value lies exactly at the limit value, and the measurement uncertainty extends to both sides of the limit value.

**Assessment:** The result is assessed as “compliant” (conforming), since the measured value is not above the limit value.

**Case E**

**Situation:** The measured value lies slightly above the limit value, while the measurement uncertainty still extends into the range below the limit value.

**Assessment:** The result is assessed as “non-compliant” (non-conforming), since the measured value exceeds the limit value.

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**Case F**

**Situation:** The measured value lies significantly above the limit value, and the measurement uncertainty extends to the limit value.

**Assessment:** The result is assessed as “non-compliant” (non-conforming).

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**Case G**

**Situation:** The measured value lies significantly above the limit value, and the measurement uncertainty exceeds the limit value upwards.

**Assessment:** The result is assessed as “non-compliant” (non-conforming).