


FB 35-74		Conformity of test results		
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1. Purpose of the form

This form provides information on the procedure for assessing the conformity of test results and on the decision rule applied in the context of testing services. The presentation complies with the requirements of DIN EN ISO/IEC 17025:2018 and the specifications of the German Accreditation Body (DAkkS). The aim is to provide transparent documentation of the conformity assessment procedures and decision rules applied.

2. Conformity assessment

Conformity assessment is a process that determines whether a test or measurement result meets the requirements of a specified specification, standard, or legal limit. This is based on the respective specifications, which may be defined, for example, by standards, technical regulations, or customer requirements. Conformity assessment involves systematically comparing the determined result with the specified requirements. The aim is to make a clear statement as to whether the tested object is to be classified as “conforming” (‘compliant’) or “non-conforming” (“non-compliant”).


2.1 Pure measurement value communication / actual status analysis

In certain cases, only measurement results (actual values) are determined and communicated to the client as part of tests or analyses, without any assessment of compliance with specifications, standards, or limit values. In such cases, no conformity assessment or decision rule is applied. The evaluation and interpretation of the measurement results is the responsibility of the client.

The requirements for the presentation and traceability of the measurement results continue to be based on the specifications of DIN EN ISO/IEC 17025:2018, in particular with regard to the complete and transparent documentation of all relevant information (e.g., methods used, measurement uncertainty, environmental conditions). The test report explicitly states that no conformity statement is made and that the evaluation is carried out by the client.

3. Decision rule

The decision rule describes how measurement uncertainty is handled in conformity assessment. It specifies the criteria and measurement uncertainty considerations used to decide whether a result is considered compliant or non-compliant. The decision rule may be defined by standards, legal requirements, customer requirements, or by the laboratory itself. It is a key element in managing the risk of misjudgments (e.g., false acceptance or rejection) in a transparent and comprehensible manner. The precise wording and application of the decision rule is essential for the traceability and comparability of conformity statements.

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4. Handling decision rules in CleanControlling

- Decision rules specified by specifications or standards: If specific decision rules are specified in the underlying specifications or standards, we apply only these rules. Compliance with the respective specifications has top priority here.
- Customer-specific decision rules in accordance with ILAC G8: If the client requests special handling of the decision rule (e.g., application of a specific safety band or a different risk assessment in accordance with ILAC G8), this must be communicated to the laboratory in advance in writing and explicitly. The desired procedure will then be implemented accordingly after consultation and documented in the test report.
- Standard procedure – simple acceptance: If there are no normative or customer-specific decision rules, conformity assessment is carried out according to the principle of simple acceptance with a binary decision rule. This means that a measurement result is assessed as “conforming” if it lies within the specified limits, without taking measurement uncertainty into account. Although the measurement uncertainty is not used for conformity assessment, it is always determined internally, documented, and communicated to the customer upon request in accordance with ISO/IEC 17025 and ILAC G8. The application of this decision rule is illustrated in the following diagram.

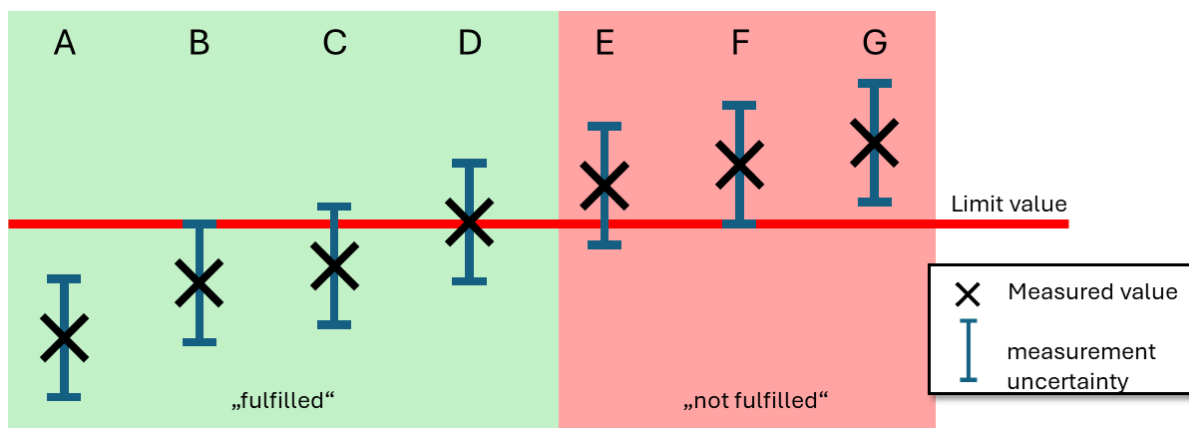



Figure 1 Application of simple acceptance (example: upper limit)

Example A

Situation: The measured value is significantly below the limit value, and the measurement uncertainty also does not approach the limit value.

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

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Example B

Situation: The measured value is below the limit value, but the measurement uncertainty does not overlap the limit value.

Assessment: The result is assessed as "met" (compliant).

Example C

Situation: The measured value is below the limit value, the measurement uncertainty reaches up to or slightly above the limit value.

Assessment: The result is assessed as "met" (compliant) because only the measured value counts for the assessment.

Example D

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

Assessment: The result is rated as "fulfilled" (compliant) because the measured value does not exceed the limit value.

Example E

Situation: The measured value is just above the limit value, and the measurement uncertainty still falls within the range below the limit value.

Assessment: The result is rated as "not fulfilled" (non-compliant) because the measured value is above the limit value.

Example F

Situation: The measured value is significantly above the limit value, and the measurement uncertainty approaches the limit value.

Assessment: The result is rated as "not fulfilled" (non-compliant).

Example G

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

Assessment: The result is rated as "not fulfilled" (non-compliant).
