

ELEMENT POLICY ON REPORTING STATEMENTS OF CONFORMITY IN TESTING

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1.0 INTRODUCTION

1.1 In the 2017 version of ISO/IEC 17025 there are requirements around reporting statements of conformity, the decision rules to be employed and how uncertainty of measurement is accounted for.

2.0 SCOPE

2.1 Element's policy outlines our approach to reporting statements of conformity. In the absence of an agreed alternative approach, Element will report test results and statements of conformity in line with this policy.

3.0 KEY TERMS

3.1 **Statement of Conformity:** 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

3.2 **Decision Rule:** rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement

3.3 **Uncertainty (of measurement):** parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand

4.0 POLICY

4.1 Element policy is to provide statements of conformity that make use of decision rules only in response to either a customer specific request or where regulation or normative documents require and prescribe the decision rule to be employed. A decision rule describes how measurement uncertainty is used to report a numerical result simply as a pass or fail based on whether the result falls within the specification limits prescribed.

4.2 TEST METHOD CLASSIFICATIONS RELATING TO UNCERTAINTY OF MEASUREMENT

4.2.1 Category I

Decision rules are not applicable to qualitative or semi-quantitative test methods as the results are reported based on observation or estimation rather than precise quantification.

4.2.2 Category II

Well-recognised standard methods that are prescriptive with regard to the possible variables controlling uncertainty of measurement are regarded as consensus standards, having been developed by a broad cross-section of stakeholders. Examples are ASTM, BSI, ISO standards or those provided by government agencies or manufacturers with full regard for their subsequent application in material or product specifications accounted for. Standards that specify limits to the values of the major sources of uncertainty of measurement and how these are to be reported are regarded to have uncertainty of measurement embedded within the method.

- 4.2.3 These standards are deemed to meet our customers' requirements unless otherwise advised and no further consideration of measurement uncertainty is required on the basis that the method and reporting instructions are adhered to.
- 4.2.4 Category II standards should be reviewed to verify that uncertainty of measurement and reporting requirements are embedded in the methods. Where this is not the case, uncertainty estimates are required and can be determined using appropriate guidance documents and procedures.
- 4.2.5 **Category III**
Element offers testing against a specification for physical, chemical, environmental, or biological/microbiological test methods based on published regulatory or consensus methods for which major sources of measurement uncertainty are not defined in the method. The actual test results will be reported for these test types and the associated uncertainty of measurement will be quoted with the numerical values. Element will not actually determine whether the item tested or calibrated conforms to a specification and our customers will determine compliance. Where our customers insist on a statement of conformity being included, the uncertainty of measurement requirements for Category IV will be applied.
- 4.2.6 **Category IV**
Non-standard and laboratory-developed methods require all components of uncertainty to be evaluated. Element will report the results as determined with the associated uncertainties for this category of methods.
- 4.2.7 Where customers require a statement of conformity to be reported by Element, based on limits, the decision rule criteria to be applied must be agreed with the Element laboratory undertaking the testing at the contract review stage.
- 4.2.8 Where the customer selects an acceptable decision rule, this rule is applied to the test results using the associated uncertainties and reported along with a statement of the origin and basis for the decision rule applied, with the statement of conformity included.
- 4.2.9 Element reserves the right to either attribute the source of any decision rule criteria applied or exclude such statements where the basis of probability of false acceptance or rejection is not, in Element's opinion, considered justifiable or defensible. In this case the numerical test values and the associated uncertainty of measurement will be reported.

5.0 REFERENCE DOCUMENTS

- 5.1 Further information can be obtained from the UKAS and ILAC websites where additional guidance is available.

6.0 REVISION HISTORY

6.1 January 2021

- 6.1.1 Definition of Category II standards clarified in paragraph 4.2.2 and 4.2.3. Paragraph 4.2.4 added.
- 6.1.2 Requirement to report results and the associated uncertainties included in paragraph 4.2.6.
- 6.1.3 Included paragraph 4.2.7 in instances where statements of conformity are required for Category IV standards.