

	<b>Quality Management System Procedure</b> [Laboratory Name]	Issue Date: <b>YYYY/MM/DD</b>	Rev.: <b>0</b>
	<b>QSP 5-04-1 – Estimation of Uncertainty</b>		Page #: <b>1 of 3</b>

Prepared by: \_\_\_\_\_ Date: \_\_\_\_\_

Reviewed by: \_\_\_\_\_ Date: \_\_\_\_\_

Approved by: \_\_\_\_\_ Date: \_\_\_\_\_

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### **Purpose**

To estimate the uncertainty of measurement in a test method.

### **Scope / Field of Application**

All measurements from test methods, except when the test methods preclude such rigorous calculations.

**Note** – It is important to understand the major factors of uncertainty and provide appropriate control for all such factors. Concurrent analysis of reference materials or control samples with the test portion can be performed in place of purely mathematical estimation of uncertainty. If possible, the reference material or control sample shall be of identical or similar matrix as the matrices routinely tested by the test method. The uncertainty of the method can be estimated for the class of matrix and the variation described as the uncertainty in testing the specific matrix class at the average amount of analyte detected.

### **Definitions and Acronyms**

**Type A Uncertainty** – determined through calculation from a series of repeated observations using statistical methods.

**Type B Uncertainty** – determined through judgment, based on data in calibration certificates, previous measurement data, experience with the behavior of the instruments, manufacturer’s specifications, and all other relevant information.

**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.

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### Responsibilities

Technical Manager ensures that this procedure is utilized where appropriate.

### Materials Required

Electronic spreadsheet capabilities

### Procedure

#### *Step 1. Specification*

Write down a clear statement of what is being measured, including the relationship between the measurand and the parameters (e.g., measured quantities, constants, calibration standards, etc.) upon which it depends. Where possible, include corrections for known systematic effects. The specification information, if it exists, is normally given in the relevant standard operating procedure (SOP) or other method.

#### *Step 2. Identify Uncertainty Sources*

List the possible sources of uncertainty. This will include sources that contribute to the uncertainty on the parameters in the relationship specified in Step 1, but may include other sources and must include sources arising from chemical assumptions. Examples for forming a structured list are given in the appendix.

#### *Step 3. Quantify Uncertainty Components*

Measure or estimate the size of the uncertainty component associated with each potential source of uncertainty identified. It is often possible to estimate or determine a single contribution to uncertainty associated with a number of separate sources. It is also important to consider whether available data accounts sufficiently for all sources of uncertainty, and plan additional experiments and studies carefully to ensure that all sources of uncertainty are adequately accounted for.

#### *Step 4. Calculate Total Uncertainty*

The information obtained in step 3 will consist of a number of quantified contributions to overall uncertainty, whether associated with individual sources or with the combined effects of several sources. The contributions have to be expressed as standard deviations, and combined according to the appropriate rules, to give a combined standard uncertainty. The appropriate coverage factor should be applied to give an expanded combined uncertainty.

### Alternate Procedure

Concurrently analyze reference materials or control samples with test samples to estimate uncertainty. This is generally achieved during validation of methods.

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### Documentation

The following records are generated and managed:

Required Record	Custodian
Uncertainty of Measurement	Laboratory Manager / Supervisor

### Reference Procedures

All test methods requiring uncertainty estimation.

### References

ISO “Guide to the Expression of Uncertainty in Measurement”.

Eurachem / CITAC. Quantifying Uncertainty in Analytical Measurement (2<sup>nd</sup> Edition).

### Revision History

Revision 0