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INTERPRETATION AND GUIDANCE ON THE ESTIMATION OF UNCERTAINTY OF MEASUREMENT IN TESTING

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LIST OF AMANDMENT

No.	Date	Part number revised	Brief description of changes	Part revision number
-	-	-	-	-

1. Introduction

This document provides interpretation and guidance for various technical disciplines. It is intended for use by laboratory accreditation bodies as well as laboratories.

It is KAN policy that testing laboratories accredited by KAN member accreditation bodies comply with the requirements of ISO/IEC 17025¹. The clauses of ISO/IEC 17025 most relevant to uncertainty of measurement are clauses 5.4.6 and 5.10.3.1 (c). Practice and recommendations stated in the documents referred to in the notes following clause 5.4.6 of ISO/IEC 17025 are not requirements.

This document is not a mandatory document. However, laboratories are expected to take note of these interpretations and guidance in preparing their uncertainty budgets.

In this document, the measurement uncertainty definition in ISO – VIM 1993² applies.

Section 2 gives general interpretation and guidance applicable to all testing disciplines. Interpretation and guidance specific to physical and mechanical testing, construction materials testing, electrical testing, chemical testing and microbiological testing are given in sections 3 to 7 respectively.

Further guidance may also be found in ILAC G17³ and EA 4/16⁴.

2 Interpretation and Guidance

2.1 Tests for Which Uncertainty Applies

Where a test produces numerical results (or the reported result is based on a numerical result), the uncertainty of those numerical results should be estimated. In cases where the nature of the test method precludes rigorous, metrologically and statistically valid estimation of the measurement uncertainty, a testing laboratory should make a reasonable attempt to estimate the uncertainties of the results. This applies whether the test methods are rational or empirical.

Where results of tests are not numerical or are not based on numerical data (e.g., pass/fail, positive/negative, or based on visual or tactile or other qualitative examinations) estimates of uncertainty or other variability are not required. However, laboratories are encouraged to have an understanding of the variability of the results where possible.

The significance of the uncertainty of qualitative test results is recognised and so is the fact that the statistical procedure required to handle the calculation of this uncertainty exists. However, in view of the complexity of the issue and the lack of agreed approaches, laboratories are not required to estimate the uncertainty of qualitative test results at this time. This will, however, be kept under review.

2.2 Defining the Measurand

It is recognised that in testing the measurand is sometimes defined in terms of the method (empirical method) and may not be directly traceable to SI units.

Note:

An empirical test method is a method intended to measure a property that is dependent on the test method used to measure it. Different methods for the same test parameter may return different results that may not be related. In many cases, one method cannot be verified using another test method. Examples of empirical test methods are the leachable concentration of chemicals and the hardness of a material. For the former, different solvent and leaching conditions will produce different results. For the latter, different indenter shapes, sizes and applied forces will produce different numerical results according to the applicable hardness scale.

A rational test method is a test method intended to measure a property that is defined independent of any test method. There is an objective “true” value to that property and a method can be verified using other test methods. Examples of rational test methods are the total concentration of a chemical in a sample and the voltage generated by a thermocouple at a specified temperature difference. It is recognised that, although there is an objective “true” value, it may be very difficult to measure that value.

2.3 Identifying the Components of Uncertainty

The laboratory should identify all the significant components of uncertainty for each test. One component with an uncertainty of less than $\frac{1}{5}$ to $\frac{1}{3}$ of the total measurement uncertainty will not usually have much impact on the total measurement uncertainty. However, if there is several or more of such components, their combined contribution to the total measurement uncertainty may become significant and cannot be ignored

Even where reliance is to be made on overall precision data or where note 2 of clause 5.4.6.2 of ISO/IEC 17025 is to apply, the laboratory should at least attempt to identify all significant components. This will provide information to confirm that the approach taken is reasonable and all significant components have been accounted for.

Flowcharting the steps of the test method and using fish-bone diagrams to present the uncertainty components provide useful approaches.

In some cases, groups of steps in a test method may be common to several different test methods and, once an estimate of uncertainty has been obtained for that group of steps, it may be used in the estimates of uncertainty for all methods where that group of steps applies.

2.4 Approaches to the Estimation of Uncertainty

There are various published approaches to the estimation of uncertainty and/or variability in testing. ISO/IEC 17025 does not specify any particular approach. Laboratories are encouraged to use statistically valid approaches. All approaches that give a reasonable estimate and are considered valid within the relevant technical discipline are equally acceptable and no one approach is favoured over the others. The following are examples of approaches.

- a. Both the intermediate precision and reproducibility (from inter-laboratory comparisons) described in ISO 5725⁵ (see clause 5.4.6.3, note 3 of ISO/IEC 17025) may be used in estimating measurement uncertainty. However, these may omit some uncertainty sources that should also be estimated and combined with the precision, if significant.
- b. Guide to the Expression of Uncertainty in Measurement (GUM⁶) (see clause 5.4.6.3, note 3 of ISO/IEC 17025) is often regarded as having the more rigorous approach to the estimation of uncertainty. However, in certain cases, the validity of results from a particular mathematical model may need to be verified, e.g. through inter-laboratory comparisons.
- c. In those cases where a well-recognised test method specifies the limits to the values of the major sources of uncertainty of measurement, and specifies the form of presentation of calculated results, the laboratory can be considered to have satisfied the uncertainty of measurement requirements (see clause of 5.4.6.2, note 2 ISO/IEC 17025) by following that test method.

2.5 Degree of Rigour

The degree of rigour and the method used for estimating uncertainty should be determined by the laboratory in accordance with note 1 of clause 5.4.6.2 of ISO/IEC 17025.

To do this, the laboratory should:

- a. consider the requirements and limitations of the test method and the need to comply with “good practice” in the particular testing sector;
- b. ensure that it understands the requirements of the customer (see clause 4.4.1 (a) of ISO/IEC 17025). It is often the case that the customer understands the problem but does not know what tests are required, and thus needs guidance on the uncertainty required for solving the problem;
- c. use methods, including methods for estimating uncertainty, which meet the needs of the customer (see clause 5.4.2 of ISO/IEC 17025). It should be noted that what a customer wants may not be what is appropriate for the testing under consideration;

- d. consider the narrowness of limits on which decisions on conformance with specification are to be made;
- e. consider the cost effectiveness of the approach adopted.

In general, the degree of rigour relates to the level of risk. To properly evaluate safety or substantial property risk or financial risk, a relatively rigorous uncertainty estimate is required for the associated tests or measurements. For property evaluations where the test result supports a “fitness for purpose” conclusion, the associated test or measurement uncertainty may have a minor effect on the conclusion and would thus require a less rigorous estimate.

In general, if less rigour is exercised in estimating measurement uncertainty, the estimated measurement uncertainty value will be larger than an estimate obtained from a more rigorous approach. Semi-quantitative measurements require less rigorous treatment of measurement uncertainty.

If there is a large margin between the measured results and the specified limits, test results with a larger uncertainty are acceptable and a less rigorous approach to the estimation of measurement uncertainty can be justified. See 1.1.6 of APLAC TC004⁷ for a more detailed discussion on how measurement uncertainty affects the ability to distinguish compliance from non-compliance.

If the estimated uncertainty is not acceptable to the laboratory’s customer or is too large for determination of compliance with the specification, the laboratory should endeavour to reduce the uncertainty, e.g. through identification of the largest contributors to uncertainty and working on reducing these.

2.6 Uncertainty Arising from Sampling

Measurement uncertainty strictly applies only to the result of a specific measurement on an individual specimen.

During contract review there should be consideration and agreement with the customer as to whether the test result and uncertainty are to be applied to the specific sample tested or to the bulk from which it came.

Where sampling (or sub-sampling) is to be treated as part of the test, the uncertainty arising from such sampling should be considered by the laboratory. Estimating the representativeness of a sample or set of samples from a larger population requires understanding of the homogeneity of the larger population and additional statistical analysis.

Where a test method includes specific sampling procedures designed to characterise a batch, lot or larger population, the measurement uncertainties for individual measurements are often insignificant relative to the statistical variation of the batch, lot or larger population. In cases where the measurement uncertainty of individual measurements is significant in relation to the standard deviation of the sampling, the measurement uncertainty should be taken into consideration when characterising the batch, lot or larger population.

Where the test procedure includes a specific sub-sampling procedure, it is necessary to analyse the representativeness of the sub-sample as part of the measurement uncertainty estimation. Where there is doubt about the representativeness of a sub-sample, it is recommended that multiple sub-samples be taken and tested to evaluate the homogeneity of the prepared sample from which sub-samples were drawn.

Where only one sample is available and is destroyed during the test, the precision of sampling cannot be determined directly. However, the precision of the measurement system should be considered. A possible method for estimation of the precision of sampling is to test a batch of “homogeneous” samples for a highly repeatable measurand and to calculate the standard deviation of sampling from the results obtained.

2.7 Reporting Measurement Uncertainty

Laboratories should have the competence to interpret measurement results and their associated measurement uncertainties for their customers.

For quantitative test results, measurement uncertainty should be reported, where required, by clause 5.10.3.1 (c) of ISO/IEC 17025, which includes the following circumstances:

- a. when it is relevant to the validity or application of the result;
- b. when a customer's instructions require it;
- c. when the uncertainty affects compliance with a specification limit.

When measurement uncertainty is not reported under the provision of the third paragraph of clause 5.10.1 of ISO/IEC 17025, its absence should not affect the accuracy of the conclusion, clarity of the reported information nor should it introduce any ambiguity in the information provided to the customer.

The requirement that it is necessary to report measurement uncertainty when the uncertainty is relevant to the validity or application of the test result will often need to be interpreted. In such cases, the customer's needs and the ability of the customer to use the information should be taken into consideration. Although in the short term some customers will not be in a position to make use of measurement uncertainty data, this situation can be expected to improve.

When reporting measurement uncertainty, the reporting format recommended in the GUM⁶ is recommended. The results of the uncertainty estimations should be reported based on a level of confidence of 95%. The indiscriminate use of a coverage factor of 2 is not recommended. Not all combined uncertainties are normally distributed and, where practicable, the uncertainty appropriate to the 95% confidence level for the appropriate distribution should be used. The coverage factor used for calculating the expanded uncertainty should be reported.

When reporting the test result and its uncertainty, the use of excessive numbers of digits should be avoided. Unless otherwise specified, the primary result should be rounded to the number of significant figures consistent with

measurement uncertainty. When the test method prescribes rounding to a level that implies greater uncertainty than the actual measurement uncertainty, the uncertainty implied by this rounding should be reported as the measurement uncertainty of the reported result. On the other hand, if the actual uncertainty is larger than that implied by the reporting requirement, the laboratory should include a statement of the estimated measurement uncertainty in the report.

2.8 Determining Compliance with a Specification

Decisions on when and how to report compliance or non-compliance vary according to the requirements of the customer and other interested parties. However, the laboratory should take measurement uncertainty into consideration appropriately when making compliance decisions, and customers should not be misled in relation to the reliability of such decisions.

2.9 Assessment for Accreditation

During assessment and surveillance of a laboratory, an accreditation body should evaluate the capability of the laboratory in estimating the measurement uncertainty for tests included in its scope of accreditation. The assessment team should check that the methods of estimation applied are valid, all significant uncertainty components have been included, and all the criteria of the accreditation body are met. The assessment team should also ensure that the smallest uncertainties claimed can be achieved by the laboratory.

Specific Interpretations

Sections 3 to 7 below give, where required, additional interpretations of the guidance given above for some specific technical disciplines.

Section 8 gives the requirements and guidance for equipment calibrations carried out in-house by testing laboratories.

3. Physical and Mechanical Testing

- 3.1 This section gives specific additional guidance in relation to all physical and mechanical tests, including NDT and flammability tests, and for all materials and products, including textiles and garments.
- 3.2 For tests covered under note 2 of clause 5.4.6.2 of ISO/IEC 17025, assessing the capability of the laboratory to evaluate the measurement uncertainty of the test results may not be required because an estimation of uncertainty for the test is not specifically required by the standard. However, as laboratory customers may request a laboratory to report the measurement uncertainty of such results, an accreditation body may need to evaluate the capability of the laboratory to make such estimates of measurement uncertainty.

Interpretation of the terms used in note 2 of clause 5.4.6.2 of ISO/IEC 17025 should be as follows.

- a. “Well-recognised” test methods (or procedures) should generally be taken as those meeting the conditions stated in clause 5.4.2 of ISO/IEC 17025, paragraph 2. That is, those test methods published as international, regional, or national standards, or by reputable technical organisations, or test methods specified in a governing code, law, regulation or specification applying to the specific item under test. Certain test methods specified by reputable manufacturers of testing equipment may also be considered to be “well-recognised”. The laboratory should provide sufficient evidence to demonstrate that these test methods are valid and are well accepted within the relevant technical discipline.
- b. “Specifies limits to the values of the major sources of uncertainty” is taken to mean that the test method specifies (i) the maximum allowable uncertainty or maximum permissible limits for each required measurement, and (ii) limits for environmental conditions or other factors that are known to have a significant influence on the outcome of the test(s). The specified limits should apply to all uncertainty sources that, in combination, contribute at least 95% to the combined uncertainty. A laboratory intending to apply note 2 of clause 5.4.6.2 of ISO/IEC 17025 should demonstrate that the conditions detailed above are satisfied. The laboratory should also demonstrate that, in applying the test method, all such measurements and factors are controlled within the specified limits.
- c. “Specifies the form of presentation of calculated results” is taken to mean that the standard includes a specific statement regarding the number of significant figures to which a result is to be reported, the rounding procedure or other specific form of expression of results. If the test method (or procedure) refers to another document which specifies any of the following, then the requirement that the test method (or procedure) “specifies the form of presentation of calculated results” should be considered to have been satisfied:
 - i. the number of significant figures used to report the result;
 - ii. the way the reported results are to be used or interpreted;
 - iii. the method for calculating the reported results limits the number of significant figures.

Where all of these conditions are met, no further work in estimating measurement uncertainty is needed and no statement of measurement uncertainty needs to be reported.

4. Construction Materials Testing

- 4.1 The types of test and measurement included in this discipline may be classified into three categories, and the uncertainty reporting requirements for each of them are stated as follows.

- a. For purely quantitative tests, the measurement uncertainties should be determined and, where required by 5.10.3.1 (c) of ISO/IEC 17025, should be reported.
 - b. For results of pure qualitative evaluations, including those stated in numerical terms but not obtained from a quantitative measurement, reporting the measurement uncertainty is not necessary.
 - c. For qualitative evaluations based on the application of controlled and measured conditions and, where the allowable variation in conditions has a significant potential effect on the outcome of the evaluation (often a “pass/fail” conclusion), it is recommended that the measurement uncertainty of the conditions and their potential effects on the test result be evaluated and discussed in the report to the extent practicable.
- 4.2 a. Conditions for application of note 2 of clause 5.4.6.2 of ISO/IEC 17025 are as follows.
- i. “Well recognised test method” is taken to mean a test method published by a nationally or internationally recognised standards setting body or a test method specified in a governing code, law, regulation or specification applying to the item under evaluation. It may also include industry standards.
 - ii. “Specifies limits to the values of the major sources of uncertainty” is taken to mean that the test method specifies the maximum allowable uncertainty for each required measurement and specifies limits for environmental conditions or other factors that are known to have a significant influence on the outcome of the test(s).
 - iii. “Specifies the form of presentation of calculated results” is taken to mean that the standard includes a specific statement regarding the number of significant figures to which the result is to be reported, the rounding procedure or other specified forms of expression of results.
- b. Where all these conditions are met, no further statement of measurement uncertainty needs to be reported.
- c. In cases where the actual measurement uncertainty is larger than that implied by the reporting requirement, the laboratory should include a statement of the estimated measurement uncertainty in the report.
- 4.3 If the general approaches to estimation of uncertainty discussed in clause 2.4 above cannot be applied, a reasonable estimate of measurement uncertainty based on professional judgement may be used. Such an estimate should be based on substantial relevant experience and analysis of available data.

5. Electrical Testing

- 5.1 Electrical tests may be categorised under five general areas and this document is applicable to all of them:

- a. electrical characteristic tests (for materials, components, sub-assemblies, instruments and apparatus)
 - b. environmental and reliability tests
 - c. electromagnetic compatibility tests
 - d. telecommunications tests
 - e. electrical safety tests.
- 5.2 Measurement uncertainty for quantitative electrical tests should be evaluated. Laboratories should have the required procedures and uncertainty budgets in place for estimation of measurement uncertainty for all quantitative tests.
- 5.3 For quantitative tests, GUM⁶ procedures should be taken as the general approach in the estimation of measurement uncertainty. In addition, the following documents may be used as references in the specific testing areas:
- a. electromagnetic compatibility tests: UKAS LAB 34⁸
 - b. telecommunication tests: ETR 028⁹
- 5.4 For electrical testing, ISO 5725 should not be used as a general approach for measurement uncertainty estimation as it is not applicable.

6. Chemical Testing

6.1 Introduction

This section elaborates, for chemical testing, the requirements of ISO/IEC 17025 and the general interpretations and guidance given in section 2 above. Guidance on measurement uncertainty in analytical chemistry is available from Eurachem and CITAC¹⁰.

In considering measurement uncertainty requirements, it is necessary to also consider the measurement specification, method validation and traceability. These issues need to be considered for all measurements, but the degree of rigour required depends on the particular circumstances (see clause 2.5).

The measurand needs to be carefully defined, paying particular attention to whether sampling or sub-sampling is included or excluded from the customer's requirements. Sub-sampling in the laboratory will usually be included but sampling of a shipment will often be excluded from the defined measurand.

Method validation and verification data from repeat analysis of matrix reference materials, in-house standards, replicate analyses, inter-laboratory comparison programs, etc., will be useful in establishing method precision which, for chemical testing, is usually the major component of uncertainty.

The uncertainty of chemical measurements, in most cases, includes components from physical measurements, such as weighing, temperature measurement, volume measurement, etc. Such measurements are traceable

to SI units and full uncertainty budgets should be available if such measurements make a significant contribution to the overall uncertainty. Traceability of the final chemical estimation is usually to a reference material which, although often not complying with the VIM definition of a certified reference material, should be the best available. Where specified sample preparation, extraction, digestion, chemical reactions, etc are included in the method and no correction for method bias (e.g. recoveries) is specified, the method is regarded as empirical and is traceable to its specific instructions. A different method purporting to measure the same test parameter as a given method would often give a different result.

The uncertainty of physical measurements, the purity of calibration reference materials and their uncertainties, the uncertainties associated with recovery (bias) trials (when recovery factors are applied to results), as well as precision data should all be considered in the evaluation of measurement uncertainty.

6.2 Measurement Uncertainty Evaluation Strategies

Measurement uncertainty estimates should cover all significant sources of uncertainty that can be reasonably attributed to the measurand.

The following approaches to the evaluation of measurement uncertainty may be taken, depending on circumstances.

- a. Rigorous consideration of individual sources, combined with mathematical combination to produce a measurement uncertainty. This approach is often considered appropriate for the most critical work, including for the characterisation of reference materials. However, where an inappropriate model is used, this approach will provide an inaccurate measurement uncertainty and is not necessarily better than the following approach.
- b. Estimation of measurement uncertainty based on the overall estimate of precision through inter-laboratory studies and method validation, taking into consideration additional uncertainty sources. Additional sources that need to be considered may include sample homogeneity and stability, calibration/reference material used, bias/recovery, equipment measurement uncertainty (where only one item of equipment was used in obtaining the precision data).

The following give some practical steps for routine chemical testing:

- a. specify the measurand;
- b. identify significant sources of measurement uncertainty;
- c. consider reproducibility data (ISO 5725). In the field of chemical analysis it is considered acceptable to group sources of uncertainty together;
- d. consider the additional components of uncertainty. Precision data alone may not be sufficient and additional effects should be considered. Additional studies may be needed to evaluate uncertainty sources, which have not been covered by precision data. The additional work required need not involve major research and development;

- e. combine the precision data with the additional components to determine overall uncertainty of the method.

For empirical methods, the method bias is by definition zero and only individual laboratory and measurement standard bias effects need to be considered. Advice on the treatment of recovery is available in Thompson¹¹.

It is important to ensure that all appropriate effects are covered but not double counted. Where appropriate, effects of matrix type and changes in concentration should be included in the measurement uncertainty.

Where proficiency testing precision data are used, it is important to ensure that the data used to estimate the measurement uncertainty are relevant. In particular, they should relate to the same measurand, same test method and matrix.

In chemical testing it is customary to evaluate the uncertainty at selected concentration levels for a particular test method. However, when a measurement is being made to test compliance with specified, standard or limit values, it is necessary to use an uncertainty value attributable to measurement results close to the specified, standard or limit values. Therefore, it is useful to select the specified, standard or limit values as the levels at which the uncertainty is estimated. This approach is most likely to provide the best estimate of the measurement uncertainty at test result levels adjacent to the specified, standard or limit values.

Professional judgement may be used for estimating the magnitude of uncertainty attributed to certain sources where better estimates are not available or readily obtainable. In such cases, at least a short-term precision estimate of the source should be included in the evaluation. Where professional judgement has to be used for significant sources, it must be based on objective evidence or previous experience. Estimates of measurement uncertainty containing significant sources evaluated by professional judgement should not be used for applications demanding the most rigorous evaluation of uncertainty.

7. Microbiological Testing

7.1 There are four main types of microbiological tests:

- a. general quantitative procedures
- b. MPN procedures
- c. qualitative procedures
- d. specialist tests, e.g. pharmaceutical testing

Various approaches to estimating measurement uncertainty are available for general quantitative testing.

- 7.2 The Poisson distribution and confidence limit approaches as described in BS 5763¹² and ISO 7218¹³ may significantly underestimate uncertainty as not all sources of uncertainty are taken into account. The distribution of particles or organisms in a liquid may be described using the Poisson distribution but other components of uncertainty associated with the test procedure are not included. Indeed some components of uncertainty such as dilutions and consistency of reading plates will not be described by the Poisson distribution.
- 7.3 The negative binomial model described in ISO TR 13843¹⁴ may be more appropriate as it covers the Poisson distribution plus “over-dispersion” factors.
- 7.4 Some of the approaches described in the Eurachem / CITAC Guide may also be applicable for microbiology. “Intermediate precision” as set out in ISO 5725 is considered to incorporate most if not all of the significant uncertainty components of microbiological tests.

Any components of uncertainty not included in intermediate precision, such as performance of different batches of media, variation in incubator conditions (where only one incubator is available for replicates), etc., may be examined for significance by other statistical means.

- 7.5 The distribution of results from plate count tests is not normal but skewed (long right tail). Such data may first be transformed by taking the \log_{10} of each result, to obtain close to a normal distribution. The log standard deviation and confidence limits may then be calculated before anti-logging each limit separately.

Where other components of uncertainty such as sampling or equipment variations need to be combined with a precision result estimated using logs and anti-logs, sophisticated mathematical calculations may be required.

For those situations where test results are less than about 10 CFU, the distribution may be closer to normal and estimation of precision, perhaps without logs, for these particular ranges, will be necessary.

For one-off analyses, the Poisson distribution approach will give a quick estimate of the uncertainty (see note to clause 10.1.6 of BS 5763¹²). However, this is likely to significantly underestimate the actual uncertainty.

- 7.6 Any uncertainty associated with method bias is not relevant as quantitative microbiological tests are empirical tests with the result of an analysis being dependent on media, incubation times and temperatures specified.

A few CRMs are available for quantitative tests. Where they are available, their certified results are mostly obtained from collaborative studies. Therefore only consensus values from the specified method are available and, as with all other microbiological test methods, these methods are also empirical.

- 7.7 It is traditional in Most Probable Number (MPN) analyses to refer to McCrady's Tables to obtain a test result as well as the 95% confidence limits. These data have been established statistically but possibly without consideration of all sources of uncertainty. Laboratories are encouraged to identify unusual combinations of positive tubes and to reject such results. If this is done effectively, the uncertainties quoted in the tables will, in the meantime, be

regarded as a reasonable estimate of uncertainty for these methods.

- 7.8 In some areas of specialist testing e.g., pharmaceutical microbiological assays, note 2 of clause 5.4.6.2 of ISO/IEC 17025 may be applicable, as the methods concerned include validation of the assay parameters, specify limits to the values of the major sources of uncertainty of measurement and define the form of presentation of calculated results.
- 7.9 At this stage, very little method performance data are available from collaborative trials, although this situation may change in the future.

Proficiency testing data may not always provide suitable measurement uncertainty data because significant aspects may not have been taken into account.

- a. Matrix differences may occur between the proficiency test samples and the samples routinely tested by a laboratory.
- b. The population levels may not be the levels routinely tested in a laboratory and/or may not cover the full range of population levels encountered in routine laboratory work.
- c. Participating laboratories may use a variety of empirical methods (different measurands) to produce the results for the proficiency testing programs.

However, statistical analysis of results from proficiency testing programs may give an indication of the precision obtainable from a particular method.

- 7.10 At present, microbiological laboratories often do not have to report uncertainty unless required by customers or unless the interpretation of results may be compromised without it. When reporting uncertainty, a description of the procedure used to estimate the uncertainty should also be included because of the various methods used around the world that give different results.
- 7.11 Guidelines for reporting compliance with specification are given in APLAC TC 004. However, implementing these guidelines may not be straightforward.
- a. Specifications rarely quote the empirical method to be used.
 - b. Depending on how a laboratory estimates its uncertainty, situations may arise where, if results are close to a specification limit, one laboratory may state that a sample complies with the specification whereas another laboratory may state that there is doubt as to whether or not that same sample complies with the specification.

Where the uncertainty estimate indicates that there is doubt about compliance or non-compliance, the laboratory should report a result and its associated uncertainty without making a statement on compliance or non-compliance.

8. Calibrations Done by Testing Laboratories

For calibrations affecting test results significantly, the laboratory should have the calibrations performed by an accredited calibration laboratory. Where a testing laboratory opts to carry out its own calibrations in-house, the accreditation body should ensure that the calibration procedures are valid and that the uncertainty is determined following appropriate procedures. The accreditation body will need to ensure that the assessment team includes adequate expertise to make this determination.

Accreditation bodies may provide some guidance on estimation of uncertainty for common instruments, e.g., balances, thermometers, volumetric glassware and pressure gauges.

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