# HOKLAS Supplementary Criteria No. 20

## 'Chemical Testing', 'Chinese Medicine', 'Construction Materials', 'Miscellaneous', 'Pharmaceutical Products' and 'Toys and Children's Products' - Chemical Testing

### 0 Introduction

(a) This document serves to clarify and supplement the requirements of ISO/IEC 17025:2017 and HKAS Policy Document No. 1 for the accreditation of chemical tests. The following sections set out specific technical criteria. They also provide guidance for selected aspects. This document is not applicable to chemical testing to the Hong Kong Chinese Materia Medica Standards (HKCMMS), laboratories shall refer to HOKLAS Supplementary Criteria No. 44 for details on the related testing.

(b) The technical criteria specified in this document apply to accreditation of chemical tests under the 'Chemical Testing', 'Chinese Medicine', 'Construction Materials', 'Miscellaneous', 'Pharmaceutical Products' and 'Toys and Children's Products' Test Categories. Laboratories performing doping control testing shall also refer to HOKLAS Supplementary Criteria No. 51 for additional criteria.

(c) Laboratories should note that complying with this document might not necessarily meet the requirements of all test standards. Individual test standards may have specific requirements which shall be met when conducting the tests.

### 1 Scope

(No additional explanation)

### 2 Normative references

(No additional explanation)

### 3 Terms and definitions

(No additional explanation)

## 4 General requirements

(No additional explanation)

## 5 Structural requirements

(a) The technical management of the laboratory shall include at least a member who has in-depth knowledge of and extensive experience in analytical chemistry. He/she shall be part of the technical management that is responsible for the technical operation of the laboratory with respect to chemical analysis.

## 6 Resource requirements

### 6.1 General

(No additional explanation)

### 6.2 Personnel

(a) Tests shall be performed by staff who have adequate training in chemical analysis. For tests involving the use of sophisticated analytical instruments such as AAS, GF-AAS, cold vapour AAS, ICP-OES, ICP-MS, GC-MS/MS, LC-MS/MS, etc., testing staff are normally expected to have completed a post-secondary curriculum in chemistry such as higher diploma or above in chemistry or related disciplines. Special training shall be given to staff operating specialised equipment such as high-resolution mass spectrometer, GC-ICP/MS, LC-ICP/MS, etc.

(b) A training programme shall be outlined. The programme shall include training on the analytical techniques involved as well as the test procedures and the quality assurance plans. Records of initial training and continuing competence monitoring, including all associated raw data, shall be maintained.

(c) Approved signatories

(i) Approved signatories shall either have

(1) at least a Bachelor of Science degree, or equivalent, in chemistry or other relevant technical disciplines, with at least 3 years' relevant testing experience; or

(2) an Associate Degree or a Higher Diploma, or equivalent, in chemistry or other relevant technical disciplines, with at least 5 years' relevant testing experience.

***Note:*** *Alternatively, appropriate membership of professional bodies is acceptable. Special consideration may be given to persons without the qualifications in Cl. 6.2 (c)(i) but with extensive experience (at least ten years) in the testing area concerned.*

(ii) Irrespective of the person's academic qualifications, the nominee shall have at least six months' experience in the areas of testing for which signatory approval is sought.

(iii) In all cases, candidates shall demonstrate to the assessors that his/her technical competence in the test areas under consideration before signatory approval can be granted.

(d) When training is conducted on specific techniques, as opposed to specific methods, the laboratory should define and document the technique-based competence required for an analyst to perform each test and the additional requirements related to the technique concerned.

(e) Laboratory personnel responsible for visual assessment of colour difference of test samples, as well as approved signatories for the visual tests concerned, shall have normal colour vision for colour assessment.

6.3 Facilities and environmental conditions

(a) Acceptable ranges for the environmental conditions such as temperature and humidity shall be defined and documented. Cases where environmental conditions fall outside the acceptable ranges shall be recorded and the effects, if any, on test results shall be evaluated. Suitable corrective actions shall be taken to rectify the situation as soon as possible.

(b) Laboratories shall identify instruments that require special environmental conditions. It should be noted that both temperature and humidity fluctuations may affect the performance of some instruments, e.g. analytical balances and infrared spectrometers. Laboratories shall ensure that these instruments are placed in an environment that ensures their optimum performance and fitness for the intended use. Voltage stabiliser should be used for instruments sensitive to voltage fluctuation.

(c) When selecting designated areas for special work, laboratories shall consider the previous use of the area and take appropriate measures to ensure that the area is free of contamination. Such laboratory areas include open bench, fume hoods, sample storage area, oven/furnace area, and apparatus soaking/washing area.

(d) Trace analyses are particularly susceptible to contamination. Laboratories shall lay down procedures and precautions to be taken to prevent contamination or interference on laboratory activities from the environment. Particular attention should be given to, for example, the presence of dust in the laboratory environment for trace metal analyses. Precautions shall be taken to avoid the ingress of dust as far as possible. Materials used for furniture, hoods and other fixtures shall not cause contamination, by generation of air-borne particulate, to test samples, calibration standards and other reagents during the whole process of sample preparation and analysis. Good housekeeping is essential to minimise contamination by air-borne particulate.

6.4 Equipment

(a) For chemical testing, it is essential to avoid contamination of test samples and/or standard solutions by labware. Laboratories shall document procedures for washing labware and the types of labware to be used (glass, PTFE, etc.) for particular tests. Attention should also be given to the possible presence of analytes in commercial detergents. Laboratories shall use, if necessary, different washing, storage and segregation procedures for labware used for different analyses such as soaking of labware in acid solution to remove traces of metals for trace metal analysis. It is also necessary to have a set of labware dedicated for trace metal analysis to prevent possible cross-contamination. Similarly, dedicated labware is required for incompatible tests. Procedures or precautions for labware cleaning, if given in test standards, shall be followed.

(b) The grade of reagents used (including water) shall be stated in the methods together with guidance on precautions which shall be observed in their preparation or use. The absence of analytes in reagents, especially solvents and acids, used in the test procedures is of particular importance for trace analyses. Laboratories shall ensure that reagents used are suitable for the applications. Critical reagents prepared by the laboratory shall be labelled to identify substance, strength, solvent (other than water), any special precautions and restrictions of use, date of preparation and period of validity.

The person responsible for the preparation of the reagent shall be identifiable from records.

(c) Water is one of the most widely used reagents in chemical analysis. Hence, means to ensure that reagent water is of the required quality is necessary. Performance of water purification system shall be checked regularly to confirm the water produced meets testing requirements. Records of such checks shall be maintained.

6.5 Metrological traceability

(a) HOKLAS Supplementary Criteria No. 2 'All Test Categories – Equipment Calibration and Verification' provides HKAS policy on metrological traceability of measurement results. Requirements given in the Supplementary Criteria relevant to chemical analysis shall be fulfilled. For chemical analyses, it is not uncommon that the calibration procedure forms an integral part of the test procedure and is given in test standards. If that is the case, the calibration procedure given in the test standard shall be followed.

(b) Reference materials used for calibration shall provide the necessary metrological traceability. The requirements given in HOKLAS Supplementary Criteria No. 1 'Acceptability of Chemical Reference Materials and Commercial Chemicals Used for the Calibration of Equipment' shall be followed.

6.6 Externally provided products and services

(No additional explanation)

## 7 Process requirements

7.1 Review of requests, tenders and contracts

(No additional explanation)

7.2 Selection, verification and validation of methods

7.2.1 Selection and verification of methods

(a) Laboratories shall ensure that each selected method is adequate for its intended purpose and the needs of the customers. For compliance testing, it is

essential that the limits of reporting are well below the compliance limits and that the method gives reliable results at the limits. Due regard shall also be given to the limitations, concentration ranges and sample matrices specified in the test standards.

(b) Method verification is usually done by comparing the performance data obtained by the laboratory when performing a standard method with those claimed by the same method. If specified in the standard method, the procedure for determination and/or verification of method performance characteristics such as limits of detection and quantitation, precision, recovery, etc, shall be followed.

(c) The verification work to be carried out should be appropriate to the purpose of the method, such as identification or quantification of analytes at low and high concentrations. In general, the laboratory shall demonstrate their technical competence in performing the standard method such that the method performance characteristics, such as trueness, precision, limits of detection/quantitation, measurement uncertainty calculated from the verification data, meet the criteria specified in the standard method for all the matrices and concentrations that the laboratory will apply the method. International guidelines such as those published by the Analytical Laboratory Accreditation Criteria Committee (ALACC) of AOAC International may be followed.

*Note: Repeatability limit (r)/repeatability standard deviation ($\sigma_r$) and reproducibility limit (R)/reproducibility standard deviation ($\sigma_R$) are often stipulated in a standard method as benchmark performance criteria. References such as ISO 5725-6 'Accuracy (trueness and precision) of measurement methods and results Part 6: Use in practice of accuracy values' describe how a laboratory could demonstrate that it is able to use a standard measurement method with given R (or $\sigma_R$) and r (or $\sigma_r$) in a satisfactory way, including fulfilment of precision requirement in terms of r (or $\sigma_r$) and verifying if laboratory bias is acceptable with regard to the specifications of R (or $\sigma_R$) and r (or $\sigma_r$).*

(d) Some standard methods for organic analytes by using non-selective technique/instrumentation may specify the confirmation requirements. The identities of the analytes may be considered as confirmed if such requirements are fulfilled. For pharmaceutical testing, on the other hand, the methods stipulated under various Pharmacopoeias usually assume the correct identity

of the analytes of interest. However, in applying such methods to the laboratory samples, the laboratory shall ensure correct identity of the analytes. Specificity is considered as the ability to assess unequivocally the analytes in the presence of components which may be expected to be present. Typically, these might include impurities, degradants, matrix, etc. The lack of specificity of the analytical procedures shall be compensated by other supporting analytical procedures, e.g. using UV or mass spectra of the analytes. Guidelines such as those published by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) may be followed.

(e) The use of a technique 'more advanced' than that specified in the test standard may sometimes constitute a deviation. This is particularly true when the analytes are defined by the analytical method. When modifications of this nature are made, the laboratory shall assess the possible effects on the test results and, where necessary, obtain supporting evidence to justify the deviations. HKAS shall be informed of such deviations. The test shall be described as particular standard with modifications. Test report shall indicate the modifications.

7.2.2 Validation of methods

(a) Standard test methods shall be strictly adhered to and only be used for the intended concentration ranges and sample matrices. If they are used outside their intended concentration ranges or applied to different sample matrices, validation is required. Laboratories should ensure their competence to perform the test by use of certified reference materials and participation in proficiency testing programmes, if available.

(b) Non-standard methods shall be validated and authorised before use. The validated non-standard methods shall be documented and scope of application, performance characteristics, quality control plans and calibration shall be well defined. Reference to ISO 78-2 'Layouts for Standards – Part 2: Methods of Chemical Analysis' may be useful.

(c) For chemical tests, some of the performance characteristics are of particular importance. These include, for example, limits of detection/quantitation, precision and trueness, applicable concentration ranges and sample matrices. It is thus important that laboratory-developed methods should be validated against, amongst others, these characteristics. Laboratories shall define and explain how various limits of detection/quantitation and reporting, if

applicable, are derived. These procedures shall be in line with guidelines given by reputable professional bodies and the limits shall not give an unrealistic impression of the method's capability. Reporting limits shall be set at a level at which quantitative results may be obtained with a specified degree of confidence. Limits of detection/quantitation and reporting shall be suitably verified. Examples of such guidelines are given in IUPAC Technical Report 'Harmonized Guidelines for Single-Laboratory Validation of Methods of Analysis', EURACHEM Guide 'The Fitness for Purpose of Analytical Methods: A Laboratory Guide to Method Validation and Related Topics', ISO 11843-2 'Capability of Detection – Part 2: Methodology in the Linear Calibration Case' and AOAC Peer-verified Methods Program 'Manual on Policies and Procedures' AOAC International.

(d) Method bias shall be assessed using matrix certified reference materials (CRMs), if available. The CRMs used shall be of the same matrices as the sample matrices. The levels of the analytes shall also be within the ranges of applicability of the method. The procedure given by ISO Guide 33 'Reference Materials – Good practice in using reference materials' should be used to assess the trueness of the test method. If suitable matrix CRMs are not available, recovery studies or comparisons with standard reference methods shall be carried out. The recovery studies shall be carried out by spiking the analyte into matrix blank or sample blank. The variety of matrices used for method validation should be representative to serve the intended purpose of the method. Additional guideline is given in IUPAC Technical Report 'Harmonized Guidelines for the Use of Recovery Information in Analytical Measurement'.

(e) Confirmation of the identity of organic compounds is necessary for non-selective methods such as gas chromatographic methods employing electron capture detector, flame ionisation detector, or thermal conductivity detector, etc.; or liquid chromatographic methods employing refractive index detector or evaporative light scattering detector, etc. Procedures and criteria for confirmation of organic compounds shall be documented. The confirmation method shall be able to reliably confirm the identity of the organic compound at the reporting limit.

(f) The performance of a validated method may change due to many reasons. It is therefore necessary to review the performance characteristics of test methods at suitable intervals and perform revalidation if necessary. Such review may also be required when the performance of the method is affected by changes such as changes in equipment, environmental conditions, etc.

(g) The results of method validation shall be in line with international practices, such as those stipulated by Association of Official Analytical Collaboration (AOAC International).

7.3 Sampling

(a) Sampling from sample lot or site is not covered by this document. Customers taking their own samples should be made aware of proper storage, sampling and transportation procedures.

(b) Laboratories should never assume that a sample is homogeneous, even when it appears to be. Where a sample is clearly in two or more physical phases, the distribution of the analyte may vary within each phase. It may be appropriate to separate the phases and treat them as separate samples. Laboratories shall have documented procedures for taking test portions from laboratory samples and shall have measures to ensure that the test portion is representative of the sample.

(c) Equipment used for subsampling, packaging, sample extraction, etc. shall be selected to avoid unintended changes to the nature of the sample which may influence the final results. Preparation of laboratory samples and test portions, if not specified in test standards, should be based on national or international standards relevant to the tested samples. If necessary, customer's clarification should be sought.

7.4 Handling of test or calibration items

(a) Laboratories shall examine and record the condition and appearance of the samples upon receipt. Items to be checked should include, where appropriate, number, volume or amount of sample, temperature, colour, etc. Any deviations of test item from specified conditions shall be handled in accordance with Cl. 7.4.3 of ISO/IEC 17025:2017.

(b) Test samples shall be suitably stored as soon as practicable upon receipt. Laboratories shall define the storage conditions for different types of samples particularly for perishable samples. Maximum holding time shall be set for samples of which the analytes to be determined may be affected by prolonged storage. Tests of such samples shall be performed within the set time limits.

(c) Frequently, it is necessary to split the sample for testing of different properties. It is essential that such sub-samples represent the original samples and that

their identities are maintained at all times. Attention should be paid to possible contamination of samples by metals or plasticisers leached from containers or stoppers into the sub-samples. In choosing containers for sub-samples, the properties of the analyte of interest should be taken into account.

(d) Access to the sample storage shall be controlled and only authorised persons shall have access to the sample storage. For litigation samples, procedures shall be in place both to ensure and to demonstrate that samples are secured and their integrity is maintained. Chain-of-custody shall be established.

7.5 Technical records

(No additional explanation)

7.6 Evaluation of measurement uncertainty

(a) It is recognised that there is more than one method for evaluating measurement uncertainty and there is no general consensus on the method to be used in chemical testing. HKAS accepts methods for evaluating measurement uncertainty given by reputable professional and standard writing bodies. However, the uncertainty value obtained should be in line with the definition given in JCGM 200 'International Vocabulary of Metrology – Basic and General Concepts and Associate Terms' (VIM) and should include all major components of uncertainty in its evaluation. Reference to the EURACHEM/CITAC Guide 'Quantifying Uncertainty in Analytical Measurement' and 'VAM Project 3.2.1 Development and Harmonisation of Measurement Uncertainty Principles, Part (d): Protocol for uncertainty evaluation from validation data' published by LGC, UK, may be useful.

(b) The laboratory shall identify all the significant components of uncertainty for each test.

(c) In general, the degree of rigor relates to the level of risk. To properly evaluate safety, substantial property risk or financial risk, or for litigation purpose, a relatively rigorous uncertainty evaluation is required for the associated tests.

(d) Where sampling (or sub-sampling) is to be treated as part of the test, the uncertainty arising from such sampling shall be considered by the laboratory. In other words, it is necessary to analyse the representativeness of the sub-sample (i.e. test portion) as part of the measurement uncertainty evaluation. EURACHEM/CITAC Guide 'Measurement uncertainty arising from sampling:

A guide to methods and approaches' produced jointly by Eurachem, EUROLAB, CITAC, Nordtest and the RSC Analytical Methods Committee may be followed.

(e) 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 shall be considered in the evaluation of measurement uncertainty.

(f) Where professional judgement has to be used for significant sources, it shall be based on objective evidence or previous experience. Evaluation of measurement uncertainty containing significant sources evaluated by professional judgement shall not be used for applications demanding the most rigorous evaluation of uncertainty.

*Notes:*

*(1) Measurement uncertainty may be evaluated by rigorously considering 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 characterization of reference materials.*

*(2) Another approach to evaluate measurement uncertainty is based on interlaboratory studies, quality control and method verification/validation data, taking into consideration additional uncertainty sources. Additional sources that need to be considered may include sample homogeneity and stability, calibration/reference material, bias/recovery, equipment uncertainty (where only one item of equipment was used in obtaining the precision data). For evaluating measurement uncertainty of methods and laboratory bias from proficiency testing data, reference such as EUROLAB Technical Report 'Measurement uncertainty revisited: Alternative approaches to uncertainty evaluation' may be useful.*

*(3) In standard methods where method performance characteristics such as repeatability standard deviation ($\sigma_r$) and reproducibility standard deviation ($\sigma_R$) determined in accordance with ISO 5725-2 are provided, the information may be adopted for uncertainty estimation as per ISO 21748 'Guidance for the use of repeatability, reproducibility and trueness estimates in measurement uncertainty evaluation'*

7.7 Ensuring the validity of results

(a) Laboratories shall document their quality control plans and procedures for each test method and matrix. The plans shall include frequency of performing quality control checks, their acceptance criteria and actions to be taken in cases of acceptance criteria not being met.

(b) The quality control plans and procedures, including acceptance criteria whenever stipulated in the relevant test standards shall be followed strictly. If such plans are not given, Cl. 7.7 (b) to 7.7 (d) shall be followed where appropriate.

(i) Blank
Method blank shall be performed at a minimum frequency of one per preparation batch of samples or one per twenty samples, whichever is more frequent. A method blank should consist of reagent water and all reagents, in same amounts as test samples, that are in contact with or added to a sample during the entire analytical procedure. Method blank shall be processed through the entire analytical procedure simultaneously with other test samples within the same preparation batch. Values of method blank above the acceptance limit indicate possible contamination of the batch of samples analysed simultaneous with the blank.

(ii) Laboratory control sample (LCS)
LCS shall be analysed at a minimum frequency of one per twenty samples or one per each batch of samples, whichever is more frequent. LCS should be prepared in a matrix and at a level that are normally encountered.

(iii) Spike
Matrix spike shall be performed at a minimum frequency of one per batch of samples or type of matrix or twenty samples, whichever is more frequent. Spiking shall be done before the sample is analysed and should be at the concentration of the analyte present, or the concentration of the mid-range of the calibration curve, or other relevant concentrations. The amount of spike added shall not alter the matrix of the sample significantly. The spike and the calibration standards used in the same run should be prepared from different stock solutions or by different analysts, if possible.

(iv) Duplicate
Duplicate sample (or duplicate spike/LCS, if applicable) shall be analysed at a minimum frequency of one per batch of samples or type of matrix or

twenty samples, whichever is more frequent.

(c) The calibration curve shall be constructed as specified in the test standards. Normally, at least three standards (excluding blank) shall be used to establish a linear calibration graph. The standards used shall cover the concentration range of the test samples. The lowest standard shall be at a level at or below the reporting limit of the test method. Criterion o the correlation coefficient of linear calibration graph shall be defined and implemented. Guidelines given in ISO 11095 'Linear Calibration using Reference Materials' should be consulted for further details. More calibration standards are required for non-linear calibration functions. Bracketing technique should be used, if appropriate.

(d) Calibration graphs shall be checked regularly using mid-point calibration standard. The frequency of such check depends on the stability of the equipment and a frequency of around 5 per cent is normally considered as adequate, except otherwise specified by the test standards or the stability of the equipment merits more frequent checking. Acceptance criteria shall be established and shall commensurate with the testing uncertainty.

(e) Control charts shall be used where appropriate to monitor the performance of the laboratory. Control and warning limits of such charts shall be based on statistical principles. Laboratories shall also observe any trend that is indicated in control charts. Procedures for constructing control charts and the associated acceptance criteria, if stipulated in the test standard, shall be followed. Otherwise, recommendations given in ISO 5725-6 'Accuracy (Trueness and Precision) of Measurement Methods and Results – Part 6: Use in Practice of Accuracy Values', IUPAC 'Harmonized Guidelines for Internal Quality Control in Analytical Chemistry Laboratories', ISO 7870-2 'Control charts - Part 2 Shewhart control charts', ISO 7870-4 'Control charts – Part 4 Cumulative sum charts' and ISO 7870-6 'Control charts – Part 6 EWMA control charts', may be followed, if appropriate.

(f) Proficiency testing programme

(i) Laboratories shall establish schedules for verifying their performance by analysing matrix CRMs and participating in proficiency testing programmes at intervals commensurate as far as possible with the volume of work undertaken. Participation in proficiency testing programmes or inter-laboratory comparison studies, when proficiency testing programmes are not available, at least once a year for each major test area

is required.

(ii) Laboratories shall document procedures for rectifying unsatisfactory performance in proficiency testing programmes. If unsatisfactory results are obtained, the laboratory shall promptly investigate the cause(s), take action to rectify the problem and further demonstrate that it can achieve satisfactory performance for the test/method in question. All findings and actions taken in connection with unsatisfactory performance shall be recorded.

7.8 Reporting of results

(a) A description of the samples as received shall normally be given in test reports. The description shall include, where relevant to the interpretation of test results, a description of the number/set, appearance and volume/amount of samples, type of container and condition when received.

(b) When test results are below the reporting limits, an indication of the reporting limits shall be given in test reports.

(c) If results to be reported are numerical values, policy and instructions shall be given on the required number of significant figures and rounding of numbers.

(d) Other information necessary for the proper interpretation of the test results (e.g. quality control results, relevant information provided by the customers, measurement uncertainty, etc.) shall be reported. Qualifying statements on test results shall be given, if necessary.

(e) The sample preparation procedure shall be given if it is required for the proper interpretation of test results. For solid samples, the weight basis on which test results are calculated (e.g. dried basis, as received basis or wet basis) shall be given. Dry to wet weight ratios of samples shall be reported, where necessary.

(f) Some test standards require the reporting of additional information. In these cases, the test reports shall include all the information required by the test standards.

(g) When stating conformity with a legislation, specification or standard, decision rule shall be clearly defined and documented. In determining decision rule, international guideline, such as ILAC-G8 ‘Guidelines on Decision Rules and

Statements of Conformity' and EURACHEM/CITAC Guide 'Use of uncertainty information in compliance assessment' and EUROLAB Technical Report 'Decision rules applied to conformity assessment' may be followed.

(h) When selecting methods for compliance testing, laboratories shall observe the following:

(i) If a piece of legislation (or the regulatory authority), a standard, or other published documents specify the compliance testing method(s)/procedure(s) to be used, that specified test method(s)/procedure(s) shall be used for the compliance testing.

(ii) If a piece of legislation (or the regulatory authority), a standard, or other published documents do NOT specify the compliance testing method(s)/procedure(s) to be used, but a relevant test standard (e.g. ISO, EN, reputable professional bodies like AOAC International, APHA, USP, EP, BP, etc.) is available which states, in its scope of application, that it can be used for compliance testing against the specifications, that standard testing method(s)/procedure(s) can be used for the compliance testing.

(iii) If a piece of legislation (or the regulatory authority), a standard, or other published documents do NOT specify the compliance testing method(s)/procedure(s) to be used, and there is NO test standard which states that it can be used for compliance testing against the specifications, but the parameter concerned is a well-defined measurand which does not depend on the method used (e.g. total lead in paint), then a validated test method can be used for compliance testing.

(iv) If a piece of legislation (or the regulatory authority), a standard, or other published documents do NOT specify the compliance testing method(s)/procedure(s) to be used, and there is NO test standard which states that it can be used for compliance testing against the specifications, and the parameter concerned is NOT a well-defined measurand, then the laboratory could not be accredited for compliance testing. It may only be accredited for the test concerned.

7.9 Complaints

(No additional explanation)

7.10 Nonconforming work

(No additional explanation)

7.11 Control of data and information management

(No additional explanation)

## 8 Management system requirements

(No additional explanation)

**Annex**
**(Informative)**

## Bibliography

1 ISO 11095 *Linear Calibration using Reference Materials*

2 ISO 78-2 Chemistry Layouts for Standards – Part 2: *Methods of Chemical Analysis*

3 Pure & Appl. Chem., Vol. 74 No. 5 IUPAC Technical Report '*Harmonized Guidelines for Single-Laboratory Validation of Methods of Analysis*'

4 EURACHEM Guide *The Fitness for Purpose of Analytical Methods: A Laboratory Guide to Method Validation and Related Topics*

5 ISO 11843-2 *Capability of Detection – Part 2: Methodology in the Linear Calibration Case*

6 AOAC Peer-verified Methods Program '*Manual on Policies and Procedures*' *AOAC International.*

7 ISO Guide 33 *Reference Materials – Good practice in using reference materials*

8 Pure & Appl. Chem., Vol. 71 No. 2 IUPAC Technical Report '*Harmonized Guidelines for the Use of Recovery Information in Analytical Measurement*'

9 ALACC, AOAC International 2007: *How to meet ISO 17025 requirements for method verification*

10 ICH Harmonised Tripartite Guideline: *Validation of Analytical Procedures – Text and Methodology*

11 JCGM 200 *International Vocabulary of Metrology – Basic and General Concepts and Associated Terms (VIM)*

12 EURACHEM/CITAC Guide CG 4 *Quantifying Uncertainty in Analytical Measurement*

13 V. J. Barwick and S. L. R. Ellison, *VAM Project 3.2.1 Development and Harmonisation of Measurement Uncertainty Principles, Part (d): Protocol for uncertainty evaluation from validation data*, LGC

14 EURACHEM/CITAC Guide *Measurement uncertainty arising from sampling: A guide to methods and approaches*

15 EUROLAB Technical Report No. 1/2007: *Measurement uncertainty revisited: Alternative approaches to uncertainty evaluation*

16 ISO 5725-2 *Accuracy (trueness and precision) of Measurement Methods and Results – Part 2: Basic method for the determination of repeatability and reproducibility of a standard measurement method*

17 ISO 21748 *Guidance for the use of repeatability, reproducibility and trueness estimates in measurement uncertainty evaluation*

18 ISO 5725-6 *Accuracy (Trueness and Precision) of Measurement Method and Results – Part 6: Use in Practice of Accuracy Values*

19 Pure & Appl. Chem., Vol. 67 No. 4 IUPAC Technical Report '*Harmonized Guidelines for Internal Quality Control in Analytical Chemistry Laboratories*'

20 ISO 7870-2 *Control charts – Part 2: Shewhart control charts*

21 ISO 7870-4 *Control charts – Part 4: Cumulative sum charts*

22 ISO 7870-6 *Control charts – Part 6: EWMA control charts*

23 ILAC-G8 *Guidelines on Decision Rules and Statements of Conformity*

24 EURACHEM/CITAC Guide *Use of uncertainty information in compliance assessment*

25 EUROLAB Technical Report No. 01/2017: *Decision rules applied to conformity assessment*

26 ILAC G18 *Guideline for describing scopes of accreditation*

Remark: For dated references in the whole Annex, only the edition cited applies. For undated references cited, the latest edition (including any amendments) applies.