HOKLAS Supplementary Criteria No. 8

'Chinese Medicine', 'Environmental Testing', 'Food', 'Miscellaneous', 'Pharmaceutical Products', 'Textiles and Garments' and 'Toys and Children's Products' - Microbiological Testing

0 Introduction

(a) This document serves to clarify and supplement the requirements of ISO/IEC 17025:2017 and HKAS PD001 for the accreditation of laboratories performing microbiological tests.

(b) The technical criteria specified in this document apply to accreditation of laboratories performing microbiological tests under the test categories of 'Chinese Medicine', 'Environmental Testing', 'Food', 'Miscellaneous', 'Pharmaceutical Products', 'Textiles and Garments' and 'Toys and Children's Products'.

(c) Laboratories should note that fulfilling 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 with knowledge of and hands-on experience in microbiological testing. He/she is responsible for the technical operation of the laboratory with respect to microbiological testing and the training of staff for routine microbiological testing.

6 Resource requirements

6.1 General

(No additional explanation)

6.2 Personnel

(a) The minimum level of qualification and experience necessary for all posts within the laboratory shall be defined.

(b) Testing shall be performed by staff members who have formal training in microbiological testing. A training programme shall include, in addition to the testing procedures, training on biosafety precautions, basic microbiological techniques, procedures of sample collection and handling, media preparation, sterilisation, aseptic techniques, staining techniques, use of microscope, counting, data handling, use of control strains, and other quality control techniques. Training materials should be documented and authorised. Full records of training shall be maintained. Staff members are allowed to analyse real samples only after they have been fully trained and their competence has been assessed to be satisfactory. Their performance shall be evaluated regularly to ensure continuing competence.

(c) Approved signatories

(i) Approved signatories shall have a bachelor degree, or equivalent, in microbiology or biological science (major in microbiology), or he/she is a registered medical laboratory technologist; and shall have at least six-month experience in the areas for which signatory approval is sought.

(ii) Approved signatories who have a degree in science other than microbiology shall have taken

(1) at least 3 undergraduate relevant microbiology courses of different levels with substantial coverage in laboratory techniques and microbiological testing, or

(2) successfully completed a certificate course in microbiological testing at an academic institute,

and shall have at least one-year experience in the areas for which signatory approval is sought.

(iii) Approved signatories for specific pathogens shall possess appropriate academic or professional qualifications in microbiology. He/she shall have received training and hands-on testing experience for that specific pathogen(s). Documented evidence shall be available to indicate the training received before signatory approval is sought.

(iv) For those dealing only with microbial indicators, a bachelor of science degree together with formal training in microbiology at an appropriate academic institute and one-year experience in the areas for which signatory approval is sought may be considered satisfactory depending on the merits of each individual case.

Note: Special consideration may be given to persons for dealing only with microbial indicators without the above qualifications but with extensive experience for at least 10 years in the test areas concerned depending on the merits of each individual case.

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

6.3 Facilities and environmental conditions

(a) Laboratory facilities shall be clean, temperature and humidity controlled, and have adequate lighting at bench tops. Acceptable ranges for temperature and humidity should be defined. There shall be effective

separation between neighbouring laboratory areas to minimise the risk of contamination. A distinct space, if not a separate room, shall be used for microbiological testing in a laboratory complex. In the absence of a separate room, exceptionally good housekeeping and strict control of traffic would need to be demonstrated. The laboratories shall lay down procedures and precautions to be taken to prevent risks of cross-contamination. Suitable hoods shall be used when necessary. Instructions shall be available for the sterilisation and wiping down of bench tops.

(b) The risk of contamination of both experiments and personnel is usually due to overcrowding. Sufficient bench space should be provided for each analyst at one time. Space is crucial when dealing with pathogens. The space provided should be commensurate with the volume of analyses handled.

(c) When environmental monitoring plan and procedures are not specified in test standards, laboratories shall devise an appropriate monitoring programme such as use of air settling plates to measure the trends in levels of contamination. Acceptable background counts shall be assigned and there shall be a documented procedure for dealing with situations in which these limits are exceeded. Records of such situations, evaluation of the effects, if any, on the test results, and corrective actions taken shall be maintained.

(d) Separate locations or clearly designated areas should be provided for the following processes:

(i) sample reception;
(ii) sample preparation;
(iii) manipulation of pathogens (in conditions relevant to their hazard level);
(iv) preparation and sterilisation of culture media;
(v) cleaning of labware; and
(vi) decontamination of contaminated culture media and samples (recommended to be performed in a separate room).

(e) Separate enclosures shall be provided for the following materials:

(i) reference and working stocks of reference microorganisms (store

pathogens under secure conditions);

(ii) retained test cultures;

(iii) samples;

(iv) serological and biochemical reagents/prepared media; and

(v) dehydrated media.

(f) For procedures that involve the handling of pathogens and reference stock cultures, they shall be operated within a biological safety cabinet of a class commensurate with the risk level of the respective microorganisms handled, where necessary, to avoid cross contamination and protect the operator. Most microorganisms encountered in a non-clinical setting microbiology laboratory belong to Risk Group 2 microorganisms (e.g. salmonellae and *Staphylococcus aureus*). Guidelines on the appropriate handling of these microorganisms can be found in the WHO Laboratory Biosafety Manual. Especially, when working with samples containing microorganisms transmissible by the respiratory route (e.g. legionellae), or when the work produces a significant risk from aerosol production, a biological safety cabinet of Class I or Class II shall be used.

6.4 Equipment

(a) General

Commonly used equipment in a microbiology laboratory includes autoclave, balance, thermometer, pH meter, timer, incubator/oven and volumetric labware. Performance of these items of equipment shall meet the specifications of the tests. The requirements and recommendations relating to verification and calibrations of these items of equipment described in HOKLAS SC-02 apply.

(b) Autoclave

(i) Autoclave shall not be used to sterilise clean equipment/materials and to decontaminate used equipment/materials during the same sterilisation cycle. It is preferable to use separate autoclaves for these two processes. Records of autoclave operations, including temperature and time, shall be maintained. Acceptance and rejection criteria for operation conditions shall be set and implemented.

(ii) The temperature of each cycle shall be indicated by either use of

(1) a thermocouple and recorder to produce a chart or printout, or equivalent;
(2) chemical indicators such as Brownes tubes, Thermalog strips, etc.;
(3) biological indicators such as spore strips; or
(4) a maximum thermometer

(iii) In addition to monitoring of temperature, the effectiveness of operation of the autoclave shall be checked monthly with biological indicators. Temperature-sensitive tape shall be applied for each load. However, they are used simply as an indicator that the load is 'processed' but not as a monitor of the actual process applied.

(c) Hot-air oven

Performance of ovens shall be checked monthly with biological indicators. Temperature-sensitive tape shall be used to identify materials that have been exposed to sterilisation temperature.

(d) Incubator, water bath or metal block

Temperature of equipment used for incubation shall be verified against the specifications of the test standards at least annually. Temperatures at different levels and / or different positions at the same level, where applicable, shall be verified at defined time intervals. The maximum and minimum temperature in the course of incubation shall be monitored.

(e) Refrigerator, freezer or cold-storage room

Allowable ranges of operation shall be specified and records of temperature monitoring shall be maintained. The temperature monitoring procedure shall be capable of detecting short periods of temperature rise (e.g. temperature rise caused by electricity failure for a short period of time).

(f) Temperature monitoring device

Where the accuracy of temperature measurement has a direct effect on the validity of the result of an analysis, the temperature measuring devices used in incubators and autoclaves shall be of the appropriate quality to achieve the specifications in the test methods. The resolution of the device shall be appropriate for the required measurement accuracy. Metrological traceability of measurement of the temperature measuring device has to be established and the measurement uncertainty shall be evaluated and appropriate for the measurement.

(g) Biological safety cabinet or laminar flow cabinet

Laboratories shall establish a programme to check the rate of airflow and particle count in the cabinet. Criteria shall be defined and records of checks shall be maintained. The cabinet should be maintained and serviced in accordance with the manufacturer's recommendations. Such services include monitoring of use of UV lamp (if applicable) and HEPA filter and their regular replacement. Appropriate disinfection shall be carried out before maintenance.

(h) Automated system

Laboratories shall carry out performance checks of the automated system in accordance with the manufacturer's instruction at least once a year, or at the frequency recommended by the manufacturer, whichever is more frequent.

(i) Quality and grade of reagents including detergent should be appropriate for the tests concerned. They shall not contain any impurities that may inhibit bacterial growth. Guidance on precautions, which should be observed in the preparation or use of reagents, should be documented. These precautions relate to toxicity, flammability, stability to heat, air and light, reactivity to other chemicals, etc. Reagents prepared in laboratories shall be labelled to identify substance, strength, solvent, any special precautions or hazards, any restrictions on use, and date of preparation and/or expiration. Persons responsible for preparation of reagents shall be identifiable from records.

(j) The sources and history of supplies having an effect on the validity of tests such as media, antisera, reagents in commercial test kits and membrane filters shall be recorded. Record on information such as supplier, lot

number, date received, date put into use, date of verification and date of expiration of all such materials shall be maintained.

(k) Media, supplements, additives and commercial test kits

(i) All dehydrated or pre-prepared media and purified agars shall be checked for their physical states and verified for their microbiological performance prior to release for use. Selective media shall be checked using positive strains with typical characteristics and completely inhibited strains, where appropriate. Quantitative performance of media, where relevant, shall also be evaluated using appropriate spiked samples or methods as required by test standards. Acceptance criteria shall be established and records of verification shall be maintained.

(ii) Laboratories shall establish and record an appropriate re-ordering schedule to maintain sufficient stocks while preventing holding of stocks beyond their expiry dates. Schedules for checking media for decomposition, discoloration, deterioration and caking shall be documented. It is important to prevent dehydrated culture media from absorbing moisture during storage. Dehydrated media should be stored in a dry, cool and dark environment. Acceptance ranges of storage conditions and criteria for rejecting media should be documented. Records of monitoring the storage conditions and checks of media shall be maintained.

(iii) All media recipes and procedures for preparation shall be fully documented and authorised. Records shall be kept of all relevant details of each batch of medium prepared. The records should include medium name, lot number, manufacturer, ingredient quantities (if applicable), final pH, sterilisation process, date of preparation and name of operator preparing the medium. Prepared media not put into use immediately shall be labelled with medium names or codes, date of preparation, and date of expiration if applicable. Information on the life expectancy of prepared media under specific storage conditions shall be specified and documented. Guidance on the preparation, sterilisation and storage of media can be found in ISO 11133 ‘Microbiology of food, animal feed and water – Preparation, production, storage and performance testing of culture media’ and American Public Health Association (APHA)

Standard Methods for the Examination of Water and Wastewater section 9020 B.

(iv) Supplements, additives and consumables in commercial test kits should be stored and handled as directed by the manufacturer, or as determined by in-house storage procedures.

(l) Quality of reagent water used for critical processes shall be specified and checked regularly for compliance against the requirements.

(m) Serological and biochemical kits shall be verified with positive and negative strains with typical and negative characteristics, if applicable.

(n) Apart from reagents, laboratories shall ensure that labware such as culture dishes, culture tubes, sample containers, sample bags, spatulas, pipettes and pipette tips be pre-sterilised or sterilisable.

(o) Membrane filtration units shall be stainless steel, glass, or autoclavable plastic, not scratched or corroded and shall have no leakage. Diameter and pore size of membrane filters, and diameter and absorption capability of absorbent pads shall meet the requirements specified in the test standards. They shall be confirmed of their sterility prior to release for use.

(p) Sterile metal or disposable plastic loops, sterile wood applicator sticks, sterile swabs, etc. should be used as inoculating equipment. Metal inoculating loops should be made of alloys that do not interfere with any biochemical tests.

6.5 Metrological traceability

(a) Reference microorganisms

(i) Laboratories shall demonstrate traceability by use of reference microorganisms obtained from a recognised national collection such as American Type Culture Collection (ATCC), National Center for Medical Culture Collections (CMCC) and National Collection of Type Cultures (NCTC).

(ii) Reference microorganisms may be sub-cultured once to provide

reference stocks. Reference stocks shall be preserved by a technique such as freeze-drying, liquid nitrogen storage, cryo-beads, etc., which maintains desired characteristics of the strains. Laboratories shall have a policy and procedures for purchase, handling, storage, preservation, maintenance and use of reference microorganisms and stocks.

(iii) Reference stocks shall be used to prepare working stocks for routine work. Working stocks should not normally be sub-cultured. However, working stocks may be sub-cultured up to a defined number of generations (normally not more than five passages from the original national collection culture as recommended by US Pharmacopoeia) provided that it is required by test standards or documentary evidence demonstrating that there has been no loss of viability, no changes of biochemical activity and/or no change in morphology. Procedures for preparation and verification of working stocks shall be documented. Desired characteristics of the strains shall be verified by serological, biochemical and/or morphological tests. Verification procedures shall be enhanced, such as full biochemical identification including the characteristics of the reference microorganisms, if the reference microorganisms are used beyond the recommended five passages.

(iv) Reference microorganisms not obtained directly from, but claimed to be traceable to a national collection may be used for quality control checks, but the requirements on number of passages and the relevant verification procedures required as mentioned in 6.5(a)(iii) shall also be observed. They shall not be further sub-cultured if no information on passage number is available from the supplier.

(v) The following records shall be maintained:

(1) the sources, lot numbers, dates of receipt and expiration, dates put into use, conditions and integrity of packaging of reference microorganisms;
(2) verification records of reference and working stocks;
(3) history of subculture from reference stocks with dates of preparation and expiration, and name of operator; and
(4) methods used for preservation of reference stocks and records of monitoring of environmental conditions for storage of

reference microorganisms, reference and working stocks.

(b) Reference materials and certified reference materials

Reference materials and certified reference materials, if available, should be used to provide metrological traceability in measurements, demonstrate the accuracy of test results, monitor laboratory performance and validate method, and enable comparison of methods. Furthermore, they shall be stored and handled under conditions that do not alter their integrity, in accordance with a documented procedure.

Calibration of equipment critical to test results shall be traceable to the International System of Units (SI). Where traceability of measurements to SI units is not possible, traceability to, for example, certified reference materials, certified reference microorganisms, agreed methods and/or consensus standards, are required.

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 may use national and international standard methods and in-house methods. Laboratories shall ensure that each particular method is adequate for its intended purpose and the needs of the customers. When standard methods are used, laboratories shall verify their own ability to achieve satisfactory performance against the documented performance characteristics of the method by using appropriate reference microorganisms and participation in proficiency testing programmes, when available. ISO 16140-3 ‘Microbiology of the food chain – Method validation – Part 3: Protocol for the verification of reference methods and

validated alternative methods in a single laboratory provides guidance on verification of standard methods for microbiological examination of foodstuff. Laboratories should pay attention to the limitations and sample matrices specified in the test standards. Standard test methods that are used outside their scope of application shall be validated.

(b) It is essential to avoid contamination of test samples and reagents introduced by labware or water used for tests. Therefore, procedures for the washing of labware and generation of distilled, deionised or reagent water shall be available.

7.2.2 Validation of methods

(a) Commercialised test kits/systems may not require further validation if validation data based on collaborative testing are available, or when they are approved by professional bodies like AOAC INTERNATIONAL. Otherwise, the laboratory shall be responsible for validation of the method.

(b) Non-standard microbiological test methods shall be validated by evaluating, if appropriate, the sensitivity, specificity, relative bias, positive deviation, negative deviation, ruggedness, limit of detection, limit of determination, matrix effect, repeatability and reproducibility. Validation results of the non-standard methods shall be documented and scope of application shall be well defined. Guidance on the validation of microbiological testing can be found in ISO 13843 ‘Water quality – Requirements for establishing performance characteristics of quantitative microbiological methods’ and ‘AOAC INTERNATIONAL Methods Committee Guidelines for Validation of Microbiological Methods for Food and Environmental Surfaces’.

(c) The use of certain proprietary methods for microbiological examination of foodstuffs is acceptable if the methods are certified by an independent body in accordance with the protocol set out in ISO 16140-2 ‘Microbiology of the food chain – Method validation – Part 2: Protocol for the validation of alternative (proprietary) methods against a reference method’ or other internationally accepted similar protocols. When these alternative (proprietary) methods are used, laboratories shall verify their own ability to achieve satisfactory performance when conducting the method.

7.3 Sampling

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

(b) Laboratories shall document the procedures for taking test portions from laboratory samples and shall have measures to ensure that the test portion is as representative of the sample as possible, and the composition of the sample would not be altered in a way that would affect the concentration or identification of the organisms being determined. Preparation of laboratory samples and test portions, if not specified in test standards, should be based on national or international standards specific to the tested products and the general guidance given in ISO 6887-1 'Microbiology of the food chain – Preparation of test samples, initial suspension and decimal dilutions for microbiological examination – Part 1: General rules for the preparation of the initial suspension and decimal dilutions' and ISO 7218 'Microbiology of food and animal feeding stuffs – General requirements and guidance for microbiological examinations'.

(c) Sampling procedure can form part of test methods and shall include procedures for sterilisation of sampling equipment and precautions in performing aseptic techniques.

7.4 Handling of test or calibration items

(a) Laboratories shall examine and record the conditions and appearance of samples upon receipt. Where appropriate (e.g. environmental samples for quantitative results), the time of sampling should also be recorded. Items to be checked include nature and characteristics of sample, volume/amount of sample, storage temperature of sample on receipt, conditions of sample container i.e. whether it has been sterilised before sampling, characteristics of the sampling operation (sampling date and condition), etc. If there is insufficient sample or the sample is in poor condition due to physical deterioration, incorrect temperature, torn packaging or deficient labelling, laboratories shall handle the situation in accordance with Cl. 7.4.3 of ISO/IEC17025:2017.

(b) Samples awaiting test shall be stored under suitable conditions to minimise any modifications to any microbial population present. Storage

conditions and maximum holding times for different types of samples shall be documented and shall fulfil the requirements of test standards.

(c) Frequently, it is necessary to split or transfer samples for testing of different properties. It is essential that procedures are available for preventing contamination, delivery of samples including special transportation such as refrigeration and exclusion of light, disposal and decontamination processes and unbroken chain of identification of the sub-samples/samples shall be provided.

7.5 Technical records

(No additional explanation)

7.6 Evaluation of measurement uncertainty

(a) The uncertainty evaluation methods given by reputable professional and standard writing bodies generally accepted within the testing discipline may be used. It is important that the measurement uncertainty evaluated should be in line with the definition given by JCGM 200 'International Vocabulary of Metrology - Basic and General Concepts and Associated Terms (VIM)' and includes all major components of uncertainty. Reference to the EURACHEM/CITAC Guide CG4 'Quantifying Uncertainty in Analytical Measurement', ISO 19036 'Microbiology of the food chain – Estimation of measurement uncertainty for quantitative determinations', ISO 29201 'Water quality – The variability of test results and the uncertainty of measurement of microbiological enumeration methods', and 'Uncertainty of quantitative determinations derived by cultivation of microorganisms' published by Centre for Metrology and Accreditation, Finland may be useful.

7.7 Ensuring the validity of results

(a) Laboratories shall establish and implement quality control plans to ensure and demonstrate that the measurement process is in-control and test results generated are accurate and reliable. The plans shall include types of quality control checks, their frequency and acceptance criteria, and actions to be taken when results have been out of specifications.

(b) It is common that quality control plans are stipulated in test standards.

These plans and the specified criteria shall be followed strictly. If such plans are not given, the followings shall be followed where applicable.

(i) Sterility control
Uninoculated samples shall be run at a minimum of once for every test run. Sterility controls are used to detect the presence or absence of possible laboratory contamination.

(ii) Split sample (Duplicate) for quantitative tests
Split samples comprise a sample divided into 2 sub-samples. Analysis of spilt samples are normally expected to be conducted at a frequency of once per test run. Where a batch of samples exceeds 20 numbers, duplicate analysis shall be conducted at the beginning and end of each test run. Analysts shall be able to duplicate their own colony counts within the criteria established based on precision of test methods.

(iii) Confirmation/verification of presumptive positive samples
Positive and negative characteristic strains, if applicable, shall be tested concurrently with any biochemical, serological and morphological tests for confirmation of presumptive microorganisms. The number or percentage of colonies stipulated in test standard required for confirmation process shall be followed. Laboratories shall define the minimum number of colonies for confirmation if such requirements are not specified in the test methods.

(iv) Establish precision of quantitative test method
The laboratories shall establish the precision of quantitative test methods. Acceptance limits for precision can be established by running spiked samples in duplicate. Criteria used to set acceptance limits for precision (e.g. relative standard deviation or range) shall be based on statistical principles and clearly presented for each quantitative test method. Recommendations given in APHA section 9020B ‘Intralaboratory Quality Control Guidelines’ and ISO 5725-6 ‘Accuracy (trueness and precision) of measurement methods and results Part 6: Use in practice of accuracy values’, should be followed, if appropriate. The laboratory shall also document the application of the precision criteria in monitoring acceptance of daily test results.

(v) Verification of continuing competence

Laboratories shall establish schedules, in compliance with the verification frequency stipulated in test standards, for checking the continuing competence to perform positive tests for each test method if no positive samples are encountered. Reference microorganisms shall be maintained for all tests conducted, and suitable suspensions of fresh subcultures shall be spiked into appropriate matrix and run through each entire test procedure. For quantitative test methods, the analyst is required to make parallel analyses with another analyst. Criteria shall be set for maximum allowable difference between the counts based on precision of test methods. Control charts should be used to monitor the performance of the laboratory. Furthermore, confirmation of colonies' identity shall be conducted as stipulated in relevant test standards or methods, using appropriate biochemical or serological tests.

(vi) Proficiency testing programme

Proficiency testing programme shall be scheduled and implemented on a regular basis. The frequency of participation shall, as much as possible, commensurate with the volume of work encountered and shall be at a minimum frequency of once per year for each technique/type of test and for each type of microorganism.

7.8 Reporting of results

(a) The general requirements in ISO/IEC 17025:2017 shall be applied and test reports shall include:
- (i) the information specified by test standard;
- (ii) the conditions and characteristics of samples when received;
- (iii) the conditions of packaging, if required for proper interpretation of results;
- (iv) a reference to the test standard including specific clause/section;
- (v) the techniques used for tests such as MPN, pour plate, etc.;
- (vi) any deviations from the quoted test standard;
- (vii) sampling time and method, if required for proper interpretation of results; and
- (viii) an indication that the count is an estimated value if the count is beyond the counting range specified in test standard.

(b) In determining a decision rule to be applied when stating conformity with a legislation, specification or standard, international guidelines, 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.

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

Laboratory staff members responsible for microbiological tests are strongly advised to consult the following references.

1. EURACHEM Guide *Accreditation for Microbiological Laboratories*

2. *AOAC INTERNATIONAL Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food, Dietary Supplements, and Pharmaceuticals*

3. *AOAC INTERNATIONAL Methods Committee Guidelines for Validation of Microbiological Methods for Food and Environmental Surfaces*

4. American Public Health Association *Standard Methods for the Examination of Water and Wastewater*

5. ISO 7218 *Microbiology of food and animal feeding stuffs – General requirements and guidance for microbiological examinations*

6. ISO 16140-2 *Microbiology of the food chain – Method validation – Part 2: Protocol for the validation of alternative (proprietary) methods against a reference method*

7. ISO 16140-3 *Microbiology of the food chain – Method validation – Part 2: Protocol for the verification of reference methods and validated alternative methods in a single laboratory*

8. ISO 11133 *Microbiology of food, animal feed and water – Preparation, production, storage and performance testing of culture media*

9. ISO 13843 *Water quality – Requirements for establishing performance characteristics of quantitative microbiological methods*

10. ISO 6887-1 *Microbiology of the food chain – Preparation of test samples, initial suspension and decimal dilutions for microbiological examination – Part 1: General rules for the preparation of the initial suspension and decimal dilutions*

11. ISO 707 *Milk and milk products – Guidance on sampling*

12. ISO 5725-3 *Accuracy (trueness and precision) of measurement methods and results – Part 3: Intermediate precision and alternative designs for collaborative studies*

13. ISO 5725-6 *Accuracy (trueness and precision) of measurement methods and results – Part 6: Use in practice of accuracy values*

14. ISO 19036 *Microbiology of the food chain – Estimation of measurement uncertainty for quantitative determinations*

15. JCGM 200 *International Vocabulary of Metrology - Basic and General Concepts and Associated Terms (VIM)*

16. EURACHEM/CITAC Guide CG4 *Quantifying Uncertainty in Analytical Measurement*

17. Seppo I. Niemelä, Centre for Metrology and Accreditation, Publication J4/2003: *Uncertainty of quantitative determinations derived by cultivation of microorganisms.*

18. ISO 29201 *Water quality – The variability of test results and the uncertainty of measurement of microbiological enumeration methods*

19. Australian/New Zealand Standard AS/NZS 2243.3 *Safety in laboratories Part 3: Microbiological safety and containment*

20. World Health Organization *Laboratory Biosafety Manual*

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

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

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

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