حكومة دبي
GOVERNMENT OF DUBAI

مركز الإمارات العالمي للاعتماد
Emirates International Accreditation Centre

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Emirates International Accreditation Centre

متطلبات اعتماد مختبرات الأغذية والبيئة

Accreditation Requirements for Food & Environmental Laboratories

EIAC-RQ-LB-001

Signatories	
Approved:	Head of Laboratories Accreditation Department

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Contents

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1 Objective

This document is Emirates International Accreditation Center (EIAC) "Food, Water and Environmental Testing Laboratories" Scheme. It is an independent third party accreditation scheme intended for Food, Water & Environmental testing laboratories.

The scheme supplements the ISO/IEC 17025 standard by providing specific guidance for both assessors and for the laboratories. The guidance is applicable to the performance of all objective measurements, whether routine, non-routine, or as part of research and development. Although it is written primarily for food, water and environmental microbiological testing, the general principles may be applied to other areas. ISO/IEC 17025 remains the authoritative document and in cases of dispute, accreditation bodies will adjudicate on unresolved matters. Further, the laboratory shall follow the national and local laws and regulations as applicable.

It also provides the accreditation procedures followed by EIAC to grant such accreditation.

2 Scope Definitions and abbreviations

The following definitions shall apply in addition to the terms and definitions of ISO/IEC 17025 and ISO/IEC 17011:

2.1 Food Testing Laboratory

Any laboratory that is performing microbiological, physical, chemical, toxicological, molecular biology (including genetically modified organisms), testing such as but not limited to:

- Milk and Dairy Products
- Seafoods
- Meat Products
- Fruits & Vegetables
- Food Additives
- Food Contact Materials
- Environmental Swabs e.g. food production areas
- Flavoured Mineral Water

2.2 Water Testing Laboratory

A laboratory that is performing microbiological, physical, chemical, toxicological, molecular biology testing such as but not limited to:

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- Potable (Drinking) Water
- Other Potable or Clean Waters e.g. Shower, Dental Units, Water Features
- Bottled Mineral Water (not flavoured).
- Swimming pool or Spa
- Waste or Effluents
- Recreational
- Surface
- Process including purified
- Cooling Tower

2.3 Environmental Testing Laboratory

A laboratory that is performing microbiological, physical, chemical, air quality monitoring, testing such as but not limited to:

- Swabs
- Soil/ Sludge/Deposits/Sediments/Slimes
- Air
- Solid/Semisolid Hazardous Waste
- Water Testing

3 Accreditation Requirements for Labs

3.1 General requirements:

The laboratory applying for accreditation as per this program must have a system which includes the following as minimum:

3.1.1 That laboratory activities are undertaken impartially and with integrity.

3.1.2 Proper documentation system of its policies, procedures and operations starting from receiving the request for a testing, up to the issuing of the final reports in accordance with the documentation requirements of ISO/IEC 17025 and any additional requirements set by EIAC here within this document and other related documents. These systems may include the sampling and transport of test materials prior to receipt in the laboratory.

3.1.3 Facilities properly equipped with the equipment and instruments appropriate for the type of testing under accreditation. Suitable accommodation and environmental conditions that do not affect the validity of results.

3.1.4 Employ suitable, qualified and competent managerial, technical and administrative staff.

3.2 Structural requirements:

The laboratory applying for accreditation must be able to demonstrate the following as a minimum:

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3.2.1 That the laboratory is the legal entity or a defined part of a legal entity, that is legally responsible for its laboratory activity.

3.2.2 That requirements of Regulatory and other equivalent organisations providing recognition are met.

3.2.3 Laboratory resources are adequate.

3.3 Resource requirements:

3.3.1 Personnel:

3.3.1.1 Laboratory Management with Technical responsibilities:

a) Education: Qualifications of minimum graduation or equivalent with food related discipline (B.Sc. degree in Food Science and / or Technology / Chemistry / Microbiology or equivalent).

b) Work Experience: 5 years work experience in laboratory sector as managerial or supervisory position with ability to demonstrate competence in specific technical processes used within the industry sector (where applicable).

Note: The work experience requirement may be 4 years in case of educational qualifications above B.Sc. degree level.

c) Other Qualification: Have knowledge of current regulatory requirements (Local Order 11/2003) and applicable Codes of Practice.

3.3.1.2 Chemists/ Microbiologists/ Analysts/Technicians or equivalent positions:

a) Education: Qualifications of minimum graduation or equivalent with food or related discipline (Diploma/B.Sc. degree in Food Science and / or Technology / Chemistry / Microbiology or equivalent).

b) Work Experience: For B.Sc. degree holders 2 years work experience in relevant field of testing, and for diploma 3 years work experience in relevant field of testing.

Note: Higher qualifications such as Masters Degree or above shall be considered as the ability

3.3.1.3 Competency for opinions and interpretation:

If the laboratory includes opinions and interpretations of test results in reports, this shall be done by authorized personnel with suitable experience and relevant knowledge of the specific application, including, for example, legislative, technological requirements and acceptability criteria.

3.3.1.4 All staff

The laboratory management shall ensure that all personnel shall act impartially as well as having received adequate training for the competent performance of tests and operation of equipment. This should include training in basic techniques, e.g. plate pouring, counting of colonies, aseptic technique, etc., with acceptability determined using objective criteria. Personnel may only perform tests on samples if they are either recognized as competent to do so, or if they do so under adequate supervision. On-going competence should be monitored objectively with provision for retraining where necessary. Where a method or technique is not in regular use or staff infrequently perform them, verification of personnel performance before testing is undertaken may be necessary. The critical interval between performances of tests should be established and documented.

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3.4 Facilities and Environmental Conditions

(In addition to clause 6.3 of ISO/IEC 17025)

3.4.1 The laboratories are designed to provide space, engineering controls, and proper environmental conditions for optimal sample storage, sample handling, analysis, and calibrations, in accordance with general laboratory practices, safety, and applicable Dubai Municipality Regulations.

3.4.2 Laboratory shall ensure that the environmental condition does not invalidate the results or adversely affect the required quality of any measurement. The laboratory shall monitor, control and record the environmental parameters which may affect testing including temperature, humidity, biological sterility etc. The tests must be stopped when the environmental condition jeopardizes the results of the tests and evaluation of impacts investigated.

3.4.3 Laboratory shall monitor, control and record the environmental parameters including temperature and humidity, etc, as per the requirement, and shall meet documented requirements in monitoring and controls when above mentioned parameters are specified in a test method or by regulation.

3.4.4 Bench surfaces and hoods in microbiology laboratories should be monitored for microbiological contamination. Frequency should be based on risk assessment. Additionally, air sampling shall be performed periodically to monitor microbiological contamination. Decontamination regimes should be used in the microbiology laboratory to minimize any potential microbial contamination.

3.4.5 Microbiological laboratories shall monitor reagent water quality for pH, conductivity, total organic carbon, heavy metals, ammonia/organic nitrogen, heterotrophic plate count and total chlorine periodically as per the requirements of APHA or ASTM or ISO 11133.

3.4.6 Laboratory facilities must meet the required environmental conditions. There must be effective separation between neighboring areas in which there are incompatible activities.

3.4.7 Measures shall be taken to prevent cross-contamination. Laboratories are equipped with climate and ventilation control.

3.4.8 The temperature and humidity within the laboratory are maintained within limits for the proper performance of each test or analysis and maintained according to the manufacturer's specifications for the proper operation of

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instruments. (Optimal working conditions are usually; The ambient temperature 18°C to 27°C relative humidity of 35 to 55%)

3.4.9 Food chemical laboratories shall be equipped with chemical hoods to capture hazardous or odorous materials used or produced in the analyses and to protect employees from hazardous concentrations of airborne toxic substances.

3.4.10 Microbiological laboratories should be equipped with Class II bio-safety cabinets.

3.4.11 The laboratory maintains illumination sufficient for the procedure being performed. Ultraviolet light should be properly protected in order to avoid exposure to direct eye contact.

3.4.12 Access to and the use of areas affecting the quality of the tests shall be controlled.

3.4.13 The laboratory shall determine the extent of control based on its particular circumstances. Measures shall be taken to ensure good housekeeping in the laboratory. Special procedures shall be prepared when necessary.

3.5 Equipment

(In addition to clause 6.4 of ISO/IEC 17025)

3.5.1 Maintenance

3.5.1.1 Maintenance of essential equipment shall be carried out at specified intervals as determined by factors such as the rate of use.

3.5.1.2 Attention should be paid to the avoidance of cross-contamination arising from equipment, e.g.:

a) disposable equipment should be clean and sterile when appropriate;
b) re-used glassware should be properly cleaned and sterilized when appropriate;
c) ideally, laboratories should have a separate autoclave for decontamination. However, one autoclave is acceptable provided that adequate precautions are taken to separate decontamination and sterilization loads, and a documented cleaning program is in place to address both the internal and external environment of the autoclave.

3.5.1.3 Typically, the following items of equipment will be maintained by cleaning and servicing, inspecting for damage, general verification and, where relevant, sterilizing:

a) General service equipment - filtration apparatus, glass or plastic containers (bottles, test tubes), glass or plastic petri dishes, sampling instruments, wires or loops of platinum, nickel/chromium or disposable plastic.
b) Water baths, incubators, microbiological cabinets, autoclaves, homogenizers, fridges, freezers.
c) Volumetric equipment - pipettes, automatic dispensers, spiral platers.
d) Measuring instruments - thermometers, timers, balances, pH meters, colony counters.

3.5.2 Calibration and Performance Verification

The laboratory must establish a program for the calibration and performance verification of equipment which has a direct influence on the test results. The frequency of such calibration and performance verification will be

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determined by documented experience and will be based on need, type and previous performance of the equipment. Intervals between calibration and verification shall be shorter than the time the equipment has been found to take to drift outside acceptable limits. Examples of calibration intervals and typical performance checks for various laboratory instruments are given in Appendix A and Appendix B.

3.5.3 Temperature Measurement Devices

a) Where temperature has a direct effect on the result of an analysis or is critical for the correct performance of equipment, temperature measuring devices, e.g. liquid-in-glass thermometers, thermocouples and platinum resistance thermometers (PRTs) used in incubators and autoclaves shall be of an appropriate quality to achieve the accuracy required.

b) Calibration of devices shall be traceable to national or international standards for temperature. Where the accuracy permits, devices that can be demonstrated to conform to an appropriate and nationally or internationally accepted manufacturing specification may be used (e.g. ISO 1770 for liquid-in-glass thermometers). Such devices may, for example, be used for monitoring storage fridges and freezers and also incubators and water baths where acceptable tolerance around the target temperature permits. Verification of the performance of such devices is necessary.

c) Calibration certificate content must be reviewed to verify device performance suitability. Errors and uncertainty of measurements may need to be applied e.g. to temperature ranges, depending upon criticality.

3.5.4 Incubators, Waterbaths, Ovens

3.5.4.1 The stability of temperature, uniformity of temperature distribution and time required to achieve equilibrium conditions in incubators, water baths, ovens and temperature-controlled rooms shall be established initially and documented, in particular with respect to typical uses (for example position, space between, and height of, stacks of Petri dishes). The constancy of the characteristics recorded during initial validation of the equipment shall be checked and recorded after each significant repair or modification.

3.5.4.2 Laboratories shall monitor the operating temperature of this type of equipment and retain records.

3.5.5 Autoclaves, including Media Preparators

The following outlines the generally expected approach to calibration and the establishment and monitoring of performance. However, it is recognized that quantitative testing of materials and items processed by autoclaving, able to comment suitably on variation within and between batches may also provide equivalent assurance of quality.

3.5.5.1 Autoclaves should be capable of meeting specified time and temperature tolerances. Pressure cookers fitted only with a pressure gauge are not acceptable. Sensors used for controlling or monitoring operating cycles require calibration and the performance of timers verified.

3.5.5.2 Initial validation should include performance studies (spatial temperature distribution surveys) for each operating cycle and each load configuration used in practice. This process must be repeated after significant repair or

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modification (e.g. replacement of thermo-regulator probe or programmer, loading arrangements, operating cycle) or where indicated by the results of quality control checks on media. Sufficient temperature sensors should be positioned within the load (e.g. in containers filled with liquid/medium) to enable location differences to be demonstrated. In the case of media preparators, where uniform heating cannot be demonstrated by other means, the use of two sensors, one adjacent to the control probe and one remote from it, would generally be considered appropriate. Validation and re-validation should consider the suitability of come-up and come-down times as well as time at sterilization temperature.

Clear operating instructions should be provided based on the heating profiles determined for typical uses during validation/re-validation. Acceptance/rejection criteria should be established and records of autoclave operations, including temperature and time, maintained for every cycle.

3.5.5.3 Monitoring may be achieved by one of the following:

- Using a thermocouple and recorder to produce a chart or printout.
- Direct observation and recording of maximum temperature achieved and time at that temperature. In addition to directly monitoring the temperature of an autoclave, the effectiveness of its operation during each cycle may be checked by the use of chemical or biological indicators for sterilization/ decontamination purposes.
- Autoclave tape or indicator strips should be used only to show that a load has been processed, not to demonstrate completion of an acceptable cycle.

3.5.6 Volumetric equipment

3.5.6.1 Volumetric equipment such as automatic dispensers, dispenser/diluters, mechanical hand pipettes and disposable pipettes may all be used in the microbiology laboratory. Laboratories should carry out initial verification of volumetric equipment and then make regular checks to ensure that the equipment is performing within the required specification. Verification should not be necessary for glassware which has been certified to a specific tolerance. Equipment should be checked for the accuracy of the delivered volume against the set volume (for several different settings in the case of variable volume instruments) and the precision of the repeat deliveries should be measured.

3.5.6.2 For 'single-use' disposable volumetric equipment, laboratories should obtain supplies from companies with a recognized and relevant quality system. After initial validation of the suitability of the equipment, it is

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recommended that random checks on accuracy are carried out. If the supplier has not a recognized quality system, laboratories should check each batch of equipment for suitability.

3.5.7 Other equipment

3.5.7.1 Conductivity meters, oxygen meters, pH meters and other similar instruments should be verified regularly or before each use. The buffers used for verifications purposes should be stored in appropriate conditions and should be marked with an expiry date.

3.5.7.2 Where humidity is important to the outcome of the test, hygrometers should be calibrated, the calibration being traceable to national or international standards.

3.5.7.3 Timers, including the autoclave timer, should be verified using a calibrated timer or national time signal.

3.5.7.4 Where centrifuges are used in test procedures, an assessment should be made of the criticality of the centrifugal force. Where it is critical, the centrifuge will require calibration.

3.6 Metrological Traceability

(In addition to clause 6.5 of ISO/IEC 17025)

3.6.1 General

3.6.1.1 All Equipment used for tests, including equipment used for subsidiary measurements, having a significant effect on the accuracy or validity of the result of the test or sampling shall be calibrated before being put into service and verified on a daily basis or more frequently during service.

3.6.1.2 The laboratory shall have an established documented program and procedure for calibration, verification and maintenance of its equipment in-house.

3.6.1.3 In a case where the calibration cannot be qualified or is unavailable in the region, in these cases calibration shall provide confidence in measurements by establishing traceability to appropriate measurement standards such as:

3.6.1.4 The use of certified reference material supplied by a competent supplier to give reliable, physical or chemical characterization of the material.

Examples: Atomic absorption spectrometers, ICP, GC-MS, HPLC.

3.6.1.5 It is recommended that for any instrument whose function directly affects the test results substantially, a six month calibration schedule is put in place along with a strong maintenance, and verification check list documented on a day to day basis.

3.6.1.6 The laboratory should have the equipment calibrated by an authorized or accredited calibrating agency in the working range with demonstrated traceability to national / international standards or by the supplier's qualified engineer in case of analytical instruments .

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3.6.2 Certified Reference Materials (CRM)

3.6.2.1 CRM's are to be procured from reliable suppliers, preferred ISO 17034 accredited and subsidiaries and stored as per requirements. Supplier CRM performance or QC checks may also be accredited to ISO/IEC 17025 to provide further confidence.

3.6.2.2 The concentrations of the secondary standards shall be cross-checked against the master CRM from time to time.

3.6.2.3 The laboratory shall have procedures for safe handling, transport, storage and use of reference standards in order to prevent contamination or deterioration, misuse and safety of the personnel working with the same.

3.6.3 Microbiological Reference cultures: Usage and Handling

3.6.3.1 Reference cultures are required for establishing acceptable performance of media (including test kits), for validating methods and for assessing/evaluating on-going performance. Traceability is necessary, for example, when establishing media performance for test kit and method validations. To demonstrate traceability, laboratories must use CRM reference strains of microorganisms obtained directly from a recognized national or international collection, where these exist. Alternatively, commercial derivatives for which all relevant properties have been shown by the laboratory to be equivalent at the point of use may be used.

3.6.3.2 Following the guidance in ISO 11133:2014+A1:2018 reference strains may be sub-cultured once to provide reference stocks. Purity and biochemical checks should be made in parallel as appropriate. It is recommended to store reference stocks in aliquots either deep-frozen or lyophilized. Working cultures for routine use should be primary subcultures from the reference stock. If reference stocks have been thawed, they must not be re-frozen and re-used.

3.6.3.3 Working stocks should not be sub-cultured unless it is required and defined by a standard method or laboratories can provide documentary evidence that there has been no change in any relevant property. Working stocks shall not be sub-cultured to replace reference stocks. Commercial derivatives of reference strains may only be used as working cultures.

3.6.4 Externally provided products and services

Products and services must be procured from reputable suppliers. A supplier is the person, establishment or place where products and services are sourced. A distributor is an agent who provides goods from the supplier.
Suppliers, for example, include proficiency testing providers and any external individuals who provide auditing services.

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3.6.5 Reagents including Media

3.6.5.1 Laboratories should ensure that the quality of reagents used is appropriate for the test concerned. They should verify the suitability of each batch of reagents critical for the test, initially and during its shelf life, using positive and negative control organisms which are traceable to recognized national or international culture collections.

3.6.5.2 In methods where purity of reagents is not specified, analytical reagent grade shall be used.

3.6.6 In – house prepared media

3.6.6.1 The suitable performance of culture media, diluents and other suspension fluids prepared in-house should be checked (quality controlled (QC)) per batch*, where relevant, with regard to:

a) Recovery or survival maintenance of target organisms.
b) Inhibition or suppression (selectivity) of non-target organisms.
c) Biochemical (differential and diagnostic) properties.
d) Physical properties (e.g. pH, volume and sterility).

**A batch is defined as one prepared lot i.e. one autoclave run or one heated lot plus additives/supplements.*

3.6.6.2 Raw materials (both commercial dehydrated formulations and individual constituents) should be stored under appropriate conditions, e.g. cool, dry and dark. All containers, especially those for dehydrated media, should be sealed tightly. Dehydrated media that are caked or cracked or show a color change should not be used. Distilled deionised, or reverse osmosis produced water, free from bactericidal, inhibitory or interfering substances, should be used for preparation unless the test method specifies otherwise.

a) Shelf life of prepared media under defined storage conditions shall be determined and verified.
b) Batches of media must be identifiable.

Guidance can be found in ISO 11133:2014+A1:2018.

3.6.7 Ready – to – use– media

3.6.7.1 Media that have been performance tested by a laboratory with accreditation to ISO/IEC 17025 for the performance testing of media:

Media will require commissioning to assess effects of transport and shelf-life. QC checks as described above will need to be performed.

The laboratory will need to set its own acceptable performance specifications for bought-in media. It maybe that the supplier's specifications are found acceptable but justification is required.

Supplier QC certificates per media batch will need to be reviewed to ensure laboratory specifications are met on an on-going basis. The user laboratory should ensure that it will be notified by the manufacturer of any changes to the quality specification.

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3.6.7.2 As part of the commissioning, the user laboratory needs to have adequate knowledge of the manufacturer's quality specifications, which include at least the following:

- Name of the media and list of components, including any supplements
- Shelf life and the acceptability criteria applied
- Storage conditions
- Sample regime / rate
- Sterility check
- Check the suitability and growth of target and non-target control organisms used (with their culture collection references) and acceptability criteria
- Physical checks and the acceptability criteria applied
- Date of issue of specification

Once media performance has been demonstrated as being satisfactory i.e. meeting the laboratory's requirements, QC checks can be periodic rather than every batch. It is for the laboratory to risk assess on-going QC frequency after satisfactory commissioning.

New media supplies or changes to media formulations will need commissioning.

3.6.7.3 Media supplied by a manufacturer with a quality management system certified as conforming to ISO 9001 or equivalent:

Commissioning of media is required as described above.

Having established the laboratory's specification and demonstrated suitability, intermittent QC is required, again based upon a risk assessment.

3.6.7.4 Media from other manufacturer's (without ISO/IEC 17025 or ISO 9001) or media with no evidence for meeting 3.7.7.1 or 3.7.7.2:

Media QC must be performed per batch as for in-house prepared media. See 3.7.6.

3.6.8 Labeling

Laboratories shall ensure that all reagents (including stock solutions), media, diluents, and other suspending fluids are adequately labeled to indicate, as appropriate, identity, concentration, storage conditions, preparation date, validated expiry date and /or recommended storage periods. The person responsible for preparation should be identifiable from records.

3.7 Process requirements

3.7.1 Review of requests, tenders and contracts

(In addition to clause 7.1 of ISO/IEC 17025)

When undertaking contract review and selecting methods, personnel need to understand the nature of the food they are testing, and the reasons for the testing.

Customer specifications for conformity, if provided, must be reviewed for appropriateness.

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Customers must be made aware of test uncertainty of measurement (U of M) and how test results and specifications may be affected e.g. if near to a specification. Also see reporting section 3.8.8.1.

3.7.2 Selection, verification and validation of methods

(In addition to clause 7.2 of ISO/IEC 17025)

Method selection will need to be justified.

3.7.3 Requirements for Chemical Testing

3.7.3.1 Method Selection

a) A reference method is a method issued by an organization generally recognized as competent to do so. (When ISO refers to a standard method, that term is equivalent to reference method). When a laboratory is required to analyze a parameter by a specified method due to a regulatory requirement, the parameter/method combination is recognized as a reference method.

b) As a non-reference method if it can be analyzed by another similar reference method of the same matrix and technology. The inclusion of the parameter in the method shall meet all required calibration requirements and the quality control requirements of the method to which the parameter is being added.

c) If no QC exists in the method, the laboratory shall adhere to the requirements outlined in the similar method.

d) When it is necessary to use methods not covered by reference methods, these shall be subject to agreement with the customer and shall include a clear specification of the customer's requirements and the purpose of the test. The method developed shall have been validated appropriately before use.

3.7.3.2 Validation of Chemical test Methods

General

a) The laboratory shall verify reference methods via the procedures specified in Sections 7.1.2.2 and 7.1.2.3

b) The laboratory shall validate non-reference methods, laboratory-designed/developed methods, reference methods used outside their published scope, and amplifications and modifications of reference methods to confirm that the methods are fit for the intended use.

c) The validation shall be as extensive as is necessary to meet the needs of the given application or field of application. The laboratory shall record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use. In the absence of other specifications, the minimum requirements for method validation are given in Sections 7.1.2.2, 7.1.2.3 and 7.1.2.4.

3.7.3.2.1 Limit of Detection and Limit of Quantitation Quantification (However Named)

a) Procedures used for determining limits of detection and quantitation shall be documented.

b) Documentation shall include the matrix type. All supporting data shall be retained.

3.7.3.2.2 Limit of Detection (LOD)

a) If the laboratory is not reporting a value below the Limit of Quantification, a Limit of Detection study is not required.

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b) The laboratory shall utilize a method that provides an LOD that is appropriate and relevant for the intended use of the data. If a mandated method or regulation includes protocols for determining detection limits, these shall be followed. The laboratory shall document how LODs were derived from the determinations. If the protocol for determining the LOD is not specified, the selection of the procedure shall reflect instrument limitations and the intended application of the method.

c) All sample-processing and analysis steps of the analytical method shall be included in the determination or validation of the LOD.

d) When required, the laboratory shall determine or verify the LOD for the method for each target analyte of concern in the quality system matrices.

e) The validity of the LOD shall be verified by detection (a value above zero) of the analyte(s) in a QC sample in each quality system matrix. This QC sample shall contain the analyte at no more than 3X the LOD for single analyte tests and 4X the LOD for multiple analyte tests. This verification shall be performed on every instrument that is to be used for analysis of samples and reporting of data. The validity of the LOD shall be verified as part of the LOD determination process. This verification shall be done prior to the use of the LOD for the sample analysis.

f) An LOD study is not required for any component for which spiking solutions or quality control samples are not available such as temperature.

g) The LOD shall be initially determined for the compounds of interest in each method in a quality system matrix in which there are neither target analytes nor interferences at a concentration that would impact the results or the LOD shall be performed in the quality system matrix of interest.

h) An LOD shall be performed each time there is a change in the method that affects how the test is performed, or when a change in instrumentation occurs that affects the sensitivity of the analysis.

i) The LOD, if required, shall be verified annually for each quality system matrix, technology, and analyte.

3.7.3.2.3 Limit of Quantification (LOQ)

a) All sample-processing and analysis steps of the analytical method shall be included in the determination of the LOQ.

b) The LOQ study is not required for any component or property for which spiking solutions or quality control samples are not available or otherwise inappropriate (e.g., pH).

c) The validity of the LOQ shall be verified by successful analysis of a QC sample containing the analytes of concern in each quality system matrix at 1 to 2 times the claimed LOQ. A successful analysis is one where the recovery of each analyte is within the laboratory established method acceptance criteria or client data quality objectives for accuracy

d) When an LOD is determined or verified by the laboratory, the LOQ shall be above the LOD.

e) The LOQ shall be verified annually for each quality system matrix, technology, and analyte. However, the annual LOQ verification is not required if the LOD was determined or verified annually on that instrument

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3.7.3.2.4 Evaluation of Precision and Bias

a) Reference Methods: The laboratory shall evaluate the precision and bias of a reference method for each analyte of concern for each quality system matrix ,when the analyte cannot be spiked into the sample matrix and QC samples are not commercially available.

b) Non-Reference Methods: For laboratory-developed methods or non-reference methods, the laboratory shall have a documented procedure to evaluate precision and bias. The laboratory shall also compare results of the precision and bias measurements with criteria established by the client, by criteria given in the reference method or criteria established by the laboratory.

c) Precision and bias measurements shall evaluate the method across the analytical calibration range of the method. The laboratory shall also evaluate precision and bias in the relevant quality system matrices and shall process the samples through the entire measurement system for each analyte of interest. Examples of a systematic approach to evaluate precision and bias could be the following:

d) Analyze QC samples in triplicate containing the analytes of concern at or near the limit of quantification, at the upper-range of the calibration (upper 20%) and at a mid-range concentration. Process these samples on different days as three (3) sets of samples through the entire measurement system for each analyte of interest. Each day, one (1) QC sample at each concentration is analyzed. A separate method blank shall be subjected to the analytical method along with the QC samples on each of the three (3) days. (Note that the three (3) samples at the LOQ concentration can demonstrate sensitivity as well.) For each analyte, calculate the mean recovery for each day, for each level over each day, and for all nine (9) samples. Calculate the relative standard deviation for each of the separate means obtained. Compare the standard deviations for the different days and the standard deviations for the different concentrations. If the different standard deviations are all statistically insignificant (e.g., F-test), then compare the overall mean and standard deviation with the established criteria from above.

e) A validation protocol, such as the Tier I, Tier II, and Tier III requirements in US EPA Office of Water's Alternate Test Procedure (ATP) approval process.

3.7.3.2.5 Evaluation of Selectivity

a) The laboratory shall evaluate selectivity by following the checks established within the method, which may include mass spectral tuning, second column confirmation, ICP inter-element interference checks, chromatography

b) retention time windows, sample blanks, spectrochemical absorption or fluorescence profiles, co-precipitation evaluations, and electrode response factors.

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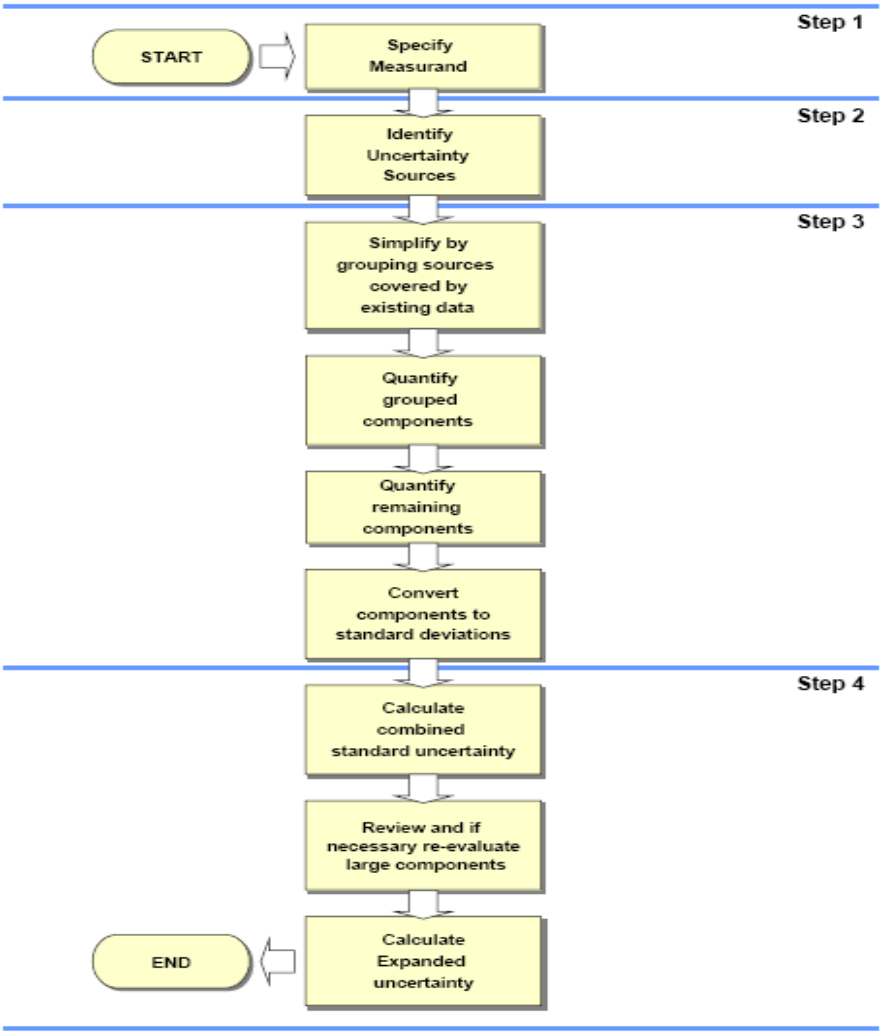
3.7.3.2.6 Uncertainty of measurement (Chemical test Methods)

Figure 1: The Uncertainty Estimation Process



3.7.3.2.7 Specification of the Measurand

a) In the context of uncertainty estimation, "specification of the measurand" requires both a clear and unambiguous statement of what is being measured, and a quantitative expression relating the value of the measurand to the parameters on which it depends. These parameters may be other measurands, quantities which are not directly measured, or constants. It should also be clear whether a sampling step is included within the procedure or not. If it is, estimation of uncertainties associated with the sampling procedure need to be considered. All of this information should be in the Standard Operating Procedure (SOP).

b) Identifying Uncertainty Sources

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c) The cause and effect diagram is a very convenient way of listing the uncertainty sources, showing how they relate to each other and indicating their influence on the uncertainty of the result. It also helps to avoid double counting of sources.

d) Typical sources of uncertainty are: Sampling, storage conditions, instrument effects, reagent purity, assumed stoichiometry, measurement conditions, sample effects, computational effects, blank correction, operator effects, and random effects.

3.7.4 Requirements for Microbiological Testing

3.7.4.1 Verification and Validation of Microbiological test methods

3.7.4.1.1 The verification or validation of microbiological test methods should reflect actual test conditions. This may be achieved by using naturally contaminated products or products spiked with a predetermined level of contaminating organisms. The analyst should be aware that the addition of contaminating organisms to a matrix only mimics in a superficial way the presence of the naturally occurring contaminants. However, it is often the best and only solution available. The extent of verification or validation necessary will depend on the method and the application. The laboratory shall validate the performance of standard methods applied to matrices not specified in the standard procedure.

3.7.4.1.2 Qualitative microbiological test methods, such as where the result is expressed in terms of detected / not detected and confirmation and identification procedures, should be verified/validated by determining, if appropriate, the specificity, relative trueness, positive deviation, negative deviation, limit of detection*, matrix effect, repeatability and reproducibility (see Appendix A for definitions).

*NB: *There may be Regulatory and/or customer limits of detection requirements to be met.*

3.7.4.1.3 For quantitative microbiological test methods, the specificity, sensitivity, relative trueness, positive deviation, negative deviation, repeatability, reproducibility and the limit of determination within a defined variability should be considered and, if necessary, quantitatively determined in assays. The differences due to the matrices must be taken into account when testing different types of samples. The results should be evaluated with appropriate statistical methods.

3.7.4.1.4 Automated or semi-automated technologies may also require carry-over verification.

3.7.4.1.5 Laboratories shall retain verification/validation data on commercial test systems (kits) used in the laboratory. These validation data may be obtained through collaborative testing and from validation data submitted by the manufacturers and subjected to third party evaluation (e.g. AOAC). If the validation data are not available or not wholly applicable, the laboratory shall be responsible for completing the validation of the method.

3.7.4.1.6 If a modified version of a method is required to meet the same specification as the original method, then comparisons should be carried out using replicates to ensure that this is the case. Experimental design and analysis of results must be statistically valid.

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3.7.4.1.7 Even when validation is complete, the user will still need to verify on a regular basis that the documented performance can be met, e.g. by the use of spiked samples or reference materials incorporating relevant matrices.

3.7.4.2 Uncertainty of measurement (Microbiology)

3.7.4.2.1 Microbiological tests generally come into the category of those that preclude the rigorous, metrological and statistical valid calculation of uncertainty of measurement. It is generally appropriate to base the estimate of uncertainty on repeatability and reproducibility data alone, but ideally including bias (e.g. from proficiency testing scheme results). The individual components of uncertainty should be identified and demonstrated to be under control and their contribution to the variability of results evaluated. Some components (e.g. pipetting, weighing and dilution effects) may be readily measured and easily evaluated to demonstrate a negligible contribution to overall uncertainty. Other components (e.g. sample stability and sample preparation) cannot be measured directly and their contribution cannot be evaluated in a statistical manner but their importance to the variability of results should be considered also.

3.7.4.2.2 It is expected that accredited microbiological testing laboratories will understand the distributions of organisms within the matrices they test and take this into account when sub-sampling. However, it is not recommended that this component of uncertainty is included in estimates unless the client's needs dictate otherwise. The principal reasons for this are that uncertainty due to distribution of organisms within the product matrix is not a function of the laboratory's performance and may be unique to individual samples tested and because test methods should specify the sample size to be used taking into account poor homogeneity.

3.7.4.2.3 The concept of uncertainty cannot be applied directly to qualitative test results such as those from detection tests or the determination of attributes for identification. Nevertheless, individual sources of variability, e.g. consistency of reagent performance and analyst interpretation, should be identified and demonstrated to be under control. Additionally, for tests where the limit of detection is an important indication of suitability, the uncertainty associated with the inocula used to determine the limit should be estimated and its significance evaluated. Laboratories should also be aware of the incidence of false positive and false negative results associated with the qualitative tests they use.

3.7.4.2.4 For some methods in microbiology, for example enzyme assays and PCR testing, quantitative results such as Ct values are obtained. Uncertainty of measurement may therefore be quantified.

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3.7.5 Sampling

3.7.5.1 The laboratory shall have a documented sampling plan (SOP), which may be provided by the customer and procedures for sampling, sampling plans should be referenced to international standards, where appropriate and reviewed on an annual basis.

3.7.5.2 The samplers shall have,

- Basic safety training from an authorized training agency.
- Sampling procedures in the form of flowcharts and, photographs if necessary.
- Knowledge of the types of containers to be used.
- Knowledge of the transport conditions required for the samples.
- Basic writing skills in English or Arabic.
- Documented training and competency records including records for on-going competency
- A basic sense of cleanliness and appearance.

3.7.5.3 The samples shall be accompanied in all cases by a chain of custody sheet (COC)/ sampling certificate (SC) as per DMS 11/12 : 2001 with the full primary details but not limited to regarding the,

- Type of sample.
- Date/ time of sample collection.
- Time/temperature/condition of sample on collection.
- Time/temperature/condition of sample on receipt in the laboratory.
- Tests required/requested
- Number of days required for test completion
- COC /SC authenticated by client
- Client's contact details to advise failures immediately if any based on its impact on the local population
- Site tests such as pH, DO conducted

There may be other requirements when following standards or industry guidance e.g. BS 7592: 2008 (Legionella sampling).

When samples are submitted by the customer directly to the laboratory, an acknowledgement should be signed / received by the client and the laboratory, for the deviation / departure from normal sampling procedure which could affect the accuracy of the final test results.

3.7.6 Handling of test or calibration items

(In addition to clause 7.4 of ISO/IEC 17025)

The laboratory should have a system for identifying test items .This system aids in traceability and confidentiality, preferably a LIMS system with automatic back-up in case of a system failure. Samples shall be transported to the laboratory after collection from the site in clean temperature controlled vehicles or ice boxes.

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3.7.6.1 The system shall be designed and operated in a way wherein test items are easily traceable .The system shall, if appropriate accommodate a sub- division of groups of items such as potable water, waste water and pool waters.

3.7.6.2 The laboratory must note any deviation from initial conditions received on the COC and communicate to the customer.

3.7.6.3 Samples awaiting test shall be stored under suitable conditions to minimize changes to any microbial population present. Storage conditions should be defined and recorded.

3.7.6.4 The packaging and labels from samples may be highly contaminated and should be handled and stored with care so as to avoid any spread of contamination.

3.7.6.5 Sub-sampling by the laboratory immediately prior to testing is considered as part of the test method. It should be performed according to national or international standards, where they exist, or by validated in-house methods. Sub-sampling procedures should be designed to take account uneven distribution of micro-organisms and mycotoxins.

3.7.6.6 A procedure for the retention and disposal of samples shall be written. Samples should be stored until the test results are obtained, or longer if required. Laboratory sample portions that are known to be highly contaminated should be decontaminated prior to being discarded.

3.7.6.7 The chemicals and solid waste emanating from the chemistry laboratory must be disposed of by approved municipal contractors.

3.7.6.8 Disposal of contaminated waste must follow national/international regulations.

3.7.7 Ensuring the validity of results

(In addition to clause 7.7 of ISO/IEC 17025)

3.7.7.1 Internal Quality Control

3.7.7.1.1 Internal quality control consists of all the procedures undertaken by a laboratory for the continuous evaluation of its work. The main objective is to ensure the consistency of results day-to-day and their conformity with defined criteria.

3.7.7.1.2 A program of periodic checks is necessary to demonstrate that variability (i.e. between analysts and between equipment and materials etc.) is under control. All tests included in the laboratory's scope of accreditation need to be covered. The program may involve:

- the use of spiked samples
- the use of reference materials (including proficiency testing scheme materials)
- replicate testing
- replicate evaluation of test results

The interval between these checks will be influenced by the construction of the program and by the number of actual tests. It is recommended that, where possible, tests should incorporate controls to monitor performance.

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3.7.7.1.3 In special instances, a laboratory may be accredited for a test that it is rarely called on to do. It is recognized that in such cases an ongoing internal quality control program may be inappropriate and that a scheme for demonstrating satisfactory performance which is carried out in parallel with the testing, may be more suitable.

3.7.7.2 External Quality Assessment (Proficiency Testing)

3.7.7.2.1 It is EIAC policy that all accredited testing laboratories shall participate in proficiency testing where such schemes are available and relevant to their scope of accreditation. Selection of the schemes and proficiency testing programs by the providers are available on EIAC website www.eiac.gov.ae or on www.eptis.org. PT Providers with accredited to ISO/IEC 17043 are preferred.

3.7.7.2.2 Laboratories should use external quality assessment not only to assess laboratory bias but also to check the validity of the whole quality system.

3.7.7.2.3 Laboratories must be prepared to justify their policy and approach to both frequency of participation and any non-participation in readily available proficiency testing programs where one or more appropriate schemes exist.

3.7.7.2.4 Laboratories preparing for accreditation are required to participate in proficiency testing/inter laboratory comparisons where such schemes are available and relevant to their scope of application before accreditation can be granted.

3.7.7.2.5 Where no proficiency testing services or inter laboratory comparisons are available, laboratories shall demonstrate the on-going validity of their tests by other means (use of certified reference materials, replicate testing, etc).

3.7.7.2.6 Laboratories are required to have appropriate acceptance criteria (normally those used by the scheme provider) and a procedure for investigating flagged (or anomalous) results and carrying out appropriate corrective/preventive actions. Laboratories are also required to monitor and review their on-going participation and performance and to monitor trends in results as appropriate.

3.7.7.2.7 Laboratories are required to investigate scheme availability and also determine the appropriateness of the scheme. All EIAC accredited laboratories shall participate in proficiency testing programs as a minimum, but not limited to:

Section	Test	Minimum No. of Distributions per year
Microbiology (Matrix Water)	Faecal Coliforms and E.coli Legionella spp.	4
Microbiology (Matrix Food)	Salmonella E. coli E.coli O157/STEC	4
Microbiology (any)	All tests	2
Food Chemistry	All tests	1
Environmental Chemistry	All tests	2

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3.7.8 Reporting of results

(In addition to clause 7.8 of ISO/IEC 17025)

a) If the result of the enumeration is negative, it should be reported as "not detected for a defined unit" or "less than the detection limit for a defined unit". The result should not be given as "zero for a defined unit" unless it is a regulatory requirement. Qualitative test results should be reported as "detected/not detected in a defined quantity or volume". They may also be expressed as "less than a specified number of organisms for a defined unit" where the specified number of organisms exceeds the detection limit of the method and this has been agreed with the client.

b) Where an estimate of the uncertainty of the test result is expressed on the test report, any limitations (particularly if the estimate does not include the component contributed by the distribution of micro-organisms within the sample) have to be made clear to the customer.

3.7.8.1 Decision rules

Definition: A decision rule is a rule that describes how measurement uncertainty is accounted for when stating conformity with a specific requirement.

When a statement of conformity is required this shall be clearly reported by the laboratory, including reference to the decision rule used. Statements must be agreed with the customer during contract review. Statements may be part of a regulation or standard or as well as a customer request.

Test reports must include the uncertainty of measurement where this affects conformity to a specification limit.

Where a decision rule is prescribed by the customer, regulations or standards, further consideration of the level of risk is not usually necessary.

It is the laboratory's responsibility to decide whether a decision rule proposed by the customer is appropriate at point of contract review. The decision rule must not impact on the integrity and outcome of the test.

3.8 Legionella Testing Additional Requirements:

Background:

Monitoring of Legionellae in water systems is important for public health reasons to identify environmental sources that pose risks of Legionellosis. Waters that create a fine mist are of particular high risk to humans as Legionellae are able to penetrate deep into the lungs. Only susceptible individuals are at high risk of Legionellosis. Legionellae can readily be found in various water sources. Numbers vary depending upon the effectiveness of water system management. The aim is to keep numbers very low or ideally eliminate Legionellae. Expectations are that laboratories will regularly isolate Legionellae given the wide distribution and ideal growth conditions of the organism in water systems.

For further information please refer to:

https://legionella.ae/

https://www.cdc.gov/legionella/index.html

www.hse.gov.uk/legionnaires/index.htm

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Laboratory staff must demonstrate knowledge as to the importance of monitoring and ensuring the validity of test results.

3.8.1 Sampling

(in additional to clause 7.3 of ISO 17025: 2017)

The laboratory must be responsible for Legionella water sampling and accredited for this activity.

Sampling must follow the latest BS 7592: Sampling for Legionella bacteria in water systems. Code of Practice.

Request form information must include all listed information in section 2 A1.

Additionally, wherever possible, free chlorine, pH and turbidity measurements should be taken and recorded on the sample collection form.

3.8.2 Selection, verification and validation of methods

(in additional to clause 7.3 of ISO 17025: 2017)

The laboratory must follow ISO 11731:2017 protocols and justify selected approach particularly for matrix selection as defined in figure J.1.

The laboratory must be familiar with Dubai Municipality Guidelines when testing samples originating from the Emirate of Dubai. https://legionella.ae/legionella-regulations/legionella-regulations-dubai/. The Abu Dhabi Code of Practice can also be found on this website.

Matrix A must be used for fountains, water features, dental units, evaporative air coolers, misters, air washers, humidifiers where the limit of detection requirement is 1cfu/L for Dubai Municipality Public Health. It would be prudent to sample 1000mls x2 and use matrix B protocol for the second sample as a back-up in case of any background contamination.

Matrix B: Legionellae and background flora levels cannot be predicted in any given sample therefore Matrix B protocol has to be followed for all other samples.

Matrix C: Filtered concentrates can be used to carry out further dilutions if necessary, however the test sensitivity will be decreased and must be considered accordingly.

3.8.3 Culture reading

Cultures that are overgrown or are difficult to read or compromise the accuracy of Legionella colony observation must be reported as 'overgrown' or similar wording. It must be made clear that the result is invalid.

Use of a plate dissection microscope is strongly recommended.

3.8.4 Reporting

ISO 11731:2017 section 10 must be followed alongside ISO 17025 section 7.8 (7.8.5 states sampling requirements).

Decision rules will be considered at a later date however the laboratory must have test uncertainty of measurement available if customers request it.

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All sample results from Dubai Municipality must be reported using the latest Public Health reporting template. This includes cultures that are overgrown or were difficult to read. This is a regulatory requirement.

4 References

- Regulation No. 2/ 2010 regarding arranging the operation of conformity assessment bodies operating in the Emirates of Dubai.
- ISO/ IEC 17025 General requirement for the competence of testing and calibration laboratories.
- ISO/IEC 17043, Conformity assessment – General requirements for proficiency testing.
- ILAC-G17 ILAC Guidelines for Measurement Uncertainty in Testing
- ILAC-P9 ILAC Policy for Participation in Proficiency Testing Activities
- ILAC-P10 ILAC Policy on Metrological Traceability of Measurement Results
- EIAC-RQ-GEN-001 "General Accreditation Requirements".
- EIAC-RQ-GEN-002 "The Conditions for the Use of EIAC Accreditation Symbol and ILAC MRA/ IAF MLA Marks".
- EIAC-RQ-GEN-003 "Emirates International Accreditation Centre Fees Structure".
- EIAC-RQ-LB-011 Measurement Uncertainty in Testing, Calibration
- EIAC-RQ-LB-012 Metrological Traceability of Measurement Results
- DMS 12 Testing of wastewater for compliance with EPSS requirements
- APLAC TC 007: APLAC Guidance for Food Testing Laboratories
- Eurachem/ EA guide 04/10: Accreditation in Microbiological Laboratories
- TNI standard, NELAC Institute: Management and Technical Requirements for Laboratories Performing Environmental Analysis
- CRC Hand Book of Laboratory Safety
- USFDA Office of regulatory affairs Laboratory Manual of Quality policies
- APHA Examination of water and wastewater
- ISO 11731 Water quality – enumeration of Legionella
- BS 7592 Sampling for Legionella bacteria in water systems – Code of Practice.
- ISO 11133:2014 +A1:2018 Microbiology of food, animal feed and water – Preparation, production, storage and performance testing of culture media.
- ISO 7218: General requirements and guidance for microbiological examinations
- Dubai Municipality website and downloadable Guidelines for Control of Legionella in Water Systems

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5 Annex 1

Guidance of calibration and calibration checks

Type of equipment	Requirement	Suggested frequency
Reference thermometers (liquid-in-glass)	Full traceable re-calibration	Every 5 years
	Single point	Annually
Reference thermocouples	Full traceable re-calibration	Every 3 years
	Check against reference thermometer	Annually
Working thermometers & Working thermocouples	Check against reference thermometer at ice-point and/or working thermometer range	Annually
Balances	Full traceable calibration	Annually (Annually in the first 3 years, followed by less frequently, based on satisfactory performance)
Calibration weights	Full traceable calibration	Every 5 years
Check weight(s)	Check against calibrated weight or check on balance immediately following traceable calibration	After balance calibration
Volumetric glassware	Gravimetric calibration to required tolerance	Annually
Microscopes	Traceable calibration of stage micrometer (where appropriate)	initially
Hygrometers	Traceable calibration	Annually
Centrifuges	Traceable calibration or check against an independent tachometer , as appropriate	Annually

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6 Annex 2

Guidance on equipment validation and verification of performance

Type of equipment	Requirement	Suggested frequency
Temperature controlled equipment (incubators , baths ,fridges, freezers)	Establish stability and uniformity of temperature Monitor temperature	Initially , every 2 years and after repair/modification Daily/ each use
Sterilizing ovens	Establish stability and uniformity of temperature Monitor temperature	Initially , every 2 years and after repair/modification Each use
Autoclaves	Establish characteristics for loads/cycles Monitor temperature/time	Initially , every 2 years and after repair/modification Each use
Safety cabinets	Establish performance Microbiological monitoring Air flow monitoring	Initially , every year and after repair/modification Weekly Each use
Laminar air flow cabinets	Establish performance Check with sterility plates	Initially , and after repair/modification Weekly
Timers	Check against national time signal	Annually
Microscopes	Check alignment	Daily/each use
pH meters	Adjust using at least two buffers of suitable quality	Daily/each use
Balances	Check zero, and reading against check weight	Daily/each use
De-ionizers and reverse osmosis units	Check conductivity Check for microbial contamination	Weekly Monthly
Gravimetric diluters	Check weight of volume dispensed Check dilution ratio	Daily/each use Daily/each use

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Type of equipment	Requirement	Suggested frequency
Media dispensers	Check volume dispended	Each adjustment or replacement
Pipettors/pipettes	Check accuracy and precision of volume dispensed	Regularly (to be defined by taking account of the frequency and nature of use)
Spiral platers	Establish performance against conventional method Check stylus condition and the start and end points Check volume dispensed	Initially and annually Daily/each use Monthly
Colony counters	Check against number counted manually	Annually
Centrifuges	Check speed against a calibrated and independent tachometer	Annually
Anaerobic jars/ incubators	Check with anaerobic indicator	Each use
Laboratory environment	Monitor for airborne and surface microbial contamination using , e.g. air samplers , settle plates , contact plates or swabs	Frequency to be justified by laboratory dependent upon background norm and risks to testing.

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7 Annex 3

Guidance on maintenance of equipment

Type of equipment	Requirement	Suggested frequency
Incubators **Fridges** **Freezers , ovens**	Clean and disinfect internal surfaces	Monthly When required (e.g. every 3 months) When required (e.g. annually)
Water baths	Empty , clean , disinfect and refill	Monthly , every 6 months if biocide used, immediately if any turbidity
Centrifuges	Service Clean and disinfect	Annually Each use
Autoclaves	Make visual checks of gasket, clean/drain chamber Full service Safety check of pressure vessel	Regularly , as recommended by manufacturer Annually or as recommended by manufacturer Annually
Safety cabinets **Laminar flow cabinets**	Full service and mechanical check	Annually or as recommended by manufacturer
Microscopes	Full maintenance service	Annually
pH meters	Clean electrode	Each use
Balance, gravimetric diluters	Clean Service	Each use Annually
Stills	Clean and de-scale	As required (e.g. every 3 months)
De-ionizers, reverse osmosis units	Replace cartridge/membrane	As recommended by manufacturer
Anaerobic jars	Clean/disinfect	After each use
Media dispensers, volumetric equipment, pipettes , and general service equipment	Decontaminate , clean and sterilize as appropriate	Each use

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Type of equipment	Requirement	Suggested frequency
Spiral platers	Service	Annually
	Decontaminate, clean and sterilize	Each use
Laboratory	Clean and disinfect working surfaces	Daily, and during use
	Clean floors, disinfect sinks and basins	Weekly
	Clean and disinfect other surfaces	Every 3 months

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