ACCREDITATION SCHEME FOR LABORATORIES

Technical Notes C&B and ENV 001

Specific Requirements for Chemical & Biological Testing and Environmental Testing Laboratories

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Contents

1. INTRODUCTION

1.1 This document describes the specific requirements to be complied by chemical and biological testing and environmental testing laboratories.

1.2 This document shall be studied in conjunction with ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories, SAC-SINGLAS 002-Requirements for the Application of ISO/IEC 17025, Proficiency Testing Technical Note 001 and other C&B and ENV Technical and Guidance Notes published by SAC-SINGLAS. For the use of Reference Materials, refer to ISO Guide 33:2015 Reference materials – Good practice in using reference materials. For undated references, the latest edition of the referenced document (including any amendments) applies.

2. SCOPE

2.1 The scope of Chemical and Biological testing field covers chemical, biological, microbiological and biochemical testing and measurement of materials and products including food, drugs, pharmaceuticals and petrochemicals. It covers instrumental and automated methods of analysis and detection, and also associated physical testing such as measurement of viscosity. Chemical tests on polymeric or metallic materials can also be included under this field.

2.2 The scope of the Environmental Testing field covers measurement of environmental parameters including physical, chemical and microbiological testing of materials and products such as air, water/wastewater, trade effluent and solid/semisolid samples. Testing of environmental noise can be included.

3. EQUIPMENT

3.1 Reagents and Culture media

3.1.1 Control of materials used in testing is essential in the overall quality assurance program. It is essential that specifications for various items be established and adhered to.

3.1.2 When specifications are prepared, the following points shall be considered: identity, purity, potency, source, tests to be conducted for quality and purity, need for further purification, storage and handling procedures, replacement dates, and so forth.

3.1.3 Laboratory personnel shall be made aware of their responsibilities in the use of suitable reagents, solvents, culture media, reference materials and laboratory ware in terms of the types of analysis they conduct.

3.1.4 Proper storage of reagents and culture media shall be observed according to the requirements set up by the manufacturers or validated by the laboratory that the quality of reagents and culture media does not affect the results of analysis.

3.1.5 Chemical reagents, solvents, and gases are generally available in various grades and purity. The appropriate grade of materials as specified in the

methods or procedures shall be used.

3.1.6 All reagent containers shall be labelled and tightly closed. They shall bear the original label, or, as minimum: reagent name, date of receipt, strength, solvent (if not water), any special precautions or hazards and date of expiry (where applicable). The person responsible for the preparation of the reagent shall be identifiable either from the label or from records.

3.1.7 As a general rule, reagents shall be purchased in containers of such size that the contents will be completely used within a few months to reduce any possible deterioration in quality. Leftovers shall never be returned to the containers.

3.1.8 Laboratory shall establish written procedures for preparation of reagent solutions and culture media. Records of such preparation shall be maintained for later reference in case of doubtful test result. Records for reagent solutions shall include measured weights and volume, burette readings, pH readings, calculation of standardisation factor and solution concentration, and that for culture media shall include medium name, batch number, amount prepared, pH before and after autoclaving, autoclave time and pressure.

3.1.9 Where laboratory prepares its own media, the chemicals and solvents used for such preparation shall be verified to be of the appropriate quality and grade before use.

3.1.10 Laboratory shall have procedures for verifying the suitability of culture media used. Both positive and negative controls shall be applied simultaneously together with the material to be tested under the same testing condition. The size of the inoculum used in positive controls shall be appropriate to the sensitivity required.

3.1.11 The laboratory shall observe and comply with all statutory requirements related to the importation, storage and handling of chemicals and drug substances.

3.1.12 For substances that are classified as “hazardous substance” under prevailing national regulations, they shall be kept separately from other reagents and held in locked cabinets.

3.1.13 For substances classified as controlled drugs under the Misuse of Drugs Act and its regulations, when used as reagents or received by laboratory for testing, they shall be kept in locked cabinets and entrusted to the responsibility of an authorised staff who shall also maintain the required register of such substances.

3.2 Reagent Water

3.2.1 Reagent water can be defined as water with no detectable concentration of the compound or element to be analyzed at the detection limit of the analytical method. Reagent water is used in the dilution of reagents and for blank analysis. Failure to prepare reagent water properly and to ensure that it is free of contaminants may account for the poor performance of analytical methods.

3.2.2 Preparation of reagent water can be through various methods including distillation, reverse osmosis, ion exchange and adsorption. Ultrafiltration and/or ultraviolet treatment may also be used as part of the process. The method of preparation shall ensure that the required quality of reagent water is obtained. (Refer to APHA 1080B)

3.2.3 The quality of reagent water (i.e. high, medium or low) should be based on the appropriateness for the analysis. The sensitivity of high quality reagent water shall be > 10 megohms-cm at 25°C and its conductivity shall be < 0.1 µS/cm at 25°C. The sensitivity of medium quality water shall be > 1 megohms-cm at 25°C and its conductivity shall be < 1 µS/cm at 25°C. Low-quality water, which may only be used for glassware washing, preliminary rinsing of glassware, and as feedwater for production of higher-grade waters, shall have a resistivity of > 0.1 megohm-cm at 25°C and conductivity < 10 µS/cm at 25°C. (Refer to APHA 1080C, Table 1080:II)

3.2.4 Reagent water used for preparation of culture media and reagents for microbiological tests shall be free from toxic metals, bactericidal or inhibitory compounds. The bacteriological quality of purified water shall be monitored frequently and the bacterial populations shall not be more than 500 CFU/mL. (Refer to APHA 9020B, Table 9020:II)

3.3 Certified Reference Materials (CRM)

3.3.1 Reference material, accompanied by documentation (e.g. COA) issued by an authoritative body* and providing one or more specified property values with associated uncertainties and traceabilities, using valid procedures.

3.3.2 Values associated with CRMs (by definition) are metrologically traceable.

3.3.3 For traceability provided by reference material producers, refer to SAC-SINGLAS 006 Clause 5.2

***Note**: Reference materials supplied by other commercial companies have to be accredited by their national accreditation bodies for their competency for preparing and supplying CRMs in accordance with ISO Guide 30/31/32/33/34/35.*

3.4 Reference Materials

3.4.1 Material, sufficiently homogeneous and stable with reference to specified properties, which has been established to be fit for its intended use in measurement or in examination of nominal properties.

3.4.2 Values associated with reference materials may not be metrologically traceable.

3.4.3 For microbiology testing, refer to 3.5.

3.5 Reference Microorganisms

3.5.1 The laboratory shall hold reference cultures of microorganisms, where

appropriate, from a recognised national/international collection to demonstrate traceability.

3.5.2 Reference cultures may be subcultured preferably once but not more than five times removed from the original culture to provide reference stocks. The reference stocks must be used to prepare working stocks for routine work and they must not be re-frozen and re-used once thawed. Working stocks shall not be sub-cultured to replace reference stocks. Records of subculturing shall be kept.

3.5.3 Appropriate technique shall be used to preserve the reference microorganisms so that the desired characteristics of the strains are maintained. The laboratory shall assign suitable staff for maintenance of reference microorganisms. Written protocols for culture maintenance shall be available in the laboratory.

3.5.4 Standard solutions may be classified as Certified Reference Materials or Reference Materials.

3.6 Volumetric Glassware

3.6.1 Volumetric measurement is an essential element in an analytical laboratory as many types of determination require specific dilutions and controlled delivery of various amounts of accurately prepared solutions.

3.6.2 Volumetric equipment shall be suitably maintained and checked. Regardless of type of volumetric glassware, where accuracy is required, especially for quantitative analysis, all of such volumetric equipment shall be calibrated. Exemption is made for the case of Class A volumetric equipment, with valid calibration certificates. ASTM E542 sets out the standard practice for calibration of volumetric ware.

3.6.3 A number of extraneous conditions may influence the precision of a given measurement. They include temperature, method of delivery, depth of colour of the solution, type of meniscus, calibration to contain or deliver a definite volume, and so forth. Thus proper training of personnel and continuing observation of their operations shall be instituted as part of the quality assurance process to minimise or eliminate problems associated with these extrinsic factors which can affect precise liquid measurements.

3.7 Cleaning of Laboratory Ware

3.7.1 The laboratory shall follow the International Standards (e.g. ISO, APHA, ASTM, IP) for cleaning requirements of the test methods. For test methods that do not have cleaning requirements, the laboratory should follow clauses 3.7.2 – 3.7.9.

3.7.2 Clean laboratory ware - glassware and non-glassware, such as polyethylene, polypropylene and Teflon ware, is an essential part of laboratory operations and a vital element of the quality assurance program. Attention to the cleanliness of these items must increase in proportion to the importance of the test, the required accuracy of the measurement, and the decrease in concentration of the analyte to be determined.

3.7.3 Each laboratory shall establish sound cleaning procedures for glassware and non-glassware used in various types of determinations. For trace determinations, special cleaning instructions shall be available. Where certain test methodology requires specific cleaning procedures, these shall be followed accordingly.

3.7.4 Cleaning may require several steps, and, whenever possible, cleaning should begin immediately after the apparatus is used.

3.7.5 Laboratory personnel shall be instructed on the disposal of dangerous contents and removal of corrosive agents before the apparatus is released for cleaning.

3.7.6 Manual or automatic washing equipment shall be used with detergents that are suitable for the purpose.

3.7.7 Organic residues may require treatment with a chromic acid cleaning solution, and apparatus for trace determinations may require rinsing with hot 50% nitric acid, followed by water and distilled water.

3.7.8 Glassware shall be dried and stored under conditions that will not allow it to become contaminated with dust or other substances.

3.7.9 Glassware used for microbiological testing shall be sterilised by autoclave or other appropriate means. Detergent residue checks shall also be performed before the initial use of a washing compound and whenever a new washing procedure is used. This is to ensure that glassware are free inhibitory residues which may result in residual bacteriostatic action. (Refer APHA 9020).

4. CLASSIFICATION, LISTING AND VALIDATION OF TEST METHODS

4.1 Classification and Listing of Test Methods

4.1.1 Test methods (including work instructions) shall be classified and listed in the SAC Schedule in accordance with the following principles:

a. A test method which conforms exactly to a standard method will be listed as such i.e. “name of standard method, version no./year”;

b. When a test method is modified from a standard method, the laboratory is required to demonstrate* that the modified method has equal performance as the standard method. If the review committee, as recommended by the assessment team, is satisfied with the demonstration, the modified method will be listed as an in-house method that is modified from the standard. i.e. “Name of in-house method, version no./year” (modified from “name of standard method, version no./year”) The modifications shall also be clearly stated on the test reports;

c. Any other test method will be described as an in-house method i.e. “Name of in-house method, version no./year”, without mention to any particular standard or reference.

**includes on-site witnessing by Technical Assessor(s) and review of*

relevant documentation including method validation by the assessment team

4.2 Validation of Test Methods

4.2.1 Methods shall be validated by carrying out analyses of reference standards of known concentration, both in isolation and in the form of spiked samples, and determining the recovery through each stage of the procedure (i.e. extraction, concentration of the extract and clean-up of the extract).

4.2.2 Matrix effect shall be adequately evaluated to ensure the accuracy of quantification.

Where applicable, the method of quantification shall be evaluated using solutions of the analyte in a suitable solvent. An internal standard shall be included where possible.

4.2.3 The detection limits, linearity, repeatability and reproducibility of analysis shall be evaluated on spiked material containing standards covering the expected concentration range.

4.2.4 The stability of the analyte in the sample matrix during storage and throughout the analysis procedure shall be evaluated.

4.2.5 Method validation may also consist of analysing the same sample material by different methods and comparing the recovery of known amounts of reference standard.

5. REQUIREMENTS FOR EVALUATION OF MEASUREMENT UNCERTAINTY

5.1 All testing laboratories shall identify the sources of uncertainty to their test results for both qualitative and quantitative tests.

5.2 For qualitative tests, the evaluation of measurement uncertainty is not required.

5.3 For quantitative tests, the evaluation of measurement uncertainty is required

5.4 For quantitative measurements where the final results are expressed in a qualitative way (e.g. pass/fail), evaluation of measurement uncertainty is still applicable (ILAC-G17:01/2021 – ILAC Guidelines for Measurement Uncertainty in Testing) and required to be taken into consideration when reporting the results qualitatively.

Note 1: If a laboratory has performed method verification to demonstrate its competence to implement the method in full and the method is a standard method, the laboratory could directly make use of the measurement uncertainty data provided by the method.

Note 2: The equipment used shall also comply to what the test method

has specified in order to use the measurement uncertainty data directly (e.g. the equipment type and accuracy etc.)

6. INFREQUENT LABORATORY ACTIVITIES

6.1 For accreditation of infrequent laboratory activities, the laboratory shall plan for and produce records of performance checks to verify and demonstrate their continuing competence. Such performance checks shall be done at least once every 2 years.

7. ACCOMODATION AND SAFE PRACTICES

7.1 Prevention of Cross Contamination

7.1.1 The laboratory shall be able to demonstrate that the accommodation and practices cannot lead to the contamination of sample or sample extracts. Work areas in which the analysis is done should preferably be separated from all other laboratory operations.

7.1.2 Separate work areas shall be available for the following operations:-

a) Cleaning of glasswares, purification of reagents and solvents;

b) Dismantling of sampling trains following the taking of samples;

c) Highly contaminated samples must be extracted and clean up in a separate work area from relatively low-level samples;

d) Analytical instruments must be housed in a separate area provided with adequate air-conditioning;

e) Adequate and appropriate storage facilities must be available for

(i) the storage of sample before, during and following analysis;

(ii) the storage of materials used in the course of analysis;

(iii) the safe storage of hazardous and non-hazardous wastes prior to disposal

Decontamination of persons and protective clothing.

7.1.3 Washing-up procedures shall be rigorous enough to ensure no carry-over of residues. All efforts shall be made to prevent possible sources of cross-contamination.

7.1.4 Reference standards, standard solutions and spiked samples shall be stored in a dedicated refrigerator and away from samples for analysis.

7.2 Safety

7.2.1 Laboratory shall uphold certain standard of safety. Reference could be made to standards on safe working practices, such as APHA 1090, ASTM E50, AS 2243, etc.

7.2.2 Laboratory shall ensure that its personnel wear protective clothing and safety equipment appropriate to the duties being performed.

7.2.3 Laboratory shall also provide fire extinguisher, safety shower and eye-bath in close proximity to the laboratory working area.

7.2.4 Many of the compounds and materials used during the extraction, cleanup and analytical stages are hazardous. Due care shall be taken to recognise the specific hazards presented by each compound and to ensure the safety of analysts involved in testing by:

a) using a system of labelling that identifies the substance and the hazards involved, and sets out simple precautionary measures to be followed;

b) having available material safety data sheets for all substances in use in the laboratory;

c) providing all testing staff with appropriate training in safe handling procedures;

d) following strict procedures written into analytical methods;

e) ensuring that good housekeeping practices are adhered to, that all spillages are cleaned up without delay and apparatus are cleaned up after use;

f) providing adequate and safe means of containing and disposing of all waste materials in accordance with waste disposal authorities and statutory requirements.