Jordanian Accreditation System
نظام الاعتماد الأردني
Accreditation Unit

POLICY FOR LABORATORIES PERFORMING ENVIRONMENTAL AND WATER TESTING GOOD LABORATORY PRACTICE

Issued on 2007-09-01
Revised on 2021-04-05
JAS-P13, rev.e

Purpose

This document describes the necessary instructions to be followed to ensure Good Laboratory Practice (GLP) and good house keeping in the laboratories performing Environmental **AND** Water Testing while still in accordance with the requirements of the international standard ISO/IEC 17025: **2017.**

Scope

This policy is developed to ensure the suitability of laboratory practices and the adequacy of measures taken to maintain Good laboratory practices (GLP) in the laboratories performing Environmental **AND** Water Testing.

Good laboratory practices (GLP) should, also, be followed by monitoring field work in order to eliminate: bottle contamination, breaking, and sample miss-labeling, and to ensure optimum performance of field instruments.

Authorship

This publication has been written by the Technical Committee, and approved by the Accreditation Director.

Official language

The text may be translated into other languages as required. The English language version remains the definitive version.

Copyright

Further information

This policy is mandatory for laboratories, and shall be implemented within four months from its issuance date.

For further information about this publication, kindly contact **JAS-A**U.

This document is also available at **JAS-AU WEBSITE** where you can check updates directly.

Contents

1. Introduction

This document includes additional accreditation requirements for Laboratories performing Environmental **AND** Water Testing **ACCREDITED OR INTEND TO BE ACCREDITED BY JAS-AU**; while still abiding to the requirements stated in the international standard ISO/IEC 17025: **2017.** This document provide**S** a **REFERENCE**for JAS-**AU A**ssessors in the assessments of Environmental **AND** Water Testing Laboratories.

2. Responsibilities

- Lab **PERSONNEL** are Responsible for assuring the proper cleaning of all instruments in the lab

- Section supervisors are responsible for setting up the acceptance criteria for the support equipment, and verifying that the results in the calibration certificates meet these criteria. Also; they are responsible for assigning the **PERSONNEL** who **ARE R**esponsible for monitoring the performance of support equipment in the related sections.
- Laboratory cleaning **PERSONNEL ARE** responsible for cleaning the floors, walls, doors, offices and outside floors surrounding the building, in addition to emptying the trash. The cleaning procedures in the analytical sections are witnessed and supervised by the laboratory analyst.
- Laboratory Janitors are responsible for cleaning laboratory glassware, bench tops and laboratory general refrigerators on a routine basis; except in cases of chemical spill were it will be the responsibility of the analyst himself. In all cases; cleaning procedures will be witnessed, supervised and checked by the laboratory analysts.
- Maintenance engineers in the laboratory are responsible for carrying out in-house periodic preventive maintenance, and for repairing simple instruments which are not covered by contracts. In addition, they are responsible for ensuring proper performance of safety equipment.

3. Definitions

The following terms and phrases, whenever they occur in this policy, shall have the meanings specified there-under unless otherwise indicated by the context:

- **Laboratories:** Laboratories Performing Environmental **AND** Water Testing.
- **Laboratory Director:** Laboratory Top Management.
- **Laboratory supervisors:** Personnel supervising analysis, Quality Assurance **AND** Quality Control (QA & QC) measures and day to day work activities in their respective sections.
- **Laboratory Janitors: PERSONNEL** for cleaning laboratory glassware, bench tops and laboratory general refrigerators on a routine basis
- **Laboratory cleaning PERSONNEL: PERSONNEL** for cleaning floors, walls, doors, offices and outside floors surrounding the building, in addition to emptying the trash
- **Quality Assurance Officer (QAO):** the person in charge of quality system management in the laboratory.
- **Personnel of analytical sections:** Any analyst working in a laboratory area.
- **Standard Methods:** Standard Methods for the Examination of Water and Wastewater Not always the applied method?
- **Verification:** The documented evidence that a reference method is properly executed in the laboratory.

- **Validation:** The documented evidence that the method as performed at this laboratory is fit for its intended use

4. Policy

4.1 Laboratory Personnel

(Clause **4.1)** of ISO/IEC 17025:**2017;** requires that the laboratory staff avoids involvement in any activities that would diminish confidence in competence, impartiality, judgment and operational integrity.
Analytical **personnel are** required to demonstrate their capabilities to perform the required tests. Each Analytical Section Head authorizes the **personnel** of that section to perform the tests based on the IDC "Internal Demonstration of Capability" results of that test. Ongoing competence **shall** be monitored objectively with provision for retraining where necessary. The competence of personnel to perform tests shall be documented in relation to the results of internal and external quality control. The identification of training needs, **shall** also be evaluated based on these results. Also, competence criteria have been specified for other laboratory personnel and competence certificates shall be issued accordingly with the authorization to perform the required jobs. Competence records and training records for the personnel shall be retained in the laboratory within reach and ease of retrieval.

The Lab. Director is required to verify that key personnel, their deputies and any other **personnel** who provide instructions and technical opinions on testing and test results are properly qualified **and authorized.** The Director **shall** approve any opinions, interpretation of results or instructions on technical process before being released to the Customers.

4.2 Premises

A typical laboratory is comprised of the testing facilities and ancillary facilities (entrances, corridors, administration blocks, cloak rooms and toilets, storage rooms, archives, etc.). In general, there are specific environmental requirements for the testing facilities. Depending on the type of testing being carried out; access to the controlled analytical areas, especially, to the Microbiological laboratory shall be restricted only to authorized personnel. Where such restrictions are in force, personnel **shall** be made aware of:

(a) The intended use of a particular area;
(b) The restrictions imposed on working within such areas;
(c) The reasons for imposing such restrictions;

Access to the Laboratory Information Management System (LIMS) and the operating software for analytical instrument is authorized to specific relevant personnel by given passwords.

The laboratory **shall** be arranged in a way so as to minimize risks of cross contamination, where these are significant to the type of test being performed. Ways to achieve these objectives are, for example:
(a) Construct the laboratory to the 'no way back' layout principle;
(b) Carry out procedures in a sequential manner using appropriate precautions to ensure test and sample integrity (e.g. use of sealed containers);
(c) Segregate activities by time or space.
(d) The appropriate containment levels.

It is generally considered as good practice to have separate locations, or clearly designated areas, for the following:

- Sample receipt and storage areas;
- Sample preparation;
- Examination of samples;
- Maintenance of reference materials;
- Storage of hazardous chemicals.
- manipulation of presumptive pathogens;
- Storage of culture media and reagents;
- Media and equipment preparation, including sterilization;
- Sterility assessment;
- Decontamination.
- Cleaning of glassware and other equipment;
- Storage of hazardous chemicals.

- Laboratory equipment should not routinely be moved between areas to avoid accidental cross-contamination. In the Microbiology laboratory: dedicated pipettes, tips, centrifuges, tubes, etc. should be located in each working area, as well as in the molecular biology laboratory Where PCR primers and probes are prepared, suitable segregation of these tasks **shall** be ensured to minimize DNA cross-contamination

- Contents of refrigerators/ freezers like reference standard materials or ordinary water samples are completely segregated from samples to minimize the possibility of cross contamination.
- Personnel **shall** be aware of the potential for contamination of production areas, and should demonstrate that they have taken appropriate measures to avoid such occurrence.
- Reduction of contamination may be achieved by having a special laboratory design criteria as per

4.2.1 Laboratory Design criteria

4.2.1.1 Bench tops, sinks, floors, ceilings and walls coverings

Regardless of the type of material selected, it should provide a functional, long-lasting work surfaces when properly maintained.

- Laboratory work surfaces should be specially manufactured for laboratory use with the following features: Good chemical resistance, ease of cleaning, color suitability, strength, abrasion resistance, heat resistance, thermal shock resistance, stain resistance, bacteria and fungus resistance and corrosion – resistance.
- For Good Laboratory Practice, the tops should be selected to be: easily accessible for cleaning and decontamination, no sharp corners, cracks and open joints, tight, even and rounded-off transitions between surfaces and different materials, do not absorb or emit particles, do not permit retention of dust, dirt and moisture, resist repeated treatment with water, disinfectants and chemicals, resist symptoms of aging like cracking, flaking and corrosion and must resist wear and tear and mechanical impairment and have safety back-splash and raised edges.
- Cupboards should be up to the ceiling with no rough and bare wood. Wooden surfaces of fixtures and fittings to be adequately sealed. Items and equipment should be stored and arranged to facilitate easy cleaning.

- Sinks should have special features according to their location and intended use for example: the carbon polishing filter in the organic lab, taps operate without using the hands when dealing with hazardous chemicals, smooth finish, connected directly to the main outlet, and generally, material should resist acids.
- Wall and door coverings should be easily washed and cleaned.
- Fluid conveying pipes should not be passing above work surfaces unless placed in hermetically sealed casings.
- Ceilings should have a smooth surface with flush lighting. When this is not possible (as with suspended ceilings and hanging lights), the laboratory should have documented evidence that they control any resulting risks to hygiene and have effective means of overcoming them, e.g. a surface-cleaning and inspection program.

4.2.1.2 Hallways, Doors

In order to move the instrument into the laboratory, all the way through from the loading dock to the final position, including the entrance to the facility, the width of all hallways and doors, should be wide enough.

4.2.1.3 Floor Space

There should be a minimum distance left behind the units, which is, imperative to allow easy access to the rear of each module for service and repair to ensure that operating personnel are easily able to carry out their work, in addition to, facilitate heat dissipation.
Flow of material and personnel should not intersect during the daily activities.

4.2.1.4 Floor Conditions

The floor should be leveled to the required extent, and can sustain efficiently instrument's weights. It should be free from shock and vibrations.

4.2.1.5 Fume Hoods and Biological Safety Cabinets

All exhaust hoods are checked semiannually for average face velocity with the sash at 1/2 and full open using Anemometers and visual inspection (smoke tube) to insure: sufficient suction, flow direction, and minimal turbulence. Checks also include air circulation around the hood (six inches from the front of the hood). This should be < 20 linear feet/minute and never be > 20% of face velocity.

The average velocities range from 80-100 linear feet per minute, though higher velocities of about 125 linear feet per minute might be required. Higher velocities (150 linear feet per minute) might create turbulence.

These checks are the responsibility of the maintenance engineer, or, the supervisor of the analytical area who is also responsible for documenting and archiving these checks, and actions taken.

Responsibility of reporting the malfunction events and follow-up shall be **defined according** to laboratory policy

The biosafety cabinet, BSCs must be certified by an accredited and qualified services before they are put into service and at least annually thereafter, also whenever they are moved, repaired and after HEPA filters have been changed

(For details on fume **hoods, biological safety cabinets** and safety requirements refer to the Safety Policy for Laboratories Performing Environmental **and** Water Testing JAS-P11).

4.3 Purchasing services and supplies

Governmental Laboratories Performing Environmental & Water Testing, usually, implement the General Supplies Law (No. 32/1993) not applicable to all labs such as private labs, foreign labs. This section must describe what the good practices are in the purchasing process, such as maintaining up to date records of supplier evaluations, receiving of supplies, etc. in purchasing of services and supplies. Procedure of this law is audited through unscheduled visits by the accounting bureau and audit bureau representatives who are responsible for: checking the documents of the purchasing, receiving of supplies, and making sure that it follow the legal path, which can be done by checking the documents and the stamps and signatures on these documents.

Regarding the technical specifications in these documents, top management of the labs are responsible for setting these specifications and making sure that they will affect the quality of testing positively.

Purchasing and receiving supplies process, including, the role of other departments **shall b**e clearly documented. This document **shall** contain the following:

- Purchasing authority and responsibilities;
- The preparation of annual needs of supplies and services list;
- The bases of selection supplies and services;
- How to check supplies that affect the quality of testing;
- The basis and procedures followed for the approval, evaluation and monitoring of the performance of suppliers.

4.4 Preventive maintenance

Preventive maintenance is undertaken by the responsible personnel according to the laboratory policy. Maintenance checklists for main equipment in the laboratories are kept together with time-table of actions and troubleshooting to be done according to the instrument manual. Preventive maintenance actions with dates and signatures are recorded and retained in the section. As a common practice in most of the Laboratories Performing Environmental & Water Testing, main instruments are maintained by instrument maintenance engineer according to annual maintenance contracts. Simple repairs and maintenance like instrument checks repair, column replacing, and cleaning are performed by the analyst.

4.5 Laboratory Consumables

4.5.1 Glassware

- Glassware made from borosilicate glass is preferred to be used in the laboratory because it is resistant to heat and chemicals. Borosilicate glass or polyethylene bottles are used for storing reagents and standards.
- Volumetric glassware is calibrated to contain an accurate volume. The glassware is usually marked by the manufacturer. When volumetric measurements are required, class A glassware is to be used and is typically marked with an A (or equivalent demonstration of specification of uncertainty). This glassware, including volumetric pipettes and flasks, does not require calibration before use.
- Mechanical Pipettes are calibrated with the liquid most often used if applicable. Calibrations are recorded in logbooks with performance compared to the manufacturer's specifications.
- **Because untreated water may contain water borne pathogens, all used pipettes shall be placed in a disinfectant solution (e.g. solution of sodium hypochlorite) before glassware washing. Used pipettes shall not be placed on table tops, on lab carts, or in sinks.**
- **Used pipettes and glassware shall be clearly identified and effectively separated to prevent accidental use or staff infection.**

4.5.2 Chemicals and Reagents

Reference Materials (RM) used for calibration and verification must be purchased from two different competent suppliers; if available (or reference material with different batch number from the same supplier). These materials should be accompanied with certificate of analysis from the manufacturer**, the lab shall ensure that measurement of RM results are traceable to the international system of units through certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI, or reference material producers fulfilling the requirements of ISO 17034 are considered to be competent,** The certificates are retained in the respective analytical section

Strict control and documentation are maintained for all reagents and standards. Reagents and standards are typically of the following types:

- Neat (Pure) chemical standards
- Reagents/Standards (commercially purchased)
- Reagents/Standards (laboratory prepared)

A Chemical Inventory of all chemical standards shall be listed, maintained and kept at each analytical section. Documentation includes:

- Chemical name
- Purity
- Manufacturer
- Lot number
- Amount
- Storage location
- Date received
- Date expired

The Chemical Inventory is periodically reviewed to determine which chemicals need to be disposed and reordered. If no expiration date is available, chemical standards are disposed at 10 years after the date received.

Labels on each reagent container in the laboratory **shall** include: the name, purity or concentration of material, preparation and expiry dates, (Validity period shall not exceed 1 year). Preservation conditions, solvent used in preparation, and if relevant the name of the responsible person.
For laboratory prepared reagents/standards, a strict control and documentation of calibration standards must be maintained.
Expired standard solutions must be discarded and new standards must be prepared as needed.
Batches of media **shall** be identifiable. Each one received **shall** be accompanied by evidence that it meets the quality specification. The user laboratory **shall** ensure that it will be notified by the manufacturer of any changes to the quality specification.
For microbiology section, Traceable reference cultures are required for establishing acceptable performance of media (including test kits), for validating methods and for assessing/evaluating on-going performance. To demonstrate **metrologica**l traceability, laboratories shall use reference strains of micro-organisms obtained directly from a recognized national or international collection, where these exist. Where traceable reference cultures are not readily available, commercial derivatives traceable to them could alternatively be used, provided that the relevant properties for its intended use have been shown by the laboratory to be equivalent at the point of use.

4.5.3 Test Gases

Wherever possible, a separate external room is designed, in order to, accommodate and store all gas cylinders used in the laboratory. Gas regulators should provide continuous visual monitoring for the respective gas pressure. The empty gas cylinders are transferred in the gas cylinders main room and separated from filled cylinders. A record of all cylinders available at the laboratory is retained in the gases room accompanied by a checklist of empty and filled cylinders. A **person** is assigned by the Laboratory Director to follow up the continuous supply of gases. This person is responsible for contacting the contracted company in order to replace empty cylinders with filled ones, and to ensure safe handling and delivery of gas cylinders in that process.
(For details on health and safety handling of gas cylinders refer to the Safety Policy for Laboratories Performing Environmental **and** Water testing JAS-P11).

4.6 Cleaning procedures for sample containers and laboratory glassware

In general all reused laboratory containers and glassware are cleaned in the analytical section by the laboratory janitors using detergents and tap water followed by thorough rinsing using de-ionized water. Detailed cleaning procedures for specific testing **shall** be mentioned in the relevant analytical SOPs (Standard operating procedure) or as stated in the standard methods.
Internal Laboratory Quality Control measures are taken by analytical section to ensure the adequate cleaning for the intended purpose according to Standard Methods requirements as described in the analytical SOPs.
Note: It is not allowed for the housekeeping **personnel** to clean or transfer any equipment or device in the lab.

For quality control on sample container cleaning; random containers of cleaned glassware are filled by the responsible analyst for a certain type of testing with a method blank and analyzed to check the

effectiveness of cleaning, and to ensure that the results are below the Method Detection Limit (MDL) for that test. Cases of nonconformance will be addressed according to sections **7.10 and 8.7** and of the ISO/IEC 17025:**2017.**
In certain cases, cleaning and tracking of cleaned samples is not possible on a batch by batch basis, therefore, the procedure is random, depending on individual sample containers.

4.6.1 Cleaning procedures for bench tops

Bench top cleaning is usually performed by the Laboratory janitors.
Bench tops are cleaned daily and washed with soap and detergents weekly and whenever are needed.
In exceptional cases like for the microbiology section or in cases of chemical spills in other analytical sections, the analyst is responsible for the cleaning and disinfection.
There shall be a documented cleaning program for laboratory fixtures, equipment and surfaces. It should take into account the results of environmental monitoring and the possibility of cross contamination. There should be a procedure for dealing with spillages.

4.6.2 Special Requirements (Microbiological testing)

Quality control checks are performed according to **suitable international or well established reference such as t**he Standard Methods section 9020 B: "Intra Laboratory Quality Control Guidelines" to assure the sterility of microbiological facilities.
An appropriate environmental monitoring program shall be devised, including, for example, frequent use of air settlement plates for bacterial and fungal contaminants as well as periodic surface swabbing for a variety of relevant micro-organisms, especially pathogens. Acceptable background counts **shall** be assigned and there **shall** be a documented procedure for dealing with situations in which these limits are exceeded. Analysis of data should enable trends in levels of contamination to be determined.

4.7 Calibration and Check of Support Laboratory Equipment

Laboratory support equipment **shall** be calibrated by Organization satisfy JAS-P04, annually as a minimum, and whenever the calibration verification falls outside the specified acceptance limits.
Certain volumetric equipment that might be subject to certain conditions might be calibrated at a frequency of four times each year (every three months), otherwise, the laboratory section takes the risk of calibration verification events that might fall outside the accepted tolerance criteria between calibration intervals.

4.7.1 Balance calibration

Each balance is identified with a unique number. Balances are professionally serviced and calibrated annually on site by Organization satisf**ies** JAS-P04. Locations of the calibrated balances are kept fixed. The calibration certificate and the calibration report are placed next to the balance.
Balances are checked before each use and when needed, by using external calibration weights in the range normally used with that balance. Documented acceptance ranges

and tolerance are established for each balance based on calibration certificate issued by organization satisfies JAS-P04
The analyst is responsible for cleaning and checking calibration of the balances. Calibration checks are recorded in logbooks with performance compared to the manufacturer's specifications and the calibration certificate.

4.7.2 Temperature monitoring requirements for lab apparatus

A unique identifier is assigned for laboratory refrigerators, freezers, lab ovens, incubators, water baths and hot plates…..etc. Temperatures of these apparatus are checked each working day and documented in a sheet attached to the apparatus. Completed sheets are archived in a special folder within reach and easy access of the analytical section **personnel**.
Acceptance ranges and uncertainties are assigned to each unit based on the calibration certificate issued by Organization satisfies JAS-P04.
Refrigerators, water baths, hot plates are equipped with calibrated (digital thermometers or liquid thermometers) to give continuous reading for apparatus temperatures.
Thermometers used during field work must be calibrated by Organization satisfies JAS-P04, annually, as a minimum. Certain thermometers are immersed in appropriate media to avoid temperature fluctuations during measurement.

4.7.3 Calibration and performance verification for Autoclaves, including media preparation

Autoclaves should meet a specified time and temperature tolerances by using a provided clear operating instructions based on the heating profiles. Acceptance/rejection criteria **shall** be established and the records of autoclave operations, temperature**, pressure** and time, should be maintained every cycle. Monitoring the temperature of an autoclave and the effectiveness of its operation during each cycle may be checked by the use of chemical or biological indicators for sterilization/decontamination purposes.

4.8 Method Verification / Validation

In the case when the testing laboratory uses standard reference methods, it is required to verify the ability of achieving satisfactory performance against the documented performance characteristics of the method. It is also required that the range and accuracy of the values obtained from reference methods as assessed for the intended use, are relevant to the customer's needs [ISO/IEC 17025 **Clause 7.2**]
In house developed methods, shall be validated and authorized before use. Where they are available, certified reference materials should be used to determine any systematic bias. Where this is not possible, results should be compared with other technique(s), preferably based on different principles of analysis.
The performance characteristics that must be addressed in the method verification /validation include:

- Selectivity **and** specificity
- Range
- Linearity
- Sensitivity
- Limit of detection
- Limit of quantization
- Ruggedness
- Accuracy

- Precision

Method verification **shall** be conducted on each water matrix, that, the method is applied for, i.e. raw water, surface water, groundwater, potable (finished) water, wastewater, etc…
Method verification includes analysis and documentation of the results of: Reference Materials, Certified Reference Materials, duplicate (replicate analysis), laboratory control standards, matrix spike (where it is applicable) and proficiency tests. Also, Internal Demonstration of Capabilities (IDC) constitutes a good part of the verification procedure provided that the acceptance criteria are stated in each IDC for each matrix.

Method validation is conducted for methods that deviate from the latest edition for Standard Methods for the Examination of Water and Waste Water or latest edition in certain aspects, application notes, vendor methods, manufacturer manual SOP, and in house methods.
In methods derived from the latest edition for Standard Methods for the Examination of Water and Waste Water, or latest edition **of other references bu**t deviates in some aspects, all the deviations **shall** be mentioned in the SOP.

Method validation **shall** be conducted on each water matrix that the method is applied for, i.e. raw water, surface water, groundwater, potable (finished) water, wastewater, recreational water.

Uncertainty of measurement: [Measurement Uncertainty is not relevant to the scope of this document. Must be removed]

ISO/IEC 17025, paragraph **7.6** See also ISO/TS 19036 [9], EA-4/16 [16], ISO 29201 [10] and HPA (UK) QSOP4 [17]
The international definition of uncertainty of measurement is given in the ISO International Vocabulary of Metrology (VIM 3) and the concept in general is treated in the Eurachem guide on uncertainty. ISO/IEC17025 specifies the need for laboratories to **evaluate** the measurement uncertainty taking into account all components that may affect the result. Measurement uncertainty can only be determined for the results from quantitative methods. The general approaches to evaluating and expressing measurement uncertainty in microbiological testing of food and water are based either on ISO/TS 19036 (for food), or ISO 29201 and HPA (UK) QSOP4 (for water). ISO 29201 is more versatile; covering both colony counts and MPN (Most Probable Number) results, and presents two different approaches to uncertainty **evaluation** (component approach and global approach) that can be used for different matrices.
Microbiological tests generally come into the category of those that preclude the rigorous, metro logically and statistically valid calculation of measurement uncertainty to the expression of uncertainty in measurement. It is generally appropriate to base the **evaluation** of measurement uncertainty on repeatability and intermediate precision (within laboratory reproducibility) data. The individual uncertainty components should be identified and demonstrated to be under control and their contribution to the variability of results evaluated. Some components (e.g. pipetting, weighing, dilution effects and incubator effects) may be readily measured and easily evaluated to demonstrate a negligible contribution to the overall measurement 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 also be considered.

4.9 Quality Control

Quality Control elements consist of negative and positives controls.
Negative controls ensure that a test, its components, or the environment do not cause undesired affects or produce incorrect results.
Blank data can be used to inform the data quality relative to sensitivity and accuracy. Positive controls measure the ability to determine "hits" with precision and accuracy.
It is important to note that positive controls may relate to a group of samples like Laboratory Control Standards (LCS) or Laboratory Fortified Blanks (LFB) or a specific sample (Matrix Spike (MS)/ Matrix Spike Duplicates (MSD), surrogates), which may or may not be representative of other samples.

4.9.1 Proficiency Test Samples

Proficiency Testing (PT) involves challenge testing of unknown samples and inter-laboratory comparisons. The laboratory **shall** participate in Proficiency Test programs for as many determinants as is practical and according to **JAS-P02** polices related to the related technical fields.
Any unacceptable results **shall** be brought through the corrective action process described section **(8.7)**.

4.9.2 QC Test Protocols

Verification of the system calibration followed by reagent blank analysis should be the first step in the analytical sequence (after calibration, if required); in order to confirm that the system is in control. If non-conformance is evident in either of these tests, they should be remedied before proceeding to sample analysis. The specific acceptance criteria for actions to be taken when those criteria are not met **shall** be spelled out in the individual method SOP.

QC Requirements – Chemistry		
Sample	**Type**	**Frequency**
Verification of Calibration		1 per day of analysis (not to exceed 12 hour)
Method Blank	Negative Control	1 per batch
LCS	Positive Control	1 per batch
MS- Method Spike	Positive Control	1 per batch (excluding pH, turbidity, TDS, TSS, BOD, residual chlorine)
Surrogates	Positive Control	All organic chromatographic analyses
MSD or Dup	Variability Control	1 per batch
PT or inter-laboratory comparisons.	Variability Control	Refer to **JAS-P02**
Quality Control		1 per batch

Note: a batch shall be 20 or fewer, samples all prepared together with the same reagents, glassware and analyst.

QC Requirements - Microbiology		
Sample	**Type**	**Frequency**
Method Blank (processed)	Negative Control	One/ batch
Un-inoculated media	Negative Control	One/ batch
Known non-target negative control [reference culture]	Negative Control	Perform this test with each batch of the laboratory prepared media
Positive Growth Control (known) [reference culture]	Positive Control	Perform this test with each batch of the laboratory prepared media
Equipment Temperature Performance Positive Control	Positive ATCC	One/use
Equipment Temperature Performance Negative Control	Negative ATCC	One/use
spiked samples with variable contamination levels, including target and background flora	Variability Control	Refer to a program of laboratory periodic check
spikes/naturally contaminated samples from a range of matrices	Variability Control	Refer to a program of laboratory periodic check
Sample Dup or Positive Growth Control Dup	Variability Control	5%of samples/month
PT or inter-laboratory comparisons.	Variability Control	Refer to **JAS-P02**

QC Requirements – Radiochemistry		
Sample	**Type**	**Frequency**
Method Blank	Negative Control	1 per batch
LCS	Positive Control	1 per batch
MS	Positive Control	1 per batch
Replicate	Variability Control	1 per batch
PT	Variability Control	rotate to cover all analytes in 4 years

Note: a batch shall be 20 or fewer samples all prepared together with the same reagents, glassware and analyst.

4.9.3 Long term analysis and assessment

QC test results **shall** be analyzed and assessed for signs of changes to data quality or trends which may indicate a potential non-conformance. This will be conducted through the use of control charts and annual reassessment of the estimation of uncertainty.

4.9.4 Trend Analysis

During the data review process, it is the responsibility of the Technical Management (for example; Analytical Section Heads) to identify multiple occurrences of non-conformances, such as method spike, MS recoveries beyond the acceptance criteria which may indicate a change to the analytical system and may require re-evaluation of the uncertainty estimate for a given test method.

The laboratory will monitor trends in analytical system response using Control Charts (CC).

4.9.5 Control Charts

The importance of Control Charts is to determine if the process is stable, and, therefore, if repeatable. And to enable the (QAO) and the Analytical Section Head to investigate the reasons for the change (Shift), in addition to, correct and get the process back into a stable and acceptable state.

The types of control charts employed are:

Condition	Type of Control Chart
1. Shift in average $\bar{X}$	$\bar{X}$ Chart (accuracy chart)
2. Change in spread σ	Range R chart, or σ chart
3. Change in both $\bar{X}$, σ	$\bar{X}$ chart and R chart (σ chart) (R better for smaller sample size)

When a Quality Control (QC) value exceeds the Upper or Lower Control Limit (UCL) (LCL), the system is "out of control" and work should cease. The cause **shall** be identified and work shall resume; only after it has been demonstrated that the system is back in control.

In Chemistry: Average control chart will be constructed based on percent recovery of the LCS (accuracy chart).

In Microbiology: Trends in microbiological tests **shall b**e monitored through **Chi-square chart or a** precision**,** range chart of the Relative Percent Difference (RPD) of duplicate analyses.

These trend charts **shall** be developed by senior analytical **personnel** and posted within the test area. The analysts are responsible for updating the charts by manually marking data points on each day of analysis.

When a Quality Control (QC) value exceeds the precision criterion~~,~~ the system is "out of control" and work **shall** cease. The cause **shall** be identified and work shall resume; only after it has been demonstrated that the system is back in control.

4.10 Corrective action

Non-conformance (deviations from assigned values) or observations (trends) revealed from the analysis of the quality control data **shall i**nitiate corrective action or a preventive action whichever is applicable by the QAO addressed to the concerned Section Head as per clause **8.7** in ISO/IEC 17025**:2017.** The QAO **shall** follow up with the respective sections until the problem/ observation disappears.

Complaints indicating that a process has gone or is headed outside of the specifications of the laboratory quality system; shall initiate the laboratory corrective action process.

The corrective action process consists of the following steps:

- Identify the **nonconformity**;
- Determining the significance of the **nonconformity**– act accordingly;
- Determine the cause of the **nonconformity**;
- Assess the possible actions and selecting the corrective action;
- Implement the corrective action;

- Follow-up, to confirm that corrective action has achieved desired result.

The identification of non-conforming work and the corrective action process is documented. Documentation **shall** include a brief description of the problem, corrective actions, the data of implementing the actions and the final status of the test or the non-conformance and if there is a need for further follow-up.
Corrective action is to be taken by the person closest to the source of the problem.
If a non-conformance is related to analytical methods then the analysis **shall** be stopped (by the analyst or the person closest to the source of the problem) until the **nonconformity** is resolved. The Analytical Section Head and the analyst assess any impact the non-conformance may have on current and previous samples tested and they will in turn take appropriate actions and contact the **customer**/sample submitter as needed.

4.10.1 Cause Analysis Evaluation of Non- Conformance

When a non-conformance has the potential for recurrence or the cause of the non-conformance is uncertain, a cause analysis **shall** be performed.
The cause analysis involves a diagnosis of the **nonconformity**. This diagnosis **shall** be supported by one or more of the following:

- Collected data
- Event/Sequence timeline
- Interviews of **personnel** involved in the process or technical experts
- Additional control testing

Note: cause analysis may include the following actions and checks: Raw data and calculation, laboratory reagent water criteria, the suitability of chemical reagents used in the test, the expiry date of calibration and check standards, instrument status and response, sample conditions upon delivery to the laboratory and storage conditions or preservation if applicable, and sample matrix which may contains interferences or factors that affect the analysis.

Each Section Head can propose additional actions other than listed above according to the section needs and according to the non-conforming case.
If the initial investigation does not determine a cause of the non-conformance, then the Section Head **shall** request additional testing to be performed in order to verify that the analytical system is in control. If the problem persists or the source of the problem cannot be identified, it is referred to the QAO for further investigation.

4.10.2 Assess possible action

All available alternatives **shall** be assessed before selecting a corrective action.
Sometimes, a short-term fix is needed to get a system to be functional (ensuring that all quality guidelines are met) but this must not be confused with a long-term solution.
The analysis of alternatives and selection of corrective action **shall** be **recorded** on the corrective action form.

4.10.3 Select and implement corrective action

The selection and implementation of corrective actions for analytical testing methods **shall** be conducted by the Section Head. Responsibility for conducting necessary work may be delegated to appropriate technicians under the supervision of the Section Head. Corrective actions for test procedures must include control testing to confirm that the analytical system is back in conformance with the quality system.
After confirmation testing is satisfactorily completed, testing of samples may resume.

4.10.4 Follow-up

The first data set after the corrective action has been implemented, **shall** be scrutinized by the Section Head to verify its effectiveness in assuring that the cause was eliminated and the non-conformance is not likely to re-occur.

The QAO is responsible for performing a follow-up assessment to ensure that the action taken is effective to meet the quality system requirements and is properly documented. This might require additional follow up of internal audits and surveillance visits necessary to verify and monitor effectiveness of the taken corrective actions by ensuring continuous improvement of the laboratory work and preventing the recurrence of the non-conformances.

4.10.5 Test report

4.10.4.1 For microbiological tests (In quantitative methods), results are expressed as number of colony forming units (cfu) per volume or grams of sample analyzed

4.10.4.2 In (Qualitative test), results shall 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"

4.10.4.3 Evaluation of the measurement uncertainty of the test result is expressed on the test report; any limitations (particularly if the evaluation does not include the component contributed by the distribution of micro-organisms within the sample) have to be made clear to the customer.

4.10.6 Waste management

Waste disposal procedures for specific materials and test outputs **shall** be mentioned in the analytical SOPs.

Good housekeeping is assured by proper placement and handling of hazardous wastes in order to prevent hazardous accidents, waste reaction, explosions and spills.

(For details refer to the Safety Policy for Laboratories Performing Environmental **and** Water Testing **JAS-P11)**.

Contact the national authorities regarding the waste disposal mechanisms.

5 References

- Eurachem Guide; Accreditation for Microbiological Laboratories Second Edition 2013
- **Standard Methods for the Examination of Waters and Wastewaters 23rd Edition 2017.**