ION LABS QUALITY FIRST	Standard Operating Procedure Laboratory Quality Assurance Activities Plan (Proficiency Testing)	SOP Number D-118	Revision 0
		Effective Date 11/02/21	Page Page 1 of 6

Written by/ Date	Reviewed by/ Date	Approved by/ Date
10/06/21	10/06/21	10-11-21
Title: QC Laboratory Director	Title: Analytical Development Manager	Title: VP of Quality & Regulatory Affairs

1.0 Objective and Purpose

1.1 The objective of the Quality Assurance Activities process is to monitor the validity of testing results, uncover potential errors or oversights, and learn where process and technical skill improvements may be made.

1.2 The purpose of this procedure is to describe how quality assurance activities are planned, to provide guidance for the activities used, to verify the validity of test results, and initiate action as a result of quality assurance activities.

2.0 Responsibility and Applicability

2.1 This procedure applies to testing activities performed within scope of accredited tests for Ion Labs.

2.2 QC Laboratory Management is responsible for determining the types of activities used to validate test data results and the accuracy of lab practices, for establishing, maintaining and updating a schedule of when and how such activities will be performed and for executing the planned activities.

2.3 QC Laboratory Management is also responsible for responding appropriately when the analysis results indicate that test data is suspect or inaccurate. QC Laboratory Management is responsible for ensuring that appropriate actions are taken including notifying customers, initiating report recalls and taking appropriate corrective action in accordance with the Nonconformity and Corrective Action procedure.

2.4 QC Laboratory Management is responsible for ensuring that this procedure is accurate, understood and implemented effectively. No changes may be made to this procedure without the authorization of QC Laboratory Management.

3.0 Definitions

3.1 **Proficiency Test-** An Inter-laboratory comparison that is formally organized and managed by an independent third party. Additionally, the proficiency test includes the participation of a reference laboratory and uses the results to determine participant performance. An

acceptable level of variation is determined. The results are then statistically compared. Values exceeding the acceptable threshold require the Lab to investigate their practice(s) and calculations to find the source of the test method, data analysis and/or measurement error.

3.2 **Inter-laboratory comparison-** the organization, performance, and evaluation of measurements or tests on the same or similar items by two or more laboratories or inspection bodies in accordance with predetermined conditions. The results are issued in a formal report.

3.3 **Intra-laboratory comparison-** conducted when several analysts or technicians within an organization perform testing or calibrations on the same or similar artifact, using the same method, under specified, controlled conditions.

3.4 **Blind Sample-** A sample submitted for analysis whose composition is known to the submitter but unknown to the analyst.

3.5 **Intermediate Checks-** checks performed to maintain confidence in the calibration status of measuring and test equipment.

3.6 **Working standard-** (In-house or secondary standard) is a standard that is qualified against and used instead of the reference standard.

3.7 **Reference Material-** controls or standards used to check the quality and metrological traceability of products.

4.0 References

4.1 C-502, SOP, Record Storage, Retention, and Destruction

4.2 C-501, SOP, Document Control Procedure

4.3 QS-108, SOP, Corrective and Preventative Action

4.4 A-113, SOP, Training Procedure

4.5 D-118-F1, Form, Quality Assurance Activities Schedule and Results

5.0 General

5.1 The Lab monitors its performance by comparison with results of other laboratories, where available and appropriate. This monitoring is planned (see section 5.1 below) and reviewed (see section 5.3 below) and includes participation in proficiency testing and/or participation in interlaboratory comparisons other than proficiency testing. The results of the monitoring activities are analyzed and used to control and if applicable, improve the Lab's activities.

5.2 External testing labs used to participate in interlaboratory comparisons or proficiency testing service providers will have been approved in accordance with the Purchasing and General Receiving procedure.

5.3 For any type of method selected, valid statistical analysis will be performed to determine the acceptability of the results.

6.0 Process Inputs

6.1 The inputs to the process include, but are not limited to the following:

6.1.1 Test services performed

6.1.2 Validity of test results resulting from interlaboratory and Proficiency test requirements

6.1.3 ISO 17025:2017 requirements for validating test results

7.0 Process

7.1 Planning

7.1.1 Lab Management establishes a schedule to include at least one Quality Assurance Activity for each Lab Personnel identified as competent to perform accredited tests per year. Quality Assurance Activities are planned when the issuing body revises standard test methods to verify the laboratory can properly perform the method in light of the revisions made. Activities may be performed more frequently at the discretion of Lab Management.

7.1.2 The Quality Assurance Activities Schedule and Results spreadsheet is used to plan the activities, to identify the method used, to record the results, and to evaluate the results. The activities may be planned year-by-year or for several years in advance at Lab Management's discretion.

7.1.3 External services are procured in accordance with the Purchasing and Receiving procedure.

7.1.4 Proficiency testing activities are planned where appropriate. The plan is included with all other quality assurance activities and documented on the Schedule and Results worksheet. Lab Management ensures proficiency testing includes the personnel who participate in accredited testing.

7.1.4.1 Where possible, customers' samples are not used in inter-laboratory comparisons or proficiency testing. If customers' samples are used, care will be taken to ensure that the samples are handled, stored, and transported to prevent damage or deterioration, and that customer data remains confidential. It is preferred that customers grant permission in writing prior to the use of their sample(s) for quality control activities.

7.1.4.2 An acceptable level of variation is determined during the proficiency testing process. The results are then compared using valid statistical analysis to identify valid results and outlier results. Values exceeding the acceptable threshold require the participating laboratory to investigate their practice(s) and calculations to find the source of the test method, data analysis, and/or measurement error.

7.1.5 When the laboratory has decided to participate in a proficiency test, the ISO 17025 accreditation body will be contacted upon achieving the following milestones:

7.1.5.1 When applying to participate in the proficiency test

7.1.5.2 When reference items are received applicable to the proficiency test

7.1.5.3 When the results have been submitted to the proficiency test provide

7.1.5.4 When the formal report is issued by the proficiency test provider

7.1.6 Data generated as a result of quality assurance activities are recorded and ensures trends are detectable both within the quality assurance activity immediately performed, and when compared to the results of previous quality assurance activities. Where applicable to determine clear results, statistical techniques are included in plans for quality assurance activities and analysis of results.

7.2 Methods

7.2.1 Lab Management utilizes appropriate methods for quality assurance activities. The methods may vary from year to year. Allowable methods will include where appropriate, but not be limited to:

7.2.1.1 Participation in inter-laboratory comparison or proficiency-testing programs.

7.2.1.1.1 Third-party programs such as the National Association for Proficiency Testing (www.proficiency.org) or others may be used if appropriate testing exists.

7.2.1.2 Replicate tests using the same or different methods.

7.2.1.3 Retest within the same sample (may be a retained sample).

7.2.1.4 Correlation of results for different characteristics of a sample.

7.2.1.5 Review of reported results.

7.2.1.6 Intra-laboratory comparisons.

7.2.1.7 Testing of blind samples.

7.2.1.8 Participation in inter-laboratory comparisons other than proficiency testing.

7.2.1.9 Intermediate checks on measuring equipment.

7.2.1.10 Use of check or working standards with control charts, where applicable.

7.2.1.11 Functional check(s) of measuring and testing equipment.

7.2.1.12 Use of alternative instrumentation that has been calibrated to provide traceable results.

7.2.1.13 Use of reference materials or quality control materials.

7.2.2 Work instructions for completing the quality assurance activity may be developed and provided to participants if deemed necessary by Lab Management. Resulting work instructions will be controlled in accordance with SOP C-501 Document Control Procedure.

7.3 Results

7.3.1 During planning, Lab Management determines the format used to record the results including but not limited to data tables, charts, logs, and/or statistical means to provide thorough objective evidence of the results and to complete the comparisons and analysis. The data may be added on a specified worksheet in

the Quality Assurance Activities Schedule and Results spreadsheet or maintained separately.

7.3.2 Where the results indicate an acceptable result, the Quality Assurance Activities Schedule and Results spreadsheet is updated, and the activity is designated as "pass".

7.3.3 Where the results are found to be outside the pre-defined criteria, the Quality Assurance Activities Schedule and Results spreadsheet is updated, and the activity is designated as "fail". The impact of the situation will be assessed to determine if reports with inaccurate tests have been delivered to customers. Corrective action will be taken as appropriate to prevent incorrect results from being reported in accordance with the QS-108 Corrective and Preventative Action procedure. Training is provided in accordance with SOP A-113 Training Procedure.

7.3.3.1 As a part of closure on the corrective action and a verification of the actions taken to prevent recurrence of the root cause, Management will set a time frame (without undue delay) to repeat the test data validation.

7.3.4 All records associated with the activities and data analyses will be maintained in accordance with SOP C-502 Record Storage, Retention, and Destruction.

8.0 Management Review

8.1 Results of Quality Assurance Activities are submitted for management review. The results may be submitted in their entirety, or a summary of the results and subsequent actions may be developed for submittal to top management.

9.0 Process Outputs

9.1 Process outputs include, but are not limited to:

9.1.1 Completed activities demonstrating valid test results.

9.1.2 Corrective actions taken when results are not acceptable.

10.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	10/06/21	New procedure	N/A	J. Sassman

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Quality Assurance Activities Schedule and Results

Form: D-118-F1 | CCR No. N/A | Revision: 0

Month/Year Planned	Test Involved	Quality Control Participant(s)	Third Parties Involved or NA	Method Used	Date(s) ACTIVITY Completed	RESULTS Reviewed By:	Date RESULTS Reviewed	Quality Assurance Results Details (identify report(s) reviewed, test activity observed, etc.)	Location of Actual Results Data	Results (Pass or Fail)	Follow-Up Actions Required (identify lab nonconformity, corrective action, etc.)	Comments

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