A03-2017 – RATING GUIDE APPENDIX

Revision 1.0

January 22, 2018

Laboratory Name: _____

Appendix Name: _____

Appendix Number: _____

Assessor: _____

Date: _____

CALA

Trust, measured accurately

ASSESSOR NOTES:

Clause	Requirement	Document Review 1 2 3	Implementation 1 2 3
7.2	**SELECTION, VERIFICATION AND VALIDATION OF METHODS**		
7.2.1.1	All necessary successive steps in the test procedure (including details on reagent preparation, storage and shelf life, equipment, supplies, etc.) are appropriate.	❑ ❑ ❑	❑ ❑ ❑
7.2.1.2	The test method, procedures and supporting documentation (e.g., glassware cleaning procedures, supporting test methods, equipment instruction manuals, reference texts, etc…) are up to date and are readily available to the analyst. Note: For issues related to document control, refer to Clause 8.3.	❑ ❑ ❑	❑ ❑ ❑
7.2.1.3	The test method is based on the latest valid edition of a published reference method, unless it is not possible or appropriate. The test method is supplemented with additional details to ensure consistent application.	❑ ❑ ❑	❑ ❑ ❑

7.2.1.5	There is data available to demonstrate that the laboratory verified that it could properly perform the method prior to analysis of customer samples. As a minimum, these records include detection limit, precision, accuracy, and measurement uncertainty.	❑ ❑ ❑	❑ ❑ ❑
7.2.2	For non-standard methods, laboratory-developed methods and standard methods used outside their scope or modified, there are method validation results, and a statement that the method is fit for the intended use. The level and rigour of validation will depend on whether there are modifications from the reference method or if it is an in-house developed method (see CALA Policy A12). Modifications from the reference method shall be documented. As a minimum, the lab shall maintain records of:	❑ ❑ ❑	❑ ❑ ❑
	• detection limit;	❑ ❑ ❑	❑ ❑ ❑
	• precision;	❑ ❑ ❑	❑ ❑ ❑
	• accuracy;	❑ ❑ ❑	❑ ❑ ❑
	• measurement uncertainty.	❑ ❑ ❑	❑ ❑ ❑

7.3	**SAMPLING**		
7.3.1	Sampling plans for samples are based on appropriate statistical methods and the sampling process addresses the factors to be controlled to ensure the validity of the results; i.e.	❑❑❑	❑❑❑
	• Sampling/sub-sampling methods are available and followed;	❑❑❑	❑❑❑
	• Sampling plans are statistically based;	❑❑❑	❑❑❑
	• Field sampling generates representative samples, and duplicates are routinely taken.	❑❑❑	❑❑❑
7.4	**HANDLING OF TEST OR CALIBRATION ITEMS**		
7.4.1	Sample history requirements are: 1. appropriate; 2. documented and available where required; and 3. implemented; e.g.,	❑❑❑	❑❑❑
	• field filtration;	❑❑❑	❑❑❑
	• chemical preservation;	❑❑❑	❑❑❑
	• sample containers;	❑❑❑	❑❑❑
	• storage condition	❑❑❑	❑❑❑
	• holding time.	❑❑❑	❑❑❑

	• Appropriate drying temperature is used (for solid matrices);	❑❑❑	❑❑❑
	• Dust loss and cross-contamination are minimized (for solid matrices);	❑❑❑	❑❑❑
	• Sample size reduction generates a representative portion for subsequent work;	❑❑❑	❑❑❑
	• Uncertainty of sample size reduction steps is known through the introduction of random duplicates.	❑❑❑	❑❑❑
6.4	**CALIBRATION OF EQUIPMENT**		
6.4.6	Method calibration is: 1. appropriate; 2. included or referenced in the test method; and 3. implemented; e.g.,	❑❑❑ _____ _____ _____ _____	❑❑❑ _____ _____ _____ _____
	• reagent blank to establish calibration baseline;	❑❑❑	❑❑❑
	• equivalent std/sample reagent backgrounds;	❑❑❑	❑❑❑
	• adequate number of standards (1 standard less than 10x the detection limit, where applicable – see P07);	❑❑❑	❑❑❑
	• linearity established, if appropriate, and slope and/or RRF calculated;	❑❑❑	❑❑❑

	• control standard (independent from the routine calibration standards) and reagent blank to monitor calibration accuracy/stability;	❑❑❑	❑❑❑
	• trend analysis (e.g., control charting - see P07);	❑❑❑	❑❑❑
	• criteria to identify calibration non-conformances.	❑❑❑	❑❑❑
7.7	**METHOD QUALITY CONTROL**		
7.7.1	Method quality control is appropriate; included or referenced in the test method; and, implemented. Resulting data is recorded in such a way that trends are detectable and, where practicable, statistical techniques are applied to review the results. QC includes but is not limited to:	❑❑❑ _____ _____ _____ _____ _____ _____	❑❑❑ _____ _____ _____ _____ _____ _____
	• duplicates to monitor precision;	❑❑❑	
	• reference sample to monitor accuracy/recovery;	❑❑❑	❑❑❑
	• method blank to monitor contamination;	❑❑❑	❑❑❑
	• criteria to identify method non-conformances;	❑❑❑	❑❑❑
	• procedures to evaluate interference.	❑❑❑	❑❑❑
7.7.2	The laboratory participates in proficiency testing, as per CALA P02-03; any unsatisfactory PT results have been investigated.	❑❑❑	❑❑❑

		_____ _____	_____ _____

Clause	Requirement	1 2 3
6.4	**EQUIPMENT**	
6.4.1	All equipment required for correct performance of the test procedure is available. Equipment includes measuring instruments, support equipment, computers, reagents and reference materials.	❑❑❑
6.4.4	The equipment is compliant with specifications and checked and calibrated prior to use (or when being put back into use if the equipment was outside the permanent control of the laboratory or not in use for a period of time).	❑❑❑
6.4.5	The equipment is capable of achieving the measurement accuracy and/or measurement uncertainty required to provide a valid result.	❑❑❑
6.4.8	All equipment requiring calibration or equipment with a defined period of validity (e.g., reagents, standards) is labeled so that the user can readily identify the status of the calibration or period of validity. All reagents are labeled with material, concentration or purity, date prepared and/or expiry date.	❑❑❑
6.4.9	Out of service equipment is clearly isolated or clearly labeled or marked as being out of service, and that equipment is checked and validated before return to service.	❑❑❑
6.4.12	The laboratory has taken practicable measures to prevent unintended adjustments that would invalidate results.	❑❑❑
6.3.1	Environmental conditions required for equipment are appropriate and monitored, and all supplies are stored under appropriate conditions (e.g., 1-4 degrees C) and in a manner that satisfies requirements for safety, security, separation of incompatible materials, and ease of retrieval.	❑❑❑

6.5	**METROLOGICAL TRACEABILITY**	
6.5.2	Measurement results are traceable to the SI.	❑❑❑ _____
6.5.3	When metrological traceability to the SI units is not technically possible, the laboratory demonstrates metrological traceability to an appropriate reference. Reference materials must be from accredited RMPs, where available.	❑❑❑ _____ _____ _____ _____ _____
7.8	**REPORTING OF RESULTS**	
7.8.1.1	Results are reviewed and authorized prior to release.	❑❑❑ _____ _____
7.8.3.1	If any of the analytes in an appendix are calculated: • the calculation is valid and supported by a reference method; • detection limits and MU are appropriate; • all constituent analytes are accredited at this location; and, • calculations are reported appropriately. Reference: A131 – CALA Policy on the Accreditation of Calculated Analytes	❑❑❑ _____ _____ _____ _____
7.5	**RECORD KEEPING**	
7.5.1	Records related to the performance of the test method are maintained; e.g.,	❑❑❑ _____
	• original data[1];	_____ ❑❑❑
	• record of non-conformances and actions taken[2];	❑❑❑
	• reagent preparation records[3];	❑❑❑

	• equipment maintenance records[4];	❑❑❑
	• records of gravimetric traceability[5];	❑❑❑
	• records of volumetric traceability[6];	❑❑❑
	• records of temperature traceability[7].	❑❑❑

[1] includes, as appropriate, calibration data, test data (including QC data), experimental variables (e.g., temperature, etc.); analyst ID; sample ID; equipment ID; test method ID; date and time of test.

[2] includes, as appropriate, non-conformances related to: test method variances; sample history; method performance; interferences; and data validation.

[3] includes, as appropriate, supplier, grade, batch no.; dates of preparation or verification; measurement of weights, volumes, time intervals, temperatures and related calculations; relevant processes (e.g., pH adjustment, sterilization); verification results; discard date.

[4] includes, as appropriate, identity of the item of equipment and its software; manufacturer, model, serial no.; checks that equipment complies with lab specifications; date commissioned; repair and maintenance history; calibration history; any damage, malfunction or modification to the equipment; location.

[5] includes, as appropriate, traceability of balance and/or weights to a national standard, and daily or as-used checks (see A61-CALA Traceability Policy).

[6] includes, as appropriate, traceability of auto pipettes, dilutors, etc., that play a defining role in analytical accuracy, and daily or as-used checks (see A61-CALA Traceability Policy).

[7] includes, as appropriate, traceability of working thermometers to a national standard for those thermometers that measure temperatures that play a defining role in analytical uncertainties (see A61-CALA Traceability Policy).