

A03 – Rating Guide Appendix

Revision 5.13 – March 19, 2012

Laboratory Name: _____

Appendix Name: _____

Appendix Number: _____

Assessor: _____

Date: _____



CALA
Laboratory Accreditation

ASSESSOR NOTES:

Item	Clause	Requirement	Document Review			Implementation		
			1	2	3	1	2	3
04		SAMPLING						
01	5.7	<p><u>Sample History</u> Verify that sample history requirements are:</p> <ol style="list-style-type: none"> 1) appropriate; 2) documented and available where required; and 3) implemented; e.g., <ul style="list-style-type: none"> • field filtration; • chemical preservation; • sample containers; • storage conditions; • holding time. 	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <hr/> <hr/> <hr/> <hr/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <hr/> <hr/> <hr/> <hr/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>				
02	5.7	<p><u>Sampling and Sub-sampling</u> Verify that sampling plans for samples are based on appropriate statistical methods and that the sampling process addresses the factors to be controlled to ensure the validity of the results; i.e.,</p> <ul style="list-style-type: none"> • Sampling/sub-sampling methods are available and followed; • Sampling plans are statistically based; • Appropriate drying temperature is used (for solid matrices); • Dust loss and cross-contamination are minimized (for solid matrices); 	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <hr/> <hr/> <hr/> <hr/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <hr/> <hr/> <hr/> <hr/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>				

Item	Clause	Requirement	Document Review			Implementation		
			1	2	3	1	2	3
		<p><u>Calibration</u> (Cont'd)</p> <ul style="list-style-type: none"> 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. 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
06		METHOD QUALITY CONTROL						
01	5.9	<p>Verify that method quality control is:</p> <ol style="list-style-type: none"> appropriate; included or referenced in the test method; and implemented; e.g., <ul style="list-style-type: none"> duplicates to monitor precision; reference sample to monitor accuracy/recovery (see P07); method blank to monitor contamination; trend analysis (e.g., control charting - see P07); criteria to identify method non-conformances; procedures to evaluate interference (see P07); PT, as per P02-03 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Item	Clause	Requirement	Document Review			Implementation		
			1	2	3	1	2	3
07		TEST METHOD CONTENT						
01	5.4.1	<p><u>Other Work Instructions/Procedures</u> Verify that all necessary supporting work instructions are documented and available where required; e.g.,</p> <ul style="list-style-type: none"> • glassware cleaning procedures; • supporting test methods; • equipment instruction manuals; • requisite reference texts; • computer software related procedures. 	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <hr/> <hr/> <hr/> <hr/> <hr/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <hr/> <hr/> <hr/> <hr/> <hr/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>		

Item	Clause	Requirement	1 2 3
08		CONDUCT OF TESTING	
01	5.4.1 4.2.1	Verify that the test procedure and all supporting work instructions are performed as documented.	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>
09		EQUIPMENT	
01	5.5.1 5.5.2 5.5.4 5.5.12	Verify that all instruments required for the test procedure are available, functioning properly, capable of achieving the required accuracy, compliant with specifications, checked and calibrated before use, uniquely identified, and safeguarded from adjustments that would invalidate results.	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>
02	5.5.1	Verify that all support equipment* required for the test procedure is available and functioning properly. * includes computers.	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>
03	5.5.7 5.5.9	Verify that 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.	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>
04	5.5.8	Verify that all equipment requiring calibration is labeled to indicate calibration status, including the date last calibrated and expiry criteria or date when recalibration is due.* * not required for equipment checked daily or as-used.	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>

Item	Clause	Requirement	1 2 3
10		SUPPLIES	
01	4.6.2 5.5.1	<p><u>Availability</u> Verify that all supplies required for the test procedure are available and meet requisite requirements and/or specifications.*</p> <p>* includes reagents and reference materials</p> <p>NB: For <u>records</u> of reference standard/material certificates, cite B.05.03 in A02.</p>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>
02	5.3	<p><u>Storage</u> Verify that 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.</p> <p>NOTE: For records of storage temperatures, cite B.02.03 in A02.</p>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>
03	4.13.2	<p><u>Labeling</u> Verify that all reagents are labeled with material, concentration or purity, date prepared and/or expiry date.</p>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>
04	5.5.1	<p><u>Labware</u> Verify that all labware is adequately cleaned and, where required, labware quality control incorporates analytical testing.</p>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>

Item	Clause	Requirement	1	2	3
11		RECORD KEEPING			
01		Maintain records related to the performance of the test method; e.g.,	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	4.13.2	• analyst worksheet or notebook (1);	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	4.9				
	4.13.2	• record of non-conformances and actions taken (2);	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	5.5.5				
	5.6	• reagent preparation log (3);	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		• equipment maintenance log (4);	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		• records of gravimetric traceability (5);	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		• records of volumetric traceability (6);	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		• records of temperature traceability (7).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

- (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).