2010 Disputes Summary

Requirement	Dispute Resolution and Explanation
Modify procedure so that method quality control is adequate and either included or referenced in the test method; specifically, use duplicates to monitor precision of the Technicon portion of the test. There are duplicates from the field but separate duplicate of the Technicon of a sample digest provides information on the precision of the instrumental portion of the test.	The requirement stood; i.e., the lab was required to have a duplicate of a sample in a run – not just a field duplicate.
Modify procedures so that all instruments required for the test procedure are available and functioning properly, capable of achieving the required accuracy, compliant with specifications, checked and calibrated before use, uniquely identified, and safeguarded from adjustments, specifically, separate graduated cylinders should be used in order to minimize contamination between client samples and between control samples. Some client samples are extremely oily and thus the graduated cylinder may be difficult to clean between samples.	This finding was removed from the report. The laboratory did not need to have separate graduated cylinders. Using the same graduated cylinder for QC samples and client samples serves to check the cleanliness of the glassware to show there is no carry over between samples.
Modify procedures so that sample requirements are adequately defined in the test method, specifically, section 8 in SOP ABC does not reflect actual practice of requesting triplicate samples from clients.	This was a 'copy and paste' error; this requirement was raised against a water appendix, and the laboratory was requesting triplicate samples from clients for the soil appendix. Therefore, the dispute was upheld – i.e., it was removed from the report.
Modify procedures so that all necessary supporting work instructions are either included or referenced in the test method, specifically, SOP xyz does not contain the instructions for or a reference to the laboratory's percent	The lab disputed this because the Excel spreadsheet used to do the calculation did contain the necessary calculation. Although the Excel spreadsheet

Requirement	Dispute Resolution and Explanation
solids standard operating procedure.	submitted did contain the necessary calculation, the referenced procedure on Moisture determination did not include instructions for the determination of percent solids. Therefore, this finding remained on the report.
Modify procedures so that all necessary supporting work instructions are either included or referenced in the test method, specifically, SOP xyz does not contain a reference to the laboratory's sub-sampling procedure.	This was removed from the report because the lab submitted the method current at the time of the assessment, and the reference to the sub-sampling procedure was documented. This may have just been missed during the document review, or been a 'copy and paste' error.
Modify procedures so that all necessary successive steps in the test procedure are adequately documented in the test method, specifically, method SOP abc does not specify the concentration of the CVS (10 ug/uL as reported by the analyst).	This finding stayed on the report. Although section xxx of the procedure does indicate a concentration for the Calibration Verification Standard, the notations written at the time of the assessment indicate that the analyst prepares a different concentration than that in the procedure (i.e., written procedure and practice do not agree).
Review CCME Report Checklist to ensure that all applicable checklist requirements are included on CCME-related reports.	This finding stayed on the report. Even though the lab submitted an example of a CCME report that appeared to meet all the requirements, it could not be determined which report(s) the assessor observed.
Submit documentary evidence that reagent receipt logs are maintained, specifically, for the Polyseed and Polyseed NX.	This finding stayed on the report. Although the lab submitted an example of a reagent receipt log with the Polyseed listed on it, it could not be determined what the assessor saw on site, so this finding needed to be addressed.
Submit documentary evidence that reagent receipt logs are maintained, specifically, for chlorine/bromide kit	This finding stayed on the report. Although the lab submitted an example of a reagent receipt log with the Chlorine/Bromine listed, it

Requirement	Dispute Resolution and Explanation
(e.g., lot number and date opened).	could not be determined what the assessor saw on site.
Modify procedures so that method calibration is adequate and either included or referenced in the test method, specifically, criteria to identify calibration nonconformance. SOP abc does not include QC criteria for the Matrix Spike.	This finding was removed from the report. The QC criteria were seen in the both the method submitted in an email and on the CD of the methods provided for the assessment. Not sure if this was a "copy and paste" error or it was just missed during the document review.
Submit documentary evidence that all instruments required for the test procedure are safeguarded from adjustments, specifically, the calculation fields used in the EXCEL sheet used for result processing are not protected from accidental change.	This finding stayed on the report. Although the lab submitted a file that did not allow changes to the calculation fields, according to notations in the checklist, the assessor was able to make changes to the calculation fields during the assessment.
Modify procedures so that method quality control is adequate and either included or referenced in the test method, specifically, there was no procedure to correct for natural sample colour.	This finding was removed from the report. This was documented in the method current at the time of the assessment and there was nothing documented in the checklist to indicate otherwise.
Modify procedure so that sample history requirements are included or referenced in the test method, specifically, the sample containers and holding time are not documented in the test method.	This finding was removed from the report. This was documented in the method current at the time of the assessment and there was nothing documented in the checklist to indicate otherwise.
Modify procedures so that method quality control is adequate and either included or referenced in the test method, specifically, there was no procedure to assess interference (e.g., spiking samples).	This finding was removed from the report. This was documented in the method current at the time of the assessment and there was nothing documented in the checklist to indicate otherwise.
Document and implement a procedure so that steps in the test procedure are adequately documented in the test method, specifically, according to the Toxicity Test Specific Checklist, the test report must include the name of the	This finding was removed from the report. The Environment Canada methods do state that reports must include "person(s) performing the test and

Requirement	Dispute Resolution and Explanation
person performing the test and the name of the person verifying the test results. Currently, only the name of the person performing the test is on the test report.	verifying the results". The Environment Canada method doesn't use authorizing the report as in 17025 section 5.10.2 but that is really what it means. The LIMS system has a multi-level verification process and a final approval by the accounts manager whose name does appear on the report on the first page. The lab's process meets the Environment Canada test method requirements.
Observation. Sample bottles are properly labeled and have all necessary information as to ID as well as any potential safety hazards. However, bottle caps are not labeled and it is very easy to mix caps amongst different sample bottles, creating potentially serious cross contamination problems. The same situation exists for most standards and reagents used at benches in the laboratory. Provide documentary evidence that sample bottle caps bear appropriate identification as well as have work instructions in place to ensure caps are checked before placing on sample bottles. A similar scheme needs to be applied to reagents and standards containers used at benches in the laboratory.	This finding was removed from the report. Unless the assessor observed chaos in the laboratory and recorded this finding as a means to address a lack of organization, which presented serious risk to the testing, this is not a non-conformance. Not only is this not a practical process to implement in any production laboratory, there is no known reference within Standard Methods or other reference methods that would require this. The lab must be able to demonstrate that controls are in place to ensure that the integrity of the sample is maintained during the process, and from the information provided.
Observation. Control charts for duplicates were not available. They were done in the past but it is not easy to do with the new laboratory software. Provide documentary evidence that duplicate pair data are evaluated by appropriate statistical to spot outlying events as well as identifying trends as require by the Standard. For example, using range control charts is an easy and convenient means of performing this required task.	This finding stayed on the report. Rationale: If the duplicate test is not appropriate (N/A) because of sample volume or routine non-detects, clarification in the QMS must be included and an appropriate alternative program used; however, if it is simply a matter of the computer program limitations to use control charting, then the lab needs to find an

Requirement	Dispute Resolution and Explanation
	alternate statistical evaluation program. The minimum requirements for a QC program include: 1. Evaluation of random error (precision) 2. Evaluation of systematic error (bias) The lab has indicated they are performing lab fortified blanks (spike blanks), which are necessary for evaluation of the "laboratory performance and analyte recovery in a blank matrix" (SM) and can provide a measure of bias. Duplicate samples, however, are necessary to monitor precision, (they do not effectively measure bias). However, the lab must have a means to track and evaluate precision and this appears not to be the case. (The note specific to the stratification of chart is valid, which is likely why the assessor indicated that the use of a range control chart would be appropriate.)
Submit documentary evidence that there are records of method validation, specifically, for the method detection limit. The method detection limit calculated as 1 ppm and the sample spike used for this calculation was 38 ppm. The method detection limit is not within the 1-10X the value of the spike as required by the quality system. Submit documentary evidence that there are records of method validation; specifically, redo the method detection limit for the following parameters:	Denied; the laboratory had to re-calculate MDLs. The laboratory must rerun the MDLs using a spiked blank concentration that is between 1-10 times the concentration of the calculated MDL to ensure that MDLs accurately reflect a laboratory's analytical capability at lower concentrations, and to better set the laboratory's reporting limit (MRL). In the occasional instance that a lower spiked blank cannot be prepared, the laboratory must

Requirement	Dispute Resolution and Explanation
DX100: Cl and SO4, DX120: Cl and SO4(method detection limit is zero), NO2 and NO3, Metrohm: Cl, NO2, NO3 and SO4. Unless otherwise stated, the method detection limits do not meet the quality system requirement of 1 - 10X. Submit documentary evidence that there are records of method validation, specifically, for the method detection limit for NO2 low range on the Technicon. The current method detection limit is 0. The method detection limit needs to run to get a value. It is suggested to use a lower concentration spike. This is also true of the Skalar NO2 method detection limit determination. Redo both the method detection limits until a value is obtained that satisfies the quality system. Submit documentary evidence that there are records of method validation, specifically, for the method detection limit for Total Phosphorus, mid range. Currently, the method detection limit is 0.003 mg/l and the spike value used to obtain this was 0.10 mg/l, Redo the method detection limit to meet quality system requirements of 1-10X. Submit documentary evidence that there are records of method validation, specifically, for Fluoride by ISE, the method detection limit is 0.018 ppm but the spike used to obtain this method detection limit is 0.50 ppm. Quality system states the spike must be within 1 - 10X the method detection limit. Repeat method detection limit at lower concentration so that the quality system is met.	evaluate the suitability of the MDL calculated using a higher spiked blank against client and regulatory requirements and must justify the use of the higher spiked blank, and must document a procedure for do such. The laboratory's quality manual, section 22.13 states that the laboratory calculates its MDLs based on Ontario Ministry of the Environment procedures; several MOE documents require that the spike concentration be between 1 and 10 times the calculated MDL. For items x and y, the decision was denied, and additionally, the laboratory must determine a non-zero MDL. The evidence submitted for low level nitrite did show that an MDL could be determined.

Requirement	Dispute Resolution and Explanation
Submit documentary evidence that there are records of method validation, specifically, the calculated method detection limit is zero. Recalculate the method detection limit until an acceptable number is obtained based on the quality system (1-10X). Submit uncertainty based on the new method detection limit.	
Submit documentary evidence that there are records of method validation; specifically, redo the method detection limits for both the water and solid matrix. The water method detection limit is 1.88 using a spike value of 40 ppm. This does not meet the quality system requirement of 1-10X. Solid method detection limits need to be done separately. The uncertainties need to be recalculated and submitted along with the new method detection limits.	
Submit documentary evidence that there are records of method validation, specifically, for the method detection limit for fluoride. The method detection limit calculated on January of 2010 is 0.013 and the sample spike used for this calculation was 0.50. The method detection limit is not within the 1-10X the value of the spike as required by the quality system.	
Submit documentary evidence that there are records of method validation; specifically, redo the method detection limits for both the water and solid matrix. The water method detection limit is 1.88 using a spike value of 40 ppm. This does not meet the quality	

Requirement	Dispute Resolution and Explanation
system requirement of 1-10X. Solid method detection limits need to be done separately. The uncertainties need to be recalculated and submitted along with the new method detection limits.	
The standard requires that the laboratory have appropriate instructions for the operation of equipment, where the absence of the instructions could affect the work. None of the methods includes a reference to LIMS procedures. In microbiology, this reference to LIMS could be included in Microbiology Procedures Manual, xx-yy-123-45.	This finding was downgraded to a "B" item. This item had been originally graded as a "B" item and upgraded to 'A' during editing at CALA. However, after discussion with the assessor, it was determined that the LIMS procedures were documented and that lab staff was familiar with the LIMS and the associated procedures. The assessor felt that the absence of a reference to the LIMS procedures would not adversely affect the work. Therefore, this reference could be included as documents were updated over the next 2-year period.
The standard requires that quality control data is analyzed and, if outside of pre-planned criteria, planned action is taken to correct the problem and to prevent incorrect results from being reported. Section 2.2.6 specifies that control charts are reviewed at a minimum yearly, but does not indicate who has responsibility. Modify section 2.2.6 to clarify who is responsible for reviewing control charts and trend detection. Additionally, the frequency of review of control charts must be such that the charts are reviewed for trends prior to data being reported to the client; modify procedures to include this requirement.	This finding stayed on the report. This item had been clarified to reflect that the lab's frequency of reviewing control charts did not meet CALA's P07, section 5.9.2. The laboratory quality manual, section 2.6.6, did not specify who reviews control charts and a frequency of review that meets CALA's requirements (i.e., before reporting data to the client), and did not clearly specify what constitutes a trend (definition to be used when reviewing the charts).
As per procedure, the ammonia - alkaline phenol reagent has to be stored in the fridge at 1-7 degrees Celsius. Presently, there is no label indicating	This finding stayed on the report. Upon investigation, it was determined that the analyst said the reagent was kept on the bench

Requirement	Dispute Resolution and Explanation
that. Provide evidence that, indeed, it is stored in the fridge which satisfies requirements for reagent freshness.	and reagents that needed refrigerated storage were labeled to indicate this.
Modify control chart limits for TSS Blanks. The control limits were recently changed, but not reflected on the actual chart.	This finding stayed on the report because the assessor was told that control limits had changed but charts had not.
Submit documentary evidence that the laboratory has a calibration certificate for the temperature of intended use, i.e., temperature requirement of 35 +/- 0.5 degrees C for incubator and 2-6 degrees C for the walk-in fridge. Currently the laboratory is using a traceable thermometer calibrated at 100 degrees C	This finding was removed from the report. For mercury liquid-in-glass thermometers used at </=200C, single point recalibration is valid. Although this is often done at the ice point, recalibration at another calibration point is acceptable.
Submit documentary evidence the calibration program ensures that the measurements from the laboratory are traceable to SI units; specifically when using external calibration services verify that certificates include the measurement uncertainty and/or statement of compliance with an identified metrological specification. The calibration certificates for thermometers No. xxxx used in the refrigerator for holding samples and No. yyyy used for storing media state a measurement uncertainty of x.xx that appears to relate to the reference standards used. The results for the laboratory thermometer appear to include only a correction factor. There is no measurement uncertainly or statement of compliance with an identified metrological specification for the laboratory thermometer. There is no indication that replicate measurements were performed. (Certificate by Thermco Products - dated 200x-xx-xx. **The certificate for thermometer xyxyxy used in the 35 oC incubator states a measurement uncertainty of x.xx**	Lab disputed only the bolded portion of the requirement, and that portion of the requirement was removed from the report. The accredited calibration laboratory provided an acceptable calibration certificate that included uncertainty. Although it was not obvious that replicate measurements had been performed, the procedure used by the calibration lab had been assessed for their accreditation, and thus, found to meet the requirements of ISO/IEC 17025.

Requirement	Dispute Resolution and Explanation
degrees C which is greater than the thermometer gradations of 0.1oC. There is no indication that replicate measurements were performed. (Certificate by [company] - dated 2010).	
Document and implement a procedure so that the laboratory has a calibration program for its measurement and test equipment, and meets traceability requirements as per CALA Traceability Policy (A61), specifically, for temperature devices. The laboratory has a primary calibrated reference thermometer (LIG); working thermometers are verified against the reference thermometer rather than calibrated, and do not have multiple replicate readings or measurement uncertainty calculated. Similarly, the TAG thermometers are verified against a calibrated TAG thermometer. Submit evidence that the working thermometers are calibrated rather than verified. Submit evidence for the Metals #2 thermometer and TAG thermometer in the VOA standards refrigerator. Evidence for other thermometers and TAG thermometers will be viewed at the next assessment.	Denied. This item stayed on the report.
Document and implement a procedure so that the laboratory has a calibration program for its measurement and test equipment, and meets traceability requirements as per CALA Traceability Policy (A61), specifically, for volumetric devices, specifically, syringes 25 ul and greater are not calibrated. Submit evidence that the volumetric devices that are 25 ul or greater are calibrated,	This finding stayed on the report. This is a CALA accreditation requirement.

Requirement	Dispute Resolution and Explanation
specifically for syringes used in appendices 023 and 031.	