CALA Disputes - 2008

Requirement	Dispute Resolution and Explanation
Modify procedure so that management has formulated training goals, and that there are policies and procedures for identifying training needs and provision of training, with such training evaluated for effectiveness.	Upheld. The laboratory has procedures for training staff for both quality system and technical issues, and the procedures include the requirement to evaluate effectiveness of the training.
Document and implement a procedure so that method calibration is adequate and either included or referenced in the test method; specifically, use an adequate number of calibration standards with the lowest standard < 10 X detection limit. Currently the lowest standard is only at ten times the MDL.	Upheld. Section 5.6 of ISO/IEC 17025:2005 requires that the laboratory have a programme and procedure for the calibration of its equipment and that such programme should include a system for selecting, calibrating and checking measurement standards and measuring and test equipment. The two methodologies to which these findings apply are both linear at the low end, so having the lowest standard at, for example, 9.5 times the detection limit versus 10 times the detection limit would not adversely affected the calibration for these instruments.
Document and implement a procedure so that all instruments that require calibration are capable of achieving the required accuracy, and checked and/or calibrated before use. Separate source quality control standards are implemented only at the mid-range of the calibration. Implement procedures to have verification to confirm the accuracy of the full linear range of the test method	Upheld. Section 5.6 of ISO/IEC 17025:2005 requires that the laboratory have a programme and procedure for the calibration of its equipment and that such programme should include calibrating and checking measurement standards. The laboratory is calibrating and checking the calibration of the equipment and, thus, meets the requirement of the Standard. The laboratory is not required to verify the calibration curve along the entire range of the calibration curve.

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Modify procedures so that the laboratory carries out intermediate checks needed to maintain confidence in calibration status according to defined procedures and schedules; specifically, record identification of the pipette used for the preparation of calibration standards and ensure that the pipette performance is verified at the appropriate precision level.	Denied. The lab must both record the pipette used for the preparation of each calibration standard and verify the pipette volumetric traceability at or near the volume used for the preparation of the calibration standards. Section 8.4 of the CAEAL Traceability Policy, A61, states that, for adjustable dispensing devices, the procedure of using repeated weighing of dispensed volumes of water, corrected for standard temperature and pressure, is to be performed at more than one volume.
Modify procedures so that all necessary successive steps in the test procedure are adequately documented in the test method, specifically include details for the preparation of the matrix spike in 8.3.7.	Denied. Section 5.4.1 of ISO/IEC 17025 requires that the laboratory have instruction on the preparation of items for testing where the absence of such instructions could jeopardize the results. The laboratory must include in the procedures, the details of the preparation of the matrix spike. The details may be of the form of exact volumes to use or as an acceptable percentage range (e.g., prepare the spiking solution such that it is between 40-60% of the sample concentration).
Modify procedures so that all necessary successive steps in the test procedure are adequately documented in the test method, specifically, state that the biosolids calculation is done in an excel spreadsheet.	Upheld The calculation formula is in the procedure. The manner in which the biosolids calculation is completed does not need to be listed in the procedure as whether the calculation is performed manually, for example, or using the excel spreadsheet.

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Document and implement a procedure so that method quality control is adequate and either included or referenced in the test method, specifically, criteria to identify nonconformance in method blank correction practice.	Upheld. This item was to be removed during the Closing Meeting and this was overlooked.
Document and implement a procedure so that the laboratory selects test and/or calibration methods that are in latest international, regional or national standards (unless it is not appropriate or possible); state clearly the bibliographic reference of the standard operating procedure avoiding terms like "Recent Edition". (examples of standard operating procedure with that type of reference: TSS; Oil and Grease; Carbon; Ammonia).	Upheld with conditions. The dispute arising from item 004 of your last assessment has been reviewed by CAEAL. It was felt that the use of the term recent edition by itself was a bit ambiguous. However, it would be acceptable to modify the procedures to state ***most recent edition*** or ***current edition*** and the finding will be reworded as such. It should be noted that some procedures still reference the 20th edition on Standard Methods or the year 1998(e.g. EINDSOP 00201, EINDSOP 00186) The laboratory must demonstrate that all relevant staff are aware which is the most recent edition of the reference method and that they know how and where to access it. Where other versions of the reference method are available in the laboratory, they must be suitably marked or otherwise restricted to prevent inadvertent use
Ensure all reagents and media are labeled with material; specifically, a bottle of Caledon brand MeOH in the extraction lab did not have an expiry date.	Upheld. If these are solvents direct from the supplier and unopened there is no need to put on an expiry date. Most labs put on a received and opened date for solvents. The only exception to this is prepared bottles of bases like sodium hydroxide. Bases can degrade quite quickly and really require an expiry date. Most manufactures will put on their own expiry date if the

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	material is time sensitive. Once the labs prepare a hexane/acetone solvent (for example) it would be wise to put on the preparation and expiry dates. Depending on the lab even the expiry date may not be required for prepared solvents if they are consumed fairly quickly.
Ensure all calibration criteria are either included or referenced in the test method, specifically, criteria to identify calibration nonconformance. Specifically, the CCME RM requires that during a daily calibration check, if the high standard deviates by more than 15%, recalibration should be done. This requirement is not documented in the method.	Upheld. The actual requirement in the CCME method is that if the mid-point standard (not the "high standard") deviates by more than 15%, recalibration should be done. The checklist will be revised.
Ensure appropriate calibration is adequate and either included or referenced in the test method. Specifically, the CCME RM requires chromatographic linearity be demonstrated with products within 15%, and single compounds within 10%. This requirement is not documented in the method.	Upheld. Lab established linearity during method validation.
Modify procedures so that all necessary successive steps in the test procedure are adequately documented in the test method, specifically, in Appendix C, clarify Step 4 and remove use of EC/EC MUG as per actual performance.	Upheld with conditions. The procedure shall be modified to say "verification of total coliforms into EC MUG after partitioning to NA MUG is required"
Modify procedures so that all necessary successive steps in the test procedure are adequately documented in the test method, specifically, add step to 14.2 to verify E. coli using citrate and indole (44.5°C) as per SM reference.	Upheld Once the item 21 is modified both items 32 and 34 can be removed. Although citrate and indole can be used to verify the presence of E. coli alternative verification methods including MF Partition using NA-MUG are acceptable.

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Modify procedures so that all necessary successive steps in the test procedure are adequately documented in the test method, specifically, for drinking water samples verify at least 5% of MUG (+) and MUG (-) using citrate and indole (44.5°C) and adjust counts based on verification results. SM 9b)3a) and 9222B6.	Upheld Once the item 21 is modified both items 32 and 34 can be removed. Although citrate and indole can be used to verify the presence of E. coli alternative verification methods including MF Partition using NA-MUG are acceptable.
Modify procedures so that media quality control is adequate and either included or referenced in the test method, specifically, compare positive control cultures on selective and non selective media once per batch of media, and compare recovery rates of the positive control culture, and for new lots of media, compare new lots to old lot.	Upheld Laboratory's approach is acceptable and satisfies the CALA's checklist.
Modify procedures so that method quality control is adequate and either included or referenced in the test method, specifically, add to monthly parallel analysis on at least one positive sample monthly for intra-technician comparison readings with acceptance criteria of 5% RPD and expand program to include all analysts in intertechnician program over a reasonable span of time.	Upheld Laboratory's doing sufficient to satisfy the checklist.
Modify procedures so that all necessary successive steps in the test procedure are adequately documented in the test method, specifically, for drinking water samples, verify at least one positive sample monthly and adjust counts accordingly.	Upheld Laboratory is confirming all positive colonies for drinking water samples.

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Modify procedures so that quality control is adequate and either included or referenced in the test method, specifically, use of duplicates to monitor within-run precision.	Denied The current wording of the checklist states to "perform duplicates to monitor within-run precision for quantitative methods". Since the multiple tube fermentation method is quantitative those requirements shall remain.
Modify procedures so that all necessary successive steps in the test procedure are adequately documented in the test method, specifically, perform duplicate analysis on all samples as per reference.	Upheld The laboratory needs to perform duplicate analysis at 10% or one per test run as per Standard Methods for HPC.
Modify procedures so that method quality control is adequate and either included or referenced in the method, specifically, confirmation or sample organisms as per SM 9020B 9a) 2a) e.g., lactose fermentation verified with EC MUG.	Upheld Confirmation is not required on defined substrate technology methods.
Submit documentary evidence that confidence in measurements is established by use of certified reference materials, where traceability of measurements cannot be strictly made to SI units, specifically CofA's for reagents (acetonitrile, trace nitric and HCl acids, sodium hydroxide, acetic acid, amines, etc) could not be produced. Ensure that the laboratory can readily retrieve a copy of all CofA's for these reagents as relying on what is on the bottle is insufficient to meet this requirement.	Partially upheld. The laboratory is not required to maintain certificates of analysis for the solvents/ reagents except in cases where a reagent is being used as a standard/reference. However, at a minimum the lot numbers of solvents/ reagents used in sample and standard preparations must be recorded to ensure traceability. Where a reagent in question is used as a standard or reference, a certificate of analysis must be maintained on file.

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Modify procedures so that monthly inter-technician comparison readings to monitor precision and monthly parallel analyses to monitor inter-tech precision is accomplished. Currently the laboratory specifies monitoring on a biannual basis.	Denied. Monthly inter-technician comparison readings and monthly parallel analyses are required are part of the CALA accreditation program requirements. Biannual frequency is insufficient.
Modify procedures so that spatial variability within incubators is checked annually.	Denied. Annual checking of spatial temperature variability is a requirement of the CALA accreditation program.
Modify procedures so that altered or new text is identified in the document or the appropriate attachments, as practical, specifically, document changes are detailed in the document change file but are not identified in the current revision of the document.	Upheld The laboratory makes aware all document users of the changes in a document that has been revised through their e-mail notification system. The laboratory sends the revised document and the Controlled Document Tracking Form to staff and they can look up the previous version and compare to the new one.
Submit documentary evidence that measurements from the laboratory are traceable to SI units; specifically, the six thermometers used in the sample fridges do not have traceable certificates.	Denied The CAEAL Traceability Policy (A61), requires that working thermometers are calibrated to establish traceability. A laboratory may send all working thermometers to an accredited laboratory for calibration or perform their own calibration and establish an adequate calibration frequency.
Submit documentary evidence that simplified test reports include a note that information is available for any of the items listed in section 5.10.2 of ISO/IEC 17025 that cannot be put on a test report.	Upheld The lab has no external customers only internal which has the same company name and the same address as the lab. The ISO/IEC 17025, clause 5.10.2 states that this information must be on the report unless the lab has a valid reason for not doing so.

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The finding requests comparison of a control culture organism on a new batch of agar media against the in-use batch. Page 47 of P07 does not require this comparison. The laboratory already performs a use test for each unique lot number of agar media as well as a recovery test for each batch of selective agar as per section 5.9.1 of P07; therefore this item should be removed from the assessment report.	Dispute has been upheld – i.e., the requirements will be removed from the assessment report. Although some laboratories do batch-to-batch testing, it is not a requirement of CALA as some experts are of the opinion that the use of batch to batch comparison of media may be misleading if there is a slow deterioration in performance from batch to batch. For example if batch 2 had a 90% recovery compared with batch 1, one might accept the suitability of batch 2; but if this 10% reduction was continuous and progressive, then by the time batch 5 was prepared, although there would only be a 10% difference in recovery compared with batch 4, it would be 50% if compared with batch 1.
Modify procedures for proficiency testing so that the PT samples are tested similarly to test samples. Currently PT samples are tested with a volume of 100mL while test samples are an unmeasured volume between 100mL and 120 mL.	Denied The requirement is that PT samples (after following the CALA preparation instructions) must be handled in a similar method as test samples. When CALA submits PT samples to a laboratory, CALA becomes laboratory's customer and the laboratories are required to follow the instructions of the customer. After diluting the sample to one liter, the instructions are to use that sample as a routine sample and the lab should follow its routine procedure from thereon in.

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Modify procedures so that records are maintained related to the performance of the test method, specifically, records of volumetric traceability of the method are not maintained as the sample volume is unmeasured and varies from 100-120ml.	Denied All drinking water guidelines or regulations are based on a volume of 100ml. Even if a province does not have its own guidelines or regulations, then they follow Federal guidelines that are also based on 100ml of the sample analyzed. If the lab cannot measure the volume of each sample, they must validate the measuring devices to ensure accuracy of the sample volume and must have traceability records. Using a different volume each time makes the whole process inconsistent and by using more volume than required may produce erroneous results such as more positives. Also for quality assurance and quality control purposes the lab should have a procedure for validating and controlling the volume of the sample analyzed. Although the manufacturers give certificates of traceability but they always have a lot of variance. It is the responsibility of the lab to ensure the accuracy of the measurement/markings and the volume of the sample analyzed.
Submit documentary evidence of the allocation of authority and resources to the person at the laboratory who is responsible for the onsite operation of the laboratory. As a minimum, specify the authorities to remove items from the scope of accreditation whenever resources do not support the production of technically valid results for those tests.	Denied; in the appeal process.
Submit documentary evidence of the assignment of QA/quality control duties to a member of laboratory staff so as to assist in the maintenance of the quality system in support of the laboratory supervisor.	Denied; in appeal process.

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Submit documentary evidence of the assignment of duties to an onsite member of staff in the event of the absence of the person responsible for QA/quality control. Currently the laboratory supervisor holds the primary responsibilities for this, and in her absence, the Director (also acting laboratory manager) assumes these responsibilities.	Denied; in appeal process.
Document and implement a procedure so that equipment taken out-of-service is isolated, clearly labelled or marked as being out-of-service; presently only verbal notification is used between analysts.	Partially upheld, finding reworded. The lab has procedures but the staff member interviewed was not familiar with them.
Submit documentary evidence that all necessary successive steps in the test procedure are adequately documented in the test method; specifically, keep records of reagent preparation, storage and shelf-life. At the time of the assessment, the phosphate buffer did not have an expiry date.	Denied, but reworded. The phosphate buffer bottle may have had a label that stated the expiry date was “no expiry”, but the phosphate buffer needs an expiry date.
Document and implement a procedure so that method quality control is adequate and either included or referenced in the test method; specifically, establish criteria on the use of a method blank to monitor contamination and the action to be taken when criteria are not met.	Partially upheld, finding reworded. The procedure does describe the use of the blanks but evidence of implementing that part of the method that deals with blanks was not seen.

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Conduct the method comparison as indicated in Appendix 2 of the CCME reference method (i.e.,- 4 samples in triplicate run by the benchmark PHC method and the laboratory method that uses soxtherm). The laboratory uses a performance based alternative to soxhlet extraction as permitted in section 11.2 of the CCME reference method.	Upheld with condition. The requirement was amended to say: "Ensure to optimize the extraction time using the Automated Soxhlet for all types of soil and report these times in the method". The Automated Soxhlet can be used as an alternative to the soxhlet extraction. However, as Section 11.2 of the method states: "Soxhlet extraction apparatus is the benchmark method for the C10 to C50 hydrocarbons, but other suitable extraction methods can be substituted provided that validation data demonstrate that the substitute method provides data comparable to the benchmark method" (CCME, 2001. CWS PHC in Soil Tier 1 Method). In my opinion, the Automated Soxhlet method needs to be validated by the laboratory before being used (to ensure optimum conditions e.g. time for extraction). In a review of the PHC CWS Analytical Method by Alberta Environment, the Automated Soxhlet was recommended as a Performanced-Based Alternative to soxhlet extraction (Alberta Environment, May 2003). Please note that in September 2003, Alberta Environment recommended that any modified methods must be effective in all soil conditions (e.g.Clay-Loam, Sand, Loam etc.) (Alberta Environment September 2003). Therefore, the lab must optimize the extraction time using the Automated Soxhlet for all types of soil and report these times in the method.

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Update the laboratory method to meet the reference method requirements. The CCME reference method (section 9.0) requires a performance sample (spike into clean matrix) to monitor accuracy/recovery, and that the recovery be within 20% of the expected value. Currently the laboratory uses a sample matrix spike with 30% acceptance criteria.	Denied The laboratory should be required to meet the 20% recovery. As CWS PHC Soil Tier 1 Method states: "A performance sample should be recovered within ±20%" (CCME, 2001. CWS PHC in Soil Tier 1 Method). In analysis of Performance-Based Alternative Methods, Alberta Environment recommends that even +/- 20% may not be acceptable when values are consistently low. Alberta Environment states: "The ±20% allowance around the mean for the benchmark method assumes that a future re-evaluation of the alternative method is equally as likely to fall on either side of the mean. If repeated testing (e.g. through the CAEAL PT program) shows that method recovery is consistently lower than the mean recovery of the standard method, the alternative method must be re-evaluated. Alberta Environment may withdraw their approval where method recovery is consistently below the mean regardless of whether the method continues to pass the CAEAL PT" (Alberta Environment, September 2003). In 2004, Ashworth et al. presented a comparison of extraction methods to the Environmental Services Association, Remediation Technologies Symposium, where they demonstrated that the soil type (e.g.Clay-Loam, Sand, Loam etc.) could effect recoveries (Ashworth et al., 2004). Therefore, the lab must demonstrate +/- 20% recovery.