CAEAL 2007 Assessments - Dispute Summary

Dispute	Result of the Dispute Process
Document and implement a procedure for testing duplicates to monitor precision for the oil and grease test.	**CAEAL Response: Denied** Standard Methods for the Examination of Water & Wastewater, 21st edition, the method states on page 5-36 under 5520 A. Introduction, 3. Sample Collection, Preservation, and Storage: "Collect replicate samples for replicate analyses or known-addition QA checks." The paragraph then goes on to describe appropriate duplicate sample collection methods. The importance of duplicates is emphasized under 4. Interferences: " The method is entirely empirical; duplicate results with a high degree of precision can be obtained only by strict adherence to all details." Both members recognized the problem of obtaining duplicate samples from clients, and provided the following suggestions: -purchasing and analyzing with each run a prepared reference material that comes from a real life source similar to their client samples in duplicate (not a pure sample, not spiked clean water) -duplicate reference materials or spiked blanks and have at least a best-case scenario idea of precision.
Modify procedures so that all necessary successive steps in the test procedure are adequately documented in the test method, specifically, the hold time from sampling to extraction must be identified.	**CAEAL Response: Denied** Both members determined that there was sufficient information in the CCME and relevant USEPA methodologies to determine a maximum hold time between sampling and analysis; the intent of the CCME is that there be a maximum time between sampling and analysis. The relevant USEPA method (8015) details the maximum time between sampling and analysis.
Submit documentary evidence that all supplies required for the test procedure are available and meet requisite requirements and/or specifications; specifically, check inhibitory effects of filters tested by comparison recoveries on a membrane filter and spread plate.	**CAEAL Response: Denied** All materials should be subject to internal performance verification regardless of manufacturers' claims because: - the manufacturer has internal standards that are not necessarily those of the user - within lot and lot-to-lot variation has been known to occur - materials may change in performance as a result of shipping conditions, e.g., temperature extremes, compression, etc. -just as users of commercially purchased test kits or prepared media are required to verify the performance of these materials, so too so are MFs subject to performance verification checks, including recovery, hydrophobicity and growth inhibition. If there is an issue with MF performance, then recovery of target organisms particularly at low levels is problematic. PT samples alone do not address these concerns.
Submit documentary evidence that designated staff are available to substitute for key managerial personnel, specifically, update the Quality Manual to reflect the current practice of Lab Manager as substitute for Client Services Manager and vice versa and remove Section Supervisor(s) as substitute for the Lab manager.	**CAEAL Response: Denied,** but it will be re-worded slightly. The nonconformance was that the current practice of the laboratory is not documented in the Quality Manual or any other document. The current practice needs to be documented in one way or another – the Quality Manual per se does not need to be updated and the wording of the requirement will be changed to reflect the intent. The Lab can either include or reference this arrangement in a site specific SOP or in the national Quality Manual

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Document and implement procedures so that equipment required for the test is available and functioning properly, specifically, for the GCs used in the mobile unit, analyst should perform test that does not receive samples on a regular basis (more than three months) on reference standards to ensure proper functioning of the equipment. This applies to appendices 81,82,83,and 87.	**CAEAL Response: Upheld.** The requirement is that the test is run quarterly – there is no requirement on the type of samples that must be run. The term "reference standards" was removed and the wording of the requirement has been changed on the official report that was sent to the laboratory. However, the question of where the quarterly testing should be carried out (which is not captured in the requirement) is an interesting one. Quarterly analysis should be run under the same accommodation and environmental conditions, under which the test is normally carried out – i.e., in the mobile unit – because Section 5.3 of ISO/IEC 17025:2005 states that "the laboratory shall ensure that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement. Particular care shall be taken when sampling and tests and/or calibrations are undertaken at sites other than a permanent laboratory facility."
Submit documentary evidence that quality control data are recorded to detect trends, and, where practicable, statistical techniques are applied to review the results. The control charts for the laboratory control standards or duplicates (if applicable) are not available during the assessment. This applies to appendices 22, 24, 45, 81, 82, 83, 87, 91, 95, 96, 99, 110, 111,112, 114, 117, 118, 119, 123, 125, 129.	**CAEAL Response: Denied** Records were not readily retrievable (ISO/IEC 17025:2005, Section 4.13.1.2). However, instead of printing and submitting charts for each test, it is acceptable to submit an investigation and corrective action plan, to prevent records from being readily retrievable in the future. As well, the Advisory Panel members that reviewed the scenario had concerns because it appears that the analysts may not have had access to control limits during this time period. As a response to this item, please also submit evidence to demonstrate that staff had access to control limits.
Modify procedures so that all instruments required for the test procedure are available, specifically Section 6.1 of the SOP lists five ICP's that can be possibly used, but the lab has only one instrument. Reword the SOP to reflect that the lab has only 1 ICP	**CAEAL Response: Denied** There's nothing wrong with the approach, and it can work – CAEAL recognizes that this is a reality of business today for large networks of laboratories. However, if it was unclear to the assessors as to which ICP to use, it may be unclear to analysts, as well. Perhaps the approach just needs to be refined to clarify which models are at which locations?
Submit documentary evidence that all equipment requiring calibration is labeled to indicate calibration status, including the date last calibrated and expiry date or date when calibration is due i.e.pH and electrical conductivity calibration information are not logged	**CAEAL Response: Upheld.** Appropriate changes were made on the final report.
Submit documentary evidence that the current authorized test method and necessary supporting work instructions are available to the analyst, specifically, this document should be readily available in the mobile unit	**CAEAL Response: Denied** Unfortunately, we're getting into a bit of a "he said, she said" scenario but the bottom line is that there is no evidence from CAEAL's perspective that the mobile lab has or will have access to these documents, should the mobile lab be on assignment. The lab must demonstrate that these SOP(s) and other appropriate instructions are available to the mobile unit when it is performing tests out of town and that having them in the mobile unit does not affect the main lab documentation requirement (i.e., if the SOPs are in the mobile unit, does the analyst in the main laboratory still have access to them?).

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Submit documentary evidence that the current authorized test method is readily available in the mobile unit	**CAEAL Response: Upheld.** The two were combined into one requirement (the same finding was documented twice on the report).
Modify procedures so that all necessary successive steps in the test procedure are adequately documented in the test method, specifically, document in the appropriate SOP that the GCs in the mobile unit may be move to the main lab (such as in winter time) and should be re-validated when these GC units are moved back out to the mobile lab.	**CAEAL Response: Denied.** There are concerns about the equipment being moved around - even within a permanent facility. The Advisory Panel members that reviewed the file agree that more assurance is needed that the move has not impacted the equipment. As experts in this area of testing, they indicated while instrument start-up and calibration criteria addresses instrument performance, there is a multitude of other risk factors involved with moving columns (retention times could change), the purge and trap etc…This potential for problems increases by the fact that the equipment is being moved from a permanent facility to the mobile laboratory, because the accommodation and environmental conditions are also changing. Section 5.3 of ISO/IEC 170025:2005 specifically states that "particular care shall be taken when sampling and test and/or calibrations are undertaken at sites other than a permanent laboratory facility". In discussion with the Lead and two Advisory Panel members, it was confirmed that the term "re-validate" was not intended to necessarily mean full validation such as reassessing DLs, precision, bias, and linearity. However, it was agreed that more has to be done than instrument set-up and calibration. One suggestion was that every time that the equipment is moved, pick a mid-level range and demonstrate that the precision, accuracy and MU are comparable to the values obtained in the permanent laboratory. The laboratory needs to demonstrate that the performance of the equipment is not changing because of the move. To meet this requirement, the laboratory may submit: a statement that the equipment will be dedicated to the mobile unit, and a start-up procedure for the mobile unit, or a start-up procedure that includes appropriate steps that the analyst has to do every time the equipment is moved to demonstrate that the move has not impacted the method, and some data to support this procedure. A start-up SOP for the mobile/temporary laboratory is supported by Section 5.5.6 of ISO/IEC 17025:2005 which states that "the laboratory shall have procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration". Please see the note immediately following this requirement that states "additional procedures may be necessary when measuring equipment is used outside the permanent laboratory for tests, calibrations or sampling". In the SOP, you should also address items such as how reference standards are stored, if gases also have to be moved, etc.
Submit documentary evidence that reagent preparation logs are maintained.	**CAEAL Response: Denied.** While it may be an acceptable practice, I suspect that it ended up on the report because of the general understanding that mobile unit is basically a "mini-lab" where everything is self-contained. But, rather than submitting actual reagent

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	preparation logs, this might be best handled in a start-up SOP for the mobile unit.
Submit documentary evidence that the current authorized test method is readily available in the mobile unit. This is a repeat of 115.	**CAEAL Response: Upheld.** The two were combined into one finding (the finding was just documented twice on the report).
Submit documentary evidence that records of method validation include an estimate of the measurement uncertainty.	**CAEAL Response: Upheld.** Item was removed from official report. (This was a Colilert MPN method).
Modify procedures so that the test procedure and all supporting work instructions are performed as documented, specifically all samples will be digested (option#1) and thus Option #2 will no longer be available, therefore remove reference to option #2 (see Section 9 of SOP).	**CAEAL Response: Upheld.** Item was removed from official report. Lab still needs option 2, despite the fact that option 1 has only been used to date.
Submit documentary evidence that measurement uncertainty is estimated.	**CAEAL Response: Upheld.** Measurement uncertainty is not applicable for the BART methods.
Submit documentary evidence for the sterility certificate from supplier (for Petri dishes and test tubes).	**CAEAL Response: Partially upheld.** Both AP members agreed to remove the requirement for a certificate of sterility for the test tubes; however, there is no reason for the supplier not providing a certificate with the Petri dishes. If a media "sterility" problem arise, the certificate of sterility would be evidence that the plates per se were not the source of the problem.
Document and implement a procedure so that altered or new text is identified in the document or the appropriate attachment, as practical.	**CAEAL Response: Upheld.** The lab submitted evidence that they do keep an amendment log at the end of SOPs where they record changes to the current version of the document.
Modify procedures so that sample history requirements are adequate and either included or referenced in the test method, specifically, a minimum 1 bottle from each lot of new, certified bottles is to be verified for sterility or influence on parameters. Use sterilized water instead of tap water for testing bottles. Establish frequency, criteria and corrective actions for this procedure. When the assessor was assessing this procedure he was also assessing the Coliform procedure, therefore he put the same findings for both. However, we do perform this bottle check weekly with sterilized water for the HPC method, see attached SOP (step 11.7) The criteria and corrective action will still need to be addressed.	**CAEAL Response: Upheld, with conditions.** The intent of this requirement is to ensure that each lot of new, certified bottles is checked <u>before</u> being put into circulation. So, by rights, the testing should be done prior to use of sample bottles. However, the Advisory Panel (AP) member also felt that by doing weekly testing, you're probably actually exceeding the requirement. The AP noted the criteria and corrective action is important, because you'll need a plan of action if you starting getting "hits" and investigation reveals that there was a problem with a set of sample bottles that were released to clients. Also, Section 11.7 doesn't really specify that "sterilized water" is used – is that the same as the "negative control"? Where is a "negative" control defined? If you can demonstrate that it is clear where "negative control" is defined, submission of the criteria and corrective action is sufficient to meet the response. Otherwise, Section 11.7 of the SOP needs to be clarified. The requirement will be re-worded as follows: *Submit documentary evidence that a "negative control" refers to use of sterilized water or modify Section 11.7 of Chm-412.6 to ensure that it is clear that sterilized water is used for the weekly checks. Establish criteria and corrective actions for this procedure.*

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Document all necessary successive steps in the test procedure, specifically, colony counting and reporting criteria. The Collilert method is an MPN methodology and the unit for reporting is MPN/100 mL. Review the number of significant figures based on SM 21 Ed. 9221 (2 sig fig for MPN) and make it consistent with the uncertainty of the method.	**CAEAL Response: Denied**. Results do need to be reported in the correct units so results do need to be reported as MPN/100 mL. However, the Advisory Panel member also agreed that a qualifier could be put on the report, that indicates something to the effect that for monitoring purposes etc...MPN/100 mL can be considered to be equivalent to CFU/mL.
Submit documentary evidence that reagent preparation logs are maintained, specifically, there are no records for the preparation of working Calibration Standards and working Reference Standards solutions.And Submit documentary evidence that reagent preparation logs are maintained, specifically, there is no preparation for calibration standards.	**CAEAL Response: Denied**.
Document and implement a procedure so that laboratory staff are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system, specifically, the TRNG-13 procedure is geared to "laboratory trainees". The laboratory must also ensure that the other personnel such as the Purchasing Officer, LIMS Manager, Support Services Manager and Stream managers are aware of the quality policies relating to their activities. Request to change items from “A” to “B” type Required Actions.	**CAEAL Response: Denied**.
Submit documentary evidence that altered or new text is identified in the document or the appropriate attachments, as practical, specifically, test method standard operating procedures identify the section of the standard operating procedure where modifications have taken place, but does not identify the actual change that has taken place. Request to change items from “A” to “B” type Required Actions.	**CAEAL Response: Upheld.** Downgraded on the final report. It was strongly suggested that the lab be more clear on the changes to the document in the revision history.
Document and implement a procedure so that there are procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records, including protection, back-up and access of electronic records, specifically, the laboratory does not have a procedure for the storage of quality records such as audits, management review, training logs. Refer to CAEAL Interpretation of rating guide for more examples. Request to change items fro “A” to “B” type Required Actions.	**CAEAL Response: Denied**. The lab needs to find a way to prevent further loss/misplacement of quality records.

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Modify procedures so that method validation includes records of validation, the procedure used, and a statement that the method is fit for the intended use. It was noted that the laboratory procedure for method validation does not match the procedure found in the Quality Manual. Request to change items from "A" to "B" type Required Actions.	**CAEAL Response: Denied**. The lab should be able to make the Quality Manual and the laboratory procedure match within 45 days.
Document and implement a procedure so that method validation includes records of validation, the procedure used, and a statement that the method is fit for the intended use. The laboratory does not state any method validation goals for detection limit, precision, accuracy or measurement uncertainty. Specified goals are essential to prove that the method is fit for purpose. Request to change items from "A" to "B" type Required Actions.	**CAEAL Response: Upheld.** Downgraded on the final report.
Submit documentary evidence that the laboratory has and applies a procedure to estimate the measurement uncertainty that accounts for relevant uncertainty components and uses appropriate methods, specifically, there was no documented procedure that outlines the laboratory's approach to estimating measurement uncertainty. Request to change items from "A" to "B" type Required Actions.	**CAEAL Response: Denied**. The determination of measurement uncertainty has been a requirement of ISO 17025 for several years.
Document the existing procedure to ensure that the lab provides adequate training and supervision of personnel for calibration and testing activities. Document procedures related to the management system and ensure they are communicated, understood and implemented specifically for such topics as training, document control, review of requests, change control, etc. Document existing procedures related to the review of requests. Document existing procedures for maintaining records of reviews, which include pertinent discussions with the customer and any subcontracted work.	**CAEAL Response: Denied**. Based on the wording of the requirements, it appears that Lab xyz does have existing procedures that are satisfactory, and they are just not documented. A lack of documented procedures is deemed to adversely affect the laboratory's ability to continue to produce competent results, so these items must remain as "A" items.
Submit documentary evidence that the laboratory has and applies a procedure to estimate the measurement uncertainty that accounts for relevant uncertainty components.	**CAEAL Response: Partially Upheld**. The requirement to "submit documentary evidence that the laboratory has and applies a procedure to estimate the measurement uncertainty that accounts for relevant uncertainty components" will be re-worded and downgraded to a "B" item. Based on the objective evidence you submitted, Lab xyz does have and apply a procedure to estimate measurement uncertainty, and sources of uncertainty have been identified. However, in the assessor's

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	opinion, only a few possible sources of uncertainty are noted compared to the method in the CAEAL Policy (see P19, *CAEAL Policy on the Estimation of Uncertainty of Measurement in Environmental Testing*, item number 21). The Panel members felt that continually reviewing estimates of measurement uncertainty and ensuring that all possible sources of uncertainty are covered are two things that can be done over time.
Submit documentary evidence that test reports include the date that the test was carried out, or a note on the report that it is available if it is not in the report.	**CAEAL Response: Upheld.** Based on the objective evidence provided, the requirement that "*test reports include the date that the test was carried out, or a not on the report that is available if it is not on the report*" will be removed from the assessment report.
Modify procedure so that method quality control is adequate and either include or reference in the test method, specifically procedures to evaluate interference (e.g., spikes).	**CAEAL Response: Partially Upheld.** This item will be re-worded to require that Lab xyz "submit documentary evidence that interferences are evaluated" and specific reference to use of spikes will be removed.
Ensure 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	**CAEAL Response: Denied**. The lab can do two point calibrations as long as they can demonstrate that the low range QC recovery is good. The lab is ok doing what they do as long as they demonstrate acceptable values at the low concentration.
Document and implement a procedure so that calculations and data transfers are checked in a systematic manner, specifically, a procedure is needed for the verification of manually entered data (e.g., microbiology and alkalinity).	**CAEAL Response: Upheld.** It was agreed that the procedure is adequate.
Expand existing maintenance procedures to include all equipment that may affect quality of results, specifically, for appendices 21, 22, 23, 24, 25, 26 and 27.	**CAEAL Response: Upheld.** The laboratory procedure contained the minimum equipment maintenance procedures for these tests.
Ensure that method interferences are detected through the use of sample quality control spiking. The spiking procedure shall be documented. This applies to Appendices 2, 5, 8, 10 and 12.	**CAEAL Response: Partially upheld;** reworded to: Submit documentary evidence that method quality control is adequate and either included or referenced in the test method, specifically, procedures to evaluate interference. The lab must describe other ways of evaluating interferences if spiked samples are not used.
Document and implement a procedure so that quality control data are recorded to detect trends, and, where practicable, statistical techniques are applied to review the results. This applies to all appendices.	**CAEAL Response: Denied**. The laboratory recorded QC data in LIMS for annual review, however, the lab must review the control charts more frequently (e.g., monthly) in order to detect trends.
Document and implement a procedure for non-conforming quality control points (outside the acceptable range). Have a defined protocol to be followed and corrective actions to be taken to correct the problem. This applies to all appendices.	**CAEAL Response: Upheld.** A defined procedure was seen in Section 2.6.7 of the Quality Manual.
"Same autoclave is used for media preparation and waste disposal".	**CAEAL Response: Upheld.** Item removed from report.

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Ensure the laboratory has a calibration program for working thermometers used in the Microbiology lab that meets the traceability requirements as per CAEAL Traceability Policy (A61).	**CAEAL Response: Denied**. The laboratory must calculate uncertainty for their calibration of working thermometers. (The lab had been doing monthly verification, which collectively, could be use for calibration data.)
"Submit documentary evidence that all reagents and media are appropriately labeled with material, concentration or purity, date prepared and/or expiry date, for example, DCM and Hexane bottles have no expiry dates".	**CAEAL Response: 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 material is time sensitive. Once the labs prepare a hexane/acetone solvent (for example) it would be wise to put on the prep. 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 that stainless steel membrane filtration units are given a silicone treatment after every 10th use or sooner, as per instructions in MOE Reference June 15, 2004." Our laboratory has accreditation on different membrane filtration methods (DC, m-Endo & fecal broth). These methods were based on the current versions of the Standard Methods and specific MOE microbiology methods. It has never been stated in our SOPs that the membrane filtration units have to be given silicone treatment. We asked the assessor about the finding and she said that it was cited because we had the MOE method E-3371 as a reference. However, the only reference we use on this MOE method is its section 4.4.3 about the incubation temperature.	**CAEAL Response: Upheld.** Item was removed from report. Unless it is stipulated by the manufacturer of the stainless steel MF system to treat the units with silicone at a specified frequency, the laboratory in question is justified in requesting that the assessment finding in this regard be removed. This treatment could be a recommendation or suggestion, but should not be a non-conformance requiring a corrective action.