State of Connecticut
Department of Environmental Protection
Reponses to Public Comments for the
Draft Laboratory Quality Assurance and Quality Control,
Data Quality Assessment and Data Usability Evaluation,
Guidance Document, dated November 2008

Public comments received during the 30 day public comment period from November 24, 2008 through December 24, 2008 regarding the draft "State of Connecticut Department of Environmental Protection, Laboratory Quality Assurance and Quality Control, Data Quality Assessment and Data Usability Evaluation, Guidance Document," (the Guidance) dated November 2008.

The workgroup's responses to comments on the above document received from the public are presented in ***bold italics***.

Tina Sullivan
Analytical Data Manager
GZA GeoEnvironmental, Inc.
December 24, 2008

C1. What is the difference between Hexavalent Chromium method SM3500 and the RCP [Reasonable Confidence Protocol] method 7196? Is pre-RCP data by the SM3500 method usable and similar in quality to the 7196 method?

These methods both use the same chemistry; however some of the Quality Assurance/Quality Control (QA/QC) requirements are different. Method SM 3500 (18th, 20th, or on-line versions) would be acceptable as long as all QA/QC requirements of Reasonable Confidence Protocol (RCP) method 7196 are met including deliverables and narration of all Quality Control non-conformances.

C2. Will training sessions be held for laboratories regarding techniques to minimize data quality issues, and how to report data quality issues per the RCPs? There is still variation in the RCP data packages coming from different laboratories despite over a year of working on this. More direction on how to fill out the RCP checklist and how to write the narrative would be helpful to standardize the lab reports.

Information sessions for laboratories have already been conducted. In the near future, the Remediation Division, Laboratory Quality Assurance and Quality Control Workgroup (the Workgroup) is planning to revisit this issue and may provide additional information to laboratories regarding the preparation of laboratory reports. The environmental professional should work with the laboratory to obtain laboratory reports that meet their needs. The State of Connecticut Department of Environmental Protection's (CTDEP's) reporting requirement for the RCP methods are presented in the "State of Connecticut, Environmental Protection Laboratory Quality Assurance and Quality Control Guidance, Reasonable Confidence Protocols, Guidance Document," dated November 2007, effective November 19, 2007.

C3. What is the best way to proceed if a "difficult analyte" is a constituent of concern at a Site and results need to be compared to RSR [***Remediation Standard Regulations Sections 22a-113k-1 to 22a-133K-3 of the Regulations of Connecticut State Agencies (RSRs)]*** criteria? Are there specific cases where a different method can be used to get better results, or are there different prep methods the lab could attempt? (Specifically for VOC/SVOCs.) [Volatile Organic Compounds/Semivolatile Organic Compounds].

There are a variety of methods for the laboratory to address these issues. The laboratory must make attempts to eliminate or significantly reduce any QC outliers associated with a "difficult" analyte. This may result in more frequent calibrations, instrument maintenance, etc. The solutions to these issues are method and analyte specific, are included in the analytical methods, and are therefore outside of the scope of the guidance document. The environmental professional should contact the laboratory for assistance in these matters. Laboratory data that has significant QA/QC nonconformances for a difficult analyte that is a compound of concern may have limited use for a given site.

C4. Filling out the worksheets for a typical Phase II or III report with 10-20 lab reports takes a very long time and is a burden financially. It looks like about 25 worksheets will need to be completed for every ten lab reports. In the guidance something is mentioned about electronic deliverables to reduce the burden for larger projects. Can you elaborate on how to simplify this effort? Can an alternate way of presenting the information be used?

Understanding the quality of the analytical data will help environmental professionals and responsible parties make sound technical decisions regarding data quality and usability.

The worksheets that are presented in the Guidance are intended to provide examples of how to document the thought process that was used during a Data Quality Assessment (DQA) and Data Usability Evaluation (DUE) and may be modified by the user. It is important to note that worksheets should be used to summarize nonconformances only. The worksheets provide a method for the environmental professional to inventory large quantities of QC information in an efficient manner and summarize QC issues into a smaller listing of issues to be evaluated in the DUE. The CTDEP understands that a proficient QC data reviewer can efficiently conduct a DQA and DUE. However, the CTDEP recognizes that the process of learning to conduct a DQA and DUE may involve a commitment of time, the amount of which varies by individual.

The guidance document has been edited to include additional information regarding the use of electronic deliverables and QC data manipulation. The use of computer programs such as spreadsheets and databases in conjunction with electronic deliverables can reduce human error and reduce the amount of time to complete a DQA and DUE

The environmental professional should work with the laboratory to obtain laboratory reports which meet their needs. The guidance does not limit the format for reporting laboratory QC nonconformances.

C5. It seemed like the RCP methods were going to simplify the QC review process enough that an environmental professional without a laboratory/data validation background would be able to do a QC review. Based on this new guidance, this no longer seems to be the case.

One of the primary reasons the RCPs were adopted was to simply the DQA and DUE process for the environmental professional. This is because the use of the RCP methods results in data of known and documented quality and the RCP methods provide acceptance criteria to evaluate the quality of the data generated. The Guidance provides a framework for the thought process that should be used to understand if the quality of data is acceptable for the intended purpose. This evaluation can be performed by an environmental professional. The CTDEP will be offering DQA and DUE training starting in May 2009.

C6. A common issue for groundwater samples is the presence of degradation products related to drinking water chlorination at low levels. While unrelated to the laboratory, it leads to questionable data. Is it appropriate to treat this like laboratory contamination when evaluating the concentrations?

It is not appropriate to treat the presence of compounds related to drinking water chlorination like laboratory contamination found in laboratory blanks. This is outside of the scope of this guidance.

Evan J. Glass
ALTA Environmental Corporation
December 24, 2008

C7. Please indicate that based on previous experience only occasionally will the DQA or the DUE reveal non-conformances that will affect the usability of the data for the intended purpose.

A DQA and DUE must be performed in all cases to document the thought process for concluding whether or not data are usable for the for the intended purpose. While it is true that is many cases the DQA and DUE will not reveal nonconformances that affect the usability of the data, the environmental professional must always evaluate the quality of the data in relation to the intended purpose. The outcome of DQA and DUE process provides the environmental professional with a level of confidence that the data used in decision making is appropriate.

C8. Please indicate that analytes for which no RCP method has been published should be handled the same as Pre-RCP data (i.e., existing QC data should be used, etc.., rather than having to demonstrate equivalency with the RCPs). I believe the demonstration requirement would have a poor cost/benefit ratio in light of the first bullet item (i.e., data usability is hardly ever affected in practice).

The language in Table 2-1 regarding the types of analytical data has been clarified.

For analytical data generated from samples collected after September 1, 2007 when no RCP method is published, the DQA involves an evaluation of precision, accuracy, and sensitivity using QC data deemed equivalent to a similar RCP method, as described in Section 4.5 of the CTDEP guidance document titled "Laboratory Quality Assurance and Quality Control Guidance, Reasonable Confidence Protocols, Guidance Document," dated November 2007, (the RCP Guidance).

Pre-RCP data is analytical data generated prior to September 1, 2007 that was not generated using an RCP method. The DQA involves using existing QC data to evaluate precision, accuracy, and sensitivity. If precision and accuracy QC data are not available, evaluate sensitivity. Section 4.5 of the Guidance presents information regarding data usability evaluations for Pre-RCP data. The provision for Pre-RCP data was included so that data prior to September 1, 2007, with varying amounts of QC information, could be used, and incorporated in the Conceptual Site Modeling process.

The CTDEP Policy Letter dated April 18, 2007, describes the CTDEP's expectations with respect to analytical data quality. This letter states that for samples collected on or after September 1, 2007, all analytical data used to support site investigation and remediation projects will be of known and sufficient level of quality. Data generated using the RCPs are of a known level of quality.

Please refer to C7.

C9. Take a close look at example 1 (equipment blanks) and example 2 (trip blanks) in Section 4 to make sure they are correct.

We have reviewed these and have made clarifications and corrections.

C10. Please explicitly provide more flexibility for documenting the DQA/DUE process (i.e., for non-worksheet methods, such as annotations on copies of lab reports, or other note methods).

See C4 and language modification made in guidance on page 3-1, third paragraph. It is important to summarize the thought process used in the DQA and DUE in a clear manner. The worksheets may be modified. Relying on annotations on laboratory reports may be appropriate for a limited number of samples, but will be difficult to use as a basis for a DQA and DUE with larger numbers of samples and nonconformances. Worksheets or other methods of summarizing QC information are worthwhile because all of the QC nonconformances for one sample can be shown in one place, aiding the environmental professional and reviewer in their work.

C11. Given the RCP requirements, environmental professionals should be able to trust that the laboratory has provided documentation on method blanks, LCSs and surrogates (i.e., without having to independently verify same) – Appendix C.

In order for the environmental professional to conduct a DQA, the tasks described in Appendix C-1 related to the review of the laboratory report and narrative must be conducted. Unfortunately, laboratory reporting errors occur. . It is important that the environmental professional first determine if the necessary information has been reported and then review the narrative for significant findings (i.e., QC outliers that could affect usability of the reported results) and request additional information from the laboratory, if applicable. It is an important part of the responsibilities of any professional to confirm that the services that were ordered or required were delivered, and laboratory deliverables are no exception.

Brent J. Henebry, LEP
Fuss & O'Neill, Inc.
December 24, 2008

C12. Page 2-6, Section 2.4.1 Precision, last sentence first paragraph and the last sentence of the second paragraph state

"As a conservative approach, it is appropriate to compare the greatest numeric results from a series of measurements to the applicable regulatory criteria."

When using the results from two duplicates, the results from the higher duplicate is to be used."

A similar statement is made in section 4.2.4, Field Duplicates.

There are two instances when we end up with two laboratory analyses at a single sampling location. The first occurs when we collect a duplicate sample and the second occurs less frequently when we initially get a result that does not make in sense in the context of our field observations and conceptual model. In this instance we often ask the laboratory to re-prep and analyze the sample a second time.

In both of these instances, using an average concentration of the two sample results seems appropriate to me, assuming that their [*sic*] are no nonconformance issues with either of the two analysis procedures. Soil heterogeneity, especially in fill materials often leads to primary and duplicate sample results that are an order of magnitude apart and neither the primary or duplicate sample represents the concentration present in the larger mass of material being investigated. Could you add language indicating that it is also acceptable to use an average of the two in these instances, assuming that their [*sic*] are no non-conformance issues with either of the analyses.

We agree that sample heterogeneity can lead to results for duplicate samples that are significantly different. However, as indicated in the guidance document a conservative approach is to use the higher of the two results. The language in the last sentence of the second paragraph of Section 2.4.1 has been clarified to include the word "conservative." Comparing an average of analytical results to the clean up criteria in the RSRs is not appropriate, expect in those circumstances allowed for in the RSRs.

Kathy Shaw, Chemist
Conestoga-Rovers & Associates
December 23, 2008

C13. Section 4.2.3, Example 1;
It looks like toluene was mistakenly used in place of bis(2-ethylhexyl)phthalate in the sentence beginning – Based on these results, it is likely that the ***toluene*** reported…
And perhaps again in Example 2 where it says that toluene is a common laboratory contaminate [*sic*].

We have reviewed these and have made clarifications and corrections.

C14. Section 4.3.5 Surrogates – References Appendix J as presenting SVOC surrogate and internal standard information; only the internal standards are listed.

The Appendix J does indeed list the surrogates under the appropriate internal standard. This comment seems to be in error.

C15. Section 4.6 – Says wet-weight measurements can be converted to dry-weight measurements – but does not give the calculation nor does it inform the reader that the percent solids measurement (%TS) must be done first.

If this is an issue, the environmental professional should contact the laboratory for assistance. This is outside of the scope of this guidance.

Mark Warren
Accutest QA
December 22, 2008

C16. Appendix D-4 (Summary of RCP Acceptance Criteria) for Method 8082 Holding Time:

The holding times for method 8082 are listed as 7 days to extraction for waters and 14 days to extraction for soil/sediments. Revision 4 of SW846 (Chapter 4) no longer provides a hold time for 8082 – soil or water. Accutest suggests that the hold time requirement be removed for 8082 entirely. An alternative suggestion would be to change the hold time for 8082 water and soils to a year and remove the freezing requirement.

This is outside of the scope of this guidance document. However, it is anticipated that the Reasonable Confidence Protocols will be revised in the near future and this issue will be revisited at that time.

Nick Skoularikis, Ph.D., L.E.P.
Loureiro Engineering Associates, Inc.
December 22, 2008

C17. Page v.: "EPTH" (typo)

This typographic error has been corrected.

C18. Page 1-3, bottom: "in such cases…" It may help to define which cases. I believe it implies cases where data validation will be performed.

This language has been clarified.

C19. Page 2-1, bottom: "The types of data that must be considered … if data from an environmental assessment [are] represenentative [*sic*] of site conditions…"The document appears inconsistent (data is used as singular or plural in some occasions)

This language has been clarified.

C-20 Page 2-5, Table 2-1: "Analytical data.. that [**were]** not generated…" The document reads "was"

This error has been corrected.

C-21 Page 4-6, Example 1: In the 7th line of Example 1, "toluene" should probably read "BEHP"

This error has been corrected.

C-22 Page 4-7, first line: for consistency with the RSRs "tetrachloroethene" would read "tetrachloroethylene"

This error has been corrected.

C-23 Page 4-20 "e.g., whether the data [**were]** generated…"and "Perform a critical review of [**these]** data…" (Other occurrences also exist in the document)

These errors have been corrected.

C-24 Page 4-22: add "Characterization" [*sic*] to the explanation of the TCLP acronym

This comment has been addressed.

C-25 Page 4-22, middle of the page: "Typically, sediment sampling for pesticides or PCBs need**s** extensive…" (The document reads "need")

This error has been corrected.

C-26 Appendix E, Page E-2, second bullet: "6 C more than 24 hrs after collection". This appears too tight. We have used 10 C in the past. When shipping samples to off-site lab, the 24-hour threshold is exceeded upon receipt for some samples.

There should be sufficient ice to cool samples to below 6 degrees Celsius within 24 hours.

Tina Clemmey
Loureiro Engineering Associates, Inc.
December 19, 2008

C-27 According to the EPA website, Revision 6, dated February 2007, there is no hold time for PCBs. See the attached link and scroll to Chapter 4, page 4-11.
http://www.epa.gov/epawaste/hazard/testmethods/sw846/online/index.htm#chap.

Our RCP method for 8082 states the 7 days to extraction for aqueous samples and 14 days to extraction for soil samples and then 40 days to analysis. Are we staying with that or do we need to revise the RCP method to be in sync with EPA.

This is outside of the scope of this guidance document. However, it is anticipated that the Reasonable Confidence Protocols will be revised in the near future and this issue will be revisited at that time.

Mark Warren
Accutest QA
December 16, 2008

I noticed a couple minor typos in this draft document:

C-28 Page 4-6, Example 1, on line 7: Toluene appears to be be a typo here (should be bis(2-ethylhexy)phthalate).

We have reviewed this and have made clarifications and corrections.

C-29 Page 4-6 Example 2 – should be titled Application of 10X rule (instead of 5X rule).

We have reviewed this and have made clarifications and corrections.

Mark Warren
Accutest QA
December 12, 2008

C-30 Appendix D-4 (Summary of RCP Acceptance Criteria) for Method 8082 Holding Time:

The holding times for method 8082 are listed as 7 days to extraction for waters and 14 days to extraction for soil/sediments. Revision 4 of SW846 (Chapter 4) no longer provides a hold time for 8082 – soil or water. Accutest suggests that the hold time requirement be removed for 8082 entirely. An alternative suggestion would be to change the hold time for 8082 water and soils to a year and remove the freezing requirement.

This is outside of the scope of this guidance document. However, it is anticipated that the Reasonable Confidence Protocols will be revised in the near future and this issue will be revisited at that time.

MACTEC
Nadia Glucksberg

C-31 Page ix, the term Conceptual Site Model is defined in section 2 of the CTDEP SCGD, September, 2007.

This error has been corrected.

C-32 Page 1-3, last two sentences.
The last sentence is confusing. Should it read, "in cases where formal validation is needed, the environmental professional will have to contact the laboratory to obtain a full data package and evaluate the data in accordance with the EPA evidence mentioned above."

This language has been clarified.

C-33 Please explain, does the use of RCP methods negate the need to do formal validation or will the use of RCP methods and validation be needed under certain circumstances, and if so, when?

In most cases, the CTDEP will not require formal data validation when the RCPs are used. However, the CTDEP reserves the right to request formal data validation on a site-specific basis if necessary.

C-34 Following the USEPA Region I data validation guidelines and flagging conventions (adding qualifiers to laboratory reported results) helps define any uncertainty and/or potential biases of the reported data. Does the CTDEP deem validated results not flagged as unusable (R) as being of sufficient quality to evaluate compliance with numerical RSR criteria?

Data that is not flagged still may not be usable. A Data Usability Evaluation must be conducted to evaluate the usability of the data.

C-35 Comment # 3: Page 4-5, Section 4.2.3, third paragraph, last sentence.
Add “by the laboratory” after the word ‘suffiix’.

This language has been revised.

C-36 Comment # 4: Paqe 4-6, Example 1, sixth sentence.
Revise the word ‘toluene’ to ‘BEHP’.

This error has been corrected.

C-37 Comment # 5: Paqe 4-6, Example 2, fourth sentence.
Toluene is described as being a common VOC laboratory contaminant. USEPA Region I Validation Guidelines do not list toluene as a common laboratory contaminant. Therefore, the 5X Rule would apply, and the reported concentration would need to be at least 50 µg/l in a site water sample to be considered present in groundwater at the site. As such, in this example it is likely that the toluene reported is present in the groundwater sample and is not related to contamination of the samples during collection, storage, or transportation.

Toluene has been removed from the list of common laboratory contaminants.

C-38 Comment # 6: Page 4-10, first paragraph, last sentence.
This statement does not belong in this paragraph/section.

This language has been revised.

C-39 Comment # 7: Page 4-10, Example 6.
For organic analyses, laboratories report concentrations detected above the MDL but below the RL as an estimated detection (value flagged by the laboratory with a "J" qualifier). How is this instance handled when comparing detected sample results to numerical criteria?

The RCPs report anything below the RL as not detected, unless the client asks otherwise. Since "J" flagged data is estimated, "J" flagged results must not be compared to regulatory criteria.

C-40 Comment # 8: Page 4-11, first paragraph, last sentence.
Add "by the laboratory" after the word 'suffix'.

This language has been revised.

C-41 Comment # 9: Page B-5, Appendix B Sensitivity-Method Detection Limit Studies and Calibration
Replace "Quantitation Limits(QLs)/Practical QLs (PQLs)" with "Reporting Limits (RLs)".

This table has been modified to address this comment.

C-42 Comment # 10: Page C-1, Reasonable Confidence Evaluation
Suggest 'Task' appear in bullet format. Add bullet saying "Review the narrative for significant findings (i.e., QC outliers that could affect usability of the reported results) and request additional information from the laboratory, if applicable".

This language has been revised.

C-43 Comment # 11: D-4 and D-9, Table Appendix D-4, "Holding Time" Column
Remove text "Mercury 28 days.

The holding time for mercury holding time is 28 days.

C-44 Comment # 11: Page D-5, Table Appendix D-4, "Holding Time" Column
Remove text "Soil/sediment pH and ORP 24 hours" ORP and pH should be measured during the extraction as stated in Method 3060A.

This table has been modified to address this comment.

C-45 Comment # 13: Page G-1 Appendix G.
Remove Toulene [*sic*] from the list of common laboratory contaminants.

Toluene has been removed from the list of common laboratory contaminants.