

Stakeholder Meeting
April 1, 2015
Burlington

.0802:

Municipal WWTP - Clean up last sentence, suggested alternative language: “during performance of toxicity” –it was also mentioned that the current language looks like maybe doesn’t apply during the performance of toxicity.

.0803 definitions:

Commercial Laboratory - add a definition for hold time? Sometimes the client asks the questions and do not understand how hold time is defined. Is it in days or minutes?

Municipal WWTP -Date and time would need to be documented to show holding time is met

Municipal WWTP - add a definition for approved procedures? Also recommended capitalizing “Approved Procedure”

Commercial Laboratory- add “PT” in front of acceptable results (1) and unacceptable results (28) [note that it already says this in the definition that they apply to PT samples]

Municipal WWTP -unacceptable result (28) - would like “deadline” to be more defined

Commercial and Municipal Laboratories - discussion on falsified data (9): does the word negligence need to be there? If you forget to multiply a dilution, is it negligence or error? Actively going throughout day and not being careful- is that negligent? Add “intentional or unintentional” somewhere.

Dana note - look at how negligence and falsify is used throughout

Dana - split sample (24) part (or all?) was meant to be stricken, but left in section which it applies

Commercial Laboratory - request to define “valid result”

Municipal WWTP - add definition of “Director” as mentioned on pg. 15 line 25

Municipal WWTP - add ‘Approved Procedures’

.0804:

Commercial Laboratory – they are being asked for MEP by NC clients - other extractions too – consider for inclusion?

.0805

Municipal WWTP - QC elements- look back at adding MS in?

.0805 (a)(3)(C)

Municipal WWTP- line 18- suggest requiring that a lab must *document* that supervisor contacted the lab daily.

.0805 (a)(5)

3rd party assessors (does this need a definition?)

Commercial Laboratory -define that the laboratory pays for 3rd party assessors

Commercial Laboratory - does verbiage say third party assessors would be used for initial [under Application section] inspections only and within a certain timeframe? Look into placing it under certification maintenance or in both sections

Municipal WWTP- question on separate app for facilities- how does it affect municipalities with multiple WWTP? Could they be allowed to do non-field parameters at different facilities?

Commercial Laboratory -look into wording on one field certification for multiple sites

.0805 (a)(7)line 25 (SOP update supporting records)

Municipal WWTP - define supporting records

2 separate things need to be done- keep SOPs up to date and track changes(document) anything new in SOPs

.0805 (a)(7)(C)

Discussion on residue standard frequency

Municipal WWTP - questioned what was the reason for the increase to monthly QC vs quarterly? They indicated they now purchase their QC because it was hard to get the ash in the past.

-Other methods where standards are available require daily- monthly is a good compromise between daily and quarterly (Suggestions to define monthly)

-wondering if QC monthly is even useful- what would type of conclusions would you find once a month (or quarterly) they have never discovered anything when doing the quarterly QC

Commercial Laboratory -could minimize risk of having to qualify a lot more data if failure when analyzing more frequently

- hard to find the ash- need to buy standard now (Jason mentioned that the standards don't have to be used all at once, even though they are meant to be whole volume)

- does every analyst have to analyze a QC monthly if there are multiple analysts?

Municipal WWTP - what about analyzing a QC if there have been no samples analyzed in that time frame?

Commercial Laboratory - point made that analyzing a QC even when not analyzing samples will "help you remember" the process

.0805 (a)(7)(E)

- MS corrective action- failed due to matrix interference, qualify and move on? Dana- look at other things first- LFB, other QC

.0805 (a)(7)(G)

Municipal WWTP - OK to put a box for check and initial that the meter/balance calibration was done?

- "analysis time"- some may read it as *every sample*, not start of run/batch

- line 14- change to "date, time (if needed to document holding time is met"?)

Municipal WWTP - do you have to include drying oven instrument IDs? (Cert answered with yes, if you have multiple)Then he said maybe there could be an instrument log sheet put into use instead.

Municipal WWTP - asked what to do if you have an instrument that is no longer operational. Dana responded that you would then document on an instrument log that the instrument is out of service and document the id of the new instrument.

Municipal WWTP - If you calibrate before and are following the SOP doesn't it show that it is being done instead of having to put down a calibration was done each time.

Commercial Laboratory - mentioned that for legal purposes a time of calibration would need to be documented to show that it was being done prior to samples.

Municipal WWTP - commented some parameters that have a short hold time you would still need to put down the date and time because of the instrument run.

Printable benchsheet discussion

-OK to use electronic signature?

(Dana/Gary question-did we codify electronic storage policy? see .0805(a)(7)(F)- consider adding more detail as in the policy)

Commercial Laboratory -define printable - also suggested changing the language of all labs must use printable benchsheet (electronic) language.

Municipal WWTP - commented need language for electronic signature.

- all labs must use printable benchsheets, or can you just be able to view it?

- issue is do we have software to view electronically stored data that is sent as file

- be able to turn into a PDF

.0805 (a)(7)(H)

Municipal WWTP -is there a problem using a 2nd source throughout if it is midrange? We told him it wasn't a problem and we'd look at wording

.0805 (a)(7)(H)(iii)

Commercial Laboratory -question on 3 pt calibration with metals- doesn't say calibrate, it says analyze

.0805 (a)(7)(J)

Commercial Laboratory - did not see frequency of weights being certified

- did not see balance check frequency

Municipal WWTP - question about "across the range of use"- told this means parameters analyzed, not across range of weight set or balance itself

- could you use multiple known weights to add up to a certain weight you need?

Municipal WWTP - what about process control ranges

- need to define "across the range of use"

Municipal WWTP -ask if this requirement would be defined as days for annually. How is annually defined.

.0805 (a)(7)(M)

What about storage issues? Is that considered part of preservation? That came up with a commercial lab's refrigerator breaking and samples going out of temp range. What is the process of notification/qualification?

.0805 (c) (1)

Suggestions to define year in relation to months vs days. Some questions about maybe rewording. Dana asked for suggestion in rewording. None was given at the time.

.0805(e)(5)

If 40 CFR hold time is different than SM or other methods, could we define which takes precedence?

.0805 (g)(3)

- need time to show samples analyzed within calibration window?
- need balance calibration time to show it was done before analysis?

.0805 (g)(5)(ii)

Commercial Laboratory - is it really necessary for analysts to read rules? Other sections of the rules state SOPs and QAM reflect the rules, so they should be covered by those documents.

- This part is in the field lab section and only parts of the rules pertain to field labs- why read those?

(a)(7)(O)- mirrored section in non-field lab requirements

- question again of analysts having to read rules
- managers job to assure SOPs match methods/rules/requirements
- section wording implies "and" not "or"

Commercial Laboratory - Commercial states that every analyst is required to read the QA manual and SOP. Their SOP incorporates the Certification rules. In this case the analyst would not have to read the rules since the SOP contain them.

Municipal WWTP - asked if it had to be documented and dated that the analyst read the rules.

Commercial Laboratory - mentioned that SCDHEC requires documented training.

Commercial Laboratory - mentioned that it is up to the manager to make sure that the analyst follows the SOP (which would match the certification rules).

Gary mentioned that currently field labs are not required to have an SOP but the rules revision would require them to have one.

.0806

Todd – regarding PMT fees - you still have to pay to get the parameter method technology back if decertified, but this needs to be investigated in the rules. (g) says A laboratory decertified for one or more **parameters** must pay a fee of two hundred dollars (\$200.00) for each parameter for which it was decertified prior to recertification.- see nothing about parameter method technology

See .0808 recertification- (b) (5) The laboratory must pay the required fee as specified in Rule .0806 (f) or (g) of this Section; and

But again, it says “parameter” not PMT in (f) or (g)

Other

.0805(e)(2) Whenever a certified commercial laboratory refers or subcontracts samples to another ~~laboratory certified laboratory for analyses, parameter method technology~~, the referring laboratory must supply the date and time samples were collected to insure holding times are met.

*see highlight/track change

.0807(e)(3) A commercial laboratory that has received a ~~parameter decertification~~parameter method technology decertification may make arrangements to supply analysis through another ~~certified~~ laboratory certified by the State Laboratory for the contracted parameter method technology during any decertification periods.

Commercial Laboratory – would like to see in the rule which parameters they need to do PTs for. Consider concentration levels as for TRC.

Municipal WWTP – Question about how month vs days defined for annually. - Municipal Lab responded they define it in months.

Dana asked for suggestions of how to reword the requirement for up to 4 PT’s a year. This is not new has always been in the rules just need to reword.