Laboratory Certification & Registration Standards Review Council Meeting Minutes

Tuesday, November 12, 2024

- Attendance – 30 participants
  - **9 Council members (8)**: Tad Schwartzhoff (industrial rep), Jon Anderson (commercial rep), Craig Obry (*Vice Chair* – small WWTP rep), Na Zhang (WSLH rep), Alex Zenner (livestock farmer rep), Brooke Klingbeil (demonstrated interest rep), Jennifer Buchholz (solid & hazardous waste disposal rep), Matt Schmeichel (public water utility rep),
    - *Absent - Christine LesCamela (Chair – large WWTP rep)*
  - **6 DNR staff (5)**: Zana Sijan (manager), Tom Trainor (chemist), Autumn Farrell (auditor), Brenda Anderson (auditor), Rebecca Fahney (WSLH liaison)
    - *Absent – Patty Doerflinger (auditor)*
  - **Guests (17)**: Paul Junio (Pace), Camille Danielson (WSLH), Erin Mani (WSLH), Sue Hill (WSLH), Ronesha Strozier (Public Health Madison & Dane County), Amanda Kordus (Badger), Kristen Hannon (WSLH), Jessica McCammon (Madison MSD), Steve Hefter (NLS), RT Kruger (NLS), Juli Bowling (WEAL), John Larson (Badger), Mike Tienor (NLS), Alfredo Sotomayor (Milwaukee MSD), Justin Hall (Badger), Dennis Grulkowski (Cedarburg WWTP), Meredith Polar (AgSource)
- Agenda repair
  - No changes
- September 24, 2024, minutes
  - No changes
- Lab Cert program auditing status report (July ’24 - October ’24)
  - FY 2025 partial, July 2024 – October 2024: **Large Scope**
    - Audited = 92%, Reports Issued = 83%, Closed = 92%, Revised Application Audits = 1.
    - Backlog of labs = 12, up from 6 at last meeting.
    - Reports issued within 60 days = 100%.
    - Audits not closed over 1 year from report date = 0.
    - Active labs = 116.
    - New labs applied to program since last meeting = 0.
    - Labs dropped from program since the last meeting = 0.
  - FY 2025 partial, July 2024 – October 2024: **Small Scope**
    - Audited = 85%, Reports Issued = 80%, Closed = 105%, Revised Application Audits = 3.
    - Backlog of labs = 16, up from 10 at last meeting.
    - Reports issued within 30 days = 100%.
    - Audits not closed over 1 year from report date = 0.
    - Active labs = 207.
    - New labs applied to program since last meeting = 0.
    - Labs dropped from program since the last meeting = 0.
- Other business
  - Lab Cert auditor vacancy update
    - Second round interviews will be conducted on 11-12-24. The earliest the new hire could start is January 13, 2025, due to DOA rules. DOA does not allow hiring during holidays.

- Council member DNR required annual training
  - New members must complete the “Ethics for Public Officials” training. Annually (per calendar year) all members need to complete the “WI Public Records Law” training. Must have an account in “LearnCenter” to access the trainings. Please complete trainings by the end of November. If you have not been contacted to access the trainings yet (either by DNR or by LearnCenter), let Tom know.

- FY 2026 budget first look
  - Expenses: 90% of total expenses are from salary and fringe costs. Supply and service expenses are based on actual costs from previous fiscal years. Training and training travel includes the EPA CO course and WWOA annual conference. Lab Cert attends the WWOA annual conference because approximately two thirds of the labs in our program are from wastewater treatment plants. Lab Cert had two presentations at this year’s WWOA. Lab Cert plans to continue this tradition to answer questions in person and build relationships with the operators. Tom just noticed that the budget needs to be adjusted for the EPA CO course, as two attendees will be going in FY25 and not FY26. Contractor hours are for maintenance and updating of applications, including addressing rewrite bugs.
  - This budget does not include attendance at the TNI annual conference. This could be added later based on available funding. Ronesha asked what TNI is; Tom and Paul answered “The NELAC Institute,” a national program for establishing laboratory standards. Autumn mentioned that the TNI annual conferences have been worth the trip in the past.
  - Alfredo asked how many employees are covered in the budget. Tom answered that it includes 4 auditors, the program chemist, and 40% of the section manager’s time.
  - Alfredo asked if we will be using a contract assessor. Tom answered no, there is no funding in the current budget for that. Current staff will work to meet program requirements.
  - Tom stated that the budget just presented may change. The current budget includes a 2% raise for staff in July 2025 and January 2026. It is uncertain if these will occur, and we won’t know if the governor is even going to try to add them to his budget until his budget is presented to the state legislature. Even after that, we won’t know for sure until the state legislature approves the budget sometime in the summer of 2025. The budget that is presented to the NRB will be the one with the most current information provided to us at that time.
  - Camille asked if the out of state travel is paid for by the lab. Tom said yes, out of state travel is billed back to the laboratory and is not included in the budget.
  - Zana will present this budget in April to the NRB.

- Revenue: Total RVUs is 8311. For FY26 we are budgeting a net loss of 20 RVUs. Total cost/RVU with the data as is would be $85.50, a $5 increase from the previous year and a 6.2% change. This is primarily due to staff getting raises last year.

- EPA methods with special QC “compliance” reporting requirements
  - When methods include the language, *“If XYZ QC sample fails, the sample results may not be reported or used for compliance purposes,*” Lab Cert (and EPA) require a qualifier that provides the following information: *“the result may not be reported or used for regulatory compliance purposes.”* If the result happens to exceed a permit limit, the data can be reported to the DNR with a qualifier and that qualifier does not have to say, “may not be used for regulatory compliance.”
  - Erin asked how a lab would know what the permit limit is. Tom answered that the lab would ask the client. Erin replied that the client often does not understand their permits and are relying on the lab to know what is required. Brooke shared the public link where anyone can access wastewater permits: https://apps.dnr.wi.gov/potw/. Camille stated that this is a lot of work to put on the labs, if the lab is expected to find the limit from the client’s permit. Paul stated that some clients like engineering firms won’t be willing to share the requirements. Tom answered that if the client doesn’t know or does not want to share their permit limit, that is on the client. The lab is expected to report the data with the comment. If the client wants the data reported without the comment, they need to review their permit and share the pertinent information with the lab.

- Paul asked if this requirement is being shared and communicated with all labs to avoid “lab shopping” to find a lab that will report results without the comment. Tom answered that it is required of all labs, and Lab Cert has been citing labs for not using the comment for approximately the last 6 months already. Updated communication will be shared with all labs.
- Lab Cert is aware that some lab clients are not happy with receiving results with this qualifier. Clients are asking the lab if there is anything the lab can do to prevent this. Given this question, Tom followed up with EPA. From EPA: *when resampling can’t be done, the lab should inform the client that they should collect and provide additional aliquots so the lab can investigate possible solutions*. *The lab may then perform additional work to document matrix interference and determine if allowable modifications can be made*.
- Regarding EPA method 1664, Paul asked how you can dilute the sample if the entire sample should be used. Tom answered that the solution is to use a smaller sample size, and the lab would need to know the permit limit. EPA is saying it is on the lab to fix the matrix issue, which Lab Cert feels is a big ask of labs. Paul stated that once the sample is gone, a re-sample may be different and may not have the same issue. Paul asked if method validation would be required for all sample bottle sizes for EPA 1664. Tom answered that if you find a client that routinely needs to use a different size because of matrix, the lab will need to do a new method validation. If it is a one-off, it is OK to report without a method validation. Paul asked where the line is between a one-off and routine requirement. Tom answered that if you need to do something repeatedly for a sample to work, that is routine. Erin stated that a method with more than one MDL is hard to report in LIMS, and asked how the lab would know when the sample comes in if it needs to get one code or another based on the specific sample site. This makes it a difficult task for the labs and would require additional complicated coding in LIMS. Tom stated that we understand these issues, and at this point, we are just relaying the information we received from the EPA. As these situations arrive, feel free to contact Tom for feedback.
- Camille asked who will be paying for the additional expense of researching the matrix. Tom answered that the client will be responsible for additional costs, and that either they can fund the investigation or try to fix the problem in the matrix by updating their treatment.
- Alfredo asked if this issue was purely a matrix spike issue or if it included all QC exceedances. Tom answered that it varies and depends on the method. Alfredo responded that in the last meeting it was discussed that some labs do not even need to complete matrix spikes. Tom answered that the previous discussion was for phosphorous and ammonia, which do not apply in this conversation, because those methods do not have the specific language required as listed above. The current conversation is specific to EPA methods that have the compliance language and are wastewater.
- Kristen asked regarding EPA 1633, which requires a re-extraction, what should the lab do when there is a QC failure. Tom said if you re-extract, the process starts over, and the qualifier may or may not be needed. Some of these situations may require conferring with Amy Garbe to determine the optimal conclusion. This is another case where everything is not black/white, especially considering the costs involved with resampling and reanalysis of PFAS.
- EPA also stated that additional solutions to matrix interference issues can be found on their CWA Analytical Methods webpage, available here: https://www.epa.gov/sites/default/files/2015-08/documents/solutions-analytical-chemistry-problems-cwa-methods_epa_2007_rev_bkmk.pdf. Once a matrix interference is demonstrated, the lab should document and attempt to address the issue using the suggestions in the method, the document linked above, or other techniques in scientific literature. A partial solution would be to collect additional volume of the wastewater in question to avoid the need for resampling. Paul stated that this presumes that bottles are requested on a per-sampling event basis when some clients have a bulk supply of bottles at their disposal. Tom agrees that this does make it more difficult and that clients will need to be educated. Erin stated this also presumes that the lab is not being subcontracted; sometimes the client may be another lab and not the wastewater treatment plant, and the lab running the sample may not know who or where the kits are being sent. Tom said he understands, and all we are asking is that labs do the best they can do within reason.

- EPA stated that results associated with failing QC cannot be used for compliance (in cases where the method specifies as much), but they can be used to demonstrate non-compliance (the result is over the regulatory limit). This provides incentive to the client to address the matrix interference (unaddressed, the sample is non-compliant). Alfredo stated that this conclusion may not be defensible. Tom stated that this is the EPA Clean Water Program's position communicated to us. Jon stated that from a commercial lab perspective, there may be legal ramifications and liability if the client received a biased high result with failed QC. Jon stated that they report results where QC failed high with the "data should not be used for compliance" qualifier even if the method does not require it because of liability, ease of use, and simplified coding in LIMS. Paul stated that a high QC failure may still generate usable data and that it is not for the lab to determine this. Data should be reported out and the data user can decide what to do with the qualified data. Tom said he understands that, and this is why data needs to be appropriately qualified so that the end data user can make their decisions.
- Lab Cert is proposing that to comply with these EPA method requirements, labs must qualify the data as discussed above. Lab Cert will send out an email blast to notify all labs. Labs will need to work with their clients to resolve matrix issues and discuss funding, or the facility can address the issues by providing a sample without these interferences. Lab Cert will be verifying compliance with these method requirements in evaluations. Paul and Camille stated that even if the facility can improve their treatment process, that might not mean that the interferences will be removed from the sample. Paul stated that it would be helpful to send this information to permit writers and permittees too. Zana said that Lab Cert can work with the wastewater program and notify them that they will see data coming in with this qualifier and that the data may not be usable for compliance but that the ultimate decision is up to them. Alex stated that the lab comments will go to the basin engineer who will have to sort through the data, and if the qualified results are still reported then the facility should get an NON. Tom stated that this is up to the basin engineer. Paul stated that it shouldn't be a violation that a sample was collected that didn't work for the method. If the permittee did what was expected and collected the sample, but it fails QC and the data is unusable, they should not be hit with legal action. Tom suggested that the sample could be reported without a result and only with a comment along the order of "Sample was collected but QC failed; unable to report for compliance purposes." Tom stated that SWAMP allows QC comments on the bottom of the eDMR and that the basin engineers will see this. Jon stated that if there are multiple customer samples in a batch where some are compliance and some are informative, and one MS fails, then all are implicated in the QC failure. For matrix spike failures, Tom stated that Lab Cert does not require samples to be qualified beyond the parent sample and that the matrix spike has zero effect on the other samples in the batch if the LCS passes. Alfredo stated that this allows reporting different types of pedigree data with eDMRs reporting BOD with GGA failures. RT indicated that he thought in a previous meeting that it was stated that for 1664 the MS/MSD was applicable for every sample in the run. Tom answered that he did not recall if that was correct, and if anyone found the source of this to send it to him and he will review the context.
- EPA methods with QC compliance reporting requirements where "*results may not be reported or used to demonstrate compliance*" are listed below. Note that this is only applicable to wastewater, and this list may not be conclusive.
    - ✓ Field blank failures: 245.7, 1631E, 1636
    - ✓ Method blank failures: 608.3, 624, 624.1, 625.1, 1613, 1631E, 1633, 1636, 1638, 1664A, 1664B, 1668C
    - ✓ MS/MSD failures: 245.7, 608, 608.3, 624, 625, 1631E, 1636, 1638, 1658, 1664A, 1664B, 1677
    - ✓ Analytical System (any QC) failures: 245.7, 624.1, 625.1, 1636, 1638, 1664A, 1664B
    - ✓ Labeled compound diluted out: 1613, 1633, 1668C
    - ✓ Qualitative identification criteria fail: 1613, 1668C

  Ronesha asked if this only applies to wastewater. Tom said that any program that requires use of these methods could be subject to this. In addition, there may be other methods that list similar requirements. RT said that all samples must be associated with a valid MS per EPA 1664B 9.3.4.2.

Tom said it does not make any sense to the program to apply matrix spikes failure qualifiers to samples other than the parent.

- Tom asked for final feedback from all. Paul stated that the proposed response from Lab Cert was good. Camille stated that the Wastewater program may not support this as they will be getting less data. Erin asked for more guidance to be provided to the labs as clients may be upset, and it would be helpful to have talking points and appropriate DNR contacts. Tom answered that client questions can be sent to Zana and Tom. Alfredo stated that if Lab Cert puts out a decision that is not in agreement with EPA, it puts the labs in a difficult situation and that Lab Cert will want to consider this, like with 1664. Tom said the Lab Cert program has no issues if the labs want to follow the method requirements – just that the program does not plan on enforcing them. Tom stated that Lab Cert will review the input from today's feedback and may ask EPA further questions, but we are not expecting a new opinion. Erin asked what to do when it may be a small WWTP that does not have the funds for an investigative research project. Tom answered that Lab Cert will address this when it happens. Zana stated that this is a starting point, and that Lab Cert will communicate with the lab community and the permitting community. Camille stated that labs will need to be taught that they can report when above the permitting limit. Tom said that is understood and we will provide information to them to this end.

- Council member issues
  - None.

- Guest issues
  - Paul wanted to further discuss last meeting's topic on not requiring matrix spikes for certain parameters. Paul stated that regardless of the methods used, 40 CFR 136.7 requires a precision assessment. Tom answered that Lab Cert will take this under advisement and prepare a more detailed response to our position on 136.7. Autumn stated that some of the language in 136.7 includes "where applicable" or "may not apply." Alfredo stated that the language does not release all QC measures and that there are certain tests where some apply, and if not, the lab is under obligation to prove why it wouldn't apply. Kristen stated that 1633 does not require MS/MSDs. Tom indicated that 1633 is an isotope dilution method so every sample is a MS/MSD, such that separate MS/MSDs are not necessary.

- Next meeting will be held January 21, 2025, at 9 am.