

## Laboratory Certification Standards Review Council Meeting Minutes From 2/10/2009

### Attendance

Council Members: David Kliber (Chair), Sue Hill (Vice-Chair), Steve Jossart (Secretary), Chris Groh, Randy Thater, Judy Tholen

DNR Staff: David Webb, Rick Mealy, Alfredo Sotomayor, Camille Johnson (via LiveMeeting)

Others in Attendance: Paul Harris (Davy Laboratories), Paul Junio (TestAmerica-Watertown), Kirsti Sorsa (Public Health Madison-Dane County Laboratory), Craig Martin (WE Energies), Tom Priebe (Northern Lake Service, via LiveMeeting)

### Summary and Action Items

At this meeting the Certification Standards Review Council:

- approved minutes of the November 12, 2008 meeting
- approved the fiscal 2010 budget package
- approved the fiscal 2010 fees
- reviewed program audit performance
- tentatively scheduled the Council's next meeting for Tuesday, May 5, 2009

### Agenda Items

#### **I. Check in/Agenda Repair**

- A. Council members added an agenda item for the annual election of officers.
- B. Dave Webb indicated that Camille Johnson would be appearing via Microsoft LiveMeeting to demonstrate the LiveMeeting software as an option for when travel to a meeting is difficult and to talk about the Lab-of-the-Year winners.

#### **II, Review and Approval of Draft Minutes from 11-28-07 Meeting**

- A. A motion to approve the minutes with minor typographical changes was unanimously approved (Thater/Hill).

#### **III. FY2010 Budget Presentation**

- A. Alfredo Sotomayor summarized the fiscal 2010 budget as follows:
  - ▶ As has been done historically, the program plans to spend significantly less (\$162K) than the DOA approved spending authority.
  - ▶ Salary and fringes comprise 88% of the budget and will only increase by 2.0%.
  - ▶ Supplies line item (10% of total budget) increases by 26.0%, largely due to the increased costs associated with travel (DOA vehicle charges increased last summer and have not decreased). A one-time charge of \$5,400 was assessed by DOA to maintain the fleet. Postage costs also increased by 21%.
  - ▶ The budget includes applying \$20,000 of the program's balance against next year's costs.
  - ▶ Total budget (\$677,166) is only \$26,500 over last year, a 4.08% increase.

***NOTE:** In early March 2009, one of the audit staff left the program, creating a vacancy. A revised budget was prepared for the final green sheet which was approved by the council. The revised budget assumes that the position will be vacant through the first six months of fiscal 2010, and thus 6 months of salary and fringe costs for the vacancy have been eliminated. Subsequently, the total budget was reduced to \$636,821 (- 2.1% from FY09). The Salary and Fringe line item of the budget was reduced to \$552,721(- 4.9% from FY09) All other budget line items remained unchanged from what was presented during the February meeting.*

- B. Steve Jossart asked about the one-time fleet charge of \$5,400. Sotomayor explained that every program in the Department will be assessed a similar charge. Dave Webb noted that he had discussed the increase at the previous council meeting. Audit staff use DOA fleet vehicles for most audits and the DOA fleet car rate doubled. Even though gas prices subsequently dropped, the fleet rate did not.

- C. Dave Kliber asked if the program could provide a budget variance report, showing actual funds expended vs. budgeted for a given line item, for the next Council meeting.
- D. Judy Tholen inquired about increasing the budget for staff training, which was discussed last year. Webb explained that realistically, there is only one “pot” of money split into salary and non-salary. With the audit workload and all, he’s comfortable with leaving the amount at \$5,000.
- E. Dave Kliber asked what happens if the program spends under its budgeted amounts. Webb explained that the program’s appropriation status is “continuing”, which means that unspent funds carryover into the next fiscal year. The program has maintained a balance.
- F. Kliber then followed up by asking about the opposite scenario—what would the program do if it had to exceed its budget. Webb responded that this scenario would be difficult to encounter as 90% of the budget is salary, a fixed cost. It’s actually more likely that the program would under-spend due to a vacancy (e.g., the Pils and Howald vacancies).
- G. Kliber also asked if Webb had given any thoughts about dealing with the postage increase problem by perhaps going more electronic. Webb indicated that the program has been steadily moving towards more electronic communications, such as the Status Update Applications last summer and more recently a move to send most audit reports electronically.
- H. A motion (Thater/Jossart) to approve the budget passed unanimously.

#### IV. FY2010 Accreditation Fee Adjustment

- A. Alfredo Sotomayor summarized the fiscal 2010 budget as follows:
  - ▶ Using NR149 fee formula, the key value is a cost per RVU of \$61.00, a 10.3% decrease from last year (\$68.00/RVU). This is due to the increased number of RVUs associated with the accreditation structure changes and new RVU assignments from NR 149 revisions.
  - ▶ The fee for a typical WWTP lab will be \$1,037 (vs. \$952); the fee for a typical commercial lab will be \$4,575 (vs. \$4,012); the maximum fee that could be charged is \$6,100 (vs. \$9,044).
  - ▶ The maximum fee reflects a cap charge of 100 RVU, regardless of how many RVUs a lab is actually certified for based on technologies. This means that a large lab that performs a lot of technologies will see some savings. Conversely, labs that do minimal testing will see a reduction in their fees.
  - ▶ The total number of RVU increased to 10,468 (16.2%) from 9002 last year.
  - ▶ Our fees compare favorably to those of other states. A full comparison chart will be provided in the green sheet package for the Natural Resources Board (NRB).

**NOTE:** *In early March 2009, one of the audit staff left the program, creating a vacancy. A revised budget was prepared for the final green sheet which was approved by the council. This change to the budget results in a reduction in the cost per RVU to \$57.50. The FY2010 fees for a typical wastewater lab, typical commercial lab, and maximum fee will now be \$977.50 (2.7% increase), \$4,312.50 (7.5% increase), and \$5,750.00 (36.5% decrease), respectively.*

- B. Sotomayor indicated that there was a reduction in the number of labs from 420 to 413 this year. He added that we are aware that when labs completed the Status Update Form last summer, most checked off every test for which they were eligible. The program believes that with fees this year, labs may revisit those decisions and withdraw from some of the testing.
- C. Kirsti Sorsa asked how much of the budget is supported by fee revenues. Sotomayor responded that essentially the program is 100% fee funded. This year \$20,000 of program surplus revenues were used to reduce the impact on fees. He added that, as is typically the case, the program budget falls well below the DOA approved “spending authority” of \$798,600, the amount that DOA authorizes the program to spend.
- D. Randy Thater asked how much of a rolling balance the program maintains. Dave Webb responded that the current balance is \$110,000, which leaves \$90,000 after applying \$20,000 against the budget for fiscal 2010. Sotomayor added that over the next 3 years, the program projection is to reduce the balance to about \$20,000.
- E. Craig Martin asked if the program could exceed the \$20,000 if necessary. Webb responded that fees are tied directly to the budget, so they are somewhat hard-coded. The program could, however, theoretically overspend by as much as \$90,000 and still be fine.
- F. Dave Kliber asked if this mean that the program could come to the council with a revised budget and make changes. Rick Mealy responded that administrative code and statute only allow the program to establish fees once each year, so we have to essentially work within our budget.

- G. A motion (Hill/Groh) to approve the fees passed unanimously. Dave Kliber, Sue Hill, Steve Jossart, and Dave Webb all signed a resolution to be passed on to the Natural Resources.

**V. Council Officer Elections**

- A. A motion was made (Tholen/Groh) to retain the current suite of officers. The vote was unanimous.

**VI. “Lab of the Year” Awards**

- A. Camille Johnson announced that the Spencer Wastewater Treatment Plant was selected as the Small Registered Lab of the year and the Sheboygan Wastewater Treatment Plant was selected as the recipient of the Large Registered Lab of the Year.
- B. Johnson indicated that six (6) nominations were submitted for the small lab category and four (4) for the large category. Tom Trainor and Ron Arneson generated the rankings of candidate lab nominations as neither had nominated a facility.
- C. Sue Hill asked what kind of things the program considers as part of the selection process. Johnson explained that while the process was somewhat open-ended, we are looking for labs that are going beyond minimum compliance. Typically, winners can be characterized as having minimal deficiencies in a recent audit and are doing a stellar job in many areas. On one occasion, however, an award was made to a laboratory that had received a Notice of Non-compliance in its previous audit yet responded by making drastic permanent improvements in their protocols and documentation. Johnson added that all nominees receive a certificate of achievement recognizing their nomination. The winning labs are presented with a plaque by the DNR Secretary at the March Natural Resources Board meeting.
- D. Johnson indicated that the program was looking for more input from the council regarding the selection process. The program is looking for some assistance as we revise the nomination form; refine the process, and perhaps some involvement in the selection process. Dave Webb added that the program has tried to have some structure without over-engineering things. Ron Arneson is very familiar with the program and Tom Trainor provides direct, recent program experience.
- E. Dave Kliber suggested that the council as advisors could perhaps add some objectivity to the process and that it would be beneficial to have a council representative involved. Sue Hill stated that she would be interested in providing input to the process and help review the award criteria.

**VII. Program Audit Status Report- for FY09 Year-to-Date**

- A. Rick Mealy presented Council members with program audit statistics and backlog information. He noted that, with about 58% of the fiscal year completed, the regional labs are at about 50-55% of annual goals, or well on pace. The labs designated as “central office” have made good progress in terms of the number of audit reports generated and cases closed (55% and 45% of annual target, respectively) but are bit behind the pace in the number of audits conducted (34% of goal).

**FY2009 Cumulative Totals**

|             | CENTRAL OFFICE |       | REGIONAL  |       |   |
|-------------|----------------|-------|-----------|-------|---|
|             | Total YTD      | Goals | Total YTD | Goals |   |
| Audits      | 13             | 38    | 53        | 100   | <i>(Goals based on audit every 3 years)</i> |
| Reports     | 21             | 38    | 54        | 100   |   |
| Closures    | 17             | 38    | 57        | 100   |   |
| Reports Due | 4              |       | 7         |       |   |
| Open Cases  | 29             |       | 48        |       |   |

## FY2009 Quarterly Totals

| 1st Quarter | 2nd Quarter | 3rd Quarter | 4th Quarter |
|-------------|-------------|-------------|-------------|
|-------------|-------------|-------------|-------------|

### CENTRAL OFFICE

|          |   |    |   |  |
|----------|---|----|---|--|
| Audits   | 5 | 6  | 2 |  |
| Reports  | 3 | 15 | 3 |  |
| Closures | 9 | 7  | 1 |  |

|                 | AUG | NOV | FEB | MAY |
|-----------------|-----|-----|-----|-----|
| Pending Reports | 15  | 16  | 4   |     |
| Open Cases      | 37  | 30  | 29  |     |

### REGIONAL

|          |    |    |   |  |
|----------|----|----|---|--|
| Audits   | 20 | 27 | 6 |  |
| Reports  | 19 | 29 | 6 |  |
| Closures | 29 | 22 | 6 |  |

|                 |    |    |    |
|-----------------|----|----|----|
| Pending Reports | 9  | 12 | 7  |
| Open Cases      | 45 | 51 | 48 |

| <u>Total Labs by Responsibility</u> |                       | <u>2/1/09</u> | <u>11/1/08</u> | <u>5/1/08</u> | <u>11/15/07</u> | <u>8/1/07</u> |
|-------------------------------------|-----------------------|---------------|----------------|---------------|-----------------|---------------|
| <b>CO</b>                           | <b>Central Office</b> | <b>109</b>    | <b>109</b>     | <b>110</b>    | <b>113</b>      | <b>118</b>    |
| RC                                  | Regional/Central      | ----          | ----           | ----          | ----            | ----          |
| NE                                  | Northeast             | 62            | 62             | 65            | 65              | 66            |
| NO                                  | Northern              | 29            | 29             | 31            | 31              | 31            |
| WC                                  | West Central          | 60            | 60             | 62            | 61              | 61            |
| SC                                  | South Central         | 75            | 74             | 75            | 75              | 75            |
| SE                                  | Southeast             | 69            | 69             | 69            | 69              | 69            |
| <b>Total Regional</b>               |                       | <b>295</b>    | <b>294</b>     | <b>302</b>    | <b>301</b>      | <b>302</b>    |
| <b>Total Audit Responsibility</b>   |                       | <b>404</b>    | <b>412</b>     | <b>414</b>    | <b>420</b>      | <b>423</b>    |
| O                                   | Other/Reciprocity     | 8             | 8              | 7             | 7               | 8             |

**B.** Mealy also noted the following aspects of the program data:

- ▶ As a result of applications, there are two new "Central Office and two new "regional" labs. New labs require an audit within 90 days of a completed application which can add to the backlog.
- ▶ While the backlog history indicates that the central office allocated labs are behind the pace, there is enough room in terms of audits due in fiscal 2010 to allow the program to catch up barring any personnel changes.
- ▶ The program is beginning to see a second round of labs opting to withdraw completely (Sensient Flavors, Little Rapids Corp-Shawano Specialty Papers) or withdraw certification for specific analyses.
- ▶ 76% (32 of 42) of all reports for audits performed after 9/1/08 were released within 30 days of the on-site evaluation.

**C.** Noting the growing number of open cases, Dave Kliber suggested that the program may need to establish a metric similar to that adopted by the FDA. Kliber suggested that the program could publish a top 5-- or top 10-- list of reasons why audits remain open for extended periods of time. The thinking is that labs could focus on these issues prior to the actual on-site evaluation. Kliber added that Webb had mentioned at the previous council meeting lack or poorly developed Quality Manuals and SOPs are two of the most common deficiencies being identified by auditors.

Dave Webb stated that there are three areas common enough to broadcast: Quality Manual (insufficient detail), SOPs (lacking detail or not available), and IDCs (not performing or not documenting). Camille Johnson agreed and added that, for larger labs, often the deficiencies are so intricately detailed that they wouldn't fit a "common" deficiency list.

Dave Kliber asked how often auditors find that a given lab has SOPs but has not implemented (or does not follow) them. Johnson responded that most labs have SOPs but they are either not current, or lack critical detail. Webb added that he frequently sees deficiencies indicating that a lab is either not doing something which appears in the SOP or is doing something which does not appear in the SOP.

- D. Webb offered the following six general reasons (in no specific order) that cause an audit to remain open for extended periods:
- ▶ Lab staff turnover (more common in small WWTPs; steep learning curve for the new analyst)
  - ▶ Non-responsiveness to report (simple procrastination in many cases)
  - ▶ Insufficient response to a deficiency (not necessarily intentional)
  - ▶ Enforcement (even an NON can cause a delay)
  - ▶ Custom response (usually larger labs; auditor asks "Why are you doing \_\_\_\_?" resulting in a dialog between auditor and the lab to resolve the concern: "What if we did \_\_\_\_\_? Would that be acceptable?")
  - ▶ LabCert workload (everything is a priority. Rightly or wrongly, we tend to lean heavier on getting audits performed and reports generated).

Webb concluded by saying that he feels strongly that the new NR 149 will help to address these issues. It's bigger and seems more complicated, but it adds clarity. Labs just haven't had enough time to work with it yet.

- E. Kliber commented that these are good metrics; they provide the program with something to grasp and the council something to discuss. Webb noted that there is a great deal of turnover and auditor observations suggest that there is insufficient transfer of critical information to incoming staff. It often becomes a delicate balance of helping as much as we can, but there is a point beyond which we can't help anymore.
- F. Sue Hill commented that it is great to see so many reports generated in November, December, and January. Noting that the data clearly reflects a lot of effort involved, she asked what measures were taken to facilitate the improvement and asked if the program could maintain it. Webb responded that he elevated the priority. He added that during winter months, travel becomes more difficult, allowing time to work on reports. Webb hopes not to have this kind of bubble in the future and intends to sustain this level of priority.
- G. Noting that 76% of reports issued within 30 days is considered "good", Dave Kliber asked what the practical goal was for complying with new requirement. Webb responded that expecting 100% is unrealistic but he expects to be at 90% or greater. Sue Hill commented that the goal should be 100%.
- H. Randy Thater stated that he is aware of a lab with a case that has been open for some time. He indicated that, for the lab, the issues have totally fallen off their radar screen, so to speak. The lab assumes that they have done what they need to do. Thater wondered whether, if not a formal closure, maybe a check-in is in order to see what's going on.
- I. Steve Jossart offered the other side of the coin, stating that his lab was audited on a Tuesday and had the report by that Friday. Dave Kliber agreed that we need to emphasize these positive aspects of the program. Jossart added that it makes sense to issue the report quickly while things are still fresh in your mind. Paul Junio added that his lab was audited in October and between the audit and when they got the report, he was able to supply the auditor with what they needed. Subsequently, when he received the audit report, the evaluation was completed.
- J. Judy Tholen asked how an auditor decides what the sequence of labs to audit. Camille Johnson responded that auditors have their assignments for a given fiscal year. Speaking for herself, she explained that she often schedules lab audits closer to her home base during winter months when travel becomes more difficult and then extends the range to cover labs further away during months when the weather is better.

### VIII. Other Program & DNR Business

- A. E-Reports – Webb informed the Council that the program is looking to submit audit reports electronically to labs. Conceptually, this sounds easy, but there are numerous details to work out, such as:
- ▶ How does the auditor sign the report?. With a scanned signature? E-sign?
  - ▶ How do we ensure the report is unalterable? Do we place electronic security on it?
  - ▶ In what format do we send it? PDF? Word document?

One of the biggest concerns is that a clerk at the town or city hall intercepts the report and it never actually gets to the laboratory. So, essentially, the auditor needs to work with the laboratory upfront and communicate the intent to submit an e-report, establish how that will be accomplished, and then follow-up with the lab to ensure that the report was received. If a laboratory simply prefers a hard-copy version, we can offer that as well. Kirsti Sorsa asked if labs should respond to reports via hard-copy or electronically. Webb responded that either approach is acceptable.

- B. No Rent Costs – Webb informed the Council, that while the fleet cost increase was significant, the program is not assessed rent for its downtown offices. The program does, however, reimburse the regional offices a fixed amount to offset cost associated with office space for Camille, Tom, and John.
- C. Increased interest in Operator Certification – Webb noted that the Operator Certification Program, one of 5 programs supervised by Webb, has seen a significant increase in contacts inquiring about certification.
- D. NR 219 Revision – Webb updated the Council on this rule; it's not yet law, but it is over at the legislature and in the queue.
- E. NR 528 (new rule, covered program under NR 149) – Paul Junio commented that Jack Connelly and Tom Portle spoke about NR 529 at the WELA meeting last week. The language just needs some final tweaking. In cases of landspreading of the sediments, testing may be able to be completed at a soils lab.

### IX. Council Member Issues

- A. Paul Junio asked when the next edition of LabNotes would be coming out. Rick Mealy responded that an issue is currently in progress and a spring release is planned.
- B. Randy Thater asked if any training had been scheduled. Mealy responded that a talk regarding a 6-month review of NR 149 and a workshop on the new Operator Certification Lab Study Guide were submitted for the WWOA conference.
- C. Tom Priebe asked when updated certified lab lists would be available on the website. Mealy responded that with changes to NR 149, some re-coding was required to produce the list and that is in progress.
- D. Tom Priebe asked if LabCert would still provide assistance now that the issue of reporting non-target compounds has been delegated back to the program. Mealy and Webb assured him that LabCert will assist as we are able.
- E. Tom Priebe asked about the certification for PCBs in drinking water by 505/508. Mealy responded that the Drinking Water/Groundwater programs and LabCert have to make a joint decision to offer that certification. Certainly, the NR809 and the Federal Register support the ability of a lab to be certified to screen PCBs without performing the perchlorination technique (508A). Mealy noted that historically labs have not been able to meet the requisite detection limits for the individual Aroclors. This is why the drinking Water program has required that method 508A be used exclusively for PCBs.

### X. Next Meeting Date

- A. The next Council meeting was tentatively scheduled for Tuesday, May 5, 2009 at the State Laboratory of Hygiene.