



## Laboratory Certification Bulletin, January 2002

## TABLE OF CONTENTS

LabCert Bulletin.....	3
Editor's Notes.....	3
Confusion Regarding the "80% Rule" .....	3
Welcome Info .....	4
Highlights from NELAC 7 .....	4
NELAC Quality Systems .....	5
NELAC On-site Assessment Committee .....	7
New Contact for USEPA Laboratory ID Numbers .....	7
Certification Changes .....	8
Certification Alert Stage 1 DBP Rule Effective January 2002 .....	8
PT Data Reporting Guidance.....	9
Micro Proficiency Testing Studies .....	9
Radiological PT Samples Now Available .....	10
Fax It To Us.....	10
Websites.....	10

# LabCert Bulletin

EPA 815-N-02-001a

January 2002

## ***Editor's Notes***

This issue of the Labcert Bulletin highlights NELAC with articles written by Silky Labie, the current Chair of the NELAP Board of Directors, and the Chairs of the On-Site Assessment Committee and the Quality Systems Committee. Contents of these articles are entirely the authors', printed here as information. Articles about some of the other Committees were featured in the March, 2001 Labcert Bulletin.

There is also information on new contaminants for which certification is required, new PT acceptance criteria for THMs, other Proficiency Testing requirements, and a list of helpful web sites.

As always, we want to hear from you. If there are certification topics you would like to see discussed, please call, write, fax or e-mail the editors. There is a form on the last page for you to use to add your name to our mailing list or to update your information.

Ed Glick 513 569-7939, [glick.ed@epa.gov](mailto:glick.ed@epa.gov)

Patricia Hurr 513 569-7678, [hurr.pat@epa.gov](mailto:hurr.pat@epa.gov)

Caroline Madding 513 569-7402, [madding.caroline@epa.gov](mailto:madding.caroline@epa.gov)

### MAILING ADDRESS:

U.S. Environmental Protection Agency  
Technical Support Center (MS-140)  
26 W. Martin Luther King Drive  
Cincinnati, OH 45268

### FAX NUMBER:

513 569-7191

## ***Confusion Regarding the "80% Rule"***

We have received numerous questions regarding the "80% Rule" for passing PT samples. This Rule applies to two classes of analytes, volatile organic compounds (VOCs) and the five regulated haloacetic acids (HAA5).

Realizing that successfully analyzing a PT sample containing all VOC analytes annually is difficult, EPA allows the laboratory leeway in the analysis of the VOC PT samples. Excluding vinyl chloride, if the laboratory passes 80% of the VOC analytes, it can be certified for all of the VOCs. The "80% Rule" for VOCs has recently been made more difficult to interpret since some

PT providers may include THMs in the same vial as the VOCs. The "80% Rule" does not apply to the THMs if they are present in the VOC ampule. THMs must be acceptably analyzed individually (see DBP Rule article on p.5) in order to be certified to perform TTHM analyses.

In the Stage 1 DBP rule, which becomes effective in January 2002, the "80% Rule" applies to the HAA5 certification requirement. If four of the five haloacetic acids which comprise HAA5 (80%) are successfully analyzed, the laboratory may be certified to perform HAA5 analyses.

## ***Welcome Info***

It is no longer a Federal requirement to monitor for the unregulated VOCs or to analyze PT samples for these analytes. This requirement was removed when the UCMR was signed on September 17, 1999.

## ***Highlights from NELAC 7***

by Silky S. Labie, Chair, NELAC Board of Directors

The weather was mild and sunny, and Salt Lake City was beginning to roll out the Red Carpet for the Winter Olympics. NELAC 7, hosted by the Utah Department of Health, could not have had a better setting.

The revisions to the NELAC standards can be roughly categorized as: fixes, clarifications, and major direction changes.

Fixes: These revisions were designed to "fix" something in the standard, whether it was to close loop holes, or help resolve inconsistencies of the NELAP implementation process: The revisions

- Provide specific circumstances under which a technical director can be grandfathered in. (Chapter 4).
- Outline the manner in which differing standard interpretations will be resolved. (Chapter 6).
- Provide comprehensive requirements for the content of general and technical assessor training courses (Chapter 3).
- Require that the NELAP assessment team observe the techniques used by the Accrediting Authority during an on-site audit. (Chapter 6).

Clarifications: These revisions were made to clarify or simplify existing standards, with no significant changes:

- Refined and simplified Appendix D.1., Chemical Quality Controls and Appendix D.3., Microbiological Quality Controls (Chapter 5).

Major Changes in Direction: These revisions will have a significant impact on how NELAP is implemented:

- Fields of Accreditation were changed from Program-Method-Analyte to Matrix-Technology.Method-Analyte/Analyte Group (Chapter 1).
- The Fields of Proficiency Testing were also changed to reflect to changes in Chapter 1: matrix-technology-analyte/analyte group (Chapter 2).

Conferees came to NELAC 7 with questions about EPA's continuing support. They left with the knowledge that EPA has negotiated a 5-year contract at the present level of funding to support NELAC, and that EPA has applied for recognition as a NELAP Accrediting Authority.

Further, the conferees found that NELAC was responsive to the criticisms and anxieties about inconsistencies among NELAP Accrediting Authorities by developing standards, and implementing many proactive programs designed to minimize their concerns.

A majority of the standard revisions were minor corrections that did not alter the intent of the standard. NELAC can finally settle down to focus on implementation and encouraging more states to join the NELAC community.

More information on NELAC may be found at the NELAC website: <http://www.nelac-institute.org/>.

## ***NELAC Quality Systems***

by Scott D. Siders, Illinois EPA, Springfield, IL  
Past Chair, NELAC Quality Systems Committee

The National Environmental Laboratory Accreditation Conference (NELAC) at its annual meeting (NELAC 7) which was held May 22 - 25, 2001 in Salt Lake City, Utah, adopted proposed changes to the Quality Systems standard. At the Interim Meeting (NELAC 6i) in November 2000 the NELAC 7 Quality Systems Committee:

- discussed the efforts to update the Quality System standard to the new international standard (ISO/IEC 17025);
- reviewed the Environmental Laboratory Advisory Board's (ELAB) proposed changes to the Chemical Testing section;
- presented proposed changes for the Microbiology Testing section; and
- reviewed its efforts to draft an Asbestos Testing Appendix.

A significant new direction was taken based on ELAB's presentation of a Performance-Based Measurement System (PBMS) straw model. The Committee, at the urging of other NELAC stakeholders, formed a PBMS Subcommittee to review the PBMS straw model and further investigate incorporating PBMS into NELAC.

At NELAC 7, there was overwhelming support for the Quality Systems standard to be consistent with ISO/IEC 17025 in both content and format. Some significant additions and/or changes to the standard would be sections on:

- Identification of potential conflicts of interest
- Service to clients
- Preventive action
- Corrective action
- Method validation
- Measurement uncertainty
- Document control
- Requests, tenders and contracts

Further, the proposed revisions to the Quality Systems standard will include the sections that the PBMS Subcommittee is modifying. ELAB's PBMS straw model brought two key concepts to the table:

- Method selection; and
- Method validation.

To address the PBMS straw model concepts/elements the following sections of the model are important areas to revise:

- Test methods and standard operating procedures;
- Calibration;
- Demonstration of capability; and
- Chemical testing.

As a result, the PBMS Subcommittee has essentially completely rewritten sections of the Quality Systems standard, which will be discussed at the next Interim Meeting in December. The Quality Systems Committee is currently reviewing and commenting on the PBMS Subcommittee's most recent proposal. This proposal has, at its core, language for method selection and validation including:

- A proposed model for initial method validation based upon representative matrices;
- Ongoing method validation steps to determine and document sources of uncertainty relating to actual samples and system influences.

The PBMS Subcommittee is currently, among other things, considering whether a "tiered" approach to method validation should be considered, differentiating between EPA-mandated methods and alternative methods.

Again, at NELAC 7 the Quality Systems Committee's ISO/IEC 17025 integration effort and the PBMS Subcommittee's efforts were presented publicly for the first time during a special session, as these two issues were not put to a vote. A straw poll revealed broad support for the full integration of ISO/IEC 17025 by all NELAC stakeholders (i.e., states, federal agencies, and the private sector).

The Quality Systems Committee included on the NELAC voting agenda changes to microbiology testing and ELAB's recommendations on chemical testing. These proposed

changes were adopted with minor modifications (e.g., Method Blank Criteria). The final 2001 standards are posted on the NELAC Homepage website at: <http://www.nelac-institute.org/>.

## ***NELAC On-site Assessment Committee***

by Alfredo Sotomayor, On-site Assessment Committee Chair

Certification and inspections, accreditation and on-site assessments, in NELAC parlance, are linked inextricably. It has been said that an accreditation program is only as good as the laboratory assessments it delivers. The On-site Assessment Committee is responsible for generating procedures that Accrediting Authorities (AA) use to perform on-site assessments. Through Chapter 3, the committee specifies such essentials as the frequency, mechanics, and documentation of assessments, and establishes qualifications for laboratory assessors. The On-site Assessment Committee is also responsible for generating and maintaining the NELAC Quality Systems (Chapter 5) Checklist.

At the last NELAC Annual Meeting (May 2001), the conference approved for immediate implementation two appendices in Chapter 3 that identify the content of training courses for laboratory assessors. Appendix A specifies the minimum standards for NELAC Basic Assessor Training Courses, while Appendix B does the same for Technical Training Courses. NELAC and the National Environmental Laboratory Accreditation Program (NELAP) themselves cannot offer training courses, but now that the appendices are approved, providers should start designing and marketing courses that can be used to meet NELAC training requirements for assessors.

The On-site Assessment Committee is currently drafting another appendix that specifies elements that all AAs will need to address in a Standard Operating Procedure (SOP) for planning, conducting, and closing laboratory assessments. We will present a second draft of this appendix for discussion at the next interim meeting in December. We envision that this appendix will give more specificity to the activities assessors use and the type and number of records examined to assess a laboratory's conformance to the NELAC Standards.

EPA has acknowledged that a state can meet the primacy requirements of the Safe Drinking Water Act (SDWA) regulations by obtaining NELAP recognition in the NELAC SDWA tier. As EPA makes progress in becoming an AA, the Committee will explore ways of formalizing the equivalency between SDWA laboratory certification audits and NELAC laboratory on-site assessments. The Committee welcomes your comments on Chapter 3, or any issues related to laboratory on-site assessments. Use the form posted on the NELAC website and send it electronically to [sotoma@dnr.state.wi.us](mailto:sotoma@dnr.state.wi.us).

## ***New Contact for USEPA Laboratory ID Numbers***

Effective April 1, 2001, Charles Feldmann, Office of Ground Water and Drinking Water, Technical Support Center, is the primary contact for assignment of new laboratory IDs for the PT studies. He may be reached by phone at 513-569-7671 or by FAX at 513-569-7191.

- 1) If the laboratory has ever participated in an USEPA-run study, the laboratory will already have a unique ID. Please review any previous "study results" report to locate the ID number.
- 2) If a laboratory cannot locate this information, the laboratory should contact Mr. Feldmann for assistance.
- 3) Laboratories must include this information when reporting PT results.

### ***Certification Changes***

On December 1, 1999 EPA published a final rule often referred to as MUFNR II (Methods Update Federal Register Notice II) in the Federal Register (64 FR 67450). In addition to approving several updated or new drinking water methods for chemical and microbiological contaminants, the Rule amended some laboratory certification requirements.

Specifically, the Rule amended the regulations to codify some of the provisions in the 1997 Drinking Water Laboratory Certification Manual. These amendments include a requirement to demonstrate proficiency by successful analysis of a PT sample annually for chemical contaminants using the same analytical method that is used to report compliance monitoring results. In order to receive and maintain certification for an analyte, the laboratory must successfully analyze PT samples (if available) acceptable to the EPA or the State at least once per year for each analyte and by each method used to analyze compliance samples. This does not include methods used solely for confirmation.

Because of this requirement, we are requesting that Certifying Authorities list on the certification certificate or a letter attached to the certification certificate, the methods and each analyte in that method for which the laboratory is certified.

### ***Certification Alert Stage 1 DBP Rule Effective January 2002***

The Stage 1 Disinfection By-Product (DBP) Rule, which was promulgated in December 1998, became effective for large surface water systems in January 2002 and all laboratories should be certified by this date to analyze HAA5, chlorite and bromate.

The Rule lowers the MCL for TTHMs to 0.080 mg/L and sets the MCL for HAA5 at 0.060 mg/L. Haloacetic acid 5 is the sum of the concentrations of five haloacetic acids (HAA5): monochloroacetic acid, dichloroacetic acid, trichloroacetic acid, monobromoacetic acid and dibromoacetic acid. It also sets MCLs of 0.010 mg/L for bromate and 1.0 mg/L for chlorite.

The Rule requires that laboratories be certified to perform these analyses for compliance monitoring. To be certified, the laboratory must annually pass PT samples for these analytes. The "80% Rule" applies to the HAA5, so if four of the HAA5 are successfully analyzed, the laboratory may be certified for all of the HAA5. A laboratory should not be certified for an analyte if it fails 3 consecutive PT studies.

Trihalomethane PT acceptance criteria also changed when the DBP Rule became effective in January 2002. In the past, a laboratory reported the total THM concentration in the PT sample, and passed the PT if the value reported was within  $\pm 80\%$  of the true value. Under the DBP Rule, each THM concentration must be reported, evaluated and passed individually to pass the PT sample. The DBP Rule also states that if a laboratory fails one THM, it cannot be certified for TTHMs, but must analyze another PT sample and pass all four of the THMs to be certified to analyze compliance monitoring samples for total trihalomethanes. Laboratories must use EPA Methods 502.2, 524.2, or 551.1 to analyze for THMs. Methods required for analysis of HAAs are EPA 552.1 or 552.2 or SM 6251B (552.2 is recommended over 552.1). Laboratories must use EPA Methods 300.0 or 300.1 to determine chlorite and Method 300.1 to determine bromate.

The DBP Rule also requires that water systems monitor for TOCs. The regulation requires the TOC analyses be performed by a party approved by the State. This is the same language that has been used in the past for other non-MCL requirements such as pH, turbidity, alkalinity, etc. Standard Methods 5310B, C or D must be used.

### ***PT Data Reporting Guidance***

In order for the providers to process the studies properly and more efficiently, please follow the guidelines below when reporting your PT results.

Always fill out form correctly and completely. Include the laboratory name, address, contact person and the unique EPA laboratory ID code. Procedures for finding and/or getting a unique laboratory code are explained on page 5.

If the laboratory is analyzing a subset of the contaminants in a PT sample, only enter data in the report field when that contaminant is being analyzed. That is, if you do not want to report or be evaluated for a contaminant, leave that data field blank.

If you want to be assessed for a contaminant but determine that it is not present, use a  $<$  value with your minimum reporting level (MRL) or your method detection limit (MDL) whichever the laboratory prefers. The NELAC PT committee is developing a list of PT reporting limits, which a laboratory may use and be confident that the value is lower than the acceptable range for PT samples. Never report a zero or an alpha character in the data field.

### ***Micro Proficiency Testing Studies***

What is Considered Proper Analysis?

Each microbiology performance test (PT) consists of ten samples to be analyzed as a single PT sample set. These are shipped in either lyophilized, dehydrated, or aqueous condition. Each PT sample set should be analyzed using one method only, i.e., by either the Membrane-Filtration (MF), Presence-Absence (P-A), or a Chromogenic/Fluorogenic method. Each of the ten samples must be analyzed and reported for the presence or absence of total coliform bacteria, and then for the presence or absence of fecal coliform/E. coli bacteria. Each set is randomly composed of samples that are: 1) total coliform absent, fecal coliform/E. coli absent, 2) total coliform present,

fecal coliform/E. coli absent, 3) total coliform present, fecal coliform/E. coli present, and 4) blanks.

Acceptable performance for the analysis of total coliform bacteria requires the correct analysis of a minimum of 9 out of the 10 samples, with no false negative reported values. Acceptable performance for the analysis of fecal coliform/E. coli bacteria requires the correct analysis of a minimum of 9 out of the 10 samples, with no false negative reported values. In other words, one false positive may be reported for each analyte. The PT provider will issue a report indicating the acceptable performance for the analysis of total coliform bacteria and the acceptable performance for the analysis of fecal coliform/E. coli bacteria, utilizing one technology. The PT sample set may not be split, in any manner, to run more than one technology.

### ***Radiological PT Samples Now Available***

Radiological performance testing samples are now available from a NIST approved provider. All laboratories wishing to maintain certification for these parameters should successfully analyze one set per year. If the alpha emitters and a mixed group of the other regulated contaminants are analyzed, that should suffice as a complete set.

### ***Fax It To Us***

Please add/change (circle one) my name to the Labcert Bulletin mailing list.

Name:

Company:

Address:

Telephone:

Fax #:

Fax to:

Susan Hagedorn

U.S.Environmental Protection Agency

Technical Support Center (MS-140)

26 W. Martin Luther King Drive

Cincinnati, OH 45268

513-569-7191

### ***Websites***

An electronic version of this publication and more can be found on the Office of Ground Water and Drinking Water website:

<http://www.epa.gov/safewater/methods/laboratorycertification.html>.

This site also has information about drinking water regulations and laboratory certification. The "Manual for the Certification of Laboratories Analyzing Drinking Water," the errata sheets for this manual, and past issues of the Labcert Bulletin can all be found at this address.

Other websites that you may find useful are:

<http://www.epa.gov/safewater/methods/laboratorycertification.html> lists state certification contacts for every state and also gives links to lists of state laboratories certified for drinking water analyses. There are links for those states, which have electronic lists of their certified laboratories;

[www.nelac-institute.org/](http://www.nelac-institute.org/) This site contains the NELAC Standards, lists NELAC Accrediting Authorities and accredited laboratories, and has information about past and future NELAC meetings.

<http://ts.nist.gov/Standards/Accreditation/index.cfm> lists NIST-accredited PT providers.

[www.epa.gov/safewater/regs.html](http://www.epa.gov/safewater/regs.html) You can find drinking water regulations at this site.

[www.epa.gov/safewater/methods/index.html](http://www.epa.gov/safewater/methods/index.html), lists all promulgated methods and contains copies of some methods.

[www.epa.gov/quality/](http://www.epa.gov/quality/) This is the EPA Quality Staff's home page and all EPA Quality Documents and requirements can be found at this website as well as available QA training and information about the annual EPA QA meeting.