United States Environmental Protection Agency

Supplement 1 to the Fifth Edition of the Manual for the Certification of Laboratories Analyzing Drinking Water

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Quality Management System
Supplement to: Chapter III Implementation
2. Requirements for Certification of Laboratories

Laboratories performing analysis of drinking water under the Safe Drinking Water Act (SDWA) are required to operate a formal Quality Control program. Laboratories should also have a formal Quality Management system documented and in place. Programs that operate in accordance with International Organization for Standardization (ISO) 9001, particularly ISO/IEC 17025 (*General Requirements for the Competence of Testing and Calibration Laboratories*), are encouraged. ISO/IEC 17025 includes both quality management requirements (based on ISO 9001) and a number of technical requirements specific for testing and calibration laboratories. ISO documents can be purchased from ISO (www.iso.org) or through other organizations, such as the American National Standards Institute (ANSI) (www.ansi.org). In the Unites States of America (USA), ANSI is the ISO member body and ANSI-ASQ National Accreditation Board (ANAB) is the accreditation body for management systems. Numerous organizations can issue third-party laboratory accreditation according to ISO 17025.

The NELAC Institute (TNI) (www.nelac-institute.org), formerly known as the National Environmental Laboratory Accreditation Conference (NELAC), implements an accreditation program with a Quality Management approach that is based on ISO/IEC 17025; the TNI program has also integrated SWDA-based requirements from the drinking water program into its standards.

Certification Officer Fraud and Ethics Training
Supplement to: Chapter III Implementation
3. Individual(s) Responsible for the Certification Program

All Certification Officers (COs) are encouraged to participate in fraud detection and ethics training, where available. As stated in *Promising Techniques Identified to Improve Drinking Water Laboratory Integrity and Reduce Public Health Risks* (Report No. 2006-P-00036, U.S. Environmental Protection Agency (EPA), Office of Inspector General (OIG), Washington, D.C., 2006) (www.epa.gov/oig/reports/2006/20060921-2006-P-00036.pdf), use of the following promising techniques is encouraged, as appropriate:

- Enhance on-site and follow-up audits to include techniques to identify and deter inappropriate procedures and fraud;
- Review raw electronic data and use electronic data analysis/tape audits;
- Review inventory of laboratory supplies; and
- Conduct data accuracy reviews.

Laboratory Ethics and Fraud Detection/Deterrence
Supplement to: Chapter III Implementation
New Section

Laboratories are encouraged to have an ethics policy and implement a fraud detection and deterrence policy/program, including use of the following, as appropriate:

- Use data validation and verification techniques; and
- Use analyst notation and sign-off on manual integration changes to data.

Four key areas of concern were listed in the OIG report referenced above. These include:

1. **Inappropriate procedure:** A scientifically unsound or technically unjustified omission, manipulation, or alteration of procedures or data that bypasses the required quality control parameters, making the results appear acceptable.
2. **Laboratory fraud:** The deliberate falsification during reporting of analytical and quality assurance results that failed method and contractual requirements to make them appear to have passed requirements.
3. **Data quality:** The degree of acceptability or utility of data for a particular purpose – in this case, reporting public drinking water sample information.
4. **Laboratory integrity:** The laboratory's meeting general standards of objectivity, data quality, and ethical behavior, thus reporting accurate, complete, and valid information.

If a laboratory employee suspects that fraudulent behavior is occurring, they should follow reporting procedures established by their State; States should communicate these procedures to their laboratories. States should also advise laboratories as to the appropriate State point-of-contact should they have further questions related to suspected fraud. COs should familiarize themselves with their appropriate State and/or Regional reporting procedures and follow them upon becoming aware of suspected fraudulent behavior. EPA's Office of Enforcement and Compliance Assurance (OECA) may also be used as a resource (www.epa.gov/compliance/complaints/index.html) for questions and concerns related to suspected fraud. To the extent that suspected waste, fraud or abuse involves EPA staff, programs or contracts, EPA's OIG should be notified (www.epa.gov/oig/contactus.htm).

Additional information can be found in *Best Practices for the Detection and Deterrence of Laboratory Fraud* (California Military Environmental Coordination Committee, Chemical Data Quality/Cost Reduction Process Action Team, Version 1.0, March 1997) (www.epa.gov/region09/qa/pdfs/labfraud.pdf) and in the Department of Defense (DoD) *Policy and Guidelines for Acquisitions Involving Environmental Sampling or Testing* (November 2007) (www.navylabs.navy.mil/Archive/ProcPolicyGuideDec07.doc). Laboratories are particularly encouraged to become familiar with the prohibited practices identified in the DoD Guidelines. These include, but are not limited to:

- Fabrication, falsification, or misrepresentation of data;
- Improper clock setting (time traveling) or improper date/time recording;
- Unwarranted manipulation of samples, software, or analytical conditions;

- Misrepresenting or misreporting QC samples;
- Improper calibrations;
- Concealing a known analytical or sample problem;
- Concealing a known improper or unethical behavior or action; and
- Failing to report the occurrence of a prohibited practice or known improper or unethical act to the appropriate laboratory or contract representative, or to an appropriate government official.

Radiochemistry Certification Officer Training
Supplement to: Chapter III Implementation
17. Training

Radiochemistry Certification Officers (COs) should complete the inorganic portion of the Chemistry COs Training Course and should also complete additional radiochemistry-specific training such as that offered by States, Universities, TNI, private organizations, EPA/Office of Radiation & Indoor Air (ORIA), or Association of Public Health Laboratories (APHL). Since EPA Method 200.8 is addressed during the inorganic portion of the Chemistry COs Training Course, and since this method includes uranium in its scope, completion of the inorganic portion of the Chemistry COs Training Course is sufficient to audit for uranium by EPA Method 200.8.

Chemistry Sample Collection
Supplement to: Chapter IV Critical Elements for Chemistry
6. Sample Collection, Handling, and Preservation

Sample temperatures should be noted upon receipt. Samples that arrive at the laboratory within 24 hours of sample collection, due to the close proximity of a public water system to the laboratory, may not yet have reached the appropriate temperature by the time they arrive at the laboratory. These samples should be considered acceptable ONLY if packed on ice or with frozen gel/ice packs immediately after sample collection and hence, delivered while the samples were in the process of reaching an appropriate equilibrium temperature.

Microbiology Methodology
Supplement to: Chapter V Critical Elements for Microbiology
5. Analytical Methodology

In section 5.2.4.2, A-1 Medium, section 5.2.4.2.5 should be replaced with:

A1 broth may be held up to 7 days in a tightly closed screw-cap tube at 4 ^{o}C.

Microbiology Sample Collection
Supplement to: Chapter V Critical Elements for Microbiology
6. Sample Collection, Handling, and Preservation

The time from sample collection to placement of the sample in the incubator (i.e. the 'holding time') for total coliforms and fecal coliforms in surface water sources, and heterotrophic bacteria in drinking water, must not exceed eight hours for samples being analyzed in compliance with the Surface Water Treatment Rule (40 CFR 141.74(a)(1)). Per 40 CFR 141.704, for surface water *E. coli* samples being analyzed in compliance with the Long Term 2 (LT2) rule, the holding time for the sample must not exceed 30 hours, unless an exception is granted by the State. The State may approve, on a case-by-case basis, the holding of an LT2 *E. coli* sample for up to 48 hours if the State determines that analyzing the sample within 30 hours is not feasible.

Appendices
Supplement to: Appendix C: Definitions and Abbreviations

The NELAC Institute (TNI) was created in November 2006 as an outgrowth of NELAC. References to "NELAC" are replaced with "TNI."