

## Water, Contaminants and the EPA: What You Should Know

By Robin Stomler



### **EPA Revises Total Coliform Rule**

On February 13, 2013, the Environmental Protection Agency (EPA), the federal agency charged with oversight of the nation's drinking water from "source to tap," issued a final rule to the National Primary Drinking Water Regulations: Revisions to the Total Coliform Rule. The revisions require public water systems with an indication of coliform contamination to assess the problem and take corrective action.

The document notes that *E. coli* is a more specific indicator of fecal contamination and the potential presence of associated pathogen occurrence than fecal coliforms. The final rule establishes a maximum contaminant level goal and maximum contaminant level for *E. coli*, and eliminates public notification requirements based only on the presence of total coliforms. The maximum contamination level goal for *E. coli* will be zero.

For laboratories, the EPA is considering how to review and revise the microbial test protocol. The agency plans to encourage certified laboratories to be aware of the importance of timely notification of positive results. This final rule also contains modifications to the Table of Analytical Methods.

### **Supplement on *Cryptosporidium* Posted**

The EPA issued its second supplement to the Fifth Edition of the *Manual for the Certification of Laboratories Analyzing Drinking Water* in November 2012. The Manual serves as a guideline for the

agency to use when certifying laboratories for the analysis of drinking water contaminants. It implies the agency's preferred approach to laboratory quality assessment.

The second supplement to the Manual focuses on *Cryptosporidium* monitoring. Public water systems are required to have *Cryptosporidium* samples analyzed by a laboratory approved under the EPA Laboratory Quality Assurance Evaluation Program or by a laboratory certified for analysis of this pathogen by an equivalent state laboratory certification program. The second supplement outlines critical elements for good laboratory practices under parasitology, specifically *Cryptosporidium* and *Giardia*. Critical elements range from personnel qualifications to laboratory equipment and supplies to analytical methods to sample collection and handling and quality control.

Under quality control (QC) for *Cryptosporidium*, the second supplement states that laboratories "must analyze samples spiked with *Cryptosporidium* oocysts to assess ongoing laboratory and method performance in accordance with EPA Method 1623 and 1623.1 QC requirements." Ongoing spiked sample analyses including an IPR (initial precision and recovery) test, ongoing demonstration of laboratory capacity and method performance using the matrix spike test, method blank test, OPR (ongoing precision and recovery) test, staining controls and analyst verification tests. If quality control data are unsatisfactory or insufficient, certification officers may not recommend certification.

The supplement includes examples of checklists that may be used during the onsite laboratory evaluation for *Cryptosporidium* and *Giardia*. The sample checklists cover the audit package and data review for EPA Method 1623 and 1623.1, laboratory standard operating procedures, and a technical review of sample processing and microscopy.

The fifth edition of the Manual was issued in January 2005. The last supplement was posted in June 2008.

### **Microbial Risk Assessment Guideline Released**

The EPA and the Food Safety and Inspection Service issued its first *Microbial Risk Assessment Guideline: Pathogenic Microorganisms with Focus on Food and Water* in July 2012. The document provides fundamental risk assessment principles for microbial risks to human health. It is intended to address the entire risk process from planning, to hazard identification and hazard characterization, to dose-response assessment, to exposure assessment, and risk communication. It seeks to approach risk assessment in a transparent manner using available data or through acknowledged science-policy choices.

The document suggests that assessors of risk become knowledgeable about laboratory approaches for identifying and quantifying microorganisms, noting the importance of issues related to sensitivity, specificity, detection limits, sampling methods and size. Bacteria, fungi, viruses, protozoan, algae,

and “indeterminate” agents are labeled the major microbial categories that cause adverse outcomes in humans. The guideline lists examples of pathogens within each category along with their morphological, physiological, genetic and pathogenicity features.

The guideline, with its emphasis on overall risk assessment processes, does not provide extensive detail on laboratory testing operations. It does outline, however, possible concerns with various microbial detection methods. This federal guideline suggests that risk assessors consider laboratory evidence in their analyses.

### **EPA Expedites Alternative Testing Methods for Drinking Water**

The EPA issued a final rule providing expedited approval of alternative testing methods that may be used in measuring contaminant concentrations in drinking water. The ten additional methods were approved and posted so that public water systems, laboratories, and primary agencies would have access to new measurement techniques. Public water systems now have the flexibility to use existing test procedures or the new alternatives. The methods, issued in June 2012, are listed below:

- EPA Method 536 (USEPA 2007) – direct injection liquid chromatography tandem mass spectrometry method for determination of atrazine and simazine.
- EPA Method 523 (USEPA 2011) – gas chromatography mass spectrometry (GC/MS) method for determination of atrazine and simazine
- EPA Method 525.3 (USEPA 2012) – GC/MS method for determination of semi-volatile organic compounds in finished drinking water
- EPA Method 1623.1 (USEPA 2012) – microbiological method for the detection of *Cryptosporidium* in drinking water treatment plant source waters by concentration, immunomagnetic separation, and immunofluorescence assay microscopy
- Standard Method (revised) 3125, 21<sup>st</sup> edition (APHA 2005) for uranium
- Standard Method (revised) 3112 B-09, online version (APHA 2009) for mercury
- ASTM Method D859-10 (2010a) for silica
- ASTM Method D1179-10 B (2010b) for fluoride
- ASTM Method D5673-10 (2010c) for uranium
- ASTM Method D6239-09 (2009) – analysis of uranium in drinking water by alpha scintillation with pulse shape discrimination

The final rule states that laboratories performing EPA Method 1623.1 are expected to have more accurate detection and will be meeting more stringent quality control (QC) criteria than laboratories following the existing Method 1623. EPA references data from EPA Method 1623.1 validation studies that were used to develop new QC criteria for laboratory performance.

The Safe Water Drinking Act provides the EPA with the authority to approve the use of testing methods in drinking water regulations.

### **Quality Control Microorganisms and Parasites**

Microbiologics has the broadest collection of microorganism and parasite products for simple, reliable QC testing. We offer the highest quality, ready-to-use QC microorganism preparations for both qualitative and quantitative test methods to help you meet regulatory requirements with ease. Parasite Suspensions are also used in environmental water testing as a control for parasite detection methods. Visit [www.microbiologics.com](http://www.microbiologics.com) to learn more about how Microbiologics® products can save your laboratory valuable time and money without compromising quality.

### **Biography**



Robin E. Stomblor is President of Auburn Health Strategies, LLC, a strategic and business development company serving health and science clients nationwide.

Prior to founding Auburn Health Strategies, Stomblor served as the Vice President of Government Affairs for the 140,000 members of the American Society for Clinical Pathology, and directed its Washington Office for over nine years. She previously served as a Senior Washington Associate for the American College of Surgeons. Among her publications, Stomblor co-authored *Laboratory Preparedness for Bioterrorism: From Phlebotomist to Pathologist*; *Institute for Quality in Laboratory Medicine: Recognizing Excellence in Practice: Highlights from First Landmark Summit –An Opportunity to Enhance Medical Care*; and *Food Industry Could Learn from Labs*. She has been an invited participant in the Bureau of Health Professions Strategic Planning Forum at the Health Resources and Services Administration as well as a Public Health and Strategic Planning Consultant at the Centers for Disease Control and Prevention.

A veteran of Capitol Hill and state government, she has participated in a number of local community activities. Her company was awarded a Walk Visionary Award in 2006 by the Foundation Fighting Blindness for its support of research efforts to find a cure for retinal degenerative diseases. Jefferson Medical College's Department of Health Policy appointed Stomblor a Senior Scholar for 2006-2007. A member of the Board of Discipline Editors of the *Journal of the Washington Academy of Sciences*, she has served on the Boards of Directors of Women's Health Virginia and the International Registry of Pathology.