

L. Laboratory Approval

Given the potentially significant implications in terms of both cost and public health protection of microbial monitoring under the LT2ESWTR, laboratory analyses for *Cryptosporidium*, *E. coli*, and turbidity must be accurate and reliable within the limits of approved methods. Therefore, EPA proposes to require public water systems to use laboratories that have been approved to conduct analyses for these parameters by EPA or the State. The following criteria are proposed for laboratory approval under the LT2ESWTR:

- For *Cryptosporidium* analyses under the LT2ESWTR, EPA proposes to approve laboratories that have passed a quality assurance evaluation under EPA's Laboratory Quality Assurance Evaluation Program (Lab QA Program) for Analysis of *Cryptosporidium* in Water (described in 67 FR 9731, March 4, 2002) (USEPA 2002c). If States adopt an equivalent approval process under State laboratory certification programs, then systems can use laboratories approved by the State.
- For *E. coli* analyses, EPA proposes to approve laboratories that have been certified by EPA, the National Environmental Laboratory Accreditation Conference, or the State for total coliform or fecal coliform analysis in source water under 40 CFR 141.74. The laboratory must use the same analytical technique for *E. coli* that the laboratory uses for total coliform or fecal coliform analysis under 40 CFR 141.74.
- Turbidity analyses must be conducted by a person approved by the State for analysis of turbidity in drinking water under 40 CFR 141.74.

These criteria are further described in the following paragraphs.

1. *Cryptosporidium* Laboratory Approval

Because States do not currently approve laboratories for *Cryptosporidium* analyses and LT2ESWTR monitoring will begin 6 months after rule promulgation, EPA will initially assume responsibility for *Cryptosporidium* laboratory approval. EPA expects, however, that States will include *Cryptosporidium* analysis in their State laboratory certification programs in the future. EPA has established the Lab QA Program for *Cryptosporidium* analysis to identify laboratories that can meet LT2ESWTR data quality objectives. This is a voluntary program open to laboratories involved in analyzing *Cryptosporidium* in water. Under this program, EPA assesses the ability of laboratories to

reliably measure *Cryptosporidium* occurrence with EPA Methods 1622 and 1623, using both performance testing samples and an on-site evaluation.

EPA initiated the Lab QA Program for *Cryptosporidium* analysis prior to promulgation of the LT2ESWTR to ensure that adequate sample analysis capacity will be available at qualified laboratories to support the required monitoring. The Agency is monitoring sample analysis capacity at approved laboratories through the Lab QA Program, and does not plan to implement LT2ESWTR monitoring until the Agency determines that there is adequate laboratory capacity. In addition, utilities that choose to conduct *Cryptosporidium* monitoring prior to LT2ESWTR promulgation with the intent of grandfathering the data may elect to use laboratories that have passed the EPA quality assurance evaluation.

Laboratories seeking to participate in the EPA Lab QA Program for *Cryptosporidium* analysis must submit an interest application to EPA, successfully analyze a set of initial performance testing samples, and undergo an on-site evaluation. The on-site evaluation includes two separate but concurrent assessments: (1) Assessment of the laboratory's sample processing and analysis procedures, including microscopic examination, and (2) evaluation of the laboratory's personnel qualifications, quality assurance/quality control program, equipment, and recordkeeping procedures.

Laboratories that pass the quality assurance evaluation will be eligible for approval for *Cryptosporidium* analysis under the LT2ESWTR. The Lab QA Program is described in detail in a **Federal Register** Notice (67 FR 9731, March 4, 2002) (USEPA 2002c) and additional information can be found online at: www.epa.gov/safewater/lt2/cla_int.html.

Laboratories in the Lab QA Program will receive a set of three ongoing proficiency testing (OPT) samples approximately every four months. EPA will evaluate the precision and recovery data for OPT samples to determine if the laboratory continues to meet the performance criteria of the Laboratory QA Program.

2. *E. coli* Laboratory Approval

Public water systems are required to have samples analyzed for *E. coli* by laboratories certified under the State drinking water certification program to perform total coliform and fecal coliform analyses under 40 CFR 141.74. EPA is proposing that the general

analytical techniques the laboratory is certified to use under the drinking water certification program (e.g., membrane filtration, multiple-well, multiple-tube) will be the methods the laboratory can use to conduct *E. coli* source water analyses under the LT2ESWTR.

3. Turbidity Analyst Approval

Measurements of turbidity must be conducted by a party approved by the State. This is consistent with current requirements for turbidity measurements in drinking water (40 CFR 141.74).

4. Request for Comment

EPA requests comment on the laboratory approval requirements proposed today, including the following specific issues:

Analyst Experience Criteria

The Lab QA Program, which EPA will use to approve laboratories for *Cryptosporidium* analyses under the LT2ESWTR, includes criteria for analyst experience. Principal analyst/supervisors (minimum of one per laboratory) should have a minimum of one year of continuous bench experience with *Cryptosporidium* and immunofluorescent assay (IFA) microscopy, a minimum of six months experience using EPA Method 1622 and/or 1623, and a minimum of 100 samples analyzed using EPA Method 1622 and/or 1623 (minimum 50 samples if the person was an analyst approved to conduct analysis for the Information Collection Rule Protozoan Method) for the specific analytical procedure they will be using.

Under the Lab QA Program, other analysts (no minimum number of analysts per laboratory) should have a minimum of six months of continuous bench experience with *Cryptosporidium* and IFA microscopy, a minimum of three months experience using EPA Method 1622 and/or 1623, and a minimum of 50 samples analyzed using EPA Method 1622 and/or 1623 (minimum 25 samples if the person was an analyst approved to conduct analysis for the Information Collection Rule Protozoan Method) for the specific analytical procedures they will be using.

The Lab QA Program criteria for principal analyst/supervisor experience are more rigorous than those in Methods 1622 and 1623, which are as follows: the analyst must have at least 2 years of college lecture and laboratory course work in microbiology or a closely related field. The analyst also must have at least 6 months of continuous bench experience with environmental protozoa detection techniques and IFA