United States Environmental Protection Agency

Frequently Asked Questions: State Approval/Oversight of Cryptosporidium *Laboratories Supporting LT2 Monitoring*

For the first round (2006-2012) of *Cryptosporidium* monitoring under the Long Term 2 Enhanced Surface Water Treatment Rule ("LT2"), EPA's Office of Ground Water and Drinking Water (OGWDW) assumed responsibility for the approval and ongoing oversight of the laboratories that supported Public Water Systems (PWSs). In preparation for the second round of LT2 monitoring (scheduled to begin in April 2015), OGWDW's Technical Support Center (TSC) is working with States and EPA Regions to integrate *Cryptosporidium* laboratory approval/oversight into existing State certification/ accreditation programs. Participating States will approve and oversee laboratories that support the second round of LT2 monitoring.

Frequently Asked Questions and Answers

Why is EPA changing the approach to approving LT2 laboratories?

TSC's oversight of LT2 laboratories during Round 1 represented a unique exception to the traditional laboratory certification/accreditation approach. At the time, labs and States had limited experience with *Cryptosporidium* monitoring. With the experience gained by laboratories, as well as States, during the first round of monitoring, all parties should be more comfortable with the process making it possible for interested States to take their normal leadership role while EPA provides guidance and technical support. The approach for Round 2 creates consistency with the approach for approval/oversight of laboratories for all other regulated analytes and is provided for in the LT2 rule. A number of States have already expressed an interest in adding *Cryptosporidium* laboratory approval to their programs and have participated in TSC's *Cryptosporidium* Laboratory Certification Officers Training Course in 2010 and 2011.

What will participating States be responsible for?
State responsibilities for *Cryptosporidium* laboratory approval and oversight will be the same as their certification responsibilities for the chemistry and microbiology laboratories that they oversee in their current programs (e.g., initial evaluation of laboratory capability; ongoing assessment of the laboratory – including an assessment of Proficiency Test results; and on-site audits at least triennially). States will be responsible for nominating and sending certification officers to TSC's *Cryptosporidium* Laboratory Certification Officers Training Course.

What will TSC's role be (with respect to LT2 laboratories) during Round 2 monitoring?
Consistent with the longstanding laboratory certification program approach, TSC will: (1) train State/Regional Certification Officers (CO) responsible for auditing *Cryptosporidium* laboratories (TSC anticipates offering 1-2 courses per year in 2013 and 2014, and an annual course thereafter, pending interest and available resources); (2) provide written guidance to State/Regional COs (e.g., updates to the Laboratory Certification Manual and method revisions as needed); (3) provide day-to-day technical support to States, Regions, and laboratories; (4) review/assist the Regional programs responsible for the oversight of State certification/accreditation programs; and (5) maintain a list of approved laboratories on EPA's website.

How does a State establish an appropriate *Cryptosporidium* laboratory approval program?
40 CFR 141.705(a) provides for approval of *Cryptosporidium* laboratories by "an equivalent" State program (i.e., equivalent to EPA's Laboratory Quality Assurance Evaluation Program). EPA's Regional Certification Programs (in consultation with TSC as needed) will determine whether a State certification/accreditation program is equivalent/appropriate. TSC recommends that Regions judge equivalency by examining whether the State programs (1) have demonstrated substantial conformity to procedures described in Chapter 7 of "Supplement 2 to the Fifth Edition of the Manual for the Certification of Laboratories Analyzing Drinking Water" http://water.epa.gov/scitech/drinkingwater/labcert/index.cfm#two and (2) are using auditors that have passed TSC's *Cryptosporidium* Laboratory Certification Officers Training Course.

Must every State with primacy responsibility for LT2 integrate *Cryptosporidium* laboratory approval into its certification/accreditation program?
No. This is not required as a condition of LT2 primacy, although TSC encourages participation by interested States to expand oversight of pathogens that may pose a risk to public health. Whereas 40 CFR 142.10(b) generally requires the establishment and maintenance of a laboratory "certification" program for all regulated analytes, EPA believes that State approval programs for *Cryptosporidium* laboratories are optional based on the structure of the LT2 rule.

Must every State with primacy responsibility for LT2 establish "Principal State Laboratory" (PSL) capability for *Cryptosporidium*?
No. This is not required as a condition of LT2 primacy, although TSC encourages development of *Cryptosporidium* laboratory capability by interested States to help address waterborne outbreaks and to enhance the ability of the State to provide technical support to the laboratories it oversees. Whereas 40 CFR 142.10(b) generally requires the establishment and maintenance of State laboratory capability for all regulated analytes, EPA believes that *Cryptosporidium* PSLs are optional based on the structure of the LT2 rule.

If a laboratory is located in a State that does not operate a *Cryptosporidium* laboratory certification/accreditation program, can that laboratory still support LT2 monitoring?
A qualified "yes." - as long as the laboratory has been approved by another State's laboratory certification/accreditation program that has been deemed "equivalent" by EPA. 40 CFR 141.705 establishes that LT2 analyses are to be performed by a laboratory that has been approved by EPA or by an equivalent State program. If an EPA Region has deemed a particular State program "equivalent," laboratories approved by that State can generally be used to support LT2 monitoring by PWSs in any State. Some State programs are willing and able to audit laboratories in other States. PWSs should be aware that their States may establish requirements that are more stringent than EPA's regulations; State requirements would take precedence.

May a State program use Third-Party experts to support the evaluation of *Cryptosporidium* laboratories?
Yes. TSC supports the use of third-party auditors with appropriate training/expertise to assist State programs, with the understanding that the State is ultimately responsibly for the approval decision. States should be aware of, and should address, the potential for conflict of interest when using third-party support.

What are the next steps for a State interested in integrating *Cryptosporidium* laboratory approval into its certification/accreditation program?
Interested States should contact their Regional Certification Program to indicate their interest. Nominations for participation in TSC's next Certification Officer training course will likely be solicited in January 2013. Those States should also familiarize themselves with the *Cryptosporidium* chapter (Chapter 7) in Supplement 2 to the Laboratory Certification Manual.

How many labs are expected to seek approval to support the next round of LT2 monitoring?
46 labs across 23 States/Territories are currently approved. We anticipate that a similar number of labs may apply to support Round 2 monitoring, though the approved labs that did little or no Round 1 business may choose to not pursue Round 2 approval.