

EPA Region 4 (Science and Ecosystem Support Division) Equivalency Criteria for States to Establish a Program Equivalent to EPA's Program for <i>Cryptosporidium</i> Laboratory Approval	
No.	Environmental Protection Agency Region 4 Policy
1	<p><i>Introduction</i></p> <p>The Environmental Protection Agency Office of Ground Water and Drinking Water's Technical Support Center (TSC) is integrating oversight of the <i>Cryptosporidium</i> Laboratory Approval Program with EPA Regional and State Certification Programs. The <i>Cryptosporidium</i> Laboratory Approval Program supports the Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR).</p> <p>40 CFR 141.705(a) provides for approval of <i>Cryptosporidium</i> 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.</p> <p>EPA Region 4 Science and Ecosystem Support Division has set up equivalency criteria necessary for States in Region 4 desiring to establish a <i>Cryptosporidium</i> Laboratory Certification/Approval Program. All Region 4 States seeking to establish an EPA equivalent laboratory certification program for <i>Cryptosporidium</i> should submit their letter of intent to Region 4. Strict adherence to the following guidelines should be taken.</p>
2	<p><i>Guidelines</i></p> <p>A. State equivalency programs must encompass the initial evaluation of the laboratory, ongoing assessment of the laboratory, and on-site audits at least triennially.</p> <p>B. States must have auditors that have passed the Technical Support Center's <i>Cryptosporidium</i> Laboratory Certification Officers Training Course. Preferably Certification Officers (CO) should audit the <i>Cryptosporidium</i> training course again every 5 years.</p> <p>C. Initially, a newly certified <i>Cryptosporidium</i> Certification Officer in Region 4 should shadow an EPA or State <i>Cryptosporidium</i> Certification Officer with prior <i>Cryptosporidium</i> laboratory audit experience before performing an independent audit.</p> <p>D. State <i>Cryptosporidium</i> COs must evaluate laboratories to ensure that they are following the procedures described in Chapter 7 of <i>Supplement 2 to the Fifth Edition of the Manual for the Certification of Laboratories Analyzing Drinking Water Manual</i>. https://www.epa.gov/dwlabcert/supplement-2-fifth-edition-manual-certification-laboratories-analyzing-drinking-water</p>

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E. State *Cryptosporidium* COs must evaluate laboratories to ensure that only approved methods are being performed (EPA Method 1623.1, 1623 or 1622).

F. State *Cryptosporidium* COs must evaluate laboratories to ensure that they have successfully participated in two *Cryptosporidium* Proficiency Testing (PT) events per year for each approved method for which the laboratory is seeking certification/accreditation.

G. Prior to on-site inspections, State *Cryptosporidium* COs should:

- a. ensure that the laboratory's primary analysts have performed an online microscopy skills evaluation with Technical Support Center (TSC).
- b. ensure their receipt of the laboratory's Application Package for Verification of *Cryptosporidium* Laboratory Quality Assurance form (see Appendix 1).
- c. review laboratory Standard Operating Procedures (SOP), training records, Quality Management Plans (QMP), etc.
- d. ensure that the laboratory sends at least one ongoing precision and recovery (OPR) slide and one positive staining control (PSC) slide to TSC (to assist CO in identifying any deficiencies).
- e. ensure that the laboratory orders the On Site Audit Package from Wisconsin State Laboratory of Hygiene (WSLH) (608-224-6260). A description of the package may be found at the WSLH website:

<http://www.slh.wisc.edu/wp-content/uploads/2017/01/General-Program-Information-201704.pdf>

H. During the on-site audit, the State *Cryptosporidium* COs must:

- a. observe the laboratory analysts perform the analysis of the blind sample and the IMS control sample.
- b. observe the laboratory analysts perform Kohler illumination.
- c. review the laboratory's current OPR and PSC slides.
- d. ensure that the laboratory submit results of the blind samples within ten days to the CO. The CO should obtain actual spike results from WSLH.

I. After the on-site audit inspection, the State *Cryptosporidium* COs should notify EPA Region 4 of any proposed downgrading or revoking of certification status of the laboratory. Region 4 will then contact TSC of the final certification status of the laboratory, so as to update the list of approved labs on their website.

<https://www.epa.gov/dwlabcert/contact-information-certification-programs-and-certified-laboratories-drinking-water>

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3	<p><i>Review of EPA Equivalency Criteria for State <i>Cryptosporidium</i> Laboratory Approval Program by the EPA Office of Ground Water and Drinking Water (OGWDW)</i></p> <p>TSC will: (1) train State/Regional Certification Officers (CO) responsible for auditing <i>Cryptosporidium</i> laboratories; (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: https://www.epa.gov/dwlabcert/contact-information-certification-programs-and-certified-laboratories-drinking-water</p> <p>For the first round (2006-2012) of <i>Cryptosporidium</i> monitoring under the Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR), 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). For the second round of LT2ESWTR monitoring that began in April 2015, OGWDW's Technical Support Center (TSC) worked with EPA Regions and States to integrate <i>Cryptosporidium</i> laboratory approval/oversight into existing State certification/accreditation programs. State oversight of <i>Cryptosporidium</i> laboratories is provided for in the LT2ESWTR and is consistent with the laboratory oversight approach for all other regulated analytes. EPA <i>Cryptosporidium</i> laboratory approval granted by TSC did not carry over to the second round of LT2ESWTR <i>Cryptosporidium</i> monitoring that began in 2015.</p>
4	<p><i>Request for Approval from EPA Region 4</i></p> <p>The State agency should submit a letter stating their intent to establish a State program equivalent to EPA's Program for <i>Cryptosporidium</i> Laboratory Approval. The letter must state their agreement to conform to all the requirements outlined in this memorandum (USEPA Region 4 guidelines) including successful completion of the TSC's <i>Cryptosporidium</i> Laboratory Certification Officers Training Course and the adherence to the <i>Supplement 2 to the Fifth Edition of the Manual for the Certification of Laboratories Analyzing Drinking Water Manual</i>. This letter should be submitted in writing via fax, e-mail, or standard mail to Sandra Aker, the Regional QA Coordinator, for Regional approval. The laboratory should keep a copy of their request and approval letter on file for State Inspection purposes.</p>

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Contact Information

All questions, comments and submittals should be directed to:

Sandra Aker, QA Section Chief
EPA Region 4
Science and Ecosystem Support Division
Quality Assurance Section
980 College Station Road
Athens, Georgia 30605
(706) 355-8772 phone
Aker.Sandra@epa.gov

Viola Reynolds, *Cryptosporidium* Certification Officer
EPA Region 4
Science and Ecosystem Support Division
Quality Assurance Section
980 College Station Road
Athens, Georgia 30605-2720
(706) 355-8569 phone
Reynolds.Viola@epa.gov

For technical questions contact:

Dr. Leah Fohl Villegas, Contractor operating on behalf of EPA
CB&I Federal Services, LLC
26 West Martin Luther King Drive
Cincinnati, Ohio 45268
513-569-7886 phone
Villegas.Leah@epa.gov

Application Package for Verification of *Cryptosporidium* Laboratory Quality Assurance

Submit electronic package to: [Cert Officer email]
Submit any necessary hard copies to: [Cert Officer Name]
[Address]
[Phone]

Step 1: Submit all requested information

Please submit all requested elements in one package organized as follows. Your application will be evaluated for completeness.

1. Completed Audit Application Form
2. Up to date Standard Operating Procedures (SOPs) for the following:
 - a. Performance of each Method step including: sample spiking, filtration, elution, concentration, purification, slide preparation, sample staining and examination (for each method version, where applicable)
 - b. Reagent preparation
 - c. Cleaning practices
 - d. Corrective action procedures for failing to meet ongoing precision and recovery (OPR), method blank, staining controls, sample acceptance and analyst verification criteria
 - e. Sampling procedures to be followed by field or utility personnel
 - f. Procedures for data recording, checking manual calculations, and checking accuracy of all data transcriptions
 - g. Procedures for data recording and electronic storage of data, including checking for accuracy of data entry and backup of stored data
3. Training records for all analysts/technicians [FY__]
4. OPR control chart including at a minimum the last 20 OPR samples processed
5. Matrix spike (MS) control chart including at a minimum the last 20 MS samples processed
6. Submit two data packages, include a positive result if possible. Include all supporting documentation from the field sample, matrix spike, OPR, method blank and positive control slides.
7. NELAP certificate (as applicable)

Step 2: Submit slides for review

An off-site technical auditor will review one recent OPR and associated positive staining control slide. Contact [Cert Officer Name and email] or the contractor operating on behalf of EPA, Dr. Leah Villegas, CB&I, villages.leah@epa.gov or 513-569-7886 to schedule evaluation of slides. This review may occur prior to or following the on-site audit.

Step 3: Order on-site audit package

Order an on-site audit package from Wisconsin State Laboratory of Hygiene (608-224-6260), or equivalent vendor. Each package consists of two 50 mL blind samples. Order one analyst verification slide per analyst. These will be used in presence of an auditor; therefore, evaluation date should be within product expiration. Bench sheets and examination forms for the blind samples, and associated method blank and OPR samples should be submitted to [Cert Officer Name and email]. Submit the analyst verification slides and associated examination forms, if requested.

Step 4: Schedule online analyst evaluation

Contact [Cert Officer Name and email] or the contractor operating on behalf of EPA, Dr. Leah Villegas, CB&I, villegas.leah@epa.gov or 513-569-7886 to register each analyst for an online analyst verification. A computer with internet connection is needed to complete the session.

Step 5: Prepare fresh OPR and positive staining control for review during the audit

Step 6: Evaluation

The laboratory will receive a report detailing all audit findings. The laboratory should provide complete written responses to any deficiencies or recommendations identified in the report within 60 days. Laboratory status for continued approval will be based on submission of acceptable responses, proficiency test results, the quality of the positive control and OPR slide, slide counts, on-site evaluation, online analyst verification, and recovery values for blind samples initiated during audit.

Cryptosporidium Laboratory Audit Application Form

Part 1. Laboratory Information

Laboratory Name:		
Address:		
City:	State:	Zip:
Contact Person:		
Title:		
Telephone:	Fax:	
Email address:		
Type of laboratory (check one): <input type="checkbox"/> Commercial <input type="checkbox"/> Utility <input type="checkbox"/> State <input type="checkbox"/> Academic <input type="checkbox"/> Other		
Method used in the Laboratory: <input type="checkbox"/> December 2005 Method 1623 <input type="checkbox"/> January 2012 Method 1623.1		
Number of field samples your laboratory is analyzing per month using Method 1623 and/or 1623.1:		
Date of Previous Audit:	Date of Initial Approval:	

Part 2. Personnel List

Name of Current Analyst and Technicians	Current position (Principal Analyst, Analyst, or Technician)	Evaluated during Previous Audit or Documentation Submitted to EPA (Yes/No)

Part 3. Method and Equipment Information: Versions of Method for which the lab is seeking evaluation

Method Procedure		Key Equipment	Manufacturer/Model
Check all that apply		Provide manufacturer and model for relevant pieces of equipment	
Filtration			
Indicate the volume filtered for each		Cubitainer	
Pall Envirochek® HV		Pump	
IDEXX Filta-Max®		Flow control valve	
Other (describe)		Flow meter or graduated container	
Elution			
Wrist action shaker		Laboratory shaker and side arms	
Filta-Max® wash station		Filta-Max® Manual station	
Other (describe)		Filta-Max® Automatic station	
Concentration			
Centrifugation		Centrifuge - 1500 X G, swinging-bucket centrifuge for 15 mL - 250-mL tubes	
Filtration through membrane		Concentrator apparatus (Filta-Max only)	
Other (describe)			
Purification			
Dynabeads® Crypto		Flat-sided sample tubes	
Dynabeads® CG-combo		Sample mixer/rotator for 10-mL tubes	
Other (describe)		Magnetic particle concentrator for 10-mL tubes	
		Magnetic particle concentrator for 1.5-mL tubes	
Staining and Examination			
Waterborne AquaGlo™		Microscope - Epifluorescence/ differential interference contrast (HMO or DIC) microscope with stage and ocular micrometers	
Waterborne Crypt-a-Glo™		20X to 100X objectives	
Waterborne Giardi-a-Glo™		Excitation/band pass microscope filters for fluorescein isothiocyanate (FITC) assay (provide specifications)	
Meridian Merifluor®		Excitation/band-pass filters for 4',6-diamidino-2-phenylindole (DAPI) assay (provide specifications)	
BTF EasyStain™			
Other (describe)			
Other			
Descriptions of "other" method steps and other comments:		Refrigerator for sample storage	
		Refrigerator for reagent storage	

The above information is complete and accurate to the best of my knowledge.

Name and Signature of Laboratory Director or Designee

Date