Application Package for Assessment 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 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
4. OPR control chart including at a minimum the last 20 OPR samples processed
5. MS control chart including at a minimum the last 20 MS samples processed
6. Submit two data packages from the last 12 months, include a positive result if available. Include all supporting documentation from the field sample, matrix spike, method blank and positive control slide.
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] to schedule evaluation of slides. This review may occur prior to or following the on-site audit. The slides prepared for the review during the audit in Step 5 may be requested to fulfill this submission.

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 2 50 mL blind samples, 2 vials of artificial matrix, 2 IMS control samples, and 2 analyst verification slides. One slide is required per analyst and a back up slide. Additional slides may be added for a fee. 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 internet analyst evaluation

Contact [Cert Officer Name and email] to schedule internet analyst evaluation for each analyst. 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, and recovery values for blind samples initiated during audit