LABORATORY QUALITY ASSURANCE EVALUATION PROGRAM

Information Collection Request:

Supporting Statement

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Ground Water and Drinking Water

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Information Collection Request
Section 1: Part A of the Supporting Statement

1. Identification of the Information Collection

1(a) Title of the Information Collection

EPA Laboratory Quality Assurance Evaluation Program for Analysis of *Cryptosporidium* under the Safe Drinking Water Act

OMB Number: **2040 - 0246**
U.S. EPA Tracking Number: **2067.03**

1(b) Short Characterization

The U.S. Environmental Protection Agency (EPA) is requesting a renewal of the information collection request (ICR) for the Laboratory Quality Assurance Evaluation Program for Analysis of *Cryptosporidium* under the Safe Drinking Water Act (Laboratory QA Program). This voluntary program applies to public and private laboratories that analyze water samples for *Cryptosporidium*. The program will help ensure that laboratories meet the quality assurance and quality control criteria of EPA Method 1622 and EPA Method 1623 (EPA, 2001a, 2001b) when using these methods for the determination of the identity and concentration of *Cryptosporidium* in source water by filtration, immunomagnetic separation (IMS), and immunofluorescence assay (FA) microscopy. In addition, the program will assist in determining capacity at laboratories to support monitoring under the Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR).

Information collection activities required under the Lab QA Program include: a laboratory participation application; initial performance testing (IPT) results; an on-site evaluation of laboratory performance and data quality; and ongoing performance testing (OPT) results. All materials are being collected by the Office of Ground Water and Drinking Water (OGWDW). This information collection will provide EPA with data to verify that the laboratories are capable of producing reliable data from the analysis of *Cryptosporidium* using EPA Method 1622 and EPA Method 1623.

The information collection will involve approximately 65 laboratories at a total cost of approximately $274,897 or 3,980 labor hours annually. The estimated total Agency burden, including contractual costs, is estimated at $362,272, or 3,388 labor hours annually (Appendix G).

2. Need For and Use of the Collection

2(a) Need/Authority for the Collection

The information collection is needed by EPA to support the *Cryptosporidium* data gathering activities that will be required under the LT2ESWTR. The Laboratory QA Program is being renewed in advance of the LT2ESWTR because the *Cryptosporidium* laboratory evaluation program must be in place and operational before the implementation of the LT2ESWTR. In addition, EPA plans to propose under the LT2ESWTR that drinking water plants monitoring their source waters for *Cryptosporidium* prior to rule implementation may apply to have these data "grandfathered." Renewing the Laboratory QA Program will help ensure that qualified laboratories are available to drinking water plants that are interested in pursuing this option.

2(b) Practical Utility/Users of the Data

Information collected under the Laboratory QA Program will be used by EPA to verify that *Cryptosporidium* occurrence data are generated by qualified laboratories that can perform the analyses acceptably. Use of qualified laboratories for source water monitoring by drinking water utilities will help ensure that the data collected are of known and reliable quality. Data quality could potentially be compromised in the absence of a program such as the Laboratory QA Program.

A list of laboratories that meet or continue to meet the evaluation program criteria will be made available to the public at http://www.epa.gov/safewater/lt2/cla_final.html and will provide a resource to aid drinking water utilities (and others interested in monitoring water for *Cryptosporidium* occurrence for the protection of public health) in selecting a qualified analytical laboratory. Successful participation in the voluntary Laboratory QA Program also will qualify laboratories to analyze samples for *Cryptosporidium* monitoring programs requiring sample analyses only by qualified laboratories.

3. Non-duplication, Consultations, and Other Collection Criteria

3(a) Non-duplication

The information requested from the respondents under this ICR is not available from other sources. The information requested will be used to assess the current ability of a laboratory to reliably analyze *Cryptosporidium* in water using EPA Method 1622 and EPA Method 1623. Information submitted for previous programs, such as the Information Collection Rule, would not be applicable because older analytical methods were used and quality control requirements were different. The determination that this information is not available from other sources was made by the Office of Ground Water and Drinking Water Technical Support Center (TSC), who will be administering the Laboratory QA Program, and TSC's contractors, both of which have worked closely since 1996 with the limited community of capable laboratories that will be affected by this information collection**.**

3(b) Public Notice Required Prior to ICR Submission to OMB

A copy of the first Federal Register notice which announces EPA's renewal of the Lab QA Program and requests public comment on the ICR (prior to submitting the ICR to the Office of Management and Budget (OMB)) is attached in Appendix A. Further details on the Laboratory Quality Assurance Program have been added in Appendix B. EPA also has developed a webpage to provide further information on the program. the website can be accessed at http://www.epa.gov/safewater/lt2/cla_final.html.

Comments were received on the original ICR and are summarized below with the Agency's responses.

Commenters expressed concern that the Lab QA Program does not address the Agency's obligation under the FACA Agreement in Principle to identify adequate laboratory capacity to implement LT2ESWTR. The Lab QA Program does assess laboratory capacity through questions on the application on current and potential laboratory capacity to analyze *Cryptosporidium* samples and the on site evaluations. This information is being compiled as laboratory applications are received, and will be updated during on-site evaluations.

Comments were received on the burden estimates. Because laboratories that wish to begin using EPA Methods 1622 and 1623 are required by the methods to purchase the equipment necessary to demonstrate initial acceptable performance, and because this is a method requirement, rather than a program requirement (laboratories can perform the methods without ever participating in the program), the burden estimates assume that no capital costs will be incurred by laboratories participating in the program over and above the costs that would be incurred simply to use the method. Because the program application requires the laboratories applying for approval under the program to submit initial performance data, laboratories that meet these requirements should already have the capacity to perform Methods 1622 or 1623 and therefore will not incur start-up costs.

Commenters wanted to know if training would be available for labs needing help. EPA will provide limited training to laboratories needing assistance with the performance of Methods 1622 and 1623. Information on training will be posted on EPA's website as it becomes available and an on-line module providing training on microscopic examination of samples for Method 1622 and 1623 will soon be available.

Commenters wanted to know the earliest date that acceptable grandfathered data could be generated. EPA is aware of the issues regarding grandfathered data acceptability and has addressed these issues in the proposed LT2ESWTR. These issues are outside of the scope of this ICR.

3(c) Consultations

EPA conducted meetings with representatives of the drinking water treatment industry and the community of laboratories expected to seek EPA recognition under the Laboratory Quality Assurance Evaluation Program in Cincinnati, OH, on January 23 and March 12-13, 2001, and in Washington, DC, on February 13-14, 2001. EPA presented and discussed draft plans for the laboratory evaluation program at these meetings and sought input from the drinking water

utility and laboratory representatives that attended these meetings.

Four laboratories were contacted for burden estimates for participating in the Lab QA Program. Each laboratory was asked to estimate the loaded cost of a manager/hr, a technician/hr, and an average cost for a 1623 sample. The following laboratories have supplied burden estimates for participating in the Lab QA Program:

- CH Diagnostic and Consulting Services
- City of San Diego
- City of Los Angeles Department of Water and Power
- Lab/Cor, Inc

EPA provides questionaires to each laboratory after their on-site evaluation to provide feedback on the auditor process and the auditors. EPA has used the feedback received from the laboratories to improve the audit process.

3(d) Effects of Less Frequent Collections

Under the Laboratory QA Program, EPA plans on requiring laboratories to analyze single-blind OPT samples three times per year. This frequency is the minimum necessary to enable EPA to independently verify that laboratories continue to perform in a acceptable manner. Less frequent OPT samples would not sufficiently capture a laboratory's performance over time. Laboratories will be required to report OPT results within 15 days of analysis. Reporting OPT sample results at this frequency allows EPA to respond in a timely manner to any problems the laboratory may be having with analysis of *Cryptosporidium* in water.

3(e) General Guidelines

The Laboratory QA Program adheres to all of OMB's general guidelines for information collection.

3(f) Confidentiality

The Laboratory QA Program does not ask any confidential or sensitive questions.

4. The Respondents and the Information Requested

4(a) Respondents/SIC Codes

The following is a list of SIC codes associated with laboratories affected by the requirements of this ICR:

8734 - Services: Testing Laboratories

4(b) Information Requested

(i) Data Items

Report on:
- Laboratory participation application information
- Initial proficiency testing (IPT) data
- Ongoing proficiency testing (OPT) data
- Documentation of corrective actions taken in response to any deficiencies noted during the on-site evaluation

Maintain:
- IPT data
- OPT data

(ii) Respondent Activities
- Completing laboratory participation application (1 time only) (See Appendix C)
- Analyzing IPT samples (set of 8 samples, 1 time only for new laboratories) and reporting IPT data
- Analyzing OPT samples (set of 3 samples, 2 times first year only, 3 times per year, per method version), reporting OPT data, and reporting volume of LT2 samples expected
- Hosting on-site evaluation (1 time per three year period)

5. The Information Collected - Agency Activities, Collection Methodology, and Information Management

5(a) Agency Activities

Agency activities associated with the OGWDW's Laboratory QA Program consist of the following:

•Maintaining a database to review, store, and report on laboratory PT results
•Maintaining a database to store and report on laboratory evaluations
•Reviewing laboratory participation applications and notifying laboratories of application status (1 time per laboratory per three year period)
•Preparing and distributing IPT samples (1 time per new laboratory, per method version)
•Tracking receipt of and reviewing IPT data (1 time per new laboratory, per method version)
•Conducting on-site evaluations and re-evaluations of the laboratories seeking EPA recognition of laboratory capability and reporting on the results of these on-site evaluations (1 time per laboratory every three years)
•Preparing and distributing OPT samples, which may include confounding organisms (2 times first year only, 3 times per year, per laboratory, per method version)
•Tracking receipt of and reviewing OPT data and entering the data into a database (2 times first year only, 3 times per year, per laboratory, per method version)
•Developing, generating, and distributing reports on laboratory status (3 times per year)

5(b) Collection Methodology and Management

Laboratories interested in obtaining EPA recognition of laboratory capability to perform analyses using EPA Method 1622 and EPA Method 1623 should submit applications to EPA. EPA will evaluate the applications for completeness and compare the information to the recommended criteria specified in the Federal Register Notice. The criteria include:

1. Recommended personnel criteria:

Principal Analyst/Supervisor (one per laboratory) should have:

- BS/BA in microbiology or closely related field
- 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 EPA Method 1623
- A minimum of 100 samples analyzed using EPA Method 1622 and/or EPA Method 1623 (minimum 50 samples if the person was an analyst approved to conduct analysis for the ICR Protozoan Method (EPA, 1996)) for the specific analytical procedure they will be using
- Submit to EPA, along with the application package, resumes detailing the qualifications of the laboratory's proposed principal analyst/supervisor

Other Analysts (no minimum number of analysts per laboratory) should have:

- Two years of college (or equivalent) in microbiology or closely related field
- 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 EPA Method 1623
- A minimum of 50 samples analyzed using EPA Method 1622 and/or EPA Method 1623 (minimum 25 samples if the person was an analyst approved to conduct analysis for the ICR Protozoan Method) for the specific analytical procedures they will be using
- Submit to EPA, along with the application package, resumes detailing the qualifications of the laboratory's proposed other analysts

Technician(s) (no minimum number of technicians per laboratory) should have:

- Three months experience with the specific parts of the procedure they will be performing
- A minimum of 50 samples analyzed using EPA Method 1622 and/or EPA Method 1623 (minimum 25 samples if the person was an analyst approved to conduct analysis for the ICR Protozoan Method) for the specific analytical procedures they will be using
- Submit to EPA, along with the application package, resumes detailing the qualifications of the laboratory's proposed technician(s)

2. Recommended laboratory criteria:

- Appropriate instrumentation as described in EPA Methods 1622 and 1623 (EPA, 2001a,b)

- Equipment and supplies as described in EPA Methods 1622 and 1623 (EPA 2001a,

2001b)

- Detailed laboratory standard operating procedures for each version of the method that the laboratory will use to conduct the *Cryptosporidium* analyses
- Laboratory should provide a current copy of the table of contents of their laboratory's quality assurance plan for protozoa analyses
- EPA Method 1622 or EPA Method 1623 initial demonstration of capability (IDC) data, which include precision and recovery (IPR) test results and matrix spike/matrix spike duplicate (MS/MSD) test results for *Cryptosporidium*. EPA intends to evaluate the IPR and MS/MSD results against the performance acceptance criteria in the April 2001 version of EPA Method 1622 or EPA Method 1623 (EPA, 2001a, 2001b).

During on-site evaluations, EPA will evaluate laboratories' performance of the methods, as well as laboratories' data recording and quality control practices using standardized checklists. Every three years the laboratories will submit a new application.

IPT and OPT data will be reviewed against the requirements of Method 1622/1623 and the recommended criteria specified in Federal Register Notice. Data for the IPT and OPT samples will be entered into and stored in a QC database with automated data review and calculation functions. Automating data review functions reduces resources required for data review and ensures that all samples are reviewed in a consistent manner.

5(c) Small Entity Flexibility

The Laboratory QA Program is a voluntary program; any entity that believes this program will impose undue burden is not required to participate in the Laboratory QA Program. Laboratories will still be able to analyze *Cryptosporidium* in water for any purpose where evaluation of laboratory capability is not required.

Small businesses are defined as any business that is independently owned and operated and not dominant in its field as defined by the Small Business Administration (SBA) regulations under Section 3 of the Small Business Act.

Small businesses may opt to seek EPA recognition of laboratory capability to perform *Cryptosporidium* water analyses using only one version of EPA Method 1622 and EPA Method 1623 and reduce the burden associated with participation in the Laboratory QA Program.

5(d) Collection Schedule

The Laboratory QA Program is a voluntary program. No laboratories are required to participate or submit any information.

Any laboratory not currently wishing to participate in the Laboratory QA Program may submit an application for laboratory participation at any time. After the laboratory application has been evaluated by EPA and found to be acceptable, EPA will provide the

laboratory with IPT samples. The laboratory will submit IPT sample data to EPA within 15 days of receipt of the IPT samples. After successful completion of the IPT samples, the laboratory will receive a set of OPT samples every four months. Laboratories that are currently participating in the program and have already been evaluated during the original ICR time frame may be asked to submit and updated application and be re-evaluated during the period for this ICR renewal. Laboratories that have successfully completed the audit process will not be evaluated more than once per three year period.

6. Estimating the Burden and Cost of the Collection

6(a) Estimating Respondent Burden

Below are summaries of respondent burden hours for this information collection. EPA consulted with fewer than nine respondents from the community of laboratories that have or may have voluntarily applied for EPA approval of laboratory capability to perform *Cryptosporidium* analyses using EPA Method 1622 and EPA Method 1623 to obtain burden hour estimates. For specific burden breakdowns, refer to the *Laboratories Seeking Approval for One Method* and *Laboratories Seeking Approval for Two Methods* burden tables in Appendix E.

Laboratories may seek EPA approval of laboratory capability for each version of EPA Method 1622 and EPA Method 1623 that they wish to use for field sample monitoring. Therefore, laboratories seeking EPA approval of laboratory capability to perform *Cryptosporidium* analyses for one method version incur different burden hours and costs than laboratories seeking EPA recognition for two versions of the method. Hence, there are separate burden tables for laboratories seeking EPA recognition for one method (Table 1, Appendix E) and laboratories seeking EPA recognition for two methods (Table 2). Currently there are 46 laboratories participating in the EPA Lab QA Program for one method version and 4 that participate for 2 method versions. EPA estimates that 9 additional laboratories will seek EPA approval for one method for a total of 55 and 6 additional laboratories will seek EPA recognition for two methods for a total of 10.

Laboratories will submit only one application every three years, regardless of the number of method versions for which they seek EPA recognition. The laboratory participation application requires the following: 1) completing the application form and a self-audit checklist; 2) providing resumes for each staff member seeking EPA recognition under the program; 3) providing copies of existing laboratory procedures for each version of the method for which the laboratory is seeking EPA recognition; and 4) providing the results of initial demonstration of capability data for each version of the method for which the laboratory is seeking EPA recognition. There is not a deadline for application submission, and laboratories can submit applications at any time. Since laboratories only have to submit the application one time per three year period, the number of laboratories expected to submit applications were evenly distributed over a three year-period to estimate burden hours and costs per year (e.g., laboratories seeking approval for one method, 55

laboratories/3 years = approximately 18 labs/year; laboratories seeking approval for two methods, 10 laboratories/3 years = approximately 3 laboratories per year). Burden hours and costs associated with submitting the completed application package for the laboratories applying for EPA recognition of one method are estimated at 238 labor hours per year. Burden hours associated with submitting the completed application package for the laboratories applying for EPA recognition of two-method versions are estimated at 53 labor hours per year (Appendix E).

Each new laboratory will analyze a separate set of IPT samples, (8 samples per set) for each version of the method for which they are seeking EPA recognition. The burden for this task includes all labor associated with the actual process of analyzing and documenting the data for each set of IPT samples. Since laboratories only have to analyze a set of IPT samples once, the number of laboratories expected to analyze IPT samples were evenly distributed over a 3-year period to estimate burden hours per year (Appendix E). Laboratories that are already participating in the Lab QA Program will not have to repeat their IPT analysis and are not included in the burden estimates. Burden hours for all laboratories analyzing one set of IPT samples (for one method version) are estimated at 120 labor hours per year. Burden hours for all laboratories analyzing two sets of IPT samples (for two method versions) are estimated at 160 labor hours per year **(Appendix E)**.

Each laboratory seeking EPA recognition of laboratory capability under the Laboratory QA Program will undergo one on-site evaluation every three years, regardless of the number of methods for which the laboratory seeks EPA recognition. However, this evaluation may require a longer amount of time if the laboratory requests recognition for more than one method version. The burden hours associated with this task include time required to attend short briefings by the auditors before and after the audit, demonstrate the techniques for the methods for which they are seeking EPA recognition, participate in discussions with the auditors, and respond to any deficiencies noted in the audit report. Because laboratories will only undergo an on-site evaluation one time every three years, the number of laboratories expected to be evaluated were evenly distributed over a three year period to estimate burden hours per year (e.g., laboratories seeking approval for one method = 55 laboratories/3 years = approximately 18 labs/year; laboratories seeking approval for two methods = 10 laboratories/3 years = approximately 3 laboratories per year). Burden hours associated with the on-site evaluation for all laboratories applying for EPA recognition of one method version are estimated at 458 labor hours per year. Burden hours for all laboratories applying for laboratory capability recognition of two method versions are estimated at 102 labor hours per year (Appendix E).

Laboratories approved to participate in the program will analyze a set of OPT samples, which may include confounding organisms (3 samples per set) every four months for each method for which they are seeking EPA recognition. Laboratories will also submit the estimated volume of LT2 samples expected per month. The burden estimates associated with this task include all labor associated with the actual process of analyzing and documenting the data for each set of OPT samples. During the first year of participation in

the Laboratory QA Program, new laboratories will analyze two sets of OPT samples (plus one set of IPT samples) for each method version and laboratories already participating in the program will analyze three sets of OPT samples. During the second and third years of participation all laboratories will analyze three sets of OPT samples (no IPT samples). The burden hours and costs in the burden tables (Appendix E) are weighted to take into account the laboratories that only had to analyze 2 sets of OPT samples the first year. Burden hours for all laboratories analyzing one set of OPT samples every four months (for one method version) are estimated at 2503 labor hours per year. Burden hours and costs for all laboratories using two method versions (which require two sets of OPT samples every four months) are estimated at 347 labor hours.

6(b) Estimating Respondent Costs

Below are summaries of the costs for this information collection. EPA consulted with fewer than nine respondents from the community of laboratories that have or may have voluntarily applied for EPA recognition of laboratory capability to perform *Cryptosporidium* analyses using EPA Method 1622 and EPA Method 1623 to obtain labor and operations and maintenance (O&M) cost estimates, which include overhead costs. For specific cost breakdowns, refer to the *Laboratories Seeking Approval for One Method* and *Laboratories Seeking Approval for Two Methods* tables in Appendix E.

It is assumed that the laboratories wishing to participate in this program are already performing one or two versions of either EPA Method 1622 and EPA Method 1623 for the analysis of *Cryptosporidium* and already have the necessary equipment to perform the analysis, therefore no capital or startup costs were included in the cost estimates. For each task total costs were based on the combined labor and O&M costs for that task.

Cryptosporidium analyses for one method version incur different costs than laboratories seeking EPA recognition for two versions of the method. Hence, there are separate tables for laboratories seeking EPA recognition for one method and laboratories seeking EPA recognition for two methods. EPA estimates that 55 laboratories will seek EPA recognition for one method and 10 laboratories will seek EPA recognition for two methods.

Respondent costs associated with submitting the completed application package for the laboratories applying for EPA recognition of one method is $11,364 per year (approximately 18 respondents/year). Costs associated with submitting the completed application package for the laboratories applying for EPA recognition of two-method is estimated cost of $2,703 per year (approximately 3 respondents/year) (Appendix E).

Respondent costs associated with analysis of IPT samples (total of 8 samples) includes labor and O&M costs, which are estimated at $175 per analytical sample. Because laboratories only have to analyze a set of IPT samples once, the number of laboratories expected to analyze IPT samples were evenly distributed over a 3-year period to estimate burden hours and costs per year. Laboratories already participating in the PT program are

not included in this estimate. The costs for analyzing one set of IPT samples for all laboratories applying for EPA recognition of one method version (approximately 18 laboratories per year) are estimated at $9,156 per year. The costs for all laboratories applying for laboratory capability recognition of two method versions (approximately 2 laboratories per year) are estimated at $12,208 per year.

The costs associated with the on-site evaluation for all laboratories applying for EPA recognition of one method version (approximately 18 laboratories per year) are estimated at $20,020.20 per year. The costs for all laboratories applying for laboratory capability recognition of two method versions (approximately 3 laboratories per year) are estimated at $4,534.20 per year.

Cost estimates associated with the analysis of OPT samples every four months includes all labor and analytical costs associated with the actual process of analyzing and documenting the data for each set of OPT samples. Labor and costs are estimated at $175 per analytical sample. Costs for all laboratories analyzing one set of OPT samples every four months (for one method version) are estimated $188,760 per year. Costs for all laboratories using two method versions (which require two sets of OPT samples every four months) are estimated at $26,152 per year.

6(c) Estimating Agency Burden and Costs

Below are Agency burden hours and associated financial costs pertaining to implementation of the Laboratory QA Program. For a specific breakdown of burden hours and financial costs, refer to the *Agency Burden* table in Appendix F. Costs and burden hours are broken out based on activities completed by the Agency and supporting contractors. Based on the 2005 GS schedule for the Washington DC/Baltimore area and the standard government benefits multiplication factor of 1.6, EPA estimates an average hourly cost of $79.70/hour for Agency legal staff, $67.74/hour for Agency management staff, $40.22/hour for Agency technical staff, and $17.47/hour for Agency clerical staff. Based on the published schedule of contractor labor rates for the years covered by this program, the average loaded burden hours and costs for contractor labor were estimated at $110.00/hour for expert staff, $95.00/hour for management staff, and $62.00/hour for technical staff.

Agency burden is estimated based on the labor hours associated with performing each task per laboratory seeking laboratory capability recognition. To get the total annual cost hours and costs are then multiplied by the estimated number of respondents and added to the capital and O&M costs. The burden associated with each information collection task is shown in a separate row of the burden table. It is estimated that 65 laboratories (approximately 22 laboratories per year) will seek EPA recognition under the Laboratory Quality Assurance Evaluation Program. Maintenance of a QC database and lab-audit database are not affected by the number of laboratories seeking EPA recognition because these costs and labor hours will be incurred independent of the number of laboratories

participating in the program.

To facilitate data storage and data review, the Agency will maintain a QC database. The Agency burden associated with maintenance of the QC and lab audit databases is estimated at 6.5 labor hours and a total Agency cost of $425 per year.

The Agency will review the laboratory participation applications to ensure that all the required information has been submitted and that each laboratory applicant has the necessary experience and qualifications to acceptably analyze water samples for *Cryptosporidium*. The labor hours and costs associated with this task include reviewing the laboratory application and notifying the laboratory if their application is acceptable or requires submission of additional information. Since each laboratory will only be required to submit an application one time, the number of laboratories expected to seek EPA recognition is evenly distributed over three years in order to determine labor hours and costs per year. The Agency burden associated with review of laboratory participation applications is estimated at 118.8 labor hours and a cost of $7,954 per year.

To test the ability of the laboratory to acceptably analyze water samples for *Cryptosporidium*, the Agency will distribute IPT and OPT samples to the laboratories participating in the Laboratory Quality Assurance Evaluation Program. The labor hours and costs associated with this task include notifying laboratories when they will receive their next samples, preparing the samples, and shipping the samples to the laboratories. All the capital startup costs associated with preparing the performance testing samples are included in the costs of preparing the IPT samples. Because each laboratory will only be required to analyze IPT samples once, the number of laboratories expected to analyze IPT samples is evenly distributed over three years in order to determine labor hours and costs per year The Agency burden associated with preparation of IPT samples is estimated at 10 labor hours per year and a cost of $2,230 per year. The Agency burden associated with preparation of the OPT samples is estimated at 300 labor hours per year, and a total Agency cost of $55,124 per year.

The Agency will perform on-site evaluations of each laboratory to determine if the laboratory has the required equipment and facilities, has an appropriate QC program in place, and is performing the method properly. Labor hours and costs include scheduling the on-site evaluation, travel, conducting the evaluation, documenting the results of the evaluation, notifying the laboratory of the results of their evaluation, and tracking the progress and costs of these activities. The Agency burden associated with performing on-site evaluations is estimated at 2,467.8 labor hours per year and a cost of $264,513 per year.

The Agency will review the IPT data submitted by the laboratory to verify that the data submission is complete, the method requirements were met, and that the laboratory's performance was acceptable. After the review is complete, the Agency will notify the laboratory whether their performance on the IPT samples was acceptable. The Agency burden associated with reviewing IPT data is estimated at 22.5 labor hours per year and a

cost of $1531 per year.

On an ongoing basis, the Agency will review OPT data submitted by the laboratories to verify that the data submission is complete, the method requirements were met, and that the laboratories' performance was acceptable. The labor hours and costs associated with reviewing these data include data entry into the QC database, automated data review, and notification of the laboratory regarding the results. The Agency burden associated with reviewing OPT data is based on an estimated 450 labor hours per year and a cost of $29,728 per year.

The Agency will post the status of the laboratories that will be participating in the Laboratory QA Program on the LT2 website http://www.epa.gov/safewater/lt2/aprvlabs.html. The labor hours and costs associated with these reports include generation of the reports and posting of laboratory status on an EPA website. The Agency burden associated with the status reports is based on and estimated 12 hours per year and a cost of $768 per year.

6(d) Estimating the Respondent Universe and Total Burden and Costs

The affected entities include public and private water testing laboratories. EPA estimates that 65 laboratories (approximately 22 laboratories per year) will seek EPA recognition under the Laboratory QA Program. The respondent total burden and cost are provided in the *Total Respondent and Agency Burden Tables* in Appendix G and are described in greater detail in Sections 6(a) - 6(c).

6(e) Bottom Line Burden Hours and Cost Tables

(i) Respondent Tally

Refer to the burden table in Appendix G titled, *Total Respondent and Agency Burden Tables*, for a specific breakdown of the respondent costs. The Laboratory QA Program will affect approximately 65 respondents (22 laboratories per year). The respondents will engage in 4 different tasks (refer to Section 4(b)(ii)) involving 3,980 labor hours and costing approximately $166,393 per year for labor. Respondents will invest $0.00 per year in capital/start-up costs and $108,504 per year in O&M costs.

(ii) Agency Tally

Refer to the burden table in Appendix G titled, *Total Agency and Agency Burden Tables*, for a summary of Agency costs. Eight Agency tasks are associated with the Laboratory QA Program. These tasks will involve approximately 3,388 labor hours annually resulting in a cost of $268,985 per year for labor. The Agency will invest approximately $0.00 per year in capital/start-up costs and $93,783 per year in O&M costs.

6(f) Reasons for Change in Burden

Changes in burden have occurred due to inflation, an increase in the respondent universe, and re-evaluation of hours for tasks. Inflation has increased all O&M and labor costs accordingly. The increase in the respondent universe has increased the overall burden costs for the respondents. EPA's original estimates for hours to participate and maintain the Laboratory Quality Assurance Evaluation Program were made before the program began. Because the program has been continuing, the estimates have been re-evaluated based on actual time spent on the tasks, causing the burden estimates to change. Burden estimates have also changed based on some tasks such as the development of the QC database and audit checklist not being applicable to this renew ICR.

6(g) Burden Statement

The reporting and record-keeping burden for this collection is estimated to average 19 hours annually per laboratory (the combined total hours per year for one and two method laboratories divided by 65 laboratories divided by 3.3 activities per year).

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR Part 9 and 48 CFR Chapter 15.

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques, EPA has established a public docket for this ICR under Docket ID Number OW-2002-0012, which is available for public viewing at the EPA Water Docket in the EPA Docket Center (EPA/DC), EPA West, Room B102, 1301 Constitution Ave., NW, Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566-1744, and the telephone number for the EPA Water Docket is (202) 566-2426. An electronic version of the public docket is available through EPA Dockets (EDOCKET) at http://www.epa.gov/edocket. Use EDOCKET to submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. When in the system, select "search," then key in the Docket ID Number identified above. Also, you can send comments to the

Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503, Attention: Desk Officer for EPA. Please include the EPA Docket ID Number OW-2002-0012 and OMB Control Number 2040-0246 in any correspondence.

Summary of Comments on Federal Register notice can be found below and the complete list of comments and responses are included in Appendix I.

Four sets of comments were received.

One comment was received concerning the frequency of the on-site evaluations being inadequate given the potential changes in laboratory personnel during LT2 monitoring. Another comment stated the current frequency is adequate. As indicated in this supporting statement, laboratories will be audited every three years. Priority will be given to those laboratories anticipated to analyze the most samples during LT2 and those that have undergone significant personnel and facility changes.

One commenter felt that the PT samples and audit slides were not challenging enough and were not representative of real-world samples. Another commenter recommended a lower frequency of proficiency test samples. EPA is considering the use of confounding organisms in the PT samples and audit slides to make the samples more realistic and challenging.

One commenter indicated that the estimated burden hours were not sufficient for the required tasks. EPA is confident that the burden hours estimated are sufficient to accomplish all of the activities included in the Lab QA Program after consulting multiple laboratories and reevaluation of previous estimates.

One comment addressed the need to confirm that laboratories are maintaining performance criteria. EPA believes that the OPT samples analyzed three times a year are sufficient in testing the laboratory performance.

Commenters noted that the Lab QA program is a valuable tool for laboratories as well as their clients and that it is appropriate that EPA continue to provide this service. Commenters said that the on-site evaluation was helpful and that EPA sent qualified and knowledgeable auditors who provided good feedback to improve their laboratory's work.

One comment indicated that more QA/QC is needed and that EPA has not demonstrated sufficient laboratory capacity for LT2 implementation.

APPENDIX A

Federal Register Notice:
Laboratory Quality Assurance Evaluation Program/
Information Collection Request
[Published December 29, 2000]

ENVIRONMENTAL PROTECTION AGENCY

[FRL- 7152-6]

Laboratory Quality Assurance Evaluation Program for Analysis of *Cryptosporidium* under the Safe Drinking Water Act; Agency Information Collection: Proposed Collection; Comment Request

AGENCY: Environmental Protection Agency.

ACTION: Notice; Request for Comment.

SUMMARY: Today's notice invites comment on the U.S. Environmental Protection Agency's (EPA's) proposed Laboratory Quality Assurance Evaluation Program for Analysis of *Cryptosporidium* under the Safe Drinking Water Act (Lab QA Program) (Section I). EPA also plans to submit to the Office of Management and Budget (OMB) for review and approval an Information Collection Request (ICR) associated with information collections under the proposed Lab QA Program (Section II). EPA is requesting comments on specific aspects of the proposed Lab QA Program and the ICR. Finally, EPA solicits comments on its intention to seek an emergency clearance from OMB to begin collecting data from laboratories that are interested in participating in the Lab QA Program prior to OMB's final approval of the ICR.

DATES: The Agency requests comments on today's notice. Comments must be received or post-marked by midnight May 3, 2002. If EPA does not receive adverse comments on or before April 3, 2002 regarding EPA's request for an emergency clearance, the Agency intends to seek a 90-day emergency clearance from OMB to begin collecting data from laboratories that are interested in participating in the Lab QA Program.

ADDRESSES: Please send an original and three copies of your written comments and enclosures (including references) to the W-01-17 Comment Clerk, Water Docket (MC-4101), EPA, 1200 Pennsylvania Avenue, NW, Washington, DC 20460. Due to the uncertainty of mail delivery in the Washington, DC area, in order to ensure that all comments are received please send a separate copy of your comments via electronic mail (e-mail) to Mary Ann Feige, EPA, Office of Ground Water and Drinking Water, feige.maryann@epa.gov, or mail to the attention of Mary Ann Feige, EPA, Technical Support Center, 26 West Martin Luther King Drive (MS-140), Cincinnati, Ohio 45268. Hand deliveries should be delivered to: EPA's Water Docket at 401 M Street, SW, Room EB57, Washington, DC 20460. Please make certain to reference EPA ICR No. 2052.02 and OMB Control No. 2040-0229.

FOR FURTHER INFORMATION: For a copy of the ICR, contact Sharon Gonder at EPA by phone at (202) 564-5256 or by email at gonder.sharon@epa.gov or download off the Internet at http://www.epa.gov/icr and refer to EPA ICR No. 2052.02. For technical inquiries, contact Mary Ann Feige, EPA, Office of Ground Water and Drinking Water, Technical Support Center, 26 West Martin Luther King Drive (MS-140), Cincinnati, Ohio

45268, fax number, (513) 569-7191, e-mail address, feige.maryann@epa.gov.

SUPPLEMENTARY INFORMATION:

Submission of comments.

Individuals who want EPA to acknowledge receipt of their comments should enclose a self-addressed, stamped envelope. No facsimiles (faxes) will be accepted. Comments may also be submitted electronically to ow-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII, WP5.1, WP6.1 or WP8 file avoiding the use of special characters and form of encryption. Electronic comments must be identified by docket number W-01-17. Comments and data will also be accepted on disks in WP5.1, 6.1, 8 or ASCII file format. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

Availability of docket.

The record for this notice has been established under docket number W-01-17, and includes supporting documentation as well as printed, paper versions of electronic comments. The record is available for inspection from 9 a.m. to 4 p.m., Monday through Friday, excluding legal holidays at the Water Docket, EB 57, EPA Waterside Mall, 401 M Street, SW, Washington, DC 20460. For access to docket materials, please call (202) 260-3027 to schedule an appointment.

Section I: Laboratory Quality Assurance Evaluation Program for Analysis of *Cryptosporidium* under the Safe Drinking Water Act

In September 2000, the Stage 2 Microbial and Disinfection Byproducts Federal Advisory Committee (Committee) signed an Agreement in Principle (Agreement) (65 FR 83015, Dec. 29, 2000) (EPA, 2000) with consensus recommendations for two future drinking water regulations: the Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR) and the Stage 2 Disinfectants and Disinfection Byproducts Rule. The LT2ESWTR is to address risk from microbial pathogens, specifically *Cryptosporidium*, and the Stage 2 DBPR is to address risk from disinfection byproducts. The Committee recommended that the LT2ESWTR require public water systems (PWSs) to monitor their source water for *Cryptosporidium* using EPA Method 1622 or EPA Method 1623. Additional *Cryptosporidium* treatment requirements for PWSs would be based on the source water *Cryptosporidium* levels. EPA intends to take into account the Committee's advice and recommendations embodied in the Agreement when developing the regulations.

To support *Cryptosporidium* monitoring under the LT2ESWTR, the Committee Agreement recommended that "compliance schedules for the LT2ESWTR...be tied to the availability of sufficient analytical capacity at approved laboratories for all large and medium-size affected systems to initiate *Cryptosporidium* and *E.coli* monitoring..."(65 FR

83015, Dec. 29, 2000) (EPA, 2000). Further, the Agreement recommended that *Cryptosporidium* monitoring by large and medium systems begin within six months following rule promulgation. Given the time necessary for EPA to approve a sufficient number of laboratories to assure adequate capacity for LT2ESWTR monitoring, EPA would need to begin laboratory evaluation prior to promulgation of the rule in order to accommodate such an implementation schedule.

Another factor that warrants initiation of the Lab QA Program prior to promulgation of the LT2ESWTR is grandfathering of monitoring data. The Agreement recommends that systems with "historical" *Cryptosporidium* data that are equivalent to data that would be collected under the LT2ESWTR be afforded the opportunity to use those "historical" (grandfathered) data in lieu of collecting new data under LT2ESWTR. EPA intends to propose such grandfathering provisions in the LT2ESWTR. If EPA indicates that laboratories meet the criteria in the Lab QA Program described today prior to finalizing the LT2ESWTR, systems could develop monitoring data prior to the LT2ESWTR in anticipation of using it as grandfathered data.

EPA's Office of Ground Water and Drinking Water plans to request from OMB an emergency clearance that would enable expeditious implementation of a voluntary Lab QA Program to support *Cryptosporidium* monitoring under the LT2ESWTR. As such, the Agency could begin to evaluate laboratories that can reliably measure for *Cryptosporidium* using EPA Method 1622 and Method 1623. During the effective period of the emergency clearance, EPA intends to submit to OMB for review and approval a final ICR in order to continue data collection for the Lab QA Program.

As part of today's notice, EPA is inviting comment on the Lab QA Program. Under the Lab QA Program, EPA would evaluate labs on a case-by-case basis through evaluating their capacity and competency to reliably measure for the occurrence of *Cryptosporidium* in surface water using EPA Method 1622 or EPA Method 1623. The intent of this notice is not to propose establishing the Lab QA Program through a rulemaking. Rather, the criteria described in section I.C. are intended to provide guidance to laboratories that are interested in participating in the Lab QA Program.

EPA has not yet proposed rulemaking on use of such "historical" data nor on the methods themselves under the LT2ESWTR. As noted above, EPA intends to propose allowing systems to use equivalent "historical" data in lieu of collecting new data. EPA anticipates the data generated by labs which meet the evaluation criteria would be very high quality, thus increasing the likelihood that such data would warrant consideration as acceptable "grandfathered" data. However, lab evaluation would not guarantee that data generated will be acceptable as "grandfathered" data, nor would failure to meet evaluation criteria necessarily preclude use of "grandfathered" data. For these reasons, EPA is not establishing the Lab QA Program through rulemaking, but rather as a discretionary and voluntary program under the Safe Drinking Water Act, section 1442 (42 USC 300j-1(a)).

A. What is the purpose of the laboratory quality assurance evaluation program?

The purpose of the Lab QA Program is to identify laboratories that can reliably measure for the occurrence of *Cryptosporidium* in surface water. Existing laboratory certification programs do not include *Cryptosporidium* analysis. This program is designed to assess and confirm the capability of laboratories to perform *Cryptosporidium* analyses.

The program will assess whether laboratories meet the recommended personnel and laboratory criteria in today's notice. This evaluation program is voluntary for laboratories. In the LT2ESWTR, however, EPA intends to require systems to use approved (or certified) laboratories when conducting *Cryptosporidium* monitoring under the LT2ESWTR.

B. Why has EPA selected Methods 1622 and 1623 as the basis for determining the data quality of laboratories that measure for Cryptosporidium?

EPA Method 1622 and EPA Method 1623 were developed as improved alternatives to the ICR Protozoan Method (EPA, 1996). EPA validated Method 1622 for the determination of *Cryptosporidium* in ambient water in August 1998 and distributed an interlaboratory validated draft method in January 1999. In addition, EPA validated Method 1623 for the simultaneous determination of *Cryptosporidium* (and *Giardia*) in ambient water in February 1999 and distributed a validated draft method in April 1999.

In April 2001, EPA revised and updated Method 1622 (EPA-821-R-01-026) (EPA, 2001a) and Method 1623 (EPA-821-R-01-025) (EPA, 2001b) based on the following: laboratory feedback, the development of equivalent filters and antibodies for use with the methods, and method performance data generated during the ICR Supplemental Surveys (EPA, 2001e). The results of these studies are documented in the Method 1622 interlaboratory validation study report (EPA-821-R-01-027) (EPA, 2001c) and the Method 1623 interlaboratory validation study report (EPA-821-R-01-028) (EPA, 2001d).

C. What criteria should I use to determine if my laboratory should apply?

A laboratory that is interested in participating in the Lab QA Program currently should be operating in accordance with its QA plan (developed by the laboratory) for *Cryptosporidium* analyses. In addition, an interested laboratory should demonstrate its capacity and competency to analyze *Cryptosporidium* using the following recommended criteria:

1. Recommended personnel criteria:

Principal Analyst/Supervisor (one per laboratory) should have:

- BS/BA in microbiology or closely related field
- 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 EPA Method 1623
- A minimum of 100 samples analyzed using EPA Method 1622 and/or EPA Method 1623 (minimum 50 samples if the person was an analyst approved to conduct analysis for the ICR Protozoan Method (EPA, 1996)) for the specific analytical procedure they will be using
- Submit to EPA, along with the application package, resumes detailing the qualifications of the laboratory's proposed principal analyst/supervisor

Other Analysts (no minimum number of analysts per laboratory) should have:

- Two years of college (or equivalent) in microbiology or closely related field

- 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 EPA Method 1623
- A minimum of 50 samples analyzed using EPA Method 1622 and/or EPA Method 1623 (minimum 25 samples if the person was an analyst approved to conduct analysis for the ICR Protozoan Method) for the specific analytical procedures they will be using
- Submit to EPA, along with the application package, resumes detailing the qualifications of the laboratory's proposed other analysts

Technician(s) (no minimum number of technicians per laboratory) should have:

- Three months experience with the specific parts of the procedure they will be performing
- A minimum of 50 samples analyzed using EPA Method 1622 and/or EPA Method 1623 (minimum 25 samples if the person was an analyst approved to conduct analysis for the ICR Protozoan Method) for the specific analytical procedures they will be using
- Submit to EPA, along with the application package, resumes detailing the qualifications of the laboratory's proposed technician(s)

2. Recommended laboratory criteria:

- Appropriate instrumentation as described in EPA Methods 1622 and 1623 (EPA, 2001a,b)
- Equipment and supplies as described in EPA Methods 1622 and 1623 (EPA 2001a, 2001b)
- Detailed laboratory standard operating procedures for each version of the method that the laboratory will use to conduct the *Cryptosporidium* analyses
- Laboratory should provide a current copy of the table of contents of their laboratory's quality assurance plan for protozoa analyses
- EPA Method 1622 or EPA Method 1623 initial demonstration of capability (IDC) data, which include precision and recovery (IPR) test results and matrix spike/matrix spike duplicate (MS/MSD) test results for *Cryptosporidium*. EPA intends to evaluate the IPR and MS/MSD results against the performance acceptance criteria in the April 2001 version of EPA Method 1622 or EPA Method 1623 (EPA, 2001a, 2001b).

D. How can I obtain an application package?

After the OMB clearance described above, EPA plans to make applications available on EPA's website at www.epa.gov/safewater/cryptolabapproval.html. Completed applications should be sent to: EPA's Laboratory Quality Assurance Evaluation Program Coordinator, c/o Dyncorp I&ET, Inc., 6101 Stevenson Avenue, Alexandria, VA 22304-3540. If a laboratory does not have access to the Internet, the laboratory may contact Dyncorp I&ET, Inc. to request an application package.

E. If I demonstrate my laboratory's capacity and competency according to the the personnel and laboratory criteria, what do I do next?

After the laboratory submits to EPA an application package including supporting documentation, EPA intends to conduct the following steps to complete the process:

1. Upon receipt of a complete package, EPA contacts the laboratory for follow-up information and to schedule participation in the performance testing program.

2. EPA sends initial proficiency testing (IPT) samples to the laboratory (unless the laboratory has already successfully analyzed such samples under EPA's Protozoan PE program). IPT samples packets consist of eight spiked samples shipped to the laboratory within a standard matrix.
3. The laboratory analyzes IPT samples and submits data to EPA.
4. EPA conducts an on-site evaluation and data audit.
5. The laboratory analyzes ongoing proficiency testing (OPT) samples three times per year and submits the data to EPA. OPT sample packets consist of three spiked samples shipped to the laboratory within a standard matrix.
6. EPA contacts laboratories by letter within 60 days of their laboratory on-site evaluation to confirm whether the laboratory has demonstrated its capacity and competency for participation in the program.

F. My laboratory has already submitted initial demonstration of capability (IDC) and initial performance testing (IPT) data as part of the EPA Protozoan Performance Evaluation (PE) Program. Do I have to perform this demonstration testing again?

No. If a laboratory currently participates in the EPA Protozoan PE Program and acceptable IDC and IPT data have already been submitted (for the version of the method that the laboratory will use to conduct *Cryptosporidium* analyses), EPA would not expect the laboratory to repeat IDC and IPT analyses.

Section II: Paperwork Reduction Act

The information collection requirements in this notice have been submitted for approval to the OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. An ICR document has been prepared by EPA (ICR No. 2052.02) and a copy may be obtained from Susan Auby by mail at Collection Strategies Division; EPA (2822); 1200 Pennsylvania Ave., NW, Washington, DC 20460, by email at auby.susan@epamail.epa.gov, or by calling (202) 260-4901. A copy may also be downloaded off the internet at http://www.epa.gov/icr.

Since the EPA would solicit information in application packages, including supporting documentation, analytical data, and other pertinent information from laboratories that are interested in participating in the voluntary Lab QA Program, the Agency is required to submit an ICR to OMB for review and approval. Entities potentially affected by this action include public and private laboratories that wish to be evaluated to determine if they can reliably measure for the occurrence of *Cryptosporidium* in surface waters that are used for drinking water sources using EPA Method 1622 or Method 1623.

The burden estimate for the Lab QA Program information collection includes all the burden hours and costs required for gathering information, and developing and maintaining records associated with the Lab QA Program. The annual public reporting and recordkeeping burden for this collection of information is estimated for a total of 60 respondents and an average 78 hours per response for a total of 4,676 hours at a cost of $123,650. This estimate assumes that laboratories participating in the Lab QA program have the necessary equipment needed to conduct the analyses. Therefore, there are no start-up costs. The estimated total annual capital costs is $0.00. The estimated Operation and Maintenance (O&M) costs is $133,880.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to

respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR Part 9 and 48 CFR Chapter 15.

Comments are requested on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques. Send comments on the ICR to the Director, Collection Strategies Division; EPA (2822); 1200 Pennsylvania Ave., NW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th St., N.W., Washington, DC 20503, marked "Attention: Desk Officer for EPA." Include the ICR number in any correspondence. Because OMB is required to make a decision concerning the ICR between 30 and 60 days after March 4, 2002, a comment to OMB is best assured of having its full effect if OMB receives it by April 3, 2002. The final ICR approval notice will respond to any OMB or public comments on the information collection requirements contained in today's notice.

References

EPA. 1996. ICR Microbial Laboratory Manual. Office of Research and Development. EPA/600/R-95/178. April 1996.

EPA. 2000. Stage 2 Microbial and Disinfection Byproducts Federal Advisory Committee Agreement in Principle. Federal Register. Vol. 65, pp. 83015-83024. December 29, 2000.

EPA. 2001a. EPA Method 1622: *Cryptosporidium* in Water by Filtration/IMS/FA. Office of Water. Washington, DC 20460. EPA-821-R-01-026. April 2001.

EPA. 2001b. EPA Method 1623: *Cryptosporidium* and *Giardia* in Water by Filtration/IMS/FA. Office of Water. Washington, DC 20460. EPA-821-R-01-025. April 2001.

EPA. 2001c . Interlaboratory Validation Study Results for *Cryptosporidium* Precision and Recovery for EPA Method 1622. Office of Water. Washington, DC 20460. EPA-821-R-01-027. April 2001.

EPA. 2001d. Interlaboratory Validation Study Results for the Determination of *Cryptosporidium* and *Giardia* Using EPA Method 1623. Office of Water. Washington, DC 20460. EPA-821-R-01-028. April 2001.

EPA. 2001e. Implementation and Results of the Information Collection Rule Supplemental Surveys. Office of Water. Washington, DC 20460. EPA-815-R-01-003. February 2001.

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Date

APPENDIX B

Federal Register Notice:
Laboratory Quality Assurance Evaluation Program/
Information Collection Request
[Published March 4, 2002]

ENVIRONMENTAL PROTECTION AGENCY

[FRL-]

Agency Information Collection Activities: Submission for OMB Review; Comment Request; EPA Laboratory Quality Assurance Evaluation Program for Analysis of *Cryptosporidium* under the Safe Drinking Water Act/ Laboratory approval for the Long Term 2 Enhanced Surface Water Treatment Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 et seq.), this document announces that the following Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval: EPA Laboratory Quality Assurance Evaluation Program for Analysis of *Cryptosporidium* under the Safe Drinking Water Act, OMB Control Number 2040-0246, expiration date of July 31, 2002. The ICR describes the nature of the information collection and its expected burden and cost; where appropriate, it includes the actual data collection instrument.

DATES: Comments must be submitted on or before [Insert date 30 days after publication in the FEDERAL REGISTER].

ADDRESSES: Send comments, referencing EPA ICR No.2067.02 and OMB Control No.2040-0246, to the following addresses: Susan Auby, U.S. Environmental Protection Agency, Collection Strategies Division (Mail Code 2822), 1200 Pennsylvania Avenue, N.W., Washington, DC 20460; and to Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, N.W., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: For a copy of the ICR contact Susan Auby at EPA by phone at (202) 260-4901, by E-mail at auby.susan@epamail.epa.gov, or download off the Internet at http://www.epa.gov/icr and refer to EPA ICR No. 2067.02, the ICR number has changed from the last notice. All requests should refer to EPA ICR No. 2067.02 and not EPA ICR No. 2052.02. For technical inquiries, contact Mary Ann Feige, EPA, Office of Ground Water and Drinking Water, Technical Support Center, 26 West Martin Luther King Drive (MS-140), Cincinnati, Ohio 45268, fax number, (513) 569-7191, e- mail address, feige.maryann@epa.gov.

SUPPLEMENTARY INFORMATION:

Title: EPA Laboratory Quality Assurance Evaluation Program for Analysis of *Cryptosporidium* under the Safe Drinking Water Act (OMB Control No. 2040-0246 ; EPA ICR No. 2067.01) expiring 7/31/02 . This is a request for extension of a currently approved collection.

Abstract: Section I: Laboratory Quality Assurance Evaluation Program for Analysis of *Cryptosporidium* Under the Safe Drinking Water Act

In September 2000, the Stage 2 Microbial and Disinfection Byproducts Federal Advisory Committee (Committee) signed an Agreement in Principle (Agreement) (65 FR 83015, Dec. 29, 2000) (EPA, 2000) with consensus recommendations for two future drinking water regulations: The Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR) and the Stage 2 Disinfectants and Disinfection Byproducts Rule. The LT2ESWTR is to address risk from microbial pathogens, specifically *Cryptosporidium*, and the Stage 2 DBPR is to address risk from disinfection byproducts. The Committee recommended that the LT2ESWTR require public water systems (PWSs) to monitor their source water for *Cryptosporidium* using EPA Method 1622 or EPA Method 1623. Additional *Cryptosporidium* treatment requirements for PWSs would be based on the source water *Cryptosporidium* levels. To support Cryptosporidium monitoring under the LT2ESWTR, the Committee Agreement recommended that ``compliance schedules for the

LT2ESWTR * * * be tied to the availability of sufficient analytical capacity at approved laboratories for all large and medium-size affected systems to initiate *Cryptosporidium* and *E.coli* monitoring * * * " (65 FR 83015, Dec. 29, 2000) (EPA, 2000). Further, the Agreement recommended that *Cryptosporidium* monitoring by large and medium systems begin within six months following rule promulgation. Given the time necessary for EPA to approve a sufficient number of laboratories to assure adequate capacity for LT2ESWTR monitoring, EPA would need to begin laboratory evaluation prior to promulgation of the rule in order to accommodate such an implementation schedule. Another factor that warrants initiation of the Lab QA Program prior to promulgation of the LT2ESWTR is grandfathering of monitoring data. The Agreement recommends that systems with ``historical'' *Cryptosporidium* data that are equivalent to data that would be collected under the LT2ESWTR be afforded the opportunity to use those ``historical'' (grandfathered) data in lieu of collecting new data under LT2ESWTR. EPA intends to propose such grandfathering provisions in the LT2ESWTR. If EPA indicates that laboratories meet the criteria in the Lab QA Program described today prior to finalizing the LT2ESWTR, systems could develop monitoring data prior to the LT2ESWTR in anticipation of using it as grandfathered data. Under the Lab QA Program, EPA would evaluate labs' capacity and competency to reliably measure for the occurrence of *Cryptosporidium* in surface water using EPA Method 1622 or EPA Method 1623. The intent of this notice is not to propose establishing the Lab QA Program through a rulemaking. Rather, the criteria described in section I.C. are intended to provide guidance to laboratories that are interested in participating in the Lab QA Program. EPA anticipates the data generated by labs which meet the evaluation criteria would be very high quality, thus increasing the likelihood that such data would warrant consideration as acceptable ``grandfathered'' data. However, lab evaluation would not guarantee that data generated will be acceptable as ``grandfathered'' data, nor would failure to meet evaluation criteria necessarily preclude use of ``grandfathered'' data. For these reasons, EPA is not establishing the Lab QA Program through rulemaking, but rather as a discretionary and voluntary program under the Safe Drinking Water Act, section 1442 (42 USC 300j-1(a)).

A. What Is the Purpose of the Laboratory Quality Assurance Evaluation Program?

The purpose of the Lab QA Program is to identify laboratories that can reliably measure for the occurrence of Cryptosporidium in surface water. Existing laboratory certification programs do not include Cryptosporidium analysis. This program is designed to assess and confirm the capability of laboratories to perform Cryptosporidium analyses. The program will assess whether laboratories meet the recommended personnel and laboratory criteria in today's notice. This evaluation program is voluntary for laboratories. In the LT2ESWTR, however, EPA intends to require systems to use approved (or certified) laboratories when conducting *Cryptosporidium* monitoring under the LT2ESWTR.

B. How Can I Obtain an Application Package?

After the OMB clearance described above, EPA plans to make applications available on EPA's website at www.epa.gov/safewater/ cryptolabapproval.html. Completed applications should be sent to: EPA's Laboratory Quality Assurance Evaluation Program Coordinator, c/o DynCorp, 6101 Stevenson Avenue, Alexandria, VA 22304-3540. If a laboratory does not have access to the Internet, the laboratory may contact DynCorp to request an application package. Applications may be submitted at any time.

C. If I Demonstrate My Laboratory's Capacity and Competency According to the Personnel and Laboratory Criteria, What Happens Next?

After the laboratory submits to EPA an application package including supporting documentation, EPA intends to conduct the following steps to complete the process:
1) Upon receipt of a complete package, EPA contacts the laboratory for follow-up information and to schedule participation in the performance testing program.
2) EPA sends initial proficiency testing (IPT) samples to the laboratory. IPT samples packets consist of eight spiked samples shipped to the laboratory within a standard matrix.
3) The laboratory analyzes the IPT samples and submits data to EPA. EPA intends to have the laboratory's IPT data meet the IPT criteria of greater than 10% mean recovery and less than 71% relative standard deviation (these criteria were developed based on results from the first six rounds of the EPA PE program). This approach will be used unless unforeseen circumstances merit a reassessment of the approach.
4) EPA conducts an on-site evaluation and data audit. Checklist for evaluation and audit is included in ICR.
5) The laboratory analyzes ongoing proficiency testing (OPT) samples three times per year and submits the data to EPA. OPT sample packets consist of three spiked samples shipped to the laboratory within a standard matrix. The results of the laboratory's OPT data must meet the OPT criteria which will be calculated for each round of OPT testing using only the data from that round. EPA intends to calculate the lower limit as less than 2 standard deviations from the pooled mean using log it transformed data and intends to calculate the maximum RSD as 2 times the pooled RSD. This approach will be used unless unforeseen circumstances merit a reassessment of the approach.
6) EPA contacts laboratories by letter within 60 days of their laboratory on-site evaluation to confirm whether the laboratory has demonstrated its capacity and competency for participation in the program.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR Chapter 15. The Federal Register document required under 5 CFR 1320.8(d), soliciting comments on this collection of information was published on March 4, 2002 (FR). Three comments were received.

Comments requested further information on the details of the Lab Quality Assurance Program. In response, EPA has added supplementary information to the ICR, including the program application, which includes the self-audit checklist detailing the items that will be evaluated during the on-site evaluation. EPA also has also developed a webpage to provide further information on the program. The website can be accessed at http://www.epa.gov/safewater/lt2/cla_final.html.

Commenters expressed concern that the Lab QA Program does not address the Agency's obligation under the FACA Agreement in Principle to identify adequate laboratory capacity to implement LT2ESWTR. The Lab QA Program does assess laboratory capacity through questions on the application on current and potential laboratory capacity to analyze *Cryptosporidium* samples and the on site evaluations. This information will be compiled as laboratory applications are received, and will be updated during on-site evaluations. The on-site evaluation will allow EPA to validate lab capacity reported to EPA.

Comments were received on the burden estimates. Because laboratories that wish to begin using EPA Methods 1622 and 1623 are required by the methods to purchase the equipment necessary to demonstrate initial acceptable performance, and because this is a method

requirement, rather than a program requirement (laboratories can perform the methods without ever participating in the program), the burden estimates assume that no capital costs will be incurred by laboratories participating in the program over and above the costs that would be incurred simply to use the method. Because the program application requires the laboratories applying for approval under the program to submit initial performance data, laboratories that meet these requirements should already have the capacity to perform Methods 1622 or 1623 and therefore will not incur start-up costs.

Commenters wanted to know if training would be available for labs needing help. EPA will provide limited training to laboratories needing assistance with the performance of Methods 1622 and 1623. Information on training will be posted on EPA's website as it becomes available.

Commenters wanted to know the earliest date that acceptable grandfathered data could be generated. EPA is aware of the issues regarding grandfathered data acceptability and will address these issues in the proposed LT2ESWTR. These issues are outside of the scope of this ICR.

Burden Statement: The annual public reporting and record keeping burden for this collection of information is estimated to average 18 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. Respondents/Affected Entities: Testing Laboratories Estimated Number of Respondents: 60. Frequency of Response: 3 times per year. Estimated Total Annual Hour Burden: 4347 hours. Estimated Total Annualized Capital, O&M Cost Burden: $123,380.

Send comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques to the addresses listed above. Please refer to EPA ICR No. 2067.02 and OMB Control No. 2040-0246 in any correspondence.

APPENDIX C

Lab QA Program Application

OMB Control Number: 2040-0246
Expiration Date: 10/31/05

Application for the Laboratory Quality Assurance Evaluation Program for Analysis of *Cryptosporidium* under the Safe Drinking Water Act

Part 1. Laboratory Information

Laboratory Name:	**EPA Lab ID:**	
Address:		
City:	**State:**	**Zip:**
Contact Person:		
Title:		
Telephone:	**Fax:**	
Email address:		
Type of laboratory (circle one): **Commercial** **Utility** **State** **Academic** **Other**		
Was your laboratory ICR-approved for protozoa? ☐ **Yes** ☐ **No**		
Is your laboratory currently participating in the EPA PT Program? ☐ **Yes** ☐ **No**		
Number of field samples analyzed by your laboratory using Method 1622/1623:		
Number of spiked samples analyzed by your laboratory using Method 1622/23:		
Number of fields samples your laboratory can currently analyze per month using Method 1622/1623:	**Number of field samples your laboratory could potentially analyze per month using Method 1622/1623 during LT2:**	

Part 2. Method Information: Versions of Method 1622/1623 for which the lab is seeking evaluation

Method step	Method 1622 (*Cryptosporidium* only)	Method 1623 (*Cryptosporidium* & *Giardia*)
Filtration (check all that apply and indicate the volume filtered for each)		
Gelman Envirochek		
Gelman HV Envirochek		
IDEXX FiltaMax		
Whatman CrypTest		
Other (describe)		
Elution (check all that apply)		
Wrist action shaker (Envirochek)		
Stomaching of FiltaMax filter		
FiltaMax wash station plunger		
Back Wash/Sonication (CrypTest)		
Other (describe)		
Concentration (check all that apply)		
Centrifugation		
Filtration through membrane		
Other (describe)		
Purification (check all that apply)		
Dynal anti-Crypto, Dynal GC-combo		
Other (describe)		
Staining (check all that apply)		
Waterborne AquaGlo		
Waterborne Crypt-a-Glo		
Waterborne Giardi-a-Glo		
Meridian Merifluor		
Other (describe)		
Descriptions of "other" method steps and other comments:		

Part 3. Personnel Information (attach additional sheets if necessary)

1. Principal Analyst/Supervisor : one required per approved laboratory			
Name		**Current position**	
Academic training/degree(s)		**Time in current position**	
No. of samples processed for protozoa analyses		**No. of samples processed using Methods 1622/1623**	
Was this person approved as an analyst under the ICR? □ **Yes** □ **No**			
Portions of method currently performed (circle all that apply): Filtration Elution Concentration IMS Staining Examination			
2. Analyst or Technician (circle one)			
Name		**Current position**	
Academic training/degree(s)		**Time in current position**	
No. of samples processed for protozoa analyses		**No. of samples processed using Methods 1622/1623**	
Was this person approved under the ICR? □ **Yes** □ **No** **If yes then check one:** □ **Analyst** □ **Technician**			
Portions of method currently performed (circle all that apply): Filtration Elution Concentration IMS Staining Examination			
3. Analyst or Technician (circle one)			
Name		**Current position**	
Academic training/degree(s)		**Time in current position**	
No. of samples processed for protozoa analyses		**No. of samples processed using Methods 1622/1623**	
Was this person approved under the ICR? □ **Yes** □ **No** **If yes then check one:** □ **Analyst** □ **Technician**			
Portions of method currently performed (circle all that apply): Filtration Elution Concentration IMS Staining Examination			
4. Analyst or Technician (circle one)			
Name		**Current position**	
Academic training/degree(s)		**Time in current position**	
No. of samples processed for protozoa analyses		**No. of samples processed using Methods 1622/1623**	
Was this person approved under the ICR? □ **Yes** □ **No** **If yes then check one:** □ **Analyst** □ **Technician**			
Portions of method currently performed (circle all that apply): Filtration Elution Concentration IMS Staining Examination			
5. Analyst or Technician (circle one)			
Name		**Current position**	
Academic training/degree(s)		**Time in current position**	
No. of samples processed for protozoa analyses		**No. of samples processed using Methods 1622/1623**	
Was this person approved under the ICR? □ **Yes** □ **No** **If yes then check one:** □ **Analyst** □ **Technician**			
Portions of method currently performed (circle all that apply): Filtration Elution Concentration IMS Staining Examination			

Part 4. Laboratory Equipment Confirmation Checklist for Methods 1622 and 1623

Key Equipment and Reagents	Manufacturer/Model	If not Present, Proof of Purchase Attached (Y/N)
Filtration and elution		
Flow control valve - 0.5 gpm		
Centrifugal or other pump		
Low-flow meter or graduated container		
Laboratory shaker for agitating capsule filters (Envirochek only)		
Laboratory shaker side arms (Envirochek only)		
Filter housing (CrypTest or Filta-Max)		
Wash station (Filta-Max only)		
Stomacher (Filta-Max only)		
Compressed air source (CrypTest only)		
Sonicator (CrypTest only)		
Concentration		
Concentrator apparatus (Filta-Max only)		
1500 X G, swinging-bucket centrifuge for 15 mL - 250-mL tubes		
Immunomagnetic separation		
Sample mixer/rotator for 10-mL tubes		
Magnetic particle concentrator for 10-mL tubes		
Magnetic particle concentrator for 1.5-mL tubes		
Flat-sided sample tubes		
Examination		
Epifluorescence/differential interference contrast microscope with stage and ocular micrometers and 20X to 100X objectives		
Excitation/band pass microscope filters for fluorescein isothiocyanate (FITC) assay		
Excitation/band-pass filters for 4',6-diamidino-2-phenylindole (DAPI) assay		

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

_____ _____

Name and Signature Laboratory Manager or Designee **Date**

Submit application package to: *Cryptosporidium* **Laboratory QA Program Coordinator, CSC Biology Studies Group, 6101 Stevenson Avenue, Alexandria, VA 22304**

Audit Checklist (To Be Used for Self-Audit)

Part A: Facilities, Equipment, and Quality Assurance

Item to be Evaluated	Classification	Yes, No, Unknown*, or NA
1 Laboratory Equipment and Supplies		
1.1 Reagent-grade water testing		
1.1.1 Is reagent water tested monthly for these minimum parameters: conductivity, total chlorine residual; and annually for metals-Pb, Cd, Cr, Cu, Ni, Zn?	Requirement	
1.1.2 Were the results for the above parameters acceptable, total chlorine residual not greater than 0.1 mg/L, conductivity not greater than 2 μmhos/cm, and each metal not greater than 0.05 mg/L and collectively not greater than 0.1 mg/L?	Requirement	
1.1.3 Is reagent water tested monthly for heterotrophic plate count?	Requirement	
1.1.4 Are the results for the heterotrophic plate count acceptable, < 500/mL?	Requirement	
1.2 Laboratory pH meter:		
1.2.1 Accuracy ± 0.1 units, scale graduations, 0.1 units?	Requirement	
1.2.2 Is a record maintained for pH measurements and calibrations used?	Requirement	
1.2.3 Is pH meter standardized each use period with pH 7, 4 or 10 standard buffers (selection dependant upon desired pH)?	Requirement	
1.2.4 All pH buffers are dated when received and opened and are discarded before expiration date?	Requirement	
1.3 Balances (top loader or pan balance):		
1.3.1 Are balances calibrated monthly using Class S/S-1 weights, or weights traceable to Class S/S-1 weights?	Requirement	
1.3.2 Is correction data available with S/S-1 weights?	Requirement	
1.3.3 Is preventative maintenance conducted yearly at a minimum?	Recommendation	
1.4 Autoclave:		
1.4.1 Is unit equipped with a temperature gauge/operational safety valve?	Requirement	
1.4.2 Are date, contents, sterilization time and temperature recorded for each cycle?	Requirement	
1.4.3 Is a maximum registering thermometer or continuous monitoring device used during each autoclave cycle?	Requirement	
1.4.4 Is automatic timing mechanism checked with stopwatch quarterly?	Requirement	
1.4.5 Are spore strips or ampules used monthly to confirm sterilization?	Requirement	
1.5 Refrigerator/Freezer:		
1.5.1 Is refrigerator able to maintain temperature of 1°C to 5° C?	Requirement	
1.5.2 Is temperature recorded once daily for days in use?	Requirement	
1.6 Temperature recording device:		
1.6.1 Are calibration of glass/mercury thermometers checked annually (dial thermometers quarterly) at the temperature used against a reference NIST thermometer or equivalent?	Requirement	
1.7 Micropipetters:		
1.7.1 Have micropipetters been calibrated within the past year? [Section 9.2.1]	Requirement	
1.8 Centrifuge		
1.8.1 Is a maintenance contract in place, or internal maintenance protocol available?	Requirement	
1.8.2 Is RPM and RCF calibrated yearly?	Requirement	
1.9 General		
1.9.1 Are calibration and maintenance records complete and well organized?	Recommendation	

Item to be Evaluated	Classification	Yes, No, Unknown*, or NA
2 Quality Assurance		
2.1 Does the laboratory have a formal QA laboratory plan prepared and ready for examination?	Requirement	
2.2 Are employee resumes present and complete?	Requirement	
2.3 Is a training protocol for new employees present?	Recommendation	
2.4 Is the laboratory performing analyst verification of examination monthly and does the lab have corrective action procedures in place if criteria are not met? (Section 10.5)	Requirement	
2.5 Are employee training records available and up to date?	Requirement	
2.5.1 Have technicians/analysts analyzed the required number of samples using Method 1622/1623?	Requirement	
2.6 Are all relevant SOPs present and current?	Requirement	
2.7 Are sampling instructions present for clients collecting and/or filtering samples in the field?	Requirement	
2.8 Does the laboratory have criteria for sample acceptance and corrective action procedures?	Requirement	
2.9 Are data recording procedures present?	Requirement	
2.9.1 Does the laboratory have an SOP for checking all manual calculations?	Requirement	
2.10 Are corrective action contingencies present?	Requirement	
2.10.1 For OPR failures? [Section 9.7.4]	Requirement	
2.10.2 For method blank contamination?	Requirement	
2.10.3 For positive/negative staining control failures?	Requirement	
2.11 Does the quality assurance plan specifically address requirements for *Cryptosporidium* analysis under the programs for which the laboratory intends to analyze samples?	Requirement	
2.12 Is a laboratory organization chart or other information available listing staff organization and responsibilities? Does it identify the QA manager?	Requirement	
2.12.1 Is the QA manager separate from the lab manager?	Recommendation	
2.13 Does the laboratory have a list of preventative maintenance procedures and schedules?	Requirement	
2.14 Date range covered for quality control (QC) sample audit?		
2.15 When did the laboratory begin processing samples with the Envirochek filter?		/ /
2.16 When did the laboratory begin processing samples with the Filta-Max filter (if applicable)?		/ /
2.17 When did the laboratory begin processing samples with the CrypTest filter (if applicable)?		/ /
2.18 Approximately how many field samples were analyzed using methods 1622/1623 since the lab started using Method 1622/1623?		Field samples ___ MS_____
2.19 Have acceptable initial precision and recovery analyses been performed for each version of the method the laboratory is using?	Requirement	
2.20 Were method blanks run once per week or per 20 samples during this period? [Section 9.6.1]	Requirement	
2.20.1 If the answer to 2.20 is no, then at what frequency where method blanks performed?		
2.20.2 What percentage of method blanks evaluated were without contamination?		
2.20.3 Was an acceptable method blank associated with each field sample examined?	Requirement	
2.20.4 How many method blanks were evaluated?		
2.21 Were ongoing precision and recovery (OPR) samples run once per week or per 20 samples during this period? [Section 9.7]	Requirement	
2.21.1 If the answer to 2.21 is no, then at what frequency where OPR samples performed?		
2.21.2 What percentage of OPR samples evaluated met the recovery criteria? [Table 3; Section 9.7.3]		

Item to be Evaluated	Classification	Yes, No, Unknown*, or NA
2.21.3 Does the laboratory maintain control charts of OPR results? [Section 9.7.5]	Requirement	
2.21.4 Was an acceptable OPR associated with each field sample examined?	Requirement	
2.21.5 How many OPR samples were evaluated?		
2.21.6 How many OPR samples were analyzed during the past six months?		
2.21.7 What is the mean and relative standard deviation of the recoveries of the OPR samples analyzed during the past six months?		Mean_____ RSD_____
2.22 Were matrix spike (MS) samples analyzed at the method -specified frequency? [Section 9.1.8]	Requirement	
2.22.1 If the answer to 2.22 is no, then at what frequency were MS samples analyzed?		
2.22.2 How many MS samples were evaluated?		
2.22.3 How many MS samples were analyzed during the past six months?		
2.22.4 What is the mean and relative standard deviation of the MS samples analyzed during the past six months?		Mean_____ RSD_____
2.23 Were OPR and MS samples spiked with 100 - 500 organisms? [Section 9.7]	Requirement	
2.23.1 If the answer to 2.23 is no, then at what level were samples spiked?		
2.24 Are the laboratory personnel performing the QC analyses representative of the personnel seeking approval under this program?	Requirement	
2.25 Does the laboratory have records of all QC checks available for inspection?	Requirement	
2.26 Does the laboratory have an adequate record system for tracking samples from collection through log-in, analysis, and data reporting?	Requirement	
2.27 Are results from each sample maintained electronically?		
2.28 If data are stored electronically, are files backed up on more than one disk to ensure data are not lost in the eventuality of some hardware failure?	Requirement	
2.29 If data is stored electronically, does the laboratory have an SOP for checking the accuracy of data entry into an electronic system?	Requirement	
2.30 Is the laboratory using the April 2001 or the June 2003 version of Method 1622/1623?	Requirement	
3 Data Recording Procedures		
3.1 Is shipping information complete, including the time and date of sample receipt, sample condition, and noting any discrepancies between samples on the traffic report and samples received?	Requirement	
3.2 Do sample numbers on the shipping forms match the sample numbers on the report forms?	Requirement	
3.3 Are current Method 1622/1623 bench sheets used to record sample processing data?	Recommendation	
3.4 Are all primary measurements during each step recorded, including all raw data used in calculations?	Requirement	
3.5 Name of analyst or technician performing the elution is recorded?	Requirement	
3.6 Date and time of elution is recorded?	Requirement	
3.7 Name of analyst or technician performing the concentration is recorded?	Requirement	
3.8 Date and time of concentration is recorded?	Requirement	
3.9 Are batch and lot numbers of reagents used in the analysis of the sample recorded?	Requirement	
3.10 Lot number for the IMS kit is recorded?	Requirement	
3.11 Are Method 1622/1623 *Cryptosporidium* report forms used to record sample examination results?	Requirement	
3.12 Name of examining analyst is recorded?	Requirement	
3.13 Date and time of sample examination is recorded?	Requirement	
3.14 Are calculations of final concentrations and recoveries complete and correct?	Requirement	
3.15 Do values recorded on the data sheets match the reported values?	Requirement	

Item to be Evaluated	Classification	Yes, No, Unknown*, or NA
3.16 Are mistakes on all forms crossed out with a single line, initialed, and dated?	Requirement	
3.17 Are data always recorded in pen?	Requirement	
3.18 Are hardcopy records well organized, complete, and easily accessible?	Requirement	
3.19 Does the laboratory include a disclaimer on the report to the client if method QC requirements were not met?	Recommendation	
3.20 Is the manually recorded data legible?	Requirement	
3.21 Do records demonstrate each analyst's characterization of 3 oocysts and 3 cysts from positive control for each microscopy session? [Section 15.2.1.1]	Requirement	
3.22 Data shows that no more than 0.5 mL of pellet was used per IMS? [Section 13.2.4]	Requirement	
4 Holding Times		
4.1 Samples analyzed according to December 1999 version of Method 1622/1623		
4.1.1 Is time from initiation of sample collection to completion of concentration 72 hours or less? [Section 8.1]	Requirement	
4.1.2 Concentrate is held no longer than 24 hours between IMS and staining? [Section 8.2]	Requirement	
4.1.3 Are stained slides read and confirmed within 72 hours of staining? [Section 8.4]	Requirement	
4.2 Samples analyzed according to April 2001 or June 2003 version of Method 1622/1623		
4.2.1 Is sample elution initiated within 96 hours of sample collection or field filtration? [Section 8.2.1]	Requirement	
4.2.2 Are sample elution, concentration, and purification steps completed in one work day? [Section 8.2.2]	Requirement	
4.2.3 Are slides stained within 72 hours of application of the purified sample to the slide? [Section 8.2.3]	Requirement	
4.2.4 Are stained slides read and confirmed within 7 days of staining? [Section 8.2.4]	Requirement	
5 Spike enumeration procedures		
5.1 What method does the laboratory currently use to estimate spike doses:(A) flow-sorted spikes, (B) well-slide-counted spikes, (C) hemacytometer-counted spikes, or (D) membrane-filter-counted spikes		Circle one: A B C D
5.1.1 If flow-sorted spikes are used, on what date did the laboratory begin using flow-sorted spikes?		/ /
5.1.2 If counted manually, does the laboratory follow Method 1622/1623 procedures for establishing spike level? [Section 11.3]	Requirement	
5.1.3 What were the relative standard deviations of the last four spike enumerations?		1.
		2.
		3.
		4.
5.2 Source of oocysts for spikes		
5.3 If 50-L samples are analyzed, what positive control procedure does the laboratory follow for OPR and MS samples: (A) spike entire 50 L, (B) spike and filter 10 L before filtering 40 L, or (C) filter 40 L before spiking and filtering 10 L.		

*Unknown response requires an explanation

Note: All section references in [ ] refer to Method 1623 April 2001

Part B: Sample Processing and Examination

Item to be evaluated	Classification	Yes, No, NA or Unknown
6 Laboratory Facilities and Laboratory Safety		
6.1 Are laboratory coats and gloves worn in the laboratory?	Requirement	
6.2 No other safety or facility issues were observed?		
7 Sample Spiking Technician:		
7.1 What method does laboratory currently use to estimate spike doses:(A) flow-sorted spikes, (B) well-slide-counted spikes, (C) hemacytometer-counted spikes, or (D) membrane-filter-counted spikes		Circle one: A B C D
7.2 With what filter type did the laboratory demonstrate their spiking procedure?		
7.3 Is the carboy used for negative control randomly selected from carboy stock to check efficacy of cleaning system?	Requirement	
7.4 If flow-sorted spikes are used, was suspension vial vortexed for two minutes or per manufacturers instructions? [Section 11.4.3]	Method Procedure	
7.5 Was the suspension vial adequately rinsed? [Section 11.4.3.1]	Method Procedure	
7.6 Does the laboratory have an acceptable SOP for sample spiking?	Requirement	
7.7 Other than the issues noted for items 7.2 through 7.6 (if any) was sample spiking demonstrated successfully?		
8 Envirochek (Complete Sections that apply)		
8.1 Envirochek Filtration Technician:		
8.1.1 Are all components required for sample filtration present and in good condition? [Section 6.2]	Requirement	
8.1.2 Is the filter assembly set up correctly? [Figure 3, pg 48]	Method Procedure	
8.1.3 Is the pump adequate for needs? [Section 6.3.3]	Requirement	
8.1.4 Is the appropriate flow rate maintained (approximately 2L/min)? [Section 12.2.1.2]	Method Procedure	
8.1.5 Is the volume filtered measured using a flow meter or calibrated carboy? [Section 12.2.4.2]	Requirement	
8.1.6 Is the system well maintained and cleaned appropriately following use?	Requirement	
8.1.7 Is the system able to maintain seal during use with no leaks?	Requirement	
8.1.8 Does the laboratory have an acceptable SOP for Envirochek filtration?	Requirement	
8.1.9 Other than the issues noted in items 8.1.1 through 8.1.8, was Envirochek filtration demonstrated successfully?		
8.2 Envirochek capsule filter elution Technician:		
8.2.1 Is the elution buffer prepared as per Method 1622/1623? [Section 7.4]	Method Procedure	
8.2.2 Is the wrist-shaker assembly set up correctly? [Section 12.2.6.1.1]	Method Procedure	
8.2.3 Does the eluting solution cover the membrane? [Section 12.2.6.2.2]	Method Procedure	
8.2.4 Are the samples shaken at an appropriate speed? [Section 12.2.6.2.3]	Method Procedure	
8.2.5 Are the samples shaken three times for 5 minutes each time, and each in a different orientation? [Section 12.2.6.2]	Method Procedure	
8.2.6 Does the laboratory have an acceptable SOP for Envirochek capsule filter elution?	Requirement	
8.2.7 Other than the issues noted for items 8.2.1 through 8.2.7 (if any) was Envirochek filter elution demonstrated successfully?		
9 CrypTest		

Item to be evaluated	Classification	Yes, No, NA or Unknown
9.1 CrypTest Filtration **Technician:**		
9.1.1 Are all components required for sample filtration present and in good condition? [Section 6.2.3]	Requirement	
9.1.2 Is the filter assembly set up correctly?	Method Procedure	
9.1.3 Is the pump adequate for needs? [Section 6.3.3]	Requirement	
9.1.4 Is the appropriate flow rate maintained (approximately 2L/min)?	Method Procedure	
9.1.5 Is the volume filtered measured using a flow meter or a calibrated carboy?	Requirement	
9.1.6 Is the system well maintained and cleaned appropriately following use?	Requirement	
9.1.7 Is the system able to maintain seal during use with no leaks?	Requirement	
9.1.8 Does the laboratory have an acceptable SOP for CrypTest Filtration?	Requirement	
9.1.9 Other than the issues noted in items 9.1.3 through 9.1.10 (if any) was CrypTest filtration demonstrated successfully?		
9.2 CrypTest cartridge filter elution **Technician:**		
9.2.1 Does the filter seat properly in the filter housing, so there are no leaks?	Requirement	
9.2.2 Is the elution buffer prepared according to manufacturer's instructions? [Section 7.4.2]	Method Procedure	
9.2.3 Is an appropriate amount of elution solution backwashed into the filter housing? (approx. 150 mL)	Method Procedure	
9.2.4 Is the assembly well sealed (no leaks)?	Requirement	
9.2.5 Is sonication performed for 2 minutes?	Method Procedure	
9.2.6 Is the filter elution repeated, according to the manufacturer's instructions?	Method Procedure	
9.2.7 Following the last elution, is the remaining elution buffer driven from the outlet side to the inlet side and into the sample bottle?	Requirement	
9.2.7.1 Is the regulated compressed air source used, sufficient to drive the eluting buffer from the filter?	Requirement	
9.2.8 After elution is complete, is the filter removed from the housing and the base, lid, and lip of the filter housing rinsed using eluting solution and added to the sample bottle?	Requirement	
9.2.9 Does the laboratory have an acceptable SOP for CrypTest elution?	Requirement	
9.2.10 Other than the issues noted in items 9.2.1 through 9.2.9 (if any) was CrypTest filter elution demonstrated successfully?		
10 Filta-Max		
10.1 Filta-Max filtration **Technician:**		
10.1.1 Are all components required for sample filtration present and in good condition? [Section 6.2.4]	Requirement	
10.1.2 Is the filter assembly set up correctly?	Method Procedure	
10.1.3 Is appropriate flow rate maintained of <4 L per minute?	Method Procedure	
10.1.4 Is the volume filtered measured correctly using a flow meter or calibrated carboy?	Requirement	
10.1.5 Is system well maintained and cleaned appropriately following use?	Requirement	
10.1.6 Is system able to maintain seal during use with no leaks?	Requirement	
10.1.7 Does the laboratory have an acceptable SOP for Filta-Max filtration?	Requirement	
10.1.8 Does the laboratory indicate on the filter housing the correct direction of flow?	Requirement	

Item to be evaluated	Classification	Yes, No, NA or Unknown
10.1.9 Other than the issues noted in items 10.1.1 through 10.1.8 (if any) was Filta-Max filtration demonstrated successfully?		
10.2 Filta-Max filter wash station elution **Technician:**		
10.2.1 Is an automatic or manual wash station used?		
10.2.2 Is the filter wash station set up correctly?	Requirement	
10.2.3 Is PBST used to elute the filter? [Section 7.4.2]	Method Procedure	
10.2.4 Is an appropriate amount of PBST used for each wash? (approx. 600 mL)	Method Procedure	
10.2.5 During the first wash, is the plunger moved up and down 20 times?	Method Procedure	
10.2.6 Is the plunger moved up and down gently to avoid generating excess foam?	Method Procedure	
10.2.7 During the second wash, is the plunger moved up and down 10 times?	Method Procedure	
10.2.8 If the automatic washer is used, is the machine operating properly?	Requirement	
10.2.9 Is the wash station cleaned adequately between samples?	Requirement	
10.2.10 Does the laboratory have an acceptable SOP for Filta-Max elution with the wash station?	Requirement	
10.2.11 Other than the issues noted for items 10.2.2 through 10.2.10 (if any) was elution of the Filta-max filter using the wash station demonstrated successfully?		
10.3 Filta-Max filter stomacher elution **Technician**		
10.3.1 Is PBST used to elute the filter? [Section 7.4.3.4]	Method Procedure	
10.3.2 Is an appropriate amount of PBST used for each wash? (approx. 600 mL)	Method Procedure	
10.3.3 Are two washes performed for 5 minutes each?	Method Procedure	
10.3.4 Is the stomacher in good condition and operating properly?	Requirement	
10.3.5 Does the laboratory have an acceptable SOP for Filta-Max elution using a stomacher?	Requirement	
10.3.6 Other than the issues noted for items 10.3.1 through 10.3.5 (if any) was elution of the Filta-Max filter using the stomacher demonstrated successfully?		
10.4 Filta-Max filter sample concentration (as an alternative to Section 11) **Technician:**		
10.4.1 Is concentrator set up correctly?	Requirement	
10.4.2 Is the force of the vacuum maintained below 30 cm Hg?	Method Procedure	
10.4.3 Is concentration performed after each of the washes?	Method Procedure	
10.4.4 Is the concentrate from the first wash added to the 600mL of eluate from the second wash?	Method Procedure	
10.4.5 Is the sample concentrated so that some liquid remains above the filter (enough to cover the stirbar about half-way)?	Method Procedure	
10.4.6 Is the stir bar and concentration tube rinsed after each concentration and the liquid added to the concentrate?	Requirement	
10.4.7 Was the filter membrane washed twice?	Method Procedure	
10.4.8 Was 5 mL of PBST used each time?	Method Procedure	
10.4.9 Is the membrane adequately washed to remove oocysts from filter?	Method Procedure	

Item to be evaluated	Classification	Yes, No, NA or Unknown
10.4.10 Is the pellet volume determined?	Requirement	
10.4.11 Is there a set of standards for comparison of pellet size?	Recommendation	
10.4.12 Does the laboratory have an acceptable SOP for concentration using the Filta-Max concentrator?	Requirement	
10.4.13 Other than the issues noted in items 10.4.1 through 10.4.12 (if any) was sample concentration using the Filta-Max concentrator demonstrated successfully?		
11 Concentration		
11.1 Envirochek, CrypTest, and Filta-Max filter sample centrifugation Technician:		
11.1.1 Is the sample centrifuged at 1500 x G using a swinging bucket rotor? [Section 13.2.1]	Method Procedure	
11.1.2 Are the centrifuge tubes properly balanced prior to centrifugation?	Requirement	
11.1.3 Is the sample centrifuged for 15 minutes? [Section 13.2.1]	Method Procedure	
11.1.4 Is the centrifuge slowly decelerated at the end without the brake? [Section 13.2.1]	Method Procedure	
11.1.5 Is the pellet volume determined?	Requirement	
11.1.6 Is there a set of standards for comparison of pellet size?	Recommendation	
11.1.7 Does the laboratory have an acceptable SOP for sample concentration?	Requirement	
11.1.8 Is residual suspension rinsed from all containers and gloves?	Requirement	
11.1.9 Other than the issues noted in items 11.1.1 through 11.1.8 (if any) was sample concentration demonstrated successfully?		
12 Reagents, equipment and clean-up		
12.1 Source for reagent-grade water:		
12.1.1 Is still or DI unit maintained according to manufacturer's instructions?	Requirement	
12.1.2 Is reagent grade water used to prepare all media and reagents? [Section 7.3]	Requirement	
12.2 Centrifuge:		
12.2.1 Does centrifuge have a swinging bucket rotor? [Section 6.8.1]	Requirement	
12.2.2 Is the centrifugation nomograph for determining relative centrifugal force located close to the centrifuge(s)?	Requirement	
12.3 SOP's for Reagents		
12.3.1 Are SOP's available for the preparation of all essential chemicals and reagents?	Requirement	
12.3.2 Are SOP's posted or easily accessible at the bench?	Recommendation	
12.3.3 Are all reagents clearly labeled with date of preparation, technician initials, and expiration date?	Requirement	
12.4 Clean-up		
12.4.1 Is all glassware and plasticware washed well and stored appropriately between uses?	Requirement	
12.4.2 Is distilled or deionized water used for final rinse?	Requirement	
12.4.3 Is an SOP available for glassware washing?	Requirement	

	Item to be evaluated	Classification	Yes, No, NA or Unknown
13	**Purification and Slide Preparation** **Technician:**		
13.1	What IMS kit/manufacturer is used?		
13.2	Is the supernatant from the centrifuged sample aspirated no lower than 5 mL above the pellet? [Section 13.2.2]	Requirement	
13.3	Is the pellet vortexed a sufficient time for resuspension? [Section 13.2.3]	Method Procedure	
13.4	Does the lab have an appropriate SOP for dividing pellets greater than 0.5mL into subsamples and analyzing?	Requirement	
13.5	Is no more than 0.5 mL of pellet used per IMS? [Section 13.2.4]	Method Procedure	
13.6	Is the leighton tube rotated at 18 rpm for 1 hour at room temperature?	Method Procedure	
13.7	Is the resuspended pellet volume quantitatively transferred to the Leighton tube (2 rinses)? [Section 13.3.2.1]	Method Procedure	
13.8	Are the IMS beads thoroughly resuspended prior to addition to the Leighton tube? [Section 13.3.2.2]	Method Procedure	
13.9	Is the sample quantitatively transferred from the Leighton tube to the microcentrifuge tube (2 rinses)? [Section 13.3.2.13]	Method Procedure	
13.10	Is standard NaOH (5 μL, 1N) and standard HCl (50 μL, 0.1N) used? [See note on pg 37]	Requirement	
13.11	Is sample vortexed vigorously for 50 seconds immediately after the addition of acid and 30 seconds after the sample has set for 10 minutes at room temperature? [Section 13.3.3]	Method Procedure	
13.12	Is a second dissociation performed? [Section 13.3.3.10]	Method Procedure	
13.13	When the second dissociation is performed, does the laboratory: (A) use a second slide, or (B) add the additional volume to the original slide?		Circle one: A B
13.14	Are the slides clearly labeled so they can be associated with the correct sample?	Requirement	
13.15	What type of slides are used?		
13.16	Is slide dried at a) room temperature or b) 35 to 42 C? [Section 13.3.3.12]		Circle one: A B
13.17	If the slide is warmed, is incubator or slide tray calibrated and labeled?	Requirement	
13.18	Does the laboratory have an acceptable SOP for sample purification?	Requirement	
13.19	Other than the issues noted in items 13.1 through 13.18 (if any) were sample purification and slide preparation performed successfully?		
14	**Sample staining** **Technician:**		
14.1	What staining kit/manufacturer is used?		
14.2	Is FITC stain applied according to manufacturer's directions?	Method Procedure	
14.3	Are positive and negative staining controls performed?	Requirement	
14.4	Are the direct labeling reagents applied properly? [Section 15.2.1]	Method Procedure	
14.5	Are the slides incubated in a humid chamber in the dark at room temperature for approximately 30 minutes or per manufacturer's directions? [Section 14.4]	Method Procedure	
14.6	Are the labeling reagents rinsed away properly after incubation, without disturbing the sample? [Section 14.5]	Method Procedure	
14.7	Was the working DAPI stain prepared the day it was used? [Section 7.7.2]	Method Procedure	
14.8	Is stock DAPI stored at 0 to 8^{o}C in the dark? [Section 7.7.2]	Method Procedure	
14.9	Is the DAPI stain applied properly and allowed to stand for a minimum of 1 minute? [Section 14.6]	Method Procedure	
14.10	Is the DAPI stain rinsed away properly without disturbing the sample? [Section 14.7]	Method Procedure	
14.11	Is the mounting media applied properly?	Method Procedure	

	Item to be evaluated	Classification	Yes, No, NA or Unknown
	14.11.1 What type of mounting media is used?		
	14.11.2 Are all the edges of the cover slip sealed well with clear fingernail polish, unless Elvenol is used? [Section 14.9]	Method Procedure	
14.12	Are the finished slides stored in a humid chamber in the dark at 0 to 8°C (humid chamber not required for Evenol)? [Section 14.10]	Method Procedure	
14.13	Does the laboratory have an acceptable SOP for sample staining?	Requirement	
14.14	Other than the issues noted in items 14.2 through 14.13 (if any) was sample staining demonstrated successfully?		
15	**Microscope and Examination**		
15.1	Is microscope equipped with appropriate excitation and band pass filters for examining FITC labeled specimens? (Exciter filter - 450-490 nm, dichroic beam-splitting mirror - 510 nm, barrier or suppression filter: 515-520 nm)? [Section 6.9.2]	Requirement	
15.2	Is microscope is equipped with appropriate excitation and band pass filters for examining DAPI labeled specimens? (Exciter filter - 340-380 nm, dichroic beam-splitting mirror - 400 nm, barrier or suppression filter - 420 nm) [Section 6.9.3]	Requirement	
15.3	Does the microscope have HMO or DIC, objectives? [Section 6.9.1]	Requirement	
15.4	Is microscope operation easily changed from epifluorescence to DIC/HMO?	Recommendation	
15.5	Does the microscope have a 20 X scanning objective? [Section 6.9.1]	Requirement	
15.6	Does the microscope have a 100 X oil immersion objective? [Section 6.9.1]	Requirement	
15.7	Is the microscope equipped with an ocular micrometer? [Section 6.9.1]	Requirement	
15.8	Is a stage micrometer available to laboratory? [Section 10.3.5]	Requirement	
15.9	Is a calibration table for each objective located close to the microscope(s)? [Section 10.3.5]	Requirement	
15.10	Does the wattage of the mercury lamp meet the microscope specifications?	Requirement	
15.11	Has the mercury bulb been used less than the maximum hours recommended by the manufacturer? [Section 10.3.2.11]	Recommendation	
15.12	Does the positive control contain *Cryptosporidium* oocysts at the appropriate fluorescence intensity for both FITC and DIC?	Requirement	
15.13	Does the laboratory have an acceptable SOP for sample examination?	Requirement	
15.14	Other than the issues noted for items 15.1 through 15.13 (if any) were other microscope or examination issues acceptable?		

Note: All section references in [ ] refer to Method 1623 April 2001

Initial Demonstration of Capability
Data Summary Form

Laboratory Name	EPA Lab ID	Date

Method Information		
Which method was used? □ Method 1622 □ Method 1623		
Filter used:	Elution method:	Concentration method:
IMS kit used:	Staining kit used:	
Volume of water spiked (L):	Volume of water filtered (L):	

Initial Demonstration of Capability Summary Data						
Sample	***Giardia*** (not required)		***Cryptosporidium***		**Equivalent Sample Volume Analyzed** (to nearest 1/4 L)	**Turbidity (NTU)**
	Estimated No. of Cysts Spiked	No. of Cysts Detected	Estimated No. of Oocysts Spiked	No. of Oocysts Detected		
Method blank						
Spiked reagent water 1						
Spiked reagent water 2						
Spiked reagent water 3						
Spiked reagent water 4						
Mean recovery						
Precision (RSD)						
Matrix unspiked						
Matrix spike 1						
Matrix spike 2						
Mean recovery						
Precision (RPD)						

Burden Statement: The public reporting and recordkeeping burden for this collection of information is estimated to average 19 hours per response. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques to the Director, Collection Strategies Division, U.S. Environmental Protection Agency (2822T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Include the OMB control number in any correspondence. Do not send the completed application to this address.

APPENDIX D

Lab QA Program Application Cover Letter

OMB Control Number: 2040-0246
Expiration Date: 10/31/05

United States Environmental Protection Agency
Office of Ground Water and Drinking Water
Standards and Risk Management Division

April 8, 2005

Dear Laboratory Manager:

Thank you for your interest in the U.S. EPA's Laboratory Quality Assurance Evaluation Program for Analysis of *Cryptosporidium* under the Safe Drinking Water Act (Lab QA Program). This is a voluntary program open to laboratories analyzing *Cryptosporidium* in water using EPA Method 1622 and EPA Method 1623. To increase the likelihood that laboratories analyzing water samples for *Cryptosporidium* generate reliable data, EPA has established the following process for evaluating laboratory performance and quality assurance practices:

Step 1. **Application.** Laboratories must first submit the Lab QA Program application. The application forms are enclosed with this letter, and the application requirements are described in detail below. EPA will evaluate laboratory applications to confirm the following: (1) the laboratory has the equipment required in EPA Method 1622 and/or EPA Method 1623 (April 2001 or June 2003 version), (2) laboratory personnel have the recommended experience to analyze samples, and (3) the laboratory has successfully completed the initial precision and recovery and matrix spike/matrix spike duplicate tests specified in the method. Laboratories that do not meet these requirements will be requested to correct any deficiencies before proceeding to the next step in the evaluation process.

Step 2. **Proficiency testing.** After an application has been accepted, the laboratory will be sent a set of eight initial proficiency testing (IPT) samples consisting of a suspension of oocysts in a concentrated matrix. Laboratories will resuspend these spikes in reagent water to produce simulated source water samples, and analyze the samples using the version of Method 1622/1623 that the laboratory plans to use for routine *Cryptosporidium* analyses. If a laboratory wishes to be evaluated for more than one version of the method, the laboratory will receive a set of eight proficiency test (PT) samples for each version.

Laboratory IPT data will be evaluated against the mean recovery and precision (as relative standard deviation) for the IPT samples from other laboratories. Laboratories will receive two opportunities to pass the IPT test. If a laboratory fails two times, it will not be eligible for another set until after the laboratory staff has received additional training in performing the method.

Laboratories already participating in the EPA *Cryptosporidium* PT Program, may use the initial round of samples from the PT program to meet the IPT sample requirement.

Step 3. **On-site evaluation.** After a laboratory passes the IPT, an on-site evaluation of the laboratory will be scheduled. The on-site evaluation will include 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 control program, equipment, and record keeping procedures.

Each laboratory will receive an audit report, which will document deficiencies, if any, that should be corrected by the laboratory. After a laboratory has corrected any deficiencies noted in the audit report, EPA will confirm that the laboratory meets the performance criteria of the Lab QA Program.

Laboratories that meet the program performance criteria will also receive a set of three ongoing proficiency testing (OPT) samples approximately every four months that must be analyzed in the same manner as the IPT samples. 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.

Application Requirements

The first step in the laboratory evaluation process is submission of a laboratory application package. The following materials should be submitted for each laboratory application package:

1. Signed, completed application form (attached).

2. Completed self-audit checklist (attached). This checklist is similar to the checklist that will be used to audit your laboratory during the on-site evaluation.

3. Resumes detailing qualifications of your laboratory's proposed principal analyst/supervisor and each analyst and technician listed on the application form and documentation of the training, including the list of samples analyzed by each and the time period during which the samples were performed (the list for each analyst and technician should include at a minimum the number of samples specified below for personnel prerequisites).

   The recommended personnel prerequisites for the laboratory evaluation program are as follows:

   Principal Analyst/Supervisor (one required per laboratory)
   - BS/BA in microbiology or closely related field
   - A minimum of 1 year of continuous bench experience with *Cryptosporidium* and IFA microscopy
   - A minimum of 6 months experience using EPA Method 1622 and/or EPA Method 1623
   - A minimum of 100 samples analyzed using EPA Method 1622 and/or EPA Method 1623 (minimum 50 samples if the person was an approved analyst for *Cryptosporidium* under the Information Collection Rule(ICR))

   Other Analysts (no minimum requirement per laboratory)
   - Two years of college in microbiology or equivalent or closely related field
   - A minimum of 6 months of continuous bench experience with *Cryptosporidium* and IFA microscopy
   - A minimum of 3 months experience using EPA Method 1622 and/or EPA Method 1623
   - A minimum of 50 samples analyzed using EPA Method 1622 and/or EPA Method 1623 (minimum 25 samples if the person was an ICR-approved analyst)

   Technician (no minimum requirement per laboratory)
   - Three months experience with the specific parts of the procedure he/she will be performing
   - A minimum of 50 samples analyzed using EPA Method 1622 and/or EPA Method 1623 (minimum 25 samples if the person was an ICR-approved technician) for the specific analytical procedures they will be using.

4. Detailed laboratory standard operating procedures (SOP) for each version of the method your laboratory plans on using for routine *Cryptosporidium* analyses. SOP's for the following should be included:

   - Performance of each method step including, sample spiking, filtration, elution, concentration, purification, slide preparation, sample staining and examination
   - Dividing pellets greater than 0.5mL
   - Preparation of reagents
   - Dishwashing
   - Staff training
   - Corrective action procedures for failing to meet OPR, method blank, staining controls, sample acceptance, and performance verification criteria

- Sampling procedures to be followed by field or utility personnel
- Procedures for data recording, checking manual calculations, and checking accuracy of all data transcriptions

5. EPA Method 1622 or EPA Method 1623 initial demonstration of capability (IDC) data which include initial precision and recovery (IPR) test results and matrix spike and matrix spike duplicate (MS/MSD) test results for *Cryptosporidium*. The IPR test consists of four reagent water samples spiked with between 100 - 500 oocysts and one method blank. The MS/MSD test consists of one unspiked and two spiked source water samples. These tests are described in Section 9 of EPA Method 1622 and EPA Method 1623 and the results should meet the criteria in the method (April 2001 or June 2003 version). The following data should be submitted:

   - Completed EPA Method 1622/1623 bench sheets and report forms for each of the eight samples (attached)
   - Initial demonstration of capability summary form (attached)
   - Spiking suspension preparation data. This should include completed flow-cytometer calibration forms.

   Laboratories wishing to be evaluated for more than one version of the method (different volumes, filters, elution and concentration procedures, and immunomagnetic separation kits) should submit a complete set of IDC data for each version.

   If your laboratory currently participates in the EPA PT sample program and the required IDC data have already been submitted, the data do not need to be resubmitted. Please indicate this is the case on the initial demonstration of capability summary form.

6. Table of contents from your laboratory's quality assurance plan. The quality assurance plan should specifically address the requirements of *Cryptosporidium* analysis under the Lab QA Program.

7. An example of the data reporting form used to submit *Cryptosporidium* results to your clients.

8. A statistical summary of percent recoveries for all OPR and MS samples analyzed at your laboratory for the past six months.

Application materials should be submitted to the following address:

Cryptosporidium Laboratory QA Program Coordinator
CSC Biology Studies Group
6101 Stevenson Avenue
Alexandria, VA 22304

When your application package has been received and reviewed, you will be notified whether it is complete or has any deficiencies. After your application has been accepted, you will be notified of when you should expect your initial set of PT samples. If you have any questions about the laboratory application materials or evaluation process, please feel free to contact either me at moulton.carrie@epamail.epa.gov or Jennifer Scheller at jscheller@csc.com.

Sincerely,

Carrie Moulton
Manager, *Cryptosporidium* Laboratory Approval Program
Technical Support Center
26 West Martin Luther King Drive
Cincinnati, OH 45268

APPENDIX E

Laboratories Seeking Approval for One Method and
Laboratories Seeking Approval for Two Methods Burden Tables

Table 1. Laboratories Seeking Approval for One Method Version

Task	Legal $55.00/hour	Management $46.00/hour	Technical $44.00/hour	Clerical $15.00/hour	Respondent Hours	Labor Costs	Capital/Startup Costs	O&M Costs	Number of respondents/year	Total hours/year	Total cost/year
Complete and submit application	0	3	9	1	13				18	238	
$	$ -	$ 138.00	$ 396.00	$ 15.00		$ 549.00	$ -	$72.00			$ 11,364.30
Perform and report initial performance tests (IPT)	0	4	32	4	40				3	120	
$	$ -	$ 184.00	$ 1,408.00	$ 60.00		$ 1,652.00	$ -	$1,400.00			$ 9,156.00
Host on-site evaluation	0	9	15	1	25				18	458	
$	$ -	$ 414.00	$ 660.00	$ 15.00		$ 1,089.00	$ -	$5.00			$ 20,020.20
Perform and report 3 sets of ongoing performance tests (OPT)	0	5.8	35.3	4.4	45.5				55	2503	
	$ -	$ 266.80	$ 1,553.20	$ 66.00		$ 1,886.00	$ -	$1,546.00			$ 188,760.00

Table 2. Laboratories Seeking Approval for Two Method Versions

Task	Legal $55.00/hour	Management $46.00/hour	Technical $44.00/hour	Clerical $15.00/hour	Respondent Hours	Labor Costs	Capital/Startup Costs	O&M Costs	Number of respondents/year	Total hours/year	Total cost/year
Complete and submit application	0	3	12	1	16				3	53	
$	$ -	$ 138.00	$ 528.00	$ 15.00		$ 681.00	$ -	$ 138.00			$ 2,702.70
Perform and report initial Performance Tests (IPT)	0	8	64	8	80				2	160	
$	$ -	$ 368.00	$ 2,816.00	$ 120.00		$ 3,304.00	$ -	$ 2,800.00			$ 12,208.00
Host on-site evaluation	0	12	18	1	31				3	102	
$	$ -	$ 552.00	$ 792.00	$ 15.00		$ 1,359.00	$ -	$ 15.00			$ 4,534.20
Perform and report 3 sets of ongoing performance tests (OPT) for two method versions	0	11.2	67.2	8.4	86.8				4	347	
	$ -	$ 515.20	$ 2,956.80	$ 126.00		$ 3,598.00	$ -	$2,940.00			$ 26,152.00

APPENDIX F

Agency Burden Table

Agency Burden

Task	Legal GS 15 $79.70/hr	Management GS 14 $67.74/hr	Technical GS 11 $40.22/hr	Clerical GS 3 $17.47/hr	Expert $110.00/hr	Management $95.00/hr	Technical $62.00/hr	Agency hrs/yr/resp	Labor cost/yr/resp	Capital Startup Cost	O & M Costs	Number of Labs	Total hrs/yr	Total Costs per Year
Maintain QC and lab audit database		1				0.5	5	6.5					6.5	
$		$ 67.74				$ 47.50	$ 310.00		$ 425.24					$ 425.24
Review laboratory applications		1				0.5	4	5.5				22	118.8	
$		$ 67.74				$ 47.50	$ 248.00		$ 363.24		$5.00			$ 7,953.98
Prepare and distribute spiking suspensions for IPTs		0.5	0.5				1	2				5	10	
$		$ 33.87	$ 20.11			$ -	$ 62.00		$ 115.98		$330.00			$ 2,229.90
Review IPT data		1				0.5	3	4.5				5	22.5	
$		$ 67.74				$ 47.50	$ 186.00		$ 301.24		$5.00			$ 1,531.20
Prepare and distribute spiking suspensions for OPTs for each lab for each method version		0.5	0.5				3	4				75	300	
$		$ 33.87	$ 20.11			$ -	$ 186.00		$ 239.98		$ 495.00			$ 55,123.50
Review OPT data for each lab for each method version		0.5				0.5	5	6				75	450	
$		$ 33.87				$ 47.50	$ 310.00		$ 391.37		$5.00			$ 29,727.75
Conduct and review on-site evaluations		4		0.25	45	15	50	114				22	2467.8	
$		$ 270.96			$ 4,950.00	$ 1,425.00	$ 3,100.00		$ 9,745.96		$2,500.00			$264,512.74
Prepare, generate, and distribute reports on laboratory status		1.5				1.5	9	12					12	
$		$ 101.61	$ -			$ 103.62	$ 558.00		$ 763.23		$ 5.00			$ 768.23

Total $362,272.54

APPENDIX G

Total Respondent and Agency Burden Tables

Total Respondent Burden

	Number of respondents	Number of Activities	Total hours/year	Total Labor cost/year	Total Annual Capital costs	Total Annual O&M Costs	Total Annualized Cost
One Method labs	55	4	3318	$138,661.40	$ -	$ 90,639.10	$ 229,300.50
Two Method labs	10	4	662	$ 27,732.00	$ -	$ 17,864.90	$ 45,596.90
Total Burden	65	8	3980	$ 166,393.40	$ -	$ 108,504.00	$ 274,897.40

Total Agency Burden

	Number of respondents	Number of Activities	Total hours/year	Total Labor cost/year	Total Annual Capital costs	Total Annual O&M Costs	Total Annualized Cost
Total Burden	1	8	3388	$ 268,984.54	$ -	$ 93,783.00	$ 362,272.54

APPENDIX H

Federal Register Notice
Laboratory Quality Assurance Evaluation Program/
Information Collection Request
[Published June 3, 2005]

[Federal Register: June 3, 2005 (Volume 70, Number 106)]
[Notices]
[Page 32607-32609]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr03jn05-73]

ENVIRONMENTAL PROTECTION AGENCY [OW-2002-0011, FRL-7921-1]Agency Information Collection Activities: Proposed Collection; Comment Request; Laboratory Quality Assurance Evaluation Program for Analysis of Cryptosporidium Under the Safe Drinking Water Act, EPA ICR Number 2067.02, OMB Control Number 2040-0246

AGENCY: Environmental Protection Agency.
ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 et seq.), this document announces that EPA is planning to submit a continuing Information Collection Request (ICR) to the Office of Management and Budget (OMB). This is a request to renew an existing approved collection. This ICR is scheduled to expire on October 31, 2005. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection as described below.

DATES: Comments must be submitted on or before August 2, 2005.

ADDRESSES: Submit your comments, referencing docket ID number OW-2002-0011, to EPA online using EDOCKET (our preferred method), by e-mail to ow-docket@epamail.epa.gov, or by mail to: EPA Docket Center, Environmental Protection Agency, W-01-17 Comment Clerk, Water Docket (MC-4101), EPA, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Sean Conley, Environmental Protection Agency, Mail Stop 4607M, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 202-564-1781; fax number: 202-564-3767; e-mail address: conley.sean@epa.gov. For technical inquiries, contact Carrie Moulton, EPA, Office of Ground Water and Drinking Water, Technical Support Center, 26 West Martin Luther King Drive (MS-140), Cincinnati, Ohio 45268; fax number: (513) 569-7191; e-mail address: moulton.carrie@epa.gov.

SUPPLEMENTARY INFORMATION: EPA has established a public docket for this ICR under Docket ID number OW-2002-0011, which is available for public viewing at the Water Docket Docket in the EPA Docket Center (EPA/DC), EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566-1744, and the telephone number for the Water Docket is (202) 566-2426. An electronic version of the public docket is available through EPA Dockets (EDOCKET) at http://www.epa.gov/edocket. Use EDOCKET to obtain a copy of the draft collection of information, submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ``search,'' then key in the docket ID number identified above.

Any comments related to this ICR should be submitted to EPA within 60 days of this notice. EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EDOCKET as EPA receives them and without change, unless the comment contains copyrighted material, confidential business information (CBI), or other information whose public disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EDOCKET. The entire printed comment, including the copyrighted material, will be available in the public docket. Although identified as an item in the official docket, information claimed as CBI, or whose disclosure is otherwise restricted by statute, is not included in the official public docket, and will not be available for public viewing in EDOCKET. For further information about the electronic docket, see EPA's Federal Register notice describing the electronic docket at 67 FR 38102 (May 31, 2002), or go to http://www.epa.gov/edocket

Affected entities: Entities potentially affected by this action are public and private water testing laboratories. EPA estimates that a total of 65 laboratories (approximately 22 laboratories per year) will seek EPA recognition under the Laboratory QA Program.

Title: Laboratory Quality Assurance Evaluation Program for Analysis of Cryptosporidium under the Safe Drinking Water Act.

Abstract: In September 2000, the Stage 2 Microbial and Disinfection Byproducts Federal Advisory Committee (Committee) signed an Agreement in Principle (Agreement) (65 FR 83015, Dec. 29, 2000) (EPA, 2000) with consensus recommendations for two future drinking water regulations: the Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR) and the Stage 2 Disinfectants and Disinfection Byproducts Rule. The LT2ESWTR will address risk from microbial pathogens, specifically Cryptosporidium. The Committee recommended that the LT2ESWTR require public water systems (PWSs) to monitor their source water for Cryptosporidium using EPA Method 1622 or EPA Method 1623. Additional Cryptosporidium treatment requirements for public water systems (PWSs) would be based on the source water Cryptosporidium levels. EPA took into account the Committee's recommendations as it developed the proposed LT2ESWTR, which was published on August 11, 2003, (68 FR 47639), and is taking the recommendations into account as it develops the final regulation. In the LT2ESWTR proposed rule, EPA indicated that PWSs would be required to use approved laboratories when conducting Cryptosporidium monitoring under the LT2ESWTR. EPA also indicated that laboratories approved to analyze Cryptosporidium samples under the rule must meet the criteria in the Laboratory Quality Assurance Evaluation Program (Lab QA Program) described in this notice. The purpose of the Lab QA Program is to identify laboratories that can reliably measure for the occurrence of Cryptosporidium in surface water. Other existing laboratory approval programs do not include Cryptosporidium analysis.

EPA initiated the Lab QA Program prior to promulgation of the final LT2ESWTR to provide the time necessary to approve a sufficient number of laboratories to assure adequate capacity for LT2ESWTR monitoring. Early initiation of the Lab QA Program was also necessary to conform with the Agreement recommendation that water systems with ``historical'' Cryptosporidium data that are equivalent to data that will be collected under the LT2ESWTR be afforded the opportunity to use those ``historical'' data in lieu of collecting new data under LT2ESWTR. In the LT2ESWTR proposed rule, EPA proposed such provisions to allow water systems to ``grandfather'' the historical data.

EPA anticipates the data generated by laboratories which meet the evaluation criteria would be very high quality, thus increasing the likelihood that such data would warrant consideration as acceptable ``grandfathered'' data. However, laboratory evaluation would not guarantee that data generated will be acceptable as

``grandfathered" data, nor would failure to meet evaluation criteria necessarily preclude use of ``grandfathered" data. For these reasons, EPA established the Lab QA Program as a discretionary and voluntary program under the Safe Drinking Water Act, section 1442 (42 U.S.C. 300j-1(a)).

Through today's notice, EPA is inviting comment on the continuation of the Lab QA Program. Under the Lab QA Program, EPA evaluates laboratories on a case-by-case basis through evaluating their capacity and competency to reliably measure for the occurrence of Cryptosporidium in surface water using EPA Method 1622 or EPA Method 1623. To obtain approval under the program, the laboratory must submit an application package and provide a demonstration of availability of qualified personnel and appropriate instrumentation, equipment and supplies; a detailed laboratory standard operating procedure for each version of the method that the laboratory will use to conduct the Cryptosporidium analyses; a current copy of the table of contents of their laboratory's quality assurance plan for protozoa analyses; and an initial demonstration of capability (IDC) data for EPA Method 1622 or EPA Method 1623, which include precision and recovery (IPR) test results and matrix spike/matrix spike duplicate (MS/MSD) test results for Cryptosporidium.

After the laboratory submits to EPA an application package including supporting documentation, EPA and the laboratory conduct the following steps to complete the process:

1. EPA contacts the laboratory for follow-up information and to schedule participation in the performance testing program.
2. EPA sends initial proficiency testing (IPT) samples to the laboratory (unless the laboratory has already successfully analyzed such samples under EPA's Protozoan PE program). IPT samples packets consist of eight spiked samples shipped to the laboratory within a standard matrix.
3. The laboratory analyzes IPT samples and submits data to EPA.
4. EPA conducts an on-site evaluation and data audit.
5. The laboratory analyzes ongoing proficiency testing (OPT) samples three times per year and submits the data to EPA. OPT sample packets consist of three spiked samples shipped to the laboratory within a standard matrix.
6. EPA contacts laboratories by letter within 60 days of their laboratory on-site evaluation to confirm whether the laboratory has demonstrated its capacity and competency for participation in the program.

The procedure for obtaining an application package, the criteria for demonstrating capacity and competency, and other guidance to laboratories that are interested in participating in the Lab QA Program, are provided at http://www.epa.gov/safewater/lt2/cla_final.html.

An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9 and 48 CFR Chapter 15.

The EPA is soliciting comments to:

(i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(ii) Evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(iii) Enhance the quality, utility, and clarity of the information to be collected; and

(iv) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Burden Statement: The burden estimate for the Lab QA Program

information collection includes all the burden hours and costs required for gathering information, and developing and maintaining records associated with the Lab QA Program. The annual public reporting and record keeping burden for this collection of information is estimated for a total of 65 respondents. For each respondent, an average of 19 hours is estimated per response, with 3.3 responses per year, for a total of 3,980 hours at a cost of $166,393. The average cost per response is estimated at $776 per response. The proposed frequency of responses is three times a year for analysis and reporting of PT samples and once every three years for the on-site evaluation. This estimate assumes that laboratories participating in the Lab QA program have the necessary equipment needed to conduct the analyses. Therefore, there are no start-up costs. The estimated total annual capital costs is $0.00. The estimated Operation and Maintenance (O&M) costs is $108,504.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

APPENDIX I

Comments on Federal Register Notice

Comment: Beyond OPT testing, the program does not include a component for ongoing demonstration of adequately skilled staff after the initial submission of staff qualifications. Given the demand for skilled staff when LT2ESWTR is promulgated, there will be considerable pressures on laboratory staff that could lead to high turnover rates that will impact laboratory performance.

Response: EPA recognizes that there may be a turnover during the LT2 . The PT program and the on-site evaluations as well as the ongoing QC required by the method will provide a measure of ongoing laboratory performance. EPA is evaluating programs for providing analyst training including on-line microscopy modules and train-the-trainer programs. EPA is also working with UK laboratories that have had similar increases in capacity as is anticipated for LT2 to identify strategies for training and retaining laboratory staff. The laboratories' training SOPs are reviewed during the on-site evaluation to ensure that the laboratories have appropriate procedures in place to train new staff.

Comment: The initial and ongoing proficiency testing samples and lab audit slides are not sufficiently challenging to distinguish competent microscopists from those that are not. Ideally, these slides should closely resemble actual sample slides.

Response: EPA is investigating the possibility of adding confounding organisms to PT samples and/or audit slides to make them more challenging. EPA currently adds Tennessee River sediment to the PT samples to provide a more realistic sample.

Comment: The program lacks any metrics for or controls to prevent laboratory performance degradation as the volume of samples increases dramatically with ongoing LT2ESWTR implementation.

Response: The PT program will provide an ongoing assessment of laboratory performance in addition to the ongoing QC that is required by Method 1622/1623. Ongoing QC requirements include analysis of ongoing precision and recovery samples, method blanks, and staining controls every week that LT2 samples are analyzed to ensure the analytical process is in control and development and use of QC charts to assess ongoing performance.

Comment: The program is not open to the performance-based nature of EPA Method 1622 / 1623, and rigid adherence to a defined method will likely result in loss of valid samples. Consistent, high quality method performance is clearly critical, but given the acceptable performance range for the method it is important to retain reasonable flexibility.

Response: Laboratories are allowed to make modifications to the method as long as equivalent performance is demonstrated as described in Section 9.1.2 of the method. During the QA/QC application process, PT program and on-site evaluation, EPA has seen many laboratories that have made modifications as described in Method 1622/1623.

Comment: Frequency of lab audits is inadequate as some laboratories were audited several years ago and personnel and facilities have changed.

Response: EPA will be re-auditing laboratories and will focus on those laboratories that are anticipated to analyze the most samples for LT2 and those that have undergone significant changes in personnel and facilities.

Comment: Modify initial proficiency test (IPT) and ongoing proficiency test (OPT) samples to include confounding factors such as algae, debris, and organisms that are similar in appearance to *Cryptosporidium* oocysts. Sample modification should begin with the next round of samples distributed by the laboratory approval program.

Response: EPA is investigating the possibility of adding confounding organisms to PT samples and/or audit slides to make them more challenging.

Comment: Modify audit procedures to provide for increased laboratory auditing frequency. There should be a regular audit schedule so that the audit captures current practice and expectations. The audit program should place a particular focus on laboratories where facilities have changed (or require a re-certification process for laboratories that experience dramatic "change" such as significant turnover in laboratory management or key personnel, significant physical changes in the laboratory facilities, etc.). Laboratories experiencing dramatic surges in processing capacity also deserve focused attention by the audit program.

Response: EPA will be re-auditing laboratories and will focus on those laboratories that are anticipated to analyze the most samples for LT2 and those that have undergone significant changes in personnel and facilities. Another comment recommends less frequent audits. EPA believes current frequency is adequate in light of extensive QC requirements.

Comment: Require that laboratory owners / operators to state the number of Method 1622/1623 samples that the laboratory is capable of processing per week within its existing equipment, personnel, and quality assurance / quality control plan each quarter. This should be required when the laboratory submits its OPR samples.

a. This estimate should either be compared to or based on an EPA determined metric that reflects the requirements of Method 1622/1623, LT2ESWTR requirements, sound laboratory practice and QA/QC expectations.

b. This submittal could be treated as Confidential Business Information (CBI).

c. EPA should use this submittal as a measure of whether analytical performance within that laboratory is under appropriate control.

d. In using this measure EPA would have to allow enough flexibility for laboratories to demonstrate how they've streamlined the method if they have done so.

Response: EPA has been collecting information on laboratory capacity of the number of samples laboratories analyze per month as part of the audit application and plans to collect this information with increased frequency after implementation. EPA will request that laboratories submit with their PT data the average number of samples they are currently analyzing per week. This information will be considered confidential.

Comment: Ongoing communication with laboratories and on-site evaluations should recognize that modification of the method is anticipated by the EPA:

> "In recognition of advances that are occurring in analytical technology, the laboratory is permitted to modify certain method procedures to improve recovery or lower the costs of measurements, provided that all required quality control (QC) tests are performed and all QC acceptance criteria are met. Method procedures that can be modified include front-end techniques, such as filtration or immunomagnetic separation (IMS). The laboratory is not permitted to use an alternate determinative technique to replace immunofluorescence assay in this method (the use of different determinative techniques are considered to be different methods, rather than modified version of this method). ..." (EPA Method 1623, Section 9.1.2, page 11) [emphasis added]

Response: EPA agrees that communication with the laboratories is important and acknowledges that laboratories are allowed to modify Method 1623 as stated in section 9.1.2.

Comment: What efforts are made by epa that once approved the lab standards will not fail? where is the annual testing to be sure standards are kept?

Response: EPA requires ongoing proficiency testing (OPTs) every four months for the laboratories participating in the program. This ensures that laboratories are maintaining method performance. Ongoing QC requirements of Method 1622/1623 include analysis of ongoing precision and recovery samples, method blanks, and staining controls for every 20 samples every week that LT2 samples are analyzed to ensure the analytical process is in control and development and use of QC charts to assess ongoing performance.

Comment: EPA currently estimates that the burden of this information collection request will be 72 hours per respondent annually, where the respondent burden is described as the total time, effort, or

financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for the agency under this program. This estimate significantly underestimates the burden of the current program. The program requires:

1. Submission of an extensive application every 3 years;

2. Processing of eight initial proficiency testing (IPT) samples per version of EPA Method 1622 and 1623 employed in a respondent laboratory;

3. Submission to an on-site evaluation of the laboratory at least once;

4. Correction of deficiencies noted in the on-site evaluation;

5. Notice to EPA when an employee is added to the laboratory with required EPA Method 1622/1623 training.

6. Processing of three ongoing proficiency testing (OPT) samples approximately every four months per version of EPA Method 1622 and 1623 employed in the respondent laboratory;

7. Preparation of detailed laboratory standard operating procedures for each version of the method used for routine Cryptosporidium analyses; and

8. Preparation of a summary of percent recoveries for all OPR and MS samples analyzed at the laboratory for the past six months.

Response: EPA feels that the burden estimate is appropriate. The estimate was derived with input from the laboratories. Laboratories will only need to submit an application prior to their audit. If it is a re-audit, the laboratories will only be required to submit SOPs that have changes since their last audit. Only laboratories that are not currently participating in the PT program will be required to analyzed eight initial proficiency testing samples. The estimate does not include preparation of SOPs and the laboratory Quality Assurance Project Plan, which are part of formal quality assurance program as required by Method 1622/1623 and are not specific requirements of this program. Laboratories are only required to submit a summary of the percent recoveries for OPR and MS samples as part of their application which is required no more than once every three years.

Comment: This program provides an independent third-party evaluation of protozoan testing laboratories, filters and method modifications. The program is a valuable tool for laboratories as well as their clients and we believe that it is appropriate that EPA continue to provide this service.

Response: Thank you.

Comment: Considering the complexity of the Cryptosporidium analytical methods and the variability that can occur from lab to lab, it is important to retain a lab certification/approval process to assist the labs in collecting high quality data and to assist the customers of the labs in selecting labs wherein they can have confidence in the results. The EPA's Laboratory Quality Assurance Evaluation Program is important to maintain until the States obtain their own capabilities to manage a similar program and add Cryptosporidium to their list of certified parameters. In our opinion, after a few modifications as stated above, the Lab QA Program is highly beneficial and has been worth our lab's investment to achieve and maintain approval for Cryptosporidium data collection.

Response: Thank you.

Comment: We have found the Lab QA Program to be valuable and beneficial, and support its continuation. We found most helpful the on-site evaluation. The EPA sent qualified and knowledgeable auditors who provided good feedback to improve our laboratory's work. If a similar audit is done every 3-5 years by such qualified, lab-based staff as we have already experienced then it will continue to provide a benefit to the many labs that are audited.

Response: Thank you. EPA will be re-auditing laboratories and will focus on those laboratories that are anticipated to analyze the most samples for LT2 and those that have undergone significant changes in personnel and facilities.

Comment: The ongoing laboratory proficiency testing has also been helpful, especially in placing in context the information about our lab with information from other laboratories and from other methods being used. This provides a benchmark.

However, three times a year for proficiency testing is excessive considering the quality control already included in the method. We suggest that a frequency of once a year would be adequate.

Response: EPA feels that three sets of OPTs are necessary to ensure continuing acceptable performance especially as the volume of samples analyzed by laboratories increases during LT2 monitoring.

Comment: Given the LT2ESWTR timeline, under which most surface water systems will conduct sampling within a year or two of rule promulgation, it is difficult to ascertain from this Federal Register notice the availability of sufficient laboratory capacity. Without sufficient capacity of appropriately qualified laboratories that results in high-quality Cryptosporidium data, systems could be subject to inappropriate LT2ESWTR treatment requirements.

Response: EPA realizes the importance of laboratory capacity. EPA continuously evaluates the capacity as more laboratories are approved to perform the method. EPA is evaluating programs for providing analyst training, including on-line microscopy modules and train-the-trainer programs, to allow for increased laboratory capacity. EPA is also working with UK laboratories that have had similar increases in capacity as is anticipated for LT2 to identify strategies for training and retaining laboratory staff.