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Environmental Technology Verification Program

Advanced Monitoring Systems Center

Generic Verification Protocol for Rapid Beach Water Quality Screening Technologies

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GENERIC VERIFICATION PROTOCOL

for

Verification of
Rapid Beach Water Quality
Screening Technologies

August 31, 2007

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ACKNOWLEDGEMENTS

This generic protocol was developed by Battelle under a cooperative agreement with the U.S. Environmental Protection Agency's (EPA's) National Exposure Research Laboratory (NERL) and includes input from stakeholders, especially from Kenneth M. Hill, Elizabeth Essex, and Vito Minei of the Suffolk County Department of Health Services. Peer reviewers for this protocol were Kristen P. Brenner of EPA NERL; Martha Link of the Nebraska Department of Environmental Quality; and Richard H. Sakaji of the East Bay Municipal Utility District, Oakland, California. The contributions to this protocol from the EPA Project Officer Robert Fuerst and Quality Assurance Manager Elizabeth Betz are gratefully acknowledged.

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LIST OF ABBREVIATIONS/ACRONYMS

AMS	Advanced Monitoring Systems
ASW	artificial sea water
cfu	colony forming units
COA	certificate of analysis
COC	chain-of-custody
DI	deionized
DQI	data quality indicator
E. coli	*Escherichia coli*
EPA	U.S. Environmental Protection Agency
ETV	Environmental Technology Verification
LCS	laboratory control standard
LRB	laboratory record book
mTEC	membrane-Thermotolerant *Escherichia coli Agar*
MS	matrix spike
NEEAR	National Epidemiological and Environmental Assessment of Recreational
NIST	National Institute of Standards and Technology
PCR	polymerase chain reaction
pdf	Adobe portable document format
PE	performance evaluation
PT	performance test
QA	quality assurance
QC	quality control
QCS	quality control samples
QMP	quality management plan
R	percent recovery
r^2	coefficient of determination
RSD	relative standard deviation
S	standard deviation

SCCWRP	Southern California Coastal Water Research Project
SOP	standard operating procedure
TC	temperature control
TQAP	test/quality assurance plan
TSA	technical systems audit
w/v	weight/volume

SECTION A.
PROJECT MANAGEMENT

A1 VERIFICATION TEST ORGANIZATION

This protocol provides generic procedures for implementing a verification test for rapid technologies for beach water quality screening in fresh, brackish, and/or marine/estuarine water. Verification tests are conducted under the auspices of the U.S. Environmental Protection Agency (EPA) through the Environmental Technology Verification (ETV) Program. Verification tests of monitoring technologies are coordinated by Battelle, which manages the ETV Advanced Monitoring Systems (AMS) Center through a cooperative agreement with EPA. The scope of the AMS Center covers verification of monitoring technologies for contaminants and natural species in air, water, and soil. In performing verification tests, Battelle follows the procedures specified in this protocol and compiles quality requirements in the "Quality Management Plan for the ETV Advanced Monitoring Systems Center" (QMP).[(1)]

Verification tests are performed by Battelle in cooperation with EPA and the vendors whose technologies are being verified. These test procedures may be performed by Battelle, test facility staff, a qualified collaborator, and/or a qualified subcontractor. The specific staff members who will perform the test procedures are referred to as "technical staff" in this protocol. Each technology vendor is expected to provide their respective beach water quality screening technology, including installation, as appropriate, and any supplies required for its operation. Each vendor will operate, repair and/or maintain their technology during the test, unless they provide written consent for other technical staff to operate their technology. Battelle will oversee all testing activities.

Quality Assurance (QA) oversight will be provided by the Battelle Quality Manager and also by the EPA AMS Center Quality Manager, at his or her discretion. The organization chart in Figure 1 identifies the responsibilities of the organizations and individuals associated with the verification test. Roles and responsibilities are defined further below.

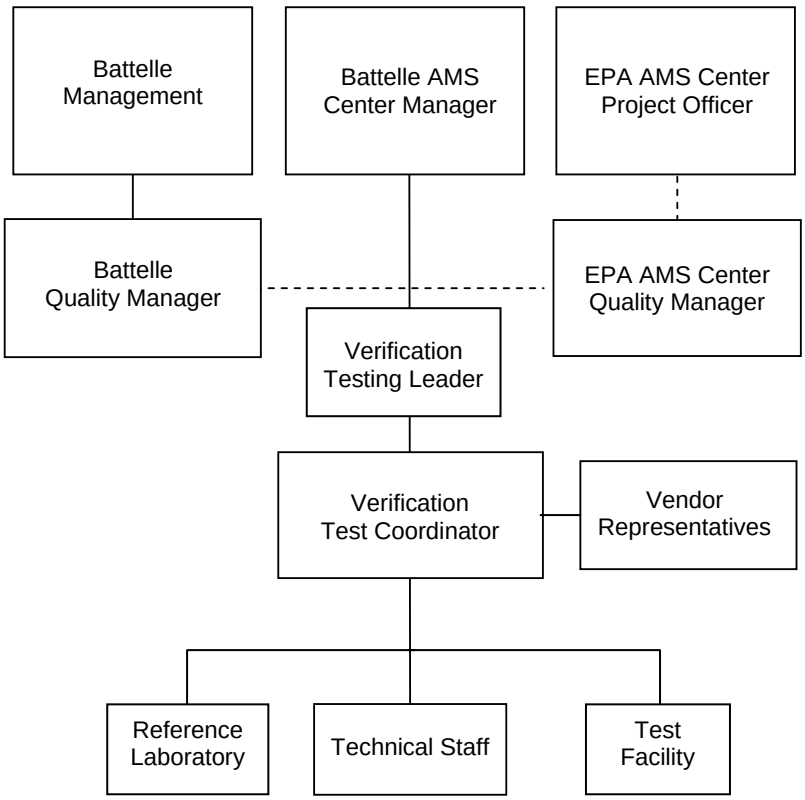

Figure 1. Organization Chart

A1.1 Battelle

The AMS Center's Verification Test Coordinator has overall responsibility for ensuring that the technical, schedule, and cost goals established for the verification test are met. Specifically, the Verification Test Coordinator will:

- Prepare a draft test/quality assurance plan (TQAP) based on this protocol and revise it in response to reviewers' comments.
- Establish a budget for the verification test and manage staff to ensure the budget is not exceeded.
- Assemble a team of qualified technical staff to conduct the verification test.

- Direct the team in performing the verification test in accordance with this protocol and any TQAP based on this protocol.
- Hold a kick-off meeting for technical staff approximately one week prior to the start of the verification test to review the critical logistical, technical, and administrative aspects of the verification test and to confirm responsibility for each aspect of the verification test.
- Ensure that all quality procedures specified in this protocol, in any TQAP based on this protocol, and in the AMS Center QMP[(1)] are followed.
- Serve as the primary point of contact for vendor representatives.
- Ensure that confidentiality of sensitive vendor information is maintained.
- Assist vendors as needed during the beach water quality screening technology installation and verification testing.
- Become familiar with the operation and maintenance of the beach water quality screening technologies, including through instruction by the vendors, if needed.
- Respond to any issues raised in assessment reports, audits, or from test staff observations, and institute corrective action as necessary.
- Prepare the draft verification reports and verification statements and revise in response to reviewer comments.
- Coordinate distribution of the final TQAP, verification reports, and verification statements.

The Verification Testing Leader for the AMS Center provides technical guidance and oversees the various stages of verification testing. The Verification Testing Leader will:

- Support the Verification Test Coordinator in organizing the test.
- Review the draft and final verification reports and verification statements.
- Attend the verification test kick-off meeting.

The Battelle AMS Center Manager will:

- Review the draft and final verification reports and verification statements.

- Ensure that necessary Battelle resources, including staff and facilities, are committed to the verification test.
- Ensure that confidentiality of sensitive vendor information is maintained.
- Support the Verification Test Coordinator in responding to any issues raised in assessment reports and audits.
- Maintain communication with EPA's technical and quality managers.
- Attend the verification test kick-off meeting.
- Issue a stop work order if Battelle or EPA QA staff discovers adverse findings that will compromise test results.

Battelle's Quality Manager for the AMS Center will:

- Attend the verification test kick-off meeting.
- Conduct a technical systems audit once during the verification test, or designate other QA staff to conduct the audit.
- Audit at least 10% of the verification data or designate other QA staff to conduct the data audit.
- Prepare and distribute an assessment report for each audit.
- Verify implementation of any necessary corrective action.
- Request that Battelle's AMS Center Manager issue a stop work order if audits indicate that data quality is being compromised.
- Provide a summary of the QA/quality control (QC) activities and results for the verification reports.
- Review the draft and final TQAP, verification reports, and verification statements.
- Assume overall responsibility for ensuring that the test/QA plan is followed.

A1.2 Beach Water Quality Screening Technology Vendors

The responsibilities of the beach water quality screening technology vendors are as follows:

- Provide their beach water quality screening technology for evaluation during the verification test.
- Provide all other equipment/supplies/reagents/consumables needed to operate their technology for the duration of the verification test.
- Supply a representative to install and maintain their technology, as appropriate, and provide training instructions, and written consent for technical staff to carry out verification testing. Alternatively, the vendor representative may operate the technology during the verification test.
- Provide written instructions for routine operation of their technology including a daily checklist of diagnostic and/or maintenance activities, if applicable.
- Provide maintenance, repair, and/or technical support for their technology, on-site if necessary, throughout the duration of the verification test.
- Review and provide comments on the draft TQAP, verification report, and verification statement for their respective technology.

A1.3 EPA

EPA's responsibilities in the AMS Center are based on the requirements stated in the "Environmental Technology Verification Program Quality Management Plan" (EPA QMP).[(2)] The roles of specific EPA staff are as follows:

The EPA AMS Center Quality Manager will:

- Perform at his or her option one external technical systems audit during the verification test.
- Notify the EPA AMS Center Project Officer of the need for a stop work order if the external audit indicates that data quality is being compromised.
- Prepare and distribute an assessment report summarizing results of the external audit.
- Review draft verification reports and verification statements.

EPA's Project Officer for the AMS Center will:

- Review the draft TQAP, verification reports, and verification statements.

- Notify the Battelle AMS Center Manager of the need for a stop work order if work of inadequate quality is discovered.
- Oversee the EPA review process for verification reports and verification statements.
- Coordinate the submission of verification reports and verification statements for final EPA approval.

A1.4 Technical Staff

Technical staff from Battelle, subcontractor(s), and/or collaborating organization(s) will support the Verification Test Coordinator in planning and conducting the verification test. The responsibilities of the technical staff may include:

- Assist in planning for the test, and making arrangements for the receipt of the beach water quality screening technologies.
- Attend the verification test kick-off meeting.
- Assist vendor staff as needed during the beach water quality screening technology verification testing.
- Perform experimental procedures specified in this protocol and/or TQAP and acquire data from the beach water quality screening technologies provided the vendor has given written consent for the technical staff to conduct testing. Contact the Verification Test Coordinator if any problems in testing or equipment operation occur.
- Record observations about the maintenance and operation of the beach water quality screening technologies during the testing period.
- Perform statistical calculations specified in this protocol and/or TQAP on the beach water quality screening data, as needed.
- Provide results of statistical calculations and associated discussion for the verification reports as needed.
- Support the Verification Test Coordinator in responding to any issues raised in assessment reports and audits related to statistics and data reduction as needed.

A1.5 Reference Laboratory

One or more analytical laboratories at Battelle, a subcontractor, and /or a collaborating organization will serve as a reference laboratory to:

- Perform reference analyses of all test and QC samples described in this protocol and/or TQAP.
- Submit the results of the reference analyses in an agreed-upon format to the Verification Test Coordinator.

A1.6 Test Facility

Either Battelle or another appropriate facility such as a laboratory that conducts beach water quality screening will serve as the test facility. The test facility personnel are expected to:

- Identify a point of contact for the test who will serve as the primary interface with the Verification Test Coordinator.
- Attend the verification test kick-off meeting.
- Ensure that test facility staff and facilities are ready for the verification test.
- Assist Battelle's Verification Test Coordinator in ensuring that verification testing is conducted in accordance with this protocol and/or TQAP.
- Assist Battelle and beach water quality screening technology vendor staff in the installation, operation, testing and removal of the beach water quality screening technologies from the test facility.
- Ensure that necessary test facility resources (*e.g.*, space and power) are committed to the verification test.

A2 BACKGROUND

The ETV Program's AMS Center conducts third-party performance testing of commercially available technologies that detect or monitor contaminants and natural species in air, water, and soil. Stakeholder committees of buyers and users of such technologies recommend

technology categories, and technologies within those categories, as priorities for testing. Beach water quality screening technologies were identified as a priority technology category through the AMS Center stakeholder process since the screening technologies have the potential to make beach closures and public health warnings more efficient and timely.

Frequent water quality monitoring of recreational waters is necessary to ensure the public's safety. Current water quality criteria require that concentrations of pathogen indicator organisms, such as *Enterococci* and *E. coli*, are below specific action levels for marine and freshwater locations. Current action levels by indicator organism and water type are summarized in Table 1.[3] Beach managers currently use results generated at least 24 hours after samples are collected to determine if public health warnings should be posted and/or beaches closed for recreational use. Rapid monitoring technologies that produce same-day results for pathogen indicator organisms in recreational waters are beginning to emerge on the commercial market. Independent performance testing of such technologies is imperative to demonstrating to EPA, state/local regulators, and coastal managers the potential applicability of these technologies to beach monitoring applications.

Table 1. 1986 Criteria for Bacteriological Indicators

Indicator Organism	Water Type	Steady State Geometric Mean Indicator Density	Single Sample Maximum Allowable Density[a]
Enterococci	Fresh water	33 colony forming units (cfu)/100 mL	61 cfu/100 mL
	Marine water	35 cfu/100 mL	104 cfu/100 mL
E. coli	Fresh water	126 cfu/100 mL	235 cfu/100 mL

(a) Designated Beach Area (upper 75% confidence limit)

Both state and Federal programs aimed at identifying and evaluating new methods for rapid determination of beach water quality are ongoing. For example, the National Epidemiological and Environmental Assessment of Recreational Water Study, which is a collaboration between two EPA laboratories and the Centers for Disease Control and Prevention, is designed to correlate human health effects with recreational water use, by application of rapid water quality methods. As part of the study, the water quality at several beaches has been evaluated using traditional and new rapid methods. The measured bacterial indicator levels are

being compared to survey data of gastrointestinal symptoms in swimmers to correlate water quality with occurrence of swimming-associated gastroenteritis.[4] Additional rapid beach water quality methods have been evaluated by the Southern California Coastal Water Research Project (SCCWRP) Authority.[5,6] The SCCWRP studies included initial testing of six technologies that detect *Enterococci* or *E. coli* and more comprehensive "beta" testing of two genetic methods; beta testing included side-by-side comparisons of the rapid and traditional methods for more than 100 samples. Although several rapid methods have demonstrated promising results in these tests, the false negative rates, in particular, have exceeded those demonstrated by traditional methods. Developers of rapid beach water quality screening technologies continue to refine and improve their methods.

Verification under this protocol will determine the performance characteristics of commercially available technologies that can provide same-day results (*i.e.*, within 8 hours) to make beach closures and public health warnings more efficient. Technologies may detect pathogen indicator organisms in fresh, brackish, and/or marine/estuarine water. Critical characteristics that will be understood as a result of this testing include the following:

- Accuracy, precision, sensitivity, and comparability of technology results relative to accepted laboratory-based methods (*e.g.*, membrane filtration)
- Rate of false positive/false negative results relative to current action levels (*e.g.*, frequency of technology reporting *Enterococci* levels above 104 colony forming units (cfu)/100 mL in marine water when the level is actually below, and vice versa)
- Operational features of each technology, including ease of use and maintenance
- Interference effects and selectivity.

A3 VERIFICATION TEST DESCRIPTION AND SCHEDULE

A3.1 Summary of Technology Category

Technologies to be evaluated in the beach water quality screening technology verification include rapid monitoring technologies that produce same-day results for pathogen indicator organisms in recreational waters. Traditional beach monitoring methods involve culture-based

methods that can take up to 24 hours to achieve results. Rapid screening technologies provide same-day results (*i.e.* in less than 8 hours) and have the potential to expedite the decision making process for regulators who monitor beach water quality. The analytical techniques employed by such technologies vary widely, and include immunoassay test strips, flow cytometry, quantitative polymerase chain reaction (PCR), and others. The mechanism of action of these technologies may vary; however, a key factor is the technology's ability to generate data on water quality results on the same day as sample collection (*i.e.*, in 8 hours or less). Rapid technologies for beach water quality screening, referred to in this protocol as "screening technologies," may be quantitative, semi- quantitative, or provide a presence/absence response with respect to a pre-defined limit. The target indicator bacteria detected by the rapid screening technology may be *E. coli, Enterococci,* and/or other such appropriate pathogen-indicating bacteria that are part of beach monitoring programs at the time of testing. In this protocol, "indicator bacteria" refers to the target pathogen-indicating bacteria detected by the screening technology and/or used by beach monitoring programs to determine the safety of water for bathing/recreational use.

Rapid screening technologies for determining beach water quality offer a number of advantages over traditional methods. Most screening methods require fewer man-hours per analysis, allowing for greater sample throughput compared to traditional methods. Same-day information on the safety of beaches can reduce the exposure of swimmers to contamination during the time for analysis of water samples using traditional methods. Thus, beaches can be closed the same day that samples are collected and determined to be above safe levels rather than the next day. Similarly, beaches can be reopened more quickly once the bacteria count has dropped to safe levels. Faster results can also provide more opportunities to track and mitigate contamination sources, protecting the ecosystem, human health, and promoting environmental sustainability. Although rapid screening technologies are not currently included in state and federal recreational water regulations for determining beach closures and openings, they can be used to augment traditional methods especially for non-regulatory applications, such as tracking the spread and dilution of known spills and tracking fecal contamination to the source.

A3.2 Verification Test Schedule

A beach water quality screening verification test following this protocol should take between six and nine months to complete after the start of testing. Table 2 shows a general schedule of testing and data analysis/reporting activities to be conducted in this verification. Test planning and site preparation may take place over a period of three to four months. The period of operation at the test facility will be approximately two weeks. The test procedures are described in Section B of this protocol. Subsequent to the field testing, a separate verification report and verification summary statement for each technology will be drafted, reviewed, revised, and submitted to EPA for final signature.

Table 2. General Verification Test Schedule

Anticipated Duration (months)	Testing Activities	Data Analysis and Reporting
3-4	• Identify test collaborators/ subcontractors and test facility • Recruit vendors • Procure necessary standards and reagents • Arrange for necessary logistical infrastructure and supplies at the test facility • Develop TQAP	• Submit TQAP for vendor review • Revise TQAP and submit final TQAP for vendor approval • Distribute final TQAP and post on ETV website
1	• Vendor to set up/install screening technologies and train technical staff on technology use	• Begin preparation of report template
1	• Conduct verification tests • Conduct reference tests • Return beach water quality screening equipment to vendors	• Review and compile testing data and records as they become available • Review and summarize verification testing staff observations • Complete common sections of reports
1	NA	• Evaluate and analyze data generated during testing
1-2	NA	• Complete draft reports and submit for vendor and peer reviews
1-2	NA	• Revise draft reports and submit final reports for EPA approval
1-3	NA	• Distribute finalized, EPA approved reports and post ETV reports and verification statements on website

NA = not applicable

A3.3 Test Location

The majority of a verification test conducted under this protocol will be performed in a laboratory setting. The test facility could be laboratory facilities at Battelle or another organization that can accommodate testing of beach water quality screening technologies and should be in close proximity to the beach sampling sites selected for the test. Use of a facility that conducts beach water quality monitoring programs may facilitate collection of water samples for use in testing and in operation of the screening technologies. Sample collection and field portability checks will be performed at the selected beach sampling field sites.

A3.4 Health and Safety

All sampling, reference analyses, and verification testing will follow the safety and health protocols in place for the test facility and the rapid screening technologies undergoing verification. This includes maintaining a safe work environment and a current awareness of microbiological pathogens. Exposure to microorganisms will be minimized, personal protective equipment will be worn, and safe laboratory practices will be followed.

A4 QUALITY OBJECTIVES AND CRITERIA FOR MEASUREMENT DATA

In performing the verification test, Battelle will follow the technical and QA procedures specified in this protocol and will comply with the data quality requirements in the AMS Center QMP.[(1)] The objective of this verification test is to evaluate the performance of beach water quality screening technologies under realistic operating conditions for each technology being tested. This evaluation will assess the capabilities of the screening technologies for determining one or more indicator bacteria in both laboratory-prepared and real-world environmental samples, and will include a comparison of the beach water quality screening technology results to those of a reference method such as membrane filtration, which is described in Section B4. Additionally, this evaluation will rely upon verification testing staff observations to assess other performance characteristics of the beach water quality screening technologies. Below is a

discussion of the quality objectives and the criteria for measurement data that have been established to ensure that the objectives of this test are met.

A4.1 Quality Objectives

The data quality objectives indicate the minimum quality of data required to meet the objectives of the beach water quality screening technology verification. The data quality objectives for this verification test include those for the preparation and analysis of reference samples, for the operation of the beach water quality screening technologies, as well as for the documentation of verification testing staff observations. The data quality objectives for the preparation and analysis of reference samples are based on the requirements of the reference methods described in Section B4, and are presented in terms of data quality indicator (DQI) criteria for the critical measurements associated with the reference methods. The data quality of the reference samples relies, in part, on the proper preparation of the samples and proper application of the reference method. The data quality of the test samples relies on proper preparation of the test samples and proper operation of the beach water quality screening technologies.

A4.2 Criteria for Measurement Data

Table 3 presents the DQIs and criteria for the critical measurements of the reference method(s). The quality of the reference measurements will be ensured by adherence to these DQI criteria. The quality of the reference measurements will be monitored by sterility checks of media, reagents, membrane filters, and sample containers and by inclusion of method blank samples, negative control samples, and positive control samples for each reference method as applicable. The quality of the screening technology measurement data will be monitored by any standard assessments, such as method blanks and positive and negative controls, identified by the screening technology vendors. The Battelle Quality Manager or his designee will perform a technical systems audit (TSA) at least once during this verification test to augment these QA/QC

requirements. The EPA Quality Manager also may conduct an independent TSA, at his or her discretion.

Table 3. Data Quality Indicators and Criteria for Critical Measurements for Reference Method(s)

DQI	Method of Assessment	Frequency	Minimum Acceptance Criteria	Corrective Action
Precision	Triplicate analyses of split samples	As required in the reference method	Refer to reference method criteria	Investigate sources of contamination or changes in instrument parameters; perform instrument maintenance as needed; reanalyze fresh standard or sample, or repeat initial calibration
Bias and Accuracy	Positive Control Samples Laboratory Control Standards (LCS) Matrix Spikes (MS)	As required in the reference method	Refer to reference method criteria	
Selectivity	Sterility of media, reagents and filters Method Blank Negative control Positive control	As required in the reference method	Refer to reference method criteria	
Completeness	Amount of valid data obtained	Overall number of data points collected for reference method	80% of overall data points collected should be valid	If feasible, analyze additional samples to meet the acceptance criterion
Method Representativeness	Performance Evaluation (PE) Test	Once, prior to verification testing	Results within ± 25% of expected value for standard solutions, results within certified limits for standard reference materials	Evaluate reference method performance; perform maintenance or recalibrate as required, repeat performance evaluation test. If performance evaluation test criteria cannot be met, consider alternative reference laboratory

A5 SPECIAL TRAINING/CERTIFICATION

Documentation of training related to technology testing, field testing, data analysis, and reporting is maintained for all Battelle technical staff in training files at their respective locations. Documentation of the expertise and experience of collaborators and/or subcontractors must be similarly available. The Battelle Quality Manager may verify the presence of

appropriate training records prior to the start of testing. If technical staff operate and/or maintain a beach water quality screening technology during the verification test, the beach water quality screening technology vendor will be required to train those staff prior to the start of testing. Battelle will document this training with a consent form, signed by the vendor, that states which specific technical staff have been trained on their technology. Battelle technical staff will have a minimum of a bachelor's degree in science/engineering or have equivalent work experience.

A6 DOCUMENTATION AND RECORDS

The records for this verification test will include this protocol, any TQAP based on this protocol, chain-of-custody (COC) forms, laboratory record books (LRB), data collection forms, electronic files (both raw data and spreadsheets), and the final verification reports and verification statements. All of these records will be maintained in the Verification Test Coordinator's office or at the test facility during the test and may be transferred to permanent storage at Battelle's Records Management Office at the conclusion of the verification test. The location (*e.g.*, specific personal computer, server, or media type and storage location) of final versions of the electronic files will be noted in the test records. All Battelle LRBs are stored indefinitely, either by the Verification Test Coordinator or Battelle's Records Management Office. EPA will be notified before disposal of any files. The QA/QC documentation and results of the reference measurements made by the reference laboratory will be submitted to Battelle immediately upon completion of all sample analyses and maintained with the records for this test. Table 4 has further details regarding the data recording practices and responsibilities.

All written records must be in ink. Any corrections to notebook entries, or changes in recorded data, must be made with a single line through the original entry. The correction is then to be entered, initialed, and dated by the person making the correction. In all cases, strict confidentiality of data from each vendor's beach water quality screening technology, and strict separation of data from different technology, will be maintained. Separate files (including manual records, printouts, and/or electronic data files) will be kept for each technology.

Table 4. Summary of Data Recording Process

Data to Be Recorded	Where Recorded	How Often Recorded	By Whom	Disposition of Data
Dates, times, and details of test events, technology maintenance, down time, etc.	ETV LRBs or data recording forms	Start/end of test procedure, and at each change of a test parameter or change of beach water quality screening technology status	Technical staff	Used to organize and check test results; manually incorporated in data spreadsheets as necessary
Beach water quality screening technology calibration information	ETV LRBs, data recording forms, or electronically	At technology calibration or recalibration	Technical staff or vendor performing the calibration.	Incorporated in verification report as necessary
Beach water quality screening technology readings	Either recorded electronically by the technology and downloaded to an independent computer or other storage media; hard copy data printed by the technology and taped into the ETV LRB; or hand-recorded data on data sheets or in the ETV LRB	Every sample analysis	Technical staff or vendor for transfer to Battelle	Transferred to or manually entered into spreadsheet for statistical analysis and comparisons
Sample collection and reference method analysis procedures, calibrations, QA, etc.	LRBs, chain-of-custody, or other data recording forms	Throughout sampling and analysis processes	Technical staff and Reference laboratory	Retained as documentation of reference method performance
Reference method results	Electronically from analytical method or hand-recorded on data recording forms or ETV LRB	Every sample analysis	Reference laboratory	Transferred to or manually entered into spreadsheets for calculation of results, and statistical analysis and comparisons

SECTION B.
MEASUREMENT AND DATA ACQUISITION

B1 EXPERIMENTAL DESIGN

This test will specifically address verification of screening technologies that provide quantitative or qualitative measurements of indicator bacteria, such as *Enterococci* and *E. coli*. Screening technologies may provide qualitative results indicating the presence or absence of the indicator bacteria within a specified concentration interval or quantitative results reporting concentrations using a digital display or an electronic output signal. The vendor will specify in which category their technology should be included, which indicator bacteria it is designed to detect, and in which matrices (*i.e.*, fresh, brackish, and/or marine/estuarine water) the technology is designed to operate.

The screening technologies will be verified by subjecting them to various concentration levels of individual indicator bacteria in several matrices: deionized (DI) water and/or artificial sea water (ASW) (prepared from DI water and a sea salt mixture). The technologies will also be subjected to two concentrations (including zero) of the indicator bacteria in the presence of possible interferents (*e.g.*, mixed humic acids, and naturally occurring non-target marine and/or fresh water bacteria) in the appropriate sample matrix. Samples will be prepared by Battelle, the reference laboratory, or other qualified collaborating organization. Finally, each technology will analyze a variety of natural water samples, including samples collected from locations that have typically exceeded standards for bacterial contamination. These samples may be from fresh, brackish, or marine/estuarine water locations, as appropriate for the screening technologies undergoing verification; however, this is not intended to be an exhaustive study or to represent all possible samples types that could be tested.

The screening technologies will be evaluated for the following parameters, as appropriate for each technology:

- Accuracy
- Reproducibility
- Linearity

- Comparability relative to accepted laboratory-based methods (*e.g.*, membrane filtration)
- Occurrence of false positive and false negative results relative to current action levels as determined by the reference method result (*e.g.*, frequency of technology reporting *Enterococci* levels above 104 cfu/100 mL in marine water when the level is actually below, and vice versa)
- Interference effects and selectivity
- Field portability
- Data completeness
- Operational factors, such as ease of use, waste production, maintenance, and throughput.

Qualitative screening technologies will not be evaluated for linearity or comparability since they only provide a positive or negative result relative to a specified concentration level. Technologies that are not designed for use outside of the laboratory will not be evaluated for field portability.

B1.1 Test Procedures

This verification test will determine the performance capability of the screening technologies to detect individual contaminants in two types of samples – performance test (PT) and natural water. The number of each sample type identified in this protocol should be regarded the minimum number; additional samples should be considered based on the variance of each method. PT samples will include all the samples prepared in DI water or ASW. The indicator PT samples will be spiked with indicator bacteria at four target concentrations listed in Table 5. The results from triplicate analysis of each indicator PT sample and comparison with the concentrations determined by the reference method will provide information on accuracy, precision, linearity, comparability, and false-positive/false-negative rates of the screening technologies.

Table 5. Spike Levels for Indicator PT Samples

Indicator Organism	Water Type	Target Spike Concentrations (cfu/100 mL)
Enterococci	Fresh water	0, 35, 104, 1000
	Marine water	0. 33. 61, 1000
E. coli	Fresh water	0, 126, 235, 1000

One type of interferent PT sample will consist of mixed humic acid in DI and/or ASW, both spiked and unspiked with each indicator bacterium. Another type of interferent PT sample will test the selectivity of the screening technology to the target indicator bacteria in the presence of natural non-target bacteria. This will be assessed by analyzing samples that contain the non-target bacteria, both spiked and unspiked with the target bacterial indicator.

Natural water samples will be collected from at least five locations, including fresh, brackish, and sea water as needed based on the screening technologies being verified (*e.g.*, if only technologies designed for sea water analysis are being evaluated, only sea water samples should be tested), so that each technology is subjected to a minimum of thirty (30) natural water samples in an appropriate matrix. Each natural water sample will be analyzed in duplicate. These samples will be used to evaluate comparability to accepted laboratory-based methods (*e.g.*, membrane filtration) and the occurrence of false-positive and false-negative results relative to current action levels. Samples should be collected using procedures and in locations that are representative of real-world beach monitoring programs. If known or potential pollution sources exist, additional samples may be collected as appropriate from those sources. Sample collection is further described in Section B2. A summary of the test samples is shown in Table 6.

Table 6. Summary of Test Samples

Sample Type	Performance Parameter	Sample Matrix	Bacterial Indicator Target Concentration (cfu/100 mL)	Minimum Number of samples	Reps[a]
Indicator PT	Accuracy Precision Linearity[b] False Positives False Negatives	DI water and/or ASW	0 35 104 1000	1 1 1 1	3 3 3 3
Interferent PT	Interference effects	DI water and/or ASW with 0.001% (w/v) mixed humic acids	0 104	1 1	3 3
	Selectivity	DI water and/or ASW with nontarget bacteria at ambient concentrations	0 104	1 1	3 3
Natural water	Comparability[b] False Positives False Negatives	Natural fresh, brackish, and/or sea water	Unspiked	30	2
Approximate total number of samples per indicator bacteria				38	84

[a] Reps = number of replicates
[b] Not determined for qualitative screening technologies

All screening technologies will be tested in the laboratory; applicable screening technologies will also be evaluated for their performance and ease of use outside of the laboratory. Field portability will be evaluated by analyzing the natural samples with the screening technology in the field, if possible, at the time of sample collection in addition to in the laboratory at the same time as the reference method measurements. It should be noted that the laboratory-based analyses may be performed up to six (6) hours after sample collection and the field portability analyses are performed; therefore, some differences in the bacterial concentrations may occur. (The allowable holding time for recreational water samples is 6 hours.)

No additional test procedures will be carried out specifically to address data completeness. This parameter will be assessed based on the overall data return achieved by each technology as a percentage of the maximum possible data return.

Operational factors such as maintenance needs, calibration frequency, data output, ease of use, repair requirements, and those that impact environmental sustainability (*i.e.*, consumables used, waste production, analysis time, etc.), will be evaluated based on observations recorded by the technical staff. A separate LRB will be maintained at the test site for each technology

undergoing testing; daily observations on operational factors will be recorded in the LRB or on data sheets. Examples of information to be recorded in the record books or on data sheets include the daily status of diagnostic indicators for the technology; use or replacement of any consumables; the effort or cost associated with maintenance or repair; vendor effort (*e.g.*, time on site) for repair or maintenance; the duration and causes of any technology down time or data acquisition failure; and operator observations about ease of use of the technology. These observations will be summarized to aid in describing the technology performance in the verification report on each technology.

B1.2 Statistical Analysis

The statistical methods and calculations used for evaluation of the quantitative performance parameters are described in the following sections.

B1.2.1 Accuracy

For screening technologies that provide quantitative results, PT and natural water sample accuracy will be assessed relative to the reference method result. The results for the three replicate analyses will be averaged, and the accuracy will be expressed in terms of a percent recovery (R) as calculated from Equation 1:

$$R = (C / C_R) \times 100 \quad (1)$$

where C is the average concentration measured by screening technology and C_R is the reference method result for the PT or natural water sample.

For qualitative results, accuracy will be assessed by evaluating how often the screening technology result correctly reports the presence of the indicator bacteria above the screening technology's reported limit of detection as determined by the reference method result. An overall percent agreement will be determined by dividing the number of correctly identified positive responses to the overall number of analyses.

B1.2.2 Reproducibility

For screening technologies that provide quantitative results, the standard deviation (S) of the results for the replicate samples will be calculated for each sample using Equation 2:

$$S = \left[\frac{1}{n-1} \sum_{k=1}^{n} \left(C_k - \overline{C} \right)^2 \right]^{1/2} \quad (2)$$

where n is the number of replicate samples, C_k is the concentration measured for the k^{th} sample, and $\overline{C}$ is the average concentration of the replicate samples. The precision for each sample will be reported in terms of the relative standard deviation (RSD) or coefficient of variation as calculated using Equation 3:

$$\%RSD = \left| \frac{S}{\overline{C}} \right| \times 100 \quad (3)$$

For screening technologies that provide qualitative results, precision will be assessed by calculating the percentage of consistent responses.

B1.2.3 Linearity

For screening technologies that provide quantitative results, linearity will be assessed by performing a linear regression with the reference method result from the indicator PT samples as the independent variable, and the individual screening technology result as the dependent. Individual replicate results will be used in the linear regression. Linearity will be expressed in terms of the slope, intercept, and coefficient of determination (r^2). Linearity will not be determined for qualitative screening technologies.

B1.2.4 Comparability

Comparability between the screening technology results and the reference method results will be assessed by linear regression using the reference method concentrations from the natural water samples as the independent variable and results from the screening technologies being evaluated as the dependent variable. Comparability will be expressed in terms of slope, intercept, and r^2. Comparability will also be calculated using Equation 1 and reported as a percent recovery. It is expected that the measured indicator bacteria concentrations will vary by at least a factor of five for the natural water samples included in this test. However, if this magnitude of variation is not achieved for the reference method results, comparability will be expressed only as a percent recovery. As appropriate, tests of statistical significance may be used in addition to or in place of linear regression analysis. Comparability will not be determined for qualitative screening technologies.

B1.2.5 False Positive/False Negative Responses

For both quantitative and qualitative screening technologies, a false-positive response is defined as a positive screening technology response with respect to the appropriate action level when the reference method result was below the action level. A false-negative response is defined as a response lower than the appropriate action level when the reference method result was greater than the action level. Indicator PT, Interferent PT, and natural water samples will be included in this analysis.

B1.2.6 Interference Effects and Selectivity

For both quantitative and qualitative screening technologies, interference effects and selectivity will be determined as the percent of samples that correctly report the presence or absence of the indicator bacteria in solutions containing humic acids and nontarget bacteria, respectively. For qualitative screening technologies, the percent recovery may also be reported.

B1.2.7 Data Completeness

Data completeness will be calculated as the percentage of the total possible data return that was actually generated by each technology. This calculation will use the total number of samples with data returned by the technology, divided by the total number of samples included in the verification test. The causes of any substantial loss of data return will be established from operator observations or technology records, and noted in the discussion of data completeness results.

B1.2.8 Operational Factors

There are no statistical calculations applicable to operational factors. Operational factors will be determined based on documented observations of the technical staff and the Verification Test Coordinator.

B1.2.9 Field Portability

The results obtained from the measurements made on samples in the laboratory and field setting will be compiled independently for each technology and compared to assess the accuracy of the measurements under the different analysis conditions. Means and standard deviations of the endpoints generated in both locations will be used to make the comparison. For qualitative screening technologies, the number of false positives and false negatives will be used to make the comparison.

B1.3 Reporting

The statistical comparisons described above will be conducted separately for each of the technologies being tested, and information on the operational parameters will be compiled and reported. The data for each technology will be kept separate from data for all other technologies, and no intercomparison of the technology data will be performed at any time. A separate verification report will be prepared for each technology tested that presents the test procedures and test data, as well as the results of the statistical evaluation of those data. Operational aspects

of the technologies will be recorded by technical staff at the time of observation during the verification test, and summarized in the verification report. For example, descriptions of the data-acquisition procedures, use of vendor-supplied proprietary software, consumables used, repairs and maintenance needed, and the nature of any problems will be presented in the report.

Each verification report will briefly describe the ETV program, the AMS Center, and the procedures used in verification testing. The results of the verification test will be stated quantitatively and in comparison to the reference method, but without comparison to any other technology tested or comment on the acceptability of the technology's performance. Each draft verification report will be reviewed by the respective technology vendor and by EPA and other peer reviewers. Comments on the draft report will be addressed in revisions of the report. The peer review comments and responses will be tabulated to document the peer review process. The reporting and review process will be conducted according to the requirements of the AMS Center QMP.[1]

B2 SAMPLING REQUIREMENTS

The following sample design, employed by the Suffolk County Department of Health Services, is included as an example.[7] If the verification test is being performed in collaboration with an existing beach monitoring program, its sampling plan may be used.

All samples should be collected at a depth of approximately 18-24 inches (knee depth), where possible, using 150 mL pre-sterilized plastic (*e.g.*, polypropylene) bottles. Prior to collecting the sample, individual bottles should be marked with the appropriate beach code on a pre-fixed label. A COC form should also be completed, noting the beach code; sampling location; sample matrix (*i.e.*, fresh, brackish, or marine/estuarine water); date and time; current and past (previous 24-hour) weather; number of bathers, animals, and boats present; and any unusual conditions noted during sampling. Immediately after collection, samples should be placed in a cooler with ice and kept at 1°- 4° C. During each sampling event, one additional sample should be collected to serve as a temperature control (TC) and be labeled accordingly. Upon arrival at the laboratory, the temperature of this sample will be measured and recorded. For the samples to be acceptable, the TC must be less than or equal to 10° C.

Other QC considerations taken during sampling include:

- Take care to avoid contamination by not touching the inside or rim of the sample bottle and cap.
- Be careful not to disturb sediments when wading out to the appropriate sampling depth.
- Avoid any surface scum layer by removing the lid after the bottle has been plunged downward to the appropriate sampling depth.
- If there is a water current present, move to a position downstream to collect the incoming flow to prevent contamination of or effect on the sample.
- Pour off a small portion of the sample before capping the sample bottle to provide an air-space that will facilitate later mixing.
- Do not allow the bottle to become immersed in cooler melt-water during transit or storage.

Samples will be delivered to the test facility as soon as possible, so that the appropriate analyses can be started within 6 hours of sample collection. Sample analysis should be completed within 8 hours of sample collection.

B3 SAMPLE HANDLING AND CUSTODY REQUIREMENTS

Sample custody will be documented throughout collection, transport, shipping (if necessary), and analysis of the samples, using COC forms. Each COC form summarizes the samples collected and analyses requested. The COC form will track sample release from the sampling location to the test facility and/or reference laboratory. COC forms will be used regardless of whether the samples are being transferred within the test facility or to an external location. Each COC form will be signed by the person relinquishing samples once that person has verified that the COC form is accurate. The original sample COC forms will accompany the samples; the shipper will keep a copy. Upon receipt at the test facility and/or reference laboratory, COC forms will be signed by the person receiving the samples once that person has

verified that all samples identified on the COC forms are present and intact. Any discrepancies will be noted on the form and the sample receiver will immediately contact the Verification Test Coordinator to report missing, broken, leaking, or compromised samples. Copies of all COC forms will be delivered to the Verification Test Coordinator, and maintained with the test records.

B4 LABORATORY REFERENCE METHODS

The reference laboratory will perform standard methods for determination of indicator bacteria (*i.e.*, *Enterococci*, *E. coli*, etc.) as the reference methods against which beach water quality screening technology data will be compared. The following are examples of reference methods which may be appropriate for beach water quality screening.

For fresh and salt water samples, *Enterococci* may be determined using EPA Method 1600: *Enterococci* in Water by Membrane Filtration Using Membrane- *Enterococcus* Inoxyl-β-D-Glucoside Agar.[8] This method provides a direct count of bacteria in water based on the development of colonies on the surface of a 0.45 μm pore size membrane filter, which retains the bacteria. Following filtration, the membrane containing the bacterial cells is placed on a selective medium, mEI agar, and incubated for 24 hours at 41º ± 0.5 ºC. All colonies (regardless of color) with a blue halo are recorded as *Enterococci* colonies. Magnification and a small fluorescent lamp are used for counting to give maximum visibility of colonies.

E. coli may be determined using EPA Method 1603: *Escherichia coli* (*E. coli*) in Water by Membrane Filtration Using Modified membrane-Thermotolerant *Escherichia coli* Agar (mTEC).[9] This method provides a direct count of *E. coli* in water based on the development of colonies that grow on the surface of a membrane filter. A water sample is filtered through a 0.45 μm pore size membrane filter, which retains the bacteria. After filtration, the membrane containing the bacteria is placed on a selective and differential medium, modified mTEC Agar, incubated at 35º ± 0.5 °C for 2 hours to resuscitate the injured or stressed bacteria, and then incubated at 44.5º ± 0.2 °C for 22 hours. The target colonies on modified mTEC agar are red or magenta in color after both incubation periods.

B5 QUALITY CONTROL

Steps will be taken to maintain the quality of the data collected during this verification test. As described in Section B4, the reference laboratory will follow standard reference methods for the determination of pathogen indicator organisms. Quality control samples (QCSs) will include sterility checks of media, reagents, membrane filters, and sample containers; method blanks; negative controls; and positive controls, as appropriate for the reference method(s). QCSs producing results not meeting the reference method or the reference laboratory's standard requirements will be reanalyzed or reported with qualifiers if reanalysis is not possible. If the outlying results persist, the affected data will be flagged and a repeat of the affected parts of the verification test may be considered. Sample results not meeting these requirements will be flagged and excluded from comparison to the beach water quality screening technology results. Reference measurements for a minimum of 30 natural water and 8 laboratory-prepared samples for each bacterial indicator used for evaluating a beach water quality screening technology must meet these QC requirements for use in this test.

B6 INSTRUMENT/EQUIPMENT TESTING, INSPECTION, AND MAINTENANCE

The equipment used by the test facility and/or reference laboratory will be tested, inspected, and maintained as per the standard operating procedures of the test facility and/or reference laboratory and/or the manufacturer's recommendations to meet the performance requirements established in this document. Examples of such equipment include, but are not limited to, laboratory balances, autoclaves, microscopes, thermometers, and incubators. When technical staff operate and maintain technologies undergoing testing, those activities will follow directions provided by the technology vendor. Otherwise, operation and maintenance of the technologies will be the responsibility of the technology vendor.

B7 CALIBRATION/VERIFICATION OF TEST PROCEDURES

Systems used for reference analyses will be calibrated as appropriate before any reference samples are analyzed and recalibrated as needed based on the reference methods and/or reference laboratory standard operating procedures (SOPs).

Technologies undergoing testing will be calibrated initially by the respective technology vendor at the time of installation at the test facility, as appropriate. Calibration checks will be performed upon direction of the vendor. In the event that recalibration is necessary, the recalibration will be carried out by the technology vendor, or by technical staff under the direction of the vendor. All calibrations will be documented as appropriate by the technical staff or vendor.

B8 INSPECTION/ACCEPTANCE OF SUPPLIES AND CONSUMABLES

Required materials, supplies, and consumables will be ordered by the Verification Test Coordinator or designee. Where possible, Battelle will rely on sources of materials and consumables that have been used previously without problems as part of ETV verification testing. Battelle will also rely on previous experience or recommendations from EPA advisors, stakeholders, test collaborators, subcontractors, or beach water quality screening technology vendors. When possible, National Institute of Standards and Technology (NIST)-traceable materials will be used. Upon receipt of any supplies or consumables, the Verification Test Coordinator or designee will visually inspect and ensure that the materials received are those that were ordered and that there are no visual signs of damage that could compromise the suitability of the materials. Certificates of analysis (COA) or other documentation of analytical purity will be checked for all reagents and standards to ensure suitability for the verification test and will be included in the test files. If damaged, unsuitable, or inappropriate goods are received, they will be returned or disposed of and arrangements will be made to receive replacement materials.

B9 NON-DIRECT MEASUREMENTS

No non-direct measurements or existing data will be used during this verification test.

B10 DATA MANAGEMENT

Various types of data will be acquired and recorded electronically or manually by Battelle, vendor, collaborator, and/or subcontractor staff during the verification test. Table 4 summarizes the types of data to be recorded. All maintenance activities, repairs, calibrations, and operator observations relevant to the operation of the screening technologies will be documented by technical staff in LRBs or on data sheets. A separate record book will be maintained for each participating technology. Results from the reference methods, including raw data, analyses, and final results, will be compiled by the reference laboratory, preferably in electronic format, and submitted to Battelle at the conclusion of reference method testing.

Records received by or generated by any technical staff during the verification test will be reviewed by a Battelle staff member within two weeks of generation or receipt, and before the records are used to calculate, evaluate, or report verification results. If a Battelle staff member generated the record, this review will be performed by a Battelle technical staff member involved in the verification test, but not the staff member who originally generated the record. The review will be documented by the person performing the review by adding his/her initials and date to the hard copy of the record being reviewed. In addition, any calculations performed by technical staff will be spot-checked by Battelle QA and/or technical staff to ensure that calculations are performed correctly. Calculations to be checked include any statistical calculations described in this protocol and any TQAP based on this protocol. The data obtained from this verification test will be compiled and reported independently for each beach water quality screening technology. Results for technologies from different vendors will be compared individually to the reference method, but will not be compared with each other.

Among the QA activities conducted by Battelle QA staff will be an audit of data quality. This audit will consist of a review by the Battelle Quality Manager or designee of at least 10% of the test data. During the course of any such audit, the Battelle Quality Manager will inform the technical staff of any findings and any need for immediate corrective action. If serious data quality problems exist, the Battelle Quality Manager will request that Battelle's AMS Center Manager issue a stop work order. The results of the data quality audit will be included in an

assessment report. The Verification Test Coordinator will ensure that a response is provided for each adverse finding or potential problem, and will implement any necessary follow-up corrective action. The Battelle Quality Manager will ensure that follow-up corrective action has been taken.

SECTION C.
ASSESSMENT AND OVERSIGHT

C1 ASSESSMENTS AND RESPONSE ACTIONS

Every effort will be made in this verification test to anticipate and resolve potential problems before the quality of performance is compromised. One of the major objectives of this protocol is to establish mechanisms necessary to ensure this. Internal QC measures described in this protocol, which is peer reviewed by a panel of outside experts, implemented by the technical staff and monitored by the Verification Test Coordinator, will give information on data quality on a day-to-day basis. The responsibility for interpreting the results of these checks and resolving any potential problems resides with the Verification Test Coordinator. Technical staff have the responsibility to identify problems that could affect data quality or the ability to use the data. Any problems that are identified will be reported to the Verification Test Coordinator, who will work with the Battelle Quality Manager to resolve any issues. Action will be taken to control the problem, identify a solution to the problem, and minimize losses and correct data, where possible. Independent of any EPA QA activities, Battelle will be responsible for ensuring that the following audits are conducted as part of this verification test.

C1.1 Performance Evaluation Audits

A Performance Evaluation (PE) audit will be conducted to assess the quality of the reference method measurements made in this verification test. The PE audit of the reference methods will be performed by supplying each reference method a blind sample or standard reference material containing the bacterial indicator. The PE audit samples will be analyzed in the same manner as for all other samples and the analytical results for the PE audit samples will be compared to the nominal concentration. The target criterion for this PE audit is agreement of the analytical result within 25% of the nominal concentration (by percent difference). If the PE audit results do not meet the tolerances shown, they will be repeated. If the outlying results persist, a change in the instrument used for the reference method and a repeat of the PE audit

may be considered. This audit will be performed once during the verification test, and will be the responsibility of the Verification Test Coordinator or designee.

C1.2 Technical Systems Audits

The Battelle Quality Manager or designee will perform a TSA at least once during this verification test. The purpose of this audit is to ensure that the verification test is being performed in accordance with the AMS Center QMP,[1] this protocol and/or TQAP, published reference methods, and any SOPs used by the reference laboratory. In the TSA, the Battelle Quality Manager, or a designee, will review the reference methods used, compare actual test procedures to those specified or referenced in this protocol and/or TQAP, and review data acquisition and handling procedures. The Battelle Quality Manager or designee will tour the test facility, observe sample collection (if possible), inspect documentation of sample COC; and review beach water quality screening technology-specific record books. He or she will also check standard certifications and technology data acquisition procedures, and may confer with the technology vendors, reference laboratory, and technical staff. The Battelle Quality Manager may also visit the reference laboratory to review procedures and adherence to this protocol, any TQAP based on this protocol, and applicable SOPs. A TSA report will be prepared, including a statement of findings and the actions taken to address any adverse findings. The EPA AMS Center Quality Manager will receive a copy of Battelle's TSA report. At EPA's discretion, EPA QA staff may also conduct an independent on-site TSA during the verification test. The TSA findings will be communicated to technical staff at the time of the audit and documented in a TSA report.

C1.3 Data Quality Audits

The Battelle Quality Manager or designee will audit at least 10% of the verification data acquired in the verification test. The Battelle Quality Manager will trace the data from initial acquisition, through reduction and statistical comparisons, to final reporting. All calculations performed on the data undergoing the audit will be checked.

C1.4 QA/QC Reporting

Each assessment and audit will be documented in accordance with Sections 3.3.4 and 3.3.5 of the AMS Center QMP.[1] The results of the technical systems audit will be submitted to EPA. Assessment reports will include the following:

- Identification of any adverse findings or potential problems
- Response to adverse findings or potential problems
- Recommendations for resolving problems
- Confirmation that solutions have been implemented and are effective
- Citation of any noteworthy practices that may be of use to others.

C2 REPORTS TO MANAGEMENT

The Battelle Quality Manager, during the course of any assessment or audit, will identify to the technical staff performing experimental activities any immediate corrective action that should be taken. If serious quality problems exist, the Battelle Quality Manager is authorized to request that Battelle's AMS Center Manager issue a stop work order. Once the assessment report has been prepared, the Verification Test Coordinator will ensure that a response is provided for each adverse finding or potential problem and will implement any necessary follow-up corrective action. The Battelle Quality Manager will ensure that follow-up corrective action has been taken. The test protocol and final verification report(s) are reviewed by EPA AMS Center QA staff and EPA AMS Center program management staff. Upon final review and approval, both documents will be posted on the ETV website (www.epa.gov/etv).

SECTION D.
DATA VALIDATION AND USABILITY

D1 DATA REVIEW, VALIDATION, AND VERIFICATION REQUIREMENTS

The key data review requirements for the verification test are stated in Section B10 of this protocol. In general, the data review requirements specify that the data generated during this test will be reviewed by a Battelle technical staff member within two weeks of generation of the data. The reviewer will be familiar with the technical aspects of the verification test, but will not be the person who generated the data. This process will serve both as the data review and the data verification, and will ensure that the data have been recorded, transmitted, and processed properly. Furthermore, this process will ensure that the beach water quality screening technology data and the reference method data were collected under appropriate testing conditions and that the reference method data meet the specifications of the reference method.

The data validation requirements for this test involve an assessment of the data quality relative to the DQIs and audit acceptance criteria specified for this test. The DQIs listed in Section B5 will be used to validate the quality of the data. The QA audits described within Section C of this document, including the performance evaluation audit and audit of data quality, are designed to validate the quality of the data.

D2 VALIDATION AND VERIFICATION METHODS

Data verification is conducted as part of the data review, as described in Section B10 for this protocol. A visual inspection of handwritten data will be conducted to ensure that all entries were properly recorded or transcribed, and that any erroneous entries were properly noted (*i.e.*, single line through the entry with an error code and the initials of the recorder and date of entry). Electronic data from the screening technologies and other instruments used during the test will be inspected to ensure proper transfer from the datalogging system. Data manually incorporated into spreadsheets for use in calculations will be checked against handwritten data to ensure that transcription errors have not occurred. All calculations used to transform the data will be

reviewed to ensure the accuracy and the appropriateness of the calculations. Calculations performed manually will be reviewed and repeated using a handheld calculator or commercial software (*e.g.*, Excel). Calculations performed using standard commercial office software (*e.g.*, Excel) will be reviewed by inspecting the equations used in calculations and verification of selected calculations by handheld calculator. Calculations performed using specialized commercial software (*i.e.*, for analytical instrumentation) will be reviewed by inspection and, when feasible, verified by handheld calculator, or standard commercial office software.

To ensure that the data generated from this test meet the goals of the test, a number of data validation procedures will be performed. Section C of this protocol provides a description of the validation safeguards employed for this verification test. Data validation and verification efforts include the completion of QC activities, and the performance of TSA and PE audits as described in Section C. The data from this test will be evaluated relative to the measurement DQIs described in Section B5, and the PE audit acceptance criteria given in Section C1.1 of this test/QA Plan. Data failing to meet these criteria will be flagged in the data set and not used for evaluation of the beach water quality screening technologies, unless these deviations are accompanied by descriptions adequately demonstrating that data quality was not compromised.

An audit of data quality will be conducted by the Battelle Quality Manager to ensure that data review, verification, and validation procedures were completed, and to assure the overall data quality.

D3 RECONCILIATION WITH USER REQUIREMENTS

The purpose of a verification test performed following this protocol is to evaluate the performance of commercial beach water quality screening technologies. In part, this evaluation will include comparisons of the results from the screening technologies to results from established reference methods. To meet the requirements of the user community, the data obtained in such a verification test should include thorough documentation of the performance of the screening technologies during the verification test. The data review, verification, and validation procedures described above will ensure that verification test data meet these requirements, are accurately presented in the verification reports generated from the test, and that

data not meeting these requirements are appropriately flagged and discussed in the verification reports. Additionally, all data generated using reference methods that are used to evaluate beach water quality screening technology results during the verification test should meet the QA requirements of the reference methods.

This generic verification protocol and any resulting ETV verification report(s) generated following procedures described in this protocol will be reviewed by participating beach water quality screening technology vendors, ETV AMS Center staff, test collaborators, EPA, and external expert peer reviewers. These reviews will ensure that this protocol, verification test(s) of beach water quality screening technologies, and the resulting report(s) meet the needs of potential users and permitters of beach water quality screening technologies. The final report(s) will be submitted to EPA in Microsoft Word and 508-compliant Adobe Portable Document Format (pdf) and subsequently posted on the ETV website.

SECTION E.

REFERENCES

1. Quality Management Plan for the ETV Advanced Monitoring Systems Center, Version 6.0, U.S. EPA Environmental Technology Verification Program, Battelle, Columbus, Ohio, November 2005.

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7. Bathing Beach Monitoring and Notification Program Workplan, Suffolk County Department of Health Services, New York, December 2005.

8. Method 1600: *Enterococci* in Water by Membrane Filtration Using membrane-*Enterococcus* Indoxyl-β-D-Glucoside Agar (mEI), EPA 821-R-02-022, U. S. Environmental Protection Agency, Washington DC, September 2002.

9. Method 1603: *Escherichia coli* (*E. coli*) in Water by Membrane Filtration Using Modified membrane-Thermotolerant *Escherichia coli* Agar (Modified mTEC), EPA-821-R-04-025, U. S. Environmental Protection Agency, Washington DC, April 2005.