QUALITY ASSURANCE PROJECT PLAN (QAPP) FOR

VARIABILITY AND RELIABILITY OF TEST CENTER AND FIELD DATA: DEFINITION OF PROVEN TECHNOLOGY FROM A REGULATORY VIEWPOINT

Funded by the

National Decentralized Water Resources Capacity Development Project
Through Washington University in St. Louis

Submitted by the

New England Interstate Water Pollution Control Commission (NEIWPCC)
Boott Mills South, 100 Foot of John Street
Lowell, MA 01852
(978) 323-7929

Thomas W. Groves, NEIWPCC Project Manager	Date
Michael Jennings, NEIWPCC QA Manager	Date
Andrea L. Shephard, Ph.D., NDWRCDP Project Coordinator	Date

TABLE OF CONTENTS (A2)

Distribution List (A3)

Project Team Members

CONTACT	PROJECT ROLE	AGENCY	ADDRESS	CITY, STATE, ZIP	PHONE	EMAIL
Thomas W. Groves	Principal Investigator, Advisory Committee	NEIWPCC	100 Foot of John Street	Lowell, MA 01852	978/323-7929	tgroves@neiwpcc.org
Michael Jennings	QA Manager	NEIWPCC	100 Foot of John Street	Lowell, MA 01852	978/323-7929	mjennings@neiwpcc.org
John Higgins	Advisory Committee	Massachusetts DEP	627 Main Street	Worcester, MA 01608	508/767-2787	john.j.higgins@state.ma.us
Ed Corriveau	Advisory Committee	Pennsylvania DEP	909 Elmerton Ave.	Harrisburg, PA 17110	717/705-4805	ecorriveau@state.pa.us
Fred Bowers	Advisory Committee	New Jersey DEP	P.O. Box 029	Trenton, NJ 08625	609/633-7021	Fred.Bowers@dep.state.nj.us
Larry Hepner	Advisory Committee	Delaware Valley College	700 East Butler Ave.	Doylestown, PA 18901	215/489-2334	HepnerL@devalcol.edu
Michael T. Hoover, Ph.D	Contractor	Onsite Corporation	805 Palmetto Drive	Cary, NC 27511	919/604-3100	mike_hoover@ncsu.edu
James F. Heltshe, Ph.D.	Contractor		161 Kenyon Ave.	Wakefield, RI 02879	401/874-4504 401/782-3165	heltshe.james@epamail.epa.gov
Andrea L. Shephard, Ph.D.	NDWRCDP Project Coordinator	NDWRCDP	6167 Potrero Drive	Newark, CA 94560	510/651-4200	a_arenovski@earthlink.net

Project Organization (A4)

NEIWPCC will act as project manager for this project. In that role, NEIWPCC Wastewater Director, Tom Groves, will coordinate all activities of the Project Advisory Committee. The Committee consists of:

Thomas Groves, NEIWPCC (Principal Investigator - PI)
John Higgins, Massachusetts DEP
Ed Corriveau, Pennsylvania DEP
Larry Hepner, Delaware Valley College
Fred Bowers, New Jersey DEP
Michael Jennings, NEIWPCC (QA Manager)

The Project Advisory Committee has met via in-person meetings and conference calls to prepare the original proposal and to begin subsequent proceedings of the project. The Project Advisory Committee will work closely with the two contractors for the project, Michael Hoover, Ph.D. (Onsite Corporation) and James Heltshe, Ph.D. to form the complete Project Team. The Principal Investigator (Groves) will be responsible for ensuring contractor compliance with the approved QAPP.

The Project Team plans to meet 4-6 times during the project period. The first meeting took place shortly after notice of approval was received by NDWRCDP. This meeting acted as a project "kick-off" meeting to help identify all the roles and responsibilities of the Team members. This meeting was held July 31, 2003 centrally in Baltimore, Maryland to best accommodate the various states and reduce travel costs. Follow-up conference calls will be scheduled by NEIWPCC with the Project Advisory Committee and the subcontractors on an as-needed basis. When in-person meetings are necessary, NEIWPCC will try to coordinate these meetings in conjunction with another existing conference or meeting (i.e., NOWRA, SORA, ASAE). NEIWPCC will closely monitor the contracts of the subcontractors to insure that all deliverables, standards, deadlines, and reporting requirements of the NDWRCDP are met.

The contractor(s) will provide NEIWPCC all draft documents and/or outputs for the project for review. NEIWPPC will circulate the outputs and draft documents from both contractors to the Project Team for review and discussion. Periodic conference calls or Project Team meetings will be arranged as necessary including the contractor(s) to discuss and review the pertinent information with relevant findings and revisions relayed to the contractor(s). The Project Advisory Committee will review all draft deliverables of the subcontractors. Final approval for all subcontractor work will be based on Project Advisory Committee final approval.

NEIWPCC will provide independent Quality Assurance/Quality Control oversight of the project. NEIWPCC's QA Manager, Michael Jennings, will assume the role of Quality Control Officer and will work closely with the project subcontractors.

Refer to Appendix A for a Project Organization Chart.

Problem Definition and Background (A5)

On-site regulators and regulatory technical review panels across the country are evaluating a growing number of manufacturers' requests for technology approvals. Technical support documentation for product approval submittals from manufacturers range from peer reviewed journal articles with attached third party research reports to simple claims that "our system works just like Product X's system that you already approved" with little (or no) supporting third party research. Test centers and demonstration projects have been and continue to be initiated throughout the country without a comprehensive assessment and national consensus regarding how much and what quality of data is necessary for decision-making regarding what constitutes a “proven technology.”

At the same time, states and provinces are remaking their entire rules into more performance-based approaches. The growing environmental focus in on-site wastewater is causing a shift in emphasis from the traditional disposal aspect to more of the treatment aspect in rule revisions.

The onsite wastewater program arena is rich with many existing data sources including test center, testing organizations, university test facilities, vendor sampling, state/county/local monitoring, and other sources. However, the program is lacking the assembly of valid quality data into unified sets needed to confirm statistical trends and relationships. Understanding these statistical relationships will optimize field-testing protocols, reduce unnecessary and costly testing, help predict field performance levels, and allow for more uniform acceptance of new technology by States, Counties and Local onsite oversight and implementing agencies.

It is important to conduct this research in order to develop these statistical relationships, provide a decision support system that integrates test center and field data to correctly predict field performance and provide the regulatory and manufacturing communities with common sense guidance regarding how much data of what quality is needed to accept a technology as “proven.” As the onsite program and industry moves towards a performance based code and approach this research will provide a baseline understanding on how to assemble, assess and interpret new and existing data sets to maximize their benefit to the onsite program.

The objectives of this research are as follows:

1. To assemble valid quality test center and field data into unified sets and evaluate their relative qualities.
2. To analyze these data sets statistically to prove or disprove the null hypothesis if test center and field data distributions are similar or dissimilar.
3. If data distributions are similar, then predict field performance relationships.
4. If data distributions are dissimilar then develop the best possible fit for these relationships
5. To develop a decision support system for ranking or weighting different types of data that guides regulators and manufacturers regarding the possible combinations of test center and field data needed to allow state/county/local approvals of new technology as “proven.”
6. To allow for greater acceptance of the NOWRA Model Code.
7. To build capacity and understanding in the onsite program arena, including vendors, testing organizations, state regulators, consultants, implementing and management agencies, and the public.
8. To provide an instructional CD on the collection, assembly, analysis, and use (weighting and ranking) of data collected at test centers and in the field that gives regulators confidence in the predictable performance of new onsite technology.

Project/Task Description (A6)

Scientific Method of Analysis:

Performance of Onsite Wastewater Treatment Systems (OWTSs) technology is routinely tested at NSF and ETV centers, or at field-testing installations such as demonstration projects like the one at La Pine Oregon. Typically, data collected at test centers differs from the data collected at field-testing installations/demonstrations. Usually, the field-testing data quality and quantity is more variable than the test center data. This is not surprising, since test centers specifically attempt to control the source and variability of the input wastewater and field-testing installations rely on the variable source of wastewater from individual residential homes. This incongruity causes state and local authorities responsible for approving technology to view test center data with skepticism. When they are asked to approve technology for general use based on test center data and evaluations, they often doubt that actual performance of individual home OWTSs will mimic the test center data. Considering this skepticism, it is remarkable that there has not been much of an effort to evaluate the relationship between the data collected by test centers and that collected by field installations. This research project is intended to overcome this knowledge gap by establishing the relationship between test data and field data. Furthermore, this project will develop a decision support system that regulators can use for assessing data type, quality and quantity for a specific technology.

Initially, the research design will test the following hypotheses:

H_o: Test Center Technology Performance = Real world System performance
H_a: Test Center Technology Performance ≠ Real world System performance

The null hypothesis will be tested by collecting raw data from both sources. The data distribution characteristic will be determined. Then, based on the characteristic shape of the data distribution (parametric or non-parametric), appropriate tests will be employed to test the hypotheses.

Test centers usually include excellent, fairly comprehensive datasets for one system (one replicate) to three systems (three replicates) of a particular technology under highly controlled conditions that may not, by their very nature (e.g. significant oversight and highly controlled), be representative of the "field conditions" that a system will be subjected to after a general approval in a state. On the other hand, field demonstrations of technologies usually include larger numbers of systems under more realistic (and varying) conditions of a range of wastewater strengths and flow rates. This "reality" can be good for assessing performance in the light of reality, but can confound attempts to truly evaluate performance since there is less experimental control. Also, field demonstration projects might not have as many samples for any one system or as high a quality of a sampling QA/QC program.

The Project Team will seek data from as many sources as possible, including the EPA ETV Program. We will attempt to incorporate this data into the study if it meets our guidelines. Until all the data is reviewed and triaged by the Project Team, it is impossible at this point to indicate which data will be used.

If the conclusion is that the data are similar (H_o true), variances will be compared to allow for the test center data to predict the expected output from individual homes.

If the conclusion is that the data represent different populations (H_a), there will be an attempt to establish a relationship between the two data sources such that data from the test centers can be used to predict the variance one would expect to find in the field. If such a relationship can be found, test center data (which can be determined much easier than field data) can be used by state authorities to assess and approve OWTSs technology for general use. If no strong predictive relationship can be established, state approval authorities will be inclined to continue to require field-testing prior to system approval. In any event, the project will develop a decision support system for data quality/quantity assessments to assist onsite regulators.

Statistical Analysis:

Task I: Organization and Evaluation of Existing Data Sets (Heltshe subcontract)
Task II: Data Analysis and Model Development (Heltshe subcontract)
Task III: Recommended Protocol for the Statistical Evaluation of the Alternative Septic System Provisional Approval Process (Heltshe subcontract)

Evaluation of Data and Dissemination of Results:

A rating scale for weighting datasets (e.g. a data decision support system) will be developed and guidance provided for integration and comparison of field data, test center data and other datasets for regulatory decision-making

Task I: Data triage (Project Advisory Committee)

This part of the project will draw upon existing datasets and the afore-mentioned purely statistical data assessment to integrate, compare and evaluate the type, quality and quantity of datasets needed to draw realistic conclusions regarding system performance from a wastewater practitioner and regulatory point of view. A comparative assessment of the qualities and strengths of different types of field and laboratory research studies will be developed, compared and reviewed.

Task II: Development of an instructional CD on the collection, assembly, analysis and use of data collected at test centers, field demonstrations and laboratory studies (part of Hoover subcontract)

This will help fill a critical information gap, providing a scientific dialogue between wastewater practitioners and regulators and inspiring further cooperation with other trade and professional organizations. The proper role of science in helping make these decisions will be demonstrated to help the regulator decide about the amount and quality of data needed for a specific product approval request. The role other factors besides "pure" scientific studies play, as a practical matter, in regulatory decision-making—such as basic environmental values like "how clean is clean" or how to use data that is not "pure"—will also be addressed.

NEIWPCC will be the primary coordinator of the instructional CD with input and oversight from the other regulatory members of the Project Team as well as Dr. Hoover. Dr. Hoover will provide the basic framework and core materials for the CD as part of his subcontract. This information will be given to the Project Team for review and incorporation into a final product. The CD will be developed in an interactive web page-like format for ease of use. It will include reports, spreadsheets, algorithms, and any other information pertinent to the project and future regulator use. Input from the State Onsite Regulators Alliance will also be sought, but will not slow down the development process. Live links will be provided so the user can directly access information from web sites. NEIWPCC will provide NDWRCDP with one master copy CD for duplication and circulation.

Project Timeline:

The project timeline for these tasks and the whole project is attached in Appendix B.

Quality Objectives and Criteria (A7)

The anticipated output of this project is a model and a decision support system that can be used by state Onsite Regulators to assist them in approving new technology. The model and the support system will help the regulator determine the amount, type, duration, and conditions of data necessary to make an unbiased evaluation of a technology's expected field performance. All collected data will be used to evaluate the model since there is not likely to be any control on subsequent field test data post-project.

Task I: Development of a **decision support system** for evaluating performance data (Hoover subcontract)

> One of the primary deliverables will be a quantitative data assessment method and rating (weighting) scale that regulatory agencies can use for defining what is a "proven technology." This **data decision support system** will assist regulators in determining how much data and what types of data are adequate for regulatory decision-making. It will also be useful for guiding regulators in providing unbiased advice to product developers regarding how much and what types of additional data must be developed and submitted to them before a decision can be reached regarding their technology.
>
> Scientific consensus never occurs based on one perfect study—at the very minimum, that study would have to be confirmed. Rather, as illustrated more fully later in this proposal, the scientific "castle" is constructed brick by brick—study by study—until the weight of evidence (the castle's foundation) is strong enough to hold up the claims asserted about that technology's performance.
>
> Regulators (and manufacturers) can use the data decision support system to determine how much additional data (of what quality) is needed before a decision is made that can be depended upon to predict performance about a technology in the field. The data decision support system will be developed in full during the project using the scientific principles described later in this proposal. But for illustration purposes here is a very brief summary of a proposed simple guide for ranking (or weighting) scientific evidence:
>
> - Unsupported performance assertions by a vendor - 0 data quality/quantity points
> - Vendor submissions of field performance data over time in one state - 1 data quality/quantity point
> - Vendor submissions of field performance data over time in one region - 2 data quality/quantity points
> - Vendor submissions of field performance data over time in many states - 3 data quality/quantity points
> - Demonstration project results – 3 - 6 data quality/quantity points depending upon scientific quality and quantity of data
> - Third party test center studies of field performance over time - 4 to 8 data quality/quantity points depending upon scientific quality and number of replicates (1, 2, 3, …. 12) studied, number of samples and length of study
> - One peer reviewed, published, third party study of a performance claim - 5 to 10 data quality/quantity points depending upon number of replicates studied and range of environmental conditions under which the product was tested in the study
> - A confirmatory published, peer-reviewed study, with the same or similar result – 6 to 12 additional data quality/quantity points

The minimum number of “data quality/quantity points” of supporting evidence needed for a submittal for a product approval could be specified by the regulatory agency (i.e. 15 points, 20 points, etc). Then, manufacturers could, for instance, have the flexibility to choose whether to submit a few of their units for detailed study at a test center or authorize a large independent, third-party study of numerous existing units that are already in operation in a different state, depending upon their finances and business plan. The amount and quality of data needed for making a decision whether the technology of interest can be appropriately considered as a “proven technology” is clearly defined in this process. This puts everybody on the same page regarding how much data of what quality is needed for decision-making, but provides flexibility at the same time. The “strawman” rating scale will be reviewed by the full project steering committee and then revised for further review by a broader group of regulators and field practitioners, including manufacturers.

Special Training/Certifications (A8)

There is no special training or certification needed by any of the Project Team for this project. The project requires expertise in statistics, model development, and decision support system development. Qualified contractors have been enlisted by the Advisory Committee to adequately address the necessary abilities, specialties, and expertise.

Documentation and Records (A9)

During the course of the project, all administrative project documents will be stored for one year after the project completion in hard copy and electronic format, when available, at NEIWPCC’s Office in Lowell, Massachusetts. These records will consist of:

- Final application package to NDWRCDP
- Signed contract with Washington University for the project
- Most current Quality Assurance Project Plan
- Subcontracts with Onsite Corporation and James Heltshe

All members of the Project Team have copies of the application package and Washington University contract. Once the QAPP is approved, the PI will insure that all members of the distribution list (section A.3) receive and abide by the QAPP. The PI will insure that all Project Team members are transmitted the most current QAPP via U.S. Mail and confirming the information through email. Any future revisions to the QAPP will be distributed and confirmed by the PI. The QAPP will include a footer indicating the modification date, QAPP revision number (if appropriate), and the total number of pages of the document.

During the course of the project, NEIWPCC and the Project Team will produce additional documents. These will include:

- Quarterly Progress Reports to the NDWRCDP Project Coordinator
- Quarterly Report Summary to the NDWRCDP Project Coordinator
- Semi-annual MBE/WBE Form
- Draft Final and Final NDWRCDP Report and Responses to Comments
- Instructional CD of the Decision Support System for Regulatory Decision-Making

NEIWPCC will transmit these documents/reports per the NDWRCDP specifications and requirements and will maintain records in hard copy and electronic copy for one year after completion of the project. All electronic files are maintained and backed up from NEIWPCC's servers via DLT nightly and monthly backup tapes are stored off site.

As part of this project, test center and field test data for many systems will be accumulated, triaged, and used to test the statistical model. Electronic data will be archived on CD. It should be noted that the data sets themselves are not a product of this project and will not be stored and maintained by NEIWPCC. The data is to be used to test the validity of the model and the decision support system, but it is not an end product of the project.

Sampling Process Design (B1)

This item does not apply since this project does not include sampling for this project.

Sampling Methods (B2)

This item does not apply since this project does not include sampling for this project.

Sample Handling and Custody (B3)

This item does not apply since this project does not include sampling for this project.

Analytical Methods (B4)

This item does not apply since this project does not include sampling for this project.

Quality Control (B5)

This item does not apply since this project does not include sampling for this project.

Instrument/Equipment Testing, Inspection, and Maintenance (B6)

This item does not apply since this project does not include sampling for this project.

Instrument/Equipment Calibration and Frequency (B7)

The project will use General Linear Mixed Models to model each data set and statistically test if the 'test' and 'site' data are equal. Because the observations within a time series are correlated with one another, the project will need to model the correlation structure of these data in order to use General Linear Mixed Models. A sensitivity analysis of the correlation structure will be performed to determine the effects on the parameter estimates generated from the General Linear Mixed Models using different correlation structures.

The general linear mixed model provides a useful approach for analyzing a wide variety of data structures which practicing statisticians often encounter. Unbalanced repeated measures data is one such data structure that can be problematic to analyze. Owing to recent advances in methods and software, the mixed model analysis is now readily available to data analysts. The model is similar in many respects to ordinary multiple regression, but because it allows correlation between the observations, it requires additional work to specify models and to assess goodness-of-fit.

Ultimately, the project will evaluate the feasibility of using 'test' data to predict 'site' data. If the 'site' data can be predicted from the 'test' data then the project will validate the models with additional 'site' data sets. If the 'site' data cannot be directly predicted from the 'test' data then we will determine where the differences lie. This could be in the overall means for the 'test' and ‘site’ data or in the variance-covariance structure of the time series. We will attempt to calibrate the ‘site’ data based upon the ‘test’ data. If there is no direct relationship between the ‘test’ and the ‘site’ data sets then we will concentrate on estimating the sources of variance in the ‘site’ data set. The two main sources of variance will be among sites and within the time series at a site. Estimates of these variance components will be used to optimally design a field-sampling plan for ‘site’ data evaluation and for determining the types, quantities and qualities of ‘site’ data that best compliment ‘test center’ data.

Inspection/Acceptance of Supplies and Consumables (B8)

This item does not apply since this project does not include sampling for this project.

Non-direct Measurements (B9)

As part of this project, we plan to use only existing data. This data will come from a variety of sources (test center and field sites) as discussed later in this section. Test Centers usually include excellent, fairly comprehensive datasets for one system (one replicate) to three systems (three replicates) of a particular technology under highly controlled conditions that may not, by their very nature (e.g. significant oversight and highly controlled), be representative of the “field conditions” that a system will be subjected to after a general approval in a state. On the other hand, field demonstrations of technologies usually include larger numbers of systems under more realistic (and varying) conditions of a range of wastewater strengths and flow rates. This “reality” can be good for assessing performance in the light of reality, but can confound attempts to truly evaluate performance since there is less experimental control. Also, field demonstration projects might not have as many samples for any one system or as high a quality of a sampling QA/QC program.

The Project Team fully expects the collected data to have some fluctuation. The outlying data points or anomalies will be evaluated by the Project Team and eliminated from inclusion if it is deemed to be non-representative of the data set.

The Project Team will seek data from as many sources as possible. We will attempt to incorporate this data into the study if it meets our guidelines. Until all the data is reviewed and triaged by the Project Team, it is impossible at this point to indicate which data will be used, but the following sources have been contacted and will tentatively be used for this project:

1. National Sanitation Foundation (NSF) Standard 40 Testing
2. NSF Environmental Technology Verification (ETV) Testing
3. Massachusetts Alternative Septic System Test Center
4. Massachusetts DEP Innovative/Alternative Technology Database
5. La Pine, Oregon Onsite Wastewater Treatment and Disposal Demonstration Project
6. National Onsite Demonstration Projects
7. Delaware Valley College Test Research and Demonstration Center for On-lot Systems and Small Flow Technologies
8. Virginia Department of Health
9. University of Rhode Island
10. Miscellaneous Field Test Data from Manufacturers

Data Management (B10)

The Advisory Committee is responsible for collecting and triaging the data from the multiple sources as listed in section B9. The majority of this data will be collected electronically from the testing agency or the manufacturers themselves. This data may be provided in many different forms. The goal of the Advisory Committee will be to collect the data sets and format them into one consistent format that can be easily transferred to our statistical consultant (Helthse). Typically, this data will be imported into a spreadsheet with only the pertinent data for this project included (i.e., BOD, TSS, time, date, temperature, etc.).

Data sets that are received in hard copy only will require additional work and assistance from support staff to import them into the desirable spreadsheet format. This introduces the risk of transposition errors. The Advisory Committee will review all data sets in spreadsheet format prior to release to the contractor to insure that no data errors have been introduced. This will be accomplished by individually reviewing all data sets and flagging those data points that are outside of the normal range within the spreadsheet. If encountered, this data will be double-checked against the incoming data sets and either corrected if an error has been made, or flagged as "questionable" if it is consistent with what was submitted.

Task: Organization and Assessment of Existing Data Sets (Heltshe subcontract)

> The Advisory Committee is responsible for collecting and triaging the data prior to submission to the contractor for developing the statistical model (refer to section C1). The data will be organized and evaluated from two sources: 1) test centers (test data), and 2) 'real world' monitoring data collected at individual residences (site data). The project will concentrate its efforts on only two variables collected in these data sets Biological Oxygen Demand (5 day) (BOD) and Total Suspended Solids (TSS). In all cases existing, electronically available datasets will be used rather than new datasets (new samples and new laboratory analyses) being developed for this project. The data consist of time series of data collected at the test site and at individual residences. It is expected that some of these data will have been collected at irregularly spaced time points and some sampled time series may have a different number of sampled times.

Assessments and Response Actions (C1)

The collection, assessment and evaluation of existing data sets will take place as described in the following task. The schedule for this task and the whole project is attached in Appendix A.

Task: Data triage (Project Advisory Committee)

> This part of the project will draw upon existing datasets and the aforementioned purely statistical data assessment to integrate, compare and evaluate the type, quality and quantity of datasets needed to draw realistic conclusions regarding system performance from a wastewater practitioner and regulatory point of view. A comparative assessment of the qualities and strengths of different types of field and laboratory research studies will be developed, compared and reviewed.
>
> The first step of this process is essentially a data "triage" step wherein the differing types of system performance datasets in the decentralized wastewater field are categorized by quality and quantity of data. The project advisory committee will solicit electronic datasets from existing projects for technologies of interest (intended initially to be pretreatment technologies). After the triage process, the scope will include at least two comprehensive comparisons of the variability, sampling quality and usefulness of actual test center data and field data for a pretreatment technology.

In order to assess the model, the contractor will evaluate the test center data vs. similar sets of field data. For instance, the NSF and NSF/ETV data sets are high quality data sets under QA control. The NSF and/or NSF/ETV data sets will be compared first against field test data from one particular site (i.e., Block Island, RI). The data will then be compared against LaPine field data, and then Massachusetts I/A data. The contractor will then try to calibrate the model based on the variation from those individual data sets so the model can be used to evaluate data over all field data sets. The goal of the project is not to evaluate the data points, but instead to verify if there is a correlation between test center and all real world data. This will prove challenging since the field data sets represent the gamut of data quality – from high quality, controlled, and QA approved testing to in the field, backyard data that is not highly controlled and without a QA plan. Unfortunately, this is the type of data that Onsite Regulators often encounter, and perennially will encounter in their technology approval positions. This is not expected to change in the future due to the highly fragmented industry and lack of resources and onsite wastewater management programs at the local level to provide the data needed.

The Advisory Committee will review the results and initial findings of the statistical contractor to discuss whether the model is meeting its design goal. The use of additional data sets will also be included to verify that the model holds true for the varying data sets likely to be encountered. The contractor will report to the Advisory Committee any corrective actions that may be needed to the model, including the reasons for the corrective actions, why they occurred, and what adjustments are necessary. The progress report of the contractor will address if the data sets are sufficient to evaluate the model, what level of confidence will the model predict, and how sound the model is. Based on the interim findings, the Advisory Committee will decide if it is prudent to pursue additional findings or report that the lack of quality data makes it impossible to predict a defensible relationship with test center data.

Reports to Management (C2)

The Principal Investigator will insure that the Project Team and NDWRDCP are provided with all reports indicating project oversight and assessment activities and findings. This will include reports such as, the most current QAPP, quarterly progress reports, quarterly summary reports. These reports will be prepared and submitted to NDWRCDP as outlined in the agreement between NEIWPCC and Washington University and will be made available for review and inspection at any time.

The QAPP will be distributed to the entire Project Team by the PI. The PI will insure that the most recent QAPP is available to all Project Team members and that it is being adhered to.

In addition, NEIWPCC will circulate the quarterly progress reports of both contractors to the Project Team prior to inclusion in the NEIWPCC quarterly report. These reports are required of the subcontractors as part of the NEIWPCC contract. These reports will provide the Project Team with information on the development of the decision support system, development of the model, testing of the model, and assessment of the model. Periodic conference calls or Project Team meetings will be arranged as necessary to discuss and review the pertinent information.

Data Validation and Usability (D1 – D3)

The project will produce time series plots for each replicate times series for the test and site data. This will allow for visual inspection for outliers and possible 'problem' data series. Each data series will be evaluated and modeled for seasonal, annual and long-term time trends. Based on these analyses the data sets may be edited. Data sets showing long-term trends will be evaluated to determine if they are indicative of a system that is not properly maintained, is used only seasonally or has other problems and should be removed from further analysis. Only datasets from permanently used sites will be used to avoid the complications of frequent start-up issues for seasonal homes. However, if seasonal or annual cycles exist then the data series will have to be combined according to season or time may need to be adjusted to 'days from start of monitoring' regardless of season. Individual outlier observations within a time series will be identified and outlier time series will be identified. Control charts will be drawn for both 'test' and 'site' combined data sets.

As mentioned previously, this project will use General Linear Mixed Models to model each data set and statistically test if the 'test' and 'site' data are equal. Because the observations within a time series are correlated with one another, the project will need to model the correlation structure of these data in order to use General Linear Mixed Models. A sensitivity analysis of the correlation structure will be performed to determine the effects on the parameter estimates generated from the General Linear Mixed Models using different correlation structures.

The project will utilize the general linear mixed model for the regression analysis of correlated data. The correlation arises because subjects may contribute multiple responses to the data set. The model assumes a continuous outcome variable which is linearly related to a set of explanatory variables; it expands on the ordinary linear regression model by allowing one to incorporate lack of independence between observations and to model more than one error term.

In classically designed experiments with balanced and complete data, covariates (or factors) typically vary either within subjects (observation level) or between subjects (subject level) but not both. Treatment and centre vary between but not within subjects. This clean separation between- and within-subject variables is a hallmark of designed experiments and has the advantage of leading to orthogonal designs and a simplified repeated measures analysis. With observational studies, unbalanced designs and/or missing data, it is rarely possible to achieve this clear separation of between- and within-subject variables.

Task: Recommended Protocol for the Statistical Evaluation of the Alternative Septic System Provisional Approval Process. (Heltshe subcontract)

> The final report will include a protocol on how to use 'test' data sets to predict 'site' data sets. If there is no relationship between the 'test' data and the 'site' data then the project will develop a field sampling plan for 'site' data evaluation to be used in conjunction with test data. The project will determine the number of samples or 'sites' to collect and the number of time series points to collect at each site. The number of sites needed and the number of time points is related to the variance among sites and within sites. Also, the project will determine the total duration of the time series. This will be a function of any seasonal or annual trends detected in earlier tasks. These recommendations will be developed for both BOD and TSS.

The Project Team will meet and review the final findings of the statistical evaluation and decide whether or not to recommend that this model will work for its intended audience, i.e., Onsite

Wastewater Regulators. These findings will be published in the final NDWRCDP report on this project and the CD deliverable.

References:

"Variability and Reliability of Test Center Data and Field Data: Definition of Proven Technology from a Regulatory Viewpoint," NEIWPCC proposal submitted to NDWRCDP, June 18, 2003.

"Tutorial in Biostatistics: Using the General Linear Mixed Model to Analyse Unbalanced Repeated Measures and Longitudinal Data," Cnaan, Laird, and Slasor. Statistics in Medicine, Vol. 16, John Wiley & Sons, Ltd., 1997.