QUALITY ASSURANCE PROJECT PLAN (QAPP) FINAL REPORT

FOR

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

JUNE 2005

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National Decentralized Water Resources Capacity Development Project
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Submitted by the

New England Interstate Water Pollution Control Commission (NEIWPCC)
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Project Organization (A4)

NEIWPCC acted as project manager for this project. In that role, NEIWPCC Wastewater Director, Tom Groves, coordinated 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 worked 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) was responsible for ensuring contractor compliance with the approved QAPP.

The Project Team plans to meet and held conference calls several 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 were scheduled by NEIWPCC with the Project Advisory Committee and the subcontractors on an as-needed basis. When in-person meetings were necessary, NEIWPCC coordinated these meetings in conjunction with another existing conference or meeting (i.e., NOWRA, SORA). NEIWPCC monitored the contracts of the subcontractors to insure that all deliverables, standards, deadlines, and reporting requirements of the NDWRCDP were met.

The contractor(s) provided NEIWPCC all draft documents and/or outputs for the project for review. NEIWPPC circulated the outputs and draft documents from both contractors to the Project Team for review and discussion. Periodic conference calls or Project Team meetings were 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 reviewed all draft deliverables of the subcontractors. Final approval for all subcontractor work was based on Project Advisory Committee final approval.

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 sought data from as many sources as possible, including the EPA ETV Program. These data are listed in Table 1 with a description of the data source, the condition of the data when received, and the data triage procedures used (if any).

Table 1: Raw Data QAPP and Data Triage:

Orenco AX20

Prepared by: Fred Bowers
Date: December 2, 2003

Data Source	Source Dataset Condition	Extent of Triage Procedure
Massachusetts DEP	The data were provided by Steven Corr, (MA DEP). Data are from numerous installations around the State. Installations included residential, commercial, and also installations that were not identified (blank in "Facility type" field)	1. Blank or unknown records in "Facility type" field were not included 2. Only residential installations were included.
Oregon DEQ, La Pine, Project Database http://www.deq.state.or.us/wq/lapinedata/SiteRptCriteria.asp	All data for Orenco AX20 were downloaded from the website on December 1, 2003.	Only records identified as AX-20 Effluent are included. Some QA duplicates exist 8/6/2002 8.1 3 QA Duplicate 3/18/2002 5.1 4 QA Duplicate 6/4/2002 18 1 QA duplicate 6/18/2002 2.2 3 QA duplicate 9/3/2002 4.6 1 QA Duplicate 10/2/2002 10 11 QA Duplicate 11/6/2002 2.4 1 QA Duplicate 12/11/2002 4.2 2 QA Duplicate 2/3/2003 7.6 4 QA Duplicate 4/1/2003 14 25 QA Duplicate 9/17/2002 3.9 2 QA Duplicate
NSF International Standard 40 Final Report	Data were keyed by hand into an Excel dataset from NSF Standard 40 product certification report.	None

Orenco Sam Carter Regulatory Relations Coordinator Orenco Systems, Inc. 814 Airway Avenue Sutherlin, OR 97479 Phone: 1-800-536-4192 Fax: 541-459-2884 Obtained by Ed Corriveau	Excel files named "Block Island Data" and "VA Test Data1"	Only data records identified as "Filtrate Effluent" are included. In Block Island (Rhode Island) dataset, "NS" means "not sampled" and connotes blank data. The Virginia dataset "AdvanTex Effluent" was used with no triage.

BioClere

Prepared by: Fred Bowers
Date: December 2, 2003

Data Source	Source Dataset Condition	Extent of triage procedure
Massachusetts DEP	The data were provided by Steven Corr, (MA DEP). Data are from numerous installations around the State. Installations included residential, commercial, and also installations that were not identified (blank in "Facility type" field)	1. Blank or unknown records in "Facility type" field were not included 2. Only residential installations were included.
NSF International Standard 40 Final Report	Data were keyed by hand into an Excel dataset from NSF Standard 40 product certification report.	None

BioMicrobics FAST

Prepared by: Fred Bowers
Date: December 1, 2003

Data Source	Source Dataset Condition	Extent of triage procedure
Massachusetts DEP	The data were provided by Steven Corr, (MA DEP). Data are from numerous installations around the State. Installations included residential, commercial, and also installations that were not identified (blank in "Facility type" field)	1. Blank or unknown records in "Facility type" field were not included 2. Only residential installations were included.
Oregon DEQ, La Pine, Project Database http://www.deq.state.or.us/wq/lapinedata/SiteRptCriteria.asp	All data for FAST were downloaded from the website on December 1, 2003.	Only "Fast Effluent Pipe" data were used in the final dataset. There are a few duplicate values (eg. 5/21/03) that were put in as quality control.
NSF International Standard 40 Final Report	Data were keyed by hand into an Excel dataset from NSF Standard 40 product certification report.	None

If the conclusion of the project is that the data is 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)

Data Triage:

As outlined in the final report, the following procedures were used for data triage for this project:

> The Committee reviewed commonly known onsite/decentralized pretreatment technologies and decided on Orenco's Advantex AX, Aquapoint's Bioclere and Bio-Microbic's FAST due to the number of data sets available from both testing sites and field sites. Committee members Fred Bowers, Ed Corriveau, and John Higgins compiled the field and test center data for the three selected technologies from a multitude of sources (i.e., NSF, ETV, NODP, MA DEP, manufacturers) screened the data, and amassed a database to facilitate statistical processing and analyses. The Committee selected the three technologies that had the most intersection points between test center and field data sources. We needed to insure a high level of NSF and ETV data sources in order to statistically compare the data.
>
> Every effort was made to not be overly judgmental about the quality of any of the data reported for analysis mainly because of the lack of available data in large enough data sets. The gathering of data targeted residential data on BOD and TSS, collected from known types of treatment units serving known facilities with five bedrooms or less (or test center simulation thereof) and preferably from locations that experience "true" winter, i.e., cold ambient temperature conditions on a regular basis for at least some part of the year.
>
> Once the data were received and known to be residential sites in a seasonally warm/cold climate, data that met these characteristics were added to an Excel spreadsheet. The merged data sets were then only edited for missing observations, '0' values, and duplicate observations on the same sampling date at a site. Missing observations were removed, '0' observations were considered as missing and thus removed. Duplicate observations on the same date at the same site were considered as "split" samples at a site and were averaged but recorded only once at a site/date combination. No data was discarded based on who collected the sample or provided the data, nor were we going to eliminate or interpret the data for any other reasons, such that we did not consider whether the range of values was outside of what was normally expected. We did not make quality or validity assumptions about any of the data sets except as mentioned earlier for missing observations, '0' values, and duplicate observations on the same sampling date at a site.

While there is a tendency to try to extrapolate test center data to resident site data, each of these two data sets is distinct, but each has great value depending on how anyone wants to value and use the data as explained further in our proposed Decision Support System. Extrapolated test center data would be less representative of accomplishing our goal of developing a model to predict the long-term performance of systems in the field. There are simply too many variables inherent with how each field system is operated and maintained, and how each system is independently and differently loaded. For the purposes of this study, it should be noted that operation and maintenance (O&M) records for any of the systems in this study were not collected and analyzed. The authors fully realize the influence of O&M on the long-term performance of these systems. Although O&M records are available for the test center sites, they were not available for the numerous residence sites. We would have had to disregard numerous residence data points if O&M records were required. This report serves as a real world example and comparison of the performance of field sites as they exist and as they are operated and maintained today. One of our goals in this study was to see if there was a basic relationship between residence sites and test center sites, and as stated above, no data were discarded. Some regulatory programs have the ability and the resources to track O&M of these systems, but most do not.