Data Quality Objectives and Statistical Design Support for Development of a Monitoring Protocol for Recreational Waters

Final Report

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Prepared by
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INTRODUCTION

On June 14, 15, and 16, 1999 members of the Environmental Protection Agency (EPA) National Exposure Research Laboratory (NERL-Cincinnati) and Office of Water (OW), Office of Science and Technology, Washington, DC (OST) held a workshop in Cincinnati, Ohio with invited non-EPA experts in environmental microbiology and statistics to plan a research study that will be used to develop guidance, to be used nationwide, for monitoring recreational waters for indicator bacteria.

Purpose of this Document

The purpose of this report is to describe the outputs of the Data Quality Objectives (DQOs) Process and discussions about developing a statistical design that will be used to implement the research study of recreational beach waters.

Background on Recreational Water Quality Monitoring

Current Environmental Protection Agency (EPA) recommended monitoring practices for bathing beach water quality were suggested in 1968, as a part of the fecal coliform guideline developed by the Federal Water Pollution Control Administration. The guideline stated that five water samples should be taken over a 30-day period and that the geometric mean of the fecal coliform count of the five samples would be used to determine compliance with the guideline. Since that time, EPA has developed improved health risk-based guidelines for bathing beach waters and improved methods for monitoring using *Escherichia coli* (*E. coli*) and enterococci as the indicators of recreational water quality. However, the recommendations to the States in 1986 used the old monitoring protocol for bathing beach waters.

The existing guidance for sampling and interpreting monitoring data is not particularly clear, and the data resulting from its use are not useful to regulatory authorities or the public. The current guidance does not address the variety of beach environments, i.e., marine or estuarine versus fresh water, lake versus river, or the dynamics and variation in pollution sources that can affect beach water sanitary quality on a daily basis. Therefore, data obtained using the current sampling protocol are not necessarily relevant with regard to the circumstances or conditions at the sampling sites on the day of sampling.

To address these problems, EPA's OW, OST and the Microbiological and Chemical Exposure Assessment Research Division (MCEARD) of NERL-Cincinnati in collaboration with the

Environmental Monitoring for Public Access and Community Tracking (EMPACT) Program are sponsoring a research project. This research has two objectives:

- develop guidance (i.e., a set of procedures) that can be used at individual beaches to develop protocols for monitoring the quality of bathing waters, and
- develop a system for translating technical monitoring data into easily understood risk information so that the public can make informed decisions on the use of recreational waters.

The research project is comprised of six phases:

1. The purpose of Phase 1 is to define all the elements that might influence the performance of an effective sampling plan for monitoring bathing beach water quality. This phase has been completed.

2. Phase 2, which has also been completed, is to conduct a pilot sampling study at selected, but representative, sites to empirically determine the magnitude of variation in indicator concentrations that would be encountered at bathing beaches under natural conditions.

3. Phase 3 (this workshop) involves developing DQOs and a statistical sampling design for a research project monitoring five characteristic recreational beach waters selected for the EMPACT study.

4. Phase 4, which will take place in the summer of 2000, involves contractors or EMPACT partner cities conducting sampling studies using the design developed in Phase 3. EMPACT partner cities will be selected based on the type of bathing beach site available, sources of fecal contamination affecting the sites and the availability of the laboratory facilities. Five sites representing five characteristic recreational water environments will be selected for monitoring:

    - ocean beach (east coast),
    - ocean beach (west coast),
    - freshwater beach (Great Lake),
    - freshwater inland river “beach” or recreational area, and
    - estuarine beach.

    The five sites that are being monitored in Phase 4 will not be surrogates for all beaches, but the data from these sites will be used to develop guidance that other cities could follow.

5. The purpose of Phase 5 is to interpret the collected data to determine the minimum number of samples that must be taken and locations for sampling each site to adequately describe the sanitary quality of the water.

6. The final phase, Phase 6, will be a workshop to develop a means to translate technical data gathered from bathing beach monitoring efforts into understandable information that can be used by the general population to make risk-based decisions about using recreational beach resources.

Summary of the Pilot Study

Phase 2 of the research project, which was conducted in the summer of 1998, estimated concentrations of two indicators of fecal contamination, *Escherichia coli* and enterococci. The purpose of collecting these data was to obtain estimates of the variability in the concentrations of these indicators, which is an important input in Step 6 of the DQO Process.

In Phase 2, sampling was done at an estuarine beach site (Tenean Beach, Boston Harbor) in Boston, ocean beach sites in New York (D.A. Beach Club, East Chesterbay, Bronx) and St. Petersburg Florida (Northshore Beach), river beach sites (Belleville Lake) in Belleville, Michigan, and Pensacola Florida (Blackwater River, Blackwater River State Park), and a lake beach site (Metro Beach, Lake St. Clair) in Detroit. At each sample site, samples were collected every other day so that samples were collected on three separate days. Samples were collected in the morning, around noon, and in the afternoon of each sample date. Samples were collected from three transects (areas of the designated beach) established along each beach; one transect was at the "end" of the beach, one in the "middle" of the beach, and one along a line where the greatest number of bathers were found. Along each transect, samples were taken where water depths were approximately 1½ and 4 feet. At each of the two locations along each transect, samples were collected 1 foot below the surface of the water. Results of the pilot study are presented in DQO Process Step 7.

The EPA Quality System, DQO Process, and Quality Assurance Project Life Cycles

The EPA Quality System was established in 1984 by EPA Order 5360.1. The Order requires all environmental programs conducted by, or on behalf of, EPA to be supported by mandatory Quality System (previously called a Quality Assurance Program). In 1997, the Order was significantly revised and reissued (EPA Order 5360.1 CHG 1) and requires EPA organizations and holders of extramural agreements to conform the requirements of the American National Standard ANSI/ASQC E4-1994, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs.* By establishing its own Quality System, EPA ensured that regulatory decisions were based on data of known quality.

The EPA Quality System, as shown in Figure 1, is comprised of three structural levels:

- policy level,
- organization/program level, and
- project level.

At the policy level, the Quality System addresses requirements for implementation of the System.

At the organizational level, the Quality System addresses implementation of:

C quality management plans,
C management system reviews,
C training, and
C the Quality Assurance Annual Report and Work Plan.

At the project level EPA's Quality System includes the following components that address planning, implementation, and assessment:

C the DQO Process,
C quality assurance project plans (QAPPs), and
C implementation of Data Quality Assessment (DQA) guidance.

The DQO Process is a part of the planning phase because it defines the problem to be studied, the limitations of the study, and the type, quantity, and quality of data required. As a result of the DQO Process, a statistical sampling design can be developed and documented in the QAPP. Methods that will be used to collect and analyze samples are documented in the QAPP. Finally, in the assessment phase, the data are analyzed and interpreted.

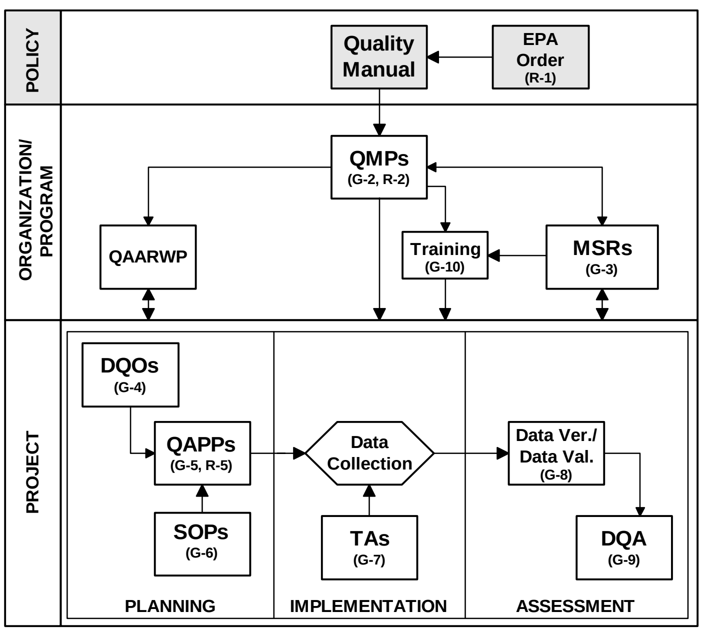

Figure 1. EPA's Quality System

An important element of EPA's Quality System is that it follows a graded approach so that the degree of quality controls applied to a project is based on the intended use of the results and the amount of confidence needed in the quality of the results.

Organization of this Report

This report is organized around the seven steps of the DQO Process, because the workshop was organized according to these steps. These seven Steps are: (1) State the Problem, (2) Identify the Decision, (3) Identify the Inputs to the Decision, (4) Define the Study Boundaries, (5) Develop a Decision Rule, (6) Specify Allowable Limits on Decision Errors, and (7) Optimize the Design.

STEP 1: STATE THE PROBLEM

The purpose of this step of the DQO Process is to describe the problem to be studied. This includes identifying the planning team members, describing the problem at hand, and summarizing the relevant deadlines.

Identify the Planning Team

The planning team is the group who will develop the DQOs for the study being designed.

The planning team for developing DQOs for the study that will provide data used to develop the recreational beach water monitoring guidance is comprised of the participants of this workshop (refer to Attachment A for the participant list and contact information).

The head of the planning team and the decision-maker for this project is Dr. Alfred P. Dufour of the U.S. EPA, National Exposure Research Laboratory (NERL).

There is also a project leadership group that assists Dr. Dufour in deciding how to proceed with the DQO Process, whose members include:

- Steve Schaub (EPA, OW, OST)
- Kristen Brenner (EPA, NERL)
- Larry Wymer (EPA, NERL)
- John Martinson (EPA, NERL)
- Walt Stutts (EPA, NERL)

Statement of the Problem

The current recommendation for monitoring the quality of recreational waters calls for the collection of 5 samples over a 30-day period and the calculation of a running geometric mean to determine if the water quality meets existing regulatory standards. This approach does not provide timely, accurate information for risk managers or the public, nor does it provide data that can be easily interpreted by any group, such as individual swimmers or decision makers. A solution to this problem is to develop a statistically valid monitoring guidance that takes into account elements that contribute to the uncertainty associated with sampling bathing beach waters and measurements of the potential health effects of bathing beach waters.

Objectives of the Study, Phase 4 of the Research Project

The purpose of this workshop, Phase 3 of the research project, was convened to develop DQOs and a statistical sampling design for the five characteristic beach environments. The objective of studying the five beach environments is to collect data to develop guidance that can be used to design and implement a site specific statistically valid and defensible sampling designs at beaches nationwide.

The purpose of the study is not to provide national estimates of bacterial contamination in recreational beach waters, but to characterize and quantify the variance in bacterial concentrations and understand the key factors that influence how bacterial concentrations vary over space and time. This variance is one of many sources of the total uncertainty affecting decision making at beaches. This information will be used to develop guidance for designing sampling protocols for use at specific sites (*i.e.*, it will provide guidelines to determine where to sample, how many samples to take, and how often to sample at a given beach site). The guidance will be applied to specific beaches based on knowledge of local site-specific physical, environmental, and recreational use factors.

In addition to the main objective, there are potential secondary uses of the data that will be generated from monitoring at the five characteristic environments. The items listed below are some of the potential additional uses for these data:

- provide data to support modeling of bacterial concentrations over time and space at beaches,
- support data collection for estimates of bacterial concentrations for national regulation development,
- support analysis of variability across sites with respect to supporting epidemiological studies, and
- identify the quantity and type of ancillary data that need to be collected.

Conceptual Model of Exposure

In 1987 the U.S. EPA published recommended guidelines[1] for maintaining the quality of recreational waters. The guidelines were based on studies which showed that the rate of swimming-associated gastroenteritis increased as the quality of the recreational water degraded[2,3]. The quality of the water was measured using bacterial indicators to estimate the extent of fecal contamination. *E. coli* levels showed the best relationship to the swimming-associated rate of

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[1]Ambient Water Quality Criteria for Bacteria – 1986, *Bacteriological Ambient Water Quality Criteria for Marine and Fresh Recreational Waters*, EPA A440/5-84-002, U.S.EPA, Washington, D.C.

[2]Cabelli, V.J., 1983, *Health Effects Criteria for Marine Recreational Waters*, EPA-600/1-80-031, U.S. EPA, Research Triangle Park, N.C.

[3]Dufour, A.P. 1984, *Health Effects Criteria for Fresh Recreational Waters*, EPA-600/1-84-004, U.S. EPA, Cincinnati, OH.

gastroenteritis in freshwater, while enterococci densities were equally effective for relating illness in swimmers to water quality in both fresh and marine waters.

Indicator organisms were used to measure the quality of the recreational water. The density of indicator bacteria indicate the level of fecal contamination and, therefore, the possible presence and extent of enteric pathogens. The organisms that cause illness in swimmers are unknown. The health endpoints are based on symptomatology, such as diarrhea, vomiting, and nausea.

The major route of exposure for swimmers with regard to microbial pathogens was ingestion, although dermal and respiratory exposures were also recognized as being potentially associated with pathogens.

Schedule

The schedule for the remaining phases, Phases 4, 5, and 6, of the overall research project is as follows.

- Phase 4 of the research project, the sample collection at the five characteristic environments, will be performed during the bathing season of year 2000. The five EMPACT cities will be selected by mid-September 1999.

- Phase 5 of the EMPACT project will be initiated in fiscal year 2000 and completed in fiscal year 2001.

- Phase 6 of the project will be initiated in fiscal year 2000 and completed in fiscal year 2001.

Social and Political Factors

Proposed legislation that possibly could be influenced by this project include H.R. 999, also known as the Bilbray bill, and S. 522, which is also called the new Lautenberg bill. Both of these bills would amend the Clean Water Act and require implementation of regulations within 4-5 years. EPA would be required to publish a monitoring strategy, i.e., how and when to monitor a beach. The data provided by the EMPACT project will support the latter requirement.

The EMPACT project is a high priority research program within the Agency, and the data from the project are high priority needs in a majority of the States. In addition, the public has a great concern in this area, mainly because of the high public profile of adverse information about the quality of beach water that is frequently seen in the print and electronic media. The public has high expectations about the quality of recreational water that they use for leisure time activities.

STEP 2: IDENTIFICATION OF DECISIONS AND RESEARCH OBJECTIVES

The purpose of this step of the DQO Process is to define the problem that the study will attempt to resolve. Figure 2 presents the general process for developing and using the beach water monitoring guidance.

Two Levels of Decisions

In developing DQOs for the study of the five characteristic beach environments, two levels of decision-making must be kept in mind. The first level relates to the decisions that must be made in developing a guidance manual that local authorities can use to develop a sampling plan to measure indicator bacteria concentrations at their local recreational beaches. This is referred to as the *guidance development decision*. The second level is the decision that local authorities make, with the help of the guidance and local regulations or national guidelines, about the daily status of a given beach (e.g., closed, posted warnings, or open for use) based on the indicator bacteria concentration and supporting data collected at that beach. This decision is referred to as the *beach decision*. Where possible, the remaining steps of the DQO Process address each level of decision-making.

Guidance Development Decision

The purpose of this step is to support the development of guidance for monitoring beach waters that will help users collect the correct type, quality, and quantity of data to make the beach decision. This research study must determine the sources and magnitude of variability in estimating indicator bacteria concentrations. In addition, the best statistic or combination of statistics (e.g., arithmetic mean, geometric mean, or percentile of the indicator bacteria concentration) to support a risk-based decision must be selected.

Potential sources of variability include:

- location of sampling,
- time and trends (timing of sampling),
- number and age of bathers in the water,
- presence or absence of point or non-point sources of fecal contamination,
- point versus non point source of fecal contamination,
- the number and magnitude of sources of fecal contamination (*e.g.*, storm water and sewage outfall at one site),
- events (*e.g.*, rain, discharges from boats),
- physical and hydrological parameters,
- sample collection and transport, and
- analytical method.

Beach Decision

The decision to be made at the beach level is to determine, based on the results of the water quality monitoring, how to classify the water quality within a locally determined risk-based classification scheme.

The risk-based classification scheme will be developed in Phase 6 of this research project. That is, a stakeholder process will be used to determine what type of index and how many categories will be used to indicate the level of risk of illness to bathers from contact with the water. For example, a color scheme could be used where red indicates beach closure, yellow is a warning to bathers, and green means the water is safe. The intent of the categorization scheme is to allow bathers to make their own decisions about going into the water or not based upon the degree of risk of illness they are willing to accept.

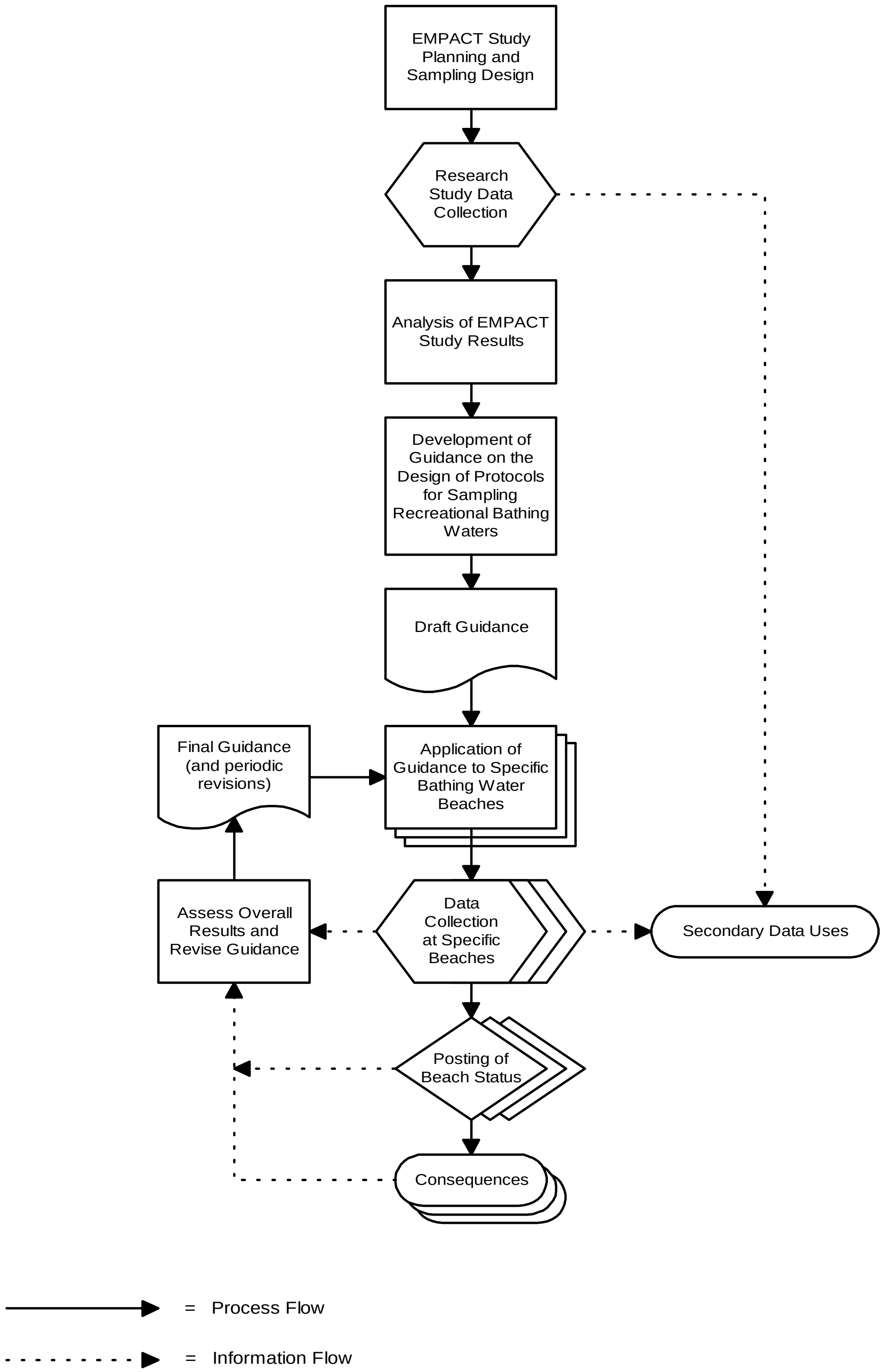

Figure 2. Development and Use of Monitoring Guidance

STEP 3: IDENTIFY THE INPUTS TO THE DECISION

The purpose of this step is to identify the informational inputs that will be required to resolve the decisions identified above in Step 2.

Inputs to the Guidance Development Decision

The impact of the parameters listed in Table 1 on the concentration of indicator bacteria should be estimated to support development of the monitoring guidance. The list of parameters in Table 1 is a modified version of a list developed at a World Health Organization (WHO) workshop on recreational waters held in Annapolis, MD November 8 to 13, 1998. The requirements for measuring each parameter at each of the characteristic environments are indicated in Table 1.

Table 1. Input Parameters for the Guidance Development Decision

INPUT PARAMETER	CHARACTERISTIC STUDY SITE				
	Fresh Water	**West Coast Beach**	**East Coast Beach**	**River**	**Estuarine**
Salinity/ Conductivity	![1]	!	!	!	!
Temperature (Air and Water)	!	!	!	!	!
Total Suspended Solids	!	!	!	!	!
Time	!	!	!	!	!
Beach Study Location	!	!	!	!	!
Rainfall	!	!	!	!	!
Wave Length/Height	!	!	!	NA[2]	!
Current [3]	!	!	!	!	!
Sunny/Cloudy [4]	!	!	!	!	!
Tidal Stage	NA	!	!	NA	!
Lake or River Level	!	NA	NA	!	NA
Wind Speed	!	!	!	!	!

INPUT PARAMETER	CHARACTERISTIC STUDY SITE				
	Fresh Water	West Coast Beach	East Coast Beach	River	Estuarine
Number and Type of Bathers in the Water	!	!	!	!	!
Number of Animals Potentially Affecting the Water	!	!	!	!	!
Number of Boats in the Water	!	!	!	!	!
Debris	!	!	!	!	!

[1] **!** = Required.
[2] NA = Not Applicable.
[3] = Current measurements should capture direction, but it may be too expensive to measure speed.
[4] = To measure light, an automated system that measures visible and long-wave ultraviolet light, which are biocidal, should be used at the sampling site.

The workshop participants also considered pH, turbidity, nutrients, and sand temperature but they were not considered the most important variables to measure.

Inputs to the Beach Decision

Using the monitoring guidance, which will be developed from estimates of the impact of the Table 1 parameters on the concentration of indicator bacteria at the five characteristic recreational water environments, local authorities will develop a sampling plan to measure indicator bacteria concentrations at their local recreational beaches. In addition to the measured concentrations of the indicator organism in the beach water, the information necessary for the local decision-makers to determine the status of the beach on a given day includes the factors listed below.

- the risk-based standard or regulatory level that is the threshold for taking action,
- status of known contamination sources (provides information on why bacteria concentration may be high and how long it may remain high),
- point sources versus nonpoint sources of fecal contamination,
- events (*e.g.*, rainfall, sewage system failure, boat discharges),
- past history of site (*e.g.*, do bacterial concentrations tend to stay high) and at nearby

beaches,

- weather conditions,
- bias and precision in the measurement method, and
- physical characteristics of the site.

STEP 4: DEFINE THE STUDY BOUNDARIES

The purpose of this step is to define the spatial and temporal boundaries of the problem to be addressed. This involves first identifying the target population from which samples will be collected. The spatial boundaries define the physical area to be studied and the locations where samples should be taken. The temporal boundaries describe the time frame the study data will represent and when the samples should be taken. In this section, the sequence of presenting the guidance development versus beach decisions has been reversed, because the boundaries of the guidance development decision are driven by how the beach decision will be made.

Identify the Target Population: Beach Decision

The target population is all the water in the defined beach area, with the primary characteristic of interest being the concentration of the indicator organism.

Geographic Boundaries

The geographic boundaries for the beach decision are the same as those of the target population: the width and extent of the designated beach, from the surface of the water to the sediment.

Temporal Boundaries

The question regarding the temporal boundaries of this study is how often does a decision regarding the quality of the beach water and the associated risk to bathers need to be made. For instance, if the indicator bacterial concentrations have been below the threshold then how often does a decision about the beach have to be made. Not enough is known about the effect of the input parameters over time to answer this question.

Temporal boundaries will be site specific. Once sites are selected there may be specific temporal issues that are relevant. For instance there may be cyclic patterns (diurnal and seasonal patterns of beach use) that could cause systematic variation in the concentration of indicator bacteria.

Identify the Target Population: Guidance Development Decision

The target population for the guidance development decision is the same as for the beach decision.

Geographic Boundaries

The geographic boundaries for the research study that will be used to develop the guidance extend beyond the beach to include the watershed around the beach and the area where significant contaminant sources may be located.

Temporal Boundaries

The temporal boundary for the research study that will be used to develop the guidance is to represent the bathing season. Currently, the time frame for data collection is during June through August of 2000. The data collection period may be different for sites in warmer climates where the bathing season isn't restricted to the summer months.

Information on temporal variability from the research study will be used to develop guidance on how to address temporal boundaries for the beach decision.

Stratified Sampling

Stratified sampling may be useful in some cases. The intent of identifying potential strata in stratified sampling is to facilitate the development of more efficient sampling designs. In this case, the intent of statistically stratifying a beach site is not to make beach-level decisions for each stratum, but to improve the sampling design to make a better decision for the entire beach. Possible statistical strata could be based on water depth or distance from the shore, proximity to point sources, areas of the beach water where contaminants may collect due to physical conditions or weather patterns, physical stratification of fresh water/salt water, or the swash zone near the shore line. The study to support the guidance decision will attempt to identify factors that might define such strata. These factors will be addressed in the sampling guidance so that managers of particular beaches will have clear guidance on how to specify statistical strata for their sampling design.

Scale of Decision-Making

The scale of decision-making refers to the smallest, most appropriate subsets of the population for which decisions will be made based on the temporal or spatial boundaries.

Samples are collected one foot below the surface because it was felt that head immersion was a key component to exposure and this depth would represent head immersion. In addition, it is difficult to achieve replicability when sampling at the surface, and a study has shown that sampling at one foot correlates well with health effects[4].

Beach Decision

The scale of decision-making is the designated beach in question. That is, one decision will be made about the status of the entire beach, not about parts of the beach over some time frame.

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[4]Kay, D., Fleisher, J.M., Salmon, R., Jones, F., Wyer, M.D., Godfree, A., Zelanauch – Jaquotte, Z. and Shore, R. 1994 "Predicting the Likelihood of Gastroenteritis from Sea Bathing: Results from Randomized Exposure" *The Lancet* 34:905-909.

Guidance Development Decision

The scale of decision making does not apply in the same way to the research study supporting the guidance decision. The research addresses a number of questions or hypotheses, hence, the scale of decision making will vary depending on the question posed or hypothesis to be tested. The scale of decision making will be incorporated into each research question or hypothesis in DQO Process Steps 5 and 7 below.

Practical Constraints

Identify any constraints or obstacles that could potentially interfere with the full implementation of the data collection design. The following constraints were identified.

- Consistently locating the sample location in the water (e.g., staying aligned with a designated point on the beach, determining the correct water depth from which to sample).
- The QA/QC requirement for analysis of water samples for indicator bacteria (samples must be received by laboratory within 6 hours of collection and analysis should be performed within 2 hours of sample receipt.).
- Other constraints could be really inclement weather, inability to simultaneously collect multiple samples from a site, and sampling in itself will alter water quality.

STEP 5: DECISION RULE FOR BEACH CLASSIFICATION DECISION

The purpose of this step is to define the parameter of interest, specify the action level, and integrate previous DQO outputs into a single statement that describes a logical basis for choosing among alternative actions. This decision rule is made of the statistical parameter that is chosen to characterize the population, the action level, and an "if.., then..." statement that defines the conditions that would cause the decision maker to choose among alternative actions.

Parameter

The parameter for the beach decision will be determined in Phase 5 of the project with stakeholder input. The current method uses the sample geometric mean of the indicator density of five samples collected over a 30-day period. The alternatives to be considered include the arithmetic mean, geometric mean, frequency of a single value exceedance, upper confidence limit for some statistic, and an upper percentile of the indicator organism distribution.

Action Level

The action level will be consistent with the parameter yet to be determined. The current action level is based on the geometric mean.

If/Then Statement

The decision rule below includes the parameter of interest whose true value the decision maker would like to know. However, decisions cannot be made about the true value of the parameter because this can only be estimated by the data collected on the indicator bacteria. One possible decision rule is presented below.

> If the true *parameter* of the concentration of the *indicator bacteria* within the designated beach waters at the time of sampling is above the health-based threshold then close the beach or post a red flag and investigate and try to solve problem causing the contamination.
>
> If the true *parameter* of the concentration of the *indicator bacteria* is below the health-based threshold but above a *warning level*, then post a warning at the beach. It may be necessary to investigate the source of the problem.
>
> Otherwise, the beach is open for normal use and posted accordingly.

Relationship of Research Questions to Guidance Development

To develop the guidance manual for monitoring recreational waters, the impact of the factors in Table 2 on the concentration of indicator bacteria must be estimated. All factors listed apply to each of the five characteristic sites except for tides, which apply only to beach and estuarine environments. Also, vertical stratification of water levels may be more important in the fresh water lake and estuarine environments.

Table 2. Research Questions for Guidance Development

Parameter	**Temporal or Spatial**	**Priority**
Direction of current with respect to sources of contamination and distance from a point source.	Spatial and temporal	High
High number of bathers versus a low number or none	Temporal and spatial	High
High number of children bathers versus a low number or none	Temporal and spatial	High
Sunny versus cloudy conditions	Temporal	Low
Rain event versus no rain	Temporal	High
High number of animals potentially affecting the beach versus a low number or none	Temporal and spatial	Low
High versus low tide	Temporal and spatial because it is a current	High
Water depth/distance from shore: ankle versus knee depth	Spatial	Very high
Water depth/distance from shore: knee depth versus chest depth	Spatial	Very high
Windy versus calm conditions	Temporal	High
Turbulent versus non turbulent conditions	Temporal	High
Storm runoff versus none	Temporal	Low
Stratification of water due to temperature, salinity, etc.	Spatial (may be temporal)	Low
High number of nearby recreational water craft versus low number or none	Spatial and temporal	High

STEP 6: SPECIFY ALLOWABLE LIMITS ON DECISION ERRORS

Allowable Limits on Errors for Beach Decision

Addressing allowable limits on uncertainty for the beach decision will be done after getting the data from this study as part of developing the guidance manual

The consequence of beach decision errors is manifested in the observation that the likelihood of pathogen occurrence increases with higher levels of fecal indicators. Although gastroenteritis of short duration is a common health result of sewage contamination, the possibility of contracting a serious diseases such as hepatitis exists and must be a concern.

One approach to structuring the beach decision and associated decision errors is presented in the following 3 x 3 matrix. The X axis of the matrix presents the “true” beach conditions at a given time for a given beach site. That is, the level of risk to bathers if the indicator bacterial concentrations could be perfectly measured. However, since all measurements contain error, the true conditions can never be known, but only estimated based on the concentrations of indicator bacteria measured at the beach site. These measurements allow a determination about the observed status of the beach, which is represented by the Y axis of the matrix. The matrix presents the possible decisions made based on the observed status and the resulting outcome depending on the true beach status.

OBSERVED STATUS

Red	Major False Alarm	Err on Safe Side	Good Agreement
Yellow	Minor False Alarm	Good Agreement	Miss
Green	Good Agreement	Slight Miss	Bad Miss
	Green	Yellow	Red

TRUE BEACH STATUS

Research Issues for Guidance Decision

C	The goal for the beach decision is to minimize the probability of misclassification, with consideration of the costs of various kinds of misclassifications.

C	The goal for the research study, upon which the guidance will be based, is to maximize the precision of estimates of variance components.

- Professional judgment can be used to set allowable Type I and II error rates (alpha and beta) and the required minimum detectable difference (delta) for hypothesis tests (formulated from a subset of research questions in step 5).

Examples of Research Hypotheses

Two examples of research hypotheses are presented below as possible models for formulating others from the larger list of research questions in Step 5. Each example is presented as two competing models for formulating hypothesis. The first, H_0 vs. H_a reflects a common method of stating a hypothesis in which there is no consideration for what level of effect or difference may be regarded as negligible; this often leads to the sometimes erroneous conclusion that there is no effect when, in fact, the only correct conclusion is that an effect could not be demonstrated. The additional set of hypotheses, H_0' and H_a', explicitly take into account the magnitude of difference to be considered as unimportant, and lead to more defensible interpretations of the results.

<u>Hypotheses for Testing the Effect of Bather Density on Concentration of Indicator Bacteria</u>

H_o: Bather density has no effect on the concentration of indicator bacteria in the beach water.

H_a: Bather density increases the concentration of indicator bacteria in the beach water.

H'_0: For each 100 bathers at the beach, the concentration of the indicator bacteria increases by M colony forming units (CFUs) per 100 ml, where M = threshold of importance.

H'_a: For each 100 bathers at the beach, the concentration of the indicator bacteria increases by less than M CFUs per 100 ml, where M = threshold of importance.

<u>Hypotheses for Testing Effect of Distance from Shore on Concentration of Indicator Bacteria</u>

H_o: Distance from shore has no effect on the concentration of indicator bacteria in the beach water.

H_a: The concentration of indicator bacteria in the beach water varies with the distance from the shore.

H'_0: The difference of the mean concentrations of indicator bacteria ($[F]_{max} - [F]_{min}$) between each of the distances from shore measured is greater than or equal to M CFUs per 100 ml, where M = threshold of importance.

H'_a: The difference of the mean concentrations of indicator bacteria ($[F]_{max} - [F]_{min}$) between each of the distances from shore measured is less than M CFUs per 100 ml, where M = threshold of importance.

References related to this reverse testing procedure are provided below[5,6,7,8,9].

[5]Anderson, S. and W. W. Hauck (1983). "A new procedure for testing equivalence in comparative bioavailability and other clinical trials." *Communications in Statistical Theory and Methods* 12: 2663-2692.

[6]Anderson, S. and W. Hauck (1986). "A proposal for interpreting and reporting negative studies." *Statistics in Medicine* 5: 203-209.

[7]Parkhurst, D.F. (1998). "Logical Interpretation of Statistical Hypothesis Tests (Abstract)." Ecological Society of America. 83rd Annual Meeting. Baltimore, MD. August 2-6, 1998. Abstracts, page 104.

[8]Parkhurst, D. (1990). "Statistical hypothesis tests and statistical power in pure and applied science." In *Acting Under Uncertainty: Multidisciplinary Conceptions*, GM von Furstenberg, ed., Kluwer Academic Publishers, Boston pp. 181-201.

[9]Parkhurst, D. F. (1985). "Interpreting failure to reject a null hypothesis." *Bulletin of the Ecological Society of America* 66: 301-302.

STEP 7: OPTIMIZE THE DESIGN

Prior Information

Prior information about developing a sampling design for recreational beach waters is available and has been applied to the development of the design for this research project. This prior information was obtained from the pilot study and a World Health Organization (WHO) workshop on recreational waters held in November, 1998.

<u>Data from the Pilot Study</u>

Analysis of the pilot study results indicates that densities of indicator organisms can be expected to vary greatly over time, within and between days, and between locations. However, there is little consistency to the variation, with no particular time of day or location along the beach exhibiting consistently higher or lower concentrations than other times or locations. The exception was distance from shore, where concentrations of the indicator organisms were found to be generally higher in water closer to the shore. Of the events and other covariates monitored in this pilot study, only rainfall was found to have a significant effect, with indicator concentrations generally higher after rainfall. The scope of the pilot study, however, was necessarily limited; the full scale study will be necessary to determine any such effects with adequate precision.

The pilot data also provide estimates of components of variance due to transect, water depth, time-of-day, and day-to-day differences in concentration. These will be utilized in the main study design for determining numbers of sampling points and sampling frequencies with respect to these various factors.

<u>Results from the WHO Workshop on Sample Design</u>

The WHO workshop proposed a sampling protocol for recreational beach waters. This protocol, which was used for discussion of a possible sampling design, is depicted in Figure 3. The design required a beach area at least 60 meters long with transect lines spaced 20 meters apart, along which the samples would be collected. Three water depths would be sampled: (1) 0.15 meters (ankle depth) where samples would be collected at 0.075 meters below the surface, (2) 0.5 meters (knee depth) where samples would be collected at 0.3 meters below the surface, and (3) 1.3 meters (chest depth) where samples would be collected at 0.3 meters below the surface.

Design Features of This Research Study

Various elements of the WHO design were discussed in relation to the design for this research study. Many of these design elements were not decided upon and need to be finalized.

Spatial Aspects

- The location of the transects within the beach area could be determined from a random starting point as shown by X_1 in Figure 3.
- Should samples be collected at the same water depths as in WHO design?

Temporal Aspects

The temporal aspect will have a systematic sampling component and an event-driven component. The systematic component will consist of daily sampling and periods of intensive sampling to detect short-scale variations over time. For example, the daily systematic sampling could consist of sampling two or three times a day using a grid to determine sampling locations. For the intensive systematic sampling, one week a month could be selected at random. During this week, one weekend day and one week day could be selected at random and samples collected every hour for ten hours (11 samples). The specifics of the systematic design still need to be resolved, such as the number of days selected for intensive sampling, the density of the grid for the routine daily sampling, and use of discrete or composite sampling.

The event-driven sampling, which still needs to be developed, is intended to measure the effects of events (such as rain [stormwater runoff], sewage system spills or failures, discharge from ships) on the concentration of the indicator bacteria. The event-driven sampling will be characterized by frequent sampling (e.g., every 1 to 2 hours) and greater spatial density (especially with respect to sources of contamination such as stormwater and sewer outfalls).

Other issues regarding the design of the event driven sampling are:

- practical constraints on event-driven sample collection may be more extreme or difficult,
- it may not be obvious when an event is occurring; therefore, the routine monitoring should detect problem events and trigger more frequent sampling,
- there could be a time lag after the event before the indicator bacteria concentration increases, and
- the goal is to determine when the beach should be closed, and subsequently can be opened.

Another issue regarding event sampling is that a different decision rule may be needed when certain events occur. For example, additional statistical testing for extreme values may be necessary. Another possibility is that the distribution of indicator organisms could change following an event, such as rain. A change in the form of the underlying distribution could imply the need for a different sampling approach to characterize events.

Replication

For the research study, triplicate analysis of one sample will be performed in the laboratory at the "normal" frequency. The use of double or triplicate sampling for field collection needs to be determined as well as the frequency for replicate sample collection. Other related issues are:

- There may be five different laboratories doing analyses; therefore, inter-laboratory variability may be an issue.
- If the differences between sites are expected to be greater than differences within sites, then fewer replicates should be taken at each site and relatively more taken across the sites. Also, replicates should be spread out over time to capture variability over time.
- There may be more variation between replicate samples than there will be between sites.

Operational Decision Rule

- Geometric mean was used in setting the current standard and is the statistic used in the current monitoring to compare to the standard.
- Different operational decision rules to be explored using EMPACT data.

Recent papers by Haas, Crump, and Parkhurst all suggest that use of the geometric mean should be re-evaluated[10,11,12].

General QA/QC

EPA's general approach to documenting the QA/QC procedures for this study will be to prepare an umbrella plan that covers general issues such as project management, assessment methods, and training; these will apply to all five sites. Site-specific requirements, such as sample collection and analysis, will be addressed in Standard Operating Procedures.

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[10] Crump, K. S. (1998). "On Summarizing Group Exposures in Risk Assessment: Is an Arithmetic Mean or a Geometric Mean More Appropriate?" *Risk analysis* 18: 293--?

[11] Haas, C. N. (1996). "How to average microbial densities to characterize risk." *Water Res.* 30: 1036-1038.

[12] Parkhurst, D. F. (1998). "Arithmetic versus geometric means for environmental concentration data." *Environmental Science and Technology* 32: 92A-98A.

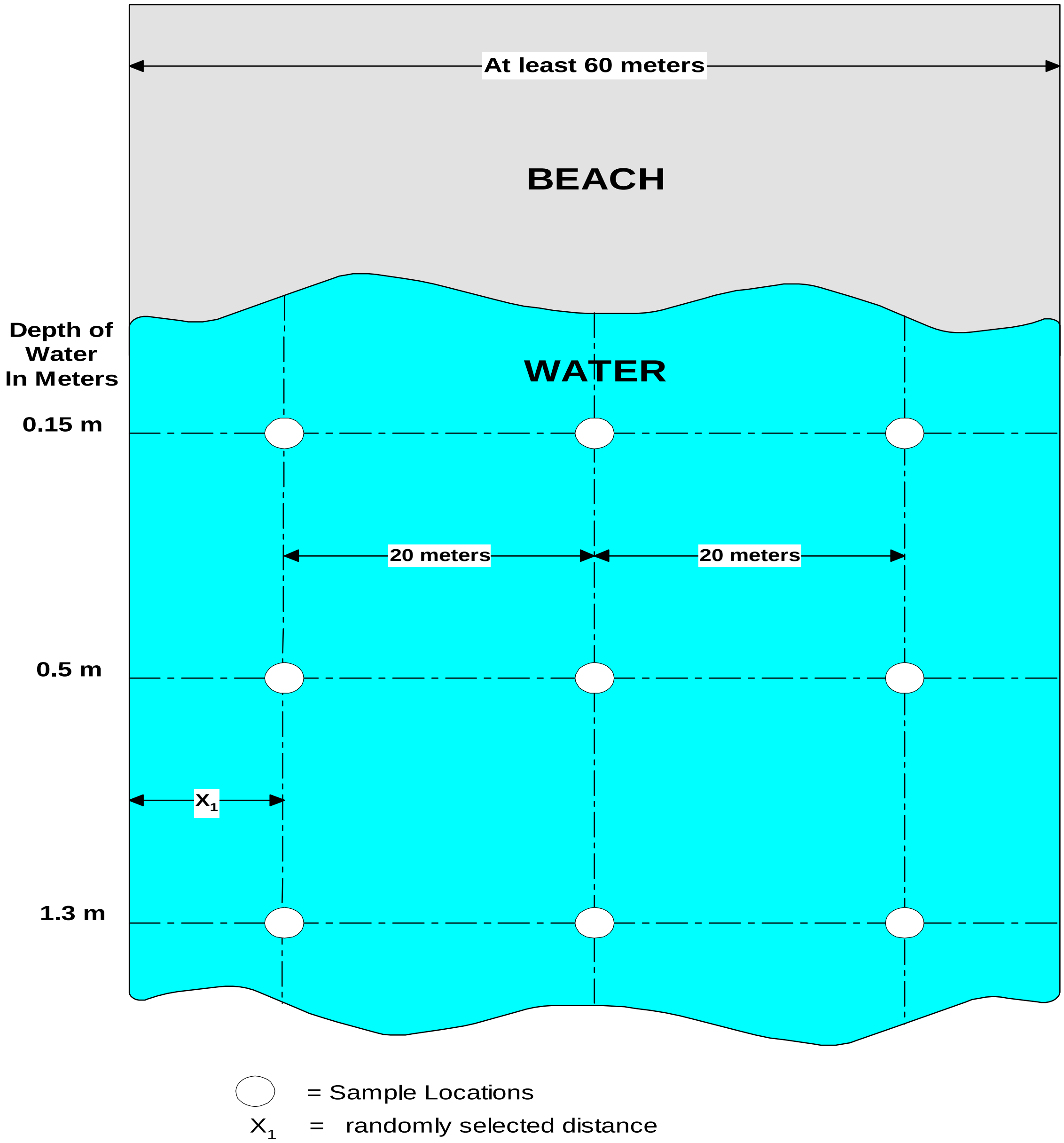

Figure 3. Plan View of a Beach Showing Elements of the Sampling Design from the WHO Report

ATTACHMENT A
WORKSHOP PARTICIPANTS

PARTICIPANT NAME AND AREA OF EXPERTISE	**CONTACT INFORMATION**
EPA Participants	
Kristen Brenner Microbiologist	U.S. Environmental Protection Agency National Exposure Research Laboratory Microbiological and Chemical Exposure Assessment Research Division (MD-314) 26 West Martin Luther King Drive Cincinnati, OH 45268 Phone: (513) 569-7317 Fax: (513) 569-7170 E-Mail: brenner.kristen@epa.gov
Gary Collins Biologist	U.S. Environmental Protection Agency National Exposure Research Laboratory Ecological Exposure Research Division (MD-642) 26 West Martin Luther King Drive Cincinnati, OH 45268 Phone: (513) 569-7174 Fax: (513) 569-7438 E-Mail: collins.gary@epa.gov
Alfred Dufour Microbiologist	U.S. Environmental Protection Agency National Exposure Research Laboratory Director, Microbiological and Chemical Exposure Assessment Research Division (MD-593) 26 West Martin Luther King Drive Cincinnati, OH 45268 Phone: (513) 569-7303 Fax: (513) 569-7464 E-Mail: dufour.alfred@epa.gov

PARTICIPANT NAME AND AREA OF EXPERTISE	**CONTACT INFORMATION**
John Martinson Quality Assurance Officer	U.S. Environmental Protection Agency National Exposure Research Laboratory Microbiological and Chemical Exposure Assessment Research Division (MD-587) 26 West Martin Luther King Drive Cincinnati, OH 45268 Phone: (513) 569-7564 Fax: (513) 569-7424 E-Mail: martinson.john@epa.gov
Stephen Schaub Microbiologist	U.S. Environmental Protection Agency Office of Water Office of Ground Water and Drinking Water Engineering and Analysis Division (4303) Waterside Mall Building 401 M Street, S.W. Washington, DC 20460 Phone: (202) 260-7591 Fax: (202) 260-1036 E-Mail: schaub.stephen@epa.gov

PARTICIPANT NAME AND AREA OF EXPERTISE	**CONTACT INFORMATION**
Larry Wymer Statistician	U.S. Environmental Protection Agency National Exposure Research Laboratory Microbiological and Chemical Exposure Assessment Research Division (MD-593) 26 West Martin Luther King Drive Cincinnati, OH 45268 Phone: (513) 569-7252 Fax: (513) 569-7464 E-Mail: wymer.larry@epa.gov
Non-EPA Participants	
Malcolm Bertoni DQO Advisor/Facilitator	Research Triangle Institute Suite 740 1615 M Street, NW Washington, DC 20036 Phone: (202) 728-2067 Fax: (202) 728-2095 E-Mail: mjb@rti.org
Michael Cross Meeting and DQO Support	Research Triangle Institute Suite 740 1615 M Street, NW Washington, DC 20036 Phone: (202) 728-2045 Fax: (202) 728-2095 E-Mail: myc@rti.org
Abdel El-Shaarawi Statistician	National Water Research Institute 867 Lakeshore Road Burlington, Ontario, Canada Phone: (905) 336-4584 Fax: (905) 336-4989 E-Mail: Abdel.El-Shaarawi@CCIW.ca

PARTICIPANT NAME AND AREA OF EXPERTISE	**CONTACT INFORMATION**
Richard Gilbert Statistician/DQOs	Battelle Washington Office 901 D Street, S.W. Suite 900 Washington, DC 20850 Phone: (202) 646-5030 FAX: E-Mail: ro_gilbert@pnl.gov
Howard Kator Microbiologist	c/o College of William & Mary 1208 Greate Road Gloucester Point, VA 23062 Phone: (804) 684-7341 Fax: (804) 684-7186 E-Mail: kator@vims.edu
Molly Leecaster Statistician	Southern California Coastal Research Program 7171 Fenwick Lane Westminster, CA 92683-5218 Phone: (714) 894-2222 Fax: (714) 894-9699 E-Mail: mollyl@sccwrp.org
David Parkhurst Statistician	SPEA - Indiana University Bloomington, IN 47405 Phone: (812) 855-4556 (Voice) Fax: (812) 855-7802 E-Mail: parkhurs@indiana.edu
William Robertson Microbiologist	Microbiology Advisor, Environmental Health Directorate, Health Canada P.L. 1912A Ottawa, Canada K1A0K9 Phone: (613) 957-1505 Fax: (613) 952-2574 E-Mail: will_robertson@hc-sc.gc.ca