

# **25th ANNUAL NATIONAL CONFERENCE ON MANAGING ENVIRONMENTAL QUALITY SYSTEMS**

**APRIL 24-27, 2006**

**Marriott Renaissance, Austin, Texas**

## **Technical Papers**

### **Quality System Development**

- D.Michael, Developing a Quality System for the National Children's Study - 8:30 AM
- M.Carter, B. Runyon Implementation of the UFP for QA Plans - 9:00 AM
- K.Boynton, Integrating the EPA Quality System with the National Water Program - 9:30 AM

## **TECHNICAL SESSION: Quality System Development**

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### **Developing a Quality System for the National Children's Study**

*Daniel Michael and Kevin Hull, Neptune and Company, Inc.  
James Quackenboss and Edward Kantor, U.S.EPA  
Warren Galke, NICHD*

A quality system is under development for a national, interagency, long-term study known as the National Children's Study. The National Children's Study is planned to be a longitudinal cohort study designed to examine the influence of environmental factors on the health, development and well being of children. The Study will evaluate the complex relationship between health and the environment for approximately 100,000 U.S. children and their families from across the country from before birth to age 21. Consistent with the enabling legislation, the Children's Health Act of 2000, environment is broadly defined to include biological, chemical, physical and psychosocial influences. Designed to obtain measures to address a wide range of hypotheses, the Study will address many of the key health concerns of our day, including pregnancy related outcomes, injury, asthma, obesity, diabetes, autism, mental health and physical development, as well as looking carefully at gene-environment interactions.

Led by the US Department of Health and Human Services' National Institute for Child Health and Human Development (NICHD) and other governmental Agencies (including US EPA, CDC, and NIEHS) and includes partners from public organizations, and private companies. The Study Plan calls for using a national multi-stage probability design that will result in recruiting children and their families from more than 100 study locations ([http://nationalchildrensstudy.gov/research/study\\_plan/index.cfm](http://nationalchildrensstudy.gov/research/study_plan/index.cfm)). Data will be collected by 30-40 regional Study Centers, working with a Coordinating Center, all under contract with NICHD. The combined resources involved in the NCS represent many of the most preeminent child health researchers in the country.

### **Planning**

During the detailed planning stage of the study the importance of quality assurance and quality control activities was recognized by the planners and specific requirements along these lines were included in RFPs issued for the CC and VCs as well as a program initiated by EPA and NICHD to engage expertise within EPA with regard to quality management. This led to an Interagency Agreement calling for the development of a Quality Management Plan. That plan is under development, however final approval and adoption of the plan is pending.

The effort to develop a Quality Management Plan (QMP) was initiated in the fall of 2005, after several years of interagency planning for the Study had already occurred. Many of the elements of an effective quality system were under consideration from the very beginning. The approach that was taken by the Interagency Coordinating Committee (ICC) accomplished many of the systematic planning activities recognized by ASTM, ASQ and EPA. For example, the planning process pulled together scientists and managers from all relevant disciplines and incorporated extensive input from Stakeholders – by developing a Federal Advisory Committee and associated working groups on the numerous topics related to the effort open to participation from a broad range of governmental and non-governmental scientists and parties. Through these working groups, and subsequent reviews by the Federal Advisory Committee, the Interagency Coordinating Committee developed a focused list of primary study hypotheses that together address the most urgent public health concerns ([www.nationalchildrensstudy.gov](http://www.nationalchildrensstudy.gov)), and formed the basis for focusing the study design. The goal of the study design is to gather data adequate to address the full list of primary hypotheses and to provide a resource for answering questions in the future. The study seeks to understand relationships between exposures and outcomes; it is not intended to be a national survey aimed at generating national estimates of specific exposures or outcomes. By understanding the relationships, future policy makers will be able to target their efforts on actions that are likely to have the most beneficial health outcomes.

An extensive evaluation of alternative statistical study designs was performed, and documented in a series of white papers ([http://nationalchildrensstudy.gov/research/analytic\\_reports/](http://nationalchildrensstudy.gov/research/analytic_reports/)). After careful consideration, internal and external review, and with advice from the Federal Advisory Committee, a national probabilistic sample, involving multistage sampling and utilizing regional study centers, was selected ([http://nationalchildrensstudy.gov/research/study\\_plan/](http://nationalchildrensstudy.gov/research/study_plan/)). This approach will ensure that the full range of exposures and outcomes is represented. In addition a series of pilot studies were initiated to evaluate a host of issues related to identifying and gathering measures that would support testing the hypotheses (akin to specifying inputs to the decision in EPA's Data Quality Objectives process).

Based on guidance from ANSI, ASQ, EPA, as well as the Intergovernmental Data Quality Task Force, the elements of a comprehensive quality system were identified and a Work Plan was developed to spell out the approach and timeline for developing each element. The Work Plan went through several rounds of reviews and revisions prior to being completed, and helped all parties understand how the effort would proceed. What follows is a brief description of the approaches that are being used to develop the content of the QMP.

## **Quality Policy**

For many of the Interagency Managers involved in the NCS, developing a QMP and the underlying formalized quality system is an unfamiliar task. The concepts are fully understood, but the quality terminology and structure are new. The strategy being taken is to make as much of the process transparent and down to earth as possible. To implement this strategy, a briefing was prepared for the Interagency Coordinating Committee (ICC) that explained what a quality policy was, and what this statement could be used to accomplish for

the NCS. Examples of things that could be included were provided. Each member of the ICC was then asked to write down statements that related the most important quality considerations from their perspective. A number of the suggestions were read during the ICC meeting to give the committee members a feel for the type of issues of concern to their fellow committee members. These statements were combined and organized into a draft policy statement, which captured the content of all contributors, and circulated for final review by the ICC and Study Management.

## **Roles and Responsibilities**

Working from organizational charts and descriptions of roles and responsibilities that had already been developed by the ICC, the goal of the QMP is to articulate additional responsibilities individuals or entities would need to take on related to implementing the quality system for the NCS. This activity is being accomplished from two perspectives: top-down as derived from the ICC, and bottom-up, as derived from a comprehensive identification of quality roles needed at each point in the study – during the planning timeframe, during the conduct of the Study, and when performing the analysis and interpretation of results. Given the complex organizational structure involving multiple Agencies, Study Steering Committees, Federal Advisory Committee, a Coordinating Center, and multiple Study Centers, the importance of clearly specified roles and responsibilities, as well as lines of communication is recognized as critical.

## **Work Processes**

In order to develop a comprehensive QMP for the NCS, it is necessary to understand the full set of activities that will be undertaken during the planning, implementation (conduct of study activities) and data evaluation (data analysis, interpretation and reporting) timeframe, including the activities related to information management system. Using a *quality system model* these work processes or activities can be described as a chain of processes (involving inputs and outputs) that together, accomplish the work of the NCS. Viewing things from the perspective of customer-supplier relationships, the same individuals implementing a work activity are customers from the previous supplier, and are suppliers to the next customer. The links between these activities frequently represent logical points for quality review or oversight activities, and development and tracking of corresponding metrics.

Several documents are providing the primary starting point for assembling the list of work activities. First, the Study Plan spells out the types of measures that will be made at each visit during the study timeframe. Second, the organization responsible for the Information Management System performed an in-depth analysis of every element they and the Study organizers and staff could envision, to anticipate requirements from the computer technology that will be employed. Third, the proposal developed by the Coordinating Center Contractor spells out the approach they plan to take to implement the scope of work. Together these documents were used to identify activities at a level appropriate for consideration in an umbrella document like the QMP – to include all significant work activities that would benefit from QA oversight and quality controls.

## Quality Tools and Documentation

For each activity we will identify potential quality concerns and possible quality tools that could be put in place to prevent, monitor or evaluate the concern(s). We will look at the appropriateness and potential use of the following generally available quality tools (or their equivalent) with respect to the NCS:

- quality assurance project plans or their equivalent,
- development and tracking of quality metrics,
- collection and evaluation of quality control samples (or their equivalent),
- standard operating procedures (procedures of operation),
- training,
- readiness reviews,
- internal reviews and oversight of work activities,
- external reviews of work activities,
- technical system audits,
- management system reviews,
- quality system audits,
- data quality evaluations to include verification and validation of laboratory results, evaluations of data comparability and completeness and statistical evaluations of data adequacy,
- technical reviews,
- peer reviews, and
- annual reviews of the effectiveness of the quality system.

A matrix will be developed to summarize work activities, inputs, outputs, quality concerns and quality tools. The QA activities in this matrix will be checked against the proposed list of QA activities specified by the Coordinating Center in their proposal to help identify gaps as well as redundancies. The final set of QA activities that are identified in the QMP will emerge from this exercise.

Quality documents will be required once the appropriate quality tool has been selected (e.g., QA Project Plans developed during planning, or Audit reports during Conduct of the Study). The type, purpose and general content for each required document will be articulated in the QMP, along with what organization is responsible for developing the document, the required sign-offs and approvals. Many of the key quality documents including the study protocol and procedures are currently under development. The QMP will acknowledge these documents, discuss the reviews that will be performed in getting them in place, discuss change control processes, and discuss procedures to make sure any changes made over the course of the study are documented, communicated, and training provided for all involved.

Training is recognized as a cornerstone of the quality system. A comprehensive training plan has been proposed by the Coordinating Center. The QMP will identify additional training needs to be incorporated into the overall training plan, to ensure that all entities involved fully understand the quality system, their specific roles, and the overall goals of the system.

## Unique Challenges

Creating a quality system for an interagency effort of this magnitude presents some unique challenges. First, given the 21 plus year timeframe, study planners anticipate significant changes in measurement technologies, creating potential data comparability issues. Second, the Study will need to address a range of quality issues associated with the wide variety of data types, including environmental samples, biospecimens, psycho-social tests and questionnaires, direct observation of subjects, and genetics data. Third, it is a major undertaking to recruit, maintain contact with, and retain 100,000 participants over a period of two decades. Fourth, the Study needs to establish clear procedures, training, and communication techniques for up to 30 Study Centers across the country comprised of nationally recognized health experts, and it needs to inculcate a uniform quality culture that promotes cooperation and a willingness to stay true to the established protocol and procedures. The recognition by Senior Management within NICHD, EPA, CDC and other participating agencies of the importance of establishing a quality system unique to this study is an important step toward creating the opportunity for success. Implementation of, and continued improvement of the quality system should help address the unique challenges faced by this important study.

*“Although this work was reviewed by EPA and approved for publication, it may not necessarily reflect official Agency policy.”*

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## **Implementation of the Uniform Federal Policy for Quality Assurance Plans**

*Mike Carter, Federal Facilities Restoration and Reuse Office  
Robert Runyon, U.S. EPA, Region 2*

The Uniform Federal Policy for Quality Assurance Plans (UFP-QAPP) has been approved by the Assistant Administrator for Solid Waste and Emergency Response and the Assistant Deputy Undersecretary of Defense (Environment, Safety and Occupational Health). Implementation of the UFP-QAPP includes an OSWER Directive and joint Guidance from OSWER and the Quality Staff on the applicability of the Policy.

The UFP-QAPP presents a new paradigm for planning and carrying out environmental data collection. For instance, sample design, sample collection and field measurements are highlighted as well as laboratory operations. The UFP-QAPP also places a priority on data review that ultimately refers back to the overall quality objectives of the project.

The Department of Defense (DoD) plans to issue a DoD Instruction that will specify the use of the UFP-QAPP in the future as the basis for QAPPs across all the services and components of DoD. The Federal Facilities Restoration and Reuse Office (FFRRO) and DoD are developing joint performance measures for evaluating the implementation of the UFP-QAPP and improvements in data quality and time and cost savings as a result.

EPA and DoD jointly developed training on the use of the UFP-QAPP, using an Interagency Agreement (IAG) with the U.S. Navy funded by FFRRO. The IAG also provides for delivery of the training in EPA Regions. Training has either been provided or is scheduled in Regions 1, 2, 4, 6, 7 and 10. Following those sessions, EPA and DoD will review student comments and revise the course as appropriate before scheduling training in the other four Regions. DoD will also provide the training at their installations, and both organizations will invite others to attend. The EPA sessions have included other federal agencies, states, tribes and local governments.

The speaker from Region 2 will provide a description of how the Region is implementing the Policy and streamlining the QAPP preparation, review and approval process. The presentation will highlight the benefits of the consistent approach provided by the UFP-QAPP in achieving data quality and making the whole process more efficient.

## **Integrating the EPA Quality System with the National Water Program**

*King Boynton, EPA/Office of Water/OWM/Water Permits Division*

The objective of this paper is to use the enterprise architecture of the National Water Program (NWP) to facilitate:

- Understanding the NWP and how data flows through it
- Determining which systems and processes would be benefited most by the EPA Quality System
- Visualizing how the Quality System could be tailored or even enhanced to provide the most benefit to the NWP
- Integrating the Quality System and NWP so they become interoperable and mutually support one another.

Two views of the enterprise architecture are presented. The operational view has three levels. Level 1 shows the major NWP programs and how they are connected together. Level 2 shows the individual components of each Level 1 program and how these components are configured. Likewise Level 3 provides greater detail showing the subcomponents of each Level 2 component. The components and subcomponents are the building blocks— programs, systems, and processes including decision-making processes— which comprise the National Water Program. The operational view provides a perspective that facilitates understanding the order and continuity of our National Water Program both horizontally across the Level 1 programs and vertically down through the details in Levels 2 and 3. This view:

- Handles the complexity of our NWP by allowing managers and their staffs to zoom in or out through a set of nested diagrams to see a greater or lesser level of detail, and
- Shows each component's inputs and outputs and how data flows through the NWP.

The project view shows the types of projects needed to support the Level I NWP programs. These are the projects (e.g., work assignments, grants) which need QAPPs. It also shows the linkages between the Quality System and the data, technology, and other types of projects. The linkage between a data project and the Quality System is expanded into an interface which shows the data-related activities, data sources, process for assuring data of known and documented quality and assuring environmental decisions are scientifically and legally defensible and able to withstand public scrutiny. Such Quality System interfaces are also provided for technology and other types of projects. These interfaces together with data modeling are the key to integrating the NWP and Quality System, so that they become one interoperable program. The paper also describes proposed enhancements to the Quality System that the Quality Policy Workgroup is considering because they will provide greater support to the NWP and facilitate the program integration. This paper uses the National Water Program as an example; however, it points out that the integration process could be used to integrate the EPA Quality System with other environmental programs.