Data Auditing and Validation Support

Technology Support Center for Monitoring and Site Characterization

The Technology Support Center for Monitoring and Site Characterization (TSC) operates at the U.S. Environment Protection Agency (EPA), National Exposure Research Laboratory-Las Vegas (NERL-LV). The TSC has a broad range of capabilities that includes data quality audits and validation, and other diverse support skills. This support includes sampling, monitoring design technologies, sampling and analytical quality assurance/quality control (QA/QC), soil and groundwater contaminant assessments and special field and analytical laboratory services. Since 1987, the TSC has provided technical support and expertise to remedial project managers (RPMs), on-scene coordinators, and other Federal personnel. TSC supports all design, planning, implementation, and reporting aspects of hazardous waste site characterizations and assessments and has provided support for Superfund and Resource Conservation and Recovery Act (RCRA) projects to all 10 EPA regions, other EPA programs, and other Federal programs. The TSC's strength is rapid response to the needs of the EPA regions. TSC personnel:

- Develop and review sampling, analytical, and QA plans
- Develop site monitoring methods
- Apply sophisticated statistical, geostatistical, and biostatistical techniques to optimize analysis
- Provide sampling and analysis support
- Conduct field and laboratory on-site audits and inspections
- Perform data reviews and digital tape audits of analytical data
- Provide case discovery support and expert witness testimony

TSC services focus on meeting the real-world needs of RPMs which, at times, must report rapidly on important data quality issues. The TSC offers tailored services and broad expertise to help ensure successful contaminant characterization projects for EPA and other clients.

Data Auditing, Validation, and Auxiliary Support

TSC data audit and auxiliary services range from supporting long-term monitoring programs that require stringent data quality objectives (DQOs) to supporting site-specific, quick turnaround projects that require limited but effective control of data quality. TSC also assists EPA Regional and other Federal personnel in defending data assessments in court. NERL-LV's well-tested approaches promote confidence in data quality and defensibility. In recent years, NERL-LV and TSC have led the way in streamlining data audit and data validation procedures. Scientific programming expertise in this area has led to the development of:

- *Computer-Aided Data Review and Evaluation (CADRE):* a microcomputer-based expert system used today by EPA and DOE to evaluate data quality for toxic organic constituents.
- *Scout:* this software provides a variety of classical and robust statistical procedures such as analysis of censored datasets, robust regression, and geostatistical techniques.

Data Audit Support Capabilities

A data audit is a technical evaluation of a data package prepared by an analytical laboratory. Typically, an audit is performed to investigate specific allegations/complaints against a laboratory and is designed to determine whether or not the laboratory followed contractual and methodological requirements in the analysis of environmental samples.

The TSC data audit approach begins with the development of a project-specific and comprehensive checklist based on the method (e.g., organic, inorganic, or dioxin), required deliverables, method QC criteria, and technical direction from the TSC requester. This approach ensures that audits are objective, complete, and comparable. Hard-copy data or electronic data (tapes) are examined, as appropriate. Errors detected are classified as critical, major, or minor based on their impact on the data quality.

The project-specific audit is guided by the particular EPA methods used for analyzing organic and inorganic samples, most of which are described in the EPA method compendium that is published by the Office of Solid Waste and Emergency Response (SW-846). Gas chromatography (GC) and gas chromatography/mass spectrometry (GC/MS) techniques are normally employed for organic analysis. Similarly, inorganic samples are analyzed using atomic absorption (AA), inductively coupled plasma (ICP), and cold vapor atom-

Data Auditing and Validation Support

ic absorption techniques. Most audits involve the review of laboratory history, timeline analyses (e.g., tuning and calibration), QC forms and results, and raw data. Audits for organic data may also require scrutiny of quantitation reports, mass spectra, and reanalysis requirements. Auditing procedures are tailored to detect improper post-acquisition manipulation of data, data reduction techniques outside the accepted norm, and even technical fraud.

Specific TSC Data Audit Services available to EPA project managers include:

Technical Assistance in Audit Planning: The data audit process is technically complex and time consuming. Early involvement of technical experts helps facilitate the data audit procedures, especially for a focused audit. No two audits are identical. TSC can provide technical support in devising methods and procedures for a focused audit and in standardizing the data audit procedures.

Preliminary Data Screening and Review: Because of the enormity of data files and other documentation to be audited, a preliminary review of hard-copy data is often useful. In this review, data files/analyses that contain anomalies can be isolated. Each method has QA/QC requirements to produce data of known quality, and these requirements are examined during preliminary review.

Comprehensive Data Audit: A comprehensive data audit is performed on selected/isolated files. Work plans, QA project plans (QAPP), contract language, and functional guidelines are reviewed. In addition to a thorough manual review of the data package, the electronic data from tapes are reprocessed by the QA evaluators. For each method, calibration requirements and results from the analysis of standards, instrument performance check compounds, surrogates, spikes, laboratory control samples, and matrix spike/matrix spike duplicates are evaluated thoroughly. Any evidence of data manipulation or other deficiencies is included in an audit report.

Data Validation Support Capabilities

Data validation is the process of evaluating collected analytical data against established acceptance criteria to determine data quality and useability. Data validation procedures are selected in accordance with the method QC criteria and with the data needs of the user.

The TSC data validation process focuses on the objectives specified in the QAPP, work plan, or other project or EPA functional guidelines. QA/QC data associated with sample data are evaluated against acceptance windows. Acceptable error limits and acceptance windows are established on the basis of project QA objectives. In most instances, the analytical methods selected have associated acceptance criteria for blank samples, surrogate or spike recovery, and other QC checks. Sample data are flagged if associated QA/QC data fall outside the acceptance windows. Flagged data include those generated when the instrumentation is outside accepted calibration limits, data exceeding the linear dynamic range of the calibration, and data associated with invalid QC checks, performance evaluation (PE) samples, or audit sample results. Detection limits and quantitation limits determined during or before sample analysis are examined, and data falling below the detection or quantitation limits are flagged. Data validation can be used as a tool for the data user to decide if the affected samples should be reanalyzed.

Depending on the project, laboratories may provide original hard-copy data with their analysis reports.

Auxiliary Data Assessment Support

Technical Support for Discovery Proceedings and Expert Witness Testimony: TSC has provided technical assistance to the Office of the Inspector General, U.S. Department of Justice (DOJ), U.S. Air Force (USAF), and U.S. Army pertaining to the data from more than a dozen laboratories over the past few years. In some cases, laboratory data evaluated by TSC are presented before grand juries and court trials.

Data Auditing and Validation Support

TSC and NERL-LV Data Audit and Validation Credentials

NERL-LV, through TSC and other programs, has provided data evaluation and performance monitoring of the laboratories participating in the EPA Contract Laboratory Program (CLP) for two decades. Approaches utilized in reviewing and auditing laboratory data were significant for the EPA Superfund Program's strategy to document the quality of hazardous waste site chemistry data. This work has involved inventorying, and reviewing raw data as well as GC/MS tape data for compliance with EPA QC gas guidelines, conducting investigative electronic and paper audits, and providing enforcement support to the Inspector General's Office.

Since 1990, NERL-LV has performed in-depth evaluations of more than 1500 organic, inorganic, and dioxin cases on more than 22,000 samples; developed software for many computer-based QA and data auditing and validation processes; prepared and reviewed more than 100 QAPPs; and conducted hundreds of field audits. Many of these activities have demanded rapid, project-specific responses to regional and site-specific issues.

NERL-LV, through TSC and other programs, has also conducted data assessment activities for environmental measurement projects at many Department of Defense (DOD) sites, including Army installations, Air Force bases (AFBs), and Navy and Marine facilities throughout the U.S. Examples include tape audits of data from Ft. Richardson, Ft. Wainwright, Ft. Ord, and The Presidio; audits of site data from Mare Island, Port Hueneme, Hunters Point, and Casmalia; and data audits for Travis, Mather, Luke, and March AFBs.

For Further Information

J. Gareth Pearson
Director
Technology Support Center
U.S. Environmental Protection Agency
National Exposure Research Laboratory
Environmental Sciences Division
P.O. Box 93478
Las Vegas, NV 89193-3478

Tel.: (702) 798-2270
Fax: (702) 798-3146