

Data Validation

Client Centered

TLI Solutions, Inc., (a TechLaw Company) uses a systematic approach to data review to ensure a high degree of technical quality, efficiency, and consistency.

An independent review of analytical data adds credibility to any environmental measurement program. TLI Solutions, Inc. (TLI) can provide a truly independent review of the data because we do not own or operate an analytical laboratory. Our unique approach to data validation is to provide a *technical* assessment that evaluates both technical and evidentiary aspects of the data.

TLI defines data validation as an independent process for reviewing a body of data against a set of criteria and data quality objectives to assure that the level of data quality is known and documented and that the data quality goals have been achieved. Data validation further enables data assessment in evaluating whether data is suitable for its intended purpose as a function of data quality assessment and in decision making.

Since 1988, TLI has validated more than 800K sample analyses for government and commercial clients. Our validation personnel have undergraduate or graduate degrees in chemistry, physical sciences, or related fields and have training or actual laboratory experience using the analytical methods being validated. Our experience results in an informed evaluation of the data that meets the toughest standards for reliability and legal defensibility.

Informed data validation includes a possible determination of the reasons for any failure to meet method, procedural, or contractual requirements, and an evaluation of the impact of such failure on the overall data quality. This experience also helps to ensure data integrity is maintained.

TLI has experience validating data under a number of different programs and we understand that each program has different criteria and reporting requirements. We can readily adapt to any validation protocol and have demonstrated this in our work for U.S. Environmental Protection Agency (EPA), the U.S. Army Corps of Engineers (USACE), U.S. Navy, and U.S. Air Force; as well as site specific criteria established in site quality documents and sampling/analytical plans. We can also work with the client to design a data validation program that is cost-effective and meets the needs of the client.

TLI has provided additional analytical chemistry support in the form of Quality Assurance Project Plan/Sampling Assurance Program (QAPP/SAP) development and review; sampling statistics and waste characterization assessments; and data usability determinations. We can provide needed resources in the area of environmental chemistry from the planning stages through project data usability assessments.



Laboratory Experience

Prior environmental and forensic laboratory bench-level experience

Audited more than 200 environmental laboratories

Clients

- U.S. Army Corps of Engineers: Albuquerque, Kansas City, Omaha, Louisville, and Sacramento Districts
 - EPA: START Regions 3, 5, 6, and 8; ARCS Regions 1, 2, 8; ESAT Regions 1, 5, 8, and 10
 - Department of Energy: RFETS, Hanford, Nevada Test Site, Mound, ORNL, Fernauld, Naval Reactors Facility (Bechtel-Bettis)
 - U.S. Air Force: Elmendorf AFB, Air Force Plant #4, Shemya AFB, Indian Mountain, Lackland AFB
 - U.S. Navy: Navy CLEAN Program (TTEMI - Long Beach Naval Shipyard, Camp Pendleton, Treasure Island, Alameda NAS, China Lake, Moffet NAS)
 - State Environmental Agencies: Utah, New Mexico, Colorado
 - Commercial: Mining, industrial, remedial engineering, public utilities
-

TLI Project Examples

U.S. Army Corps of Engineers, Kansas City

- Provided data validation support as a subcontractor to various USACE Kansas City District projects including the Former Nebraska Ordnance Plant and Kansas Army Ammunition Plant. Methods validated include SW-846, General Chemistry, and Radiochemical procedures.
- Deliverables included quarterly Quality Control Summary Reports (QCSR), data validation reports, and electronic data deliverables (EDDs).

EPA REGION 8 SUPPORT

- Provided data validation support to EPA at over 500 sites since 1995. Data Validation has been performed for organic, inorganic, general chemistry, and radiochemistry parameters. Methods validated include SW-846, Contract Laboratory Program (CLP), and Hypothetical Active Site Lattice (HASL) Radiochemical procedures.
- Developed Region 8 Data Validation Guidelines for use in all EPA Region 8 Superfund Technical Assessment & Response Team Contracts (START) radiochemical data validation activities.
- Developed Standard Operating Procedures (SOP) for EPA Region 8 regarding WinCADRE use for inorganic and organic parameters. This involved testing and evaluating the WinCADRE system, providing suggestions for improvement, and constructing a step-by-step process for the use of WinCADRE and manual data validation. TLI will also conduct a training seminar for EPA personnel and contractors providing validation support in Region 8 on how validation should be performed according to the SOP.

ROCKY FLATS PLANT

- Managed multi-year contracts to provide data validation, laboratory auditing, and quality assurance services since 1988.

- Validated over 225,000 sample analyses including organics, metals, radiochemistry, mixed wastes, waste characteristics, and water quality.
- Validated SW-846, CLP routine analytical services (RAS) and specialized analytical services (SAS) organics and metals, conventional water quality, radiochemistry, drinking water methods, and biological parameters.
- Developed data validation guidelines and SOPs for non-CLP data validation.

U.S. NAVY

- Provided data validation and quality assurance support to multiple Navy Comprehensive Long-Term Environmental Action Navy (CLEAN) Program sites.
- Validated CLP RAS and SAS, SW-846, radiochemistry, and nucleotide extension and excision-coupled signal amplification (NEESA) methods using full and partial validation criteria.

U.S. AIR FORCE

- Provided data validation services under subcontract to engineering firms providing site characterization and remediation services to the Air Force under the Air Force Center for Engineering and the Environment (AFCEE) program.
- Validated CLP RAS and SAS organics, metals, water quality, and SW-846 sample analyses.
- Developed guidelines and SOPs for non-CLP data validation.

Quality Assurance Experience

- 3 ASME/NQA-1 Lead Auditors
 - ASQC E-4
 - EPA QAMS/005/80
 - DOE Orders 5700.6C / 5400.1
 - USATHAMA
 - NEESA
 - ISO 9000
-

Auditing

In the last 20 years, an increasingly complex array of environmental laws, regulations, policies, and procedures have evolved. Increasingly, government and private industry are relying on external audits to ensure environmental compliance in their ongoing operations, remediation efforts, and asset acquisition. Through the assessment process, a facility can ensure that its regulatory compliance programs are current, compliant, pro-active, and will hold up under regulatory scrutiny.

TLI can provide truly independent audits because we do not perform engineering design or remedial activities nor do we operate any conflicting facilities such as an environmental laboratory.

Field audits ensure that sampling procedures are appropriate and documented and help identify deficiencies that could adversely affect sample analysis results. Audits examine sampling and shipping activities to ensure the precision, accuracy, representativeness, comparability, and completeness of the data collection process. During the audit, items such as sampling procedures,

sample tags, labels, chain-of-custody records, and field logbooks are thoroughly examined for effectiveness, completeness, accuracy, and consistency of information between documents.

We have conducted literally hundreds of audits of

Labor Auditing Experience

- Conducted over 200 audits of commercial, government, and research laboratories including U.S. Department of Energy (DOE) facility on-site waste characterization laboratories
- Organic, inorganic, water quality, radiochemistry, SW-846, mixed waste, and other environmental analyses
- Staff certified as ASME/NQA-1 Lead Auditors

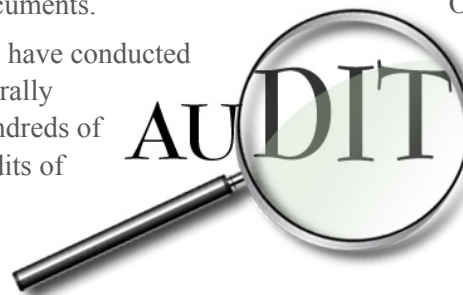
commercial, government, and research laboratories. Because we also perform data validation, we are intimately familiar with analytical chemistry operations and the influences on data quality. Our audit personnel have extensive in-lab experience performing the analyses that they are reviewing.

Evidence audits follow *the paper trail* to ensure physical evidence of compliance and corrective action. Activities may include review of sample receiving, storage, analysis, and tracking, and document control procedures. Auditors may also examine case files for adherence to chain-of-custody and document control procedures, analytical methods, quality assurance project plans, and specific contract requirements. TLI established the CLP evidence audit protocols for EPA and conducted over 500 evidence audits of CLP laboratories from 1984 until 1994. As part of the DOE Environmental Survey, TLI auditors performed evidentiary audits of sites including Hanford, Savannah River, Pantex, and

Oak Ridge National Laboratories (ORNL). Some of the participating laboratories included Argonne, Battelle, and Martin Marietta.

Field and Evidence Auditing Experience

- Auditors have comprehensive site safety training including Occupational Safety and Health Administration (OSHA) 40-hour and 8-hour updates meeting 29 CFR 1910 criteria
- Performed Waste Isolation Pilot Plant (WIPP) characterization audits in support of EPA and New Mexico U.S. Department of Energy (DOE) generator sites
- Performed field activity audits of government and contractor organizations and facilities



TLI Auditing Project Examples

ROCKY FLATS PLANT

Conducted more than 200 laboratory audits for both the Environmental Restoration Division and Waste Stream and Residue Identification and Characterization Program (WSRIC). Audited inorganic, organic, water quality, radiochemistry, low-level mixed waste, biota, and other sample analyses operations. Reviewed laboratory standard operating procedures, coordinated laboratory Quality Assurance programs (surface water and soil sampling and drill), and coordinated field sampling and analysis activities. Also performed field audits of groundwater, surface water, and soil sampling to determine that actual sampling procedures were consistent with written standard operating procedures and that adequate sampling decontamination custody and record keeping were in place.

U.S. ARMY CORPS OF ENGINEERS

Performed contractor laboratory inspections at 74 environmental laboratories in conjunction with the USACE Missouri River District laboratory certification program. Certification activities included evaluation of personnel, facilities and equipment, documentation and chain-of-custody, analytical methodology, quality control, health and safety, and waste disposal procedures.

Laboratory Standards and Methods

- GLP (40 CFR 792)
 - ANSI N42.2
 - GRRASP (DOE-RFP)
 - ISO 25
 - ISO 9000
 - SW-846
 - EPA 600 Series
 - EPA 500 Series
 - CLP RAS and SAS
 - ASTM Standard Methods
-

EPA CLP SUPERFUND PROGRAM

Developed evidentiary requirements for CLP sample chain-of-custody and sample and standard analysis documentation. Performed pre-award and routine audits of organic and inorganic laboratories to evaluate laboratory security, sample receipt and storage, standard traceability, data package assembly and completeness, standard and sample preparation and analytical documentation, internal chain of custody, and SOPs.

NEVADA TEST SITE - REECO

Performed compliance assessment to determine whether the on-site environmental laboratory was in compliance with NVO-325. The laboratory was approved for NVO-325 by the DOE. Evaluated laboratory procedures, field sampling, quality assurance, and low-level mixed waste disposal program.

EPA and STATE OF NEW MEXICO

Performed WIPP waste characterization audits at DOE waste generators to ensure compliance with 40 CFR 194 and Resource Conservation and Recovery Act (RCRA) permit requirements. Activities audited include waste solid sampling and analysis, Headspace gas sampling and analysis, drum radiography, non-destructive radioassay, process knowledge documentation, and program data management.

Data Validation

concluded

TLI has significant validation and assessment experience in the following analytical parameters:

Organics

- VOC
- SVOC
- Pest/PCB
- Dioxin/Furans
- Explosives
- Agent Breakdown Product
- DRO/GRO
- Herbicides
- Organophosphorus pesticides
- Air Methods

Metals

- ICP
- ICP-MS
- Mercury
- Cyanide

Radiochemistry

- Alpha Spectrometry
- Gamma Spectrometry
- Liquid Scintillation (tritium)
- Gas Proportional Counting
- Radon Emanation

General Chemistry

- Ion Chromatography
- Colorimetric
- Titrimetric
- Gravimetric
- Industrial Hygiene
- Asbestos
- Fecal Coliform

We have validated data under the following analytical and validation protocols:

- EPA CLP
- SW-846
- EPA Drinking Water (500 and 600 series)
- USACE
- NEESA
- AFCEE
- Navy CLEAN
- Waste Certification (NV0-325)
- DOE GRRASP
- Mixed Waste

TLI also has experience in automated sample data tracking and validation systems development capabilities.