

## Janine S. Arvizu

161 Kuhn Drive, Tijeras, NM 87059

### ▪ Education

ABD Chemistry, University of New Mexico

B.S. Biochemistry with honors; California Polytechnic State University, San Luis Obispo, 1976

### ▪ Qualifications and Skills

Certified Quality Auditor (ASQ #19856)

Trained ISO Lead Auditor (ISO 9000, 17025)

Development and assessment of laboratory quality programs

Development and assessment of prescriptive and performance-based analytical QA programs

System, technical, and data audits of laboratories and measurement programs

Management and operation of production laboratories

Independent assessment of interdisciplinary measurement programs

Identification and investigation of fraudulent laboratory practices

Data quality assessment and data rescue

Quality assurance training of laboratory personnel and data users

DOE Q clearance (inactive)

### EXPERIENCE SUMMARY

Janine Arvizu is a chemist and laboratory quality expert with more than 25 years of technical and program management experience in laboratory operations and management, quality assurance, and interdisciplinary analytical programs. She has developed and managed organizational and programmatic quality programs, and has extensive experience in the assessment of laboratory operations and analytical programs.

### RELEVANT EMPLOYMENT HISTORY

Senior Technical Consultant, Consolidated Technical Services, Inc.; Independent contractor; 1992-present. Ms Arvizu provides consulting services in laboratory assessment, quality assurance, and independent reviews. She is an experienced Lead Auditor for assessments of testing laboratories under a variety of standards, including ISO. Ms. Arvizu served as Program Manager for Navy's analytical QA program that evaluated laboratories nationwide, and provided independent technical reviews and quality assessments of major project plans and laboratory results.

Scientific Specialist, EG&G Idaho, detail assignment to Department of Energy, 1990-1991. Ms. Arvizu provided technical support to interdisciplinary quality program development and long range planning for laboratory support to DOE. Ms. Arvizu was a technical representative for DOE on interagency quality issues, and served as a technical resource on analytical and laboratory issues within the DOE complex, with other federal agencies, and with the private sector.

Unit Manager (ending position), EG&G Idaho, DOE's Idaho National Engineering Laboratory, 1981-1990. Ms. Arvizu established and managed one of the first full service analytical testing laboratories with broad radiological handling capabilities. She directed method development and validation, managed quality initiatives, and directed analytical support for national analytical programs.

### AREAS OF EXPERTISE

Strong theoretical and practical experience in prescriptive and performance-based Quality Assurance; design and execution of system, laboratory, and data audits; quality standards for laboratory operations, laboratory accreditation and proficiency testing programs (ISO 25, 17025, 43-1, 43-2, and 58)

Production laboratory operations, management, and assessment; method validation; interdisciplinary program support and independent oversight of testing programs

## PROFESSIONAL EXPERIENCE

### Quality Programs

- Developed and authored the Quality standard for testing laboratory support to Navy's Installation Restoration Program. Served as Program Manager for the Quality Assurance Program. Directed the revision of the program to comply with ISO Guide 25. Managed the independent evaluation of ~70 testing laboratories nationwide, using on-site audits, reviews of quality documentation, and blind proficiency testing. Made final recommendations for laboratory approval.
- Personally planned and served as Lead Auditor for quality systems audits and technical audits of dozens of testing laboratories (commercial and federal); included reviews of analytical chemistry, bioassay, radioanalytical, and research laboratories. Evaluated compliance with laboratory quality standards, including Good Laboratory Practices and ISO/IEC elements.
- For large federal projects involving millions of dollars of analytical work, evaluated the technical and production capabilities of proposed laboratories in relation to project-specific technical and quality objectives. Evaluated the technical acceptability of proposed sample preparation and determinative procedures, and assessed the validity of the laboratory's method validation.
- Conducted independent quality assessments of results reported by governmental and commercial forensic laboratories; areas reviewed include: sampling, toxicology, controlled substances, trace evidence, serology, DNA, blood alcohol, and gunshot residue. Provided testimony as required.
- Designed a comprehensive quality program for a new radiological handling analytical laboratory; directed preparation, review, approval, and implementation of quality and operating procedures.
- Coordinated the collection of split referee samples during the investigation of criminal environmental practices at the Rocky Flats Plant.
- Provided technical reviews of Quality Assurance Project Plans and Sampling and Analysis Plans for characterization programs at federal sites nationwide; evaluated compliance with applicable quality requirements.
- During the course of on-site audits, identified evidence of fraudulent practices and misrepresentation by analytical laboratories. Provided technical support to a federal investigation of fraudulent laboratory practices by reviewing contract files and raw data for supporting evidence.
- Planned and conducted "special" and unannounced on-site audits in response to serious data quality concerns or project-specific requirements. Planned and conducted data quality assessments.
- For the Department of Energy, chaired an independent Advisory Panel for the high level tank waste characterization program at Hanford; coordinated interdisciplinary Panel reviews of management, programmatic, quality, sampling, and laboratory issues; coordinated Panel activities with the National Academy of Sciences subcommittee reviewing the tank program, and with Defense Nuclear Facilities Safety Board findings.
- Conducted and directed technical reviews and data quality assessments for large data sets (thousands of samples for dozens of parameters) from large measurement programs. Data subject to review included routine (trace level organics and inorganics, classical testing) analytical measurements, as well as radiochemistry, fuels, alkyltins, high explosives, and other unusual parameters. Identified computational errors with major quality impact in data sets that had already been "passed" by checklist data validation. Identified serious data quality problems, including false positives and false negatives.
- Testified as a laboratory quality assurance expert witness in federal, state, and international courts.
- Co-chaired (as DOE's representative) an annual interagency (DOE/DOD/EPA) analytical quality assurance conference.

- Provided or managed independent reviews of numerous remediation project planning and reporting documents for federal sites nationwide. Assessed project data quality requirements to determine whether they were acceptable and achievable. Evaluated proposed analytical strategies to determine whether they would satisfy project objectives. Reviewed proposed analytical methods and specified QC criteria. Identified and reported deficiencies, omissions, and opportunities for improvement. Identified flawed sampling strategies and technically inappropriate sampling or analytical procedures.
- Planned and directed the initial development of a DOE-wide sampling, analysis, and quality assurance plan for characterization of transuranic wastes destined for emplacement in the Waste Isolation Pilot Plant (WIPP). The resulting Quality Assurance Program Plan was accepted without comment by EPA-HQ; the QA Program was technically rigorous and performance-based.

#### Laboratory Operations and Systems

- For the Department of Energy, established and managed one of the first full service analytical testing laboratories that handled radiologically contaminated samples. Responsible for overall laboratory management, including production, quality, safety, environmental and radiological controls; acquisition, maintenance, and management of staff, instrumentation, and new and renovated laboratory facilities.
- Designed and implemented a concise, electronically generated data reporting format to streamline technical reviews of large quantities of laboratory quality control data, and to allow effective integration and interpretation of instrument and method performance data with field data collected under related spatial or temporal conditions.
- Chaired analytical subcommittee supporting the Department of Energy in the identification and prioritization of environmental problems at DOE sites across the country.
- Founded and chaired the Department of Energy's Future Analytical Support Team chartered with developing a strategy to ensure adequate capacity of high quality analytical services; identified and assessed critical analytical and quality issues impacting analytical support.
- Conceived, planned, and managed a comprehensive and statistically valid effluent monitoring program for characterization and long-term monitoring of radioactive, process, and operational discharges from nuclear and production facilities at a large federal site
- Developed sampling and analysis plans for characterization of chemical and radiological contaminants in airborne discharges, waste sites, process effluents, groundwater, and surface soils
- For DOE-HQ, conducted a study of alpha-handling laboratories to determine which site would best be able to provide transuranic analytical services; evaluated facilities, instrumentation, staffing, data management systems, permitting and compliance, and infrastructure issues.
- Directed the acquisition, installation, and testing of more than \$1 million in laboratory instrumentation, including development of performance specifications and determination of operational performance characteristics.
- Served as technical advisor to DOE Source Evaluation Panel considering proposals to provide technical support and analytical services associated with TRU waste characterization; provided detailed review of technical proposals; conducted on-site technical assessments of each laboratory in the competitive range; evaluated Best and Final Offers for adherence to technical criteria.
- Developed and presented quality assurance courses and workshops to provide continuing education and training for laboratory technicians, engineers, scientists, lawyers, and judges. Subjects included: quality assurance, quality control practices, contamination control, data quality assessment, laboratory audits, characterization strategies, and field quality control practices.