For Opinion See 2007 WL 1875960

United States District Court, N.D. California.
USA,
v.
MAI et al.
No. 05CR00531.
April 9, 2007.

Affidavit

**Case Type:** Criminal >> Drugs/Narcotics
**Jurisdiction:** N.D.Cal.
**Name of Expert:** Janine S. Arvizu
**Area of Expertise:** Engineering & Science >> Biochemist/Microbiologist
**Representing:** Unknown

**JANINE** S. **ARVIZU**, having been duly sworn, hereby states as follows:

1. I am a quality consultant and laboratory quality auditor located in Tijeras, NM 87059.

2. My education includes a B.S. degree in biochemistry (California Polytechnic State University at San Luis Obispo, 1976) and ABD in chemistry (University of New Mexico). I am certified as a Quality Auditor (American Society for Quality, certificate #19856) and I specialize in assessments of laboratories. I have successfully completed a Lead Auditor training course for assessors of laboratory quality systems that was certificated by the International Register of Certificated Auditors.

3. From 1982 - 1992, I was employed by EG&G Idaho, Inc. (operating contractor for the Department of Energy's Idaho National Engineering Laboratory). In the course of my career, I established and managed an analytical chemistry laboratory for the Department of Energy, developed and implemented quality assurance programs, and served as Lead Auditor for dozens of laboratory audits. I served as Program Manager for the U.S. Navy's nationwide laboratory Quality Assurance Program; in this capacity I managed the audit program that evaluated government and commercial laboratories, and performed independent assessments of data quality.

4. This affidavit provides my opinion as to why the items of laboratory documentation set forth in the attached list are relevant and necessary to assess the validity and reliability of a laboratory's reported results.

5. Even under optimum conditions, laboratory analysis of an unknown material involves a degree of uncertainty. Test procedures have practical technical limitations, and laboratories are operated by people, who make mistakes. As a result, it is a matter of due diligence for any data user to ensure that they understand the reliability and limitations of forensic results that are proposed for introduction as evidence. This is done by reviewing the underlying data and supporting documentation that formed the basis for a laboratory's reported results.

6. In order for any independent party to determine whether a forensic laboratory's analysis and reported results are valid and reliable, they must have access to relevant laboratory records and supporting information. The supporting information should be sufficiently detailed and complete so as to enable an independent reviewer to understand all assumptions, and to reconstruct the sequence, events, computations, and decisions of the testing process; this is a fundamental requirement of relevant forensic and international quality standards.

7. Quality Documentation

a. Quality Manual (however named) describing the laboratory's quality policies and systems in effect at the time the subject casework was performed.

b. Quality procedures (however named; implement the laboratory's quality program. e.g., internal audit procedures, training and qualification procedures,

document control procedures, etc.)

c. Schedule for internal and external audits conducted during the period casework samples were received and tested; copies of the resulting audit reports and corrective action documentation

d. Laboratory production data: numbers and types of tests performed per year

e. Inventory of laboratory capital equipment (Make, model, acquisition date)

The requested quality documentation is needed to provide an independent reviewer with a description of the scope and the efficacy of the laboratory's quality assurance program. An understanding of the laboratory's quality program provides context for reviewing the results of testing activities. An inventory of the laboratory's capital equipment and associated production data also provided important context for understanding laboratory operations.

8. Standard Operating Procedures (SOPs)

a. SOPs for sample preparation, extraction, digestion, clean-up, as appropriate to the casework

b. SOPs for qualitative and/or quantitative analysis, calibration, interpretation

In laboratories throughout the country, written SOPs are used to provide explicit instructions for carrying out an analytical method in a consistent and acceptable manner. The use of unwritten procedures increases data variability, decreases the comparability of data, and is not considered an acceptable practice in a production laboratory. Written, approved SOPs are a requirement of forensic and international laboratory quality standards.

Independent assessment of the quality of a laboratory's reported results should be made in consideration of the SOPs used by the laboratory. Only by reviewing applicable SOPs can an independent reviewer consider a laboratory's results within the context of the practices actually performed by the laboratory. In accordance with quality standards, SOPs should provide sufficient detail to permit an independent scientist to be able to independently perform the same procedure with comparable results.

9. Evidence Collection and Integrity

a. Field records related to evidence collection and ambient environmental conditions

b. Copies of training records for evidence collection personnel

c. Diagrams, photographs, and descriptions of evidence at all stages of collection and testing

d. Case intake and control records (chain of custody records for intra- and inter-laboratory transfers of evidence, samples, and aliquots; evidence receipt log; controlled storage temperature log)

The requested records document the collection, condition, identification, and custody of the forensic evidence in a case. In data quality assessments, these records should be reviewed in order to ensure that evidence was collected, packaged, handled, managed, identified, maintained, and controlled in a manner that assures the quality of the sample was not compromised, and the unique identity of each piece of evidence was established and maintained.

10. Sampling and Contamination Control:

a. Copy of Standard Operating Procedures for sample collection (if SOPs are unavailable, copy of training materials and curricula for evidence collection personnel)

b. Copy of Standard Operating Procedure for collection of analytical samples from evidentiary materials, for collection of aliquots, and protocols for handling multiple evidence submissions (e.g., protocol for the number of discrete samples to test when multiple items of evidence are submitted; practices to ensure the representative nature of ana-

lytical aliquots)

c. Copy of the Standard Operating Procedure for contamination control and contamination monitoring in the laboratory; if formal SOPs are not available, provide any documentation generated, disseminated, or used by the laboratory on the topic (e.g., guidelines, memoranda, or instructions)

d. Results of contamination control surveys for locations and contaminants relevant to the testing performed in the case (include sampling plans, test results, and corrective action documentation)

e. Results of environmental monitoring for parameters relevant to test methods

The quality of a laboratory's test results is inherently limited by the quality of the samples that are subject to testing. For this reason, the reliability of a laboratory's reported results should be assessed in consideration of the efficacy of the laboratory's procedures and practices for sample collection and contamination control.

Written sampling and contamination control procedures are used to help ensure that sample quality is not compromised in laboratories that perform trace analysis. By reviewing these procedures, and the results of concurrent contamination surveys, an independent reviewer can assess the potential for the presence of contamination in casework.

11. Sample Preparation and Testing Records

a. Copies of records documenting observations, diagrams, notations, or measurements regarding case testing

b. Instrument or equipment run logs for the instruments used on case samples on the day(s) case samples were tested

c. Instrument calibration and tuning records (as prepared, and as determined values for initial and continuing calibrations applicable to case samples)

d. Source, preparation, and usage records for reagents and materials used during testing

e. Copies of bench notes, log books, and any other records pertaining to case samples or instruments

f. Raw and processed data for case and associated quality control samples, *including* all data excluded or not reported by an analyst

g. As prepared, and as determined values for all blanks, replicates and controls relevant to case samples

h. As appropriate to the analyses performed, electronic copies of raw and processed data identified in items 11f. and 11g., along with reference to the manufacturer and specific version of the instrumental data system used to collect and process the data.

i. The final report(s) issued by the laboratory (with addenda or revisions, as appropriate)

In order for an independent party to determine whether a laboratory's reported results are valid and reliable, they must have access to relevant laboratory records regarding testing on the case samples. The information must be sufficiently detailed and complete so as to enable an independent reviewer to reconstruct the sequence, events, computations, calibrations, and decisions of the testing process.

12. Traceability Records

a. Source, preparation and usage records that demonstrate traceability for standards and reference materials used for calibration and quality control purposes during casework testing.

Traceability of analytical results is a requirement of forensic and international quality standards. Traceability refers to the existence of an unbroken, identifiable chain of documentation that describes a complete path through a measurement process. If any link is missing, the measurement is not traceable, and the measurement's uncertainty can not be

assigned. If a laboratory's measurement is traceable, the chain of events leading to the final result can be reconstructed, and the sources of error can be identified and quantified. However, if a measurement is not traceable, as in the case where a laboratory used a reference standard of unknown origin or purity, the uncertainty in the final result can not be determined.

13. Laboratory Staff Qualification Records

a. Statement of qualifications for *each individual* who participated in casework, including technicians.

b. Internal and external proficiency testing results for each of the methods used to perform evidence testing (including sponsoring agency, dates performed, true values, reported results, raw data, scores, corrective actions, and related correspondence, as appropriate); results should be provided from the tests performed prior to and after the case samples, as appropriate.

c. Internal and external proficiency testing results for each of the analysts who performed evidence testing (to the extent it is not duplicative of #13b); results should be provided from the tests performed prior to and after the case samples, as appropriate.

Given the complexity of modern laboratory techniques, every member of a laboratory staff needs education and training commensurate with their personal responsibilities. The least trained individuals in the laboratory testing process are often the technicians who actually prepare and process samples, yet many of the most intractable and difficult to identify analytical problems occur during sample preparation.

Proficiency testing provides an objective means of demonstrating an individual's competence in performing a specific type of testing, as well as demonstrating a laboratory's ability to successfully perform the testing.

14. Method Validation

a. Results from validation studies for each method used to analyze evidence

b. If the material requested in 14a is unavailable, results verifying the laboratory's ability to meet the desired performance characteristics of the method(s) that was externally validated, and a reference to the original validation record.

A method validation study is used to determine the performance characteristics (such as accuracy, precision, linearity, sensitivity, specificity, and interferences) of an analytical method. A formal method validation study is particularly important to understanding the reliability of a method when the testing involves unique test methods, or the use of conventional methods on unusual sample materials. Method validation is a requirement of forensic and international quality standards, and a fundamental scientific necessity.

15. ASCLD Accreditation Records

a. ASCLD-LAB application for accreditation

b. Statement of Qualifications for key personnel

c. Most recent Annual Accreditation Review Report (provided to ASCLD-LAB each year)

d. Final accreditation report

If a forensic laboratory has been accredited by the American Society for Crime Laboratory Directors - Laboratory Accreditation Board (ASCLD-LAB), the laboratory acknowledges that it meets the ASCLD-LAB accreditation standards. The requested documentation provides users of the laboratory's data with documentary evidence of the laboratory's degree of compliance with ASCLD-LAB quality criteria.

16. Based on my experience as a laboratory auditor, testing laboratories throughout the country routinely make the foregoing documentation and records available for independent reviewers and laboratory auditors, either through provision of

copies, or by hosting on-site audits.

The foregoing is true and correct to the best of my knowledge, information, and belief.

END OF DOCUMENT