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Quality Assurance Guidelines for Laboratories Performing Forensic Analysis of Chemical Terrorism

Scientific Working Group on Forensic Analysis of Chemical Terrorism (SWGFACT)

Marc A. LeBeau
SWGFACT Chair
Federal Bureau of Investigation
Quantico, Virginia
mlebeau@fbi.gov

Preface

The Scientific Working Group on Forensic Analysis of Chemical Terrorism (SWGFACT) has developed the following quality assurance guidelines to provide laboratories engaged in forensic analysis of chemical evidence associated with terrorism a framework to implement a quality assurance program. This document provides guidance to laboratories that carry out forensic analysis to support the judicial system. Consideration may be given to alternate methods of achieving the intent of these quality assurance practices as outlined in these guidelines. A quality program is always evolving, and likewise, this document should be considered a living document.

Introduction

SWGFACT's mission is "to develop guidelines for the forensic identification, characterization, and attribution of evidence in planned, threatened, or actual acts of chemical terrorism." *The Quality Assurance Guidelines for Laboratories Performing Forensic Analysis of Chemical Terrorism* may be used by laboratories to structure or enhance their quality assurance practices in the analysis of chemical terrorism. SWGFACT emphasizes the importance of complying with applicable international, federal, state, and local regulations, specifically in the areas of sample shipment, hazard containment, and personnel protection.

References

American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB), *ASCLD/LAB Accreditation Manual*, July 2003.

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Suggested Reading

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Select Agents and Toxins, Title 42 CFR Part 73, U.S. Department of Health and Human Services, Washington, DC, 2003. Available: www.access.gpo.gov/nara/cfr/waisidx_03/42cfr73_03.html.

1. Scope

These guidelines describe quality assurance activities that a laboratory should follow to ensure the quality and integrity of the data and competency of the laboratory. A laboratory, in the context of these guidelines, is defined as a facility in which analyses associated with chemical terrorism is performed. These guidelines do not preclude a laboratory by itself or in collaboration with others from participating in research and development.

2. Definitions

As used in these guidelines, the following terms shall have the meanings specified:

Administrative review is an evaluation of examination documentation for consistency with laboratory policies and for editorial correctness.

Analytical procedure is an orderly step-by-step instruction designed to ensure operational uniformity and to minimize uncertainty.

Attribution is the identification of the source of a material to the degree that it can be ascertained.

Audit is an inspection used to evaluate, confirm, or verify activity and documentation related to quality.

Calibration is a set of operations that establish, under specified conditions, the relationship between values provided by a measuring instrument or measuring system and a known value.

Chain of custody is the tracking and documentation of physical control of evidence.

Chemical terrorism is the use, or threat of use, of chemicals to commit acts of terror or crime.

Equipment and instruments are apparatus capable of measuring and/or having an effect on the accuracy or validity of a technical operation used to determine one or more physical or chemical characteristics of a given test sample (e.g., gas chromatograph, balance, carrier gas generator, oven, thermometer, auto pipetter).

Examination documentation encompasses any documentation generated as a result of the analysis of submitted evidence. This may include technical notes, worksheets, charts, graphs, printouts, spectra, photographs, and other data or records used by examiners/analysts to support their reported conclusions.

Examiner or analyst (or equivalent role, position, or title as designated by the laboratory director) is a person who conducts and/or directs the analysis of samples, interprets data, and reaches conclusions and may eventually testify to those findings or conclusions.

Laboratory is a facility in which chemical forensic testing is performed.

Laboratory support personnel (or equivalent role, position, or title as designated by the laboratory director) are people who perform supportive laboratory duties but are not involved in the analysis of evidence.

Proficiency test samples are materials whose identity, type, or values are previously characterized and used to assess the performance of a laboratory or a person.

Proficiency testing is a quality assurance measure used to monitor individual or laboratory performance and identify areas in which improvement may be needed. A determination of proficiency can only be obtained when the expected results are not known by the test participant during the test administration.
Proficiency tests may be classified as

- Internal-A proficiency test that is prepared in the laboratory being tested.
- External-A proficiency test that is prepared by an external agency.

Quality assurance includes monitoring activities that are intended to verify whether practices and test results are providing reliable information.

Quality control includes laboratory activities intended to verify whether analytical procedures are performed appropriately to yield reproducible results (e.g., blind samples, negative and positive controls).

The *quality manager* is the person designated by top management who, irrespective of other responsibilities, has the defined authority and obligation to ensure that the requirements of the quality system are implemented and maintained.

A *quality manual* is a document stating the quality policy, quality system, and quality practices of an organization.

Quality system is the organizational structure, responsibilities, procedures, processes, and resources for implementing quality.

A *qualifying test* measures proficiency in technical skills and knowledge and is administered prior to a person assuming independent work

responsibility. It may also be referred to as a competency test.

Reagent is a substance used in an analytical procedure because of its chemical, biological, or physical properties.

Reference material (certified or standard) is a material for which identities, types, or values are certified by technically valid procedures and is accompanied by or traceable to, a certificate or other documentation that is issued by a certifying body.

A *sample* is the subject of an analytical procedure (e.g., evidence).

Secondary evidence is an evidentiary item separated by a physical or chemical means from the original piece of evidence (e.g., powder residue on clothing).

A *secure area* is a locked space (e.g., cabinet, vault, room) with access restricted to authorized personnel.

Subcontractor is a person or entity having a transactional relationship with a laboratory.

Technical manager (or equivalent position or title as designated by the laboratory director) is the person who is accountable for the technical operations of the laboratory.

Technical review is an evaluation of reports, notes, data, and other documents to ensure an appropriate and sufficient basis exists for the reported scientific conclusions. A technically qualified person other than the person who prepared the reports, notes, data, and other documents under review conducts this review.

Technician (or equivalent role, position, or title as designated by the laboratory director) is a person who performs analytical techniques on evidentiary items under the supervision of a qualified examiner or analyst.

Traceability is the property of a result of a measurement whereby it can be related to appropriate standards, generally international or national standards, through an unbroken chain of comparisons.

Uncertainty is the amount of variance in a stated measurement or result.

Validation is a process by which a procedure is evaluated to determine its efficacy and reliability for analysis.

3. Quality Assurance Program

3.1 The laboratory should establish and maintain a documented quality system that is appropriate to the testing activities.

3.1.1 The quality system should address at a minimum the following:

- Goals and objectives.
- Organization and management.
- Technical personnel and training.

- Facilities and security.
- Evidence control.
- Validation.
- Analytical procedures.
- Equipment calibration and maintenance.
- Reports and supporting documentation.
- Review of reports.
- Proficiency testing.
- Corrective action.
- Audits.
- Safety.
- Subcontracting.

3.2 The laboratory should identify a person as the quality manager.

4. Organization and Management

4.1 A laboratory should have the following:

- A managerial staff with the authority and resources needed to discharge their duties and meet the criteria of the guidelines in this document.
- A technical manager.
- Documentation specifying the responsibilities, authority, and interrelationships of all personnel who manage, perform, or verify work affecting the validity of forensic chemical analysis.
- A statement of the goals and objectives of the laboratory's quality system.

5. Technical Personnel and Training

5.1 Laboratory personnel should have the education, training, and experience necessary to perform examinations and provide testimony. The laboratory should have the following:

5.1.1 Written job description(s) for personnel that includes responsibilities, duties, and skills.

5.1.2 A documented training program for assuring the competence of all technical laboratory personnel.

5.1.3 Records maintained on the relevant qualifications, training, skills, and experience of the technical personnel.

5.1.4 Records maintained of security clearances, when appropriate, for laboratory personnel when evidence/information must be secure and protected.

5.2 The technical manager is the designated person who is responsible for the technical operations of the laboratory. This person is responsible for the following:

5.2.1 Evaluating and approving all analytical procedures used by the laboratory.

5.2.2 Technical problem solving of analytical procedures and the oversight of training, quality assurance, safety, and proficiency testing in the laboratory.

5.2.3 Suspending laboratory operations, when appropriate.

5.3 Examiner or Analyst.

5.3.1 An examiner or analyst is responsible for the content of a laboratory report released under his/her name and provides expert courtroom testimony, if required.

5.3.2 An examiner or analyst should have successfully completed a documented training program and qualifying test before assuming independent forensic casework responsibilities. The training program should include an understanding of forensic operations.

5.4 Technician.

5.4.1 A technician should have on-the-job training specific to the job function(s).

5.4.2 A technician should have successfully completed a qualifying test before participating in forensic casework responsibilities.

6. Facilities and Security

6.1 The laboratory should have a facility designed to provide appropriate levels of security, safety, and contamination control. Laboratory management should ensure the following:

6.1.1 Access to the laboratory is controlled and limited.

6.1.2 Evidence is appropriately secured and stored when not under examination.

6.1.3 The laboratory follows written procedures for monitoring equipment and instrumentation for cross contamination.

6.1.4 Appropriate protocols and records should be maintained when regulatory requirements apply for sample receipt, storage, containment, and protection.

6.2 A laboratory should document waste-management requirements to ensure that appropriate decontamination and disposal measures are in place and that compliance with relevant laws is being accomplished.

6.3 A laboratory should consider appropriate measures to address the following:

6.3.1 Backup-power sources for power outages to protect evidence and equipment.

6.3.2 Computer security for case-documentation records.

7. Evidence Control

7.1 The laboratory should have and follow a documented evidence control system. This system should ensure the following:

7.1.1 Items are marked with unique identifiers.

7.1.2 Documentation of evidence identity, receipt, storage, and disposition is maintained.

7.1.3 The laboratory follows documented procedures that minimize loss, contamination, and/or deleterious change to evidence.

7.1.4 The laboratory has secure areas for evidence storage including environmental control(s) consistent with the form or nature of the item.

7.2 The laboratory should have available guidelines for sample collection.

7.3 Laboratories should request the following information from the submitter of samples, when possible:

7.3.1 Sample collected from a location.

- Type of sample.
- Environmental conditions.
- Sampling tool or technique.
- Date and time collected.
- Who collected sample.
- Sampling location.
- Screening tests and the results of the screening.

7.3.2 Physiological sample collected from a person.

- Name or identifier.

- Type of sample.
- Age.
- Gender.
- Population affinity.
- Weight.
- Body temperature.
- Current medications.
- Symptomatology.
- Who collected sample.

7.4 The laboratory should maintain a chain of custody for evidence from the time of receipt in the laboratory. Individual items should be tracked. Time and date of transfers should be documented. Secondary evidence should be tracked.

7.5 When the laboratory completely consumes tested samples, that fact should be recorded in the examination documentation.

7.6 A laboratory should document and provide appropriate guidelines for sample submission, packaging, and return. Items should be shipped in accordance with federal requirements.

7.7 A laboratory should document a policy for long-term sample storage, retention, disposal, and/or return.

8. Validation

8.1 Documented validation studies for forensic analytical procedures being performed by laboratory personnel should be available. SWGFACT will publish a validation guidance document.

9. Analytical Procedures

9.1 The laboratory should have and follow current written analytical procedures approved by the technical manager.

9.1.1 The procedures should, when applicable, include or reference a list of equipment and reagents, step-by-step instructions, quality controls, test calculations, limitations, interpretation criteria, measurement uncertainty, and literature references. Procedures for measuring uncertainty should be included.

9.1.2 The laboratory should have a written policy whereby a deviation from an analytical procedure is documented and approved.

9.1.3 The laboratory should have a documented approach for testing general unknowns.

9.2 The laboratory should use reagents including commercial supplies that are suitable for the analytical procedures employed and should maintain documentation verifying suitability. Reagent containers should be labeled with the identity of the reagent, the date of preparation and expiration, the identity of the person preparing the reagent, and relevant storage instructions.

10. Equipment Calibrations and Maintenance

10.1 The laboratory should use equipment suitable for the analytical procedures employed.

10.2 The laboratory should have an inventory of its equipment and should have a documented program for calibration of instruments and equipment.

10.2.1 When available and appropriate, reference standards traceable to national or international standards should be used for calibration. When traceability to national standards of measurement is not applicable, the laboratory should provide satisfactory evidence of the quality of the reference standard.

10.2.2 The frequency of the calibration should be documented for each instrument requiring calibration. Calibration documentation should be retained in accordance with laboratory policy.

10.3 The laboratory should have and follow a documented program to ensure that instruments and equipment are properly maintained.

10.3.1 New instruments and equipment, or instruments and equipment that have undergone repair or maintenance, should be calibrated or validated before use.

10.3.2 Written records or logs should be maintained for maintenance service performed on instruments and equipment. Such documentation should be retained in accordance with laboratory policy.

10.3.3 Commercial instrument software may be considered validated. If the laboratory modifies the software, it should demonstrate the software has been validated. Internally developed software should be validated.

11. Reports and Supporting Documentation

11.1 The laboratory should have and follow written procedures for generating and maintaining documentation for tested samples.

11.1.1 The laboratory should have written procedures for the release of laboratory reports and examination results.

11.1.2 A laboratory report should include the following:

- Name of submitting agency.

- Date the sample(s) was received in the laboratory.
- Brief description of all examined evidence, including the indicated source of the sample, when available (e.g., lungs, water source, debris).
- Statement to address the specific request made of the laboratory.
- General description of analytical procedure(s) used.
- Analytical results and interpretive statement to provide clarity of result.
- Statement of recommended additional testing, when appropriate.
- Laboratory location (city, state).
- Identity of the person responsible for the technical conclusions of the laboratory report.
- Identification of all components of the analysis completed using subcontractors.

11.2 The laboratory should maintain, at a minimum, the following examination-related information:

- Analyst- and technician-generated notes including the identity of the person generating the notes.
- List of instrumentation used (by specific identifier, when available).
- All charts, graphs, photographs, and other examination-related records.
- Chain of custody.
- Description of evidence.
- Date of analysis.
- Any deviations from analytical procedures.
- Statement regarding any consumption or disposition of evidence.
- The identity of the people performing technical and administrative reviews of the report.
- Case communication documentation.

12. Review of Reports

12.1 The laboratory should have and follow written procedures for

technically reviewing all examination documentation. All reports should be administratively reviewed.

12.2 The laboratory should have a documented mechanism in place to address conflicting interpretations or conclusions between analysts and reviewer(s) and a mechanism to address unresolved conclusions or interpretations.

12.3 The laboratory should have a practice in place to review and address reports of noncompliance (e.g. findings resulting from audit reports, contamination logs, controls not functioning properly).

13. Proficiency Testing

13.1 Examiners and other personnel designated by the technical manager who are actively engaged in forensic analysis should undergo annual proficiency testing. The test samples should be processed and analyzed in the same manner as casework. Successful completion of annual proficiency testing should be required to continue casework. Quality control samples should not be considered proficiency tests.

13.1.1 The laboratory should maintain the following proficiency test documentation:

- Source of test (internal or external).
- Test set identifier.
- Identity of the test participant(s).
- Distribution date and due date.
- Date of analysis and completion.
- All data and notes supporting the conclusions.
- Proficiency test results.
- Any discrepancies noted.
- Corrective actions taken.
- Retention, if possible, of a portion of each proficiency test for reanalysis and comparison, if circumstances dictate.

13.1.2 Records for each person tested should be maintained, including all notes, records, reports, and evaluations.

13.2 The following proficiency test information should be documented for tests prepared in the laboratory:

- Identity of person(s) who prepared the test samples.

- Date test samples were prepared.
- Test identifier.
- Sufficient information to duplicate test preparation.
- Expected results, including criteria for acceptable limits (if appropriate).

13.3 A laboratory may choose to employ a revolving matrix (food/water/air) in order to encompass the possible areas for which casework may be performed.

14. Corrective Action

14.1 The laboratory should establish and follow procedures for corrective action when analytical errors and/or proficiency testing discrepancies are detected. The laboratory should maintain documentation for the corrective action and monitor its effectiveness. The documentation should be retained in accordance with laboratory policy.

15. Audits

15.1 The laboratory should conduct audits annually in accordance with the guidelines outlined herein.

15.1.1 Audit procedures should address at a minimum the following:

- Goals and objectives.
- Organization and management.
- Technical personnel and training.
- Facilities and security.
- Evidence control.
- Validation.
- Analytical procedures.
- Equipment calibration and maintenance.
- Proficiency testing.
- Corrective action.
- Reports and supporting documentation.
- Review of reports.
- Audits.

- Safety.
- Previous audits.

The laboratory should retain all documentation pertaining to audits in accordance with laboratory policy.

15.2 When a laboratory uses a subcontractor, documented audits of the subcontractor should be submitted to the laboratory for retention.

15.3 Laboratories are encouraged to have external agencies perform the audits.

16. Safety

16.1 The laboratory should have and follow a documented environmental health and safety program. This program should include a documented on-going safety-training program for laboratory personnel and should be in accordance with federal and state laws.

16.2 The laboratory should identify a person as the safety officer and ensure he/she has or receives appropriate training.

17. Subcontracting

17.1 The laboratory should notify and gain the approval from the submitting agency of any use of subcontracting laboratories.

17.2 A laboratory operating under the scope of these guidelines should require certification of compliance with those portions of these guidelines appropriate to the analysis when a subcontractor performs analyses for the laboratory and may choose to require documentation of this before submitting samples for analysis.

17.2.1 The laboratory should establish and use appropriate review procedures based on the type of work being provided by the subcontracting laboratory. This is to verify the integrity of the data received from the subcontractor. The review should include but is not limited to the following:

- Inspection and evaluation of all results and/or data.
- Inclusion of quality control samples.
- Annual on-site visits.

17.3 The contracting laboratory should define a policy for notification of applicable technical personnel changes by the subcontracting laboratory.

Contributors

The following SWGFACT members contributed to this document:

Marc A. LeBeau
Anja R. Einseln
Dean D. Fetterolf
Federal Bureau of Investigation
Laboratory
Quantico, Virginia

Armando Alcaraz
Lawrence Livermore National
Laboratory
Forensic Science Center
Livermore, California

Shauna Darby
Battelle
Arlington, Virginia

Mary Drummond
Research, Development and
Engineering Command
Forensic Analytical Center
Aberdeen Proving Ground,
Maryland

Martin Harper
Centers for Disease Control and
Prevention
National Institute for
Occupational Safety and Health
Health Effects Laboratory
Division
Morgantown, West Virginia

Charles Hooper
U.S. Environmental Protection
Agency
Athens, Georgia

Eugene Kennedy
Centers for Disease Control and
Prevention
National Institute for
Occupational Safety and Health
Chemical Exposure and
Monitoring Branch
Cincinnati, Ohio

Mathew Magnuson
U.S. Environmental Protection
Agency
National Risk Management
Research Laboratory
Cincinnati, Ohio

Madeline A. Montgomery
Federal Bureau of Investigation
Laboratory
Quantico, Virginia

Eric Nottingham
U.S. Environmental Protection
Agency
National Enforcement
Investigations Center
Denver, Colorado

James Peterson
Batelle
Aberdeen Proving Ground,
Maryland

Charles F. Quenzer
Federal Bureau of Investigation
Laboratory
Quantico, Virginia

R. Duane Satzger
U.S. Food and Drug
Administration
Forensic Chemistry Center
Cincinnati, Ohio

James Seidel
U.S. Environmental Protection
Agency
Office of Criminal Enforcement
Forensics and Training
Denver, Colorado

Karen Wolnik
U.S. Food and Drug
Administration
Forensic Chemistry Center
Cincinnati, Ohio