Dolan Chemical Laboratory

Method # ACS-DCL-GP-QAQC-001: AEP DOLAN CHEMICAL LABORATORY QUALITY ASSURANCE MANUAL

American Electric Power
John E. Dolan Engineering Laboratory
Dolan Chemical Laboratory
4001 Bixby Road
Groveport, OH 43125

Revision 18.0
Effective Date: December 1, 2012

Prepared by
Analytical Chemistry Services, American Electric Power
Groveport, Ohio

Issued by:	**Lannie D. Rowe**	**Issue Date: 01/14/93**
Revised by:	**Amy C. Russell** **Quality Assurance Officer for DCL**	**Revision Date: 09/01/12**
Approved by:	**Daniel G. Adkinson** **Manager of ACS** **Laboratory Manager of DCL**	**Approval Date: See below** **Effective Date: 12/ 01/12**

Document Controlled Copy Number: 1

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For
Dolan Chemical Laboratory, American Electric Power
4001 Bixby Road, Groveport, Ohio 43125
614-836-4221

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Manager, Analytical Chemistry Services
Laboratory Manager, Dolan Chemical Laboratory

Amy C. Russell (Approval Date)
Quality Assurance Officer, Dolan Chemical Laboratory

Acknowledgments

This document was prepared by Quality Control Department at Dolan Chemical Laboratory under the direction of Lannie D. Rowe (Laboratory Manager) of AEP Analytical Chemistry Services.

This document has undergone the following revision history since its original effective date of January 3, 1994 (a more detailed record of revisions is located in Appendix Z:

Effective Date	Rev. No.	Description/ Section Changed	Author(s)	Approver(s)
01/14/93	0.0	Original Issue	Lannie D. Rowe (LDR)	Geoff E. Campbell (GEC)
01/03/94	1.0	Original Issue	LDR	GEC
01/1995	2.0	1995 updates	LDR	GEC
01/1996	3.0	1996 updates	LDR	GEC
01/1997	4.0	1997 updates	LDR	GEC
01/1998	5.0	1998 updates	LDR	GEC
01/1999	6.0	1999 updates	LDR	GEC
01/2000	7.0	2000 updates	LDR	GEC
01/2001	8.0	2001 updates	LDR	GEC
01/2002	9.0	2002 updates	LDR	GEC
01/2003	10.0	2003 updates	LDR	GEC
01/2004	11.0	2004 updates	LDR	GEC
01/2005	12.0	2005 updates	LDR	GEC
01/2006	13.0	2006 updates	LDR	GEC
01/2007	14.0	2007 updates	LDR	GEC
06/2007	14.1	Convert to MS Word/pdf	Ralph L. Evick (RLE)	LDR
09/14/07	14.2	Updated for NVLAP	RLE	LDR
11/06/07	14.3	Re-organized into ISO format	Amy C. Russell (ACR)	LDR
01/11/08	15.0	2008 updates	ACR/RLE	LDR
06/01/09	16.0	2009 updates	ACR/RLE	LDR
09/01/11	17.0	2010 & 2011 updates	ACR	Daniel G. Adkinson (DGA)
12/01/2012	18.0	2012 Updates	ACR	DGA

Letter of Promulgation

AEP AMERICAN ELECTRIC POWER

Letter of Promulgation

The quality management system described in this Quality Assurance Manual has the absolute and unqualified support of the Analytical Chemistry Services management and of the direct laboratory management at the Dolan and Shreveport Chemical Laboratories.

The Dolan and Shreveport Chemical Laboratories exist because of the need for solutions to problems of a chemical nature and the need for analytical services necessitated by regulatory and operational requirements of the AEP System. These laboratories have gained the respect of people in the AEP System because of our ability to provide these services with results that are accurate, precise, cost-effective and timely.

Every member of the laboratory staff can share in the credit for our reputation of high quality analytical work. However, each member must also share in the responsibility for maintaining and improving analytical quality to ensure the continued satisfaction of our clients. The provisions of the manual are, therefore, binding on the individuals given the responsibilities outlined here.

I will expect everyone concerned to use this manual as a guide to the continued maintenance and improvement of the quality of our analytical services.

Sincerely,

Daniel G. Adkinson

Daniel G. Adkinson
Manager, Analytical Chemistry Services
July 8, 2011

Disclaimer

This document has been reviewed by Analytical Chemistry Services of American Electric Power (AEP), for Dolan Chemical Laboratory in Groveport, Ohio.

This document presents guidance for the quality assurance and quality control (QA/QC) imposed upon laboratory operations— i.e. the implementation and maintenance of the quality management system— as contemplated by AEP as part of its initiative to standardize laboratory methods throughout the Analytical Chemistry Services (ACS) laboratories.

Mention of trade names or commercial products does not constitute endorsement or recommendation for use.

Table of Contents

(pages denoted are within the appropriate Section)

Table of QAM Documents

(pages denoted are within the appropriate Section, as noted in first part of Document number)

Table of Other Quality Documents (Referenced in QAM)

(pages denoted are within the appropriate Section)

LIST OF EQUATIONS:

ACS-DCL-GP-QAQC-001: AEP DOLAN CHEMICAL LABORATORY QUALITY ASSURANCE MANUAL

1.0 Management Requirements: Organization

1.1 Purpose and Scope— This section describes the organization of the Dolan Chemical Laboratory, introduces the Quality Assurance Officer* (QAO) (and other Key Personnel) and is designed to specifically identify the position of Quality Assurance Management within the general structure of the Dolan Chemical Laboratory organization, including organizational charts. General job descriptions and educational requirements for laboratory personnel are outlined in **Sections 1.2.3 and 1.2.4,** but more detailed job descriptions and duties are delineated in **Chapter 16.0 – Technical Requirements: General and Personnel.**

Note: Regarding the asterisk (*), statements related to the responsibilities of the Quality Assurance Officer* (QAO) have been marked with an asterisk throughout the QA Manual (QAM) and have been summarized in Section 16.3.1.

1.1.1 The Dolan Chemical Laboratory provides analytical laboratory services, consultation, and research to assist in solving problems of a chemical nature throughout the American Electric Power (AEP) System. Analytical services include the chemical analyses of coal, oil, water, deposits and other materials. Consultation is provided to individuals and groups of the American Electric Power System to assist in the choice, continued use, or replacement of fluids and materials. The Dolan Chemical Laboratory also gives advice on regulatory policies and procedures affected by contaminants or chemical components of water, flue gas and workspace atmospheres. Research efforts are provided to improve methods of chemical analysis and chemical treatment and to modernize or maintain applications of materials and equipment.

1.1.2 Problems of a chemical nature may arise in any area of the generation, transmission and distribution of electricity. Any functional group or individual in the American Electric Power System may need the services of the Dolan Chemical Laboratory. Their need may be continual, as in the monthly analysis of effluent wastewater from a power plant, or their need may be a one-time event, such as a deposit caused by malfunctioning equipment. The Dolan Chemical Laboratory should meet these needs when the services can be provided at a lower cost, with greater accuracy and convenience, or in a shorter period than the same services could be obtained from non-affiliated laboratories.

1.1.3 A trained staff of chemists, technicians and support personnel must be maintained to meet the needs of the American Electric Power System. Modern instrumentation and equipment must be purchased and maintained in good working order. The laboratory facility must be arranged and, if necessary, rearranged to meet the present and future needs for analysis and research.

1.2 Quality Organization

1.2.1 The AEP Dolan Chemical Laboratory (DCL) is part of American Electric Power Corporation, Analytical Chemistry Services (ACS), Groveport, Ohio.

1.2.1(A) The Manager of ACS is responsible for both the technical and administrative direction of the laboratory, is committed to the QA program described in this plan, and heads the ACS section.

1.2.1(B) The Manager of ACS also serves as the Laboratory Manager of Dolan Chemical Laboratory. In this role, the Laboratory Manager is responsible for day to day laboratory activities, for ensuring that staff is cognizant of the objectives and requirements of the QAM, and for ensuring that data submitted to the Laboratory Manager and the QAO* meet the requirements set forth in this plan.

(a) In the absence of the Laboratory Manager, the Laboratory Manager shall designate one of the Laboratory Chemists to serve as the backup for management duties. This designation shall be communicated to all laboratory personnel.

1.2.1(C) The Laboratory Supervisor at DCL is currently vacant.

1.2.1(D) The Quality Assurance Officer (QAO) * is responsible for the production and timely revision of the QAM and for ensuring that regular audits are conducted to demonstrate that the objectives of the QAM are being met.

(a) In the absence of the QAO, the Laboratory Manager shall serve as the backup for QA/QC duties.

1.2.2 Relevant American Electric Power and Dolan Chemical Laboratory organizational charts are included in **Documents 01-01 through 01-07** and current Organization Chart Records (ORG Rec):

1.2.2(A) **Document 01-01** is the organizational chart for the entire AEP Quality Organization.

1.2.2(B) **Document 01-02** is the organizational chart for the Dolan Chemical Laboratory with an administrative emphasis.

(a) The organizational chart of the Dolan Chemical Laboratory, illustrating the placement of the quality function and the chemical hygiene function is **Document 01-02** (Administrative Emphasis).

1.2.2(C) **Documents 01-03** is the organizational chart for the Dolan Chemical Laboratory with emphasis on the Analytical Groups.

1.2.2(D) **Document 01-04** is the organizational chart for all personnel at the Dolan Chemical Laboratory.

1.2.2(E) Organizational Chart records (ORG Rec) are retained by the QAO and are available on Sharepoint. These records are maintained in **QCDOC-001 QAM Maintenance:**

QC File 00 1— "QCDOC 001: QAM Maintenance " (in Section 1)

1.2.3 Responsibilities of Key Personnel — Laboratory Management

1.2.3(A) Manager of Analytical Chemistry Services (ACS) (based in Groveport, OH)

(a) The Manager of ACS directs activities of the Dolan Chemical Laboratory and is responsible for both the technical and administrative direction of the laboratory, including budget preparation and administration.

(b) The Manager of ACS serves as the Manager for Laboratory operations in Groveport, Ohio (Dolan Chemical Laboratory) and Shreveport, LA (Shreveport Chemical Laboratory). The Manager of ACS reports to the Vice President of Environmental Services.

(c) The minimum education requirements of the Manager of ACS is the same as all chemists — a Bachelor of Science (B.S.) degree in Chemistry or the equivalent in education and experience.

1.2.3(B) Laboratory Manager of Dolan Chemical Laboratory (DCL)

(a) The Laboratory Manager of DCL serves as manager of day to day laboratory operations and responsibilities include overseeing the laboratory's operational performance in work quality, production, and efficiency; and providing consultation to and coordination of work requested. During periods of absence these responsibilities will be assigned to the Laboratory Supervisor.

(b) The Laboratory Manager of DCL serves as a "Section Manager" over the Laboratory and is identified as a "Manager of Environmental and Industrial Lab Services" (per ID # 7619 from May 2005) according to AEP Corporate Human Resources position titles. The Laboratory Manager reports to the Manager of ACS (and in the current organization, to the Vice President of Environmental Services).

(c) The minimum education requirements of the Laboratory Manager is the same as all chemists — a Bachelor of Science (B.S.) degree in Chemistry or the equivalent in education and experience.

Document 1-1 Organizational Chart for the AEP Quality Organization (Rev 0, 05/2012)

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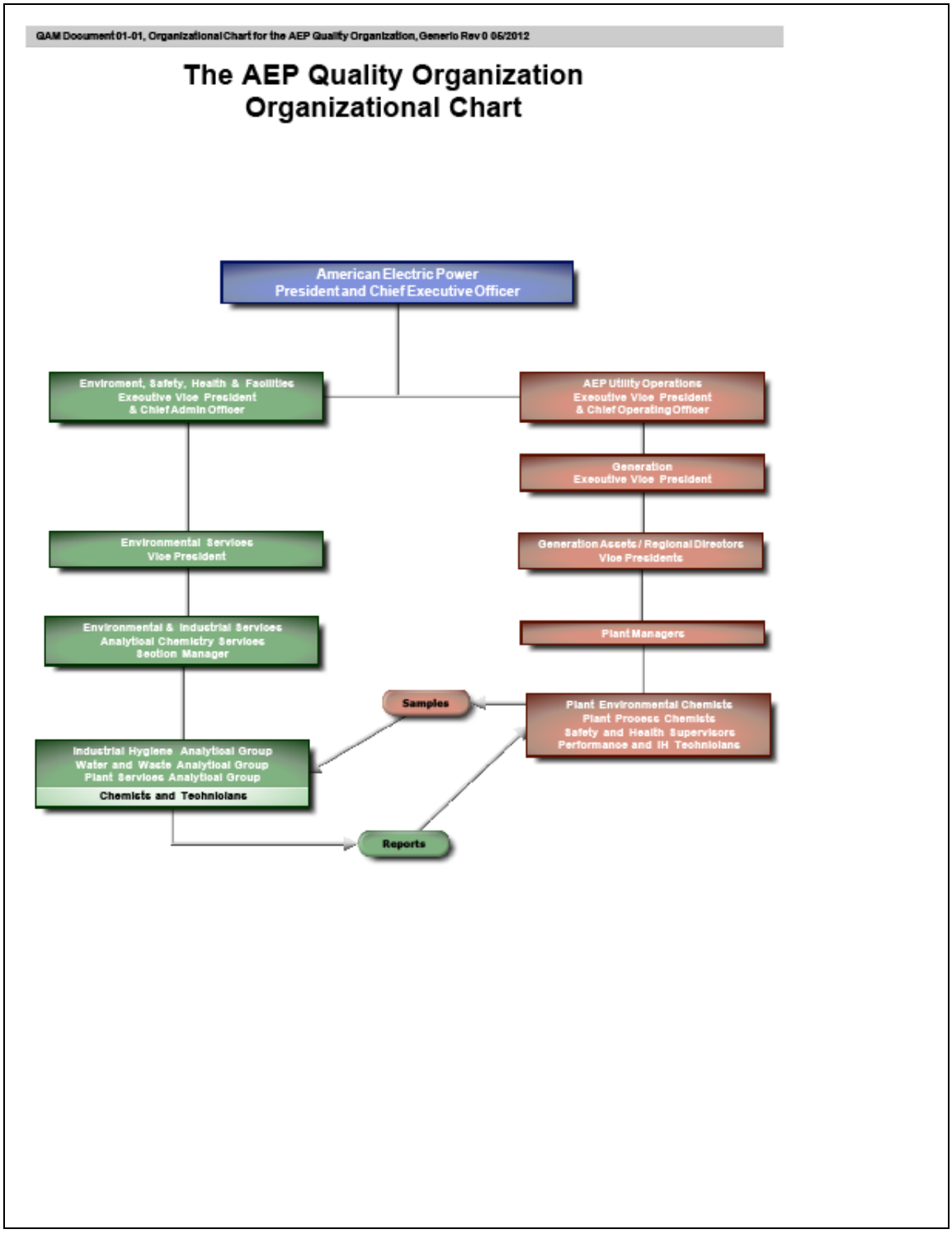

Document 1-2 Organizational Chart for DCL- Administrative Emphasis (Rev 0, 05/2012)

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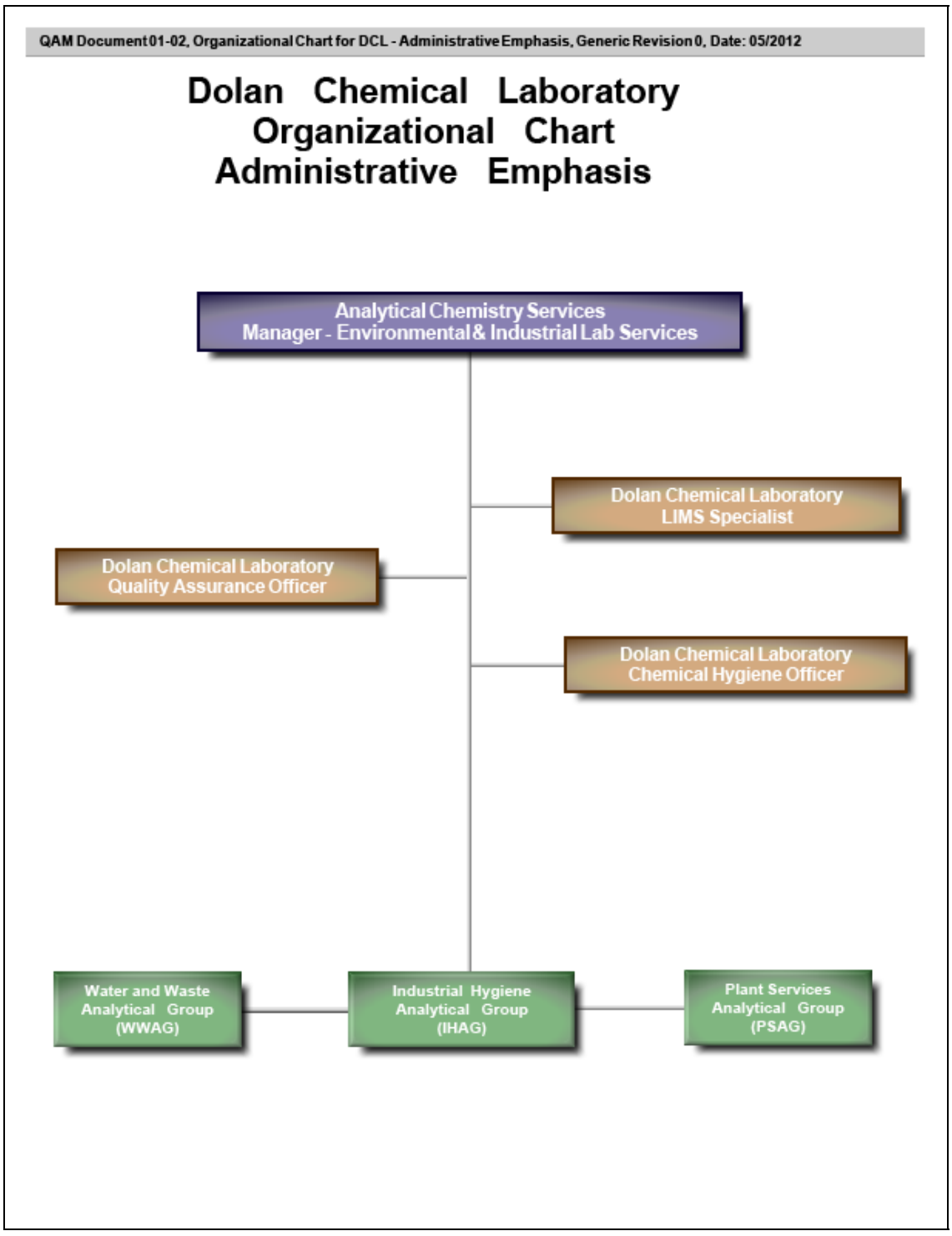

Document 1-3 Organizational Chart for DCL Analytical Groups (Rev 0, 05/2012)

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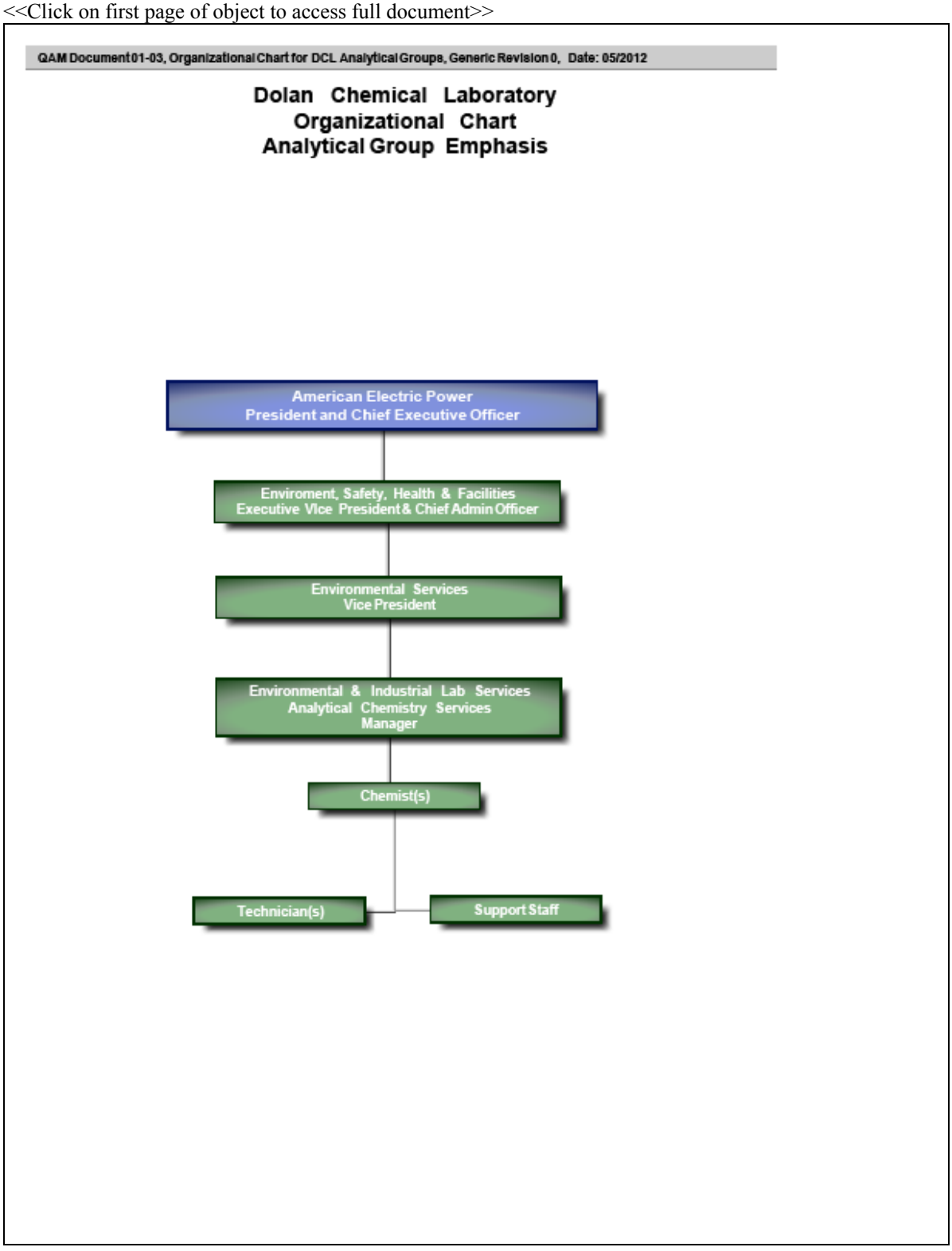

Document 1-4 Organizational Chart for All Personnel in Analytical Chemistry Services (Rev 0, 05/2012)

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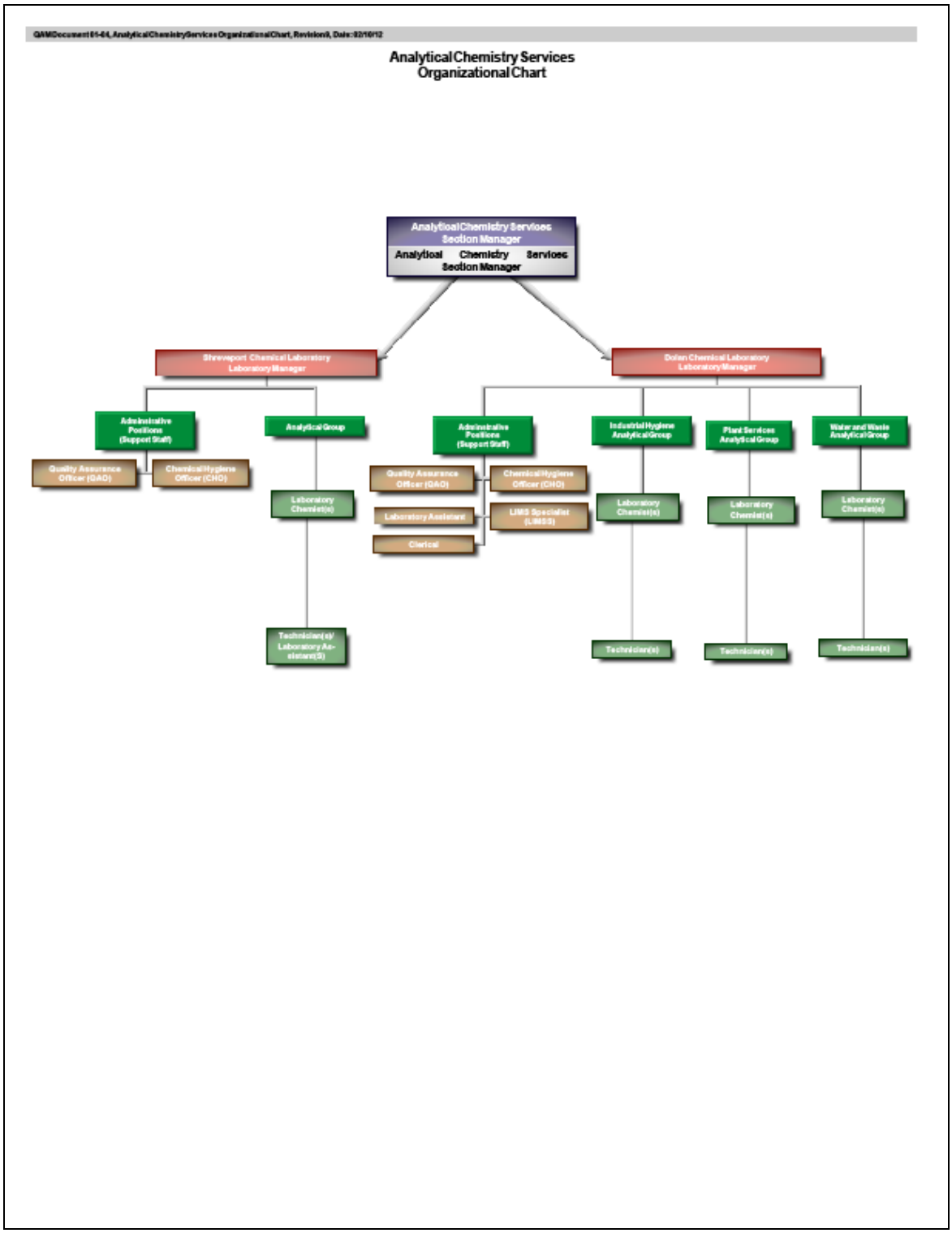


(d) Additionally, the Laboratory Manager (as the "Technical Director", as named by NELAC requirements) must have completed "at least 24 college semester credit hours in chemistry and have at least two years of experience in the environmental analysis of representative inorganic and organic analytes for which the laboratory seeks or maintains accreditation. A masters or doctoral degree in one of the above disciplines may be substituted for one year of experience" [Reference 18.4.1].

1.2.3(C) Laboratory Supervisor of Dolan Chemical Laboratory – (open position, no longer in use)

1.2.3(D) Quality Assurance Officer (QAO)* at Dolan Chemical Laboratory

(a) The management of a Quality Assurance Program as described in this manual requires the services of a QAO* (the designated quality manager) within the Dolan Chemical Laboratory to carry out the monitoring, record keeping, statistical techniques, calibration and other functions required by the quality assurance system. The QAO* of the Dolan Chemical Laboratory reports to laboratory management.

(b) The QAO* initiates and oversees all internal QA/QC audits.

(c) The QAO* responsibilities include the production and timely revision of the QAM, and ensuring that regular audits are conducted to demonstrate the objectives of the QAM are being met.

(d) The QAO* manages the laboratory's blind proficiency program and other duties as assigned

(e) The QAO* is responsible for the periodic (at least yearly) generation of quality control reports, establishment and implementation of record keeping and data compilation.

(i) The periodic report should include information regarding the on-time percentage for the laboratory, CPARs, Non-conformances, and Lessons Learned (Improvements and Preventative Action) generated and resolved, the Industrial Hygiene QC samples percentage, results from Pop-Audits, DOCs, Training and On-site Assessments.

(ii) The periodic report shall be provided to laboratory management and the chemists for review and comments.

(f) During periods of absence from the Dolan Chemical Laboratory these responsibilities will be assumed by the Laboratory Manager, or other designee.

(g) The QAO* shall have documented training and/or experience in QA/QC procedures and statistics and be knowledgeable in the quality system as defined under NELAC and VAC Title 1, Agency 30, Chapter 46 (1VAC30-46) for Virginia Laboratory Certification [Reference 18.4.20].

(h) The description of responsibilities of the QAO* are included throughout this quality manual, but are summarized in QAM Document 16-02.

(i) The minimum education requirements of the QAO* is the same as all chemists — a Bachelor of Science (B.S.) degree in Chemistry or the equivalent in education and experience.

1.2.3(E) The organizational chart of the Dolan Chemical Laboratory, illustrating the placement of the quality function is **Document 01-02** (Administrative Emphasis).

1.2.3(F) Chemical Hygiene Officer (CHO) for Dolan Chemical Laboratory. (Reserved)

1.2.3(G) Laboratory Information Management System Specialist (LIMSS) at Dolan Chemical Laboratory.

(a) The LIMS Specialist is the individual responsible for the operation, validation, and implementation of the laboratory information management system. (the LIMS consists of the computer and software used to identify, schedule, prioritize, perform calculations, generate reports, store results, and perform any other computerized function necessary to control the flow of samples through the laboratory.)

(b) This position is recommended in laboratories with sophisticated data handling systems; however, it is not required for accreditation through AIHA. This person should have a bachelor's degree and/or appropriate laboratory and/or computer skills and education. [per Section 2A.5.2.1.3 in Reference 18.4.18]

1.2.3(H) Radiation Safety Officer (RSO) for Dolan Chemical Laboratory. (Reserved)

1.2.3(I) Learning Coordinator for Dolan Chemical Laboratory. (Reserved)

1.2.3(J) "Technical Manager" refers to the primary chemist of the Industrial Hygiene Analytical Group (IHAG) as defined by AIHA and NVLAP guidance.

(a) The "Technical Manager" is responsible for and has the authority to accomplish the day-to-day operations of the Industrial Hygiene Analytical Group (IHAG) of the Dolan Chemical Laboratory.

(b) The responsibilities of this position include the performance, or delegation of, all maintenance and calibration activities associated with the analysis of bulk asbestos samples.

(c) The development and maintenance of all routine data quality programs, such as control charts, monitoring records, etc. are included in this position's responsibilities.

(d) "For laboratories performing lead in air analysis, the Technical Manager must possess knowledge of IH chemistry calculations with respect to lead in air principles and calculations. Additionally, the Technical Manager must have at least three (3) years of nonacademic analytical chemistry laboratory experience, of which two (2) years shall be metals analysis experience." [per Section 2C.3.1 in Reference 18.4.18]

1.2.3(K) Other Guidance - Functional direction for some of the analytical activities of the Dolan Chemical Laboratory originates from specialists located elsewhere in the American Electric Power System. These resource personnel provide advice and direction in engineering and regulatory matters that affect chemical problems and samples. The Dolan Chemical Laboratory designs its analytical activities based on this input and on its imbedded knowledge of chemistry and analytical procedures.

(a) Members of AEP's corporate Industrial Hygiene Group have been assigned the responsibility for functional oversight for industrial hygiene activities related to Fossil and Hydro Production with the AEP System and provide advice and direction. Members of the Industrial Hygiene Analytical Group (IHAG) perform analyses on industrial hygiene samples.

(i) All IHAG analysts are responsible for the actual analytical work in the Industrial Hygiene section. This includes analytical work related to a variety of analyses. Examples of these are: Asbestos determination, Metals by AA & ICP, Silica concentration and Dust (Nuisance and Respirable). Capability with any of the associated equipment for analysis in this section is a requirement for this designation.

(ii) All IHAG analysts must participate in all Proficiency Programs as appropriate and designated, specific to the analyses.

(iii) All IHAG analysts are responsible for the analysis of sufficient samples and quality control standards to adequately demonstrate the validity, accuracy and precision of their individual analyses. Each individual analyst must be able to demonstrate their proficiency in the analyses they perform.

(iv) Analyst Back-up —In the absence of the Analyst their designated back-up is responsible for the above duties.

(b) Members of the Plant Services Analytical Group (PSAG) perform analyses to support the plants in testing products, and by-products from plants and engineers throughout the AEP system. Tests are also performed on pieces of equipment in order to assist in determining root-cause analyses of equipment failure.

(c) Members of the Water and Waste Analytical Group (WWAG) perform analyses of environmental and waste samples from plants and engineers throughout the AEP system.

(i) All WWAG analysts must participate in all Proficiency Programs as appropriate and designated, specific to the analyses.

(ii) All WWAG analysts are responsible for the analysis of sufficient samples and quality control standards to adequately demonstrate the validity, accuracy and precision of their individual analyses. Each individual analyst must be able to demonstrate their proficiency in the analyses they perform.

(iii) Analyst Back-up —In the absence of the Analyst their designated back-up is responsible for the above duties.

1.2.3(L) Copies of transcripts and/or verification of education and experience are maintained on file with the AEP corporate Human Resources department.

1.2.3(M) Archived Quality Assurance documents and reports are maintained in **QCDOC-019 Quality Assurance Reports**:

QC File 00 2— "QCDOC 019: Quality Assurance Reports " (in Section 1)

1.2.3(N) Archived management documents and reports are maintained in **QCDOC-021 Management Tools**:

QC File 00 3— "QCDOC 021: Management Tools " (in Section 1)

1.2.4 Other Laboratory Position Descriptions — "Analysts shall be responsible for complying with all quality assurance and quality control requirements pertaining to their technical functions" – i.e. adhering to SOPs requirements, performing acceptable calibration and calibration verification(s), performing MDL Studies, performing DOC studies or other demonstrations of proficiency, etc.. "Analysts shall have demonstrated ability to produce reliable results through accurate analysis of certified reference materials (CRMs), proficiency testing (PT) samples, or in-house quality control samples. Their performance must be documented." [per Section 2A.5.2.1.3 in Reference 18.4.18]

1.2.4(A) **Laboratory Chemists** (See also Document 16-03, the Chemist Position Description Matrix Table, in Section 16.4) — Chemists report directly to the Laboratory Manager, or designee. The minimum education requirement of all chemists is a Bachelor of Science (B.S.) degree in Chemistry or the equivalent in education and experience. Chemists guide and direct the work of technicians in their area. Chemists also review the data and generate final reports for designated test parameters. Chemists may also provide peer review for Chemists in other analytical areas.

(a) Principal Chemist (Advanced Level) — The Principal Chemist may be responsible for multiple areas of the laboratory— guiding personnel, serving as an expert in a technical field, influencing the policies, practices, standards and rules of the company throughout AEP, as well as regulations and procedures required by external agencies. The Principal Chemist also directs laboratory activities in the absence of management.

(b) Senior Chemist (Senior Level) — The Senior Chemist leads a primary analytical group or function—coordinating work activities of others within a work group, team and corporate entity. The Senior Chemist also provides guidance to personnel and towards policies, practices, standards and rules of the company and those regulations and procedures required by external agencies.

(c) Chemist I (Journey Level) — The Chemist I coordinates and conducts training sessions; leads, facilitates and coordinates work activities; and performs non-routine analytical activities with minimal direction from higher-level employees.

(d) Chemist II (Intermediate Level) — The Chemist II provides basic training and guidance to lower level employees and performs routine analytical activities with minimal direction from higher-level employees. and

(e) Chemist III (Basic Level) — The Chemist III performs certain ongoing activities with established procedures and direction from higher-level employees; and directs the work of technicians.

(f) Chemist IV (Entry Level) — The Chemist IV performs work activities as assigned and directed by higher-level employees, accepting responsibility for actions.

1.2.4(B) **Laboratory Technicians—** (See also Document 16-04, the Technician Matrix Table in Section 16.5) The minimum education requirements of all technicians is an Associate of Science (A.S.) degree in Chemistry or a related science, or the equivalent in education and experience. Technicians are guided and directed by the associated Chemist in their analytical area, but report directly to the Laboratory Manager, or designee.

(a) Senior Laboratory Technician (Senior Level) — The Senior Laboratory Technician is responsible to plan and perform a variety of non-routine, multitask analytical projects requiring a unique knowledge and mastery of analytical procedures and instruments; direct the issuance of reports for routine analyses under the supervision of the Laboratory Manager or designee; conduct effective and productive team meetings; decide on the proper course of corrective action when quality control results indicate that invalid data or analytical results are possible; and lead process improvement and problem solving teams as assigned.

(b) Chemical Laboratory Technician I (Journey Level) — The Chemical Laboratory Technician I is responsible for the performance of routine, non-routine, and R&D analyses independently in accordance with established procedures. The technician is also responsible for the detection of any abnormalities that may have occurred in any analysis being performed. These abnormalities must be reported immediately to the responsible laboratory chemist.

(c) Chemical Laboratory Technician II (Intermediate Level) — The Chemical Laboratory Technician III is responsible for the performance of routine and non-routine analyses independently in accordance with established procedures. Abnormalities, quality control issues and other observations must be reported immediately to the responsible laboratory chemist.

(d) Chemical Laboratory Technician III (Entry Level) — The Chemical Laboratory Technician III is responsible for the performance of routine analyses as assigned and directed by higher level personnel within the laboratory. Abnormalities, quality control issues and other observations must be reported immediately to the responsible laboratory chemist.

1.2.4(C) **Flue Gas Technicians—** (Removed 04/2008)

1.2.4(D) "**Administrative" Laboratory Personnel—** (See also Document 16-06, the Administrative Associate Matrix Table, in Section 16.6) The "Administrative" personnel are guided by, directed by, and report directly to the Laboratory Manager, or designee.

(a) Senior Administrative Associate (Reserved)

(b) Administrative Associate (Reserved)

(c) Administrative Associate I (Reserved)

(d) Administrative Associate II (Reserved)

(e) Administrative Associate III (Reserved)

(f) Senior Laboratory Assistant (Reserved)

(g) Laboratory Assistant (Reserved)

1.2.4(E) More detailed job descriptions and duties for laboratory personnel are outlined in **Chapter 16.0 – Technical Requirements: General and Personnel.**

(a) The formal certificates associated with the training of personnel at the Dolan Chemical Laboratory are retained by the Quality Assurance Officer* (QAO) in **QCDOC 009**. Training is also monitored by the "Training Coordinator" using the AEP system.

QC File 00 4— "QCDOC 009: Personnel Records" (in Section 1)

1.2.5 Primary Analytical Area Assignments

1.2.5(A) The primary analytical assignments for the Dolan Chemical Laboratory within each analytical group are defined in the Analytical Assignment Records (ORG Rec). These assignments establish the primary responsibilities for each type of analysis within a given analytical group. The technicians assigned to each analytical area are also listed.

(a) These records also list the personnel in each Analytical Group and any other support personnel from the Dolan Chemical Laboratory who directly contribute to the production of quality laboratory work for that Analytical Group, and the "primary and back-up" work assignments for personnel within the group.

1.2.5(B) **Back-ups**—Each area of testing may assign personnel as **"back-ups"** to be utilized when the primary chemist (or primary technician for an analytical assignment) is unable to perform their duties.

(a) Back-up personnel must meet the same requirements as the primary personnel (i.e. education, experience, required demonstration's of capability) and should be trained and validated prior to reporting analytical results.

1.2.5(C) Analytical Assignment records (ORG Rec) are retained by the QAO and are available on Sharepoint. These records are maintained in **QCDOC-001 QAM Maintenance:**

QC File 00 5— "QCDOC 001: QAM Maintenance " (in Section 1)

1.3 Laboratory Location

1.3.1 Building Layout

1.3.1(A) The geographical site plan, floor plan and the two area location maps for the building occupied by the Dolan Chemical Laboratory are shown in **Documents 1-5 through 1-8**.

(a) Dolan Chemical Laboratory is located at 4001 Bixby Road in Groveport, Ohio (zip code 43125).

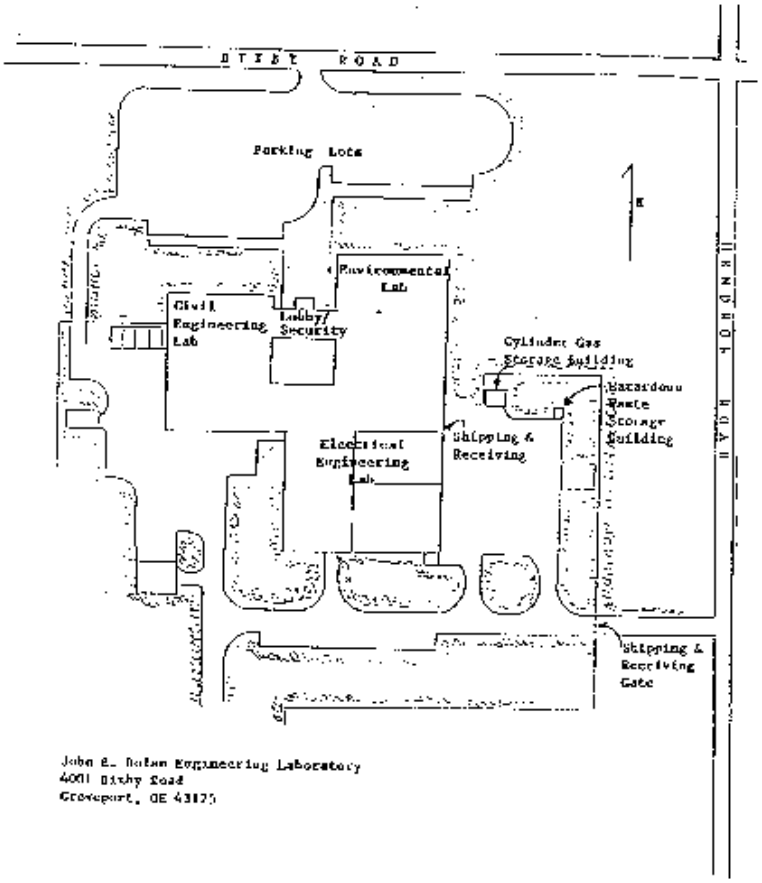
1.3.2 The Dolan Chemical Laboratory is designated a **"Fixed, Single Laboratory Site"**, per AIHA and NELAC Standards. The Dolan Chemical Laboratory does not participate as a mobile/temporary facility. In rare instances where it is warranted for personnel to perform site visits (i.e. sampling, on-site assessment), the laboratory quality policies and operating procedures shall continue to be adhered to.

Document 1-5 AEP Dolan Chemical Laboratory, Site Plan (Overview)

<<Click on first page of object to access full document>>

QAM Document 01-05
AEP Dolan Chemical Laboratory, Site Plan (Overview), Revision 0, 7.1992,
Page 1 of 1

Environmental Laboratory
Site Plan



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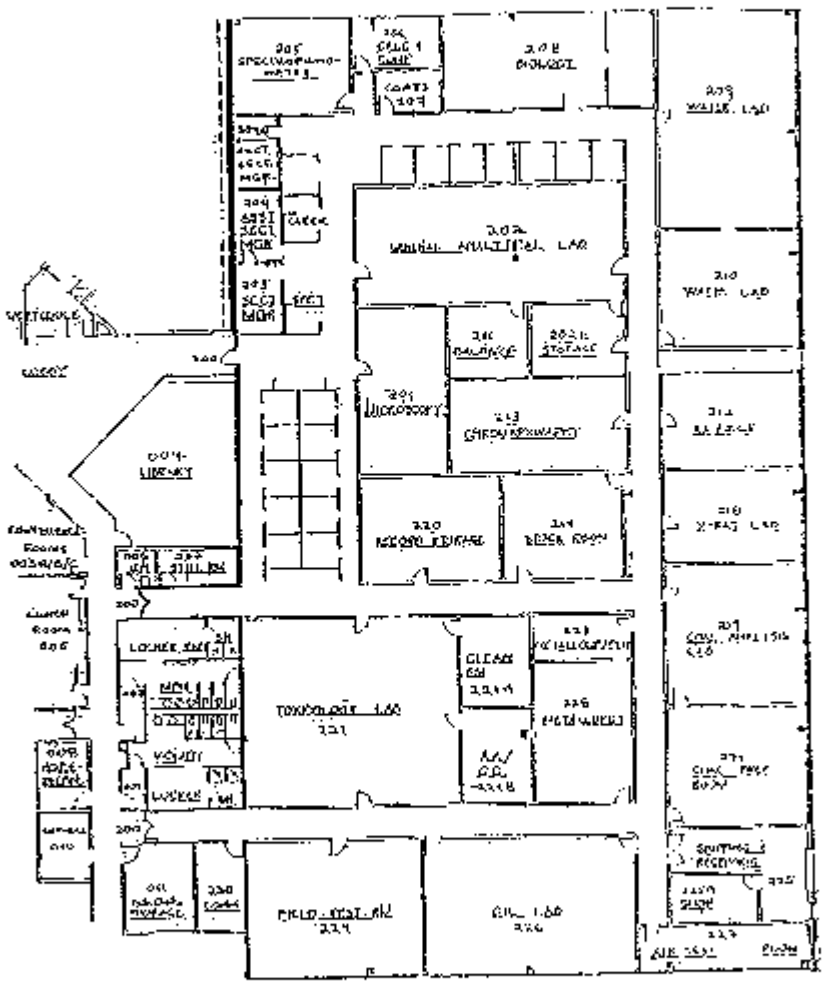
Document 1-6 AEP Dolan Chemical Laboratory, Floor Plan
<<Click on first page of object to access full document>>

QAM Document 01-06
AEP Dolan Chemical Laboratory, Floor Plan, Revision 0, 7.1992,
Page 1 of 1

Environmental Laboratory
Floor Plan



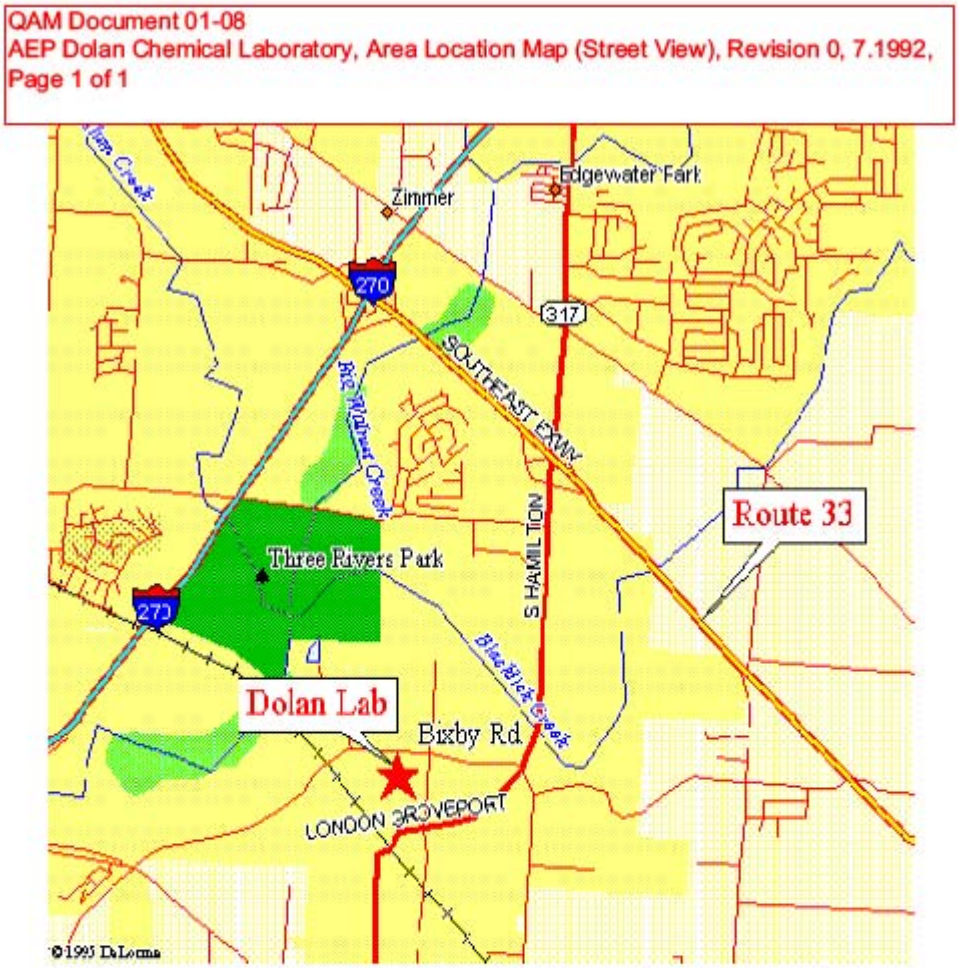
07/29/92

Document 1-7 AEP Dolan Chemical Laboratory, Area Location Map (Overview)

<<Click on first page of object to access full document>>

Document 1-8 AEP Dolan Chemical Laboratory, Area Location Map (Street View)

<<Click on first page of object to access full document>>



1.3.3 Travel Instructions – John E. Dolan Engineering Laboratory

Instructions on how to travel to the John E. Dolan Engineering Laboratory from various other locations.

1.3.3(A) **Inbound, North on St. Rt. 23:**

When traveling north on State Route 23 from the Chillicothe area, continue through Circleville and South Bloomfield to the small town of Shadeville. This town is where the junction of St. Rt. 665 and St. Rt. 317 is located. St. Rt. 665 travels west from this town, while St. Rt. 317 travels to the east. This junction is defined by the presence of a stoplight. Turn right at this stoplight onto St. Rt. 317. Proceed past the bridge over Big Walnut Creek (0.3 mile) to the red light at Alum Creek Drive (3.6 mile). Continue straight through the light to another red light at Port Road (4.1 mile). Again, continue straight through this light to another light at Groveport Road (6.4 mile). Continue through this light to the intersection of St. Rt. 317 and Hendron Road (7.4 mile). This is the first intersection past Groveport Road. Make a left-hand turn (north) onto Hendron Road and continue to the intersection of Bixby Road and Hendron Road (7.7 mile). Turn left (west) on to Bixby Road. The primary entrance to the John E. Dolan Laboratory is located on the left (south) approximately 0.1 mile from this intersection.

1.3.3(B) **Inbound, Northwest on St. Rt. 33:**

When traveling northwest on State Route 33 from the Athens-Logan-Nelsonville areas, continue through Lancaster toward Columbus. The junction of St. Rt. 33 and St. Rt. 22 is located in Lancaster. The exit from St. Rt. 33 toward the John E. Dolan Engineering Laboratory is approximately 21 miles from this junction. Turn off St. Rt. 33 at the Hamilton Road exit. At the red light at the end of the exit ramp, turn left onto Hamilton Road (St. Rt. 317). Proceed south, passing the Groveport-Madison High School and the Eastland Career Center, approximately 1.2 miles, to Bixby Road. Look for the 345 kV lines crossing the road. Turn right onto Bixby Road. The primary entrance to the John E. Dolan Laboratory is located on the left (south) approximately 0.6 mile from this intersection.

1.3.3(C) **Inbound, West on Interstate 70:**

When traveling west on Interstate 70 from the Wheeling-Cambridge-Zanesville areas, continue toward Columbus until you approach I-270 (the Columbus Outer belt). At Exit 108A, exit toward Cincinnati on I-270. Continue for 3 miles on I-270 to the St. Rt. 33 exist toward Lancaster (Lancaster exit, Exit 46B). Travel approximately 1.5 mile on St. Rt. 33 toward the southeast. Take the Hamilton Road/St. Rt. 317 exit. At the red light at the end of the exit ramp, turn right onto Hamilton Road (St. Rt. 317). Proceed south, passing the Groveport-Madison High School and the Eastland Career Center, approximately 1.2 miles, to Bixby Road. Look for the 345 kV lines crossing the road. Turn right onto Bixby Road. The primary entrance to the John E. Dolan Laboratory is located on the left (south) approximately 0.6 mile from this intersection.

1.3.3(D) **Inbound, South on Interstate 71:**

When traveling south on Interstate 71 from the Cleveland-Mansfield areas, continue toward Columbus until you approach Interstate 270 (the Columbus Outer belt). At Exit 119, exit toward the east to Cincinnati on I-270. Continue for 20.4 miles on I-270 (past the Cleveland Avenue exit [1.5 miles], past St. Rt. 161 [4.7 miles], past Interstate 670 [9.3 miles], past Interstate 70 [17.0 miles]) to the St. Rt. 33 exit toward Lancaster (Lancaster exit, Exit 46B). Travel approximately 1.5 mile on St. Rt. 33 toward the southeast. Take the Hamilton Road/St. Rt. 317 exit. At the red light at the end of the exit ramp, turn right onto Hamilton Road (St. Rt. 317). Proceed south, passing the Groveport-Madison High School and the Eastland Career Center, approximately 1.2 miles, to Bixby Road. Look for the 345 kV lines crossing the road. Turn right onto Bixby Road. The primary entrance to the John E. Dolan Laboratory is located on the left (south) approximately 0.6 mile from this intersection.

1.3.3(E) **From Port Columbus International Airport (airport code CMH):**

When traveling from the Port Columbus International Airport, exit the airport premises north-bound, then turn left (west) onto International Gateway. Turn right onto Sawyer Road (turning right to STAY on Sawyer Road). Turn left (north) onto North Hamilton Road (St. Rt. 317) until reaching the Exit 37 ramp for Interstate 270 (the Columbus Outer belt) South towards Wheeling and merge onto the ramp going South. Continue for 9 miles on I-270 to the St. Rt. 33 exit toward Lancaster (Lancaster exit, Exit 46B). Travel approximately 1.5 mile on St. Rt. 33 toward the southeast. Take the Hamilton Road/St. Rt. 317 exit. At the red light at the end of the exit ramp, turn right onto Hamilton Road (St. Rt. 317). Proceed south, passing the Groveport-Madison High School and the Eastland Career Center, approximately 1.2 miles, to Bixby Road. Look for the 345 kV lines crossing the road. Turn right onto Bixby Road. The primary entrance to the John E. Dolan Laboratory is located on the left (south) approximately 0.6 mile from this intersection.

1.4 Laboratory Security

1.4.1 Physical Security

1.4.1(A) The front (outer door) entrance to the John E. Dolan Engineering Laboratory is unlocked on business days between the hours of 7:30 A.M. and 5:30 P.M. All other access doors are enclosed within the fenced areas of the laboratory property.

1.4.1(B) The doors to the Dolan Chemical Laboratory (the actual analytical laboratory) are locked twenty-four hours a day. Dolan Chemical Laboratory employees have access through these doors twenty-four hours a day using their AEP I.D. badge.

1.4.1(C) All employees, contractors, and visitors are required to display AEP-issued ID cards at all times in a visible location on their garment when on AEP property.

1.4.1(D) Employees are requested to be alert for fellow employees and others on company property who may not be properly displaying a company-issued ID. Those persons should be reminded of the company policy and, if necessary, referred to Human Resources for appropriate follow-up. It is every employee's responsibility to uphold AEP security policies and to maintain the security of the Dolan facility.

1.4.1(E) Employee Access

(a) All AEP employees must enter the building through the main entrance or through the delivery gate. These entrances require the use of the AEP ID card.

(i) For entry after business hours at the main entrance, the AEP ID card possesses a magnetic strip on its back and a proper reading of the strip by the automatic magnetic card reader should allow for a permissible entry. All entries at the delivery gate by laboratory personnel must use the AEP ID card and the magnetic card reader.

(b) Upon entering the building during working hours, AEP employees should display their ID.

(c) If an employee loses or misplaces the card, they should sign in at the security desk and obtain a visitor's ID card for that particular day. The card must be returned every evening to the security desk as the employee exits through the front entrance.

(d) There are three levels of access granted to AEP employees through the magnetic strip on their AEP ID badges. The laboratory manager may request specific AEP personnel (e.g. Telecommunications, IT personnel) be granted the third level of access for necessary operations of the laboratory.

(i) The first level grants all AEP employees access to the entrance of all AEP locations during normal business hours of the weekdays.

(ii) The second level grants all AEP employees at the Dolan facility access to the Dolan building 24 hours per day/ 7 days per week.

(iii) The third level grants applicable personnel (i.e. Dolan Chemical Laboratory employees, Groveport Fire Department, cleaning and maintenance personnel, specified contractors, and other AEP employees as necessary for operation of the Dolan Chemical Laboratory) access to the Dolan Chemical Laboratory portion of the Dolan facilities 24 hours per day/7 days per week.

1.4.1(F) Visitors, Vendors, Deliveries

(a) All visitors must enter the building through the front (main) entrance. They must sign in with the Workplace Services Employee. A visitor's badge is required for access to all departments.

(b) Upon leaving, visitors must turn in their visitor's badge.

(c) Only authorized personnel are allowed access to areas behind the security desk.

(d) Vendors and delivery personnel, except the PONY personnel employed by AEP, are not allowed beyond the Shipping and Receiving Room (Room 225) without a visitor's badge. Access to this room is controlled by security through limited access at the delivery gate and the Dolan Chemical Laboratory entrance.

(e) After normal work hours, delivery personnel may request access to the Dolan facility foyer by pressing a call button outside the facility front door. Upon the permission of the AEP Security Personnel at "1RP" (AEP Corporate Headquarters at 1 Riverside Plaza in Columbus, Ohio), the delivery personnel shall be granted access and the delivered item may be left secure in the foyer.

1.4.2 Data Accuracy, Integrity and Confidentiality – Transmission

1.4.2(A) Data may be transmitted by either facsimile or e-mail.

1.4.2(B) While data transmission by phone may occur, it is strongly discouraged. If verbal transmission of data via the phone does, however, occur, then immediate follow-up of this transmission with a facsimile or e-mail communication is required.

1.4.2(C) All e-mail communications issued by the Dolan Chemical Laboratory primary chemists are required to include a confidentiality statement. This e-mail confidentiality statement reads as follows:

(a) IMPORTANT! This e-mail message is intended for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential, and exempt from disclosure under applicable law. If the reader of this message is not the intended recipient or the employee or agent responsible for delivering this message to the intended recipient, you are hereby notified that any dissemination, distribution or copying, or other use of this message is strictly prohibited. If you receive this message in error, please notify the sender immediately by reply e-mail, and destroy all copies of the original message.

1.4.2(D) All facsimile communications issued by the Dolan Chemical Laboratory primary chemists must include cover pages that include a similar confidentiality statement. This facsimile cover page confidentiality statement reads as follows:

(a) **IMPORTANT! The Accompanying message is intended for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential, and exempt from disclosure under applicable law.** If the reader of this message is not the intended recipient or the employee or agent responsible for delivering this message to the intended recipient, you are hereby notified that any dissemination, distribution or copying, or other use of this communication is strictly prohibited. If you receive this communication in error, please notify us immediately by telephone, and return the message to us at the address above via the United States Postal Service, postage due.

1.4.2(E) **Document 1-9** is a copy of the facsimile cover sheet currently in use by Dolan Chemical Laboratory primary chemists.

1.4.2(F) **AEP's Information Technology Security Policy** is defined in Section 3.3.

Document 1-9 Fax with Confidentiality Statement

<<Click on first page of object to access full document>>

QAM Document 01-09 Fax with Confidentiality Statement, Revision 1, 10.2008.pdf

Revision 1, 10/2008
Form GEN-001

Dolan Chemical Laboratory
4001 Eby Rd
Groveport, OH 43125
Phone: 614-836-4221
Fax: 614-836-4165

GET Environmental Lab East

Fax

To: **From:**

Fax: **Date:**

Phone: **Pages:**

Re: **CC:**

☐ Urgent ☐ For Review ☐ Please Comment ☐ Please Reply ☐ Please Recycle

Comments:

IMPORTANT: This fax message is intended for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential, and exempt from disclosure under applicable law. If the reader of this message is not the intended recipient or the employee or agent responsible for delivering this message to the intended recipient, you are hereby notified that any dissemination, distribution or copying, or other use of this message is strictly prohibited. If you receive this message in error, please notify the sender immediately and destroy all copies of the original message.

1.4.3 Electronic Data and Records, Backup Procedures

1.4.3(A) **Data Reports Generated Electronically —** Electronic data generated by the analytical instruments of the Dolan Chemical Laboratory exist in two primary categories:

(a) Electronic data and records generated by analytical instruments or other laboratory software connected to the AEP Network. This data is backed up in the following manner.

(i) The data shall be copied to the company intranet to a predetermined server space on **at least a weekly schedule**. This may be performed manually or using scheduled backup files.

(b) Electronic data and records generated by analytical instruments or other laboratory software NOT connected to the AEP Network. This data in backed up in the following manner.

(i) The data from the computer shall be backed up at least **weekly** using portable media (e.g. writable CD-ROM or 'memory stick'). The data is then immediately transferred to the AEP network to the predetermined server space.

1.4.3(B) **Laboratory Information Management System (LIMS)**

(a) The Dolan Chemical Laboratory uses dedicated servers to provide computer network access and operations to its internal activities. The Dolan Chemical Laboratory also utilizes "Microsoft SQL Server Software" located on the AEP server to routinely backup the database information from the LIMS.

(b) The Laboratory Information Management System (LIMS) is the primary sample tracking and information management tool used by the Dolan Chemical Laboratory.

(i) The current LIMS is Sample Master, Version 9.0, from Accelerated Technology Laboratories (ATL), Inc. The front end of the system utilizes Microsoft Access 2010, Jet Version 14.0; and the back end of the system utilizes Microsoft SQL Server 2008 R2 (SP1).

(c) Access to the LIMS is password-protected through Windows authentication as opposed to SQL Server authentication (which would require an additional password). (Note: Windows authentication is considered a more secure way of protecting the server and therefore the data.) Each laboratory employee is granted specific levels of access by the LIMS Administrator.

(i) Changes made to analytical data field in the LIMS are documented in an audit trail linked to the user logged into the system.

(d) The LIMS maintains all sample information and other data repository services in multiple "Microsoft SQL Server Software" databases. These files are 1) "SMV9" - Data repository for most current data, 2) "SMV9 Archive" -Data repository for archived data, and 3) "SMV9 Temp" – Temporary data repository that holds data queried by users so that the application will run faster. These hardware and software for these three LIMS database are located on an onsite server ("ohdolandb001").

(e) Periodically sample information for completed samples is transferred from the "SMV9" database to the"SMV9 Archive" database. The archive process is triggered by the size of the "SMV9" database, when the size begins to significantly affect performance. This archive process is generally applicable to all completed and reported samples with review (by QAO*) dates greater than 3 months old.

1.4.3(C) There are two independent backup procedures to these electronic data and records:

(a) Corporate IT Procedures

(i) The laboratory server is backed up to the main corporate servers using an enterprise backup solution called "Tivoli Storage Manager" (TSM). All aspects of the Tivoli system are automated including initiation of backups. Storage volume changes are handled by a virtual storage library which stores data on disk or tape, and which requires no user intervention. The only procedures currently available for the Tivoli System include: adding and removing servers from the backup schedule, dealing with failed backups, and restoring files. These procedures are available from the AEP Information Technology organization.

(ii) The current backup method is incremental. Incremental means that the backup system only backs up files that have changed since the last successful backup. The Tivoli system is configured to retain the last seven revisions of any changed file that still exists, and the last three revisions of any file that has been deleted. Some things that can affect a successful backup are locked files, as in database files; server(s) down, and bad network connections.

(iii) All other policies and procedures concerning AEP IT, its IT security policy, its data retention & backup standard may be accessed through the AEP Intranet.

(b) Dolan Chemical Laboratory Procedures

(i) The LIMS files and all other data stored on the dedicated Dolan Chemical Laboratory servers are included in the nightly tape backup to corporate IT. Because of the need to have immediate and dependable availability of backups, the Dolan Chemical Laboratory also performs multiple daily backups.

(ii) These multiple daily backups are performed every two hours by the “Microsoft SQL Server Software”. The SQL Server software backs up LIMS information into the appropriate database on the Dolan server.

(iii) The Dolan server is then in turn backed up onto the AEP server during the nightly backup.

1.4.3(D) Per ISO 17025 - Section 5.4.7, "computers and automated equipment must be maintained to ensure proper functioning and must be provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data." [Reference 18.4.9]

1.5 Documentation — Controlled quality documents from this Section shall be maintained separately from the Quality Assurance Manual in the following collection (which is itself, a controlled laboratory document):

1.5.1 QCDOC 001 records (relating to the Quality Management System and the QAM, itself) shall be maintained indefinitely, and the quality documents within should be reviewed annually.

QC File 00 6— "QCDOC 001: QAM Maintenance" (in Section 1)

2.0 Management Requirements: Quality System

2.1 Purpose and Scope

2.1.1 Purpose —The purpose of this section is to delineate the Quality Goals and Objectives of the Laboratory and to list the policies to be implemented to achieve the objectives set forth in the furtherance of the overall quality assurance program. This section also serves to define the tasks and responsibilities relating to the preparation, distribution, of the Laboratory's Quality Assurance Manual (QAM) into the proper standardized format.

2.1.2 Scope

2.1.2(A) The objective of the Laboratory Quality Assurance Program is to assure the accuracy, precision and reliability of laboratory results produced for the AEP System or at the request of regulatory or accrediting bodies. Management, administrative, statistical, investigative, and preventive and corrective techniques will be employed to maximize reliability of the data.

2.1.2(B) This section sets forth only the outlines of the management's policies with regard to Quality Assurance. Details for carrying out these policies appear in later sections of the manual. The term 'management system' in the QA Manual means the quality, administrative and technical systems that govern the operations of the Laboratory. The Laboratory's management policies related to quality, including a quality policy statement, are defined in this manual. The overall objectives are also established, and are reviewed during management review (See Chapter 15.0).

2.1.2(C) The instructions in this section regarding the Laboratory Quality Assurance Manual (QAM) apply to all individuals responsible for its preparation or its revisions, as well as other quality manuals.

2.2 Quality Goals and Objectives

2.2.1 The Laboratory shall be willing to cooperate with its customers or their representatives in clarifying the customer's requests and in monitoring the laboratory's performance in relation to the work performed, provided that the laboratory ensures confidentiality to the degree required. Currently, all of the Laboratory's customers are internal to American Electric Power.

2.2.2 Needed improvements and potential sources of nonconformities, either technical or concerning the management system, shall be identified. When improvement opportunities are identified or if preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement.

2.2.3 Quality Policy Statement: The Laboratory management is committed to providing the highest quality analytical data to its customers and demands all laboratory personnel to perform all duties with professionalism, integrity and irrefutable ethical behavior.

2.2.3(A) The Quality Management System, defined in this Quality Assurance Manual, shall serve as guide, a training document, and an undisputed reference for all laboratory personnel in accepting their responsibility to comply with the “International Standard“ (ISO 17025) and to continually improve the effectiveness of the Quality Management System.

2.2.3(B) All laboratory personnel are required to implement the policies, procedures, and guideline defined herein and within other controlled quality documents (e.g. standard operating procedures, SOPs) in order to meet the quality objectives outlined in the next sections (Specific Objectives and Management Objectives) in a safe and efficient manner. [per ISO 17025 Section 4.2.2, Reference 18.4.9]

2.2.4 Specific Objectives

2.2.4(A) To aid in the protection of American Electric Power's system operations by providing legally defensible and scientifically credible analytical and technical support to the corporation.

2.2.4(B) To develop and put into service rugged methods capable of meeting the user's needs for precision, accuracy, sensitivity and specificity.

2.2.4(C) To ensure that all staff members receive training in basic quality technology, in sufficient depth to enable them to carry out the provisions of this manual.

2.2.4(D) To establish the level of quality of the Laboratory's routine performance as a baseline against which to measure the effectiveness of quality improvement efforts.

2.2.4(E) To make any changes in routine methodology found necessary to make it compatible with performance needs as established in Section 2.2.3(D) above.

2.2.4(F) To monitor the routine operational performance of the laboratory through participation in appropriate inter-laboratory testing programs and to provide the corrective actions as necessary.

2.2.4(G) To participate in method validation studies as available and appropriate.

2.2.4(H) To provide a permanent record of instrument performance as a basis for data validation. In addition, this record should provide a means for estimating instrument repair and replacement needs.

2.2.4(I) To establish and maintain a system of effective laboratory record keeping, record storage and retrieval.

2.2.4(J) To document the standard operating procedures (SOP) for the analyses performed by the Laboratory.

2.2.4(K) To continually improve the effectiveness of the management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

2.2.4(L) Specific Objectives for the Flue Gas Analytical Group (FGAG) (Removed 04/2008)

2.2.4(M) Specific Objectives for the Industrial Hygiene Analytical Group (IHAG)

(a) To maintain accreditation for the Industrial Hygiene Analytical Group and the Dolan Chemical Laboratory from the American Industrial Hygiene Association (AIHA).

(b) To maintain accreditation for the Industrial Hygiene Analytical Group and the Dolan Chemical Laboratory from the National Voluntary Laboratory Accreditation Program (NVLAP).

(c) To maintain accreditation for the analysis of bulk asbestos though the states of Virginia and West Virginia.

2.2.4(N) Specific Objectives for the Water and Waste Analytical Group (WWAG)

(a) To maintain accreditation for the analysis of analytes and parameters required by customers of the laboratory though the State of West Virginia's Department of Environmental Protection (DEP).

(b) To maintain accreditation for the analysis of analytes and parameters required by customers of the laboratory though the National Pollutant Discharge Elimination System (NPDES) Stormwater Permitting Program.

(c) To acquire and maintain accreditation for the analysis of analytes and parameters required by customers of the laboratory though the State of Virginia's VELAP (Virginia Environmental Laboratory Accreditation Program) per VAC Title 1, Agency 30, Chapter 46 (1VAC30-46) for Virginia Laboratory Certification [Reference 18.4.20].

2.2.4(O) Specific Objectives for the Plant Services Analytical Group (PSAG) (Reserved)

2.2.5 Management Objectives

2.2.5(A) The Laboratory's management is committed to generating data of the highest quality necessary for fulfilling the Specific Objectives of the department as stated in Section 2.2.3.

2.2.5(B) Laboratory management shall ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system.

2.2.5(C) Top management shall ensure that the appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system.

2.2.5(D) Top management shall provide evidence of commitment to the development and implementation of the management system and to continually improve its effectiveness.

2.2.5(E) Top management shall communicate to the organization the importance of meeting customer requirements as well as statutory and regulatory requirements.

2.2.5(F) Top management shall ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented.

2.2.5(G) The management of the laboratory shall formulate goals with respect to the education, training and skills of the laboratory personnel. The laboratory shall have a policy and procedures for identifying training needs and providing training of personnel. The training program shall be relevant to the present and anticipated tasks of the laboratory. The effectiveness of the training actions taken shall be evaluated.

2.3 Quality Policies

2.3.1 Laboratory Quality Policies

2.3.1(A) Quality activities shall emphasize the prevention of quality problems rather than detection and correction of problems after they occur.

2.3.1(B) All employees engaged in making decisions affecting the quality of Laboratory output shall undergo training programs designed to be commensurate with their positions, duties and responsibilities.

2.3.1(C) The Laboratory shall use published analytical test methods where available.

2.3.1(D) The Laboratory shall have a comprehensive calibration program involving all instrumentation used for making determinations; the results of which are reported.

2.3.1(E) The Laboratory shall use appropriate, fresh reagents and chemicals, certified when necessary, and appropriate, calibrated glassware.

2.3.1(F) The Laboratory shall establish and maintain a total intra-laboratory quality control system to assure continued precision and accuracy of laboratory results.

2.3.1(G) The Laboratory shall participate in inter-laboratory testing programs as prescribed by cognizant accrediting organizations.

2.3.1(H) The Laboratory management is committed to comply with this document (see Section 2.4) and to continually improve the effectiveness of the management system.

2.3.1(I) Specific Quality Policies for the Flue Gas Analytical Group (FGAG) (Removed 04/2008)

2.3.1(J) Specific Quality Policies for the Industrial Hygiene Analytical Group (IHAG)

(a) The Industrial Hygiene Analytical Group of the Dolan Chemical Laboratory shall participate in all AIHA PAT analytes deemed appropriate to the types of samples received by the laboratory. At a minimum, these analytes should include metals, silica, fibers, and bulk asbestos. The inclusion of other offered analytes will be considered, when appropriate under normal laboratory operation.

(b) The Industrial Hygiene Analytical Group of the Dolan Chemical Laboratory shall participate in the NVLAP PAT analytes deemed appropriate to the types of samples received by the laboratory. At a minimum, this should include bulk asbestos. The inclusion of other offered analytes will be considered, when appropriate under normal laboratory operation.

2.3.1(K) Specific Quality Policies for the Plant Services Analytical Group (PSAG) (Removed)

2.3.1(L) Specific Quality Policies for the Water and Waste Analytical Group (WWAG)

(a) The Water and Waste Analytical Group of the Dolan Chemical Laboratory shall participate in all "WP studies" from an approved vendor on analytes deemed appropriate to the types of samples received by the laboratory, as required by the Virginia Environmental Laboratory Accreditation Program (VELAP) and State of West Virginia's Department of Environmental Protection (DEP).

(b) The Water and Waste Analytical Group of the Dolan Chemical Laboratory shall participate in all "DMR studies" from an approved vendor on analytes deemed appropriate to the types of samples received by the laboratory, as required by the National Pollutant Discharge Elimination System (NPDES) Stormwater Permitting Program.

2.3.1(M) In compliance with NELAC 5.4.2.3(p) ["NELAC 2003 Standard", Reference 18.4.1] and 1VAC30-46 [Reference 18.4.20], departures from the laboratory's quality policies and procedures, and the allowance of exceptions and consideration of contingent situations may only be permitted by written approval by the laboratory management or the appropriate designee. All such departures, exceptions, or contingencies shall be documented in the appropriate report packet in addition to documentation as a Non-conformance in the CPAR database (See Section 9.2.3(C)).

2.3.2 Laboratory Principles of Conduct

2.3.2(A) Ethical conduct means doing the right thing. It means being correct from the standpoint of law, propriety and social judgment. It also means avoiding any actions which would violate or appear to violate these standards.

(a) As a practical matter, though, laboratory personnel can encounter situations in which one's ethical compass can become disoriented. Sometimes laboratory personnel may not be familiar with the relevant body of law. Other times, prevailing custom or practice may not offer suitable guidance.

(b) Depending on the situation, AEP has developed various procedures and resources for resolving ethical questions. As employees of AEP, Dolan Chemical Laboratory personnel are responsible for knowing and complying with the laws and standards of ethical conduct related to the performance of the laboratory's jobs.

2.3.2(B) Employees and their contributions to the laboratory workplace are the AEP Dolan Chemical Laboratory's most valuable assets. Recognizing this, it is to the AEP's competitive advantage to help create a culture that, among other things:

(a) fosters innovation and creativity,
(b) encourages participation and teamwork,
(c) enables open communication and the sharing of best practices,
(d) rewards excellence,
(e) promotes safety and health,

(f) does not tolerate discrimination or harassment,
(g) mandates all employees be treated with dignity and respect, and
(h) provides opportunities for training, development, and the resources needed to do the jobs in a professional manner.

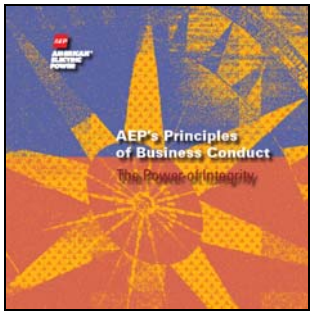
2.3.2(C) The goal of these principles of conduct is to nurture a culture that supports ethically sound behavior and instills a sense of shared accountability among employees. Additionally, these principles prevent involvement in any activities that would diminish confidence in the competence, impartiality, judgment or operational integrity of the laboratory and its employees. In order to meet this policy, employees must adhere to AEP's Drug and Alcohol Testing Program and AEP's Principles of Business Conduct (See Document 02-01).

2.3.2(D) All employees should read, and refer to **AEP's Principles of Business Conduct** in **Document 02-01.** Procedures for resolving ethical questions are given in the following reference and subjects such as business relationships, political and governmental relations, protection of corporate assets, and responsibility to the environment are addressed. Compliance with the policies cited in this document is required of all personnel.

(a) The following is a link to the AEP intranet webpage: "AEP's Principles of Business Conduct" with links to a printable version of "AEP's Principle of Business Conduct- the Power of Integrity", Revision 02/2006 (which is identical to Document 02-01 below) :
http://ethics.aepsc.com/Principles/default.htm

Document 2-1 AEP's Principles of Business Conduct – The Power of Integrity

(38 page pdf) <<Click on first page of object to access full document>



(b) All employees should also view the corresponding video **"AEP's Principles of Business Conduct"** in **Document 02-02.** The following is a link to the AEP intranet webpage(s): "AEP's Principles of Business Conduct" with links to the video (and downloads in different video formats), "AEP's Principle of Business Conduct- the Power of Integrity", Revision 2007:

(i) http://aepnow.aepsc.com/aeptv/chooser.asp?clipID=949&bhcp=1 (link to intranet video)

(ii) http://aepnow.aepsc.com/aeptv/download.asp?clipID=949 (link to downloads)

Document 2-2 AEP Principles of Business Conduct (video)

<<Click on the link to access full document>>

Use the following link for Document 02-02:
http://aepnow.aepsc.com/aeptv/chooser.asp?clipID=949&bhcp=1 (link to intranet video)

2.3.2(E) Personnel of the Laboratory must avoid involvement in any activity that would diminish confidence in the laboratory's competence, impartiality, judgment, or operational integrity.

2.3.2(F) Undue pressure may adversely affect the quality of a laboratory's work. As such, the Laboratory attempts to ensure that management and employees are free of such undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work. If, in the opinion of any individual employee, a situation arises that the employee feels undue pressure that is affecting or may affect the quality of work done, then the Laboratory Manager must be immediately notified. This notification must be documented.

(a) Dolan Chemical Laboratory is separate from financial, production, marketing and plant-induced stresses, which may be viewed as potential conflicts of interest. AEP is compliant with Sarbanes-Oxley Act of 2002, and the organizational relationships have been outlined in the organizational charts (See Documents 01-01 through 01-07).

2.3.2(G) Action with respect to ascertaining the scope and origin of this pressure shall be taken. Follow-up actions to alleviate this pressure must occur and be documented. If, in the opinion of the employee, this action does not provide a resolution to the situation, then this situation and all its particulars must be relayed to the Office of Corporate Compliance. Contact with this office may be made through the following link:

(a) The following is a link to the AEP intranet webpage: **"Ethics and Compliance; FAQ for the Concerns Line"** which is shown in **Document 02-03:** http://ethics/Report/FAQsforConcernLine.htm

(b) Ethical questions or concerns can be relayed anonymously to the AEP Concerns Line by calling 1-800-750-5001 (TTY 1-877-576-2569) or can be filed online by the weblink – http://www.aepconcernsline.com .

(c) Issues that do not require anonymity may be placed to the Ethics and Compliance Helpline within AEP by calling using the Audinet 8+200-6226. Detailed descriptions of how this hotline works and its call processes are outline on the AEP Ethics and Compliance Website – http://ethics/ -.

2.3.3 All employees of the laboratory should also read, understand, and refer to **the American Chemical Society's (ACS) "The Chemical Professional's Code of Conduct"** in **Document 02-04.**

2.3.3(A) The following is a link to the American Chemical Society (ACS) internet webpage: http://portal.acs.org/portal/acs/corg/content?_nfpb=true&_pageLabel=PP_ARTICLEMAIN&node_id=1095&content_id=CTP_004007&use_sec=true&sec_url_var=region1;

(a) This can also be accessed from the ACS Home Page (**http://www.chemistry.org**) by choosing "Careers", then the link to **"The Chemical Professional's Code of Conduct" under** "Ethics and Professional Guidelines".

Document 2-3 FAQ's for Concern Line
(Page 1 of 2) **<<Click on first page of object to access full document>>**

Frequently Asked Questions

Our goal is to nurture a culture that supports ethcally sound behavior and instills a sense of shared accountability among employees.

What is the AEP Concerns Line?

The AEP Concerns Line is a simple way for you to report on activities that may involve potential violations of *AEP's Principles of Business Conduct*, other Company policies, or the law. The AEP Concerns Line is managed by an independent communications firm hired by AEP to ensure the integrity and objectivity of compliance reporting. You can call the AEP Concerns Line toll-free, 24 hours a day at 1-800-750-5001 or report a concern online at https://www.aepconcernsline.com/

Why is the AEP Concerns Line important to the Company?

As outlined in *AEP'S Principles of Business Conduct*, AEP is committed to conducting business within high ethical standards in compliance with all applicable laws. The AEP Concerns Line - with the support of all employees - is an effective, alternative way to report potential violations of *AEP's Principles of Business Conduct*, other Company policies, or the law.

Who should use the AEP Concerns Line?

You should... if you have information about possible violations of *AEP's Principles of Business Conduct*, other Company policies, or the law. Call the AEP Concerns Line if you are uncomfortable with the direct approach or if you believe further action is warranted.

What should be my first step?

We encourage you to discuss your concerns with your supervisor or others in your management. If you feel unable to do this or your previous concerns have not been addressed, contact AEP Ethics & Compliance (E&C) directly or through the AEP Concerns Line.

Document 2-3 FAQ's for Concern Line
(Page 2 of 2) <<Click on first page of object to access full document>>

What should I report to the AEP Concerns Line?
If you are reluctant to address questions to your own management first or if you feel you need further guidance, you can call the AEP Concerns Line about a wide variety of issues outlined in *AEP's Principles of Business Conduct*, as well as other illegal conduct that may affect you, your co-workers, or the company in our day-to-day business lives.

Questions seeking guidance on ethical issues not requiring anonymity can be addressed directly to E&C through the Ethics & Compliance Helpline at audinet number 8-200-OCCO (6226) or, again anonymously through the AEP Concerns Line.

Do I have to give my name?
No. Your call to the AEP Concerns Line is answered by an independent, third-party, communications firm. Your call is assigned a special coded number you can refer to during any follow-up calls. You are not required to identify yourself.

What happens when I call?
The communications specialist will document the reported information and generate a written report that will be forwarded to E&C. After review, the report either will be assigned to the appropriate department to initiate an inquiry or will be investigated directly by E&C. AEP's Chief Compliance Officer has mandated that all concerns must be adequately investigated and brought to closure.

After investigation, only substantiated allegations will result in disciplinary or legal action if deemed appropriate.

We are as concerned with preserving the reputation of those who are the subject of a call as we are with preserving the identity of the caller. And remember, your name is never required.

What if I don't have all the facts?
Call the AEP Concerns Line even if you do not have all the facts. E&C will look into the information that you provide, attempt to verify it and take appropriate action.

Document 2-4 The Chemical Professional's Code of Conduct
(Page 1 of 2) <<Click on first page of object to access full document>>

From the American Chemical Society webpage (www.chemistry.org) — (Revision 12/13/07)

American Chemical Society

Publications Meetings Careers Membership & Networks Education
Policy Funding & Awards Press Room
You Are Here: Home > Careers > Ethics & Professional Guidelines

The Chemical Professional's Code of Conduct

The American Chemical Society expects its members to adhere to the highest ethical standards. Indeed, the Federal Charter of the Society (1937) explicitly lists among its objectives **"the improvement of the qualifications and usefulness of chemists through high standards of professional ethics, education and attainments..."** The chemical professional has obligations to the public, to colleagues, and to science.

"The Chemist's Creed," was approved by the ACS Council in 1965. The principles of The Chemist's Code of Conduct were prepared by the Council Committee on Professional Relations, approved by the Council (March 16, 1994), and replaced "The Chemist's Creed". They were adopted by the Board of Directors (June 3, 1994) for the guidance of Society members in various professional dealings, especially those involving conflicts of interest. The Chemist's Code of Conduct was updated and replaced by The Chemical Professional's Code of Conduct to better reflect the changing times and current trends of the Society. It was approved by Council on March 28, 2007 and adopted by the Board of Directors on June 2, 2007.

Chemical Professionals Acknowledge Their Responsibilities

To the Public

Chemical professionals have a responsibility to serve the public interest and safety and to further advance the knowledge of science. They should actively be concerned with the health and safety of co-workers, consumers and the community. Public comments on scientific matters should be made with care and accuracy, without unsubstantiated, exaggerated, or premature statements.

To the Science of Chemistry

Chemical professionals should seek to advance chemical science, understand the limitations of their knowledge, and respect the truth. They should ensure that their scientific contributions, and those of their collaborators, are thorough, accurate, and unbiased in design, implementation, and presentation.

Document 02-04 The Chemical Professional's Code of Conduct
(Page 2 of 2) <<Click on first page of object to access full document>>

To the Profession

Chemical professionals should strive to remain current with developments in their field, share ideas and information, keep accurate and complete laboratory records, maintain integrity in all conduct and publications, and give due credit to the contributions of others. Conflicts of interest and scientific misconduct, such as fabrication, falsification, and plagiarism, are incompatible with this Code.

To Their Employer

Chemical professionals should promote and protect the legitimate interests of their employers, perform work honestly and competently, fulfill obligations, and safeguard proprietary and confidential business information.

To Their Employees

Chemical professionals, as employers, should treat subordinates with respect for their professionalism and concern for their well-being, without bias. Employers should provide them with a safe, congenial working environment, fair compensation, opportunities for advancement, and proper acknowledgment of their scientific contributions.

To Students

Chemical professionals should regard the tutelage of students as a trust conferred by society for the promotion of the students' learning and professional development. Each student should be treated fairly, respectfully, and without exploitation.

To Associates

Chemical professionals should treat associates with respect, regardless of the level of their formal education, encourage them, learn with them, share ideas honestly, and give credit for their contributions.

To Their Clients

Chemical professionals should serve clients faithfully and incorruptibly, respect confidentiality, advise honestly, and charge fairly.

To the Environment

Chemical professionals should strive to understand and anticipate the environmental consequences of their work. They have a responsibility to minimize pollution and to protect the environment.

For more information about the Department of Career Services, Please see our Contacts List.

2.3.4 Laboratory Ethics and Data Integrity

2.3.4(A) Laboratory Ethics and Data Integrity Policy

(a) All laboratory personnel shall adhere to the **Laboratory Ethics and Data Integrity Procedures** (See Section 2.3.4(B)(d)).

(b) All laboratory personnel shall promote data integrity principles and promote ethics in the lab by discouraging improper conduct and encouraging proper conduct. Laboratory personnel shall remain honest and impartial and serve with devotion to their employer, customers, and the public. Laboratory personnel shall strive to provide accurate results with clearly defined limitations; and to present reports protected from misinterpretation or misuse. Laboratory personnel shall also strive to enhance the reputation of their profession throughout the company, with customers, and from external perceptions.

(c) No laboratory personnel shall condone nor participate in fraudulent practices including, but not limited to fabricating data, misrepresenting QC results, performing unacceptable equipment calibrations, altering samples, improperly manipulating sample results, substituting samples/files/data, or falsifying records. Laboratory personnel shall oppose and refrain from incompetent and fraudulent sample handling, preparation, analyses, testing, validation and reporting. Laboratory personnel shall report any discoveries of misconduct to their immediate supervisor or through the company's Ethics and Compliance Program.

(d) All laboratory personnel must inform their employer of any business connections, interests, or affiliations that might influence their judgment or prevent unbiased decision-making and performance. Laboratory personnel must also declare potential adverse consequences that may occur if their professional judgment is ignored. No laboratory personnel shall disclose information concerning the business affairs or technical processes of the company (or former employer) or customer without their consent.

(e) Laboratory employees must understand that any breach of the laboratory data integrity procedures shall result in an investigation that could lead to very serious consequences including termination or civil/criminal prosecution.

(f) The handling of complaints due to an ethics investigation is discussed in Section 8.2.1(F).

2.3.4(B) **NELAC Requirements —** The NELAC standard requires the laboratory to establish and maintain data integrity procedures that address the following four elements: "1) data integrity training, 2) signed data integrity documentation for all laboratory employees, 3) in-depth, periodic monitoring of data integrity, and 4) data integrity procedure documentation." ["NELAC 2003 Standard", Reference 18.4.1]

(a) **Laboratory Ethics and Data Integrity Training** (as defined in Section 16.9.3) for all Laboratory personnel with special emphasis on laboratory situations and activities shall be conducted annually.

(b) **Documentation** — Attendance and training content records shall be developed. These records shall be kept in **QADOC 009: Personnel Records**.

QC File 00 7— "QCDOC 009: Personnel Records" (in Section 2)

(c) **Data Integrity Monitoring** (as defined in Section 24.4.3)— In-depth periodic monitoring shall be performed by the QAO* (or designee) during the Data Validation of analytical reports. This too, requires **documentation** as it is performed.

(d) **Laboratory Ethics and Data Integrity Procedures** are outlined in detail in the relevant procedure (Section 16.9.3(B)). This procedure must be authorized and reviewed annually by management. The procedure and the annual review requires signature(s) and date(s) from the laboratory management.

2.4 Quality Assurance Manual (QAM)

2.4.1 Role of the QAM

2.4.1(A) This manual is issued to describe the quality assurance system employed at the Laboratory in compliance with the intent of general management system requirements.

(a) This document is the Quality Assurance Manual (QAM) for the Dolan Chemical Laboratory, a department of the American Electric Power Corporation's Analytical Chemistry Services.

(b) The QAM details the activities and evaluation criteria necessary to ensure that analytical data generated by the laboratory are of high and known quality and meet the scientific objectives of the department and are in compliance with NELAC standards and VAC Title 1, Agency 30, Chapter 46 (1VAC30-46) for Virginia Laboratory Certification [Reference 18.4.20].

(c) American Electric Power Corporation's Analytical Chemistry Services believes that adherence to the policies detailed in this document will help meet these objectives and that all employees of the Dolan Chemical Laboratory must become familiar with this and other quality system documents.

(d) The QAM also documents procedures intended to ensure that all data generated within the department are subjected to sound quality assurance (QA) management practices.

2.4.1(B) The policy of the Dolan Chemical Laboratory is to apply this quality assurance system to all testing and analytical activities undertaken for the American Electric Power (AEP) System or an accrediting organization.

2.4.1(C) The manual provides personnel and users of the Dolan Chemical Laboratory with a description of company policy for maintaining an effective and economical quality assurance system planned and developed in conjunction with other management planning functions.

2.4.1(D) Written procedures for implementing the policy described herein are amplified by the several sections comprising this manual. These procedures represent minimum standards that are binding on all personnel of the Dolan Chemical Laboratory.

2.4.2 Preparation of the QAM and other quality manuals

2.4.2(A) The Quality Assurance Officer (QAO)* (or designee) bears the primary responsibility for the preparation, issue, review and upkeep of the Laboratory Quality Assurance Manual (also referenced in Section 3.4.2(A).).

2.4.2(B) The Quality Assurance Manual will be published using the standard format on which this section appears. For details on the use and implementation of this format, see "Method # ACS-DCL-GP-QAQC-002: Guidelines and Format for Methods at AEP Analytical Chemistry Services" [Reference 18.4.11].

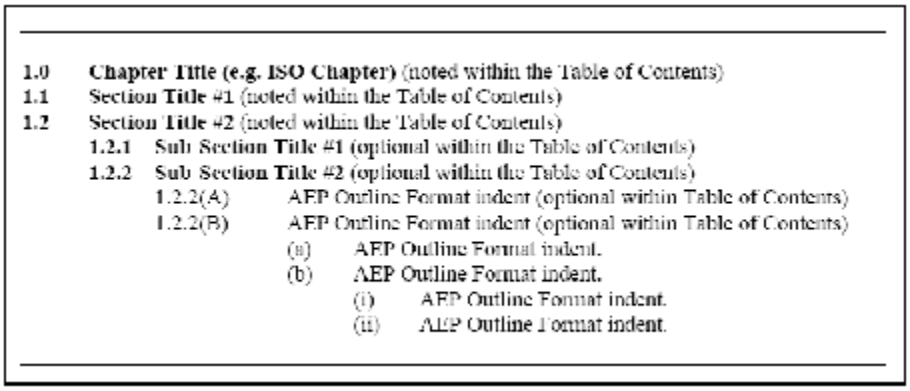
(a) The "Guidelines and Format for Methods at AEP Analytical Chemistry Services" has been prepared to promote consistency among analytical methods and laboratory procedures, and to streamline the method promulgation process. Methods produced or approved by outside organizations must be revised into the guidelines and format presented in this document.

(b) This document adheres to the guidelines and format presented herein, when applicable.

2.4.2(C) This quality manual utilizes the Modified Decimal Numbering (MDN) system to organize material in a standardized outline format such as in the subsequent example in **Document 02-05**. (The proper outline format is designated the "AEP Outline Format" style within formatting instructions for individual documents.)

Document 2-5 Quality Documents Outline Format

<<Click on first page of object to access full document>>



1.0 **Chapter Title (e.g. ISO Chapter)** (noted within the Table of Contents)
1.1 **Section Title #1** (noted within the Table of Contents)
1.2 **Section Title #2** (noted within the Table of Contents)
1.2.1 **Sub Section Title #1** (optional within the Table of Contents)
1.2.2 **Sub Section Title #2** (optional within the Table of Contents)
1.2.2(A) AEP Outline Format indent (optional within Table of Contents)
1.2.2(B) AEP Outline Format indent (optional within Table of Contents)
(a) AEP Outline Format indent.
(b) AEP Outline Format indent.
(i) AEP Outline Format indent.
(ii) AEP Outline Format indent.

2.4.3 QAM Organization

2.4.3(A) The Quality Assurance Manual contains all procedures and policies relating to the overall operation of the Laboratory. As such, it describes those activities that encompass common activities and actions. Examples are material and sample receipt, sample retention and equipment calibration and maintenance.

2.4.3(B) Those practices and procedures that are unique to the operation of a specific analytical group of the Laboratory are also delineated in the QAM. Most practices and procedures are not unique and are therefore referenced to the Laboratory's Quality Assurance Manual.

(a) In addition, if the practice or procedure is felt to be unique and for a single type of analysis, then such practice or procedure will be included in the individual SOP manual appropriate to the practice or procedure.

(b) The individual SOPs contain information specific to that analytical procedure, such as the specific analytical method, specific analytical references and the quality assurance/quality control activities specifically required by that analytical procedure.

2.4.4 Quality Manual Format—Use of the Manual Standard Format Sheet

2.4.4(A) The Laboratory Quality Assurance Manual Format will be prepared as a Microsoft Word document and shall cite the following information:

(a) The Section Title shall correspond to the quality element from the ISO Sections in Chapters 4 and 5 of ISO 17025:2005(E) [Reference 18.4.9].

(b) Cite the name (or initials) of the individual preparing (or revising) this document.

(c) Cite the name (or initials) of the individual approving this document.

(d) Cite the Revision Number of the document

(i) It is suggested to increase the revision number by a whole number each year (i.e. Revision 1.0 in 1995, Revision 2.0 in 1996, etc.) and to increase the first decimal for revisions throughout the year (e.g. Revision 2.1 as the first revision changes in 1996, Revision 2.2 next, etc.).

(ii) It is also suggested to attach a letter for un-approved drafts which have been circulated for review (e.g. designate the draft of changes to be approved as Revision 2.3, as "Revision 2.3A".

(e) Cite the Revision Date as described below in Section 2.4.4(C)(b).

(f) Cite the Effective Date as described below in Section 2.4.4(C)(b).

(g) Type the text material in the AEP Outline Format using MDN numbering as described in Section 2.4.2.

2.4.4(B) The Section Number of the element (based on the ISO elements from Chapters 4 and 5 from ISO 17025:2005) [Reference 18.4.9], taken from the primary listing in the Table of Contents. As listed, each page and Attachment will include a numbering that includes the Section Number as the primary element.

2.4.4(C) **Format Notes**

(a) Each page of the manual shall have a header. This header is composed of two lines.

(i) The first line of the header shall read: "Method # ACS-DCL-GP-QAQC-001: AEP DOLAN CHEMICAL LABORATORY QUALITY ASSURANCE MANUAL".

(ii) The second line of the header shall designate the Section Number and Section Title (i.e. based on ISO 17025 chapters).

(iii) This header is left-justified.

(b) Each page of the manual shall contain a footer. This footer is composed of two parts.

(i) The first, left-justified part includes the name (or initials) of the person(s) generating (or revising) and/or approving that section of the document and the entire document Revision Number (As stated on the Cover and Title Pages).

(ii) The second right-justified part of the footer includes the Revision Date, the Effective Date and the page numbers.

— The Revision Date refers to the date the section was last revised (or generated).

— The Effective Date refers to the date that this section was originally generated and became effective.

— The page numbers should be in a format to include the Section Number, and shall differentiate the actual page number ("x") in relation to the total number of pages in the particular section ("y") (i.e. "Page 2-x of 2-y")

(c) The end of each section of the Quality Assurance Manual may be identified by locating the last page in the "total number of pages in the particular section ("y")" as described in the previous paragraph.

2.4.5 Standard Operating Procedures (SOP)

2.4.5(A) **SOP Identification —** Each SOP will have its own unique identification, which consists of five different elements. The five identification elements consist of:

(a) "ACS" - to signify an Analytical Chemistry Services document;
(b) "DCL" - to signify an Dolan Chemical Laboratory document;
(c) "IH", "PS", "WW" , or "GP" – to signify the Analytical Group Designation;
-Industrial Hygiene Analytical Group (IH)
-Plant Services Analytical Group (PS)
-Water and Waste Analytical Group (WW)
- General Purpose (GP)
(d) (matrix designation) – four to five letter matrix designation (e.g. water, waste, ih, oils, coal, pw);
(e) (three-digit number) – each SOP has its own number.

(f) **The resulting SOP manual identification would appear, for example, as follows:**

(i) ACS.DCL.WW.water.028 is the WWAG Sulfide in water SOP;
(ii) ACS.DCL.WW.waste.005. is the WWAG Flash Point of Waste SOP; and
(iii) ACS.DCL.IH.ih.001. is the IHAG Bulk Asbestos SOP.

(g) SOPs are saved with the SOP Identification, the Revision Number and the Effective Date in the file name.

2.4.5(B) **SOP Forms —** Each form will have its own unique identification, which consists of two elements. The two identification elements are as follows of:

2.4.5(C) **Laboratory Forms —** Each form will have its own unique identification, which consists of two elements. The two identification elements are as follows of:

(a) (two or three letter designation) – designates use of Form. Examples of Forms associated with:

- Chemical Hygiene Plan (CHP)
- Demonstration of Capability (DOC)
- General Laboratory Use (GEN)
- Method Detection Limits (MDL)
- QA Reports (QAR)
- Safety (SAF)
- Training (TR)
- Verification (VER)

(b) (three or four-digit number) – each Form has its own number.

(i) To identify the Analytical Group, use 10x for IHAG, 40x for PSAG and 70x for WWAG.

(ii) To identify Quality Control Report Forms (000x general, 030x doc control, 080x Complaints, 090x NC, 130x records control, 140x audits, 150x MR, 160x personnel, 180x method, 240x reports)

(iii) This identification may include a combination of eight characters and/or numbers divided into six primary elements.

2.5 Documentation — Controlled quality documents from this Section shall be maintained separately from the Quality Assurance Manual in the following collection (which is itself, a controlled laboratory document):

2.5.1 QCDOC 001 records (relating to the Quality Management System and the QAM, itself) shall be maintained indefinitely, and the quality documents within should be reviewed annually.

QC File 00 8— "QCDOC 001: QAM Maintenance" (in Section 2)

3.0 Management Requirements: Document Control

3.1 Purpose and Scope — This section describes how the Laboratory controls the issue and retrieval of all documents relating to the analytical and testing activities of the laboratory, to the control of quality of these activities and to the storage and security of the technical documentation generated by these activities. The controls described in this section are limited to the documents and reports listed below, and do not affect documentation related to other laboratory management activities. Such document control procedures are described in other laboratory standard operating procedures. This section also serves to define the tasks and responsibilities relating to the review and maintenance of the Quality Assurance Manual (QAM).

3.1.1 More detailed procedures for the document control of specific items within the laboratory are outlined in **Chapter 13.0 – Control of Records.**

3.2 Quality Documentation and Records Control

3.2.1 Document Control Elements-The most important elements of the quality assurance program to which document control is applicable include:

3.2.1(A) Sampling Procedures (See Section 21.0, **QCDOC 014**)
3.2.1(B) Calibration Procedures (See Section 19.0, **QCDOC 012**)
3.2.1(C) Reference Analytical Test Methods and Procedures (See Section 18.0, **QCDOC 0015**)
3.2.1(D) Data Collection and Reporting Procedures ** (See **QC DOC 006**)
3.2.1(E) Auditing Procedures (See Section 14.0, **QCDOC 007 and QCDOC 008**)
3.2.1(F) Data Collection and Reporting
3.2.1(G) Computational and Data Validation Procedures** (See **QC DOC 006**)
3.2.1(H) The Quality Assurance Manual (QAM) (See Section 3.4.2, **QCDOC 001**)
3.2.1(I) The Quality Assurance Plans for the Associated Analytical Groups (See Section 18.3, and **Quality System (QS) Records)**
3.2.1(J) Analytical and Testing Reports ** (See **QC DOC 006**)
3.2.1(K) Laboratory Notebooks ** (See **QC DOC 006**)
3.2.1(L) Validation Reports (See Section 18.0, See **QCDOC 011**)
3.2.1(M) Vendor and Internal Audit Reports (See Section 14.0, **QCDOC 007**)
3.2.1(N) Calibration and Preventive Maintenance Records (See Section 19.0, **QCDOC 012**)
3.2.1(O) Chain-of-Custody Documentation ** (See **QC DOC 006**)

3.2.1(P) Technical Documentation and Regulations ** (See **QC DOC** list in **Document 03-02**)

3.2.1(Q) Corrective Action Requests (See Section 11.0, **QCDOC 005**)

3.2.1(R) Software (See Section 3.3, **QCDOC 001, and the "Document Control- Master List of Controlled Documents"**)

3.2.1(S) Equipment Manuals (See Section 19.0, **QCDOC 015**)

3.2.1(T) Forms (See Section 2.4.5(C), **QCDOC 001, and the "Document Control- Master List of Controlled Documents"**)

3.2.1(U) Client Communications (See Section 7.0, **QCDOC 004**)

Note: ** Items marked with an (**) are addressed within Section 13.0 Control of Records and are maintained in **QCDOC 006**. The remaining items in this list are addressed in the Sections listed in the parentheses.

3.2.2 Document Maintenance and Disposition- The maintenance and disposition of documents are different for the three analytical groups. It should be noted that the individual analytical notebooks will be stored in the laboratory areas appropriate to their usage. After their completion, they may be kept for a short time in that area, but should eventually be transferred to the Record Storage Room (Room 220). All such notebooks generated by the Water and Waste Analytical Group may be discarded after 5 years. All other notebooks are kept indefinitely. All raw data generated by instrumental output are stored similarly to the analytical notebooks.

3.2.2(A) Industrial Hygiene Analytical Group (IHAG)—The Industrial Hygiene Analytical Group (IH) records listed above that are generated and maintained as hard copy reports will be retained for at least one year in the primary Laboratory files. These files will then be transferred to the Record Storage Room (Room 220) and **retained indefinitely.**

3.2.2(B) Plant Services Analytical Group (PSAG) — The Plant Services Analytical Group (PS) records listed above that are generated and maintained as hard copy reports will be retained in the primary Laboratory files for at least one year. A copy of the records may also be retained by the primary analyst. These files will then be transferred to the Record Storage Room (Room 220) and **retained for five years.** Long-term retention of PS records is determined on a case-by-case basis.

3.2.2(C) Water and Waste Analytical Group (WWAG) — The Water and Waste Analytical Group (WW) records listed above that are generated and maintained as hard copy reports will be retained in the primary Laboratory files for at least one year. A copy of the report may also be maintained by the primary chemist. These files will then be transferred to the Record Storage Room (Room 220) and **retained for five years.** All raw data (analysis notebooks, instrument printouts, strip charts, etc.) are also stored in their designated laboratory area for at least five years and may be discarded with the associated primary files.

3.2.2(D) Records and controlled quality documents stored in the Record Storage Room (Room 220) are protected due to the nature of the room. The room is fire-proof and is protected from destructive environmental conditions. Additionally, it is a requirement to sign a Record Storage Logbook when removing and returning controlled documents from the room.

3.2.2(E) All records shall be retained for the required retention time from final report date. The laboratory must maintain all information necessary for the historical reconstruction of data. Records stored on personal computers will be backed up on the company net where the AEP Information Technology division can recover it if necessary.

3.2.2(F) In the event that the laboratory transfers ownership or goes out of business, clients will be contacted and arrangements to either destroy or transfer the copies of their information will be made.

3.2.3 Document Control Protocol

3.2.3(A) **Master List—** The "**Document Control- Master List of Controlled Documents**" identifying the current revision status, distribution, and "date of last review" of quality system documents in the Laboratory management system is retained by the QAO. These records are maintained in **QCDOC-001 QUALITY SYSTEM (QS) Records.** Referral to this list shall preclude the use of invalid and/or obsolete documents.

(a) **The** "**Document Control- Master List of Controlled Documents"** contains the following parts (and the entire document is included in this QAM):

(i) Master List of External Sources
(ii) Master List of Laboratory Forms
(iii) Master List of Laboratory-Generated Documents
(iv) Master List of QAM Documents
(v) Master List of QC DOC Records
(vi) Master List of Software
(vii) Master List of SOPs / Analytical Procedures
(viii) Master List of SOP Forms

(b) The parts of **the** "**Document Control- Master List of Controlled Documents"** contain a description of the quality document, its location, revision number and date (when applicable), Effective Date, cross-reference (when applicable), the date of last (annual) review, and the QA maintenance frequency requirements.

(c) As items require to be updated, the controlled Excel document (located on the AEP shared intranet server) is updated. For the most up to date version of this document, refer to the controlled copy as provided by the QAO, or designee.

3.2.3(B) **Quality System Documents Format**— All quality system documents (QAM, SOPs, etc.) generated by the Laboratory shall be uniquely identified and shall conform to the following document control procedures:

(a) The Revision identification number;
(i) Note: the Original Issue Identification should always be given an identification number of "Revision 0.0".

(b) The original Issue Date and/or Revision Date identification;

(c) Official Approval – approved by signature of:
(i) Manager - Analytical Chemistry Services (Required on QAM only)
(ii) Laboratory Manager - Dolan Chemical Laboratory
(iii) Laboratory Quality Assurance Officer* (QAO);
(iv) Chemical Hygiene Officer (if necessary).

(d) The Approval Date by authorized key personnel;

(e) The Effective Date, which is the date designated by laboratory management that the document shall become valid and in use and shall have been reviewed by the affected personnel.

(i) The Effective Date signifies the date when changes within the revision shall have been implemented until further notification.

(ii) Controlled copies of the previous revision of the quality system document shall be removed from points of use/storage and shall cease to be used by laboratory personnel.

(f) Pagination – Page numbering (where possible),

(i) All quality system documents shall be page-numbered following the "Page X of Y" format, to designate the total number of pages (or another mark to signify the end of the document).

(ii) In addition to indicating the Total Pages in the format of "Page X of Y", the QAM indicates the Section Pages in the format of "Section-Page X of Section-Page Y".

(g) Standard operating procedures (i.e. "SOPs") should be published using the standard format as detailed in "Method # ACS-DCL-GP-QAQC-002: Guidelines and Format for Methods at AEP Analytical Chemistry Services" [Reference 18.4.11]. This format requires the same information that is outlined in the National Environmental Laboratory Accreditation Conference (NELAC) Quality System Document, Chapter 5.0 ["NELAC 2003 Standard", Reference 18.4.1].

3.2.3(C) **Issue —** All quality system documents issued (made available and accessible) to personnel in the Laboratory as part of the management system shall be reviewed and approved by the Laboratory Manager and the QAO* (or designees) prior to use.

(a) The QAO* (or designee) will maintain full control over the distribution of documents listed in Section 3.2.1, above. All individuals seeking a controlled copy of a quality document(s) must approach the QAO* (or designee) with their request. This person shall then become responsible for the location of the controlled document(s) and its subsequent return to the QAO* upon request.

(b) Security — Controlled quality documents are prepared in flexible electronic formats (e.g. Microsoft Excel, Microsoft Word, etc.) with locks and password protection required for modification.

(i) The file recommends (and will open without a password) as "Read-only".

(ii) Controlled quality documents that are electronically available shall automatically add a watermark notation (e.g. "Uncontrolled Copy") upon printing.

(iii) Cells containing formulas and/or critical formatting within spreadsheets shall be locked and the document protected from unauthorized amendments.

(iv) Electronic records shall be protected from unauthorized amendments.

(v) Where feasible, the document is stored and shared after being converted to a secure file format (i.e. Adobe Acrobat, locked Microsoft Word, etc.), which may also be password protected to additionally prevent copying from and edits to such controlled documents.

3.2.3(D) **Access—** Only certain personnel (as listed in the **Document Control Access Control List, Document 03-01**) have "Read/Write" capabilities (and access to the password(s)) to edit such controlled quality documents. This means that the "Editor" personnel can make any editorial changes, per the guidelines of this document.

(a) Many controlled quality documents are then converted to a secure locked .pdf (portable document format) file (i.e. Adobe Acrobat format). Some controlled quality documents remain in the original flexible format (e.g. Microsoft Excel, Microsoft Word, etc.) for use as "Fill- in" forms or spreadsheets with (locked) formula cells.

(b) Access to controlled quality documents in the AEP intranet depository of shared internal files for Laboratory is controlled by the "manager" of the database. Currently, this "manager" is the QAO* (or designee).

(i) All other Laboratory personnel attempting access to these controlled quality documents have a "Reader" status (as listed in the **Document Control Access Control List, Document 03-01**). This means that the "Reader" personnel can view and copy documents from the database, but can not make any editorial changes.

(ii) AEP personnel outside of the Laboratory do not have access to this intranet server.

(c) All individuals seeking "Reader" access to controlled quality documents must approach the QAO* (or designee) for inclusion onto the **Document Control Access Control List** (**Document 03-01**).

3.2.3(E) **Amendments/Revision**— Whenever a change is made to a controlled document, the QAO* (or designee) will issue the new document after necessary laboratory management approval.

(a) This statement is meant to address major changes in the document layout, header and/or footer elements or in the purpose of the original document. Changes of a cosmetic nature, those required by data entry errors or changes dictated by the variable nature of a particular method analyte are not appropriate to this notification procedure.

(b) The QAO* (or designee) is also responsible for monitoring activity to ensure that approved changes are incorporated into the laboratory's routine work activity.

Document 3-1 Document Control Access Control List

<<Click on first page of object to access full document>>

Document Control Access Control List

Personnel	Access Level *
ACS Laboratory Manager, & Manager of DCL QA Officer, DCL Laboratory Supervisor, SCL QA Officer, SCL	**EDITOR** — Read / Write capabilities for controlled quality documents. Access to locked and password-protected controlled quality documents.
Chemists Technicians Clerical All Dolan Chemical Lab Personnel All Shreveport Chemical Lab Personnel	**READER** — Read capabilities for controlled quality documents. No access to locked and password-protected controlled quality documents.

***Other personnel of the AEP System may be allowed access to the QA Manual (or other controlled quality documents) on a reader level.**

QAM Document 03-01 Document Control Access Control List, Revision 4, 07.07.11 Page 1 of 1

(c) Amendments of a cosmetic nature may be performed by hand pending reissue of an approved document. These amendments must be clearly marked, initialed, and dated. The revised approved document must be formally reissued as soon as practicable.

3.2.3(F) **Record of Changes**—A record of changes made within a quality systems document shall be maintained (see Section 3.2.4).

3.2.3(G) **Periodic Review**—All management system documents of the Laboratory shall be reviewed periodically by the QAO* (or designee) as stated in **the "Document Control- Master List of Controlled Documents"** and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements.

(a) The Master list should be updated with the "Date of Last Review" for each quality system document.

(b) All invalid or obsolete documents will be promptly removed from all points of issue or use, or otherwise assured against unintended use. The QAO* (or designee) is responsible for seeing that these copies of invalid or obsolete documents are removed from points of use and are destroyed.

(c) The QAO* (or designee) shall suitably mark all obsolete documents that must be retained for either legal or knowledge preservation purposes.

(d) Periodic Minimums

(i) SOPs (standard operating procedures) should be evaluated every year, or as required.
(ii) Forms should be evaluated at least every five years.
(iii) External Reference Documents should be evaluated at least every five years.
(iv) Other Controlled documents should be evaluated at least every five years.

3.2.4 Procedure for Document Changes

3.2.4(A) A request for such changes to methods, sampling data sheets or calibration instructions, as appropriate to the above qualifications, may be made by anyone; the request shall be made in writing to the QAO*. The changes must be approved by the appropriate laboratory management before the changes are published and distributed.

3.2.4(B) Changes may be promulgated by the issue of entirely new documents, of replacement pages thereto, or for correction of errata, etc. by pen and ink posting on the original document with this action noted on all controlled copies of the document.

3.2.4(C) Amendments of a cosmetic nature may be performed by hand pending reissue of an approved document. These amendments must be clearly marked, initialed, and dated. The revised approved document must be formally reissued as soon as practicable.

3.2.4(D) When feasible, significant changes in documents should be distinguished with a vertical bar on the right side of the page and the new or changed text should be in red font.

3.2.4(E) A synopsis of document changes (revisions) should be addressed in the **Record of Revisions** (i.e. **Appendix Z** for the QAM) or in a **Revision History/ Log** on the **Acknowledgments** page (or elsewhere).

3.2.4(F) The new revision (i.e. from the Original Issue of Revision 0.0, or another Revision) requires an increase in the revision number, as follows:

(a) The revision number identification should be increased in a whole number increment (e.g.. from 4.0 to 5.0), except;

(b) For procedural documents (SOPs, the QAM, etc.), the revision number identification should be increased in a whole number increment if the changes are the result of the annual review.

(i) Otherwise, for changes made throughout the year, the decimal place should be increased (e.g. from 4.0 to 4.1, then 4.2, etc. until the next annual review changes are reflected as 5.0) of the revision number identification.

3.2.4(G) Information related to the quality system document in **the "Document Control- Master List of Controlled Documents"** shall be updated.

3.2.4(H) If the changes from the quality system document have an impact on information in the QAM, corrections to QAM shall also be performed.

3.2.4(I) Upon approval, the relevant authority(ies) shall sign and date the quality system document (thus, yielding the Approval Date). An agreed Effective Date shall also be noted on the quality system document.

3.2.4(J) During the time between the Approval Date and the Effective Date, the laboratory management is required to distribute the (new or revised) quality system document to the affected personnel using one (or more) of the following actions:

(a) NOTIFICATION— The laboratory shall notify affected personnel of changes in the quality system document.

(b) REVIEW— The laboratory allows affected personnel to review the document and all changes since the last revision, and allow personnel to be given the opportunity to ask questions of management or to make comments.

(c) TRAINING—The laboratory may need to train the affected personnel on the proper use of the quality system document, especially noting changes since the last revision.

3.2.4(K) Documentation showing that the affected personnel are aware of, familiar with, and shall adhere to the quality system document shall be produced and maintained. This documentation shall include the personnel signature (or initials) and a date.

3.2.4(L) For Original Issued Documents, upon the Effective Date:

(a) All personnel are required to implement the contents of the quality system document as it relates to their work duties.

(b) Controlled hard copy(ies) of the quality system document (each with a different "Controlled Document Number") shall be distributed to the relevant personnel.

(c) The relevant personnel and the "Controlled Document Number" which they were issued (and a physical location, if possible) shall be noted in **the "Document Control-Master List of Controlled Documents".**

(d) The quality system document shall also be made available to relevant personnel electronically in a secure place in the AEP intranet depository.

(e) A notification shall be sent to relevant personnel with a link to the electronic version of the quality system document, stating that the link is the "Controlled copy".

(i) Copies printed from the AEP intranet depository are deemed "Uncontrolled" and it shall be the responsibility of the person in possession of the "Uncontrolled copy" to verify its ongoing effectiveness (i.e. that no new Revisions have been issued) at the intranet site.

3.2.4(M) For Revised Documents, upon the Effective Date:

(a) All personnel are required to implement the changes to the contents of the quality system document as it relates to their work duties. The previous revision shall become obsolete and shall be superseded by all subsequent revisions.

(b) Controlled hard copy(ies) of the Revised quality system document (each with a different "Controlled Document Number") shall be distributed to the relevant personnel (as listed in **the "Document Control- Master List of Controlled Documents".**

(i) All controlled hard copies of the previous revision of the quality system document shall be retrieved and removed from points of use to prevent further use.

(c) The **"Document Control- Master List of Controlled Documents"** shall be updated.

(d) The electronic version of the Revised quality system document shall be replaced (which is available to relevant personnel electronically in a secure place in the AEP intranet depository).

(e) A notification shall be sent to relevant personnel with a link to the electronic version of the Revised quality system document, stating that the link is the "Controlled copy".

(i) Copies printed from the AEP intranet depository are deemed "Uncontrolled" and it shall be the responsibility of the person in possession of the "Uncontrolled copy" to verify its ongoing effectiveness (i.e. that no new Revisions have been issued) at the intranet site.

(ii) Previous "Uncontrolled copy" revisions of the quality system document shall be destroyed and/or removed from use.

(iii) Copies kept for historic purposes shall be clearly marked as "Obsolete" to prevent their erroneous use within the laboratory.

(iv) Electronic copies of obsolete documents shall automatically contain a watermark notation (e.g. "Obsolete" or "Retired") upon viewing and printing.

3.2.5 Document Distribution and Storage

3.2.5(A) The QAO* (or designee) is responsible for the distribution and retrieval of documents (as detailed in Sections 3.2.4(L) and 3.2.4(M)) and for obtaining all required signatures (as detailed in Section 3.2.4(I).

3.2.5(B) All documents not assigned to an individual will be stored in either a secure file or in the Record Storage Room (Room 220). The security of the individual copies is the responsibility of the individual to whom they are assigned.

3.2.5(C) It is the responsibility of the analyst(s) to verify that the most recent authorized version of a quality document is in use by checking the revision number of the current electronic version (versus any hardcopies in use).

3.2.6 Document/Data Security —All documents, when not in use, will be kept in the appropriate file locations or in the Record Storage Room (Room 220).

3.2.6(A) **The AEP Data Confidentiality Classification Standard** is used by the Laboratory to identify the level of confidentiality of computerized AEP data based on the use, content, and value of the data. The three levels are AEP Public, AEP Confidential, and AEP Confidential Special Handling.

(a) Use of levels of confidentiality helps ensure that sensitive data can be adequately protected from unauthorized alteration, copying, transmission, or destruction as appropriate.

(b) Data generated and used by the Laboratory is classified as "confidential", as this data "could be detrimental to an employer or customer if improperly disclosed".

3.2.6(B) **Confidentiality and Proprietary Rights**

(a) Due to the considerable confidential and proprietary information produced at AEP Dolan Chemical Laboratory, the policy of this organization is to prohibit the communication of any business information about AEP to anyone outside the organization without specific approval from laboratory management. Such information might take the form of analysis data, a customer listing, business plans, financial data, development projects, employee training methods, or any other data.

(b) In addition, all new methods or improvements, products, or inventions developed at AEP Dolan Chemical Laboratory become the exclusive property of AEP.

3.2.6(C) **Client Confidentiality**

(a) Procedures obtained from AEP vendors or suppliers shall remain confidential information unless the laboratory obtains written permission. The written permission must include:

(i) Expressly to whom the information may be sent (company and/or person),

(ii) Exactly what information may be sent, and

(iii) Signature of authority allowing the information to be sent with date of signature.

(b) The written permission, signed, dated and containing all pertinent information discussed above, shall be kept.

3.2.6(D) **Internal Clients**

(a) Data produced for internal clients (those employed by AEP) is considered to be the property of AEP and may be accessed by anyone in the Company with the known authority to do so.

3.2.6(E) **Document Access**

(a) The laboratory shall provide access to records and controlled documents to the relevant parties, as needed. This access shall be maintained for the required document retention period as defined throughout the quality system.

(i) Electronic access shall be secure and shall maintain confidentiality and security as discussed in this section.

(ii) Access to hardcopies shall be maintained secure and confidential due to the limited access and security of the AEP facilities.

(b) Current hardcopies of records are maintained in laboratory file cabinets in the lobby of the Dolan Chemical Laboratory. Current hardcopies of controlled documents are maintained as detailed in **the "Document Control-Master List of Controlled Documents"**.

(c) Archived hardcopies of records and controlled documents are maintained in the Record Storage Room (Room 220). Personnel are required to document the retrieval of items from this location

(d) In the event that the Dolan Chemical Laboratory ceases to exist, all records and documents requiring continued retention shall be transferred to the AEP Corporate storage area, with the appropriate storage and retention directions.

3.3 AEP Information Technology Security Policy

3.3.1 The Laboratory applies prudent business practices regarding security and quality of computer software. As such, the Laboratory follows the requirements and guidelines as set forth in the AEP IT Security Policy.

3.3.2 The purpose and benefits of this policy for the American Electric Power (AEP) System is to ensure the security and quality of computer software. In addition to programs, computer software includes data, operating procedures, and documentation.

3.3.3 This policy describes the AEP information systems security for protection of software against loss and unauthorized alteration or use.

3.3.4 AEP has instituted an information systems security program to ensure that the design, modification, and operation of information systems are performed in a secure manner. Information is an asset of the company and, as such, must be protected from unauthorized modifications, destruction, or disclosure, whether accidental or intentional.

3.3.5 All AEP organizations that develop, procure, maintain, or use software, requiring compliance with this policy, shall as a minimum provide the following:

3.3.5(A) All applications must be documented, including instructions for using and maintaining the software.

3.3.5(B) Change control procedures must be in place to ensure that only authorized changes to the software are made.

3.3.5(C) All software and data must be secured to ensure that only authorized personnel have access to them.

3.3.5(D) All software and data must be backed up off-site to ensure that they can be recreated in accordance with the AEP Data Retention & Backup Standard.

3.3.6 Upon request, the Laboratory shall perform services based upon information furnished to it by its customers, and shall be entitled to rely upon such information. Both parties shall take reasonable precautions to preserve the confidentiality of all shared information. Any information so furnished which is marked "Proprietary" shall be treated by the other party as confidential, shall be for use only by specific agreement, and shall not be disclosed to any third parties. This provision shall not apply to information within any one of the following categories or any combination thereof:

3.3.6(A) Information that was in the public domain prior to receipt thereof from the other party or which subsequently becomes part of the public domain by publication or otherwise except by the party's wrongful act.

3.3.6(B) Information that was in the receiving party's possession without obligation of secrecy prior to its receipt from the disclosing party.

3.3.6(C) Information received from a third party having no obligation of secrecy with respect thereto.

3.4 Management of the Quality Manual

3.4.1 The purpose of this section is to define the tasks and responsibilities relating to the distribution, review, and maintenance of the Laboratory's Quality Assurance Manual. This section deals primarily with those manuals issued under controlled conditions.

3.4.2 Issues, Distribution, and Maintenance of the Manual

3.4.2(A) The QAO* (or designee) bears the primary responsibility for the preparation, issue, review and upkeep of the Laboratory Quality Assurance Manual. (also referenced in Section 2.4.2(A).)

3.4.2(B) After the preparation of the manual, the QAO* (or designee) is responsible for the initial distribution of controlled copies of the manual (as detailed in Sections 3.2.3, 3.2.4, and 3.2.5).

(a) Currently only one controlled paper copy of the manual exists. This paper copy is a direct printout of the official copy of the Quality Assurance Manual and is held by the QAO * (or their designee).

(b) The official copy of the Quality Assurance Manual resides <u>electronically</u> in a secure place in the AEP server depository.

(c) It is the responsibility of the analyst(s) to verify that the most recent authorized version of the Quality Assurance Manual is in use by checking the revision number of the current electronic version (versus any hardcopies in use).

3.4.2(C) Document Control for the Quality Assurance Manual is identical as for other controlled quality documents (See Sections 3.2.3, 3.2.4, and 3.2.5) That is:.

(a) Master List- The **"Document Control- Master List of Controlled Documents"** contains a section of controlled documents found within the QAM.

(b) Format- The QAM shall maintain a specific format (e.g. pagination), with clear use of Issue, Revision, Approval, and Effective Dates; and documented authorization.

(c) Issue- The QAM shall be prepared in a flexible electronic format (e.g. Microsoft Word, etc.) with locks and password protection required for modification. This password protection prevents the QAM from being altered.

(d) Issue- The QAM shall be issued (made available and accessible) as a controlled document to certain personnel, while others shall have access to an electronic version.

(e) Access- The QAM shall remain secure due to limited access control to the electronic version to Laboratory personnel. Furthermore, the electronic version is available as a "Read Only" (except to those with "Read/Write" capabilities and access to the password).

(f) Amendments/Revisions- Changes to the QAM shall conform to the Document Change policy outlined in Sections 3.2.3 and 3.2.4.

(i) Changes that impact the role of the Laboratory Manager/laboratory management, the Quality Assurance Officer (QAO), or the Chemical Hygiene Officer (CHO)/Chemical Hygiene Plan (CHP) shall be reflected in the appropriate summary, i.e. Section 16.2.2, QAM Document 16-02, and Section 16.3.2, respectively.

(g) Record of Changes— A record of all document changes that have been made in the Laboratory management system (and thus the QAM) will be kept in **Appendix Z**, Record of Revisions, in the Laboratory Quality Assurance Manual. Maintenance of this record is the responsibility of the QAO* (or designee).

(h) Annual Review- The QAO* (or designee) is responsible for the timely annual review of the contents of the manual to ensure that its requirements reflect current operating conditions and meet with needs.

(i) This will normally be done in conjunction with and immediately following internal management system audits or audits, assessments or site visits by outside accrediting organizations.

(ii) Information and any corrective actions resulting from these audits will be documented.

3.4.2(D) The purpose of this control is to make sure that changes are available to all personnel in the Laboratory when necessary and that access to the database is restricted when personnel changes require that the manual no longer be available to the affected individual.

3.4.2(E) Uncontrolled copies of the manual may be distributed from time-to-time to individuals or organizations outside the laboratory. These copies will not be numbered or logged and will not receive changes as they occur. Uncontrolled copies will be so marked.

3.4.2(F) This manual is a controlled document, unless otherwise marked. Revisions, additions or deletions occurring because of periodic review or other authorized changes will be controlled through the placement of revisions into the official **Record of Revisions** (**Appendix Z**) of this manual. The QAO* (or designee) shall maintain the **Record of Revisions.**

(a) When changes are made to the QAM, the **Table of Contents** (including the **Table of QAM Documents** and **Table of Other Quality Documents**) must be updated. This is performed by choosing "Select All" under Edit, and then choosing "Update Field" from the (right-mouse click) pop-up menu.

(b) (As stated in Section 3.2.4(F)—) Additionally, the revision number should increase by a whole number upon annual review (i.e. from 14.0 in 2007 to 15.0 in 2008). As revisions are implemented throughout the year, increase the decimal of the revision number (e.g. Revision 15.0 in 2008 is edited once to become Revision 15.1, then another time to become Revision 15.2, etc.).

3.4.2(G) Access to the database by other "readers" in the AEP organization may be granted by the QAO* (or designee), as needed.

3.4.2(H) All individuals seeking "Reader" access to this manual and other controlled quality documents must approach the QAO* (or designee) for inclusion onto the **Document Control Access Control List** (**Document 03-01**).

3.5 Quality Documentation: Throughout the Laboratory, records are maintained to provide support documentation of all aspects of quality, as specified by the **ISO 17025 Standard** [Reference 18.4.9]. These compilations of documents and evidence have been designated as "**QCDOC" files**.

Note: Throughout the QAM, as supporting files, documents, and other data are required to be maintained, the collection is designated by the term "QC File #", the **QCDOC** title, and the  symbol. These QC Files are also compiled in the Table of Contents of this QAM.

3.5.1 **QCDOC** documentation have been created in accordance with the ISO chapters (and thus, the chapters of this QAM) as shown in **Document 03-02.** The QCDOC files, their subparts, and location within the laboratory are also listed in the "**Document Control-Master List of Controlled Documents".**

Document 3-2 Organization of QCDOC Documentation Files

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ORGANIZATION OF "QCDOC" FILES

ISO Chapter	QAM Chapter	Quality Description	QCDOC No.		Supporting Documentation Included
4.1	1	Organization	QCDOC 001-QAM Maintenance		(See QAM Documents in QAM).
4.2	2	Quality System	QCDOC 001		(See Appendix Z, Record of Revisions in QAM).
4.3	3	Documentation Control	QCDOC 001		(See QAM Document 03-01 (Document Control, Master List of Controlled Documents) in QAM).
4.4	4	Review of Requests	QCDOC 002 - Laboratory Review		Review of requests from notes in LIMS.
4.5	5	Subcontracting of Tests	QCDOC 002		Subcontracting of tests from notes in LIMS.
4.6	6	Purchasing of Services and Supplies	QCDOC 003-Purchasing		Purchase orders, packing slips, invoices, etc. See also QCDOC 0020 for MSDS files.
4.7	7	Service to the Customer	QCDOC 004-Customer Service		Feedback results, client questionnaires and surveys, compilation of customer notes from LIMS, client communications.
4.8	8	Complaints	QCDOC 004		Complaints, and their resolution.
4.9	9	Control of Nonconforming Work	QCDOC 005 - CPAR Info		List of Nonconformances from CPAR database.
4.10	10	Improvement	QCDOC 005		List of Nonconformances and/or Lessons Learned from CPAR database.
4.11	11	Corrective Action	QCDOC 005		List of Nonconformances and/or Corrective Action from CPAR database.
4.12	12	Preventive Action	QCDOC 005		List of Nonconformances and/or Lessons Learned from CPAR database.

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ORGANIZATION OF "QCDOC" FILES

ISO Chapter	QAM Chapter	Quality Description	QCDOC No.		Supporting Documentation Included
					Documentation for items listed in QAM Chapter 13, "Control of Records":
4.13	13	Control of Records	QC DOC 006-Control of Laboratory Records		1) Data Collection and Reporting Procedures (see filed/stored report packets); 2) Computational and Data Validation Procedures (see filed/stored report packets); 3) Analytical and Testing Reports (see filed/stored report packets); 4) Laboratory Notebooks (see filed/stored report packets); 5) Chain-of-Custody Documentation (see filed/stored report packets); 6) Technical Documentation and Regulations (see filed/stored report packets).
4.14	14	Internal Audits	QC DOC 007-Internal Audits		Internal Quality system audits and vendor audits.
4.15	15	Management Reviews	QC DOC 008-Management Reviews		Annual management review audits.
5.1 & 5.2	16	General and Personnel	QC DOC 009-Personnel Records		Personnel records- training, education, qualifications, responsibilities, personal DOC's, etc. See QCDOC 011 for Method DOC's (Demonstrations of Capability).
5.3	17	Accommodation and Environmental Conditions	QC DOC 010-Environmental Conditions		Records of environmental and/or laboratory test conditions.
5.4	18	Test Methods and Method Validation	QC DOC 011-Test Methods and Method Validation		(2nd copy of) Demonstrations of Capability (DOC's) for Test Methods, MDL Studies
5.5	19	Equipment	QC DOC 012-Certificates of Calibration		Certificates of Calibrations- Routine instrumentation and miscellaneous equipment calibration; and Periodic calibration and preventative maintenance.
5.6	20	Measurement Traceability	QC DOC 013-Certificates of Analysis		Certificates of Analyses- "permanent" reference standards (NIST, ASTM, NBS, etc.) and "temporary" standards (stock standards with high turn-over due to expiration).
5.7	21	Sampling	QC DOC 014-Sample Info		Sampling Plans from customer, noted in the LIMS.

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ORGANIZATION OF "QCDOC" FILES

ISO Chapter	QAM Chapter	Quality Description	QCDOC No.		Supporting Documentation Included
5.8	22	Handling of Test Items	QCDOC 014		Sample Receipt and Handling information in the LIMS: For Chain of Custody Documentation, See QCDOC 006- (see file/stored report packets). Sample progress reports (and test groups/parameters) from LIMS (and associated statistics) may be compiled in this QCDOC.
5.9	23	Assuring the Quality of Test Results	(QCDOC 006)		See QCDOC 006- (see file/stored report packets), quality checks compiled from LIMS.
5.10	24	Reporting the Results	(QCDOC 006)		See QCDOC 006- (see file/stored report packets).
NA	NA	NA	QC DOC 015-Reference Documents in Laboratory		List of Reference documents (literature, etc.) used throughout the Dolan Chemical Laboratory, including Manufacturer's Equipment Manuals.
NA	NA	NA	QC DOC 016-Miscellaneous Inspection Logs		Miscellaneous Inspection Logs (e.g. Cylinder Inspection Logs, Milli-RO Inspection checklist, Acid Neutralization Tank Inspection, etc.)
NA	NA	NA	QC DOC 017-Inter-laboratory Comparisons		Proficiency Testing (PT) Studies, Round Robin Studies, Inter-laboratory comparison data, etc.
NA	NA	NA	QC DOC 018-Accrediting Bodies		Accreditation Documentation, Regulatory Bodies
NA	NA	NA	QC DOC 019-Quality Assurance Reports		QA Reports - quarterly reports, annual reports, etc.
NA	NA	NA	QC DOC 020-Material Safety Data Sheets (MSDS's)		Collection of Material Safety Data Sheets from chemicals in use in the laboratory.
NA	NA	NA	QC DOC 021-Management Tools		Management Tools include a collection of (end of the year) Variance Reports, Jobs Online records, Budget information, the Business Plan for the laboratory (objectives, goals, purpose, and achievements), and instructions on proper accounting in time-reporting within the laboratory.

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3.5.2 Documentation— Controlled quality documents from this Section shall be maintained separately from the Quality Assurance Manual in the following collection (which is itself, a controlled laboratory document):

3.5.2(A) QCDOC 001 records (relating to the Quality Management System and the QAM, itself) shall be maintained indefinitely, and the quality documents within should be reviewed annually.

QC File 00 9— "QCDOC 001: QAM Maintenance" (in Section 3)

3.5.2(B) Other quality documents maintained throughout the laboratory (unless otherwise specified) shall be maintained for at least five (5) years, and may require periodic review.

4.0 Management Requirements: Review of Requests, Tenders, Contracts

4.1 Purpose and Scope — This section describes how the Laboratory reviews the capabilities of the laboratory with the requirements of the customer. This review may be needed during sample receipt (**Section 22.4.1**) or during the evaluation of subcontracting (**Section 5.0**).

4.2 Laboratory Capability Assessment and Evaluation

4.2.1 The Dolan Chemical Laboratory is an integrated portion of the American Electric Power (AEP) System. As such, the collection of samples and their submittal to the Laboratory generally follows well established protocols within the company. The majority of all samples submitted to the Laboratory originate within established practices and programs concerning routine maintenance, operational, environmental and health monitoring processes. Within this framework, the sample and resultant analysis load to the Laboratory is fairly consistent.

4.2.2 For those exceptions to the routine receipt of samples, specifically those projects and programs expected to generate either a "significant" number of samples and/or individual tests, a laboratory assessment is necessary.

4.2.3 A "significant" number of samples and/or individual tests are dependent upon the analytical area and the specific type of test requested. In general, those programs that are expected to generate in excess of 200 samples may be expected to fall under this laboratory capability assessment. Other factors which may be sufficient to impact this definition of "significant" concerns the type of analysis that has been requested and the initial determination as to the impacts on the available personnel. One last factor is the impact of the requested due date for the analyses.

4.2.4 The initial judgment of "significant" shall be made by the Primary Chemist responsible for the analytical area through which the majority of samples will be processed. If the analyses requested entail the use of other analytical areas, this judgment should be made in consultation with the other affected primary chemists.

4.2.5 If, in the judgment of the primary chemist, the project or program is felt likely to generate a "significant" number of samples or to generate a "significant" impact on either the laboratory's employees or the ability of the laboratory to function within the normal expected rates of sample throughput or a decline in the quality of work to be otherwise performed may be expected, then a laboratory capability assessment and evaluation should be made.

4.2.6 The Laboratory capability assessment and evaluation should be conducted through the input of the following personnel: Laboratory manager, all primary chemists to which analytical work would be expected, and the Laboratory QAO* (or designees). A review of the laboratory capability should include the following possible impact areas:

4.2.6(A) Personnel scheduling and training,
4.2.6(B) Due date considerations,
4.2.6(C) Expected quality impacts,
4.2.6(D) Sample handling considerations with respect to space and logistics (Refer to **Subcontracting Section 5.0**), and
4.2.6(E) Any other aspect of the sampling and sample receipt and analysis that may be expected to impact the normal laboratory operations (Refer to **Sample Receipt Section 22.4.1**).

4.2.7 The final decision as to whether the samples are accepted is the responsibility of laboratory management. The use of these procedures ensures that the Laboratory reviews all "significant" new work to ensure that it has the appropriate facilities and resources before commencing such work.

4.2.8 The possibility exists that an amount of analytical work may originate from assorted Associated Business Development (ABD) activities with AEP. This work and any other work that may originate external to the AEP System is also subject to the above procedures.

4.2.9 See also "SOP 750- Analytical Chemistry Services Standard Operating Procedure for Large, Non-Routine Projects" from the Engineering, Projects and Field Services (EPFS) Quality Assurance Program.

4.3 Documentation — Controlled quality documents from this Section shall be maintained separately from the Quality Assurance Manual in the following collection (which is itself, a controlled laboratory document):

4.3.1 QCDOC 002 records (and the majority of laboratory documentation, unless otherwise specified) shall be maintained for at least five (5) years, and may require periodic review.

QC File 00 10— "QCDOC 002: Laboratory Review" (in Section 4)

5.0 Management Requirements: Subcontracting of Tests

5.1 Purpose and Scope — Upon evaluation of the capabilities of the laboratory (per **Section 4.0**), it may be necessary to subcontract the analyses of certain test items. This section describes the requirements for control of the quality of work imposed upon outside laboratories doing analytical or testing tasks for the Laboratory. These tasks may be required by either the Chemical Hygiene Plan (CHP) or the Quality Assurance Program or may be needed as part of a specific analytical project. In general, only those tasks that are beyond the capabilities of the Laboratory are considered for subcontracting.

5.1.1 This section applies not only to outside laboratories doing analytical or testing work on a contract basis, but also to metrology laboratories providing calibration services in accordance with **Section 19.0** (Equipment).

5.1.2 The Industrial Hygiene Analytical Group (IHAG) at the Dolan Chemical Laboratory **shall not** subcontract any samples for analyses and reporting to its' clients.

5.1.3 Authorization of Subcontracting of Samples:

5.1.3(A) Upon review of the situation, the primary chemist responsible for a set of samples may request permission to subcontract the analyses of specific tests on the samples. The analysis of samples may be subcontracted upon the authorization of the Laboratory Manager, or the designated backup.

5.1.3(B) In the absence of both the Laboratory Manager and the Laboratory Supervisor, the Primary Chemist may subcontract "critical analyses", based upon their best judgment. "Critical analyses" are situations where it would be detrimental to the client if the decision to subcontract was postponed until the Laboratory Manager was contacted or returned to the premises.

5.2 Quality Assurance in Contract Laboratories

5.2.1 Where the laboratory sub-contracts any part of the testing covered under a scope of accreditation, this work shall be placed with a similarly accredited laboratory for the tests to be performed.

5.2.1(A) Where a laboratory sub-contracts any part of the testing not covered under a scope of accreditations, this work should be placed with a reputable laboratory for the tests to be performed. It is the laboratory's policy to seek contract laboratories that hold certificates form an accrediting body (e.g. AIHA, NVLAP, NELAC, etc.) to ensure the highest quality.

5.2.2 The laboratory should evaluate subcontracted laboratories per the customers' requirements. This evaluation may be preempted if the contract laboratory can demonstrate that it has achieved ISO accreditation of the relevant scope required. An accreditation certificate for each approved subcontractor will be obtained and the certificates will be kept on file by the QAO* (or designee).

5.2.2(A) The laboratory personnel may request a contract laboratory be added to the approved subcontractor list if it can be shown that the vendor (or their expertise) is an "expert in their field".

5.2.3 The list of approved subcontractor shall be maintained by the QAO* (or designee) and will be provided to all laboratory personnel, laboratory management, and the laboratory purchasing representative. The current "**List of approved subcontractors for Dolan Chemical Laboratory"** is retained by the QAO and is available on Sharepoint. These records are maintained in **QCDOC-001 QUALITY SYSTEM (QS) Records.**

5.2.4 Each contract laboratory, which the Laboratory employs for providing testing services, should maintain its own internal quality assurance system. The capability of the contractor to maintain a high level of quality work will be considered as a part of the contract process and will be weighed heavily in that process.

5.2.5 Each contract laboratory, which the Laboratory employs for providing testing services, chemical analyses or calibration services of an environmental nature, is responsible to Laboratory personnel for the maintenance of a high level of work quality.

5.2.5(A) Audits may be conducted on these contract laboratories. These audits may include "audit" or "user check" spiked samples. These samples should serve the dual purpose of testing the contractor's proficiency in performing the method and testing the clarity and technical proficiency of the method language.

5.2.6 Measurement Traceability – Subcontractors that perform external calibration services for the laboratory must conform to the Measurement Traceability requirements in this quality system.

5.2.6(A) **Refer to Section 20.1.3 for further guidance on Measurement Traceability and to Section 19.2.5 for Measurement Traceability Requirements for external calibration services.**

5.2.7 If it is necessary to conduct an audit of a subcontractor's management system, see Section 14.4 for more details.

5.3 Responsibility to Client When Subcontracting

5.3.1 The laboratory shall advise the client of its intention to sub-contract any portion of the testing to another party.

5.3.2 If possible, the laboratory shall document the client's authorization prior to subcontracting testing to another party.

5.3.3 The client's authorization should be documented in some manner. If personal correspondence is not available (e.g. hardcopy or electronic communication), notes regarding the conversation with the client should be maintained— identifying the person who provided authorization, their role in the client's organization / department, the date (and time, if possible) of the conversation, and pertinent information from the discussion.

5.3.3(A) See Section 7.2 for maintaining client communications.

5.4 Subcontracting Results on the Analytical Report

5.4.1 All analyses, performed by a subcontracting laboratory for the Laboratory, will be clearly and unambiguously identified on any issued reports.

5.4.2 The laboratory shall retain records demonstrating that this requirement has been met.

5.4.3 All reports generated by a third party laboratory will be included, in its original form, with the analytical report to the client.

5.5 Documentation — Controlled quality documents from this Section shall be maintained separately from the Quality Assurance Manual in the following collection (which is itself, a controlled laboratory document):

5.5.1(A) QCDOC 002 records (and the majority of laboratory documentation, unless otherwise specified) shall be maintained for at least five (5) years, and may require periodic review.

QC File 00 11— "QCDOC 002: Laboratory Review" (in Section 5)

6.0 Management Requirements: Purchasing of Services and Supplies

6.1 Purpose and Scope— This section describes the procedures for including technical and quality requirements in blanket purchase orders, and procurement cards. It also describes those procedures used for marking, receiving and storing reagents, chemicals, and testing supplies and materials. This section deals only with chemicals, reagents, supplies and materials used in testing and analytical work. It is not concerned with test or analytical samples or testing equipment.

6.2 Procurement

6.2.1 Vendor Standards

6.2.1(A) A vendor of testing or analytical supplies and materials is regarded as a resource to and an extension of the laboratory organization. The expected vendor quality standards should, therefore, be the same as those self-imposed on the Laboratory.

6.2.1(B) The laboratory should evaluate suppliers of critical consumables, supplies, and services that may affect the quality of testing. Current suppliers of these consumables, supplies, and services are pre-approved, as their past usage and acceptance by the laboratory analysts is considered as sufficient evaluation.

6.2.1(C) All new or first-time suppliers should be evaluated with respect to whether their product or service is sufficient to maintain or improve the current quality of laboratory testing. This evaluation will be developed on a case-by-case basis and documented, prior to use, by laboratory personnel.

(a) This evaluation may be preempted if the supplier can demonstrate that it has achieved ISO 9001 accreditation. An accreditation certificate for each approved supplier will be obtained and the certificates will be kept on file by the QAO* (or designee).

(b) All material, supplies, reagents and/or chemicals purchased from the National Institute of Standards and Technology (NIST), the American Society for Testing and Materials (ASTM), Research Triangle Institute (RTI), or the American Industrial Hygiene Association (AIHA) shall be permanently exempted from the demonstration of achievement of ISO 9001 accreditation. As these potential suppliers are the recognized experts and sources for reference materials and programs, the use by the Dolan Chemical Laboratory of their services is to be encouraged and as such should provide quality assurance at the highest level. [Note: these suppliers are listed as "Exempt"]

(c) The laboratory personnel may request a vendor be added to the approved supplier list if it can be shown that the vendor (or their expertise) is an "expert in their field". [Note: these suppliers are listed as "Expert"]

(d) Vendors of "non-critical" supplies (e.g. office supplies) are exempt from the demonstration of achievement of ISO 9001 accreditation. [Note: these suppliers are listed as "NC"]

(e) Vendors of "critical" supplies (e.g. affect the quality of the analyses) may be exempt from ISO certification upon a formal evaluation of the quality of the item (or service) in relation to the quality needs and requirements of the laboratory. [Note: these suppliers are listed as "EVAL"]

6.2.1(D) Additionally, an exemption is allowed as the Laboratory Manager may "grandfather" the use of certain reliable, necessary, or exclusive suppliers without performing the formal evaluation, verification, and authorization process given above. [Note: these suppliers are listed as "Exempt-LM"]

6.2.1(E) The list of approved suppliers shall be maintained by the QAO* (or designee) and will be provided to all laboratory personnel, laboratory management, and the laboratory purchasing representative. The current "**List of approved suppliers for Dolan Chemical Laboratory"** is retained by the QAO and is available on Sharepoint. These records are maintained in **QCDOC-001 QUALITY SYSTEM (QS) Records.**

(a) The Industrial Hygiene Analytical Group may only order from vendors that have a valid ISO accreditation (or equivalent) or have been exempted per Section 6.2.1(D). Other vendors may be approved upon further evaluation of quality and upon request of the primary chemist and approval of the QAO* or designee. [Note: these suppliers are listed as "IHAG"]

6.2.1(F) If it is necessary to conduct an audit of a vendor's management system, see Section 14.4 for more details.

6.2.2 General Purchase Order Information

6.2.2(A) All references to purchase order(s) (or to PO(s)) are to include AEP blanket purchase orders and procurement card orders. The term "purchase order" within the framework established by this section also refers to the "order sheets" used by the laboratory purchasing representative.

6.2.2(B) The purchase order (PO) instructs vendors to mark packing slips with the following information, when applicable:

(a) vendor's name (and address, if available)
(b) name and/or description of material
(c) purchase order number or blanket order number
(d) vendor's catalog number
(e) quantity and size ordered
(f) customer number
(g) confirmation number

6.2.2(C) The purchase order used internal to the laboratory should also include the above information.

6.2.2(D) This assures that the material was ordered and is identified properly.

6.2.3 Purchase Order Approval

6.2.3(A) All purchase orders are approved by the Laboratory Manager or their designee(s). In addition, if the Laboratory Manager has a question concerning the applicability, the amount or any other aspect of a specific chemical and/or reagent on a particular order, the advice and review of that order by the Chemical Hygiene Officer (CHO) should be requested. This approval and review process assures compliance with the chemical procurement restrictions of the Chemical Hygiene Plan (CHP) [Reference **Appendix A**] and with the latest purchasing requirements.

6.2.4 Purchasing Information, General

6.2.4(A) Purchase orders, receiving documents and accompanying certifications are used as part of the receiving control procedure and to identify the material being received.

6.2.4(B) Items may be purchased through the use of a procurement card, i.e. MasterCard. These items are approved on an informal basis by the laboratory management. The quality of materials purchased through the procurement card procedure is the sole responsibility of the purchaser.

6.3 Control of Incoming Materials– The control of incoming materials into the laboratory and the associated documentation is discussed in detail in the Receipt Procedure for Incoming Materials.

6.4 Documentation — Controlled quality documents from this Section shall be maintained separately from the Quality Assurance Manual in the following collection (which is itself, a controlled laboratory document):

6.4.1(A) **QCDOC 003** records (and the majority of laboratory documentation, unless otherwise specified) shall be maintained for at least five (5) years, and may require periodic review.

QC File 00 12— "QCDOC 003: Purchasing" (in Section 6)

7.0 Management Requirements: Service to the Customer

7.1 Purpose and Scope— This section sets forth the procedures and responsibilities of the Laboratory personnel in its goal to provide the customer, not only with quality analytical results, but results in a timely manner. The manner in which the laboratory deals with its customers and generates a high level of customer satisfaction is critical in maintaining its reputation of quality throughout the AEP organization.

7.1.1 As stated in the Quality Goals and Objectives (**Section 2.21),** the Laboratory shall be willing to cooperate with its customers or their representatives in clarifying the customer's requests and in monitoring the laboratory's performance in relation to the work performed, provided that the laboratory ensures confidentiality (See Section 3.2.6) to the degree required.

7.2 Client Communications

7.2.1 Client communications shall be maintained. Hardcopies may be archived with sample data (laboratory report packets, Section 24.5) or a summary of communications may be noted in the LIMS (See Section 1.4.3(B) for background information on the LIMS).

7.2.1(A) Client communications in relation to subcontracting is detailed in **Section 5.2**.

7.2.1(B) Client communications in relation to sample receipt is detailed in **Sections 22.5.3(E) and 22.5.4(D)**.

7.2.2 It is recommended to document conversations with the customer (e.g. complaints, conversations, clarifications, etc.) in the LIMS under the "Complaints Management" menu of the Tools tab.

7.2.3 The laboratory shall notify clients promptly, in writing, of any event (i.e. identification of defective measuring or test equipment) that casts doubt on the validity of results given in any test report or amendment to a report. This notification must be sent within one week past the completion of the investigation. (Same statement in Section 24.3.3(C))

7.3 Feedback

7.3.1 The laboratory should seek feedback from its clients to better understand the customers' requirements and expectations. Feedback received by the laboratory— whether positive or negative, and whether solicited or unsolicited— should be appropriately documented.

7.4 Surveys and Questionnaires

7.4.1 Periodically, the laboratory should circulate surveys and/or questionnaires to its customer base (or some sub-section of relevant customers) in order to evaluate its performance, perception, and ability to meet the expectations of its customers. Information from these analyses should be utilized to make improvements within the laboratory as detailed in **Section 10.0**.

7.5 Documentation — Controlled quality documents from this Section shall be maintained separately from the Quality Assurance Manual in the following collection (which is itself, a controlled laboratory document):

7.5.1(A) **QCDOC 004** records (and the majority of laboratory documentation, unless otherwise specified) shall be maintained for at least five (5) years, and may require periodic review.

QC File 00 13— "QCDOC 004: Customer Service " (in Section 7)

8.0 Management Requirements: Complaints

8.1 Purpose and Scope— This section sets forth the procedures and responsibilities for handling AEP System complaints and negative audit results. This section applies to all technical complaints regardless of the source.

8.1.1 A complaint shall be defined as an event where the laboratory was notified that its actions did not meet the expectations of the customer (regardless of fault). Complaints are an informal reflection of customer dissatisfaction.

8.2 Complaints Procedure

8.2.1 All technical and negative comments or suggestions from the AEP System, government agencies or other sources outside of the Laboratory shall be relayed to the QAO* (or designee) for review, handling and reply.

8.2.1(A) The initial conversation should be documented in the LIMS as detailed in Section 7.2.2 under Client Communications (i.e. in the LIMS under the "Complaints Management" menu of the Tools tab).

8.2.1(B) Chemists should notify (i.e. by email) the Laboratory Manager and the QAO* of any unresolved complaints for additional documentation and investigation (e.g. using the CPAR process).

8.2.1(C) A complaint, may lead to an audit of the analytical area, as described in Section 14.4.

8.2.1(D) Records of the complaint and subsequent actions shall be maintained.

8.2.1(E) All inputs will be addressed promptly by laboratory management and resolved without delay or implemented when feasible. Other items will be investigated and handled in an expedient manner. All internal complaints will be documented, and a response to the complaint and a record of the complainant's acceptability shall be held on file at the laboratory.

8.2.1(F) Ethics investigations shall be handled through the Office of Ethics and Corporate Compliance as defined in **Document 02-01** (AEP's Principles of Business Conduct).

(a) Ethical issues should be addressed to laboratory management or may be anonymously reported using the AEP Concerns Line by calling 1-800-750-5001 (See **Document 02-03** "Ethics and Compliance; FAQ for the Concerns Line" for more information).

(b) AEP's Office of Ethics and Corporate Compliance shall perform and independent and external (i.e. external to the laboratory division) investigations.

(c) Disciplinary action may be authorized and executed by the Laboratory Manager and/ or AEP corporate. Any disciplinary action shall be documented.

8.2.2 In each case, the individuals concerned will be advised as to the nature of the complaint(s).

8.2.3 Additionally, corrective action measures will be initiated when necessary. Upon completion of corrective action and the finding of a solution to the problem, the QAO* (or designee) will advise the complainant accordingly. In case of corrective action taken to satisfy the comments or suggestions of outside auditors from accrediting organizations, detailed explanations will be given of measures taken to prevent recurrence of problems causing the negative comments.

8.2.3(A) Complaints (either as a "Nonconformance" as discussed in Section 9.0, or as a Corrective Action as discussed in Section 11.0) may be evaluated, resolved, corrected, and documented using the **CPAR database** (**Document 11-01**) as described in **Section 11.3.1**.

8.2.4 The laboratory shall seek feedback, both positive and negative, from its customers. The feedback shall be used and analyzed to improve the management system, testing and calibration activities and customer service (See **Section 7.3**).

8.3 **Documentation —** Controlled quality documents from this Section shall be maintained separately from the Quality Assurance Manual in the following collection (which is itself, a controlled laboratory document):

8.3.1(A) **QCDOC 004** records (and the majority of laboratory documentation, unless otherwise specified) shall be maintained for at least five (5) years, and may require periodic review.

QC File 00 14— "QCDOC 004: Customer Service " (in Section 8)

9.0 Management Requirements: Control of Nonconforming Testing

9.1 Purpose and Scope—The purpose of this section is to prescribe actions that may be taken when improvement opportunities are identified, or there is sufficient reason to suppose that a nonconformity has occurred during testing or analytical operations. Such nonconformances may be discovered during data validation procedures, found during independent audit, observed during equipment malfunctions, or related from customer complaints. They may also occur due to equipment malfunctions.

9.1.1 When a nonconformity is discovered there are several steps that may be taken, the most important of which is corrective action. Corrective Action is discussed in further detail in **Section 11.0**.

9.1.2 Nonconformances may be evaluated, resolved, corrected, and documented using the **CPAR database** (**Document 11-01**) as described in **Section 11.3.3**.

9.2 Definitions

9.2.1 A nonconformity is defined as: "A departure of a quality characteristic from its intended level or state that occurs with a severity sufficient to cause an associated product or service not to meet a specification requirement".

9.2.2 Examples of significant nonconformances specifically include:

9.2.2(A) Any operation or action that may jeopardize the integrity of a sample or samples, such as:

(a) Improper preservation, such as when the required preservative is not used or an inappropriate preservative is used.

(b) Improper sample shipping/storage practices, such as those which violate protocols established by regulatory agencies or are inappropriate due to possible contamination or bias of the sample.

9.2.2(B) Any operation or action that may jeopardize the integrity of data, such as:

(a) Computer systems malfunctions, especially those situations where data may be lost or corrupted due to server failures or inappropriate laboratory information management systems operations.

(b) Analytical problems, QC trends, etc.

9.2.3 Other nonconformances may include:

9.2.3(A) Complaints (See Section 8.2.4),
9.2.3(B) Review of (internal or external) audit findings (see Sections 14.2 and 14.3.3),
9.2.3(C) Departures, exceptions, or contingencies given approval by laboratory management (See Section 2.3.1(M)).
9.2.3(D) Quality control,
9.2.3(E) Instrument calibration,
9.2.3(F) Checking of consumable materials,
9.2.3(G) Staff observations or supervision,
9.2.3(H) Reviews of analytical reports.

9.2.4 **Preventive Action**—Needed improvements and potential sources of nonconformances, either technical or concerning the management system, shall be identified. Preventative Action is discussed in further detail in **Section 12.0.**

9.3 Actions Procedure

9.3.1 When a significant nonconformity is discovered, it shall be communicated promptly to the primary chemist/ responsible analyst in charge of the process or analytical procedure and, if appropriate, a note detailing the particulars of the significant nonconformity should be entered in the analytical notebook or on the hard copy printout of the results.

9.3.2 All "significant" nonconformances (i.e. nonconforming process or procedure that cannot be immediately corrected or if the consequences / implications of the nonconformance are of a sufficient magnitude that they can not be adequately addressed and resolved solely by the primary or responsible chemist) must be communicated by the primary chemist or responsible analyst and then forwarded to the QAO* (or designee). The information must then be transferred to an electronic version in the CPAR database (See **Document 11-01** and **Section 11.3**).

9.3.2(A) The CPAR database is capable of generating **Nonconformance (NC) Reports** to investigate and document nonconformances encountered in the laboratory.

9.3.2(B) Non-conformance (NC) Reports are defined in Section 11.3.3(C). See also "SOP 830- Control of Nonconforming Products and Services" from the Engineering, Projects and Field Services (EPFS) Quality Assurance Program.

9.3.3 "When the identification of a non-conformance or departure casts doubts on the laboratory's compliance with its own polices and procedures", or on its compliance with the NELAC standard or the LAC 33.I [References 18.4.1 and 18.4.17], the laboratory shall audit the appropriate areas of activity as soon as possible. The audit should be performed using the procedure(s) listed in Section 14.3 ("System and Performance Audits"), or equivalent. [per ISO 17025 Section 4.11.5, Reference 18.4.9]

9.3.3(A) The QAO* (or designee) will be responsible for reviewing all significant nonconformances to determine whether long-term corrective action should be taken. In addition, in consultation with the notified primary chemist or responsible analyst, questions as to whether new samples are required, if the customer should be notified, if retesting or re-analysis is necessary, or whether the results should be confirmed by independent third party testing or analysis, should be resolved.

9.3.3(B) Actions associated with this review may be either remedial or long-term. Remedial actions are those actions taken by the primary chemist or responsible analyst to provide relief of the noted nonconformity. Long-term corrective actions are those actions associated with a formal corrective action plan and, as such, may involve other individuals or groups in the process of resolving the nonconformity.

9.3.3(C) Remedial action documentation should be prepared by the primary chemist or responsible analyst appropriate to the action taken. The documentation should be as complete as necessary and sufficient to the purpose of answering any questions arising from the nonconformity about the integrity of the samples or data.

9.3.3(D) The QAO* (or designee) will see that the steps necessary to prevent the repetition of any nonconformity are taken.

9.3.3(E) Upon further review, QAO* (or designee) may pursue the issue as a full corrective action (CA) as detailed in Section 11.0.

9.4 **Exceptions**: Arrangements for exceptionally permitting departures from documented policies and procedures or from standard specifications may be permitted by laboratory management and shall be documented (see Section 9.5) as a non-conformance.

9.5 **Documentation —** Controlled quality documents from this Section shall be maintained separately from the Quality Assurance Manual in the following collection (which is itself, a controlled laboratory document):

9.5.1(A) **QCDOC 005** records (and the majority of laboratory documentation, unless otherwise specified) shall be maintained for at least five (5) years, and may require periodic review.

QC File 00 15— "QCDOC 005: CPAR Information " (in Section 9)

10.0 Management Requirements: Improvement

10.1 Purpose and Scope—The purpose of this section is to establish a method for developing and maintaining detailed plans that will provide for the quality aspects of producing and delivering precise, accurate tests or analytical results.

10.1.1 "The laboratory shall continually improve the effectiveness of its quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review." [per ISO 17025 Section 4.10, Reference 18.4.9]

10.1.2 Quality Assurance Planning takes place in two phases - the initial phase takes place when the management system is being developed and installed. The planned management system elements, gathered in an authoritative collection of written procedures and their accompanying forms, constitute the Quality Assurance Manual. This first phase is discussed in this section.

10.1.3 The second phase is the continual planning that takes place during the implementation and conduct of the quality program. This phase has been discussed in the preceding Section 3.4 (Document Control- Management of the Quality Manual) involving the handling of changes in procedures brought about by changes in technology, personnel, regulatory or accrediting requirements, management decisions, etc., which result in changes to the Laboratory Quality Assurance Manual.

10.1.4 Improvements may be evaluated, resolved, corrected, and documented using the **CPAR database** (**Document 11-01**) as described in **Section 11.3.3**. The improvement may be designated a nonconformance, lessons learned, or corrective action.

10.1.4(A) **Lessons Learned (LL)** Reports should be created to document an event, issue, situation, etc. and to ensure that the information gained from experience is shared with others throughout the company and for others in the future.

10.1.4(B) Lessons Learned (LL) Reports are defined in Section 11.3.3(C). See also "SOP 852.01- Lessons Learned" from the Engineering, Projects and Field Services (EPFS) Quality Assurance Program.

10.2 Approach to Planning

10.2.1 The act of planning is thinking out in advance the sequence of actions necessary to accomplish a proposed course of action for doing work to accomplish certain objectives. The plan is written out together with necessary criteria, diagrams, tables, etc., so that the planner may communicate the plan to the person or persons expected to execute it.

10.2.2 Planning for laboratory quality assurance must be geared for delivering acceptable quality data at an acceptable cost. These objectives are realized only by carefully planning many individual elements that relate properly to each other and that make up the Quality Program Requirements set forth in this manual.

10.3 Development of a Quality Plan

10.3.1 The first step in the quality planning sequence is to determine which quality assurance elements should be included as a part of a quality assurance plan (QA Plan). This is done by considering:

10.3.1(A) management direction,
10.3.1(B) regulatory or accrediting requirements,
10.3.1(C) applicable consensus quality standards,
10.3.1(D) budgetary and cost consideration, and
10.3.1(E) industry practices.

10.3.2 The culmination of the initial quality planning should be a document that includes the essential information, directives, and documents or forms that will make up the Laboratory Quality Assurance Manual. The Laboratory Quality Assurance Manual is designed to serve several functions:

10.3.2(A) Most importantly, it is the result of a planning effort to design a system that will ensure that the Laboratory's results will be of the highest precision and accuracy.

10.3.2(B) It represents a historical record that documents the procedures and subsystems established to control laboratory performance quality.

10.3.2(C) It provides management with a document that can be used to assess whether the quality control and quality assurance activities described are being implemented. In other words, it provides a check list against which the quality program can be audited.

10.3.2(D) It will be used as a training document for the indoctrination of new employees.

10.3.2(E) It provides the description of the Laboratory Management System that can be used as evidence in litigation involving the validity of test or analytical reports.

10.3.2(F) It will serve to meet requirements of regulatory or accrediting organizations.

10.3.2(G) It describes the elements of the Laboratory Quality Assurance System to all concerned.

10.4 Participation in Inter-laboratory Studies

10.4.1 The Laboratory participates in various inter-laboratory studies to provide comparison to other laboratories and to objectively evaluate its performance.

10.4.1(A) The Flue Gas Analytical Group (FGAG)— (Removed 04/2008)

10.4.1(B) The Industrial Hygiene Analytical Group (IHAG) regularly participates in the following proficiency testing (PT), "round robin" (RR), and/or inter-laboratory comparison studies:

(a) AIHA PT program for full scope of accreditation (quarterly). The RR is administered through RTI;
(b) NVLAP PT program for bulk asbestos (semiannually). The RR is administered through NIST; and
(c) Thomas Pang RR for asbestos fibers (semiannually).
(d) To satisfy requirements for the accrediting bodies, DOCs shall be used when a PT program or RR is not available for that field of testing (FoT).

10.4.1(C) The Plant Services Analytical Group (PSAG) regularly participates in the following proficiency testing (PT), "round robin" (RR), and/or inter-laboratory comparison studies:

(a) ASTM Cross-Check inter-laboratory comparison study for insulating oil (periodically). The RR is administered through ASTM;

(b) ASTM Cross-Check inter-laboratory comparison study for lubricating oil (periodically). The RR is administered by ASTM;
(c) Utility Laboratory Managers Association (ULMA) inter-laboratory comparison study for insulating oil (periodically). The RR is administered through Manitoba Hydro Labs;
(d) Analytical Products Group (APG) "Power Check" PT program for (quarterly) — has been discontinued;
(e) Cement and Concrete Reference Laboratory (CCRL) RR for pozzolan samples (annually);
(f) LQSI RR for ash samples (quarterly);
(g) LQSI RR for coal samples (quarterly);
(h) Turbine Oil Cross-Check inter-laboratory comparison study for turbine oil (periodically); and
(i) "Inter-laboratory Coal RR" for coal — has been discontinued.

10.4.1(D) The Water and Waste Analytical Group (WWAG) regularly participates in the following proficiency testing (PT), "round robin" (RR), and/or inter-laboratory comparison studies:

(a) Discharge Monitoring Report (DMR) PT study for scope of accreditation (annually). The RR is administered through Environmental Resource Associates (ERA);
(b) Wastewater Proficiency (WP) PAT PT study for scope of accreditation (quarterly). The RR is administered through ERA; and
(c) Soils inter-laboratory comparison study for TCLP metals (quarterly). The RR is administered through ERA.

10.4.2 Findings from external performance audits should be evaluated, resolved, corrected, and documented using the **CPAR database** (**Document 11-01**) as described in **Section 11.3.3**.

10.4.2(A) Any "Unacceptable" result must be documented using the Corrective Action Report (Corrective Action is discussed in Section 11.0).

10.4.3 Archived Inter-laboratory Comparison documents and reports are maintained in **QCDOC-017 Inter-laboratory Comparisons**:

QC File 00 16— "QCDOC 017: Inter-laboratory Comparisons " (in Section 10)

10.5 Accreditation Status

10.5.1 The Dolan Chemical Laboratory maintains various accreditations and certifications for regulatory reasons and as symbol of quality and excellence to our customers. Dolan Chemical Laboratory is accredited by the following accrediting bodies in the fields of testing listed:

10.5.1(A) Accreditation through AIHA, American Industrial Hygiene Association) — (see Scope of Accreditation).

10.5.1(B) Accreditation through NVLAP, National Voluntary Laboratory Accreditation Program — for Analysis of Bulk Asbestos.

10.5.1(C) Certification through the state of Virginia – Virginia Environmental Laboratory Accreditation Program (VELAP) for environmental analyses (see Scope of Accreditation) and for Virginia Department of Professional and Occupational Regulation (DPOR) for Analysis of Bulk Asbestos.

10.5.1(D) Certification through the West Virginia Department of Environmental Protection (WV DEP) — (see Scope of Accreditation) and for asbestos analysis.

10.5.2 It is required to participate in inter-laboratory studies and achieve acceptable results in order to maintain accreditation (See Section 10.4).

10.5.2(A) When the laboratory receives an "Unacceptable" result from a PT study for a parameter within the Scope of Accreditation the Root Cause Analysis must be documented using the Corrective Action Report (Corrective Action is discussed in Section 11.0).

10.5.2(B) When the CPAR associated with an "Unacceptable" PT result is complete, the laboratory should make a copy available to the Virginia Accrediting Body with a copy of the final report documenting the failed PT result(s), the investigation, and the resulting corrective action. [per NELAC 2.7.4, Reference 18.4.1]

10.5.3 Archived Accreditation documents and reports are maintained in **QCDOC 018 Accrediting Bodies**:

QC File 00 17— "QCDOC 018: Accrediting Bodies " (in Section 10)

10.6 Further Improvements

10.6.1 The Dolan Chemical Laboratory has sought to meet compliance with the ISO 17025 Standards in order to continually improve on its performance and quality.

10.6.2 The Dolan Chemical Laboratory adheres to the requirements of AIHA-LAP, LLC (for AIHA Accreditation), NIST 150 Handbook (for NVLAP Accreditation), 1VAC30-46 (Virginia code for commercial laboratory certification) and 47CSR32 (West Virginia code for laboratory certification) [Reference 18.4.18, 18.4.19, 18.4.20, and 18.4.21].

10.6.3 Issues relevant to the Laboratory's Quality Management System and its associated laboratory operations should be addressed on an ongoing basis at the bimonthly Chemist Meeting. This meeting is chaired by the Laboratory Manager and serves as a management's focus for communication of information related to the laboratory's operations. The regularly scheduled date for these meetings is every other Tuesday. Hand-written notes from chemist meetings are available from the Laboratory Manager.

10.7 Documentation — Controlled quality documents from this Section shall be maintained separately from the Quality Assurance Manual in the following collection (which is itself, a controlled laboratory document):

10.7.1(A) **QCDOC 005** records (and the majority of laboratory documentation, unless otherwise specified) shall be maintained for at least five (5) years, and may require periodic review.

QC File 00 18— "QCDOC 005: CPAR Information " (in Section 10)

11.0 Management Requirements: Corrective Action

11.1 Purpose and Scope—This section describes the Laboratory procedures for correcting a nonconformity, assigning responsibility for the action to be taken, documenting the steps taken, and securing a report on the resolution of the problem. Nonconformities are discussed in further detail in **Section 9.0**.

11.1.1 This section deals with both remedial and long-term corrective action taken to avoid recurrence of the problem. Corrective action may be performed in the following areas of the laboratory:

11.1.1(A) Use of the Corrective and Preventive Action Processes (LAB CPAR3) database to generate and track a formal Corrective Action Request (CAR) (see **Section 11.3**);

11.1.1(B) Analytical Corrective Action **(see Section 11.4)**; and

11.1.1(C) Management Corrective Action **(see Section 11.5)**.

11.1.2 Steps defining a closed-loop corrective action system are:

11.1.2(A) Define the problem.

11.1.2(B) Assign responsibility for investigating the problem.

11.1.2(C) Determine a corrective action to eliminate the problem.

11.1.2(D) Assign and accept responsibility for implementing the corrective action.

11.1.2(E) Establish the effectiveness of the corrective action and implement the correction.

11.1.2(F) Verify that the corrective action has eliminated the problem.

11.1.3 Corrective action procedures recognize the need for a designated individual to test continually the effectiveness of the system and the corrective actions.

11.1.4 The QAO* (or designee) shall provide reports to laboratory management regarding quality assurance problems and a summary of corrective and preventive actions (i.e. Lessons Learned, Non-conformances, and CPARs) at least quarterly. This summary will be provided to laboratory management and will be reviewed by all laboratory primary chemists and laboratory management.

11.1.4(A) Archived Quality Assurance documents and reports are maintained in **QCDOC 019 Quality Assurance Reports**:

QC File 00 19— "QCDOC 019: Quality Assurance Reports " (in Section 11)

11.2 Definition — The Laboratory formally recognizes the following specific situations as requiring the generation of a Corrective Action Request (CAR) Report:

11.2.1 Any time a report needs to be reissued to remedy a situation where the content of the issued report misrepresents information concerning the samples, such as the sample identifications, the method identification, or the analysis data.

11.2.2 Any situation where the integrity of a particular sample is compromised so severely that an accurate analysis is no longer possible.

11.2.3 When participation in a Proficiency Evaluation Testing program indicates an "unacceptable" or failure condition for any parameter of participation.

11.2.4 In addition to the Corrective Action Request (CAR) Reports, the CPAR database may also be used to generate Nonconformance (NC) Reports (See Section 9.3.2(A)) and Lessons Learned (LL) Reports (See Section 10.1.3(A)) as needed.

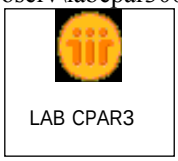
11.3 Corrective and Preventive Action Request (CPAR) Database

11.3.1 The Laboratory uses the Laboratory Corrective and Preventive Action Processes (LAB CPAR3) database for the generation, capture and tracking of information relating to all Corrective Action plan documents.

11.3.1(A) The LAB CPAR3 database was split from the CPAR3 database in January 2011 and is maintained by laboratory management. The CPAR3 database, which is maintained by AEP Generation for Engineering, Technical and Environmental Services (ET&ES) was utilized from June 2004 through December 2010.

11.3.2 The **CPAR database** in **Document 11-01** is a Lotus Notes application database and may be accessed internally by AEP employees using a link similar to the icon or by accessing the Server DSAPP50R/SERVERS/AEPIN, and the database file database\Proserv\labcpar300a.nsf.

Document 11-1 Corrective and Preventive Action Request (CPAR) Database (Reserved icon)
(DSAPP50R/SERVERS/AEPIN/database\Proserv\labcpar300a.nsf.)



11.3.3 What does this database do?

11.3.3(A) Corrective and Preventive Action Processes are the heart of an effective Quality Assurance Program. This database has been designed to communicate ideas for continuous improvement of products and services, work processes, systems, and work environment. It was also established to report nonconforming work processes, capture lessons learned, resolve customer complaints, and correct nonconforming work products, services and processes. Additionally this database provides the tools necessary to investigate, determine root cause, and provide corrective and preventive action to prevent recurrence.

11.3.3(B) The **CPAR database** (**Document 11-01**) shall be used to evaluate, resolve, correct, and documented events that may be useful to others throughout the AEP Quality organization, now and in the future. Records may be designated a nonconformance, lessons learned, or corrective action. The need for these tools is described elsewhere in **Sections 8.0, 9.0, 10.0, and 12.0 (Complaints, Control of Nonconforming Work, Improvement, and Preventative Action, respectively**).

(a) CPAR Reports are defined in Section 11.3.3(C). See also "SOP 852 - Corrective Action Process" from the Engineering, Projects and Field Services (EPFS) Quality Assurance Program.

11.3.3(C) Three types of reports can be generated in the LAB CPAR3 database :

(a) Corrective Action Request (CAR) Reports (described throughout this section);

(b) Nonconformance (NC) Reports (See Section 9.3.2(A)); and

(c) Lessons Learned (LL) Reports for Improvement (See Section 10.1.3(A)) and for Preventative Action (See Section 12.3).

11.3.4 When should a Corrective Action Request (CAR) Report be created?

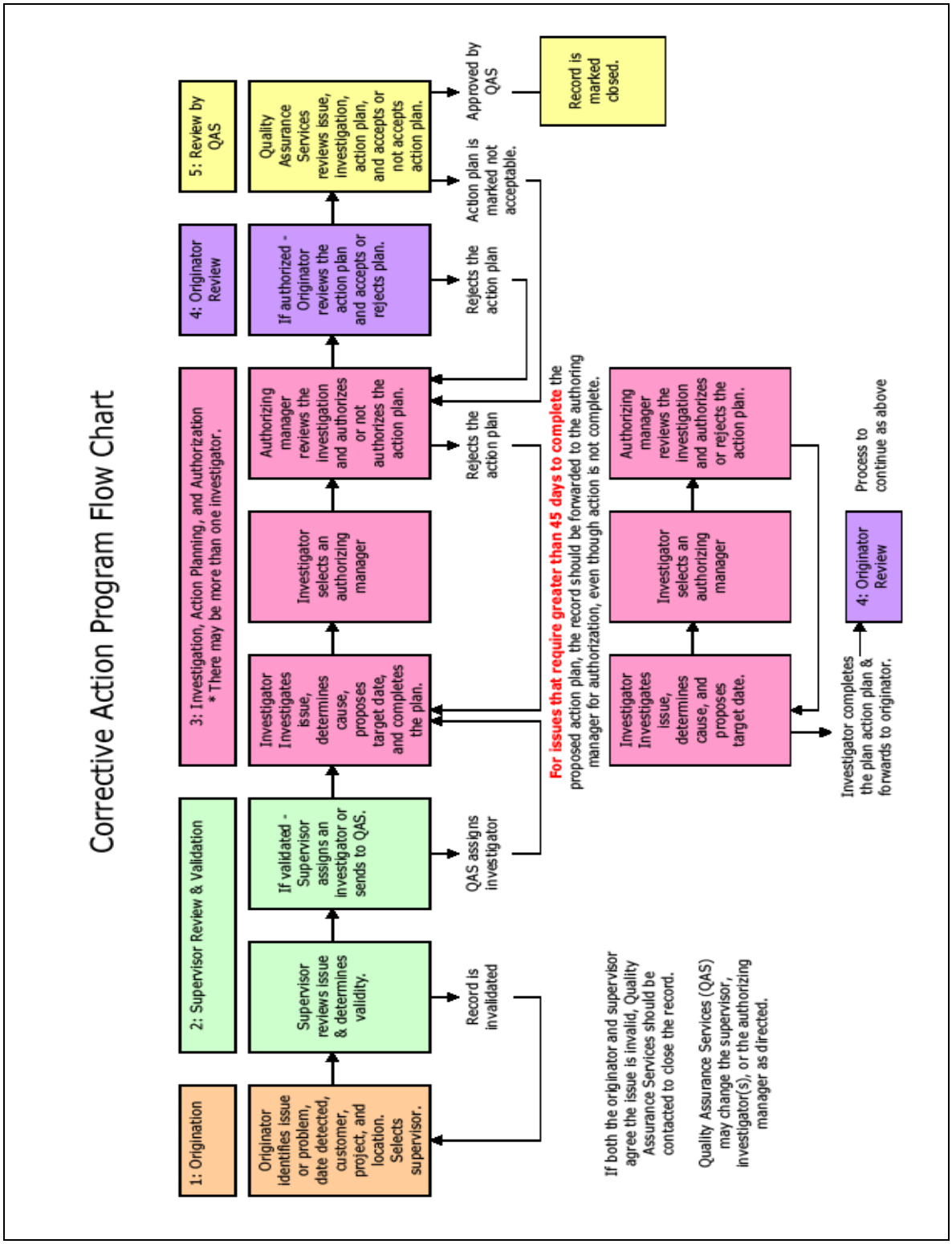
11.3.4(A) Criteria for creating a CAR Report include audit findings, complaints, conflicting work procedures, cost or schedule overruns, design errors and omissions, environmental permit issues, equipment performance trends, human performance trends, lab errors or omissions, lessons learned, nonconforming products and services, nonconforming work processes, process improvements, and other items, as necessary.

11.3.4(B) A flow chart is attached in **Document 11-02** to assist in understanding of the corrective and preventive action process from origination to closure.

11.3.4(C) The personnel of the Laboratory are required to generate a corrective and preventive action record (CPAR) for all situations noted in **Section 11.3.** Other situations as noted above may be used to generate a CPAR at the originator's discretion. To improve database consistency, CPARs and NCs should be created in the CPAR database by the QAO* (or designee). Personnel should notify the QAO*, or designee, in writing of potential issues they encounter that may need addressed by the CPAR database (e.g. customer complaints, potential nonconformities, lessons learned, etc.).

(a) Lessons Learned (LL) Reports – Issues that have been observed or resolved that may provide useful to others in the organization or to future laboratory efforts should be documented as a Lessons Learned Report in the CPAR database. Lessons Learned may also be non-reactionary in addressing preventative actions.

Document 11-2 Corrective Action Program Flowchart
<<Click on first page of object to access full document>>



(b) Nonconformity (NC) Reports- Findings from external and internal audits shall be documented as NC Reports in the CPAR database. Revisions in controlled quality documents that require a policy change, additional laboratory implementation, training, or further follow-up are also documented as a NC Report in the AEP CPAR database.

(i) PT results exceed the warning limits of the PT Study (beyond two standard deviations units) shall be monitored for a trend. If a trend become apparent and there is increased risk of PT failure and questionable results, the results should be documented as a NC Report in the CPAR database.

(c) Corrective Action Request (CAR) Reports- PT results exceed the control limits of the PT Study (beyond three standard deviations units) shall be documented as a CAR Reports in the CPAR database. These results are termed "Not Acceptable" by the PT provider.

(i) If PT results have consistently exceeded the warning limits of the PT Study (beyond two standard deviations units) and a NC Report has not solved the problem, a CAR Report may be documented in the CPAR database to further investigate the issue.

11.3.5 Who will use this database?

11.3.5(A) Employees of Analytical Chemistry Services (ACS) have the authority, responsibility, and obligation to identify, report, and record customer complaints, nonconforming work processes, and products and services that do not conform to specified requirements in accordance with the requirements of the quality management system.

11.3.5(B) A CAR for the Laboratory can be initiated by anyone in the Company using the Corrective and Preventive Action (LAB CPAR3) database. The Laboratory prefers to have a single person (i.e. the QAO*, or designee) initiate CAR for tracking purposes.

(a) Step 1 - Origination: When a nonconformity in the quality management system has been detected, as defined in Section 11.3.4 and 9.2, the "Originator" (i.e. the laboratory QAO*, or designee) initiates the appropriate report (LL, NC or CPAR) and the CPAR database generates a unique report number. The "Originator" selects the date detected, selects the suggested category (See Section x y z), generates the title, selects the location, provides "a brief description of the problem, concern, nonconformity or customer complaint", and identified the critical level. When Step 1 is complete the "Originator" Selects and Forwards the report to the "Supervisor" (i.e. Laboratory Manager).

(i) The laboratory utilizes the following suggested categories for consistency: Lessons Learned for LL reports, Nonconformity for NC report, and Lab Errors &/or Omissions for CA reports.

(ii) The laboratory utilizes the following title format for consistency: "Dolan Lab: (Issue), (Analytical Group), (Simple Description) ".

(iii) Regarding the critical level, the laboratory typically chooses "Non-critical". "Critical-Safety" pertains to personnel safety and "Critical-Equipment" pertains to the protection of plant equipment.

(iv) **Set Target Completion Date (for Step 5) within six weeks from "Origination" of the record.** This allows sufficient time to perform a suitable RCA investigation while monitoring for repeat occurrences of the error or NC event; and to provide the necessary documentation of the completed (or implemented) CAP.

- Exceptions to the six-week timeframe may be granted on a case-by-case basis by laboratory management and should be documented in the CPAR record.

(b) Step 2 – Supervisor Review & Validation, Investigator Assigned: Once the action is initiated a copy is forwarded to the "Supervisor" (i.e. the Laboratory Manager) for Validation. The Laboratory Manager must then assign someone (e.g. including them self) to take on the responsibility to investigate the cause of the problem and to develop a corrective action plan to resolve the issue in question. There is an opportunity for "Supervisor" comments.

- For NC Reports, the Supervisor selects the target completion date during Step 2. This must be chosen within six weeks.

(c) Step 3 – Investigation & Action Planning: Once assigned, the Investigator for the Root Cause Analysis is notified.

- For CA reports, the Investigator selects the target completion date. This must be chosen within six weeks.

(i) The first step of the Root Cause Analysis (RCA) is to speculate what has caused the nonconformity. **Refer to QAM Document 11-3 for Guidance on Determining the RCA of a Nonconformance.** The second step is to propose a Corrective Action Plan (CAP) "to correct the situation and prevent recurrence". Once the Investigation of the RCA is complete and a CAP has been proposed, the Investigator must select and notify an "Authorizing Manager(s)" to review the Investigation results.

(ii) The "Authorizing Manager(s)" is not required to be the same person as the CPAR "Supervisor". The laboratory typically selects the Laboratory Manager, and possibly, another person to review the Investigation results.

Document 0-1 Guidance for Determining the Root Cause Analysis (RCA) of a Nonconformance
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Guidance For Determining the Root Cause Analysis (RCA) of a Nonconformance [a]

Introduction: Each investigation into the root cause analysis (RCA) will vary based on the type of nonconformance (i.e. whether it is a person or an event), the complexity of the problem, and the range of the impact. Utilize the Work Flow Chart below with the accompanying suggestions to initiate a successful investigation. The suggestions are not intended to be exhaustive but to give guidance to the investigator(s). The nature of the matter requiring corrective action will determine the starting point of the investigation.

W o r k F l o w →

A	B	C	D	E
Personnel	Sample	Method	Controls	Data
Policies	Log-in	Validation	Preparation	Sample Trail
Procedures	Routing	Reagents	Handling/Storage	Logbook entries
Training	Storage	Instrumentation	Control Charts	Calculations
				Software
				Final Report

A. Personnel

- Interviews: Interviewing all employees involved in the work associated with the affected sample(s) is a key element of the investigation.
- Training: What was the level of expertise of the staff members involved in the matter under investigation? Could any training or skill deficiencies have been a causal factor?

B. Sample

- Were all minimum sample receipt criteria met? Was anything unusual about the sample(s) noted upon receipt?
- Log-in Check for discrepancies in the log-in records. Can the paperwork received with the sample(s) be reconciled with the LIMS log-in records?
- Routing: Was the sample split or simply transferred from one employee to another? If split, was there a written procedure (record)? If transferred, is the chain of custody (COC) intact? Were analyses perform by two or more persons within the laboratory?
- Storage: Were the sample(s) stored properly upon receipt and up to the time of analysis?

Document 11-3 Guidance for Determining the Root Cause Analysis (RCA) of a Nonconformance
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C. Method
- Was the technical procedure followed? Are there deficiencies in the standard operating procedure (SOP) as written? Are there discrepancies between the SOP and the reference method?
- Validation: Review records compiled during the validation of the method. Have any of the established method parameters changed over time?
- Reagents: Check the preparation of standards, QC check of reagents, and any test supplies having a critical impact on the test results.
- Instrumentation: Were the calibration procedure requirements carried out? If the event under investigation is occurring over a given period of time, it is important to review the calibration history of the instrument. Review the instrument logbook records.

D. Controls
- Critically review all aspects of the QC data itself.
- Preparation: Review all preparation steps for the controls (e.g. if a spike was used, was the spiking procedure followed?).
- Handling/Storage: Were control material(s) properly stored prior to use? Are there storage issues regarding the control samples during the analysis time frame? Had any control materials expired?
- Control Charts: Review the raw data and its transfer to the control charts carefully. Check the embedded formulas within the spreadsheet for automatic calculations.

E. Data
- Review the raw data carefully. Transcription or transposition errors can be culprits.
- Sample Trail: Check for gaps from sample receipt until the final report was issued.
- Logbook entries: Can the history of the sample be constructed from the logbook(s) used?
- Calculations: Recheck the calculations.
- Software: Ensure the integrity of formulas used in the LIMS and for computerized calculations steps.
- Final report: Is all the information provided on the final report accurate? Are there any inconsistencies between the final report and the analytical history traced via the investigation?

* Root cause guidance provided by Moheb Khalil, AIHA Auditor for the Dolan Chemical Laboratory in 2011.

QAM Document 11-03 Guidance for Determing RCA of a Nonconformance,
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(d) Step 4 – Authorization: Once selected, the "Authorizing Manager" either Authorizes or Rejects the Investigation and CAP. The date of this action is documented and there is an opportunity for the "Authorizing Manager(s)" to include comments. The "Authorizing Manager" then selects and notifies a person to complete the CAP.

(i) If the proposed CAP (or RCA) is rejected, the report is forwarded back to the Investigator with comments to re-evaluate and re-submit Step 3. This provides an opportunity to provide a response to the comments, revise the proposed CAP, and select a revised target completion date.

(e) Step 5 – Action Plan Completion: Once selected, the person notified to complete the CAP implement the CAP as defined in Step 3. The selected person must document the action CAP completion date and the person(s) who completed the CAP (i.e. them self or another person). There is an opportunity to include "comments and/or additional documentation as necessary". The report is them forwarded back to the "Originator"

(i) The person selected to implement the CAP is not required to be the same person as the CPAR "Investigator". Step 5 must be completed within the Target Completion Date.

(ii) Step 5 is used to provide sufficient documentation that the CAP has been implemented and that it has addressed the problem, thus far. Some CAPs may simply require documentation of a changed process or procedure and possibly, proof of improvement or stability.

(iii) In the instances of failed PT samples, the documentation must include the successful analysis of a supplemental PT sample (or equivalent). This should occur before the next round of PT (or blind) samples is analyzed by the laboratory in order to prevent recurrence of the event/error.

(iv) If the results of the supplemental PT sample are unacceptable, the CAP will be rejected by the "Originator" (QAO).

(f) Step 6 – Originator Review: Once the completed report has been returned to the "Originator", they must decide whether the implemented CAP is acceptable or not. There is an opportunity to proved comments/explanation. The report is them forwarded to "QAS for Review".

(i) If the implemented CAP (or RCA) is rejected by the "Originator", the report is forwarded back to the Investigator with comments to re-evaluate and re-submit Step 3. This provides an opportunity to provide a response to the comments, revise the proposed CAP, and select a revised target completion date.

(g) Step 7 – To be completed by Quality Assurance Services (QAS): Once the completed, authorized, and accepted report has been forwarded to "QAS", the following evaluations must be performed. These evaluations are necessary to finalize the CPAR for the most efficient communication of the issue throughout the laboratory. This is necessary to continually improve the quality management system as required by ISO 17025.

(i) Currently, "QAS" is performed by the Dolan Chemical Laboratory QAO*. The "QAS Review" includes the option whether the Corrective and Preventative Action (CPA) was acceptable, or not. As long as laboratory management and the QAO* have accepted the previous Steps, Step 7 is typically granted "CPA Accepted". (IF it were rejected, the report would likely be forwarded back to the Investigator with comments to re-evaluate and re-submit Step 3.)

(ii) The "QAS review" designates a Final Category (i.e. Refer to **Document 11-4** for a full list) and provides an opportunity for comments. The Final Category shall be used to document which sample phase within the laboratory process experienced nonconformity. NC records automatically select a Final Category of "Nonconformity Record". Currently the comments field is used to reiterate the Final Category with the associated laboratory process, as defined in **Document 11-4**.

(iii) The date the action was completed is documented for future follow-up actions (as defined in Section 11.3.5(D)).

(iv) During the "QAS Review" the CPAR report may be chosen to be utilized in the "New employee reader file". When this is selected the CPAR report is segregated in a file in the CPAR database for ease of access and review. These files need to be organized regarding which "new employees" should review these files and when.

(v) During the "QAS Review" the CPAR report may be chosen to be reviewed periodically (in increments of one to four years) and the date of last review is selected. This allows the issue to be re-visited at a future date to evaluate the effectiveness of the CAP, the impact on the laboratory, etc.

(h) Once the CPAR has been marked "QAS Accepted CPA", (currently) the QAO* re-iterates the final comments and recommendations in an email to the "Investigator" and other affected personnel. This ensures that the expectations from the Investigation and Implemented CAP are clear with all personnel and that these expectations will be reviewed for effectiveness during the CPAR Follow-up Process (as defined in Section 11.3.5(D)). The QAO* shall also update the CPAR tracking database with the final information.

11.3.5(C) This plan must be reviewed and approved by the Laboratory manager, as well as the party who initiated the corrective action.

(a) If action is not taken this information is also forwarded to laboratory management and, if necessary, assistance will be given to help resolve the issue**.**

(b) The QAO* should monitor the progress of Corrective Actions (as well as Lessons Learned and Nonconformance) in the database.

Document 0-2 Final Categories for QAS Accepted CPARs
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LAB CPAR3 database

Categories Assigned to QAS Accepted CPARs

Final CPAR Category	Associated Laboratory Process
Audit Findings	Audit Findings
Communication	Communication
Complaints	Complaints
Conflicting Work Procedures	- Analytical disagreement
Cost or Schedule Overruns	(not currently used)
Design Errors &/or Omissions	Sample reporting errors
Dolan Lab CPAR	** no longer used – choose specific category
Environmental Permit Issue	(not currently used)
Equipment Performance Trends	- Analytical issues – preventative maintenance
Human Performance Trends	- Sample handling issues
Lab Errors &/or Omissions	** no longer used – choose specific category
Lessons Learned	Lessons Learned
Nonconforming Products & Services	- Sample receipt issues (check in, login, preservation and LIMS issues)
Nonconforming Work Processes	- Sample analysis and preparation
Nonconformity	Nonconformity
Other	- Quality policies and guidelines
Potential Nonconformity	- Preventative Action
Process Improvements	(not currently used)
Root Cause Analysis	(not currently used)
Safety	(not currently used)
Shreveport Lab CPAR	** no longer used – choose specific category
Training	(not currently used)
Contract Nonconformity Closure Differs from AEP	(not currently used)

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11.3.5(D) **CPAR Follow-up Process:** All Nonconformity and CPAR reports in the CPAR database relevant to the Laboratory shall be monitored by the QAO*. Upon completion, the QAO shall verify that the changes have been implemented and/or evaluate the effectiveness of the corrective action plan.

(a) **This follow-up should initially occur within twelve months of the completion of the CAR or NC Report. (updated) If the corrective action has not been implemented, repeat this step to restart the follow-up process and/or re-evaluate the CAR or NC Report.**

(b) **If it is determined that the corrective action implemented has not been effective at resolving the nonconformity, the entire issue should be re-addressed with a new CAR or NC Report.**

11.3.5(E) "When a serious issue or risk to the business has been identified by the CPAR process, following the implementation of the corrective actions, the laboratory shall perform an additional audit to confirm their effectiveness." The audit should be performed using the procedure(s) listed in Section 14.3 ("System and Performance Audits"), or equivalent. [per Note in ISO 17025 Section 4.11.5, Reference 18.4.9]

11.4 Types of Corrective Action- There are two types of corrective action available to the Laboratory. Remedial corrective action can be taken on-the-spot or immediately to correct or repair nonconforming data, equipment or processes. There can also be long-term corrective action; that is, action taken to eliminate causes of nonconforming data and processes and to ensure that they do not reoccur.

11.4.1 Remedial Corrective Action

11.4.1(A) This is the process of corrective action that includes, but may not solely consist of, the repair of malfunctioning equipment and/or the adjustment for obvious sample-specific problems. The operator/analyst has the responsibility for conducting immediate corrective action when a problem arises.

11.4.1(B) Appropriate procedures may be:

(a) Found in the method being used,
(b) Provided by the laboratory as a troubleshooting checklist,
(c) Provided by the equipment manufacturers as troubleshooting guides,
(d) Provided by the equipment manufacturers in the form of service representatives, whose knowledge and technical ability may contribute to an easy resolution of the problem, or
(e) Provided by a knowledgeable operator/analyst.

11.4.1(C) No data shall be reported until the root cause(s) of the problem is determined and corrected, or until the laboratory demonstrates that cause was a random event and no longer affects data.

11.4.1(D) In the event that the solution to the problem is not found in the sources above, or is beyond the capabilities of the operator, then the operator will report the findings to higher authority. **Documentation of remedial corrective actions is not required.**

11.4.2 Long-term Corrective Action

11.4.2(A) Long-term corrective action taken for problems associated with a series of identified nonconformities will be initiated by using the "Corrective and Preventive Action Request" (CPAR) database in Lotus Notes. The decision as to whether any long-term corrective action request is valid and whether an investigation and action plan should be generated for a particular problem or problem(s) rests with laboratory management.

11.4.2(B) Regardless of whom initiates the CAR, QAO* (or designee) is responsible for the preparation of any periodic CPAR status report required by laboratory management.

11.5 Analytical Corrective Action

11.5.1 If the level of acceptability set by the methodology is not met, corrective action shall be taken immediately by the analyst performing the analysis to correct the problem. The follow steps shall be taken to correct the problem:

11.5.1(A) Identification and definition of the problem.

11.5.1(B) Investigation and determination of the cause of the problem.

11.5.1(C) Determination of a corrective action to eliminate the problem.

11.5.1(D) Implementing the corrective action and evaluating its effectiveness.

11.5.1(E) Verifying that the corrective action has eliminated the problem.

11.5.2 A myriad of corrective action procedures are presented in **Document 11-03.**

11.5.2(A) The keys to the QC checks listed, QC acceptance criteria, and corrective actions for this table are given on the last page of Document **11-03.**

11.5.3 Corrective actions are usually initiated based on either the internal QC checks listed on **Document 11-03**, data validation by reviewing authority, or performance audits.

11.5.3(A) Additional corrective action protocol for individual procedures may be described within the pertinent standard operating procedures (SOPs).

11.5.4 Authority and Responsibility

11.5.4(A) Analysts have the responsibility to maintain control over the sample integrity, the analytical system and the security of analytical data and records.

(a) When any of these items are at risk of being violated in reference to the laboratory's quality assurance policies or the QC criteria outlined in the relevant procedures, the analyst has the authority to halt analytical work to pursue corrective action.

(b) The analyst should notify the appropriate personnel, as necessary, to avoid further potential damage; should prevent others from utilizing the affected item(s) if there is potential for shared use (e.g. tag out suspect equipment); and should notify management for guidance or to document significant non-conformities if the problem has been solved.

(c) Once it is certain that the corrective action has resolved the situation, the analysts have the authority to resume work.

11.5.4(B) If the corrective actions have proven to be ineffective, the Laboratory Manager (or designee), may approve the reporting of the analytical data along with information indicating the failed quality control measure.

11.5.4(C) Also, areas of persistent problems should be reviewed as part of corrective action and may require use of the formal CPAR database as described in **Section 11.3.**

Document 11-5 Analytical Corrective Action Chart (Reserved)

11.6 Management Corrective Action (Reserved)

11.6.1 Internal Audits
11.6.2 External Audits
11.6.3 CPARs
11.6.4 Management Reviews
11.6.5 Other observations

11.6.6 Authority and Responsibility

11.6.6(A) Management has the responsibility to maintain control over the laboratory's adherence to the quality system, the NELAC ["NELAC 2003 Standard", Reference 18.4.1] and the requirements of the relevant accrediting bodie(s) [LAC 33:I§5301.C.14, Reference 18.4.17],

(a) Management has the authority to halt laboratory operations and/or analytical work to pursue corrective action, to prevent non-conformances, to maintain a minimum level of quality, or for any reason they deem important based on expertise and sound judgment.

(b) Management shall notify the appropriate personnel, as necessary, to maintain control over the quality system and the affected laboratory operations.

(c) After confidence in the affected area has been restored and the risk(s) to laboratory operations have been addressed, management has the authority to resume work.

11.7 Documentation — Controlled quality documents from this Section shall be maintained separately from the Quality Assurance Manual in the following collection (which is itself, a controlled laboratory document):

11.7.1(A) **QCDOC 005** records (and the majority of laboratory documentation, unless otherwise specified) shall be maintained for at least five (5) years, and may require periodic review.

QC File 00 20— "QCDOC 005: CPAR Information " (in Section 11)

12.0 Management Requirements: Preventative Action

12.1 Purpose and Scope—The purpose of this section is to identify potential sources of nonconformances and to prescribe actions that may be taken to avoid such potential nonconformances during testing or analytical operations. Nonconformities are discussed in further detail in **Section 9.0**.

12.1.1 This section also describes the QAO*'s responsibilities for carrying out a comprehensive preventive maintenance program for instruments and test equipment used in the Laboratory's analytical testing activities. This section applies to all measuring equipment and test instruments included in the Laboratory's calibration program, i.e. any equipment, whose determinations or readings must be recorded and reported.

12.1.2 Preventive action may require Quality Planning and Improvements (detailed in **Section 10.0**) and may require Corrective Action (as discussed in **Section 11.0**). ”Procedures for preventive actions include the initiation of such actions and application of controls to ensure that they are effective”. [per ISO 17025 Section 4.12.2, Reference 18.4.9] This has been fulfilled by the implementation of Enviance Task reminders (See Section 12.5.5) for preventative action behaviors.

12.1.3 Preventive action may be evaluated, resolved, corrected, and documented using the **CPAR database** (**Document 11-01**) as described in **Section 11.3.3**. The preventive action should be not be a reactionary item, but should be evaluated prior to the issue developing into a non-conformance using the lessons learned process.

12.2 Laboratory Preventive Action Processes

12.2.1 The Preventative Action Report is a proactive approach that requires anticipation of problems within the laboratory in order to improve the performance of the organization.

12.2.2 Lessons Learned reports in the CPAR database shall be utilized to document and monitor preventative actions, to improve the performance of the organization, and to capture best practices and knowledge that should be taught to others in the organization or to future employees.

12.2.3 Preventative Maintenance (PM) of the laboratory equipment is another form of preventative action, in which definitive maintenance issues are identified, responsible parties are chosen, maintenance frequency is defined, and reminders are provided.

12.2.4 Trending. Apart from the review of the operational procedures, the preventive action might involve analysis of data and QC data, proficiency-testing results, and laboratory workload— including trending and risk analyses.

12.3 Preventive Action Report

12.3.1 Needed improvements, potential sources of nonconformances, and employee suggestions — either technical or concerning the management system — may be identified by any laboratory employee. Upon identification, the laboratory employee shall gather and review the information pertaining to the preventative action by completing the Preventative Action Report form (Form QAR 1201, See **Document 12-01**). This form shall then be forwarded to the QAO* (or designee) for completion.

12.3.2 The completed Form QAR 1201 shall be logged into a database by the QAO* or designee. The QAO* (or designee) and laboratory management shall review, discuss and a decide whether to act upon the identified preventive action. This decision (and any proposed action plan) requires formal authorization by the laboratory management.

12.3.3 If preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformances and to take advantage of the opportunities for improvement.

12.3.4 Procedures for preventive actions shall include the initiation of such actions and application of controls to ensure that they are effective.

12.3.5 It should be noted that preventive action is a proactive process to identify opportunities for improvement rather than a reaction to the identification of problems, complaints, or existing nonconformities.

Document 12-1 Preventative Action Report form (Form QAR 1201)
<<Click on first page of object to access full document>>

Form QAR-1201
(Rev. 1, 01.12.09)

Preventive Action Report Form

Preventive Action Title:

Preventive Action Description:

Preventive Action Resolution:

Supervisor's Comments:

Originator: **Supervisor:**

Created: **Resolved:** **Ref. ID #:**

Print Form

12.4 Lessons Learned (LL)

12.4.1 Lessons Learned (LL) Reports are defined in Section 11.3.3(C). See also "SOP 852.01- Lessons Learned" and "SOP 853.- Preventative Action Process" from the Engineering, Projects and Field Services (EPFS) Quality Assurance Program.

12.5 Preventive Maintenance (PM)

12.5.1 Preventive Maintenance (PM) Program

12.5.1(A) The Laboratory will conduct an orderly program of positive actions (equipment cleaning, lubricating, reconditioning, adjusting, and/or testing) to prevent instruments or equipment from failure during use. The purpose of this preventive maintenance program is to increase measurement system reliability. Conversely, if the preventive maintenance program is not properly carried out, the results will be:

(a) increased measurement system downtime.
(b) increased maintenance costs and a distrust in the validity of the data.

12.5.2 Preventive Maintenance (PM) Schedules

12.5.2(A) The QAO* (or designee) should prepare and implement a preventive maintenance schedule for the laboratory measurement systems under the calibration system.

12.5.2(B) The preventive maintenance schedule should relate the level of operator skills and the recommendations of the appropriate service contract, if applicable.

12.5.3 Preventive Maintenance (PM) Responsibility

12.5.3(A) Since instrument calibration is commonly the responsibility of the operator, in addition to preventive maintenance tasks, a combined preventive maintenance-calibration schedule will be used in those cases.

12.5.3(B) Each primary analytical instrument in the Laboratory is assigned a primary chemist. This primary chemist is responsible for all routine maintenance and resulting paperwork for that instrument. Refer to the Preventative Maintenance Responsibility record for full details.

12.5.3(C) For the more valuable instruments, a service contract with the manufacturer is the favored option for a structured preventive maintenance program. The primary chemist is responsible for scheduling the maintenance and ensuring that the maintenance was conducted appropriately.

12.5.4 Preventive Maintenance (PM) Record

12.5.4(A) An instrument maintenance log of all routine and non-routine maintenance and service reports will be maintained for each instrument by the primary chemist. Generally, maintenance should follow the manufacturer or vendor's instructions. Other considerations are the type of use, how many individuals use the instrument, how often it is used and the operating environment.

(a) For this reason, a user log is kept at each instrument, where applicable. A record of these daily users and any problems encountered upon these daily uses may be recorded by each individual analyst.

(b) Documentation will include a brief description of the maintenance procedure performed, the initials of chemist/technician, the date and the time of the maintenance performed.

(c) Consult the Laboratory's Instrument Maintenance Manual for guidance in scheduling maintenance activity.

12.5.4(B) The responsibility for the maintenance program for each instrument remains with the assigned primary chemist or a designated substitute. The QAO* (or designee) will maintain surveillance by periodically and randomly auditing for compliance.

Document 12-2 Preventative Maintenance Schedule for IHAG (update)
2 Pages <<Click on first page of object to access full document>>

Laboratory Equipment Preventative Maintenance Schedule
Industrial Hygiene Analytical Group

Equipment / Instrument Type	Minimum PM Frequency	Routine Preventative Maintenance (PM) ('NA' Not Applicable)	'E' for Enviance Task
General Equipment for Dolan Chemical Laboratory			
Acid Neutralization Tank for Dolan Chemical Laboratory	Daily	Daily log- observe/document daily system checks	
	Quarterly	Document quarterly check	E
	Semiannually	Two (2) pH cell calibrations	E
	As needed	Maintenance	
Reverse Osmosis (RO) System for Dolan Chemical Laboratory	Twice daily	Observe/Document Daily System Checks	
	Daily	Daily Log- Document Daily System Checks	
	As needed	Maintenance	
	Semiannually, as needed	Replace Sum pre-filter	E
	Annually	Calibrate Conductivity Meter	
	Annually, as needed	Replace Vent Filters	E
	Annually, as needed	Replace Cartridges	
	Ongoing	Instrument use / calibration / PM logbook	
Industrial Hygiene Analytical Group			
Asher, Low Temperature	Each use	Inspection	
	Ongoing	Instrument use / calibration / PM logbook	
Balances, Analytical	Daily	Check with class S weight	
	Daily	Daily log- document daily weight checks	
	Before each use	Check alignment and balance	
	After each use	Clean pans and compartment	
	Annually	Authorized balance technician PM visit	E
Balance, Micro	Each Use	Inspection	
	Daily	Check with class S weight	
	Daily	Daily log- document daily weight checks	
	Before each use	Check alignment and balance	
	After each use	Clean pans and compartment	
	Annually	Authorized balance technician PM visit	E
Block Digester for IH Tests	Each day of use	Inspection and temperature log	
	Annually	Check thermometer with NIST calibrated thermometer	
Deionized Water Systems (for ultrapure water)	Each use	Inspection and conductivity verification	
	Daily	Document daily observation of conductivity	
	Annually, as needed	Change cartridges and filter	
	Semiannually, as needed	Change UV lamp	
	Ongoing	Instrument use / calibration / PM logbook	
Environmental Chamber	Each day of use	Inspection and temperature log (at start and end of analysis)	
Fourier Transform Infrared Spectrophotometer (FTIR) (for IH Analyses)	Each use	Inspection	
	Ongoing	Instrument use / calibration / PM logbook	
	Not required- but must maintain hardcopies	Computer file back-up	

File - QAM Document 12-02 Preventative Maintenance Schedule for IHAG, Revision 1, 10.05.12.xls Page 1 of 2

Document 12-3 Preventative Maintenance Schedule for PSAG (update)
5 Pages <<Click on first page of object to access full document>>

Laboratory Equipment Preventative Maintenance Schedule
Plant Services Analytical Group

Equipment / Instrument Type	Minimum PM Frequency	Routine Preventative Maintenance (PM) ('NA' Not Applicable)	'E' for Enviance Task
General Equipment for Dolan Chemical Laboratory			
Acid Neutralization Tank for Dolan Chemical Laboratory	Daily	Daily log- observe/document daily system checks	
	Quarterly	Document quarterly check	E
	Semiannually	Two (2) pH cell calibrations	E
	As needed	Maintenance	
Reverse Osmosis (RO) System for Dolan Chemical Laboratory	Twice daily	Observe/Document Daily System Checks	
	Daily	Daily Log- Document Daily System Checks	
	As needed	Maintenance	
	Semiannually, as needed	Replace Sum pre-filter	E
	Annually	Calibrate Conductivity Meter	
	Annually, as needed	Replace Vent Filters	E
	Annually, as needed	Replace Cartridges	
	Ongoing	Instrument use / calibration / PM logbook	
Plant Services Analytical Group			
Auto - Titrator (TAO)	Before use	Clean reaction vessels	
	Before use	pH electrode check	
	Before use	Check calibration? (no standards)	
	Ongoing	Instrument use / calibration / PM logbook	
	Annually	Performance evaluation	E
Balances, Analytical	Daily	Check with class S weight	
	Daily	Daily log- document daily weight checks	
	Before each use	Check alignment and balance	
	After each use	Clean pans and compartment	
	Annually	Authorized balance technician PM visit	E
Balance, Qualitative (Trip) Top-loading	Daily	Check with class S weight	
	Daily	Daily log- document daily weight checks	
	Before each use	Check alignment and balance	
	After each use	Clean pans and compartment	
	Annually	Authorized balance technician PM visit	E
Barometer	Each Use	Inspection	
	Annually	Calibrate versus NIST reference	E
Calorimeter(and Bomb Vessel) (for Coal Testing)	Each use	Inspection	
	After each use	Clean combustion vessel	
	Semiannually, or with changes in instrument setup	Ten (10) calibration runs vs. NIST SRM 39i benzoic acid calorimetric standard	
	As needed (> 5000 firings)	Bomb vessel recertification— Oxygen combustion vessel must pass hydrostatic and proff testing as recommended practice for safe use. (Checks of each bomb, in use, done every year to determine need for integrity recertification.)	E
	Ongoing	Instrument use / calibration / PM logbook	
	Not required- but must maintain hardcopies	Computer file back-up	

File - QAM Document 12-03 Preventative Maintenance Schedule for PSAG, Revision 1, 10.05.12.xls Page 1 of 5

Document 12-4 Preventative Maintenance Schedule for WWAG (updated)
4 Pages <<Click on first page of object to access full document>>

Laboratory Equipment Preventative Maintenance Schedule
Water and Waste Analytical Group

Equipment / Instrument Type	Minimum PM Frequency	Routine Preventative Maintenance (PM) ('NA' Not Applicable)	E for Enviance Task
General Equipment for Dolan Chemical Laboratory			
Acid Neutralization Tank for Dolan Chemical Laboratory	Daily	Daily log- observe/document daily system checks	
	Quarterly	Document quarterly check	E
	Semiannually	Two (2) pH cell calibrations	E
	As needed	Maintenance	
Reverse Osmosis (RO) System for Dolan Chemical Laboratory	Twice daily	Observe/Document Daily System Checks	
	Daily	Daily Log- Document Daily System Checks	
	As needed	Maintenance	
	Semiannually, as needed	Replace Sum pre-filter	E
	Annually	Calibrate Conductivity Meter	
	Annually, as needed	Replace Vent Filters	E
	Annually, as needed	Replace Cartridges	
	Ongoing	Instrument use / calibration / PM logbook	
Water and Waste Analytical Group			
As/Se Speciation	As needed	Change tubing	
	As needed	Change guard column	
	As needed	Inspect check valves	
	Ongoing	Instrument use / calibration / PM logbook	
	Not required- but must maintain hardcopies	Computer file back-up	
Auto - Analyzer - Skalar	Before use	Inspection	
	Annually	Warranty PM visit	
	Ongoing	Instrument use / calibration / PM logbook	
	WEEKLY	Computer file back-up	
Auto - Analyzer (Discrete) - Seal	Before use	Inspection	
	Annually	Warranty PM visit	
	Ongoing	Instrument use / calibration / PM logbook	
	WEEKLY	Computer file back-up	
Auto - Titrator	Before use	Clean reaction vessels	
	Before use	pH electrode check	
	Before use	Check calibration	
	Ongoing	Instrument use / calibration / PM logbook	
Balances, Analytical	Daily	Check with class S weight	
	Daily	Daily log- document daily weight checks	
	Before each use	Check alignment and balance	
	After each use	Clean pans and compartment	
	Annually	Authorized balance technician PM visit	E
Balance, Qualitative (Trip) Top-loading	Daily	Check with class S weight	
	Daily	Daily log- document daily weight checks	
	Before each use	Check alignment and balance	
	After each use	Clean pans and compartment	
	Annually	Authorized balance technician PM visit	E
Block Digester for COD	Annually	Check block is 150 °C within 3% with NIST calibrated thermometer or reference thermometer	E
	Ongoing	Instrument use / calibration / PM logbook	E

File - QAM Document 12-04 Preventative Maintenance Schedule for WWAG, Revision 1, 10.05.12.xls

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12.5.5 Enviance Tasks

12.5.5(A) The Enviance System is an internet-based environmental, health and safety (EHS) compliance management software. The software provides complete data collection, reporting and analysis.

12.5.5(B) Enviance tasks may be created to remind the responsible person to perform specific periodic calibration and maintenance activities.

12.5.5(C) Laboratory personnel are assigned Enviance tasks as reminders for various quality management system issues. It is expected that the personnel manage their assigned tasks in a timely manner and that final documentation (e.g. calibration forms, DOC documentation, vendor certificates, etc.) associated with the tasks are forwarded to the QAO* (or designee) for review.

12.5.5(D) When Enviance tasks are in progress or have been completed the assigned personnel may follow the link in email communications to update the status of the task. The percent completion, "completion" date (or progress date), and comments should be added to the "Task's Objects" to document within the Enviance system. (Time and hours to complete the task are optional fields). Save updated information.

(a) Tasks will remain open and periodic reminders will continue to be sent until the task is marked 100%.

(b) The same progress information may be accessed from the Enviance Task & Workflows List or the Enviance Calendar by right-clicking on the task icon. The progress screen is accessed by selecting "Complete/Dismiss".

(c) The task may be edited by authorized personnel by right-clicking on the task icon (i.e. in the Enviance Task & Workflows List or the Enviance Calendar) and selecting "Edit Task Properties" to make amendments.

(d) The authorized laboratory Enviance manager may also allow a task to be skipped and to move to the next recurrence. This is done by right-clicking on the task icon (i.e. in the Enviance Task & Workflows List or the Enviance Calendar) and selecting "Create Exception". This allows a new due date to be chosen, while documenting the change in the Enviance system.

12.5.5(E) Enviance tasks for the laboratory shall be maintained by laboratory management, or a designee. Currently, the Enviance tasks are managed by the QAO*, or designee.

(a) For consistency, task names should follow similar formats – Describe item and/or quality task; include frequency, if possible (e.g. annual, quarterly, etc.); include pertinent details (e.g. serial number, location, test group, analyst initials, etc); (list analytical group, AG).

(b) For consistency, the task descriptions should follow similar formats, as described for the task name above. This field allows for more text information and should adequately describe the task and effectively direct the responsible person.

(c) The Selected object(s) link the task with the associated quality or compliance requirements for the specific AEP departments and facilities (e.g. "AEP\ Environment Safety & Health\ Dolan Laboratory\ Compliance Calendar\ General QA-QC Requirements", etc.).

(d) Tasks are assigned to the responsible person(s), usually Chemists, or Group(s) in the Enviance system. Pertinent documents may be included for additional information.

(e) Tasks are assigned a "Recurrence schedule" based on the required frequency. Most tasks have a set frequency based on the "time after last completion", while others are set to recur at a set frequency, regardless of the last task completion. Yet, others may not recur at all and are one-time requirements.

(i) When a recurring task is being removed from use, the authorized laboratory Enviance manager should adjust the Recurrence schedule to "End date after" a specified date to allow the task to expire from use. (Otherwise, if the option of "Delete Task Series" is selected, the current task and all previous completed tasks - and their associated comments and documentation - are deleted from the Enviance system.)

(f) Tasks are assigned "Notifications" to remind affected personnel of an upcoming or overdue task which are < 100% complete. These notifications are sent by email to laboratory personnel (<u>not</u> through the Enviance "Inbox", which would most likely be overlooked).

(i) Currently, the laboratory assigns several preliminary reminders in the days, weeks and months prior to and after the due date to be sent to the Task "Assignee(s)".

(ii) Typically, when the task is < 100% complete and overdue one month, the Task "Assignor" is added to the notifications.

(iii) Typically, when the task is < 100% complete and overdue two months, the Laboratory Manager (added under "Other Users") is added to the notifications. **Typically, this is the last notification sent to all laboratory personnel.**

(iv) Typically, the Task "Assignor" is notified when the task is 100% complete. As stated in Section 12.5.5(C), laboratory personnel should forward any final documentation to the QAO* (or designee) at this time.

12.5.6 Spare Parts

12.5.6(A) The Laboratory attempts to maintain, for each instrument, a quantity of spare parts sufficient to replace worn-out parts with a minimum of downtown.

12.5.7 Out-of-Service Equipment

12.5.7(A) Equipment, which has been deemed nonfunctional either through an equipment failure or through the production of unreliable data for an unknown reason, should be tagged as out-of-service using the tags such as "Do Not Operate Equipment Locked Out". These tags are available from the QAO* (or designee).

12.6 Trending

12.6.1 It is the responsibility of the QAO* (or designee) to perform trend analyses of proficiency-testing results, QC data (i.e. review of control charts); and laboratory workload (i.e. on time / due date evaluation).

12.7 Documentation — Controlled quality documents from this Section shall be maintained separately from the Quality Assurance Manual in the following collection (which is itself, a controlled laboratory document):

12.7.1(A) **QCDOC 005** records (and the majority of laboratory documentation, unless otherwise specified) shall be maintained for at least five (5) years, and may require periodic review.

QC File 00 21— "QCDOC 005: CPAR Information " (in Section 12)

13.0 Management Requirements: Control of Records

13.1 Purpose and Scope — This section describes how the Laboratory controls the quality documents relating to the analytical and testing activities of the laboratory (i.e. "control of laboratory records").

13.1.1 More information on procedures for document control within the laboratory is outlined in **Chapter 3.0 – Document Control.** (See **Section 3.2.1** for a list of all controlled documents).

13.1.2 Record Keeping System and Design — A record shall be maintained of all analytical data generated in the laboratory.

13.1.2(A) These records may exist in at least one of four formats:

(a) Handwritten in the analyst's notebook;
(b) Printouts and reports generated by analytical instrumentation;
(c) Information generated and stored electronically by analytical instrumentation; and
(d) Bound books for specific analyses.

13.1.2(B) **The record keeping system must allow historical reconstruction of all laboratory activities that produced the resultant sample analytical data.**

(a) The history of the sample must be readily understood through the documentation.
(b) This shall include inter-laboratory transfers of samples and/or extracts.
(c) Electronic files saved should be sufficient to re-create the analytical sequence - chromatograms, background changes, method changes, etc. - as if they were opened in a new place using the appropriate software.

13.1.2(C) The records shall include the identity of personnel involved in sampling, preparation, calibration, or testing.

13.1.2(D) All information relating to the laboratory facilities equipment, analytical test methods, and related laboratory activities, such as sample receipt, sample preparation, or data verification shall be documented.

13.1.2(E) Information that is generated and stored electronically by analytical instrumentation must be "backed up" and stored in a stable electronic medium unless:

(a) The pertinent historical information has been recorded in the analyst's notebook

(b) an accurate printed report with all the pertinent historical information can be obtained and stored instead.

(c) Any generated data not recorded in an electronic database shall be maintained in a laboratory notebook, which shall meet the requirements given in Section 13.5.

13.1.3 A record shall also be maintained for the following information:

13.1.3(A) Instrument Calibration;
13.1.3(B) Instrument Maintenance;
13.1.3(C) Oven and refrigerator temperatures;
13.1.3(D) All laboratory notebooks, instrument logbooks, standards logbooks and records for data reduction, validation storage and reporting;
13.1.3(E) All analysis reports and attached data sent to clients; and
13.1.3(F) All computer worksheets of analytical data

13.1.4 When mistakes occur in records, using non-erasable ink each mistake shall be crossed out with a single line, not erased, made illegible or deleted, and the correct value entered alongside. When applicable, a reason for the change should be documented in the margin. The use of correction fluid or pencils is not allowed. All such alterations to records shall be signed or initialed by the person making the correction. In the case of records stored electronically, equivalent measures shall be taken to avoid loss or change of original data.

13.1.5 Records Handling — Refer to the **"Control of Records - Master List of Laboratory Records"** for lists of laboratory records and guidance on handling records - including how records are indexed, filed and stored; who has access to certain records, how long records are maintained and proper disposal of records. This list is retained by the QAO. These records are maintained in **QCDOC-001 QUALITY SYSTEM (QS) Records.**

13.1.6 The QAO* also maintains a list of material signatures and initials for all Laboratory Analysts.

13.2 Data Collection and Reporting Procedures

13.2.1 Recording Instrument Generated Reports

13.2.1(A) Files will be created and maintained for printed reports generated by analytical equipment. These reports will contain the same type of information that would be written in an analyst's notebook.

13.2.1(B) If the instrument lacks the capability to record the required information, then it must be written in by hand (See Section 13.5).

13.2.1(C) **See Section 1.4.3(A) for preservation of electronically generated reports.**

13.2.1(D) "All calibration curves should be dated and labeled with applicable method, instrument identification, analysis date, analyte concentrations, and instrument response." [Reference 18.4.18] (also referenced in Section 19.3.6(C)).

13.2.1(E) The reliability and original entirety of raw calibration reports and raw data files should be maintained to the extent that is possible.

(a) When changes (i.e. manual integration) are made to such raw files, the amended electronic file should be renamed to designate the version of amendment and to prevent erasing or overwriting the file.

(b) Changes to raw data and records should be documented with the name of the person making the change, the date of change, and the reason for the change per the SOP for the appropriate parameter. Examples of documentation include:

(i) printing the raw and amended data, and including the name, data, and reason for change;
(ii) documenting within the instrument log book;
(iii) documenting within the parameter preparation log book; or
(iv) documenting the name, data, and reason for change in a viewable "notes" or text field in the electronic file;

(v) When possible, utilizing analyst's initials in software audit trail.

13.3 Computational and Data Validation Procedures

13.3.1 "Calculations (manual, spreadsheet- assisted, or imbedded in the LIMS) and data transfers shall be subject to appropriate checks in a systematic manner. Additionally, computer software developed by the user must be documented in sufficient detail and be suitably validated as being adequate for use." [per ISO 17025 Sections 5.4.7.1 and 5.4.7.2, Reference 18.4.9]

13.3.1(A) The IHAG shall perform and document spreadsheet validations for all calculations in the LIMS.

13.4 Analytical and Testing Reports (Reserved)

13.5 Laboratory Notebooks – Laboratory Notebooks must be maintained when files generated by analytical equipment are not available (See Section 13.2.1).

13.5.1 Analytical Notebook Format

13.5.1(A) Specific guidelines are needed for recording analytical data in laboratory notebooks when the analytical work and results may be subject to regulatory review, accreditation review, or subject to litigation. These guidelines are recommended for all laboratory notebooks in use at Laboratory. Other analyses and sample types may be subjected to these guidelines if the potential exists for regulatory review or litigation.

13.5.1(B) Handwritten analytical data including calibration data and pertinent quality control results shall be recorded in notebooks that conform to the following specifications:

(a) All laboratory notebooks shall be hardcover, bound and have consecutively numbered water-proof and chemical resistant pages (i.e. Nalgene # 6300-1000, Fisher Catalog #11-900, or equivalent).

(b) To avoid loss or misplacement of notebooks, each notebook shall be identified with the analyte or sample type and the dates of usage on both the spine and front cover. It is also recommended to include the span of analysis numbers on the spine and front cover.

(c) Hand-written data shall be entered directly in the notebook as it is acquired. It is not acceptable to record data on a scrap of paper and enter it into the book at a later date.

(d) Any generated data not recorded in an electronic database shall be legibly recorded in permanent ink.

(e) A table of contents is recommended listing the analysis numbers, abbreviated sample ID and page number of all samples included.

(f) All data entries shall be in non-erasable ink, preferably black. Pencil entries are not allowed.

(g) All data entries shall be signed by the person making the entry and dated. Use a legal signature (not just initials). If the entry takes up more than one page in the book, separately sign and date each page.

(h) Cancel errors by drawing a line through the entry so that the erroneous entry can still be read. Entries in records shall not be obliterated by methods such as erasures, overwritten files or markings. The use of correction fluid is not allowed. Changes must be initialed and dated, and a reason for the change should be noted in the margin, when applicable.

(i) Each project, sample run or page should have the following information:
   (i) Date
   (ii) Customers' Sample IDs
   (iii) Laboratory Analysis numbers
   (iv) Time of analysis or run start
   (v) Signatures of the analyst and primary
   (vi) Example calculation, if applicable

(j) Formulas used in the calculations should be written or typed on a page taped to the inside front cover of the notebook.

(k) These criteria also shall apply to electronically maintained records.

13.5.1(C) In general, analytical notebooks are used for the recording of data associated with the preparation of standards and samples. All other data is initially recorded as either direct instrument output or is recorded through the use of data input sheets (as used in IHAG).

13.5.2 Recording in Laboratory Notebook— Each analyst will maintain a notebook for the purpose of recording "raw" analytical data.

13.5.2(A) The information to be recorded is raw data, the date and time the analysis is performed, any information needed to refine the data (calibration and standardization of data, equations, and etc.) and quality control data generated to validate the analysis (replicates, duplicates, spikes, and laboratory check samples).

13.5.2(B) Samples, standards and quality control samples must be clearly and legibly identified.

13.5.2(C) The analyst shall also record any anomalies and/or conditions that existed during the analysis process that may have an impact on the data generated.

13.5.3 Use and Maintenance Logs

13.5.3(A) Use and maintenance logs shall be maintained for instrumentation and shall contain pertinent observations; calibration information; periodic maintenance by the analyst/user; observations for equipment overload or failure; and logs of service, maintenance or repair by an outside vendor.

13.5.3(B) To avoid loss or misplacement, each logbook shall be identified with the instrument/equipment name, model number and serial number and the dates of usage on both the spine and/or front cover.

13.5.3(C) Data, observations and records shall be entered directly in the logbook as it is acquired.

13.5.3(D) Any generated data not recorded in an electronic database shall be legibly recorded in permanent ink. All data entries shall be in non-erasable ink, preferably black. Pencil entries are not allowed.

13.5.3(E) All data entries shall be signed or initialed by the person making the entry and dated. If the entry takes up more than one page in the book, separately sign and date each page. Provide a detailed explanation, when applicable.

13.5.3(F) Cancel errors by drawing a line through the entry so that the erroneous entry can still be read. Entries in records shall not be obliterated by methods such as erasures, overwritten files or markings. The use of correction fluid is not allowed. Changes shall be initialed and dated with the reason for the change noted in the margin.

13.5.3(G) The analyst shall also record any anomalies and/or conditions that existed during the analysis process that may have an impact on the data generated.

13.6 Chain-of-Custody Documentation (Reserved)

13.7 Technical Documentation and Regulations

13.7.1 Quarterly QA/QC Report — The QAO* (or designee) shall provide a QA/QC report to laboratory management regarding quality assurance issues, projects, and problems at least quarterly. The Quarterly QA/QC report shall summarize:

13.7.1(A) Laboratory performance measurements;
13.7.1(B) Results of proficiency testing (PT) and round robin (RR) studies;
13.7.1(C) Corrective and preventive actions reports (i.e. Lessons Learned, Non-conformances, and CPARs) generated and resolved;
13.7.1(D) Progress of laboratory performance projects (i.e. MDL and DOC studies) and other relevant personnel training;
13.7.1(E) Status of significant calibration and laboratory equipment issues;
13.7.1(F) Results from various laboratory evaluations (i.e. on-site assessments, and other accreditation achievements);
13.7.1(G) Other significant laboratory issues, feedback, etc.

13.7.2 Bi-Monthly Update of Fiber Precision Data—The QAO* (or designee) shall perform and communicate a bi-monthly update (i.e. every other month) of the Fiber Sr Precision for each analyst in the Industrial Hygiene Analytical Group (IHAG). The details of this report are summarized in the Asbestos Fibers by PCM SOP.

13.7.3 Monthly Bulk Asbestos Summary —The QAO* (or designee) shall provide a monthly QA analyses summary of Bulk Asbestos activities to laboratory management and analysts in the Industrial Hygiene Analytical Group (IHAG). The details of this report are summarized in the Bulk Asbestos SOP, but is essentially a summary of all QA activities – blank analyses, duplicate analyses, PT testing results, other inter-laboratory analyses, a listing of all sample analyses performed during the month, and a summary of all CPARs associated with Bulk Asbestos analyses that were generated during the month.

13.7.3(A) This report includes calculations for the Monthly Asbestos Error Rate as described in the Bulk Asbestos SOP.

13.7.4 Monthly Update of Fiber Control Charts—The QAO* (or designee) shall perform a monthly update of the Fiber Control Charts to laboratory management and analysts in the Industrial Hygiene Analytical Group (IHAG). The details of this report are summarized in the Asbestos Fibers by PCM SOP.

13.7.5 Monthly Incomplete Samples Audit —The QAO* (or designee) shall provide a monthly summary to laboratory management and all laboratory personnel which contains a list of sample analyses that were listed as completed and/or reported in the LIMS but still contained incomplete test groups or tests.

13.7.6 Monthly Missing Reports Audit —The QAO* (or designee) shall provide a monthly summary to laboratory management and all laboratory personnel which contains a list of samples that are marked "Reported" in the LIMS, but no hard copy has been circulated for review and filing. Samples in the list have been marked "Reported" for greater than one month.

13.7.7 QAO Pop Audits — The QAO* (or designee) shall perform random QC audits on a representative sampling of final reports. Results from the Pop Audits will be recorded “conforming” or “non-conforming” and will be communicated to laboratory management and all laboratory personnel.

13.7.8 Weekly Management Reports — The QAO* (or designee) shall provide the following weekly reports to the laboratory management for use in evaluating laboratory activities:

13.7.8(A) Weekly On Time Delivery Reports summarize the list of samples that were reported on time, according to the regulatory and customer requirements in the LIMS. The lists of samples are organized by type, by testgroup and by test. These On Time Delivery reports should be generated on Monday mornings (because the report is generated by the date and cannot be "back-dated").

13.7.8(B) Weekly Samples in Progress Reports summarize the list of samples in the LIMS that are currently in progress between two calendar dates. The lists of samples are organized by type, by testgroup and by test. These Samples in Progress reports are usually generated on Monday mornings.

13.7.8(C) Weekly Samples Logged this Week Reports summarize the list of samples in the LIMS that were logged in between two calendar dates. The lists of samples are organized by type, by testgroup and by test. These Samples Logged this Week reports are usually generated on Wednesdays to be used during the ACS Weekly Report.

13.7.8(D) Weekly Flagged QC Reports summarize the list of QC samples that have been flagged in the LIMS for failing the associated acceptance criteria.

13.7.8(E) ACS Weekly Reports summarizes pertinent information regarding laboratory activities. Results of the ACS Weekly Report will be communicated to corporate departmental management, laboratory management and all laboratory personnel in the Analytical Chemistry Services (ACS) group.

13.8 Laboratory Ethics and Data Integrity Documentation

13.8.1 As detailed in the Laboratory Ethics and Data Integrity Procedures, documentation is required to detail laboratory personnel training; ongoing data integrity monitoring; authorization and annual review of the procedure by management.

13.9 Documentation — Controlled quality documents from this Section shall be maintained separately from the Quality Assurance Manual in the following collection (which is itself, a controlled laboratory document):

13.9.1(A) **QCDOC 006** records (and the majority of laboratory documentation, unless otherwise specified) shall be maintained for at least five (5) years, and may require periodic review.

QC File 00 22— "QCDOC 006: Control of Laboratory Records " (in Section 13)

14.0 Management Requirements: Laboratory Audits

14.1 Purpose and Scope— This section describes the conduct of various laboratory audits by AEP Analytical Chemistry Services and outside agencies.

14.1.1 Quality Audit Procedures

14.1.1(A) The QAO* (or designee) is responsible for arranging for the conduct of the Quality Audits. They will be carried out by an audit team selected from Laboratory management and selected Laboratory personnel.

(a) Internal quality audit teams, consisting of appropriate laboratory personnel, will be formed for the purpose of reviewing and auditing the contents of specific portions or sections of the QA Manual.

(b) These teams will specifically be charged with the audit and review of identified areas with less than optimum activities. The review and audit of other areas may be undertaken with the express purpose of the education of the laboratory personnel comprising the team concerning the specific identified area.

(c) The audit results and other information concerning the activities of the audit teams will be documented and any identified changes will be documented by the QAO* (or designee) and updated (when necessary) in the QAM.

(d) The audit teams will be periodically formed and will be active until resolution of the original identified reason for formation.

14.1.1(B) The audit team will use one of the Audit Check Lists as a guide when conducting the audit and will use this manual to establish the criteria for determining the degree of compliance with the requirements of this document.

14.1.1(C) When conducting an audit, the following protocol is recommended:

(a) Notify all individuals concerned of the dates and times of the planned audit.
(b) Hold pre-audit conference.
(c) Conduct the audit.
(d) Hold post-audit conference, critique, and wrap-up.

(e) Follow-up to determine if deficiencies discovered during the audit have been corrected.

14.1.1(D) Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited. Personnel shall not audit their own activities except when it can be demonstrated that an effective audit will be carried out.

14.1.1(E) All personnel whose activities have been audited will be given the results; however, no pass/fail grade will be established, as the primary reason of the audit will be to identify areas of weakness and nonconformity with policies and procedures established in the Quality Assurance Manual.

14.1.2 Quality Audit Findings—

14.1.2(A) Results of Quality Audits (and management reviews) shall be shared with all laboratory personnel prior to its archive into **QCDOC 007** (and **QCDOC 008** for the management reviews), as stated in **Section 14.5**.

(a) The results of Quality Audits must be documented and submitted in separate reports to the Laboratory Manager.

14.1.2(B) Corrective actions should be implemented to resolve any identified serious nonconformance issues. Findings from Internal and External Quality Audits should be evaluated, resolved, corrected, and documented using the **CPAR database** (**Document 11-01**) as described in **Section 11.3.3**.

(a) Findings should initially be documented using the Nonconformance report ("Nonconformance" is discussed in Section 9.0), but significant issues may require further investigation using the Corrective Action Report (Corrective Action is discussed in Section 11.0), if ordered by the QAO*.

(b) The QAO* (or designee) is responsible for initiating any Corrective and Preventive Action Request (CPAR) (Section 24.0) made necessary because of the Quality Audit.

(c) Findings shall be used to generate action items. ”The laboratory management shall ensure that those actions are carried out within an appropriate and agreed timescale. [per ISO 17025 Section 4.15.2, Reference 18.4.9]

14.1.2(C) CPAR Follow-up activities shall verify and document the implementation and effectiveness of the recommended actions taken, along with planned goals and objectives for the coming year.

14.1.2(D) When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's environmental test results, the laboratory shall take timely corrective action, and shall notify clients in writing if investigations show that the laboratory results may have been affected.

14.1.2(E) The laboratory shall notify clients promptly, in writing, of any event (i.e. identification of defective measuring or test equipment) that casts doubt on the validity of results given in any test report or amendment to a report. This notification must be sent within one week past the completion of the investigation. (Same statement in Section 24.3.3(C))

14.1.3 Types of Quality Audits

14.1.3(A) Internal Quality System Audits are performed by AEP Analytical Chemistry Services. A Quality System audit is an on-site, formal inspection and review of the Analytical Chemistry Services laboratories' Quality Control Systems. This type of audit takes place annually on a periodic, announced basis and is used to verify the effectiveness of the laboratory's quality programs, as described in the several sections of this manual.

14.1.3(B) External Quality System Audits may be performed by outside agencies to maintain accreditation or to ensure compliance with regulatory agencies.

14.1.3(C) Vendor or Subcontractor Audits may be performed to evaluate the effectiveness of their quality assurance program and its degree of compliance with the requirements of the Laboratory's quality management system.

14.2 Internal Quality System Audit —The Internal Quality System Audit process shall be documented using the "Quality System Audit Checklist" (Form QAR 1405). The form defines the Internal Audit procedure as follows:

14.2.1 Section I: Internal Audit Schedule — The audit has been split into ten Sections that must be performed annually on a pre-determined schedule. The pre-determined schedule for each year must be defined during or before the first month of the year (i.e. by January 31).

14.2.2 Section II: ISO 17025 Quality System Audit — The QAO* or designee shall review the requirements of the current ISO 17025 standard using a current Accrediting Body Checklist (i.e. an AIHA site assessment checklist or a NELAC-state site assessment checklist). This review must be documented and may utilize the previous year's evaluation, making pertinent updates. A summary of significant deficiencies shall be included on the form.

14.2.3 Section III: Accreditation Compliance Audit — The QAO* or designee shall review the current Accreditation requirements using a current Checklist from the Accrediting Authority (i.e. the relevant AIHA Modules, NVLAP requirements, and/or NELAC requirements within the site assessment checklist(s)). These review(s) must be documented utilizing the relevant Accreditation checklist and a summary of significant deficiencies shall be included on the form.

14.2.4 Section IV: Method Compliance Audit — The QAO* or designee shall review the current Method requirements of at least two accredited test parameters within the Scope of Accreditation of the laboratory. The review shall verify compliance of the bench procedure and analyst with the current laboratory SOP. This review must be documented using a Checklist from a reputable source or Accrediting Authority (i.e. method checklist from a NELAC-state agency) or using the generic format in the checklist.

14.2.5 Section V: Data Package Audit — The QAO* or designee shall compile at least one full data package from a random sample containing accredited results and reported by the laboratory. The Data Package Audit shall follow the progress of the sample(s) from the time of receipt, through storage, preparation and analysis, and reporting. Tier I includes a data package completeness check; Tier II includes Tier I procedures, plus a review of tabulated QC and sample data; and Tier III includes Tier I and II procedures, plus a review of raw instrument data.

14.2.6 Section VI: Documentation Audit — The QAO* or designee shall review the Record-keeping practices associated with the test parameters within the Scope of Accreditation of the laboratory at least two times per year.

14.2.6(A) The review shall verify record-keeping compliance with the historical reconstruction of the data set(s) using printed records, electronic records, control charts, and handwritten logbooks/forms.

14.2.6(B) The records retained shall document equipment use, analytical data sets, instrument logs, reagent, and/or standard preparation, and sample preparation (as defined in Section 13.0)

14.2.6(C) QC charts are also retained in the LIMS to document the statistical trending of specific QC samples (as defined in Section 23.5)

14.2.6(D) This historical reconstruction shall adhere to the ISO standard (and other Accrediting Bodies) as outlined in the QA Manual.

14.2.6(E) This review shall be documented using a Form QAR1301 or an equivalent review summary.

14.2.7 Section VII: PT Trends Audit. — The QAO* or designee shall review the results from PT Studies quarterly and document identified trends, repeat issues, near-misses, and results that pass (within 3-sigma) but fall within the "warning limits" (within 2-sigma). This review must be documented using the format in the checklist.

14.2.8 Section VIII. Audit(s) for Cause. — The QAO* or designee shall evaluate a specific issue which has cast doubt on the laboratory's compliance with specific portions of the quality management system. This review is only performed on an "As Needed" basis and must be documented using the format in the checklist.

14.2.9 Section IX: Follow-up Review of Internal Audit(s), External Audit(s), and CPAR Record(s)

14.2.9(A) The QAO* or designee shall review the action items and summarize the remaining items documented in the previous Internal Audit(s).

14.2.9(B) The QAO* or designee shall review the Findings and summarize the remaining items documented in the previous External Audit(s).

14.2.9(C) The QAO* or designee shall review the CPAR Records generated within the past year and document the effectiveness of proposed Corrective Action at prevent recurrence of the observed nonconformitie(s). Those CPARs that were ineffective shall be re-opened as new CPAR records and shall be summarized.

14.2.9(D) These Follow-up reviews must be documented within the form.

14.2.10 **Section X: Internal Audit Conclusions** – The QAO* or designee shall summarize the issues from the internal audit; list action items to be addressed; and provide compliments and suggestions for improvement. Issues and action items should be organized using the Sections/Requirements of the ISO standard .

14.3 **External Quality System Audit —**The External Quality System Audits are conducted by outside agencies for continued accreditation or certification.

14.3.1 The Dolan Chemical Laboratory undergoes the following External Audits:

14.3.1(A) Virginia Environmental Laboratory Accreditation Program (VELAP) Protection (WV DEP), every two years, for accreditation renewal;

14.3.1(B) West Virginia Department of Environmental Protection (WV DEP), annually, for certification renewal;

14.3.1(C) NVLAP, every two years, for accreditation renewal;

14.3.1(D) AIHA, every two years, for accreditation renewal;

14.3.2 In addition to documenting Findings from the External Audit in the CPAR database, the QAO* must respond accordingly to the accrediting body or state agency with a Proposed Corrective Action Plan (CAP) within the allotted time per the accreditation/certification requirements. A Revised CAP may be allowed if the Proposed CAP is partially (or fully) rejected. Refer to the specific accreditation/certification reference documents for further detail.

14.4 Vendor/Subcontractor Audit

14.4.1 If it is necessary to conduct an audit of a vendor's or a subcontractor's management system, the Form QAR 1404 (Vendor Audit Checklist) should be used as a guide.

14.4.2 As suggested in Form QAR 1404, the Vendor Audit should be used to review and evaluate the Vendor/Subcontractor's quality management system (i.e. QA Manual), standard operating procedures (SOPs), Scope or Accreditation, and organization chart.

14.4.3 If an on-site assessment is warranted, the laboratory should use For QAR 1404 (or equivalent) and the procedures defined in Section 14.1.1.

14.5 **Documentation —** Controlled quality documents from this Section shall be maintained separately from the Quality Assurance Manual in the following collection (which is itself, a controlled laboratory document):

14.5.1(A) **QCDOC 007** records (and the majority of laboratory documentation, unless otherwise specified) shall be maintained for at least five (5) years, and may require periodic review.

QC File 00 23— "QCDOC 007: Internal Audits " (in Section 14)

15.0 Management Requirements: Management Reviews

15.1 Purpose and Scope — This section describes the requirement for a periodic review (at least annually) of the Laboratory's Quality Management System and the associated testing activities by its executive management.

15.1.1 The laboratory management of the Laboratory shall periodically conduct a review of the laboratory's quality system and testing and/or calibration activities to ensure the laboratory's continuing suitability and effectiveness, and to introduce necessary changes or improvements.

15.1.2 All management reviews will be conducted annually.

15.1.2(A) The findings and results of these reviews and the actions that arise from them shall be documented and should feed into the Laboratory's planning system and should include the goals, objectives, and action plans for the coming year.

15.1.2(B) Corrective actions should be implemented to resolve any identified serious nonconformance issues. Management shall ensure that any actions resulting from this yearly review are carried out, if possible, before the next scheduled management review.

15.1.3 The Management Review (MR) shall include the following:

15.1.3(A) Suitability of policies and procedures
15.1.3(B) Management reports
15.1.3(C) Summarizing internal audit results
15.1.3(D) Corrective and preventive actions
15.1.3(E) Assessments by accrediting bodies or regulatory agencies (i.e. external audits)
15.1.3(F) Results of proficiency tests and inter-laboratory comparisons
15.1.3(G) Changes in the volume or type of testing (i.e. work-load evaluations)
15.1.3(H) Customer complaints, communications, and feedback
15.1.3(I) Staffing resources and training requirements
15.1.3(J) Recommendations for improvement
15.1.3(K) Quality control activities (i.e. quarterly QA/QC report)

15.1.3(L) Other relevant factors (e.g. Employee performance appraisals and Managerial communications to staff— Other areas that affect the quality of the Laboratory output may also be considered. (e.g. The management review shall also include consideration of related subjects discussed at the regularly scheduled periodic Chemist Meetings and Environmental Services Department management staff meetings.)

15.2 Management Review Process — The Management Review (MR) Audit process shall be documented using the "Quality System Management Review" (Form QAR 1501). The following Four-Step Process shall be used to prepare the annual MR:

15.2.1 Information Gathering:

15.2.1(A) Collect Ideas— Issues listed in Section 15.1.3 and in the Audit shall be discussed in chemist meeting(s) or from a written request for comments. Comments, suggestions and ideas generated shall be used to draft the MR, in addition to those comments presented by the laboratory management.

15.2.1(B) Create Draft — The comments, suggestions and ideas from each chemist, the QA Officer, and laboratory management will be summarized into the draft MR document.

15.2.2 Interactive Meeting of Key Personnel :

15.2.2(A) Discuss Draft — A draft of the MR shall be provided to the chemists for discussion in a subsequent chemist meeting.

15.2.3 Action Plan:

15.2.3(A) Finalize Management Review — The laboratory management shall then finalize the MR taking the chemists' comments into consideration.

15.2.3(B) Generate Action Items — The laboratory management shall generate and prioritize action items from the findings of the MR and shall ensure that those actions are carried out within an appropriate and agreed timescale. Findings from the MR may be evaluated, resolved, corrected, and documented using the CPAR database (initially using the NC report).

15.2.3(C) Review Audit Findings — The QA Officer may provide some trends or comparison analyses for year to year. A copy of the MR shall be made available to all employees of the laboratory.

15.2.4 Implementation and Follow-up:

15.2.4(A) Complete NC Report — The QA Officer must ensure that the selected action items are evaluated, resolved, corrected, and documented using the CPAR database (initially using the NC report).

15.2.4(B) CPAR follow-up — The QA Officer must follow-up with the CPAR progress quarterly to verify that the action items have been implemented and to evaluate the effectiveness of the corrective action plan(s) (CAPs). The CPAR must be complete before the next MR is finalized.

15.3 Management Review Findings — Handle MR Findings (Action Items) in the same manner as the Quality Audit findings in Section 14.1.2.

15.4 Documentation — Controlled quality documents from this Section shall be maintained separately from the Quality Assurance Manual in the following collection (which is itself, a controlled laboratory document):

15.4.1(A) **QCDOC 008** records (and the majority of laboratory documentation, unless otherwise specified) shall be maintained for at least five (5) years, and may require periodic review.

QC File 00 24— "QCDOC 008: Management Reviews " (in Section 15)

16.0 Technical Requirements: General and Personnel

16.1 Purpose and Scope — This section delineates the detailed job descriptions and duties for all laboratory personnel. This section also describes the training methods, evaluation and qualification procedures, and motivational program responsibilities used in the Laboratory. More general job descriptions and educational requirements for laboratory personnel are outlined in **Section 1.2.3.**

16.1.1 All personnel involved in any function effecting data quality control (sample collection, testing, data reduction, and quality control and assurance) will have sufficient training in their appointed positions to contribute to the reporting of complete, high quality data.

16.1.1(A) The Laboratory Manager is responsible for seeing that the required training is made available to personnel.

16.1.1(B) The QAO* is responsible for seeing that records are maintained with the QA/QC data developed from each analytical test.

16.1.1(C) Each test method should also include a check-off to ensure compliance with the Chemical Hygiene Plan (CHP) requirements. This may be accomplished using Form CHP-001 - Chemical Hygiene Plan (CHP) Compliance Checklist.

16.1.1(D) Based on the minimum education requirements, laboratory personnel that serve as analysts are expected to be knowledgeable and proficient in "basic laboratory skills". These basic laboratory skills are summarized in a training module, required by newly hired personnel and available, as needed, to all laboratory personnel. Such basic laboratory skills include (but are not limited to):

(a) Proper use of analytical balances,
(b) Proper use and selection of graduated versus volumetric lab ware,
(c) Proper use of laboratory pipettes and bottle pipettors,
(d) Proper use of syringes,
(e) Proper use of titration burette and "automated" burette,
(f) Reading a meniscus,
(g) Practice of quantitative transfer of chemicals, reagents and samples,

(h) Understanding significant figures,
(i) Understanding reagent preparation and sample (or standard) dilution procedures,
(j) The importance of reproducible and consistent behaviors, and
(k) The importance of documentation.
(l) Centrifuge
(m) pH and conductivity meters
(n) read thermometer
(o) mixing (vortexing), filtering, decanting
(p) basic math, rounding
(q) calculations using dilution factor, concentration factors and converting between wet and dry weight basis,
(r) density
(s) using desiccator
(t) using Bunsen burner, cutting & heating glass, heating objects
(u) taking an aliquot
(v) pipet calibration
(w) heating liquids
(x) using litmus paper
(y) handling solids- do not return to container
(z) handling liquids – do no obtain from sample container
(aa) lab notebooks – reminders
(bb) acid dilutions
(cc) drying oven, hotplate, water bath, burner, incubator
(dd) dilute to mark, spikes, etc.

16.1.2 It shall be the responsibility of the Laboratory Management, with the assistance of all laboratory personnel, to recognize and initiate a request for training of laboratory personnel.

16.1.2(A) Training requirements are likely to be indicated when new or existing employees receive new assignments in any functional or analytical area of the Laboratory; when there is new laboratory equipment; or when there is a change in an analytical procedure.

16.1.2(B) It shall be the responsibility of the Laboratory Management to provide for the appropriate training so that assigned responsibilities can be carried out safely and accurately.

16.1.2(C) Training records, certificates of completion, and formal authorization will be maintained as described in the Laboratory Quality Assurance Manual (QAM) (**Sections 16.8.3 and 16.11**).

16.1.2(D) "The laboratory shall use personnel who are employed by, or under contract to, the laboratory. Where contracted and additional technical and key support personnel are used, the laboratory shall ensure that such personnel are adequately trained, supervised and competent and that they work in accordance with the laboratory's quality management system." [see ISO 17025 Section 5.2.3, Reference 18.4.9]

16.1.3 The Laboratory shall have managerial and technical personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including the implementation, maintenance and improvement of the management system, and to identify the occurrence of departures from the management system or from the procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimize such departures.

16.2 Personnel Descriptions of Responsibility — Laboratory Management

16.2.1 See **Document 16-01** for the full job description of all Laboratory personnel, including the following laboratory management:

16.2.1(A) Laboratory Manager (i.e. Manager, Environmental and Industrial Laboratory Services)

16.2.1(B) Laboratory Supervisor (i.e. Supervisor, Dolan Chemical Laboratory)

16.2.2 **Role of Laboratory Management—** The following lists the basic functions of the "Laboratory Manager" and/or "laboratory management" as described within this QAM:

16.2.2(A) **Laboratory Manager (or designated substitute)**

The Manager of Analytical Chemistry Services also serves as the Laboratory Manager of Dolan Chemical Laboratory. In this role, the Laboratory Manager is responsible for day to day laboratory activities, for ensuring that staff is cognizant of the objectives and requirements of the QAM, and for ensuring that data submitted to the Laboratory Manager and the QAO* meet the requirements set forth in this plan. In the absence of the Laboratory Manager, the Laboratory Manager shall designate one of the Laboratory Chemists to serve as the backup for management duties. This designation shall be communicated to all laboratory personnel. (See Sections 1.2.1(B) and 1.2.1(B)(a))

Document 16-1 AEP Laboratory Position Descriptions
(26 pages) <<Click on first page of object to access full document>>

AMERICAN ELECTRIC POWER POSITION DESCRIPTIONS

[Current Laboratory Positions]

As of April 30, 2008, the following position descriptions are available in the Laboratory:

Position Description	Salary Grade	Years Experience	Position Description Revision Date
Laboratory Manager	29	n/a	May-05
Laboratory Supervisor	26	n/a	May-02
Principal Chemist	21	19	~2006
Senior Chemist	18	13	~2006
Chemist I	14	9	~2006
Chemist II	11	4	~2006
Chemist III	09	2	~2006
Chemist IV	07	None	~2006
Senior Laboratory Technician	19T	12	May-02
Chemical Laboratory Technician I	17T	7	May-02
Chemical Laboratory Technician II	14T	2	May-02
Chemical Laboratory Technician III	11T	None	May-02
Senior Administrative Associate	09A	8	unknown
Administrative Associate	08A	6	unknown
Administrative Associate I	06A	3 to 4	unknown
Administrative Associate II	04A	1.5	unknown
Administrative Associate III	02A	6-9 mos	unknown
Senior Laboratory Assistant	05A	5	Apr-07
Laboratory Assistant	02A	None	Sep-87

Rev 0 02/2008 (ACR) >>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>(END OF POSITION DESCRIPTION)
Rev 1 04/2008 (ACR) >>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>(END OF POSITION DESCRIPTION)
(Removed Flue Gas Technicians from Job Descriptions)

File - QAM Document 16-01 AEP Laboratory Position Descriptions, Revision 1, 04.2008 .xls
Tab - Current Laboratory Positions

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(a) In the absence of the QAO, the Laboratory Manager shall serve as the backup for QA/QC duties. (See Section 1.2.1(C)(a))

(b) If, in the opinion of any individual employee, a situation arises that the employee feels undue pressure that is affecting or may affect the quality of work done, then the Laboratory Manager must be immediately notified. This notification must be documented. (See Section 2.3.2(F))

(c) All documents issued to personnel in the Laboratory as part of the management system shall be reviewed and approved by the Laboratory Manager and the QAO* prior to use. (See Section 3.2.3(C))

(d) The Laboratory capability assessment and evaluation should be conducted through the input of the following personnel: Laboratory manager, all primary chemists to which analytical work would be expected, and the Laboratory QAO*. (See Section 4.2.6)

(e) The analysis of samples may be subcontracted upon the authorization of the Laboratory Manager, or the designated backup - the Laboratory Supervisor. (See Section 5.1.3)

(f) Additionally, an exemption is allowed as the Laboratory Manager may "grandfather" the use of certain reliable, necessary, or exclusive suppliers without performing the formal evaluation, verification, and authorization process given above. [Note: these suppliers are listed as "Exempt-LM"] (See Section 6.2.1(D))

(g) All purchase orders are approved by the Laboratory Manager or his designate(s). In addition, if the Laboratory Manager has a question concerning the applicability, the amount or any other aspect of a specific chemical and/or reagent on a particular order, the advice and review of that order by the Chemical Hygiene Officer (CHO) should be requested. (See Section 6.2.3(A))

(h) Upon receiving a complaint, chemists shall notify the Laboratory Manager or the QAO* . … Disciplinary action may be authorized and executed by the Laboratory Manager and/ or AEP corporate. (See Sections 8.2.1(B) and 8.2.1(F)(c))

(i) Issues relevant to the Laboratory's Quality Management System and its associated laboratory operations should be addressed on an ongoing basis at the bimonthly Chemist Meeting. This meeting is chaired by the Laboratory Manager and serves as a management's focus for communication of information related to the laboratory's operations. (Section 10.6.3)

(j) Once the (CAR) action is initiated a copy is automatically forwarded to the Laboratory Manager. The Laboratory Manager must then assign someone (e.g. including them self) to take on the responsibility to investigate the cause of the problem and to develop a corrective action plan to resolve the issue in question. …This plan must be reviewed and approved by the Laboratory manager, as well as the party who initiated the corrective action. (Sections 11.3.5(B)(a), 11.3.5(B)(b), and 11.3.5(C))

(k) If the corrective actions have proven to be ineffective, the Laboratory Manager (or designee), may approve the reporting of the analytical data along with information indicating the failed quality control measure. (Section 11.5.4)

(l) Typically, when the [Enviance] task is < 100% complete and overdue two months, the Laboratory Manager (added under "Other Users") is added to the notifications. (Section 12.5.5(E)(f)(iii))

(m) Internal System Audits are performed by the QAO* and Laboratory Manager and focus on a specific analytical area or analytical test. (See Section 14.1.2(A))

(n) The Laboratory Manager is responsible for seeing that the required training is made available to personnel. (See Section 16.1.1(A))

(o) Copies of purchase orders for all reagents are to be reviewed and approved by the Laboratory Manager. In the Manager's absence, the Laboratory Supervisor or the Chemical Hygiene Officer (CHO) are designated backups to perform these duties. (Section 19.4.2(E))

(p) The Laboratory Manager for Dolan Chemical Laboratory is responsible for enforcement of the Uncertainty policy. (See Section 23.5.3(A))

16.2.2(B) "**Laboratory management"**

(a) See the Responsibilities of Key Personnel – Laboratory Management. (See Section 1.2.3)

(b) The laboratory management at the Laboratory is committed to providing the highest quality analytical data to its customers and demands all laboratory personnel to perform all duties with professionalism, integrity and irrefutable ethical behavior. (See Section 2.2.3)

(c) See the Management Objectives. (See Section 2.2.5)

(d) See the Quality Policies(See Section 2.3)

(e) The Effective Date [of quality system documents], which is the date designated by laboratory management that the document shall become valid and in use and shall have been reviewed by the affected personnel. (See Section 3.2.3(B))

(f) **Amendments/Revision**— Whenever a change is made to a controlled document, the QAO* (or designee) will issue the new document after necessary laboratory management approval. (See Section 3.2.3(E))

(g) A request for such changes to methods, sampling data sheets or calibration instructions, as appropriate to the above qualifications, may be made by anyone; the request being made in writing to the QAO*. The changes must be approved by the appropriate laboratory management before the changes are published and distributed. (See Section 3.2.4(A))

(h) During the time between the Approval Date and the Effective Date, the laboratory management is required to distribute the (new or revised) quality system document to the affected personnel. (See Section 3.2.4(J))

(i) Due to the considerable confidential and proprietary information produced at AEP Dolan Chemical Laboratory, the policy of this organization is to prohibit the communication of any business information about AEP to anyone outside the organization without specific approval from laboratory management. (See Section 3.2.6(B)(a))

(j) The final decision as to whether the samples are accepted is the responsibility of laboratory management. The use of these procedures ensures that the Laboratory reviews all "significant" new work to ensure that it has the appropriate facilities and resources before commencing such work. (See Section 4.2.7)

(k) Items may be purchased through the use of a procurement card, i.e. MasterCard. These items are approved on an informal basis by the laboratory management. The quality of materials purchased through the procurement card procedure is the sole responsibility of the purchaser. (See Section 6.2.4(B))

(l) All inputs [from complaints procedure]] will be addressed promptly by laboratory management and resolved without delay or implemented when feasible. Ethical issues should be addressed to laboratory management or may be anonymously reported using the AEP Concerns Line. (See Sections 8.2.1(E) and 8.2.1(F)(a))

(m) Other nonconformances may include: Departures, exceptions, or contingencies given approval by laboratory management (See Section 9.2.3(C)).

(n) **Exceptions**: Arrangements for exceptionally permitting departures from documented policies and procedures or from standard specifications may be permitted by laboratory management and shall be documented as a non-conformance. (See Section 9.4)

(o) The LAB CPAR3 database was split from the CPAR3 database in January 2011 and is maintained by laboratory management. (Section 11.3.1(A))

(p) Exceptions to the six-week timeframe may be granted on a case-by-case basis by laboratory management and should be documented in the CPAR record. (Section 11.3.5(B)(a))

(q) If (CAR) action is not taken, this information is also forwarded to laboratory management and, if necessary, assistance will be given to help resolve the issue**.** (Section 11.3.5(C)(a))

(r) The decision as to whether any long-term corrective action request is valid and whether an investigation and action plan should be generated for a particular problem or problem(s) rests with laboratory management. (See Section 11.4.2(A)

(s) See Management Corrective Action (Reserved). (See Section 11.6)

(t) The completed [Preventative Action] Form QAR 1201 shall be logged into a database by the QAO* or designee. The QAO* (or designee) and laboratory management shall review, discuss and a decide whether to act upon the identified preventive action. This decision (and any proposed action plan) requires formal authorization by the laboratory management. (See Section 12.3.2)

(u) Enviance tasks for the laboratory shall be maintained by laboratory management, or a designee. Currently, the Enviance tasks are managed by the QAO*, or designee. (See Section 12.5.5(E))

(v) See Management Reviews. (See Section 15.0)

(w) It shall be the responsibility of the Laboratory Management to provide for the appropriate training so that assigned responsibilities can be carried out safely and accurately. (See Section 16.1.2(B))

(x) See Annual Performance Management Reviews (PMR). (See Section 16.9.4)

(y) See Formal Authorization Process. (See Section 16.9.5)

(z) Most violations will result in the need to determine the loss of integrity and a decision regarding the disposition of the sample. This decision should be the joint responsibility of the primary chemist, in consultation with the Plant or sampling personnel, laboratory management and the QAO* (or designee). (See Section 22.4.4(B))

(aa) All reports issued by the Industrial Hygiene Analytical Group are reviewed by laboratory management…All reviews by laboratory management and the QAO* (QAO) are documented by initialing the reports in the upper right corner of the report. (See Section 24.3.2(D))

16.2.2(C) Archived management documents and reports are maintained in **QCDOC 021 Management Tools**:

QC File 00 25— "QCDOC 021: Management Tools " (in Section 16)

16.3 Personnel Descriptions of Responsibility — Other Functions Within Laboratory Management

16.3.1 Quality Assurance Officer* (QAO), (Revision Date: 05/19/00)

16.3.1(A) Basic Function: The Quality Assurance Officer (QAO)* (or designee) is responsible for the conduct of the Dolan Chemical Laboratory Quality Assurance Program. The responsibilities include taking or recommending measures to ensure the fulfillment of the quality objectives of management and the carrying out of Quality Policies in the most efficient and economical manner. These actions must be commensurate with ensuring continuing accuracy and precision of the data produced.

16.3.1(B) Responsibilities and Authority:

(a) Develops and carries out quality control programs, including statistical procedures and techniques, which will enable the Dolan Chemical Laboratory to meet desired quality standards at minimum cost. Advises and assists management in the installation, staffing and supervision of such programs.

(b) Monitors quality control activities of the Dolan Chemical Laboratory to determine conformance with authorized policies and procedures and with sound practice. Makes appropriate recommendations for correction and improvement as may be necessary.

(c) Seeks out and evaluates new ideas and current developments in the field of quality control and recommends means for their application wherever advisable.

(d) Reviews new technology, methods and equipment and advises management as to such use with respect to quality aspects.

(e) Advises Dolan Chemical Laboratory management, the laboratory purchasing agent and the AEP Purchasing Department with regard to the quality of purchased equipment, materials, reagents and chemicals.

(f) Recommends packing materials and procedures and necessary changes thereto.

(g) Performs such other related duties as may be assigned.

16.3.1(C) Role of Quality Assurance Officer* (QAO) — Document 16-02. lists the basic functions of the QAO as described throughout this QAM (wherever denoted with "Quality Assurance Officer*, QAO"):

Note: In addition to the basic job description (in Section 16.2.3), and the responsibilities and authorities listed, the QAO shall either maintain or oversee the maintenance of all **QCDOC** Files listed in Document 03-02.

16.3.1(D) Archived Quality Assurance documents and reports are maintained in **QCDOC 019 Quality Assurance Reports**:

QC File 00 26— "QCDOC 019: Quality Assurance Reports " (in Section 16)

16.3.1(E) Archived Inter-laboratory Comparison documents and reports are maintained in **QCDOC 017 Inter-laboratory Comparisons**:

QC File 00 27— "QCDOC 017: Inter-laboratory Comparisons " (in Section 16)

16.3.1(F) Archived Accreditation documents and reports are maintained in **QCDOC 018 Accrediting Bodies**:

QC File 00 28— "QCDOC 018: Accrediting Bodies " (in Section 16)

Document 16-2 Role of the Quality Assurance Office for Dolan Chemical Laboratory (updated)
(9 pages) <<Click on first page of object to access full document>>

QAM Document 16-02: Role of the Quality Assurance Officer for Dolan Chemical Laboratory

1. **Organization**
   a. The QAO is responsible for the production and timely revision of the QAM and for ensuring that regular audits are conducted to demonstrate that the objectives of the QAM are being met. (See Section 1.2.1(C))

   b. Organizational Chart records (ORG Rec) are retained by the QAO and are available on Sharepoint. (See Section 1.2.2(E))

   c. The QAO shall carry out the monitoring, record keeping, statistical techniques, calibration and other functions required by the quality assurance system within the Dolan Chemical Laboratory. The QAO of the Dolan Chemical Laboratory reports to laboratory management. (See Section 1.2.3(D)(a))

   d. The QAO initiates and oversees all internal QA/QC audits. (See Section 1.2.3(D)(b))

   e. The QAO responsibilities include the production and timely revision of the QAM, and ensuring that regular audits are conducted to demonstrate the objectives of the QAM are being met. (See Section 1.2.3(D)(c))

   f. The QAO manages the laboratory's blind proficiency program and other duties as assigned. (See Section 1.2.3(D)(d))

   g. The QAO is responsible for the periodic (at least yearly) generation of quality control reports, establishment and implementation of record keeping and data compilation. (See Section 1.2.3(D)(e))

   h. The QAO shall have documented training and/or experience in QA/QC procedures and statistics and be knowledgeable in the quality system as defined under NELAC and Title 1, Agency 30, Chapter 46 (1VAC30-46) for Virginia Laboratory Certification. (Section 1.2.3(D)(g))

   i. The formal certificates associated with the training of personnel at the Dolan Chemical Laboratory are retained by the QAO in QCDOC 009. Training is also monitored by the "Training Coordinator" using the AEP system, "OnTrack Online". (See Section 1.2.4(E)(a))

   j. Analytical Assignment records (ORG Rec) are retained by the QAO and are available on Sharepoint. (See Section 1.2.5(C))

   k. This archive process is generally applicable to all completed and reported samples with review (by QAO) dates greater than 3 months old. (See Section 1.4.3(B)(e))

2. **Quality System**
   a. In-depth periodic [Data Integrity] monitoring shall be performed by the QAO* (or designee) during the Data Validation of analytical reports. This too, requires documentation as it is performed. (See Sections 2.3.4(B)(c) and 24.4.3(B))

   b. The QAO bears the primary responsibility for the preparation, issue, review and upkeep of the Laboratory Quality Assurance Manual (See Sections 2.4.2(A) and 3.4.2(A).).

16.3.2 Chemical Hygiene Officer (CHO)

16.3.2(A) Basic Function: (Reserved)

16.3.2(B) Responsibilities and Authority: (Reserved)

16.3.2(C) Role of the Chemical Hygiene Officer (CHO)— The following list are the basic functions of the CHO as described throughout this QAM:

(a) If the Laboratory Manager has a question concerning the applicability, the amount or any other aspect of a specific chemical and/or reagent on a particular (purchase) order, the advice and review of that order by the Chemical Hygiene Officer (CHO) should be requested. This approval and review process assures compliance with the chemical procurement restrictions of the Chemical Hygiene Plan (CHP) [See **Appendix A**] and with the latest purchasing requirements. (See Section 6.2.3(A))

(b) The individual SOPs are prepared to document the exact manner in which the Laboratory performs the reference method. Each individual SOP is reviewed periodically (or when method changes occur) by the QAO* and the Chemical Hygiene Officer (CHO) and is revised as necessary. (See Section 18.2.4)

16.3.2(D) **The CHO is also responsible for the Chemical Hygiene Plan, which has the following internal references within the QAM:**

(a) Upon evaluation of the capabilities of the laboratory (per **Section 4.0**), it may be necessary to subcontract the analyses of certain test items. This section describes the requirements for control of the quality of work imposed upon outside laboratories doing analytical or testing tasks for the Laboratory. These tasks may be required by either the Chemical Hygiene Plan (CHP) or the Quality Assurance Program or may be needed as part of a specific analytical project. In general, only those tasks that are beyond the capabilities of the Laboratory are considered for subcontracting. (See Section 5.1)

(b) This approval and review process (for Purchase Orders) assures compliance with the chemical procurement restrictions of the Chemical Hygiene Plan (CHP) [[See **Appendix A**] and with the latest purchasing requirements. (See Section 6.2.3(A))

(c) Each test method should also include a check-off to ensure compliance with the Chemical Hygiene Plan (CHP) requirements. This may be accomplished using Form CHP-001 - Chemical Hygiene Plan (CHP) Compliance Checklist. (See Section 16.1.1(C))

(d) Sample Retention Guidelines (and thus, the eventual disposal of samples) for each Analytical Group is outlined in Section 22.6. (See Section 22.6)

(e) The appropriate guidelines for disposal of all samples received by the Laboratory are given in the latest revision of the Chemical Hygiene Plan (CHP). (See Section 22.7.1)

16.3.3 Laboratory Information Management Systems Specialist (LIMSS), (Revision Date: 05/19/00)

16.3.3(A) Basic Function: The Laboratory Information Management Systems Specialist (LIMSS) is responsible for the operation, validation, and implementation of the laboratory information management system (LIMS). The responsibilities include developing and carrying out programs, including validation procedures and techniques, which ensure that the Dolan Chemical Laboratory meets desired standards with respect to LIMS operation and reliability, at minimum cost. These programs must be commensurate with ensuring continuing accuracy of the records produced.

16.3.3(B) Responsibilities and Authority:

(a) The LIMSS is responsible for the operation, validation, and implementation of the laboratory information management system (LIMS). Develops and carries out programs, including validation procedures and techniques, which will enable the Dolan Chemical Laboratory to meet desired standards with respect to LIMS operation and reliability, at minimum cost. Advises and assists management in the installation, staffing and supervision of such programs.

(b) Monitors laboratory information management system (LIMS) activities of the Dolan Chemical Laboratory to determine conformance with authorized policies and procedures and with sound practice. Makes appropriate recommendations for correction and improvement as may be necessary.

(c) Seeks out and evaluates new ideas and current developments in the field of laboratory information management systems and recommends means for their application wherever advisable.

(d) Reviews new technology, methods and equipment and advises management as to such use with respect to laboratory information management system aspects.

(e) Advises Dolan Chemical Laboratory management, AEP IT personnel, the laboratory purchasing agent and the AEP Purchasing Department with regard to the applicability of purchased equipment, particularly with respect to its impact on the operations and reliability of the LIMS.

(f) Performs such other duties related to the operation, validation, and implementation of the LIMS, as may be assigned.

16.3.3(C) Role of the Laboratory Information Management Systems Specialist (LIMSS) — (Reserved)

16.3.4 Radiation Safety Officer (RSO)

16.3.4(A) Basic Function: (Reserved)
16.3.4(B) Responsibilities and Authority: (Reserved)
16.3.4(C) Role of the Radiation Safety Officer (RSO)— (Reserved)

16.3.5 Training Coordinator

16.3.5(A) Basic Function: Training is monitored by the "Training Coordinator" using the AEP system, "KEY".
16.3.5(B) Responsibilities and Authority: (Reserved)
16.3.5(C) Role of the Training Coordinator — (Reserved)

16.4 Personnel Descriptions of Responsibility — Chemists

16.4.1 The general chemist job descriptions are given in **Section 1.2.4**, and see **Document 16-01** for the full job description of all Laboratory personnel, including the following chemist positions:

16.4.1(A) Principal Chemist
16.4.1(B) Senior Chemist
16.4.1(C) Chemist I
16.4.1(D) Chemist II
16.4.1(E) Chemist III
16.4.1(F) Chemist IV

16.4.2 See **Document 16-03** for the **Chemist Position Description Matrix Table,** which details the skills and qualifications necessary to achieve the above-mentioned chemist levels within the Dolan Chemical Laboratory.

16.4.2(A) These skills include:

- technical expertise;
- leadership and guidance;
- planning and organizational ability;
- problem-solving and initiative;
- communication skills;
- interpersonal skills;
- decision-making; and
- business awareness characteristics.

16.4.2(B) The qualifications portion addresses:

- education,
- previous experience,
- years of experience within AEP, and
- job performance expectations.

Document 16-3 Chemist Position Description Matrix Table
(5 pages) <<Click on first page of object to access full document>>

Chemist Position Description Matrix Table

Level	Technical Expertise	Leadership And Guidance
Principal Chemist (Advanced Level) Salary Grade 21 Job Code 13701	• Is recognized as an expert in a technical field throughout the AEP System. • Possesses unique knowledge in a specialized area. • Exhibits advanced knowledge and understanding of procedures in multiple areas. • Works to advance the application of chemical knowledge to improve System processes, procedures and improve the financial strength of the company.	• Guides, assigns and influences the largest and most complex chemical studies and analysis. • Influences the direction of thinking throughout AEP in an area of analytical expertise. • Directs laboratory activities in the absence of management. • Influences and shapes policies, practices, standards and rules of the company and those regulations and procedures required by external agencies.
Senior Chemist (Senior Level) Salary Grade 18 Job Code 13700	• Demonstrates a level of technical expertise sufficient to assume responsibility for a given analytical area or function. • Develops a knowledge and understanding of procedures in multiple areas.	• Leads a primary analytical group or function. • Leads, facilitates and coordinates work activities of others within work group, team and corporate entity. • Advises and guides policies, practices, standards and rules of the company and those regulations and procedures required by external agencies.
Chemist I (Journey Level) Salary Grade 14 Job Code 13699	• Exhibits a clear understanding of responsibilities relevant to an area of assignment. • Learns to apply analytical skills to AEP system problems. • Keeps abreast technical advances in analytical equipment and procedures. • Develops and applies enhanced QA/QC procedures where appropriate to improve the quality of results	• Coordinates and conducts training sessions. • Leads, facilitates and coordinates work activities. • Performs non-routine analytical activities with minimal direction form higher-level employees. • Provides feedback on policies, practices, standards and rules of the company and those regulations and procedures required by external agencies.
Chemist II (Intermediate Level) Salary Grade 11 Job Code 13698	• Exhibits a fundamental understanding of responsibilities relevant to an area of assignment. • Assists in the development of environmental, health and safety policies for everyday tasks. • Recognizes the need for and applies established QA/QC procedures where needed to check or improve precision and accuracy of analytical data.	• Provides basic training and guidance to lower level employees. • Follows policies, practices, standards and rules of the company and those regulations and procedures required by external agencies. • Perform routine analytical activities with minimal direction form higher-level employees.
Chemist III (Basic Level) Salary Grade 9 Job Code 13697	• Learns to perform additional laboratory procedures. • Independently assesses analytical procedures for compliance with regulations. • Directs the work for specifically assigned laboratory procedures in a given area. • Demonstrates knowledge QA/QC procedures and their application.	• Demonstrates working knowledge of appropriate policies and procedures. • Performs certain ongoing activities with established procedures and direction from higher-level employees. • Directs the work of technicians.
Chemist IV (Entry Level) Salary Grade 7 Job Code 13696	• Develops the required computer skills. • Learns to perform laboratory procedures in a given field. • Develops knowledge of sampling and analytical procedure requirements necessary for chemical analyses to comply with the various environmental, health and safety regulations. • Develops knowledge of QA/QC procedures.	• Performs work activities as assigned and directed by higher-level employees. • Develops accountability skills by accepting responsibility for actions.

QAM Document 16-03 Chemist Position Description Matrix Table, Revision 0, 01.2006.doc
Revision 0, 01/2006

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16.5 Personnel Descriptions of Responsibility — Technicians

16.5.1 See **Document 16-01** for the full job description of all Laboratory personnel, including the following technician positions:

16.5.1(A) Senior Laboratory Technician
16.5.1(B) Chemical Laboratory Technician I
16.5.1(C) Chemical Laboratory Technician II
16.5.1(D) Chemical Laboratory Technician III

16.5.2 See **Document 16-04** for the **Technician Position Description Matrix Table**; which details the skills and qualifications necessary to achieve the above-mentioned technician levels within the Dolan Chemical Laboratory.

16.5.2(A) These skills include:

- technical proficiency;
- leadership and guidance;
- planning and organization ability;
- problem-solving and initiative;
- communication skills and interpersonal skills; and
- decision-making and business awareness characteristics.

16.5.2(B) The qualifications portion addresses:

- education,
- previous experience,
- years of experience within AEP, and
- job performance expectations.

Document 16-4 Technician Position Description Matrix Table
(4 pages) <<Click on first page of object to access full document>>

Technician Position Description Matrix Table

LEVEL	TECHNICAL PROFICIENCY	LEADERSHIP AND GUIDANCE
SENIOR LABORATORY TECHNICIAN (SENIOR LEVEL)	• Shows mastery of requirements for all technician grades plus a comprehensive knowledge of laboratory procedures. • Demonstrates a mastery of routine and non-routine analysis and laboratory techniques and equipment. • Assists higher classified employees in handling portions of non-routine problems. • Issues reports for routine analyses under supervision of the Laboratory Manager or a designate.	• Ensures that all work activities are performed in accordance with the policies, practices, standards, and rules of the company. • Demonstrates ability to perform with minimal guidance a variety of non-routine analytical assignments of a complex nature. • Provides direction to employees having an equal or lower classification and provides training to familiarize other personnel with advanced procedures and instrumentation.
CHEMICAL LAB TECHNICIAN I (JOURNEY LEVEL)	• Possess the skills and techniques required of technician II and III levels. • Demonstrates ability to perform with proper guidance a variety of independent, non-routine, more complex quantitative and qualitative analyses, prepares work completion reports, shows competency in the operation of sophisticated laboratory equipment. • Serves as a member of process improvement teams as assigned.	• Performs routine, non-routine and R&D procedures independently. • Provides independent initial evaluation of analytical results and modifies procedures within established limits as required. • Provides direction to employees having an equal or lower classification and provides training to familiarize other personnel with routine laboratory procedures. • Participates in problem solving teams and efforts.
CHEMICAL LAB TECHNICIAN II (INTERMEDIATE LEVEL)	• Possesses entry-level knowledge plus experience in procedures and techniques as indicated for entry position. • Performs, with moderate supervision, a variety of duties of a technical nature requiring some independent analysis, exhibits fundamental understanding of laboratory procedures. • Exhibits enabling competencies required for accuracy and precision of analytical data for laboratory certification. • Assists higher classified employees in more complex technical work activities, shows proficiency in mathematical calculations, and demonstrates knowledge of the laboratory information management system. • Understands and practices safe laboratory procedures, serves as a member of the safety team.	• Performs routine and non-routine analyses independently ensuring that all are performed in accordance with established procedures. • Demonstrates a mastery of routine analyses and the procedural knowledge and techniques to perform non-routine analyses. • Participates in training of lower level technicians and exempts who need to become familiar with laboratory procedures. • Maintains equipment and assists in the formulation of recommendations for safety improvements as a member of the safety committee.
CHEMICAL LAB TECHNICIAN III (ENTRY LEVEL)	• Performs routine analytical procedures under direct supervision of higher level employees and assists higher classified employees in performing well-defined portions of routine laboratory projects. • Gains familiarity with sampling techniques, sample and reagent preparation, laboratory instrumentation, routine calculations, record keeping, safety procedures, and general bench skills. • Possesses basic computer skills needed to enter data, keep time records, receive and send information, and operate computer-interfaced equipment.	• Performs routine analyses as assigned and directed by higher level employees • Demonstrates the ability to work with higher level technicians and experienced personnel in the performance of routine and non-routine analytical procedures. • Develops and demonstrates competency in routine procedures and analytical techniques under the guidance of experienced technicians and exempt personnel.

QAM Document 16-04 Technician Position Description Matrix Table, Revision 0, 05.2002.doc
Revision 0, 05/2002

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Document 16-5 Flue Gas Technician Position Description Matrix Table (Removed)

16.6 Personnel Descriptions of Responsibility — Other Laboratory Personnel

16.6.1 See **Document 16-01** for the full job description of all Laboratory personnel, including the following laboratory positions:

16.6.1(A) Senior Administrative Associate
16.6.1(B) Administrative Associate
16.6.1(C) Administrative Associate I
16.6.1(D) Administrative Associate II
16.6.1(E) Administrative Associate III

16.6.1(F) Senior Laboratory Assistant
16.6.1(G) Laboratory Assistant

16.6.2 See **Document 16-06** for the **Administrative Associate Position Description Matrix Table**, which details the skills and qualifications necessary to achieve the above-mentioned administrative associate levels within the Dolan Chemical Laboratory.

16.6.2(A) These skills include:

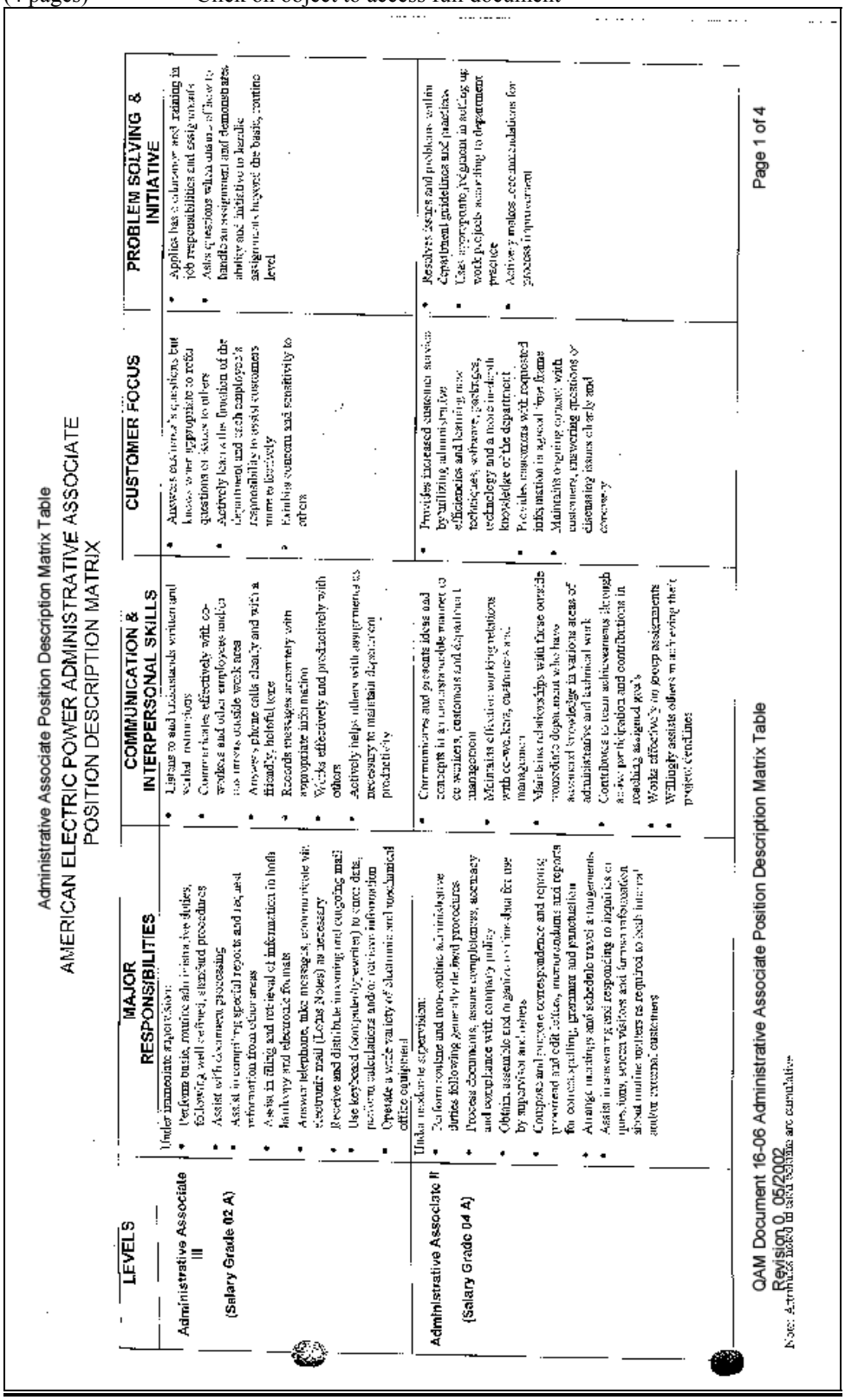
- major responsibilities;
- communication skills and interpersonal skills;
- customer focus; and
- problem-solving and initiative.

16.6.2(B) The qualifications portion addresses:

- education,
- previous experience,
- years of experience within AEP, and
- job performance expectations.

16.6.3 See **Document 16-01** for the full job description for the **Senior Laboratory Assistant and the Laboratory Assistant**.

Document 16-6 Administrative Associate Position Description Matrix Table
(4 pages) <<Click on object to access full document>>


Administrative Associate Position Description Matrix Table

AMERICAN ELECTRIC POWER ADMINISTRATIVE ASSOCIATE
POSITION DESCRIPTION MATRIX

LEVELS	MAJOR RESPONSIBILITIES	COMMUNICATION & INTERPERSONAL SKILLS	CUSTOMER FOCUS	PROBLEM SOLVING & INITIATIVE
Administrative Associate III **(Salary Grade 02 A)**	Under immediate supervision: • Performs basic, routine administrative duties, following well defined, established procedures • Assist with document processing • Assist in compiling special reports and request information from other areas • Assist in filing and retrieval of information in both hardcopy and electronic formats • Answer telephone, take messages, answer/route via electronic mail (Lotus Notes) as necessary • Receive and distribute incoming and outgoing mail • Use keyboard (computer/typewriter) to enter data, memos, calculations and/or retrieve information • Operate a wide variety of electronic and mechanical office equipment	• Listens to and understands written and verbal instructions • Communicates effectively with co-workers and other employees within the immediate work area • Answers phone calls clearly and with a friendly, helpful tone • Records messages accurately with appropriate information • Works effectively and productively with others • Actively helps others with assignments as necessary to maintain department productivity	• Answers customer questions, but knows when appropriate to refer questions or issues to others • Actively learns the function of the department and each employee's responsibility to assist customers more effectively • Exhibits concern and sensitivity to others	• Applies basic training and job responsibilities and assignments • Asks questions when unsure of how to handle an assignment and demonstrates ability and initiative to handle assignments beyond the basic, routine level
Administrative Associate II **(Salary Grade 04 A)**	Under moderate supervision: • Performs routine and non-routine administrative duties following generally established procedures • Process documents, assure completeness, accuracy and compliance with company policy • Obtains, assemble and organizes information for use by supervisor and others • Composes and processes correspondence and reports, reviewed and edit letters, memorandums and reports for correct spelling, grammar and punctuation • Arranges meetings and schedules travel arrangements • Assist in research and responding to inquiries on questions, issues, procedures and furnish information about routine matters as required to both internal and/or external customers	• Communicates and presents ideas and concepts in an organized manner to co-workers, customers and department management • Maintains effective working relations with co-workers, customers and management • Maintains relationships with those outside organization who have necessary knowledge in various areas of administrative and technical work • Contributes to team achievements through active participation and contribution in reaching assigned goals • Works effectively in group assignments • Willingly assists others when having their project deadlines	• Provides increased customer service by utilizing administrative efficiencies and learning new techniques, software, paradigms, technology and a more in-depth knowledge of the department • Provides information in special type forms • Maintains ongoing contact with customers, answering questions or discussing issues clearly and concisely	• Resolves issues and problems within department guidelines and practices • Uses appropriate judgment in setting up work projects according to department practice • Actively makes recommendations for process improvement

QAM Document 16-06 Administrative Associate Position Description Matrix Table
Revision 0, 05/2002
Note: Asterisks added to each routine are cumulative

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16.7 Personnel Descriptions of Responsibility —Obsolete Job Descriptions

16.7.1 See **Document 16-07** for a listing of obsolete job descriptions from the Laboratory.

Document 16-7 AEP Obsolete Laboratory Position Descriptions
(28 pages) <<Click on object to access full document>>

AMERICAN ELECTRIC POWER POSITION DESCRIPTIONS

[Obsolete Laboratory Positions]

As of April 30, 2008, the following OBSOLETE position descriptions have been removed from the Laboratory:

Position Description	Position Description Revision Date
Laboratory Manager	Sep-89
Senior Chemist	Nov-90
Senior Laboratory Chemist	Nov-90
Laboratory Chemist	Nov-90
Associate Laboratory Chemist	Nov-90
Assistant Laboratory Chemist	Nov-90
Chemical Laboratory Supervising Technician	Nov-90
Chemical Laboratory Technician I	Nov-90
Chemical Laboratory Technician II	Nov-90
Chemical Laboratory Technician III	Nov-90
Flue Gas Technician Specialist	unknown
Flue Gas Technician Senior	unknown
Flue Gas Technician I	unknown
Flue Gas Technician II	unknown
Senior Secretary B	Dec-84
Clerk- General	Aug-86
Clerk- Typist	Aug-86
Chemical Assistant	Unknown

Rev 0 02/2008 (ACR) >>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>(END OF POSITION DESCRIPTION)
Rev 1 04/2008 (ACR) >>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>(END OF POSITION DESCRIPTION)
Flue Gas Technicians removed from Job Descriptions (jobs transferred to USTI).

File - QAM Document 16-07 AEP Laboratory OBSOLETE Position Descriptions, Revision 1, 04.2008.xls
Tab - Obsolete Laboratory Positions Page 1 of 33

16.8 Personnel Training

16.8.1 Quality Training Objectives

16.8.1(A) Quality Control training programs have objectives seeking solutions to laboratory quality problems. These training objectives help to develop for all laboratory personnel involved in any aspect or function affecting quality, those attitudes, knowledge and skills that enable each person to contribute to the production of high quality data continuously and effectively.

16.8.1(B) All laboratory personnel will be provided training, when required, on any procedure that they are required to perform and on instruments they are required to operate. When appropriate, this training will be conducted by and under the guidance of an experienced analyst. When necessary and when such classes are available this training can be supplemented by training offered by instrument manufacturers, private vendors, and regulatory agencies. The training shall include:

(a) Laboratory safety

(b) Quality control

(c) Training specific to the proper performance of the analytical method in question. The steps to be followed or:

(i) The trainee is given a copy of the method and SOP, when available;
(ii) This information is reviewed with the trainee;
(iii) The trainee observes the procedure being performed;
(iv) The trainee performs the procedure, with assistance from the trainer;
(v) The trainee analyzes LCS's, unassisted;

(vi) The trainee analyzes a blind standard unassisted.

(d) Training on the proper operation and maintenance of the instrumentation in question.

(e) Training courses in ethical and legal responsibilities including the potential punishments and penalties for improper, unethical or illegal actions.

(f) Training on corporate policies, practices, and procedures.

16.8.2 Available Training Methods

16.8.2(A) Experience training—This is on-the-job training (OTJ), learning to cope with problems using prior experience or knowledge as the basis for action.

16.8.2(B) Guidance training—This is OTJ with help from supervisors or coworkers. The advice may be solicited or provided on an informal or planned basis. On-the-job training will be conducted as follows:

(a) Observe an experienced operator perform the different tasks in the measurement process.
(b) Perform the operations under the guidance of an experienced operator.
(c) Perform the operations independently, but with a high level of quality control checks using the techniques described in Section 21.5 below, which deals with operator proficiency evaluation procedures.

16.8.2(C) Independent study

(a) This may be voluntary attendance at night school classes, outside reading, attendance at seminars or professional society meetings, etc. (See Personnel Department Policy No. 1130 [Educational Assistance Program] for information on tuition and fee payment by AEP.)

16.8.2(D) In-house training

(a) This is formal class room study, held during working hours. Courses may be given by qualified laboratory personnel or outside instructors.

16.8.2(E) Outside part-time courses

(a) It is the policy of the Dolan Chemical Laboratory to encourage continued education in all job-related areas. Many sources of quality control training are available.

16.8.3 Training Records

16.8.3(A) Upon completion of training, the training certificate should be forwarded to the Training Coordinator to be filed in the employee's personnel file. Training shall be documented in laboratory records and include a description of the content and duration of the program.

(a) The full documentation for each employee at the Dolan Chemical Laboratory is compiled in **QCDOC 009: Personnel Training Files** along with the Formal Authorization documentation as described in Section 16.9.5.

(b) **APPENDIX C** contains a summary of personnel files, (education, experience, training, and responsibilities) for each person at the Dolan Chemical Laboratory.

16.9 Personnel Evaluation

16.9.1 Training Evaluation

16.9.1(A) Training will be evaluated in terms of:

(a) the level of knowledge and skill achieved by the operator from the training,
(b) the effectiveness of the training including a determination of the training areas that need improvement.

16.9.1(B) When a quantitative performance rating is made on the operator during the training period, in terms of skill and knowledge achieved, this rating will also provide an assessment of the effectiveness of the training program.

16.9.1(C) Several techniques are available to evaluate the operator and the effectiveness of the training program. One or more of these techniques will be used during the evaluation. The most common types of evaluation techniques applicable to a measurement system training program are the following:

(a) Sample Preparation-When applicable, the trainee will be asked to list all steps involved in the preparation of a hypothetical sample. In addition, the trainee will be asked to perform selected calculations.

(b) Testing or Analysis-The trainee will be provided with performance evaluation samples to which a prescribed method is to be applied. As used here, a performance evaluation sample is a sample whose composition or identity is known to the supervisor or instructor, but unknown to the trainee. Proficiency is judged in terms of accuracy.

(c) Data Reduction-The trainee responsible for the data reduction will be given data sets to validate. Proficiency will be judged in terms of completeness and accuracy.

16.9.2 AEP Corporate Training

16.9.2(A) Safety Training, for example:
(a) Initial Safety Awareness Training for Engineering, Projects and Field Services (EP&FS) ;
(b) Security Awareness Training.

16.9.2(B) FERC Training, for example:
(a) Federal Energy Regulatory Commission (FERC) Standards of Conduct Training.

16.9.2(C) Ethics Training, for example:
(a) OHIO Rules of the Road- online training.

16.9.2(D) Other Corporate Training, for example:
(a) Unlawful Harassment Prevention;
(b) Diversity in the Workplace ;
(c) Introduction to Web-Based Training.

16.9.3 Laboratory Ethics and Data Integrity Training — New employees and all laboratory personnel annually are required to complete Laboratory Ethics and Data Integrity Training which addresses the following topics and areas of concern:

16.9.3(A) NELAC Ethics & Data Integrity requirements
16.9.3(B) An overview of the Laboratory Ethics and Data Integrity Procedure (SOP)
16.9.3(C) Data integrity references throughout the QA Manual
16.9.3(D) Recordkeeping expectations

16.9.3(E) In-depth, periodic data monitoring
16.9.3(F) Reporting suspected data integrity violations — the process and consequences
16.9.3(G) Management's annual review and authorization of the Laboratory Ethics and Data Integrity Procedure
16.9.3(H) Personnel responsibilities
16.9.3(I) Training content
16.9.3(J) Required documentation
16.9.3(K) Examples of acceptable and unacceptable laboratory practices
16.9.3(L) Examples of breaches of ethics and improper practices
16.9.3(M) Examples of typical laboratory vulnerabilities

16.9.4 Annual Performance Management Reviews (PMR)

16.9.4(A) Purpose - The Purpose of a Performance Management Review is to evaluate and communicate the employee's level of performance in each of the operating principles and leadership traits, to recognize and reinforce good performance, and to identify areas for improvement.

16.9.4(B) Schedule –

(a) Employees shall receive the upcoming years' professional development goals by approximately the end of the first quarter using the "Talent Solutions" software

(b) The laboratory management shall complete a six-month "status" review with the employee to discuss progress on the goals and to allow the employee to express concerns or request modification to the goals.

(c) The laboratory management shall assess the employee in relation to the agreed-upon professional development goals (i.e. "performance goals, competencies and development goals") and submit recommendation for compensation requirements to corporate management.

(d) The laboratory management shall disclose the final PMR evaluation, discuss the PMR findings, and share recommendations with the employee. The next year's professional development goals shall also be determined in a separate meeting.

(e) Corporate management shall review the laboratory management's recommendations and determine an equitable compensation adjustment. The compensation adjustment shall be reflected on the employee's compensation from April 1st onward.

16.9.4(C) Performance-Pay Correlation

(a) In this division of the AEP Corporation, the review of job performance and a comparison of such performance with that of other employees should result in a reasonable distribution of employee performance ratings among the various pay levels.

(b) Performance Categories

shareholder focus/ business results
teamwork and cooperation
responsibility and accountability
continuous improvement
safety
technical proficiency
communication
integrity/ethics

(c) Performance Ratings –

"5" - Performance results far exceed expectations for this position. Performance stands out as being exceptional.

"4" - Performance results exceed expectations for this position.

"3" - Fully meets expectations for this position in all key areas.

"2" - Performance needs improvement, or incumbent is still learning job, i.e. incumbent has been in job 2 years or less. More experience in the job is needed, or effort and execution is less than expectations.

"1"- Performance is far below expectations. Immediate improvement, growth, and development are expected for continued employment.

"N" - Too new to evaluate, for use in Overall Performance Rating only. Incumbent has been in job 1 year or less.

"0" - Promotion only, for use in Overall Performance Rating.

(d) It is expected that the majority of employees will attain performance level 3 after a reasonable period of time and experience in the job. Some will reach the more difficult to attain performance levels 4 or 5, and some will be appraised in the two lowest performance levels.

16.9.4(D) References — The following resources are recommended for review and/or use prior to participation and completion of the attached PMR forms.

(a) Exempt Performance Management Review and Salary Administration Manual (see AEP NOW - HR - Compensation)

(b) AEP System Employee Handbook (see AEP NOW - HR - Work/Life - Employee Handbook)

(c) Prior performance evaluations

(d) Additional Resources (e.g. Front-Line Leadership Performance Management Module; Expectations Process

16.9.4(E) Discussion Guidelines

(a) Evaluator - Prepare by familiarizing yourself with this document and the reference materials. Complete the PMR form using specific examples of the employee's behavior. Send completed form to your supervisor for review and approval, before meeting with the employee. Once the approved form is returned to you, meet with the employee and complete the discussion. During the discussion, follow the interaction guidelines and key principles described below. At the end of the discussion, ask for and record employee comments. Give a copy of the completed PMR to the employee. Send the completed form back to your supervisor for review only if significant employee comments were recorded on the form. File a copy in the employee's personnel file according to local procedures.

(b) Assessor (evaluator's supervisor) - Review PMR form to signify your agreement with the completed evaluation. Sign and return the form to the evaluator. Once the discussion is complete, review employee comments and the response of the evaluator according to the need.

16.9.4(F) Interaction Guidelines — The following five step interaction guidelines improves the effectiveness of meetings and discussions.

(a) **Open**: Begin the conversation by stating the purpose and importance of the performance management review (PMR).

(b) **Clarify**: Describe the background and preparation process up to this point. Review the operating principles, traits, and performance ratings. Explain that a performance rating has been recorded for each of the operating principles as well as an overall performance rating. Note that additional discussion topics will include individual strengths, areas for improvement, and goals for next year.

(c) **Develop**: During the meeting, ask employee if they feel ratings and examples are appropriate. Discuss rationale for ratings as appropriate.

(d) **Agree**: Agree on the development plan for next year.

(e) **Close**: Ask the employee to sign the form and/or make any desired comments in the comment box. A signature merely indicates that the review has taken place, not that the employee agrees or disagrees with the content. Express thanks for time and involvement.

16.9.5 Formal Authorization Process

16.9.5(A) **No analyst shall analyze client samples (except for comparison with an authorized analyst) or report analytical results prior to authorization by laboratory management.**

(a) Newly hired laboratory personnel, current employees performing new FoT, and persons identified as potential backup analyst(s) (in a new FoT) must achieve Formal Authorization.

(b) The Formal Authorization process involves documented training under the guidance of the primary chemist and an authorized analyst for that parameter, completion of an acceptable MDL study and initial DOC to demonstrate proficiency, and maintenance of continued proficiency by performing an MDL study and a continued DOC annually, and by participating in PT studies, as necessary.

(c) Exemption prior to December 1, 2010: Analysts informally authorized by laboratory management (i.e. upon hire, from a lateral position shift within the laboratory, from performing work to assist the primary analyst with workloads, etc.) to perform specific analytical duties are exempt from the Formal Authorization Process for the Fields of Testing (FoT) being reported as of December 1, 2010.

16.9.5(B) **The steps in the Formal Authorization process include:**

(a) Identification – The laboratory management identifies the need for additional analyst(s) in specified Fields of Testing (FoT).

(b) Definition of Training – The primary chemist defines the necessary training using the General Training form or by using training forms from a similar FoT. This training plan requires approval by laboratory management.

(c) Documented Training – The analyst-in-training performs the necessary training plan, including additional documentation with MDL studies and DOC forms. The training form must contain the analyst-in-training's initials and date, instructor's initials, and the initials of person(s) attesting to the successful completion of each task.

(d) Formal Authorization – Once the training plan is complete, the analyst-in-training shall sign and date the form. The primary chemist then performs a Training Review and shall sign and date the form. The QA Officer reviews the information and provides Training Approval by signing and dating the form. Finally, the Laboratory Management shall sign and date the form, providing "Analytical Authorization by Management".

(e) Documentation – The completed training form and all relevant documentation shall be returned to the QA Officer. A formal notification shall then be sent to the authorized analyst and other affected personnel. This note and all documentation shall be filed in the appropriate laboratory files.

(f) Maintenance – The QA Officer and primary chemist monitor QA activities and notify the authorized analyst of the necessary steps and tasks to maintain proficiency. This process is supported by the use of controlled documents and forms for MDL studies, DOCs, and Training Checklists, as well as the definitions for MDL, initial DOC, continued DOC, and PT samples already in the QA Manual.

16.10 Personnel Motivation

16.10.1 Quality Monitoring

16.10.1(A) The QAO* is responsible for conducting, from time to time, such motivational campaigns as deemed necessary. Recommendations will be made to Dolan Chemical Laboratory management with regard to efforts to increase employee awareness of each individual's responsibility for the quality laboratory output.

16.10.2 Employee Involvement

16.10.2(A) From time to time, there will be organized teams of employees who may meet regularly to identify and work on solutions to problems that are specific to the Dolan Chemical Laboratory.

16.10.3 Personnel – Education, Professional Development and Experience

(a) The full documentation for each employee at the Dolan Chemical Laboratory (training certificates, etc.) are compiled in **QCDOC 009: Personnel Training Files** of the Quality Assurance Manual.

16.11 Documentation — Controlled quality documents from this Section shall be maintained separately from the Quality Assurance Manual in the following collection (which is itself, a controlled laboratory document):

16.11.1(A) **QCDOC 009** records (and the majority of laboratory documentation, unless otherwise specified) shall be maintained for at least five (5) years, and may require periodic review.

QC File 00 29— "QCDOC 009: Personnel Records " (in Section 16)

17.0 Technical Requirements: Accommodation and Environmental Conditions

17.1 Purpose and Scope— This section describes the environmental controls required for Dolan Chemical Laboratory operations and deals with the control of environmental conditions in the working areas of the Dolan Chemical Laboratory. Environmental controls for any calibration area shall also be maintained as designated in **Section 19.3.**

17.1.1 In instances when the laboratory environment has a significant impact on the results or the quality of results, an **environmental log** shall be maintained for the specific conditions during relevant testing (and/or calibration).

17.1.2 An **environmental log** shall also be maintained when required by a specific laboratory procedure, regulatory committee, or accrediting body.

17.2 Environmental Controls in the Working Area

17.2.1 The environment in the working areas of the Dolan Chemical Laboratory is controlled only to the extent afforded by normal, commonly used heating, ventilating, and air-conditioning equipment. The laboratory has no special requirements beyond normal good housekeeping practices, with the exceptions of the environmental chambers in the Clean Room (Room 221A) and the Biology Laboratory (Room 208) and the lighting capabilities in the Biology Laboratory (Room 208).

17.2.2 "Tests and calibrations shall be stopped when the environmental conditions jeopardize the results of the tests and/or calibrations." [per ISO 17025 Section 5.3.2, Reference 18.4.9]

17.2.3 Environmental Controls in the Environmental Chamber, Room 221A

17.2.3(A) The Industrial Hygiene Analytical Group environmental chamber is located in the Clean Room (Room 221A). The environment in this chamber is controlled separately from all other areas in the laboratory. This chamber requires its own environmental controls for heating, humidity, and air-conditioning. The procedural requirements for the chamber are $20^{O}C \pm 1^{O}C$ ($68^{O}F \pm 2^{O}F$) and 50% ± 5% relative humidity for the analysis of industrial hygiene crystalline silica by NIOSH Method 7602.

17.2.4 Environmental Controls in the Environmental Chamber, Room 208

17.2.4(A) The environment in the environmental chamber of the Biology Laboratory (Room 208) is controlled separately from all other areas in the laboratory. This chamber requires its own environmental controls for heating, light-cycle, and air-conditioning. The procedural requirements for the chamber are for a variable, controlled day/night cycle and a variable, controlled temperature, usually maintained between 21^{O}C - 25^{O}C.

17.2.5 Environmental Controls in the Biology Laboratory, Room 208 (Removed 3/19/08)

17.3 Fume Hoods – The proper use and maintenance of laboratory fume hoods is discussed in detail in the Laboratory Operations of Support Equipment Procedure.

17.4 Laboratory Activities

17.4.1 "There shall be effective separation between neighboring areas in which there are incompatible activities and measures shall be taken to prevent cross-contamination." [per ISO 17025 Section 5.3.4, Reference 18.4.9] For example(s):

17.4.1(A) Preparation and analyses for low-level mercury testing is performed in Room 205. Additional procedures are defined in the laboratory's analytical SOP.

17.4.1(B) No acids are handled in Room 213, to prevent contamination of the ion chromatography systems.

17.4.1(C) Industrial hygiene analyses for asbestos determination and fiber counting are performed in Room 201 where adequate controls prevent cross-contamination issues.

17.4.2 "Access to and use of areas affecting the quality of tests and/or calibrations shall be controlled. The laboratory shall determine the extent of control based on its particular circumstances." [per ISO 17025 Section 5.3.4, Reference 18.4.9]

17.4.3 "Measures shall be taken to ensure good housekeeping in the laboratory. Special procedures shall be prepared when necessary." [per ISO 17025 Section 5.3.5, Reference 18.4.9]

17.4.3(A) The Dolan Chemical Laboratory has assembled a Housekeeping Inspection Team to perform periodic inspections and to provide feedback and guidance on housekeeping issues.

17.5 Documentation — Controlled quality documents from this Section shall be maintained separately from the Quality Assurance Manual in the following collection (which is itself, a controlled laboratory document):

17.5.1(A) **QCDOC 010** records (and the majority of laboratory documentation, unless otherwise specified) shall be maintained for at least five (5) years, and may require periodic review.

QC File 00 30— "QCDOC 010: Environmental Conditions " (in Section 17)

18.0 Technical Requirements: Test Methods and Method Validation

18.1 Purpose and Scope— The Laboratory performs analyses on a variety of samples from many different matrices, including ground water, surface water, wastewater, solid/liquid wastes, metals, soils, ashes, process solutions, operational/equipment malfunctions, bulk materials (e.g. bulk asbestos), and ambient air. This variety demands close attention to the development and use of an analysis plan appropriate to the analytical needs of the project.

18.1.1 Preparation and Test Methods

18.1.1(A) Reference Methods (RM) - The Laboratory normally uses a variety of published analytical test methods while performing the needed analyses. These analytical test methods are primarily EPA-approved procedures or other official analytical test methods and practices such as those produced by ASTM, OSHA and/or NIOSH.

(a) "The laboratory shall ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so" (i.e. when not allowed by regulatory agency or accrediting body). [per ISO 17025 Section 5.4.2, Reference 18.4.9]

(b) A list of the analytical test methods normally used by the Laboratory is retained by the QAO. These records are maintained in **QCDOC-001 QUALITY SYSTEM (QS) Records.** This list does not include every possible analytical test method that could be performed by the laboratory.

(c) The analytical test methods have been organized into groups of methods performed primarily within a specific analytical group of the Laboratory.

18.1.1(B) Deviations from RM / Modifications of RM — Analytical necessities often require modification of the published test method (i.e. in the Plant Services Analytical Group, PSAG) in order to determine parameters or constituents that are not specifically covered in the standard method. When this occurs, proper documentation should accompany results, signifying and outlining modifications that were necessary to obtain the results.

(a) "When necessary, the SOP shall be supplemented with additional details to ensure consistent application." The letters "MOD" shall be used with the specified reference method to denote the SOP Modifications. [per ISO 17025 Section 5.4.2, Reference 18.4.9]

18.1.1(C) "The laboratory shall inform the customer when the method proposed by the customer is considered to be inappropriate or out of date." [per ISO 17025 Section 5.4.2, Reference 18.4.9]

(a) "When the customer does not specify the method to be used, the laboratory shall select appropriate methods that have been published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment." [per ISO 17025 Section 5.4.2, Reference 18.4.9]

18.1.1(D) "Non-Standard Methods — When it is necessary to use methods not covered by standard methods, these shall be subject to agreement with the customer and shall include a clear specification of the customer's requirements and the purpose of the test and/or calibration. The method developed shall have been validated appropriately before use." [per ISO 17025 Section 5.4.4, Reference 18.4.9]

(a) "Laboratory-Developed Methods — The introduction of test methods developed by the laboratory for its own use shall be a planned activity and shall be assigned to qualified personnel equipped with adequate resources. Plans shall be updated as development proceeds and effective communication amongst all personnel involved shall be ensured." [per ISO 17025 Section 5.4.3, Reference 18.4.9]

(b) "Any method developed or non-standard test method shall have been validated appropriately before use." (See Sections 18.1.2, 23.7.5 and 23.7.6)

(c) The IHAG and WWAG must use methods as allowed by regulatory agencies and per the Scope of accreditation for various state agencies and accrediting bodies (AB).

(d) The PSAG may develop laboratory methods or use non-standard methods, but must perform validations as indicated in Section 18.1.1(D)(b).

18.1.2 Quality Assurance (QA) Validation and Evaluation of Test Methods—The analytes, preparation and analytical methods, matrices, recent accuracy and precision targets, and recent MDL's and ML's are retained by the QAO. These records are maintained in **QCDOC-001 QUALITY SYSTEM (QS) Records.** These records document the analytes, their CAS numbers (if applicable), the analytical test method, the method detection limit (MDL), the percent (%) recovery laboratory fortified blank standard objective or an appropriate substitute, the percent (%) recovery matrix spike objective and the relative percent difference between laboratory replicates objective.

18.1.2(A) **Matrices** — Matrices are denoted in the LIMS, when possible.

18.1.2(B) **Accuracy and Precision**

(a) The base QA target for laboratory fortified blanks, LFB, (i.e. standards prepared in a clean quality matrix which are processed through the entire procedure, in the same manner as a sample), is defined as within the range of **85 - 115 %** for accuracy and within 10 % RPD (or Range) for precision.

(b) The base QA target for laboratory fortified matrices , LFM (i.e. spiked samples which are processed through the entire procedure, in the same manner as a sample), is defined as within the range of 75 - 125 % for accuracy and within 20 % RPD (or Range) for precision.

(c) It is the laboratory's policy that method defined accuracy and/or precision requirements will be followed if more stringent than those described in these sections.

(d) Laboratory-generated data may also indicate that tighter control limits can be routinely maintained.

(e) At least annually, all QA targets are re-evaluated (and updated, if necessary) against laboratory-generated data to ensure targets continue to reflect methodologically-achievable goals.

18.1.2(C) **Method Detection Limits (MDLs)**

(a) MDLs are defined such that the risk of reporting a false positive is less than 1%. (See Section 18.3.2 for more information on MDL). The laboratory analyzes seven replicates of a laboratory fortified blanks, and calculates the MDL from the standard deviation and the 99% confidence interval.

(i) MDLs are determined using the method specified in the Federal Register, 40 CFR Part 139 Appendix B unless the possibility exists for significant systematic bias from analytical steps.

18.1.2(D) **Method Limits (MLs)**

(a) MLs are defined as ten times the standard deviation determined in the MDL study. (See Section 18.3.3 for more information on ML).

(b) In procedures that require ML level checks, ease of preparation of commercial analytical mixes may dictate to some extent the reported ML.

18.1.2(E) **Note about detection limits**:

(a) Final report limits (RL) may vary from those published, due to moisture content, dilution effects, interferences, special reporting requirements, etc.

18.2 Standard Operating Procedure (SOP) Manual

18.2.1 The fundamental divisions of the Laboratory SOP manuals reflect the three analytical groups organized within the Laboratory. These groups are the Industrial Hygiene Analytical Group (IHAG), the Plant Services Analytical Group (PSAG) and the Water and Waste Analytical Group (WWAG). Each group has its own SOP binders with its own analytical test methods organized within the framework of the complete Laboratory Quality Assurance Manual.

18.2.2 The analytical group SOP manuals are subdivided into individual SOP manuals reflective of each of the analysis types performed in the analytical group.

18.2.3 All the individual SOP manuals contain the following sections (when applicable):

18.2.3(A) Title Page
18.2.3(B) Acknowledgments and Disclaimer
18.2.3(C) Table of Contents
18.2.3(D) Introduction
18.2.3(E) Method Notice
18.2.3(F) Scope and Application
18.2.3(G) Summary of Method
18.2.3(H) Definitions
18.2.3(I) Interferences
18.2.3(J) Safety
18.2.3(K) Equipment and Supplies
18.2.3(L) Reagents and Standards
18.2.3(M) Sample Collection, Preservation and Storage
18.2.3(N) Quality Control
18.2.3(O) Calibration and Standardization
18.2.3(P) Procedure
18.2.3(Q) Data Analysis and Calculations
18.2.3(R) Method Performance
18.2.3(S) Pollution Prevention
18.2.3(T) Waste Management
18.2.3(U) References
18.2.3(V) Revision History

18.2.4 The individual SOPs are prepared to document the exact manner in which the Laboratory performs the reference method. Each individual SOP is reviewed periodically (or when method changes occur) by the QAO* and the Chemical Hygiene Officer (CHO) and is revised as necessary. Reviews may also be performed by the primary chemist and analyst(s).

18.2.4(A) The Scope and Application section of the SOP should identify test method, components to be analyzed, applicable matrice(s), and a typical method detection limit (MDL). Any deviations from or Modifications to the Reference Method should also be detailed in this section of the SOP.

18.2.4(B) The Safety section of the SOP should include health warnings and cautions.

18.2.4(C) The Equipment and Supplies section of the SOP may include a troubleshooting section, if necessary.

18.2.4(D) The Calibration and Standardization section of the SOP should address instrument calibration as well as calibration of support equipment.

18.2.4(E) The Data Assessment section of the SOP should include data analysis and calculations; data records management; data assessment and acceptance criteria for QC measures; corrective actions for out-of-control data; and contingencies for handling out-of-control or unacceptable data.

18.2.4(F) The Method Performance section of the SOP should include relevant, method specific personnel qualifications.

18.2.4(G) The Appendices of the SOP may include any tables, diagrams, flowcharts and validation data.

18.2.5 The master copy of each of the individual SOP manuals is kept, numerically by analytical group, in the Record Storage Room (Room 220). All information pertaining to the individual SOP manuals is electronically maintained on the AEP Shared Intranet server. This AEP Shared Intranet server is available at every LAN-connected computer at the Laboratory and is available to all Laboratory personnel.

18.2.6 A list of the primary analytical test method references used at the Laboratory is given in **Section 18.4**.

18.2.7 A copy of 40 CFR Part 136 - Guidelines Establishing Test Procedures for the Analysis of Pollutants, Table IB - List of Approved Inorganic Test Procedures shall be maintained by the laboratory and shall be listed in **the "Document Control- Master List of Controlled Documents"**. This is the primary reference for the analytical test methods used for water analyses performed by the Laboratory.

18.2.8 A copy of 40 CFR Appendix C to Part 136 - Inductively Coupled Plasma - Atomic Emission Spectrometric Method for Trace Element Analysis of Water and Wastes, Method 200.7, shall be maintained by the laboratory and shall be listed in **the "Document Control- Master List of Controlled Documents"**. This is the primary reference of the metal analysis test method used for water analyses performed by the Laboratory.

18.3 Test Method Validation

18.3.1 Procedure for Instrument Detection Limit (IDL) (Reserved)

18.3.2 Method Detection Limit (MDL)

18.3.2(A) The method detection limit (MDL) values were determined according to the procedure found in 40 CFR Part 136,Appendix B. (which is located in **Document 18-01**) [In Reference 18.4.2 "Appendix B to Part 136 - Definition and Procedure for the Determination of the Method Detection Limit, Revision 1.11"]. The values listed were determined in reagent (blank) water and were not iterated. MDL values are listed only if applicable and appropriate to the specific method.

18.3.2(B) The Laboratory utilizes MDL forms for the various procedures throughout the laboratory. Each form is contained in a locked Microsoft Excel spreadsheet to protect the integrity of the statistical and MDL calculations.

18.3.2(C) All analytical sections of the Dolan Chemical Laboratory determine a new set of MDLs/RLs annually. Additionally, new procedures, or major updates to existing procedures require the performance of MDL/RL studies.

(a) For analytical tests that have no available spiking solutions (e.g. asbestos, fibers, viscosity, pH, color, odor, temperature, dissolved oxygen, turbidity and "solids"), an MDL study does not have to be performed. The MDL is defined using the precision of the measurements.

18.3.2(D) MDL Check – Per NELAC, each analytical procedure reported by the Laboratory also requires determination of an "MDL check" annually. This qualitative identification near the MDL is achieved during the annual MDL study. [Reference 18.4.1]

Document 18-1 MDL Procedure at Dolan Chemical Laboratory
(from Appendix B to Part 136- Definition and Procedure for the Determination of the Method Detection Limit—Revision 1.11)
(4 page pdf) <<Click on first page of object to access full document>>

QAM Document 18-01 MDL Procedure

Home Page > Executive Branch > Code of Federal Regulations > Electronic Code of Federal Regulations

Electronic Code of Federal Regulations
e-CFR™

e-CFR Data is current as of April 26, 2012

Title 40: Protection of Environment

PART 136—GUIDELINES ESTABLISHING TEST PROCEDURES FOR THE ANALYSIS OF POLLUTANTS

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Appendix B to Part 136—Definition and Procedure for the Determination of the Method Detection Limit—Revision 1.11

Definition

The method detection limit (MDL) is defined as the minimum concentration of a substance that can be measured and reported with 99% confidence that the analyte concentration is greater than zero and is determined from analysis of a sample in a given matrix containing the analyte.

Scope and Application

This procedure is designed for applicability to a wide variety of sample types ranging from reagent (blank) water containing analyte to wastewater containing analyte. The MDL for an analytical procedure may vary as a function of sample type. The procedure requires a complete, specific, and well defined analytical method. It is essential that all sample processing steps of the analytical method be included in the determination of the method detection limit.

The MDL obtained by this procedure is used to judge the significance of a single measurement of a future sample.

The MDL procedure was designed for applicability to a broad variety of physical and chemical methods. To accomplish this, the procedure was made device- or instrument-independent.

Procedure

1. Make an estimate of the detection limit using one of the following:

(a) The concentration value that corresponds to an instrument signal/noise in the range of 2.5 to 5.

(b) The concentration equivalent of three times the standard deviation of replicate instrumental measurements of the analyte in reagent water.

(c) That region of the standard curve where there is a significant change in sensitivity, *i.e.* , a break in the slope of the standard curve.

(d) Instrumental limitations.

It is recognized that the experience of the analyst is important to this process. However, the analyst must include the above considerations in the initial estimate of the detection limit.

2. Prepare reagent (blank) water that is as free of analyte as possible. Reagent or interference free water is defined as a water sample in which analyte and interferent concentrations are not detected at the method detection limit of each analyte of interest. Interferences are defined as systematic errors in the measured analytical signal of an established procedure caused by the presence of interfering

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species (interferent). The interferent concentration is presupposed to be normally distributed in representative samples of a given matrix.

3. (a) If the MDL is to be determined in reagent (blank) water, prepare a laboratory standard (analyte in reagent water) at a concentration which is at least equal to or in the same concentration range as the estimated method detection limit. (Recommend between 1 and 5 times the estimated method detection limit.) Proceed to Step 4.

(b) If the MDL is to be determined in another sample matrix, analyze the sample. If the measured level of the analyte is in the recommended range of one to five times the estimated detection limit, proceed to Step 4.

If the measured level of analyte is less than the estimated detection limit, add a known amount of analyte to bring the level of analyte between one and five times the estimated detection limit.

If the measured level of analyte is greater than five times the estimated detection limit, there are two options.

(1) Obtain another sample with a lower level of analyte in the same matrix if possible.

(2) The sample may be used as is for determining the method detection limit if the analyte level does not exceed 10 times the MDL of the analyte in reagent water. The variance of the analytical method changes as the analyte concentration increases from the MDL, hence the MDL determined under these circumstances may not truly reflect method variance at lower analyte concentrations.

4. (a) Take a minimum of seven aliquots of the sample to be used to calculate the method detection limit and process each through the entire analytical method. Make all computations according to the defined method with final results in the method reporting units. If a blank measurement is required to calculate the measured level of analyte, obtain a separate blank measurement for each sample aliquot analyzed. The average blank measurement is subtracted from the respective sample measurements.

(b) It may be economically and technically desirable to evaluate the estimated method detection limit before proceeding with 4a. This will: (1) Prevent repeating this entire procedure when the costs of analyses are high and (2) insure that the procedure is being conducted at the correct concentration. It is quite possible that an inflated MDL will be calculated from data obtained at many times the real MDL even though the level of analyte is less than five times the calculated method detection limit. To insure that the estimate of the method detection limit is a good estimate, it is necessary to determine that a lower concentration of analyte will not result in a significantly lower method detection limit. Take two aliquots of the sample to be used to calculate the method detection limit and process each through the entire method, including blank measurements as described above in 4a. Evaluate these data:

(1) If these measurements indicate the sample is in desirable range for determination of the MDL, take five additional aliquots and proceed. Use all seven measurements for calculation of the MDL.

(2) If these measurements indicate the sample is not in correct range, reestimate the MDL, obtain new sample as in 3 and repeat either 4a or 4b.

5. Calculate the variance (S^2) and standard deviation (S) of the replicate measurements, as follows:

$$S^2 = \frac{1}{n-1}\left[\sum_{i=1}^{n} X_i^2 - \frac{\left(\sum_{i=1}^{n} X_i\right)^2}{n}\right] \qquad S = \left(S^2\right)^{\frac{1}{2}}$$

where:

Xi; i=1 to n, are the analytical results in the final method reporting units obtained from the n sample aliquots and Σ refers to the sum of the X values from i=l to n.

6. (a) Compute the MDL as follows:

MDL = t(n-1,1-α=0.99) (S)

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where:

MDL = the method detection limit

t(n-1,1-α=.99)= the students' t value appropriate for a 99% confidence level and a standard deviation estimate with n-1 degrees of freedom. See Table.

S = standard deviation of the replicate analyses.

(b) The 95% confidence interval estimates for the MDL derived in 6a are computed according to the following equations derived from percentiles of the chi square over degrees of freedom distribution (χ^2 /df).

LCL = 0.64 MDL

UCL = 2.20 MDL

where: LCL and UCL are the lower and upper 95% confidence limits respectively based on seven aliquots.

7. Optional iterative procedure to verify the reasonableness of the estimate of the MDL and subsequent MDL determinations.

(a) If this is the initial attempt to compute MDL based on the estimate of MDL formulated in Step 1, take the MDL as calculated in Step 6, spike the matrix at this calculated MDL and proceed through the procedure starting with Step 4.

(b) If this is the second or later iteration of the MDL calculation, use S^2 from the current MDL calculation and S^2 from the previous MDL calculation to compute the F-ratio. The F-ratio is calculated by substituting the larger S^2 into the numerator S^2_A and the other into the denominator S^2_B. The computed F-ratio is then compared with the F-ratio found in the table which is 3.05 as follows: if $S^2_A/S^2_B<3.05$, then compute the pooled standard deviation by the following equation:

$$S_{pooled} = \left[\frac{6S_A^2 + 6S_B^2}{12}\right]^{\frac{1}{2}}$$

if $S^2_A/S^2_B>3.05$, respike at the most recent calculated MDL and process the samples through the procedure starting with Step 4. If the most recent calculated MDL does not permit qualitative identification when samples are spiked at that level, report the MDL as a concentration between the current and previous MDL which permits qualitative identification.

(c) Use the S_{pooled} as calculated in 7b to compute The final MDL according to the following equation:

MDL=2.681 (S_{pooled})

where 2.681 is equal to t(12,1−α=.99).

(d) The 95% confidence limits for MDL derived in 7c are computed according to the following equations derived from precentiles of the chi squared over degrees of freedom distribution.

LCL=0.72 MDL

UCL=1.65 MDL

where LCL and UCL are the lower and upper 95% confidence limits respectively based on 14 aliquots.

Tables of Students' t Values at the 99 Percent Confidence Level

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Number of replicates	Degrees of freedom (n-1)	$t_{cn-1,.99}$)
7	6	3.143
8	7	2.998
9	8	2.896
10	9	2.821
11	10	2.764
16	15	2.602
21	20	2.528
26	25	2.485
31	30	2.457
61	60	2.390
00	00	2.326

Reporting

The analytical method used must be specifically identified by number or title aid the MDL for each analyte expressed in the appropriate method reporting units. If the analytical method permits options which affect the method detection limit, these conditions must be specified with the MDL value. The sample matrix used to determine the MDL must also be identified with MDL value. Report the mean analyte level with the MDL and indicate if the MDL procedure was iterated. If a laboratory standard or a sample that contained a known amount analyte was used for this determination, also report the mean recovery.

If the level of analyte in the sample was below the determined MDL or exceeds 10 times the MDL of the analyte in reagent water, do not report a value for the MDL.

[49 FR 43430, Oct. 26, 1984; 50 FR 694, 696, Jan. 4, 1985, as amended at 51 FR 23703, June 30, 1986]

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18.3.3 Method Limit (ML) /Report Limit (RL)

18.3.3(A) Where applicable, minimum report limits shall be included on all final reports for all Industrial Hygiene samples and regulated Waster and Waste samples. These report limits are defined in the Glossary (**Appendix B**) of the Laboratory Quality Assurance Manual.

18.3.3(B) The process for establishing these method limits is also given in **Document 18-02** [Reference 18.4.5 " Definition and Procedure for the Determination of the Minimum Level of Quantitation (ML) – Proposed Rule, March 2003"]. This initial establishment of the report limits requires the analysis of media-spiked samples, prepared at the desired report limit concentration, and taken through the entire analytical process.

18.3.3(C) RL reflects the lowest concentration or amount of the target analyte allowed to be reported from a data collection project, based on matrix interferences elevating the MDL, requiring dilution or other analytical consequences.

18.3.3(D) The ML/RL will be determined in conjunction with the determination of the MDL and the MDL must be less than the ML/RL.

(a) By calibrating with the lowest calibration standard at the RL, the Report Limit Verification (RLV) shall be considered complete if a linear regression calculation of the entire calibration curve yields no lower then 0.995.

(b) Documentation of the established and verified report limit (RL) for each Analytical Group shall be kept in the appropriate fields in the Laboratory Information Management System (LIMS) (See Section 1.4.3(B) for background information on the LIMS) and in **QCDOC-001 QUALITY SYSTEM (QS) Records**.

Document 18-2 ML Procedure at Dolan Chemical Laboratory (from Definition and Procedure for the Determination of the Minimum Level of Quantitation (ML) – Proposed Rule, Revision 0, March 2003)
(4 page pdf) <<Click on first page of object to access full document>>

Definition and Procedure for the Determination of the Minimum Level of Quantitation (ML) – Proposed Rule, (Revision 0) March 2003

1.0 Definition

1.1 The minimum level of quantitation (ML) is the lowest level at which the entire analytical system gives a recognizable signal and acceptable calibration point for the analyte. The ML represents the lowest concentration at which an analyte can be measured with a known level of confidence. It may be equivalent to the concentration of the lowest calibration standard, assuming that all method-specified sample weights, volumes, and cleanup procedures have been employed. It is functionally analogous to the "determination limit" described by Currie (1968) and the Limit of Quantification (LOQ) described by the American Chemical Society (Keith et al., 1980, McDougal *et al.*, 1983, and Currie (1995).

Note to Section 1.0: The ML is directed at obtaining a 10% relative standard deviation for determination of an analyte in an environmental sample. This error may be reduced by making multiple determinations of the analyte in the sample.

2.0 Scope and Application

2.1 The ML is typically established by the organization that develops or modifies an analytical test method. A laboratory that employs the method would be expected to include calibration standards that encompass the ML when it calibrates an analytical system, unless a higher quantitation level is acceptable for a specific application. If an ML is not specified in a method, a laboratory may use the ML procedure to establish the lowest calibration point.

2.2 This procedure is intended for use in EPA's Clean Water Act (CWA) programs. An alternative procedure may be used (*e.g.*, from a voluntary consensus standards body) to establish the sensitivity of an analytical method provided the resulting quantitation limit meets the sensitivity needs (*i.e.*, data quality objective) for the specific application.

2.3 Laboratories are encouraged, but not required, to periodically demonstrate recovery of the target analyte near the published ML or laboratory-established ML by preparing a reference matrix sample spiked at the ML and analyzing it using sample handling and processing steps described in the method. If the method does not provide acceptance criteria for such an ML standard, the laboratory can make an assessment of whether acceptance criteria for other spiked reference matrix samples (e.g., laboratory control samples, laboratory fortified blanks, ongoing precision and recovery samples, etc.) are appropriate to evaluate analyte recovery at the ML. Alternatively, the laboratory may develop its own acceptance criteria based on data gathered by the laboratory over time.

Document 18-02 ML Procedure at Dolan Chemical Laboratory (Page 2 of 4)
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3.0 Procedure

3.1 The ML is based on 10 times the standard deviation of the results of replicate analyses of a matrix containing the analyte. The method detection limit (MDL) is also based on the same standard deviation, multiplied by the Student's t-value appropriate for a 99% confidence level and corresponding degrees of freedom. Because the standard deviation may not be readily available, the ML is often calculated as a factor times the MDL.

3.1.1 Calculating the ML based on MDL study data.

3.1.1(A) When available, obtain the actual standard deviation value from the MDL study and calculate the ML directly, as 10 times the standard deviation. If an iterative MDL study is performed, calculate the MDL as 10 times the pooled standard deviation.

3.1.2 Calculating the ML based on the MDL

3.1.2(A) Assuming a single iteration of seven replicates is used to determine the MDL, the number of degrees of freedom is 6, and the Student's t-value is 3.143. Therefore, the MDL is:

MDL = 3.143 x s, and the ML is: ML = 10 x s = (10/3.143) x MDL = 3.18 x MDL

3.1.3 If the MDL is calculated from other than seven replicates or using the iterative procedure, the factor of 3.18 will change, and the table below is used to establish the correct multiplier. For example, if an iterative MDL study is performed consisting of exactly 78 replicates in each iteration, the resulting polled MDL would incorporate 12 degrees of freedom, and the equation for the ML above would be modified accordingly, using a multiplier of 3.73.

Document 18-02 ML Procedure at Dolan Chemical Laboratory (Page 3 of 4)
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TABLE OF STUDENT'S t-VALUES AT THE 99% CONFIDENCE LEVEL AND MULTIPLIERS

Number of replicates for				
Single MDL (df= n-1)	Iterative MDL (dr = n-2)	Degrees of Freedom (df)	t(n - 1, 1 - a=0.99)	ML Multiplier
7	NA	6	3.143	3.18
8	NA	7	2.998	3.34
9	NA	8	2.896	3.45
10	NA	9	2.821	3.54
11	NA	10	2.764	3.62
12	NA	11	2.718	3.68
13	14	12	2.681	3.73
14	15	13	2.650	3.77
15	16	14	2.624	3.81
16	17	15	2.602	3.84
17	18	16	2.583	3.87
18	19	17	2.567	3.90
19	20	18	2.552	3.92

Note to Table: Degrees of freedom = (n - 1) if a single iteration MDL study is performed and nh - nj - 2) if an iterative MDL study is performed; N/A indicates that the number of degrees of freedom in this row does not apply to an iterative MDL study.

4.0 Rounding

4.1 The ML may be used to establish the lowest calibration point for the analyte. Therefore, in order to facilitate the preparation of calibration standards containing the analyte without undue difficulty, the ML may be rounded to the nearest multiple of 1, 2, or 5 x 10n, where n is an integer.

4.2 The Dolan Chemical Laboratory always rounds the ML (and the resulting equivalent report limit) up to the nearest multiple of 1, 2, or 5 x 10n, where n is an integer. An integer is defined as any of the natural numbers, the negatives of these numbers, or zero. This practice should generate a series of allowed ML, ranging, for example, from ... 0.01, 0.02, 0.05, 0.1, 0.2, 0.5, 1, 2, 5, 10, 20, 50, 100, 200, 500 ... and above, for those integers where n = ... -2, -1, 0, 1, 2 ....

(from Definition and Procedure for the Determination of the Minimum Level of Quantitation (ML) – Proposed Rule, Revision 0, March 2003)

Document 18-02 ML Procedure at Dolan Chemical Laboratory (Page 4 of 4)
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5.0 References

5.1 Currie, Lloyd A. (1968), Limits for Quantitative Detection and Quantitative Determination, Analytical Chemistry 40; 586 - 593.

5.2 Currie, Lloyd A. (1995), Nomenclature in Evaluation of Analytical Methods including Detection and Quantification Capabilities, Pure and Appl. Chem. 67:10, 1699 - 1722.

5.3 Glaser, J. A., D. L. Foerst, J. D. McKee, S. A. Quave and W. L. Budde, Trace Analyses for Wastewaters, Environ. Sci. Technol., 15:1426.

5.4 Keith, Lawrence H., et al. (1983), Principles of Environmental Analysis, Analytical Chemistry 55:14, 2210 - 2218.

5.5 McDougal, Daniel, et al. (1980), Guidelines for Data Acquisition and Data Quality Evaluation in Environmental Chemistry, Analytical Chemistry 52:14, 2242 - 2249.

18.3.3(E) The IH Analytical group does not report a numerical RL for bulk asbestos, but reports samples identified with a "trace" of asbestos, as "***Less than 1% asbestos***" ("< 1%"), and samples which contain no identifiable amounts of asbestos as "***No Asbestos Fibers Detected***." (per the IH Bulk Asbestos SOP)

18.3.3(F) During the analysis of samples, instrument performance at the report limit level (i.e. lowest standard in the calibration curve) shall be verified with each analytical batch, through the analysis of an analytical standard prepared at the analyte's reporting limit concentration. This analysis shall be deemed acceptable if the correlation coefficient for the calibration curve is at least 0.995.

18.3.3(G) At least annually, or when there is a change in methodology or instrumentation, report limits shall be re- established by the same process used for the initial determinations. These annual or change report limit analyses shall be deemed acceptable if the correlation coefficient for the calibration curve is at least 0.995.

18.3.4 Demonstration of Capability (DOC) [Reference 18.4.1 NELAC 2003, Section 5.5.4.2.2]

18.3.4(A) The laboratory shall confirm that it can properly operate all methods before introducing the environmental tests through the use of a standardized "demonstration of capability" (DOC). If the method changes, the confirmation shall be repeated.

(a) For analytical tests that have no available spiking solutions (e.g. asbestos, fibers, viscosity, pH, color, odor, temperature, dissolved oxygen, turbidity and "solids"), the DOC study must be performed using a known standard.

(b) A DOC should be completed each time there is a change in instrument type, personnel, or method and should be required for new personnel.

(c) The DOC may be used to perform an initial test method evaluation of a new (or changed) test method.

(d) The DOC should be used to evaluate precision and bias.

(e) The DOC shall be repeated as required by the relevant accrediting bodies, or at a minimum, annually.

(f) DOCs may also be used to evaluate and verify proper implementation of a procedure when a PT program or Round Robin is not available for that field of testing (FoT).

18.3.4(B) DOC Procedure: See **Document 18-03** which has been copied directly from Appendix C to Chapter 5 of the NELAC 2003 Standard. [In Reference 18.4.1 in Appendix C to Chapter 5].

(a) The Laboratory utilizes DOC forms for the various procedures throughout the laboratory Each form is contained in a locked Microsoft Excel spreadsheet to protect the integrity of the statistical and DOC calculations.

(b) Per AIHA [Module 6B, Reference 18.4.18] and NVLAP policies, and where available — the IHAG utilizes acceptable performance of a blind sample (e.g. single blind to the analyst, or PT sample) in lieu of the traditional DOC study. The laboratory must determine the acceptable limits of the blind performance sample prior to analysis or utilize the limits supplied by the PT provider.

Document 18-3 NELAC Demonstration of Capability –
Appendix C to Chapter 5 from NELAC revised Standards 03/24/06
(5 page pdf) <<Click on first page of object to access full document>>

QUALITY SYSTEMS
APPENDIX C

DEMONSTRATION OF CAPABILITY

Document 18-03. NELAC Demonstration of Capability (Cont.) (Page 2 of 5- left intentionally blank)

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Appendix C - DEMONSTRATION OF CAPABILITY

C.1 PROCEDURE FOR DEMONSTRATION OF CAPABILITY

A demonstration of capability (DOC) must be made prior to using any test method, and at any time there is a change in instrument type, personnel or test method (see 5.5.4.2.2).

Note: In laboratories with specialized "work cells" (a well defined group of analysts that together perform the method analysis), the group as a unit must meet the above criteria and this demonstration must be fully documented.

In general, this demonstration does not test the performance of the method in real world samples, but in the applicable and available quality system matrix (a sample in which no target analytes or interferences are present at concentrations that impact the results of a specific test method), e.g., drinking water, solids, biological tissue and air. However, before any results are reported using this method, actual sample spike results may be used to meet this standard, i.e., at least four consecutive matrix spikes within the last twelve months. In addition, for analytes which do not lend themselves to spiking, e.g., TSS, the demonstration of capability may be performed using quality control samples.

All demonstrations shall be documented through the use of the form, *Demonstration of Capability Certification Statement*, in this appendix. All data applicable to the demonstration need not be attached to the form, but must be retained and available.

When an analyte not currently found on the laboratory's list of accredited analytes is added to an existing accredited test method, an initial evaluation must be performed for that analyte.

The following steps shall be performed if required by mandatory test method or regulation. It is the responsibility of the laboratory to document that other approaches to DOC are adequate, this shall be documented in the laboratory's Quality Manual, e.g., for Whole Effluent Toxicity Testing see section D.2.1.a.1.

a) A quality control sample shall be obtained from an outside source. If not available, the QC sample may be prepared by the laboratory using stock standards that are prepared independently from those used in instrument calibration.

b) The analyte(s) shall be diluted in a volume of clean quality system matrix sufficient to prepare four aliquots at the concentration specified, or if unspecified, to a concentration of 1-4 times the limit of quantitation.

c) At least four aliquots shall be prepared and analyzed according to the test method either concurrently or over a period of days.

d) Using all of the results, calculate the mean recovery in the appropriate reporting units and the standard deviations of the population sample (n-1) (in the same units) for each parameter of interest. When it is not possible to determine mean and standard deviations, such as for presence/absence and logarithmic values, the laboratory must assess performance against established and documented criteria.

e) Compare the information from (d) above to the corresponding acceptance criteria for precision and accuracy in the test method (if applicable) or in laboratory-generated acceptance criteria (if there are not established mandatory criteria). If all parameters meet the acceptance criteria, the analysis of actual samples may begin. If any one of the parameters do not meet the acceptance criteria, the performance is unacceptable for that parameter.

Document 18-03. NELAC Demonstration of Capability (Cont.) (Page 4 of 5)
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f) When one or more of the tested parameters fail at least one of the acceptance criteria, the analyst must proceed according to 1) or 2) below.

1) Locate and correct the source of the problem and repeat the test for all parameters of interest beginning with c) above.

2) Beginning with c) above, repeat the test for all parameters that failed to meet criteria. Repeated failure, however, confirms a general problem with the measurement system. If this occurs, locate and correct the source of the problem and repeat the test for all compounds of interest beginning with C.1. c).

C.2 CERTIFICATION STATEMENT

The following certification statement shall be used to document the completion of each demonstration of capability. A copy of the certification statement shall be retained in the personnel records of each affected employee (see 5.5.2.5 and 5.4.12.2.5.4.b).

Document 18-03. NELAC Demonstration of Capability (Cont.) (Page 5 of 5)
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QAM Document 18-03

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Demonstration of Capability
Certification Statement

Date: Page __of __
Laboratory Name:
Laboratory Address:
Analyst(s) Name(s):

Matrix:
(examples: laboratory pure water, soil, air, solid, biological tissue)
Method number, SOP#, Rev#, and Analyte, or Class of Analytes or Measured Parameters
(examples: barium by 200.7, trace metals by 6010, benzene by 8021, etc.)

We, the undersigned, CERTIFY that:

1. The analysts identified above, using the cited test method(s), which is in use at this facility for the analyses of samples under the National Environmental Laboratory Accreditation Program, have met the Demonstration of Capability.

2. The test method(s) was performed by the analyst(s) identified on this certification.

3. A copy of the test method(s) and the laboratory-specific SOPs are available for all personnel on-site.

4. The data associated with the demonstration capability are true, accurate, complete and self-explanatory (1).

5. All raw data (including a copy of this certification form) necessary to reconstruct and validate these analyses have been retained at the facility, and that the associated information is well organized and available for review by authorized assessors.

Technical Director's Name and Title	Signature	Date
Quality Assurance Officer's Name	Signature	Date

This certification form must be completed each time a demonstration of capability study is completed.

(1) True: Consistent with supporting data.

Accurate: Based on good laboratory practices consistent with sound scientific principles/practices.

Complete: Includes the results of all supporting performance testing.

Self-Explanatory: Data properly labeled and stored so that the results are clear and require no additional explanation.

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18.3.5 "Validation includes specification of the requirements, determination of the characteristics of the methods, a check that the requirements can be fulfilled by using the method, and a statement on the validity. Other forms of Test Method Validation may include: [per ISO 17025 Section 5.4.5, Reference 18.4.9]

18.3.5(A) calibration using reference standards or reference materials;
18.3.5(B) comparison of results achieved with other methods;
18.3.5(C) interlaboratory comparisons;
18.3.5(D) systematic assessment of the factors influencing the result;
18.3.5(E) assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience.

18.3.6 Validation is always a balance between costs, risks and technical possibilities. There are many cases in which the range and uncertainty of the values (e.g. accuracy, detection limit, selectivity, linearity, repeatability, reproducibility, robustness and cross-sensitivity) can only be given in a simplified way due to lack of information."

18.4 **Analytical Procedure References**— Below is a listing of the major sources for analytical procedures throughout the Laboratory. For a more extensive list, refer to the "External Sources and References" list in **the "Document Control- Master List of Controlled Documents".**

18.4.1 "2003 NELAC Standard", National Environmental Laboratory Accreditation Conference, EPA/600/R-04/003, approved June 5, 2003, and effective July 1, 2003. (Chapter 5, "Quality Systems" dated July 12, 2002, Revision 16). For a downloaded copy of the latest revision, see the EPA website—(http://www.epa.gov/nelac).

18.4.2 40 CFR part 136: Title 40, part 136 of the *Code of Federal Regulations*. This part specifies the EPA's test procedures for the analysis of pollutants regulated under the Clean Water Act (CWA). Appendix B contains a procedure for MDL determination.

18.4.3 American Electric Power (AEP) Chemical Manual, Chemical Engineering Section, Mechanical Engineering Division, Revised February, 1982

18.4.4 "Annual Book of ASTM Standards, American Society for Testing and Materials, Complete Set of 1992 Standards, 68 volumes, 16 sections, Available from: ASTM International, 100 Barr Harbor Drive West, Conshohocken, PA 19428 or 1916 Race Street, Philadelphia, PA 19103.

18.4.4(A) (Including Section 11, Water and Environmental Technology", American Society for Testing and Materials (ASTM), 1994, 1996, and 1999.)

***Note**: This reference is designated as "ASTM" throughout the QAM.*

18.4.5 "Definition and Procedure for the Determination of the Minimum Level of Quantitation (ML) – Proposed Rule, March 2003 within "Guidelines Establishing Test Procedures for the Analysis of Pollutants; Procedures for Detection and Quantitation; "Federal Register: March 12, 2003 (Volume 68, Number 48); Proposed Rules, Page 11770-11790; DOCID:fr12mr03-19. (EPA link: http://www.epa.gov/fedrgstr/EPA-WATER/2003/March/Day-12/w5712.htm)

18.4.6 EPA Water Methods

18.4.6(A) "Methods for Determination of Organic and Inorganic Compounds in Drinking Water, Volume 1", National Exposure Risk Laboratory - Cincinnati (NERL-CI), EPA/815/R-00/014, Rev. 1.0, 1997.

(a) (Includes "Method 300.1 Determination of Inorganic Anions in Drinking Water by Ion Chromatography," Revision 1.0, 1997 (Daniel P. Hautman, David J. Munch).

18.4.6(B) "Methods for Determination of Metals in Environmental Samples", Supplement I, National Exposure Risk Laboratory - Cincinnati (NERL-CI), EPA/600/R-94/111, May 1994, Rev. 2.4, 1993. [Available from: National Technical Information Service (NTIS) as Publication # PB95-125472, 5285 Port Royal Road, Springfield, Virginia 22161 (703) 487−4650.]

(a) (Includes EPA Methods 200.15, 200.2, 200.7, 200.8, 200.9, 218.6, and 245.1.)

18.4.6(C) "Methods for Determination of Inorganic Substances in Environmental Samples", National Exposure Risk Laboratory - Cincinnati (NERL-CI), EPA/600/R-93/100, August 1993, Rev. 1.0, 1997. [Available from: National Technical Information Service (NTIS) as Publication # PB94-120821, 5285 Port Royal Road, Springfield, Virginia 22161 (703) 487−4650.

(a) (Includes EPA Methods 180.1, 300.0, 335.4, 350.1, 351.2, 353.2, 365.1, 375.2, 410.4, and 420.4.)

18.4.6(D) "Methods for Chemical Analysis of Water and Wastes (MCAWW)," Environmental Protection Agency, Environmental Monitoring Systems Laboratory-Cincinnati (EMSL-CI), EPA-600/4-79-020, Revised March 1983 and 1979 where applicable. Available from: National Technical Information Service (NTIS) , 5285 Port Royal Road, Springfield, Virginia 22161 (703) 487−4650.

(a) (Includes original and outdated EPA Methods from 1970, 1974, 1979, and 1983)

18.4.7 "Hach Handbook of Water Analysis", 1979, Hach Chemical Company, PO Box 389, Loveland, CO 80537.

18.4.8 "Handbook for Sampling and Sample Preservation of Water and Wastewater", EPA-600/4-82-029, September, 1982: U. S. Environmental Protection Agency, Environmental Monitoring and Support Laboratory

18.4.9 ISO/IEC 17025:2005 (E), Quality Management System for Calibration and Testing Laboratories.

18.4.10 Manufacturer and Equipment Manuals – See **the "Document Control- Master List of Controlled Documents"**- under the :External Sources and References" for a full listing of equipment manuals in use throughout the laboratory.

18.4.10(A) Equipment manuals should be maintained as Reference documents and should be monitored (summarized) in the following collection (which is itself, a controlled laboratory document):

18.4.11"Method ACS-DCL-GP-QAQC-002: Guidelines and Format for Methods at AEP Analytical Chemistry Services", AEP internal document: Original issue date 01/08/2007, Revision 0, and later revisions.

18.4.12"NIOSH Manual of Analytical Methods"

18.4.12(A) "NIOSH Manual of Analytical Methods", 2nd edition, April, 1977, Volumes 1,4,5 and 7; U. S. Department of Health and Human Services, Center for Disease Control

18.4.12(B) "NIOSH Manual of Analytical Methods", 3rd edition, February, 1984; U. S. Department of Health and Human Services, Center for Disease Control

18.4.12(C) "NIOSH Manual of Analytical Methods", 4th edition, August, 1994; U. S. Department of Health and Human Services, Public Health Service, Center for Disease Control and Prevention, National Institute for Occupational Safety and Health, Division of Physical Sciences and Engineering.

18.4.13"Official Methods of Analysis of the Association of Official Analytical Chemists," methods manual, 16th ed. (1998), 4th Revision. Available from: The Association of Official Analytical Chemists, 1111 N. 19th Street, Suite 210, Arlington, VA 22209.

***Note**: This reference is designated as "AOAC" throughout the QAM.*

18.4.14"OSHA Analytical Methods Manual", 1985; Occupational Health and Safety Analytical Laboratory

18.4.15"Standard Methods for the Examination of Water and Wastewater", Joint Editorial Board, American Public Health Association (APHA), American Water Works Association (AWWA), and Water Pollution Control Federation (WPCF), 18th ed. 1992 and later revisions (19th and 20th ed. And 2000 Online ed.).

18.4.15(A) Previous versions are not allowed by the Method Innovation Rule (MIR)

(a) 1975, 14th edition
(b) 1980, 15th edition
(c) 1985, 16th edition
(d) 1989, 17th edition

18.4.15(B) Allowed versions:
(a) 1992, 18th edition
(b) 1995, 19th edition
(c) 1998, 20th edition
18.4.15(C) Online version is equivalent to 2005, 21st edition
18.4.15(D) Available from: American Public Health Association, 1015 15th Street NW, Washington, DC 20005.

***Note**: This reference is designated as "SM" throughout the QAM.*

18.4.16"Techniques of Water-Resources Investigations (TWRI) of the U.S. Geological Survey (USGS)"; Book 5 (Laboratory Analysis), Chapter A1 – Methods for Determination of Inorganic Substances in Water and Fluvial Sediments, Fishman, M.J., et al. 3rd ed., 1989; Available from: U.S. Department of the Interior (DOI), USGS, Federal Center, Box 25286, Denver, Colorado 80225; or USGS, 604 S. Pickett Street, Alexandria, VA 22304. For a downloaded copy of the latest revision or to request a copy, see the USGS website—(http://pubs.usgs.gov/twri/twri5-a1/).25286

***Note**: This reference is designated as "USGS" throughout the QAM.*

18.4.17"Test Methods for Evaluating Solid Waste, Physical/Chemical Methods", U.S. Environmental Protection Agency, SW-846, 2nd edition, July, 1982

18.4.17(A) Office of Solid Waste and Emergency Response, SW-846, 3rd edition (09/1986), with Final Update I, November, 1990: Final Updates I (7/1992), II (9/94), IIA (9/1993), IIB (1/1995), III (12/1996); IVA (01/2008) , and IVB (01/2008), USEPA Office of Solid Waste and Emergency Response, Washington, D.C.

(a) Volume IA: Laboratory Manual
(b) Volume IB: Laboratory Manual
(c) Volume IC: Laboratory Manual
(d) Volume II: Field Manual

18.4.17(B) Available from: U.S. Government Printing Office (GPO), Superintendent of Documents, Washington, DC 20402, (202) 512−1800 (Publication Number: 955−001−00000−1). Also, available on-line at http://www.epa.gov/epaoswer/hazwaste/test/sw846.htm.

***Note**: This reference is designated as "SW846" throughout the QAM.*

18.4.18 AIHA Policy Modules – "2010 AIHA Laboratory Accreditation Programs, LLC Policy Revision", Effective April 1, 2010. Module 1 – Accreditation Overview; Module 2a – General Management System Requirements; Module 2b – IHLAP Program Specific Additional Requirements; Module 2c – ELLAP Program Specific Additional Requirements; Module 2d – EMLAP Program Specific Additional Requirements; Module 2f – FoodLAP Program Specific Additional Requirements; Module 3 – Accreditation, Maintenance, and Re-Accreditation Processes; Module 4 – Suspension, Revocation, or Denial of Accreditation; Module 5 – Appeals Porcess; Module 6a – Proficiency Testing (PT); Module 6b – PT for Industrial Hygiene Laboratories; Module 6c – PT for Environmental Lead Laboratories; Module 6d – PT for Environmental Microbiology Laboratories; Module 6f – PT for Food Laboratories; Module 7 – Reference to Accreditation and Advertising Policy; Module 8 – Miscellaneous; and Module 9 – Terms and Acronyms.

18.4.19 NVLAP Policy Modules – "NIST 150 Handbook"

18.4.20 Virginia Administrative Code (VAC) — VAC Title 1 (Administration), Agency 30 (Department of General Services), Chapter 46 (Certification for Ccommercial Environmental Laboratories), abbreviated 1VAC 30-46 § (Section reference).

18.4.21 West Virginia Code of State Rules (CSR) — CSR Title 47 (Department of Environmental Protection), Section 32 (Environmental Laboratories Certification and Standards of Performance), abbreviated 47 CSR 32 § (Section reference).

18.4.22 Statistical Analysis of Laboratory Data 950114-24-1, Stanley N. Deming, Copyright 1995. ACS Short Course by Dr. Stanley N. Deming and Dr. Stephen L. Morgan

18.5 QA Targets and QC Acceptance Criteria

18.5.1 Accuracy—The closeness of agreement between an observed value and an accepted reference value. When applied to a set of observed values, accuracy will be a combination of a random component and of a common systematic error (or bias) component.

18.5.1(A) Accuracy is calculated as the percent recoveries (See Section 23.4.1(B)) of a standard solution spiked into a matrix.

18.5.1(B) Accuracy may be measured on the measurement (e.g. LCS, laboratory control sample), the procedure (e.g. LFB, laboratory fortified blank), or the sample matrix (e.g. LFM, laboratory fortified matrix).

18.5.2 Bias—Bias is the deviation due to matrix effects of the measured value from a known spiked amount and can be assessed by comparing a measured value to an accepted reference value in a sample of known concentration or by determining the recovery of a known amount of contaminant spiked into a sample (matrix spike). Thus, the bias (B) due to matrix effects based on a matrix spike is calculated as:

Equation 1: Bias

$$B = Bias = (x_s - x_u) - K$$

18.5.2(A) Where: x_s = measured value for spiked sample,
x_u = measured value for unspiked sample
(or zero for blank matrix), and
K = known value of the spike in the sample

18.5.3 Precision—Precision is the agreement, among a set of replicate measurements, without assumption of knowledge of the true value. Precision is estimated by means of duplicate/replicate analyses. These samples must contain concentrations of analyte above the MDL, and may involve the use of matrix spikes.

18.5.3(A) The most commonly used estimates of precision (See Sections 23.4.1(C) through (E)) are:

(a) Relative Standard Deviation (RSD) (or the "Coefficient of Variation (CV)"),
(b) Relative Percent Difference (RPD), and
(c) Range (R).

18.5.3(B) The minimum acceptance limit for standards is **RPD ± 10 % (or within 10% of the average value)** for concentrations at least five times the MDL. For samples, the minimum acceptance limits is **RPD (or Range) ± 20 %.** At lower concentrations (e.g. near the MDL), the RPD and RSD values appear skewed and it may be more appropriate to monitor the **Range**.

***Note**: See **Section 23.4** for statistical tools and techniques and for the formulae for mean, standard deviation, etc. See **Section 23.5** for the use of Control Charts and **Section 23.6** for an explanation of Uncertainty.*

18.6 Documentation — Controlled quality documents from this Section shall be maintained separately from the Quality Assurance Manual in the following collection (which is itself, a controlled laboratory document):

18.6.1(A) **QCDOC 011** records (and the majority of laboratory documentation, unless otherwise specified) shall be maintained for at least five (5) years, and may require periodic review.

QC File 00 32— "QCDOC 011: Test Methods and Method Validation " (in Section 18)

19.0 Technical Requirements: Equipment

19.1 Purpose and Scope—This section is written to ensure that all gauges and instruments, whose determinations or reading must be recorded and reported, are properly and currently calibrated. This section also includes those practices and procedures, specific to certain pieces of laboratory equipment, which must be performed and the results of which must be monitored and properly documented to ensure a high quality production of laboratory data.

19.1.1 In order to ensure that analytical instrumentation performs within acceptable criteria, it is necessary to calibrate instruments in accordance with specified guidelines. These guidelines for calibration depend on a number of factors, which include:

19.1.1(A) Manufacturer or vendor recommendations,
19.1.1(B) Regulator and applicable test specifications, and
19.1.1(C) Laboratory experience with the particular instrument and sample.

19.1.2 Calibrations (or verification of calibration) must be properly documented in the analyst's instrument log book, along with the analytical data generated, or in the appropriate instrument log maintained for that purpose.

19.1.2(A) Details of calibration and standardization procedures, frequencies and documentation protocols are presented in Sections 19.1 through 19.6.
19.1.2(B) It is the laboratory's policy that method calibration requirements will be followed if more stringent than those described in these sections.

19.1.3 The calibration of laboratory instruments falls into two categories:

19.1.3(A) calibration conducted routinely prior to each use, and

19.1.3(B) periodic, scheduled calibration (and **Preventive Maintenance**, per **Section 12.0**) of instruments and gauges against known standards, traceable to the National Institute of Science and Technology (NIST) or an appropriate standards body, to ensure the continuing precision and accuracy of such instruments and gauges. The calibration policies and procedures set forth in this Section (**Section 19.0)** apply to all instruments and gauges that require this periodic, scheduled calibration.

19.1.4 Instruments and gauges that require this periodic, scheduled calibration include:

19.1.4(A) Analytical and test equipment in the Laboratory,
19.1.4(B) Flow rate (e.g. rotameter), pressure, vacuum and temperature measurement equipment, balances, pH meters, etc.

19.1.5 Both types of calibration (routine and periodic) records, documented in the analyst's instrument log book and analytical (calibration) data generated, shall be maintained in the following collection (which is itself, a controlled laboratory document):

QC File 00 33— "QCDOC 016: Miscellaneous Inspection Logs " (in Section 19)

19.1.5(A) Actual Certificates of Calibration (from a Calibration facility) or laboratory forms prepared in-house to document calibration shall be maintained in the following collection (which is itself, a controlled laboratory document):

QC File 00 34— "QCDOC 012: Certificates of Calibration " (in Section 19)

19.1.6 Manufacturer's instruction and/or manuals shall be maintained as reference documents in the following collection (which is itself, a controlled laboratory document):

QC File 00 35— "QCDOC 015: Reference Documents in Laboratory " (in Section 19)

19.1.7 A full "**List of Leased Equipment"** at the Laboratory is retained by the QAO. These records are maintained in **QCDOC-001 QUALITY SYSTEM (QS) Records.**

19.1.7(A) This list details the equipment type/description, the AEP tag number, the manufacturer, the lessor, the model number, the serial number, and the approximate cost of the item when purchased. The list may also include the PO#, the age of the equipment, the current location of the equipment, and the primary contact for the instrument (if so assigned).

19.1.7(B) **Laboratory personnel are required to notify the QAO*** (or designee) **when critical supplies** (e.g. pipettes, thermometers, major equipment, analytical instrumentation, etc.) **are purchased, disposed of, or removed from use** (i.e. properly labeled "Out of Service") to manage and maintain control of these critical laboratory processes.

19.1.8 The Calibration and Maintenance Sections have been separated into those procedures and practices for **Shared Laboratory Equipment (Section 19.4)** and for **Specific Analytical Laboratory Equipment (Section 19.5).**

19.1.8(A) **Calibration issues** are listed in **Documents 19-01 through 19-03** for the different Analytical Groups.

19.1.8(B) **Preventative Maintenance (PM) issues (i.e. PM schedule** are listed in **Documents 12-02 through 12-04** for the different Analytical Groups.

19.1.8(C) **Preventative Maintenance (and Routine Maintenance)** is discussed in further detail in **Section 12.4.**

19.2 Quality of Calibration

19.2.1 Quality of Calibration Standards

19.2.1(A) The primary standards and calibration gases used in the Laboratory measurement system must meet the requirements of traceability outlined in **Section 20.0.**

(a) The preparation of working standards and reagents from primary stock standards, neat standards, or reagents shall be documented in laboratory notebooks, reagent logbooks, and SOPs. (See also Section 20.5)

(b) As stated in Section 20.1.3, the certified values listed on the certificates of analyses for all certified standards shall be utilized when preparing calibration curves.

19.2.1(B) NIST-Traceable Reference Materials (NTRM) used in the Laboratory measurement system must also meet the requirements of traceability outlined in **Section 20.0.**

19.2.2 Environmental Conditions — Measuring and test equipment and calibration standards should be calibrated in an area that provides control of environmental conditions to the extent necessary to ensure required accuracy and precision.

19.2.3 Calibration Intervals

19.2.3(A) All calibration standards and instruments and gauges will be assigned an established calibration interval. The Calibration Method and Frequency Schedule for the Industrial Hygiene, Plant Services, and Water and Waste Analytical Groups are located in **Documents 19-01, 19-02, and 19-03, respectively**. This format is used to designate which instruments are primarily used in each of the analytical groups. This organizational arrangement may allow a type of instrument to be listed on more than one form.

Note: See Section 12 for Preventative Maintenance for the instruments used in each analytical group.

19.2.3(B) Lacking an established interval based on the equipment manufacturer's recommendations, an initial calibration period will be assigned by the QAO* (or designee). The calibration intervals will be adjusted from time-to-time, based on experience gained through use over a period of time, as indicated by data from the gauge calibration records. The calibration intervals will be specified in terms of time.

19.2.3(C) The choice of significant intervals will be based on the inherent stability and sensitivity of the instrument, its purpose or use, accuracy, conditions of use, and frequency or amount of usage. The intervals will be shortened or lengthened after evaluating the results of present and past calibrations and adjusting the schedule to reflect the findings. These evaluations must provide positive assurance that calibration interval adjustments will not adversely affect the accuracy of the system.

19.2.3(D) The QAO* (or designee) will maintain surveillance by periodically and randomly auditing for compliance with the calibration control system.

Document 19-1 Calibration Methods and Frequency Schedule for IHAG (updated)
2 pages <<Click on first page of object to access full document>>

Laboratory Equipment Calibration Methods and Frequency Schedule
Industrial Hygiene Analytical Group

Equipment / Instrument Type	Minimum Calibration Frequency	Calibration Method	"E" for Enviance Task
General Equipment for Dolan Chemical Laboratory			
Acid Neutralization Tank for Dolan Chemical Laboratory	Semiannually	Two (2) pH cell calibrations	E
Reverse Osmosis (RO) System for Dolan Chemical Laboratory	Annually	Conductivity meter calibration	E
Industrial Hygiene Analytical Group			
Asher, Low Temperature	None	None	
Balances, Analytical	Daily, as used (calibration check)	1 g class "S-1" weight	
	Annually	Calibration with PM visit	E
Balance, Micro	Daily, as used (calibration check)	20 mg and 200 mg class "S-1" weight	
	Annually	Calibration with PM visit	E
Block Digester for IH Tests	[Thermometer]- Annually	NIST certified thermometer	
Deionized Water Systems (for ultrapure water)	Daily	Check the conductivity of the ultrapure water produced	
Environmental Chamber	None Required	None Required	
Fourier Transform Infrared Spectrophotometer (FTIR) (for IH Analyses)	Each use	Interferometer/ electronics calibrations, applications software	
Inductively Coupled Plasma Spectrometer (ICP)	[Every metal]- Daily, as needed	Calibration blank and minimum three (3) standard calibration curve	
Microscope, Phase-Contrast (PCM)	Initial setup, any significant changes in optics	Graticule scale calibration	E
	Quarterly	Walton Becket Graticule verified versus Stage Micrometer	E
	Annually	Annual calibration during PM visit	E
	Replace or Recalibrate every 5 years	Stage micrometer	E
Microscope, Polarized Light (PLM)	Initial setup, any significant changes in optics	Walton Becket Graticule scale calibration	E
	Quarterly	Walton Becket Graticule verified versus Stage Micrometer	E
	Annually	Annual calibration during PM visit	E

File - QAM Document 19-01 Calibration Methods and Frequency Schedule for IHAG, Revision 4, 10.24.12.xls

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Document 19-2 Calibration Methods and Frequency Schedule for PSAG (updated)
3 pages <<Click on first page of object to access full document>>

Laboratory Equipment Calibration Methods and Frequency Schedule
Plant Services Analytical Group

Equipment / Instrument Type	Minimum Calibration Frequency	Calibration Method	"E" for Enviance Task
General Equipment for Dolan Chemical Laboratory			
Acid Neutralization Tank for Dolan Chemical Laboratory	Semiannually	Two (2) pH cell calibrations	E
Reverse Osmosis (RO) System for Dolan Chemical Laboratory	Annually	Conductivity meter calibration	E
Plant Services Analytical Group			
Auto - Titrator	Each use	Calibration curve (based on specific procedures)	
Balances, Analytical	Daily, as used (calibration check)	One (1) random class "S-1" weight	
	Annually	Calibration with PM visit	E
Balance, Qualitative (Trip) Top-loading	Daily, as used (calibration check)	One (1) random class "S-1" weight	
	Annually	Calibration with PM visit	E
Barometer	Annually	NIST certified barometer	E
Calorimeter (and Bomb Vessel) (for Coal Testing)	Each Use	ASTM check standard (benzoic acid)	
	Semi-Annually, or with changes in instrument setup	Ten calibration runs vs. NIST SRM 39i benzoic acid calorimetric standard	
Carbon/ Hydrogen/ Nitrogen Analyzer	Initially	Calibration with seven (7) replicates of single point standard	
	Each use	Single point calibration check	
Deionized Water Systems (for ultrapure water)	Daily	Check the conductivity of the ultrapure water produced	
Dielectric Analysis (for oil samples)	Annually	Recalibration of dielectric tester	E
	Each use	Single point calibration check	
Dosimeter	Annual	Calibration	E
Flashpoint Apparatus (closed vessel)	[Thermometer]- Annually	NIST certified thermometer	E
	Each Use	Two (2) equal p-xylene standards are Analyzed (No Calibration Curve)	
Fourier Transform Infrared Spectrophotometer (FTIR) (for inhibitor analysis in oils)	Initially; Annually thereafter	Minimum of five (5) standard calibration curve	
	Each use	Single point calibration check	
HPLC (Dionex) (for furan analysis in oils)	Annually	Minimum of seven (7) standard calibration curve	

File - QAM Document 19-02 Calibration Methods and Frequency Schedule for PSAG, Revision 4, 10.24.12.xls Page 1 of 3

Document 19-3 Calibration Methods and Frequency Schedule for WWAG (updated)
2 pages <<Click on first page of object to access full document>>

Laboratory Equipment Calibration Methods and Frequency Schedule
Water and Waste Analytical Group

Equipment / Instrument Type	Minimum Calibration Frequency	Calibration Method	"E" for Enviance Task
General Equipment for Dolan Chemical Laboratory			
Acid Neutralization Tank for Dolan Chemical Laboratory	Semiannually	Two (2) pH cell calibrations	E
Reverse Osmosis (RO) System for Dolan Chemical Laboratory	Annually	Conductivity meter calibration	E
Water and Waste Analytical Group			
As/Se Speciation	Each Use	Calibration blank and minimum five (5) standard calibration curve	
Auto - Analyzer - Skalar	Each day, as used	Calibration blank and minimum five (5) standard calibration curve	
Auto - Analyzer (Discrete) - Seal	Each day, as used	Calibration blank and minimum five (5) standard calibration curve	
Auto - Titrator	Each use	Calibration blank and three (3) standard calibration curve	
Balances, Analytical	Daily, as used (calibration check)	THREE (3) class "S-1" weights; two bracketing the expected range and one near the typical sample weight (per WVDEP)	
	Annually	Calibration with PM visit	E
Balance, Qualitative (Trip) Top-loading	Daily, as used (calibration check)	5 g class "S-1" weight	
	Annually	Calibration with PM visit	E
Block Digester for COD	[Thermometer]- Annually	NIST certified thermometer	
	[Thermometer]- Quarterly	Verification of (digital) thermometers	E
Block Digester for Metals Digestions	[Thermometer]- Annually	NIST certified thermometer	E
	[Thermometer]- Quarterly	Verification of (digital) thermometers	E
Conductivity Meter	Annually	Cell constant determination: five (5) standard calibration curve	E
Deionized Water Systems (for ultrapure water)	Daily	Check the conductivity of the ultrapure water produced	
Desiccator	None Required	None Required	
Environmental Chamber (for TCLP)	[Thermometer]- Annually	NIST certified (digital) thermometer	E
	[Thermometer]- Quarterly	Verification of (digital) thermometers	E
Flashpoint Apparatus (open vessel)	[Thermometer]- Annually	NIST certified thermometer	E
Ion Chromatograph (IC) - ANIONS (Dionex)	Weekly, or As Needed	Matrix blank and minimum four (4) standard calibration curve	
Ion Chromatograph (IC) - CR8 (Dionex)	Weekly, or As Needed	Matrix blank and minimum four (4) standard calibration curve	

File - QAM Document 19-03 Calibration Methods and Frequency Schedule for WWAG, Revision 4,10.24.12.xls Page 1 of 2

19.2.4 Calibration Sources

19.2.4(A) All calibrations performed by the Laboratory will be traced through an unbroken chain, supported by reports or data sheets, to ultimate or national reference standards maintained by a national organization such as the National Institute of Science and Technology (NIST). See also **Section 20.0** on **Measurement Traceability.**

19.2.4(B) The laboratory may also use, at its discretion, as an **ultimate reference standard**, an independent, reproducible standard, such as a standard that depends on accepted values of a natural physical constant. An up-to-date calibration report for each NIST standard used in the Laboratory will be retained in **QCDOC 013: Certificates of Analysis**:

QC File 00 36— "QCDOC 013: Certificates of Analysis " (in Section 19)

19.2.4(C) When **calibration services** are provided by an **outside metrology laboratory**, on a contract basis, copies of the calibration reports furnished by the contract laboratory will also be kept on file in **QCDOC 012: Certificates of Calibration**.

QC File 00 37— "QCDOC 012: Certificates of Calibration " (in Section 19)

19.2.4(D) All standard calibration reports should contain the following information:

(a) Report number
(b) Identification number of the calibration standard to which the report pertains
(c) Conditions under which the calibration was performed
(d) Required accuracy of the calibration standard
(e) Deviations or corrections
(f) Corrections that must be applied, if standard conditions of temperature, etc. are not met or differ from those at the place and time of calibration.

19.2.4(E) Contracts let for calibration services should require the metrology laboratory to furnish records on the traceability of their calibration standards.

19.2.5 Measurement Traceability - When possible, calibrations of critical equipment and hence the measurement results generated by that equipment, must be traceable to the SI through an unbroken chain of calibrations. (per AIHA Appendix H, Policy on Traceability of Measurement [Reference 18.4.18]) **Refer to Section 20.1.3 for further guidance on Measurement Traceability.**

19.2.5(A) External calibration services shall, wherever possible, be obtained from providers accredited to ISO/IEC 17025 by an ILAC recognized signatory. Calibration certificates shall be endorsed by a recognized accreditation body symbol. Certificates shall indicate traceability to the SI or reference standard and include the measurement result with the associated uncertainty of measurement.

19.2.5(B) Calibrations performed in-house shall be documented in a manner that demonstrates traceability via an unbroken chain of calibrations regarding the reference standard/material used, allowing for an overall uncertainty to be estimated for the in-house calibration.

19.2.5(C) Calibrations and Periodic verifications shall be repeated at appropriate intervals as defined in **QAM Documents 19-01, 19-02, and 19-03.** The frequency of these activities are dependant on the uncertainty required, the frequency of use and verification, the manner of use, the stability of the equipment, and the risk of failure considerations.

19.3 Equipment Procedures

19.3.1 Preventative Maintenance Procedures — Refer to Section 12.5 for Preventative Maintenance programs, frequency and responsible parties.

19.3.2 Calibration Procedures — Procedures for calibration of measuring and test equipment, and for calibration standards, will be used to eliminate possible measurement inaccuracies due to differences in techniques, environmental conditions, choice of higher-level standards, personnel changes, etc.

19.3.2(A) Refer to Section 19.4 for the specified frequency of calibration and calibration checks. [per Section 2A.5.5.4 in Reference 18.4.18]

19.3.2(B) "Where calibrations give rise to a set of correction factors, the laboratory shall ensure that copies (e.g., in computer software) are correctly updated." [per ISO 17025 Section 5.5.10, Reference 18.4.9]

19.3.3 These calibration procedures may be prepared by the Laboratory, may be published standard practices or may be written instructions that accompany purchased equipment. These procedures should contain the following information:

19.3.3(A) The specific equipment or group of equipment to which the procedure is applicable. Like equipment or equipment of the same type, having compatible calibration points, environmental conditions, and accuracy requirements, may be serviced by the same calibration procedure.

19.3.3(B) A brief description, or abstract, of the scope, principle and/or theory of the calibration method.

19.3.3(C) Fundamental calibration specifications, such as calibration points, environmental conditions, and accuracy requirements.

19.3.3(D) A list of calibration standards and accessory equipment required to perform the calibration steps. The manufacturer's name, model number, and required instrument accuracy should be furnished, as applicable.

19.3.3(E) The complete procedure for performing the calibration, arranged in a step-by-step manner, clearly and concisely.

19.3.4 Initial Use —"Before being placed into service, equipment shall be calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications." [per ISO 17025 Section 5.5.2, Reference 18.4.9]

19.3.4(A) "Equipment critical to the generation of the test results shall be subject to performance checks prior to use for analysis of samples. Such checks may include evaluation of instrument sensitivity, alignment, linearity, noise level and/or response levels versus historical values. Acceptance criteria for these checks shall be stated in the analytical SOP." [per Section 2A.5.5.2 in Reference 18.4.18]

19.3.5 Operation — "Equipment shall be operated by authorized personnel. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) shall be readily available for use by the appropriate laboratory personnel." [per ISO 17025 Section 5.5.3, Reference 18.4.9]

19.3.5(A) "Analytical, measuring and calibration equipment, including both hardware and software, must be safeguarded from adjustments which would invalidate the test and/or calibration results." [per ISO 17025 Section 5.5.12, Reference 18.4.9]

19.3.5(B) "When possible, any external calibration service used must be a calibration laboratory accredited to ISO/IEC 17025:2005 by a recognized accreditation body." [per Section 2A.5.5.5 in Reference 18.4.18]

19.3.6 Calibration Protocol

19.3.6(A) Calibration Blank — Calibration blanks are samples of media to which all reagents have been added in the same volumes or proportion as used in the sample processing. The calibration blank is not carried through the entire analysis scheme.

(a) A calibration blank shall be prepared with each set of calibration standards used during the analysis in the development of the calibration curve.

(b) Calibration blanks are used as "zero" standards and are used in the calibration curve to calibrate the instrument or procedure.

19.3.6(B) Calibration Curve — Every procedure (where applicable) shall have a curve specific to its usage defined by an appropriate number of standards and calibration blank.

(a) Calibration curves must be prepared in accordance with the analytical procedure. In the absence of this type of instruction, a minimum of two (2) standard dilutions must be prepared and analyzed.

(i) These standards must bracket the expected concentration of the samples being analyzed. Values higher than the highest standard or lower than the lowest standard must not be reported unless an applicable linear range has been demonstrated or the data is appropriately qualified.

(ii) Any analysis samples yielding values greater than 10% above the established high calibration standard for the linear range shall be diluted and rerun.

(b) This curve should be characterized by linear range and analyte sensitivity. The minimum correlation coefficient must be 0.995.

(c) NIST-traceable, reagent-grade standard materials (if available) shall be used for the preparation of calibration standards. If not available, ACS-reagent grade materials are used and will be at least 95% purity.

(i) Standards must be prepared at the frequency specified in the appropriate procedure.

(ii) Calibration standards should be prepared by successively diluting a standard solution to produce working standards that cover the working range of the instrument.

(iii) The calibration standards must be prepared using the same type of acid or solvent and at the same concentration as would result in the samples following sample preparation.

(d) A detection limit should be determined for each procedure. (See Detection Limits).

19.3.6(C) "All calibration curves should be dated and labeled with applicable method, instrument identification, analysis date, analyte concentrations, and instrument response." [Reference 18.4.18] (also referenced in Section 13.2.1(D)).

19.3.6(D) Calibration Verification — "When intermediate checks are needed to maintain confidence in the calibration status of the equipment, these checks shall be carried out according to a defined procedure." [per ISO 17025 Section 5.5.10, Reference 18.4.9]

(a) **Calibration Blanks**

(i) Initial calibration blank (ICB), an aliquot of calibration blank, should be analyzed immediately after the calibration curve has been generated, to verify its validity.

(ii) Continuing calibration blank (CCB), an aliquot of calibration blank, should be analyzed periodically throughout an analytical sequence (e.g. every ten analyses) and at the end of the analytical sequence to verify the ongoing validity of the calibration curve.

(b) **Independent calibration verification (ICV)** must be analyzed immediately after the calibration curve has been generated using certified second source standards. The following states the requirements for "second source":

(i) Standards must be prepared from independent starting material and certified, as such;
(ii) Standards can be purchased from a second vendor; or
(iii) Standards can be purchased from the same vendor, with different lot numbers, as long as letters of explanation of independence are kept on file and maintained.

(c) **Continuing calibration verification (CCV)** should be performed to verify the ongoing validity of the calibration curve (usually at a mid-level point) and may utilize one of the calibration standards and/or the same stock standard used to prepare the calibration standards.

(i) These CCV should be analyzed initially (after the calibration curve has been generated), periodically throughout an analytical sequence (e.g. every ten analyses), and at the end of the analytical sequence to verify the validity of the calibration curve.

(ii) The CCV is primarily applicable to those analytical systems where calibration curve drift may be a problem. The CCV is used to check the curve in those cases and to verify the absence or presence of drift.

19.3.7 Equipment / Calibration Records

19.3.7(A) "Whenever practicable, all equipment under the control of the laboratory and requiring calibration shall be labeled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due." [per ISO 17025 Section 5.5.8, Reference 18.4.9]

19.3.7(B) "Each item of equipment and its software used for testing and calibration and significant to the result shall, when practicable, be uniquely identified." [per ISO 17025 Section 5.5.4, Reference 18.4.9]

19.3.7(C) "Records shall be maintained for each item of equipment and its software significant to the tests and/or calibrations performed." [per ISO 17025 Section 5.4.2, Reference 18.4.9] Equipment records shall include at least the following:

(a) the identity of the item of equipment and its software (See the **List of Leased Equipment** and **the "Document Control- Master List of Controlled Documents"**);
(b) the manufacturer's name, type identification, and serial number or other unique identification (See the **List of Leased Equipment**);
(c) checks that equipment complies with the specification (see Use and Maintenance Logs, Section 13.5.3);
(d) the current location, where appropriate (See the **List of Leased Equipment**);
(e) the manufacturer's instructions, if available, or reference to their location (See **the "Document Control- Master List of Controlled Documents"**);
(f) dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration (see Section 19.5.5(D));
(g) the maintenance plan, where appropriate, and maintenance carried out to date (see Section 12.5);
(h) any damage, malfunction, modification or repair to the equipment (see Use and Maintenance Logs, Section 13.5.3).

19.3.7(D) Enviance Tasks (see Section 12.5.5) are assigned as reminders for equipment calibration and maintenance. Upon calibration, sequential calibration labels are affixed to equipment, where applicable. Calibration labels should include the sequential # (if provided), the equipment serial number (or other clear identification), the date of calibration, the person performing the calibrations, and the due date of next calibration.

(a) Equipment calibration labels may be provided by external vendors upon completion of calibration or certification (often during a preventive maintenance service call). If not provided, see Section 19.5.7(B)(c). Calibration certificates shall be filed in the appropriate manner.

(b) Other equipment calibration labels are provided by the QAO* upon notification of calibration. The equipment calibration labels are located in the Dymo "large calibration labels database".

(c) Pipette (and dispenser) calibration labels are provided by the QAO* upon notification of calibration. The pipette labels are located in the Dymo "small calibration labels database".

(d) Critical processes and major equipment (e.g. instrumentation, balances, thermometers, pipettes, etc.) shall be labeled with the calibration (and/or PM status) or linked to a record of calibration. The label/record shall identify the equipment (i.e. serial number or other unequivocal identification), the date of calibration/PM, the employee that performed the calibration /PM and the date of expiration.

(i) The QAO* (or designee) shall supply calibration labels with consecutively sequenced numbers upon receipt of the appropriate documentation.

19.4 Calibration Protocol for Shared Laboratory Equipment

19.4.1 Glassware

19.4.1(A) The Laboratory uses laboratory glassware for a variety of purposes, including the storage of reagents and sample solutions and the exact volumetric measurement of such solutions. All glassware used by the laboratory for an analytical function should meet ASTM E 438-92 Type I, Class A requirements.

19.4.1(B) These requirements are, in general, met with "Pyrex" or "Kimax" Class A borosilicate glassware.

19.4.1(C) Pipettes with chipped or broken tips should not be used for quantitative analytical purposes. These pipettes should be discarded and replaced.

19.4.1(D) Soda-lime glass (soft glass) is not recommended.

19.4.1(E) Volumetric Glassware-The Laboratory uses volumetric glassware that meets the general specifications of Class A grade. This grade signifies the use of glassware meeting the requirements of applicable construction and accuracy.

19.4.1(F) The use of Class A glassware is required for the following:
(a) preparation of all primary standards
(b) preparation and dilution of all primary and/or stock standards
(c) all standardizations

19.4.1(G) Glassware which has been found to be chipped, cracked, or broken is discarded in a safe and appropriate manner.

19.4.1(H) **Glassware Cleaning Protocols**

(a) All laboratory glassware and plastic-ware must be scrupulously cleaned to prevent any contamination of the sample or of the reagents.

(b) The Flue Gas Testing Analytical Group — (Removed 04/2008)

(c) The glassware cleaning procedures, used by the Industrial Hygiene Analytical Group, are given in the Industrial Hygiene Analytical Group SOP entitled "Glassware Cleaning Policies and Procedures" (Method # ACS-DCL-IH-ih-008)

(i) A general summary of the glassware cleaning procedure used in the Industrial Hygiene Analytical Group is given in **Document 19-04.**

(d) The Plant Services Analytical Group Currently has no additional specific glassware cleaning procedures.

(i) A general summary of the glassware cleaning procedure used in the Plant Services Analytical Group is given in **Document 19-05 (Reserved).**

(e) The glassware cleaning procedures, used by the Water and Waste Analytical Group, are given in the Water and Waste Analytical Group SOP entitled "Glassware Cleaning Policy and Procedure" (Method #- **Reserved**).

(i) A general summary of the glassware cleaning procedure used in the Water and Waste Analytical Group is given in **Document 19-06**.

Document Laboratory Glassware Cleaning Procedures Summary (FGAG) (Removed)

Document 19-4 Laboratory Glassware Cleaning Procedures Summary (IHAG) (updated)

QAM Document 19-04
Revision 1, 10/25/12

Dolan Chemical Laboratory
Industrial Hygiene Analytical Group
Laboratory Glassware Cleaning Procedures

One of the most important tasks in a modern analytical laboratory is the proper cleaning of glassware. This is evident when one realizes that instrumentation is now being produced that will detect parts per billion, even parts per trillion levels of many species. Realizing this, one can see that contamination of glassware can render an analysis totally useless to the analyst.

What follows below is a general outline of proper methodologies and techniques to be used in the cleaning of glassware.

1) Prior to Washing
   a. All glassware, including pipettes, must be completely immersed and soaked in soapy water overnight before it may be washed. Water for soaking should be changed often.

2) Washing
   a. After soaking overnight, the glassware should be washed by hand with a brush or sponge (it is important that the Phillips beakers be thoroughly scrubbed with a brush).
   b. Following the wash, all glassware should be thoroughly rinsed with hot tap water.
   c. After rinsing the detergent-washed glassware, inspect for cleanliness. If visible dirt is present, scrub the glassware again with detergent and brush. If dirt still persists, soak in 1:1 nitric acid overnight. If dirt still persists, discard the glassware.
   d. Immediately after the rinse, place all Erlenmeyer flask, Phillips beakers, watch glasses and stoppers in the industrial dishwasher to be washed again with detergent soap. All other glassware does not need to be washed in the dishwasher and is ready for acid wash.

3) Acid Wash
   a. All glassware is to be rinsed with 1:1 nitric acid following detergent wash or following the wash in the dishwasher and rinsed three (3) to five (5) times (thoroughly!!!) with de-mineralized water.

4) Pipettes
   a. After soaking overnight, the pipettes are transferred into the pipette cleaner. Two (2) detergent tablets are added at this time and hot tap water needs to be run through the system until the water runs clear (approximately one (1) hour) followed by one (1) hour of de-mineralized water.

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Document 19-5 Laboratory Glassware Cleaning Procedures Summary (PSAG) (Reserved)

Document 19-6 Laboratory Glassware Cleaning Procedures Summary (WWAG) (updated)

<<Click on first page of object to access full document>>

QAM Document 19-06
Revision 6
10/25/2012

Dolan Chemical Laboratory
Water and Waste Analytical Group
Laboratory Glassware Cleaning Procedures

Parameter	Cleaning Procedure (in order specified)
Minerals	1 – 3, 9, 4, 8, 4, 11
Nutrients	1 - 6
Oil and Grease	1 – 4, 7, 10
Trace Metals	1 – 3, 9, 4, 8, 4, 11
Mercury, Low-Level (EPA Method 1631)	(per SOP)

Number Code/Explanation of Specific Cleaning Procedure

1. Remove all labels.
2. Wash with hot tap water using, if possible, a laboratory grade detergent such as "Micro".
3. Rinse thoroughly with hot tap water.
4. Rinse thoroughly with deionized water.
5. Rinse thoroughly with > 25% H_2SO_4 (Sulfuric acid).
6. Rinse three times with deionized water.
7. Rinse thoroughly with Hexane.
8. Rinse or soak with 1:1 HCl (Hydrochloric acid).
9. Rinse or soak with 1:1 HNO_3 (Nitric acid).
10. Dry at 105 ^{o}C for 3 – 4 hours and store in a desiccator.
11. Store inverted or capped containing an amount of deionized water.

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19.4.2 Reagents

19.4.2(A) The quality of reagent needed by a specific procedure is usually designated by that procedure. If not so designated, only those reagents that meet American Chemical Society (ACS) reagent grade standards will be used. If not available, the next highest grade will be used.

19.4.2(B) Primary standard grade reagents will be used in the preparation of all calibration standards and in the preparation/standardization of all volumetric standards.

19.4.2(C) All standards used for atomic absorption (AA) and inductively coupled plasma spectrophotometry (ICP or ICP/MS) are purchased commercially and should be traceable to standards approved by the National Institute of Standards and Technology (NIST).

19.4.2(D) High-purity acids (hydrochloric, nitric, perchloric and/or sulfuric) are used for all metal analysis preparations.

19.4.2(E) Copies of purchase orders for all reagents are to be reviewed and approved by the Laboratory Manager. In the Manager's absence, the Laboratory Supervisor or the Chemical Hygiene Officer (CHO) are designated backups to perform these duties.

19.4.2(F) Expired reagents/standards—

(a) Dispose of reagent and/ or standards when their volume falls below 10% of the original container volume.

(b) Standards that have passed their expiration date should be properly disposed of according to the Chemical Hygiene Plan (See Appendix A) or should be labeled to prevent use for quantitative work (e.g. " EXPIRED- Do not use for quantitative work or sample analyses").

(c) See Sections 6.3.2(H)(d) and 6.3.3(E) for information on assigning expiration dates to chemicals with no manufacturer's expiration date and on assigning a re-evaluation date to critical supplies.

19.4.2(G) Refer to **Sections 6.4.4 and 6.5** for guideline for receipt, storage, and disposal of **Bulk Reagents**.

19.4.3 Laboratory Operations — The laboratory specifications, calibration procedures and frequency of calibration are outlined in the "**Laboratory Operations Procedure"**. This procedure contains a list of required procedures used to ensure accuracy and proper operation of laboratory equipment devices used routinely. The scope of this procedure encompasses:

19.4.3(A) **general laboratory equipment,**
19.4.3(B) **safety equipment,**
19.4.3(C) **temperature-measuring equipment,**
19.4.3(D) **temperature-maintaining equipment,**
19.4.3(E) **volume-measuring equipment,**
19.4.3(F) **volume-dispensing equipment,**
19.4.3(G) **weight-measuring equipment,**
19.4.3(H) **shared measuring equipment,**
19.4.3(I) **other support equipment, and**
19.4.3(J) **reference standards.**

19.5 Calibration Protocol for Specific Analytical Laboratory Equipment — See the individual analytical SOPs for daily calibration details, calibration verification requirements and other QC criteria associated with the specific pieces of analytical equipment.

19.6 Control of Measurement Equipment

19.6.1 Refer to the **Master List of Calibrated Items and Laboratory Tasks** for laboratory calibration records associated with shared laboratory equipment and several items detailed in the "**Laboratory Operations Procedure"** This list is retained by the QAO. These records are maintained in **QCDOC-001 QUALITY SYSTEM (QS) Records.**

19.6.2 Handling, Transport and Storage of Measurement Equipment

19.6.2(A) **Handling.**

(a) The measurement equipment shall be handled as necessary to prevent contamination or remove potential contamination between analyses. Practices that may cause equipment malfunction, failure or shortened lifespan should be avoided.

(b) When measurement equipment has been overloaded, actions must be taken to return the system to its original state. Until these measures have been implemented and the system operation has been verified, the equipment should be adequately labeled (e.g. "Do not use. Equipment signal overload, Date overloaded, and Responsible analyst") to prevent its use on sample analyses.

(c) Equipment that has been determined not to be operating effectively (e.g. whether the calibration has expired, a calibration verification method has failed, or it has been malfunctioning), shall be removed from service until the situation has been resolved. Equipment removed from service should be adequately labeled (e.g. "Out of Service, Date removed from service, and Responsible analyst") to prevent its use on sample analyses.

(i) Additionally, the laboratory has "Lock Out" tags available to label equipment that has been removed from service for maintenance or repair. These tags list the responsible analyst, the department and the date as well as an expected completion date.

(d) "When, for whatever reason, equipment goes outside the direct control of the laboratory, the laboratory shall ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service." [per ISO Section 5.5.9, Reference 18.4.9]

(i) "Results of the function and calibration status checks required for equipment that goes outside the direct control of the laboratory shall be documented." [per Section 2A.5.5.3 in Reference 18.4.18]

19.6.3 Transport.

19.6.3(A) Measurement equipment shall be transported per the manufacturer's instructions or the accepted industry practices.

19.6.4 Storage.

19.6.4(A) Measurement equipment shall be stored per the manufacturer's instructions or the accepted industry practices.

19.7 Documentation — Controlled quality documents (both routine and periodic calibration records, and records for both laboratory instrumentation and miscellaneous laboratory equipment) from this Section shall be maintained in the following collection (which is itself, a controlled laboratory document):

19.7.1 QCDOC 012 records (and the majority of laboratory documentation, unless otherwise specified) shall be maintained for at least five (5) years, and may require periodic review.

QC File 00 38— "QCDOC 012: Certificates of Calibration " (in Section 19)

20.0 Technical Requirements: Measurement Traceability

20.1 Purpose and Scope — This section discusses Reference Standards used to calibrate equipment and Standard Reference Materials used in analyses and tests. These Measurement Traceable items shall be traceable to the National Institute of Science and Technology (NIST) or another recognized standardization body.

20.1.1 This section also relates to the measurement standards used to calibrate test equipment as discussed in **Section 19.0** (**Equipment**).

20.1.1(A) The certified values listed on the certificates of analyses for all certified standards shall be utilized when preparing calibration curves and for using other quality control activities. (See also Section 19.2.1(B) regarding calibration).

***Note**: For example: If a "1000 ppb stock standard is diluted to 200, 100, 50, and 25 ppb for working calibration standards, and the certified value on the certificate of analysis states a value of 1010 ppb; then the calibration curve shall be prepared using the values, 202, 101, 50.5, and 20.25 ppb.*

20.1.2 Refer to the **Master List of Measurement Traceable Items** for periodic calibration records associated with reference standards. This list is retained by the QAO. These records are maintained in **QCDOC-001 QUALITY SYSTEM (QS) Records.**

20.1.3 The Laboratory establishes "traceability of its measurement standards and measuring instruments to the SI by means of an unbroken chain of calibrations or comparisons linking them to relevant primary standards of the SI units of measurement." [per ISO 17025 Section 5.6.2.1, Reference 18.4.9]

20.1.3(A) "The link to SI units may be achieved by reference to national measurement standards. National measurement standards may be primary standards, which are primary realizations of the SI units or agreed representations of SI units based on fundamental physical constants, or they may be secondary standards which are standards calibrated by another national metrology institute.

20.1.3(B) When it can be established that the associated contribution from the calibration contributes little to the total uncertainty of the test result, the uncertainty can be provided for the equipment used upon request.

20.1.3(C) Where traceability of measurements to SI units is not possible, reasonable and/or relevant, the calibration shall provide confidence in measurements by establishing traceability to appropriate measurement standards such as the use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material; or the use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned." [per ISO 17025 Section 5.6.2.2, Reference 18.4.9]

(a) A competent supplier is a national metrology institute (NMI) or an accredited reference material provider that conforms to ISO Guide 34 in combination with ISO/IEC 17025 (or ILAC Guidelines for the Competence of Reference Material Producers, ILAC G12). (per AIHA Appendix H, Policy on Traceability of Measurement [Reference 18.4.18]).)

20.1.3(D) Measurement Traceability requirements for subcontractors and for equipment calibration are addressed in **Sections 5.2.6 and 19.2.5**, respectively.

20.1.3(E) The reference materials defined in Sections 20.2, 20.3 and 20.4 (Calibration Standards, Reference Standards**,** and Standard Reference Materials (SRM)) shall have a Certificate of Analysis (CoA) that documents traceability to a primary standard or certified reference material and associated uncertainty, when possible. When applicable, the certificate must document the specific NIST SRM® or NMI certified reference material used for traceability.

(a) These certificates of analysis (CoA) shall, wherever possible, be endorsed by a recognized accreditation body symbol, indicate traceability to the SI or reference standard, and include the certified result with the associated uncertainty of measurement.

20.2 Calibration Standards

20.2.1 These calibration standards refer to those defined in **Section 19.2** for calibration of equipment. Calibration standards purchased from commercial vendors will be required to have a certificate of analysis

20.2.2 Use of Calibration Standards

20.2.2(A) The standards used in the Laboratory measurement system will be calibrated against primary standards having demonstrated reference property values of high accuracy. These high-level standards will be certified by NIST or other recognized standardization bodies. Internal standards may be used in those situations where an externally certified primary standard does not exist.

20.2.2(B) Calibration gases purchased from commercial vendors will be required to have a certificate of analysis. Whenever a certified, calibration gas is available from NIST, commercial gas vendors will be required to establish traceability of the certificate of analysis to the certified gas.

20.2.3 Handling, Transport and Storage of Calibration Standards

20.2.3(A) Care must be taken in the handling and transport of calibration standards.

20.2.3(B) A copy of the certified results paperwork should be available to the analyst for use in calibration.

20.2.4 A copy of **Certificates of Analysis** for calibration standards shall be maintained in the following collection (which is itself, a controlled laboratory document):

QC File 00 39— "QCDOC 013: Certificates of Analysis " (in Section 20)

20.2.5 See the individual laboratory areas for the full documentation of pertinent information. Documentation for calibration standards shall be maintained in individual Standard and Reagent Logbooks, and Standard and Reagent Preparation Books, as described in **Section 20.5.** The information in the master log should include the supplier, standard identification (and part number), as well as the location and/or user.

20.3 Reference Standards

20.3.1 Reference Standards purchased from commercial vendors are required to have a certificate of traceability (traceable to NIST standards or another recognized standardization body), and may require periodic re-certification by an outside vendor.

20.3.1(A) Examples of reference standards that may be used by the laboratory include NIST-traceable thermometers or certified weights for analytical balance calibration.

20.3.1(B) Enviance Tasks (see Section 12.5.5) are assigned as reminders for reference standards re-calibration. Calibration certificates shall be filed in the appropriate manner.

20.3.1(C) "Reference standards shall be calibrated by a body that can provide traceability" as described in Section 20.1.3. Reference standards shall be calibrated before and after any adjustment. [per ISO 17025 Section 5.6.3.1, Reference 18.4.9]

20.3.2 Use of Reference Standards

20.3.2(A) Reference Standards are used in the periodic calibration of laboratory equipment, as stated in **Section 19.2**

20.3.2(B) "Reference Standards shall be used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated." [per ISO 17025 Section 5.6.3.1, Reference 18.4.9]

20.3.3 Handling, Transport and Storage of Reference Standards

20.3.3(A) Reference Standards are to be handled as necessary to prevent contamination or deterioration of the materials. The integrity of these materials should be viewed as essential to their use.

20.3.3(B) Reference standards should not be used for analytical purposes.

20.3.3(C) A copy of the certified results paperwork should be available to the analyst for comparison and/or calibration adjustments.

20.3.3(D) Reference Standards shall be stored as recommended by the manufacturer to prevent contamination or deterioration of the materials. The integrity of these materials should be viewed as essential to their use.

20.3.3(E) Care must be taken in the handling and transport of reference standards. Manufacturer's recommendations should be followed.

(a) For example, the following procedure shall be followed when shipping the NIST-traceable thermometer for re-certification to minimize the chance of damage. A couple small o-rings shall be placed around the thermometer stem (to make it fit snugly inside the bore of the plastic tube) prior to inserting it inside the plastic tube. This tube shall then be surrounded by bubble wrap and placed in a box. That box shall then be placed in a larger box surrounded by other packing materials, as available. The outer box must then be taped and shipped, as usual.

20.3.4 A copy of the **Certificate of Traceability for every Reference Standard** used at the Laboratory shall be maintained in the following collection (which is itself, a controlled laboratory document) by the QAO* (or designee):

QC File 00 40— "QCDOC 013: Certificates of Analysis " (in Section 20)

20.3.5 All Reference Standards are to be logged into the **Master List of Measurement Traceable Item**s upon receipt.

20.3.5(A) This master log includes an identification, part number and serial number (if available); the QA frequency and responsibility; the date received, certified and due to expire (if known); the location; and other information form the Calibration Laboratory (certificate, calibration procedure, tolerances, etc.).

20.4 Standard Reference Materials (SRM)

20.4.1 Standard Reference Materials (SRM) purchased from commercial vendors are required to have a certificate of analysis and are often traceable to NIST standards or another recognized standardization body.

20.4.2 Use of SRMs

20.4.2(A) SRMs are used for calibration of instruments, for preparation of lower tier standards, or for comparison as reference standards against samples to be analyzed or tested as applicable.

20.4.2(B) "SRMs shall, where possible, be traceable to SI units of measurement, or to certified reference materials. Internal reference materials shall be checked as far as is technically and economically practicable." [per ISO 17025 Section 5.6.3.2, Reference 18.4.9]

20.4.2(C) SRMs may be used as "intermediate checks to maintain confidence in the calibration status of reference, primary, transfer or working standards" (e.g. second source material used to prepare Calibration Verification standards as described in Section 19.5.8. [per ISO 17025 Section 5.6.3.3, Reference 18.4.9]

20.4.3 Handling, Transport and Storage of Standard Reference Materials

20.4.3(A) SRM are to be handled, transported and stored as necessary to prevent contamination or deterioration of the materials. The integrity of these materials should be viewed as essential to their use.

20.4.3(B) Care must be taken in the handling and transport of SRM.

20.4.3(C) A copy of the certified results paperwork should be available to the analyst for comparison and/or calibration adjustments.

20.4.3(D) Local areas, such as the Coal Lab, Oil Lab, etc., should establish locations within each of the labs that protect the standard from excessive light and heat, and should be locations that are as protective as possible of the integrity of the standard.

20.4.4 A copy of the **Certificate of Analysis for every SRM** used at the Laboratory shall be maintained in the following collection (which is itself, a controlled laboratory document):

QC File 00 41— "QCDOC 013: Certificates of Analysis " (in Section 20)

20.4.5 See the individual laboratory areas for the full documentation of pertinent information. Documentation for SRM shall be maintained in individual Standard and Reagent Logbooks, and Standard and Reagent Preparation Books, as described in **Section 20.5.** The information in the master log should include the SRM number and identification, the number of bottles or sets currently residing in the Laboratory, a unique bottle or box number as assigned by the Laboratory and marked on the bottle/box itself, the date the SRM was received, the expiration date (if given), and the laboratory room location of the standard.

20.5 Documentation and Labeling of Standards and Reagents

20.5.1 The laboratory shall retain records for all standards and reagents including the manufacturer/vendor, the manufacturer's Certificate of Analysis (CoA) or purity (if supplied), the date of receipt, recommended storage conditions, and an expiration date after which the material shall not be used unless it is verified by the laboratory.

20.5.1(A) CoA binders - Certificates of Analyses (CoAs) received with each chemical, reagent, media or other critical supply shall be placed in the binder associated with the test location.

(a) Form QAR-2001, which is provided for items received without an accompanying CoA shall also be placed in the binder associated with the test location.

(b) Once the completed form is received (whether with the supporting documentation, CoA, or with the laboratory exemption), it shall be placed in the binder associated with the test location.

20.5.1(B) Original containers - Original containers (such as provided by the manufacturer or vendor) shall be labeled with the date (and person's initials) received and an expiration date per Section 6.3.2(G).

(a) Containers shall also be labeled with the date (and person's initials) opened.

20.5.1(C) **Reagent Log —** A Reagent Log shall also be maintained by the laboratory that includes the chemical, manufacturer/vendor, lot number, date of receipt, expiration date (if given), and the date the reagent was removed from use.

(a) As already stated in Section 6.3.2(F)(b), all purchased chemicals, solutions, and standards shall be labeled with dates of receipt, the date of expiration on the container, and the date when the container is opened.

(b) Laboratory reagents shall meet or exceed requirements as outlined by specific methods.

(c) Typically reagents are ACS grade or better, as required by specific method protocol. (See also Section 23.2.6)

(d) When a reagent aliquot is removed from a container, it shall be used entirely or the unused portion properly discarded. Unused portions of a reagent shall not be returned to the original container.

20.5.1(D) **Standard Log—** A Standard Log shall be kept on the source of the standard stock solution (reference materials) including lot number and expiration date and manufacturer; a summary of formulation of the standard stock solution, the date of preparation, expected expiration date (if known), and the initial of the preparer. Assign a AEP lot number to the stock solution utilizing the abbreviation of the parameter and the date (example: for a TPH standard prepared on September 15, 1999 = TPH990915)

(a) Records shall be maintained on reagent and standard preparation. These records shall indicate traceability to purchased stocks or neat compounds, reference to the method of preparation, date of preparation, expiration date and preparer's initials.

20.5.1(E) **Standard Preparation Log—** The preparation of stock and working standards shall be maintained in a log book for each area. The preparation method shall be established, and the manufacturer/vendor, lot number (of standard and reagent(s)), stock concentrations, and final concentrations shall be documented. The analyst preparing the standard, date of preparation and date of expiration shall also be documented.

(a) Stock and working standard solutions shall be checked regularly for signs of decomposition and expiration. All solutions shall be labeled with identification of the compound, concentration, date prepared, analyst who prepared the solution, and expiration date.

(b) A copy of **Certificates of Analysis** for standards and reagents shall be maintained in the following collection (which is itself, a controlled laboratory document):

QC File 00 42— "QCDOC 013: Certificates of Analysis " (in Section 20)

20.5.2 Reagents

20.5.2(A) As already stated in Section 6.3.2(F)(b), all purchased chemicals, solutions, and standards shall be labeled with dates of receipt, the date of expiration on the container, and the date when the container is opened.

(a) **Reagent Log —** A Reagent Log shall also be maintained by the laboratory that includes the chemical, manufacturer/vendor, lot number, date of receipt, expiration date (if given), and the date the reagent was removed from use.

20.5.2(B) Laboratory reagents shall meet or exceed requirements as outlined by specific methods.

20.5.2(C) Typically reagents are ACS grade or better, as required by specific method protocol. (See also Section 23.2.6)

20.5.2(D) When a reagent aliquot is removed from a container, it shall be used entirely or the unused portion properly discarded. Unused portions of a reagent shall not be returned to the original container.

20.5.2(E) Reagent grade water

(a) Reagent grade water must be free of substances that interfere with the analytical method. Reagent grade water shall not contain a measurable quantity (i.e. no measurable concentration above the ML) of the analytes being determined by the method. (See also Section 23.2.6)

20.5.3 Stock and Working Standards

20.5.3(A) Stock and working standard solutions shall be checked regularly for signs of decomposition and expiration. All solutions shall be labeled with identification of the compound, concentration, date prepared, analyst who prepared the solution, and expiration date.

20.5.3(B) **Standard Preparation Log—** The preparation of stock and working standards shall be maintained in a log book for each area. The preparation method shall be established, and the manufacturer/vendor, lot number (of standard and reagent(s)), stock concentrations, and final concentrations shall be documented. The analyst preparing the standard, date of preparation and date of expiration shall also be documented.

20.5.4 A copy of **Certificates of Analysis** for standards and reagents shall be maintained in the following collection (which is itself, a controlled laboratory document):

20.6 Documentation — Controlled quality documents from this Section shall be maintained separately from the Quality Assurance Manual in the following collection (which is itself, a controlled laboratory document):

20.6.1(A) **QCDOC 013** records (and the majority of laboratory documentation, unless otherwise specified) shall be maintained for at least five (5) years, and may require periodic review.

QC File 00 43— "QCDOC 013: Certificates of Analysis" (in Section 20)

21.0 Technical Requirements: Sampling

21.1 Purpose and Scope— This section defines the sampling requirements for analyses at the Laboratory. Only sampling plans performed by Dolan Chemical Laboratory personnel have been included in this section.

21.1.1 The AEP Dolan Chemical Laboratory group does not provide field-sampling services except on a "special needs" basis (see exceptions listed in Sections 21.3.2, 21.3.3, 21.3.4 and 21.3.5). This section addresses the sampling requirements for various parameters and analytes for reference and guidance.

21.1.1(A) The Industrial Hygiene Analytical Group (IHAG) does not provide field sampling services, without exception. Sampling procedures and requirements are summarized in specific SOPs, where relevant.

(a) The IHAG has no direct control over the sampling procedures used by those submitting samples. As such, the submittal of blanks with samples is the responsibility of the originator of the samples or sample set.

(b) For those procedures where the submittal of blanks (field) is required or satisfies a demonstrated quality control need, the lack of blank submittal will be noted on the reports for that batch of samples.

(c) This process should provide notification to the originator that blanks, in the future, should be collected and submitted with all sample batches of that type.

(d) **This process was implemented as of March 20, 1995.**

21.1.1(B) The Plant Services Analytical Group (PSAG) does not provide field sampling services, without exception. Sampling procedures and requirements may be summarized in specific SOPs, where relevant. The PSAG has no direct control over the sampling procedures used by those submitting samples.

21.1.1(C) The Water and Waste Analytical Group (WWAG) does not typically sampling services, except where noted. Sampling procedures and requirements are summarized in specific SOPs, where relevant. The WWAG has no direct control over the sampling procedures used by those submitting samples.

21.1.2 The laboratory may provide sampling bottles (sampling kits) to its customers upon request.

21.1.3 **Sampling — "**Sampling is a defined procedure whereby a part of a substance, material or product is taken to provide for testing or calibration of a representative sample of the whole. Sampling may also be required by the appropriate specification for which the substance, material or product is to be tested or calibrated. In certain cases, the sample may not be representative but is determined by availability." [per ISO Section 5.7.1, Reference 18.4.9]

21.1.3(A) "Sampling procedures should describe the selection, sampling plan, withdrawal and preparation of a sample or samples from a substance, material or product to yield the required information."

21.1.4 **Sub-sampling — "**Sub-sampling' refers to withdrawing a representative portion of a sample (i.e. an aliquot) for analytical testing.

21.2 Sampling Materials and Procedures

21.2.1 Information regarding sampling materials, sampling containers, preservatives, and shipping instructions shall be available to clients through the Dolan Chemical Laboratory.

21.2.1(A) See **Document 21-01** for more information on sampling containers, preservatives, and holding times for various environmental tests.

Document 21-1"Table II"- Required Containers Preservation Techniques, and Holding Times

(per EPA MUR 05.18.12) (updated)

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provided to assure such changes in sample preservation, containers or holding times do not adversely affect the integrity of the sample. The Regional ATP Coordinator or permitting authority will review the application and then notify the applicant and the appropriate State agency of approval or rejection of the use of the alternate test procedure. A decision to approve or deny any request on deviations from the prescribed Table II requirements will be made within 90 days of receipt of the application by the Regional Administrator. An analyst may not modify any sample preservation and/or holding time requirements of an approved method unless the requirements of this section are met.

TABLE II—REQUIRED CONTAINERS, PRESERVATION TECHNIQUES, AND HOLDING TIMES

Parameter number/name	Container [1]	Preservation [2,3]	Maximum holding time [4]
Table IA—Bacterial Tests:			
1–5. Coliform, total, fecal, and *E. coli*	PA, G	Cool, <10 °C, 0.0008% $Na_2S_2O_3$ [5].	8 hours.[22,23]
6. Fecal streptococci	PA, G	Cool, <10 °C, 0.0008% $Na_2S_2O_3$ [5].	8 hours.[22]
7. Enterococci	PA, G	Cool, <10 °C, 0.0008% $Na_2S_2O_3$ [5].	8 hours.[22]
8. *Salmonella*	PA, G	Cool, <10 °C, 0.0008% $Na_2S_2O_3$ [5].	8 hours.[22]
Table IA—Aquatic Toxicity Tests:			
9–12. Toxicity, acute and chronic	P, FP, G	Cool, ≤6 °C [16]	36 hours.
Table IB—Inorganic Tests:			
1. Acidity	P, FP, G	Cool, ≤6 °C [19]	14 days.
2. Alkalinity	P, FP, G	Cool, ≤6 °C [19]	14 days.
4. Ammonia	P, FP, G	Cool, ≤6 °C [19], H_2SO_4 to pH <2.	28 days.
9. Biochemical oxygen demand	P, FP, G	Cool, ≤6 °C [19]	48 hours.
10. Boron	P, FP, or Quartz	HNO_3 to pH <2	6 months.
11. Bromide	P, FP, G	None required	28 days.
14. Biochemical oxygen demand, carbonaceous	P, FP G	Cool, ≤6 °C [19]	48 hours.
15. Chemical oxygen demand	P, FP, G	Cool, ≤6 °C [19], H_2SO_4 to pH <2.	28 days.
16. Chloride	P, FP, G	None required	28 days.
17. Chlorine, total residual	P, G	None required	Analyze within 15 minutes.
21. Color	P, FP, G	Cool, ≤6 °C [19]	48 hours.
23–24. Cyanide, total or available (or CATC) and free.	P, FP, G	Cool, ≤6 °C [19], NaOH to pH >10 [3,4], reducing agent if oxidizer present.	14 days.
25. Fluoride	P	None required	28 days.
27. Hardness	P, FP, G	HNO_3 or H_2SO_4 to pH <2	6 months.
28. Hydrogen ion (pH)	P, FP, G	None required	Analyze within 15 minutes.
31, 43. Kjeldahl and organic N	P, FP, G	Cool, ≤6 °C [19], H_2SO_4 to pH <2.	28 days.
Table IB—Metals: [7]			
18. Chromium VI	P, FP, G	Cool, ≤6 °C [18], pH = 9.3–9.7 [20].	28 days.
35. Mercury (CVAA)	P, FP, G	HNO_3 to pH <2	28 days.
35. Mercury (CVAFS)	FP, G; and FP-lined cap [17]	5 mL/L 12N HCl or 5 mL/L BrCl [17].	90 days.[17]
3, 5–8, 12, 13, 19, 20, 22, 26, 29, 30, 32–34, 36, 37, 45, 47, 51, 52, 58–60, 62, 63, 70–72, 74, 75. Metals, except boron, chromium VI, and mercury.	P, FP, G	HNO_3 to pH <2, or at least 24 hours prior to analysis [19].	6 months.
38. Nitrate	P, FP, G	Cool, ≤6 °C [19]	48 hours.
39. Nitrate-nitrite	P, FP, G	Cool, ≤6 °C [18], H_2SO_4 to pH <2.	28 days.
40. Nitrite	P, FP, G	Cool, ≤6 °C [19]	48 hours.
41. Oil and grease	G	Cool to ≤6 °C [18], HCl or H_2SO_4 to pH <2.	28 days.
42. Organic Carbon	P, FP, G	Cool to ≤6 °C [18], HCl, H_2SO_4, or H_3PO_4 to pH <2.	28 days.
44. Orthophosphate	P, FP, G	Cool, to ≤6 °C [18,24]	Filter within 15 minutes; Analyze within 48 hours.
46. Oxygen, Dissolved Probe	G, Bottle and top	None required	Analyze within 15 minutes.
47. Winkler	G, Bottle and top	Fix on site and store in dark.	8 hours.
48. Phenols	G	Cool, ≤6 °C [18], H_2SO_4 to pH <2.	28 days.
49. Phosphorous (elemental)	G	Cool, ≤6 °C [19]	48 hours.
50. Phosphorous, total	P, FP, G	Cool, ≤6 °C [18], H_2SO_4 to pH <2.	28 days.
53. Residue, total	P, FP, G	Cool, ≤6 °C [19]	7 days.
54. Residue, Filterable	P, FP, G	Cool, ≤6 °C [19]	7 days.

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TABLE II—REQUIRED CONTAINERS, PRESERVATION TECHNIQUES, AND HOLDING TIMES—Continued

Parameter number/name	Container[1]	Preservation[2,3]	Maximum holding time[4]
55. Residue, Nonfilterable (TSS)	P, FP, G	Cool, ≤8 °C[18]	7 days.
56. Residue, Settleable	P, FP, G	Cool, ≤8 °C[18]	48 hours.
57. Residue, Volatile	P, FP, G	Cool, ≤8 °C[18]	7 days.
61. Silica	P or Quartz	Cool, ≤8 °C[18]	28 days.
64. Specific conductance	P, FP, G	Cool, ≤8 °C[18]	28 days.
65. Sulfate	P, FP, G	Cool, ≤8 °C[18]	28 days.
66. Sulfide	P, FP, G	Cool, ≤8 °C[18], add zinc acetate plus sodium hydroxide to pH >9.	7 days.
67. Sulfite	P, FP, G	None required	Analyze within 15 minutes.
68. Surfactants	P, FP, G	Cool, ≤8 °C[18]	48 hours.
69. Temperature	P, FP, G	None required	Analyze.
73. Turbidity	P, FP, G	Cool, ≤8 °C[18]	48 hours.
Table IC—Organic Tests:[9]	.		
13, 18–20, 22, 24–28, 34–37, 39–43, 45–47, 56, 76, 104, 105, 108–111, 113. Purgeable Halocarbons.	G, FP-lined septum	Cool, ≤8 °C[18], 0.008% $Na_2S_2O_3$[5].	14 days.
6, 57, 106. Purgeable aromatic hydrocarbons	G, FP-lined septum	Cool, ≤8 °C[18], 0.008% $Na_2S_2O_3$[5], HCl to pH 2[9].	14 days.[9]
3, 4. Acrolein and acrylonitrile	G, FP-lined septum	Cool, ≤8 °C[18], 0.008% $Na_2S_2O_3$, pH to 4–5[10].	14 days.[10]
23, 30, 44, 49, 53, 77, 80, 81, 96, 100, 112. Phenols[11].	G, FP-lined cap	Cool, ≤8 °C[18], 0.008% $Na_2S_2O_3$.	7 days until extraction, 40 days after extraction.
7, 38. Benzidines[11,12]	G, FP-lined cap	Cool, ≤8 °C[18], 0.008% $Na_2S_2O_3$[5].	7 days until extraction.[12]
14, 17, 48, 50–52. Phthalate esters[11]	G, FP-lined cap	Cool, ≤8 °C[18]	7 days until extraction, 40 days after extraction.
82–84. Nitrosamines[11,14]	G, FP-lined cap	Cool, ≤8 °C[18], store in dark, 0.008% $Na_2S_2O_3$[5].	7 days until extraction, 40 days after extraction.
88–94. PCBs[11]	G, FP-lined cap	Cool, ≤8 °C[18]	1 year until extraction, 1 year after extraction.
54, 55, 75, 79. Nitroaromatics and isophorone[11]	G, FP-lined cap	Cool, ≤8 °C[18], store in dark, 0.008% $Na_2S_2O_3$[5].	7 days until extraction, 40 days after extraction.
1, 2, 5, 8–12, 32, 33, 58, 59, 74, 78, 99, 101. Polynuclear aromatic hydrocarbons[11].	G, FP-lined cap	Cool, ≤8 °C[18], store in dark, 0.008% $Na_2S_2O_3$[5].	7 days until extraction, 40 days after extraction.
15, 16, 21, 31, 87. Haloethers[11]	G, FP-lined cap	Cool, ≤8 °C[18], 0.008% $Na_2S_2O_3$[5].	7 days until extraction, 40 days after extraction.
29, 35–37, 63–65, 107. Chlorinated hydrocarbons[11].	G, FP-lined cap	Cool, ≤8 °C[18]	7 days until extraction, 40 days after extraction.
60–62, 66–72, 85, 86, 95–97, 102, 103. CDDs/CDFs[11].	.		
Aqueous Samples: Field and Lab Preservation	G	Cool, ≤8 °C[18], 0.008% $Na_2S_2O_3$[5], pH <9.	1 year.
Solids and Mixed-Phase Samples: Field Preservation.	G	Cool, ≤8 °C[18]	7 days.
Tissue Samples: Field Preservation	G	Cool, ≤8 °C[18]	24 hours.
Solids, Mixed-Phase, and Tissue Samples: Lab Preservation.	G	Freeze, ≤ −10 °C	1 year.
114–118. Alkylated phenols	G	Cool, <6 °C, H_2SO_4 to pH <2.	28 days until extraction, 40 days after extraction.
119. Adsorbable Organic Halides (AOX)	G	Cool, <6 °C, 0.008% $Na_2S_2O_3$ HNO_3 to pH <2.	Hold at least 3 days, but not more than 6 months.
120. Chlorinated Phenolics		Cool, <6 °C, 0.008% $Na_2S_2O_3$ H_2SO_4 to pH <2.	30 days until acetylation, 30 days after acetylation.
Table ID—Pesticides Tests:			
1–70. Pesticides[11]	G, FP-lined cap	Cool, ≤8 °C[18], pH 5–9[15]	7 days until extraction, 40 days after extraction.
Table IE—Radiological Tests:			
1–5. Alpha, beta, and radium	P, FP, G	HNO_3 to pH <2	6 months.
Table IH—Bacterial Tests:			
1. *E. coli*	PA, G	Cool, <10 °C, 0.0008% $Na_2S_2O_3$[5].	8 hours.[22]
2. Enterococci	PA, G	Cool, <10 °C, 0.0008% $Na_2S_2O_3$[5].	8 hours.[22]
Table IH—Protozoan Tests:	.		
8. *Cryptosporidium*	LDPE; field filtration	1–10 °C	96 hours.[21]
9. *Giardia*	LDPE; field filtration	1–10 °C	96 hours.[21]

[1] "P" is for polyethylene; "FP" is fluoropolymer (polytetrafluoroethylene (PTFE); Teflon®), or other fluoropolymer, unless stated otherwise in this Table II; "G" is glass; "PA" is any plastic that is made of a sterilizable material (polypropylene or other autoclavable plastic); "LDPE" is low density polyethylene.

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[2] Except where noted in this Table II and the method for the parameter, preserve each grab sample within 15 minutes of collection. For a composite sample collected with an automated sample (*e.g.*, using a 24-hour composite sampler; see 40 CFR 122.21(g)(7)(i) or 40 CFR Part 403, Appendix E), refrigerate the sample at ≤ 6 °C during collection unless specified otherwise in this Table II or in the method(s). For a composite sample to be split into separate aliquots for preservation and/or analysis, maintain the sample at ≤ 6 °C, unless specified otherwise in this Table II or in the method(s), until collection, splitting, and preservation is completed. Add the preservative to the sample container prior to sample collection when the preservative will not compromise the integrity of a grab sample, a composite sample, or aliquot split from a composite sample within 15 minutes of collection. If a composite measurement is required but a composite sample would compromise sample integrity, individual grab samples must be collected at prescribed time intervals (*e.g.*, 4 samples over the course of a day, at 6-hour intervals). Grab samples must be analyzed separately and the concentrations averaged. Alternatively, grab samples may be collected in the field and composited in the laboratory if the compositing procedure produces results equivalent to results produced by arithmetic averaging of results of analysis of individual grab samples. For examples of laboratory compositing procedures, see EPA Method 1664 Rev. A (oil and grease) and the procedures at 40 CFR 141.34(f)(14)(iv) and (v) (volatile organics).

[3] When any sample is to be shipped by common carrier or sent via the U.S. Postal Service, it must comply with the Department of Transportation Hazardous Materials Regulations (49 CFR part 172). The person offering such material for transportation is responsible for ensuring such compliance. For the preservation requirement of Table II, the Office of Hazardous Materials, Materials Transportation Bureau, Department of Transportation has determined that the Hazardous Materials Regulations do not apply to the following materials: Hydrochloric acid (HCl) in water solutions at concentrations of 0.04% by weight or less (pH about 1.96 or greater; Nitric acid (HNO_3) in water solutions at concentrations of 0.15% by weight or less (pH about 1.62 or greater); Sulfuric acid (H_2SO_4) in water solutions at concentrations of 0.35% by weight or less (pH about 1.15 or greater); and Sodium hydroxide (NaOH) in water solutions at concentrations of 0.080% by weight or less (pH about 12.30 or less).

[4] Samples should be analyzed as soon as possible after collection. The times listed are the maximum times that samples may be held before the start of analysis and still be considered valid. Samples may be held for longer periods only if the permittee or monitoring laboratory has data on file to show that, for the specific types of samples under study, the analytes are stable for the longer time, and has received a variance from the Regional Administrator under Sec. 136.3(e). For a grab sample, the holding time begins at the time of collection. For a composite sample collected with an automated sampler (*e.g.*, using a 24-hour composite sampler; see 40 CFR 122.21(g)(7)(i) or 40 CFR part 403, Appendix E), the holding time begins at the time of the end of collection of the composite sample. For a set of grab samples composited in the field or laboratory, the holding time begins at the time of collection of the last grab sample in the set. Some samples may not be stable for the maximum time period given in the table. A permittee or monitoring laboratory is obligated to hold the sample for a shorter time if it knows that a shorter time is necessary to maintain sample stability. See 136.3(e) for details. The date and time of collection of an individual grab sample is the date and time at which the sample is collected. For a set of grab samples to be composited, and that are all collected on the same calendar date, the date of collection is the date on which the samples are collected. For a set of grab samples to be composited, and that are collected across two calendar dates, the date of collection is the dates of the two days; *e.g.*, November 14–15. For a composite sample collected automatically on a given date, the date of collection is the date on which the sample is collected. For a composite sample collected automatically, and that is collected across two calendar dates, the date of collection is the dates of the two days; *e.g.*, November 14–15. For static-renewal toxicity tests, each grab or composite sample may also be used to prepare test solutions for renewal at 24 h, 48 h, and/or 72 h after first use, if stored at 0–6 °C, with minimum head space.

[5] ASTM D7365–09a specifies treatment options for samples containing oxidants (*e.g.*, chlorine). Also, Section 9060A of Standard Methods for the Examination of Water and Wastewater (20th and 21st editions) addresses dechlorination procedures.

[6] Sampling, preservation and mitigating interferences in water samples for analysis of cyanide are described in ASTM D7365–09a. There may be interferences that are not mitigated by the analytical test methods or D7365–09a. Any technique for removal or suppression of interference may be employed, provided the laboratory demonstrates that it more accurately measures cyanide through quality control measures described in the analytical test method. Any removal or suppression technique not described in D7365–09a or the analytical test method must be documented along with supporting data.

[7] For dissolved metals, filter grab samples within 15 minutes of collection and before adding preservatives. For a composite sample collected with an automated sampler (*e.g.*, using a 24-hour composite sampler; see 40 CFR 122.21(g)(7)(i) or 40 CFR Part 403, Appendix E), filter the sample within 15 minutes after completion of collection and before adding preservatives. If it is known or suspected that dissolved sample integrity will be compromised during collection of a composite sample collected automatically over time (*e.g.*, by interchange of a metal between dissolved and suspended forms), collect and filter grab samples to be composited (footnote 2) in place of a composite sample collected automatically.

[8] Guidance applies to samples to be analyzed by GC, LC, or GC/MS for specific compounds.

[9] If the sample is not adjusted to pH 2, then the sample must be analyzed within seven days of sampling.

[10] The pH adjustment is not required if acrolein will not be measured. Samples for acrolein receiving no pH adjustment must be analyzed within 3 days of sampling.

[11] When the extractable analytes of concern fall within a single chemical category, the specified preservative and maximum holding times should be observed for optimum safeguard of sample integrity (*i.e.*, use all necessary preservatives and hold for the shortest time listed). When the analytes of concern fall within two or more chemical categories, the sample may be preserved by cooling to ≤ 6 °C, reducing residual chlorine with 0.008% sodium thiosulfate, storing in the dark, and adjusting the pH to 6–9; samples preserved in this manner may be held for seven days before extraction and for forty days after extraction. Exceptions to this optional preservation and holding time procedure are noted in footnote 5 (regarding the requirement for thiosulfate reduction), and footnotes 12, 13 (regarding the analysis of benzidine).

[12] If 1,2-diphenylhydrazine is likely to be present, adjust the pH of the sample to 4.0 ± 0.2 to prevent rearrangement to benzidine.

[13] Extracts may be stored up to 30 days at < 0 °C.

[14] For the analysis of diphenylnitrosamine, add 0.008% $Na_2S_2O_3$ and adjust pH to 7–10 with NaOH within 24 hours of sampling.

[15] The pH adjustment may be performed upon receipt at the laboratory and may be omitted if the samples are extracted within 72 hours of collection. For the analysis of aldrin, add 0.008% $Na_2S_2O_3$.

[16] Place sufficient ice with the samples in the shipping container to ensure that ice is still present when the samples arrive at the laboratory. However, even if ice is present when the samples arrive, immediately measure the temperature of the samples and confirm that the preservation temperature maximum has not been exceeded. In the isolated cases where it can be documented that this holding temperature cannot be met, the permittee can be given the option of on-site testing or can request a variance. The request for a variance should include supportive data which show that the toxicity of the effluent samples is not reduced because of the increased holding temperature. Aqueous samples must not be frozen. Hand-delivered samples used on the day of collection do not need to be cooled to 0 to 6 °C prior to test initiation.

[17] Samples collected for the determination of trace level mercury (<100 ng/L) using EPA Method 1631 must be collected in tightly-capped fluoropolymer or glass bottles and preserved with BrCl or HCl solution within 48 hours of sample collection. The time to preservation may be extended to 28 days if a sample is oxidized in the sample bottle. A sample collected for dissolved trace level mercury should be filtered in the laboratory within 24 hours of the time of collection. However, if circumstances preclude overnight shipment, the sample should be filtered in a designated clean area in the field in accordance with procedures given in Method 1669. If sample integrity will not be maintained by shipment to and filtration in the laboratory, the sample must be filtered in a designated clean area in the field within the time period necessary to maintain sample integrity. A sample that has been collected for determination of total or dissolved trace level mercury must be analyzed within 90 days of sample collection.

[18] Aqueous samples must be preserved at ≤ 6 °C, and should not be frozen unless data demonstrating that sample freezing does not adversely impact sample integrity is maintained on file and accepted as valid by the regulatory authority. Also, for purposes of NPDES monitoring, the specification of "≤ °C" is used in place of the "4 °C" and "< 4 °C" sample temperature requirements listed in some methods. It is not necessary to measure the sample temperature to three significant figures (1/100th of 1 degree); rather, three significant figures are specified so that rounding down to 6 °C may not be used to meet the ≤6 °C requirement. The preservation temperature does not apply to samples that are analyzed immediately (less than 15 minutes).

Document 21-01"Table II"- Required Containers Preservation Techniques, and Holding Times (per EPA MUR 05.18.12) (updated) (Page 4 of 4) <<Click on first page of object to access full document>>

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[19] An aqueous sample may be collected and shipped without acid preservation. However, acid must be added at least 24 hours before analysis to dissolve any metals that adsorb to the container walls. If the sample must be analyzed within 24 hours of collection, add the acid immediately (see footnote 2). Soil and sediment samples do not need to be preserved with acid. The allowances in this footnote supersede the preservation and holding time requirements in the approved metals methods.

[20] To achieve the 28-day holding time, use the ammonium sulfate buffer solution specified in EPA Method 218.6. The allowance in this footnote supersedes preservation and holding time requirements in the approved hexavalent chromium methods, unless this supersession would compromise the measurement, in which case requirements in the method must be followed.

[21] Holding time is calculated from time of sample collection to elution for samples shipped to the laboratory in bulk and calculated from the time of sample filtration to elution for samples filtered in the field.

[22] Sample analysis should begin as soon as possible after receipt; sample incubation must be started no later than 8 hours from time of collection.

[23] For fecal coliform samples for sewage sludge (biosolids) only, the holding time is extended to 24 hours for the following sample types using either EPA Method 1680 (LTB–EC) or 1681 (A–1): Class A composted, Class B aerobically digested, and Class B anaerobically digested.

[24] The immediate filtration requirement in orthophosphate measurement is to assess the dissolved or bio-available form of orthophosphorus (i.e., that which passes through a 0.45-micron filter), hence the requirement to filter the sample immediately upon collection (i.e., within 15 minutes of collection).

21.2.2 Sampling Containers, Preservatives and Holding Times

21.2.2(A) The sampling container types, preservation techniques and holding times for environmental parameters analyzed by the laboratory are summarized in Document 21-01. This table, in which P, G and FP denote plastic, glass and fluoropolymer containers respectively, is adapted from federal protocols.

(a) Protocol for treatment of temperature-preserved samples (customer responsibility): All samples, solid/liquid, shall be packed on ice for reducing temperature to ≤ 6º C (without freezing).

(b) Sample packing – Environmental samples are segregated according to sample location. Packed in individual shipping containers for transportation. All sampling containers are packed in the upright position with ice around each container. The shipping container should be a "waterproof, metal or plastic ice chest or cooler".

21.2.3 Sampling Container — All sampling containers are commercially purchased and are new containers. The main sources for all bottles are:

21.2.3(A) Fisher Scientific
21.2.3(B) VWR Scientific Products

21.2.4 Types of Bottles — Various sizes of bottles are utilized and examples of the types of bottles routinely utilized include:

21.2.4(A) Plastic bottles—1000 mL, 500 mL, 250 mL, 125 mL;
21.2.4(B) Amber glass bottles with Teflon-lined caps— 1000 mL, 250 mL, 125 mL;
21.2.4(C) Glass jars with Teflon-lined caps— 1000 mL, 500 mL, 250 mL.

21.2.5 Reuse of Bottles and Bottle Cleaning

21.2.5(A) Sample bottles are not to be reused.

21.2.6 Pre-preserved Bottles

21.2.6(A) The Dolan Chemical Laboratory group encourages its customers to preserve their samples in the field following EPA's instructions and/or their field sampling QA Plans. However, if the customer requests, the laboratory will add preservatives to the bottles before shipment. Metals are preserved upon receipt of samples back in the laboratory upon customer request.

21.2.7 Shipment of Bottles (Sampling Kits)

21.2.7(A) Instructions are prepared for the chemists responsible for assembling the sampling kit each time a request is made. Sample kits are prepared in accordance with a sample checklist for most sample bottle orders.

21.2.7(B) Bottles are marked for specific analyses and are packed into containers. When a kit preparation is completed for shipping, the analyst checks the containers to ensure that all bottles requested are included and properly labeled (if requested).

21.2.8 When any sample is to be shipped by common carrier or sent through the United States Mail, it must comply with the Department of Transportation Hazardous Material Regulations (49 CFR Part 172). The person offering such material for transportation is responsible for ensuring such compliance.

21.2.9 Where appropriate, the Dolan Chemical Laboratory shall request that the clients submit field blanks and field duplicates with their samples.

21.3 Sampling Plans

21.3.1 Method of Collection

21.3.1(A) Grab – A grab sample is an individual sample collected over a period of time not exceeding fifteen (15) minutes.

21.3.1(B) Discrete Sample – (manual or electronic) individual grabs of equal portions at set time intervals.

21.3.1(C) Flow Composite – (electronic) individual grabs, varying portions regulated by the flow, composited as collected.

21.3.1(D) Time Composite – (electronic) individual grabs at set times, equal portions and composited at time of collection.

Note: No sampling plans are available from the Dolan Chemical Laboratory that pertain to the location where the sampling was undertaken.

21.3.2 Low Level Mercury Sampling – EPA 1669 (Reserved)

21.3.3 Landfill Monitoring Well Sampling (Reserved)

21.3.4 Flue Gas Sampling (and Analyses) (Removed 04/2008)

21.3.5 Special Cases Sampling (Reserved)

21.4 Documentation — Controlled quality documents from this Section shall be maintained separately from the Quality Assurance Manual in the following collection (which is itself, a controlled laboratory document):

21.4.1(A) **QCDOC 014** records (and the majority of laboratory documentation, unless otherwise specified) shall be maintained for at least five (5) years, and may require periodic review.

QC File 00 44— "QCDOC 014: Sample Information " (in Section 21)

22.0 Technical Requirements: Handling of Test Items

22.1 Purpose and Scope — This section describes the sample handling procedures of the Laboratory and outlines the duties and responsibilities with respect to shipping, packaging, and handling and storage of samples.

22.1.1 This section provides guidance in making decisions pertinent to the validity and acceptability of samples submitted for testing or analysis. While it is particularly appropriate to samples submitted to the Laboratory for chemical analysis, its principles apply broadly to all types of samples. The goal is the preservation of the integrity of the sample. It is applicable to all in-house and contract laboratory activities dealing with the handling of samples.

22.1.2 This section details the custody procedures utilized when handling samples. It also describes the procedures to be followed when strict chain-of-custody protocols for samples received by the Laboratory must be followed. The custody of a sample is defined as one of the following:

22.1.2(A) It is in the sampler's or transferee's actual possession;
22.1.2(B) It is in the sampler's or transferee's view, after being in his/her physical possession;
22.1.2(C) It was in the sampler's or transferee's physical possession and then he/she secured it or placed in a designated secure area to prevent tampering.

22.1.3 This section describes general sample handling and shipping information and the sample receipt, login, and storage procedures.

22.1.4 Lastly, this section provides sample retention and disposal guidelines for the various analytical groups within the Dolan Chemical Laboratory.

22.2 Sample Submittal Procedures

Note: The original sample submittal procedures for the Dolan Chemical Laboratory were located in "Subpart O" (last revised March 20, 1990) of a previous revision of the QAM (Revision 5 and earlier). That procedure was then superseded by "Subpart M— Listing of Analytical Services" (issued May 1997) also from QAM Revision 5 or earlier. "Subpart M" is also contained in the Lotus Notes database "EVL Sample Submittal Requests". The following is an adaptation of these procedures.

22.2.1 Instructions for Submitting Samples to Dolan Chemical Laboratory —These instructions are for use by anyone who requests the analytical services of the Dolan Chemical Laboratory in Groveport, OH. The Dolan Chemical Laboratory has a broad range of analytical services which it provides for the AEP System. Most of these services are listed in the pages that follow. The list has been compiled so that you will know what the Dolan Chemical Laboratory can do, and so that you can properly identify the analytical services which need to be performed. When requesting the analytical services offered, several steps must be followed to ensure that samples are handled in a proper and efficient manner.

22.2.1(A) **Laboratory Analysis Request Forms**

(a) The forms in **Section 22.3** are for use by anyone within the AEP System who needs to request the analytical services of the AEP Dolan Chemical Laboratory and does not have "ready" access to the Lotus Notes' based "EVL - Sample Submittal Database".

22.2.1(B) **Sample Information**

(a) The most critical aspect of providing analytical services is having the knowledge of exactly what the customer needs and requires. The Dolan Chemical Laboratory uses an Analysis Request Form or Chain of Custody as the primary vehicle for this information transfer. This form should accompany all samples submitted to the laboratory.

(b) Alternatives to the Analysis Request Form will, however, be acceptable. These alternatives may be a phone call, a formal letter of transmittal, an e-mail letter or other forms specific to individual programs and/or sample types (ENV-01 for insulating oils, for example). Phone calls must be properly documented per **Section 7.2**.

(c) It should be noted, however, that whatever the mode of information transmittal, the object is to provide the laboratory with sufficient information to do its job properly. The laboratory needs sufficient information so that the customer understands what the laboratory did, what the sample was and what were the results when viewing the analytical report.

(d) In addition, if a professional opinion concerning the results is desired, then sufficient information must be provided to generate informed advice.

22.2.1(C) **Problem Definition**

(a) If the problem can be defined, or at least the symptoms described, then the laboratory may be able to help by suggesting analyses that should be performed. The problem may be as simple as the need for a routine check of turbine oil quality. However, for a complex problem, a proper and complete definition and description will ensure a more efficient and focused analytical approach.

22.2.1(D) **Sample Description**

(a) Proper identification of time and location of sampling, appearance, environmental conditions, sample orientation, flow direction (for tubes and pipes), unusual conditions prior to sampling, and other factors may not seem important at the time of sampling. However, all of these factors can be extremely important to the analyst in arriving at a conclusion based on the results of the analysis. If these factors are not described before or during sampling, then they may be difficult to recall later.

22.2.1(E) **Sample Identification**

(a) Tags, labels, or legible markings need to be affixed to the sample.

(b) Proper sample submittal forms should be completed and copies of the forms should be enclosed with the sample. Proper identification is important. Be certain to include your name, your location, your telephone number, your fax number (optional), and your email address.

22.2.1(F) **Sample Shipment**

(a) Physical damage to the sample container may be the fault of the carrier due to careless handling or may be the fault of the sender because of faulty packaging. If damage to the container is evident and such damage invalidates the reason or purpose for the analysis, the sender shall be notified and the invalid sample discarded.

(b) Proper packaging to protect the sample in shipment is necessary.

(c) Proper preservation may be needed to ensure that the sample remains as it was when collected.

(d) If there are questions concerning packaging, preservation and/or shipment, contact the Dolan Chemical Laboratory.

(e) An analysis is only as good as the sample. Damaged or altered samples can lead to false conclusions.

22.2.1(G) **Sample Turnaround**

(a) Please indicate a calendar date to communicate to the laboratory your desired turnaround time. The use of ASAP or "As Soon As Possible" is ambiguous and is strongly discouraged. The due date that is requested should be a reasonable estimate of when the data is needed and will be used.

(b) Turnaround time for normal samples begins upon sample receipt. Rush service turnaround varies with the type of analysis required. Advance communication with the laboratory is recommended. Results will be faxed or sent electronically by email. A hard copy report will only be provided upon request.

(c) Turnaround times vary depending upon sample load and analysis complexity. The Dolan Chemical Laboratory must set priorities due to its workload. The due date for an analysis should reflect the customers need for the results. However, it may be that the laboratory cannot perform the required analyses in time. This is especially true for large numbers of samples and for types of analyses with which the laboratory is not immediately familiar. Communication is important; advance notification may be required.

22.2.2 Laboratory Information (Last Revised 01/11/08)

22.2.2(A) Mailing Address

AEP, Dolan Chemical Laboratory
John E. Dolan Engineering Laboratory
4001 Bixby Road
Groveport, Ohio 43125

22.2.2(B) Shipping Address:

AEP, Dolan Chemical Laboratory
John E. Dolan Engineering Laboratory
4001 Bixby Road
Groveport, Ohio 43125

22.2.2(C) Laboratory Manager: Daniel G. Adkinson
Ext. (614) 836-4222, Aud. 210-4222

22.2.2(D) Secretary: Mary Grimm
Ext. (614) 836-4221, Aud. 210-4221

22.2.2(E) Laboratory Phone: (614) 836-4211, Aud. 210-4211

22.2.2(F) Laboratory Fax: (614) 836-4168, Aud. 210-4168

22.3 Sample Custody Forms and Procedures

22.3.1 Routine Sample Custody

22.3.1(A) It is primarily the responsibility of the originator of a sample or sample set to determine the type of chain-of-custody documentation required and to send the proper documentation with the sample(s). The Dolan Chemical Laboratory will process all chain-of-custody documentation received with samples, but will not assume responsibility for chain-of-custody information that was submitted improperly or not at all. When the Dolan Chemical Laboratory has been informed that strict chain-of-custody procedures must be followed for certain particular samples, the analytical reports will note the occurrence of the improper chain-of-custody procedures.

22.3.1(B) Formal chain-of-custody documents exist for NPDES water samples (Chain-of-Custody Record and Analysis Request Form, Form COC-2) and for Industrial Hygiene samples (AEP Air Sampling Worksheet, Form (IHI-I99). The COC-2 form is frequently received with water samples which require chain-of-custody documentation and with most solid source sampling monitoring programs where official chain-of-custody information is required. The AEP Air Sampling Worksheet is frequently received with IH samples originating from other sources within the company.

22.3.1(C) Substitutes are acceptable, but may not be preferred. However, in all cases, information must be sufficient to ensure the identity, integrity and validity of each sample.

22.3.1(D) Field personnel, utilizing procedures identified within their field QA Plans, collect samples. After collection, the samples are shipped to the laboratory by common carrier or are hand-delivered by field staff.

(a) Collectors are encouraged to include complete the chain-of-custody. At a minimum the following information is requested:

(i) a unique sample location/field ID combination.,
(ii) date and time of sample collection,
(iii) the collector's name,
(iv) the submitting group,
(v) the sample matrix,
(vi) sample preservatives,
(vii) the analysis requested

(b) If the chain of custody does not contain required information, or if the sample container is damaged, adulterated or mislabeled, telephone or email contact with the customer will be attempted. Verbal instructions or directions from the customer shall be documented.

(c) If the information cannot be obtained, the sample is subject to rejection. (See Section 22.5.2 and the Sample Receipt SOP for the Acceptance or Rejection of samples during sample log-in.)

(d) Proceed with sample check-in procedures as detailed in Section 22.5.

22.3.2 Inter-laboratory Custody

22.3.2(A) Inter-laboratory Custody shall also be created in necessary instances. Samples that are sent to an overflow contract laboratory (per **Section 5.0, Subcontracting**) will show transfer to that contract lab in the custody record. A new COC will document the date/time it was sent out and the identity of the custodian responsible. The laboratory staff responsible for delivery and the recipient at the contract lab must sign the chain of custody form.

22.3.2(B) The accountability record portion of each form, although not expressly delineated in each form, constitutes and establishes a record of possession of the sample while it is being processed in the Dolan Chemical Laboratory. It is to be completed by the primary chemist or analyst to whom the sample has been assigned.

22.3.3 Archived **Chain of Custody** records are maintained with other laboratory-generated documents and records in **QCDOC 006: Control of Records**:

QC File 00 45— "QCDOC 006: Control of Records " (in Section 22)

22.4 Sample Handling and Shipping

Note: For incoming PURCHASES see **Section 6.3**.

22.4.1 Incoming Sample Receipt- Samples may be transported to the Dolan Chemical Laboratory by one of four possible modes. These modes are as follows:

22.4.1(A) "PONY"— This is the American Electric Power intra-system mail and parcel carrier. Samples may be delivered from any location on the AEP System to the Dolan Chemical Laboratory. These deliveries are coordinated and managed by the Workplace Services of AEP, located at 1 Riverside Plaza, Columbus, Ohio.

(a) Delivery by van/station wagon/car to the Dolan Chemical Laboratory occurs once daily on Monday Wednesday and Friday at approximately 3:50 PM and twice daily on Tuesday and Thursday at approximately 1:25 PM and 3:20 PM. (Effective 10/18/2010)

(b) No deliveries are made Saturday or Sunday or after the normal business hours of 7:00 AM to 5:00 PM. All deliveries by PONY are received through the Shipping and Receiving Room (Room 225) of the Dolan Chemical Laboratory.

22.4.1(B) UPS or other common carrier - Normal Delivery — These deliveries are directed to the Shipping and Receiving Room (Room 225) and the packages are delivered to the Workplace Services laboratory representative, who signs for their receipt. The appropriate Dolan Chemical Laboratory personnel are then alerted of the arrival. For UPS, this delivery occurs at approximately 10:00 AM and includes any express or overnight packages handled by their system. The packages are placed on a designated shelf in the Shipping and Receiving Room until they are opened by the responsible Dolan Chemical Laboratory personnel and the samples are checked-in.

22.4.1(C) Express Carriers — These deliveries are directed to either the Shipping and Receiving Room (Room 225) or to the Workplace Services laboratory representative at the main entrance of the John E. Dolan Engineering Laboratory. The deliveries to the Shipping and Receiving Room are received by the Workplace Services laboratory representative, who signs for their receipt. The appropriate Dolan Chemical Laboratory personnel are then alerted of the arrival. The packages are placed on a designated shelf in the Shipping and Receiving Room until they are opened by the responsible Dolan Chemical Laboratory personnel and the samples are checked-in.

(a) The deliveries to the main entrance are noted by the Workplace Services laboratory representative in the delivery log along with the required signature of the transport driver. The Dolan Chemical Laboratory is then notified of the delivery. The package(s) is picked-up by the responsible Dolan Chemical Laboratory personnel and delivered to the Shipping and Receiving Room to be opened and the sample(s) checked-in.

22.4.1(D) Custom Deliveries — Custom deliveries to the Dolan Chemical Laboratory occur in many manners. These deliveries may be by AEP personnel or by people unaffiliated with AEP. In general, these deliveries occur through the general processes established with the express delivery companies. An exception is the delivery of samples by the affiliated personnel. This type of delivery does not require the use of a log or the collection of the transport personnel's signature. The responsible Laboratory personnel are, in general, contacted by the Workplace Services laboratory representative, informing them of the presence of company personnel in the lobby. The laboratory personnel are then responsible for the pickup of the sample(s) and their delivery to the Shipping and Receiving Room for check-in.

(a) In addition, situations may occur where the Workplace Services laboratory representative is not available at the lobby desk during non-business hour deliveries. In these situations, the inner doors to the lobby remain locked. However, the west-most entry door to the inner vestibule is unlocked and a cart is available for the placement of samples and associated information. Upon return of the Workplace Services laboratory representative, the samples are removed to the main lobby area and held until the next scheduled arrival of Dolan Chemical Laboratory personnel.

22.4.2 Laboratory Security

22.4.2(A) The Dolan Chemical Laboratory believes that the entire laboratory is a secure area, and that all samples received by the laboratory should be considered in the custody of the appropriate laboratory personnel until the time of their disposal.

22.4.3 Physical Condition of the Sample Container

22.4.3(A) Physical damage to the sample container may be the fault of the carrier due to careless handling or may be the fault of the sender because of faulty packaging. If damage to the container is evident, the package should be carefully opened and its contents inspected. In case of damage to the sample that invalidates the reason or purpose for the analysis, the sender shall be notified by the primary analyst or designated substitute of the specific sample analysis type and the invalid sample discarded.

22.4.3(B) Where contract laboratory samples are involved, it will be the responsibility of the QAO* (or designee) to notify the contractor concerning any suspect samples. The QAO* (or designee) will then contact the sender and make any necessary decision regarding sample disposition.

22.4.3(C) In general, reasonable attempts to insure a valid sample should be made. If the damage is too severe, the sample must be invalidated and discarded, when appropriate.

22.4.4 Sample Integrity

22.4.4(A) Sample integrity refers to the cumulative result of those factors that contribute to the validity of a sample. Sample integrity is promoted and preserved by adhering to adequate custodial, handling and identification procedures by those individuals collecting the samples up to the point of receipt of samples by the laboratory. When the samples are received for testing or analysis, they are checked for:

(a) Physical damage to samples because of inadequate packing and protection,

(b) Loss of sample because of inadequate or improper sealing. This includes leakage of liquids from vials, loss of particulate material from filters or containers, inadequate sealing of solid sorbent sampling tubes, etc.

(c) Contamination of samples due to inadequate separation of sample types or bulk sampling materials. An example is collected airborne vapor samples shipped in the same container with bulk liquid organics.

(d) Improper use of special shipping procedures designed to preserve the samples at temperatures other than ambient. This applies to those samples which must be shipped cold, possibly by express carrier.

22.4.4(B) Most violations will result in the need to determine the loss of integrity and a decision regarding the disposition of the sample. This decision should be the joint responsibility of the primary chemist, in consultation with the Plant or sampling personnel, laboratory management and the QAO* (or designee).

22.4.4(C) All occurrences of improper shipping procedures should be noted in the LIMS Complaints Management Section by the receiving personnel. These departures from procedure may then be addressed by the QAO* (or designee) as nonconformances to establish their frequency and severity. This information may then be used to establish the proper corrective action.

22.4.4(D) If any of the above situations occur, but do not invalidate the sample(s), the analyses should be performed. However, the fact of their possible invalidation should be noted in the final report.

22.4.5 Reshipment of Samples

22.4.5(A) If a sample must be shipped to another location, the following instructions must be followed:

(a) Check the method to determine if packing and shipping instructions are included. If so, follow the instructions given.

(b) Divide samples into appropriate and compatible shipping groups. Liquids should be kept separate from other materials.

(c) Select appropriate shipping containers and packing material.

(d) Make sure that the samples are properly and accurately identified and that all necessary paperwork accompanies the shipping.

22.4.6 Sample Identification

22.4.6(A) A basic requirement of sample integrity is accurate sample identification. Samples that cannot be related to an associated AEP Dolan Chemical Laboratory Analysis Request Forms (from **Section 22.3**) because of inadequate, ambiguous, or nonexistent labeling, will be held until the requester is able to provide adequate identification. Under these circumstances, where sample identification is not obvious, Dolan Chemical Laboratory personnel should make a special effort to identify and correlate unidentified samples. If, after a reasonable effort, no additional information can be obtained and the requester and/or location remain unidentified, then the sample(s) shall be discarded, if appropriate.

22.4.7 AEP Dolan Chemical Laboratory Analysis Request Form

22.4.7(A) The primary means by which sample information is received by the Dolan Chemical Laboratory is with the AEP Dolan Chemical Laboratory Analysis Request Form, (See **Section 22.3**). This form, when completed, supplies to the laboratory the information necessary to proceed with a complete analysis specific to the reason for the analysis request. However, given the variability of the types of samples received and their varying information requirements, some samples may not require the submittal of the Analysis Request Form.

(a) An acceptable alternative to the AEP Dolan Chemical Laboratory Analysis Request Form is sample information submittal via a computerized Lotus Notes-based Sample Submittal Request database. This alternative is essentially a computerized version of the Analysis Request Form that electronically submits the sample information to the Dolan Chemical Laboratory while at the same time providing the sample submitter the option of a hard-copy version of the request for shipping and/or filing and a receipted acknowledgement from the Dolan Chemical Laboratory that the information has been received. The Sample Submittal Request database is available to all AEP System personnel with access to Lotus Notes. Substitutes are acceptable, but may not be preferred. Letters-of-transmittal, personal notes and direct telephone communication (followed by a hardcopy or email, and documented per **Section 7.2**.) may be sufficient for certain samples. However, the information must be sufficient to ensure the identity, integrity and validity of each sample.

(b) In general, the information must be sufficient to ensure a proper completion of an Analysis Request Form. The information is then input into the Dolan Chemical Laboratory's computerized Laboratory Information Management System (LIMS) (See Section 1.4.3(B) for background information on the LIMS). This system is used for management data collection, sample tracking and work assignments.

22.4.7(B) The Analysis Request Form should be as complete as needed to adequately identify the sample(s) and to design the proper analysis to address the reason for the sample collection. Communication between the primary/analyst and the person who submitted the sample and/or requested the analysis is critical. If insufficient information about a sample is received, then an inadequate or incorrect analysis report may result.

22.4.7(C) Several types of analysis requests use substitute forms in lieu of the Analysis Request Form. The forms are for specific sample types and relate to information specific to the sample type. See the QAO* for additional forms.

22.4.7(D) Corrections and/or changes made to chain of custody or analysis request forms must be initialed and dated by the laboratory personnel and an explanation should be included, if necessary.

22.5 Sample Receipt, Log-in, and Storage — For a full description of Sample Receipt (i.e. sample custodians, sample acceptance/rejection policy, sample preparation and receipt checks, sample log-in, sample tracking sheets, and sample handling), refer to the Dolan Chemical Laboratory's Sample Receipt SOPs.

22.5.1 Sample Custodians'

22.5.1(A) Upon their receipt at the laboratory, sample custodians are responsible to prepare and check samples according to standard laboratory protocol (Section 22.5.3). Furthermore, upon receipt, all samples shall be logged into the LIMS (Section 22.5.4) with the corresponding information— including additional observations, notable nonconformances, and/or client communications.

22.5.1(B) Before any samples from a new client or samples for an analysis that has not previously been performed in the laboratory may be accepted, the work must be reviewed (per Section 4.2) to ensure that the laboratory is capable of meeting the customer's expectations.

22.5.2 Sample Acceptance /Rejection Policy — Evaluate the analyses requested per **Section 4.0.** Upon evaluation of the capabilities of the laboratory, it may be necessary to subcontract the analyses of certain test items per **Section 5.0**

22.5.3 Sample Preparation and Receipt Checks

22.5.3(A) **Temperature Preservation Check—** At the time of receipt, custodians check and document the temperature of each bottle using an infrared thermometer.

22.5.3(B) **Sample Preservation Check—** The pH of all water samples are checked and documented by the sample custodian prior to sample log-in.

(a) As the Dolan Chemical Laboratory is not responsible for the actual sampling protocol or operation (except as noted in Section 21.3), the responsibility for proper preservation of the sample falls to the people who collect the sample. These people are primarily AEP employees at the power generation or transmission/distribution facilities.

(b) Guidelines for the proper collection and preservation of samples are issued for most projects and for each type of analysis/ sample. These guidelines are the joint responsibility of the Dolan Chemical Laboratory, the Environmental Services Department of AEP, the Safety and Health Sections of AEP, the power generation or transmission/distribution personnel and the Fossil and Hydro Generation Department of AEP.

(c) The EPA-recommended preservation techniques for water and wastewater samples and for concentrated waste samples are listed in the previous Section, **Document 21-01**. The Dolan Chemical Laboratory implicitly follows all recommendations as established by the EPA and as listed in these figures. This includes requiring more than the minimum sampling volumes and meeting all holding time requirements. (see **Section 21.2**)

22.5.3(C) **Sample Integrity Check—** Sample integrity such as leaking, broken, or improper bottles or improper preservation, etc., are noted on the COC or in the appropriate field in the LIMS.

22.5.3(D) **Sample Holding Times—** The Dolan Chemical Laboratory uses as its established holding times for the analysis of all water and wastewater samples and concentrated waste samples those requirements as established by the EPA and listed in **Document 21-01** (see **Section 21.2**).

22.5.4 Sample Log-in— The samples are then logged into the LIMS (See Section 1.4.3(B) for background information on the LIMS) for a permanent record with all the information listed above, especially identifying information as required in Section 22.3.1(D)(a).

22.5.4(A) Laboratory Information Management System (LIMS) Information

(a) The LIMS is the primary sample tracking and information management tool used by the Dolan Chemical Laboratory. The current LIMS is Aspen, Version 7.5, from Telecation, Inc. (2008).

(b) The LIMS provides for the computerized entry of the Sample ID, the Submitter, the Collect Date, the Collect Time, and the Collected By identification, along with other relevant information, such as the due date and the analyses requested. This information is then automatically linked to the Lab Analysis Number assigned to each sample.

(c) The LIMS may also be used to automatically prepare labels for uniquely identifying each sample with the appropriate sample number. It may be sufficient to mark the sample container itself with a permanent marker if sufficient space for a label is not available on the container.

22.5.4(B) Sample Laboratory Identification— The Laboratory Information Management System (LIMS) generates a unique record for each sample received for analysis by the Dolan Chemical Laboratory. (This computer data base is an essential part of the Dolan Chemical Laboratory sample tracking system and is also used to generate weekly, monthly and annual administrative reports.)

(a) Although the LIMS will allow numbers to be deleted, it is the policy of the Dolan Chemical Laboratory not to delete such numbers. Erroneous entries are marked appropriately and remain in the LIMS record. Regardless, the laboratory identification numbers deleted (or erroneous) cannot be reused within the LIMS system.

22.5.4(C) Other Sample Log-in Information— During the log in process the client/project name is linked to the packet information along with the date and time of laboratory receipt and the unique laboratory ID number so that the records are easily retrievable upon request and readily available to individuals who will process the sample.

22.5.4(D) Client Communications — Conversations with the client should be documented in the appropriate LIMS field.

(a) All communications between Dolan Chemical Laboratory staff and clients concerning laboratory samples (including their sampling, receipt, handling and analysis) shall be documented using the LIMS.

22.5.5 Sample Tracking Sheets — Sample Tracking Sheets may be directly issued from the LIMS to enable a specific lab employee to determine their work backlog and parameter. These sheets are used where need in the laboratory to allow the personnel to more efficiently monitor their workload and due dates.

22.5.5(A) Chemists and analysts who schedule their work priority from the chain of custody have the responsibility to complete their individual work within the holding time and the client's due date.

22.5.6 Sample Handling

22.5.6(A) After the paperwork/computer check-in process has been completed, the sample(s) may be stored in refrigerators, if needed, on the sample shelves provided in the Shipping & Receiving Room (Room 225), or at designated areas in the individual labs.

22.5.6(B) Individual laboratory analytical groups, such as Industrial Hygiene, may have designated areas for the placement of received samples after check-in. These areas are within the analytical areas of the appropriate groups.

22.5.7 Sample Storage

22.5.7(A) Samples, sample fractions, extracts, leachates, and other sample preparation products shall be stored until the end of the sample's holding time according to the conditions specified by preservation protocols.

22.5.7(B) Samples shall be stored away from all standards, reagents, food and other potentially contaminating sources. Samples shall be stored in such a manner to prevent cross contamination.

22.5.7(C) Where a sample or portion of the sample is to be held secure (for example, for reasons of record, safety or value, or to enable check calibrations or tests to be performed later), the sample will be marked as such and segregated from other samples to protect the condition and integrity of the secured items or portions concerned.

22.5.7(D) Stable samples may be retained for use in the laboratory's internal quality control program. [Section 2A.5.9 in Reference 18.4.18]

(a) e.g. IHAG fiber slides (IHPAT samples and interesting samples) and ELPAT samples (soils and paints) may be re-used for control QC samples.

(b) e.g. PSAG may reexamine CCRL ash, LQSI coal mineral ash, LQSI limestone, ASTM Insulating Oil samples, ASTM Lubricating Oil samples and XR Labs limestone PT samples as additional QC samples.

(c) e.g. WWAG ERA PT samples may be re-used for control QC samples.

22.6 Sample Retention Guidelines—The Dolan Chemical Laboratory analyzes a diverse array of samples. The retention of this array of samples has evolved depending upon the exact sample types and the physical/personnel arrangements most convenient for efficient operation. These retention guidelines utilized by the Dolan Chemical Laboratory are given throughout this Section.

22.6.1 Sample Retention Guidelines for **Flue Gas Analytical Group** (FGAG) based on sample type: (Removed 04/2008)

22.6.2 Sample Retention Guidelines for **Industrial Hygiene Analytical Group** (IHAG) based on sample type:

22.6.2(A) **Asbestos (Bulk) —**The as-received bulk sample is stored, prior to analysis, in the Microscopy Room (Room 200).A split of the as-received bulk sample is used as the analysis sample. This analysis split is returned to the as-received container when the analysis is completed. The bulk sample is retained for a minimum of three months in the Microscopy Room (Room 200). The as-received bulk sample is discarded as a hazardous material under the appropriate CHP guidelines.

22.6.2(B) **Fibers—**The as-received sample is stored, prior to analysis, in the Microscopy Room (Room 200). A pie- shaped portion of each as-received sample is used as the analysis sample. The analysis sample is examined and is then retained for a minimum of three months in a labeled drawer in the Microscopy Room (Room 200). The remaining sample is retained for a minimum of one month in the drawer. Both the analysis sample and the remaining as-received sample are discarded as hazardous materials under the appropriate CHP guidelines.

22.6.2(C) **Dust, Nuisance; Total and Respirable —**The as-received sample is **s**tored, prior to analysis, in the Clean Room (Room 221A). The entire as-received nuisance dust sample is used in the preparation of the analysis sample. The analysis sample is retained in a labeled box in the Toxicology Lab for a minimum of three months and is then discarded under the appropriate CHP guidelines.

22.6.2(D) **Bulk Samples for Arsenic, Metals or Crystalline Silica —** A representative split of each bulk sample is collected and is used as the bulk analysis sample. The remaining bulk sample is discarded under the appropriate CHP guidelines. Separate splits of the bulk analysis sample may be collected for the separate analyses of crystalline silica, metals and/or arsenic. The remaining portion of the bulk analysis sample is retained indefinitely in a labeled vial in the Toxicology Lab.

(a) **Silica:** Upon completion of the analysis, the analysis sample for crystalline silica is retained in a desiccator for one month and is discarded under the appropriate CHP guidelines.

(b) **Metals:** The analysis sample split for arsenic and for metals is used to prepare the analysis sample. The analysis sample for arsenic and for metals is usually consumed entirely by the analysis. If some analysis sample remains, it is retained for a minimum of three months in the Toxicology Lab (Room 221) and is discarded under the appropriate CHP guidelines.

22.6.2(E) **Filter Samples for Arsenic, Metals, Welding Fumes, or Crystalline Silica —** The entire as-received filter sample for crystalline silica, arsenic, metals or welding fume is used in the preparation of the analysis sample. The analysis sample is stored, prior to analysis, in the Clean Room (Room 221A).

(a) **Silica:** Upon completion of the analysis, the analysis sample for crystalline silica is retained for one month in a desiccator in the Clean Room and is then discarded under the appropriate CHP guidelines.

(b) **Metals:** The analysis sample for arsenic, metals or welding fume is usually consumed entirely by the analysis. If part of the analysis sample remains, it is retained for a minimum of three months in the Toxicology Lab (Room 221) and is then discarded under the appropriate CHP guidelines.

22.6.2(F) **Solvents — (Removed 03/19/08)**

22.6.2(G) **Paint samples:** The as-received sample is stored, prior to analysis, in the Clean Room (Room 221A). A representative sample of each sample is split from the bulk sample to yield the analysis split. Frequently, the entire sample is prepared to yield the analysis split. Any remainder from the bulk sample is retained in the Clean Room (Room 221A) for a minimum of three months. The analysis split is also retained at the same location. The as-received sample and analysis split are discarded under the appropriate CHP guidelines. The analysis sample, derived from the analysis split, is kept for a minimum of two weeks after the issuance of the analysis report. It is then discarded under the appropriate CHP guidelines.

22.6.3 Sample Retention Guidelines for **Plant Services Analytical Group** (PSAG) based on sample type:

22.6.3(A) **Ash —**The as-received bulk sample is stored, prior to sample preparation, in the General Analytical Lab (Room 202), immediately adjacent to the sample preparation table. Up to four splits may be prepared from each as-received bulk sample, depending upon the exact sample type and analysis requirements.

(a) Three of these splits are common to fly and bottom ashes and boiler slags. These splits represent:

(i) A split that is used for the mineral ash analysis,
(ii) A split that is used for the required slurry analysis, and
(iii)A split that is used for the toxicity leachate testing.

(b) The fourth split is prepared only for bottom ash/boiler slag samples and is used for the required stain test analysis. Any remaining as-received bulk material is retained in the Main Cage Lab (Room 211 or 214) for a minimum of three months. The bulk as-received samples are then discarded under the appropriate CHP guidelines. The mineral ash analysis split, the slurry split and, if required, the stain test split are stored in the General Analytical Laboratory (Room 202) in the designated storage area near the preparation table until the analysis is begun. The toxicity leachate split is stored in the Biology Lab (Room 208) at the designated storage area until the analysis is begun. The analysis sample, derived from the mineral ash analysis split, is stored in the General Analytical Lab for a minimum of two weeks after the report of that analysis is issued. The analysis sample is then discarded under the appropriate CHP guidelines. The remaining analysis sample is retained in the Coal Lab Room for a minimum of three months. The analysis sample is then discarded under the appropriate CHP guidelines. The remaining material left from the slurry and the stain test splits are discarded immediately after the analysis has been completed under the appropriate CHP guidelines. The analysis sample, derived from the toxicity leachate split, is retained in Water Lab B for a minimum of two weeks after the report of that analysis has been issued.

(c) The analysis sample is then discarded under the appropriate CHP guidelines. The remaining material left from the toxicity leachate split is retained in Biology Lab (Room 208) for a minimum of three months. It is, then, discarded under the appropriate CHP guidelines.

22.6.3(B) **Coal—** The as-received coal sample is stored, prior to analysis, in the Coal Preparation Room (Room 224). In general, the entire as-received sample is prepared to yield the analysis sample. Occasionally, the as-received sample is so large as to preclude this procedure. A representative portion of the sample is then split from the bulk sample to yield the analysis sample. The remainder is stored in the Coal Preparation Room (Room 224) for a minimum of two weeks after the issuance of the report and is discarded under the appropriate CHP guidelines. The analysis sample is retained in the Coal Laboratory (Room 219) until the appropriate storage space is exhausted. All samples over three months in age are discarded under the appropriate CHP guidelines.

22.6.3(C) **Deposits—** The as-received sample is stored, prior to analysis, in the General Analytical Lab (Room 202). A representative sample of each sample is split from the bulk sample to yield the analysis split. Frequently, the entire sample is prepared to yield the analysis split. Any remainder from the bulk sample is retained in the Main Cage Lab (Room 211 or 214) for a minimum of three months. The analysis split is also retained at the same location. The as-received sample and analysis split are discarded under the appropriate CHP guidelines. The analysis sample, derived from the analysis split, is kept for a minimum of two weeks after the issuance of the analysis report. It is then discarded under the appropriate CHP guidelines.

22.6.3(D) **Insulating Fluid/ Lubricants —** The as-received sample is stored, prior to analysis, in the Oil Lab (Room 226). Only some of as-received sample is used in the analysis. The remainder of the as-received sample is retained in the Oil Lab for at least one month after the issuance of the report and is discarded under the appropriate CHP guidelines.

22.6.3(E) **Metallurgical —** The as-received samples are stored, prior to analysis, in the Metallurgy Lab (Room 228). These samples are retained in the Metallurgy Lab indefinitely depending upon the uniqueness of the individual sample and its educational/technical benefits. If the sample is deemed as unworthy, it is discarded two weeks after the issuance of the report in accordance with the appropriate CHP guidelines. All mounted preparations of the as-received samples are retained indefinitely in the Metallography Lab (Room 223).

22.6.3(F) **Paints — (Removed 03/19/08)**

22.6.3(G) **Tubes—** The as-received tube samples are stored, prior to analysis, in the Shop (Room 225) or in the Metallurgy Lab (Room 228) depending upon the exact analysis requested. If the analysis requires the use of the large band-saw or the drill press, then the tube samples are generally stored in the Shop. If the tube sample may initially be sectioned by the cutoff machine, then the tube samples are generally stored in the Metallurgy Lab. Tube samples may be retained indefinitely depending upon the uniqueness of the individual sample and its educational/technical benefits. If the sample is not considered significant, it is retained for at least three months after the issuance of the report and is then discarded according to the appropriate CHP guidelines. All analysis samples, derived from a tube's deposit or analysis, are retained for two weeks after the issuance of the analysis report and are discarded according to the appropriate CHP guidelines. All mounted preparations of the as- received tube samples are retained indefinitely in the Metallography Lab (Room 223).

22.6.3(H) **Miscellaneous, General (Trona, Gypsum, etc)—** These samples are stored in various laboratory locations depending upon the exact analysis that may be appropriate. The samples may be retained in the Coal Lab Room (Room 219), Record Storage Room (Room 220) or the Main Cage Lab (Rooms 211 and 214) indefinitely depending upon the individual sample's uniqueness and educational/technical status. If deemed unworthy, the samples are retained for a minimum of three months after the issuance of the report and are discarded according to the appropriate CHP guidelines.

22.6.3(I) **Miscellaneous, Chemical Cleanings — (Removed 10/22/08)**

22.6.3(J) **Miscellaneous, EHC Fluid —** The as-received sample is stored, prior to analysis, in the Oil Lab (Room 226). Only some as-received sample is used in the analysis. The remainder of the as-received sample is retained in the Oil Lab for at least one month after the issuance of the report and is discarded under the appropriate CHP guidelines.

22.6.3(K) **Miscellaneous, Resin — (Removed 10/22/08)**

22.6.4 Sample Retention Guidelines for **Water and Waste Analytical Group** (WWAG) based on sample type:

22.6.4(A) **Biological —** (Removed 03/19/08)

22.6.4(B) **Waste —**The as-received waste sample is stored, prior to analysis, in the Biology Lab (Room 208). If necessary, this as-received sample is split to yield a representative sample for the waste testing and the remaining as-received sample is retained in the Biology Lab (Room 208). The split sample is then used to prepare the needed leachate analysis solutions. If the split sample is not completely used, it is also stored with the remaining as-received sample in the Biology Lab (Room 208). **These retained materials are kept for a minimum of six months** after the date of the actual leach procedure.

(a) The leachate analysis solutions are digested and/or preserved in accordance with standard waste procedures and are held either with refrigeration in Water Lab A (Room 209), if required, or on the appropriate shelf in Water Lab B (Room 210) or Record Storage (Room 220).

(i) The leachate analysis solutions are held as appropriate to the tests to be performed on that particular solution. If the solution was prepared for a 24-hour holding time parameter, the analysis is performed within the 24-hour deadline and any remaining leachate analysis solution is disposed of according to the appropriate CHP guidelines after the final report has been issued.

(ii) If the solution was prepared for a 28-day holding time parameter, the leachate analysis solution is refrigerated in Water Lab A (Room 209) or in Shipping and Receiving (Room 225), until the tests have been completed. If the 28-day holding time has not yet expired, then the solution is kept refrigerated until the expiration date. After the expiration of the 28-day holding time, the leachate analysis solutions are removed from the refrigerator and placed on the appropriate shelves in the Shipping and Receiving Room (Room 225) in preparation for disposal.

(b) Metals: The metals leachate analysis solution (which has six-month holding time) must be digested before analysis. The digestate, itself, is stored before analysis in Water Lab B. After analysis, the digestate is retained in the AA/ICP Lab (Room 212) for about two weeks after the issuance of the report and is discarded according to the appropriate CHP guidelines. The remaining metals leachate analysis solution is kept in Water Lab A or Record Storage (Room 220) for a maximum of six months after the date of the actual leach procedure.

(i) Depending upon sample load and the available shelving, the oldest of these samples (metals leachate analysis and other leachate analysis solutions) may be also retained in the Record Storage Room (Room 220). In any case, **the leachate analysis solutions are retained in either Water Lab B or in the Record Storage Room for a minimum of six months** after the date of the actual leach procedure and are then discarded according to the appropriate CHP guidelines.

(ii) **If storage becomes a limitation**, an aliquot of metals leachate sample may be retained in a smaller container, allowing disposal of the majority of the leached solution prior to the six month retention period.

22.6.4(C) **Water —** The primary objectives of the water sample retention policy are to preserve the samples integrity for the entire legal holding period and to retain the sample for another month after the report is issued to provide additional information if necessary. The as-received samples which must be kept cold and are stored, in the refrigerators in the Shipping and Receiving Room (Room 225), Water Lab A (Room 209), or Water Lab B (Room 210).

(a) Samples will be stored in a refrigerator for at least a month after they were collected. When they are removed from the refrigerators, they are stored on the shelves in Shipping and Receiving (Room 225) until they are at least two months old.

(i) Samples which have a 24-hour holding time will be analyzed on the day of receipt or as soon after receipt as possible. Any remaining sample for this test may be stored for some period of time in the refrigerator in Water Lab A, but will ultimately be stored on the shelves in Shipping and Receiving (Room 225) for a period of at least two months after collection.

(ii) Samples which have no allowable holding time (e.g. pH), are analyzed immediately upon receipt and are stored in the Water Lab A or Water Lab B refrigerator for at least one month. All samples more than a month beyond their legal holding time may be removed from the shelves and discarded, when time is available, according to the appropriate CHP guidelines.

(b) Metals: The water samples for metals analysis (which have a six-month holding time) are taken immediately at the time of sample check-in to Water Lab A (Room 209). Most of these samples must undergo some type of sample preparation which may include digestion. The prepared samples are taken to Water Lab B (Room 210) where information about the preparation is entered into the LIMS system. The prepared samples are then taken to the area where they are to be analyzed (generally the AA/ICP Lab (Room 212)).

(i) Prepared metals samples remain on the bench tops in the AA/ICP Lab and are disposed of within three months.

(ii) The remaining portion of the acidified sample that was not prepared is stored on the shelves in Water Lab B for at least one month until they are transferred to the shelves in the Record Storage Room (Room 220) where they are stored for the remainder of their six month shelf life. The samples are then discarded, as time is available, according to the appropriate CHP guidelines.

22.7 Sample Disposal

22.7.1 The appropriate guidelines for disposal of all samples received by the Dolan Chemical Laboratory are given in the latest revision of the **Chemical Hygiene Plan (CHP)** (located in **Appendix A**).

22.7.2 Laboratory sample wastes are stored in appropriate drums in the Biology Lab (Room 208) according to the waste type.

22.7.3 Non-hazardous, unpreserved aqueous samples are poured down the sink drain while flushing with tap water. Non-hazardous, preserved aqueous samples are also poured down the sink drain while flushing with tap water, and shall be neutralized by the "Acid Neutralization Tank" system (See Section 19.7.17). Non-hazardous solid samples are disposed of by a waste disposal service.

22.7.4 Samples deemed hazardous are returned to the client for disposal.

22.8 Documentation — Controlled quality documents from this Section shall be maintained separately from the Quality Assurance Manual in the following collection (which is itself, a controlled laboratory document):

22.8.1(A) **QCDOC 014** records (and the majority of laboratory documentation, unless otherwise specified) shall be maintained for at least five (5) years, and may require periodic review.

QC File 00 46— "QCDOC 014: Sample Information " (in Section 22)

23.0 Technical Requirements: Assuring the Quality of Test Results

23.1 Purpose and Scope— This section defines the essential quality control elements utilized to generate legitimate data at the Laboratory, and describes control measures necessary to identify sources of measurement error within the Laboratory and to estimate the measurement system's bias and precision (repeatability and reproducibility).

23.1.1 This section also lists the statistical tools and techniques available to Laboratory personnel. These tools and techniques are used to gain more information about data produced by testing and analytical procedures. This information will be used to make predictions or come to conclusions about the nature of the data. The list given is provided to familiarize the user with the type of statistical tools that are currently being used by the Laboratory but will not provide detailed use instructions for such tools or techniques.

23.1.2 Definitions and tools for statistical quality control analyses are explained throughout this section.

23.1.2(A) First the essential quality control items are identified (as defined within the NELAC standard [Reference 18.4., NELAC 2003]) in Section 23.2.

23.1.2(B) Section 23.3 describes function and control checks and Section 23.4 defines the terms and use of various statistical tools and techniques.

23.1.2(C) The concept for the estimation of uncertainty of measurements is developed in Section 23.5.

23.1.2(D) Finally, the laboratory QC protocol for the Dolan Chemical Laboratory is summarized in Section 23.6.

23.2 Essential Quality Control Elements—The Laboratory incorporates the following essential quality control elements [Reference 18.4., NELAC 2003] as practices necessary to validate the use of test methods and to ensure the consistency and validity of generated test data. The Laboratory recognizes the use of the following elements as primary tools available to the analyst for quality control of each analytical process. These elements should be recognized and used with each analytical procedure to the extent possible and practical. In addition, any governmental or regulatory quality control requirements, applicable to a specific procedure or method, will serve as the minimum requirements for that procedure. Quality control data shall be analyzed and, where they are found to be outside pre-defined criteria, planned action shall be taken to correct the problem and to prevent incorrect results from being reported. The elements and a brief discussion of their utility follow:

23.2.1 Implementation of Positive and Negative Controls

23.2.1(A) **Negative controls (Blanks) —** The negative controls are essentially blank samples used to assess for possible contamination during the preparation and processing steps. Blanks should be processed along with and under the same conditions as the associated samples to include all steps of the sampling and/or analytical procedure.

(a) Calibration Blank: A calibration blank is a volume of reagent grade water of the specific type required by the designated procedure to which all reagents have been added in the same volumes or proportions as used in sample processing.

(b) Field Blank: A field blank is a sample of media taken from the laboratory to the sampling site, exposed to the prevalent environmental conditions, preserved (if needed), and returned to the laboratory for analysis. This blank is carried through the entire analytical scheme.

(c) Laboratory Reagent Blank (Method Blank): A laboratory reagent blank (or method blank) is a sample of media to which all reagents have been added in the same volumes or proportions as used in the sample processing. This blank is carried through the entire analytical scheme and should serve to characterize any contamination due to glassware cleanliness and/or reagent deterioration.

(d) Trip Blank: A trip blank is a sample of media taken from the laboratory to the sampling site and returned unopened to the laboratory. This blank is carried through the entire analytical scheme.

23.2.1(B) **Positive controls (Standards and Spike Recoveries)—** Positive controls should be used to evaluate the performance of the total analytical system, including all preparation and analysis steps. Positive controls may evaluate the system in the blank matrix, (e.g. laboratory control samples, laboratory fortified blanks), or in the sample matrix (e.g. laboratory fortified matrix spikes). Additionally, surrogate spikes may be added prior to sample preparation/extraction to provide a measure of recovery for every sample matrix and to reflect the chemistries of the targeted components of the method.

(a) Laboratory Control Standard (LCS): The laboratory control standard is a standard, usually certified by an outside agency, used to measure the bias in a procedure. NIST standards are to be used when they are available.

(b) Laboratory Fortified Blank (LFB) or appropriate substitute: An aliquot of blank matrix to which a known quantity of the method analytes has been (blank spike) added is analyzed. This spike is carried through the entire analytical scheme. The percent blank spike recovery is calculated by dividing the final result by the amount added and multiplying by 100. The LFB is used as the historical control value to find out if the analytical procedure is in a state of statistical control. Appropriate substitutes may be used as best applicable to each procedure.

(c) Laboratory Fortified Sample Matrix, (LFM) or "Matrix Spikes": A sample (matrix spike) with a known amount of target parameter (analyte) added is analyzed. This spike is carried through the entire analytical scheme. Any background in the sample is subtracted from the spike measurement. Background refers to the concentration of the analyte already in the sample before spiking. The percent matrix spike recovery is calculated by dividing the final result by the amount added and multiplying by 100.

(i) Matrix spikes are used to determine if the analytical procedure is applicable to the particular matrix for the particular analyte. Recoveries should be evaluated against the historical control limits or against limits appropriate to the particular procedure and data usage.

(ii) Surrogate spike is defined in Section 23.2.7(C).

23.2.2 Evaluation of Accuracy

23.2.2(A) Accuracy: Accuracy is a combination of the bias and precision of an analytical procedure that reflects the closeness of a measured value to a true value.

23.2.2(B) Bias: Bias is a consistent deviation of the measured value from the true value caused by systematic errors in a procedure.

23.2.2(C) Accuracy Statistics

(a) Percentage accuracy or percentage recovery is defined in Section 23.4.1(B).

23.2.3 Evaluation of Variability

23.2.3(A) Field Duplicate: Field Duplicate specifically refers to two samples collected in two sample containers taken simultaneously from one location.

23.2.3(B) Duplicate/Replicate/Matrix Spike Duplicate: Duplicate analyses serve to define the precision of the analytical method and are essential for evaluating the applicability and dependability of a specific method.

23.2.3(C) Precision: Precision refers to the measure of the degree of agreement among replicate analyses of a sample, usually expressed as the standard deviation. (Other variability statistics are defined in Section 23.2.3(E)).

23.2.3(D) Replicate: A replicate is a repeated operation occurring within an analytical procedure. Two or more analyses for the same constituent in separate extracts (aliquots) of a single sample constitute replicate analyses. For samples analyzed in replicate, one of the replicate samples must be designated as the "actual" sample and its analytical result should be reported. The other analyses composing the replicate are used to calculate any needed precision statistic.

23.2.3(E) Variability Statistics

(a) Range is defined in Section 23.4.1(C).

(b) Relative percent difference (RPD) is defined in Section 23.4.1(D).

(c) Relative standard deviation (RSD) is defined in Section 23.4.1(E).

(d) Standard deviation is defined in Section 23.4.1(F).

23.2.4 Determination of Method Capability— The laboratory should evaluate test methods for their capability, and such determination of limit of detection (LOD) should be appropriate and relevant for the intended use of the data. Detection limits, report limits, and demonstration of capability are discussed in further detail in **Section 18.3**.

23.2.4(A) **Detection Limits**

(a) Instrument Detection Limit (IDL): The instrument detection limit refers to the constituent concentration that produces a signal greater than five times the signal/noise ratio of the instrument. This is similar, in many respects, to "critical level" and "criterion of detection." The latter limit is stated as 1.645 times the standard deviation (s) of the reagent blank analyses.

(b) Method Detection Limit (MDL): The method detection limit refers to the constituent concentration that, when processed through the complete method, produces a signal with a 99% probability that it is different from the reagent blank. This reflects only the detection limit set by the method and does not take any other factors into account. The Laboratory performs its MDL determinations by the method listed in 40 CFR, Part 136, Appendix B.

(c) MDL Check: The LOD check verifies a qualitative response at the MDL level and must be analyzed annually. See Section 18.3.2(D). This is accomplished during the annual MDL study.

23.2.4(B) **Report Limits**

(a) Report Limit (RL)/Minimum Level (ML)/Limit of Quantitation (LOQ): The lowest level at which the entire analytical system must give a recognizable signal and acceptable calibration point for the analyte. It is equivalent to the concentration of the lowest calibration standard, assuming that all method-specified sample weights, volumes, and cleanup procedures have been employed. The RL/ML is calculated by multiplying the MDL by 3.18 and rounding the result up to the number nearest to (1, 2, or 5) x 10^n , where n is an integer.

(b) The reporting limit will be determined in conjunction with the determination of the MDL. Verification of this lowest calibration standard shall be considered complete if a linear regression calculation of the entire calibration curve yields no lower then 0.995. (Same statement in 18.3.3(D)(a)).

(c) RL Verification (RLV): The RLV confirms a quantitative response at the RL level and must be analyzed annually. See Section 18.3.3(D)(a).

23.2.4(C) **Method Capability**

(a) Certification: Certification of a management system is sometimes also called registration.

(b) Control Check: Control check is defined in Section 23.3.1(B) and is discussed in further detail in Section 23.3.

(c) Demonstration of Capability (DOC): Test methods and the analysts who perform test methods should verify adequate performance through the analysis of a specified set of samples. In order to properly evaluate accuracy and precision, the samples should be of known concentration (either re-analysis of previously analyzed samples, laboratory standards, or matrix spikes) and in an available quality system matrix (a sample in which no target analytes or interferences are present at concentrations that impact the results of a specific test method). (See also **Section 18.3.4**)

(d) Proficiency Testing (PT) samples — These samples are defined as third-party prepared laboratory control standards, whose values are known only to the third party prior to analysis. Typically, these samples are analyzed by many laboratories and the results are reported to reference them to overall laboratory performances.

Note: Archived Inter-laboratory Comparison documents and reports are maintained in **QCDOC 017 Inter-laboratory Comparisons**:

QC File 00 47— "QCDOC 017: Inter-laboratory Comparisons " (in Section 23)


(e) Quality Control Sample (QCS): The QCS serves as the outside check on the analytical system to ensure that the system is producing verifiable, correct analyte values.

23.2.5 Selection of Data Reduction Techniques

23.2.5(A) The procedures for data reduction, (e.g. the use of linear regression) should be appropriate and relevant for the intended use of the data and should be documented per Section 13.0 (Data Validation is discussed in Section13.3)

23.2.6 Selection of Reagents

23.2.6(A) Reagent Quality: In methods where the purity of reagents is not specified, analytical reagent grade shall be used. Reagents of lesser purity than those specified by the test method shall not be used. The labels on the container should be checked to verify that the purity of the reagents meets the requirements of the particular test method. Such information shall be documented per Section 6.3.2.

(a) At a minimum, **Analytical Reagent (AR) Grade (or ACS reagent grade)** reagents must be used throughout the laboratory.

23.2.6(B) Reagent Checks: The laboratory shall verify the concentration of titrants in accordance with written laboratory procedures.

23.2.6(C) Source of Standards: The source of standards shall comply with traceability requirements as stated in **Section 20.0.**

23.2.6(D) Water Quality: The quality of water sources shall be monitored and documented per **Section 19.7.3** and shall meet method specified requirements as defined in **Section 19.7.3**.

(a) **Reagent Water — Reagent water shall meet the** performance specifications for ASTM Type I water.

(b) **Organic-Free Reagent Water—** Organic-free reagent water requires additional preparation steps to provide adequate quality reagent water for volatiles, semi-volatiles, and non-volatiles organic analyses. The Laboratory does not currently perform such organic analyses.

23.2.7 Assurance of Selectivity of Technique

23.2.7(A) The laboratory shall evaluate selectivity by following the checks established within the method.

(a) Examples of measures for evaluation of selectivity include mass spectral tuning, second column confirmation, ICP inter-element interference checks, chromatography retention time windows, sample blanks, spectrochemical absorption or fluorescence profiles, co-precipitation evaluations, and electrode response factors.

23.2.7(B) Internal Standard (IS): An internal standard is a pure compound added to a sample extract just before instrumental analysis to permit correction for inefficiencies.

23.2.7(C) Surrogate Spike: The surrogate spike consists of pure substance(s) with properties that mimic the analyte(s) of interest, but are unlikely to be found in environmental samples. These compounds are added to evaluate the effectiveness of the preparation steps of the analytical method and provide positive and sample-specific control.

23.2.8 Maintenance of Constant and Consistent Test Conditions

23.2.8(A) **Environmental Conditions**

(a) When it has a direct effect on the validity of results or when mandated by the procedure or test method, the laboratory may be required to impose environmental controls on laboratory equipment and in the working areas of the Laboratory. Any special requirements, accommodations, or environmental conditions should be monitored, controlled, and documented (per **Section 17.0**) to ensure the quality of the measurement(s).

(b) Examples requiring additional environmental controls may include biological sterility, dust, electromagnetic disturbances, radiation, lighting, humidity, electrical supply, temperature, sound levels, and vibration levels.

(c) Glassware Cleaning: Glassware shall be cleaned to meet the sensitivity of the test method. Any cleaning and storage procedures that are not specified by the test method shall be documented in laboratory records and SOPs as directed in **Section 19.7.1**.

23.2.8(B) **Sample Conditions -** These sample conditions are discussed in detail in **Document 21-01**.

(a) Holding Time: The holding time is the length of time during which a sample can be stored after collection and preservation without significantly affecting the accuracy of the analysis. The maximum holding time is dependent upon the matrix used and the specific analyte of interest. 40 CFR Part 136 lists the maximum times that water samples may be held before analysis and the analysis still be considered legally valid. Some samples may not be stable for this maximum time. In these cases, the laboratory is obligated to hold the sample for a shorter time, if knowledge exists to show that this is necessary to maintain sample stability.

(b) Preservation Techniques - Chemical Preservative: A chemical preservative is a chemical compound added to the sample to maintain the target compounds in the same concentration and state as at the time of sampling. This technique may encompass pH and oxidative state control.

(c) Preservation Techniques - Filtration: This technique is applicable to the determination of dissolved metals in samples with suspended solids, but must be performed before any pH adjustment.

(d) Preservation Techniques - Sample Container Control: One technique that may be used to minimize the degree of sample degradation is the use of amber and opaque bottles. This technique may decrease the exposure to ultraviolet exposure induced changes in the sample.

(e) Preservation Techniques - Temperature Control: Temperature control is sometimes used to minimize the potential for volatilization or biodegradation. This control may be established by refrigeration or packing the samples in ice. Storage at 4^{o}C (+/- 2 ^{o}C) is recommended for most water samples.

23.2.8(C) **Instrument Conditions** — The laboratory shall assure that the test instruments consistently operate within the specifications required of the application for which the equipment is used.

(a) Calibration Curve and Blank: Every procedure (where applicable) should have a curve specific to its usage defined by an appropriate number of standards and a calibration blank. This curve should be characterized by a linear range and an analyte sensitivity. A detection limit should be determined for each procedure. The Laboratory uses the method detection limit (MDL) for all analyses except where an alternative is specifically designated by the referenced procedure or associated regulations.

(b) Calibration Check Standard (CCS): The calibration check standard (CCS) is a standard used to determine the state of calibration of an instrument between periodic recalibrations. The CCS is primarily applicable to those analytical systems where calibration curve drift may be a problem. This standard is used to check the curve in those cases and to verify the absence or presence of drift. Typically, the historical control limit or an absolute limit is used to evaluate the severity of the slope condition.

(c) Function check: Function check is defined in Section 23.3.1(A) and is discussed in further detail throughout Section 23.3.

(d) Internal standard: Internal standard is defined in Section 23.2.7(B).

23.3 Statistical Tools and Techniques

23.3.1 Summary Statistics— Summary statistics, such as the mean (x) and the standard deviation (s), are used to simplify the presentation of data and summarize essential characteristics.

Note: *Where* K = *known value of the spike in the sample*
n = *total number of data points in the sample population*
s = *standard deviation of sample population*
x_i = *individual data point*
$\overline{x}$ = *mean value for a sample population,*
x_1 = *measured value for first sample,*
x_2 = *measured value for second sample,*
$x_{highest}$ = *measured value for highest sample in population,*
x_{lowest} = *measured value for lowest sample in population,*
x_s = *measured value for spiked sample, and*
x_u = *measured value for unspiked sample (or zero for blank matrix).*

23.3.1(A) Mean- The mean is the arithmetic average of a set of data. It is calculated as the sum of all results divided by the number of results. Means should be reported at one significant figure more than the data used to calculate them. The mean is a measure of the central tendency of a frequency distribution.

Equation 2: Mean

$$\overline{x} = \frac{\sum_{i-1}^{n} x_i}{n}$$

23.3.1(B) Percentage Recovery: The percentage recovery is a measure of data accuracy that is simply the ratio of the observed value to the actual value normalized to 100%.

Equation 3: Percentage Recovery

$$\%\,\text{Recovery} = \frac{(x_s - x_u)}{K} * 100$$

23.3.1(C) Range: The range is a measure of data variability that is simply the difference between the highest and lowest value in a set of data.

Equation 4: Range

$$Range = (x_{highest} - x_{lowest})$$

23.3.1(D) Relative Percent Difference (RPD): The relative percent difference (RPD) is used as the control value for duplicates. It is calculated as the absolute difference between the replicate or field duplicate measurements divided by the mean of the replicate or field duplicate measurements multiplied times 100. The RPD provides an indication of the precision (reproducibility) of the measurements. The RPD should be reported with one significant figure more than the results used in the calculation.

Equation 5: Relative Percent Difference (RPD)

$$RPD = \frac{(x_2 - x_1)}{\overline{x}} * 100$$

23.3.1(E) Relative Standard Deviation (RSD)/ Coefficient of Variation (CV): The relative standard deviation (RSD) is used as the control value for replicates. It is calculated as the standard deviation of the measurements divided by the mean, multiplied times 100. The RSD provides an indication of the precision (reproducibility) of the measurements. The RSD should be reported with one significant figure more than the results used in the calculation.

Equation 6: Relative Standard Difference (RSD)

$$RSD = CV = \left(\frac{s}{\bar{x}}\right) * 100$$

23.3.1(F) Standard Deviation: The standard deviation (i.e. sample standard deviation) is a measure of variability or dispersion of a frequency distribution. It is defined as the root-mean-square deviation from the mean. It is calculated as the square root of the sum of the squares of the differences (result minus mean) divided by the number of results minus one. In a normal distribution, the standard deviation is a measure of the amount of dispersion from the mean and can be used to help determine the probability that a certain result lies within a specific distribution. Standard deviation should be reported with the same number of significant figures as the mean for the same set of data.

Equation 7: Standard Deviation

$$s = \sqrt{\frac{\sum_{i-1}^{n} (x_i - \overline{x})^2}{n - 1}}$$

23.4 Control Limits and Control Charts

23.4.1 Control charts are, perhaps, the most useful statistical tool available to the laboratory. They will be used by the Laboratory as prescribed by the methods and as directed by the QAO* (or designee). *The primary chemist for each individual analysis is responsible for the day-to-day maintenance of any established control charts.*

23.4.1(A) Acceptance criteria (control limits) should be established for QC elements to monitor performance and validate the method and should be implemented on a control chart. The laboratory should add results that pass the acceptance criteria to update control charts to form a graphic representation of laboratory performance.

23.4.1(B) The Laboratory utilizes a Microsoft Access database linked to the LIMS system to create control charts. The database calculates the mean, standard deviation, and warning and control limits for data sets of QC elements. These control charts are "Shewhart-type" charts which utilize the multiples of the standard deviation from the Normal distribution of plotted values (as defined in Sections 23.5.4 and 23.5.5, "Warning" and "Control" Limits)

(a) The Industrial Hygiene Analytical Group (IHAG) also uses Microsoft Excel to create control charts for Bulk Asbestos testing data. The specific types of control charts used and the associated actions are described in the Bulk Asbestos SOP.

23.4.1(C) The statistical program looks at historical data and re-calculates accuracy and precision acceptance limits for a specific sample matrix, instrument type and QC element. Warning and control limits are calculated when at least twenty or more data points are available. They are updated when:

(a) At least 20 new (or the 20 most recent) data points are obtained
(b) Significant changes are made to the instrument or analytical method.

23.4.1(D) A control chart is considered "current' if it is printed every 20 data points, or at a minimum quarterly. When a control chart is required for a specific parameter, a "current" printed control chart must be kept at each analyst's work area.

23.4.2 Initial control limits— Initially (before there is sufficient internal laboratory data), the acceptance criteria may be assigned from the published method, or using the minimum requirements dictated in **Section 23.7.**

23.4.3 Laboratory-generated acceptance criteria—When sufficient internal performance data become available (usually a minimum of twenty (20) analyses), laboratory-generated acceptance criteria may be developed based on the assumption that 99 % of the observations should be confined within three (3) standard deviations of the sample population.

23.4.3(A) The laboratory-generated acceptance criteria (control limits) must be equal to or better than the minimum requirements.

23.4.3(B) The user selects at least 20 new, or the 20 most recently generated, data points (accuracy, precision, MDL or blank values).

23.4.3(C) After each twenty (20) new measurements (accuracy, precision, MDL, or blank values), new laboratory-generated acceptance criteria (control limits) may be calculated. The laboratory control chart should then be updated per laboratory policy stated in the laboratory QA Manual.

Note: *See Section 23.4 for statistical tools and techniques and for the formulae for mean, standard deviation, etc.*

23.4.4 Warning limits (WL) —The WARNING limits (based on a 95% confidence level) are bound between **two (2) standard deviation (s) units** and should serve to monitor the performance of the analytical system and serve as a notification of potential errors and issues before the system is officially deemed "out of control" ("OOC"). The lower WARNING limit (LWL) and upper WARNING limit (UWL) are described below.

Equation 8: Warning Limits (LWL and UWL)

$$LWL = \bar{x} - 2s$$
$$UWL = \bar{x} + 2s$$

23.4.4(A) where: $\bar{x}$ = mean value (accuracy, precision, MDL, blank or any data points) for a sample population, and
s = standard deviation of sample population

23.4.5 Control limits (CL) —The CONTROL limits (based on a 99% confidence level) are bound between **three (3) standard deviation (s) units** and should serve to monitor the performance of the analytical system and serve as official notification that it has become "out of control" ("OOC"). The lower CONTROL limit (LCL) and upper CONTROL limit (UCL) are described below.

Equation 9: Control Limits (LCL and UCL)

$$LCL = \bar{x} - 3s$$
$$UCL = \bar{x} + 3s$$

23.4.5(A) where: $\bar{x}$ = mean value (accuracy, precision, MDL, blank or any data points) for a sample population, and
s = standard deviation of sample population

23.4.6 Use of control charts— The precision and recovery data are used for the diagnosis of analytical problems and to indicate when a problem in a given test is occurring. Lack of control is indicated when: [Reference 18.4.22]

23.4.6(A) **Rule 1:** One or more data points fall outside the Control Limits (exceed three standard deviation units) on either the Accuracy or Precision charts.

23.4.6(B) **Rule 2:** Two or more consecutive values fall on the same side as, and outside the Warning Limits (exceed two standard deviation on the same side) on either the Accuracy or Precision charts.

23.4.6(C) **Rule 3:** At least eight successive values fall on the same side of the mean or central line (8 on the same side) on the Accuracy charts.

23.4.6(D) **Handling Out of Control (OOC) Data –** Use of the Rules indicates a potential "out of control" (OOC) situation which must be addressed.

(a) When an OOC event occurs, the analysis should be halted pending troubleshooting and remedial action, followed by rejection of the results in the analytical run and re-analysis of the test samples.

(b) The analyst should refer to the specific method or the instrument manufacturer's manual for guidance in corrective actions.

(c) Determine where the lack of control may have occurred and opportunities to reduce variation in the data. If an assignable cause has been determined, take preventative action so that the event will not recur.

(d) If the OOC situation continues after remedial actions have been taken, the analyst shall notify the primary chemist of the event.

(e) If the OOC situation appears to have been resolved after remedial actions have been taken, the test samples shall be re-prepared and re-analyzed.

(f) If corrective action is not possible (i.e. insufficient sample volume or suspected matrix interference, etc.), the analyst shall notify the primary chemist of the situation.

(g) Results associated with an OOC event may be reported with the appropriate data qualifiers.

(h) [Note: Statistically, there is a chance of a false alarm (i.e. a "statistical event"). In applying Rule 1 alone, there is a 1 in 35 chance of a false alarm, and the average number of data points between false alarms will be about 200. As additional Rules are applied, these probabilities will increase as will the points between false alarms.]

(i) All data points – including OOC data points – must be included when calculating control limits on the control charts unless: (1) there is documentation substantiating an analytical error (e.g., spilled spike solution, etc.), or (2) the data point is determined to be an "outlier" by the QA Officer according to accepted statistical tests.

23.4.6(E) **Documentation of all corrective action is required** (e.g. notes on the control chart, in the associated laboratory notebook, as a formal NC report, etc.).

23.5 Estimation of Uncertainty of Measurements

23.5.1 Introduction — "Laboratories shall be able to demonstrate their ability to estimate measurement uncertainty for all accredited quantitative test methods. In those cases where a rigorous estimation is not possible, the laboratory must make a reasonable attempt to estimate the uncertainty of test results and for significantly different matrices. Estimations of measurement uncertainty are not required where the reported test results are qualitative." [per ISO 17025 5.4.6, Reference 18.4.9]

23.5.1(A) Uncertainty is associated with most of the results obtained in laboratory testing. It is meaningful to estimate the extent of the uncertainty associated with each result generated by the laboratory. It is also useful to recognize that this measurement uncertainty is likely to be much less than that associated with sample collection activities.

23.5.1(B) This standard operating procedure addresses policies and procedures to estimate (as applicable) the uncertainty associated with pertinent laboratory measurements.

23.5.1(C) In practice, the uncertainty of a result may arise from many possible sources. It is useful to consider the relative contribution of major sources of error. Many sources of error are insignificant compared to the processes of sample preparation, calibration, and instrumental measurement. The uncertainty associated with these processes can be estimated from quality control data. Accordingly, the laboratory may estimate uncertainty from data derived from quality control samples carried through the entire analytical process. A rationale for this approach is provided.

23.5.1(D) Each estimate of uncertainty is associated with a specific combination of analytical method and sample matrix.

23.5.1(E) This standard operating procedure includes an analysis that demonstrates that the contribution attributable to random error far exceeds contributions due to bias (with the exception of uncertainties associated with solution standards). Since random error can be assessed by data generated using statistical quality control techniques, the approach discussed uses the statistical processing of pertinent quality control data to estimate the uncertainty associated with each specific type of measurement.

23.5.2 Scope

23.5.2(A) The policy applies only to laboratory measurements associated with industrial hygiene analytical work.

23.5.2(B) The policy applies only to quantitative measurements; it does not apply to qualitative analyses.

23.5.2(C) Uncertainty data are maintained in laboratory records; uncertainty data are not included in reports of analytical results, unless they have been requested by the client.

23.5.2(D) This estimation of uncertainty relates only to measurements conducted in the Laboratory. For example, uncertainty associated with sampling activities and related processes is not considered.

23.5.3 Responsibilities

23.5.3(A) The Dolan Chemical Laboratory Manager is responsible for enforcement of the policy.

23.5.3(B) As an AIHA accredited laboratory, the Dolan Chemical Laboratory (DCL) is required to maintain a procedure for the estimation of uncertainty (per AIHA Appendix G, Estimation of Uncertainty of Measurement [Reference 18.4.18]).

(a) The Laboratory shall "re-estimate measurement uncertainty when changes to laboratory operations are made that may affect sources of uncertainty."

(b) The Laboratory shall "report the expanded measurement uncertainty, along with the reported analyte concentration, in the same units as analyte concentration, when — it is relevant to the validity or application of the test results, or a customer's instructions so requires, or the uncertainty affects compliance to a specification limit."

23.5.3(C) The primary chemist for the Industrial Hygiene Analytical Group assigns tasks required for the estimation of uncertainty and for the maintenance of records of uncertainty. The primary chemist also calculates each estimate of uncertainty.

23.5.3(D) The QAO* (or designee) implements practices and conducts audits to ensure that required estimates of uncertainty are in place and that pertinent records are maintained.

23.5.3(E) Analysts conduct the testing required to generate the data used to estimate uncertainty; the analysts also organize the data files and records employed to document estimates of uncertainty.

23.5.4 Discussion of Error

23.5.4(A) There are two sources of uncorrectable error: random error and uncorrectable bias. Correctable bias, quantified and addressed by analytical protocol, is not a part of uncertainty.

23.5.4(B) Random error is caused by the normal variation experienced in quantitative laboratory work. This error is bidirectional; results cannot be corrected for its effects. Random error can, however, be reduced in some cases. When an error is determined to be random, it is not separately estimated, but the total random error is quantified applying statistical techniques to data generated from the analysis of quality control samples.

23.5.4(C) Uncorrectable bias is caused by the uncertainty in calibration and, in some cases, the lack of appropriate control of environmental conditions. This error is unidirectional; since its direction is not known, however, it is treated statistically as random error. Accordingly, this error can also be addressed by applying statistical techniques to data compiled from the analysis of quality control samples.

23.5.5 Definitions- The following definitions apply to the discussions of this procedure.

23.5.5(A) Uncertainty – A parameter associated with the result of a measurement that characterizes the dispersion of the values that could reasonably be attributed to the measurand. This definition focuses on the range of values that the analyst believes could reasonably be assigned to the measurand. The term uncertainty relates to the general concept of doubt.

23.5.5(B) Measurand – The quantity being measured. In many cases involving laboratory measurements the measurand is the quantity or concentration of an analyte. In chemical analysis, however, other quantities such as pH and conductivity are determined. Therefore, the general term measurand is applicable.

23.5.5(C) Source of Uncertainty – An individual item, practice, factor, process, or consideration that can contribute to the uncertainty of a final result. The uncertainty of a result can arise from many possible sources; examples are sampling, sample matrix effects, interferences, environmental conditions, uncertainties of masses and of volumetric measurements, the stability of detector response, and reference values. "Sources contributing to the uncertainty include, but are not necessarily limited to, the reference standards and reference materials used, methods and equipment used, environmental conditions, properties and condition of the item being tested or calibrated, and the operator." [per ISO 17025 5.4.6, Reference 18.4.9]

23.5.5(D) Expanded Uncertainty – The quantity defining an interval about the result of a measurement that may be expected to encompass a large fraction of the distribution of values that could reasonably be attributed to the measurand. The fraction may be regarded as the coverage probability or level of confidence of the interval. In accordance with this procedure, an expanded uncertainty is calculated by multiplying the relative standard deviation of pertinent quality control results by a factor of two. This corresponds to a confidence level of approximately 95%. Refer to **Section 23.5.4**.

23.5.5(E) Error of Measurement – The result of a measurement minus a true value of the measurand.

23.5.5(F) Random Error – Result of a measurement minus the mean that would result from an infinite number of measurements of the same measurand carried out under repeatability conditions. Random error is equal to error minus systematic error.

23.5.5(G) Systematic Error – Mean that would result from an infinite number of measurements of the same measurand carried out under repeatability conditions minus a true value of the measurand. Systematic error is equal to error minus random error. Like true value, systematic error and its causes cannot be known.

23.5.5(H) Relative Standard Deviation – The estimated standard deviation of a population derived from a sample of n results divided by the mean of the n results for that sample. This quantity is often referred to as the coefficient of variation. It is frequently stated as a fraction or a percentage.

23.5.6 Description of Approach Used to Estimate Uncertainty

23.5.6(A) The following steps are applied in establishing practices and procedures for the estimation of the uncertainty associated with laboratory measurements.

(a) Identification of major sources of uncertainty for applicable types of laboratory measurements
(b) Determination of the nature of the error associated with each major source of uncertainty

(c) Estimation of the extent of the error of each major source
(d) Conversion of the estimate of error for each major source to a standard deviation
(e) Estimation of the combined standard deviation for the entire process
(f) Estimation of the combined, total uncertainty through a consideration of the combined standard deviation for all major sources of error
(g) Identification of sources of uncertainty of significant importance and of insignificant importance
(h) Estimation of error solely from significant sources (The insignificant sources of error are not included in this estimation.)
(i) Calculation of expanded uncertainty based only on significant sources of error.

23.5.6(B) A brief summary of the process described in the preceding is presented in following flow chart (**Document 23-01**).

23.5.7 Major Sources of Uncertainty— The following describes each of several major sources of uncertainty in laboratory determinations, the nature of the uncertainty associated with each, and an estimation of the extent of the error.

23.5.7(A) Mass: Both analytical balances and the weights used for verification of performance have uncertainties associated with them. Of the two, the balance uncertainty is greater by 1 – 2 orders of magnitude; accordingly, the latter can be ignored. Balance measurements have both random and bias uncertainties. The bias, based on the claims of manufacturers, is approximately 0.3 mg; this tends to be a fixed error over a wide range of weights. If one assumes a typical sample weight of 1 gram, the estimated uncertainty associated with mass determinations is approximately 0.03%.

23.5.7(B) Volume: Volumetric measurements include the use of volumetric flasks, pipets, and burettes. Measurements accomplished with the use of these items have both random and bias uncertainties. Conservative estimates establish error associated with volumetric measurements typically addressed in the chemical analysis laboratory at 0.05%.

23.5.7(C) Temperature: Devices used for the measurement of temperature have both random and bias uncertainties, but the random uncertainty is generally less than the resolution of the measuring device. Uncorrectable bias is rarely greater than 0.1ºC. Careful control of temperature can minimize error associated with gross variation in temperature. This factor is generally addressed in the stipulations of the methodology. Temperature, as an environmental control issue, will have a random error, but the bias over 0.1ºC is not significant. Therefore, the only significant impact of temperature on most analytical chemistry measurements is related to volume measurement; this is frequently a separate uncertainty quantifiable by the thermal expansion of water. The uncertainty associated with this consideration is approximately 0.012% assuming the laboratory applies correction procedures.

23.5.7(D) Pressure: Pressure is rarely a factor in analytical chemistry measurements. Accordingly, this SOP does not consider the influence of this factor in the analysis presented here.

23.5.7(E) Calibration Standards: Calibration standards frequently have published (provided) uncertainties; these are generally 0.5 – 1% for solution standards and much less for solid standards. In many cases, the uncertainty is provided as a conservative estimate of uncertainty (a guaranteed value). Accordingly, actual uncertainty associated with calibration standard is likely much less than values provided by suppliers. Using the provided data, therefore, represents a conservative approach.

23.5.7(F) Atomic Weights: The uncertainty of published atomic weights can contribute to total, combined uncertainty in processes in which atomic weights are used for calculations contributing to the generation of results. The largest uncertainty associated with this contributing factor is estimated at 0.02%.

Document 23-1 Flowchart for Calculating Uncertainty

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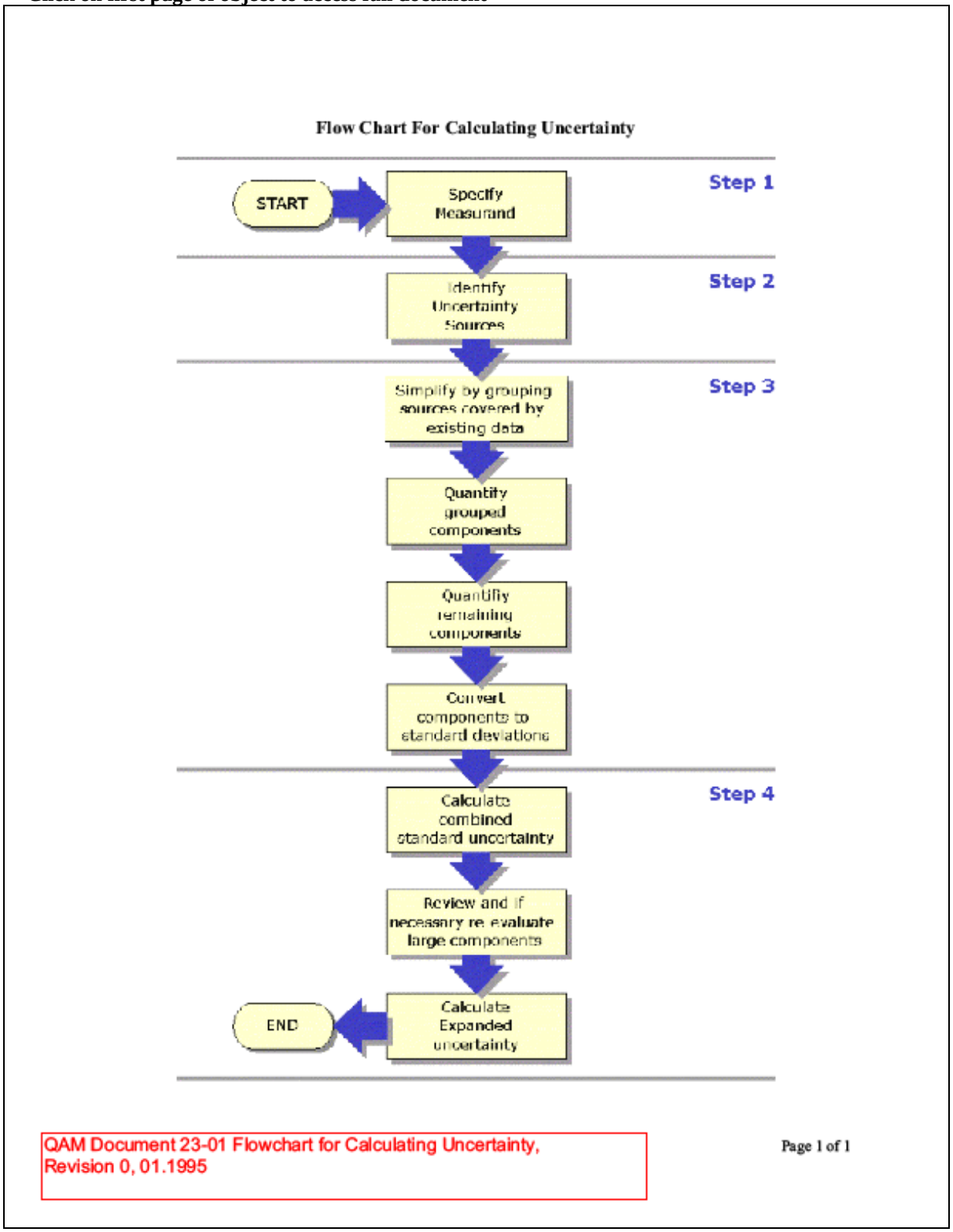

23.5.7(G) Standardization Process: The standardization process for most instrumental analyses introduces uncertainty because of the inexact nature of the process. With a linear correlation coefficient of 0.999, the standard error of estimate is approximately 3%. For a specific determination, this is a bias error, but the contribution of the standardization process can be considered as random error if this process is applied repeatedly over time. This is the case for most of the instrumental analyses addressed by most laboratories. Therefore, this procedure treats error associated with the standardization process as random error.

23.5.7(H) Instrumentation Sensors: Sensors have uncertainty because of lack of stability. The error associated with this process is random error.

23.5.8 An Analysis of the Effect of Contributing Sources on Combined Uncertainty

23.5.8(A) In a generalized approach, one may consider the contribution (to uncertainty) of each of the major sources discussed in the preceding. These considerations involve both the application of the estimates listed in **Section 23.6.7** of this document and the principles discussed in detail in the following: EURACHEM/CITAC Guide – "Quantifying Uncertainty in Analytical Measurement," Second Edition; Editors: S.L.R. Ellison, M. Rosslein, and A. Williams.

(a) Type A contributors are those that may be determined statistically (random contributors). (See Section 23.6.10)

(b) Type B contributors are those that must be determined by non-statistical methods.

23.5.8(B) A summary table of the generic analysis follows (**Document 23-02**):

Document 23-2 Summary of Sources of Uncertainty

<<Click on first page of object to access full document>>

Summary of Sources of Uncertainty

Source	Random Error	Bias	Estimated Error (%)	Category of Distribution	Standard Deviation	Square of the Standard Deviation
Mass	Yes	Yes	0.03	Rectangular	0.0173	0.000300
Volume	Yes	Yes	0.05	Rectangular	0.0289	0.000833
Temperature	Yes	Yes	0.012	Rectangular	0.0069	0.000048
Calibration Standards	No	Yes	1	Gaussian	0.333	0.111111
Atomic Weights	No	Yes	0.02	Gaussian	0.0066	0.000044
Standardization Process	Yes	No	3	Gaussian	1	1
Instrumentation Sensors	Yes	No	Not Considered	Not Considered	Not Considered	Not Considered

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23.5.8(C) Discussion of analysis

(a) Since combined error is generally addressed by a consideration of the sum of the squares of the standard deviations of the contributing factors, the data of the preceding table demonstrate that the effects of the uncertainty associated with mass, volume, temperature, and atomic weight are insignificant compared to uncertainty attributable to random error associated with the calibration and measurement process. Although the performance of instrumentation sensors is not quantitatively addressed in the preceding table, the instability of instrumentation sensors contributes to the uncertainty associated with calibration and measurement.

(b) Since random error associated with the calibration and measurement process is the most significant contributor to the uncertainty of most measurements, and since this error can be assessed by a consideration of quality control data, this procedure addresses the use of quality control data to estimate uncertainty.

23.5.9 Procedure for Estimation of Uncertainty

23.5.9(A) Results for quality control samples are used to estimate the uncertainty associated with the industrial hygiene samples processed by the Laboratory.

(a) When data for Laboratory Control Samples (LCS) and Laboratory Control Sample Duplicates (LCSD) are available, these are used to estimate uncertainty. LCSs and LCSDs are media-spiked samples carried through the complete analytical procedure.

(b) Results for quality control samples other than LCSs and LCSDs can also be used to estimate uncertainty. The primary chemist for the Industrial Hygiene Analytical Group and the Quality Control* (or designee) must approve use of these data. Examples of materials that could be used to estimate uncertainty include quality control check samples, calibration verification standards, and proficiency test samples. When materials other than LCSs and LCSDs are used for estimating uncertainty, the processes must be defined in pertinent laboratory records.

23.5.9(B) Results from a minimum of 50 quality control samples are used to estimate uncertainty. Preliminary indications of uncertainty can be assessed by fewer than 50 results.

23.5.9(C) The relative standard deviation is calculated for the set of recovery percentages (results) obtained for the quality control samples (normally LCSs and LCSDs) selected for the estimation of uncertainty.

23.5.9(D) The expanded uncertainty for an analytical process (specific method and specific sample matrix) is calculated as two times the relative standard deviation (Sr) of recovery data. The expanded uncertainty is used to define the uncertainty interval associated with a result. For example, if X is the measured result obtained for a sample, the interval of uncertainty for this result can be represented as: $X(1 \pm 2Sr)$

(a) Note that Sr is the relative standard deviation (expressed as a fraction) calculated from the pertinent set of **50** quality control results.

23.5.9(E) The laboratory can also apply uncertainty data published in documentation of pertinent analytical methodology in defining the uncertainty associated with determinations conducted by the laboratory. In general, these published uncertainties will be those promulgated by recognized agencies such as the National Institute for Occupational Safety and Health (NIOSH) and the Occupational Safety and Health Administration (OSHA). Uncertainty data from other sources can also be used.

23.5.9(F) The following assumptions/observations apply to the procedures listed in this document for the estimation of uncertainty:

(a) The procedure relates only to measurement error.
(b) Sampling error and related factors are not considered.
(c) Sample heterogeneity is not considered.
(d) Unless addressed by specific procedures incorporated into the analytical methodology, the effect of matrix interferences is not addressed.
(e) It is assumed that corrections for bias are inherent in the method or are implemented as appropriate. Unless indicated otherwise, the statistical approach addressed by this procedure to assess uncertainty does not consider the effects of bias.
(f) The approach of this procedure assumes that the recovery data used for the estimation of uncertainty are normally distributed.
(g) The approach described in this procedure results in an estimate of minimum measurement uncertainty. The actual uncertainty might be larger than that indicated.

23.5.10 Another Uncertainty procedure:

23.5.10(A) Type A contributors (See Section 23.6.8) may be used for estimating the overall uncertainty in the entire analytical process by measuring the dispersion of values obtained from well-chosen standards or samples.

(a) The laboratory may derive this information from Quality Control Charts, so a separate effort is not required.

(b) The control chart data used to determined uncertainty in the laboratory in duplicate samples (two samples taken from and representative of the same population) or duplicate analyses (the analysis of the variable of interest on two sub-samples of the same sample).

(c) The two values are usually compared by their relative percent difference, RPD: (AB)/(average of A and B). The average RPD for many duplicate pairs can be used as a surrogate for the expected precision component of uncertainty of a sample. To properly estimate precision using duplicate analyses, a proper number of QC data points (typically twenty or more) should be considered.

23.5.11 Uncertainty—Generation of an accuracy statement and estimation of uncertainty—An on-going **accuracy statement** for the level of concentrations for data that pass the acceptance criteria specification and an **estimation of uncertainty** should be established using the standard deviation data and control charts described in Section 12.3, and should be updated on a regular basis

23.5.11(A) The **estimation of uncertainty** is specified by the precision achieved by the laboratory and may simply be reported as the LWL and UWL (Section 23.5.4).

(a) Uncertainty data from published sources may also be used/reported with the appropriate references.

23.5.11(B) The expression of an **accuracy statement** utilizes the estimation of uncertainty (Sections 23.6.9 and 23.6.10) in conjunction with a sample result in a similar concentration range and/or with accuracy achieved by the laboratory on a relevant QC standard.

Note: *As an example, if the average percent recovery achieved by the laboratory over an interval of time was R = 90%, and the standard deviation was s = 10%, then the accuracy statement would simply be from R ± 2s and the accuracy interval may be expressed as 70–110%.*

23.5.11(C) When reporting measurement uncertainty, the test report:

(a) shall include the coverage factor and confidence level used in the estimations (typically k = approximately 2 at the 95% confidence level);

(b) shall include the calculated bias; and

(c) shall be reported in the same units as the sample.

23.5.11(D) "When the test method has a known and uncorrected systematic bias, it shall be reported separately from the test result and uncertainty estimation, as a probable bias value" (per AIHA Appendix G, Estimation of Uncertainty of Measurement [Reference 18.4.18]).

23.5.11(E) **To determine the Expanded Measurement Uncertainty (MU) on "discrete" samples** (i.e. homogenous, non-bulk samples, in which the entire sample is processed or a homogenous aliquot is processed for measurement):

(a) Step 1: Measure a pair of LFB samples with each analytical batch to determine accuracy and precision of the analytical method. Obtain forty (40) LFB data points (i.e. from twenty pairs), if available – use the percent recovery data.

(b) Step 2: Calculate the average, the bias, the standard deviation, and ultimately, the uncertainty of the percent recovery data set.

(c) Step 3: Calculate the bias and uncertainty specific to the sample result, converting to the units of the sample.

(d) **Report the Expanded MU as follows:** "(Sample measurement with units) with and analytical uncertainty of +/- (sample uncertainty with same units as the sample result) at the 95% confidence level with probable bias of (sample bias with same units as the sample result)

(e) See **QAM Document 23-03** for an example data set, with calculations and reporting of MU for a discrete sample.

23.5.11(F) **To determine the Expanded Measurement Uncertainty (MU) on "bulk" samples** (i.e. samples that may be heterogeneous, which require additional processing to obtain a representative sub-sample to be processed for measurement):

(a) Step 1: Measure a pairs of duplicate samples with each analytical batch to determine the precision of the sub-samples and analytical process. Obtain thirty (30) duplicate data points, if available – use standard deviation of the data.

(b) Step 2: Calculate the standard deviation (SD) of the LCS percent recovery data in the data set.

(c) Step 3: Calculate the standard deviation, coefficient of variation (CV) and the CV-squared of the Duplicate data in the data set.

(d) Step 4: Calculate the % relative standard deviation (%RSD) from the CV-squared of the Duplicate data in the data set.

(e) Step 5: Calculate the combined relative standard deviation (RSDc) from the LCS SD (determined in Step 2) and the % RSD of the Duplicates (determined in Step 4).

(f) Step 6: Calculate the expanded measurement uncertainty (MU) of the full data set.

(g) Step 7: Calculate the bias and uncertainty specific to the sample result, converting to the units of the sample.

(h) **Report the Expanded MU as follows:** "(Sample measurement with units) with and analytical uncertainty of +/- (sample uncertainty with same units as the sample result) at the 95% confidence level with probable bias of (sample bias with same units as the sample result)

(i) See **QAM Document 23-04** for an example data set, with calculations and reporting of MU for a bulk sample.

23.5.12 Uncertainty References

23.5.12(A) EURACHEM/CITAC Guide, "Quantifying Uncertainty in Analytical Measurement," Second Edition; Editors: S.L.R. Ellison, M. Rosslein, and A. Williams.

23.5.12(B) Georgian, Thomas, "Estimation of Laboratory Analytical Uncertainty Using Laboratory Control Samples," Environmental Testing & Analysis, November/December 2000.

23.5.12(C) Taylor, B.N. and C.E. Kuyatt, NIST Technical Note 1297, 1994 Edition: "Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results."

23.5.12(D) Heinbaugh, Kris, "Guidelines for Uncertainty Estimation," AIHA Guidelines for Measurement of Uncertainty_R4_092906, September 29, 2006.

23.5.12(E) ISO 5725 Accuracy (trueness and precision) of measurement methods and results

(a) Part 1 General principles and definitions
(b) Part 2: Basic method for the determination of repeatability and reproducibility of a standard measurement method
(c) Part 3: Intermediate measures of the precision of a standard measurement method
(d) Part 4: Basic methods for the determination of the trueness of a standard measurement method5] Part 6: Use in practice of accuracy values

23.5.12(F) GUM, Guide to the Expression of Uncertainty in Measurement, issued by BIPM, IEC, IFCC, ISO, IUPAC, IUPAP and OIML

23.5.12(G) AIHA Appendix G [Reference 18.4.18]

Document 23-3 Expanded MU for Discrete Samples, Revision 0, 07.08.11.pdf

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DOLAN - EXPANDED MEASURMENT UNCERTAINTY (MU)
CALCULATION for Discrete (Non-bulk Samples)

Step 1 **Determine accuracy and precision using pairs of LFB from Analytical Batches**

Obtain 40 Data Points (i.e. Percent Recovery of 20 LFB pairs) for Calculation of MU
Parameter/Reference Method: ug/L Chromium on Filters by NIOSH 7300
LFB Spike Concentration: LFB/LFBD = 800 ug/L Chromium

TestID	AnalysisDate	lh-icp-lfba	TRUE	%Recov	lh-icp-lfbb	TRUE	%Recov
Cr	14-Jun-11	742.3	800	92.7875	731	800	91.375
Cr	10-Jun-11	750.5	800	93.8125	790.7	800	98.8375
Cr	03-Jun-11	799.8	800	99.975	820.6	800	102.575
Cr	01-Jun-11	807.7	800	100.9625	804.3	800	100.5375
Cr	31-May-11	808.8	800	101.1	808.4	800	101.05
Cr	19-May-11	783.8	800	97.975	786.6	800	98.325
Cr	12-May-11	809.7	800	101.2125	809.2	800	101.15
Cr	11-May-11	765.4	800	95.675	805.6	800	100.7
Cr	04-May-11	794.7	800	99.3375	805.1	800	100.6375
Cr	29-Apr-11	821.4	800	102.675	814.3	800	101.7875
Cr	19-Apr-11	796.3	800	99.5375	800.8	800	100.1
Cr	14-Apr-11	803	800	100.375	784.7	800	98.0875
Cr	06-Apr-11	788.9	800	98.6125	784.2	800	98.025
Cr	30-Mar-11	803.9	800	100.4875	795.6	800	99.45
Cr	24-Mar-11	818.3	800	102.2875	787.8	800	98.475
Cr	22-Mar-11	789.2	800	98.65	800.8	800	100.1
Cr	09-Mar-11	749.95	800	93.74375	759.25	800	94.90625
Cr	03-Mar-11	770.9	800	96.3625	776.4	800	97.05
Cr	25-Feb-11	820.9	800	102.6125	792.2	800	99.025
Cr	22-Feb-11	783.1	800	97.8875	787.1	800	98.3875

Step 2 **Calculate statistics of the Data set - Average, Bias, Standard Deviation and Uncertainty of "% Recovery"**

Average Percent Recovery of Data Set = Sum of Each % Recovery / Number of Data Points (i.e. 40)
40-pt Avg = 98.92 % Rec

Bias of Data Set = Avg % Recovery - 100% = 98.91625% - 100%
40-pt Bias: = -1.08 % (biased low)

$$s = \sqrt{\frac{\sum_{i=1}^{n} (x_i - \bar{x})^2}{n - 1}}$$

Standard Deviation of Data Set =
40-pt Std Dev = 2.731 %

Uncertainty of Data Set = (Std Dev of Data Set) * (k-value) = 2.73% * 2
where k= 2 represents 2 std dev for 95% confidence interval
Expanded MU = 5.463 %

Note: Certified reference materials (CRM) used for calibration indicates and assat of 99.5%. The Expanded MU of the CRM at 95% confidence interval (i.e 0.5% divided by k=2) yields 0.25% rsd, which is insignificant when compared to the the bias of the data set and can be eliminated from the calculation.

Step 3 **Calculate statistics for a specific sample result - Bias and Uncertainty - in the same units of measurement.**

Example A - Sample Concentraion is 800 ug/L Chromium
Sample Concentration: 800 ug/L Cr
Bias = (% Bias of Data set) (Sample Result) = (-1.084%)(800ug/L Cr) = -8.67 ug/L Cr
Uncertainty = (% Uncertainty of Data set) (Sample Result) = (5.463%)(800ug/L Cr) = (+/-) 43.7 ug/L Cr

Example B - Sample Concentraion is 20 ug/sample Chromium
Sample Concentration: 20 ug/sample Cr
Bias = (% Bias of Data set) (Sample Result) = (-1.084%)(20ug/sample Cr) = -0.217 ug/sample Cr
Uncertainty = (% Uncertainty of Data set) (Sample Result) = (5.463%)(20ug/sample Cr) = (+/-) 1.09 ug/sample Cr

Step 4 **Report the Expanded MU for the Sample Result with the Uncertainty at 95% confidence level (k=2) and with probable bias in the same units as the sample.**

Example A - Sample Concentraion is 800 ug/L Chromium
"800 ug/L Chromium with an analytical uncertainty of +/- 43.7 ug/L at the 95% confidence level (k=2) with probable bias of -8.67ug/L."

Example B - Sample Concentraion is 20 ug/sample Chromium
"20 ug/Sample Cr with an analytical uncertainty of +/- 1.09 ug/Sample Cr at the 95% confidence level (k=2) with probable bias of -0.217ug/Sample Cr."

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Document 23-4 Expanded MU for Bulk Samples, Revision 0, 07.08.11.pdf

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DOLAN - EXPANDED MEASURMENT UNCERTAINTY (MU) CALCULATION for Bulk Samples

Step 1 **Determine precision using standard deviation of LFB data set and pairs of duplicate samples from Analytical Batches**

Obtain 30 Data Points (i.e. standard deviation of LFB set and of duplicate pairs) for Calculation of MU
Parameter/Reference Method: mg/kg Lead in Paint samples by NIOSH 7300

From 30 batches, extract sample duplicate data from the LIMS (See Tab).
From 30 batches, extract LCS data from the LIMS (See Tab).

Step 2 **Calculate statistics of the LCS Data set - Standard Deviation of the LCS "%Recovery".**

$$s = \sqrt{\frac{\sum_{i=1}^{n} (x_i - \bar{x})^2}{n-1}}$$

Standard Deviation of Duplicate LCS Set = STD (LCS) =
30-pt Std Dev (LCS) = 7.880 %

Note: **Certified reference materials (CRM) used for calibration indicates and assay of 99.5%. The Expanded MU of the CRM at 95% confidence interval (i.e 0.5% divided by k=2) yields 0.25% rsd, which is insignificant when compared to the the bias of the data set and can be eliminated from the calculation.**

Step 3 **Calculate statistics of the Duplicate Data set - the Standard Deviation (STD), the Coefficient of Variation (CV), and CV squared of the Duplicates sample results.**

Standard Deviation of Duplicate Data Set = STD = $s = \sqrt{\frac{\sum_{i=1}^{n} (x_i - \bar{x})^2}{n-1}}$

Coefficient of Variation (CV) of Duplicate Data Set = STD / (Avg of the Duplicates)
CV-squared = $(CV)^2$ = (CV)(CV)

Step 4 **Calculate% RSD of the Duplicates sample results (i.e. the square root of the Sum of CV-squared's)**

% RSD = CV_{pooled} = $\sqrt{(CV)^2 / (\text{Number of Data points})} = \sqrt{(CV)^2 / (30)}$
30-pt % RSD (Dupes) = 23.2 %

Step 5 **Calculate the Combined RSD (RSDo) of the LCS and Duplicates result.**

RSDo = $\sqrt{SD1^2 + SD2^2} = \sqrt{(SD_{LCS})^2 + (\%\ RSD_{DUPES})^2} = \sqrt{(7.88)^2 + (23.2)^2}$
RSDo = 24.5 %

Step 6 **Calculate statistics of the Full Data set - Expanded Measurement Uncertainty at 95% Confidence Interval**

Expanded MU = (Combined RSD) * (k-value) = SDc (2) = 24.5% * 2
where k= 2 represents 2 std dev for 95% confidence interval
Expanded MU = 49.0 %

Step 7 **Calculate statistics for a specific sample result - Bias and Uncertainty - in the same units of measurement.**

Example A - Sample Concentraion is 4400 mg/kg Lead in Paint, with LCS at 97.3% Recovery (i.e. -2.7% Bias)
Sample Concentration 4400 mg/kg Pb
Bias = (% Bias of Data set) (Sample Result) = (-2.7%)(4400 mg/kg Pb) = -118.8 mg/kg Pb
Uncertainty = (% Uncertainty of Data set) (Sample Result) = (49.0%)(4400 mg/kg Pb) = (+/-) 2156 mg/kg Pb

Step 8 **Report the Expanded MU for the Sample Result with the Uncertainty at 95% confidence level (k=2) and with probable bias in the same units as the sample.**

Example A - Sample Concentraion is 800 ug/L Chromium
"4400 mg/Kg Pb in paint with an analytical uncertainty of +/- 2156 mg/Kg at the 95% confidence level (k=2) with and a probable bias of -118.8 mg/Kg.

QAM Document 23-04 Expanded MU for Bulk Samples, Revision 0, 07.08.11.xls (Tab - Uncertainty)
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23.6 QC Protocol for Dolan Chemical Laboratory—

23.6.1 The Dolan Chemical Laboratory recognizes the use of the following elements as primary tools available to the analyst for the quality control of each analytical process. These elements are recognized and used with each analytical procedure to the extent possible and practical. In addition, any governmental or regulatory quality control requirements, applicable to a specific procedure or method, serve as the minimum requirements for that procedure. The elements and a brief discussion of their utility follow:

23.6.1(A) The requirements listed in this section are minimum requirements. If the procedure requires more stringent criteria than those listed, those limits or requirements must also be met.

23.6.1(B) Deviations from this QC protocol should be noted and discussed in the standard operating procedure (SOP) (e.g. changes in QC protocol per the requirements of the reference method).

23.6.2 General Laboratory Protocol

23.6.2(A) Reagent Water — The laboratory shall use water that meets the performance specifications for ASTM Type I water. For organic analyses, see the discussion of organic-free reagent water.

23.6.2(B) Reagent Grade Chemicals — The laboratory shall at a minimum use analytical reagent (AR) grade, (or ACS reagent grade) chemicals and reagents that conform to the current specifications of the Committee on Analytical Reagents of the American Chemical Society, whenever possible.

23.6.2(C) Standards— Certified stock standards, from which working standards are to be prepared, should be purchased from a reputable and reliable vendor.

(a) The certified values from standards should be used in creating calibration curves and performing calculations.

(b) These standards must not be used beyond the stated expiration date.

23.6.2(D) Data Validation —The process of evaluating the available data against the project DQOs (see definition below) to make sure that the objectives are met.

(a) Data validation may be very rigorous, or cursory, depending on project DQOs. The available data reviewed should include analytical results, field QC data, laboratory QC data, and may also include field records.

(b) **Data Quality Objectives (DQOs) —**A statement of the overall level of uncertainty that a decision-maker is willing to accept in results derived from environmental data. This is qualitatively distinct from quality measurements such as precision, bias, and detection limit.

23.6.2(E) Proficiency Test Samples — In an effort to evaluate and improve overall performance and to meet the requirements for certification, the laboratory will analyze Proficiency Test (PT) samples at minimum of two (2) times per year (when available).

(a) These PT samples shall be obtained from approved vendors (per accrediting bodies), when possible.

(b) These samples will be treated in the same manner as actual samples in terms of the analytical methods and instrumentation used as well laboratory personnel who perform the analyses.

(c) In addition to conducting these “blind” checks, AEP Dolan Chemical Laboratory will also participate in applicable "blind" sample and “round robin” programs.

(d) For test parameters which are in the laboratory's Scope of Accreditation, the laboratory must achieve "Acceptable Results" (i.e. within three standard deviation units) for a minimum frequency per the accrediting authority.

(i) For parameters that exceed the "Warning Limits of the PT study (i.e. exceed two standard deviation units), should be monitored for a trend and may require the creation of a Nonconformity record or CPAR record as defined in Sections 11.3.4(C)(b)(i) and 11.3.4(C)(c)(i).

(ii) For parameters that receive an "Not Acceptable " result and that exceed the "Control Limits" of the PT study, require the creation of a CPAR record as defined in Section 11.3.4(C)(c).

(iii) Upon finalization of the CPAR record for a "Not Acceptable" result, the WWAG must order, analyze, and achieve acceptable results on an additional PT sample ordered from an approved PT provider. These are often called "Quick Response" samples. An acceptable "Quick Response" sample serves to verify the effectiveness of the corrective action plan from the CPAR and usually count towards the two out of three PT studies required for accreditation.

(iv) In cases where the laboratory has not achieved "Acceptable Results" for the minimum frequency, the laboratory is usually required to notify the Accrediting Authority in writing. This notification usually includes the finalized Corrective Action Plan (CPAR) resolving the issue and the appropriate number of acceptable PT samples required for re-accreditation for that parameter.

(e) PT samples should be logged into the LIMS and the results, final report, and data package should be assembled together for quick reference.

23.6.2(F) Other types of samples:

(a) MDL studies and DOC studies — Samples for MDL studies and DOC studies should be logged into the LIMS and the results, final report, and data package should be assembled together for quick reference.

23.6.3 Calibration QC Protocol —

23.6.3(A) Instrumentation Checks — A routine check of the instrumentation used in the laboratory should be done periodically to ensure quality performance.

(a) This includes scheduled maintenance and calibration on the various apparatus and instruments. For detailed discussion of maintenance activities see **QAM Documents 12-01, 12-02, and 12-03,** and for detailed discussion of calibration activities see **QAM Documents 19-01, 19-02, and 19-03**

23.6.3(B) Calibration Curve — Where applicable, the calibration curve shall be generated with a calibration blank as the "zero standard" and a minimum of two (2) calibration standards bracketing the expected concentration of the samples being analyzed. This calibration curve must achieve a correlation coefficient of 0.995 or greater. (See Section 19.5.2 for additional information on calibration procedures and Section 19.5.3 for additional information on calibration verification procedures.)

(a) The independent calibration verification (ICV) standard must be obtained or prepared from a secondary source and must yield ± 10% of the certified value.

(b) Calibration blanks (CB) analyzed throughout the analytical sequence (initial, ICB and continuing, CCB) must not exceed the ML.

(c) Continuing calibration verification (CCV) standards must also yield ± 10% of the certified value.

(d) Sample results yielding values greater than 10% above the established high calibration standard for the linear range shall be diluted and rerun. Sample results shall not be reported below the lowest calibration standard (i.e. below the ML level) without a data qualifier.

(e) When any of the above criteria are not acceptable, the analytical sequence must be halted and corrective action may be necessary. The calibration curve may be re-generated and the analytical sequence may continue when the calibration and calibration verification requirements have been met.

(f) Acceptable sample results must be bracketed between two successful CCV standards. When the CCV recovery exceeds 10% from the expected value, then the instrument shall be re-sloped or re-calibrated and the set of analyses after the last successful calibration check shall be repeated.

23.6.3(C) Detection Limits—

(a) A detection limit shall be determined for each laboratory parameter initially, prior to any sample reporting, and annually thereafter.

23.6.4 Batch QC Protocol— Certain QC checks are performed on a routine basis to ensure quality performance.

23.6.4(A) Analytical Batch — A group of ten or less samples requiring measurement during an analytical sequence.

23.6.4(B) Preparation Batch — The laboratory shall group samples which behave similarly with respect to the sampling or the testing procedures being employed into a unit defined as a preparation batch.

(a) For QC purposes, if the number of samples in a group is greater than 20, then each group of 20 samples or less will all be handled as a separate batch.

23.6.4(C) Field Samples - The preparation batch is defined as 20 or less field samples, which includes any samples submitted by the client (e.g. field blanks, field duplicates, field spikes, etc.).

(a) Field Blank — Field blanks are samples of media taken from the laboratory to the sampling site, exposed to the environmental conditions, and returned to the laboratory for analysis. Field blanks are carried through the entire analytical scheme and are treated as samples.

(i) Field blanks (when received) are analyzed with the batch of samples and are used to document contamination attributable to media and/or the handling of samples prior to analysis.

(ii) Per customer request or when required by the test procedure (e.g. IH samples) field blank results may be subtracted from sample results.

Note: Known CRM standards should be used in place of spiked solutions for analytical tests that have no available spiking solutions (e.g. asbestos, fibers, viscosity, pH, color, odor, temperature, dissolved oxygen, turbidity and "solids")

23.6.4(D) Laboratory Control Sample (LCS), which is prepared by spiking a known amount of standard into a blank matrix and performing the measurement of the analyte. The LCS defines the accuracy of the measurement system only.

(a) The initial acceptance limits for LCS are **90-110 %** Recovery. This is defined further in the explanation of the ICV in Section 23.7.3(B)(a).

23.6.4(E) Laboratory Reagent Blank (LRB) (or "Method Blank") —LRB are samples of analyte-free media/matrix to which all reagents have been added in the same volumes or proportions as used in the sample processing.

(a) An LRB shall be prepared with each preparation batch of samples prepared for analysis. It is then carried through the entire analysis scheme (i.e. sample preparation and analytical procedure) in exactly the same manner as the samples in the analysis set.

(b) LRB are used to measure the contribution of the reagents to the analyte response during the preparation of the samples. In addition, the LRB may serve to characterize any contamination due to glassware cleanliness and/or reagent deterioration during sample processing.

(c) The LRB must not exceed the ML.

(i) In general, if the analyte value of a LRB exceeds the determined ML for a specific analyte, then laboratory or reagent contamination should be suspected. Any determined source of contamination should be corrected and the samples reanalyzed, if possible.

(ii) If the LRB concentration exceeds the ML, batch sample concentrations must be greater than ten times the batch LRB result. For samples in the LRB batch not meeting this guidance, preparation and analysis must be repeated.

(d) The LRB results must be maintained on a current control chart as defined in Section 23.5. The control chart should be monitored as an indicator of problems.

23.6.4(F) Laboratory Fortified Blank (LFB) ("blank spike" or appropriate substitute) — An LFB is prepared by spiking a known amount of method analyte into a blank matrix and processing the standard through the entire analytical process.

(a) A pair of LFB shall be prepared and analyzed with each preparation batch of samples analyzed (i.e. sample preparation and analytical procedure). The spike is then carried through the entire analytical scheme.

(b) The LFB defines the accuracy and precision of the entire analytical process (i.e. the entire procedure).

(c) The LFB results must be maintained on current control charts as defined in Section 23.5. The control chart should be monitored as an indicator of problems.

(i) The LFB 1 shall be charted on an accuracy control chart. The minimum (and initial) acceptance limits for LFB are **85-115 %** Recovery.

(ii) The precision between the two LFB measurements shall also be charted on a precision control chart.

(iii) LFB performance is monitored on the control charts and is not utilized to determine the acceptability of the sample data. If either the % accuracy or precision control chart for LFB is judged to be "out of control", it is recommended to reanalyze the samples.

(iv) If there is not enough samples to repeat the preparation/analytical batch and it is deemed that the sample results have not been grossly affected, the sample results should be reported with a qualifying statement. If it is determined that the sample results have been grossly affected, the sample results shall not be reported.

23.6.4(G) Laboratory Fortified Matrix (LFM) (i.e. "matrix spike" or "spiked sample" — An LFM is prepared by spiking a known amount of standard into a sample matrix and processing the spiked sample through the entire analytical process.

(a) A pair of LFM shall be prepared with each analytical batch of (10 or less analyses) samples (i.e. unless LFM are not able to be performed on that specific procedure, analyte or sample type). This spike is carried through the entire analytical scheme (i.e. sample preparation and analytical procedure).

(i) The amount and concentration must be sufficient to yield a concentration of between one (1) and ten (10) times the ambient concentration of the sample.

(b) The LFM defines the accuracy and precision of the entire analytical process (i.e. the entire procedure) in the specific sample matrix.

(c) Any background in the sample is subtracted from the spike measurement. Background refers to the concentration of the analyte already in the sample before spiking.

(d) The acceptance limits for LFM are **75-125%** Recovery and **less than 20% RPD (or within 20% of their average, using the Range)**.

(i) Although it is not required, the LFM results may be maintained on a current control chart as defined in Section 23.5. The control chart should be monitored as an indicator of problems.

(ii) If the LFM fail to meet the accuracy or precision criteria, the laboratory performance of the analyte (i.e. LRB and LFB preparation batch data) must be evaluated. If the laboratory performance parameters are suspect, the analyst should recalibrate and reanalyze the necessary samples and QC elements (preparation batch).

(iii) If the laboratory parameters are within acceptable limits, the sample and LFM sample shall be reanalyzed to confirm the problem.

(iv) If the problem persists, the sample and LFM may be diluted (to reduce matrix interferences) and re-analyzed; the sample may be analyzed using the Method of Standard Additions (MSA) (to adjust for matrix interferences); or the sample and LFM may be analyzed using an alternative technique (to avoid the matrix interferences).

(v) If the matrix interference issue cannot be resolved, the relevant sample result should be reported with an appropriate data qualifier on the final report.

23.6.4(H) Other QC Elements —

(a) Quality Control Sample (QCS) — The QCS serves as the outside check on the analytical system to ensure that the system is producing verifiable, correct analyte values. These QCS samples may be NIST materials or NIST-certified samples purchased from an outside vendor.

(i) In any case, an effort is made to verify all calibration standards and materials through the use of additional independent sources of reference and calibration check standards and materials.

(ii) For the ICP operation, an effort is made to ensure that the calibration standard has a different origin than the material used for the preparation of the LFB, LFM, or ICV.

(b) Duplicate or Replicate Analyses — Duplicate analyses serve to define the precision of the analytical method and are essential for evaluating the applicability and dependability of a specific method.

(i) The Dolan Chemical Laboratory analyzes the LFM in duplicate to monitor the precision of the method.

(ii) For Sample Replicates : When samples are analyzed in duplicate, the difference in the analysis results for replicate samples should be within 85-115% recovery for low level sample concentrations (less than 20 times the MDL). High-level sample concentrations (greater than 20 times the MDL) should be within 95-105% recovery.

(iii) Since replicates are performed for QC purposes to monitor precision; the result of the sample testing should be reported as only the first analysis value rather than an average of the initial analysis and the replicate(s). (**An exception** is for COD analyses, where all analyses are performed in duplicate and the average result is reported.)

(iv) The precision between sample replicate should be at most 20% RPD **(or within 20% of their average, using the Range)**.

23.6.5 Non-Routine Sample Protocol — Non-routine sample submissions to the Dolan Chemical Laboratory require the following elements of quality control:

23.6.5(A) Sample (matrix) spikes — These spikes are used to establish whether the sample matrix contributes to the analytical results. The recovery of known addition shall be calculated on a percent recovery basis. A percent recovery of between **75-125%** is acceptable.

23.6.5(B) Method of Standard Additions (MSA) — If applicable to the specific analysis procedure required by the non-routine sample submittal, the method of standard additions could be performed. A failure by this particular technique may indicate that the chosen analysis procedure is inappropriate for the required analyte.

23.6.5(C) Replicate analyses — If appropriate, the analysis should be performed in duplicate to establish whether the analysis produced acceptable precise results. The level of precision required should be decided upon before the analysis and that level used as the decision criteria as to whether the analysis was successful or not.

23.6.5(D) Reference samples — If available and appropriate, NIST or other approximately equivalent reference samples should be run with every set of samples. A recovery of at least 85-115% of the reference standard is indicative of an acceptable analysis.

23.6.5(E) Blank determinations — Reagent blanks are analyzed with every set of non-routine samples. Ideally, no analytical response should be determined for the reagent blank. However, typically some response is noted. This response must be evaluated by the analyst to determine whether the noted response is too high or is unacceptable. Part of this evaluation should be a consideration of the typical sensitivity of the analyte under the analysis conditions.

23.6.5(F) Calibration curve — A calibration curve shall be determined, where appropriate, for every analysis of a non-routine sample. A linear regression analysis of the curve of at least 0.995 is required to establish linearity over the range of standards.

23.6.6 Method Validation Protocol — All method validation studies performed for the purpose of adding new procedures to the laboratory repertoire of routine analyses must include the following elements:

23.6.6(A) Method Detection Limit (MDL) — A method detection limit must be determined for the new procedure. This determination should be performed in accordance with the procedure found in 40 CFR Part 136, Appendix B. This procedure is located in the Dolan Chemical Laboratory Quality Assurance Manual as **Document 18-01**.

(a) The IHAG and WWAG of the Dolan Chemical Laboratory determine a new set of MDLs once every year.

(b) No MDL studies are performed for analytical tests that have no available spiking solutions (e.g. asbestos, fibers, viscosity, pH, color, odor, temperature, dissolved oxygen, turbidity and "solids").

23.6.6(B) Demonstration of Capability (DOC)

(a) The DOC shall be repeated as required by the relevant accrediting bodies, or at a minimum, annually.

23.6.6(C) Calibration Curve — The calibration curve developed for use with the new procedure must be composed of at least three standards and a calibration blank. The calibration range of the curve must be established as linear by a standard linear regression of at least 0.995. The upper concentration standard of this curve establishes the concentration at which a sample concentration greater than 10% of this value must be diluted to be analyzed properly.

23.6.6(D) Precision — The precision of the new procedure must be established at the appropriate concentration level. The repeatability standard deviation (Sr) is the parameter that should be determined to satisfy this requirement.

23.6.6(E) Bias — The bias of the new procedure must be determined at one level on the calibration curve. This may be done through the use of the appropriately chosen laboratory fortified blank. The bias is determined as the absolute value of the average percent (%) recovery of these LFBs subtracted from 100%.

23.6.6(F) Performance — Quality Control Samples, such as those provided by NIST or other similar organizations, must be analyzed according to the new procedure. Acceptable results are indicated if the analysis result falls within three standard deviations derived from the LFB analyses of the "true" certified QCS value.

23.7 Documentation — Controlled quality documents from this Section shall be maintained separately from the Quality Assurance Manual in the following collection (which is itself, a controlled laboratory document):

23.7.1(A) **QCDOC 006** records (and the majority of laboratory documentation, unless otherwise specified) shall be maintained for at least five (5) years, and may require periodic review.

QC File 00 48— "QCDOC 006: Control of Records " (in Section 23)

24.0 Technical Requirements: Reporting the Results

24.1 Purpose and Scope—This section defines the proper use of significant figures and defines the analysis report format in use at the Laboratory. This section also explains the need for data validation and the methods of data validation that will be employed by the Laboratory.

24.2 Significant Figures

24.2.1 To avoid ambiguity in reporting results, the Laboratory customarily reports only those digits expected to be known definitely, except the last digit, which may be in doubt. Reports, in general, should contain only such digits as are justified by the accuracy of the work.

24.2.2 Rounding should occur by dropping digits that are not significant. If the digit 5, 6, 7, 8 or 9 is dropped, the preceding digit should be increased by one. If the digit 0, 1, 2, 3, or 4 is dropped, then the preceding digit should not be altered.

24.3 Analytical Report

24.3.1 Analysis Report Format —All reports of analytical data issued by the Laboratory should, at a minimum, include the following primary elements:

24.3.1(A) Title of the Report (example: “Laboratory Results”);

24.3.1(B) Name and address of laboratory; and contact person with phone number of laboratory;

24.3.1(C) Unique identifier (e.g. Batch I.D.);

24.3.1(D) Pages identified as a number of the total report pages;

24.3.1(E) Date Reported;

24.3.1(F) Name and address of client and project name, if applicable;

24.3.1(G) Laboratory assigned sample number, and client identification code or name of sample;

24.3.1(H) Exceptions to sample acceptance requirements and sample integrity issues;

24.3.1(I) Date of receipt of sample, date of sample collection (if available);

24.3.1(J) Date sample analysis was performed and time of sample analysis (i.e. for tests with holding times of 48 hours of less);

24.3.1(K) QC results and flags denoting QC that fails to meet acceptance criteria. The effected sample (those associated with flagged QC) shall also be clearly marked and a description of the relevant data qualifier(s) shall be included on the report;

24.3.1(L) Test method used (where available);

24.3.1(M) Deviations from, additions to, or exclusions from the test method;

24.3.1(N) Results with reporting units;

24.3.1(O) A signature and title of the person accepting responsibility for the content of the report, and date of issue; and

(a) Reports must contain the signature of an "Approved Signatory". The List of Approved Signatories (and their backups) for the various Analytical Groups throughout the Laboratory is contained in the **Approved Signatories** record for full details.. The QAO* also maintains a list of material signatures for all Approved Signatories.

24.3.1(P) Identification of all test data provided by outside sources (subcontracted labs).

24.3.2 Peer Review — Prior to release of data to customer the chemist should have their report peer reviewed. In some groups, the use of historical data for verification of analytical results is an acceptable alternative.

24.3.2(A) Peer review should follow the samples in the report from sample log-in, bench sheets, preparation logs, as well as analytical results. Peer review should also include a review of the **data integrity and QC validation** as detailed in **Section 24.4.3**. Generated data should be compared to reported data to catch transcription and transposition errors made by manual data entry into the LIMS.

24.3.2(B) A copy of these reports along with any accompanying information shall be maintained as part of the laboratory's permanent records.

24.3.2(C) The Industrial Hygiene Analytical Group (IHAG) of the Dolan Chemical Laboratory maintains a data review process that begins with sample receipt and extends through the report process. This data review process shall be an independent review, conducted by a qualified individual other than the analyst. For all industrial hygiene analyses, this peer review is to be conducted by a chemist assigned responsibility for industrial hygiene analyses. This peer review is to be conducted by a chemist other than the directly responsible analyst.

(a) The IHAG review is documented using a peer review checklist sticker which is affixed to every report folder. When a rush sample occurs and samples are sent without a prior review, samples can be marked "for information only" to allow time for the report to be reviewed by another analysts and the final report submitted. In the absence of another industrial hygiene-assigned chemist, the QAO* (or designee) is responsible for this peer review.

(b) All reports issued are reviewed by the Industrial Hygiene Analytical Group are reviewed by laboratory management. This review is used to establish the amounts and specific types of analyses being performed.

(i) In addition, all reports are reviewed by the QAO* (or designee) quality assurance and/or data validation. This general review includes specific reviews of report format, report distribution, report form designation and title, analysis number designation and sample identification, and validation of the reported data.

(ii) The validation review includes a review for the appropriate significant figures, the use of the appropriate detection limit (if appropriate), and whether the performed analysis was appropriate for the original analysis request.

(iii) All reviews by laboratory management and the QAO* are documented by initialing the reports in the upper right corner of the report.

(iv) The reviewed reports are filed in the appropriate sample information envelope. This envelope is filed in the laboratory supervisor current year files. Sample information for previous years is stored in the Record Storage Room (Room 220).

24.3.2(D) Current practice is for this data review to occur (See Section 24.4), covering all aspects beginning at sample receipt and extending through the report process. This will generally encompass the review of available information provided and retained in the sample information packet. After review of the packet and all contained information, the chemist should mark acceptance of the packet with a PR followed by their initials and date. This review information should be place on the front left bottom of the packet/envelope.

24.3.3 Issuance of Analytical Report (and Amendments)— After issuance of the report, the laboratory report shall remain unchanged.

24.3.3(A) Material amendments to a test report after issue shall be made only in the form of a further document, or data transfer including the statement such as "**Amended Analysis Report**" or "**Reissued Report**"

24.3.3(B) Such amendments shall meet all the relevant requirements of this manual.

24.3.3(C) The laboratory shall notify clients promptly, in writing, of any event (i.e. identification of defective measuring or test equipment) that casts doubt on the validity of results given in any test report or amendment to a report. This notification must be sent within one week past the completion of the investigation. (Same statement in Section 7.2.3)

24.3.4 Confidentiality — All analytical data shall be deemed the property of the client and the Laboratory and as such access is limited to members of the Environmental Staff and the Client or those designated by the client.

24.3.5 Delivery of Analytical Report— Reports are routinely delivered to customers electronically. Other methods can be used at the customer's request, however, the customer assumes the responsibility for confidentiality of these requests.

24.3.5(A) All faxed reports will include a coversheet stating the confidential nature of the report (See **Document 01-09**).

24.3.6 Other elements may be necessary to ensure a responsible report. These elements may include the identity of the test method(s) used or any deviations from the method necessitated by the sample condition or analysis. Additional elements may also be included as desired or required.

24.3.7 If any situation and/or condition exits or occurs that could be expect to affect materially the reliability of any reported result, then laboratory comments and observations relating to this situation and/or condition should be included on the final report.

24.4 Data Validation

24.4.1 Data validation is the process by which data are checked and accepted or rejected based on a set of established criteria. This involves a critical review of a body of data to identify spurious values or outlying observations. The review may be only a quick scan to detect extreme values or a detailed evaluation requiring the use of a computer. In either situation, when a spurious value is located, it is not immediately rejected. Each questionable value or anomaly must be checked for validity. Records of values judged to be invalid or otherwise doubtful will be retained, if appropriate. These records become a useful resource of information for judging data quality.

24.4.2 Data validation is accomplished by several methods. The validation process is manual and/or computerized.

24.4.2(A) Data validation is the process by which data are checked and accepted or rejected based on a set of criteria. Validation is performed to isolate spurious values when such values are not automatically rejected. Records of invalid data found will be retained in accordance with established records retention policies.

24.4.2(B) Validation methods will include review by the primary chemists and Laboratory management. Criteria will depend upon the types of data and on the purpose of the measurement. A two step data review system is used to detect erroneous data entries. In addition to the analyst reviewing the data while entering it into the LIMS, a Chemist reviews the data and approves it in the LIMS, then another Chemist reviews the data when a report is issued.

24.4.2(C) Various statistical techniques are useful. Periodic checking of manually reduced data is imperative.

24.4.3 Data Integrity and QC Validation

24.4.3(A) Each analyst is responsible for determining that the results of each analytical determination have all the associated QC measurements and that the acceptance criteria are met and documented according to protocol. Prior to reporting the results, each primary chemist shall verify that all the associated QC measurements were performed and that the acceptance criteria were met and documented according to protocol.

(a) The analyst is responsible for checking calculations, completing sample preparation, calibration, analysis and instrument logs, and completing all internal custody documentation.

(b) The data verification procedures consist of all the QC validations and calculations checks discussed above.

(c) In addition, soundness of all data is evaluated by the nature of the sample, the inter-relationship among the parameters and the historical values, etc.

(d) Any discrepancy or inconsistency will initiate a recheck of data or reanalysis of the sample(s).

24.4.3(B) The QAO* (or designee) is responsible for **periodic data integrity monitoring** as stated in Section 2.3.4(B)(d). This monitoring must be documented and may be accomplished through review of Data Audit packages; periodic verification of records and documentation associated with the analytical report; or inspection of various laboratory vulnerabilities listed in the Laboratory Ethics and Data Integrity Procedure SOP.

24.4.4 Data Validation – Manual

24.4.4(A) Both technicians and laboratory chemists will inspect daily and weekly results for questionable values. This kind of inspection is most useful for the detection of extreme values or outliers appearing as unusually high or low data points. The criteria for determining extreme values are derived from prior data obtained from similar tests or analytical work. The data used to determine extremes may be the minimum and maximum data points for all prior data from similar tests or analysis. The time spent on checking data that have been manually reduced by technicians depends on the time available and in the demonstrated ability of the technicians.

24.4.5 Data Validation – Computerized Techniques

24.4.5(A) As possible and necessary, the computer will be used not only to store and retrieve data, but also to validate data. Currently this is limited to the accumulation and evaluation of quality control checks (i.e. quality control reference samples, sample spikes, and sample duplicates). This process will be used to determine control limits. These control limits will be used as part of the data validation process. Another indication of spurious data is a large difference in concentrations reported in two successive periods. The difference in concentration that might be considered excessive may vary from one analyte to another and quite possibly may vary from one sample source to another for the same analyte.

24.5 Analysis Report Packets (Reserved)

24.6 Documentation — Controlled quality documents from this Section shall be maintained separately from the Quality Assurance Manual in the following collection (which is itself, a controlled laboratory document):

24.6.1(A) **QCDOC 006** records (and the majority of laboratory documentation, unless otherwise specified) shall be maintained for at least five (5) years, and may require periodic review.

QC File 00 49— "QCDOC 006: Control of Records " (in Section 24)

Appendix A: Chemical Hygiene and Hazard Communication Plan

A.1 The current version of the Chemical Hygiene and Hazard Communication Plan (referred to commonly as the "**CHP**" is **Revision 2, effective date 05/15/2008.** This document is the responsibility of the Chemical Hygiene Officer (**CHO**) and is available to all laboratory employees on the AEP shared intranet.

B.0 Appendix B: Subpart P: Glossary of Definitions and Purposes

Glossary of Definitions and Purposes (Rev 4, 09/15/12)

1.1 The definitions and purposes below are specific to this method, but have been conformed to common usage as much as possible.

1.2 **Abbreviations and Acronyms—**including units of weight and measure and abbreviations.

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AB	accrediting body
ACGIH	American Conference of Governmental Industrial Hygienists
ACS	Analytical Chemistry Services, or American Chemical Society
ADP	analytical data package
AEP	American Electric Power
AG	analytical group
AIHA	American Industrial Hygiene Association
amp	ampere
amu	atomic mass unit
APHA	American Public Health Association
AR	analytical reagent (grade)
ASTM	American Society for Testing and Materials
avg	average
AWWA	American Water Works Association

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BAPAT	Bulk Asbestos Proficiency Analytical Testing
BG	background
BOD	biochemical / biological oxygen demand
bp	boiling point
BTU, Btu	British thermal unit

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^{o}C	degree Celsius
CA	corrective action
CAA	Clean Air Act
CAL	calibration standard
CAR	corrective action report
CASRN	Chemical Abstracts Service Registry Number
CCB	continuing calibration blank
CCS	calibration check standard

CCV	continuing calibration verification
CDC	Centers for Disease Control and Prevention
CDOC	continued demonstration of capability
CEM	continuous emission monitoring
CERCLA	Comprehensive Environmental Response Compensation and Liability Act
CFC	chlorofluorocarbons
CFR	Code of Federal Regulations
CHO	Chemical Hygiene Officer
CHP	Chemical Hygiene and Hazard Communication Plan
CI	confidence interval
CLP	contract laboratory program
cm	centimeter
cm^3	cubic centimeter
CNS	central nervous system
COD	chemical oxygen demand
conc	concentrated/concentration
CPAR	corrective and preventative action report
CRM	certified reference material
CV	coefficient of variation
Cr(VI)	hexavalent chromium
CWA	Clean Water Act

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day	(do not abbreviate)
DBP	disinfection by-product
DCL	Dolan Chemical Laboratory
dia	diameter
DMR-QA	Discharge Monitoring Report (Quality Assurance)
DO	dissolved oxygen
DOC	demonstration of capability
	dissolved organic carbon
DQO	data quality objectives
dupe	duplicate

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ECD	electron capture detector
EDOC	equivalency demonstration of capability
ELLAP	Environmental Lead Laboratory Accreditation Program
ELPAT	Environmental Lead Proficiency Analytical Testing
EMMC	Environmental Monitoring Methods Council
EMSL-Cincinnati	Environmental Monitoring Systems Laboratory in Cincinnati

EPA	Environmental Protection Agency
Eq.	equation (only when followed by a numeral)
ETV	Environmental Technology Verification (program)
EX	to deliver (for glassware)

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^oF	degree Fahrenheit
FAAS	flame atomic absorption spectroscopy
FDA	Food and Drug Administration
FG	flue gas (analytical group)
FID	flame ionization detector
FIFRA	Federal Insecticide, Fungicide and Rodenticide Act
Fig.	figure (only when followed by a numeral)
FoT	field of testing
fp	freezing point
FPD	flame photometric detector
FR	Federal Register
ft	foot

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>	greater than
g	gram
GAC	granular activated carbon
gal	gallon
GC	gas chromatograph/chromatography
GC/MS	gas chromatography/mass spectrometry
GFAA	graphite furnace atomic absorption spectroscopy
g/L	grams per liter
GPC	gel permeation chromatograph/ chromatography
gpl	grams per liter

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h	hour
[H+]	hydrogen ion concentration (negative logarithm of pH)
HEPA	highly efficient particulate air (filter)
HPLC	high performance liquid chromatograph/chromatography
HRGC	high resolution GC
HRMS	high resolution MS
HWSB	hazardous waste storage building

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IARC	International Agency for Research on Cancer
IC	ion chromatography
	inorganic carbon
ICB	initial calibration blank
ICP	inductively coupled plasma
ICP-AES	inductively coupled plasma-atomic emission spectroscopy
ICP-MS	inductively coupled plasma-mass spectrometry /spectroscopy
ICP-OES	inductively coupled plasma-optical emission spectroscopy
ICRE	ignitability, corrosivity, reactivity, extraction
ICS	interference check standard
ICV	initial calibration verification
ID	inside diameter
IDL	instrument detection limit
IDLH	immediate danger to life and health
IDOC	initial demonstration of capability
IEC	interelement correction
IH	industrial hygiene (analytical group)
IHLAP	Industrial Hygiene Laboratory Accreditation Program
IHPAT	Industrial Hygiene Proficiency Analytical Testing
IMIS	Integrated Management Information System
	(an OSHA classification)
IN	to contain (for glassware)
inch	(do not abbreviate within text)
IPR	initial precision and recovery
IR	infra-red
ISE	ion selective electrode
ISO	International Organization for Standardization

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k-	kilo- (prefix)
K	degree Kelvin
K-D	Kuderna-Danish (concentrator)
kg	kilogram

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<	less than
L	liter
lb	pound
LC	liquid chromatography
LCL	lower control limit
LCS	laboratory control standard

LDR	linear dynamic range
LFB	laboratory fortified blank
LFM	laboratory fortified (sample) matrix
LIMS	laboratory information management system
LOD	limit of detection
log	logarithm (common)
$\log_e$ or ln	logarithm (natural)
LOQ	limit of quantitation
LRB	laboratory reagent blank
LWL	lower warning limit

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m	meter
m-	milli- (prefix)
m- (italicized)	meta
M	molar/ molarity, or molecular ion
M-	mega- (prefix)
m^3	cubic meter *(air volume equivalent to 1000 L)*
max	maximum
MBAS	methylene-blue-active substances
MCL	maximum contaminant level
MCLG	maximum contaminant level goal
MDL	method detection limit
MDN	modified decimal numbering
ME	marginal exceedance
meq	milli-equivalent
mg	milligram
mg/g	milligram per gram
mg/L	milligram per Liter
mg/m^3	milligram per cubic meter
mg/mL	milligram per milliliter
min	minimum
min	minute
mL	milliliter
ML	minimum level (of quantitation)
mm	millimeter
mm Hg	millimeter of mercury (pressure)
mol	mole
molal	(do not abbreviate)
month	(do not abbreviate)
mp	melting point
MPN	most probable number

ms	millisecond
MS	matrix spike, or mass spectrometer/spectrometry
MSD	matrix spike duplicate
MSDS	material safety data sheet
mV	millivolt
m/z	mass to charge ratio
u-	*micro- (prefix)*
ug	*microgram*
ug /L	*microgram per Liter*
uL	*microliter*
um	*micrometer*

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n-	nano- (prefix)
N	normal / normality
NCTR	National Center for Toxicological Research
NELAC	National Environmental Laboratory Accreditation Conference
NELAP	National Environmental Laboratory Accreditation Program
ng	nanogram
ng/L	nanogram per liter
NIEHS	National Institute of Environmental Health Sciences
NIH	National Institutes of Health
NIOSH	National Institute of Occupational Safety and Health
NIST	National Institute of Standards and Technology
NLLAP	National Lead Laboratory Accreditation Program
nm	nanometer
No.	number (only when followed by a numeral)
NMI	National Metrology Institute
NPDES	National Pollutant Discharge Elimination System
NPOC	non-purgeable organic carbon
NTIS	National Technical Information Service
NTP	National Toxicology Program
NVLAP	National Voluntary Laboratory Accreditation Program

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o-(italicized)	ortho
OD	outside diameter
"OOC"	"out of control"
OPR	ongoing precision and recovery
ORP	oxidation-reduction potential
OSHA	Occupational Safety & Health Administration

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/	per (when used in expressions with unit symbols)
%	percent
#	pound
lb	pound
p- (italicized)	para
p-	pico- (prefix)
p. or pg.	page (when used in expressions with unit symbols)
PAC	powdered activated carbon
PAH	polynuclear aromatic hydrocarbons
PAR	precision and recovery (standard)
PAR-i	insoluble PAR standard
PAR-s	soluble PAR standard
PAT	proficiency analytical testing
PB	performance-based (method)
PCB	polychlorinated biphenyl
.pdf (file)	portable document format
PEL	permissible exposure limit
pg	picogram
PLM	polarized light microscopy
PM	preventative maintenance, or particulate matter
POC	purgeable organic carbon
pp.	pages (when used in expressions with unit symbols)
ppb	part per billion
PPE	personal protective equipment
ppm	part per million
ppq	part per quadrillion
ppt	part per trillion
PQL	practical quantitation limit
PS	plant services (analytical group)
psig	pounds-per-square inch gauge
PT	proficiency testing
PTFE	polytetrafluoroethylene
PtOC	particulate organic carbon
Pub.	publication
PVC	polyvinyl chloride

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QA	quality assurance
QA / QC	quality assurance/ quality control
QC	quality control
QCS	quality control sample

qt	quart

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RCF	relative centrifugal force
RCRA	Resource Conservation and Recovery Act
Ref.	reference (only when followed by a numeral)
REL	recommended exposure limit
rep	replicate
RF	response factor
RL	report limit
RM	reference method
RO	reverse osmosis
RPD, rpd	relative percent difference
rpm	revolutions per minute
RR	relative response
RSD	relative standard deviation

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s	second
SARA	Superfund Amendments and Reauthorization Act
SCL	Shreveport Chemical Laboratory
SCR	selective catalytic reduction
SDS	Soxhlet/Dean-Stark (extractor)
SDWA	Safe Drinking Water Act
SI	Le Systeme of International d Units
SICP	selected ion current profile
SMCL	secondary maximum contaminant levels
S/N	signal-to-noise ratio
SOP	standard operating procedure
SPE	solid phase extraction
sp gr	specific gravity
SRM	standard reference material
STEL	short term exposure limit
SWDA	Solid Waste Disposal Act

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TBD	to be determined
TC	to contain (for glassware)
	total carbon
TCLP	toxicity characteristic leachate procedure
TD	to deliver (for glassware)
TDS	total dissolved solids

TIC	tentatively identified compound
TLV	threshold limit value
TOC	total organic carbon
TS	total solids
TSCA	Toxic Substances Control Act
TSS	total suspended solids
TWA	time-weighted average

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UCL	upper control limit
US EPA	United States Environmental Protection Agency
UV-VIS	ultra violet-visible
UWL	upper warning limit

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V	volt
Vol.	volume (of a publication) (only when followed by a numeral)
v/v	volume per unit volume

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W	watt
WET	whole effluent toxicity (test)
WHO	World Health Organization
w/v	weight per unit volume
w/w	weight per unit weight
WW	water and wastewater (analytical group)

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XRD	x-ray diffraction
XRF	x-ray fluorescence

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year	(do not abbreviate)

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ZHE	Zero Headspace Extractor

1.3 Other Federal Laws and their acronyms

AHERA	Asbestos Hazard Emergency Response Act (1986)
ASHAA	Asbestos School Hazard Abatement Act (1984)
ASHDCA	Asbestos School Hazard Detection and Control Act (1980)
CAA	Clean Air Act (1955, 1963)
CERCLA	Comprehensive Environmental Response Compensation & Liability Act (1980)
CWA	Clean Water Act (1948, 1972, 1990) (aka Federal Water Pollution Control Act)
CZMA	Coastal Zone Management Act (1972)
EPCRKA	Emergency Planning and Community Right to Know Act (1986)
ESA	Endangered Species Act (1973)
FFDCA	Federal Food, Drug, and Cosmetic Act (1938)
FIFRA	Federal Insecticide, Fungicide and Rodenticide Act (1947, 1972)
FWPCA	Federal Water Pollution Control Act (1948) (aka Clean Water Act, CWA)
HMTA	Hazardous Materials Transportation Act (1975)
IRAA	Indoor Radon Abatement Act (1988)
LBPPA	Lead-Based Paint Poisoning Act (1971)
LCCA	Lead Contamination Control Act (1988)
MPRSA	Marine Protection, Research, and Sanctuaries Act (1972)
MWTA	Medical Waste Tracking Act (1988)
NEEA	National Environmental Education Act (1990)
NEPA	National Environmental Policy Act (1970)
NWPA	Nuclear Waste Policy Act (1982)
ODA	Ocean Dumping Act (1972)
ODBA	Ocean Dumping Ban Act (1988)
PPPA	Pollution Prevention Packaging Act (1970)
RCRA	Resource Conservation and Recovery Act (1976)
RRA	Resource Recovery Act (1970)
SARA	Superfund Amendments and Reauthorization Act (1986)
SDWA	Safe Drinking Water Act (1974)
SECDA	Shoreline Erosion Control Demonstration Act (1974)
SEPA	Shoreline Erosion Protection Act (1965)
SMCRA	Surface Mining Control and Reclamation Act (1977)
SPA	Shore Protection Act (1988)
SWDA	Solid Waste Disposal Act (1965)
TSCA	Toxic Substances Control Act (1976)
UMTRCA	Uranium Mill-Tailings Radiation Control Act (1978)

A

1.4 absorbance: A measure of the decrease in incident light passing into a detector. Absorbance (A) is defined mathematically as $A = - \log (I/I_o)$, where I is the radiation intensity of a sample and I_o is the radiation intensity of a blank.

1.5 accuracy: A measure of the closeness of an individual measurement or the average of measurements to the true value which includes the combination of the bias (systematic error) and precision (random error) from an analytical procedure. Accuracy may be reported as a percent recovery (%) for a single measurement and may include a precision component for data sets.

1.6 ACS reagent grade: See reagent grade.

1.7 adsorbate: The material being removed by the adsorption process.

1.8 adsorbent: The material (i.e. activated carbon) that is responsible for removing the undesirable substance in the adsorption process.

1.9 adsorption: The retention of atoms, ions, or molecules on the surface of another substance; also, the adhesion of molecules of gas, liquid, or dissolved solids to a surface. (e.g. Removal of a pollutant from air or water by collecting the pollutant on the surface of a solid material.)

1.10 aliquot: A measured portion of a sample taken for analysis. One or more aliquots make up a sample.

1.11 ambient: Environmental or surrounding conditions.

1.12 amenable cyanide — The fraction of cyanide in a sample that can be easily treated by oxidizing with chlorine or sodium hypochlorite (i.e. chlorination treatment). Amenable cyanide is also referred to as "free cyanide".

1.13 American Conference of Governmental Industrial Hygienists (ACGIH): ACGIH is an organization which recommends upper limits (called TLV or threshold limit values) for exposure to workplace chemicals.

1.14 analyte: The element, ion, or compound (or group of compounds) of interest that an analytical process seeks to qualitatively identify (i.e. confirm presence or absence) and/or quantify (i.e. determined concentration). Also referred to as the target analyte.

1.15 analytical batch: During analysis of a preparation batch, a group of no more than 10 field samples is designated as an analytical batch. The analytical batch may include an initial calibration check standard and an end calibration check standard (and associated calibration blanks). Within an analytical batch, for every group of ten field samples, at least one laboratory duplicate or a duplicate of the laboratory fortified matrix may be analyzed. When more than 10 samples are analyzed, a continuing calibration standard (and calibration blank) may be analyzed after every tenth analysis. See also "batch".

1.16 analytical data package (ADP): Submission of all relevant analytical methodology, technical information, and quality assurance results concerning a particular type of analysis for which there is no current proficiency testing (PT) program and in lieu of PT results. [Reference 18.4.17]

1.17 analytical reagent (AR) grade: See reagent grade.

1.18 asphyxiant: A chemical (gas or vapor) that can cause death or unconsciousness by suffocation. Simple asphyxiants such as nitrogen, either use up or displace oxygen in air. They become especially dangerous in confined or enclosed spaces. Chemical asphyxiants, such as carbon monoxide and hydrogen sulfide, interfere with the body's ability to absorb or transport oxygen to the tissues.

1.19 assay: A test for a particular chemical or effect.

1.20 authorization date: The authorization date is the date when the responsible parties (i.e. management, etc.) sign and approve the issuance (or revision) of a quality document.

1.21 authorized analyst: An analyst who has completed the required training, demonstrated proficiency, and received formal authorization by laboratory management to perform analytical testing (and reporting) on client samples. Authorized analysts are required to maintain their continued proficiency.

B

1.22 background: The concentration of a substance in media that occurs naturally or is not the result of human activities. In the instance of laboratory fortified matrices (LFM), background concentration is the concentration of target analyte present in the sample(s) prior to spiking and is determined by analysis of an unspiked aliquot of sample.

1.23 backup- 1) A backup analyst may perform the duties of the qualified personnel. Backup analysts must maintain the same qualifications as the primary analyst (e.g. DOC, training, etc.).
2) Other personnel may be formally approved as backups for other duties (e.g. backup for approved signatories, backup for laboratory management, etc.
3) Backup also refers to the process of securing information, especially electronic information.
See also "designee".

1.24 batch: A group of samples which behave similarly with respect to the sampling or the testing procedures being employed and which are processed as a unit are defined as a batch. See also preparation batch or analytical batch.

1.25 bias: A consistent deviation, causing errors in one direction, of the measured value from the true value caused by systematic errors in a procedure or in the matrix.

1.26 bioaccumulation/biomagnification: A process where chemicals are retained in fatty body tissue and increase in concentration over time. Biomagnification is the increase of tissue accumulation in species higher in the natural food chain as contaminated food species are eaten.

1.27 bioassay: An evaluation using organisms to measure the effect of a substance, factor, or condition, by comparing before and after data.

1.28 biochemical/biological oxygen demand (BOD): An indirect measure of the concentration of biologically degradable material present in organic wastes or the measure of the oxygen required to break down organic materials in water. Higher organic loads require larger amounts of oxygen and may reduce the amount of oxygen available for fish and aquatic life below acceptable levels. Large amounts of organic waste use up large amounts of dissolved oxygen, thus a greater BOD is associated with a greater degree of pollution.

1.29 blank: An aliquot of analyte-free media which is carried through part or all of the analytical scheme. Blanks can further be characterized, as necessary, to determine source and level of contamination from successive steps in an analytical process. Blanks provide negative control of method performance and function to characterize (i.e. identify and quantify) contamination acquired during the affected processing steps or due to glassware cleanliness and/or reagent deterioration.
See also calibration blank, equipment blank, field blank, laboratory reagent blank (LRB), method blank, reagent blank, trip blank.

1.30 blank spike recovery: See laboratory fortified blank (LFB).

1.31 blind recounts: For quality assurance purposes, a designated percentage of samples slide are re-labeled by a person other than the original counter. These re-labeled slides are then recounted (unknowingly) by the original counter and the results are statistically analyzed. Differences will be observed between the first and second counts of the same filter slide. Most of these differences will be due to chance alone, that is, due to the random variability (precision) of the count method. Statistical recount criteria enables one to decide whether observed differences can be explained due to chance alone or are probably due to systematic differences between analysts, microscopes, or other biasing factors.

1.32 borosilicate glass (class A): The quality of glassware required for analytical testing which is often inappropriately referred to by trademark names such as "Pyrex" or "Kimax". Class "A" glassware is guaranteed to comply with volumetric tolerances prescribed in ASTM E694 (and subsequent revisions). True volumetric glassware should not be "blown-out" (as is commonly done in graduated, serological type pipettes), but should utilize the touch-off method (i.e. two seconds after free flow stops). It should also be noted when glassware is marked "TC" or "IN" for "To Contain" or "TD" or "EX "for "To Deliver".

1.33 bottom ash: Ash that collects at the bottom of a combustion chamber. That is, the non-airborne combustion residue from burning pulverized coal in a boiler; the material which falls to the bottom of the boiler and is removed mechanically; or a concentration of non-combustible materials, which may include toxics.

1.34 brackish: Mixed fresh and salt waters.

1.35 buffer: A solution or liquid whose chemical makeup is such that it minimizes changes in pH when acids or bases are added to it.

C

1.36 calibration blank—An aliquot of analyte-free media, containing all of the calibration reagents except the calibration standard, and that is used as the lowest standard for the calibration curve. The calibration blank may also utilized for calibration verification as the initial calibration blank (ICB) and continuing calibration blanks (CCB).

1.37 calibration curve: A curve established through the measurement and correlation of an appropriate number of standards (minimum of two) and a calibration blank to meet all calibration requirements as needed. The calibration curve should correlate the concentration of the calibration standards to the instrument response of the target analyte. The curve is used to define the linearity, linear dynamic range (LDR), and the analyte sensitivity (represented by the method detection limit, MDL) and, with the requirement of a minimum correlation coefficient (linearity) of 0.995, provides assurance for the data generated.

See also standard curve.

1.38 calibration standard(s): A set of an appropriate number of standards that contain known and verified amount of target analyte which are analyzed to generate a calibration curve or standard instrument response factors. The calibration standards should be prepared from separate aliquots of the calibration working stock standard and should contain all reagents. The lowest standard, referred to as the calibration blank, contains no calibration working standard.

1.39 calibration stock standard: A concentrated standard, prepared from a NIST-traceable source, or a source that will attest to the purity and authenticity of the material, that contains a known and verified amount of target analyte.

1.40 calibration verification: A series of processes used to determine the state of calibration of an instrument between periodic recalibrations, to check for calibration curve drift, and to assure the accuracy of the calibration curve and its subsequent generated data results. This is achieved using calibration blanks, the initial calibration verification (ICV) and continuing calibration verification (CCV) standards, and verification of the lowest standard (at the ML/RL level).

1.41 calibration working standard: A master solution that contains a known and verified amount of target analyte, which is used to prepare the calibration standards. The calibration working standard should be prepared from the calibration stock standard.

1.42 carcinogenic: Causing or contributing to the production of cancer in humans or animals.
See also select carcinogen.

1.43 catalyst: A substance that changes the speed or yield of a chemical reaction without being consumed or chemically changed by the chemical reaction.

1.44 CCB: See continuing calibration blank.

1.45 CCV: See continuing calibration verification.

1.46 CDOC: See continued demonstration of capability.

1.47 centrifugation: Separation of particles from a suspension in a centrifuge. By suspending and balancing tubes at opposite ends of rapidly rotating arms about a central point, the suspended particles in a sample are forced outwards and collected at the bottom.

1.48 centrifuge: A mechanical device that uses centrifugal or rotational forces to separate solids from liquids.

1.49 certified reference material (CRM): A type of laboratory control standard (LCS) which is media that contains known and verified concentrations of target analyte(s), and is certified by an outside agency. NIST standards are to be used when they are available. CRM should be in solution or in a homogeneous matrix and may be used to document the bias of the analytical process.
See also reference material.

1.50 CFR: See Code of Federal Regulations.

1.51 chemical oxygen demand (COD): An indirect measure of the amount of oxygen used by inorganic and organic matter in water, which is based on a chemical oxidant and therefore does not necessarily correlate with biochemical oxygen demand. COD is a measure of the oxygen-consuming capacity of inorganic and organic matter present in water or wastewater or specifically, the amount of oxygen consumed from a chemical oxidant in a specific test.

1.52 chemisorption: The process of chemical adsorption.

1.53 chlorinated hydrocarbons: Compounds consisting of chlorine substituted hydrocarbon molecules that may be saturated, unsaturated, or aromatic compounds. These include industrial solvents, pesticides, and PCBs, which can pose a substantial or potential threat to public health if allowed to contaminate sediments, soils, or surface water or are not properly disposed of. These compounds linger in the environment and accumulate in the food chain. Among the insecticides, include DDT, aldrin, dieldrin, heptachlor, chlordane, lindane, endrin, mirex, and toxaphene.

1.54 chlorofluorocarbons (CFC): Family of anthropogenic compounds including chlorofluorcarbons (CFCs), bromofluorcarbons (halons), methyl chloroform, carbon tetrachloride, methyl bromide, and hydrochlorofluorcarbons (HCFCs) that have been used in great quantities in industry, for refrigeration and air conditioning, and in consumer products. These compounds can deplete the ozone layer when they slowly rise into the stratosphere, are broken down by strong ultraviolet radiation, release chlorine atoms, and then react with ozone molecules. The most ozone-depleting of these compounds are being phased out under the Montreal Protocol; and the Clean Air Act includes provisions for reducing releases (emissions) and eliminating production and use of these chemicals.

1.55 chromatography: A method of separating and analyzing mixtures of chemical substances by selective adsorption in a column of powder or on a strip of paper. The analysis of chemical substances is achieved as the various components of the substance move through the adsorbent at different rates of speed according to their degree of attraction.

1.56 Clean Air Act (CAA): The 1963 federal law (after amending the 1955 law) that gives EPA authority to set standards for air quality and to control the release of airborne chemicals from industries, power plants, and cars. Amendments in 1970 and 1990 have molded the national air pollution control and regulate air emissions from area, stationary, and mobile sources. CAA limits the emission of pollutants into the atmosphere in order to protect human health and the environment from the effects of airborne pollution.

1.57 Clean Water Act (CWA): The 1972 federal law (formerly referred to as the Federal Water Pollution Control Act from 1948 or Federal Water Pollution Control Act Amendments), that sets the basic structure for regulating discharges of pollutants to surface waters of the United States. CWA imposes contaminant limitations or guidelines for all discharges of wastewater into the nation's waterways and controls the discharge of pollutants into surface water in a number of ways, including discharge permits.

1.58 Code of Federal Regulations (CFR): A periodic publication of the regulations established by United States law that codifies all rules of the executive departments and agencies of the federal government. It is divided into fifty volumes, known as titles. Title 40 of the CFR (referenced as 40 CFR) lists all environmental regulations, as enforced by the EPA.

1.59 codification: The process by which final regulations are incorporated into the CFR, which is published annually. Codification is the process of collecting and arranging systematically, usually by subject, the laws of a state or country, or the rules and regulations covering a particular area or subject of law or practice.

1.60 coefficient of variation: See relative standard deviation (RSD).

1.61 colorimetric: Any technique by which an unknown color is evaluated in terms of standard colors; the technique may be visual, photoelectric, or indirect by means of spectrophotometry.

1.62 combustible: A substance that will burn. For example a liquid, as defined by the U.S. Department of Transportation and the National Fire Protection Association, as having a flash point at or above 100^{o}C (37.8^{o}F). Combustible liquids do not ignite as easily as flammable liquids, but can be ignited under certain circumstances, and must be handled with caution. Some "ordinary combustibles" include wood, paper, etc.

1.63 composite sample: A collection of individual samples obtained at regular intervals, usually every one or two hours during a 24-hour time span. Each individual sample is combined with the others in proportion to the rate of flow when the sample was collected and the resulting mixture forms a representative sample to be analyzed to determine the average conditions during the sampling period.

1.63.1 Combination of individual samples obtained at regular intervals over a time period. Either the volume of each individual sample is proportional to discharge flow rates or the sampling interval (for constant volume samples) is proportional to the flow rates over the time period used to produce the composite. The maximum time period between individual samples shall be two hours. [WVDEP definition]

1.64 Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA): The federal law enacted in 1980 that established prohibitions and requirements concerning closed and abandoned hazardous waste sites; provided for liability of persons responsible for releases of hazardous waste at these sites; and established a trust fund to provide for cleanup when no responsible party could be identified. This act is commonly known as "Superfund" and was amended in 1986 by Superfund Amendments and Reauthorization Act (SARA).

1.65 concentration: The amount of solute in a given amount of solvent or solution expressed as a weight/weight or weight/volume relationship. The conversion from a weight relationship to one of volume incorporates density as a factor, but for dilute aqueous solutions, the density of the solvent is approximately equal to the density of the solution. Thus, aqueous concentrations expressed in milligrams per liter (mg/L) are approximately equal to parts per million (ppm); those expressed in micrograms per liter (ug/L) are approximately equal to parts per billion (ppb). In addition, concentration can be expressed in terms of molarity, normality, molality, and mole fraction.

1.66 constant weight: Constant weight refers to repeated drying steps until two consecutive weights agree within a specified precision.

1.67 constituent: An essential part or component of a system or group or an ingredient of a chemical mixture (e.g. benzene is one constituent of gasoline).

1.68 continued demonstration of capability (CDOC): The process through which a laboratory or analyst validates that results generated continue to be of acceptable accuracy and precision. This CDOC must be achieved on a periodic basis (e.g. annually) in order to validate the performance of the analyst.

1.69 continuing calibration blank (CCB): An aliquot of calibration blank analyzed periodically throughout an analytical sequence (e.g. every ten analyses) and at the end of the analytical sequence to verify the ongoing validity of the calibration curve.

1.69.1 A portion of analyte-free media, containing all of the calibration reagents except the calibration standard, (i.e. calibration blank) analyzed at least every ten samples throughout the analytical sequence and at the end of the analytical sequence. The CCB is analyzed in conjunction with (and after) the CCV as calibration verification that analyte does not carry-over between measurements.

1.70 continuing calibration verification (CCV): An additionally prepared aliquot of the calibration stock analyzed periodically throughout an analytical sequence (e.g. every ten analyses) and at the end of the analytical sequence to verify the ongoing validity of the calibration curve. The concentration of the CCV should be near the mid-level of the calibration curve. The CCV may also be fulfilled by analyzing one of the calibration standards as an unknown.

1.71 contract Laboratory (Re: DMR-QA): A laboratory contracted by a Permittee to provide some or all of the routine testing listed on the permit. Contract laboratories can only be used for DMR-QA testing if the contract laboratory is the entity that routinely performs the Permittee's testing. If an in-house laboratory performs the routine testing, the in-house laboratory must complete the DMR-QA testing. If a Permittee uses a contract laboratory, it is the responsibility of the contract laboratory to provide the Permittee with their final graded results within the time frame specified.

1.72 control sample: A QC sample introduced into a process to monitor the performance of the system.

1.73 corrosive: A substance, as defined by the U.S. Department of Transportation, as causing visible destruction or permanent changes in human skin tissue at the site of contact, or is highly corrosive to steel and other structural materials. Generally, a substance that has a very low or a very high pH.

1.74 critical supplies: Critical supplies are materials that may affect the quality or magnitude of the analytical results. Examples of critical supplies are reagents used in the test procedure, media which comes in contact with test samples (i.e. filters, tubing, etc.), and method-specific laboratory-ware (i.e. sterilized vessels, trace-cleaned containers, etc.).

1.75 CRM: See certified reference material.

1.76 Cr(VI): See hexavalent chromium.

1.77 CV: See coefficient of variation.

D

1.78 data quality: The degree of acceptability or utility of data for a particular purpose – in this case, reporting public drinking water sample information.

1.79 data quality objectives (DQO): A statement of the overall level of uncertainty that a decision-maker is willing to accept in results derived from environmental data. This is qualitatively distinct from quality measurements such as precision, bias, and detection limit.

1.80 data validation: The process of evaluating the available data against the project DQOs (data quality objectives) to make sure that the objectives are met. Data validation may be very rigorous, or cursory, depending on project DQOs. The available data reviewed will include analytical results, field QC data, laboratory QC data, and may also include field records.

1.81 decontamination: The process of reducing or eliminating the presence of harmful substances, such as infectious agents, to reduce the likelihood of disease transmission from those substances. Removal of harmful substances such as noxious chemicals, harmful bacteria or other organisms, or radioactive material from exposed individuals, rooms and furnishings in buildings, or the exterior environment.

1.82 desiccator: A closed container into which heated weighing or drying dishes, samples, or dried samples are placed to cool in a dry environment. Desiccators contain a substance, such as anhydrous calcium chloride, which absorbs moisture and keeps the relative humidity near zero so that the dish or sample will not gain weight from absorbed moisture.

1.83 designee- The person authorized to act, make decisions and perform the duties for another employee.
See also "backup".

1.84 digestion: The biochemical decomposition of organic matter, resulting in partial gasification, liquefaction, and mineralization of pollutants.

1.85 diluent: Any liquid or solid material used to dilute or carry an active ingredient.

1.86 dilution: The addition of some quantity of less concentrated liquid (e.g. water) that results in a decrease in the original concentration.

1.87 Discharge Monitoring Report -Quality Assurance (DMR-QA): Quality Assurance study that helps regulatory agencies monitor the quality of the data used by laboratories to ensure the safety of our nation's waters. According to Section 308 (a) of the Clean Water Act, this study is mandatory. See also "DMR-QA"

1.88 disinfection by-product (DBP): A chemical byproduct of the disinfection process which is formed by the reaction of a disinfectant (e.g. chlorine) with organic material in the water supply.

1.89 dissolved organic carbon (DOC): DOC refers to organic carbon remaining in a sample after filtering the sample, typically using a 0.45 micron filter.

1.90 DMR-QA: See Discharge Monitoring Report - Quality Assurance.

1.91 DQO: See data quality objectives.

1.92 dry-weight: The weight of the sample, excluding the weight of the water in the sample. Prior to chemical analysis the water may be removed by any reproducible method that does not alter the target analyte (e.g. air drying at ambient temperature, filtration, decantation, heating at low temperature followed by cooling in the presence of a desiccant, etc.). Analytical procedures may also calculate the dry weight concentration by adjusting for moisture content.

1.93 dupe: See duplicate.

1.94 duplicate: A second replicate is referred to as a duplicate and is a second aliquot, test, sample, organism, concentration, or exposure chamber that is treated the same as the original sample in order to determine the precision of the analytical method. Duplicate samples are analyzed by subjecting separate sample aliquots through the entire analytical process, according to the full procedure. Duplicate samples are used to assess variance of the total method, including sampling and analysis; to determine the effect of the sample matrix on the precision of the results; and may be used to provide sample-specific control of method performance by evaluating the applicability and dependability of the method to the specific sample matrix. An intra-laboratory split sample may also be used to document the precision of a method in a given sample matrix.
See also aliquot, field duplicate, laboratory duplicate, matrix duplicate (MD), matrix spike duplicate (MSD), replicate.

E

1.95 EDOC: See equivalency demonstration of capability.

1.96 effective date: The effective date is a set date when the quality document (and any changes there within) shall take effect. The effective date is set such that enough time shall have passed since issuance, to notify, train, and /or document the understanding of affected personnel.

1.97 element: A substance which cannot be separated into its constituent parts and still retain its chemical identity. There are 92 naturally occurring elements of the 116 known elements, where the others have been made in laboratories or are unstable products of natural decay. Elements serve as the basic building blocks of all matter and the combination of two or more forms compounds that make up most of the world's matter.

1.98 emulsion: A stable dispersion of one liquid in a second immiscible liquid.

1.99 Environmental Protection Agency (EPA): EPA is the federal agency responsible for regulating environmental hazards.

1.100 equipment blank: A sample of analyte-free media which is exposed solely to a specific set of equipment in the analytical process (e.g. sampling equipment, filtration steps, etc.), which is used to document contamination attributable to specific portions of the analytical process.

1.101 equivalency demonstration of capability (EDOC): The process through which a modification is validated under specific conditions, as an acceptable alternative to the original performance-based (PB) or reference method. This process ensures the modified method generates results equal or superior in accuracy and precision to those from the original method.

1.102 ethics: A code of right and wrong which dictates personal and professional conduct.

F

1.103 Federal Insecticide, Fungicide and Rodenticide Act (FIFRA): A 1972 federal law (after amending the 1947 law) that requires labels on pesticides that provide clear directions for safe use; authorizes EPA to set standards to control how pesticides are used; and provides procedures for the registration of pesticide products to control their introduction into the marketplace.

1.104 Federal Register (FR): A list of government proposals of regulation created to enforce an act or law, which is open to members of public for consideration.

1.105 field blank*:* An aliquot of analyte-free media taken from the laboratory or in the field, and treated as a sample in all respects, including exposure to sampling site conditions, storage, preservation, and all analytical procedures. The purpose of the field blank is to provide information about contaminants that may be introduced during sample collection, storage, and transport. This blank is used to document contamination attributable to the entire sampling process, as well as the analytical scheme.

1.105.1 For industrial hygiene air samples, a sample of analyte-free media which is transported to the sampling site, transferred to a sample container in the field, (exposed to the same equipment and operations as a sample at the sampling site), and treated as a sample in all respects, including contact with the sampling devices and exposure to sampling site conditions, storage, and all analytical procedures. The field blank is used to demonstrate that the sample has not been contaminated by the sampling, sample transport systems, or the environment; and is used to document contamination attributable to the entire sampling process, as well as the analytical scheme.

1.106 field duplicates/replicates: Independent samples which are collected as close as possible to the same point in space and time. These samples are taken from the same source, stored in separate containers, and analyzed independently and the results are used to document the precision of the sampling process.

1.107 field matrix spike: A spiked sample (i.e. similar to a laboratory fortified matrix, LFM) prepared at the sampling point (i.e. in the field) by adding a known amount of the target analyte to a specified amount of the sample. Field matrix spikes are used, for example, to determine the effect of the sample preservation, shipment, storage, and preparation on analyte recovery efficiency and analytical bias.

1.108 field of testing (FoT) – Defining a parameter as the combination of the parameter with a specific technology, instrumentation, or process for analysis and measurement.

1.109 field sample: Samples collected for analysis.

1.110 field spike: See field matrix spike.

1.111 field split samples: Two or more representative portions taken from the same sample and submitted for independent analysis. Two or more aliquots sent to different laboratories may be used to estimate inter-laboratory precision and two or more aliquots submitted to the same laboratory may be used to estimate intra-laboratory precision.

1.112 flammable: A substance that will ignite and burn rapidly under normal ambient conditions. For example a liquid, as defined by the U.S. Department of Transportation and the National Fire Protection Association, as having a flash point below 100^{o}C (37.8^{o}F); or a gas that, at an ambient temperature and pressure, forms a flammable mixture with air at a concentration of 13 percent by volume or less, or a range of flammable mixtures with air wider that 12 percent by volume regardless of the lower limit; or a solid that is liable to cause a fire through friction, absorption of moisture, spontaneous chemical change, or retained heat from manufacturing or processing, which can be ignited readily and burns so vigorously and persistently that it creates a serious hazard.

1.113 flash point: The lowest temperature at which evaporation of a substance produces sufficient vapor to form an ignitable mixture with air.

1.114 fluoropolymer: The generic term to refer to chemically resistant fluorinated plastic substances which are preferred for their inertness and thermal stability in laboratory operations. "Teflon" is the trademarked name for one such compound.

1.115 fly ash: Finely divided particles of ash that are entrained in flue gases resulting from the combustion of fuel or other material. These particles of ash may contain incompletely burned fuel, other pollutants, and attached metals that are carried up the stack of a combustion unit with gases during combustion. This ash is carried out of the furnace by the gas stream and collected by mechanical precipitators, electrostatic precipitators, and/or fabric filters. Economizer ash is included when it is collected with fly ash.

1.116 FoT: See field of testing.

1.117 FR: See Federal Register.

1.118 fraud: An intentional act of deceit performed for personal gain or to damage another individual; and may result in legal prosecution.

G

1.119 gas chromatography: A separation technique involving passage of a gaseous moving phase through a column containing a fixed phase; it is used principally as a quantitative analytical technique for volatile and semi-volatile organic compounds.

1.120 grab sample: A single sample collected at a particular time and place that represents the composition of the water, air, or soil (i.e. the matrix) only at that time and place, regardless of time or flow (e.g. a discrete volume of water collected, by hand or machine, during one short sampling period).

1.121 gravimetric: A means of measuring unknown concentrations of water quality indicators in a sample by weighing a precipitate or residue of the sample.

1.122 guidelines: Information and suggested actions for particular circumstances.

H

1.123 half-life The time required for a pollutant to lose one-half of its original concentration (e.g. the biochemical half-life of DDT in the environment is 15 years), the time required for half of the atoms of a radioactive element to undergo self-transmutation or decay (e.g. the radioactive half-life of radium is 1620 years), or the time required for the elimination of half a total dose from the body.

1.124 halo-acetic acids (five): The sum of the concentrations in milligrams per liter of the haloacetic acid compounds (monochloroacetic acid, dichloroacetic acid, trichloroacetic acid, monobromoacetic acid, and dibromoacetic acid), rounded to two significant figures after summation.

1.125 halocarbons: Chemicals consisting of carbon, sometimes hydrogen, and halogen atoms (i.e. chlorine, fluorine, bromine, or iodine).

1.126 halogenated compound: A substance containing halogen atoms (i.e. chlorine, fluorine, bromine, or iodine).

1.127 halon: Bromine-containing compounds, also known as bromofluorocarbons, that contain bromine, fluorine, and carbon and have long atmospheric lifetimes whose breakdown in the stratosphere causes depletion of ozone. Halons are used in firefighting.

1.128 hard water: Alkaline water containing dissolved salts and dissolved minerals (e.g. calcium, iron, and magnesium), which may interfere with some industrial processes, prevents soap from lathering, and in the presence of some pesticide chemicals, will curdle or settle out. Water may be considered hard if it has a hardness value greater than the typical hardness of water from the region, although some textbooks define hard water as water with a hardness of more than 100 mg/L as calcium carbonate.

1.129 hardness: A characteristic of water caused mainly by the salts of calcium and magnesium (e.g. bicarbonate, carbonate, sulfate, chloride, and nitrate). Excessive hardness in water is undesirable because it causes the formation of soap curds, increases the use of soap, increases deposition of scale in boilers, causes damage in some industrial processes, and sometimes causes objectionable tastes in drinking water.

1.130 heavy metal: Metallic elements with a high density (e.g., mercury, chromium, cadmium, arsenic, and lead) that tend to be toxic at low concentrations, can bio-accumulate, and do not degrade over time.

1.131 hexavalent chromium, Cr(VI): A group of chemical substances that contain the metallic element chromium in its positive-6 valence (hexavalent) state.

1.132 high-efficiency particulate air filter (HEPA): A filtering system capable of trapping and retaining at least 99.97 percent of airborne particles 0.3 microns in diameter or larger.

1.133 holding time: The maximum amount of time a sample may be stored after collection and preservation without significantly effecting the accuracy of the analysis. The maximum holding time is dependent upon the matrix used and the specific analyte of interest. 40 CFR Part 136 lists the maximum times that water samples may be held before analysis and the analysis remain legally valid per EPA protocol. Some samples may not be stable for this maximum time, thus if knowledge exists to show that this is necessary to maintain sample stability, the laboratory is obligated to hold the sample for a shorter time,

I

1.134 ICB: See initial calibration blank.

1.135 ICS: See interference check standard.

1.136 ICV: See initial calibration verification.

1.137 IDL: See instrument detection limit.

1.138 IDOC: See initial demonstration of capability.

1.139 IEC: See interelement correction.

1.140 ignitable: A solid, liquid, or compressed gas that has a flash point less than 140^{o}C.

1.141 impurity: A chemical substance which is unintentionally present with another chemical substance or mixture.

1.142 inappropriate procedure: A scientifically unsound or technically unjustified omission, manipulation, or alteration of procedures or data that bypasses the required quality control parameters, making the results appear acceptable.

1.143 "in control": An analytical system is deemed to be "in control" when each QC element in the analytical batch has performed within the specifications of the procedure or within the laboratory-generated acceptance criteria.

1.144 in-house Laboratory (Re: DMR-QA): A laboratory that is part of the Permittee's organization. The in-house laboratory must be used to test DMR-QA samples if it routinely tests the normal samples as required by the permit.

1.145 initial calibration blank (ICB): An aliquot of calibration blank analyzed immediately after the calibration curve has been generated, to verify its validity.

1.145.1 A portion of analyte-free media, containing all of the calibration reagents except the calibration standard, (i.e. calibration blank) analyzed immediately following the generation of the calibration curve. The ICB is analyzed in conjunction with (and after) the ICV as calibration verification that analyte does not carry-over between measurements.

1.146 independent calibration verification (ICV): A standard prepared independent of calibration standards that is analyzed immediately after the calibration curve has been generated, to verify its validity. When available, the ICV should be prepared from a NIST-traceable, secondary manufacturer (i.e. "Second Source", separate source from the calibration standards) to verify the accuracy of the calibration standards and the resulting calibration curve and should be near the mid-level of the calibration curve.

1.147 initial demonstration of capability (IDOC): The process through which a laboratory or analyst validates that results generated using the method are of acceptable accuracy and precision. This IDOC must be achieved prior to the analysis of samples.

1.148 initial precision and recovery (IPR): The IPR test (i.e. the set of standards to be analyzed) is performed the first time a method is used; any time the method or instrumentation is modified; and periodically (e.g. annually); and is part of the initial demonstration of capability (IDOC). The IPR requires the analysis of a set number of aliquots of the diluted precision and recovery (PAR) standard to establish the ability to generate acceptable precision and accuracy and to provide positive control of method performance.

1.149 inorganic carbon (IC) – IC (sometimes referred to as total inorganic carbon, TIC) is comprised of carbonate, bicarbonate, and dissolved carbon dioxide (CO2); a material derived from non-living sources. IC may be further divided into a particulate and a dissolved fraction.

1.150 instrument detection limit (IDL): The instrument detection limit refers to the constituent concentration that produces a signal greater than five times the signal/noise ratio of the instrument. This is similar, in many respects, to "critical level" and "criterion of detection." The latter limit is stated as 1.645 times the standard deviation (s) of the reagent blank analyses.

1.150.1 The concentration equivalent to the analyte signal which is equal to three times the standard deviation of a series of 10 replicate measurements of the calibration blank signal at the same wavelength.

1.151 interelement correction (IEC) standard / factor: A type of interference check standard (ICS) used in ICP analysis to check for spectral interferences where elements may overlap. An IEC correction factor is then utilized in subsequent quantifications that calculates and removes contributions from interfering elements to the overall concentration.

1.152 interference check standard (ICS): An analytical standard that is used to verify an accurate analyte response in the presence of possible interfering materials present in samples. A standard that contains a known concentration of analyte and other compounds or elements that may interfere with the analysis. This standard should be analyzed at least once after the calibration curve has been run to verify the performance of the curve in the presence of other elements, to assure the selectivity of the method towards the target analyte, and to identify and account for known and unknown interferences present in the matrix that may affect the quality of the analytical results. The ICS should be a NIST-traceable secondary source standard, separate from the calibration standards, if possible.

1.153 internal standard (IS): A pure compound added to a sample extract just before instrumental analysis to permit evaluation and/or correction for inefficiencies in the analytical system. Internal standards should have similar chemical characteristics to the compounds of interest, but are not normally found in the environment or do not interfere with the compounds of interest. The concentration of a compound in a sample is based on the response of the internal standard in the sample relative to the response of the compound and internal standard in the calibration standard.

1.153.1 Pure analyte(s) added to a sample, extract, or standard solution in known amount(s) and used to measure the relative response of other method analytes that are components of the same sample or solution. The internal standard must be an analyte that is not a sample component.

1.154 International Agency for Research on Cancer (IARC): IARC is a scientific group that classifies chemicals according to their cancer-causing potential.

1.155 ion exchange: The process in which ions are exchanged between a solution and an insoluble solid, usually in a resin.

1.156 ionizing potential (IP): The energy required to ionize a particular molecule.

1.157 IPR: See initial precision and recovery.

1.158 issue date: The issue date is the date when the quality document was originally issued or when changes were finalized (i.e. see revision date).

J

1.159 jelly roll: Self explanatory.

K

1.160 Kimax (trademark): See borosilicate glass.

L

1.161 laboratory control standard (LCS): A standard that contains a known and verified concentration of target analyte that may be used to measure the bias in a procedure. The LCS provides positive control of method performance, and is used to quantify the bias and accuracy achieved by the method. Laboratory fortified blanks (LFB) and certified reference materials (CRM) are both types of LCS. LCS may be utilized as PAR standards (that will be made into initial precision and recovery, IPR and ongoing precision and recovery, OPR, standards), as laboratory fortified matrices (LFM), and even as quality control standards (QCS).

1.162 laboratory duplicate – Two sample aliquots, taken in the laboratory from a single sample bottle, and analyzed separately with identical procedures. Analysis of laboratory duplicates indicates precision associated specifically with the laboratory procedures.

1.163 laboratory fortified blank (LFB): A type of laboratory control standard (LCS) in which a known and verified concentration of target analyte(s) is added to an aliquot of analyte-free (blank) media. This spiked media is then carried through the entire analytical scheme and the accuracy is calculated as the percent spike recovery.

1.163.1 An aliquot of reagent water or other blank matrices to which known quantities of the method analytes are added in the laboratory. The LFB is analyzed exactly like a sample and its purpose is to determine whether the methodology is in control. Analysis of the LFB indicates accuracy and precision associated with the analytical procedure.

1.164 laboratory fortified matrix (LFM): An aliquot of a sample to which known and verified quantities of the target analytes are added in the laboratory and which is then carried through the entire analytical scheme exactly like a field sample. The LFM provides positive and sample-specific control of method performance and is used to demonstrate recovery, to evaluate method accuracy and precision, to evaluate applicability and dependability; and to monitor and quantify interferences caused by the sample matrix through bias and imprecision. The background concentrations of the analytes in the sample matrix must be determined in a separate aliquot and the measured values corrected for these background concentrations. More specifically, LFM include matrix spike (MS) and matrix spike duplicate (MSD) samples.
See also matrix spike (MS), matrix spike duplicate (MSD), surrogate spike.

1.165 laboratory fraud: The deliberate falsification of analytical and quality assurance results, where failed method and contractual requirements are made to appear acceptable during reporting.

1.166 laboratory integrity: The laboratory's meeting general standards of objectivity, data quality, and ethical behavior, thus reporting accurate, complete, and valid information.

1.167 laboratory reagent blank (LRB): An aliquot of reagent water or analyte-free media that is treated exactly as a sample, according to the full procedure, including exposure to all glassware, equipment, solvents, reagents, internal standards, and surrogates that are used with samples. LRB are used to provide negative control of method performance, to demonstrate freedom from contamination, and to characterize contamination (i.e. both target analytes and interferences) due to the entire laboratory environment — glassware cleanliness, apparatus used, reagent quality, reagent deterioration, etc.

1.167.1 An aliquot of reagent water or other blank matrices that are treated and analyzed exactly as a sample, including exposure to all glassware, equipment, reagents, etc. The LRB is used to determine if method analytes or other interferences are present in the laboratory environment, the reagents or the apparatus. The LRB is a measure of contamination present during analysis of samples.

1.168 LCL: See lower control limit.

1.169 LCS: See laboratory control standard.

1.170 LDR: See linear dynamic range.

1.171 leachate: Liquid that has percolated through solid waste or other media (e.g. landfills, pesticides, fertilizers) and has extracted dissolved or suspended materials from it. Leaching may occur in farming areas, feedlots, and landfills, and may result in hazardous substances entering surface water, ground water, or soil.

1.172 linear dynamic range (LDR): The concentration range over which the analytical curve remains linear and where quality data is produced. The calibration curve is deemed linear by maintaining at least 0.995 correlation coefficient and should be enclosed between the lowest calibration standard (i.e. at the minimum level (ML) of quantitation) and the highest calibration standard at the upper limit.

1.173 linearity: The degree by which a set of data (e.g. calibration curve) correlates to a simple linear regression. A linearity of at least 0.995 correlation coefficient is required for validated linear calibration curves.

1.174 LFB: See laboratory fortified blank.

1.175 LFM: See laboratory fortified matrix.

1.176 limit of detection (LOD): Instead of using the NELAC term, limit of detection (LOD), the laboratory uses the term, method detection limit (MDL). See method detection limit (MDL).

1.177 limit of quantitation (LOQ): Instead of using the NELAC term, limit of quantitation (LOQ), the laboratory uses the term, minimum level (ML) of quantitation. See minimum level (ML) of quantitation.

1.178 LOD: See limit of detection.

1.179 LOQ: See limit of quantitation.

1.180 lower control limit (LCL): Lower limit at negative three (3) standard deviation units, used to determine if an analytical system is "in control".

1.181 lower warning limit (LWL): Lower limit at negative two (2) standard deviation units, used to monitor the quality of QC results of an analytical system.

1.182 LRB: See laboratory reagent blank.

1.183 LWL: See lower warning limit.

M

1.184 material safety data sheet (MSDS): A compilation of information required under the OSHA Communication Standard on the identity of hazardous chemicals, health and physical hazards, exposure limits, and precautions; including its physical properties, hazards to personnel, fire and explosion potential, safe handling recommendations, health effects, fire fighting techniques, reactivity, and proper disposal. The Superfund Amendments and Reauthorization Act (SARA) requires facilities to submit MSDSs under certain circumstances. MSDS are prepared by manufacturers and marketers of products containing toxic chemicals.

1.185 matrix (pl., matrices): This sub-category of media, is the component or substrate which surrounds and contains the analyte of interest. This may include the environmental component (e.g. surface water, drinking water, soil, etc.),the sampling medium (e.g. air filter, sampling cartridge, etc.), and the reagents added (i.e. to release, to stabilize, etc.) the analyte of interest.

1.186 matrix duplicate (MD): See also duplicate.

1.187 matrix spike (MS): A laboratory fortified matrix (LFM), in which an aliquot of a sample is spiked prior to sample preparation with known and verified quantities of the target analytes and is then carried through the entire analytical scheme exactly like a field sample. The accuracy is calculated as percent spike recovery (which has been background corrected, for the amount present in the sample). A matrix spike is used to document the bias of a method in a given sample matrix.

1.188 matrix spike duplicate (MSD): A second aliquot of laboratory fortified matrix (LFM) that is spiked prior to sample preparation in order to determine the precision of the method. The intra-laboratory precision is calculated as relative percent difference (RPD) between the two LFM analyzed.

1.189 may: This action, activity, or procedural step is neither required nor prohibited.

1.190 may not: This action, activity, or procedural step is prohibited.

1.191 MDL: See method detection limit.

1.192 mean: The arithmetic average of a set of data, calculated as the sum of all results divided by the number of results, which measures the central tendency of a frequency distribution. The mean should be reported at one significant figure more than the data used to calculate them.

1.193 media: The component or substrate which contains and transmits the analyte of interest. This may include the environmental matrix (e.g. surface water, drinking water, soil, etc.) or the sampling type (e.g. air filters, sampling cartridges, etc.).

1.194 media blank: See reagent blank.

1.195 method blank: See laboratory reagent blank (LRB). For industrial hygiene, see also reagent blank.

1.196 method-defined analyte: An analyte without a specific, known composition where the analytical result depends totally on the measurement procedure. Method-defined analytes are not chemically distinct (e.g. “oil and grease", and "chemical oxygen demand"), and thus do not have a specific Chemical Abstracts Service Registry Number (CASRN). These analytes are often identified by the identification number taken from EPA's Environmental Monitoring Method Index codes.

1.197 method detection limit (MDL): The minimum concentration of a substance that can be measured and reported with a 99 percent confidence that the analyte concentration is greater than zero (i.e. 99% probability that it is different from the blank) which is determined from the analysis of a sample in a given matrix containing the target analyte. The MDL represents approximately 2.5 to 5.0 times the signal-to-noise (S/N) ratio, or about 3 standard deviations of the instrument precision. MDL is analogous to "limit of detection" (LOD).—— The Laboratory method for determining MDL is derived directly from 40 CFR, Part 136, Appendix B, and is given in full in **Document 18-01** of the QA Manual.

1.198 method limit: See minimum level of quantitation (ML).

1.199 method of standard additions (MSA): The quantitative technique of adding a known amount of a target analyte to a sample immediately prior to analysis, which is used to evaluate and overcome interferences.

1.200 minimum level of quantitation (ML): The lowest level (concentration) at which the entire analytical system must give a recognizable signal and thus, the lowest acceptable calibration point for the analyte. ML is the minimum concentration of an analyte or category of analytes in a specific matrix that can be identified and quantified above the method detection limit within specified limits of precision and bias during routine analytical operating conditions. The ML represents approximately ten standard deviations of the instrument precision. The ML is set equal to the report limit (RL) and may be used as the concentration of the lowest calibration standard, assuming that all method-specified sample weights, volumes, and cleanup procedures have been employed. ML is often referred to as method limit or minimum limit of quantitation and is analogous to the term "limit of quantitation" (LOQ).——The DCL method for determining ML is derived directly from EPA's "Definition and Procedure for the Determination of the Minimum Level of Quantitation (ML)- Proposed Rule, March 2003" and is given in full in **Document 18-02** of the QA Manual.
See also level of quantitation (LOQ).

1.201 mistake: An unintentional act that, although acceptable, was not committed with the intent to deceive. A mistake is an error in action, calculation, opinion, or judgment caused by poor reasoning, carelessness, insufficient knowledge.

1.202 ML: See minimum level of quantitation.

1.203 Montreal Protocol: An international agreement reached in 1988 by over thirty countries, aimed at protecting the ozone layer by controlling the emissions of chlorofluorocarbons (CFCs) and halons. It provides for the end of production of ozone-depleting substances, the continuation of various research groups to assess the ozone layer, and the promotion of developing nations to make the transition to ozone-safe technologies. In the United States, the Protocol is implemented under the rubric of the Clean Air Act Amendments of 1990.

1.204 MS: See matrix spike.

1.205 MSA: See method of standard additions.

1.206 MSD: See matrix spike duplicate.

1.207 must: This action, activity, or procedural step is required.

1.208 mutagenic: Causing the genetic characteristics of an organism to change in such a way that future generations are permanently affected.

N

1.209 National Institute of Occupational Safety and Health (NIOSH): NIOSH is a federal agency that is part of the Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services. NIOSH tests equipment and conducts research; evaluates and approves respirators; conducts studies of workplaces standards; and proposes standards and makes recommendations to OSHA for the prevention of work-related injury and illness.

1.210 National Institute of Standards and Technology (NIST): NIST is a non-regulatory federal agency within the U.S. Commerce Department's Technology Administration whose mission is to promote U.S. innovation and industrial competitiveness by advancing measurement science, standards, and technology in ways that enhance economic security and improve our quality of life.

1.211 National Metrology Institute (NMI): An NMI is an institute designated by national decision to develop and maintain national measurement standards for one or more quantities. Some countries have a single organisation as the NMI (e.g. NIST, the National Institute of Standards and Technology, is the NMI of the USA), whereas other countries have a more distributed system. In the UK there are four laboratories which make up the NMI (the four NMS laboratories). NPL is main UK NMI laboratory and maintains the majority of the measurement standards in the UK. In addition LGC maintains some of the chemical and biochemical standards; NEL maintains standards of flow; and NMOis responsible for managing and developing the National Measurement System and is also responsible for legal metrology.

1.212 National Pollutant Discharge Elimination System (NPDES): As authorized by the Clean Water Act, the NPDES permit program controls water pollution by regulating point sources that discharge pollutants into waters of the United States. Point sources are discrete conveyances such as pipes or man-made ditches. Individual homes that are connected to a municipal system, use a septic system, or do not have a surface discharge do not need an NPDES permit; however, industrial, municipal, and other facilities must obtain permits if their discharges go directly to surface waters.

1.213 National Toxicology Program (NTP): NTP is an inter-agency program whose mission is to evaluate agents of public health concern by developing and applying tools of modern toxicology and molecular biology with special emphasis panels for independent scientific peer review and advice on targeted issues. The three agencies that form the core of the NTP are National Institute of Environmental Health Sciences (NIEHS) of the National Institutes of Health (NIH); National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC); and National Center for Toxicological Research (NCTR) of the Food and Drug Administration (FDA). The NTP publishes the biennial "Report on Carcinogens", which is an informational scientific and public health document first ordered by Congress in 1978 that identifies and discusses agents, substances, mixtures, or exposure circumstances that may pose a hazard to human health by virtue of their carcinogenicity.

1.214 neurotoxic: Adversely changing the structure or function of the nervous system following exposure to a chemical agent.

1.215 non-amenable cyanide — The fraction of cyanide in a sample that cannot be treated by chlorination. Non-amenable cyanide is also referred to as "complexed cyanide".

1.216 non-authentic data: The intentional or accidental reporting of incorrect data.

1.217 non-critical supplies: Non-critical supplies are materials that have no affect the analytical results. Examples of non-critical supplies are re-usable laboratory-ware (i.e. properly cleaned, of the appropriate level of accuracy and precision, etc.), general laboratory supplies (i.e. paper towels, spatulas, etc.), and general office supplies (i.e. laboratory notebooks, etc.).

1.218 non-purgeable organic carbon (NPOC) – NPOC is the organic carbon remaining in an acidified sample after purging the sample with gas. NPOC is commonly referred to as TOC. NPOC may be further divided into a particulate and a dissolved fraction.

1.219 NPDES: See National Pollutant Discharge Elimination System .

O

1.220 Occupational Safety & Health Administration (OSHA): OSHA is a federal agency in the U.S. Department of Labor that is responsible for creating and enforcing workplace safety and health regulations.

1.221 oncogenic: Causing or tending to cause the formation and development of tumors.

1.222 ongoing precision and recovery (OPR): The OPR test is performed with every analytical batch by subjecting an aliquot of a precision and recovery (PAR) standard through the entire analytical process, according to the full procedure. Each analytical batch must contain an acceptable OPR to generate acceptable precision and accuracy, demonstrate the analytical system is in control, quantify the accuracy and bias of the method, and to provide positive control of method performance.

1.223 "OOC": See "out of control".

1.224 OPR: See ongoing precision and recovery.

1.225 organic-free reagent water: Organic-free reagent water can be generated by passing tap water through a carbon filter bed containing about one pound of activated carbon or using a water purification system to generate organic-free deionized water. Organic-free reagent water may also be prepared by boiling water for fifteen (15) minutes) and, subsequently, while maintaining the temperature at 90^{o}C, bubbling a contaminant-free inert gas through the water for one hour.

1.225.1 For semivolatiles and nonvolatiles, all references to water in the methods refer to water in which an interferant is not observed at the method detection limit of the compounds of interest.

1.226 "out of control" ("OOC"): An analytical system is deemed to be "out of control" ("OOC") when one or more QC element in the analytical batch have not performed within the specifications of the procedure or within the laboratory-generated acceptance criteria.

1.227 oxidant: A substance containing oxygen that reacts chemically with other materials to produce new substances. Oxidants are the primary ingredients in smog.

1.228 oxidation: A chemical reaction that results in the addition of oxygen, the removal of hydrogen, or the loss of electrons from an element or compound. Oxidation using (aerobic) bacterial and chemical means may be used to break down organic wastes and pollutants (e.g. destruction of chemicals such as cyanides, phenols, and organic sulfur compounds in sewage) to produce more stable substances.

1.229 oxidizer: A material that causes the ignition of combustible materials without an external source of ignition. When mixed with combustible materials, an oxidizer increases the rate of burning. Oxidizers are usually unstable or reactive and can evolve oxygen, therefore supporting combustion in an oxygen-free atmosphere.

P

1.230 PAR: See precision and recovery standard.

1.231 PAT: See proficiency analytical testing.

1.232 particulate organic carbon (PtOC) – PtOC refers to the carbon in particulate form that is too large to pass through a filter (typically using a 0.45 micrometer filter). PtOC is also called suspended organic carbon.

1.233 performance evaluation samples (PES): PES are reference samples provided to a laboratory for the purpose of demonstrating that the laboratory can successfully analyze the sample within a set of specified performance limits and whose true value of the concentration of the reference material is unknown to the laboratory at the time of the analysis.

1.234 permanent record: For the purposes of this manual, permanent records are information that is kept for no less than five (5) years.

1.235 policy: Direction or position to guide present and future actions.

1.236 post-digestion spikes (PDS): A type of laboratory fortified matrix (LFM) in which the sample spike has not been processed through the entire analytical process and may be utilized to isolate steps in the method and evaluated accuracy and precision within portions of the procedure. As with the LFM, this QC element consists of an aliquot of sample matrix with known and verified amounts of target analyte added to the sample matrix; however, the PDS is spiked after digestion and/or preparation steps to isolate differing portions of the procedure.

1.237 polytetrafluoroethylene: One form of inert fluoropolymer coating. See also PTFE.

1.238 PQL: See also practical quantitation limit.

1.239 practical quantitation limit (PQL): The lowest concentration that can be reliably achieved within specified limits of precision and accuracy during routine laboratory operating conditions. The PQL is generally three to ten times the MDL. However, it may be nominally chosen within these guidelines to simplify data reporting. The PQL analyte concentration is selected as the lowest non-zero standard in the calibration curve. Sample PQLs are highly matrix-dependent. The PQLs in Test Methods for Evaluating Solid Waste SW-846 are provided for guidance and may not always be achievable. PQL is analogous to the term "limit of quantitation" (LOQ).

1.240 precision: A measure of the degree of agreement, without assumption of knowledge of the true value, among replicate analyses of a sample caused by random error. Precision may be expressed as standard deviation, relative standard deviation (RSD), coefficient of variation (CV), or relative percent difference (RPD).
See also reproducibility.

1.241 precision and recovery standard (PAR): A secondary standard that is diluted and spiked to be use as the initial precision and recovery, IPR and ongoing precision and recovery, OPR, standards, and possibly as laboratory fortified matrices (LFM). The PAR standard contains a known quantity of target analyte and is required to be a NIST-traceable secondary source standard, obtained from a source separate and independent from the calibration standards. The PAR standard may be a laboratory control standard (LCS), or, if necessary, performance evaluation samples (PES). The PAR may also be designated, PAR-i, for insoluble and, PAR-s, for soluble forms of the standard.

1.242 preparation batch: A set of samples, plus QC elements, processed at the same time with the same lots of reagents, which validates the integrity of the analytical system and the results of the samples within that batch. Each preparation batch must be accompanied by a successful laboratory reagent blank (LRB) and a successful pair of laboratory fortified blanks (LFB) and may require a successful pair of laboratory fortified matrix (LFM) or sample duplicate (dupe); resulting in a minimum of six analyses (1 sample, 1 LRB, 2 LFB, and 2 LFM/dupe). If greater than **the set number of** samples is to be analyzed at one time, the samples must be separated into multiple preparation batches. Samples in each batch should be of similar composition. (Preparation batches may be in sets of ten or twenty, or another set number, depending on the procedure). See also "batch".

1.242.1 A group of no more than 20 field samples and associated QC samples. (Field sample analyses include only those samples derived from sampling shipments. These include the initial and duplicate field samples submitted). The preparation batch must include a laboratory reagent blank and a pair of laboratory fortified blanks.

1.243 primary: The primary employee (e.g. primary chemist, primary analyst, primary signatory, etc.) has received the formal authorization to perform the defined duties and is considered the foremost person given specific responsibilities.

1.244 procedure: Step-by-step instructions, conducted in a sequence, required to accomplish a task.

1.245 proficiency analytical testing (PAT): A solution or sample whose concentration is unknown to the laboratory and are submitted by an external body for an inter-laboratory study. Results are compared to other laboratories results to generate statistically derived limits and to define the competency of the laboratory to perform the method.

1.246 proficiency testing (PT): See proficiency analytical testing (PAT).

1.247 PT: See proficiency testing.

1.248 PTFE (polytetrafluoroethylene) – Inert fluoropolymer material (e.g. "Teflon ®") with fundamental properties (i.e. non-reactive, low friction, and high melting points). See polytetrafluoroethylene.

1.249 purge and trap: Analytical technique and device used to isolate purgeable (i.e. volatile) organics by stripping the compounds from water or soil with a stream of inert gas, trapping the compounds on an adsorbent such as a porous polymer trap, and thermally desorbing the trapped compounds into a gas chromatographic (GC) column.

1.250 purgeable organic carbon (POC): POC is the organic carbon that has been removed from a neutral or acidified sample by purging with an inert gas. These are the same compounds referred to as Volatile Organic Compounds (VOC) and usually determined by Purge and Trap Gas Chromatography.

1.251 PVC filter: Polyvinyl chloride air filter.

1.252 Pyrex (trademark): See borosilicate glass.

Q

1.253 QA/QC: See quality assurance/quality control.

1.254 quality assurance/quality control (QA/QC): In the laboratory, QA/QC activities are typically applied by technical personnel and may include the use of control samples during sample collection, handling, and analysis; activities such as data review and data validation; as well as the implementation of protocols designed to assure that the final sampling or analytical results are reliable. QA/QC is an overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the end user (i.e. customer). QA/QC are implemented to document and control the quality of a product, an outcome, or a service; and to provide routine application of procedures, operational techniques, and activities for attaining prescribed levels of performance.

1.255 quality control standard (QCS): A solution of method analytes of known concentration obtained from a source different than the calibration standard. This solution is used to check the laboratory performance with externally prepared test materials and is used to prepare the ICV for this procedure.

R

1.256 radioactive tracer: A radioactive isotope which, when injected into a biological or physical system, can be traced by radiation detection devices, permitting determination of the distribution or location of the substance to which it is attached.

1.257 radioelement: An element that is naturally radioactive.

1.258 radioisotope: Chemical variants of radioactive elements with potentially oncogenic, teratogenic, and mutagenic effects on the human body.

1.259 radionuclide: An unstable form of a chemical element, both man-made and naturally-occurring, that radioactively decays, resulting in the emission of nuclear radiation. Prolonged exposure to radionuclides increases the risk of cancer.

1.260 random error: See precision.

1.261 range: A measure of data variability that is simply the difference between the highest and lowest value in a set of data.

1.262 reactive cyanide: The fraction of cyanide in a sample that could generate toxic fumes when exposed to mild toxic conditions.

1.263 reactivity: A substance's tendency to undergo chemical reaction either by itself or with other materials with the release of energy. Undesirable effects such as pressure build-up; temperature increase; or formation of noxious, toxic, or corrosive by-products may occur because of the substance' reactivity to heating, burning, direct contact with other materials, or other conditions in use or in storage. Reactive substances may vigorously polymerize, decompose, condense, or become self-reactive due to shock, pressure, or temperature.

1.264 reagent: A substance or solution used in a chemical reaction, especially those used in laboratory work to detect, measure, or produce other substances.

1.265 reagent blank: An aliquot of analyte-free reagent (e.g. omit filters, etc), to which all reagents have been added in the same volumes or proportions as used in the sample processing. The reagent blank may not be carried through the entire analytical scheme to pinpoint contamination at specific steps, and direct analysis is used to document contamination attributable entirely from the quality of the laboratory reagents, chemicals and dilution media; and not from glassware, etc.

1.265.1 In industrial hygiene, reagent (method) blanks (a.k.a. media blanks) are samples of media to which all reagents have been added in the same volumes or proportions as used in the sample processing.

1.266 reagent grade: Analytical reagent (AR) grade, ACS reagent grade, and reagent grade are synonymous terms for reagents which conform to the current specifications of the Committee on Analytical Reagents of the American Chemical Society.

1.267 reagent water: Water that has been generated by any method which would achieve the performance specifications for ASTM Type II water. ASTM Type I purified water with 18 megohm-cm or greater specific resistance which may be prepared by distillation followed by ion-exchange removal of trace levels of contaminants. The reagent water should contain no target analyte above the minimum level of quantitation (ML) of this method. For organic analyses, see the definition of organic-free reagent water.

1.268 reduction: A chemical reaction that results in the removal of oxygen, the addition of hydrogen, or the gaining of electrons from an element or compound.

1.269 reference material: A material containing known quantities of a target analyte in solution or in a homogeneous matrix. It is used to document the bias of the analytical process. Commonly referred to as certified reference materials (CRM) or standard reference materials (SRM).

1.270 reference slides: In industrial hygiene, reference slides are previously prepared slides with an "accepted" amount of fiber density. The accepted amount may be derived from the true value as given by the PT provider, from the accepted values given by the course instructor, or from mean results of analysts. The Laboratory Reference Library of previously prepared reference slides consists of old PATs, slides from external course-work, and slides of interesting or challenging samples.

1.271 reference standard: Reference standards refers to a material, device, or instrument whose assigned value is known relative to national standards or nationally accepted measurement systems. Reference standards usually have a certificate of traceability and may require periodic re-certification.

1.272 relative percent difference (RPD, rpd): A statistic that expresses the precision (reproducibility) of two measurements or duplicate samples. RPD equals the absolute difference between the two measurements, divided by the mean, multiplied by 100. The RPD should be reported with one more significant figure than the data.

1.273 relative standard deviation (RSD): A statistic (also referred to as coefficient of variation) that expresses the precision of a sample set. RSD equals the standard deviation (i.e. the square root of the variance), divided by the mean, multiplied by 100.

1.274 replicate: Two or more additional aliquots, tests, samples, organisms, concentrations, or exposure chambers that are treated the same as the original sample in order to determine the precision of the analytical method and is used in evaluating the applicability and dependability of a specific method. A replicate may also be a repeated operation occurring within an analytical procedure. When two replicates are analyzed, the second is referred to as the duplicate.
See also aliquot and duplicate (dupe).

1.275 report limit (RL): The lowest concentration or amount of the target analyte allowed to be reported from a data collection project. Report limits are determined in conjunction with the determination of the MDL and are set equal to the minimum level of quantitation (ML). Any data below the RL are considered to be estimated. Instrument calibrations may have a low standard at this level.
See also level of quantitation (LOQ) and minimum level of quantitation (ML).

1.276 reproducibility: The precision, usually expressed as variance, that measures the variability among the results of measurements of the same sample at different laboratories.

1.277 reproductive toxin: A chemical which affects the reproductive capabilities including chromosomal damage (mutations) and effects on fetuses (teratogens).

1.278 Resource Conservation and Recovery Act (RCRA): A 1976 federal law that authorizes the EPA to set standards for companies producing, handling, transporting, storing, and disposing of hazardous waste. This law established a regulatory system to track hazardous substances from generation to disposal; requires safe and secure procedures to be used in treating, transporting, storing and disposing of hazardous substances.

1.279 revision date: The revision date is the date when the quality document changes were finalized.

1.280 RL: See report limit.

1.281 "round up": Increasing the last retained digit by one, when the first digit discarded is five or greater.

1.282 "round down": Retaining the last digit unchanged, when the first digit discarded is less than five.

1.283 RPD, rpd: See relative percent difference.

1.284 RSD: See relative standard deviation.

S

1.285 Safe Drinking Water Act (SDWA): A 1974 federal law that authorizes the EPA to set national standards for drinking water and gives it the authority to control the disposal of hazardous waste into groundwater. The law was designed to protect the nation's drinking water supply by establishing national drinking water standards and establishes a cooperative program among local, state, and federal agencies to ensure safe drinking water for consumers.

1.286 sample: A portion of material to be analyzed that is contained in single or multiple containers.
See also field sample.

1.287 sample custodian: Laboratory personnel performing sample receipt duties. The sample custodian(s) are responsible to prepare and check samples according to standard laboratory protocol.

1.288 "second source": 1) Standards must be prepared from independent starting material and certified, as such; 2) Standards can be purchased from a second vendor; and 3) Standards can be purchased from the same vendor, with different lot numbers, as long as letters of explanation of independence are kept on file and maintained (as detailed in Section 19.5.3(B)).

1.289 select carcinogen: A "Select Carcinogen" is defined by the OSHA Lab Standard as any substance which is regulated by OSHA as a carcinogen; is listed under the category, "known to be carcinogens," in the Annual Report on Carcinogens published by the National Toxicology Program (NTP); is listed under Group 1 ("carcinogenic to humans") by the International Agency for Research on Cancer Monographs (IARC); or is listed under Group 2A ("probably carcinogenic to humans") or Group 2B (" possibly carcinogenic to humans") by the IARC, or under NTP as "reasonably anticipated to be carcinogens", and causes statistically significant tumor incidence in experimental animals in accordance with any of the following criteria:
(1) After inhalation exposure of 6-7 hours per day, 5 days per week, for a significant portion of a lifetime to dosages of less than 10 mg/m^3;
(2) After repeated skin application of less than 300 mg/kg (of body weight) per week; or (3) After oral dosages of less than 50 mg/kg of body weight per day.
With regard to mixtures, OSHA requires that a mixture "shall be assumed to present a carcinogenic hazard if it contains a component in concentrations of 0.1% or greater, which is considered to be carcinogenic."
See also carcinogenic.

1.290 selectivity: The property of being highly specific in activity or effect, and thus having the capability to specifically distinguish and measure the target analyte without interference from other compounds. Selectivity may be monitored and evaluated using QC checks within the method (e.g. mass spectral tuning, second column confirmation, ICP inter-element interference checks, chromatography RT windows, sample blanks, spectrochemical ABS or fluorescence profiles, co-precipitation evaluations, and electrode response factors).

1.291 semi-qualitative: Identification of a compound by class rather than identification of the specific compound (i.e. semi-qualitative would identify aromatic hydrocarbons whereas qualitative would identify benzene).

1.292 sensitivity: The property of being capable of detecting and distinguishing minor differences. Sensitivity is evaluated in terms of instrument detection limit (IDL) and method detection limit (MDL) and is related to the degree of measurement change caused by a quantity of target analyte (i.e. slope of the calibration curve).

1.293 shall: This action, activity, or procedural step is required.

1.294 shipping custodian: Laboratory personnel performing incoming shipment receipt duties. The shipping custodian(s) are responsible for the disposition of the package.

1.295 should: This action, activity, or procedural step is suggested but not required.

1.296 silica gel treated n-hexane extractable material(SGT-HEM): n-Hexane extractable material (HEM) that is not adsorbed by silica gel.

1.297 Solid Waste Disposal Act (SWDA): The 1965 federal law that formed the framework for states to better control the disposal of trash from all sources, including safety for local landfills. The SWDA was amended by the Resource Conservation and Recovery Act (RCRA) of 1976.

1.298 SOP: See standard operating procedure.

1.299 split samples: See field split samples.

1.300 SRM: See standard reference materials.

1.301 standard: Specific rule established to conform to policies. Also, compounds, reagents, solutions or reference material of known and verified composition.

1.302 standard addition: See method of standard additions (MSA).

1.303 standard curve: See calibration curve.

1.304 standard deviation: A statistic that expresses the precision of a sample set and is a measure of the variability, dispersion, or imprecision of a sample or population distribution. The standard deviation has the same unit of measurement and the same number of significant figures as the mean for the set of data. The standard deviation is defined as the root-mean-square deviation from the mean and is calculated as the square root of the sum of the squares of the differences (result minus mean), divided by the number of results minus one. It is also equivalent to the positive square root of the variance.

1.305 standard operating procedure (SOP): A written document that details the method for an operation, analysis, or action with thoroughly prescribed techniques and steps, and that is officially approved as the method for performing certain routine or repetitive tasks.

1.306 standard reference materials (SRM): See reference material.

1.307 stock solution: A solution containing a target analyte that is prepared using a reference material traceable to EPA, the National Institute of Science and Technology (NIST), or a source that will attest to the purity and authenticity of the reference material.

1.307.1 A concentrated solution containing one or more method analytes prepared in the laboratory using assayed reference materials or purchased from a reputable commercial source.

See also calibration stock standard.

1.308 Superfund: Superfund refers to the entire CERCLA program as well as the trust fund established to fund cleanup of contaminated sites where potentially responsible parties cannot be identified, or are unwilling or unable to pay. This program operated under the legislative authority of CERCLA and SARA that funds and carries out EPA solid waste emergency and long-term removal and remedial activities.

1.309 Superfund Amendments and Reauthorization Act (SARA): The 1986 amendment to CERCLA that include additional enforcement authorities, technical requirements, community involvement requirements, and various clarifications associated with superfund issues.

1.310 supernatant: Liquid removed from settled sludge. Supernatant commonly refers to the liquid between the sludge on the bottom and the water surface of a basin or container.

1.311 supersaturated: An unstable condition of a solution (e.g. water) in which the solution contains a substance at a concentration greater than the saturation concentration for the substance.

1.312 surrogate spike: A specific type of laboratory fortified matrix (LFM) that is used in organic analyses in which known and verified amount(s) of a surrogate compound(s) are added to the sample and is then carried through the entire analytical scheme exactly like a field sample. The surrogate compound(s) are pure substance(s) with properties that mimic the analyte(s) of interest (in chemical composition and behavior), but are unlikely to be found in environmental samples. These are added to evaluate the effectiveness of the preparation steps of the analytical method and provide positive and sample-specific control.

1.313 systematic error: See bias.

T

1.314 target analyte: See also analyte.

1.315 Teflon (trademark): See fluoropolymer.

1.316 tentatively identified compound (TIC): A non-targeted compound detected in a sample using a GC/MS analytical method which has been tentatively identified using a mass spectral library search. An estimated concentration of the TIC may also be determined.

1.317 teratogenic: Capable of causing nonhereditary birth defects in a developing fetus. That is, causing physical defects in the developing embryo or fetus when a pregnant female is exposed.

1.318 total carbon (TC): TC refers to all the carbon in the sample, including both inorganic carbon and total organic carbon.

1.319 total cyanide — A representation of all cyanide compounds present, including metal cyanide complexes and cyano complexes of transition metals which have low solubility. Cyanide exists in different forms that vary in their reactivity and ease of destruction. Some of these are listed below.

1.320 total organic carbon (TOC): TOC refers to all carbon atoms covalently bonded in organic molecules, such as material derived from decaying vegetation, bacterial growth, and metabolic activities of living organisms or chemicals. TOC may be further divided into a purgeable and a non-purgeable organic carbon fraction.

1.321 toxic: Having the capacity to produce bodily injury or illness to humans through ingestion, inhalation, or absorption through any body surface, or being poisonous to an organism.

1.322 Toxic Substances Control Act (TSCA): A 1976 federal law that empowers the EPA to require the chemical industry to test chemicals and provide safety information before they are sold; and controls the manufacture and sale of certain chemical substances.

1.323 toxicity: The degree to which a substance or mixture of substances can harm humans or animals. Acute toxicity involves harmful effects in an organism through a single or short-term exposure. Chronic toxicity is the ability of a substance or mixture of substances to cause harmful effects over an extended period, usually upon repeated or continuous exposure sometimes lasting for the entire life of the exposed organism. Sub-chronic toxicity is the ability of the substance to cause effects for more than one year but less than the lifetime of the exposed organism.

1.324 trace element: Any of various chemical elements that occur in very small amounts in organisms or in the media under analysis.

1.325 traceability: The ability to trace the history, application, or location of an entity by means of recorded identifications. In a calibration connotation, traceability relates measuring equipment to national or international standards, primary standards, basic physical constants or properties, or reference materials. In a data collection connotation, it relates calculations and data generated throughout the project back to the requirements for the quality of the project.

1.326 trip blank: An aliquot of analyte-free media taken from the laboratory to the sampling site and returned unopened to the laboratory without having been exposed to sampling procedures. This blank is carried through the entire analytical scheme and is used to document contamination attributable to shipping and field handling processes.

1.326.1 This type of blank is useful in documenting contamination of volatile organic samples.

U

1.327 UCL: See upper control limit.

1.328 uncertainty: Uncertainty represents a lack of knowledge about factors affecting exposure or risk and can lead to inaccurate or biased estimates of exposure.

1.329 upper control limit (UCL): Upper limit at positive three (3) standard deviation units, used to determine if an analytical system is "in control".

1.330 upper warning limit (UWL): Upper limit at positive two (2) standard deviation units, used to monitor the quality of QC results of an analytical system.

1.331 UWL: See upper warning limit.

V

1.332 vapor pressure: The partial pressure exerted by the vapor (gas) of a liquid or solid substance under equilibrium conditions. A relative measure of chemical volatility, vapor pressure is used to calculate air-water partition coefficients (i.e. Henry's Law constants) and volatilization rate constants.

1.333 variance: A statistic that expresses the precision of a sample set and is equivalent to the square of the standard deviation.

1.334 viscosity: A measure of the internal friction of a fluid that provides resistance to shear within the fluid. The greater the forces of internal friction (i.e. the greater the viscosity), the less easily the fluid will flow.

W

1.335 weak acid dissociable (WAD) cyanide: WAD cyanide refers to all forms of cyanide except cyanide bound to iron.

1.336 whole effluent toxicity (WET) test: Tests to determine the toxicity levels of the total effluent from a single source as opposed to a series of tests for individual contaminants.

X

1.337 xenobiotic: A term for non-natural or man-made substances found in the environment (i.e. synthetics, plastics) which would not normally be found, and usually means a toxic chemical which is entirely artificial, such as a chlorinated aromatic compound or an organo-mercury compound.

Y

1.338 yellow-bellied: A term used by John Wayne to refer to cowards.

Z

1.339 zizzer zazzer zuzz: Creature whose name starts with "z" as defined in Dr. Seuss' A to Z book.

Z.0 Appendix Z: Record of Revisions

Date	Manual Reference	Action	Responsible Person
1994	-	Updates made throughout the year to maintain QAM.	LDR
1995	-	Updates made throughout the year to maintain QAM.	LDR
1996	-	Updates made throughout the year to maintain QAM.	LDR
1997	-	Updates made throughout the year to maintain QAM.	LDR
1998	-	Updates made throughout the year to maintain QAM.	LDR
1999	-	Updates made throughout the year to maintain QAM.	LDR
2000	-	Updates made throughout the year to maintain QAM.	LDR
2001	-	Updates made throughout the year to maintain QAM.	LDR
2002	-	Updates made throughout the year to maintain QAM.	LDR
12/07/01		Change "Environmental Laboratory" to "Dolan Chemical Laboratory" Changed Distilled Water to Demineralized water in Section 5.0	LDR
1/09/02		Replace C.L. White with T. T. Palmer, from 05/19/01 to 01/09/02, and from Rev 7 to Rev 8	
		Entire paragraph on Computer Data Security deleted and replaced- Section 13.9	LDR
		NVLAP policy on use of Logo added to IH QAP.	
1/24/02		Fig 8-1 ARCR, and revised Fig 8-2, 8-3, 8-4	
		Rework Fig 5-1, 5-4 G.E. Campbell, Mgr of Env. And Industrial Lab Services- Analytical Chemistry Services- Dolan Chemical Laboratory. Dolan Floor Plan, and Fig 5-10 Street view	LDR
02/11/02		Added FG techs to groups	LDR
02/20/02	EVL - QAM, Subpart H	Copy of McCrone certificate filed in Personnel Training Certificates, Subpart H. File H-34, Tamisha Palmer, updated to reflect addition of certificate.	LDR
08/09/02	EVL - QAM, Section 3.0	Quality Goals & Objectives Renumbered Paragraph 3.3.1 to Paragraph 3.3	LDR
08/09/02	EVL - QAM, Section 5.0	Revised Figure 5-1, The Quality Organization personnel chart.	LDR
08/14/02	EVL - QAM, Section 5.0	Revised Figure 5-2, Dolan Chemical Laboratory Organizational Chart, Industrial Hygiene emphasis.	LDR
08/14/02	EVL - QAM, Section 5.0	Revised Figure 5-4, Dolan Chemical Laboratory Organizational Chart, All Personnel.	LDR
08/14/02	EVL - QAM, Section 5.0	Revised Figure 5-5, Dolan Chemical Laboratory, Analytical Assignments.	LDR
08/14/02	EVL - QAM, Section 8.0	Revised Figure 8-2, Dolan Chemical Laboratory, Flammable Storage Cabinet Locations, (Delivery Locations): Added RWT, TRB, and JLB	LDR
08/14/02	EVL - QAM, Section 8.0	Revised Figure 8-3, Dolan Chemical Laboratory, Material Delivery Locations: Added RWT, TRB, and JLB	LDR
08/14/02	EVL - QAM, Section 9.0	Revised Section 9.0, Paragraph 3.4; Changed delivery to include addition of the vestibule cart.	LDR
08/14/02	EVL - QAM, Section 9.0	Revised Section 9.0, Paragraph 3.2; Changed the normal PONY delivery and pickup times.	LDR
08/14/02	EVL - QAM, Section 14.0	Revised Section 14.0, Paragraph 3 & 4; Added statements so as to included policy at the Dolan Chemical Laboratory for the wearing of company ID badges.	LDR
11/22/02	EVL-QAM, Section 4.0	Added Paragraph 4.0 entitled "Laboratory Principles of Conduct". Response to AIHA Site Visit, Deficiency No.1	LDR
12/03/02	EVL - QAM, Section 4.0	Added Paragraph 5.0 and 6.0 in response to AIHA Site Visit, Deficiency No. 1	LDR

12/03/02	EVL- QAM, Section 26.0	Added explanation as to footer and header, and the end section delineator for the Format page; Paragraph 4.0 of Section 26.0. Renumbered the paragraphs in this section from 26.1...26.3 to 1.1 .... 1.4.	LDR
12/12/02	EVL-QAM, Section10.0	Revised Section to delete all references to the APCO IH form. Added Form COC-2, Form ENV-03, and Form IHI-I99 as Figures in the section.	LDR
04/30/03	-	Eliminate AEP ProServ Inc from Title Page main entry "Changed or ___ and new/revised MSDS have been on the appropriate Safety Precautions Sheet Changed Section Mgr to Lab. Mgr. Add …hood/ glove box Changed all >>> to * for notation purposes Added all MSDS links to AEP MSDS database Revised Table of Contents	LDR
2003	-	Updates made throughout the year to maintain QAM.	LDR
2004	-	Updates made throughout the year to maintain QAM.	LDR
2005	-	Updates made throughout the year to maintain QAM.	LDR
3/14/05		Revised 2.2- of such instruments>>>Of such instruments and gauges Revised 2.2- set forth I this section >> set forth in Sect. 14.0 control of Measuring & Test Equipment Sect 2.3 add to clarify categories Sect 3.1 round to Sect 7.1 added NIST Sect 8.3.3-8.3.5, 8.3.8- All references to Balances …facilities mgmt ? Sect 8.8.4- revised- "The ___ normally may be ___ with a good mercury filled centigrade thermometer" Sect 13.5.1-13.5.3- remove reference to portable CD drive and include reference to memory stick Sect 13.2 MS access 100 tables to MS Access files IHAG- Section 11- changed "must be within 10%" to "must be within 15%"	
02/10/05	-	Corrective Action Report changed to Corrective ad Preventative Action Report (CPAR) Fig 25-2 Rev 1 02/2005- Audit and System Mgmt Review Checklist Fig 8-2- Flammable Cabinets edited Fix Rev date for Sections 21, 23, 24 (revise Par. 3), 25 and fixed typos Edit 8.9.1, 8.15.1 and Fig 14-2 , Section15- "out of order" changed to "Do not operate. Equipment Locked out." Sect 4.3 "at least 3 years" changed to at least 5 years" Sect 8.3.3 -8.3.8 LaSalle personnel and Galbraith Maint. Personnel changed to Building Services rep Sartorius an. Balance changed to Mettler AT 200 Section 5.0- delete job spec for Lab. Supervising Tech.; Add job spec for Sr. Lab Tech, revise org charts; changed CRVance to CR Jameson; Add ICP/MS responsibility to DPConover as official backup for ICP Sect 3.4 Security guard changed t Office Services Lab. Representative, and security desk to main lobby area. Sect 9.2 Aspen Version 4.0 to 5.5 Sect 11.1 Fossil and Hydro Prod. Changed to Fossil and Hydro Generation Sect 14 Lab security completely revised to reflect absence of security guard and introduction of key card entry system into lab Add Sect 8.0 Par 3.6 exempting NIST , AIHA and RTI from accreditation requirement for vendor standards	LDR

		Revised lot of approved suppliers (Rev 3 01/05) Sect 5.3 WWAG of DCL determines a new set of MDLs (every 6 mos..changed to) annually Fig 11-2 AE P Service Corp changed to AEP Section 13.0- par 4.0 WWAG discard after (3 yr changed to) 5 yr. Par 4.1 "in the desk files of the primary chemist" to "in the primary laboratory files." Par 4.2 ___ stored indefinitely, retention of PS records is determined on a case by case basis. Sect 11.0- par 3.1 add FGAG; changed 3.3.12; "The master copy of each of ht individual SOP manual is kept, numerically by Analytical Group (AG) in the wall cabinets of Spectroscopy room (Rm 205) changed to "the center floor shelved in record storage (Rm 220). Par 6.0 Imprest (Petty) Cash paragraph created Sect 13.0- Par 13- delete AEP tables .mdb, into worvar mdb; describe archive process; batch file located at L:\ Aspen55\AspBack.mdb	
2007	-	Updates made throughout the year to maintain QAM. (Revision 5.0)	LDR
06/13/07			RLE
09/14/07			RLE
09/15/07		Updates made to QAM (Revision 6.0)	RLE
11/06/07		Changed QAM Revision numbering, to align revision with number of years it has been in effect. This revision in Nov. 2007 is designated Revision 14.3.	ACR

2007 REVISIONS FOR REVISION 15.0

Revisions 11/07/07 (EVL QAM – ACR)

Rearranged sections from QAM into ISO format—
Moved Section 1 (Intro) to ISO Chapter 1 (Org) and ISO Chapter 2 (Qual System—QAM)
Moved Section 2 (Promulgation) to front matter
Moved Section 3 (Goals and Objectives) to ISO Chapter 2 (Qual System)
Moved Section 4 (Policies) to ISO Chapter 2 (Qual System)
Moved Section 5 (Organization) to ISO Chapters 1 (Org) and 16 (Personnel)

Moved Section 6 (Mgmt of QAM) to ISO Chapters 2 (Qual System) , 3 (Doc control), 14 (internal audits), and 16 (personnel—QAO)
Moved Section 7 (Planning) to ISO Chapter 10 (Improvement)
Moved Section 8 (Procurement) to ISO Chapters 6 (Purchasing…), and 14 (internal audits)
Moved Section 9 (Sample Handling…) to ISO Chapters 22 (Handling of Test Items), 1 (Org- Lab security), 4 (review of requests), 21 (sampling)
Moved Section 10 (Chain-of-Custody) to ISO Chapter 21 (Sampling)

Moved Section 11 (Analytical Test Methods) to ISO Chapters 18 (Test Methods and Method Validations), 23 (Assuring Qual of test results), and 24 (reporting of results)
Moved Section 12 (Laboratory Testing and Analysis Control) to ISO Chapter 23 (Assuring the Qual of Test Results)
Moved Section 13 (Quality Documentation and Records Control) to ISO Chapters 3 (Document Control), 1 (Organization-security), 13 (control of records- lab records), and 24 (reporting of results)
Moved Section 14 (Control of Measuring and Test Equipment) to ISO Chapters 18 (Test Methods and Method Validations), and 6 (Purchasing…)
Moved Section 15 (Prev Maint) to ISO Chapter 12 (Prev Action)

Moved Section 16 (Ref Standards) to ISO Chapter 20 (Measurement Traceability)
Moved Section 17 (Data Validation) to ISO Chapter 24 (Reporting the Results)
Moved Section 18 (Environmental Controls) to ISO Chapter 17 (Accommodation and Env Conditions)
Moved Section 19 (Customer Complaints) to ISO Chapter 8 (Complaints)
Moved Section 20 (Subcontracting) to ISO Chapter 5 (Subcontracting of Tests)

Moved Section 21 (Personnel Training, Qualifications and Motivation) to ISO Chapter 16 (General and Personnel)
Moved Section 22 (Statistical Methods) to ISO Chapter 23 (Assuring the Qual of Test Results)
Moved Section23 (Nonconformities) to ISO Chapters 9 (Control of Nonconforming Testing), and 12 (preventative action)
Moved Section 24 (Corrective Action) to ISO Chapter 11 (Corrective Action)
Moved Section 25 (Quality Audits) to ISO Chapter 15 (Management Reviews)
Moved Section 26 (Quality Manual Format) to ISO Chapter 2 (Qual System)

Rearranged Appendices as follows—
App A (Chemical Hygiene Plan) remains App A (CHP);
App B (ASTM E882-87, QC in Lab) omitted;
App C (Qualified supplier list for Cook Plant) omitted (see Documents 06-01 through 06-04);
App D (AEP Chemical Manual QC-1, 09/81, Rev 04/82) omitted;
App E (List of Leased Equip) to 19 (Equipment; Document 19-01)

Rearranged Subparts as follows—
Subpart A (Cert of Analysis- MT) remove archive, and reference QCDOC-0013 in 20.3.2 (Meas Trace.);
Subpart B (Cert of Cal- MT) remove archive, and reference QCDOC-0012 in 19.6.1 (Equip.);
Subpart C (Nonconf reports) , omitted but reference CPAR database in 9 (Nonconf);
Subpart D (As Rec'd Chem Report-MT), omitted (obsolete form);
Subpart E (Misc Cal Report-MT), remove archive, and reference QCDOC-0012 in 19.7.6(D) (Equip);

Subpart F (MilliRO Insp -MT), remove archive, blank form is Document 19-06, imbed text and reference QCDOC-0015 in 19.7.3(C)(b) (Equip);
Subpart G (Cylinder Insp Log-MT), remove archive, blank form is Document 06-07, and reference QCDOC-0015 in 6.4.6(E) (Purchasing);
Subpart H (Personnel Train. Cert.) job responsibilities moved to Appendix C and Personnel Training Files moved to QCDOC-009, referenced within 16 (Personnel);
Subpart J (Corr Action Requ), omit and refer to CPAR database in 11 (Corr Action.).
Subpart K (An. Test Methods) moved to Document 18-01 (Test Meth and Meth Val);
Subpart L (Lab Position Descr.) moved to 16 (Personnel);
Subpart M (DCL List of Analytical Services-MT), omit and imbedded Introduction and General Information Section from "EVL Sample Submittal Requests" database **into 22.2** (Handling of Test Items / Sample Submittal Procedures);
Subpart N (MDL) moved to DOC 18-03 in 18 (Test Meth and Meth Val);
Subpart N-1(ML) moved to DOC 18-04 in 18 (Test Meth and Meth Val);
Subpart O (outdated Instructions for Submitting Samples) omit and imbedded **into 22.2** (Handling of Test Items / Sample Submittal Procedures);
Subpart P (Glossary) moved to Appendix B;
Subpart Z (Record of Revisions) moved to Appendix Z.

Rearranged Figures and Tables as follows— (ACR/RLE)

Fig 5-1 Organizational Chart; AEP Quality Organization (AEP, IH Emphasis), 12/19/05,
(renamed Att # 01) then moved to Document # 01-01
Fig 5-2 Organizational Chart; Dolan Chemical Laboratory Industrial Hyg Emphasis,
(renamed Att # 02), then moved to Document # 01-04
Fig 5-3 Organizational Chart; Dolan Chemical Laboratory, Administrative Emphasis,12/05,
(renamed Att # 03), then moved to Document # 01-02
Fig 5-4 Organizational Chart; Dolan Chemical Laboratory; All Personnel, 12/19/05,
(renamed Att # 04), then moved to Document # 01-07
Fig 5-5 Dolan Chemical Laboratory Analytical Assignments, 08/02,
FGAG (renamed Att # 05), then moved to Document # 01-08
IHAG (renamed Att # 06), then moved to Document # 01-09
PSAG (renamed Att # 07), then moved to Document # 01-10
WWAG (renamed Att # 08), then moved to Document # 01-11
Fig 5-6 Description of Responsibility, Quality Assurance Officer, 05/19/00,
(imbed), **imbedded in Section 16.2.3**
Fig 5-7 Description of Responsibility, Laboratory Information Management Systems Specialist (LIMSS), 05/19/00,
(imbed), **imbedded in Section 16.2.6**
Fig 5-8 AEP, Dolan Chemical Laboratory, Site Plan (Overview), 07/29/92,
(renamed Att # 09), then moved to Document # 01-12
Fig 5-9 AEP, Dolan Chemical Laboratory, Floor Plan, 07/29/92,
(renamed Att # 10), then moved to Document # 01-13
Fig 5-10 AEP, Dolan Chemical Laboratory, Area Location Map (Overview), 08/97,
(renamed Att # 11), then moved to Document # 01-14
Fig 5-11 AEP, Dolan Chemical Laboratory, Area Location Map (Street View), 08/97,
(renamed Att # 12), then moved to Document # 01-15
Fig 5-12 Travel Instructions - John E. Dolan Engineering Laboratory, 08/05/97,
(imbed), imbedded in Section 1.3.2
Fig 6-1 Access Control List, 01/21/02,
(imbed), then moved to Document # 03-02
Fig 8-1 As-Received Chemicals Report (ARCR), 01/02,
(omitted- no longer in use), omitted
Fig 8-2 Flammable Liquid Storage Cabinet Locations (Delivery Locations), 8/2002,
(renamed Att # 13), then moved to Document # 06-05

Fig 8-3 Material Delivery Locations, 8/14/2002,
(renamed Att # 14), then moved to Document # 06-06
Fig 8-4 Deletions from Chemical Inventory Report (DCI), 01/02,
(omitted- no longer in use), omitted
Fig 8-5 Management System Survey Evaluation Check List, 11/02,
(renamed Att # 15), then moved to Document # 14-03
Fig 8-6 List of Approved Suppliers,
(renamed Att # 16), then moved to Document # 06-02
Fig 9-1 AEP Dolan Chemical Laboratory Analysis Request Form (ENV-03), 01/02,
(renamed Att # 17), then moved to Document # 22-03
Fig 9-2 AEP Air Sampling Worksheet, 10/02,
(renamed Att # 18), then moved to Document # 22-02
Fig 9-3 Table II - Required Containers, Preservation Techniques, and Holding Times; 136.3 rev at 56 FR 50759, 10/08/92,
(renamed Att # 19), then moved to Document # 21-01
Fig 9-4 Adaptation from Table 3-1 in Test Methods for Evaluating Solid Waste, SW- 846, EPA, Rev 0, Nov 1990, 11/01/90,
(imbed), then moved to Document # 21-02
Fig 9-5 Sample Retention Guidelines, 08/12/00,
(imbed), imbedded in Section 22.5

Rearranged Figures and Tables as follows (Continued)—

Fig 9-6 Client Communication Form (Form IHC-01), Revision 0, 12/2002 (Retired)
(omitted- no longer in use), omitted
Fig 10-1 AEP, COC & ARF (Form COC-2), 04/02,
(renamed Att # 20), then moved to Document # 22-01
Fig 10-2 AEP Air Sampling Worksheet (Form IHI-I99), 12/02,
(renamed Att # 21), SAME AS Document # 22-02
Fig 10-3 AEP Dolan Chemical Laboratory Analysis Request Form (Form ENV-03), 01/02,
renamed Att # 22), then moved to Document # 22-03
Fig 11-1 Analytical Procedure References, 08/08/97,
(imbed), then moved to Document # 22-04
Fig 11-2 Quality Assurance Objectives and Analytical Methods, Water and Waste Analytical Group, 05/22/00,
then moved to Document # 18-02
Fig 13-1 Document Control Master List, Revision 2, 01/05,
(renamed Att # 24), then moved to Document # 03-01
Fig 13-x FAX with Confidentiality Statement,
(renamed Att # 23), then moved to Document # 01-16
Fig 14-1 Calibration/Preventative Maintenance Frequency Schedules, 11/02,
FGAG (NA), then moved to Document # 19-02
IHAG (renamed Att # 26), then moved to Document # 19-03
PSAG (renamed Att # 27), then moved to Document # 19-04
WWAG (renamed Att # 28), then moved to Document # 19-05
Fig 14-2 MILLI-RO Inspection Checklist, 11/02,
(renamed Att # 29), then moved to Document # 19-06
Fig 14-3 Dolan Chemical Laboratory - Laboratory Glassware Cleaning Procedures, 11/02,
(renamed Att # 30), then moved to Document # 19-08
Fig 14-4 Cylinder Gas Storage Building (CGSB) Cylinder Inspection Log, 02/01/93,
(renamed Att # 31), then moved to Document # 06-07
Fig 14-x Standard Practice for Calibration of Pipettes, Rev 3,
(renamed Att # 25), then moved to Document # 19-07
Fig 14-y Minimum Operating Pressures,
(imbed), then moved to Document # 06-08
Fig 16-1 Certificate of Analysis NIST Standard Reference Material 2676c Metals on Filter Media, 08/05/97,
(renamed Att # 32), then moved to Document # 20-01

Fig 16-2 Master List of NIST Standard Reference Materials (SRM), Revision 08/06,
(renamed Att # 33), then moved to Document # 20-02
Fig 22-1 AEP, Dolan Chemical Laboratory Industrial Hygiene Analytical Group, Silica, Crystalline (IR) - NIOSH Method 7602% Recovery Control Chart and Associated Data, 10/02,
(renamed Att # 34), then moved to Document # 23-01
Fig 22-2 AEP, Dolan Chemical Laboratory Industrial Hygiene Analytical Group Metals, Cadmium - NIOSH Method 7300% Recovery Control Chart and Associated Data, 10/02,
(renamed Att # 35), then moved to Document # 23-02
Fig 22-x Uncertainty flowchart,
(imbed), then moved to Document # 23-03
Fig 22-y Sources of Uncertainty,
(imbed), then moved to Document # 23-04
Fig 23-1 Nonconformity Event Review Report, 11/02,
(renamed Att # 36), then moved to Document # 09-01
Fig 24-1 Corrective Action Request Form, 11/02, (does not exist), "omitted" (does not exist)
Fig 24-2 Corrective Action Master Log, 11/02, (does not exist), "omitted" (does not exist)
Fig 24-x Corrective Action flowchart,
(imbed), then moved to Document # 11-02

Rearranged Figures and Tables as follows (Continued)—

Fig 25-1 Quality Control, Quality System Audit Check List, 11//02,
(renamed Att # 38), then moved to Document # 14-01 & 14-02
Fig 25-2Quality Control, Quality Management Review Check List, 02/2005,
(renamed Att # 39), then moved to Document # 15-01
Fig 26-1 Quality Manual Format Sheet, 11/02,
(omitted- no longer in use), omitted

New Figures added to QAM

Document 02-01 AEP's Principles of Business Conduct - The Power of Integrity, AEP Revision 0, 02.2006;
Document 02-03 FAQ's for Concern Line, Revision 0, 12.28.07;
Document 02-04 The Chemical Professional's Code of Conduct, ACS Revision 3, 12.13.07;
Document 02-05 Outline Format;
Document 03-03 Organization of QCDOC Documentation Files (New);
Documents 06-01 to 06-04- Qualified Supplier lists (reserved);
Document 06-07 Blank Cylinder Inspection Log (from Subpart G);
Document 06-09 Safe Handling of Compressed Gases in the Laboratory (from Subpart G);
Document 18-01 List of Analytical Test Methods (from Subpart K) ;
Document 18-03 MDL Procedure at Dolan Chemical Laboratory (from Subpart N);
Document 18-04 ML Procedure at Dolan Chemical Laboratory (from Subpart N-1);
Document 19-01 List of Leased Equipment (from Appendix E);
Document 20-01 Master List of Measurement Traceable Items (New, replaced Master list of NIST Standards);
Document 20-02 Example Certificate of Analysis for calibration standards (New);
Document 20-03 Example Certificate of Traceability for NTRM (New);
Document 22-04 Types of Analyses at DCL (from Subpart O);
Appendix C- Personnel job responsibilities (also from Subpart H)

Designations Given for All Quality Documents Maintained by Laboratory (i.e. QC Binders previously stored in QAO's office):

QCDOC 001- QAM Maintenance
QCDOC 002 -Laboratory Review
QCDOC 003- Purchasing
QCDOC 004- Customer Service
QCDOC 005 - CPAR Info
QCDOC 006 - Control of Laboratory Records
QCDOC 007- Internal Audits

QCDOC 008- Management Reviews
QCDOC 009- Personnel Records(from Subpart H)
QCDOC 010- Environmental Conditions
QCDOC 011- Test Methods and Method Validation
QCDOC 012- Certificates of Calibration(from Subpart B) (from Subpart E)
QCDOC 013- Certificates of Analysis(from Subpart A)
QCDOC 014- Sample Info
QCDOC 015- Reference Documents in Laboratory
QCDOC 016- Miscellaneous Inspection Logs(from Subpart F) (from Subpart G)
QCDOC 017- Inter-laboratory Comparisons
QCDOC 018- Accrediting Bodies
QCDOC 019- Quality Assurance Reports
QCDOC 020- Material Safety Data Sheets (MSDS's)
QCDOC 021- Management Tools

01/11/08 *** ***** ***** UPDATED ALL FIGURES IN QAM (ALL CONTROLLED DOCUMENTS IN LIST). THE 2008 QAM IS DESIGNATED REVISION 15.0. ***** ***** *******

2008 REVISIONS FOR REVISION 16.0

Revisions 02/08/08 (EVL QAM – ACR)

Front matter & Footer — Revised Cover and Title Page to include ISSUE date, REVISION date, APPROVAL date, and EFFECTIVE date (using new definition of "effective" as stated in 3.2.3(C). Also revised footer to only include Rev # and Eff date and Page #, as well as names of reviser and approver.
§ 1.1.1(A) and (B) added from SCL QAP (Shreveport Chemical Laboratory Quality Assurance Plan)
§ 1.2.1 added from SCL QAP — General job descriptions for lab management.
§ 1.2.3 added from SCL QAP — Responsibilities and AEP Corp titles of Key personnel.. Also added LIMSS, CHO, RSO , and Learning Coordinator.
§ 1.2.4 added from SCL QAP — Responsibilities for chemists and technicians. Also inserted Chemist and Technician Matrix Tables and places for Clerical staff.
§ 1.2.5(B) Added text to describe "back-u roles in analytical assignments.
§ 1.3.1(A)(a) Added Dolan's mailing address. § 1.3.3(E) Added directions from the Columbus airport.
§ 1.4.3(A) (b t o e) added from SCL QAP — Added information regarding electronically generated data reports and their backup. § 1.4.3(B) added from SCL QAP — Added information regarding LIMS system.
§ 2.2.3(A) and 2.2.4(A) added from SCL QAP — Added one each of a specific and management objective.
§ 2.3.2(G) (b to c) added from SCL QAP — Added clarification of AEP ethics website.
§ 2.4.1 added from SCL QAP — Added information on the Role of the QAM.
§ 3.2.2(D) and (E) added from SCL QAP— Added information on record retention.
§ 3.2.3 added from SCL QAP and inserted new text— Completely updated Document Control Protocol, rearranging text from other areas, adding text form SCL QAP, and defining actual document change procedure step by step. Broke Doc Control into groups.
Same for § 3.2.4
§ 3.2.6 added from SCL QAP — Added confidentiality text to Doc/Data security. Also added the 3 levels of AEP Confidentiality Classification.
§ 3.4.2(C) – Updated parts of Mgmt of QAM, moved references to other quality documents upward to 3.2.3 and 3.2.4.
Section 4 - No additions or changes were made to this Section.
Revised section 5 to include three subparts— "Responsibility to the Client When Subcontracting", "QA in Contract Laboratories", and "Subcontracting Results on the Analytical Report." § 5.2, 5.3.1, 5.4.2, and 5.4.3 Added from SCL QAP
§ 6.3.2(F) (a and b) added from SCL QAP — Added clarification of chemical classification and added that the expiration date SHALL be marked on incoming containers, and the date opened SHOULD be marked on containers as they are opened..
§ 6.5 and 6.6 added from SCL QAP — Added information on Waste Disposal and Pollution Prevention. Also included pollution prevention text that was originally in every SOP (but will be cut out to be added to QAM) .
§ 7.2.1(A) Added statement to see client communications in subcontracting.
§ 8.2.1(A to D) added from SCL QAP—Added information to clarify the complaints procedure. Also defined complaint as Nonconformance or a Corrective Action in § 8.2.3(A).
§ 9.2.3 Added text to describe complaints and audit findings as nonconformance.
Inserted description of Nonconformance (NC) Reports into § 9.3.2(A).
Inserted description of Lessons Learned (LL) into § 10.1.3(A).
Inserted information into § 10.4.1 regarding PT studies that the lab participates in, and § 10.5.1 regarding accreditations held by the lab.
§ .11.1.1 Inserted Reference to Analytical and Management CA (in addition to the CPAR database).
§ .113.3(C) Inserted information on the 3 CPAR reports- CAR, LL, and LL.
§ .11.3.5 Added text from SCL QAP and inserted other text- to clarify the use of the CPAR database.
§ .11.5 and 11.6- Added text from SCL QAP regarding Analytical CA and Reserved a place in the QAM for Management CA. Inserted Analytical CA table (from SCL QAP) as **Doc 11-3**
§ .12.3.4(A) Added text from SCL QAP regarding the instrument maintenance log.
Inserted PM table (from SCL QAP) **as Doc 12-1**
§ 13.1.2 and 13.1.3 Added Recordkeeping System and Design; § 13.2.1 Recording Instrument –generated reports; § 13.5.3 Recording in Lab notebooks
§ 14.1.2 and 14.1.3 added in support of broadening this chapter from "internal audits" to "laboratory audits" (also changed Section title).

Revisions 02/08/08 (EVL QAM – ACR) - Continued

§ 14.2.3(A and B);14.3.3(C); and 14.3.4(C) — Added that audit findings should be evaluated using CPAR db, initially using NC report, then CPA if needed (except failed performance audits must be addressed using CPA).
§ 14.3 Added Section on System and Performance Audits (and moved Vendor Audits down to 14.4). Insert SCL's Laboratory System Audit checklist.
§ 15.2.4(A and B) — Added that management review findings should be evaluated using CPAR db, initially using NC report, then CPA if needed. Also Added QC activities (from SCL) to § 15.2.1(B) for the mgmt review.
Created QAM Documents 16-01- Lab job description; 16-02 Role of the QAO; 16-03, 16-04, 16-04, and 16-05 Matrix tables for chemists, technicians, flue gas technicians, and administrative associates; and 16-07 Obsolete job descriptions.
Section 17- No changes
§ 18.1.2- Added QA Validation and Evaluation of Test Methods (from SCL); Cleared up References in 18.4.; Added 18.5 (Accuracy, Bias, and Precision) QA Targets and QC Acc Criteria.
§ 19.1.1, 19.1.2- Added from SCL; Added 19.2.3 Cal Ver description; Changed Document 19-02- split off PM **into Doc 12-1 and 12-2**.; Insert SCL info into Balances (19.7.4), Ovens (19.7.6), Refrigerators (19.7.7), Thermometers (19.7.8). Pipettes (19.7.9), Cond Meter (19.7.10), pH Meter (19.7.11), ISE (19.7.13). Added Hot block digester, microwave digester, and distillation apparatus to Shared equipment.. Insert SCL info into UV Vis Spec (19.8.1), ICP (19.8.2), IC (19.8.6), FIMS (19.8.7). Reserved spots for Titrator, Flashpoint, Calorimeter, and Moisture, Particle and Sulfur Analyzers
§20.5- Added Doc and Labeling Stds and Reagents from SCL
§21.1.1/21.1.2 Revised and added from SCL (added IH does NOT sample).; Added 21.2.2 – 21.2.7; **Reserved Doc 21-3 and 21-4** for Labels and Bottle request forms.; Added 21..3.1 for types of samples (from SCL); New- 21.3.5 Special Cases Sampling (Reserved)
§22.1.2 and 22.3.3- Sample custody from SCL, Added22.5 Sample receipt, login and Storage from SCL. **Reserved Doc 22-02 Project Receipt Form, Added 22.6 and 22.8- Sample Storage and Disposal**
§ Added info under 23.2.6- Selection of Reagents from SCL- regarding reagents and reagent water; Added info under 23.5.1- control limits from SCL; added definition for Type A and Type B in 23.6.8; added 23.6.10 – another Uncertainty procedure from SCL. Create 23.7 QC Protocol based on SCL's QAP" Deviations from this QC protocol should be noted and discussed in the standard operating procedure (SOP) (e.g. changes in QC protocol per the requirements of the reference method)."
§24.3.1- Added info on the analytical report format from SCL; Added info on Peer Review and **Document 24-0x analytical report checklist** ; also added 24.3.3— 24.3.5, and 24.4.3 from SCL
SCL- Changed QAP/QA Plan / Quality Assurance Plan to Quality Assurance Manual (or QA Manual or QAM).
Changed all reference to the "QCC", "QC Coordinator", and "Quality Control Coordinator" to Quality Assurance Officer (QAO).

Revisions 03/19/08 (EVL QAM – ACR) - **Inserted information from IHAG QA Plan** (and retired remainder of document, which overlaps much of this QAM).

IHAG QAP Reference >>Moved to DCL QAM (description)
Section 5, 3.4 >> §1.2.3(J) (Guidance from other personnel in AEP system)
Section 5, Fig 5-5 >> Doc 01-09 (description of IH activities)
Section 21, Fig 21-1 >> Doc 01-09 (List of IHAG personnel)
Section 21, Fig 21-2 >> Doc 01-09 (IHAG work assignments)
Section 3, 4.0 >> §2.2.3(M) (IHAG specific objectives)
Section 4, 4.0 >> §2.3.1(J) (IHAG specific quality policies)
Section 6, Fig 6-1 >> Doc 03-02 (Access control list for IHAG)
Section 23, 1.0, 4.4, 4.9 >> § 9.1, 9.32, 9.37 (Nonconformances)
Section 24, 3.0, 3.4 >> § 11.1.2, 11.1.3, 11.5.2(B), 11.5.2(C) (Corrective Action) Section 24, Fig 24-1 and Fig 24-2 >> ( )
Section 15, Fig 15-1 >> Doc 12-02 CREATED (PM Responsibility)
Section 13, 11.0 >> § 13.5.5 (re: analytical notebooks)
Section 25, 3.2, 3.4>> §14.2.2(B)(c) and 14.2.2(F) (Lab Audits)
…….and added Doc 14-05 and 14-06 (NVLAP checklists) 1st QTR, 3rd for MR
Section 25, 4.1, 4.2, 4.4, 4.6 >> §15.1.1, 15.1.2, 15.1.3, 15.2.1(B)(l) (Mgmt Reviews)
Section 11, 1.0, 2.0 >> § in 18.1 and in 18.1.1(A)
(Add bulk asbestos / bulk materials matrices and OSHA and NIOSH ……..approved test methods)
Section 11, Fig 11-2 and 11-3 >> Doc 18-02 (IHAG Qual Assur Objectives)
Section 11, 7.4 >> §18.3.2 (IHAG annual MDL)
Section 11 Fig 11-1, # 1-5 and # 11-26 >> § 18.4.11(B), 18.4.25 (B,C, E), and 18.4.26 through 18.4.33 (IHAG References)
Section 12, 3.7 >> §21.1.1(B) (IHAG Sampling policy)
Section 9, 8.1 par 3 >> §22.3.2(A) (COC substitutes)
Section 9, 10.0 >> §22.5.4(A) (LIMS log-in)
Section 12, 3.4>> §23.3.2(D) (ooc analysis)
Section 11, 4, 5, 6, 7.2>> §23.7.1, 23.7.2, 23.7.3 (QC Protocol)
Section 13, 12.0 >> §24.3.2(D)(b) (Peer review)
App B - Added issue, authorization, and effective date to the glossary.
Added a note to Doc 18-02 regarding updated information.

Changes to QAM from 2006 & 2007 annual review of QAM by chemists.
-Removed from §1.4.1(B) —" Employees of Burns Security are on-duty at the John E. Dolan Laboratory security desk, located at the front (main) door, 24 hours a day."."
-Added to §1.4.1(B) —" The doors to the Dolan Chemical Laboratory (the actual analytical laboratory) are locked 24 hours a day. DCL employees have access through these doors 24 hours a day using their AEP I.D. badge."
-Added to §9.2.2(B) —" Analytical problems, QC trends, etc."
-Removed from §14.2.4 —"Minutes for these meetings will be prepared and saved in the Lotus Notes database entitled "Environmental Lab Discussions"."
-Removed §17.2.4 — Env Control of Room 208- no longer required.
-Added to §18.1 —" process solutions, operational/equipment malfunctions"
-Added to §18.1.1(C) —regarding modification and documentation of standard methods for non-routine parameters.
-Added to §18.4.34 —EPRI FGD Reference.
-Added to §20.4.4(D) —" with a copy of the certified results paperwork."
-Omitted § 22.7.2(E) regarding sample retention of organic solvent samples (IHAG no longer analyzes these samples).
- Omitted § 22.7.3(F) regarding sample retention of paint samples in PS (PSAG no longer analyzes these samples). And added a reserved section to IHAG sample
retention for paint samples (§ 22.7.2(F)).
- Omitted § 22.7.4(A) regarding sample retention of biological samples (WWAG no longer analyzes these samples).
-Added to §23.3.2(B)(e)(i) — defines the use of primary standards.
-Added to §23.6.2(C) —" unless they have been requested by the client."
?? 20.4.4 D and G NIST SRM store and xfer in box ?? sig figs and rounding for all sections?

Revisions 03/31/08 (EVL QAM – ACR) - **Changes from Shreveport's NELAC Audit Findings:**

Added information regarding minimum qualifications (A.S. for technicians and B.S. for chemists and laboratory management) to Sections 1.2.3 (A), 1.2.3(B), 1.2.3(C), 1.2.4(A), and 1.2.4(B). It was also noted that" Copies of transcripts and/or verification of education and experience are maintained on file with the AEP corporate Human Resources department"

Section 1.2.3(C)(g) added regarding QAO's training requirements (" shall have documented training and/or experience in QA/QC procedures and statistics and be knowledgeable in the quality system as defined under NELAC ").

Section 9.4 added, " Exceptions: Arrangements for exceptionally permitting departures from documented policies and procedures or from standard specifications may be permitted by laboratory management and shall be documented (see Section 9.5) as a non-conformance."

Section 11.4.4(D)(a to c) defined Lessons Learned, Nonconformity Records and CPAR records.

Section 19.7.2(F) added, "Expired reagents/standards— a) Dispose of reagent and/ or standards when their volume falls below 10% of the original container volume, b) Standards that have passed their expiration date should be properly disposed of according to the Chemical Hygiene Plan (See Appendix A) or should be labeled to prevent use for quantitative work (e.g. " EXPIRED- Do not use for quantitative work or sample analyses").

Section 20.1.3 added, "The certified values listed on the certificates of analyses for all certified standards shall be utilized when preparing calibration curves and for using other quality control activities. " and cross referenced in 19.2.1(B) for calibration.

Regarding Standard and Reagent logs- sections were added to Sections 20.5.1(C) for Standard Log, 20.5.2(A)(a) for Reagent Log, and 20.5.4(B) for Standards Prep Log.

Section 22.5.3(B)— added " Except in the case of samples for Oil and Grease, " to sample preservation

Note added to Section 22.5.3(D) regarding the need for a Sample Receipt SOP.

Section 23.7.6(E) (d) — added information regarding PT results and accreditation, the requirement for 2 of last 3 PT studies to be acceptable for parameters in Scope of Accreditation.

Added "and sample integrity issues noted on the Project Receipt form" to the analytical report in Section 24.3.1(G).

Added " QC results and flags denoting QC that fails to meet acceptance criteria. The effected sample (those associated with flagged QC) shall also be clearly marked" to the analytical report in Section 24.3.1(J).

Revisions 04/05/08 (EVL QAM – ACR) - **Removed all references to Flue Gas Analytical Group** (FGAG) when FGAG broke off from DCL to USTI within the AEP system:

Update Doc 01-02, 01-07, 18-01, 18-02, App C
Removed Doc 01-03, 01-08, 06-01, 16-05, 19-02, and 19-06.
Removed § 1.2.4(C), 2.2.3(L), 2.31 (I), 10.4.1(A), 16.5.1 (E to H), 22.6.1, 19.4.1(A)(a), 19.7.1(G)(b), 21.3.4
Removed FG reference within § 2.4.5(A)(b)(ii), 18.2.1, 18.3.2(B)

Revisions 09/18/08 (EVL QAM – ACR) - **Changes to QAM from 2007 DCL audit versus ISO and NELAC and 2008 annual review of QAM by chemists/DCL Mgmt.**

- Added § 1.2.3(J) added definition of Technical Mgr (IHAG primary chemist) as used by AIHA , removed from IHAG SOPs. Also added analysts' responsibilities (to 1.2.3(K)) for IHAG (as removed from IHAG SOPs) , PSAG and WWAG- ex participate in PT, run QC, etc…. .
- Added § 1.3.2 regarding the lab being a "fixed site lab".
- Changed security guard, Office Services and Facilities Mgmt to "Workplace Services" § 1.4.1 and throughout 22.4. Also changed hours to 7:30 to 6:00. Added info on afterhours deliveries using the call button (§ 1.4.1(F)(e))
- § 1.4.1(E)(e) Added info regarding three levels of access granted by AEP badges.
- Updated all org. charts and analytical assignments (Doc 01-01 through 11)
- § 1.4.3 (B)(b)(i) Updated to Aspen Version 7.5 (2008) for LIMS upgrade performed July 2008.
- § 1.4.3 (D) Removed requirement for daily backup of ICP files for IH. Also added " or some permanent storage media".
- § 1.4.3- updated Lab and AEP Corporate backup procedures (for LIMS db).
-Added § 2.3.1(M) (I) for SCL and 9.2.3(C) — regarding authorized departures from quality policies
- Added § 2.3.2(F)(a) — Sarbanes- Oxley and undue pressures.
- § 3.2.2(B) Retain PSAG records changed from "2 years on a space available basis" to "at least one year".
- § 3.2.3(C)(b)(v) (Security) defined use of pdf where feasible and password protection of controlled documents.
- § 3.2.4(D) Changes in documents should be denoted by a vertical bar on the right side of the page and the changed/new text in red.
- § 3.4.2(B)(a) at least one controlled copy of QAM with QAO or designee. Added "This password protection prevents the QAM from being altered" to .§ 3.4.2(C)(c)
- § 3.2.6(E) defined Document Access- addressing E-copies, hardcopies, current and archived – documents and records. The stipulation if the DCL ceases to exist is also defined (send to 1 RP storage).
- § 4.2.9 EPFS QAP "SOP 750- ACS SOP for large, non-routine projects".
- § 5.0 – added information for List of Approved Subcontractors (Doc 05-01) and evaluation of subcontractors (throughout 5.0). Section 5.1.3 was added to define the authorization to subcontract as per the Lab Mgr (or Lab Supervisor as backup). Primary chemist may make decision to proceed for "critical analyses" (Also added to Lab Mgr responsibilities- 16.2.2(A)).
- § 6.2.1(C) changed from must to SHOULD. § 6.2.1(C) updated to include ASTM as an exempt supplier, to allow for vendors as "experts in their field", to exempt "non-critical" supplies, and the option for the Lab Manager to "grandfather" suppliers (§ 6.2.1(D)). All Approved suppliers for DCL updated in QAM Doc 06-02 (Doc 06-01, 06-03, 06-04 all removed). IHAG is required to use an approved supplier (per ISO or formal exemption). (Section 6.2.1 (E)(b)).
- Removed § 6.2.4 — Imprest / Petty Cash., and moved information regarding credit card purchases to § 6.2.5.
- Added § 6.3.1(D) and 19.1.7(C). "Laboratory personnel are required to notify the QAO* (or designee) when critical supplies (e.g. pipettes, thermometers, major equipment, analytical instrumentation, etc.) are purchased, disposed of, or removed from use (i.e. properly labeled "Out of Service") to manage and maintain control of these critical laboratory processes. "
- changed § 6.3.2(H)(c)(i) –from maintaining MSDS at least 5 years to INDEFINITELY
- changed § 6.3.4(D)(e) so that chemist should notify QAO of PES, study closing date and fwd final results.
- § 6.4.4(G) (and 19.7.2(E) and Lab Mgr Resp 16.2.2Ag and CHO Resp. 16.3.2Cf) updated to reflect Lab mgr to review AND APPROVE PO of chemicals. Also designated Lab Supervisor and CHO as backups.
- Updated § 6.4.5(A) – Inventory- remove physical inv every 5 yr in LIMS, with annual printout. The revision states that we use an electronic inv (barcode) that is continually updated- and that a phys inv should be done every 5 yrs to reconcile. The e- inv is available electronically and in the CHP.
- Removed helium, hydrogen, and P-5 from gases used at Dolan and added P-10 (per M. Baker) in § 6.4.6(B). (Remains in QAM Doc 06-07 and 06-08).
- Add information regarding bar coding and chemical inventory to § 6.4.5.
- Changed § 6.5.2 — From Lab Mgr to Lab Supervisor primarily responsible for admin of chem. waste disposal. Also removed statement from 16.2.2(A)(h).
- Added § 7.2.2 and 8.2.1(A) — Client communications in the LIMS.
- Added § 8.2.1(F) description of Ethics Investigation with references to Documents 02-01 and 02-02. Referenced in § 2.3.4(C)

Revisions 09/18/08 (EVL QAM – ACR) - Continued

- § 9.3.2(B) EPFS QAP "SOP 830- Control of NC products and services".
- § 10.1.3(B) EPFS QAP "SOP 852.01 – Lessons Learned ".
- § 11.3.3(B)(a) EPFS QAP "SOP 852 – Corrective Action Process ".
- 11.3.4(C) added " To improved database consistency, CPARs and NCs should be created in the CPAR database by the QAO*."
- Remove 11.5.2(B) regarding a CPAR "Master Log (was an IHAG QAP item).
- Also created QAM Docs 12-01 through 12-05 for PM responsibility and schedules for instruments. (except 12-02 was omitted for FGAG)
- Added § 13.5.2(A)- Nalgene PN 6300-1000, and water proof and chemical resistant pages. Added " It is also recommended to include the span of analysis numbers on the spine and front cover. " to 13.5.2(B) and Changed "Data" to "Hand-written data" in 13.5.2(C).
- Updated QAM Doc 14-01. Removed pdf of extra pages in Section 14 and 15. Remove SCL' s Management Review Document (was Doc 15-2). Added QAM Docs 14-5 and 14-6 (NVLAP NIST checklists for bulk asbestos)
- 14.2.4- notes from biweekly (every other Tues) chemist meetings are available from Lab Mgr.
- Section 16.1.1(D) added to introduce "New Employee Checklist" (Doc
- § 16.10.2 reduced from a formal AEP EIP (employee involvement program) to broad statements about employee involvement.
- Added Training issues in 16.9.2 to 16.9.4.
- Added "capabilities" to "lighting capabilities" in § 17.2.1. Also removed "-that maintains a working temperature of 68^{O}F - 76^{O}F and a relative humidity of approximately 50%.".
- Changed AEP Building Services /Office Services to AEP Workplace Services — Facilities Mgmt personnel in § 17.3.2(A).
- Removed majority of references in Section 18.4 and referred to "External Sources and References" in QAM Doc 03-01- Master List
- Added QAM Docs 18-6 through 18-10 (DOC forms and an example MDL form).
- Added "(i.e. lowest standard in the calibration curve) " after RL level.
- Updated QAM Doc 19-1 and added § 19.1.7(B) to explain use of file on H Drive and periodic creation of a "snapshot" for QAM Doc 19-01.
- Corrected Doc 19-9 – replaced Freon with hexane; also corrected Doc 19-5 (for WWAG) ph cal 3 stds; and AA cal blank plus 4 stds.
- Removed § 19.4.1(A) which referred to filling out forms. Created new QAM Docs 19-03, 04, 05 (removed 19-02 for FGAG) for calibration frequency and method of instruments. Also created QAM Docs 12-01 through 12-05 for PM responsibility and schedules for instruments. (except 12-02 was omitted for FGAG)
- Added QAM Doc 19-07 Glassware cleaning for IHAG
— Rearranged Section 19- added temperature check and calibration references to Thermometer.
- Added § 19.7.2(F)(c) to refer to sections on 5 yr chem. retention and 5 yr critical supply re-evaluation.
- Updated QAM Doc 19-10 for RO system. Updated QAM Doc 19-11.
- RO system— Removed information the reference to MILLI-RO throughout § 19.7.3 and the QAM. Changed to new system (LC Vantage RO system) in § 19.7.3 (A).
- Added RO- reverse osmosis to § B1.2- Appendix B- Abbreviations. Added QCDOC 012 for maint and cal. Also added 19.7.3(K) to reference Barnstead ultrapure water— added QCDOC 016 for daily logs and QCDOC 012 for maint and cal.
- Balances— removed references to specific balances in WWAG (19.7.4(E)) and reorganized section for cal ver and cal. Noted that balances used irregularly, should be cal at least monthly and before use — added QCDOC 016 for daily logs. Added spec 0.1% for > 100 mg wts, and 0.5% for 100 mg or less wts (19.7.4(D)(a) and 19.7.4(E)(b)
added 19.7.5(A)(e) – regarding the prohibition of mercury thermometers, unless an exception is given.
added QCDOC 016 for daily logs for drying ovens and refrigerators (19.7.6 and 19.7.7).
added " If an adequate solution cannot be found, the Quality Assurance Officer* (or designee) should then be notified of the nonconformity. " to Balances (19.7.4Ba) and Refrigerators (19.7.6Ba)
- Removed information from § 19.7.12 (Spec. Ion Meter) and Reserved space for possible future use.
- Added QAM Doc 19-12 for Acid tank check which pushed ASTM ref to QAM Doc 19-13.
- Changed 19.8.2(I) (for ICP) from "at least one hour" to "a minimum of 30 minutes" warm-up before analyses.
- Removed PSAG from AA references in 19.8.4

Revisions 09/18/08 (EVL QAM – ACR) - Continued

- Section 19.8 – removed details about daily cal, cal ver and QC and added note to " See the specific laboratory SOPs for daily calibration details, calibration verification requirements and other QC criteria.". Also re-organized equipment in Section 19.8 alphabetically.
- Revised Doc 21-2 (from 100 mL to 50 mL digestion volume for Total Metals and Total Mercury ONLY; an changed minimum collection volume from 600 to 200 mL for total metals, and 400 to 200 mL for Total Mercury.)
- Section 22.2.1(B)(b) added….." Phone calls must be properly documented per **Section 7.2**."
- Removed from 22.2.1 (E) and (G)(b) to request faxes (rle)
- Added the use of fax and email to requested client information and manner of sending the final report in Sections 22.2.1(E)(b) and 22.2.1(G)(b). Updated and reorganized Section 22.
- 22.5.3(B)(a) – DCL does not sample "except as noted in Section 21.3"
- 22.3.1- COC is not an option. (rle)
- Changed § 22.4.4(B) from "primary analyst" to "primary chemist" per LDR.
- Removed 22.4.7(C) – Kept IHI99, ENV01, and MED30. Remove the retired COC forms App Power form, ENV02, MED 77.
- Added 22.4.7(D) regarding initial and date changes/corrections on COC/ARF.
- Updated QAM Docs 22-01, 22-02, and 22-03, as well as list in 22.7.4 to remove ***
- § 24.3.1(M)(a) – detailed Approved Signatory (and backups) as introduced in Doc 24-1 SCL – § 24.3.1 (N)(a)
- § 23.2.1(B)(b) (LFB) removed "any background in the blank is subtracted from the spike measurement"
- § 23.3.7 removed because analysis date is now on EVERY report ("In addition, for all reports issued by the Water and Waste Analytical Group (WWAG), when the report date exceeds the specified holding time, designated for any particular analyte, then that particular analyte result on that particular report will be recorded with the date of its actual testing in the laboratory. This policy should help to ensure that no analyte is analyzed and reported in a period in excess of the specified holding time. ")
- § 24.5.4(A) (was § 24.4.8) Added third designation for Bottle ID under "Sample Laboratory Identification"..
- § 24.5.4(C) (was § 24.4.8) Updated to Aspen Version 7.5 (2008) for LIMS upgrade performed July 2008.
- § 22.5.8 (was § 22.4.13(A)) Updated to note client communications for entire lab (not just IHAG).
- Changed samples retention guidelines for PSAG in Section 22.6.3 from 6 months to 3 months minimum per Mark Baker's request 08/05/08 (and L. Rowe and D. Adkinson). Removed Chemical cleanings and resins (RLE 8/22/08). Store samples in ~~Field Test~~ and Coal Lab. TCLP leachates stored in Biol lab. No PSAG samples stored in Field Test (01/15/09)
-22.7.2 wastes stored in Biol lab.
- § 24.2.2 Changed rounding rules FROM Round up at 6, and down below 5 TO Round up at 5 or more.
- Glossary – Added authorization date, backup, batch, control sample, designee, DQO, effective date, issue date, PAT, PT, PQL, primary, reference material, revision date, second source, SOP, split samples,
- Added SRM, standard reference material, reference standard to the Glossary.
- Added "snapshot" of Appendix C file" to Appendix C. (Rev 0, 10/27/08) (and note describing "snapshot"

Revisions 12/12/08 (EVL QAM – ACR) - **Revisions made per AIHA Audit Findings from 11/11/08 – 11/13/08**(D = deficiency, S = suggestion, O = Other Discussions)

D1 – (Integrity Policy) added " ISO 4.1.5d, and AEPs drug and alcohol policy and princ of business conduct " to § 2.3.2(C) and " business relationships, political and governmental relations, protection of corporate assets, and responsibility to the environment " to § 2.3.2(D). (Integrity Procedure) see Doc 02-01.
D2— (appoint backup deputies) – Lab Supervisor for Lab Manager (§ 1.2.1(B)(a)) and Asst QAO for QAO (§ 1.2.1(D)(a)) . Also fixed drafts of Doc 01-02 (added DGA- Lab Supervisor) and Doc 01-07 (added rest of techs to PSAG). Also revised draft of Doc 01-09, changing CT Pugh backup to call from DG Adkinson to JL Bechtle.
D3— (Document Control)- See Master List of Controlled Quality Documents (QAM Doc 03-01), and revisions already prepared throughout Section 3.2.3- Document Control Protocol which controls, issue, security, access, etc .
Changed § 3.2.3(G) from annual review of controlled documents to periodic review per the master list (QAM is still annually per § 3.4.2(C)(h)). Periodic suggestions – SOPs 1 yr, forms 5 yr, references 5 yr. and all other controlled documents 5 yr. (§ 3.2.3(G)(d))
D4— NA for QAM.
D5— (Document Control) Created total page numbers using bookmarks (i = A through CC, ZZ) at the end of each section and numbering ——Page {={page} + SUM of {pageref i}} of {numpages}.
D6— (Purchasing Services and Supplies- Critical Supplies) Introduced critical (§ 6.3.1(B)) and non-critical supplies (§ 6.3.1(C)). Critical supplies include ACS grade chemicals, Class A volumetric glassware, or either an evaluation prior to use or a C of A/C of Cal. Also noted this evaluation at § 6.3.3(E). Additionally added that the QAO should be notified of arrival, closing date and final results from receipt of PES (§ 6.3.4(D)(e))
D7— (Prev Action) Added information to (§ 12.1.3) note that prev action should be non-reactionary; Added 12.2.1 (and 12.3) for PA Report (Form QAR 1201) ; to § 12.2.2 defining LL used for prev action, and added workload to the trending (§ 12.2.3). LL EPFS SOP 853 defined in § 12.3.1 and Enviance described and Enviance tasks explained in § 12.4.5. PA Section fully updated due to audit findings.

S7 — (Trend analysis listed as a duty for QAO) added to § 12.2.3(A)

S12 — (Prev action should be in Qtrly report) Added items that should be in the quarterly report and who it is provided to in § 1.2.3(C)(e) (i and ii).
D8— (unauthorized access to electronic records- LIMS) Added § 1.4.3(B)(c) defining the LIMS as password protected and defining the audit trail.
D9— (identify critical processes for audit trail) Add § 13.6 to label Use and Maint Logs similarly to analytical lab notebooks ("shall").
D10— (control of records) add "when applicable" to § 13.5.2(H) – which "suggested" (should) to date, and initial changes and give a reason for the change. Also changed to a requirement (must) Added similar statement to § 13.1.4 to encompass ALL RECORDS.
D11— (Mgmt Review) –Add § 15.2.4(C)- that states that MR findings shall be used to generate action items. Add § 15.2.2(B) which defined the MR process— collect ideas and create draft — discuss draft— finalized MR — generate action items – review audit findings.

S8 — Add "Feedback" to § 15.2.1(B)(h).
D12— (Personnel, Training) - Add § 16.9.4 text to the Reserved section for PMR. Used AEP PMR forms and instructions in use in Generation.
D13— (analyst SOP training) - NA
D14— (Equipment validation) - NA
D15— (Equipment and Measurement Traceability) Added Section 19.9- Control of Meas Eq., which created a Master list of Cal items and Lab Tasks (Doc 19-14) as well as addressed handling, support and storage of measurement equipment (contamination, overload and OOS).

Also updated "snapshot" documents to include pertinent snapshot note and snapshot in the name (Docs 3-1, 18-2, 19-1, 19-14, 20-1, and App C-1).

Revisions 12/12/08 (EVL QAM – ACR) - Continued

In Section 20- Meas Traceablilty, the section was rearranged for Reference Stds (not "NIST traceable reference materials, NTRM) and SRMs. Statements were added to the Ref Stds regarding Use, Handling, Transport and Storage. Statements were also removed from the SRM section (20..4.4 —(C) primary lab location for SRM is stock room; (D) Keep SRMS in original cardboard box with copy of certified results; (E) Exceptions to stock room on case by case basis) Also added to take extra care in transport of SRM (but not in original cardboard box).The NIST traceable thermometer shipping procedure (CPAR- Lessons Learned) was added to Section 20.3.3(D)(a).

D16— (Meas Traceability) – See Doc 20-01- Master List of Meas Traceability (SRM, Std Ref, etc)

D17— (Cert of Cal) – NA – update Doc 20-1 (stage micrometer and Abbe std are reference std); and Cal Doc 19-03- (replace/recal ref stds every 5 yr, cal graticule with micrometer quarterly, Abbe for PLM, and stage micrometer for PCM and PLM (PCM has graticule).

D18— (Reporting the Results) -

D19— (Uncertainty)- already in § 23.6.11.

D20— (Chemicals/ Meas Trace) § 6.3.2(C)(a) / 6.3.3(D)(a)- initial and date received on containers. § 6.3.2(H)(d) – 5 yr chem. ret policy if no mfr expiration date § 6.3.2(H)(e) – Lab staff shall transfer date received to bottles and mark date opened § 6.3.3(E) - Date rec and opened, verify critical supplies and 5 yr re-evaluation date for critical supplies § 6.4.4(E) ref the 5 yr chem. ret policy { five (5) year retention policy. for chemicals and reagents that have no documented expiration date. (per RLE email 9/25/08) }

D21— (Chemicals/ Meas Trace)- NA revised forms

D22— (IHLAP) – NA - DOCs and RR for gravimetric (fibers)

S11 — NA – RR

D23— (RLV) § 18.3.4(A)(b)(i)- RLV and § 18.3.4(A)(c)(i) – IH "trace" instead of asbestos RL. 18.3.2(A)

D24— (Equipment)- update Doc 19-3 and Doc 20-1 for calibrations (graticule) and ref stds (abbe test slide, stage micrometer)

D25— (Analytical Reports) – Sr for PCM reports

D26— (PT samples) – Added § 18.3.4(A)(d) " The DOC shall be repeated as required by the relevant accrediting bodies, or at a minimum, annually." And § 18.3.4(A)(e) "DOCs may also be used to evaluate and verify proper implementation of a procedure when a PT program or Round Robin is not available for that field of testing (FoT)."

S1 — §

S10 — Add log book to record storage § 3.2.2(D).

Revisions 02/23/09 (EVL QAM – ACR) - **Revisions made prior to finalizing the QAM (per LDR and RLE review)**

Doc 01-05 – Fix PSAG org chart to include DG Adkinson, RW Mayer, and LJ Miller.
Doc 01-11 Fix WWAG Analytical Assignments to replace TE Arnold with EJ Locigno (new since PMR)
3.2.6(B) – Removed references to external clients. Added "Procedures obtained from AEP vendors or suppliers shall remain confidential information unless the laboratory obtains written permission."
6.1 (and throughout 6.0) Removed references to imprest (petty) cash fund and local "C" order accts
6.2.2(B) Updated info on PO form
6.3.2(A)(a) Added "with side shield" to safety glasses requirement.
Also in section 6- updated Doc 06-05 (new acid cabinet) and 06-06 – added mercury lab and 06-08- changed argon from 90 to 100.
8.2.1(B) Re-phrased to " Chemists should notify (i.e. by email) the Laboratory Manager and the QAO* of any unresolved complaints for additional documentation and investigation (e.g. using the CPAR process). "
10.5.1(D) Added cert for asbestos analysis from WV DEP
13.5.1 and 13.5.3 – omitted loophole allowing an "option" to follow analytical notebooks and Use and Maint. Log guidelines
18.3.3(B) and (C) clarified to define RLV with at least 0.995 correlation coefficient (and not 80-120% recovery).
From QAO Memo on QC requirements—

Removed acceptance criteria details from 18.5.1(B) and generalized 18.5.1(A) to include LCS, LFB and LFM. (Moved information to Section 23.7)

Moved calibration verification details from 19.2 to 19.5. Also added details about calibration requirements (from Section 23.7) in to this section. Section 23.7 now refers back to 19.5.2 and 19.5.3.

19.7.9- Cal of pipettes, at least every 6 mos, except areas with regulatory requirements, must calibrate on a quarterly basis.
…..Updated Section 23.5 for "current" control charts and use of control charts. Section 23.7 refers back to Section 23.5.

Updated Section 23.7 (QC Protocol at DCL) ,- define analytical and preparation batches, required control charts, batch requirements, and cal verification requirements.

22.5.1(A) Added QAM Doc 22-5 (Form QAR 2201- Sample Receipt Checklist). Section 24 Added QAM Doc 24-1 (Report checklist) and QAM Doc 24-2 (List of Approved Signatories at DCL).
Added "analytical batch" to glossary and renamed old "analytical batch" as a "preparation batch".
Add precision information regarding use of Range wherever "RPD" is discussed, since AGs use both.
Section 14.3.3- omit annual requirement. Kept 14.3.3 and 14.3.4 as options/QA tools.
Section 17.2.3- Env. Chamber in room 208- temp maintained (per TCLP Method 1311, 23 ± 2 ^{o}C) 21-25 ^{o}C.
Section 18.2.5 (and 16.3.2(C)(i)) – changed SOP review by QAO and CHO from annually to periodically (or when method changes occur).
Note: Section 19.5.2Bii- successive dilutions recommended (should) for cal std.
Omit Section 19.7.3(D) which refers to checking the inlet feed water for the RO system per ASTM D1125 (sensor no longer available).
Section 19.7.4Aa- omitted requirement for all balances to be able to measure 1 mg.
Section 19.7.5C quarterly CHECK all thermometers, quarterly verify all digital thermometers vs NIST.
Section 19.7.6Aa- changed liquid for thermometers in refrigerator from mineral oil to 50/50 ethylene glycol (or equiv)
Section 19.7.7(B)- added " the corrected observation from the thermometer and its current calibration curve"
Section 19.7.8(C)- added " Handling desiccant may be harmful and such operations must be performed in a laboratory hood using the required PPE. "
Section 19.7.10- Changed Conductivity calibration steps to MUST, for WVDEP
Section 19.7.13A- Added statement "Thermometer hot block location and temperature reading s are recorded each day of use. (per WVDEP)
Omitted ICP details from 19.8.11D (type of nebulizer, etc.)
Section 21.2.2(A) Changed sample to "environmental" in " The sampling container types, preservation techniques and holding times for environmental
parameters **"**
Section 22.2.1(G)(b) Added " A hard copy report will only be provided upon request. **"**

Revisions 02/23/09 (EVL QAM – ACR) - Continued

Edited Section 24.3.2 (Peer Review)- " Prior to release of data to customer the chemist should have their report peer reviewed. In some groups, the use of historical data for verification of analytical results is an acceptable alternative. **"**
App B - Glossary Added TOC & DOC (and POC, NPOC, IC, PtOC, TC). Added QCS, PTFE, symbols for TS, TSS, TDS. Added Cyanide definitions (amenable, total, etc.).—Rev 2 04/29/0975

Added Equation numbers and Eq Table in TOC

05/01/09 *** ***** ***** * UPDATED ALL FIGURES IN QAM (ALL CONTROLLED DOCUMENTS IN LIST). THE 2009 QAM IS DESIGNATED REVISION 16.0. ***** ***** ***** ***

2009 - 2010 REVISIONS FOR REVISION 17.0

Revisions 11/17/10 (EVL QAM – ACR) - EVL QAM **UPDATES**

11/17/10 DRAFT A Removed all markings from Revision 16.0.

11/18/10 DRAFT B **Performed amendments to align with SCL QAM (Revision 7.0) –**

Revisions made per Shreveport's LELAP Audit Findings from 04/28/10:

LELAP F#1 – Added Section 10.5.3 and ADP definition and abbeviation — Define use of "analytical data package (ADP)" in lieu of PT results per LAC [LAC 33:I§4711.B] definition. Also added LAC to reference [Reference 18.4.17].

Added to login PT, ADP, DOC and MDL samples into LIMS and compile results for quick reference (See Sections 23.6.2(E)(f) and 26.6.2(F)).

LELAP F# 2A – Updated Section 1.2.3(B)(c) to include Lab Mgr requirements to have "at least 24 college semester credit hours in chemistry and have at least two years of experience" per NELAC 4.1.1.1(a).

LELAP F# 2B — Correct Org Chart in Doc 01-02, 01-03, and 01-04 to reflect D. Phelps as SCL QAO and A Russell as DCL QAO ("designated QAO " , when needed). Also removed S. Epperson from org chart.
LELAP F# 2C — Correct title page to have D Phelps sign as Lab Manager and QAO for SCL
LELAP F# 2D — Added LAC to reference [Reference 18.4.17] and added LAC to NELAC citations in Sections 1.2.3(C)(g), 2.2.3(L), and 2.3.1(I).

LELAP F# 2E – the authority to halt and resume work was defined in Sections 11.5.4 (then indent 11.5.5 and 11.5.6 to become 11.5.4(B-C) and 11.6.6.
LELAP F# 2F — CDOC — Updated Section 18.3.4(B) to allow DOC by PT sample, 4 consecutive LCS, NELAC procedure or statistically equivalent sample results. — Per NELAC 5.5.2.6

LELAP F# 2G See 24.3.1(N)(a) and Doc 24-2. Updated Doc 24-2 with all chemists and their initials and signatures.
LELAP F# 2H Added Ethics & DI training content to Section 16.9.3. — per NELAC 5.4.2.6, LAC 5307(C)b, 5615(A)2

LELAP F# 2I (Sample Rejection – Sample Receipt SOP and QAM) – update section 22.0 and extract all of section 22.5 into Sample Receipt SOP. Change all "insure" to "ensure". Omit 22.4.2(A) and 1.4.1E (which is a duplicate paragraph).

LELAP F# 2J & 2K Added laboratory policy for Ethics & DI to Section 2.3.4, and made reference to SOP for Ethics & DI.. Also added DI documentation to Section 13.8.1A and periodic DI monitoring to Section 24.4.3B.
LELAP F# 2L Added "This notification must be sent within one week past the completion of the investigation. (Same statement in Section 24.3.3(C)) " to Section 24.3.3C and entire statement to Section 7.2.2. regarding notifying clients "promptly if an event casts doubt…—— per NELAC 5.4.13.2
LELAP F# 2M Basic Lab skills defined in Section 16.1.1D.

LELAP F# 3A – NA to QAM— NELAC 5.5.3.1, NELAC 5.4.3.2

LELAP F# 4 Added section 9.3.3 that states to perform an audit ASAP when a NC casts doubt on the lab's compliance with its policies, NELAC and LAC 33. This statement became the primary and the following statements regarding QAO duties for NC were indented in the "outline" of the section. —-per NELAC 5.4.10.5.

LELAP F# 5 Added Section 6.4.4 "No reagents, chemicals, or standards shall be stored with samples, processed samples, or sample extracts. " — per NELAC 5.5.3.3 and 5.5.8.4.a.2

LELAP F# 6A & 6B – Added Section 13.2.1(E) to address preventing overwriting e-files, and documenting person, date and reason for changes (ex. Logbooks, hardcopies, etc.) — per NELAC 5.5.12.2.3

LELAP F# 7— Added Sections 10.5.2(A) through (C) to address notifying LELAP when CPAR for failed PT is complete. — per NELAC 2.7.4

LELAP # 8A — Added to lock pdf and require people to request a controlled copy in Sections 3.2.3(a) and 3.2.3(C)(b)(ii) . Can no longer print pdf docs from H: or Sharepoint — per 5.4.3.2.2.c
#8B – (Doc Control measures)

LELAP # 9A — Deleted "Copies of transcripts and/or verification of education and experience are maintained on file with the AEP corporate Human Resources department." from Sections 1.2.3Ac, 1.2.3Bc, 1.2.3Ci 1.2.4A and 1.2.4B, and MOVED TO Sections 1.2.3(H) and 1.2.4(D)(c).
Added 1.2.3Bc i and ii for grandfathered Tech director and future TD.

LELAP # 9B & #9C – NA to QAM
LELAP # 10 -17, 19, 21,24, 27, 32-34 – NA to QAM (SCL SOPs and documents)

LELAP # 18 Added requirements in 24.3.1(J, P, Q) for data qualifiers, NELAC compliance, and results on samples as received — on final report — per 5.5.10.2 L & M

LELAP # 20 – NA to QAM (see 5 SCL CPARs to be re-assessed)

LELAP # 22 Added information about access log to Section 3.2.2B — per NELAC 5.4.12.2.4.e

LELAP # 23 (MDL issues) – Added ref to MDL Check in 23.2.4(A)(c). Added Section 18.3.2(D) for MDL check – annual, qualitative ID at 2-3x mdl (or 1-4x mdl for multiple analytes) — per NELAC C.3.1 "LOD Check" and D.1.2.1c & d (annual MDL required, relation of MDL and ML required)

Similar for RLV- 18.3.3(G)(a) and 23.2.4(B)(c).

LELAP # 25 Updated SOP format in Section 18.2.1 to include MDL (in Scope), Data Assessment, Poll Prevention, and Method performance. Additional descriptions were included in Sections 18.2.2 (A-G)

LELAP # 26 & 29 – NA to QAM (legibility – Reminder and review Section 13) & (spelling and grammar)

LELAP # 28 Added Section 13.2.2 to address electronic backup of electronic records – esp. log books (see also Section 13.5.4).

LELAP # 30, 31 – NA to QAM (Hach Methods); (address use of maintenance logs)

LELAP # 35 (Flag non-NELAC tests on final report) Added requirements in 24.3.1(R) for non-NELAC results

Other Revisions

11.3.5(D) Revised from 1, 3, and 12 mo follow-up to… 3 mo and ~1yr during next internal audit

12.5.5 – Updated Enviance task section with details of use and management of the Enviance system.

14.2.1(B)(c) Added 1 yr follow-up to annual internal audit

16.9.5 – Added Formal Authorization process as detailed in NC 20100716-101542

Updated Section 22.5 – Removed paragraphs that were covered in the WWAG Sample Receipt SOP and inserted broader terms elsewhere.

Updated Section 23.6.4 "Batch QC Protocol"
23.6.4(F) LCS Limit changed from 80-120% To 85-115%
23.6.4(G) LFM Limit changed from 80-120% To 75-125% (and < 20% rpd)
23.6.4(H)(b) Duplicates precision changed from 10% to 20 % rpd

Updated Section 23.6.5 "Non-routine Sample Protocol"
23.6.5(A) Sample (matrix) spikes changed from 85-115% To 75-125%

Section 23.6.4(H)(b)(i) The pair of LFM may be used to monitor the precision of the method.

Section 16.9.5 (Formal Authorization Process) added in response to Dolan Nonconformity Record NC20100716101542. Also added definition of authorized analyst and FoT.

10.6.2 and 18.x references The Dolan Chemical Laboratory adheres to the requirements of AIHA-LAP, LLC (for AIHA Accreditation), NIST 150 Handbook (for NVLAP Accreditation), 1VAC30-45 (Virginia code for laboratory certification) and 47CSR32 (Virginia code for laboratory certification).

1/01/11 (DRAFT C) **Performed Revisions triggered by 2010 AIHA Checklist (vs ISO and AIHA LAP)**

1.2.1(D)(a) & 1.2.3(D)(f)– QAO backup changed from "Asst QAO" to Lab Manager

Updated Org Charts QAM Doc 01-01 through 01-07.
Also Updated QAM Docs 01-09, 10, 11 – need reviewed and updated by each AG
And updated Doc 03-02 – Doc Control Access List

1.2.3(A) Removed Corpus Christi Lab

1.2.3(B)d – Define Lab Mgr (TD) - per NELAC

1.2.3(G)b – Added info from AIHA 2A.5.2.1.3 (LIMSS educ and experience)

1.2.3(J)d - Added info from AIHA 2C.3.1 (TM req for ELPAT)

1.2.3(L) HR copies of ed and exp verification Verified with Holly Antos 8-909-4070

1.2.4 – Added AIHA info from AIHA 2A.5.2.1.3 – (analyst responsible for QAQC, must demonstrate proficiency with CRM, PT or in-house QC, etc)

1.4.3(E) added per ISO 5.4.7 – AEP lifecycle policy is no longer to replace laptops every 3 yr and desktops every 4 yr — due to monetary constraints.

2.2.3 Created QUALITY POLICY STATEMENT to meet requirements of ISO 4.2.2 (and Note) and the upcoming TNI standard TNI 4.8.3(h) - with mgmt's commitment to quality and ethical practices and upholding the ISO standard.

2.3.1(L)(c) – removed redundant list of DMR "minimum" parameters.

2.3.4 Lab Ethics & Data Integrity (See above from LELAP audit)

6.3.3(C) text Removed – repeated elsewhere – refer to Section 6.3.2(D)

7.2.3 – Notify clients within 1 week of investigation when id NC that casts doubt on validity of results (See above from LELAP audit)
9.3.3 – SHOULD audit area when NC casts doubt (See above from LELAP audit) – then indent 9.3.4 through 9.3.9 to become 9.3.3(A-G) — ISO 4.11.4

9.2.3 – added other examples of NC per ISO NOTE in Section 4.9.1

10.1.1 – added info from ISO 4.10 for continual improvement

10.5.2 – added that the AB SHOULD be notified once CPAR Root cause complete . ADP's not required by VELAP — ***1VAC30-45-500. Laboratory enrollment in proficiency testing program.*** *A. Required level of participation. 1. To be certified initially and to maintain certification, a laboratory shall participate in two single blind, single-concentration PT studies, where available, per year for each PT field of testing for which it seeks or wants to maintain certification.*

10.6.2 Adhere to AB policies – AIHA, NVLAP, NELAP and WVDEP

11.3.1 Updated with new LAB CPAR3 database
11.3.4C - added "Personnel should notify the QAO* in writing of potential issues they encounter that may need addressed by the CPAR database (e.g. customer complaints, potential nonconformities, lessons learned, etc.)"
***11.3.5B – Defined actions taken in Steps 1-7 of CPAR process.
Doc 11-4 Added Doc with Final CPAR categories used in Step 7
11.3.5(E) – Added info from ISO Note 411.5 – additional audit if serious issue or risk is identified.

12.1.2 – added info from ISO 4.12.2 for initiation of PA and application of controls —- using Enviance Tasks

Updated Doc 12-04 – PM Responsibility – Add Skalar COD, remove EJ Locigno and LJ Miller, Change TL Miller to TL Tucker, & T.D. Fernandez
Updated Doc 12-5 – PM Schedule for WWAG – Add Skalar COD

13.2.1(E) AND 19.3.6(C) – Added info recommended on all cal curves (SHOULD — since this is not explicit in ISO or NELAC and is an ELPAT requirement AIHA 2C.4.6)

13.3 – Added info from ISO 5.4.7.1 and 5.4.7.2- about spreadsheets and LIMS calcs – Last IHAG validation on ASPEN LIMS in 2008.
14.2.1(B)(c) Added 1 yr follow-up to annual internal audit

Updated Doc 15-01 – Mgmt Review to most recent fill in pdf form – Rev 3 , 02/2009

15.2.4(C) – Added info from ISO 4.15.2 – Mgmt must ensure actions from Mgmt Review are carried out within am "appropriate and agreed" timescale.

16.1.2(D) added info from ISO 5.2.3 – regarding contract employees and all are bound to Quality System

16.8.3(A) - Training shall be documented in laboratory records and include a description of the content and duration of the program.
17.2.2 added info from ISO 5.3.2 – regarding stopping when env conditions jeopardize the results.

CREATED 17.4 — Lab Activities – from info in ISO 5.3.4 and 5.3.5 — includes DCL examples

18.1.1 - added info from ISO 5.4.2, 5.4.3 and 5.4.4 – regarding latest test methods, deviations from RM and customer communications about test methods; Non std Test Methods and Laboratory Developed methods.

18.3.2(F) – annual MDL check – qual ID – use annual MDL study
per NELAC 5.5.9.2.a.4 – Essential QC Proc- required to "measure to evaluate test method capability, eg LOD, LOQ or range of applicability, such as linearity"
per NELAC App C.3.1 and C.3.2 – states that LOD and LOQ must be determined — but not necessarily annually.but continues to say " the validity of the LOD shall be confirmed by Qualitative identification"… and similarly, "the validity of the LOQ shall be confirmed by successful analysis of QC sample"… i.e. MDL check and RLV in Section 18.3.2F and 18.3.3Da >>> reiterated MDL check and RLV in Sections 23.2.4Ac and 23.2.4Bc.

Updated Example MDL form to Doc 18-6 and Example DOC form to Doc 18-7, removed other documents (Doc 18-8 to 18-10)

Rearranged 19.0 into 1) Scope & Purpose, 2) Quality of Cal, 3) Equipment Procedures, 4) Shared Equ, 5) Analytical Eq and 6) Control of Measuring Eq
Moved 19.7 and 19.8 into 19.4 and 19.5.
Moved Cal protocol to 19.3.6 and inserted Cal Verification at end of 19.3.6
Added 19.3.1 to refer to PM in Section 12.5
19.3.2 - added info from ISO 5.5.10 (and AIHA 2A.5.5.4) – cal frequency and correction factors
19.3.4 Added info from ISO Sections5.5.2 (and AIHA 2A.5.5.2) for Initial Use
19.3.5 Added info from ISO Sections 5.5.3 and 5.5.12 (and AIHA 2A.5.5.5) for Operation
19.3.7 – Added info from ISO Sections 5.5.8, 5.5.4, 5.4.2 defining Equip/Cal Records including use of Enviance Tasks and sequential cal labeling system at DCL.
19.3.6(D).8 Added info from ISO Sections 5.5.10 for cal ver (intermediate checks)

19.4.4(C) - Balance Cal Ver changed from one to THREE wts – per 47CSR 32 WVDEP

19.5 " See the individual analytical SOPs for daily calibration details, calibration verification requirements and other QC criteria. All Analytical Laboratory Equipment are calibrated daily when in use, except where noted."

This instrument is not calibrated daily. Refer to the individual analytical SOP(s) for calibration frequency and other calibration requirements.
- DGA 19.5.9; IC 19.5.13, TOC 19.5.28 and xray 19.5.32.

19.6.2(A)(d)Added info from ISO Section 5.5.9 (and AIHA 2A.5.5.3) for Equip that leaves lab's control

20.1.3 Added info from ISO 5.6.2.1 and 5.6.2.2 regarding Meas trace and SI units

20.3.1 and 20.3.2(B) added info from ISO Section 5.6.3.1 – define traceability and defined use of Enviance tasks

20.4.2 added info from ISO Sections 5.6.3.2 and 5.6.3.3 – define traceability

21.1.1 Added sampling issues for each AG- refer to SOPs, where relevant, AG has no direct control over sampling by clients

21.1.3 Added info from ISO 5.7.1 regarding SAMPLING
21.1.4 created section for "sub-sampling: aliquots

23.6.1 and 23.6.5(C) added info from ISO 5.4.6
23.6.12 – added ISO 5725, GUM and AIH App G references

23.7.6 Added DOC to DCL Method Validation Protocol

24.3.1(T)to (W) – per ISO 5.10.2, 5.10.3.1c and d – IHAG and WWAG do not provide opinions or interpretations.

2011 CHEMIST QAM REVIEW – sent 02/01/11, request comments by 02/15/11 , rec'd response (see below)

LDR – Chapters 1-15 – rec'd		03/07/11			
DGA – Chapters 16-24 – rec'd			03/16/11		
TEA – Chapters 1-3 – rec'd			03/18/11		
MEB – Chapters 4-15 – rec'd	02/22/11				
JLB – Chapters 16-19 – rec'd	02/17/11				
DPC – Chapters 20-24 – rec'd		03/04/11			(No Comments)
TLT – Chapters 1-3 – rec'd				03/22/11	
DAM – Chapters 4-15 – rec'd	02/21/11				(No Comments)
CTP – Chapters 16-19 – rec'd	02/24/11				
BSS – Chapters 20-24 – rec'd	(charts only 03/02/11)			**MISSING**	

Xtra documents for Chemist Review – AG Assignments (Docs 01-09 through 01-11); Cal method & frequency (Doc 19-3 through 19-5; Section 22.6.2 – 22.6.4 Sample Retention Guidelines; QAM Doc 06-05 and 06-06, Flammable Cabinets & Materials Delivery; and Section 22.5.7(D) – Retained samples for each AG.

Comments from DCL Chemists — Evaluate and address in next internal audit and/or the NEXT QAM Revision

2.2.5G – procedure for id training needs …"I do not know that this is available" (LDR)

4.2.2 – 4.2.4 – regarding handling a "significant" number of samples in a project — "Who decides this? Should submitters be made / asked to talk to Dan or Lannie?? This is fairly ambiguous. We were recently contacted about a set of 24 samples coming from a plant. When they arrived there were 38 samples, most of which had to be split into liquids and solids. Total sample count was likely over 50 and there were 5 plants involved instead of 1. End result: 24 turned into 200+ " (MEB)

5.3.3 – documenting clients' authorization – "Should we develop an authorization slip to be filled out & sent in before sending samples out? This protects us on disputes on payment also." (MEB)

5.4.3 - include entire 3rd party lab report with analytical reports – "This needs to be enacted. Civil Lab Reports??" (LDR)

* * * 6.3.2 – Receiving chemicals and reagents – "We need a revision appropriate to how we handle incoming peroxide formers, such as MIBK (LDR 3/7/11)

6.3.4(D) – PT samples should be handled like chemicals upon receipt — "Is this done? Not sure that LQSI & CCRL samples are done this way." (MEB) >>> Should these be handle as SAMPLE RECEIPT?? (ACR)

9.3.2 & Doc 9-1 – manual NC report – "I do not know that we have used the NCERR form in the last 5 yrs. Maybe it should go away." (LDR)

13.1.4 – correcting mistakes in records & 13.2 instrument reports -"Not sure this is possible on all instruments. (MEB)

* * * 13.2.1D – all cal curves dated and labeled… instrument response – "This will need publicized. Define instrument response." (LDR)

14.4 – vendor /subcontractor audit – "Is this actually done?? " (MEB)

16.1.1C – "Each test method should be reviewed to ensure compliance with the CHP" (JLB >> This is being done (ACR)

16.2.2By- Lab mgmt – 22.4.4B – determine loss of integrity - "Does that all really happen?" (JLB)

16.3.2Dh – Sample Ret guidelines- This does not seem related to the CHP (JLB)

16.3.5 Replace "OnTrack Online" with "Key" software (JLB)

* * * 16.5.1 – Technician Job Responsibility – "Unknown if this changes due to Union at DCL" (JLB)

* * * 16.9.4 – PMRs – "This needs revised to specifically segregate the represented employees, so that the does not apply" (LDR) – Lab is no longer under Generation – is under AEP Utilities (ACR)

* * * 16.9.5A c – Exemption prior to Dec 1, 2010 – "Do not quite understand. Before Dec 1, we could , and now we can't . or vice versa? To me, nothing has changed from that date." (JLB) – date chosen from when AEP created formal job descriptions for all lab personnel (ACR)

///********//////////*********//////////*******

7/01/11 (DRAFT D to M) **Updates after June IH Audits**

- Updated Footers and Title Pages with new QAO (ACR) and new Lab Mgr (DGA). Changed Revision date and Effective Date (to Aug 1, 2011)
- New Letter (s) of Promulgation for DCL and SCL
- 1.1.2B changed from "In the absence of the Laboratory Manager, the Laboratory Supervisor shall serve as the backup for management duties." To "shall designate one of the Laboratory Chemists to serve as the backup for management duties. This designation shall be communicated to all laboratory personnel."
- Updated all org charts QAM Docs 01-01 to 01-07 (and charts within QAM Docs 01-09 to 01-11). Remove LDR, SAK, LJM RLE, EJL SDE. Move DGA to Lab Mgr, remove Lab Supervisor and Corpus Christi Oil Lab, Changes in AEP Corp Mgmt, New Chemist – TDF (was tech), new Tech MAD. New WWAG Tech (vacant). Added Support Staff to each AG. Added backups from other AG's that have been assisting in lab dutes.
- Updated QAM Doc 03-01 – Removed records and verified that Ref Methods are included for IH and other AG's (per AIHA **Def #2**)
- Updated QAM Doc 03-02 – removed names, just kept titles. Removed Lab Supervisor position from DCL.
- 3.2.3(G)(d)(i) – changed SOP evaluation from 1 yr to 3 yrs, or "as required". (per **AIHA Sugg #5**)
- Updated QAM Docs 05-01 and 06-02 – Approved Subcontractors and Suppliers.
- Updated QAM Doc 06-05 and 06-06 – removed obsolete names, and added new personnel . Also updated Doc 06-07 and 06-08 per MEB.

Omit He, H2, P-10 gas from Doc 6-7 (no longer in CGSB- tank in lab) & note in Section 6.4.7(A)(a) above – "Tanks of Gases used inside bldg @ various locations : Nitrogen, P-10, high purity O2, high purity Argon, compressed air, Hydrogen, HP Argon and HP zero Air"

- Omit P-10 gas from Doc 6-8 (no longer in CGSB- tank in lab)
- Added QAM Doc 11-3 as Guidance for RCA (From M Khalil) per **AIHA Suggestion #1**
- Updated QAM Doc 12-2 – MEB is now the primary chemist over Coal Lab
- Updated QAQC report details in section 12.7.>>>>Ended up Moving 12.7 and12.2.5 all to Section 13.7.1
- Section 13.7.x added Bimonthly Update of Fiber Precision data, Monthly Bulk Asbestos Summary, Monthly update of Fiber Control Charts, Monthly Incomplete Samples Audit, Monthly Missing Reports Audit, Monthly QC Audit, QAO Pop Audits, Weekly Management Reports
- Created QAM Doc 13-01 – Compiled records and Section 13.1.5 (per AIHA **Def #4**)
- Updated the steps added to the internal audit process in Section 14.2.2(G)
- Sections 17.3.1C and 17.3.4(A). Corrected fume hood face velocity range (from 100 to 160) to 100 to 200 fpm. IH Room 221 is referred to as the "clean room", but it is only humidity and temp controlled, not "clean" as in positive pressure.
- 18.1.2 – corrected QC acceptance criteria. LFB 85-115 (from 80-120) , and LFM 75-125 (from 70-130). Since DOCs near ML, the criteria is 80-120%. (ALSO in Section 23.7.4 Batch QC Protocol for DCL lab)
- Corrected Section 18.3.3(E) that IH does NOT report "trace", changed to text from Bulk Asbestos SOP. — samples identified with a "trace" of asbestos, as "***Less than 1% asbestos***" ("< 1%"), and samples which contain no identifiable amounts of asbestos as "***No Asbestos Fibers Detected***." (per the IH Bulk Asbestos SOP)"
- Updated Section 19.4.9(B) and QAM Docs 19-03, 19-04, and 19-05 per the primary chemist(s) comments, especially to correct pipette cal from semiannual to quarterly across the lab.
- Corrected Section 19.4.9(B) Updated 22.4.1(A)(a) with PONY schedule, effective 10/18/2010.
- Section 19.5.9 – added DGA to GC instrument in PSAG
- MEASUREMENT TRACEABILITY - Updated Sections 5.2.6 (MT req for Subcontractors – external cal); 6.3.1(B)(d) (MT req for Certs of analysis etc – critical supplies)19.2.5 (MT with Equipment Cal); and 20.1.3 with text from AIHA App H regarding Measurement Traceability (per **AIHA Suggestion #8.)**
- Section 22.6.2 – IH sample retention – ALL sample types – 3 mos minimum (except for analysis sample for silica which is kept for one month in the dessicator). Combined Silica with metals and created a Bulk and a Filter paragraph to address differences.
- Section 22.6.3 – PS sample retention – made simple corrections to PSAG
- Section 22.6.4 – WW sample retention – Currently WWAG shall retain waste samples and metals samples for six months and may need to pull a retention aliquot if storage is an issue
- DCL (not for SCL) Sections 23.5.1(B) and 23.5.1(B)(a)- added that DCL control charts are "Shewhart-type" charts and that the Bulk Asbestos SOP describes the use of specific asbestos charts.
- DCL (not for SCL) **Section 23.5.6 (Use of Control Charts) updated from :**
    - The precision and recovery data are used for the diagnosis of analytical problems and to indicate when a problem in a given test is occurring.
    - A series of values outside the warning limits (WL) prompts an investigation and correction of the system.
    - A single value outside the control limits (CL) prompts an investigation and correction of the system.
    - Documentation of all corrective action is required. Refer to the specific method or the instrument manufacturer's manual for guidance in corrective actions.
- DCL (not for SCL) **Added Stat Course ref [18.4.22] and Section 23.5.6 (Use of Control Charts) updated to :**

- **Rule 1:** One or more data points fall outside the Control Limits (exceed three standard deviation units) on either the Accuracy or Precision charts.
- **Rule 2:** Two or more consecutive values fall on the same side as, and outside the Warning Limits (exceed two standard deviation on the same side) on either the Accuracy or Precision charts.
- **Rule 3:** At least eight successive values fall on the same side of the mean or central line (8 on the same side) on the Accuracy charts.
- **Handling Out of Control (OOC) Data –** Use of the Rules indicates a potential "out of control" (OOC) situation which must be addressed.
- When an OOC event occurs, the analysis should be halted pending troubleshooting and remedial action, followed by rejection of the results in the analytical run and re-analysis of the test samples.
- The analyst should refer to the specific method or the instrument manufacturer's manual for guidance in corrective actions.
- Determine where the lack of control may have occurred and opportunities to reduce variation in the data. If an assignable cause has been determined, take preventative action so that the event will not recur.
- If the OOC situation continues after remedial actions have been taken, the analyst shall notify the primary chemist of the event.
- If the OOC situation appears to have been resolved after remedial actions have been taken, the test samples shall be re-prepared and re-analyzed.
- If corrective action is not possible (i.e. insufficient sample volume or suspected matrix interference, etc.), the analyst shall notify the primary chemist of the situation.
- Results associated with an OOC event may be reported with the appropriate data qualifiers.
- [Note: Statistically, there is a chance of a false alarm (i.e. a "statistical event"). In applying Rule 1 alone, there is a 1 in 35 chance of a false alarm, and the average number of data points between false alarms will be about 200. As additional Rules are applied, these probabilities will increase as will the points between false alarms.]
- All data points – including OOC data points – must be included when calculating control limits unless on the control charts unless: (1) there is documentation substantiating an analytical error (e.g., spilled spike solution, etc.), or (2) the data point is determined to be an "outlier" according to accepted statistical tests.
- **Documentation of all corrective action is required** (e.g. notes on the control chart, in the associated laboratory notebook, as a formal NC report, etc.).

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- DCL (not for SCL) Updated Sections 23.6.1 and 23.6.11 with text from AIHA App G regarding Measurement Uncertainty. Added Two examples as QAM Docs 23-5 and 23-6 per **AIHA Def #8.** QAM Docs 23-5 and 23-6 derived from AIHA Auditor's training on Uncertainty calculations.
- DCL (not for SCL) Section 24.4.1 (Data Validation) "A two step data review system is used to detect erroneous data entries. In addition to the analyst reviewing the data while entering it into the LIMS, a Chemist reviews the data and approves it in the LIMS, then another Chemist reviews the data when a report is issued." Based on CAP from CPAR # 20071206074752.
- App B – added DMR definitions – contract lab, in-house lab, DMR-QA, NPDES (from ERA website)
- Updated Appendix C for EJL, TDF, MAD; SAK, LDR, DGA and temp employees

2011 - 2012 REVISIONS FOR REVISION 18.0

- ~ 1.4.3 a(i) The data shall be copied to the company intranet to a predetermined server space on at least a weekly schedule. This may be performed manually or using scheduled backup files. (b)(i) The data from the computer shall be backed up at least weekly using portable media (e.g. writable CD-ROM or 'memory stick'). The data is then immediately transferred to the AEP network to the predetermined server space.
- 1.4.3 – deleted other descriptions of memory sticks, etc; MOVED "back up" electronic data to stable medium unless… to 13.1.x; DELETED Lab Mgr required to decide what is transcribed from instrument to notebook. (~~The Laboratory Manager, or designee, will decide when and under what circumstances analytical data need not be transcribed from instrument generated electronic reports into an analyst's notebook. (See also Section 13.2.1(B)(a)~~)
- Need to REVIEW Doc 3-3 - Org of QCDOC files
- ~ 3.2.3C Are data edits documented in electronic files? AIHA 2A.4.13.3
- ~6 or ~20 – New Appendix H - Traceability of Measurement
- Section 6.3 Control of Incoming Materials, esp. 6.3.2 C and 6.3.2(D)LDR Comment - The use of label pre-empted certain statements in these sections.
- - 6.4.4 "No reagents, chemicals, or standards shall be stored with samples, processed samples, or sample extracts. *Check with Water Lab A refrigerators!!! ERA (old PT) used as CRM in fridge…Water Lab A & B ?...oil stds in IC fridge?*
- Update Section 6.x to better reflect handling incoming shipments. Maybe remove as a SOP.
- Also Review 16..2.2A, 16.2.2B & 16.3.2
- Section 17.4.x – Still a Work in Process (WIP) – "The Dolan Chemical Laboratory has established appropriate signage in areas where limited access or secure access is required. Areas may be restricted for trace analytical issues, security issues, or safety concerns. "
- Doc 18-01 SOP Manual and Prec designations for Analytical Test Methods — See website??
- Doc 18-02 QA Objectives and Analytical Methods — See website??
- Doc 22-4 Types of Analyses at DCL — See website??
- Need Sample receipt SOPs for other AG's and condense Section 22.x
- Update Section22.6.4 WWAG Sample Retention
- Remove Doc 24-1 An Report Checklist

4/30/12

- Changed VELAP Chapter 45 to Chapter 46 throughout
- Added NELAC 2003 Ref 5.4.13.2 to Section 14.1.4
- Updated Doc 18-3 MDL procedure from online 4/26/12; no changes to section 18.3.2 required
- Doc 01-01 through Doc 01-07 replaced with FOUR Generic org charts. Removed Documents 01-08 through 01-11 (renumber starting with Doc 01-05 to 01-09 at document Doc01-08 and onward).
- Section 1.2.2(E) Organizational Chart records (ORG Rec) are retained by the QAO and are available on Sharepoint. These records are maintained in **QCDOC-001 QAM Maintenance:**
- Section 1.2.5(C)Analytical Assignment records (ORG Rec) are retained by the QAO and are available on Sharepoint. These records are maintained in **QCDOC-001 QAM Maintenance:**
- Updated 3.2.3(G)(d) "SOPs should be evaluated every year, or as required. " (from three yrs)
- 18.3.2Da For analytical tests that have no available spiking solutions (e.g. asbestos, fibers, viscosity, pH, color, odor, temperature, dissolved oxygen, turbidity and "solids"), an MDL study does not have to be performed.
- 18.3.3Dc For analytical tests that have no available spiking solutions (e.g. asbestos, fibers, viscosity, pH, color, odor, temperature, dissolved oxygen, turbidity and "solids"), the DOC study must be performed using a known standard.
- 23.7.6Ab No MDL studies are performed for analytical tests that have no available spiking solutions (e.g. asbestos, fibers, viscosity, pH, color, odor, temperature, dissolved oxygen, turbidity and "solids").
- Before 23.7.4D *Note: Known CRM standards should be used in place of spiked solutions for analytical tests that have no available spiking solutions (e.g. asbestos, fibers, viscosity, pH, color, odor, temperature, dissolved oxygen, turbidity and "solids")*
- Updated SOP ID in Section 2.4.5(A)
-

6/1/12

- 1.2.3C Removed Lab Supervisor (see below)

The Laboratory Supervisor serves as supervisor of designated Analytical Groups and responsibilities include assisting the Laboratory Manger in duties, as assigned. During periods of absence these responsibilities will be assigned to a qualified chemist.

The Laboratory Supervisor of DCL is identified as a "Supervisor" (per position description from May 2002) according to AEP Corporate Human Resources position titles. The Supervisor of DCL reports to the Laboratory Manager of DCL.

The minimum education requirements of the Laboratory Supervisor is the same as all chemists — a Bachelor of Science (B.S.) degree in Chemistry or the equivalent in education and experience.

- 1.4.1 (E) Removed references to "workplace services" since front desk is now empty
- 1.4.3(A) updated Electronic backup to weekly – direct to network or with portable device
- 1.4.3(B) & (C) updated – LIMS >> The current LIMS is Sample Master, Version 9.0, from Accelerated Technology Laboratories (ATL), Inc. The front end of the system utilizes … etc. … Access to the LIMS is password-protected through Windows authentication as opposed to SQL Server authentication (which would require an additional password). (Note: Windows authentication is considered a more secure way of protecting the server and therefore the data.) Each laboratory employee is granted specific levels of access by the LIMS Administrator. ~~is required to have their own, private and secure password.~~ >>> "aspendata" and "aspenarch" replaced by SMV9 and SMV9 Archive, plus added SMV9 Temp (on ohdolandb001)- 1.4.3(D) – DELETED - stated that IHAG backed up monthly
- 1.4.3(D) – all IHAG instrument back up to AEP network – REMOVED because this is lab-wide per 1.4.3
- 2.4.3 updated QAM Org- removed individual AG Plans and reference of an "overview manual"
- 2.4.5 – updated SOP ID, SOP forms and added Lab Forms
- 3.2.3Bf Added special pagination for QAM with "Sections"
- 3.2.3Gd SOP review changed back from 3yr to EVERY YEAR, OR AS NEEDED.
- 6.3.2 Updated CoA in Accompanying documentation
- Doc 9-1 Omitted NCERR (NC Event Review Report Form which is no longer used.
- 10.1.5C added VELAP to accreditations
- 10.5.2B make final PT CPAR available to VELAP
- 11.3.5B- updated CPAR process regarding 6-wk Target Completion Date and Mgmt exemptions
- 11.3.5D – CPAR followup – changed from 3 and 12 mos to within 12 mos
- 14.1.4 When audit findings cast doubt on the effectiveness of the operations .. laboratory shall take timely corrective action, and shall notify clients in writing ..plus repeat statement from Section 24.3.3(C)
- 14.3.3B- add VELAP and change AIHA & NVLAP from cert renewal to accreditation renewal.
- 16.9.4B Added details for PMR using Talent Solutions
- Add 18.3.2(D)(a) and 18.3.4(A)(a) For analytical tests that have no available spiking solutions (e.g. asbestos, fibers, viscosity, pH, color, odor, temperature, dissolved oxygen, turbidity and "solids"), an MDL study does not have to be performed. The MDL is defined using the precision of the measurements.
- (Per 2012 LELAP Finding 6) 18.3.3(D) updated with "and MDL must be < ML/RL"
- DCL - 20.5.1A Added info about CoA binders and Form QAR-2001
- 21.3.1 removed "12" from " flow composite
- 22.2.2 updated Mailing address from 1RP to Bixby rd & Lab Mgr from LDR to DGA
- 23.7.2(E)(d)(iii) – supplemental PT required by WWAG (not entire lab)
- 23.7.4G and 23.7.4 LFM corrected to 75-125%
- 24.3.5 – removed "telefax" for report delivery
- added shipping custodian, critical supplies and non-critical supplies to the Glossary- as well as constant weight; and updated LOD LOQ MDL and PQL (all related)

Section 14 – Laboratory Audits – rearranged and updated.

Reorganized so that 14.1 lists Quality Audit Procedures, Findings, and Types; then 14.2-14.5 describes Internal, External and Vendor Audits. Archived Forms QAR-1401 and 1402 which include subjective ratings and the entire ISO language with comments. New Internal Audi t form is Form QAR 1405 – which addresses ISO standard, in addition to specific accreditation requirements. New Form also requires Method Audits, Data Package Audit, Documentation Audits and Follow-up Reviews. Vendor Audit form also updated in Rev 1 or QAR 1404, using guidance fro man ISO 17025 article..

Removed details on filling out Audit Checklists and the checklists themselves.

Moved Section 14.2.4 to Improvements Section 10.6.3 (..bimonthly chemist meeting to discuss laboratory operations..)

Removed all references to System and Performance Audits (from original QAM), including submission of double blind samples (which is not done) and discussion of reviewing generated data.

Removed Quality System Records Lists (i.e. Master List of Documents, List of Approved Suppliers, etc) – QAM Doc 03-01, 05-01, 06-02, 13-01, 18-02, 19-01, 19-14, 20-01 and App C were all removed from QAM (and throughout text) as Records as QS Rec -0301, 0501, 0601, 1301, 1801, 1901, 1902, ans 2501.

Section 6.3 (Incoming Materials) moved into QMS-601 SOP Receipt Proc for Incoming Materials (including all QAP Docs) — The control of incoming materials into the laboratory and the associated documentation is discussed in detail in the Receipt Procedure for Incoming Materials.

Removed QAM 09-01 – NCERR Form (Nonconformance Event Review report) which is manual form that is NOT used – only use CPAR database system.

Updated Doc 12-2 to 12-4

Added Section 13.1.6 - The QAO* also maintains a list of material signatures and initials for all Laboratory Analysts.
13.7.7 – Monthly QC audit removed – moved to 2x per year in Internal Audit
Added 13.1.2Bc - Electronic files saved should be sufficient to re-create the analytical sequence - chromatograms, background changes, method changes, etc. - as if they were opened in a new place using the appropriate software.
DELETED 13.1.2E - ~~All (hard copies of) analytical reports shall be reviewed and initialed by the Laboratory Manager or QAO* after the report has been issued.~~

QAO Duties removed – 3.2.3F – QAO NOT required to maintain record of changes (in quality documents).
- 6.3.2G – MSDS and CoA do not have to be delivered to QAO
- 9.3.2, 9.3.3 C, D, E – removed use of NCERR
- 19.2.4C, 20.2.4, 20.4.4, 20.5.1Eb, 20.5.5 QAO does NOT maintain records for CoA (only for ref stds)
- 22.1 – QAO not responsible for checkin, etc.

Section 15 – Mgmt Review – rearranged and updated. Removed details on filling out Mgmt Review Checklist and the checklist itself. Removed references to Internal Audit and NIST checklists, which have been incorporated into Internal audit. Moved the list of MR items (from ISO) up to 15.1.3 and clearly defined the FOUR step process (Info Gathering, Interactive Mtg, Action Plan, and Implementation and F/U) in 15.2 and replaced rest of 15 (which defined the use of action items CPARs, etc) with this ("**Management Review Findings —** Handle MR Findings (Action Items) in the same manner as the Quality Audit findings in Section 14.1.2.") in 15.3.

Section 17.3 – removed — The proper use and maintenance of laboratory fume hoods is discussed in detail in the Laboratory Operations of Support Equipment Procedure.

Removed Doc 18-01 and 18-02 and Details associated with them. Removed text from Section 18.3 and Example MDL and DOC forms. These items will be contained in the QS records – Scopes and MDL studies. MDL moved to 18-01, ML moved to 18-02, and DOC moved to 18-03.

Reorganized Section 19 – removed Doc 19-01 and moved other Docs up. Docs 19-01, 19-02, 19-03 for Cal frequencies; Docs 19-04, 19-05, 19-06 for Glassware Cleaning procedures.
Updated Doc 19-1 to 19-3
Updated Doc 19-4, to 19-6

(SCL only - Removed directions in 19.2.3B, and removed use of labels for equipment and pipettes in 19.3.7(D) b and c).

Moved most of 19.4.x (19.4.3 – 19.4.17) to Lab Ops SOP - RO Systems, Analyt Balances , Thermometers, Refrig Equipment, Ovens, Desiccators, Pipettes, pH meters, Spec Ion Meters Hot Blocks, Microwaves, Distillation, Acid Neutralization Tanks, and General Labware. – and ALL the Forms.

Removed 19-14 – and refer to as Records. Most of Section 19.5 – Equipment – removed and added this statement: The laboratory specifications, calibration procedures and frequency of calibration are outlined in the Laboratory Operations Procedure. This procedure contains a list of required procedures used to ensure accuracy and proper operation of laboratory equipment devices used routinely. The scope of this procedure encompasses: general laboratory equipment, safety equipment, temperature-measuring equipment, temperature-maintaining equipment, volume-measuring equipment, volume-dispensing equipment, weight-measuring equipment, shared measuring equipment, other support equipment, and reference standards.

Removed Doc 20-1 and examples of certificates. Master List of Meas Trace Items – ONLY ref stds – removed cal stds and SRM , which are maintained by each test.

Document 21-1 updated with pdf from CFR with 05.18.12 MUR. Removed Examples of Labels and Bottle order (Docs 21-3,4). Removed Doc 21-2 (Volumes and Hold times) – use CFR Table for Hold times and Record on ENV website for suggested volumes.

Section 22.0 – removed examples of COC, ARF etc. (Docs 22-01 to 03) and details to fill in COC (Secrions 23..3.3 and 22.3.4 A to E). Remove "Analysis Codes" (Doc 22-04, originally Subpart O), which are no longer used. (e.g. Ash A, Deposits E, Insul Oils J, Waste Char O, etc). Removed placeholders for Docs 22-5 to 7.
22.4.4Ad- removed those samples "SUCH AS HEXAVALENT CHROMIUM IN WATER," …
22.6.4Cai – removed details for Cr6, generalized for samples with 24hr hold time
Section 23 – removed Control Chart examples (Doc 23-1, 23-2).
Removed 23.3 – Function and Control Checks which are discussed throughout 23

Removed Doc 24-1 and 24-2; (24-1 is a form and 24-2 – Approved Signatories- save as record.) Deleted sentence 24.3.2(A)
Section 24.3.2(D)(a) – Added info From IHAG CPAR (# 20110524165039) about peer review (and checklist)

Removed App C and all references throughout QAM.
Removed all references to Snapshots
Removed all references to DCL, Dolan, Shreveport or SCL and replaced with the "Laboratory" (except in Sections 1, parts of 2, 16, 17, 21, 22 and the Lab protocol in 23)

ISSUES TO ADDRESS IN NEXT QAM REVISION (most Comments from LDR review)
1.2.3C – LDR suggested to keep Lab Supervisor in Org Charts, Etc
1.4.3Cb – review Dolan procedures
2.2.2 review " action plans"
2.3.2 – Doc 2-2 AEP Princ of Business Conduct – NEW emplyoyees – read and view doc and video- proof?
Need to REVIEW Doc 3-3 - Org of QCDOC files
3.2.2B Long-term retention of PS records is determined on a case-by-case basis.
3.2.3C – LDR Comment - All ProServ documents should be discarded.
3.2.3 – DOC Control Protocol – FORMS and spreadsheets
3.2.3Cb – Issue "Uncontrolled Copy" watermark – LDR printed QAM from Sharepoint – no watermark!
Review "3.3.5(A) All applications must be documented, including instructions for using and maintaining the software."
5.1.3 – chem. request permission to subcontract …upon authorize. Of Lab Mgr…>>LDR comment - Does this require "written" documentation of approval/permission to subcontract i.e. for phenolics/Cyanide, does the lab have documentation to demonstrate this permission to subcontract?
5.2.2 – LDR Comment - is a certificate of accreditation available for Microbac? Elemental Analysis?
5.4.3 – include 3rd party report with FINAL report – LDR Comment - is this consistently followed b WWAG?
6.2.2 – Needs REVIEWED IN DETAIL – General Purchase Order info
Materials Receipt SOP??
7.2.2 – NB- "7.2.2 It is recommended to document conversations with the customer (e.g. complaints, conversations, clarifications, etc.) in the LIMS under the "Complaints Management" menu of the Tools tab. "
7.4 – DEFINE SURVEY FREQUENCY? – Quarterly?? – 1 x per year per 3 groups?
8.2 & 22.4.4C– Complaints Procedure needs updated for new LIMS (Sample master)
10.6.3 – (Improvementrs) – Chemist Mtg – Lab Mgr Handwritten notes available?
11.1.4 – QAO reports to lab Mgmt – AT LEAST QUARTERLY - QA issues, CPARs. Etc
NB – 13.5.1B – notebook id analyte or sample type … (g) sign & date – not just initials … 13.5.3E – signed or initialed …
13.7.5 & 13.7.6 – monthly summaries to lab mgmt AND ALL LAB PERSONNEL
13.7.8 – Weekly Reports – by TYPE, TESTGROUP and TEST (correct terminology for Sample Master?)
15.1.2B- CA – carried out before next scheduled MR
16.8.2C –(See Department Policy No. 1130) ???
16.9.4Cb – List AEP Core Values?
16.9.4E – needs updated for Talent Solutions and Electronic format
EVAL Doc 16-8 NEW EMPLOYEE Checklist
17.3 and 19.x – LAB OPS SOP?
17.4.3A – Housekeeping Inspection Team?
18.1.2A – "Matrices are denoted in the LIMS when possible"
EVAL 18.1.2B "(e) At least annually, all QA targets are re-evaluated (and updated, if necessary) against laboratory-generated data to ensure targets continue to reflect methodologically- achievable goals. "
EVAL 18.2.2 "The analytical group SOP manuals are subdivided into individual SOP manuals reflective of each of the analysis types performed in the analytical group. "
Need to updated Doc 19-14 and 20-1 with better details
Need to update with upcoming MUR 2011- None as of 7/12/11
Need to complete Lab Ops SOP and remove or condense Sections 19.4.3 – 19.5 and all of Section 19.5
19.2 – Consider moving 19.2, 19.3, 19.4 to appropriate sections – Cal, stds, and records
19.3.4 = Initial Use – Do we have documentation for NEW ICP IN IHAG???
Copy of CoA for (20.2.4) cal stds … (20.3.4) Ref Stds… (20.4.4) SRM …(20.4.5) std and reagents
EVAL? "20.4.3(D)Local areas, such as the Coal Lab, Oil Lab, etc., should establish locations within each of the labs that protect the standard from excessive light and heat, and should be locations that are as protective as possible of the integrity of the standard. "

- Section 19.4.3(B)(b) - DGA (Do we need this and is it performed?)
- Section 19.4.5(A)(e) – handling list of mercury thermometers (see H: drive), who is responsible?
- Section 19.5.x – Consider if WWAG adds Cr6 by IC to FoTs.

REMOVED From 19.x — Lab Ops?

-The Chemical Hygiene Officer (CHO) shall review the annual certification report and take steps to have all laboratory fume/HEPA hoods repaired that fall below their minimum recommended face velocity limits. (See Section 17.3.3(C))

The Chemical Hygiene Officer (CHO) shall maintain records of the velocity checks and the annual certification. (See Section 17.3.4(B))

The use of mercury thermometers is prohibited in the laboratory unless required by a specific test. An exception to use mercury-containing thermometers must be authorized by the Laboratory Manager and the Chemical Hygiene Officer (CHO). The CHO shall maintain a list containing the location of mercury thermometers in use within the laboratory. (See Section 19.7.5(A)(e))

Section 19.5.x – Consider if WWAG adds Cr6 by IC to FoTs.

Need Sample receipt SOPs for other AG's and condense Section 22.x

Control Charts — If a standard tests outside the control limits, repeat the analyses immediately if possible. If it again falls outside the CLs, stop the analyses and determine the problem with the procedure.

22.2.1Aa "ready access to Lotus Notes based EVL ??? My Env Asst? Lotus db? Env Services website?

EVAL ?? 22.4.1 - PONY

EVAL? 22.4.7Aa – Lotus Notes Based sample submittal request db; avail to all AEP personnel with access to Lotus Notes…

22.5.3C and 22.5.4 – update for new LIMS

Update Section22.6.4 WWAG Sample Retention

Review 22.6 – Update Sample Ret guidelines and create SOP? (PSAG – shelves in balance room?), urea, Lime, LS, Trona, Gypsum?, (WWAG record storage shelves?) – WWAG – waste and metals – keep for max of 6 mos — WWAG 24 hr hold time?

22.7.2 – drums in Biol Lab?

22.7.3 – Non haz solid disposed by "waste disposal service" ? LDR – throw in trash??

23.5.1B – Control Charts – from LIMS? Or from MS Access db linked to LIMS????

EVAL – 23.5.6 USE of Control Charts – between Rule 2 and Rule 3 …." LQSI – Rule 3 "At least 4 out of successive values fall on the same side of, and more than 1 sigma away from, the central line. "

NB 23.6.3D – QAO ..audits … estimate uncert

Section 23.6 Uncertainty needs condensed to WHAT WE DO. – Check UNCERTAINTY statements in SOPs.

QUESTIONS about uncertainty >>>> Does IHAG need to document these uncertainties somewhere and if so, at what frequency? In SOP??? Or annually with MDL study?

IHAG -Refer to individual SOP (e.g. Bulk Asbestos SOP, Fibers SOP)

PSAG – qualitative – particle size, particle counting, some xray methods

WWAG – qualitative?? Paint filter test, Any other Pass/Fail tests ?

EVAL Doc 24-1 Analytical Report Checklist

EVAL 24.3.2D "(i) All reviews by laboratory management and the QAO* are documented by initialing the reports in the upper right corner of the report. "

24.3.3A and B – STAMP Amended Reports (AMENDED OR REISSUED)…?

Eval Checklist Doc 24-1

Records? Remove Doc 24-2

- Address Rules of Sig Figs

(1) In addition and subtraction, the result is rounded off to the last common digit occurring furthest to the right in all components. Another way to state this rule is as follows: in addition and subtraction, the result is rounded off so that it has the same number of decimal places as the measurement having the fewest decimal places (or digits to the right).

2) In multiplication and division, the result should be rounded off so as to have the same number of significant figures as in the component with the least number of significant figures.

- Postpone 24.3.1(Q to W) until DCL installs new LIMS

NELAC compliance statement for test results. [Reference 18.4.1]

A statement saying that "The results apply only to the samples as received in the laboratory" shall be added to print at the bottom of every analytical report. [Reference 18.4.1]

For non-NELAC accredited parameters (i.e. parameter(s) which are not on the laboratory's Scope of Accreditation), the results shall be flagged with a statement saying that "This is a non-NELAC accredited test result. This laboratory is not certified to perform this test in compliance with NELAC requirements" which shall be printed at the bottom of the affected analytical report(s). [Reference 18.4.1]

It is recommended "A statement specifying that the test report or calibration certificate shall not be reproduced except in full, without written approval of the laboratory." [per ISO 17025 Note in Section 5.10.2, Reference 18.4.9]

"Where applicable or requested, a statement on the estimated uncertainty of measurement (information on uncertainty is needed in test reports when it is relevant to the validity or application of the test results, when a customer's instructions so requires, or when the uncertainty affects compliance to a specification limit)"; [per ISO 17025 Section 5.10.3.1c, Reference 18.4.9]
"Where appropriate and needed, opinions and interpretations – clearly marked as such." [per ISO 17025 Section 5.10.3.1d, Reference 18.4.9] **Dolan IHAG and WWAG do not provide opinions or interpretations.**
"Any additional information which may be required by specific methods, customer, or groups of customers." [per ISO 17025 Section 5.10.3.1d, Reference 18.4.9]
The QAM does not outline a formal policy for the possibility of the termination of Dolan's existence, beyond notifying the clients. A policy for records from internal clients and for the

>>Regarding Measurement Traceability (AIHA App H)

- >>> **Section 19.2.5 states "The frequency of these activities are dependant on the uncertainty required, the frequency of use and verification, the manner of use, the stability of the equipment, and the risk of failure considerations." And AIHA App H also states:**
  >>>**Table 5-1 provides the minimum frequencies that are required.**
  >>> **The laboratory shall have procedures describing their external and internal calibration and verification activities and frequencies, and the actions to follow if the equipment is found to be out of acceptable specification.**
  >>> **Laboratory staff performing in-house calibrations and verifications shall have received documented training**

Table 5-1 —- Minimum Calibration/Verification Frequency Requirements for Common Reference Standards and Support Equipment

Reference Standard / Equipment	Calibration Frequency	Verification Frequency
Reference Thermometer	Initial and every 5 years	Not applicable
Working Thermometer	Initial and when verification fails	Annually
Reference Masses	Initial and every 5 years	Not applicable
Working Masses	NA	Initial and then annually
Stage Micrometer	Initial and if damaged	Not applicable
Balance	Initial and following service/repair or when verification fails	Each day of use
Mechanical Pipettes	Initial and when verification fails	Annual
Volumetric Containers for critical functions (non-Class A)	Not applicable	Each lot prior to use

TOC errors in repeated page nos
Outline spacing throughout
TOTAL page # count skipping starting in Section1

xxx END OF CONTROLLED QUALITY DOCUMENT ***xxx***