ENVIRONMENTAL MONITORING LABORATORY

LABORATORY and MONITORING QUALITY CONTROL PLAN FOR CHEMICAL MATERIALS AGENCY (CMA) AND FOR CHEMICAL AGENT STANDARD ANALYTICAL REFERENCE MATERIAL (CASARM)

REVISION NO. 2

COPY NUMBER _____

UNCONTROLLED COPY

U.S. ARMY
EDGEWOOD CHEMICAL BIOLOGICAL CENTER
DIRECTORATE OF PROGRAM INTEGRATION
CB OPERATIONS

Approved by:

Chief, Environmental Monitoring Laboratory

12/30/11
Date

UNCONTROLLED COPY

Record of Change

- Revision 2. Generated to comply with changes made in Revision 6 of the CASARM Quality Assurance Plan dated May 2010. Reference numbers in paragraphs titles conform to the following convention: numbers in parentheses refer to the CASARM QA Plan and numbers preceded by an asterisk (*) refer to the LMQAP.

  Deleted references to FTIR System, changed the name of the EML Lab Manager, added title of Air Monitoring Manager and description of duties. Deleted Remediation Team Duties and all references to it. Updated the entire document to reflect current EML QC Operations, correct minor typos, and bring the EML QC Plan into conformance with changes to the CASARM QC Plan.

- Revision 1 Changed page numbering system. Reformatted document and made the following changes:

  Changed pages 3, 14, 25, 27, 28, 34, 38, 39, 42, 43, 44, 45, 49, 50, 51, 52, 55, 56, 57, 58

  Pg 3 – Updated Record of Change

  Pg 14 – Added Remediation Team Leader duties.

  Pg 25 – Paragraph 4.7-Changed wording to reflect current operations.

  Pg 27 – Changed SOP CR4-2NP001 to SOP CNG-044.

  Pg 28 – Changed 4.8.1.1, paragraph 3 to reflect current operations.

  Pg 34 – changed Table 1-2 (Number of samples column to reflect correct sample sizes in accordance with change 1 to CASARM Plan.

  Pg 38, Paragraph 4.1.1 – Added bullets to reflect current operations.

  Pg 42, Paragraph 4.14.2.1 – Changed wording to reflect current operations.

  Pgs 43 & 44, Paragraph 4.14.4 – Changed wording to reflect current operations.

  Pg 45, Paragraph 4.15 – Changed wording to reflect current operations.

  Pg 49, Paragraph 4.17.1.1.1 – Changed 1.5 Z to 2.0 Z.

  Pg 50, Paragraph 4.17.1.1.2, Table 2-1 – Changed 1.5 Z to 2.0 Z.

  Pg 51, Paragraph 4.17.1.2.1 – Added clarification to certification requirements.

  Pg 52, Paragraph 4.17.3 – Changed 1.5 Z to 2.0 Z.

  Pg 55, Paragraph 4.19 – Changed wording to reflect current operations.

  Pg 56, Paragraph 4.20 – Changed wording to reflect current operations.

  Pg -57, Paragraph 4.21 – Changed Table 2-3 to reflect actual AEL requirements.

  Pg 58, Paragraph 4.21 – Changed Table 2-4 to reflect current CDC requirements.

- Revision 0 December 2004

  Previous revisions of this document did not incorporate a record of change page.

  CASARM – This document includes all basic guidelines and information contained in Revision #7 of the Environmental Monitoring Laboratory QC Plan except as modified to meet the requirements of CMA mandated changes.

  CMA – Revision 0 of the Environmental Monitoring Laboratory QC Plan is designed to meet requirements of the US Army Chemical Materials Agency Programmatic Laboratory and Monitoring Quality Assurance Plan dated June 2004 (CMA LMQAP) and the CASARM requirement as contained in the CASARM QA PLAN, Revision #5 dated November 2004.

UNCONTROLLED COPY

Table of Contents

Page
Record of Change 3
Table of Contents 4
0.0 INTRODUCTION 8
1.0 SCOPE AND FIELD OF APPLICATION 9
2.0 REFERENCES 9
3.0 DEFINITIONS 9
4.0 QUALITY SYSTEMS REQUIREMENTS 9
4.1 Management Responsibility 9
4.1.1 Quality Policy (3.1) *2.1 9
4.1.2 Organization (3.2) *2.2 10
4.1.2.1 Responsibility and Authority *3.2 11
4.1.2.1.1 Chief of the Environmental Monitoring Laboratory 11
4.1.2.1.2 Analytical Chemistry Manager 12
4.1.2.1.3 Air Monitoring Manager 13
4.1.2.1.4 Analytical Chemistry Team 13
4.1.2.1.5 Quality Assurance Coordinator *3.4.3 14
4.1.2.1.6 MINICAMS Team Leader 15
4.1.2.1.7 MINICAMS Team 15
4.1.2.1.8 Sample Team Leader 16
4.1.2.1.9 Sample Team 17
4.1.2.1.10 Calibration Coordinator *3.4.4 & (6.1, pg 34) 17
4.1.3 Resources *3.2.1 17
4.1.3.1 Management Representative *3.2 18
4.1.3.2 Management Review (3.3) *2.3, pg 4 18
4.2 Quality System (3.4) *2.4 19
4.2.1 Quality Planning *2.4.2, pg 5 19
4.2.2 Quality Objectives (4.1.1 & 4.1.2) *2.4.2.2 19
4.3 Contract Review 19
4.4 Work Requests 20
4.5 Document and Data Control *16.1 20
4.5.1 Document and Data Approval and Issue *pg 65 21
4.5.2 Document and Data Changes 21

UNCONTROLLED COPY

4.5.2.1 Minor Document and Data Changes *16 21
4.5.2.2 Major Document and Data Changes 22
4.5.3 Retention of Documentation 22
4.6 Purchasing *11, pg 54 22
4.6.1 General 22
4.6.2 Assessment of Sub-Contractors *pg 55 22
4.6.3 Purchasing Data *pg 55 23
4.7 Customer Supplied Product *pg 68 23
4.8 Product Identification and Traceability (14.3, pg 94) *pg 40 24
4.9 Process Control 24
4.9.1 QC of Methods and Monitors *pg 44 25
4.9.1.1 Control Samples (12.2, pg 79) *pg 44 25
4.9.1.2 Control Sample Loading *pg 43, 44, 45 26
4.9.1.2.1 DAAMS Methods 26
4.9.1.2.2 Near-Real-Time (NRT) Systems (Table 10.3, pg 58 & 12.2.1, pg 79) *pg 45 27
4.9.2 Class 1 Method Control Charts *pg 95 28
4.9.2.1 Contents of QL Control Charts *pg 95 28
4.9.2.2 Updating & Maintaining Control Charts *pg 95 29
4.9.2.3 Out-of-Control and Out-of-Statistical-Control Situations 29
4.9.3 Class 1 Monitor QP Data/Performance Charts *pg 93 29
4.9.3.1 Contents of Performance Charts and Associated Data 29
4.9.3.2 Performance Chart Calculations 29
4.9.3.3 Out-of-Control and Out-of-Statistical-Control Situations for Class 1 Monitors 30
4.9.4 Special Processes 30
4.9.5 Quality Control of Heated Sample Lines (HSL) *pg 50 30
4.9.6 Quality Control of DAAMS Tubes (Table 9-1, pg 47) *12.2.1, pg 56-58 30
4.9.7 Quality Control of Preconcentrator Tubes (PCT) 31
4.9.8 Quality Control of Silver Fluoride Conversion Pads 31
4.9.8.1 Initial Testing *12.2.4, pg 59 31
4.9.8.2 Nitrogen Oxide filters (NO_x) *pg 58 32
4.10 Inspection and Testing *12.0, pg 56 32
4.10.1 Receiving and Inspection Testing 32
4.10.1.1 Verification of Incoming Supplies *11, pg 54 32
4.10.2 In-Process Inspection and Testing *12.3, pg 59 33

UNCONTROLLED COPY

4.10.3 Final Inspection and Testing *pg 59 & 60 33
4.10.4 Inspection and Test Records 34
4.11 Inspection, Measuring, and Test Equipment (9.1) *pg 35 34
4.11.1 Analytical Systems *pg 36 & 37 34
4.11.2 Edgewood Area Calibration Program (11, pg 67) *pg 34 35
4.12 Sample Storage and Handling (14.5, pg 95) *pg 41 35
4.13 Control of Non-conforming Product (4.5) *pg 60 36
4.14 Corrective Action (4.2) *pg 63 36
4.14.1 Immediate Corrective Action 36
4.14.2 Long term Corrective Actions 36
4.14.3 Preventive Action (4.3) *pg 63 37
4.14.4 Customer Satisfaction (4.1.2, pg 11) *pg 62 38
4.15 Sample Collection, Handling, Delivery, and Analysis 38
4.15.1 Sample Collection (14.2, pg 94) *pg 40 38
4.15.2 Handling (14.4, pg 95) *pg 41 38
4.15.2.1 Sample Management (14.1, pg 94) *pg 41 &42 38
4.15.3 Delivery (14.4, pg 95) *pg 42 39
4.15.4 Analysis (14.4, pg 95) *pg 41 & 42 39
4.15.4.1 GC/LC Analysis: 39
4.15.4.2 MINICAMS Monitoring *pg 42 40
4.15.4.3 Confirmation of Positive Responses *pg 51 40
4.15.4.4 Correction for Method Recovery *pg 52 41
4.16 Quality Records (15.4, pg 98) *pg 66 41
4.17 Internal Quality Audits *pg 61 43
4.18 Training (5) *pg 24 44
4.18.1 Individual Training Plans 44
4.18.1.1 Analyst/Operator Certification (5) *pg 29 & 30 45
4.18.1.1.1 Class 1 Methods/Monitoring Tasks *pg 30 45
4.18.1.1.2 Class A, Class 2, Class 3 Methods *pg 30 46
4.18.1.1.3 Semi-Annual Evaluation of Personnel *pg 31 46
4.18.1.2 Re-certification of Analysts/Operators * pg 30 47
4.18.1.2.1 Class 1 Methods/Monitoring Tasks 47
4.18.1.2.2 Class 2 Methods 47
4.18.1.3 Sample Collection Personnel 48

UNCONTROLLED COPY

4.18.2 P&A Method Certification Requirements (9.2, 10.3) *pg 24, 26, 27 48
4.18.2.1 Off Site Method Certification 50
4.18.2.2 Class 2 Method Certification 50
4.18.2.3 P&A Method Certification 50
4.18.2.4 Method Documentation and Configuration Control 50
4.18.3 Certification of Additional Instruments (9.2, pg 46) *pg 32 51
4.18.3.1 Class 1 NRT Monitors *pg 37 51
4.18.4 Significant Changes in Methods/Monitoring Tasks *pg 33 51
4.18.5 Systemization of NRT Monitor/Data Acquisition System Interface (9.3, pg 46) 52
4.19 Statistical Techniques *pg 67 52
4.20 Preventive Maintenance (4.4) *pg 53 53
4.21 Reference Materials (8.2) *pg 19, 22, 23 54
4.21.1 Glassware Cleaning Procedure *pg 22 55
4.22 Action Level (Airborne exposure limits) *pg 88 56
Appendix 1 Glossary of Terms 58
Appendix 2 Acronyms 63

Figure 1 Environmental Monitoring Laboratory Reporting Interface 11

Table 1-2 Sample Sizes for Normal Inspection for Maximum of 2.5 Percent Non-Conformance 31
Table 2-1 Analyst/Operator Certification Test Requirements 46
Table 2-2 P&A Method Certification Requirements 49
Table 2-3 Action Level for DAAMS Monitoring 56
Table 2-4 Action Limits for NRT Monitoring at STEL 57

UNCONTROLLED COPY

LABORATORY and MONITORING QUALITY CONTROL PLAN
FOR CHEMICAL MATERIALS AGENCY (CMA)
AND
FOR CHEMICAL AGENT STANDARD ANALYTICAL REFERENCE MATERIAL
(CASARM)

0.0 INTRODUCTION

The Environmental Monitoring Laboratory (EML) is a supporting branch of the Chemical Biological Operations Division of the Edgewood Chemical Biological Center. The EML is a full service laboratory capable of providing analytical services for chemical and biological threat agents, and toxic industrial compounds. The full range of analytical services can be provided at the fixed laboratories and facilities at the Edgewood Area of Aberdeen Proving Grounds or anywhere in the world using a variety of customized mobile configurations to meet customer needs.

The EML consists of three specialized areas including Air Monitoring, Analytical Chemistry, and Biological Monitoring (not covered in this document).

The EML uses these areas to provide sustainment support to operations within ECBC and outside the organization.

Examples include but are not limited to Near-Real-Time (NRT) monitoring of an agent operation, historical monitoring for personnel safety during chemical operating, and general agent sample characterization.

The EML employs a variety of technologies to accomplish its mission such as:

- Miniature Continuous Air Monitoring Systems (MINICAMS) equipped with Flame Photometric Detectors (FPD) and Halogen Specific Detectors (XSD)
- Detectors (FPD) and Halogen Specific Detectors (XSD)
- Depot Area Air Monitoring Systems (DAAMS) packed with various sorbent materials for thermal desorption analysis or extraction analysis.
- Open Path-Fourier Transformer Infrared Spectroscopy (OPFTIR)
- Gas Chromatography using FPD, Flame Ionization Detectors (FID), Nitrogen Phosphorus Detectors (NPD), and single and tandem Mass Spectroscopy using Electron Impact (EI) and Chemical Ionization (CI) techniques (GCMS, GCMS-MS)
- Liquid Chromatography using wavelength detectors (HPLC) and single and tandem Mass Spectrometry (LCMS, LCMS-MS)
- Inductively Coupled Plasma Optical Emission Spectrometers (ICPOES)
- Graphite Furnace/Flame Atomic Adsorption (GFAA)
- Flow Induced Mercury Systems (FIMS)
- Hand held gas detectors

This document addresses the overall monitoring activities involving sample collection and analysis, handling of reference materials, and all related Quality Control activities. Additional monitoring and analysis requirements are detailed in the appropriate operating procedures and project specific documentation.

UNCONTROLLED COPY

1.0 SCOPE AND FIELD OF APPLICATION

Scope

This Quality Control (QC) Plan specifies the Environmental Monitoring Laboratory's requirements for compliance with the CASARM Quality Assurance (QA) Plan for Chemical Agent Air Monitoring (CQAPCAAM) dated May 2010 and U.S. Army Chemical Materials Agency Programmatic Laboratory and Monitoring Quality Assurance Plan dated December 2007 with change 1 dated October 2008 (CMA LQAP)

2.0 REFERENCES

U.S. Army Chemical Materials Agency Programmatic Laboratory and Monitoring Quality Assurance Plan (CMA LMQAP), December 2007 with Change 1 dated October 2008.

ISO Q9001-2008 Quality Management Systems

CASARM QA Plan for Chemical Agent Air Monitoring, Revision No.6, May 2010

DA PAM 385-61. Army Toxic Chemical Safety Program

AR-385-10 The Army Safety Program

AR 50-6 Chemical Surety

DOD-Quality System Manual Version 4.1

Internal Operating Procedures (IOP) for the Environmental Monitoring Laboratory

Standard Operating Procedures (SOP) for the Environmental Monitoring Laboratory

EML Master Documentation List, latest revision.

3.0 DEFINITIONS

Definitions used in this QC Plan are contained in Appendix 1 to this document.

4.0 QUALITY SYSTEMS REQUIREMENTS

4.1 Management Responsibility

4.1.1 Quality Policy (3.1) *2.1

It is the policy of the Director, CB Operations, located at U.S. Army Edgewood Chemical Biological Center, Aberdeen Proving Ground, to meet all regulatory requirements and customers' needs during agent monitoring. This will be accomplished by supporting all Environmental Monitoring Laboratory efforts associated with the collection, handling, and analysis of chemical warfare agents, and assuring that all of these operations are in accordance with (IAW) all appropriate Procedures, Plans and this QC plan. Executive management will ensure that the Quality Policy is disseminated and understood at appropriate levels of the organization.

The Environmental Monitoring Laboratory will provide analysts, operators, and sample technicians with the appropriate training and resources to perform quality work. The Environmental Monitoring Laboratory will implement a sound QA/QC Program for sample collection and analysis of DAAMS tubes, extraction and analysis of soil and liquid samples, and the operation of near real time monitors. The Environmental Monitoring Laboratory will strive for continuous improvement by stressing personnel,

UNCONTROLLED COPY

facility, and process improvement. Quality Objectives are addressed in paragraph 4.2.2 (4.1.1). Need for Improvements are generated from discussions with EML personnel, Team leaders and customers. Continuous improvement of the EML Quality System is demonstrated by changes/improvements to quality documents, Customer Surveys, Corrective Actions, Preventive actions used by EML,

The Environmental Monitoring Laboratory will collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to determine where appropriate continual improvement can be made to the system. Data to be evaluated include:

- Customer Surveys – Paragraphs 4.2.2 & 4.14.4
- Preventive action – Paragraph-4.14.3
- Ongoing/continual improvement – Paragraphs 4.1.1, 4.5.1, & 4.14.3, Data reports 4.10.3

These objectives will be evaluated by the Quality Management Team (Branch Chief, Analytical Team Manager, Air Monitoring Manager, and QC representative).

This team will meet quarterly to discuss quality objective data, preventative actions, and continual improvement.

4.1.2 Organization (3.2) *2.2

The Environmental Monitoring Laboratory Office and Analytical Chemistry Team are located in Building E3330 of the Aberdeen Proving Ground, Edgewood Area. Additionally, the Sample Collection Team is located in Building E3344 and the MINICAMS team in Buildings E3330 and E3348. EML provides and maintains the necessary infrastructure to carry out its mission to include laboratory space, admin/office space, equipment, services, and other key functions. There is a satellite laboratory located at the Pine Bluff Arsenal. The Pine Bluff satellite laboratory will operate under this QC Plan and may designate Pine Bluff responsibilities as necessary.

Additional information about each team is contained in subsequent paragraphs of this document.

The Environmental Monitoring Laboratory Analytical Operations and Monitoring Operations are conducted in controlled environments to the extent possible, to promote worker health and safety.

The organizational chart in Figure 1 depicts the Environmental Monitoring Laboratory reporting Interface within Directorate of Program Integration.

UNCONTROLLED COPY

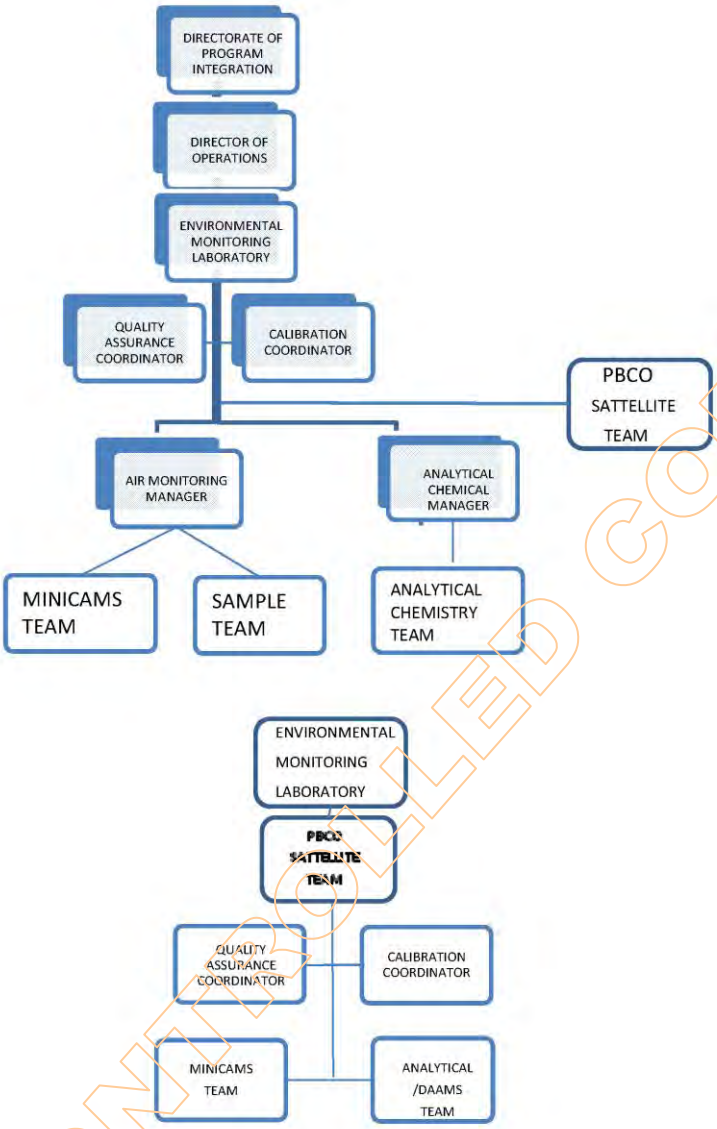

Figure 1 Environmental Monitoring Laboratory Reporting Interface

4.1.2.1 Responsibility and Authority *3.2

4.1.2.1.1 Chief of the Environmental Monitoring Laboratory

The Chief of the Environmental Monitoring Laboratory shall:

a) Be responsible for the fulfillment of quality assurance requirements throughout the monitoring program.

b) Brief the Director CB Operations on status of operations and/or problem areas.

c) Provide overall administrative support and technical guidance to the program.

d) Monitor charges versus funding levels.

UNCONTROLLED COPY

e) Review status of workload and labor requirements.

f) Review new work requests for their effect on operations and mission capabilities.

g) Appoint an Air Monitoring Manager (AMM).

h) Appoint a Calibration Coordinator (CC).

i) Appoint a Quality Assurance Coordinator (QAC).

j) Appoint an Analytical Chemistry Manager (ACM).

k) Appoint a Sample Team Leader (STL).

l) Appoint a MINICAMS Team Leader (MTL).

m) Ensure that the Environmental Monitoring Laboratory Quality Policy is implemented, maintained, and understood at all levels in the organization.

n) Be the point of contact for the Environmental Monitoring Laboratory's Contractor.

o) Assign an internal auditor that is independent of the work being performed.

p) Conduct a Management Review of the Environmental Monitoring Laboratory Quality System, once a year with emphasis on changing business environments, new regulations, and organizational changes that could affect the Quality System.

4.1.2.1.2 Analytical Chemistry Manager

The Analytical Chemistry Manager (ACM) shall:

a) Have overall responsibility for data validation and for assuring that validated data is properly initialed and dated as required.

b) Have overall responsibility for the chemical analyses, including the technical merit of the analytical methodology, the fundamental analytical chemistry applied, and the fulfillment of quality assurance requirements.

c) Have overall responsibility for documenting all analytical methods used by the Analytical Chemistry Team (ACT and ensuring that the ACT is adhering to the methods.

d) Recommend additional personnel or equipment needs to Chief of the Environmental Monitoring Laboratory.

e) Coordinate laboratory efforts and schedules with Sampling Team.

f) Maintain close liaison with QAC. Provide for validation of analytical methods upon request from the QAC.

g) Inform Chief of the Environmental Monitoring Laboratory of problems that make laboratory data questionable, including out of control situations identified by the QAC.

UNCONTROLLED COPY

h) Take corrective actions and document corrections for review by QAC and Chief, Environmental Monitoring Laboratory.

i) Have overall responsibility for the analysis of all QC blinds submitted.

j) Inform the appropriate personnel as soon as possible of the need to conduct confirmation analysis, especially on samples collected during operations involving personnel.

k) Have overall responsibility for making and maintaining a supply of fresh and reliable agent standards.

l) Have overall responsibility for standards validation to assure that standards have not degraded.

m) Have overall responsibility for reviewing analytical data in the LIMS for conformance to requirements and approving these data.

4.1.2.1.3 Air Monitoring Manager

The Air Monitoring Manager (AMM) shall:

a) Be responsible for the planning, staffing and execution of air monitoring for all field projects.

b) Have oversight of all personnel on the Sample Collection and MINICAMS teams.

c) Participate in site visits, on board reviews and pre-operational surveys.

d) Review emerging technologies and recommend equipment that will streamline operations.

e) Make recommendations on staffing and equipment levels.

f) Take corrective actions and document corrections for review by QAC and Chief Environmental Monitoring Laboratory.

g) Write and/or review Air Monitoring Plans and procedures.

h) Review and provide comments on various documents pertaining to Air Monitoring methodologies and concepts.

4.1.2.1.4 Analytical Chemistry Team

The Analytical Chemistry Team (ACT) shall:

a) Be responsible for the chemical analysis of monitoring samples originating at U.S. Army Edgewood Chemical Biological Center (USAECBC) or collected at field operation sites.

b) Be directly responsible to the ACM to accomplish the objective stated above.

c) Conduct all analyses in accordance with safety and technical procedures provided by the ACM or in accordance with the appropriate site plan for field operations.

UNCONTROLLED COPY

d) Analyze the QC and monitoring samples in an acceptable time frame.

e) Review QC sample data and provides data to the QAC or designated field personnel for final review.

f) Initial and date all analytical data sheets.

g) Maintain equipment maintenance logs in laboratory and/or MAP and inform appropriate personnel of equipment breakdown.

h) Each team member is to read and sign the appropriate IOP's, as required.

i) Follow established protocols for entering analytical data into the LIMS (e.g., flows, times, results). Review all input information for correctness.

j) Review analytical data for completeness. Make corrections to data sheets before entering the data into the computer (or submitting sheets to Sampling Technicians for data entry).

k) Recall and print data or reports on request.

l) Review equipment calibration logs to ensure that all equipment is up to date. Report expired equipment to coordinator for replacement.

m) Maintain a current inventory of equipment and submit timely purchase requests for replacement as directed by the ACM.

n) Immediately inform ACM (and field designated POC for off-site operations) of a monitoring sample greater than the Z for that chemical agent. Conduct confirmation analyses for all positive results greater than 1 Z.

o) Monitor the instrument control charts for "out of control situations" and report problem to the ACM and/or QAC.

4.1.2.1.5 Quality Assurance Coordinator *3.4.3

The Quality Assurance Coordinator (QAC) shall:

a) Provide guidance/interpretations/Training regarding Quality Requirements to Environmental Monitoring Laboratory Personnel as required.

b) Review analytical data in the LIMS for conformance to requirements and inform ACM of problems.

c) Review MINICAMS data for conformance to requirements and provide reports as required.

d) Review QC Control charts as applicable. Review analyst certification data for conformance to requirements.

e) Provide reports to ACM/EML Chief as required.

UNCONTROLLED COPY

f) Review the QC standards and QC sample results submitted by team members.

g) Inform ACM and Branch Chief if the review of QC results shows the laboratory "out of control" or trending in that direction.

h) Maintain a discrete distance from laboratory operations; will not become part of the analytical team.

i) Review/generate corrective action reports.

j) Publish required reports.

k) Generate and Maintain EML Personnel Certification data and provide data to Management.

4.1.2.1.6 MINICAMS Team Leader

The MINICAMS Team Leader (MTL) shall:

a) Assure the analytical data obtained through MINICAMS monitoring is provided to the QAC as required.

b) Have overall responsibility for MINICAMS Operations and preventive maintenance.

c) Be responsible for the fulfillment of Quality Assurance Requirements.

d) Provide/review IOPs of all analytical methodologies used by the MINICAMS Team (MT) and ensure that the MT is adhering to the methods.

e) Recommend/document additional personnel or equipment needs to Air Monitoring Manager

f) Maintain close liaison with QAC. Provide for analytical methods validation upon request from the QAC.

g) Inform Air Monitoring Manager and QAC of MINICAMS problems that could impact data quality.

h) Initiate corrective actions and document corrections for review by QAC and Air Monitoring Manager

i) Have overall responsibility for the analysis of MINICAMS QC blinds submitted.

j) Inform the appropriate personnel when MINICAMS detections occur and request confirmation monitoring as necessary.

k) Maintain a current inventory of equipment and submit timely purchase requests for replacement.

4.1.2.1.7 MINICAMS Team

The MINICAMS Team (MT) shall:

a) Be responsible for the analysis of samples using MINICAMS at USAECBC and other site locations.

UNCONTROLLED COPY

b) Report all problems affecting data quality to the MTL and other appropriate personnel.

c) Conduct all analyses in accordance with safety and technical procedures developed for MINICAMS operations, as specified in appropriate IOPs.

d) Maintain proper records on quality control samples using MBFORM-4; MBFORM-2, MBFORM-34, and MBFORM-38, as appropriate.

e) Perform QC verification during monitoring activities within specified time frames.

f) Maintain operator certification by providing QC sample data to the QAC.

g) Initial and date all analytical data sheets.

h) Maintain normal maintenance on the MINICAMS and record information on QC sample data sheet.

i) Immediately inform the MTL, or designated field POC, of a MINICAMS sample greater than the alarm set point for the target analyte.

j) Inform MTL of required or depleted supplies (e.g., gases, pre-concentrator tubes).

k) Each team member is to read and sign the appropriate IOPs, as required.

l) Maintain Certification and perform Proficiency tests as required.

4.1.2.1.8 Sample Team Leader

The Sample Team Leader (STL) shall:

a) Maintain liaison with all agencies involved in surety operations and provide sampling support upon request.

b) Schedule and provide oversight of all DAAMS Sampling operations.

c) Assure all Sample Technicians are trained. Assure all temporary, detailed, and auxiliary personnel are trained or work under the oversight of trained personnel while performing sample collection procedures.

d) Review with the Air Monitoring Manager the selection of sampling sites and the proposed sampling setup.

e) Inform the Air Monitoring Manager of problem areas and periodically review status.

f) Inform the Air Monitoring Manager of faulty equipment identified and replaced during monitoring, as required.

UNCONTROLLED COPY

g) Maintain a current inventory of sampling equipment and submit timely purchase requests for replacement.

h) Maintain liaison with the LIMS Administrator, QAC, and ACM to assure that adequate sampling data are being recorded.

i) Maintain a sufficient supply of solid sorbent tubes to conduct daily sampling.

j) Oversee the data entry by Sampling Team members to assure that the data are accurate, correct, and completed in a timely manner.

4.1.2.1.9 Sample Team

The Sample Team (ST) shall:

a) Conduct all sampling operations. Trained sample technicians will conduct or oversee all sample collection operations. Temporary, detailed, and auxiliary personnel shall be trained or work under the oversight of Trained sample technicians while performing sample collection procedures.

b) Set-up, collect, retrieve, log-in, and deliver samples to analysts.

c) Conduct all operations safely and in accordance with sampling IOPs (MT-11 and any site-specific IOPs).

d) Accurately record all required sampling data. Make corrections on scratch logs and data sheets and have sampling data and/corrections reviewed for accuracy by another individual before entering the data into the computer/LIMS. Reviewing individual will also initial and date to indicate review has been made.

e) Recall and print data or reports on request.

f) Inform STL of problem areas and periodically review status.

g) Replace faulty equipment noted during monitoring setup and report corrections to the STL.

h) Each team member is to read and sign the appropriate IOP's, as required.

4.1.2.1.10 Calibration Coordinator *3.4.4 & (6.1, pg 34)

The Calibration Coordinator (CC) shall:

Submit flow meters, balances, thermometers, etc. (equipment used to calibrate sampling equipment) for annual calibration and keep current record of the calibration. Review calibration documentation received from TMDE and report problem area's that could impact data quality, to the Chief EML.

4.1.3 Resources *3.2.1

The Chief of the Environmental Monitoring Laboratory shall plan and organize the resources of the Environmental Monitoring Laboratory to ensure that adequate resources are available for the work to be performed, to satisfy customer requirements and implement, maintain and improve the quality system. The Chief of the Environmental

UNCONTROLLED COPY

Monitoring Laboratory shall ensure that the personnel assigned to verify the quality system are adequately trained. Personnel assigned to perform internal reviews of the Environmental Monitoring Laboratory shall be independent of those having direct responsibility of the work being performed.

4.1.3.1 Management Representative *3.2

The Chief of the Environmental Monitoring Laboratory has been assigned the responsibility and authority for ensuring that the requirements of CMA LMQAP and the CQAPCAAM are implemented and maintained. The Management Representative will keep executive management informed as to the performance of the QMS, any need for improvement, and assure that all appropriate personnel are provided a copy of the QC Plan for their review and retention.

4.1.3.2 Management Review (3.3) *2.3, pg 4

The Chief of the Environmental Monitoring Laboratory is responsible for reviewing all aspects of the Quality System at least annually to ensure its suitability and effectiveness in satisfying the requirements of this QC Plan, its quality policy and objectives. The management review will be performed annually prior to the external party audit. The Chief of the EML shall:

a) Review and evaluate follow-up actions from the last management review, corrective actions, internal and external audit reports, performance charts and out of control records for the determination and implementation of preventive actions.

b) Review and evaluate supplier performance for purchases under $2500 to assure that materials and services used by the Environmental Monitoring Laboratory are procured from suitable sources. A record of acceptable sources is maintained.

c) Consider external influences such as business risks, new technology, changing or new regulations, organizational changes etc.

d) Generate recommendations, necessary changes, and courses of action along with suspense dates as deemed necessary.

e) Initiate corrective actions, and monitor status of each action until all corrective actions are implemented, effective, and documented.

f) Review customer suggestions, comments, concerns, and complaints for necessary action. (4.1.2)

g) Evaluate whether quality policy objectives are adequate and are being met.

h) Review, assess, and document that the EML quality system including its suitability, performance, and effectiveness is adequate to meet all specified requirements.

i) Retain a record of each management review and forward an information copy to the Director Chemical Operations.

UNCONTROLLED COPY

4.2 Quality System (3.4) *2.4

The Environmental Monitoring Laboratory Quality Management system includes the QC Plan and references all SOPs, IOPs and other associated documents. A Master List of Documents listing all of the documents comprising the quality system is maintained at the offices of the Environmental Monitoring Laboratory. Required changes to the quality management system will be evaluated to assure that the integrity of the quality system is not affected by the change.

4.2.1 Quality Planning *2.4.2, pg 5

Subsequent paragraphs of this QC Plan describe the procedures, processes and controls used by the Environmental Monitoring Laboratory to assure that all data generated is correct, defensible and in accordance with the requirements of the CMA LMQAP and the CQAPCAAM.

4.2.2 Quality Objectives (4.1.1 & 4.1.2) *2.4.2.2

The following quality objectives have been selected for evaluation as part of the organizations efforts for continual improvement of the Quality Management System. Quality objectives data will be analyzed and documented on a yearly basis as part of the continual improvement of the QMS. Sample turnaround time and customer survey results will be analyzed and documented. Analysis results of turnaround times or customer satisfaction or complaints will determine the necessity for changes to the system.

- Quality Objective: Complete sample analysis within a maximum of 72 hours after receipt of samples. This objective is charted and reviewed monthly. Greater than 10% non-compliance shall be cause for special evaluation to determine cause(s).
- Quality Objective: Report analytical results to customer within a maximum of 24 hours after completion of samples for analysis. This objective is charted and reviewed monthly. Greater than 10% non-compliance shall be cause for special evaluation to determine cause(s).
- Quality Objective: Review results of customer satisfaction surveys and document results of the analysis in an ongoing effort to improve customer service and satisfaction. This objective is evaluated yearly using customer surveys. Individual customer complaints will be addressed when received and corrected to the customers satisfaction if possible.

4.3 Contract Review

All contracts or work requests for services will be reviewed by the Chief of the Environmental Monitoring Laboratory or his designee, to ensure that the scope of each contract is clearly defined, contract requirements are adequately documented, and the capability to fulfill the contract exists. Verbal contracts or work requests shall be documented and reviewed as specified above and shall be signed or initialed and dated after the review. The Chief of the Environmental Monitoring Laboratory shall resolve differences with the point of contact originating the request. All questions/concerns and any amendments shall be documented on, or attached to, the original request form. All affected Environmental Monitoring Laboratory or contractor personnel shall be notified of any amendment.

UNCONTROLLED COPY

4.4 Work Requests

All work requests for services will be reviewed by the Chief of the Environmental Monitoring Laboratory or his designee, to ensure that the scope of each request is clearly defined, requirements are adequately documented, and the capability to fulfill the request exists. Verbal requests shall be documented and reviewed as specified above. The Chief of the Environmental Monitoring Lab or his designee shall resolve differences with the point of contact originating the request. All questions/concerns and any amendments shall be documented. All affected Environmental Monitoring Laboratory personnel shall be notified of any amendment.

All work request and job related documentation will be saved electronically to a drive specific to the EML to allow the entire management team access to this information. The management team shall perform and document the review and approval of work requests prior to the start of work to ensure adequate communication with customers. Statutory and regulatory requirements applicable to the work request will be determined.

4.5 Document and Data Control *16.1

The Environmental Monitoring Laboratory QC Plan will be controlled by assigning a revision number to the plan. Revisions will be published and distributed as necessary to keep the plan current. SOPs are not controlled by the Environmental Monitoring Laboratory. SOPs are maintained, revised and distributed IAW "Preparation of SOPs, Version 3." Additional documents of external origin are listed on the master list and their distribution is controlled. Documents of external origin will be checked for updates periodically.

All documents, data (including forms), and internally developed computer software impacting data quality or the quality system, are controlled Quality documents. These documents are controlled by revision number, date and document number and are legible, identifiable, reviewed for adequacy, and approved by authorized personnel prior to use. Quality documents are maintained electronically. A master list is maintained electronically that includes all authorized documents and forms with their current revision number and date that is available to all EML Personnel. The master list also serves as a roadmap to specific quality requirements.

IOPMT-25 describes the process for generation and control of Quality Documents for the EML.

Site Specific Plans will be developed as required. Site Specific Plans will contain information and requirements as agreed to by the customer and will be reviewed, approved and distributed IAW Environmental Monitoring Laboratory procedures and/or as directed by the customer. "CMA site-specific plans for CMA operations will be approved and signed IAW site requirements and will take precedence over CASARM QC requirements when requested."

Distribution of the Environmental Monitoring Laboratory QC Plan is controlled and managed as follows:

a) Each controlled copy is assigned a sequential control identification number. The Environmental Monitoring Laboratory maintains a log of controlled copies. The log contains the control identification number and the name of the copyholder.

b) Procedure for distribution of QC Plan:

   1) Notify all holders of record via e-mail to turn in old document and pick up and sign for the new document within 2 weeks of notification.

UNCONTROLLED COPY

2) Holders of documents who have not complied within the 2-week time frame will be contacted via telephone and advised to bring their old document for turn-in and sign for the new document.

3) Off site holders will be notified via e-mail and/or telephone that their current document is obsolete, that they should return the old document and sign for the new one. If they no longer require an updated copy, the old copy may be returned or marked obsolete and they will no longer be holders of record for the new document.

4) A copy of the new document will be "hand carried" to on site personnel who have not responded to the original notification within six weeks. They will be asked to turn in the obsolete copy and sign for the new one.

c) Changes to the document will be furnished to all copyholders of record.

d) Uncontrolled copies of the plan shall be marked "Uncontrolled" at the time of issue.

e) Each page of the QC Plan shall contain a revision number.

4.5.1 Document and Data Approval and Issue *pg 65

The Environmental Monitoring Laboratory QC Plan shall be denoted with an approval authority signature from the Chief, Environmental Monitoring Laboratory, revision date, and revision number. The Environmental Monitoring Laboratory IOPs shall be denoted with an approval authority signature from the Chief of the Environmental Monitoring Laboratory, revision date, and revision number.

All official documentation is maintained in the EML office. All electronic copies of documentation are available to all personnel through access to the network drive. Only QC staff has access to master documentation and sign off on all changes. EML staff is notified of changes to procedures electronically through email. Distribution to outside entities is only on an as-needed basis. Example: Supporting documentation for existing work agreements.

The Environmental Monitoring Laboratory shall maintain a master list of all QC Plans, internal operating procedures, forms, applicable external documents. The list shall identify the current revision and date of each item to preclude the use of non-applicable and obsolete documents. All operating personnel shall have access to the latest revision of all appropriate SOP's and IOPs for their reference and use.

Information used as work instructions that have been extracted from any quality document shall be annotated with the revision number and date of the original document from which it was taken.

4.5.2 Document and Data Changes

4.5.2.1 Minor Document and Data Changes *16

Minor and editorial changes to Environmental Monitoring Laboratory quality documents and SOPs may be made in ink and approved by the Chief EML. When minor changes are made, all copyholders of the controlled document shall be notified.

Any change in data that affects data quality shall contain the initials of the person making the change and the date of the change. The change must be made in such

UNCONTROLLED COPY

a way that the original data are still legible (i.e., make a single line through the data).

4.5.2.2 Major Document and Data Changes

As a result of document and/or data review, major changes to data and documents are made as necessary and shall be recorded. Records of changes to documents shall be maintained as they are made including the nature of change, revision number, and date of revision. Major changes to documents and data shall be reviewed and approved by the same functions that performed the original review. Personnel performing the review shall have access to the pertinent background information upon which to base their review and approval. A written record of review and approval of major changes shall be maintained. This record shall be documented by signature authority of the Chief of the Environmental Monitoring Laboratory.

When major changes are made to the Environmental Monitoring Laboratory QC Plan, the revision number and the date of revision shall be updated. In the interim, changes will be made by sequentially numbered change notice.

Obsolete or superseded procedures and documents in the work area shall be removed unless marked accordingly.

4.5.3 Retention of Documentation

To ensure traceability, a copy of the previous revision of the Environmental Monitoring Laboratory QC Plan, IOPs, and SOPs shall be retained in the Environmental Monitoring Laboratory records.

Analytical results are retained in the Environmental Monitoring Laboratory files for a minimum of one year on electronic media. Analytical results are retained for forty years in accordance with regulatory requirements and may be retained/stored on hard copy or electronically on disc as applicable.

All Quality records are currently maintained electronically and on CDs or hard copy. Laboratory analytical results are maintained electronically on the Laboratory Information Management System (LIMS) and on hard copy until put on CDs. Off site data is maintained electronically on the instruments and on hard copies that are then scanned to a CD for long-term storage. MINICAMS monitoring data is printed on hard copy and also stored electronically, then ultimately transferred to CDs for long-term storage. See IOPMT-28 for details of indexing, filing, storage, and retrieval of analytical data records.

4.6 Purchasing *11, pg 54

4.6.1 General

The Chief, Environmental Monitoring Laboratory, shall ensure that all products purchased for the operation of the Environmental Monitoring Laboratory conform to the specified requirements.

All chemicals required to make reagents and standards are to be at least reagent grade.

4.6.2 Assessment of Sub-Contractors *pg 55

The local procurement directorate maintains a list of approved contractors/sub-contractors with a history of successful performance for supplying

UNCONTROLLED COPY

quality goods. This list is used for procurement of routine supplies except as indicated below. These purchases are reviewed and approved by the Chief EML or his designee, in accordance with the Government approved system. A list of acceptable vendors will be maintained for locally procured supplies. Unacceptable vendors shall be removed from the list and the reason for removal shall be documented.

For sub-contractors performing analyses, monitoring equipment operation and/or maintenance, the Environmental Monitoring Laboratory Chief ensures that the sub-contractor's quality performance is in accordance with the Environmental Monitoring Laboratory Quality Control Plan. This is accomplished by: meetings, ongoing discussions, e-mail, etc., with the subcontractor to discuss QC procedures and data results. All operations performed by the sub-contractor that relate to chemical agent air monitoring are subject to audit by Environmental Monitoring Laboratory personnel as part of the internal auditing process.

4.6.3 Purchasing Data *pg 55

The Chief, Environmental Monitoring Laboratory, or his designee, will verify, review, and approve purchase requests by initialing and dating an electronic copy or the hard copy of the purchase request prior to forwarding to procurement. The initialed copy will be maintained in the EML files. The Chief, Environmental Monitoring Laboratory or his designee, shall assure the request contains the appropriate information prior to approval, such as the following:

a) Supplier name, address, phone, and point of contact

b) Catalog number, description, unit cost, quantity needed, and justification of need

c) Type, style, class, grade, or other precise identification

d) Title or other precise identification and applicable issue for: specifications, drawings, process requirements, inspection instructions, and other relevant technical data.

e) Certification requirements for purchased supplies shall be detailed on the purchase order.

Each Team Manager is responsible for purchasing operating supplies for each EML team.

The Air Monitoring Manager and Analytical Chemical Manager usually delegate purchase of necessary supplies to the team leaders or other selected EML personnel. The responsible personnel review specific operational requirements and generate purchase requests and submit them to EML administration personnel who complete the purchase request and submit it for required reviews prior to placing the order with vendors. See Section 4.10 for receipt and acceptance of purchased supplies.

4.7 Customer Supplied Product *pg 68

The Environmental Monitoring Laboratory has an agreement to provide DAAMS tubes to “off site” customers that are used to sample designated areas at the customers facility; these DAAMS tubes are then returned to the Environmental Monitoring Laboratory for analysis. These “off site” DAAMS tube samples are subjected to the same analytical and reporting procedures used for on-site DAAMS tube sample analysis. **Damaged samples deemed to be unacceptable for analysis are not analyzed. Customer is notified to re-sample and resubmit the samples.**

UNCONTROLLED COPY

4.8 Product Identification and Traceability (14.3, pg 94) *pg 40

DAAMS tubes used in the collection of samples by Environmental Monitoring Laboratory or contractor personnel shall be collected in duplicate and have a unique ID number. A field label is attached to each DAAMS tube carrier. The field label shall contain both DAAMS tubes numbers, initial and final flow rates, Flow Meter ID, location, Agent & item sampled, and collection start and stop times.

The information from the field label is transferred to the Air Sample Work Order (MBFORM-39) then to the LIMS, which assigns the unique sample ID number and generates a sample label and scratch log (MBFORM-12). The sample label is placed with the field label and the sample is delivered to the analyst. The sample label remains with the sample until the analysis is determined to be in control. The label is then removed from the sample, attached to the corresponding quantitation report. If the second tube is analyzed, there is no sample label attached. Quantitation reports are printed, placed in data packages, reviewed and scanned to a database, then subsequently transferred to CD for long term storage.

The LIMS generates the unique sample ID number before each sample is analyzed, using the following rules:

a) The first two numbers are the last two numbers of the year.

b) The third and fourth numbers are the number of the month in which the sample is collected.

c) The fifth and sixth numbers are the day of the month the sample is collected.

d) The seventh through tenth numbers are the sequential number of samples collected in the month. (These numbers reset at beginning of each month.)

e) The final digits are separated from the first ten digits by a dash, and indicate the location where the sampling data were entered in the computer. These last digits are called Site Extensions. Samples entered at the Environmental Monitoring Laboratory Sample Team office have an extension of EML. Other locations have unique extensions defined in the LIMS.

An example of a sample ID number is 9209180125-EML. This ID number indicates that the sample was taken 18 September 1992, was sample number 125 for the month, and the data were input on the computer at the Environmental Monitoring Laboratory.

When a sample is cleared, the sample ID number (with the agent of interest appended) serves as the clearance number for Environmental Monitoring Laboratory customers.

NRT data shall be traceable to a specific NRT unit via the unit serial number, the date collected, and the time of analysis.

4.9 Process Control

The processes that must be controlled are the following:

1) Sample Collection

2) Sample Analysis

3) Data Reporting

4) Data Storage.

UNCONTROLLED COPY

The specific controls for each of these processes are specified in EML Procedures, SOPs and IOPs listed in the Master List of Documents.

There are no other special processes that require special controls. *8.4, pg 51

The Environmental Monitoring Laboratory has instituted a process of scanning Hardcopy Data for storage on CDs. This process is used by EML for long-term data storage,

4.9.1 QC of Methods and Monitors *pg 44

In addition to the certification requirements for instruments, monitors, and analysts/operators, quality control samples shall be analyzed to provide quantitative evidence that the entire method or monitor is performing at a level comparable to or better than that demonstrated during certification (See Table 12.1 of CMA-LMQAP). Control samples are introduced into the train of samples to function as checks on the performance of the analytical method. Data generated from the control samples may be plotted on control charts and/or other forms of documentation. Data generated from field operations control samples may be control charted if deemed appropriate. A continuing baseline study of field QC samples will be done when required, for CMA operations to validate monitoring systems.

4.9.1.1 Control Samples (12.2, pg 79) *pg 44

A Quality-Process (QP) sample is a quality control sample that has been spiked with a solution of dilute chemical agent that falls within 5% of the mass equivalent of the target level of the agents of interest, and exposed to the sampling environment. The QP sample is carried through every step of the sampling and analysis system being used identical to the samples to which the QP is associated. QPs within 5% of the 1 Z TC are routinely employed to assess the recovery performance of the MINICAMS and DAAMS methods. The QP sample is carried through every step of the sampling and analysis system being used, including as appropriate, the VX conversion pad, the heated sample line, pumps, instruments, and data processing. DAAMS tubes are spiked with solution of dilute chemical agent, collected in the same manner as the samples which they are associated, and analyzed in accordance with applicable IOP requirements.

A Quality-Laboratory (QL) sample is a quality control sample that has been spiked with a solution of dilute chemical agent that falls within 5% of the mass equivalent of the target level of the agents of interest. QLs are spiked with a solution containing all the analytes of interest and analyzed in accordance with applicable IOP requirements. These samples are routinely employed to assess the performance of the DAAMS method instruments.

Quality Control Sample Documentation. The following information shall be included in the DAAMS tube analysis documentation packages.

- Sample number
- DAAMS tube number, when applicable
- Dates of sample analysis
- Sample location
- Agent(s)

UNCONTROLLED COPY

- Agent standard number.
- Found concentration(s) (FC)
- Instrument number
- Analyst name or initials
- Target Concentration

The following information shall be recorded for QC samples analyzed using the MINICAMS and Hewlett Packard Dynatherm system (HPD):

- Date
- Monitor ID
- Agent(s)
- Operator
- Found concentration (FC)
- Target concentration
- Time of challenge
- Agent standard ID
- Location

Note: NRT Calibrations, QP challenges and continuous sampling data are traceable by date and location.

4.9.1.2 Control Sample Loading *pg 43, 44, 45

4.9.1.2.1 DAAMS Methods

DAAMS tube samples are generally analyzed using GC/LC techniques that are considered Class 1 methods. Control samples will be introduced and evaluated as follows:

- 1-Z QP samples shall be run for each batch or sampling event.
- 1-Z QL samples shall be run on each instrument for each method and day of operation to assure that the instrument is operational and in control before and after sample analysis.
- Control sample preparation is outlined in the appropriate IOP.

a) A QL is required before and after all samples to bracket the samples, so passing QLs are run for all samples. Since successful QP samples are part of every batch, a QL is run after all QPs – passing or failing.

b) When possible a successful QP is reported with the corresponding samples. If possible, the samples are re-collected if both QPs fail.

c) Corrective action for failing QLs is addressed in each IOP.

UNCONTROLLED COPY

d) QP recoveries and sample detections are always reported with the most conservative approach. QP recoveries less than 100% are used to correct sample detections and in many cases any detection is a cause for concern for specific sample matrices.

e) The pass/fail status of each QP is tracked on the instrument daily run log. If the QP passes, the status indicates "ok." If the QP fails, the status indicates xx and a second QP is run. If both QPs fail, the LIMS report indicates PF and the item is re-sampled. All of this is part of daily operations and certification/training of GC analysts. The requirements are described in Section 4.9.1 and in each analytical IOP.

Class 2 or Class 3 methods/instruments will be used where appropriate. Class 1 certified instruments may be used as class 2 or class 3 without additional certification testing. Class 3 Method is used for Qualitative Analysis only. Other classes may be used for monitoring as appropriate with CMA approval.

4.9.1.2.2 Near-Real-Time (NRT) Systems (Table 10.3, pg 58 & 12.2.1, pg 79) *pg 45

The near-real-time (NRT) systems deployed by Environmental Monitoring Laboratory are MINICAMS and/or GCFPD/Dynatherm systems (called HPDs) equipped with heated sample lines. These systems are certified, calibrated, and operated as Class 1 monitors in accordance with appropriate IOPs. Certified Class 1 instruments are also considered certified as Class 2 instruments and may be operated/used as Class 2 instruments.

Fixed-site NRT systems shall be calibrated and challenged at least once per working day. If the HL QP response is not within ± 25% of the TC, the unit shall be re-challenged. Operations may proceed if the 2nd challenge is acceptable. Corrective action shall be taken and documented if the re-challenge is not acceptable. If the agent being monitored changes for a given monitor at any time during the operational day, the MINICAMS will be challenged for the new agent prior to starting operations with the new agent.HSL must be challenged at least every three months. The frequency and method of challenges are described in IOP MT-2.

Mobile NRT systems (MINICAMS or HPDs) shall be calibrated and challenged through the heated sample line before operations, every four to five hours, (if operations exceed five hours), and at the end of daily operations. If the HL QP response is not within ± 25% of the TC, the unit shall be re-challenged. Operations may proceed if the 2nd challenge is acceptable. Corrective action shall be taken and documented if the re-challenge is not acceptable. If the agent being monitored changes for a given monitor at any time during the operational day, the NRT will be challenged for the new agent prior to starting operations with the new agent. A NRT system is considered mobile if the system is mounted in a vehicle, or if sampling/analysis

UNCONTROLLED COPY

equipment is moved to various locations in support of a particular monitoring application, for example, first entry monitoring.

First challenge acceptance tracking is usually performed to monitor calibration stability over two or more days. NRT systems used by the Environmental Monitoring Laboratory are calibrated daily and the calibration is verified with a QP challenge using a different standard. Consequently, the rate of first challenge acceptance is not a relevant measure and is not tracked. Special CMA reports shall be IAW the CMA LMQAP and/or as agreed to during work negotiations.

4.9.2 Class 1 Method Control Charts *pg 95

Control Charting is not required but may be used for internal information, tracking, and/or control.

Control charts are used to monitor variations in GC method precision and accuracy and to detect trends in these variations. The average and range of the daily QLs for each method and instrument may be control charted or statistically evaluated for internal tracking information as deemed necessary.

If Control charts are used, they may be generated using the computer software provided by the CASARM Quality Assurance Team (CQAT), generated by EML software, or generated using the QC package module from the LIMS.

4.9.2.1 Contents of QL Control Charts *pg 95

The average percent recovery and range of recovery is plotted on the y-axis and data points are plotted on the x-axis.

Control charts shall clearly state the following:

- Instrument ID.
- Title of the chart
- Analyte (agent) and Z
- Method (e.g. DAAMS)
- Laboratory identity
- Month and year; date of preparation
- Analysis data for each point plotted (tabular)
- Percent Recovery or Range of Recovery on the Y-axis
- Upper and lower control limits (UCL and LCL)
- Grand mean average X doublebar on the X-bar chart as the central line (solid line).
- Mean range R-bar on the R-chart as the central line (solid line).

X-bar and R control charts may be plotted on different pages.

UNCONTROLLED COPY

4.9.2.2 Updating & Maintaining Control Charts *pg 95

Initial QL control charts are prepared from the first 20 data points for each agent and instrument (see 4.9.2.). A minimum of 20 data points will be used to establish control chart data limits. If a known process change requires updating the control chart data limits, a minimum of 20 data point will be required prior to changing the data limits.

4.9.2.3 Out-of-Control and Out-of-Statistical-Control Situations

See appropriate IOP.

4.9.3 Class 1 Monitor QP Data/Performance Charts *pg 93

The purpose of performance charting or baseline study statistical evaluation is to monitor variations in the QP challenge results of NRT analyses (as defined in Section 4.9.1.2.2) and to detect trends in those variations. Performance charts are based on QP data for each Class 1 monitor. Performance charts for Class 1 monitors are not required if instruments are calibrated each workday but may be used as an aid for NRT Monitor operators.

4.9.3.1 Contents of Performance Charts and Associated Data

The performance charts/associated data will contain the following information:

- Title of the Chart
- Identification of Agent
- Identification of first and, if required, second Class1 monitor challenge for a given day
- Date of data collection
- Found Concentration on the y-axis
- Data point on the x-axis
- Performance bounds
- Initials of operator
- Instrument Identification

See appropriate IOP for performance chart limits.

4.9.3.2 Performance Chart Calculations

Due to the difficulty of preparing a spiking solution at exactly 1.0 the laboratory is permitted to deviate from this value by ± 5%. The QP target concentration (TC) is normalized to 1.0 for the hazard level standard as follows, where TC (Z) is calculated from the CASARM certificate of analysis (purity) and any working standard dilutions:

$$\frac{TC\,(Z)}{1.0\,(Z)} = Z - \text{factor}$$

UNCONTROLLED COPY

The QP response is calculated as follows:

$$\frac{\text{Found Concentration}}{\text{Z – factor for 1.0 Z}} = \text{QP response}$$

4.9.3.3 Out-of-Control and Out-of-Statistical-Control Situations for Class 1 Monitors

See appropriate IOP for details of out of control & out of statistical control, e.g., IOPMT-2 & IOPMT-16.

4.9.4 Special Processes

There are no special processes whose processing deficiencies may become apparent only after the product is in use. Therefore, this section does not apply.

4.9.5 Quality Control of Heated Sample Lines (HSL) *pg 50

All heated sample lines must be challenged before their initial use. The challenge shall consist of a 1 Z injection of each agent to be sampled through that HSL. A found concentration within ±25% of the target concentration is the criterion for acceptance. Two successive failures call for corrective action or replacement. The flow rate through the HSL shall be checked concurrently with the 1 Z challenge IAW IOP requirements and the data recorded as required.

See 4.10.2 below for additional information.

HSLs installed on systems at fixed sites at ECBC shall be challenged every three months (not to exceed 100 working days) with each agent used in that line to ensure that the line is functioning correctly except when under the purview of CMA, then the HSLs shall be challenged every two months (not to exceed 60 working days) or as dictated by the site monitoring plan. The challenge acceptance criteria shall be the same as that used for initial acceptance. Records shall be maintained to demonstrate conformance to this requirement. These records shall include agent, date, operator, instrument identification, flow meter id, heated sample line id, target concentration, and found response. Lines that do not meet challenge criteria will be cleaned in accordance with requirements of appropriate IOP and re-challenged. HSL that still do not meet specified requirements shall be marked as unacceptable and removed from use. Multiple sample lines used with stream selection systems shall be challenged as indicated above while in use. Lines not being used continuously shall be challenged prior to use and at the required intervals while in use. If multiple HSL are connected to a manifold for simultaneous use each line flow rate shall be within 25% of the average flow rate for all HSLs connected to the manifold.

HSLs on mobile monitors shall be challenged each day of operation IAW requirements of the appropriate IOP.

4.9.6 Quality Control of DAAMS Tubes (Table 9-1, pg 47) *12.2.1, pg 56-58

New DAAMS tubes shall be subjected to the following tests, or the manufacturer shall supply documentation with each lot purchased, attesting that the lot of DAAMS tubes has been subjected to these tests and meets all requirements. The number of tubes to be pulled for testing is found in Table 1-2.

UNCONTROLLED COPY

- Sampling/Acceptance Requirements:
  - Sample number is IAW ANSI/ASQC Z1.4, AQL of 2.5% non-conformance
- Inspection Requirements:
  - Visual Inspection for loose packing, warped tube ends, loose sorbent material, and a minimum bed depth of 3 cm
  - Pressure-drop test to assure sufficient airflow through the tube
- Agent tests shall be conducted to demonstrate a minimum of 75% recovery of the HL spike IAW with the requirements of IOPMT 4.

Table 1-2 Sample Sizes for Normal Inspection for Maximum of 2.5 Percent Non-Conformance

LOT OR BATCH SIZE	GENERAL INSPECTION LEVEL 1, number of samples	REJECTION NUMBER[a]
2 – 8	5	1
9 – 15	5	1
16 – 25	5	1
26 – 50	5	1
51 – 90	5	1
91 – 150	5	1
151 – 280	20	2
281 – 500	20	2
501 – 1200	32	3
NOTE: [a] Reject the entire lot if this number of samples is found to be defective.		

4.9.7 Quality Control of Preconcentrator Tubes (PCT)

Each PCT shall be successfully challenged with a 1 Z challenge before use.

4.9.8 Quality Control of Silver Fluoride Conversion Pads

4.9.8.1 Initial Testing *12.2.4, pg 59

New silver fluoride (AgF) conversion pads shall be subjected to the following tests or the manufacturer shall supply documentation with each lot purchased attesting that the lot of pads has been subjected to these tests and meets all requirements. The number of pads to be pulled for testing is found in Table 1-2.

- Sampling/Acceptance Requirements:
  - See Table 1-2 for Accept/Reject requirements.
- Inspection Requirements:

  The requisite number of samples from each new batch of conversion pads will be challenged with a spike of approximately 3.6 ng VX and an equal molar GB spike (1.89 ng GB is the molar equivalent at 100% pad efficiency). Acceptable conversion pad performance shall be recovery of at least 75%.

UNCONTROLLED COPY

Conversion pads have a shelf life expiration date of 1 year from date of manufacture. Shelf life may be extended for one year based upon a successful retest as indicated above.

Conversion pads shall be stored out of direct sunlight to maximize the pad's ability to convert VX to its G analog and to minimize exposure to atmospheric contamination. Note: During DAAMS operations at field sites, the Conversion pads will be changed weekly or more frequently if required.

Expired/used conversion pads will be discarded IAW approved procedures.

As described in Section 4.9.1.2.2, the Environmental Monitoring Laboratory performs challenges of NRT systems through the conversion pads (where appropriate) at the inlet or at the end of the heated sample line. During VX operation, a new pad is installed in the system weekly or as required. After a successful challenge, samples are analyzed through the pad according to operating protocols. When using conversion pads and heated sample lines for VX detection, the conversion pad shall be located at the distal end of the sample line.

4.9.8.2 Nitrogen Oxide filters (NO_x) *pg 58

If NO_x filters are used by EML, they will be subjected to a visual inspection for cracks, packing separation and checked for cracks etc. prior to being used.

"NO_x filters shall not be used past their expiration date and shall be changed on an as needed basis."

"The use of NO_x filters is based on QP sample recovery and customer requirements. Based on these requirements, the EML may set change out requirements. NO_x filter change out frequency may be modified provided that QP sample results support change out frequency. "

4.10 Inspection and Testing *12.0, pg 56

4.10.1 Receiving and Inspection Testing

Products received by the Environmental Monitoring Laboratory that must be inspected or certified include chemicals, glassware, analytical equipment, pre-concentrator tubes, conversion pads, and DAAMS Tubes. Also see Sections 4.9.6, 4.9.7, and 4.9.8.

4.10.1.1 Verification of Incoming Supplies *11, pg 54

All products received by the Environmental Monitoring Laboratory shall be verified upon receipt for condition, completeness, identification, and general compliance with the procurement document requirements. A knowledgeable person shall initial and date the incoming receipt form to indicate acceptance. Any problems with the product shall be noted on the incoming receipt form and the procurement activity shall be notified. Unusable supplies shall be returned to the supplier activity, if possible. A copy of the Purchase order and the dated and initialed incoming acceptance form shall be retained in the EML office files.

Supplies and products received from the Environmental Monitoring Laboratory support contractor are verified as described above. A copy of the purchase order

UNCONTROLLED COPY

accompanies the products that are delivered to the contractor representative at the EML. A copy of the Purchase order and the dated and initialed incoming acceptance form shall be retained in the EML office files.

After inspection and verification, the copy of the purchase order is initialed and dated, and returned to the contractor's main office for payment and permanent storage. The contractor's purchasing agent ensures that unusable supplies are returned for credit and that any problems are resolved.

4.10.2 In-Process Inspection and Testing *12.3, pg 59

Environmental Monitoring Laboratory personnel responsible for collecting samples shall inspect the DAAMS tube flow rates before and after an operation to assure that the proper flow rate is achieved. Flow rates that do not meet specifications shall be reported on the corresponding Sample Record. Sample times and any out of the ordinary weather conditions shall also be recorded.

Samples received at the laboratory will be inspected and verified by the laboratory chemists. Samples that do not pass visual inspection will not be analyzed. Receipt will be noted on the scratch log along with any discrepancies or anomalies.

The average flow rate for MINICAMS is printed with Instrument parameters. Any flow rate that does not meet the method specification shall be cause for corrective actions to assure that the proper flow rate for that particular operation can be achieved before starting the operation. All corrective actions shall be documented on the challenge record.

Flow rates of heated sample lines on fixed site monitoring stations shall be checked each three months (not to exceed 100 working days) except when under the purview of CMA (See Section 4.9.5 above). All flow rates shall be documented on MBFORM-34. Corrective actions shall be taken to assure that the proper flow rate can be achieved. Corrective actions taken shall be recorded on the challenge data record. A flow meter shall be attached to the distal end of the heated sample line during the three-month check to assure that required flow rate is achieved throughout the HSL. This flow rate shall be recorded on the form.

4.10.3 Final Inspection and Testing *pg 59 & 60

Samples whose integrity is questionable during sample collection (e.g., broken or discolored) may be rejected and re-sampled. Sample technicians responsible for collecting DAAMS samples shall inspect the sample label for completeness and accuracy, and sign and date the appropriate section of the scratch log prior to its release to the laboratory (See IOP MT-11). All questionable sample results shall be qualified when reported.

The Environmental Monitoring Laboratory shall establish and maintain records to demonstrate that final inspection has been completed for the following items:

Analysis results (transcriptions and calculations) are recorded on the Daily Run Log and are verified and distributed by the ACM or designee. The Daily Run Log will be initialed and dated to demonstrate the verification. After review and acceptance by Environmental Monitoring Laboratory personnel, analytical results are reported to the designated POC for the requesting agency/group.

UNCONTROLLED COPY

4.10.4 Inspection and Test Records

Records of inspection shall be maintained where appropriate. Records of inspections of incoming material shall be made on the copy of the request (reviewers will initial and date) and filed in Environmental Monitoring Laboratory files. Contractor procured items shall be handled as described in paragraph 4.10.1.1.

4.11 Inspection, Measuring, and Test Equipment (9.1) *pg 35

All equipment requiring periodic calibration shall have a sticker/tag affixed to the instrument (or readily available) indicating the calibration status of the equipment. Equipment that is not in use shall be annotated as such. Obsolete or unusable equipment is turned in for disposal. See Section 4.11.2 below for details about the calibration program.

"Operators shall refrain from making adjustments to items calibrated by TMDE that would invalidate the calibration of the item. Operators shall handle all calibrated items in such a way as to protect the items from damage and/or deterioration during handling, maintenance, use, and storage.

4.11.1 Analytical Systems *pg 36 & 37

Calibration shall be performed in accordance with the appropriate IOP (see master list).

As a minimum, the following information shall be recorded as part of the analytical data package:

- Analysis Date and Time
- Instrument ID
- Analyst/Operator
- Sample ID Numbers
- Regression Parameters
- Target Concentrations
- Calibration Date
- Instrument ID
- Method ID
- Cal Standard ID
- QC Standard ID
- Regression Result (0.99 correlation coefficient minimum to pass)
- Retention Time and Response
- Results of Calibration (e.g. pass/fail)
- Minimum Calibration response for NRT Systems
- Sample Work Order Form and Chain of Custody for Laboratory Systems
- Daily Run Log Indicating Hazard Level for Laboratory Systems.
- Instrument Response
- QC Challenge Result

UNCONTROLLED COPY

4.11.2 Edgewood Area Calibration Program (11, pg 67) *pg 34

Balances, thermometers, flow controllers, flow calibrators, and flow meters used within the EML are currently included in the calibration program at Aberdeen Proving Ground, Edgewood Area. The Edgewood Area Internal Calibration Facility (EAICF) maintains the calibration program and provides a calibration report on equipment calibrated at APG. Pine Bluff calibration services are handled by the local TMDE facility. The calibration report contains the following information:

- Acceptance and rejection criteria for instrument being calibrated,
- Name of person performing the calibration, and
- Reference standard used to calibrate the instrument.

Equipment not meeting calibration requirements is tagged and removed from service. The TMDE facility shall provide a calibration report (including actual test results, measurement uncertainty, and as found condition) for all calibrated equipment to the EML calibration coordinator for use and review by authorized personnel. Measurements attributed to instruments/equipment not meeting calibration requirements may be reviewed by EML to determine if the quality of the generated data has been affected.

When the Environmental Monitoring Laboratory receives new measuring equipment, the Calibration Coordinator must inform the EAICF and provide the stock number and interval of calibration so that this equipment can be added to the calibration list. Periodically, the EAICF/TMDE provides a list of the type of equipment, model and serial numbers, date of the last calibration, and calibrations due during the next 60 days. The Calibration Coordinator monitors this list and coordinates the calibration of the expiring measuring equipment with the EAIFC/TMDE. The Calibration Coordinator ensures that all equipment requiring calibration has a completed calibration label DA80 attached or readily available. The date of the last calibration, and the date the calibration expires are noted on the label. Equipment that fails calibration, has exceeded the calibration date, equipment not being used, or equipment that requires calibration before use is marked accordingly. Items in the EAICF/TMDE calibration system are automatically recalled. The Calibration Coordinator arranges for the item to be delivered to the calibration team. The Calibration Coordinator keeps the current calibration report on file. Calibration records shall be maintained in the Environmental Monitoring Laboratory. When measurements are taken using calibrated equipment such as flow controllers, flow meters etc, the serial number of the equipment shall be noted on the document on which the measurements are recorded.

4.12 Sample Storage and Handling (14.5, pg 95) *pg 41

Samples not analyzed on the day received shall be stored in a refrigerator at or below 4°C. DAAMS tubes are stored in tube carrier. Each tube will be labeled and tracked through analysis. After the sample is analyzed, the sample ID label is removed from the sample container and placed on the analysis report for the sample indicating that the analysis is complete. Samples not analyzed are held for 48 hours prior to re-conditioning for re-use. The following information is displayed on the sample label, sample work order form and/or the sample chain of custody:

- Sample ID number
- DAAMS tube number
- Name of sample collection technician

UNCONTROLLED COPY

- Average flow each tube
- Time (sample interval minutes)
- Agent(s) sampled
- Building number/location
- Item/position number
- Date collected
- Point of contact
- Organization (Client/Project)
- SOP number, if applicable.

4.13 Control of Non-conforming Product (4.5) *pg 60

If the Sample Technician detects a nonconforming sample by physical inspection (both tubes bad), he/she shall notify the STL or designee that the sample is compromised and that the site needs to be re-sampled. If only one tube is bad, the reason for rejection shall be noted in the database, and the second tube shall be delivered to the lab for analysis, at the discretion of the STL.

If the analyst detects a nonconforming sample by physical inspection, he/she shall record that the sample is rejected for analysis and the second sample tube shall be run. If the second sample also fails, the ACM or designee will notify the STL or designee that the site needs to be re-sampled. For a sample that fails analysis criteria, the sample is rejected and the sample label shall be affixed to the analysis report.

The laboratory shall be responsible for the disposition of the samples. Broken tubes are destroyed; all others are conditioned for subsequent use.

Reports/data which are determined to be incorrect in the final inspection shall be annotated with the correct information, including the date and initials of person making the notation. The results are returned to the originating personnel for correction, or the reviewing official or the QAC will make the correction (*pg 61).

Non-conformity Review and Disposition. The responsibility for review and authority for the disposition of non-conforming data are given to the Chief of the Environmental Monitoring Laboratory or his designee. The customer shall be notified when data is found to be non-conforming after results are initially reported and corrected results furnished to the customer.

4.14 Corrective Action (4.2) *pg 63

4.14.1 Immediate Corrective Action

Immediate corrective actions are taken when QC Samples are unacceptable. See appropriate IOPS for details.

4.14.2 Long term Corrective Actions

When problems in a Quality System are identified, the Chief EML or QAC shall assign staff members to investigate the problem. The assigned staff member shall initiate a Corrective Action Report (CAR), (if one has not been initiated). The CAR shall include:

UNCONTROLLED COPY

a) Description of the problem

b) Date the problem was discovered

c) Investigator(s)

d) Result of investigation, including causes of the problem

e) Corrective actions to be taken

f) Corrective action implementation date

g) Changes resulting from corrective actions (also noted in operating procedures, as necessary)

h) Procedural changes resulting from corrective actions will be made to quality documents as required.

i) Verification to include:

1) Date

2) Effectiveness of corrective actions

The staff member shall then perform a Root Cause investigation to determine the cause(s) of the problem. This investigation shall also include the development of corrective actions that correct the problem and prevent its reoccurrence. The results of the investigation shall be documented on the CAR, signed by the investigator, and reviewed and approved by the Team Leader prior to implementation. The Team Leader shall verify the effectiveness of the corrective action. Root Cause Investigations may be conducted if requested by CMA.

4.14.3 Preventive Action (4.3) *pg 63

Preventive actions are addressed in as follows:

Preventive actions required to prevent or reduce problems associated with routine Monitoring Operations shall be addressed during branch meetings, during ongoing reviews of routine monitoring operations, and other times deemed necessary in an ongoing effort to improve the quality of Environmental Monitoring Laboratory operations. Once a potential problem is identified, the Branch chief may proceed as indicated below:

The Branch Chief or QAC may assign staff members to investigate/determine what actions are required to prevent the potential problem. The assigned staff member shall:

a) Determine potential root cause(s) of the problem.

b) Determine actions required to prevent the problem from occurring.

c) Initiate preventive actions or request appropriate personnel to initiate actions to prevent the problem.

d) Review completed preventive actions and report such action(s) has/have been completed and is effective.

UNCONTROLLED COPY

4.14.4 Customer Satisfaction (4.1.2, pg 11) *pg 62

Customer satisfaction shall be monitored by the use of:

- Annual Customer Surveys
- Reviewing customer feedback etc.
- Completed customer surveys shall be evaluated by the Environmental Monitoring Laboratory chief.
- Survey results indicating problems will be addressed on an individual basis.
- Customer complaints shall be addressed as received. If deemed necessary, a CAR will be issued for the complaint.

4.15 Sample Collection, Handling, Delivery, and Analysis.

4.15.1 Sample Collection (14.2, pg 94) *pg 40

DAAMS tubes shall be collected by trained personnel. DAAMS tubes shall be collected IAW an approved EML IOP. DAAMS tube samples from off-site locations shall be collected IAW the appropriate appendices of IOPMT-11 or specific IOPs as specified in site plan. Minimum sample times are calculated for DAAMS tube samples used for confirmation to insure that the desired level of confirmation is obtained.

DAAMS QP sample preparation records shall include:

- Name of the preparer
- Sample ID/tube number
- Standard ID
- Date

4.15.2 Handling (14.4, pg 95) *pg 41

The ST will initiate efforts at the time of sampling to preserve the integrity of the samples. All tubes shall be placed into their glass carriers, frit end down, as soon as they are removed from the sampling station. The samples shall be transported as soon as possible to the point of analysis. Upon receipt, an AT member will prioritize the tubes for analysis. Sample analysis will be conducted IAW appropriate IOP. Samples not analyzed on the day collected are refrigerated until analyzed, as described in Section 4.12.

Data (analytical results) are furnished to the agency/personnel who originally requested that the sample(s) be analyzed. Data shall be documented in such a manner as to minimize ambiguity, uncertainty, and/or loss. Hard copies and/or electronic media copies of all analytical data will be maintained for 40 years. All hard copy data will be handled as described in Section 4.8. Electronic storage of data will be maintained where possible.

4.15.2.1 Sample Management (14.1, pg 94) *pg 41 &42

The sample team enters the sample data into the LIMS and prints labels and a scratch log (chain of custody) then physically transports the samples to the lab) for analysis. The scratch log is signed and dated by person receiving the samples to indicate receipt of samples for analysis. The sample team retains the scratch log as a record of delivery/receipt. If samples are received too late on a given day

UNCONTROLLED COPY

for analysis to be completed, the samples will be preserved and stored by the ACT (see Section 4.11) who will perform analysis as soon as possible. Samples shall be analyzed within 72 hours of receipt. Sample results are entered in the LIMS, and reported.

4.15.3 Delivery (14.4, pg 95) *pg 42

Samples are immediately transported by ST to the Environmental Monitoring Laboratory for analysis at USAECBC, Pine Bluff, or to the point of analysis in field operations. Flow rates for each sample are recorded on the Air Samples Workorder (MBFORM-39). Sample labels and field labels accompany the samples to the laboratory for analysis. The sample custodian, the QAC, or an analyst verifies receipt of the samples by signing and dating the chain of custody at the bottom of the scratch log. The official copy of the scratch log is returned to the Sample Team for filing.

All data that are results of a monitoring operation shall be handled IAW approved procedures (See Section 4.5).

4.15.4 Analysis (14.4, pg 95) *pg 41 & 42

4.15.4.1 GC/LC Analysis:

After completion of a successful calibration exercise or performance check, the analyses of actual samples may begin. This will be done in accordance with approved IOPs and SOPs. These IOPs and SOPs are shown on the Master List of Documents.

Sample analysis shall be done by certified personnel using certified instruments. The analyst shall document the following information on the daily report form:

- Instrument number
- Analyst name or initials
- Analysis date
- Batch number
- Sample ID number
- Tube number
- Analytical run number
- Analytes of interest
- Sample analysis results
- QC sample results, including percent recovery
- Retention time (if required
- Standard ID

Analytical results of both field and QC samples shall be included in the documentation. The analyst shall upload these results to the LIMS where the data will be reviewed and approved by authorized personnel and sample results sent to the appropriate POC. Specific data results required by CMA shall be provided to CMA as requested.

UNCONTROLLED COPY

4.15.4.2 MINICAMS Monitoring *pg 42

After completion of a successful calibration exercise monitoring may begin. The operator shall document the following applicable information on the QC Data Sheet (MBFORM-4) in accordance with the appropriate IOP requirements:

- Operator initials
- Date
- Time
- Cal Height
- Found Concentration
- Corrective actions
- Location
- Monitor I.D.
- Agent
- Flow Rate Check shall be on MINICAMS printout only (not on MBFORM-4)
- Standard ID
- Hazard/monitoring level

4.15.4.3 Confirmation of Positive Responses *pg 51

Acceptable instrument sensitivity is determined by the successful Method P&A.

Specific step by step guidance for confirming positive responses is found in the corresponding EML internal operating procedure. Unique situations or analytical anomalies may require specific samples to undergo sample confirmation when requested.

DAAMS samples analyzed using mass spectrometer detection are considered confirmed based on both acceptable quality control and the combination of retention time and mass fragment data provided by the mass spectrometer.

DAAMS samples yielding a result greater than or equal to 0.75 Z and analyzed using non-MSD methods shall be confirmed by analyzing the second tube. The second tube shall be analyzed using a method employing a column of differing polarity/stationary phase or differing detector.

DAAMS samples collected for MINICAMS alarm confirmation are qualitative and do not always require a QP. If agent is detected on tube 1, then the MINICAMS alarm is confirmed and no further analysis is required. If no agent is detected on tube 1, then tube 2 will be analyzed under the following conditions: Tube 2 will be post spiked with an agent mass equivalent of 1.0 Z or a mass equivalent as determined from the Class 3 P&A. If agent is detected, the qualitative method is satisfactory and the MINICAMS alarm is considered to be

UNCONTROLLED COPY

false positive. If no agent is detected, the method is unsatisfactory and the MINIMCAMS alarm is considered confirmed.

In non-routine monitoring situations and with an approved site monitoring plan, a second MINICAMS method employing a column of differing polarity/stationary phase or differing detector may be used to confirm the primary MINICAMS method.

4.15.4.4 Correction for Method Recovery *pg 52

For samples that have been confirmed for the presence of agent, the found concentration shall be corrected for method recovery using QP results. The recovered QP concentration is found by subtracting the sample analytical result from the QP analytical result. The method recovery is calculated as follows:

$$r = \frac{J}{T_c}$$

where:

r = Method recovery

J = Lowest recovered QP concentration (from 2 QPs aspirated with the sample).

T_c = Target concentration of the 1 Z (4 µl) QP samples

If the calculated method recovery is less than 1.0, found concentrations of samples are corrected as follows:

$$CC = \frac{FC}{r}$$

where:

CC = Corrected concentration for non-QC samples

FC = Found concentration in non-QC samples

r = Method recovery from QP samples

The corrected concentration is the best estimate of the true vapor concentration and shall be the value reported to the necessary organizations.

4.16 Quality Records (15.4, pg 98) *pg 66

All quality records are subject to review and audit and shall be maintained in such a way as to ensure traceability. Records shall be readily retrievable for the current audit period. Records shall be generated electronically or manually using permanent ink and maintained to support and substantiate all quality related activities. These records shall provide evidence of the quality of the analytical data and compliance with the specified requirements, including federal and state regulations where applicable. Analytical results will be identified by sample ID number, date, instrument ID number and/or batch number.

To ensure traceability, analyst/operator names and initials shall be legible when the entry is used to identify the analyst/operator.

Records shall be stored in a manner to minimize deterioration or damage, to prevent loss and unauthorized use, and stored on shared drives where possible to ensure accessibility. Electronic records shall be kept in the LIMS and electronic databases; hardcopy records shall be kept in Environmental Monitoring Laboratory files until they are scanned and put on CDs (see 4.5.3).

UNCONTROLLED COPY

Handling and scanning of hardcopy data associated with monitoring operations is described in IOPMT-28.

The LIMS database is backed up daily and the backup data are stored at a location away from the primary database.

The DD Form 1911 accompanying the CASARM standard ampoules received from the CTF will be placed in the 1911 Binder. Each CASARM standard vial is intended for a one time use. Any CASARM material remaining from a single preparation event will be destroyed. A new CASARM vial will be opened the next time standards are prepared. A DD Form 1911 is prepared and stored in the 1911 Binder for the working standards. An entry is made in the Accountability Logbook on a CSM Custodial Stock and Usage Record (MBFORM-15) when a working standard is prepared and when working standards are issued to analysts/operators. MBFORM-15 states the quantity of each working standard dispensed and the quantity remaining. An entry is also made on a Record of CSM Destruction (MBFORM-14) in the Accountability Log when working standards are destroyed. These logs are stored at the Environmental Monitoring Laboratory. Standards are prepared IAW SOP CNG-048

The Standard Number provides traceability from the working standard back to the CASARM-certified standard. The number has the following structure:

Standards Logbook (roman numeral) – Page number – Entry number

For example, the preparation of Standard III-81-1 is described in the third Standards Logbook, and is the first entry on page 81.

The information recorded in the agent preparation standard logbook and on the working standard containers is described in Section 4.21.

The Standard numbers, preparation date, expiration date, and initials of person preparing the standard are also stored in the LIMS.

GC/LC Calibration data will be stored on the LIMS and documented in the analytical package. MINICAMS calibration data are stored electronically in the Chrom-Link and are recorded on the MINICAMS QP Data Sheet (MBFORM-4), that is subsequently scanned to a pdf file for long term storage.

All major instrument repairs will be noted in a log that will be kept for each laboratory instrument. Instrument serial numbers substituted with instrument names (e.g., GCMS39) will be clearly traceable through LIMS and property inventories back to the original serial number. Each instrument shall have its own logbook. Laboratory Instrument logbooks shall contain the following types of information:

1) Instrument manufacturer, model number and serial number
2) Site specific instrument ID number (if applicable)
3) Date instrument was received (if known)

NRT instruments are not considered Laboratory instruments. Quality records will be maintained for NRT instruments.

All data generated by the Environmental Monitoring laboratory regardless of personnel are stored electronically at the EML are backed up on disks, tape, or CD, and made part of the 40-year record maintenance system.

UNCONTROLLED COPY

When an organization utilizes monitoring personnel from another organization, the certification records of those individuals should be included as part of the 40 year record.

4.17 Internal Quality Audits *pg 61

The Chief of the Environmental Monitoring Laboratory shall annually initiate an internal audit of the entire Quality Management System (QMS) to assess the effectiveness of the QMS and to identify opportunities for improvement. Findings will be reviewed for necessary corrective actions. The auditors will use check sheets to record audit findings and corrective action request(s) (CAR) to specify corrections required to bring the system into conformance.

All necessary actions will be taken by management to expeditiously eliminate detected nonconformities and eliminate their causes. Personnel performing the internal audit will be trained in the auditing process. Auditing personnel will not audit their own areas of performance. A record of this review/audit shall be maintained. Internal audits should include documentation review for long-term offsite locations generating data for more than 12 consecutive months.

Permanent off-site monitoring locations (labs) operated by the EML shall undergo internal audits.

Audits shall include an evaluation of the following:

a) Activities, work areas, and work and services being generated by Environmental Monitoring Laboratory personnel and its contractor which relate to chemical agent air monitoring.

b) Quality practices and procedures as they relate to CMA LMQAP requirements.

c) Certification, documentation, and records

d) Recommendations/findings of previous audits.

e) Review of completed and outstanding CARs.

f) Review of purchasing documentation.

The following information shall be recorded concerning the internal audits:

a) Date of the audit

b) Name of the auditor

c) Recommendations/findings of the audit

d) Checklist or inspection sheet used for the audit

e) Date and findings of any follow-up audits

The Chief of the Environmental Monitoring Laboratory shall review audit results, implement and document corrective actions required to correct and prevent a recurrence of the deficiency. The QMS will be updated by incorporating necessary changes resulting from deficiencies/corrective actions into quality documents as required to maintain the integrity of the QMS.

All action taken to correct deficiencies shall be reviewed to verify compliance and effectiveness and a closeout report issued.

Findings by External Audit teams, CARS, Observations etc. will be reviewed by the EML Management Team to determine the need for changes to the EML Quality System. This review will be documented. Changes will be made and implemented when required.

UNCONTROLLED COPY

The EML will address written observations of potential non-conformances that are transmitted as part of an audit. The written response will be filed as a quality record and be included as part of the audit records. EML management may choose to include the topics of observation in subsequent internal quality reviews.

Quality records shall be available for the current audit period and be provided to auditors prior to the end of the audit.

4.18 Training (5) *pg 24

4.18.1 Individual Training Plans

Personnel performing assigned tasks are qualified on the basis of appropriate training, education, and/or experience as required. All Environmental Monitoring Laboratory personnel will have an individual training plan that is tailored to each type of operation performed by that individual. These training plans may be in the form of check sheets, written procedures, or a combination of both. In any case, the plans will document that the individual has completed the required training in a satisfactory manner and will be signed by both the trainee and the trainer. A copy of the individual training plan and evidence of successful completion of training will be filed in each employee's training file. "All records including training, certifications, and semi-annual evaluations are maintained as part of the EML data archive and can be accessed easily at anytime."

Environmental Monitoring Laboratory Individual Training, as outlined below, includes requirements to provide training for:

- GC/FPD, GC/MSD & LC/MS/MS analysts/operators
- MINICAMS operators
- Sample Technicians.

Analysts and Operators: Analysts and Operators for GC/FPD, GC/MSD, and LC/MS/MS will be trained/certified IAW requirements outlined in "GC Certification Checklist" (MBFORM-7). This completed checklist will provide objective evidence of satisfactory completion of "on-the-job" (OJT) training and will be signed by the trainer and trainee.

MINICAMS Operators: MINICAMS Operators will be trained/certified IAW requirements outlined in "Checklist for Certification of a MINICAMS Operator" (MBFORM-8). This completed checklist will provide objective evidence of satisfactory completion of OJT training and will be signed by the trainer and trainee.

Sample Technicians: Technicians will be provided OJT and certified IAW requirements outlined in Sample Technician Training Checklist (MBFORM-48). This completed checklist will provide objective evidence of satisfactory completion of OJT training and will be signed by the trainer and trainee.

Satisfactory completion of other required/specialized training shall be demonstrated/ documented by methods such as:

a) Examination

b) Testing

c) Certification

d) Letter/record of attendance

UNCONTROLLED COPY

New sample technicians shall be trained in established procedures by experienced sample technicians or the STL. The procedures are detailed in SOPs, IOPs, and/or check sheets.

Analysts are certified IAW the following subsections.

4.18.1.1 Analyst/Operator Certification (5) *pg 29 & 30

The analyst must demonstrate proficiency in conducting chemical analyses prior to becoming certified to analyze samples. The first phase of the analyst certification involves instruction in the methods of analysis, covering both theoretical concepts and practical considerations. The instruction shall include, but not limited to, the items in the appropriate checklist (MBFORM-7 or 8, as appropriate). The instructor shall sign and date each checklist completed by the individual indicating that the training was received and comprehended.

The second phase of certification involves successful completion of a precision and accuracy (P&A) study or certification test. A P&A study or certification test begins with the analysis of synthetic samples whose analyte concentrations are known. P&A or certification test samples used in certification of an analyst can be either QP or QL samples. The analyst/operator must pass a P&A study or certification test for each method or monitor that he/she shall be using.

The types of certification tests are outlined in the following subsections.

4.18.1.1.1 Class 1 Methods/Monitoring Tasks *pg 30

The certification test for Class 1/Type 1 methods and monitoring tasks requires the candidate to perform an instrument calibration then perform two days of QL or QP analyses. For two (preferably) successive days, each candidate will challenge an instrument or monitor with two samples at each level of 0.5 Z, 1.0 Z, and 2.0 Z. If one of the twelve samples in the personnel certification test is not within acceptable limits, an additional three sample-set challenge must be performed. The analyst is certified if all three re-samples are within acceptable limits. The analyst must repeat the entire twelve-sample certification test if more than one sample of the twelve original samples is outside the limits and if one of the re-analyzed samples is not within acceptable limits. Environmental Monitoring Laboratory personnel use QL's or QP's for Class 1 DAAMS certification and QP's for MINICAMS certification. The agent standard ID used for certification challenges is recorded on the form used for recording the certification data.

Acceptance criteria: QLs + 15%

Acceptance criteria: QPs + 25%

Both the training and the assessment of proficiency of the analyst/operator trainee will be the responsibility of the Team Leader. However, the Team Leader may, if desired, delegate all or part of this responsibility to another analyst/operator who is already certified for performing the analysis/monitoring task.

UNCONTROLLED COPY

4.18.1.1.2 Class A, Class 2, Class 3 Methods *pg 30

Class 2 and Type 2 method certification requirements listed in Table 2-1. Tests performed for operator certification IAW with Table 2-1 requirements will also serve as method and instrument certification or re-certification as applicable. The certification test for Class 2, Type 2, and Class 3 methods will be as indicated in Table 2-1. In addition, the operator/analyst shall read and sign the appropriate IOP indicating that he/she understands the requirements. Class A methods require CMA approval prior to use during CMA operations. Class A operator/instrument certification requirements are the same as Class 1 certification requirements. Analyst/operators who are certified to generate class 1 method data on a given analytical system are automatically certified to generate data for all other method types for that analytical system. Class 1 certification requirements exceed all other method class certifications.

4.18.1.1.3 Semi-Annual Evaluation of Personnel *pg 31

The competency of individuals performingclass1 methods/monitoring tasks shall be evaluated and maintained semi-annually by having each analyst or operator analyze a blind sample(s) for all Class 1 methods (See Paragraph 4.18.1.2) for which the individual is certified. Individuals whose analytical data meet the specified acceptance criteria specified remain certified. Individuals whose analytical data fails to meet specified criteria will be required to re-analyze the blind samples. Two consecutive failures will require re-certification specified in 4.18.1.1.1.

Table 2-1 Analyst/Operator Certification Test Requirements

Class 1/ Type 1	Calibrate Instrument 1st day, then 2 days of duplicate sample QPs or QLs at 0.5, 1.0, & 2.0 Z each day. Analyst is certified if FC for each QL is ± 15% or FC for each QP is ± 25%. See 4.18.1.1.1 for additional criteria.
Class A	Same as Class 1/Type 1
Type 2	Calibrate Instrument 1st day, and analyze 4 QP samples at 1 Z level for 2 preferably consecutive days and 1 blank each day. Analyst is certified if all 8 samples have a detectable signal above a 3:1 signal to noise ratio and none of the blanks yield a positive response above the signal to noise ratio.
Class 2	Calibrate Instrument 1st day, and analyze 4 QP samples at 1 Z level for 2 preferably consecutive days and 1 blank each day. Analyst is certified if all 8 samples yield a positive response and none of the blanks yield a positive response.
Class 3	Calibrate the instrument. Analyze 3 QP samples at 1 Z level and 1 blank. Analyst is certified if all 3 QP samples yield a positive response and the blank does not yield a positive response. A positive response is defined during method development/P&A study.

Blind samples are prepared from blind standard material, but are tracked in the standard logbook like normal standards. The identification number of the blind sample is recorded with blind testing data.

UNCONTROLLED COPY

If blind samples are used for semi-annual evaluation of personnel, then use of the lowest monitoring level as a target is not applicable, since the samples are truly blind.

4.18.1.2 Re-certification of Analysts/Operators * pg 30

4.18.1.2.1 Class 1 Methods/Monitoring Tasks

To remain certified the analyst shall meet the following requirements:

1) Analyst shall "Perform DAAMS sample analysis" at least one calendar day every two months to include completion of an entire analytical package. If the package requires multiple corrections to meet laboratory quality requirements, the Lab Manager or designee may require additional days of analysis for the analyst to remain certified.

2) Analyst shall perform and meet requirements of the Semi Annual Competency test specified in paragraph 4.18.1.1.3 of the QC Plan.

To remain certified the MINICAMS Operators shall perform instrument calibration and QP verification test on at least 1 MINICAMS every 2 months and perform the semi-annual competency test requirements of paragraph 4.18.1.1.3 of the QC Plan.

For re-certification purposes a method is defined as each unique type of instrument/detector combination. For MINICAMS methods, methods shall be grouped into loop methods, sorbent XSD methods, and sorbent FPD methods. To maintain certification operators need only calibrate and challenge at least one agent on each method type (loop/XSD/FPD) once every 60 days. Agent STD ID used for re-certification challenges is recorded on the form used for recording the re-certification data.

Recertification of analysts and operators is based on demonstrated proficiency on an instrument or monitor, not on proficiency in performing specific methods or monitoring tasks. An individual who has not used a Class 1 instrument/monitor for six months shall be trained and certified as outlined in Sections 4.18 and 4.18.1.1.1 before using the instrument or monitor. An individual who has not used a Class 1 instrument/monitor for two calendar months shall read the appropriate IOP or SOP, document that it has been read and perform the Class 1 certification test per Table 2-1.

Acceptance criteria: QLs $\pm$ 15%

Acceptance criteria: QPs $\pm$ 25%

4.18.1.2.2 Class 2 Methods

An individual who has not used a Class 2 instrument or monitor for more than one year shall be trained and certified as outlined in Sections 4.18 and 4.18.1.1.2 before using the Class 2 instrument or monitor. An individual who has not used a Class 2 instrument or

UNCONTROLLED COPY

monitor for longer than six months shall read the appropriate procedure or SOP, document that it has been read, and perform Class 2 certification test per Table 2-1.

4.18.1.3 Sample Collection Personnel

Sample collection personnel shall receive a period of training followed by hands on instruction in the appropriate collection procedures. The training and instruction shall be documented. In addition to the initial training and instruction, sample collection personnel shall read and sign the appropriate SOPs and IOPs as required. Sample collection personnel who have not collected a sample in 12 months shall be re-trained prior to collecting samples.

4.18.2 P&A Method Certification Requirements (9.2, 10.3) *pg 24, 26, 27

The first step in the P&A process is to document the method in accordance with Appendix A of the CQAPCAAM and Section 10 of CMA LMQAP. All chemical agent air methods shall undergo a precision and accuracy study prior to being used to generate data under the EML quality system.

Each method is documented in the form of an Internal Operating Procedure (IOP) to meet the required criteria. P&A results are generated by the instrument software and reported in the P&A documentation package. The pass/fail results are generated by the Certify or CQAT supplied software and reported as part of the P&A results. A copy of the analytical method and instrument parameters are maintained as part of the data package with each P&A method certification. The P&A samples are prepared, collected from a representative sample matrix of the project or location where operations occur, and analyzed IAW the appropriate IOP requirements. Daily instrument calibrations and controls are designed to conform to the requirements demonstrated by the Method P&A. Only trained analysts or operators shall analyze P&A study samples and certify methods. A minimum of 2 analysts/operators and 2 instruments shall be used for Class 1 method certification. The total number of samples shall be divided as equally as possible among all analysts or operators performing the study.

The P&A study for Class 1/type 1 methods or monitors consists of analyzing 48 total QP agent challenges over four (preferably consecutive) days. Class 1 methods must be performed within a 10-day period. The QPs will be collected/handled as specified in the appropriate IOP. The twelve daily P&A samples shall consist of two samples at each of the following concentrations: 0.0 Z, 0.5 Z, 0.75 Z, 1.0 Z, 1.5 Z, 2.0 Z, where Z is the applicable hazard level Z. The data shall be evaluated by pooling all four days of data into a single group and performing a linear-regression analysis of target concentration (TC) versus found concentration (FC). Method certification shall be completed within a 10 day period. The computer software used to calculate the P&A study detection limits and pass/fail criteria will be supplied by the CQAT or CMA. When historical or confirmation methods are identical for spiked mass, but not for aspiration/sampling time and monitoring level, only the method using the longest sampling period shall require a P&A study.

The method shall pass the P&A study and the analyst(s) and the instrument(s) shall be certified if the following conditions are met:

a) The Target Action Level (TAL) is greater than the statistically calculated limit of quantification (LOQ), as calculated by the P&A software.

UNCONTROLLED COPY

b) The Uncertainty in Found Mass (UIFM) is less than or equal to ±25% (40% for MSD).

c) Average Recovery at the 1.0 Z shall be within 75 to 125 percent.

The P&A study requirements for Class 2 and 3 methods require a minimum of one operator and one instrument analyzing 20 samples in accordance with Table 2-2. For Class 2 and 3 methods, a positive response shall be defined during method development and can be based on signal height, area counts, signal-to-noise ratios, or percent recovery. Sample analyses for routine operations shall use the same definition of a positive response used during the certification process.

Table 2-2 P&A Method Certification Requirements

Type of Certification	Number of Operators	Number of Instruments	Number of days [a]	Target Concentrations [b]	Total number of points	Criteria
Class 1	2 or more	2 or more	4	8 each at 0.0, 0.5, 0.75, 1.0, 1.5, & 2.0 times the monitoring level (Z)	48	Target action level (TAL) is greater than the statistically calculated limit of quantitation (LOQ). Recovery at the Monitoring level is within 75 to 125%. For MSD methods, UIFM is less than or equal to ± 40%; Non-MSD ± 25%.
Modified Class 1	1 or more	1 or more	4	8 each at 0.0, 0.5, 0.75, 1.0, 1.5, & 2.0 times the monitoring level (Z)	48	
Class A	1	1	1	6 each at 0.1, 0.5, 1.0, and 2.0 Z	24	Estimated analytical recovery must demonstrate accuracy within ± 25% with 95% confidence at 1 Z.
Class 2	1	1	2	4 at 1.25 Z, 8 each at 1.0 and 0.5 Z	20	All samples at 1.25 and 1.0 Z yield a positive response. No more than 25% of 0.5 Z yield a positive response at reporting level
Type 2	1	1	2	8 each at 1.0 Z, 2 at 0.0	20	All challenges at 1.0 Z yield ≥ 3:1 and all 0 Z challenges yield no response or response at or below noise level
Class 3	1	1	2	16 at 1.0 Z, 4 at 0.0	20	All challenges at 1.0 Z yield a positive response. None of the blanks yield a positive response.
USEPA SW-846	1	1	1	Minimum of 7 replicate samples at the PQL	7	Recovery and precision defined by method development.

[a] Preferably consecutive days
[b] The CMA laboratory shall request approval from CMA-Monitoring Office to use different levels than those values recommended for use.
[c] Statistically determined outliers, not to exceed the square root of the total number of data points, may be excluded from the set. Assignable cause data shall be repeated with documentation as to why the data point(s) was repeated.

UNCONTROLLED COPY

The P&A study requirements for type 2 methods are intended to provide an indication of the presence of agent at or above the action level and shall be certified by analyzing, on each of two preferably consecutive days, two blanks and 8 QP samples at the confirmation/reporting level. The sampling and analysis operations will be performed as set forth during the P&A. Type 2 methods shall be certified for use if 100% of the action level challenges yield a detectable response at or above a 3:1 signal-to-noise ratio and 100% of the blanks yield no response or a response at or below the noise level.

To certify a Type 2 method, on each of two preferably consecutive days, a trained instrument operator prepares and analyzes two blanks and eight separate 1 Z QP sample challenges (the QP sample shall be exposed to air regularly sampled during routine operations). Type 2 methods shall be certified for use if 100% of the action level challenges yield a detectable response at or above a 3:1 signal to noise ratio and 100% of the blanks do not yield a response.

See Table 2-2 for a summary of Method acceptance and Certification Requirements.

4.18.2.1 Off Site Method Certification

A method P&A shall be performed for each method used at each off site location in IAW P&A method certification requirements outlined in 4.18.2. Class 2 methods will be applicable instead of Class 1 method requirements where approved by the Chief of EML. When Class 2 methods are approved for off-site use, the Class2 certified instruments shall be calibrated and challenged the same as the Class I certified instruments.

More stringent CMA requirements shall also be incorporated for method certification in addition to compliance with CASARM requirements.

4.18.2.2 Class 2 Method Certification

The certification for Class 2 methods consists of a trained analyst performing the analysis of four QP samples at the level which the organization is required to confirm and/or report values and one blank on each of two preferably consecutive days. To pass the certification test, a detectable signal at or above a 3:1 signal to noise ratio shall be obtained for all eight samples and the blanks must yield no response (*pg 28).

4.18.2.3 P&A Method Certification

Method Certification is performed IAW with the EML QC Plan and associated IOP requirements. The results are documented in the P&A Data package. Acceptance/Reject requirements are generated by the software program used (Certify or CQAT P&A program). P&A data is scanned into pdf format, placed on CD for retention IAW specified requirements. A copy of the analytical method is maintained as part of the analytical data package.

4.18.2.4 Method Documentation and Configuration Control

NRT methods should be documented in a format similar to Appendix A of the CQAPCAAM.

Method documentation and configuration control are established during the method precision and accuracy study. The method specifics and tolerances are determined during the precision and accuracy study and affected by the applicable

UNCONTROLLED COPY

internal operating procedure. The documentation generated to support certification of the method is scanned and stored as a permanent record in accordance with this document and serves to document the method.

4.18.3 Certification of Additional Instruments (9.2, pg 46) *pg 32

All "additional instruments" are routinely certified to Class 1 method requirements and may be used to monitor/analyze samples to Class 2 requirements without additional certification.

For Class 1 methods the instrument will always be calibrated on the first day of certification. Additional instruments/monitoring systems will be certified by having a certified operator calibrate the instrument in accordance with specified procedures, then challenge the instrument with duplicate QL or QP challenges of 0.5 Z, 1.0 Z and 2.0 Z on each of two different (preferably consecutive) days. If one of the twelve samples in the instrument certification test is not within acceptable limits, an additional three sample-set challenge must be performed. The instrument is certified if all three re-samples are within acceptable limits. The analyst must repeat the entire twelve-sample certification test if more than one sample of the twelve original samples is outside the limits or if one of the re-analyzed samples is not within acceptable limits.

Acceptance criteria: QLs $\pm$ 15%

Acceptance criteria: QPs $\pm$ 25%

Instruments/monitors used for Class 1 or Class 2 methods that have undergone extensive repair require re-certification. These instruments will be re-certified by completion of an acceptable calibration curve and initial calibration verification (ICV). Instruments/ monitors that fail to meet these requirements shall be tagged for repair or replacement.

Class 2 Instruments: The certification of additional instruments used for Class 2 methods consists of a trained analyst performing the analysis of four QP or QL sample at the level which the organization is required to confirm and/or report values and one blank on each of two preferably consecutive days. To pass the certification test, a detectable signal at or above a 3:1 signal to noise ratio shall be obtained for all eight samples and the blanks must yield no response at or above the noise level. Class 2 Instruments shall be re-certified by generating an acceptable calibration and QL or QP for MINICAMS.

4.18.3.1 Class 1 NRT Monitors *pg 37

Calibration and Minimum Response Requirements are specified in the MINICAMS IOPs (see Section 4.11 of IOPs).

4.18.4 Significant Changes in Methods/Monitoring Tasks *pg 33

The following items are significant changes in a method/monitoring task and require the performance of a new P&A study as described in Sections 4.18.2 and 4.18.3.

- A change in the volume of the air sample collected only if the volume collected would theoretically contain an amount of agent that is less than the lowest standard or greater than the highest standard used during the original P&A study, based on the mass of agent equal to the Z Value.
- A change in the type of media or process used to collect the sample during sampling or analysis.

UNCONTROLLED COPY

- A change in the type of liquid (stationary) phase in a GC column.
- When historical or confirmation methods are identical for spiked mass, but not for aspiration/sampling time and monitoring level, only the method using the longest sampling period shall require a P&A study.

4.18.5 Systemization of NRT Monitor/Data Acquisition System Interface (9.3, pg 46)

A NRT Monitor system selected for systemization to demonstrate field acceptance shall be calibrated IAW IOP requirements. The NRT system shall then be challenged to demonstrate that the data acquisition system displays the same value within 5.0% as the NRT monitor display, and the same station number, location description, and alarm status and that the alarm printer prints the date, time, station number and alarm status. In addition, verify that the NRT shows a blank cycle value below 0.2 Z and that the data acquisition system no longer displays the station number, location description, and alarm status. Verify that when power is removed from the NRT monitor utility bus, the NRT monitor continues to operate and that no alarms are activated as a result of loss of utility power.

4.19 Statistical Techniques *pg 67

Environmental Monitoring Laboratory shall use the statistical programs that are developed in house, the LIMS QC Module, software provided by CMA, or the CQAT for verifying the acceptability of process capability and product characteristics. Commercially available statistical programs may also be used as appropriate. Configuration control of NRT (MINICAMS) software systems are as purchased from the manufacturer. Parameters are defined by the approved Methods and are part of the printout. GC & Detector instrument Methods are inherent within the saved Method and may be printed as required. Method parameters may be changed to meet changing conditions as required. Changes to methods will be saved. Copies of previous method configurations are saved for future reference.

The verified program software furnished by CASARM will be used as the comparison/transfer standard to verify in-house developed and/or other software used by the Environmental Monitoring Laboratory. CMA specified software may be used as appropriate. When the verified software furnished by CASARM will not provide an adequate check of the in-house developed software, Verification of the in house developed software will be accomplished by conducting a representative sample of manual calculations for each field of the software using a set of data. Subsequent revisions will be verified using the same set of data when possible.

Excel Spreadsheets have been programmed for in house analysis and the built in functions are used when possible, e.g., max, min, average, and standard deviation.

Percent Recovery:

$$\%\ Recovery = \left\{\frac{[Found\ Concentration]}{Target\ Concentration}\right\}(100)$$

Relative Response Factor (RRF):

$$RRF = \{\frac{(AREA\ Working)(CONC\ Verification)}{(AREA\ Verification)(CONC\ Working)}\}$$

In-house developed software/database will be evaluated and verified for adequacy by using a standard set of numbers. These standard numbers will be input into both the CASARM software

UNCONTROLLED COPY

and the in-house software. The resulting output data will become a part of the verification package that includes: Program Identification, Authors name, Date of Issue, Revision number, Data used for verification, and Program output. No special signature authority is required since acceptable data comparison with CASARM furnished program is proof that the programs are in conformance with requirements. The person performing the verification will sign or initial and date the verification data to indicate that the programs are acceptable.

Where in-house-developed software programs are used (for the capture, processing, manipulation, recording, reporting, storage, or retrieval of data), verification procedures will be used to ensure the computer software satisfies the intended application, which will be performed before initial use and reconfirmed when the software is revised or updated. When possible, the set of data used to test the software include some non-routine numbers (e.g., a negative value or value out of calibration range) to give a true test of the software is not addressed.

Verification of the initial program will be accomplished by conducting manual calculations for each field of the program using a set of data. Verification of subsequent revisions will be performed with the same data set used to verify the original issue of the software. This data set will be retained for use when evaluating subsequent revisions of the program.

A verification package for each software revision will be compiled and retained. The package will contain:

a) Program identification
b) Author's name
c) Date of issue
d) Revision number
e) Verifier's name
f) Date of verification
g) Data used for verification
h) Equations used for verification
i) Verified program or program output
j) Additional calculations required verifying changes
k) Approval signature of designated authority

4.20 Preventive Maintenance (4.4) *pg 53

If a vendor is used to perform preventive maintenance, the vendor shall document all maintenance activities performed in accordance with the maintenance contract and shall make the records available.

Preventive maintenance stickers may be used on laboratory equipment for contract maintenance tracking purposes and are not indicative of the calibration status of the equipment.

Serial numbers of components critical to the monitoring process/instrument should be recorded in the maintenance records for the instrument.

Instrument maintenance is performed as required for optimum instrument operation by Environmental Monitoring Laboratory personnel. Each instrument has a logbook that is unique to that instrument and all maintenance/repair performed on that instrument is documented in the logbook. The person performing routine maintenance shall initial and date the logbook entry.

UNCONTROLLED COPY

EML maintains a stock of components required for routine maintenance of laboratory instruments and NRT Monitors.

Environmental Monitoring Laboratory has a service contract for non-scheduled instrument repair and maintenance with an instrument vendor.

Environmental Monitoring Laboratory maintains a contract with the manufacturer of the MINICAMS to perform PM on MINICAMS IAW with contract requirements.

Each MINICAMS is tracked by CMS using individual stickers that contain the PM date. PM is routinely performed by EML personnel on all MINICAMS as required to maintain satisfactory functional performance; however, PM by the contractor will be scheduled and performed within a one year period not to exceed fourteen months duration.

Instruments that exceed routine PM time lines will be serviced at the next available interval. PM stickers are used to track contract maintenance services and are not related to calibration status.

The EML will track only the MINICAMS chassis serial number for preventive and corrective maintenance activities. Since all instruments are either calibrated or challenged prior to use, the EML considers this sufficient to meet the QC requirements of the CQAPCAAM Section 10 with regard to subcomponents.

4.21 Reference Materials (8.2) *pg 19, 22, 23

CASARM stock solutions are received annually. Upon receipt of the stock solutions, the Shipment Status Report (SSR) is completed and returned to the CASARM Quality Assurance Team.

CASARM and Stock Solutions shall be shall be stored below 4°C under the same conditions as working standards (see paragraph below).

Working Standard Solutions. **Two sets of working standards will be prepared on an as-needed basis.** Working standards are prepared by serial dilution of dilute CASARM solutions in accordance with SOP# CNG-048, Preparation of Near Drinking Water Level Chemical Agent Standards. Calibration standards shall be labeled with a "C" and the separate QC challenge standards shall be labeled with a "Q." The "C" and "Q" standards shall be prepared by different individuals.

The working standards will be tested on a monthly basis in the following manner:

When new working standards are made, aliquots of each standard will be sealed and stored for monthly verification. Each month, a verification standard will be removed from the refrigerator to be tested against the QC working standards. The instrument used for standards verification will be in control in accordance with the appropriate IOP, e.g., MINICAMS or Laboratory IOP. Three injections of the verification standard will be analyzed. The average response of the verification standard and the working standard QL injections (2 QL injections minimum that bracket the verification standard injections) will be compared using the relative response factor (RRF) formula. If the averages are within 10%, the standards shall be usable for an additional month. If the concentrations are greater than the ranges listed above, the process can be repeated on a separate instrument and with a different verification vial. If the verification data still does not pass, then the working standard of concern will remade and tested.

This process will apply to both lab and MINICAMS air standards. Lab personnel and MINICAMS personnel will perform this verification monthly and report the data information to management.

UNCONTROLLED COPY

If CASARM grade agent is unavailable, the best available agent material is obtained from the CTF or from the Client for use in making working standards.

At a minimum, reagent grade organic solvents shall be used to prepare all standard solutions. Each solvent lot used shall be evaluated to determine that an adequate amount of the solvent lot is available to complete the task. Organic solvents must be kept as water free as possible while in use.

Minimum information on the label attached to the solution container is:

- Agent name
- Solvent name
- Concentration
- Date Prepared or Expiration Date

For each serial dilution, the following information shall be recorded in the STDs Logbook:

- Preparation date and Expiration Date
- Agent identity and identification information
- Amount used for Dilution
- Initials of preparer
- Lot number of the standard "C" or "Q" as applicable
- Concentration of the standard
- Solvent type and quantity added
- Solvent purity
- Solvent Manufacturer
- Solvent lot number
- Total volume of the standard

Working solutions have a shelf life not to exceed the shelf life of the parent standard. Working standards are verified monthly.

Working standards shall be stored below 4°C. The temperature of the refrigerator shall be verified daily, initialed and dated by the person verifying the temperature to provide objective evidence that the temperature is being checked on a daily basis. CMA & the CQAT will be notified if refrigerator temperature is above 4°C for more than 96 hours. Operations with CASARMs outside cold storage will be kept to a minimum.

The EML Chief or his designee will arrange for a supply of necessary reference materials, such as CASARM or best available standard.

The ACM will specify which reference materials are acceptable for use in a given procedure.

4.21.1 Glassware Cleaning Procedure *pg 22

Extractions and sample preparations involve the use of disposable items. Standards are made using volumetric glassware that is re-used. This glassware is washed using

UNCONTROLLED COPY

"Alconox," "Sparkleen," or their equivalents. The glassware is rinsed with tap water, de-ionized water, and then solvent. The glassware is allowed to air dry and is then put away.

4.22 Action Level (Airborne exposure limits) *pg 88

Analytical results exceeding the actions levels in Tables 2-3 & 2-4 shall be reported to the Chief of the Environmental Monitoring Laboratory or Designee, as soon as possible.

Table 2-3 Action Level for DAAMS Monitoring

Agent	Allowable mg/m^3 (AEL)*	Sample Volume (L)	Required Action Level*** (ng on the tube)	Concentration of Agent in the Calibration Standard (µg/ml)
Action Level for Worker Population Limit (WPL)				
GA, GB	0.00003	24	0.72	0.18
GD, GF	0.00003	24	0.72	0.18
VX	0.000001	24	0.024	0.006
HD	0.0004	24	9.6	2.4
L	0.003	24	72	18**
HN-1, HN-3	0.003	24	72	18**
* Action Level for General Population Limit (GPL)				
GA, GB	0.000001	24	0.024	0.006
GD, GF	0.000001	24	0.024	0.006
VX	0.0000006	24	0.0144	0.0036
HD	0.00002	24	0.48	0.12

* Airborne Exposure Limit

** Due to instrument sensitivity, standard concentrations of these analytes are lower, typically 1-2 µg/ml or ng/µl.

*** Required Action Level Calculation:

$$D\,(ng) = \frac{A\,(mg)}{m^3} \times \frac{m^3}{1000\,l} \times \frac{1000\,(\mu g)}{(mg)} \times \frac{B\,(l)}{(min)} \times C\,(min) \times \frac{1000\,(ng)}{(\mu g)}$$

Where: A = AEL
B = Flow rate
C = Sampling Interval
D = Required Action Level

UNCONTROLLED COPY

Table 2-4 Action Limits for NRT Monitoring at STEL

NRT MONITORING AT STEL
DAILY EXPOSURE LIMIT 15 MINUTES WITHOUT PROTECTION.

**Required action Level for NRT Air Monitoring when monitoring at the STEL.

Agent	Allowable AEL[a] mg/m^3	Sampling Interval (min)	Flow Rate (l/min)	Required Action Level** (ng on the tube)	Concentration of Agent in the Calibration Standard (µg/ml)
GA, GB	0.0001	6	0.4	0.24	0.06
GD, GF	0.00005	6	0.4	0.12	0.03
VX[b]	0.00001	6	0.4	0.024	0.006
HD	0.003	3 6	0.4 0.4	3.6 7.2	0.9 1.8
L	0.003	6	0.4	7.2	1.8
HN-1, HN-3	0.003	3 6	0.4 0.4	3.6 7.2	0.9 1.8

Airborne exposure limits (AELS) are taken from DA PAM 385-61, 17 DEC 2008.
AELS are concentration only values, regardless of duration. PPE may be used to limit potential exposure to workers.

[a] An additional reduction factor for statistical assurance of action is not needed because of safety factors already built into the derivation of the exposure limit.

[b] VX STEL limit of $1x10^{-5}$ mg/m^3 for 15 minutes (not more than one time per day) is based on technical capabilities of existing air monitoring technologies.

** Required Action Level Calculation:

$$D\,(ng) = \frac{A\,(mg)}{m^3} \; x \; \frac{m^3}{1000\,l} \; x \; \frac{1000\,(\mu g)}{(mg)} \; x \; \frac{B\,(l)}{(min)} \; x \; C\,(min) \; x \; \frac{1000\,(ng)}{(\mu g)}$$

Where: A = AEL
B = Flow rate
C = Sampling Interval
D = Required Action Level

UNCONTROLLED COPY

Appendix 1 Glossary of Terms

ACCURACY: The agreement of a measurement with an accepted reference of true value. Accuracy is usually expressed in terms of percent recovery.

AIR SAMPLES WORKORDER (MBFORM-39): A form used to record all DAAMS air method sampling information in the form required for entry into the LIMS. This record contains the sampling times and flow rates for each DAAMS tube sample.

AIRBORNE EXPOSURE LIMITS: Allowable concentrations in the air for occupational and general population exposures.

ALLOWABLE STACK CONCENTRATION (ASC): A non-regulatory ceiling value that serves as a source emission limit (SEL) and not as a health standard. It is used for monitoring the furnace ducts and common stack.

ANALYTE: The substance to be detected and/or measured when performing the chemical analysis of a sample.

ASSIGNABLE CAUSE: Assignable cause is defined as a known reason for the occurrence, usually determined to be operator or systematic error that does not correctly indicate the performance of the instrument or monitoring system.

AUDIT: A planned and documented investigative evaluation of an item or process to determine its adequacy, effectiveness, and compliance with established procedures, instructions, drawings, quality control (QC) plans, and/or other applicable documents.

CALIBRATION: The process of determining response factors used to calculate absolute concentrations by injecting specially prepared calibration samples. Establishing a relationship between known concentrations of analyte and the detector response.

CASARM: Chemical Agent Standard Analytical Reference Material (CASARM) is a high purity certified chemical agent standard used by the U.S. Army Chemical Materials Agency (CMA) laboratory/monitoring group to prepare stock agent solutions and subsequent working standards.

CHEMICAL AGENT STANDARD ANALYTICAL REFERENCE MATERIAL (CASARM): Chemical Surety Material (CSM) or dilute solutions of CSM used for research, development, testing, and evaluation (RDT&E) whose purity or concentration has been accurately determined, that is stored in a manner that minimizes degradation, and whose concentration or purity is periodically confirmed.

CEILING VALUE: The maximum exposure concentration at any time, for any duration. Practically, it may be an average value over the minimum time required to detect the specified concentration.

CHAIN OF CUSTODY (COC): An unbroken trail of accountability that ensures the physical security of samples, data, and records.

CHALLENGE: An injection of a known standard at a required monitoring level to validate that the instrument is still in control and that the calibration is valid.

CHEMICAL WARFARE MATERIEL (CWM): Equipment, munitions, devices, and containers designed for use directly in connection with the employment of chemical weapons or containerization of chemical agents or industrial chemicals. This term includes the chemical weapons stockpile; chemical weapons production facilities; binary weapons and components; buried, range recovered, or found chemical munitions, containers, or chemical agent identification sets (CAIS).

COLORIMETRIC TUBES: Small glass tubes filled with solid adsorbents, such as silica gel, activated alumina, or inert granules, and impregnated with detecting chemicals through which air is aspirated at a controlled rate. The detector chemical undergoes a color change in the presence of the contaminant; the contaminant concentration is proportional to the intensity of color change or the length of the stain within the colorimetric tube.

CONFIDENCE (OR SIGNIFICANCE) LEVEL: A value corresponding to the probability that a single future measurement will yield a particular result or fall within a particular interval of values.

CONFIRMATION: The process of validating or invalidating a positive response from another monitoring system.

CONTINUING CALIBRATION VERIFICATION (CCV): A quality laboratory (QL) sample analyzed at prescribed intervals throughout the entire analytical run and used to verify the continued accuracy of the instrument calibration and to monitor instrument drift and overall instrument performance.

CORRECTIVE ACTION: Any action taken to rectify adverse conditions, and where possible, to preclude their recurrence.

CUSTOMER: The recipient of a product provided by the organization.

UNCONTROLLED COPY

DAILY REPORT (MBFORM-36, MBFORM-52): A form used by the analyst to write the analytical results and/or comments for each field and QC sample.

DATA SHEET (MBFORM-11): A computer generated printout containing pertinent sample results and clearance information.

DEMILITARIZATION: The mutilation, destruction, or neutralization of chemical materiel, rendering it harmless and ineffectual for military purposes.

DIAGNOSTIC QUALITY PLANT (QP) CHALLENGE: QP challenges performed as part of corrective actions to determine if a problem has been resolved and are not included in the baseline calculations.

DILUTE RESEARCH, DEVELOPMENT, TEST, AND EVALUATION (RDT&E) STANDARDS: Solutions in concentrations and quantities not exceeding the levels defined in Army Regulation 50-6, Chapter 6, *Research Chemical Agents*.

DUPLICATE SAMPLES: Also known as replicate samples or split samples, duplicate samples are two aliquots taken from the same sample container and analyzed separately to test repeatability of an analysis.

FIELD LABEL: A hand written label containing sample information that will be entered into a computer-based Laboratory Information Management System (LIMS).

FOUND CONCENTRATION (FC): Concentration of a standard analyte solution measured by a sampling and analysis method after a challenge with a known standard concentration (target concentration [TC]).

GENERAL POPULATION LIMIT (GPL): The allowable concentration for indefinite unprotected exposure (that is, 24 hours per day, 7 days per week for a 70-year lifetime) of the general public without adverse health effects.

HOLDING TIME: The maximum time allowable between sample collection and/or extraction and analysis. Some samples may have a time limit to be analyzed/extracted from the start time when the sample was collected. Some samples may have a time limit to be analyzed once they have been extracted.

IMMEDIATELY DANGEROUS TO LIFE AND HEALTH (IDLH):

a. A condition posing an immediate threat to life or health, or an immediate threat of severe exposure to contaminants likely to have adverse delayed effects on health. This condition includes atmospheres where oxygen content by volume is less than 19.5 percent.

b. The maximum concentration from which, in the event of a respirator failure, one could escape within 30 minutes without a respirator and without experiencing any escape-impairing (for example, severe eye irritation) or irreversible health effects.

IDLH levels have not been established for vesicants because workers are required to wear supplied air or self-contained breathing apparatus at vesicant concentrations much lower than IDLH levels. IDLH levels for industrial chemicals that may be encountered during non-stockpile operations are adopted from the National Institute for Occupational Safety and Health (NIOSH).

INDUSTRIAL COMPOUNDS: Chemicals developed or manufactured for use in industrial operations or research; these chemicals are not primarily manufactured for the specific purpose of producing human casualties or rendering equipment, facilities, or areas dangerous for use by man

INITIAL CALIBRATION VERIFICATION (ICV): A QL sample that is analyzed immediately following instrument calibration and is used to verify the accuracy of the instrument calibration and to monitor instrument drift and overall instrument performance.

LABORATORY/MONITORING GROUP: Person or person(s) responsible for performing all environmental, analytical, and safety laboratory/monitoring activities at a given site. This group has the responsibility to collect, analyze, and document samples, preserve samples, prepare samples for offsite transportation, calibrate and challenge monitoring instruments, review sample analysis results, and report sample analysis results from laboratory/monitoring instruments to the Site Project Officer.

LABORATORY QUALITY CONTROL PLAN: A quality assurance/quality control (QA/QC) plan developed to implement the requirements of the Laboratory Monitoring and Quality Assurance Plan (LMQAP) in support of CMA laboratory and monitoring activities for each site, project, or operation.

LIMS: Laboratory Information Management System, e.g., computer software used for management of samples, laboratory users, instruments, standards, and other laboratory functions such as invoicing and work flow automation.

UNCONTROLLED COPY

MATRIX: The component or substrate that contains the analyte of interest.

MATRIX SPIKE SAMPLE (MS): A sample that is spiked with the appropriate analyte prior to sample preparation and analysis.

MATRIX SPIKE SAMPLE DUPLICATE (MSD): A second spiked sample that is spiked with the appropriate analyte prior to sample preparation and analysis.

METHOD: A set of procedures and techniques for systematically performing an activity (for example, sampling, chemical analysis, quantification). A method will encompass certain parameters that, when changed significantly, may result in a new method. Methods shall be placed under configuration control and critical parameters shall identify tolerances that, when exceeded, will result in a "new" method.

METHOD BIAS: A systematic error inherent in a method or caused by some artifact or idiosyncrasy of the measurement system. Examples are temperature effects, extraction inefficiencies, contamination, mechanical losses, and calibration errors. Bias may be both positive and negative, and several types can exist concurrently so that net bias is all that can be evaluated, except under special conditions.

METHOD BLANK: Analyte-free water or soil, processed in the exact manner as the samples within a batch, using identical reagents and solvents.

METHOD DETECTION LIMIT (MDL): The MDL refers to waste methods only. The minimum concentration of a substance that can be measured and reported with 99 percent confidence that the analyzed concentration is greater than zero and is determined from analysis of a sample in a given waste matrix containing the analyte. The MDL is the lowest level at which an analyte may be reported using that method (source is 40 CFR, Part 136, Appendix B)

METHOD OR MEASUREMENT ACCURACY: The degree of agreement of a measured value with the true or expected value of the quantity of concern. Method accuracy depends on the lack of bias and imprecision of the method.

MOBILE STATION: A mobile station is comprised of near real-time (NRT) instruments and sampling points that change location in accordance with operational requirements to include real-time analytical platforms (RTAPs) and first entry monitoring.

MONITORING: The continued or periodic act of seeking to determine whether a chemical agent is present (Department of the Army [DA] Pamphlet [Pam] 385-61).

MONITORING LEVEL: The level to which monitoring is performed. Responses at or above the monitoring level indicate the monitoring level has been met or exceeded and corrective actions are required. For waste screening purposes, the monitoring level is the negotiated treatment value for a specific analyte within a specific matrix.

MONITORING PLAN: A detailed, site-specific plan that covers all laboratory and monitoring objectives and strategies for a given site. The plan describes methods and equipment used, locations, number and type of samples, safety requirements, transportation and shipping instructions, scheduling, and any other site-related monitoring requirements.

NEAR REAL-TIME (NRT) CONFIRMATION: Confirmation of the detection of agent at the required monitoring levels in the event of an NRT monitor chemical agent alarm.

NEAT CHEMICAL AGENT: An undiluted, full-strength (as manufactured) chemical agent or agent at concentrations above RDT&E dilute level. Chemical agent manufactured by the binary synthesis route will also be considered a neat agent, regardless of purity.

NRT MONITOR: A monitor that has the capability to automatically collect a sample, analyze the sample, and report/display the sample analysis results within 15 minutes or less.

PERMISSIBLE or PUBLISHED EXPOSURE LIMIT (PEL): The exposure inhalation or dermal PEL specified in 29 CFR Part 1910, Subparts G and Z.

PERSONNEL ROSTER (MBFORM-42): This form is used to record the personnel entering a building room or other designated exclusion areas during the monitoring of a Standing Operating Procedure (SOP). Information on this form includes the building and room number, the SOP number and the agent being used. Personnel entering the room during SOP operations are to sign in, write their level of protective clothing. This information is entered into a 40-year database maintained by the Monitoring Branch.

UNCONTROLLED COPY

pH: A measure for the activity of the hydrogen ions in a substance. The hydrogen ion activity determines the acidic, neutral, or alkaline character of a substance.

PRACTICAL QUANTITATION LIMIT (PQL): The lowest concentration that can be reliably determined with specified limits of precision and accuracy for a given analytical method. The PQL is 10 times the method detection limit (MDL) as defined by USEPA SW-846. The PQL is applied to waste screening methods.

PRECISION: A measure of mutual agreement among individual measurements of the same property, usually under prescribed similar conditions, generally expressed in terms of the standard deviation.

PRODUCT: The result of activities or processes. A product may include service, hardware, processed materials, software, or a combination thereof. A product can be tangible or intangible or a combination thereof. Products, for organizations that fall under this QA Plan, are analytical data and samples.

PROFICIENCY TESTING PROGRAM (PTP): This program plan specifies the program requirements adopted by the CASARM Quality Assurance Team (CQAT) for conducting a PTP for chemical agent monitoring. The PTP describes actions and activities required to operate an effective proficiency test plan to support the Army's CASARM Quality Assurance Program. The PTP may be used to check the consistency and comparability of data for individual testing personnel, establish the effectiveness and comparability of test methods, achieve systemic improvement, and assist with the determination of reasons for interlaboratory differences.

PUBLISHED EXPOSURE LEVEL: The exposure limits published in *NIOSH Pocket Guide to Chemical Hazards*, dated 1994, incorporated by reference, or if none are specified, the exposure limits published in the standards specified by the American Conference of Governmental Industrial Hygienists in their publication, *Threshold Limit Values and Biological Exposure Indices*, dated 1994, incorporated by reference.

QUALITY: The totality of features and characteristics of a product or service that bear on its ability to meet the stated or implied needs and expectations of the user.

QUALITY ASSURANCE (QA): An integrated system of management activities involving planning, implementation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the customer.

QUALITY CONTROL (QC): The overall system of technical activities that measure the attributes and performance of a process, item, or service against defined standards to verify that it meets the stated requirements established by the customer.

QUALITY LABORATORY (QL) SAMPLE: A sample medium that has been spiked with a solution of dilute chemical standard analytical reference material (SARM). The exact amount of SARM is recorded and documented with the sample identification. The purpose of the sample is to verify the in-control status of the laboratory instrument.

QUALITY PLANT (QP) SAMPLE: A sample medium that has been spiked with a solution of dilute chemical SARM prior to being placed in the field or following aspiration of the blank tube in the field. The sample is spiked and then carried out to the sample collection point and exposed to the sample collection point atmosphere. The exact amount of SARM is recorded and documented with the sample identification (target concentration). Upon analysis in the laboratory, the QP's found mass must be within an acceptable tolerance. The purpose of the sample is to identify sources of sample contamination or sample degradation in the field at the sample collection location.

QUALITY SYSTEM: The organizational structure, responsibilities, procedures, and resources for implementation of quality management.

RANDOM ERROR: A component of total error that is not assignable to appropriate specific source and the magnitude of which can be predicted only in terms of probability.

REPORTABLE LIMIT (RL): A predetermined value for historical method, which when equaled or exceeded will be reported as chemical materiel that may have exceeded the monitoring level.

SAMPLE LABEL: An official label generated from the LIMS containing information obtained in the field as well as point of contact information for each sample.

SAMPLING PLAN: A detailed, site-specific plan that covers all sampling objectives and strategies for a given site. The plan describes methods and equipment used, locations, number and type of samples, safety requirements, transportation and shipping instructions, scheduling, and any other site-related sampling requirements.

SCRATCH LOG (MBFORM-12): A computer generated printout containing pertinent sample information and a chain-of-custody, which is used to track a sample.

UNCONTROLLED COPY

SHORT-TERM EXPOSURE LIMIT (STEL): The maximum concentration not to be exceeded in a 15-minute period.

SOLID WASTE: Discarded material, including solid, liquid, semisolid, or contained gaseous material resulting from industrial, commercial, mining, and agricultural operations, and from community activities, but does not include solid or dissolved materials in irrigation return flows or industrial discharges that are point sources subject to permits under Section 402 of the Federal Water Pollution Control Act, as amended.

SOURCE EMISSION LIMIT (SEL): The SEL replaces the previously used allowable stack concentration (ASC).

SPIKED QC SAMPLE: A separate aliquot of a sample that is spiked with a known and documented amount of reference material to check for matrix or sampling effects on percent recovery.

STANDARD: A known concentration of a known chemical that is used to perform quantitative analysis.

STANDING 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.

TARGET ACTION LEVEL (TAL): The highest target or true analyte concentration that can be distinguished as lower than the monitoring level 97.5 percent of the time using a test whose probability of a false positive response is 2.5 percent. The TAL is determined by an approved statistical software package and applies to air methods only.

TARGET CONCENTRATION (TC): The expected concentration based on 100 percent recovery.

TREATMENT LEVEL: A negotiated concentration for a specified contaminant in a specified extract or total waste that must be met by any method designed to physically or chemically change the nature of a hazardous waste.

UNCERTAINTY IN FOUND MASS (UIFM): In the regression of FC versus TC, this is one-half the difference between the upper and lower 95 percent prediction bounds of the TC when the TC is equal to the monitoring level.

VAPOR SCREENING LEVEL (VPL): The VSL is equivalent to the absolute STEL concentration, but it is independent of a designated sampling time (for example, time-weighted average) and may be used to define the level of item cleanliness, or alternately the read-out of the NRT monitor.

WORKER POPULATION LIMIT (WPL): The WPL represents the TWA concentration not to be exceeded during a given work period. WPL values are identified in Section 4.22 of this document.

Z: Generic designation for the applicable monitoring level.

UNCONTROLLED COPY

Appendix 2 Acronyms

Acronym	Definition
ABB	Asea Brown Boveri, Inc.
AC	Hydrogen cyanide
ACEM	Automatic Continuous Emissions Monitor
ADAM	Agilent Dynatherm Agent Monitor
AEC	U.S. Army Environmental Center
AEL	Airborne exposure limit
AgF	Silver Fluoride
AMC	U. S. Army Materiel Command
ANSI	American National Standards Institute
APG	Aberdeen Proving Ground
AQL	Acceptable Quality Level
AR	Army Regulation
ASC	Allowable stack concentration; also known as the source emission limit (SEL)
ASQC	American Society for Quality Control
AT	Analytical Team
ACM	Analytical Team Leader
BFB	Bromofluorobenzene
BZ	3-quinuclidinyl benzilate
CAIS	Chemical agent identification set
CAR	Corrective Action Request
CARC	Chemical Agent Resistant Coating
CASARM	Chemical Agent Standard Analytical Reference Material
CCV	Continuing calibration verification
CDC	Centers for Disease Control and Prevention
CEMS	Continuous Emission Monitoring System
CFR	Code of Federal Regulations
CHP	Chemical Hygiene Plan
CHPPM	Center for Health Promotion and Preventive Medicine
CI	Chemical ionization
CK	Cyanogen chloride
CMA	Chemical Materials Agency
COC	Chain of custody
CQAT	CASARM Quality Assurance Team
CRL	Certified Reporting Limit
CSDP	Chemical Stockpile Disposal Project
CSM	Chemical Surety Material
CTF	Chemical Transfer Facility
CV	Coefficient of variation
CW	Chemical Weapon
CWM	Chemical warfare materiel
DA	Department of Army
DAAMS	Depot Area Air Monitoring Systems
DC	Diphenylarsine
DHHS	Department of Health and Human Services
DL	Detection Limit
DM	Adamsite
DOD	Department of Defense
EAICF	Edgewood Area Internal Calibration Facility
ECBC	Edgewood Chemical Biological Center
ECD	Electron Capture Detector

UNCONTROLLED COPY

FAL	Found action level
FC	Found (or measured) concentration
FM	Field Manual
FPD	Flame-photometric detector
FR	Federal Register
GC	Gas chromatograph, gas chromatography
GPL	General population limit
g	Gram
g/mole	Gram per mole
GA	Tabun; ethyl N,N-dimethylphosphoroamidocyanidate
GB	Sarin; isopropyl methylphosphonofluoridate
GC-AED	Gas chromatograph-atomic emission detector
GC-FPD	Gas chromatograph-flame photometric detector
GC-MSD	Gas chromatograph-mass selective detector
GC-MSD/FPD	Gas chromatograph-mass selective detector/flame photometric detector
GD	Soman; pinacolyl methyl phosphonofluoridate
H	Levinstein mustard
HBESL	Health Based Environmental Screening Levels
HD	Distilled mustard; bis(2-chloroethyl)sulfide
HF	Hydrogen fluoride
Hg	Mercury
HL	Mustard-lewisite mixture
HL	Hazard level
HN-1	Nitrogen mustard; bis-(2-chloroethyl)ethylamine
HN-3	Nitrogen mustard; tris(2-chloroethyl)amine
HSL	Heated sample line
HT	A mixture of 60 percent HD and 40 percent T
ICV	Initial Calibration Verification
ID	Identification
IAW	In accordance with
IDLH	Immediately Dangerous to Life and Health
IOP	Internal Operating Procedure
IPA	Isopropyl alcohol
ISO	International Organization for Standardization
ITMS	Ion trap mass spectrometry
L	Lewisite; chlorovinyl dichloroarsine
L/mole	Liters per mole
LAMP	Laboratory Analysis and Monitoring Plan
LCO	Limiting condition of operation
LCL	Lower control limit
LCS	Lowest Concentration Standard
LIMS	Laboratory Information Management System
LMQAP	Laboratory and Monitoring Quality Assurance Plan
LOP	Laboratory Operating Procedure
LOQ	Limit of quantitation
LPL	Lower performance limit
LQCP	Laboratory Quality Control Plan
LQCPP	Laboratory Quality Control Plan and Procedures
m^3	Cubic meter
MAP	Mobile Analytical Platform
MDL	Method detection limit
µg/ml	Microgram per milliliter
mg	milligram
mg/m^3	Milligram per cubic meter

UNCONTROLLED COPY

mg/mL	Milligram per milliliter
ml	Milliliter
mL/min	Milliliter per minute
mm	Millimeter
MINICAMS	Miniature Continuous Air Monitoring System
MSD	Mass Selective Detector
MSS	Matrix spike sample
MSSD	Matrix spike sample duplicate
MT	MINICAMS Team
MTL	MINICAMS Team Leader
N/A	Not applicable
NIOSH	National Institute for Occupational Safety and Health
NIST	National Institute of Standards and Technology
NO_x	Nitrogen oxide
NRT	Near Real Time
NS	Not specified
NSCM	Non-stockpile chemical materiel
O&M	Operations and maintenance
OJT	On-the-job training
ORNL	Oak Ridge National Laboratory
OSHA	Occupational Safety and Health Administration
P&A	Precision and accuracy (study)
Pam	Pamphlet
PCT	Preconcentrator tube
PD	Phenyldichloroarsine
PDARS	Process data acquisition and recording system
PEL	Permissible exposure limit
PFDTD	Perfluoro-5,8-dimethyl-3,6,9-trioxidodecane
PFPD	Pulsed flame photometric detector
PFTBA	Perfluorotributylamine
PL	Public law
PMCD	Program Manager for Chemical Demilitarization
PMT	Photomultiplier tube
PPE	Personal protective equipment
ppm	Parts per million
ppmv	Parts per million volume
PQL	Practical quantitation limit
PS	Chloropicrin
psia	Pounds per square inch absolute
PM	Preventive Maintenance
POC	Point of contact
PTP	Proficiency Test Program
QA	Quality Assurance
QAC	Quality Assurance Coordinator
QC	Quality Control
QL	Quality-Laboratory Sample (QC sample prepared in the laboratory)
QL	O-(2-diisopropylaminoethyl) O'-ethyl methylphosphonite
QP	Quality plant
QP	Quality Process Sample (QC sample prepared in the laboratory then aspirated with ambient air)
RCRA	Resource Conservation and Recovery Act
RDT&E	Research, development, testing and evaluation
RL	Reportable limit
RPD	Relative percent difference
RRF	Relative response factor

UNCONTROLLED COPY

RSD	Relative standard deviation
RTAP	Real-time analytical platform
RTM	Real Time Monitor
RT	Retention time window
SA	Arsine
SCBA	Self contained breathing apparatus
SC	Systems Contractor
SCF	Standard cubic feet
SD	Standard deviation
SEL	Source emission limit; also known as the allowable stack concentration (ASC)
SMP	Site Monitoring Plan
SOP	Standing Operating Procedure
SPM	Site Project Manager
SRR_{AL}	Statistical response rate at alarm level
SRR_{RL}	Statistical response rate at the reportable limit
SSR	Shipment Status Report
ST	Sample Collection Team
STEL	Short term exposure limit
STL	Sample Collection Team Leader
T	Bis[2-(2-chloroethylthio)ethyl] ether
TAL	Target action level
TC	Target (or true) concentration
TM	Technical Manual
TMDE	Testing and Measuring Diagnostic Equipment
TOCDF	Tooele Chemical Agent Disposal Facility
TPA	Triphenylarsine
TWA	Time-weighted average
UCL	Upper control limit
UIFM	Uncertainty in the found mass
UPL	Upper performance limit
USACE	U.S. Army Corps of Engineers
USACHPPM	U.S. Army Center for Health Promotion and Preventive Medicine
USA CMA	U.S. Army Chemical Materials Agency
USAECBC	U.S. Army Edgewood Chemical Biological Center
USAPHC	U.S. Army Public Health Command
USATHAMA	U.S. Army Toxic and Hazardous Materials Agency
USC	United States Code
USEPA	U.S. Environmental Protection Agency
VX	O-ethyl S-(2-diisopropylaminoethyl)methylphosphonothioate
WPL	Worker population limit
XSD	Halogen Specific Detector
Z	Monitoring level

UNCONTROLLED COPY

Environmental Monitoring Laboratory

Issue date: 28 January 2014

Change Notice #1

EML QC Plan, Revision 2 dated December 2011

Section 4.18.1.2.1: Remove the reference to instrument calibration from the paragraph describing how MINICMAS Operators remain certified. After modification, the paragraph shall read:

> To remain certified the MINICAMS Operators shall perform QP verification on at least 1 MINICAMS every 2 months and perform the semi-annual competency test requirements of paragraph 4.18.1.1.3 of the QC Plan.

This change is consistent with Section 5.4.1.3.1 of the CASARM QC Plan, which does not require instrument calibration. The change also makes this paragraph consistent with the specifications in the last paragraph of Section 4.18.1.2.1.

UNCONTROLLED COPY