SECTION A - ADMINISTRATION

A1 TITLE AND APPROVAL PAGE

EPA REVOLVING LOAN FUND GRANT ASSISTANCE
EPA Cooperative Agreement No. BF97764501 & BIL96709001
City of Clinton, IA via East Central Intergovernmental Association (ECIA)

TITLE: Data Quality Objectives & Site-Specific Quality Assurance Project Plan
Asbestos Containing Materials Abatement and Mold Remediation
Former YMCA at 480 South 3rd Street, Clinton, Iowa 52732
Revision No. 0 – June 10, 2024

PREPARED BY:

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U.S. EPA PROJECT MANAGER APPROVAL:

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U.S. EPA QUALITY ASSURANCE APPROVAL:

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EPA Regional Quality Assurance Manager

A2 TABLE OF CONTENTS

APPENDICES:

A Project Location Map and Structure Identification Map

B OSHA ID 160

C Example Chain of Custody

D Health and Safety Plan

E EMSL Analytical Laboratory Quality Assurance / Quality Control Manual

F Activity Summary Forms/Field Sheets

G Standard Operation Procedures

H NIOSH 7400

A3 DISTRIBUTION LIST

Copies of the *Brownfield Cleanup Project Plan* will be distributed as follows. These persons will also receive copies of routine report distributions as set forth in section C2.

A3.1 United States Environmental Protection Agency, Region 7
11201 Renner Boulevard
Lenexa, KS 66219
Jennifer Morris, EPA Project Officer (electronic copy)

A3.2 ECIA Administrative File
7600 Commerce Park
Dubuque, IA 52002
Dawn Danielson, Brownfields Project Manager (electronic copy)

A3.3 City of Clinton Administrative File
611 S 3rd Street
PO Box 2958
Clinton, IA 52732
Tammy Johnson, Community Development Director (electronic copy)

A3.4 Project Coordinator Project File
Impact7G, Inc.
8951 Windsor Parkway
Johnston, Iowa 50131
Jon Reis, Project Coordinator (electronic copy)

A3.5 Field/Project Use
Impact7G, Inc.
600 4th Street, Suite 808
Sioux City, Iowa 51101
Tyler Silverthorn, Fieldwork Coordinator (electronic copy)

A3.6 Quality Assurance Review
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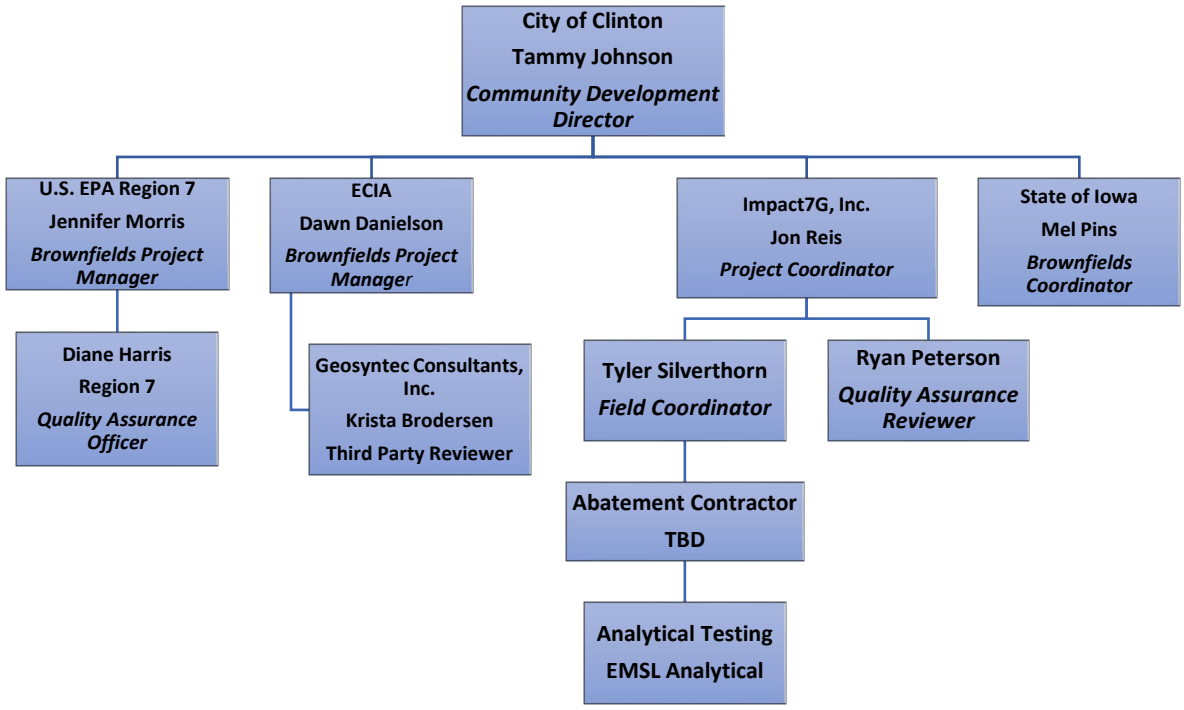
8951 Windsor Parkway
Johnston, Iowa 50131
Ryan Peterson, Reviewer (electronic copy)

A3.7 EMSL Analytical, Inc.
6340 Castleplace Drive
Indianapolis, IN 46250
Nicholas Straccione, Quality Assurance Coordinator (electronic copy)

A4 PROJECT ORGANIZATION



East Central Intergovernmental Association (ECIA) has designated Development Coordinator and Brownfields Project Manager Ms. Dawn Danielson as the Brownfields Project Manager. Ms. Danielson is responsible for coordinating efforts between the City of Clinton, consultant, and state and federal reviewers. Ms. Tammy Johnson, Community Development Director, will oversee the project on behalf the City of Clinton. Mr. Jon Reis of Impact7G, Inc. (Impact7G) will serve as the Project Coordinator and will oversee all consultant activities for the project and report to Ms. Johnson.

Mr. Tyler Silverthorn, with Impact7G will coordinate fieldwork activities and project contractors. Mr. Ryan Peterson of Impact7G will perform Quality Assurance/Quality Control (QA/QC) audits and checks and assist in document and project reviews relative to the Project Plan.

Ms. Jennifer Morris is the EPA Project Manager and is the EPA point of contact for ECIA's EPA Brownfields RLF Grant. Ms. Morris is responsible for reviewing and providing comments on the Site-Specific Quality Assurance Project Plan (SSQAPP), for responding to questions regarding the grant process, and for review of all project submittals.

A5 PROBLEM DEFINITION AND BACKGROUND

The primary objective of the SSQAPP is to abate materials containing greater than 1% asbestos analyzed via point count analysis identified in the former YMCA building located at 480 South 3rd Street in Clinton, Iowa 52733 (the Property). The former YMCA building consists of an approximate 27,000 basal square-foot structure constructed in 1905 with additions in 1961, 1978, and 1980 (Appendix A). The structure is multi-story and includes basements and sub-levels. Construction is typically brick, limestone, and concrete. The property operated as a Young Men's Christian Association (YMCA). In addition to providing activities and programs for men and boys in the community, there were sleeping rooms for young men living in the community. Building additions included swimming pools, gymnasiums, a running track, and other facilities. The YMCA closed circa 2010 following an agreement to combine with the YWCA. From 2010 to 2020 the Property was utilized as transitional housing for Victory Center Rescue Mission. In August of 2020, the City of Clinton became the owner of the Property due to non-payment of property taxes. The Property was vacated by January 1, 2021 and has been vacant since. Asbestos Containing Material (ACM) surveys were completed at the Property in 2021 and 2022 that followed appropriate OSHA Regulation 1926.1101 and 40 CFR Part 61 – National Emission Standards for Hazardous Air Pollutants (NESHAPs). An additional ACM survey was completed in 2024. A total of 407 building materials were analyzed for asbestos, 71 of which were identified as regulated ACM (RACM). The identified asbestos containing materials included:

• Heat Exchanger Mag Insulation	• Cement Board Ceiling	• Door Gasket
• Mudded Fitting(s)	• Ceiling Tile(s)	• 12" x 12" Vinyl Floor Tile
• Woolsfelt Pipe Insulation	• Air Handler Vibration Cloth	• 12" x 12" Vinyl Floor Tile Mastic
• Mud on Breeching	• Floor Tile(s)	• 2' x 2' Cement Board
• Mudded Joint Fitting(s)	• Floor Tile Mastic	• Roof Tar
• Mag Pipe Insulation	• Caulk(s)	• Flashing Tar
• 9" x 9" Floor Tile(s)	• Built-Up Roof Layers	• Parapet Tar
• 9" x 9" Floor Tile Mastic(s)		

The three-story original 1905 building, a portion of a 1961 addition, and the 1980 addition are currently structurally sound and ACM abatement will be occurring in these portions of the structure. Mold remediation will occur in the three-story original 1905 building. The remaining structures have been determined to be structurally unsound. **All debris from the remaining structures shall be treated as asbestos containing/contaminated and the entire structures shall be removed and disposed of as RACM.** In the absence of lead-based paint (LBP) testing, all painted surfaces will be treated as LBP during ACM abatement and mold remediation activities of the three-story original 1905 building, portion of the 1961 addition, and the 1980 addition.

This SSQAPP is intended to provide an overview of EPA Brownfields cleanup activities performed in support of the ECIA's EPA Brownfields RLF Cleanup initiatives and provide a program of decision for cleanup that provides sufficiently balanced data in quantity and quality needed by EPA under this RLF Cleanup and to help ensure the reliability of data generated from those activities. The major objective of the Project is to remove the major health hazards and risks to public safety associated with ACMs, LBP, and mold. A secondary objective is to make the Property attractive for redevelopment purposes by addressing and eliminating concerns associated with the existing ACM and mold. To protect workers and future occupants, painted surfaces disturbed by ACM abatement and mold remediation activities will be treated as LBP.

This SSQAPP can be used to produce quality data in conjunction with the abatement of materials containing greater than 1% asbestos located on the Property. The purpose of the Project and the Project Plan is to provide a program of decision and assessment with data quantity and quality sufficiently balanced between the requirements of the EPA RLF and those required by state programs. This must be done with limited funds and must provide sufficient value to ECIA and be meaningful for planning.

This SSQAPP covers activities associated with the site cleanup performed by ECIA's RLF Program and its consultants pursuant to the Small Business Liability Relief and Brownfields Revitalization Act of 2002 and will be in effect through the duration of the RLF grant or up to five years from the date of final approval. The SSQAPP will be reviewed periodically during this time for applicability. If the RLF cleanup continues beyond five (5) years, the SSQAPP will be updated and resubmitted for approval. Assessment and cleanup activities addressed in this SSQAPP will be pursuant to:

- Title 29 Code of Federal Regulations (CFR), Sections 1910.1001, 1910.134, 1910.2, 1910.1200 1926.58, and 1926.1101. Occupational Safety and Health Administration (OSHA), US Department of Labor
- Title 40 CFR, Part 61 - National Emission Standards for Hazardous Air Pollutants (NESHAPS), Subparts A and M. US Environmental Protection Agency
- Title 40 CFR, Part 763 - Toxic Substances Control Act (TSCA), Subparts E and G
- Title 29 CFR, Part 1926 - OSHA Safety and Health Regulations for the Construction Industry
- Title 40 CFR, Part 260 - Hazardous Waste Management System: General
- Title 40 CFR, Part 261 - Identification and Listing of Hazardous Waste
- Title 40 CFR, Part 262 - Standards Applicable to Generators of Hazardous Waste
- Title 40 CFR, Part 263 - Standards Applicable to Transporters of Hazardous Waste
- Title 40 CFR, Part 264 - Standards for Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities
- Title 40 CFR, Part 265 - Interim Status Standards for Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities
- Title 40 CFR, Part 745 - Lead-Based Paint Poisoning in Certain Residential Structures
- Chapter 88B of the Code of Iowa, removal or encapsulation of Asbestos, Division of Labor Services
- Chapter 81 of Iowa Administrative Code, Asbestos Control Procedures, Iowa Bureau of Labor
- Iowa Administrative Code 641, Chapter 69 - Renovation, Remodeling, and Repainting – Lead Hazard Notification Process
- Iowa Administrative Code 641, Chapter 70 - Lead-Based Paint activities
- Iowa Bureau of Labor Guidelines for remove of non-friable ACM
- American Society for Testing and Materials International (ASTM) E-2356 Standard
- Occupational Health and Safety Administration (OSHA) Regulation 1926.1101

- Minimize the number of site visits
- Collect only the data needed to assess the site and cleanup appropriately.

It is not anticipated additional asbestos or mold samples will be collected. In the event additional asbestos samples are to be collected, sampling strategies will be addressed in an addendum and will be developed in accordance with the American Society for Testing and Materials International (ASTM) E-2356 standard, Occupational Health and Safety Administration (OSHA) Regulation 1926.1101, IDNR, National Emissions Standards for Hazardous Air Pollutants (NESHAP) regulations as adopted by the U.S. Environmental Protect Agency (EPA), and Asbestos Hazard and Emergency Response Act of 1986 (AHERA) protocols

A6 PROJECT DESCRIPTION

The Project intends to make use of this DQO/SSQAPP to address the Project area conditions and for which funding is available.

The SSQAPP will address ACM abatement and mold remediation activities associated with the former YMCA located at 480 South 3rd Street in Clinton, Iowa. The facility consists of a three-story, 6,504 basal square foot brick and limestone structure with a basement and a two-story 2,820 basal square foot brick and block structure with a basement both constructed circa 1905; a two-story 6,764 basal square foot precast concrete and brick addition with a basement/sub-level was constructed circa 1961; a three-story 10,283 basal square foot precast concrete addition with a sub-level was constructed circa 1978; and a one-story 492 basal square foot precast concrete addition was constructed circa 1980. The Property historically operated as a former YMCA (Appendix A).

Project work at the former YMCA will consist of three phases: Phase 1a, Phase 1b, and Phase 2. A structure identification map detailing the different parts of the structure, is included in Appendix A.

<u>Phase 1a</u>
The initial phase of the project will consist of ACM abatement of the three-story original 1905 building (Building A) and Building C1, and separating Building A from the remainder of the structure. The purpose of separating Building A from Buildings B1 and C1 is to try and preserve Building A. Following the separation, Building A will be properly enclosed to protect the interior from the elements. To accomplish the separation, Building B1 will be removed entirely. The portion of Building C1 immediately adjacent to Building A will be removed following ACM abatement. As Building B1 is not structurally sound, all debris will be treated as ACM and removed and disposed of as RACM.

<u>Phase 1b</u>
Following ACM abatement and prior to redevelopment, mold remediation will occur in Building A. Mold remediation will not occur immediately as there is no electricity to Building A and water intrusion from the remainder of the structure is a problem. Without the ability to control moisture and temperature in Building A, it would be difficult to limit re-growth of mold if mold remediation was conducted concurrently with asbestos abatement.

Phase 2

The remaining structure (Buildings B2, C2, and C3 and a portion of Building C1) will be removed. As Building C1 will have been abated, debris can be removed and disposed of as general construction debris. Since Buildings B2, C2, and C3 are not structurally sound, all debris will be treated as ACM and removed and disposed of as RACM.

Impact7G personnel will collect air samples for laboratory analysis during ACM abatement activities to document that the contractor is removing ACM in accordance with the plans, specifications and regulations. In addition, Impact7G personnel will also be performing a visual confirmation of the removal of ACM in order to document the cleanup process. Mold remediation oversight will consist of a visual clearance inspection following remediation to document removal of the mold. As disturbance of presumed LBP will be occurring in containment areas, the asbestos and mold visual clearance inspections will be the confirmation that any LBP in the Project area has been properly cleaned.

The Project area ACM sampling and abatement and mold remediation, which includes treating disturbed painted surfaces as LBP, will comply with governing OSHA, IDNR, and EPA notification regulations and the following reference standards:

- Title 29 Code of Federal Regulations (CFR), Sections 1910.1001, 1910.134, 1910.2, 1910.1200 1926.58, and 1926.1101. Occupational Safety and Health Administration (OSHA), US Department of Labor
- Title 40 CFR, Part 61 - National Emission Standards for Hazardous Air Pollutants (NESHAPS), Subparts A and M. US Environmental Protection Agency
- Title 40 CFR, Part 763 - Toxic Substances Control Act (TSCA), Subparts E and G
- Title 29 CFR, Part 1926 - OSHA Safety and Health Regulations for the Construction Industry
- Title 40 CFR, Part 260 - Hazardous Waste Management System: General
- Title 40 CFR, Part 261 - Identification and Listing of Hazardous Waste
- Title 40 CFR, Part 262 - Standards Applicable to Generators of Hazardous Waste
- Title 40 CFR, Part 263 - Standards Applicable to Transporters of Hazardous Waste
- Title 40 CFR, Part 264 - Standards for Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities
- Title 40 CFR, Part 265 - Interim Status Standards for Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities
- Title 40 CFR, Part 745 - Lead-Based Paint Poisoning in Certain Residential Structures
- Chapter 88B of the Code of Iowa, removal or encapsulation of Asbestos, Division of Labor Services
- Chapter 81 of Iowa Administrative Code, Asbestos Control Procedures, Iowa Bureau of Labor
- Iowa Administrative Code 641, Chapter 69 - Renovation, Remodeling, and Repainting – Lead Hazard Notification Process
- Iowa Administrative Code 641, Chapter 70 - Lead-Based Paint activities
- Iowa Bureau of Labor Guidelines for remove of non-friable ACM
- American Society for Testing and Materials International (ASTM) E-2356 Standard

A7 QUALITY OBJECTIVE AND CRITERIA FOR MEASUREMENT DATA

The objective of this project is to abate all ACMs located on the Property that have been previously identified in existing inspection reports in accordance with local, state and federal regulations. This will eliminate the hazard and will allow for redevelopment of the Property. Additional objectives include the protection of site workers, the public and the environmental through adherence with Project Specifications. In addition, the Project Manager may rely upon EPA's *Generic Guide to Statistical Aspects of Developing and Environmental Results Program* (2003) for advice in making decisions related to optimizing the following aspects of data quality for this project which consists of precision, accuracy, representativeness, comparability and completeness.

As the abatement of ACMs will rely on the generation of data, this SSQAPP seeks to verify that the quality objectives are appropriate for the regulatory and non-regulatory decisions to be made based upon that data. The data quality objectives will follow both the best practices for similar projects and the resources available for this project.

Precision is the measurement of agreement or reproducibility among replicate samples of the same media under prescribed similar conditions. It is normally expressed as the relative percent difference (RPD) between two values. For field sampling, precision is increased by following SOPs and by collecting all samples using the same sampling procedures. Field QC samples that are collected to measure precision may include field blind replicate samples and field duplicate samples from each media type. No field blind replicate samples and no field duplicate QC air samples will be collected as part of this project. Field duplicate samples will be collected at a rate of 1 per 50 bulk samples. Analytical QA/QC methods will determine if bulk sample field duplicate samples are acceptable. Field measurement precision is monitored by taking replicate measurements. Field measurement precision is increased through proper operation and maintenance of field equipment. For analytical procedures, precision may be specified as either intra-laboratory (within the same lab) or interlaboratory (between different labs). Intra-laboratory precision is more common and is the variability when a single lab uses the same method to make repeated measurements on the same sample. Interlaboratory precision is the variability when multiple labs use the same method to make measurements on the same or identical samples. The accuracy of the analysis is based on a discussion with the laboratory and a recommendation of a variation factor of 20% will be deemed acceptable. For example, if a PCM air sample is analyzed with 140 fibers/mm², a precision factor of 28 fibers/mm² will be deemed acceptable for a field blind replicate/field duplicate sample.

Accuracy is a measure of the closeness of an individual measurement, or the average of a number of measurements, to the true value. Bias is the systematic or persistent distortion of a measurement process that causes error in one direction. Accuracy is normally expressed as a percent recovery. To assess sample accuracy, field QC samples such as field blanks or field replicate/field duplicate samples are typically incorporated into the sampling scheme for each media type. Impact7G will collect 10% field blanks with a minimum of 2 blanks for any set on all PCM air sampling. Field blanks are cassettes which are taken to allow an estimation of any contamination that may occur as a result of handling apart from actual air flow through the filter. They are to be opened and held open for about 30 seconds face down at the same place where area samples are set. They are then closed, stored and sent to the analysis laboratory with the rest of the sampling set. When analyzed, any set represented by a blank concentration in excess of 7 fibers per 100 fields will be rejected. The data acquired from the analysis of blanks are useful in their ability to evaluate errors, which can arise from cross-contamination. The occurrence of cross contamination can result from the improper handling of samples by field and/or lab

personnel, improper decontamination procedures, improper shipment and storage, and on-site atmospheric contaminants. Field duplicate samples will be collected at a rate of 1 per 50 bulk samples. EMSL Analytical QA/QC methods will determine if bulk sample duplicate samples are acceptable. Therefore, to facilitate sample collection accuracy, it is essential to maintain frequent and thorough review of field procedures so that deficiencies can be quickly documented and corrected.

Representativeness is an expression of the degree to which a sample accurately and precisely represents a characteristic of a population, parameter variations at a sampling point or an environmental condition. Representativeness is a qualitative parameter, which relies upon the proper design of a sampling program and proper laboratory protocol. Making certain that sampling locations are properly selected, and a sufficient number of samples are collected that best satisfies this criterion. Therefore, collecting field duplicates will assess sample representativeness. Traditionally, field duplicates are equally representative of a given point in space and time. Field duplicate samples for this project will only be collected for bulk samples.

Comparability is defined as an expression of the confidence with which one data set can be compared to another. In most instances, the proficiency of field sampling efforts will be the determining factor that affects the overall comparability of environmental measurement data. To optimize the comparability of environmental measurement data, sample collection activities should always be performed using standardized procedures whenever possible. When performing a site investigation, adhering to the quality control criteria will facilitate these efforts.

Completeness is defined as the measurement of the amount of data obtained from a measurement system compared to the amount that was expected to be obtained under correct normal conditions. Data completeness is often expressed as the percentage of valid data obtained from a given measurement system. To consider data valid, it is customary to assess if a set of data satisfies all of the specified acceptance/performance criteria (accuracy measures, precision measures, etc.) to render a determination. This necessitates that the data acquired for all confirmatory analysis critical to a site investigation sampling program be validated (100%). Air clearance samples are considered critical samples. No bulk samples are considered critical samples. The goal for all samples (air and bulk) is to be validated. If non-critical air samples are not validated, sampling procedures, field equipment, and laboratory analyses will be reviewed. ACM abatement areas will not be cleared until critical air samples are validated.

If either field blank samples or field duplicate samples are deemed unacceptable, the course of action will be: ensure sample collection data is accurate, check field equipment to ensure sampling equipment was not compromised, and/or determine if laboratory equipment was functioning properly. If all three do not yield data to explain sample results, samples will not be utilized, and resampling will occur.

A8 SPECIAL TRAINING REQUIREMENTS AND CERTIFICATIONS

The selected cleanup contractor will be required to possess a State of Iowa Asbestos Abatement Contractor license. The onsite contractor personnel will have at least one person possess a State of Iowa Asbestos Contractor/Supervisor license and additional personnel at a minimum possess a State of Iowa Asbestos Worker license. The onsite field personnel representing the City of Clinton will possess a State of Iowa Asbestos Inspector license.

The laboratory conducting the analysis will maintain all required certifications, accreditations, and validations associated with that State. Please refer to Appendix E to review the laboratory's Quality Assurance/Quality Control Manual.

A9 DOCUMENTATION AND RECORDS

Field personnel will maintain a field logbook to record all pertinent activities associated with sampling or cleanup activities. Any difficulties encountered in the field will be recorded in the field logbook and reported to the Impact7G Project Coordinator. Appropriate documentation pertaining to photographs taken by field personnel will also be recorded in the field logbook. Information pertaining to air and bulk samples (i.e., sampling dates and times, locations, etc.) collected during this event will be recorded on sample field sheets and within the field logbook. Examples of field sheets are included in Appendix F. Sample labels will be affixed to sample containers, identifying sample numbers, dates, and time collected, and requested analyses.

The Impact7G project Coordinator, in conjunction with the EMSL Analytical QA manager, has the primary responsibility for defining site-specific data reporting requirements and relating them to the Fieldwork Coordinator. These requirements, the turnaround time for receipt of deliverables specified, and any site-specific requirements for retention of samples and laboratory records, will be clearly defined in requests for analytical services. The EMSL Analytical QA manager is responsible for ensuring that all laboratory data reporting requirements in the SSQAPP are met. It is also the responsibility of the Impact7G Project Coordinator to provide the field team with the most recent version of the EPA-approved SSQAPP.

Project records will be in keeping with end-use by the ECIA for feasibility comparison. The Impact7G Project Coordinator will be responsible for supervising the administrative support personnel in maintaining the project files for the duration of the project. The project files will be kept in Impact7G's Johnston office while the project remains active. Upon completion of the project, Impact7G will archive the project files at a secure storage facility for a period of ten years after the completion of the project. After ten years, the disposition of the project files will be determined by the ECIA.

SECTION B - MEASUREMENT AND DATA ACQUISITION

B1 SAMPLING PROCESS DESIGN

Impact7G will periodically provide onsite personnel during ACM abatement and mold remediation activities. Services will include the following:

- Observe and document the ACM abatement and mold remediation activities to assess substantial compliance with the plans, specifications, and contract documents;
- When on-site, conduct air sampling in and around the ACM abatement areas to document compliance;
- Visually inspect the areas upon completion of ACM abatement and mold remediation. Recommendations for additional cleaning will be made if an area does not pass visual inspection;
- Assist the contractor in interpreting the plans and specifications when necessary;
- Photograph work in progress and document post ACM abatement and mold remediation conditions;
- Document that appropriate signage is posted at all entrances/exits to work areas;
- When on-site, prepare daily field progress reports detailing major work completed, problems encountered, and compliance with specifications;
- Compile ACM abatement air sample analytical results and visual inspection logs on a weekly basis; and
- Assist City of Clinton in a final field observation of the Project area to assess substantial compliance with the plans, specifications, and contract documents.

If it is determined additional bulk samples need to be collected prior to ACM abatement activities, Impact7G personnel will accomplish all tasks necessary to identify all ACM, which will include, but is not necessarily limited to, the following:

- Conduct thorough on-site visual inspections of all accessible areas of the building. During the inspection, the certified asbestos inspector will identify and document the condition of the suspected material and other factors deemed appropriate;
- Indicate all areas of homogenous material, without regard to the results of subsequent laboratory bulk analysis, either on a set of floor plans, on schematic drawings, or in tabular form;
- Identify all locations where ACM may be present but cannot be sampled, including the reason it cannot be sampled;
- The certified asbestos inspector will conduct bulk sampling of all friable and non-friable suspected ACM. Sample locations will be clearly identified on copies of the schematic diagrams (drawings or floor plans), if available, and will be marked with an identification number corresponding to the respective sample number. Each sample will be listed on the Chain of Custody record that will accompany the samples to the laboratory.

B1.1 Sampling Methodologies

Environmental air monitoring shall be conducted at locations and frequencies that will accurately characterize any airborne asbestos fiber concentrations. Sample locations will be based on Judgmental Sampling:

- Judgmental Sampling – The subjective selection of sampling locations based on historical information, visual inspection, and the best professional judgment of the sampler.

Asbestos fiber air monitoring will occur on a periodic basis throughout the abatement process. Air monitoring will consist of sampling the duration of a work shift at locations including, but not limited to: outside entrances to a regulated area; close to glovebag operations; representative locations outside of the perimeter of a regulated area; and at the exhaust discharge point of local exhaust system (negative air machines) ducted outside of a containment. If the sampling outside regulated area (including glovebag operations and negative air machines) shows airborne fiber levels have exceeded background or 0.01 f/cc, whichever is greater, work shall be stopped immediately, and the condition causing the increase shall be corrected.

Asbestos abatement clearance sampling for each enclosed area will be completed upon passing of visual inspection by Impact7G personnel. Clearance air monitoring will not be completed for any outside abatement.

The samples will be collected from low flow volume pumps to reduce the risk of overloading, which would make the samples unreadable. One sample will be collected from each sampling location per day while abatement activities are ongoing. The samples will be analyzed using the NIOSH Method 7400 (PCM) in accordance with appropriate regulations by a certified laboratory.

The equipment will consist of a field calibrated air pump, tubing, and a sterile filter cassette. Based on the type of sampling to be completed, decontamination will consist of wiping down the equipment with bleach wipes after sampling procedures.

B1.2 Management of Investigation-Derived Waste and Decontamination Procedures

Efforts will be made to achieve the following goals pertaining to waste management:

- Leave the site in no worse condition than it existed prior to the site activity;
- Remove wastes that pose an immediate threat to human health or the environment;
- Leave wastes onsite that do not require off-site disposal or extended containerization;
- Comply with state and federal requirements to the extent practicable; and
- Minimize the quantity of wastes generated.

Decontamination of personnel and equipment will be conducted in accordance with the site-specific health and safety plan (see Appendix D).

B2 SAMPLING METHOD REQUIREMENTS

This element of the SSQAPP sets forth directly or by reference the procedures for collecting samples and identifies sampling methods. It includes protocols for sample collection, handling, documentation, transport, testing and disposition within the Project area. As there is no requirement or regulation for air sampling while removing ACM from buildings other than those regulated under AHERA, Impact7G is proposing to adopt OSHA's PEL for asbestos exposure for construction workers (Asbestos Standard for the Construction Industry. OSHA-3096. 2002 Revised). These protocols were developed based on accepted EPA procedures as outlined in numerous guidance documents and industry standard operating procedures (SOPs) adopted by OSHA. Methods for general use will be equivalent or exceed the Iowa industry standard of professional care currently in practice and comply with OSHA, NESHAPS, and NIOSH regulations. Additionally, air samples will be collected and analyzed according to NIOSH's Method 7400, which is included in Appendix G.

Per OSHA ID 160 (Appendix B) and NIOSH 7400 (Appendix H) regulations, the suggested minimum air volume to determine time-weighted average compliance is 25 L. For Short Term Excursion Limit (30-minute sampling time) evaluations, a minimum air volume of 48 L is recommended. Suggested maximum air sample volumes for specific environments are: 100 L when there is visible dust, 240 L when there is little dust, and 400-2,400 L in office environments. Air sample volume for final clearance air samples will be a minimum of 1,200 L. Flow rates will be chosen to not produce overloaded filters.

Bulk asbestos sampling strategies are developed in accordance with the ASTM E-2356 standard, OSHA regulation 1926.1101, IDNR, NESHAP regulations as adopted by the U.S. EPA, and AHERA protocols. The number and locations of bulk suspect building material samples to be collected will be determined after a review of the Asbestos Containing Materials Inspection report completed for the Property by Impact7G dated May 24, 2024. No limitations were identified in the report; however, due to the size of the structure it is possible there are suspect building materials which were not sampled. Bulk suspect building material samples will be collected of materials that have not already been sampled.

The following table details media type, analytical method, container type, preservation and holding time for both asbestos air and bulk samples.

Media Type	Analytical Method	Container Type	Preservation	Holding Time
Bulk Asbestos	Polarized Light Microscopy (PLM) – NIOSH 9002	Plastic Bag	N/A	N/A
Asbestos Fibers in Air	Phase Contrast Microscopy (PCM) – NIOSH 7400	PCM Canister w/ MCEM filter (0.8 micron pore size)	N/A	N/A

In addition, to the above table, sample collection for both air and bulk asbestos samples will be completed in accordance with Impact7G Standard Operation Procedures, which are included in Appendix G. Field Sampling Guides provided by EMSL Analytical for both bulk and air sampling have also been included.

B3 SAMPLE HANDLING AND CUSTODY REQUIREMENTS

This section sets forth the requirements and provisions for sample control and proper custody in the field, during transport and in the laboratory. Chain-of-custody (COC) protocol will be adhered to during all phases of the sample collection, storage, shipment, and analysis procedures. An example of a COC document is discussed below and is included in Appendix C.

The transfer of sample custody will be limited between Impact7G personnel, the express carrier and laboratory personnel. The primary objective of custody requirements for this project is simply to track that samples are handled by authorized personnel and document that handling occurred within the parameters of the Plan. Individual custody seals will not be necessary unless the Fieldwork Coordinator holds the samples overnight.

In general, the outline for sample handling and custody will be as follows.

- The Fieldwork Coordinator will brief sampling personnel on custody procedures and will implement tracking procedures until samples are received by the laboratory.
- Samples will remain in the custody of the field team at all times.
- Samples will be removed from the project site on a weekly basis and delivered to the laboratory for analysis.
- Clearance samples will be removed from the project site on a daily basis and delivered to the laboratory for expedited analysis.
- Laboratory will implement tracking and custody documentation upon receiving samples.
- Post-analysis samples will be disposed of properly.
- Impact7G will maintain chain-of-custody documentation after reporting.

B4 ANALYTICAL METHODS REQUIREMENTS

Air samples will be collected and analyzed according to NIOSH's Method 7400, which is included in Appendix G. Bulk asbestos sampling strategies are developed in accordance with the ASTM E-2356 standard, OSHA regulation 1926.1101, IDNR, NESHAP regulations as adopted by the U.S. EPA, and AHERA protocols and will be analyzed according to NIOSH's Method 9002.

B5 QUALITY CONTROL REQUIREMENTS

The Project Coordinator is responsible for auditing and controlling the overall quality and implementation of field sampling to produce acceptable data. Identified failures will be documented in the field book. Field audits will be randomly completed, but not less than once a week, during cleanup activities. While conducting field audits, the Project Manager will document failures noted and corrected in the field book.

The Fieldwork Coordinator is responsible for similar management control while on the site and will make similar use of the previously referenced forms.

Impact7G has anticipated some preliminary default corrective action responses to maintain quality of the field data collection program. Default corrective action responses do not need to be approved by the Project Manager or Fieldwork Coordinator but must be logged in the field book or annotated on data forms to clearly reflect the change. In the unlikely event that air samples exceed the OSHA permissible exposure limit (PEL) of 0.1 fibers per cubic centimeter over a time-weighted average (TWA), work will be stopped on the site and a meeting will be held to determine the best corrective action.

B5.1-6 Representative Samples through Accuracy

This section is not applicable to the Cleanup SSQAPP.

B6 INSTRUMENT AND EQUIPMENT TESTING, INSPECTION AND MAINTENANCE REQUIREMENTS

Field equipment will be calibrated and maintained in accordance with the manufacturers' specifications and applicable Impact7G SOPs. If applicable, spare parts for field equipment will be stored in a secured container per manufacturer specifications and kept onsite during field activities. Laboratory equipment will also be calibrated and maintained in accordance with the manufacturers' specifications and applicable analytical SOPs and applicable EMSL Analytical SOPs.

B7 INSTRUMENT/EQUIPMENT CALIBRATION AND FREQUENCY

Instruments for conducting field measurements for which response must be checked against standards for acceptable performance are as follows.

- Air monitors and sampling pumps will be factory calibrated by the manufacturer prior to use in the field. Additional daily field calibrations will be completed each day of ACM abatement activities.
- All field instruments will be routinely calibrated before and after each use, and the calibration results will be documented. Check standards will be supplied by the equipment manufacturer and relied upon as certified and accepted as the industry standard.
- All field instruments will receive scheduled factory calibration prior to each field mobilization to check measurement response to accepted check standards. Calibration methods and results will be documented on calibration logs and placed in the project file.
- All field instruments will receive regular and scheduled calibrations in the field to check measurement response to accepted check standards. Calibrations will be recorded daily in the project field book/calibration logbook. All instrument and equipment calibration checks and frequency will be logged and included in the final closeout report.

Laboratory instrument calibration and maintenance information is included in Appendix E in accordance with OSHA's methodology.

B8 INSPECTION AND ACCEPTANCE REQUIREMENTS FOR SUPPLIES AND CONSUMABLES

EMSL Analytical will provide pre-cleaned sampling containers for use by field sampling personnel. Cleaning is verified by the EMSL Analytical QA manager and are obtained from reputable container manufacturers. In addition, Impact7G field personal will visually inspect containers for gross contamination, necessary preservatives, and appropriate size, number, and material for the required analyses.

B9 NON-DIRECT MEASUREMENTS

Data from other sources including other analytical data, reports, photos, maps, etc. will not be used for decision-making purposes. This information is mentioned for informational purposes only and is not to be used for decision-making purposes without verification by an independent professional qualified to verify such data or information.

B10 DATA MANAGEMENT

The Impact7G Project Coordinator will be responsible for supervising the administrative support personnel in maintaining the project files for the duration of the project. The project files will be kept in Impact7G's Johnston, Iowa office while the project remains active. Upon completion of the project, Impact7G will archive the project files at a secure storage facility for a period of ten years after the completion of the project. After ten years, the disposition of the project files will be determined by the ECIA.

Impact7G will use desktop and portable laptop computers along with data loggers to record, process, and manage project data. The following software potentially will be used to process and report data findings: Access®, ArcView®, AutoCAD®, DQO/DEFT®, Excel®, and Word®.

Laboratory data management will focus on a level requisite of EPA protocols and the standard methods. These procedures are set forth in Appendix E.

SECTION C - ASSESSMENT AND OVERSIGHT

C1 ASSESSMENT AND RESPONSE ACTIONS

C1.1 Performance and System Audits

Both internal performance and system audits may be conducted on field operations. Performance audits include verification that field sampling activities and measurements and laboratory analyses of performance evaluation samples are being conducted in accordance with the requirements of this SSQAPP. System audits involve a qualitative examination of an environmental data collection system, including records, personnel, and QA management activities.

This section describes the selection of audit personnel, the scope of field and laboratory audits, audit frequencies, and typical audit reports for internal audits initiated by the Impact7G QA Reviewer.

The laboratory performance and system audits by EMSL Analytical will be as outlined in the EMSL Analytical Quality Assurance/Quality Control Manual (Appendix E).

C1.1.1 Audit Personnel

The QA/QC reviewer will direct and execute all internal audit activities during an investigation. The QA/QC reviewer will prepare an audit plan; coordinate and schedule the audit with the project team or subcontractor; participating in the audit; coordinate the preparation and issuance of audit reports and corrective action request forms; and evaluate audit responses and resulting corrective action responses. The QA/QC reviewer had the authority to stop work if protocol deficiencies are observed to allow time to put corrective action measures in place.

C1.1.2 Audit Scope of Work

Performance audits of field activities will be conducted to evaluate compliance with the requirements of the SSQAPP. Performance audits may include an examination of the following items:

- Sample collection records.
- Sample collection, handling, packaging, shipping, and custody records.
- Equipment operation, maintenance, and calibration records.

The laboratory performance and system audits will be as outlined in EMSL Analytical's Quality Assurance/Quality Control Manual (Appendix E).

C1.1.3 Audit Frequencies

Quarterly audits will be conducted during the investigation. The QA/QC Reviewer may also randomly audit the activities proposed within this SSQAPP.

Unscheduled follow-up audits may occur if any deficiencies are discovered during an audit or review. Follow-up audits serve to ensure that all necessary corrective actions have been properly implemented to address deficiencies.

C1.1.4 Audit Reports

Audit reports will be prepared for performance and system audits of field and laboratory activities and all laboratory evaluation studies that are conducted under this Brownfields Agreement. Reports will be prepared by the QA/QC reviewer. Audit reports will identify participants, describe the activity audited, summarize audit findings, and detail any deficiencies or deviations from protocol that were discovered during the audits, as well any corrective actions that are proposed. Any field or laboratory analytical data that is generated during performance evaluation must be validated. The validated date will be included in the audit report.

Audit reports are distributed to the Impact7G Project Coordinator and the field supervisor or laboratory QA manager, as appropriate. The QA/QC reviewer has primary responsibility for ensuring that audits are conducted thoroughly and properly. The Impact7G Project Coordinator and field supervisor or laboratory QA manager are responsible for implementing corrective actions that result from the audit. The QA/QC reviewer is responsible for verifying that recommended corrective actions have been implemented.

C1.2 Corrective Action

Corrective actions will be taken whenever there appears to be problems that could adversely affect data quality and/or resulting decisions affecting future response actions pertaining to the site. When such conditions are identified, the following corrective actions will be taken:

- Document that suspect data have been obtained.
- Review the system in question to ensure that all procedures were properly performed.
    - If all procedures were not carried out properly, document the errors and repeat the procedures in accordance with the proper methodologies, including all applicable quality control checks.
    - If any control checks give out-of-control results, advise the project supervisor, and do not continue until the problem has been resolved.
    - If all of the control checks give satisfactory results after corrective actions have been taken, document the correction actions and continue.

C2 REPORTS TO MANAGEMENT

Reports describing the project activities, status, results of audits, corrective actions, needs for resolution among participating parties, and schedule changes will be distributed electronically and in writing. These are summarized below in the following table.

Routine Reports				
Document	**Party**	**Preparer**	**Distribute**	**Frequency**
Grant Reports	ECIA	Brownfields Project Manager	Section A3.1-3	Quarterly throughout RLF Grant and as determined by ECIA
Daily Job Reports	Impact7G	Field Supervisor	Project Coordinator	Daily when Phase II field work in progress with logbook copies
Performance and System Audits Reports	Impact7G	QA/QC reviewer	Section A3.3-4 and A3.6	Throughout the Project
Project / E-Status Reports	Impact7G	Project Coordinator	Section A3.1-5	Weekly during field activities otherwise monthly
Community Outreach	Impact7G	Project Coordinator	Section A3.1-3 Public	Updated at final report for project activities or as requested by ECIA for public education or outreach
Project Closeout Report	Impact7G / ECIA	Project Coordinator / Brownfields Project Manager	Section A3.1-3	End of Project

SECTION D - DATA VALIDATION AND USABILITY

D1 DATA REVIEW, VERIFICATION, AND VALIDATION

Data review and verification will be performed by a qualified laboratory analyst and the laboratory's operations manager as described in the EMSL Analytical Quality Assurance/Quality Control Manual (Appendix E).

Verification of the data shall be the responsibility of the Impact7G Project Manager, who will review the data for completeness and obvious discrepancies. Field notes, Chain of Custodies (COCs), and activity summary forms will be reviewed and compared for consistency and any anomalies documented by the Impact7G Project Manager. Examples of activity summary forms and field notes are included in Appendix F. The Impact7G Project Manager will also inspect the data to provide final review and approval to ensure that the data meet the sampling requirements.

D2 VALIDATION AND VERIFICATION METHODS

The Impact7G Project Manager will be responsible for validation of project implementation, conducting a direct comparison of the project records to the SSQAPP for the assessments prior to writing the assessment report. This will be initiated immediately upon completion of the field sampling activity on the property to be assessed. Data verification will be presented to the users in the report for which the data was collected.

Upon completion of ACM sampling and abatement/cleanup activities, the quality assurance reviewer will evaluate the implementation of the following, relative to field and management procedures as they apply to the Brownfields assessments and cleanup oversight. Data resulting from ACM sampling and abatement/cleanup activities will be reviewed to evaluate conformance with the quality criteria set forth in the SSQAPP. These evaluations will include, but not be limited to:

- Conformance to the SSQAPP's data quality objectives,
- Conformance of the proposed sampling plan as detailed in the SSQAPP,
- Conformance with sample handling protocols and holding times,
- Results of quality control checks as they relate to field influences on data quality, and
- Results of calibration of instruments at bench mobilization and in the field from instrument records and field logbooks specific to the property enrolled and assessed.

The Impact7G Project Manager will rely on standard methods conformance and the laboratory data packages to support valid analytical data.

D2.1 Field and Management Review

The review will specifically evaluate the implementation of the SSQAPP relative to field and management procedures as they apply to the Brownfields assessments and cleanup oversight. The quality of the resultant data will be evaluated in accordance with of the following:

- Generic conformance to design parameters of the SSQAPP and DQOs;
- Sampling Design as detailed in the Work Plan;
- Sample handling protocols and chain-of-custody will be reviewed, and holding and transport times must be met for the sample to be considered valid;
- Quality control checks conducted as they relate to field influences on data quality; and
- Calibration of instruments at bench mobilization and in the field from instrument records and field logbooks specific to the property enrolled and assessed.

D3 RECONCILIATION WITH USER REQUIREMENTS

The Impact7G Project Coordinator, for completeness needed to achieve the project's goal of abating materials containing greater than 1% asbestos by point count analysis on the Property, will evaluate data according to the measurements outlined in Section A7: Data Quality Objectives and Criteria for Measurement Data. If the data quality indicators do not meet the project requirements outlined in the SSQAPP, the data may be discarded, and re-sampling may occur. In case of a failure, the project team will evaluate the cause. If the failure is due to laboratory procedures or equipment, necessary corrective measures will be taken by the EMSL QA manager and Impact7G Project Coordinator. If failure is associated with air monitoring, field procedure will be re-evaluated with any changes documented by the Impact7G Project Coordinator and included in the cleanup report.

The primary purpose of the QA system is to define a process for collecting data that is of known quality, is scientifically valid, is legally defensible, and fully supports the decisions that will be based on the data. To achieve this purpose, this SSQAPP requires the DQOs to be fully defined in Section A7. All other parts of the QA system must then be planned and implemented in a manner consistent with the DQOs. The QA system components that follow directly from the DQOs include documentation and reporting requirements (Section A9); sample network design and sampling methods (Sections B1, B2, and B3); analytical methods requirements (Section B4); QC requirements (Section B5); and data reduction, validation, and reporting methods (Sections D1 and D2).

Once environmental data has been collected, reviewed, and validated, the data must be further evaluated to determine whether the DQOs identified in the SSQAPP have been met. Impact7G will follow EPA's data quality assessment (DQA) process to verify that the type, quality, and quantity of data collected are appropriate for their intended use. The DQA process involves first verifying that the assumptions under which the data collection design and DQOs were developed have been met or taking appropriate corrective action if the assumptions have not been met. The DQA process then evaluates how well the data collected supports the decision that must be made so that scientifically valid and meaningful conclusions can be drawn from the data. These conclusions may be based upon a statistical evaluation of the data collected.

If data quality indicators do not meet the project's requirements as outlined in the SSQAPP, the data may be discarded, and re-sampling and/or re-analysis may be required. The below table identifies the evaluation methods for the project DQOs.

Data Usability Indicator	General Evaluation Method
Precision	Sampling: Precision is increased by following standard operating procedures and by collecting all samples using the same sampling procedures. Field QC samples that are collected to measure precision may include field blind replicate samples and field duplicate samples. Duplicate results, if collected, are reviewed to providing information on variability arising from medium spatial heterogeneity and sampling and analysis methods. Analysis: Intra-laboratory measurements will be reviewed to provide information on variability within a single laboratory. The recommended variation factor, based on a discussion with the laboratory, is within 20%. For example, if a PCM air sample is analyzed with 140 fibers/mm^2, a precision factor of 28 fibers/mm^2 will be acceptable for a field blind replicate sample.
Accuracy/Bias	Review results for blanks to provide information on potential contamination.
Representativeness	Review relevant field audit report findings and any field/laboratory record of modifications for potential data quality issues.
Comparability	Compare the sample collection standard operating procedures, preparation techniques, and analysis methods to previous investigations.
Completeness	Determine the precent of samples that were able to be successfully collected and analyzed (e.g., 99 of 100 samples, 99%). 100% of critical samples must be collected and considered valid. In the absence of critical samples, completeness will be confirmed by the lack of visible emissions during the project.

D4 DOCUMENTATION AND RETRIEVAL

The Project Coordinator will be responsible for completing the final report. The Project Coordinator will also be responsible for supervising the Administrative Support Personnel in maintaining the project files for the duration of the project. The project files will be kept in Impact7G's active project files while the project remains active. Upon completion of the project, Impact7G will archive the project files at a secure storage facility for a period of time consistent with EPA's guidelines. After which, the disposition of the project files will be determined by ECIA.

The Project Coordinator will be responsible for document distribution to key project personnel throughout the project. In addition, document distribution will be as follows:

- Final reports as hardcopy files at ECIA offices by the Brownfields Project Manager or successor.
- "FILE" copies of final reports will be maintained at Impact7G Johnston office, after a period of two (2) years from reporting documents will be transferred to inactive status and archived.
- Electronic copies of report text, drawings, and spreadsheets will be maintained electronically for a period of at least one (1) year from the final reporting and close of project prior to transfer to compact disk for a minimum of an additional five (5) years storage.

Retrieval of hard copy records by authorized parties can be accomplished from ECIA files through the Brownfields Project Manager.

Retrieval of hard copy records by authorized parties can be accomplished from Impact7G Project Manager.

HEALTH AND SAFETY

A Site-Specific Health and Safety Plan (HASP) defines the protocols and requirements to be followed by Impact7G personnel while sampling and observing ACM abatement and mold remediation at the former YMCA located at 480 South 3rd Street in Clinton, Iowa 52732. ECIA and Impact7G personnel will not directly perform onsite ACM abatement or mold remediation activities. ACM abatement procedures will be carried out by certified asbestos abatement subcontractors and mold remediation will be carried out by reputable, experienced subcontractors. Immediately prior to site activities, the Designated Site Supervisor will conduct a safety briefing and review the contents of this Plan with all Impact7G site personnel and ACM abatement and mold remediation subcontractors. The Designated Site Supervisor is the individual located on the site who is responsible to the employer and has the authority and knowledge necessary to implement the site safety and health plan and verify compliance with applicable safety and health requirements. The HASP is included in Appendix D of this document.

APPENDIX A

PROJECT LOCATION MAP AND STRUCTURE IDENTIFICATION MAP

APPENDIX A – PROJECT LOCATION MAP

North

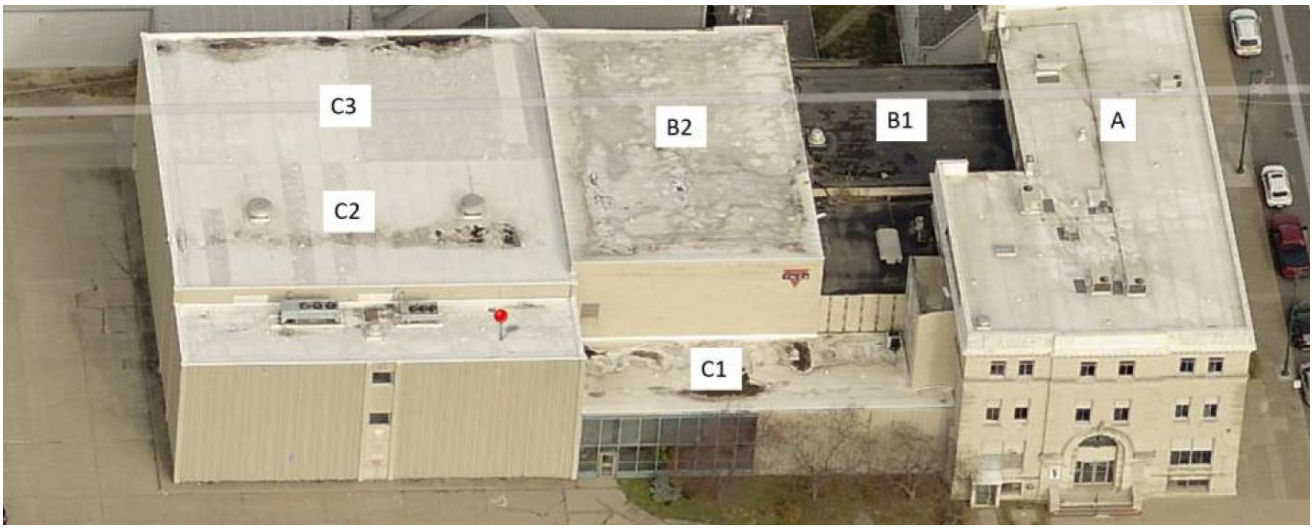
Project Location Map

ECIA / City of Clinton
Former YMCA – 480 South 3rd Street
Clinton, Iowa 52732

IMPACT7G

APPENDIX A – STRUCTURE IDENTIFICATION MAP

North



Structure Identification Map

ECIA / City of Clinton
Former YMCA – 480 South 3rd Street
Clinton, Iowa 52732

APPENDIX B

OSHA ID 160

Method No.:	*ID-160*
Matrix:	*Air*
OSHA PEL	
Time Weighted Average:	*0.1 fiber/cc*
Excursion Level (30 minutes):	*1.0 fiber/cc*
Procedure:	*A known volume of air is drawn through a 25-mm diameter cassette containing a mixed-cellulose ester filter. The cassette must be equipped with an electrically conductive 50-mm extension cowl. The sampling time and rate are chosen to give a fiber density of between 100 to 1,300 fibers/mm^2 on the filter. A portion of the sample filter is cleared and prepared for asbestos fiber counting by Phase Contrast Microscopy (PCM) at 400X.*
Recommended Sampling Rate:	*0.5 to 5.0 L/min*
Recommended Air Volumes:	
Minimum:	*25 L*
Maximum:	*2400 L*
Detection Limit:	*5.5 fibers/mm^2 or 0.001 fibers/cc (2400 L Air Volume)*
Precision	
CV:	*0.12 (at 100 fibers/mm^2)*
Status of Method:	*Fully Validated*

July 1988
Date Revised: July 1997

Daniel T. Crane

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For assistance with accessibility problems in using figures and illustrations presented in this method, please contact Salt Lake Technical Center (SLTC) at (801) 233-4900. These procedures were designed and tested for internal use by OSHA personnel. Mention of any company name or commercial product does not constitute endorsement by OSHA.

1. Introduction

This method describes the collection of airborne asbestos fibers using calibrated sampling pumps with mixed-cellulose ester (MCE) filters and analysis by phase contrast microscopy (PCM). Some terms used are unique to this method and are defined below:

Asbestos: A term for naturally occurring fibrous minerals. Asbestos includes chrysotile, crocidolite, amosite (cummingtonite-grunerite asbestos), tremolite asbestos, actinolite asbestos, anthophyllite asbestos, and any of these minerals that have been chemically treated and/or altered. The precise chemical formulation of each species will vary with the location from which it was mined. Nominal compositions are listed:

Chrysotile	$Mg_3Si_2O_5(OH)_4$
Crocidolite	$Na_2Fe_3^{2+}Fe_2^{3+}Si_8O_{22}(OH)_2$
Amosite	$(Mg,Fe)_7Si_8O_{22}(OH)_2$
Tremolite-actinolite series	$Ca_2(Mg,Fe)_5Si_8O_{22}(OH)_2$
Anthophyllite	$(Mg,Fe)_7Si_8O_{22}(OH)_2$

Asbestos Fiber: A fiber of asbestos which meets the criteria specified below for a fiber.
Aspect Ratio: The ratio of the length of a fiber to its diameter (e.g. 3:1, 5:1 aspect ratios).
Cleavage Fragments: Mineral particles formed by comminution of minerals, especially those characterized by parallel sides and a moderate aspect ratio (usually less than 20:1).
Detection Limit: The number of fibers necessary to be 95% certain that the result is greater than zero.
Differential Counting: The term applied to the practice of excluding certain kinds of fibers from the fiber count because they do not appear to be asbestos.
Fiber: A particle that is 5 µm or longer, with a length-to-width ratio of 3 to 1 or longer.
Field: The area within the graticule circle that is superimposed on the microscope image.
Set: The samples which are taken, submitted to the laboratory, analyzed, and for which, interim or final result reports are generated.
Tremolite, Anthophyllite, and Actinolite: The non-asbestos form of these minerals which meet the definition of a fiber. It includes any of these minerals that have been chemically treated and/or altered.
Walton-Beckett Graticule: An eyepiece graticule specifically designed for asbestos fiber counting. It consists of a circle with a projected diameter of 100 ±2 µm (area of about 0.00785 mm^2) with a crosshair having tic-marks at 3-:m intervals in one direction and 5-µm in the orthogonal direction. There are marks around the periphery of the circle to demonstrate the proper sizes and shapes of fibers. This design is reproduced in Figure 2. The disk is placed in one of the microscope eyepieces so that the design is superimposed on the field of view.

1.1. History

Early surveys to determine asbestos exposures were conducted using impinger counts of total dust with the counts expressed as million particles per cubic foot (8.1.). The British Asbestos Research Council (8.2.) recommended filter membrane counting in 1969. In July 1969, the Bureau of Occupational Safety and Health published a filter membrane method for counting asbestos fibers in the United States (8.3.). This method was refined by NIOSH and published as P & CAM 239 (8.4.). On May 29, 1971, OSHA specified filter membrane sampling with phase contrast counting for evaluation of asbestos exposures at work sites in the United States (8.5.). The use of this technique was again required by OSHA in 1986 (8.6.). Phase contrast microscopy has continued to be the method of choice for the measurement of occupational exposure to asbestos (8.7.).

1.2. Principle

Air is drawn through a MCE filter to capture airborne asbestos fibers. A wedge shaped portion of the filter is removed, placed on a glass microscope slide and made transparent. A measured area (field) is viewed by PCM. All the fibers meeting defined criteria for asbestos are counted and considered a measure of the airborne asbestos concentration.

1.3. Advantages and Disadvantages

There are four main advantages of PCM over other methods:

1) *The technique is specific for fibers. Phase contrast is a fiber counting technique which excludes non-fibrous particles from the analysis.*
2) *The technique is inexpensive and does not require specialized knowledge to carry out the analysis for total fiber counts.*
3) *The analysis is quick and can be performed on-site for rapid determination of air concentrations of asbestos fibers.*
4) *The technique has continuity with historical epidemiological studies so that estimates of expected disease can be inferred from long-term determinations of asbestos exposures.*

The main disadvantage of PCM is that it does not positively identify asbestos fibers. Other fibers which are not asbestos may be included in the count unless differential counting is performed. This requires a great deal of experience to adequately differentiate asbestos from non-asbestos fibers. Positive identification of asbestos must be performed by polarized light or electron microscopy techniques. A further disadvantage of PCM is that the smallest visible fibers are about 0.2 µm in diameter while the finest asbestos fibers may be as small as 0.02 µm in diameter. For some exposures, substantially more fibers may be present than are actually counted.

1.4. Workplace Exposure

Asbestos is used by the construction industry in such products as shingles, floor tiles, asbestos cement, roofing felts, insulation and acoustical products. Non-construction uses include brakes, clutch facings, paper, paints, plastics, and fabrics. One of the most significant exposures in the workplace is the removal and encapsulation of asbestos in schools, public buildings, and homes. Many workers have the potential to be exposed to asbestos during these operations.

About 95% of the asbestos in commercial use in the United States is chrysotile. Crocidolite and amosite make up most of the remainder. Anthophyllite and tremolite or actinolite are likely to be encountered as contaminants in various industrial products.

1.5. Physical Properties

Asbestos fiber possesses a high tensile strength along its axis, is chemically inert, non-combustible, and heat resistant. It has a high electrical resistance and good sound absorbing properties. It can be weaved into cables, fabrics or other textiles, and also matted into asbestos papers, felts, or mats.

1.6. Toxic Effects

Information contained in this section is a synopsis of current knowledge of the physiological effects of asbestos and is not intended as a basis for OSHA policy.

Some possible physiologic results of respiratory exposure to asbestos are mesothelioma of the pleura or peritoneum, interstitial fibrosis, asbestosis, pneumoconiosis, or respiratory cancer (8.8.). The possible consequences of asbestos exposure are further detailed in reference 8.8 or in the asbestos standard preamble (8.6.).

2. *Range and Detection Limit*

2.1. *The ideal counting range on the filter is 100 to 1,300 fibers/mm^2. With a Walton-Beckett graticule this range is equivalent to 0.8 to 10 fibers/field. Using NIOSH counting statistics (8.9.), a count of 0.8 fibers/field would give an approximate coefficient of variation (CV) of 0.13.*

2.2. *The detection limit for this method is 4.0 fibers per 100 fields or 5.5 fibers/mm^2. This was determined using an equation to estimate the maximum CV possible at a specific concentration (95% confidence) and a Lower Control Limit of zero. The CV value was then used to determine a corresponding concentration from historical CV vs. fiber relationships. As an example:*

Lower Control Limit (95% Confidence) = AC - 1.645(CV)(AC)

Where:

AC = Estimate of the airborne fiber concentration (fibers/cc)
Setting the Lower Control Limit = 0 and solving for CV:

0 = AC - 1.645(CV)(AC)
CV = 0.61

This value was compared with CV vs. count curves. The count at which CV = 0.61 for Leidel-Busch counting statistics (8.9.) or for an OSHA Salt Lake Technical Center (OSHA-SLTC) CV curve (see Appendix A for further information) was 4.4 fibers or 3.9 fibers per 100 fields, respectively. Although a lower detection limit of 4 fibers per 100 fields is supported by the OSHA-SLTC data, both data sets support the 4.5 fibers per 100 fields value.

3. *Method Performance - Precision and Accuracy*

Precision is dependent upon the total number of fibers counted and the uniformity of the fiber distribution on the filter. A general rule is to count at least 20 and not more than 100 fields. The count is discontinued when 100 fibers are counted, provided that 20 fields have already been counted. Counting more than 100 fibers results in only a small gain in precision. As the total count drops below 10 fibers, an accelerated loss of precision is noted (8.9.).

At this time, there is no known method to determine the absolute accuracy of the asbestos analysis. Results of samples prepared through the Proficiency Analytical Testing (PAT) Program and analyzed by the OSHA-SLTC showed no significant bias when compared to PAT reference values. The PAT samples were analyzed from 1987 to 1989 (N=36) and the concentration range was from 120 to 1,300 fibers/mm^2.

4. *Interferences*

Fibrous substances, if present, may interfere with asbestos analysis.
Some common fibers are:

fiber glass	*perlite veins*
anhydrite	*plant fibers*
gypsum	*some synthetic fibers*
membrane structures	*sponge spicules and diatoms*
microorganisms	*wollastonite*

The use of electron microscopy or optical tests such as polarized light, and dispersion staining may be used to differentiate these materials from asbestos when necessary.

5. Sampling

5.1. Equipment

5.1.1. Sample assembly (The assembly is shown in Figure 3):

Conductive filter holder consisting of a 25-mm diameter, 3-piece cassette having a 50-mm long electrically conductive extension cowl. Backup pad, 25-mm, cellulose. Membrane filter, mixed-cellulose ester (MCE), 25-mm, plain, white, 0.4- to 1.2-µm pore size.

NOTES: a) DO NOT RE-USE CASSETTES.
b) Fully conductive cassettes are required to reduce fiber loss to the sides of the cassette due to electrostatic attraction.
c) Purchase filters which have been selected by the manufacturer for asbestos counting or analyze representative filters for fiber background before use. Discard the filter lot if more than 4 fibers/100 fields are found.
d) To decrease the possibility of contamination, the sampling system (filter-backup pad-cassette) for asbestos is usually preassembled by the manufacturer.
e) Other cassettes such as the Bell-mouth® may be used within the limits of validation.

5.1.2. Gel bands for sealing cassettes.

5.1.3 Sampling pump: Each pump must be a battery operated, self-contained unit small enough to be placed on the monitored employee and not interfere with the work being performed. The pump must be capable of sampling at the collection rate for the required sampling time.

5.1.4. Flexible tubing, 6-mm bore.

5.1.5. Pump calibration: Stopwatch and bubble tube/burette or electronic meter.

5.2. Sampling Procedure

5.2.1. Seal the point where the base and cowl of each cassette meet (see Figure 3) with a gel band or tape.

5.2.2. Charge the pumps completely before beginning.

5.2.3. Connect each pump to a calibration cassette with an appropriate length of 6-mm bore plastic tubing. Do not use luer connectors - the type of cassette specified above has built-in adapters.

5.2.4. Select an appropriate flow rate for the situation being monitored. The sampling flow rate must be between 0.5 and 5.0 L/min for personal sampling and is commonly set between 1 and 2 L/min. Always choose a flow rate that will not produce overloaded filters.

5.2.5. Calibrate each sampling pump before and after sampling with a calibration cassette in-line (Note: This calibration cassette should be from the same lot of cassettes used for sampling). Use a primary standard (e.g. bubble burette) to calibrate each pump. If possible, calibrate at the sampling site.

NOTE: If sampling site calibration is not possible, environmental influences may affect the flow rate. The extent is dependent on the type of pump used. Consult with the pump manufacturer to determine dependence on environmental influences. If the pump is affected by temperature and pressure changes, use the formula in Appendix B to calculate the actual flow rate.

5.2.6. Connect each pump to the base of each sampling cassette with flexible tubing. Remove the end cap of each cassette and take each air sample open face (see Figure 3). Assure that each sample cassette is held open side down in the employee's breathing zone during sampling. The distance from the nose/mouth of the employee to the cassette should be about 10 cm. Secure the cassette on the collar or lapel of the employee using spring clips or other similar devices.

5.2.7. A suggested minimum air volume when sampling to determine TWA compliance is 25 L. For Excursion Limit (30 min sampling time) evaluations, a minimum air volume of 48 L is recommended.

5.2.8. The most significant problem when sampling for asbestos is overloading the filter with non-asbestos dust. Suggested maximum air sample volumes for specific environments are:

Environment	*Air Vol. (L)*
Asbestos removal operations (visible dust)	*100*
Asbestos removal operations (little dust)	*240*
Office environments	*400 to 2400*

CAUTION:

Do not overload the filter with dust. High levels of non-fibrous dust particles may obscure fibers on the filter and lower the count or make counting impossible. If more than about 25 to 30% of the field area is obscured with dust, the result may be biased low. Smaller air volumes may be necessary when there is excessive non-asbestos dust in the air.

While sampling, observe the filter with a small flashlight. If there is a visible layer of dust on the filter, stop sampling, remove and seal the cassette, and replace with a new sampling assembly. The total dust loading should not exceed 1 mg.

5.2.9. Blank samples are used to determine if any contamination has occurred during sample handling. Prepare two blanks for the first 1 to 20 samples. For sets containing greater than 20 samples, prepare blanks as 10% of the samples. Handle blank samples in the same manner as air samples with one exception: Do not draw any air through the blank samples. Open the blank cassette in the place where the sample cassettes are mounted on the employee. Hold it open for about 30 seconds. Close and seal the cassette appropriately. Store blanks for shipment with the sample cassettes.

5.2.10. Immediately after sampling, close and seal each cassette with the base and plastic plugs. Do not touch or puncture the filter membrane as this will invalidate the analysis.

5.2.11. Attach a seal (OSHA-21 or equivalent) around each cassette in such a way as to secure the end cap plug and base plug. Tape the ends of the seal together since the seal is not long enough to be wrapped end-to-end. Also wrap tape around the cassette at each joint to keep the seal secure.

5.3. Sample Shipment

5.3.1. Send the samples to the laboratory with paperwork requesting asbestos analysis. List any known fibrous interferences present during sampling on the paperwork. Also, note the workplace operation(s) sampled.

5.3.2. Secure and handle the samples so that they will not rattle during shipment nor be exposed to static electricity. Do not ship samples in expanded polystyrene peanuts, vermiculite, paper shreds, or excelsior. Tape sample cassettes to sheet bubbles and place in a container that will cushion the samples without rattling.

5.3.3. To avoid the possibility of sample contamination, always ship bulk samples in separate mailing containers.

6. Analysis

6.1. Safety Precautions

6.1.1. Acetone is extremely flammable and precautions must be taken not to ignite it. Avoid using large containers or quantities of acetone. Transfer the solvent in a ventilated laboratory hood. Do not use acetone near any open flame. For generation of acetone vapor, use a spark free heat source.

6.1.2. Any asbestos spills should be cleaned up immediately to prevent dispersal of fibers. Prudence should be exercised to avoid contamination of laboratory facilities or exposure of personnel to asbestos. Asbestos spills should be cleaned up with wet methods and/or a High Efficiency Particulate-Air (HEPA) filtered vacuum. CAUTION: Do not use a vacuum without a HEPA filter - It will disperse fine asbestos fibers in the air.

6.2. Equipment

6.2.1. Phase contrast microscope with binocular or trinocular head.

6.2.2. Widefield or Huygenian 10X eyepieces (NOTE: The eyepiece containing the graticule must be a focusing eyepiece. Use a 40X phase objective with a numerical aperture of 0.65 to 0.75).

6.2.3. Kohler illumination (if possible) with green, blue filter, or PLM illumination, or polarized light with a first-order plate.

6.2.4. Walton-Beckett Graticule, type G-22 with 100 ±2 µm projected diameter. See Appendix C for further information regarding ordering the graticule.

6.2.5. Mechanical stage. A rotating mechanical stage is convenient for use with polarized light.

6.2.6. Phase telescope.

6.2.7. Stage micrometer with 0.01-mm subdivisions.

6.2.8. Phase-shift test slide, mark II (Available from PTR optics Ltd., and also McCrone).

6.2.9. Precleaned glass slides, 25 mm X 75 mm. One end can be frosted for convenience in writing sample numbers, etc., or paste-on labels can be used.

6.2.10. Cover glass #1½.

6.2.11. Scalpel (#10, curved blade).

6.2.12. Fine tipped forceps.

6.2.13. Aluminum block for clearing filter (see Appendix D and Figure 4).

6.2.14. Automatic adjustable pipette, 100- to 500-:L.

6.2.15. Micropipette, 5 :L.

.

6.2.16. Polarizer, analyzer and first order red plate (optional).

6.3. Reagents

6.3.1. Acetone (HPLC grade).

6.3.2. Triacetin (glycerol triacetate).

6.3.3. Lacquer or nail polish.

6.4. Standard Preparation

A way to prepare standard asbestos samples of known concentration has not been developed. It is possible to prepare replicate samples of nearly equal concentration. This has been performed through the PAT program. These asbestos samples are distributed by the AIHA to participating laboratories.

Since only about one-fourth of a 25-mm sample membrane is required for an asbestos count, any PAT sample can serve as a "standard" for replicate counting.

6.5. Sample Mounting

Note: See Safety Precautions in Section 6.1. before proceeding.

The objective is to produce samples with a smooth (non-grainy) background in a medium with a refractive index of approximately 1.46. The technique below collapses the filter for easier focusing and produces permanent mounts which are useful for quality control and interlaboratory comparison.

An aluminum block or similar device is required for sample preparation. A drawing is shown in Figure 4.

6.5.1. Heat the aluminum block to about 70 C. The hot block should not be used on any surface that can be damaged by either the heat or from exposure to acetone.

6.5.2. Ensure that the glass slides and cover glasses are free of dust and fibers.

6.5.3. Remove the top plug to prevent a vacuum when the cassette is opened. Clean the outside of the cassette if necessary. Cut the seal and/or tape on the cassette with a razor blade. Very carefully separate the base from the extension cowl, leaving the filter and backup pad in the base.

6.5.4. With a rocking motion cut a triangular wedge from the filter using the scalpel. This wedge should be one-sixth to one-fourth of the filter. Grasp the filter wedge with the

forceps on the perimeter of the filter which was clamped between the cassette pieces. DO NOT TOUCH the filter with your finger. Place the filter on the glass slide sample side up. Static electricity will usually keep the filter on the slide until it is cleared.

6.5.5. Place the tip of the micropipette containing about 200 µL acetone into the aluminum block. Insert the glass slide into the receiving slot in the aluminum block. Inject the acetone into the block with slow, steady pressure on the plunger while holding the pipette firmly in place. Wait 3 to 5 seconds for the filter to clear, then remove the pipette and slide from the aluminum block.

6.5.6. Immediately (less than 30 seconds) place 2.5 to 3.5 µL of triacetin on the filter (NOTE: Waiting longer than 30 seconds will result in increased index of refraction and decreased contrast between the fibers and the preparation. This may also lead to separation of the cover slip from the slide).

6.5.7. Lower a cover slip gently onto the filter at a slight angle to reduce the possibility of forming air bubbles. If more than 30 seconds have elapsed between acetone exposure and triacetin application, glue the edges of the cover slip to the slide with lacquer or nail polish.

6.5.8. If clearing is slow, warm the slide for 15 min on a hot plate having a surface temperature of about 50EC to hasten clearing. The top of the hot block can be used if the slide is not heated too long.

6.5.9. Counting may proceed immediately after clearing and mounting are completed.

6.6. Sample Analysis

Completely align the microscope according to the manufacturer's instructions. Then, align the microscope using the following general alignment routine at the beginning of every counting session and more often if necessary.

6.6.1. Alignment

1) *Clean all optical surfaces. Even a small amount of dirt can significantly degrade the image.*

2) *Rough focus the objective on a sample.*

3) *Close down the field iris so that it is visible in the field of view. Focus the image of the iris with the condenser focus. Center the image of the iris in the field of view.*

4) *Install the phase telescope and focus on the phase rings. Critically center the rings. Misalignment of the rings results in astigmatism which will degrade the image.*

5) *Place the phase-shift test slide on the microscope stage and focus on the lines. The analyst must see line set 3 and should see at least parts of 4 and 5 but, not see line set 6 or 7. A microscope/microscopist combination which does not pass this test may not be used.*

6) *If used, align the polarizer and analyzer at right angles to each other, and with the first order red compensator at 45 degrees to the polarization directions, as for PLM analysis. (If PLM is used, do not insert either a green of blue filter.)*

6.6.2. Counting Fibers

1) *Place the prepared sample slide on the mechanical stage of the microscope. Position the center of the wedge under the objective lens and focus upon the sample.*

2) *Start counting from one end of the wedge and progress along a radial line to the other end (count in either direction from perimeter to wedge tip). Select fields randomly, without looking into the eyepieces, by slightly advancing the slide in one direction with the mechanical stage control.*

3) *Continually scan over a range of focal planes (generally the upper 10 to 15 µm of the filter surface) with the fine focus control during each field count. Spend at least 5 to 15 seconds per field.*

4) *Most samples will contain asbestos fibers with fiber diameters less than 1 µm. Look carefully for faint fiber images. The small diameter fibers will be very hard to see. However, they are an important contribution to the total count.*

5) *Count only fibers equal to or longer than 5 µm. Measure the length of curved fibers along the curve.*

6) *Count fibers which have a length to width ratio of 3:1 or greater.*

7) *Count all the fibers in at least 20 fields. Continue counting until either 100 fibers are counted or 100 fields have been viewed; whichever occurs first. Count all the fibers in the final field.*

8) *Fibers lying entirely within the boundary of the Walton-Beckett graticule field shall receive a count of 1. Fibers crossing the boundary once, having one end within the circle shall receive a count of ½. Do not count any fiber that crosses the graticule boundary more than once. Reject and do not count any other fibers even though they may be visible outside the graticule area. If a fiber touches the circle, it is considered to cross the line.*

9) *Count bundles of fibers as one fiber unless individual fibers can be clearly identified and each individual fiber is clearly not connected to another counted fiber. See Figure 2 for counting conventions.*

10) *Record the number of fibers in each field in a consistent way such that filter non-uniformity can be assessed.*

11) *Regularly check phase ring alignment.*

12) *When an agglomerate (mass of material) covers more than 25% of the field of view, reject the field and select another. Do not include it in the number of fields counted.*

13) *Perform a "blind recount" of 1 in every 10 filter wedges (slides)*

6.7. *Fiber Identification*

As previously mentioned in Section 1.3., PCM does not provide positive confirmation of asbestos fibers. Alternate differential counting techniques should be used if discrimination is desirable. Differential counting may include primary discrimination based on morphology, polarized light analysis of fibers, or modification of PCM data by Scanning Electron or Transmission Electron Microscopy.

A great deal of experience is required to routinely and correctly perform differential counting. It is discouraged unless it is legally necessary. Then, only if a fiber is obviously not asbestos should it be excluded from the count. Further discussion of this technique can be found in reference 8.10.

If there is a question whether a fiber is asbestos or not, follow the rule:
"WHEN IN DOUBT, COUNT"

6.8. *Analytical Recommendations - Quality Control System*

6.8.1. *All individuals performing asbestos analysis must have taken the NIOSH course for sampling and evaluating airborne asbestos or an equivalent course.*

6.8.2. *Each laboratory engaged in asbestos counting shall set up a slide trading arrangement with at least two other laboratories in order to compare performance and eliminate inbreeding of error. The slide exchange occurs at least semiannually. The round robin results shall be posted where all analysts can view individual analyst's results.*

6.8.3. *Each laboratory engaged in asbestos counting shall participate in the Proficiency Analytical Testing Program, the Asbestos Analyst Registry or equivalent.*

6.8.4. *Each analyst shall select and count prepared slides from a "slide bank". These are quality assurance counts. The slide bank shall be prepared using uniformly distributed samples taken from the workload. Fiber densities should cover the entire range routinely analyzed by the laboratory. These slides are counted blind by all counters to establish an original standard deviation. This historical distribution is compared with the quality assurance counts. A counter must have 95% of all quality control samples counted within three standard deviations of the historical mean. The analyses done by the counters to establish the slide bank may be used for an interim quality control program if the data are treated in a proper statistical fashion.*

7. *Calculations*

7.1. *Calculate the estimated airborne asbestos fiber concentration on the filter sample using the following formula:*

$$AC = \frac{\left[\left(\frac{FB}{FL}\right) - \left(\frac{BFB}{BFL}\right)\right] \times ECA}{1000 \times FR \times T \times MFA}$$

where:

AC = Airborne fiber concentration

FB = *Total number of fibers greater than 5 μm counted*
FL = *Total number of fields counted on the filter*
BFB = *Total number of fibers greater than 5 μm counted in the blank*
BFL = *Total number of fields counted on the blank*
ECA = *Effective collecting area of filter (385 mm^2 nominal for a 25-mm filter.)*
FR = *Pump flow rate (L/min)*
MFA = *Microscope count field area (mm^2). This is 0.00785 mm^2 for a Walton-Beckett Graticule.*
T = *Sample collection time (min)*
1000 = *Conversion of L to mL*

NOTE: The collection area of a filter is seldom equal to 385 mm^2. It is appropriate for laboratories to routinely monitor the exact diameter using an inside micrometer. The collection area is calculated according to the formula:

Area = $\pi(d/2)^2$

7.2. Short-cut Calculation

Since a given analyst always has the same interpupillary distance, the number of fields per filter for a particular analyst will remain constant for a given size filter. The field size for that analyst is constant (i.e. the analyst is using an assigned microscope and is not changing the reticle).

For example, if the exposed area of the filter is always 385 mm^2 and the size of the field is always 0.00785 mm^2, the number of fields per filter will always be 49,000. In addition it is necessary to convert liters of air to cc. These three constants can then be combined such that ECA/(1,000 X MFA) = 49. The previous equation simplifies to:

$$AC = \frac{[(\frac{FB}{FL}) - (\frac{BFB}{BFL})] \times 49}{FR \times T}$$

7.3. Recount Calculations

As mentioned in step 13 of Section 6.6.2., a "blind recount" of 10% of the slides is performed. In all cases, differences will be observed between the first and second counts of the same filter wedge. Most of these differences will be due to chance alone, that is, due to the random variability (precision) of the count method. Statistical recount criteria enables one to decide whether observed differences can be explained due to chance alone or are probably due to systematic differences between analysts, microscopes, or other biasing factors.

The following recount criterion is for a pair of counts that estimate AC in fibers/cc. The criterion is given at the type-I error level. That is, there is 5% maximum risk that we will reject a pair of counts for the reason that one might be biased, when the large observed difference is really due to chance. (8.11.)

Reject a pair of counts if:

$$\left|\sqrt{AC_2} - \sqrt{AC_1}\right| > 2.78 \times \left(\frac{\sqrt{AC_1} + \sqrt{Ac_2}}{2}\right) \times \frac{CV_{FB}}{2}$$

Where:
AC_1 = *lower estimated airborne fiber concentration*
AC_2 = *higher estimated airborne fiber concentration*
CV_{FB} = *pooled average CV for the two concentration estimates:*

$$CV_{FB} = \sqrt{\frac{(CV_1^2 + CV_2^2)}{2}}$$

CV_1 = *Coefficient of variation associated with the lower count*
CV_2 = *Coefficient of variation associated with the higher count*

Coefficients of variation (CV) may be determined as in Appendix A of this method (ID-160) or as discussed in NIOSH Method 7400.

If a pair of counts is rejected by this criterion then, recount the rest of the filters in the submitted set. Apply the test and reject any other pairs failing the test. Rejection shall include a memo to the industrial hygienist stating that the sample failed a statistical test for homogeneity and the true air concentration may be significantly different than the reported value.

7.4. Reporting Results

Report results to the industrial hygienist as fibers/cc. Use two significant figures. If multiple analyses are performed on a sample, an average of the results is to be reported unless any of the results can be rejected for cause.

8. References

8.1. **Dreesen, W.C., et al,** *U.S. Public Health Service: A Study of Asbestosis in the Asbestos Textile Industry, (Public Health Bulletin No. 241), US Treasury Dept., Washington, DC, 1938.*

8.2. Asbestos Research Council: The Measurement of Airborne Asbestos Dust by the Membrane Filter Method (Technical Note), Asbestos Research Council, Rockdale, Lancashire, Great Britain, 1969.

8.3. **Bayer, S.G., Zumwalde, R.D., Brown, T.A.**, *Equipment and Procedure for Mounting Millipore Filters and Counting Asbestos Fibers by Phase Contrast Microscopy, Bureau of Occupational Health, U.S. Dept. of Health, Education and Welfare, Cincinnati,OH,1969.*

8.4. NIOSH Manual of Analytical Methods, 2nd ed., Vol. 1 (DHEW/NIOSH Pub. No. 77-157-A). National Institute for Occupational Safety and Health, Cincinnati, OH, 1977.pp.239-1-239-21.

8.5. Asbestos, Code of Federal Regulations 29 CFR 1910.1001. 1971.

8.6. Occupational Exposure to Asbestos, Tremolite, Anthophyllite, and Actinolite. Final Rule, Federal Register 51: 119 (20 June 1986). pp.22612-22790.

8.7. Asbestos, Tremolite, Anthophyllite, and Actinolite, Code of Federal Regulations 1910.1001. 1988. pp 711-752.

8.8. Criteria for a Recommended Standard -- Occupational Exposure to Asbestos (DHEW/NIOSH Pub. No. HSM 72-10267), National Institute for Occupational Safety and Health NIOSH, Cincinnati,OH, 1972. pp. III-1-III-24.

8.9. **Leidel, N.A., Bayer,S.G., Zumwalde, R.D.,Busch, K.A.,** *USPHS/NIOSH Membrane Filter Method for Evaluating Airborne Asbestos Fibers (DHEW/NIOSH Pub. No. 79-127). National Institute for Occupational Safety and Health, Cincinnati, OH, 1979.*

8.10. **Dixon, W.C.**, *Applications of Optical Microscopy in Analysis of Asbestos and Quartz, Analytical Techniques in Occupational Health Chemistry, edited by D.D. Dollberg and A.W. Verstuyft. Wash. D.C.: American Chemical Society, (ACS Symposium Series 120) 1980. pp. 13-41.*

8.11. **Abell, M. T**., *et al.,The Quality of Fiber Count Data, Appl. Ind. Hyg. Vol 4 No.11, November 1989, pp. 273-285*

Appendix A

The OSHA asbestos regulations require each laboratory to establish a quality control program. The following is presented as an example of how the OSHA-SLTC constructed its internal CV curve as part of meeting this requirement.

Data for the CV curve shown below is from 395 samples collected during OSHA compliance inspections and analyzed from October 1980 through April 1986.

Each sample was counted by 2 to 5 different counters independently of one another. The standard deviation and the CV statistic were calculated for each sample. This data was then plotted on a graph of CV vs. fibers/mm^2. A least squares regression was performed using the following equation:

$$CV = \text{antilog}_{10}[A(\log_{10}(x))^2 + B(\log_{10}(x)) + C]$$

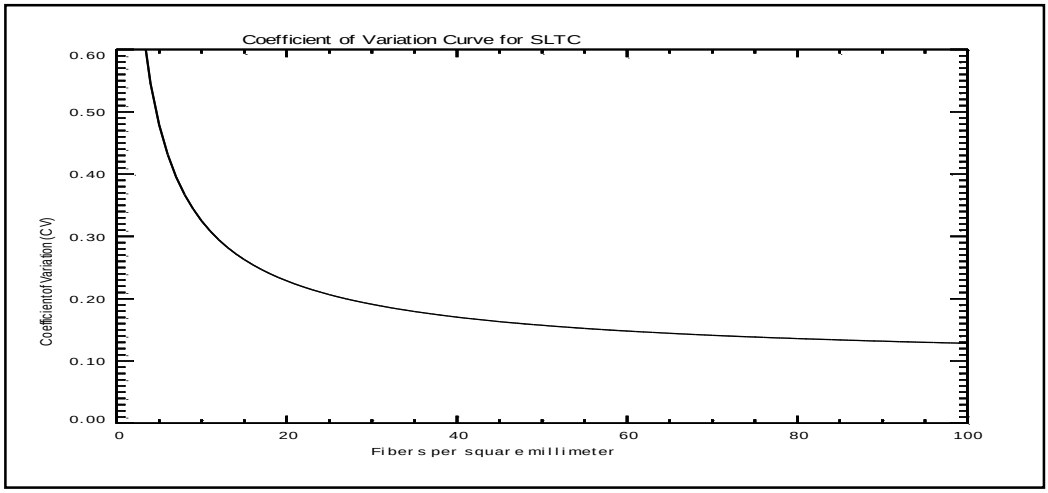
where: x = *the number of fibers/mm^2*

Application of least squares gave:

$A = 0.182205$
$B = -0.973343$
$C = 0.327499$

Using these values, the equation becomes:

$$CV = \text{antilog}_{10}[0.182205(\log_{10}(x))^2 - 0.973343(\log_{10}(x)) + 0.327499]$$



1: CV curve generated from OSHA Salt Lake Technical Center data.

Appendix B

Sampling Pump Flow Rate Corrections

This correction is used if a difference greater than 5% in ambient temperature and/or pressure is noted between calibration and sampling sites and the pump does not compensate for the differences.

$$Q_{act} = Q_{cal} \times \sqrt{\left(\frac{P_{cal}}{P_{act}}\right) \times \left(\frac{T_{act}}{Tcal}\right)}$$

Where:

Q_{act} *= actual flow rate*
Q_{cal} *= calibrated flow rate (if a rotameter was used, the rotameter value)*
P_{cal} *= uncorrected air pressure at calibration*
P_{act} *= uncorrected air pressure at sampling site*
T_{act} *= temperature at sampling site (K)*
T_{cal} *= temperature at calibration (K)*

Appendix C

Walton-Beckett Graticule

When ordering the Graticule for asbestos counting, specify the exact disc diameter needed to fit the ocular of the microscope and the diameter (mm) of the circular counting area. Instructions for measuring the dimensions necessary are listed:

1. *Insert any available graticule into the focusing eyepiece and focus so that the graticule lines are sharp and clear.*

2. *Align the microscope.*

3. *Place a stage micrometer on the microscope object stage and focus the microscope on the graduated lines.*

4. *Measure the magnified grid length, PL (:m), using the stage micrometer.*

5. *Remove the graticule from the microscope and measure its actual grid length, AL (mm). This can be accomplished by using a mechanical stage fitted with verniers, or a jeweler's loupe with a direct reading scale.*

6. *Let D = 100 :m. Calculate the circle diameter, d_c (mm), for the Walton-Beckett graticule and specify the diameter when making a purchase:*

$$d_c = \frac{AL \times D}{PL}$$

Example: If PL = 108 µm, AL = 2.93 mm and D = 100 µm, then,

$$d_c = \frac{2.93 \times 100}{100} = 2.71$$

7. *Each eyepiece-objective-reticle combination on the microscope must be calibrated. Should any of the three be changed (by zoom adjustment, disassembly, replacement, etc.), the combination must be recalibrated. Calibration may change if interpupillary distance is changed.*

Measure the field diameter, D (acceptable range: 100 ∀ 2 :m) with a stage micrometer upon receipt of the graticule from the manufacturer. Determine the field area (mm^2).

Field Area = B $(D/2)^2$
If D = 100 µm = 0.1 mm, then
Field Area = B $(0.1\ mm/2)^2 = 0.00785\ mm^2$

The Graticule is available from:	*Graticules Ltd., Morley Road, Tonbridge TN9 IRN, Kent, England (Telephone 011-44-732-359061).*
also available from:	*PTR Optics Ltd., 145 Newton Street, Waltham, MA 02154 [telephone (617) 891-6000]*
or from:	*McCrone Accessories and Components, 2506 S. Michigan Ave., Chicago, IL 60616 [phone (312)-842-7100]. The graticule is custom made for each microscope.*

Appendix D

Aluminum Block

Diagrams of the block are provided in Figure 4.

For assistance with accessibility problems in using figures and illustrations presented in this method, please contact Salt Lake Technical Center (SLTC) at (801) 233-4900. These procedures were designed and tested for internal use by OSHA personnel. Mention of any company name or commercial product does not constitute endorsement by OSHA.

The cartridge thermostat and heater used for this block have the following dimensions:

Diameter: 1/2"
Cartridge length: 2 3/8"

These heating units were obtained from:

Vulcan Electric Company
Kezar Falls, Maine 04047
(207)-625-3231

Thermostat part number: N1A1C2
Heater part number: C516

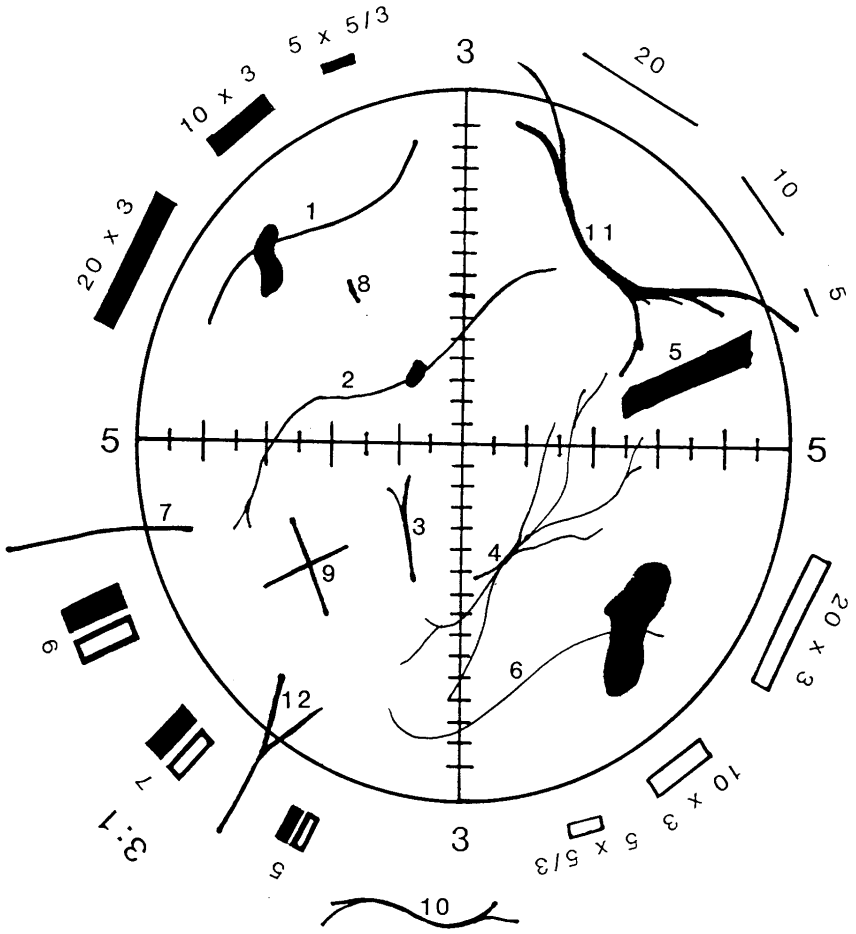


Figure 2: Walton Becket Graticule with some explanatory fibers.

Counts for the fibers in Figure 2

Structure number	*Count*	*Explanation*
1 to 6	*1*	*single fibers all contained within the circle*
7	*½*	*fiber crosses circle once*
8	*0*	*fiber too short*
9	*2*	*two crossing fibers*
10	*0*	*fiber outside graticule*
11	*0*	*fiber crosses graticule twice*
12	*½*	*although split, fiber only crosses once*

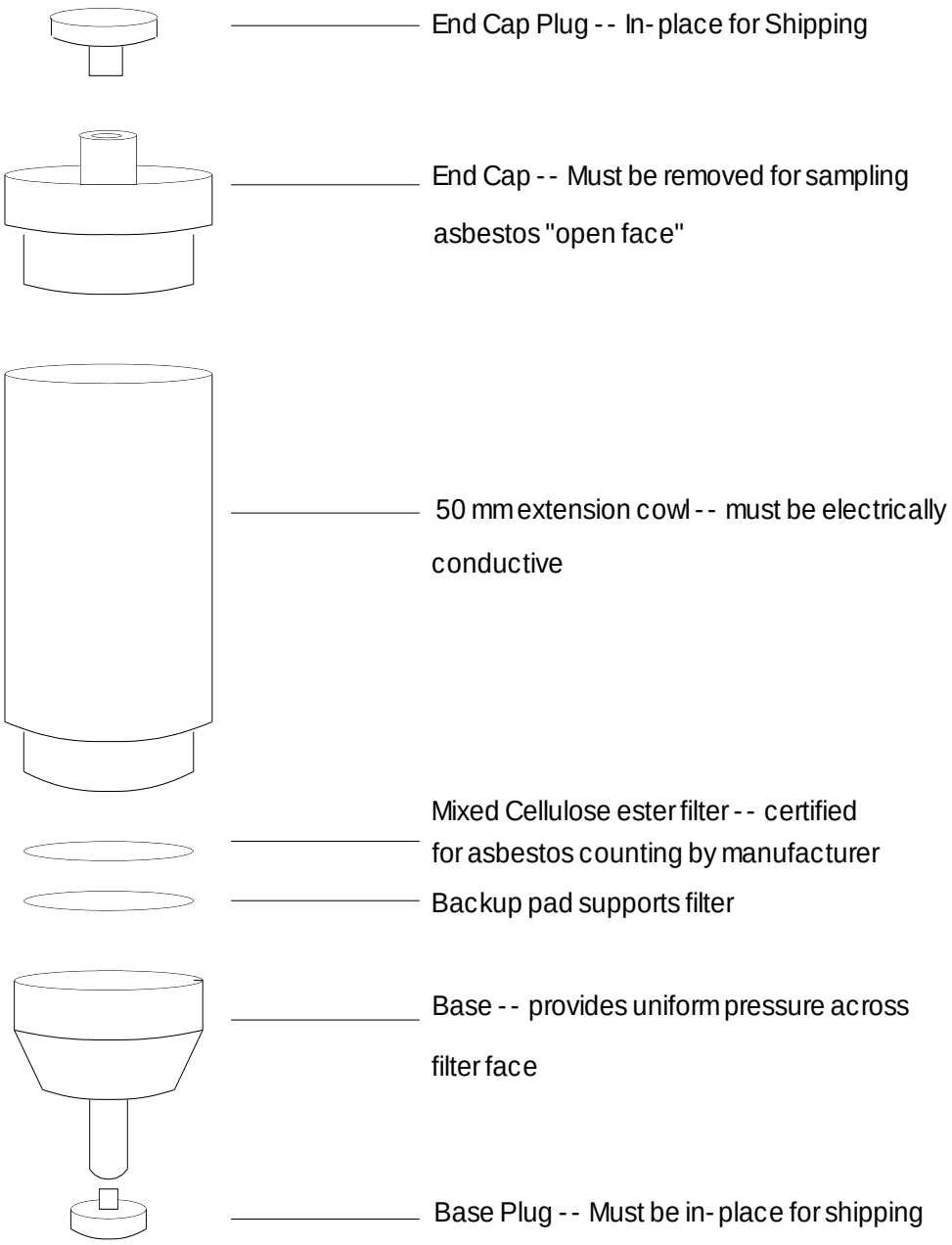


Figure 3: Exploded view of an asbestos sampling cassette.

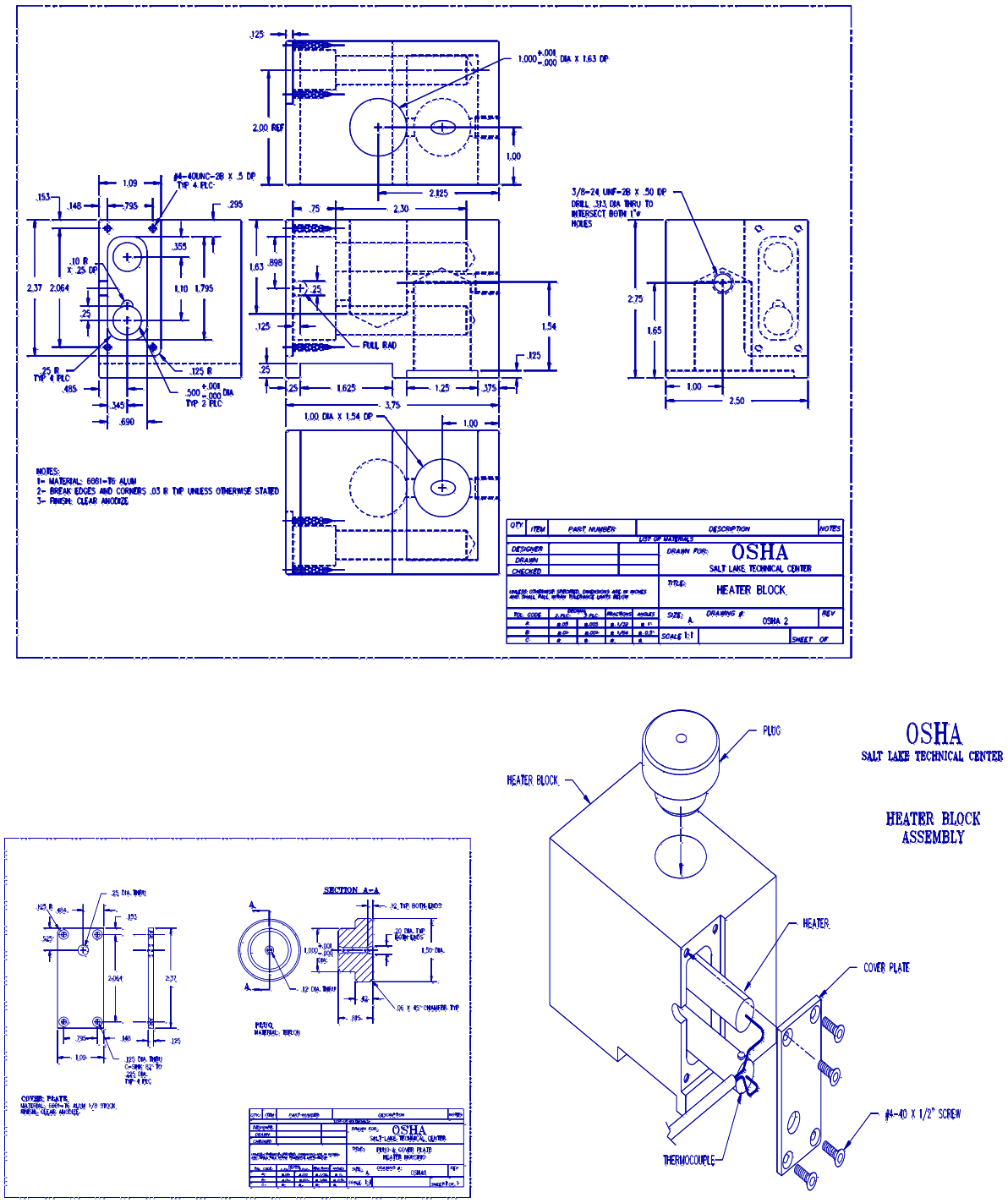


Figure 4: Engineering drawings for the aluminum "Hot Block" as used at the Salt Lake Technical Center.

APPENDIX C
EXAMPLE CHAIN OF CUSTODY

EMSL ANALYTICAL, INC.
TESTING LABS • PRODUCTS • TRAINING

Asbestos Bulk Building Materials - Chain of Custody

EMSL Order Number / Lab Use Only

EMSL Analytical, Inc.
6340 Castleplace Dr
Indianapolis, IN 46250

PHONE: (317) 803-2997
EMAIL:

Customer Information		Billing Information	
Customer ID:		Billing ID:	
Company Name:	Impact7G, Inc.	Company Name:	Impact7G, Inc.
Contact Name:		Billing Contact:	
Street Address:	8951 Windsor Parkway	Street Address:	8951 Windsor Parkway
City, State, Zip:	Johnston, IA 50131	City, State, Zip:	Johnston, IA 50131
Country:	USA	Country:	USA
Phone:	515-473-6256	Phone:	515-473-6256
Email(s) for Report:		Email(s) for Invoice:	

Project Information

Project Name/No:			Purchase Order:
EMSL LIMS Project ID: (If applicable, EMSL will provide)		US State where samples collected: IA	State of Connecticut (CT) must select project location: ☐ Commercial (Taxable) ☐ Residential (Non-Taxable)
Sampled By Name:	Sampled By Signature:	Date Sampled:	No. of Samples in Shipment

Turn-Around-Time (TAT)

☐ 3 Hour ☐ 6 Hour ☐ 24 Hour ☐ 32 Hour ☐ 48 Hour ☐ 72 Hour ☐ 96 Hour ☐ 1 Week ☐ 2 Week

Please call ahead for large projects and/or turnaround times 6 Hours or Less. *32 Hour TAT available for select tests only; samples must be submitted by 11:30am.

Test Selection

PLM - Bulk (reporting limit)

- ☐ PLM EPA 600/R-93/116 (<1%)
- ☐ PLM EPA NOB (<1%)
- ☐ POINT COUNT
  - ☐ 400 (<0.25%) ☐ 1,000 (<0.1%)
- ☐ POINT COUNT w/ GRAVIMETRIC
  - ☐ 400 (<0.25%) ☐ 1,000 (<0.1%)
- ☐ NIOSH 9002 (<1%)
- ☐ NYS 198.1 (Friable - NY)
- ☐ NYS 198.6 NOB (Non-Friable - NY)
- ☐ NYS 198.8 (Vermiculite SM-V)

TEM - Bulk

- ☐ TEM EPA NOB
- ☐ NYS NOB 198.4 (Non-Friable - NY)
- ☐ TEM EPA 600/R-93/116 w Milling Prep (0.1%)

Other Tests (please specify)

☐ Positive Stop - Clearly Identified Homogeneous Areas (HA)

Sample Number	HA Number	Sample Location	Material Description

Special Instructions and/or Regulatory Requirements (Sample Specifications, Processing Methods, Limits of Detection, etc.)

Method of Shipment:		Sample Condition Upon Receipt:	
Relinquished by:	Date/Time:	Received by:	Date/Time
Relinquished by:	Date/Time:	Received by:	Date/Time

☐ **AGREE TO ELECTRONIC SIGNATURE** (By checking, I consent to signing this Chain of Custody document by electronic signature.)

EMSL ANALYTICAL, INC.
TESTING LABS • PRODUCTS • TRAINING

Asbestos Bulk Building Materials - Chain of Custody

EMSL Order Number / Lab Use Only

EMSL Analytical, Inc.
6340 Castleplace Dr
Indianapolis, IN 46250

PHONE: (317) 803-2997
EMAIL:

Additional Pages of the Chain of Custody are only necessary if needed for additional sample information

Special Instructions and/or Regulatory Requirements (Sample Specifications, Processing Methods, Limits of Detection, etc.)

Sample Number	HA Number	Sample Location	Material Description

Method of Shipment:		Sample Condition Upon Receipt:	
Relinquished by:	Date/Time:	Received by:	Date/Time
Relinquished by:	Date/Time:	Received by:	Date/Time

Controlled Document - Asbestos Bulk R7 09/14/2021

☐ **AGREE TO ELECTRONIC SIGNATURE** (By checking, I consent to signing this Chain of Custody document by electronic signature.)

APPENDIX D
HEALTH AND SAFETY PLAN

East Central Intergovernmental Association EPA Brownfield RLF Cleanup Project: BF97764501 & BIL96709001
Former YMCA Building
480 South 3rd Street
Clinton, IA 52732

Health and Safety Plan

Prepared for:
East Central Intergovernmental Association
7300 Commerce Park
Dubuque, Iowa 52002

City of Clinton
611 South 3rd Street
Clinton, Iowa 52732

Prepared by:
Impact7G, Inc.
8951 Windsor Parkway
Johnston, IA 50131
www.impact7g.com

Date:
5/24/2024

Emergency Contact Information

Site Name: *Former YMCA Building*
Specific Location: *480 South 3rd Street, Clinton, Iowa 52732*

Table 1. Emergency Response Telephone Roster

Contact	Name	Office phone #	Mobile phone #
Local Fire Department	Joel Atkinson, Fire Chief	563.242.0125	[redacted]
Local Hospital	MercyOne	563.244.5555	
Local Police	Kevin Gyrion, Chief of Police	563.243.1455	
Spill Notification	Iowa DNR	515.725-8694	
Impact7G Principal	Mike Fisher	515.473.6256	319.551.1579
Impact7G Project Manager	Jon Reis	515.473.6256	515.231.3719
Impact7G Designated Site Supervisor	Leon Johnson	515.473.6256	515.201.8215
Impact7G Health and Safety Coordinator	Matt Deutsch	515.473.6256	515.802.7466
Client (ECIA) Contact	Dawn Danielson		563-580-1976
Client (City of Clinton) Contact	Tammy Johnson	563-594-6730	563-212-2394
Contractor:			
(Other):			
Poison Control	[redacted]	800-222-1222	[redacted]

Potential Chemicals of Concern:

Potential contaminants that may be encountered during site operations include asbestos, lead (from lead-based paint), and mold. There is potential for asbestos fibers and lead in the air above applicable Permissible Exposure Limits (PELs) or Threshold Limit Values (TLVs) during the course of this cleanup project.

Route to Hospital:

Hospital name: *MercyOne Clinton Medical Center*

Hospital Address: *1410 N 4th Street, Clinton, Iowa 52732*

Hospital Phone Number: *1 + 563.244.5555*

Description of Route to Hospital

Describe Route to Hospital with Both Turn by Turn and Google maps:

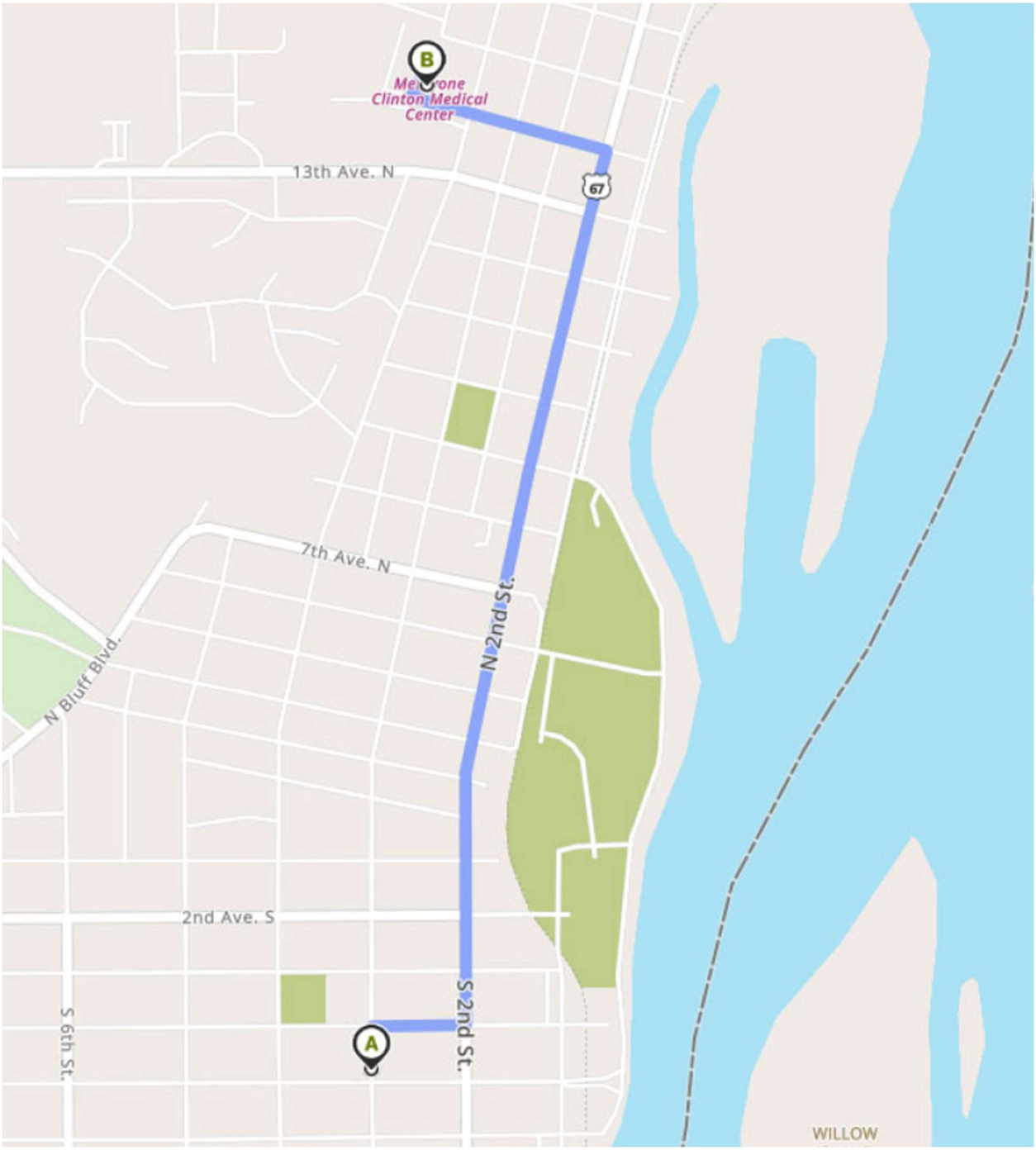
Work Site Name: *Former YMCA Building*

Work Site Address: *480 South 3rd Street, Clinton, Iowa 52732*

- *Head toward 4th Ave S on S 3rd St. (322 feet)*
- *Turn right onto 4th Ave S. (0.1 mi)*
- *Turn left onto S 2nd Street (US-67) (1.2 mi)*
- *Turn left onto 14th Ave N toward Hospital (0.3)*
- *Turn right (187 feet)*

End: MercyOne Clinton Medical Center is straight ahead.

Example Map to Hospital:



Contents

List of Tables

List of Appendices

Health & Safety Plan Review and Approval:

By signing below, it is acknowledged that this HASP identifies the activities that are anticipated to be performed in the field. In addition, this HASP identifies the personal protective and monitoring equipment that may be necessary to be on site and be available for use. It is also understood that the provisions of this HASP will be updated if there is a change of a task and/or the addition of tasks and will be approved by the individuals listed below or their designee.

Mike Fisher Principal-in-Charge	Signature	5/24/24 Date
Jon Reis Project Manager	Signature	5/24/24 Date
Matt Deutsch CSP, CHMM Health & Safety Representative	Signature	5/24/24 Date
Leon Johnson Designated Site Supervisor	Signature	5/24/24 Date
Jon Reis Designated HASP Preparer	Signature	5/24/24 Date
Matt Deutsch CSP, CHMM Designated HASP Reviewer	Signature	5/24/24 Date

This form MUST be signed prior to starting the on-site work. In addition, a copy of this form should be returned to the office Health and Safety Coordinator prior to leaving for the field. After completion of the project, the original signed HASP must be retained in the project file.

Author's Initials: JHR

1 Introduction

This HASP was prepared to inform all Impact7G personnel of known or reasonably anticipated potential hazards and safety concerns at ***the former YMCA Building.*** All personnel participating in field activities must be trained in the general and specific hazards unique to the job they are performing and, if applicable, meet recommended medical examination and/or training requirements. All Impact7G employees shall follow the guidelines, rules, and procedures contained in this site-specific HASP. Impact7G personnel shall contact the Project Manager (PM) if unexpected conditions are encountered at the site, including but not limited to new processes; changes in operation, products, services; additional or changes in the chemicals of concern; and/or unsafe conditions are encountered which were not previously addressed in this HASP.

Each contractor, subcontractor, and visitor shall be expected to review and understand the hazards, risks, and control methods (including emergency procedures) as outlined in this HASP, and sign off on the HASP. This can be accomplished either during the project planning stage or during the first safety briefing on site. However, contractors and subcontractors will be required to prepare their own HASP to address site safety and work hazards associated with their proposed site activities prior to mobilization to the site. In addition, each subcontractor will be required to provide Impact7G with their site-specific HASP, and communicate the types of hazards and control methods associated with their activities to Impact7G during the first safety briefing on site and as conditions change. Relevant Contractor information regarding the identification of hazards and appropriate control strategies for the hazards for their particular job tasks should also be presented and a site-specific HASP should be available for review by all parties. Each contractor or subcontractor must assume direct responsibility for its own employees' health and safety.

Copies of the HASPs will be kept on-site for review and reference during all site activities. Upon completion of the project, the finalized and signed copy of the HASP will be placed in the project file.

1.1 Site Description

The site includes the original 1905 buildings associated with the former YMCA along with a 1962 addition and a 1980 addition. The Client is requesting asbestos abatement activities be completed to remove the health hazard and prepare the property for redevelopment. Any painted surfaces disturbed during asbestos abatement will be presumed to be lead-based paint and treated as such. Identified mold will also be remediated to remove the health hazard.

Project work at the former YMCA will consist of three phases: Phase 1a, Phase 1b, and Phase 2.

<u>Phase 1a</u>

The initial phase of the project will consist of ACM abatement of the three-story original 1905 building (Building A) and Building C1, and separating Building A from the remainder of the structure. To accomplish the separation, Building B1 will be removed entirely. The portion of Building C1 immediately adjacent to Building A will be removed following ACM abatement. As Building B1 is not structurally sound, all debris will be treated as ACM and removed and disposed of as RACM.

Phase 1b

Following ACM abatement and prior to redevelopment, mold remediation will occur in Building A. Mold remediation will not occur immediately as there is no electricity to Building A and water intrusion from the remainder of the structure is a problem. Without the ability to control moisture and temperature in Building A, it would be difficult to limit re-growth of mold if mold remediation was conducted concurrently with asbestos abatement.

Phase 2

The remaining structure (Buildings B2, C2, and C3 and a portion of Building C1) will be removed. As Building C1 will have been abated, debris can be removed and disposed of as general construction debris. Since Buildings Bs, C2, and C3 are not structurally sound, all debris will be treated as ACM and removed and disposed of as RACM.

1.2 Specific Work Activities

The field activities currently underway or planned for the immediate future include the following work activities or tasks:

- *Task 1 – Impact7G will conduct project observation of asbestos abatement at the site.*
- *Task 2 – Impact7G will confirm mold has been physically removed from the site.*

Each of these Tasks are further described as follows:

Task 1 – Asbestos Abatement Observation

Impact7G personnel will provide project observation periodically during asbestos abatement. This task includes observing abatement, monitoring work progress, and collecting air samples to document exposure to asbestos fibers from the abatement. Impact7G will also collect final clearance air samples at the completion of asbestos removal and passing of a visual inspection.

Task 2 – Mold Remediation Confirmation

Impact7G personnel conduct a visual clearance inspection following mold remediation to document removal of the mold.

1.3 Site Safety Requirements

Impact7G personnel will stay out of containment areas unless absolutely necessary for the completion of the project. Although entry of these areas is not expected to be required until asbestos abatement and mold remediation has been completed, any Impact7G field staff entering containment areas must have a current HAZWOPER certification, respirator fit test, and medical monitoring approval (e.g. "Site" training classification), and must wear level C PPE including a half-face air purifying respirator with appropriate P100-rated cartridges for protection from dust, as detailed in Section 7. Impact7G personnel will stay at least 25-30 feet away from large machinery wherever possible. When approaching large machinery, personnel will always make eye contact with the operator before approaching. In addition to any PPE required by the facility, Impact7G personnel will also wear a high-visibility reflective vest at all times when in the vicinity of large machinery. Impact7G employees will not enter confined space areas.

2 Identification of Key Health and Safety Personnel

An efficient on-site operation requires that all key personnel be identified and that their roles and responsibilities be clearly defined. Below is a discussion of the management structure for this project.

2.1 Principal in Charge/Project Manager

Responsibilities include overall coordination of site activities. The Principal in Charge (PIC) and the project manager (PM) have overall accountability and responsibility for the safety of operations and the health and safety of all personnel.

2.2 Health and Safety Representative

The local Health and Safety Representative (HSR) is a resource for the development of the site-specific HASP and will be consulted on all related health and safety issues that arise in the field, including any changes in the scope of work. The Impact7G Health and Safety Representative will make all final decisions regarding questions on the HASP.

2.3 Designated Site Supervisor

The site supervisor is responsible for field-related activities under the direction of the PM and for maintaining field operations in accordance with project requirements. This person is responsible for enforcing daily implementation of the HASP and resolving health and safety issues. In addition, this person will:

- Establish and ensure maintenance of site work zones.
- Monitor the work area and personal breathing zone and ensure compliance of workers relative to pre-established personal protection levels.
- Evaluate site conditions (i.e., weather, chemical, physical) and recommend any modifications to existing levels of protection.
- Ensure that daily safety briefings are conducted and documented in this HASP (see Sections 12 and 13) or in the field logbook.
- Initiate emergency response procedures with immediate communication to the project manager.
- Exercise stop-work authority in the event of imminent danger to project personnel.
- Notify PM of any noncompliance and/or unsafe conditions.
- Conduct regular inspections to determine the effectiveness of the HASP.

2.4 Project Personnel

Project personnel involved in field activities are responsible for:

- Taking all reasonable precautions to prevent injury to themselves and fellow employees.
- Conducting only those tasks that they believe they can do safely.

- Reporting all occurrences and/or unsafe conditions to the supervisor and/or project manager.

Further, any person working on-site has the authority to **stop work** if any operation threatens the health and safety of on-site workers or the surrounding community. In the event that such a situation occurs, the Site Supervisor shall be notified immediately. Impact7G's Site Supervisor will update the Impact7G PIC/PM on all project-related health and safety issues as they arise.

Table 2: Impact7G Personnel Contact Information

Company/Title	Personnel	Office	Cell
Impact7G Principal in Charge	Mike Fisher	515.473.6256	319.551.1579
Impact7G Project Manager	Jon Reis	515.473.6256	515.231.3719
Impact7G Corporate Health and Safety Director	Matt Deutsch	515.473.6256	515.802.7466
Impact7G Project Health and Safety Coordinator	Matt Deutsch	515.473.6256	515.802.7466
Impact7G Designated Site Supervisor	Leon Johnson	515.473.6256	515.201.8215
Client (ECIA) Contact	Dawn Danielson		563.580.1976
Client (City of Clinton) Contact	Tammy Johnson	563-594-6730	563.212.2394

Table 3: Contractor/Subcontractor Contact Information

Company/Title	Personnel	Office	Cell

3 Medical Surveillance Requirements

Surface and air contamination may be encountered during the course of this investigation. All Impact7G personnel participating in this project shall be enrolled in a health-monitoring program in accordance with the provisions of OSHA 29 CFR 1910.134 and 29 CFR 1926.62. Each project participant shall be certified by a Doctor of Medicine as fit for respirator and semi-permeable/impermeable protective equipment use. All personnel shall have received an environmental physical examination within one year prior to the start of project activities. A consulting physician will determine the content of the physical examinations.

Follow-up medical examinations will also be provided in the event of job site injury or unprotected exposure to contaminants in excess of eight-hour time-weighted average permissible exposure limits. The Impact7G Corporate Health & Safety Director will maintain certificates of medical examinations.

4 Employee Training Requirements

All Impact7G personnel participating in this project must have completed 40-hour Hazardous Waste Operations (HAZWOPER) Training and at least three days of supervised field activity per requirements of OSHA 29 CFR 1910.120. In addition, a current 8-hour annual refresher-training will be required for all field personnel. The Impact7G Corporate Health & Safety Director will maintain training certificates for all project personnel at the Johnston Office. The Site Supervisor or other Impact7G site participant shall maintain a current certificate in basic First Aid training as provided by the American Red Cross. First Aid Guidance is included in Appendix D.

Per the scope of this project, Impact7G personnel performing asbestos abatement oversight will maintain a State of Iowa Contractor/Supervisor license. Copies of licenses will be kept in the project folder within the field vehicle, on each person, or be available digitally during the project.

Prior to the start of site activities, all Impact7G project personnel will participate in a pre-project safety and health briefing outlining the contents of this HASP. The personnel responsible for project safety and health will be addressed, as will site history, scope of work, site control measures, emergency procedures, and site communications. Daily "tailgate" safety and health briefings will be presented by the Site Supervisor at the start of each workday. Records of safety and health briefings will be maintained for the duration of this project.

Subcontractors under the direction of Impact7G are not anticipated to be necessary as part of this project.

5 Hazard Evaluation

The Project Hazard Analysis below identifies the hazards anticipated to be encountered by the project team based on the tasks presented in Section 1.2.

Table 4: Project Hazard Analysis

Chemical Hazards Present: ☐ None	☐ Flammable/combustible ☐ Compressed gas ☐ Explosive ☐ Organic peroxide ☐ Oxidizer ☐ Water-reactive ☐ Unstable reactive ☒ Dust/Fumes/Particulates	☐ Corrosive ☐ Toxic ☐ Highly Toxic ☐ Irritant ☐ Sensitizer ☐ Carcinogen ☐ Mutagen ☐ Other:
Physical Hazards Present: ☐ None	☒ Heat ☒ Cold ☒ Walking/working surfaces ☐ Visible Dust ☒ Traffic/Vehicles ☒ Noise ☐ Other:	☐ Ionizing radiation ☐ Non-ionizing radiation ☐ Electricity ☒ Severe Weather ☒ Poor lighting ☒ Overhead Hazards
Impact7G Instrument/Equipment Hazards Present: ☐ None	☒ Heavy machinery/ Drill Rigs ☐ Trenching/excavation ☐ Docks-marine operations ☐ Docks-loading ☐ Drilling ☐ Forklifts ☐ Operations on Water ☒ Elevated heights (includes fall protection) ☐ Overhead/Underground utilities ☐ Confined spaces ☐ Power tools	☐ Cranes/Hoists/Rigging ☒ Ladders ☐ Scaffolding ☐ Manlifts ☐ Gas cylinders ☐ Roadway work ☐ Railroad work ☐ Energized equipment (LO/TO) ☐ Pressurized equipment (LO/TO) ☐ Drums and containers ☐ Others:
Biological Hazards Present: ☒ None	☐ Animal/human fluids or blood ☐ Animal/human tissue(s) ☐ Poisonous/irritating plants ☐ Other:	☐ Contaminated needles ☐ Live bacterial cultures ☐ Insects/rodents/snakes ☐ Other:
Ergonomics Hazards Present: ☒ None	☐ Repetitive motion ☐ Awkward position ☐ Heavy Lifting ☐ Frequent Lifting	☐ Limited movement ☐ Forceful exertions ☐ Vibration ☐ Other:
Personal Safety/Security: ☐ None	☒ Personal safety ☒ Security issue ☐ Project site in an isolated area ☒ Employees working alone ☒ Wild/Feral Animals	☐ Employees working early/late ☐ Potentially dangerous wildlife ☐ Guard or stray dogs in area ☐ No/limited cell phone service ☐ Other:

5.1 Specific Chemicals of Concern

The chemicals listed in the table below include the identification of chemical contaminants known and/or suspected of being present on-site, the affected media, known concentrations (if applicable), the Permissible Exposure Limit (PEL) or Threshold Limit Value (TLV), and the Action Level (i.e., 50% of the PEL/TLV). This information will be inserted into Table 5 below. In addition, Appendix A contains specific hazardous property information for commonly encountered chemicals although a Material Safety Data Sheet (MSDS) (or equivalent) will also be included in Appendix A.

Table 5: Chemicals of Concern

Chemical	Environmental Media[1]	Highest Measured Concentration	PEL/TLV[2]
Asbestos	Air / Building Components, unlikely to exceed limits during sampling using appropriate sampling procedures.		1 fiber/cc PEL-TWA OSHA
Lead (from Lead-Based Paint)	Air or Surface / Building Components		50 µg/m^3 – 8-hr TWA OSHA PEL 30 µg/m^3 – OSHA Action Level

Notes:

[1] Codes for environmental media: **SL**=Sludge; **GW**=Ground Water; **SW**=Surface Water; **LW**=Liquid Waste; **SO**=Soil; **A**=Air; **OTH**= Other (Specify)

[2] PEL: Permissible Exposure Limit / TLV: Threshold Limit Value, use appropriate PEL which would be country or state specific or if one is not available may be from a recognized source.

mg/m^3: milligrams per cubic meter
mg/kg: milligrams per kilogram
ppm: Parts per million
%: Minimum percent allowed for personal entry into a space

5.2 Physical Hazards

The potential physical hazards of concern anticipated during site work are listed in Tables 4 and 6. Personnel should be aware that as personal protective equipment increases, dexterity, and visibility may be impacted and performing some tasks may be more difficult.

At any site, the potential exists to encounter unknown materials such as sharp or jagged debris, broken glass, or rusty metal which can pose puncture and potential laceration hazards.

Physical hazard exposures were estimated using process knowledge and experience from similar projects.

5.3 Biological Hazards

Surface biological hazards such as disease-causing microorganisms (bacteria, fungus, viruses) are expected to exist at the site. Disease-carrying, biting insects could be encountered on-site. Rodents, wild dogs, raccoons, and other wild animals, which could bite or carry disease, are not anticipated at the project location.

5.4 Other Site Specific Hazards

Tailgate safety meetings will include a discussion of other possible site-specific safety hazards, and will address emergency procedures for evacuation, notification of emergency response agencies, and assembly checkpoints.

Table 6: Biological and Physical Hazards

Name of Physical Hazard	Source	Exposure Level/Potential	Exposure Limit
Utilities (elect., gas, water, etc.) Overhead/Underground	Operations	Unlikely	N/A
Other (Please Specify)	Unstable portions of building	Likely	N/A
Other (Please Specify)	Uneven surface	Likely	N/A
Other (Please Specify)	Sharp Objects	Likely	N/A
Electrical	Operations	Unlikely	N/A
Heat (Ambient)	Operations	Unlikely	N/A
Inclement Weather	Operations	Likely	N/A
Material Handling	Sample	Likely	N/A
Motion of Machinery (Struck by Hazards)	Operations	Unlikely	N/A
Noise (Sound Pressure Level), dBA	Operations	Likely	90 dBA TWA OSHA
Rolling or Pinching Objects	Operations	Unlikely	N/A
Slips/Trips/Falls	Operations	Likely	N/A
Traffic-On or Near Site	Operations	Likely	N/A
Mold	Operations	Likely	N/A

6 Hazard Controls

A general summary of the hazards and an evaluation of those hazards are presented below. More detailed control procedures are provided in Appendix B or in another section of this HASP as indicated in Table 7.

Table 7: Summary of Hazards

Task Number(s)	**Hazards**	**Relative Hazard /Risk Rating***	**Hazard Controls** Appendix and/or HASP Section
1/2	Chemical	NA☐ Low☒ Medium☐ High☐	B1
1/2	Physical	NA☐ Low☐ Medium☒ High☐	B2
	Mechanical	NA☒ Low☐ Medium☐ High☐	B3
1	Traffic/Equipment	NA☐ Low☒ Medium☐ High☐	B4
1/2	Electrical Hazards	NA☐ Low☒ Medium☐ High☐	B5/B18
1/2	Fire/Explosion	NA☐ Low☐ Medium☒ High☐	B6
1	Noise (Acoustical)	NA☐ Low☐ Medium☒ High☐	B7
1/2	Ventilation / Oxygen Deficiency	NA☐ Low☒ Medium☐ High☐	B8
1/2	Heat Stress	NA☐ Low☐ Medium☒ High☐	B9
1/2	Cold Stress	NA☐ Low☐ Medium☒ High☐	B10
1/2	Insects, Spiders, Snakes	NA☐ Low☒ Medium☐ High☐	B11
	Poisonous Plants	NA☒ Low☐ Medium☐ High☐	B12
1/2	Personal Safety	NA☐ Low☒ Medium☐ High☐	B13
1/2	Working Alone	NA☐ Low☒ Medium☐ High☐	B14
1/2	Severe Weather	NA☐ Low☒ Medium☐ High☐	B15
1	Above and Underground Utilities	NA☐ Low☒ Medium☐ High☐	B16 & Sections 6.2 - 6.3
	Trenching/Excavation	NA☒ Low☐ Medium☐ High☐	Use Comprehensive HASP
	Water Safety	NA☒ Low☐ Medium☐ High☐	Use Comprehensive HASP
1/2	Ergonomics / Material Handling	NA☐ Low☒ Medium☐ High☐	B17
	Power Tools	NA☒ Low☐ Medium☐ High☐	B18
1/2	Vehicle Use	NA☐ Low☐ Medium☒ High☐	B19
	Seasonal Hunting	NA☒ Low☐ Medium☐ High☐	B20
	Demolition	NA☒ Low☐ Medium☐ High☐	Use Comprehensive HASP
	Unexploded Ordinances	NA☒ Low☐ Medium☐ High☐	Use Comprehensive HASP
	Closed/Abandoned Mines	NA☒ Low☐ Medium☐ High☐	Use Comprehensive HASP
	Confined Space	NA☒ Low☐ Medium☐ High☐	Use Comprehensive HASP
	Spills	NA☒ Low☐ Medium☐ High☐	Use Comprehensive HASP

NOTE: A single hazard may be listed under several Tasks. In this case, use the highest Severity ranking of the tasks evaluated as the overall ranking.

Table 8: *Hazard/Risk Matrix Decision Table

The Hazard…	Has No Severity	Has Minimal Severity	Has Moderate Severity	Has High Severity
Is Not Present (i.e., 0% of your on-site time does not expose you to this Hazard)	NA	NA	NA	NA
Is Rarely Present (i.e., <25% of your on-site time exposes you to this Hazard)	NA	LOW	LOW	MED
Is Sometimes Present (i.e., 25% - <50% of your time exposes you to this Hazard)	NA	LOW	MED	HIGH
Is Frequently to Constantly Present (i.e., 50% to 100% of your time exposes you to this Hazard)	NA	MED	HIGH	HIGH

*Relative Risk Rating Scale takes into account the frequency of the hazard and the severity of the injury the hazard can cause to employees without regard to PPE usage. In general,

- Minimal Severity requires first aid;
- Moderate Severity requires professional medical attention; and
- High Severity requires immediate medical attention/life-threatening.

6.1 General Subsurface Clearance Requirements

If the tasks presented in this HASP involve subsurface work, Table 9 and the specific procedures outlined in Section 6.2 are applicable and must be followed. Table 9 summarizes the steps required to be completed, including justification of any exceptions. This table must be completed in its entirety prior to conducting subsurface work.

Table 9: Subsurface Clearance (SSC) Actions

Subsurface Clearance (SSC) Pre-Project Planning Checklist Document the steps that must be followed and justify any exceptions. This checklist MUST be completed in its entirety.					
	SSC Requirements	**Yes**	**No**	**NA**	**Comments**
1	Prequalification of Contractor for the capability of ground disturbance work performed (See Section 6)	☐	☐	☒	No subsurface work will be completed as part of this project.
2	"Designated Person" for SSC work assigned (must be on-site)	☐	☐	☒	No subsurface work will be completed as part of this project.
3	Historical Site Information Review	☐	☐	☒	No subsurface work will be completed as part of this project.
4	Development of site-specific plot plan	☐	☐	☒	No subsurface work will be completed as part of this project.
5	Ground penetrating location marked prior to locate(s) and alternate locations chosen	☐	☐	☒	No subsurface work will be completed as part of this project.
6	Service notifications provided to clear/locate **public** utilities	☐	☐	☒	No subsurface work will be completed as part of this project.
7	**Private** locate contracted for on-site utilities	☐	☐	☒	No subsurface work will be completed as part of this project.
8	Designated Person present during private locating	☐	☐	☒	No subsurface work will be completed as part of this project.
9	Underground utilities identified prior to commencement of intrusive activities as reasonably feasible	☐	☐	☒	No subsurface work will be completed as part of this project.
10	Site walkover conducted to assess utility locations, visual indicators and complete SSC Field Checklist	☐	☐	☒	No subsurface work will be completed as part of this project.
11	Ground penetration locations(s)/area(s) and Critical Zones (i.e., the 5ft or 1.5m distance surrounding intrusive activities in every direction) cleared	☐	☐	☒	No subsurface work will be completed as part of this project.

6.2 Specific Subsurface Clearance (SSC) Procedures

The hazards posed by the presence of underground and overhead services are significant. Where there is a requirement for ground penetrating activity, the work shall be thoroughly vetted prior to commencing subsurface work. No intrusive work is to be conducted until the hazards associated with the possible presence of underground and overhead services have been properly identified, and safe locations for intrusion marked and agreed upon. This applies to any intrusive site work (i.e., any work which will involve the disturbance or penetration of the ground or

manmade surface by mechanical or manual means, INCLUDING: trial pit excavations, borehole excavations (shell and auger, rotary, hydraulic, percussive), gas spiking, manual excavations, hand digging, intrusion into vertical, indoor, or below ground surfaces, and/or any other on-site activity where disturbance of the ground surface is required). If conducting intrusive activities, the following tasks must be completed **and documented** prior to initiating ground disturbance activities (each is summarized below):

6.2.1 Historical Site Information Review

Obtain the most recent as-built drawings and/or site plans (including underground storage tank (UST), product and vent lines), as available. Consider requesting any other site plot plans, surveys, photographs, and information that might be instructive from the Client or other sources. Site information reviewed shall be specified in Table 9 SSC Actions (above).

6.2.2 Plot Plan

Develop a plot plan the accurately reflects all available information and site conditions as accurately as possible, including the number of facilities/pipelines or utilities, locations and alignments. The plot plan shall be updated as SSC activities commence to properly capture site-conditions or visual indicators. Intrusive activities shall not proceed without an updated plot plan or drawing.

6.2.3 Pre-Marking Ground Disturbance Locations

Whenever feasible, ground disturbance locations and/or areas shall be pre-marked using white stakes, white paint or white flags (or black in cases where snow is on the ground) prior to the public and/or private utility mark-outs. Pre-marking provides the line locators with visual boundaries as guidance in clearing locations and placing marks.

6.2.4 Line Location Services

In areas where public and private resources are available, **Impact7G will contact both public and private utility locate services for any project that involves intrusive activities.** In order to give line operators sufficient time to respond to a request to locate, a minimum of 72 business hours is required prior to the planned start of work. In the event that the driller/excavator retains these services, Impact7G will conduct a follow-up to confirm utility locate information.

Meet directly with the private locator and provide them with location plans, if possible. If an on-site meeting with the private locator is not possible, you MUST contact the private locator so that they understand the scope of the proposed subsurface work and the extent of their activities.

6.2.5 Site Walkover-Visual Indicators

The Designated Person MUST conduct a site walk-over and complete the SSC Field Checklist (Appendix C) for all projects that involve ground disturbance. The site walk-over and visual inspection is most effective when completed during locating activities, but, at a minimum, must be completed PRIOR to ground disturbance. The main intent of the SSC Field Checklist is to

identify above ground indicators which may identify the potential existence of a subsurface issue. It will also be used to confirm that common utilities have been accounted for, located and verified. Any potential underground utilities should be marked on a site plot plan and the site walkover should be documented utilizing Impact7G's Subsurface Clearance Field Checklist.

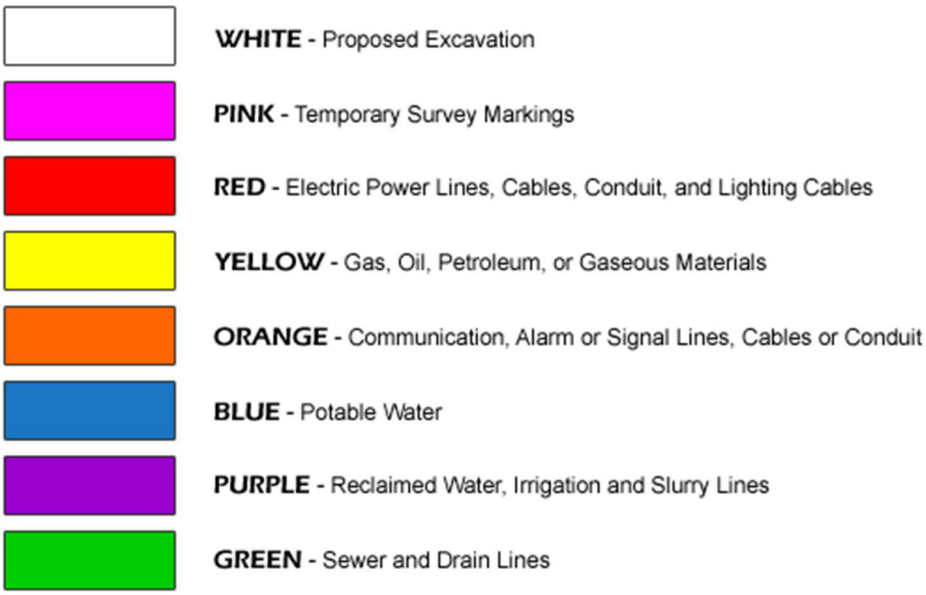
6.2.6 Utility Mark-out

All known pipelines and utilities, as noted on the plot plan, pipeline map or drawing, that pass within the search zone must be located, identified and marked to indicate location and alignment.

A qualified and competent line locator shall conduct line-locating practices utilizing available pipeline maps or plot plans for all areas within the search zone. Direct connection (clamping on) to all possible nearby underground services should be undertaken whenever possible to increase the success rate/reliability in locating. **The specific ground penetration location must be cleared to the edge of the critical zone** (5 feet or 1.5m area surrounding intrusive locations/areas in every direction) using a search and sweep method to verify maximum detection capabilities.

If anticipated services are not identified or located, drilling or ground disturbance will not occur until the service is visually identified.

Commonly used utility mark-out colors and identifiers are listed below:



Upon completion of their work (whether you are on-site or not), the private locator MUST contact you to present their results. In addition to providing you with an overall summary of their work, **they must also inform you of any unique circumstance(s) that limited their ability to locate the potential presence of underground utilities (e.g., the existence of overhead**

electrical lines); if they encountered any abnormalities (e.g., concrete surfaces with reinforced rebar); and/or any other condition which may have diminished the validity of their results and efforts.

Where doubt exists over the location of a service, request a site visit from the appropriate utility provider or abandon locations in the immediate area and contact the PM and/or PIC.

6.2.7 Clearance of Ground Disturbance Locations & Critical Zones:

After anticipated utilities have been located and marked, use the available information along with regulatory requirements and project objectives to select final ground disturbance locations.

Each specific ground penetration location must be cleared to the edge of the critical zone (5 feet or 1.5m area surrounding intrusive locations/areas in every direction) using a search and sweep method to verify maximum detection capabilities. Ensure that all detected services and those featured on location plans are outside of the critical zone of EACH location where intrusive work will occur, using a sweep and search method.

The critical zone takes into account minimum tolerance distances from facility lines (which vary by location) and uncertainties introduced by on-site conditions, human factors, and equipment. **No intrusive activities shall take place within a critical zone with which utilities or visual indicators intersect**. When known utilities intersect ground disturbance critical zones, boring and/or excavation location criteria should be reevaluated by the Designated Person and PM, and if possible, moved to a pre-cleared alternate location.

In the event that work is required to be conducted in a critical zone containing a marked utility or visual indicator, approval MUST be obtained from the PIC, PM and H&S Director prior to ground penetrating activities.

6.2.8 Overhead Lines

Ensure that any ground penetrating activities are located a minimum of 28 feet (9m) horizontally from any overhead electric cable-supported wooden poles, or 50 feet (15m) horizontally in the case of those supported on metal poles/towers. Where this cannot be achieved, contact the appropriate electricity provider for guidance as well as the PIC/PM and Director H&S.

7 Personal Protective Equipment

This section of the Site Health and Safety Plan is a reference of selection for different levels of Personal Protective Equipment (PPE). The protective equipment will be selected based on the contaminant type(s), concentration(s) in air (if any), standing liquid (if any), or other applicable matrix, and the known route(s) of entry into the human body.

Table 10: Task Specific PPE

Task Description	Level of Protection			
	A	B	C	D
Asbestos Abatement Observation	☐	☐	☒	☐
Mold Remediation Confirmation	☐	☐	☒	☐

Key:
Level D: Long sleeve shirt*; long pants*; hard hat; eye protection; hearing protection; and safety shoes.
Level C: Level D protection plus negative pressure respiratory protection with appropriate cartridges; chemical protective coveralls in lieu of general coveralls; use of inner and outer sets of hand protection.
Level B: Level C protection plus Pressure-demand supplied air respirator with escape bottle in lieu of negative pressure respirator; chemical resistant coveralls with hood; chemical resistant boots.

Level A: Level B protection plus fully encapsulating (gas tight) chemically resistant suit.

*Clothing made of natural fibers shall be worn when a shock or arc flash hazard exists.

Key: **Req** = Required; **Rec** = Recommended; **NA** = Not Applicable

Table 11: Personal Protective Equipment and Supplies Specific PPE

Equipment	Req	Rec	NA	Equipment	Req	Rec	NA
Steel-toe Boots	☒	☐	☐	SCBA	☐	☐	☒
Outer Disposable Boots	☐	☒	☐	Full-face Airline Resp.	☐	☐	☒
Long Sleeve Shirt and Pants	☐	☒	☐	Full Face Negative Pressure Resp.	☐	☐	☒
Flame Retardant Coveralls	☐	☐	☒	Half Face Negative Pressure Resp (required if potential fiber releases during sampling)	☒	☐	☐
Tyvek Suit	☐	☒	☐	Powered Air Purifying Resp	☐	☐	☒
Poly-coated Tyvek / Saranex Suit	☐	☐	☒	First Aid Kit	☒	☐	☐
Fully Encapsulated Chemical Suit	☐	☐	☒	Fire Extinguisher	☐	☒	☐
Hearing Protection	☐	☒	☐	Mobile Phones	☒	☐	☐
Leather Gloves	☐	☐	☒	Walkie Talkies	☐	☐	☒
Outer Chemical Gloves (Type): Nitrile	☐	☒	☐	Water or Other Fluid Replenishment	☒	☐	☐
Inner Chemical Gloves (Type):	☐	☐	☒	Eye Wash	☐	☐	☒
Hard Hat	☐	☒	☐	Sunscreen	☐	☐	☒
Safety Glasses with Side Shields	☐	☒	☐	Insect Repellent	☐	☐	☒
Vented (Splash proof) Goggles	☐	☐	☒	Other:	☐	☐	☒

8 Air Monitoring/Sampling Procedures

Conducting an applicable task may necessitate using one or more monitoring devices as listed in Table 12, particularly if gases, vapors, explosion hazards and/or oxygen deficient atmosphere can occur or are expected. If a monitoring device will be utilized, the corresponding device letter should be placed in the column labeled "Monitoring Instrument Required" in Table 13.

Table 12: Monitoring Devices Available

A	PID (10.6 eV)	H	Summa Canister
B	PID (11.7 eV)	I	Heat Stress Monitor
C	FID	J	Low Flow Pumps
D	OVA	K	High Flow Pumps
E	CGI/LEL	L	Radiation Detector
F	Colorimetric Indicator Tubes	M	Gas Multimeter
G	Dust Monitoring	N	Other Device:

With respect to Table 12, also insert the task and the applicable Action Level in the appropriate box using 50% of the most restrictive (lowest) PEL or TLV as the Trigger. For example, if the most restrictive PEL for a particular VOC is 50 ppm, use 25 ppm as the "Trigger" value.

Table 13: Required Monitoring

Required Monitoring **If monitoring is necessary to identify that a risk is at or above tolerable limits and/or is used in controlling a risk on site, document the task and the maximum allowable exposure or trigger, and the monitoring instrument required to be used.**	**Constituent**	**Task(s)**	**Trigger (action level)**	**Monitoring instrument required**
	Asbestos	1	1 fiber/cc	J
	Oxygen		19.5% to 23.5%	
	Carbon Monoxide		25 ppm	
	H_2S		5 ppm	
	C_2S			
	CH_4		0.5% or 5000 ppm	
	VOCs: Total		0.5 ppm	
	Semi - VOCs:			
	Metals			
	Dusts			
	Others:			
	Others:			

Note:

8.1 Action Level Guidance

In general, this HASP must address site-specific chemicals as noted in Table 13. However, there are chemicals commonly encountered in the workplace that may not be a chemical targeted for sampling but nonetheless will have adverse health effects. These chemicals are listed in Table 14 below.

Table 14. Action Levels for Commonly Encountered Compounds

Compound	Action Level
Volatile Organic Compounds (as Benzene)	0.5 ppm MAXIMUM
Methane (CH_4)	0.5% MAXIMUM or 5000 ppm
Carbon Dioxide (CO_2)	0.25% OR 2500 ppm MAXIMUM
Carbon Monoxide (CO)	25 ppm MAXIMUM
Hydrogen Sulfide (H_2S)	5 ppm MAXIMUM
Oxygen (O_2)	19% MINIMUM – 23.5% MAXIMUM

8.2 Odors

If strong odors are encountered or if personnel develop headaches, dizziness or other potential exposure symptoms, the personnel shall leave the work area to a well-ventilated area and contact the PM and HSR for further instructions.

8.3 Dusts

The permissible exposure levels for total and respirable dusts are 15 and 5 mg/m^3, respectively. In general, at these concentrations, you will not be able to read the face of a wristwatch (with your arm extended) when the total dust concentration reaches 15 mg/m^3. Particles of dust in the respirable size range cannot be seen without the aid of a microscope but in aggregate, may be perceived as a haze. More importantly and with few exceptions, when dust is noticeable in the air, more respirable particles will exist than larger particles.

Typically, controlling dusty investigative activities through the use of a water sprayer will control potential exposures. However, in the event that dusty conditions exist that are not related to investigative/remedial activities (dry, uncovered soils with high winds), personnel shall leave the area and contact the PM and HSR for further instructions.

9 Decontamination

9.1 Sampling and Construction Equipment Decontamination

Decontamination involves the orderly controlled removal of contaminants. All undedicated sampling equipment and sampling meters (if applicable) will be cleaned prior to and between each use. All on-site equipment will be decontaminated and allowed to air dry before leaving the site. Decontamination may be accomplished using an approved cleaner, water, and steam. Subcontractors will be responsible for decontamination of their own equipment used during field operations, as well as disposal of any decontamination fluids.

9.2 Personnel Decontamination

All site personnel should minimize contact with contaminants. All disposable PPE will be containerized in an approved asbestos disposal container (including respirator cartridges). Non-disposable PPE must be decontaminated, particularly the safety boots. Any PPE that cannot be decontaminated should be disposed of along with waste generated from field operations. The container will be sealed and labeled appropriately, stored at a single secure location on the site, and be disposed of appropriately off-site.

Personnel shall wash and remove PPE prior to leaving the site. At a minimum, gross removal of contaminants from the PPE, removal of the PPE, and washing of hands and face shall be required upon exiting the work area.

During emergencies, the need to quickly respond to an accident or injury must be weighed against the risk to the injured party from chemical exposure. It may be that the time lost or additional handling of an injured person during the decontamination process may cause greater harm to the individual than from the exposure that would be received by undressing that person without proper decontamination. The decision must be made by the HSR.

9.3 Investigation Derived Material Disposal

1. Decontamination solutions: Not expected to be generated
2. Used disposable PPE such as boot covers: Appropriately disposed of in accordance with facility instructions

10 Site Communications

Communication between personnel within the project areas will be via verbal communication or hand signals. Visual contact between members of task teams should be possible throughout the course of project activities. Contact with the Impact7G Site Supervisor will be through direct verbal communication. The hand signals listed below will be used by personnel wherever respiratory protection and/or equipment noise limit verbal communication.

Signal	Meaning
Thumbs up	Ok, all is well
Grab throat with both hands	Can't breathe
Shake head, thumbs down	No, negative
Point right when facing equipment operator	Move/steer left
Point left when facing equipment operator	Move/steer right
Grab partner's wrist	Leave area immediately

11 Emergency Response Plan (ERP)

NOTE: Specific emergency contact information and applicable directions to the nearest medical facility are contained in Appendix B (i.e., the FIRST AND LAST PAGES of this HASP). In the event that an emergency situation occurs, SECURE the safety of yourself and those working under your direction and then contact the appropriate site and Impact7G representatives that are referenced in Section 2.4 of this HASP.

11.1 Stop Work Authority

All Impact7G employees have the authority and obligation to stop any task or operation where concerns and/or questions regarding the control of HSE risk exist, are not clearly established, or are not understood. Management is responsible for creating a culture where Stop Work Authority is exercised freely and without fear of retribution or intimidation.

When an unsafe condition is identified, a Stop Work intervention will be initiated and treated as a "near miss". As such, an incident report will be completed in accordance with Standard Practice Instruction (SPI) 19 entitled "Incident Reporting" so that the unsafe condition can be documented, reviewed, and corrective actions and preventative measures be implemented as applicable.

These actions will be coordinated by the Site Supervisor, with support from the PM or PIC and the HSR, and all affected personnel will be notified of the Stop Work issue. No work will resume until all Stop Work issues and concerns have been adequately addressed. Most issues can be resolved in a timely manner at the job site, but occasionally additional investigation and corrective actions may be required. Work may resume when it is safe to do so.

11.2 General Emergency guidelines are as follows:

11.2.1 First Aid Procedures

Each field project should have a first aid kit available for use. The contents of which should be based on the treatment of the following potential injuries: major wounds, minor wounds (cuts and abrasions), minor burns and eye injuries including protective gloves, breathing barrier, eyewash solutions, and bandages. Since each workplace is unique, additional first aid products should be selected to augment required contents based on the particular work environment.

If an employee is injured, general first aid will be administered. If safety concerns or hazardous conditions are still present, the individual shall be moved to avoid further injury or risk. In the event that an employee is injured in a contaminated area, general first aid will be administered and then the employee will be moved to the support zone for decontamination (if applicable), additional first aid, and preparation for transportation, giving due consideration to which risk will be greater; the spread of contamination or the health/safety of the individual.

11.2.2 Fire Procedures

In the event of a fire, the Client contact and/or the local firefighting authorities shall be immediately notified. If safe and feasible, a fire extinguisher may be used to attempt to extinguish

the fire. Upon depletion of one fire extinguisher, all personnel shall evacuate the area and await local fire fighters.

11.2.3 Spill Procedures

If warranted, before any work is initiated at the site, applicable local, state, and/or Federal Emergency Response Authorities will be identified by the preparer of this HASP. In the event of a spill, the Client contact shall be immediately notified. If possible and feasible, attempts should be made to contain the spill. If it is determined by consultation with the PM and Client contact that there is no apparent threat to the population or environment, arrangements should be made with a commercial cleanup company to mitigate the spill.

11.2.4 Uncovering an Underground Service (Intact)

In the event of any damage or dislocation of any underground facility/pipeline or utility in connection with ground disturbance activity, work activities shall cease in the area of the damaged facility. The Designated Person shall immediately call the applicable emergency phone number. Then, the affected utility and One Call service shall be notified, if applicable. The One Call service may be able to assist with contact numbers for notifying member companies in the event of any damage. NO ONE should attempt to repair, clamp or constrict the damaged utility.

ALWAYS ASSUME THAT ANY UNDERGROUND PIPE OR SUBSURFACE LINE IS LIVE!

- Stop Work; remove tools if safe to do so.
- Clear all persons from the scene.
- Call the emergency number.
- Contact the One Call/utility member for guidance, if applicable.
- Contact the PM and/or PIC so they can contact the Client, MP, Director of H&S and HSR.

11.2.5 Striking an Underground Electrical/Telecom Cable

- Stop work, remove tools ONLY if safe to do so (operator seats in excavators are normally electrically isolated ALTHOUGH OTHER PARTS MAY BE LIVE IF STILL IN CONTACT WITH A LIVE CABLE).
- Evacuate the immediate area.
- In the event of injuries provide first aid and summon medical assistance.
- Contact the site contact.
- Contact the PM/Director and HSR.
- Contact the electricity/telecom provider, as directed by site contact and/or PM.
- Do not allow anyone to enter the area of the excavation until the electricity provider has made the cable safe.

11.2.6 Striking a Pressurized Gas Pipeline

- Stop work, leave tools in-place but shut off any running equipment, including engines.
- Evacuate the immediate area.
- Ensure there are no sources of ignition in the area.
- Contact the site contact.
- Contact the PM/Director and HSR.
- Contact the pipeline owner, as directed by site contact and/or PM.
- Do not re-enter the immediate area until safe to do so.

11.2.7 Striking a Pressurized Water Main

- Stop work, remove tools if safe to do so, and if necessary and safe to do so, confine jetting water, if appropriate.
- Evacuate the immediate area and inform site personnel.
- Ensure that water flowing away is not creating potential hazards (e.g., electrical shorting, flooding, contaminant migration etc) and where possible warn those likely to be affected.
- Contact the site contact.
- Contact the PM/Director and HSR.
- Contact the pipeline owner, as directed by the site contact and/or PM.
- Do not re-enter the immediate area until safe to do so.

11.3 Incident Reporting

With respect to incidents, the following types of EHS incidents are to be reported:

- All employee injuries and illnesses that include first aid, doctor/hospital visits which may or may not involve restricted work and/or lost time;
- Environmental incidents and exposures, such as spills or other unplanned releases to the environment or nonconformance to operating procedures;
- All evacuations (false or real);
- Any Property damage;
- Near miss incidents which could have resulted in an injury, an accident, environmental impact or significant loss of facilities;
- Public/third party liability - Incidents that involve injury, illness or property damage due to the actions of any non-Impact7G employee arising out of, or in connection with the Firm's contracted scope of work, operations, products, or premises.

All of the incident types outlined above MUST be communicated by the affected employee or an Impact7G employee witnessing the incident to either the local HSR, PM, or PIC immediately

following the incident, either in person or via phone, e-mail, or text messaging. This contacted person will then ensure that the other core project members, plus the Director of H&S, and the Managing Principal are informed either in person or via phone, e-mail, or text messaging, regardless of time of day. The PIC will notify the Client of the incident as appropriate in a timely fashion. In the event, an employee is killed on the job or suffers a work-related hospitalization, amputation, or loss of an eye the applicable regulatory agency will be notified by the Director of Health and Safety.

In the event of an incident, an Incident Investigation Report form will be forwarded for completion by the affected employee and sent to the core project members (i.e., the local HSR, PM, or PIC), the Director of H&S, and the Managing Principal for preliminary root cause analysis. The root cause analysis will not be deemed complete until input from the Director of H&S and the Managing Principal (and others as necessary) has been obtained. Similarly, the implementation of any corrective/preventive actions will NOT be implemented until input from the Director of H&S and the Managing Principal (and others as necessary) has been obtained.

12 Health and Safety Plan Field Team Signatures

Sign off sheet attesting that the HASP has been made available and reviewed by the individual prior to entry into the site.

I have read, understood, and agree with the health and safety protocols presented in the Health and Safety Plan (HASP) and the information discussed in the health and safety briefing. I also understand that noncompliance with the HASP may result in dismissal from the site.

Printed Name	Title	Company	Signature

Date: _____ Time: _____

Location: _____

Conducted By: _____

Signed By: _____

13 Safety Meeting Checklist

The Site Supervisor should consider discussing the following topics with all field personnel conducting work as part of this HASP, as applicable.

Date and Time of Meeting:_____

Conducted By: _____

CHECK TOPIC(S) DISCUSSED:

HASP Content
- Chemicals of Concern
- Tasks to be Performed
- Location of Tasks
- Hazards/Risks of Tasks
- Site Limitations (e.g., cell phone use)

HASP Content
- Personnel On-Site (Introductions)
- Responsibilities
- Monitoring equipment
- Other _____
- Other _____

First Aid
- Facilities
- Reporting and Records
- Treatment of _____

Industrial Sanitation and Hygiene
- Drinking water
- Restrooms/Porta toilets
- Personal Cleanliness

Personal Protective Equipment
- Glasses, Goggles, and Shields
- Hard Hats
- Respirators
- Gloves
- Other _____

Housekeeping
- Waste Containers
- Waste Materials
- Other _____

Emergency Procedures
- Communications
- Primary Rally Point:
- Secondary Rally Point:
- Headcount
- Hospital Location/Route
- PPE/Decon
- Other _____

Fire Prevention
- Extinguisher Locations
- Designated Smoking Areas
- Hot Work
- Flammable Liquids Present
- Explosives Present
- Other _____

Special Tools / Equipment
- Chain saws / Chop saws
- Other _____
- Other _____

Vehicles/Heavy Equipment
- Transportation of Employees
- Operation and Inspection
- Preventative Maintenance
- Other _____

Discussion_____
_____
_____

Appendix A
Chemical Information and Material Safety Data Sheets

Hazardous Property Information

Check if Present	Material (CAS #)	Water Solubility [a]	Specific Gravity	Flash Point °F)	Vapor Pressure [d]	LEL UEL	OSHA - Cal/OSHA PEL- TWA [f]	IDLH Level [h]	Odor Threshold Geometric mean [i] (ppm)
Volatile Organic Compounds (VOCs)									
☐	Acetic acid (64-19-7)	Miscible	1.05	103	11 mm	4.0% 19.9%	10 ppm	50 ppm	0.074 (d)
☐	Acetone (67-64-1)	Miscible	0.79	0	180 mm	2.5% 12.8%	250 ppm	2,500 ppm	62 (d) 130 (r)
☐	Acrolein (107-02-8)	40%	0.84	-15	210 mm	2.8% 31%	C 0.1 ppm Skin	2 ppm	1.8 (d)
☐	Acrylonitrile (107-13-1)	7%	0.81	30	83 mm	3% 17%	2 ppm Skin	85 ppm Ca	1.6 (d)
☐	Benzene (71-43-2)	0.07%	0.88	12	75 mm	1.2% 7.8%	1 ppm Skin	500 ppm Ca	61 (d) 97 (r)
☐	Bromodichloro-methane (75-27-4)	4500 mg/l	1.98	--	50 mm	Non-flam	None established	None determined	--
☐	Bromoform (75-25-2)	0.10%	2.89	--	5 mm	Non-flam	0.5 ppm Skin	850 ppm	1.3 [j]
☐	Bromomethane (74-83-9)	2%	1.73	--	1.9 atm	10% 16.0%	1 ppm Skin	250 ppm Ca	80 [j]
☐	Carbon Tetrachloride (56-23-5)	0.05%	1.59	--	91 mm	Non-flam	2 ppm Skin	200 ppm Ca	252 (d)
☐	Chlorobenzene (108-90-7)	0.05%	1.11	82	9 mm	1.3% 9.6%	10 ppm	1000 ppm	1.3 (d)
☐	2-Chloroethyl-vinyl Ether (110-75-8)	0.02%	1.05	61	27 mm	--	None established	None determined	--
☐	Chloroethane (75-00-3)	0.60%	0.92	-58	1000 mm	3.8% 15.4%	100 ppm Skin	3800 ppm	4.2 [j]
☐	Chloroform (67-66-3)	0.50%	1.48	--	160 mm	Non-flam	2 ppm	500 ppm Ca	192 (d)
☐	Chloromethane (74-87-3)	0.50%	0.92	--	5.0 ATM	8.1% 17.4%	50 ppm	2000 ppm Ca	10 [j]
☐	Dibromo-chloromethane (124-48-1)	2700 mg/l	2.5	--	76 mm	--	None established	None Determined	--
☐	Dibutyl phthalate (84-74-2)	0.001% (77°F)	1.05	315	0.00007 mm	0.5% --	5 mg/m^3	4,000 mg/m^3	--
☐	1,2-Dichlorobenzene (95-50-1)	0.01%	1.3	151	1 mm	2.2% 9.2%	25 ppm Skin	200 ppm	--
☐	1,1-Dichloroethane (75-34-3)	0.60%	1.18	2	182 mm	5.4% 11.40%	100 ppm	3,000 ppm	--
☐	1,1-Dichloroethylene (DCE) (75-35-4)	0.04%	1.21	-2	500 mm	6.5% 15.5%	1 ppm	None determined	190 [j]
☐	1,2-Dichloroethane (107-06-2)	0.90%	1.24	56	64 mm	6.2% 16%	1 ppm	50 ppm Ca	26 (d) 87 (r)
☐	1,2-Dichloroethylene (540-59-0)	0.40%	1.27	36-39	180-265 mm	5.6% 12.8%	200 ppm	1,000 ppm	17 - 170 [k]
☐	1,2-Dichloropropane (78-87-5)	0.30%	1.16	60	40 mm	3.4% 14.5%	75 ppm	400 ppm Ca	0.26 (d) 0.52 (r)
☐	1,3-Dichloropropene (542-75-6)	0.20%	1.21	77	28 mm	5.3% 14.5%	1 ppm Skin	None Determined Ca	1 [j]
☐	Bis-(2-Ethylhexyl)-phthalate (DEHP) (117-81-7)	0.00%	0.99	420	<0.01 mm	0.3% --	5 mg/m^3	5,000 mg/m^3 Ca	--
☐	Diethyl phthalate (84-66-2)	0.10%	1.12	322	0.002 mm	0.7% --	5 mg/m^3	None Determined	--

Check if Present	Material (CAS #)	Water Solubility [a]	Specific Gravity	Flash Point °F)	Vapor Pressure [d]	LEL UEL	OSHA - Cal/OSHA PEL- TWA [f]	IDLH Level [h]	Odor Threshold Geometric mean [i] (ppm)
☐	Dinitrotoluene (DNT) (25321-14-6)	Insoluble	1.32	404	1 mm	-- --	0.15 mg/m^3 Skin	50 mg/m^3 Ca	--
☐	Endrin (72-20-8)	Insoluble	1.7	--	0.00001 mm Low	--	0.1 mg/m^3 Skin	2 mg/m^3	--
☐	Ethyl benzene (100-41-4)	0.01%	0.87	55	7 mm	0.8% 6.7%	100 ppm	800 ppm	2.3 [j]
☐	Hydrazine (302-01-2)	Miscible	1.01	99	10 mm	2.9% 98%	0.01 ppm Skin	50 ppm Ca	3.7 (d)
☐	Methyl ethyl ketone (MEK) (78-93-3)	28%	0.81	16	78 mm	1.4% 11.4%	200 ppm	3000 ppm	16 (d) 17 (r)
☐	Methyl tert-butyl ether (MTBE) (1634-04-4)	5.1 g/100ml	0.7	-18	245 mm	1.6% 8.4%	40 ppm	None determined	0.32 – 0.47mg/m^3 [l]
☐	Methylene chloride (75-09-2)	2%	1.33	--	350 mm	13% 23%	25 ppm	2,300 ppm Ca	160 (d) 230 (r)
☐	Phenol (108-95-2)	9% (77°F)	1.06	175	0.4 mm	1.8% 8.6%	5 ppm Skin	250 ppm	0.06 (d)
☐	1,1,2,2-Tetrachloroethane (79-34-5)	0.30%	1.59	--	5 mm	Non-flam	1 ppm Skin	100ppm Ca	7.3 (d)
☐	Tetrachloroethylene (PCE) (127-18-4)	0.02%	1.62	--	14 mm	Non-flam	25 ppm	150 ppm Ca	47 (d) 71 (r)
☐	Toluene (108-88-3)	0.07% (74°F)	0.87	40	21 mm	1.1% 7.1%	50 ppm Skin	500 ppm	1.6 (d) 11 (r)
☐	1,1,1-Trichloroethane (71-55-6)	0.40%	1.34	--	100 mm	7.5% 12.5%	350 ppm	700 ppm	390 (d) 710 (r)
☐	1,1,2-Trichloro-ethane (79-00-5)	0.40%	1.44	--	19 mm	6% 15.5%	10 ppm Skin	100 ppm Ca	--
☐	1,2,4-Trichlorobenzene (120-82-1)	0.003%	1.45	222	1 mm	2.5% 6.6% (302 °F)	C 5 ppm	None Determined	3 [j]
☐	Trichloroethylene (TCE) (79-01-6)	0.1% (77°F)	1.46	--	58 mm	8% 10.5%	25 ppm	1,000 ppm Ca	82 (d) 110 (r)
☐	Trichlorofluoromethane (75-69-4)	0.1% (75°F)	1.47	--	690 mm	Non-flam	C 1,000 ppm	2000 ppm	--
☐	1,1,2-Trichloro-1,2,2-trifluoroethane (76-13-1)	0.02%	1.56	--	285 mm	-- --	1,000 ppm	2,000 ppm	--
☐	1,2,4-Trimethylbenzene (95-63-6)	0.006%	0.88	112	1 mm	0.9% 6.4%	25 ppm	None determined	2.4 (d)
☐	Vinyl Chloride (75-01-4)	0.1% (77°F)	0.91	--	3.3 atm	3.6% 33%	1 ppm Skin	None Determined Ca	--
☐	Xylene (o, p, m, mix) (1330-20-7)	Slightly soluble	0.86-0.88	81-90	7-9 mm	0.9% 7%	100 ppm	900 ppm	20 (d) 40 (r)
Metals									
☐	Aluminum metal and oxide (as Al)	[b]	2.7	--	0 mm	[e]	10 mg/m^3 (respirable)	None determined	--
☐	Antimony (7440-36-0)	[b]	6.69	--	0 mm	[e]	0.5 mg/m^3	50 mg/m^3	--
☐	Arsenic (inorganic compounds, as As)	[b]	5.73	--	0 mm	[e]	0.010mg/m^3	5 mg/m^3 Ca	--
☐	Arsenic (organic compounds, as As)	Properties vary depending upon the specific organic arsenic compound.					0.2mg/m^3	None determined	--

Check if Present	Material (CAS #)	Water Solubility [a]	Specific Gravity	Flash Point [c]F)	Vapor Pressure [d]	LEL UEL	OSHA - Cal/OSHA PEL- TWA [f]	IDLH Level [h]	Odor Threshold Geometric mean [i] (ppm)
☐	Barium chloride(as Ba) (10361-37-2)	38%	3.86	--	low	Non-flam	0.5 mg/m^3	50 mg/m^3	--
☐	Barium nitrate (as Ba) (10022-31-8)	9%	3.24	--	Low	[e]	0.5 mg/m^3	50 mg/m^3	--
☐	Beryllium and compounds (as Be)	[b]	1.85	--	0 mm	[e]	0.0002 mg/m^3	4 mg/m^3 Ca	--
☐	Cadmium dust (as Cd)	[b]	8.65	--	--	[e]	0.005 mg/m^3	9 mg/m^3 Ca	--
☐	Chromium (III) compounds (as Cr)	[b]	Properties vary depending upon the specific compound.				0.5 mg/m^3	25 mg/m^3	--
☐	Cobalt metal dust and fume (as Co) (7440-48-4)	Insoluble	8.92	--	0 mm	[e]	0.02 mg/m^3	20 mg/m^3	--
☐	Copper dust and mist (as Cu)	[b]	8.94	--	0 mm	[e]	1 mg/m^3	100 mg/m^3	--
☐	Lead	Insoluble	11.34	--	0 mm	[e]	0.05 mg/m^3	100 mg/m^3	--
☐	Manganese, Fume and compounds (as Mn) (7439-96-5)	Insoluble	7.2	--	0 mm	Comb-ustible	0.2 mg/m^3	500 mg/m^3	--
☐	Mercury compounds (as Hg) Except alkyl compound	[b]	13.6	--	0.0012 mm	[e]	0.025 mg/m^3 Skin	10 mg/m^3	--
☐	Molybdenum (7439-98-7)	Insoluble	10.28	--	0 mm	Comb-ustible	10 mg/m^3 3 mg/m^3 (resp.)	5,000 mg/m^3	--
☐	Nickel and other compounds (as Ni)	Insoluble	8.9	--	0 mm	[e]	1 mg/m^3	10 mg/m^3 Ca	--
☐	Selenium (7782-49-2)	Insoluble	4.28	--	0 mm	Comb-ustible	0.2 mg/m^3	1 mg/m^3	--
☐	Silver, metal dust, and soluble compounds (as Ag)	[b]	10.49	--	0 mm	[e]	0.01 mg/m^3	10 mg/m^3	--
☐	Thallium (soluble compouds, as Ti)	[b]	Properties vary depending upon the specific compound.				0.1 mg/m^3 Skin	15 mg/m^3	--
☐	Vanadium pentoxide dust and Fume (1314-62-1)	0.8%	3.36	--	0 mm	[e]	0.05 mg/m^3 (Respirable)	35 mg/m^3	--
☐	Zinc oxide (1314-13-2)	[b]	5.61	--	0 mm	[e]	5 mg/m^3	500 mg/m^3	--
Miscellaneous									
☐	Ammonia (7664-41-7)	34%	--	--	8.5 atm	15% 28%	25 ppm	300 ppm	17 (d)
☐	Asbestos (1332-21-4)	Insoluble	--	--	0 mm	Non-flam	0.1 fibers/cc	None determined	--
☐	Chromic Acid and chromates (1333-82-0)	63%	2.7	--	Very low	Non-flam	0.005 mg/m^3	15 mg/m^3 Ca	--
☐	Cyanide (as CN)	--	--	--	--	Non-flam	5 mg/m^3 Skin	--	--
☐	DDT (50-29-3)	Insoluble	0.99	162-171	0.0000002 mm	--	1 mg/m^3 Skin	500 mg/m^3 Ca	--
☐	Diesel Fuel #2 (68476-34-6)	Insoluble	0.81-0.90	130	--	0.6-1.3 6-7.5	None established	None determined	--
☐	Fluorides, as F	--	--	--	--	--	2.5 mg/m^3	None determined	--

Check if Present	Material (CAS #)	Water Solubility [a]	Specific Gravity	Flash Point [c]F)	Vapor Pressure [d]	LEL UEL	OSHA - Cal/OSHA PEL- TWA [f]	IDLH Level [h]	Odor Threshold Geometric mean [i] (ppm)
☐	Gasoline (8006-61-9)	Insoluble	0.72-0.76	-45	38-300 mm	1.4% 7.6%	300 ppm	Ca None determined	--
☐	Kerosene (8008-20-6)	Insoluble	0.81	100-162	5 (100ºF)	0.7% 5.0%	200 mg/m^3 [3g] Skin	None determined	--
☐	Naphthalene (91-20-3)	0.03%	1.15	174	0.08 mm	0.9% 5.9%	10 ppm	250 ppm	0.038 (d)
☐	PCB (42% chlorine) (53469-21-9)	Insoluble	1.39	--	0.001 mm	Non-flam	1 mg/m^3 Skin	5 mg/m^3 Ca	--
☐	PCB (54% chlorine) (11097-69-1)	Insoluble	1.38	--	0.00006 mm	Non-flam	0.5 mg/m^3 Skin	5 mg/m^3 Ca	--
☐	Phosphorus (yellow) (7723-14-0)	0.0003%	1.82	--	0.03 mm	-- --	0.1 mg/m^3	5 mg/m^3	--
☐	Polycyclic Aromatic Hydrocarbons (PAH)	Properties vary depending upon the specific compound. Listed in NIOSH as Coal Tar Pitch Volatiles					0.2 mg/m^3	80 mg/m^3 Ca	--

SITE-SPECIFIC SUBSTANCES
(Add hazardous property information on any substances that are of concern at the site but are not listed above.)

EXPLANATIONS AND FOOTNOTES:

[a] Water solubility is expressed in different terms in different references. Many references use the term "insoluble" for materials that will not readily mix with water, such as gasoline. However, most of these materials are water soluble at the part per million or part per billion level. Gasoline, for example, is insoluble in the gross sense, and will be found as a discrete layer on top of the ground water. But certain gasoline constituents, such as benzene, toluene, and xylene, will also be found in solution in the ground water at the part per million or part per billion levels.

[b] Solubility of metals depends on the compound in which they are present.

[c] Several chlorinated hydrocarbons exhibit no flash point in a conventional sense, but will burn in the presence of high energy ignition source or will form explosive mixtures at temperatures above 200ºF.

[d] Expressed as mm Hg under standard conditions.

[e] Explosive concentrations of airborne dust can occur in confined areas.

[f] OSHA and/or CAL/OSHA Time-weighted Average (TWA) Permissible Exposure Limits (PELs) except where noted in g. The substances designated by "Skin" in the PEL column may be absorbed into the bloodstream through the skin, the mucous membranes and/or the eye, and contribute to the overall exposure. "C" notation indicates the number given is a ceiling value.

[g] TLV-TWA adopted by the American Conference of Governmental Industrial Hygienists (ACGIH). Currently, there is no OSHA and/or CAL/OSHA PEL.

[h] The substances with a "Ca" notation in the IDLH column are considered to be potential occupational carcinogens by NIOSH.

[i] Odor thresholds values extracted from "*ODOR THRESHOLDS for Chemicals with established Occupational Health Standards*", American Industrial Hygiene Association, 1997.

(d) Odor detection threshold: Lowest concentration at which a stimulus is being detected.

(r) Odor recognition threshold: Lowest concentration at which a definite odor character is detected.

[j] Values extracted from the U.S. Environmental Protection Agency Technology Transfer Network, Air Toxics website. URL: www.epa.gov/ttn/atw/, 2006

[k] Value extracted from "*HESIS Guide to Solvent Safety*" California Department of Health Services, 2004. URL: http://www.dhs.ca.gov/ohb/HESIS/solv_cht.htm

[l] Value extracted from "*Chemical Summary For Methyl-Tert-Butyl Ether",* U.S. Environmental Protection Agency, Office Of Pollution Prevention and Toxics, August 1994. URL: http://www.epa.gov/chemfact/s_mtbe.txt

Appendix B
Control Mechanisms

The following control methods should be implemented for the listed hazards

B1 Chemical Hazards – Impact7G personnel, contractors, subcontractors, and visitors shall wear appropriate personal protective equipment (PPE) while performing site activities. At a minimum, equipment shall include safety glasses, steel-toed boots, and hard hats (when overhead work being performed or when overhead hazards exist). Impact7G personnel shall familiarize themselves with the appropriate health and safety responses for exposure to known on-site chemicals prior to beginning work at the site. See Attachment A for chemical safety data. Consult with your local Health and Safety Coordinator (HSR) for any personal air monitoring requirements.

B2 Physical Hazards – Impact7G personnel shall minimize the risk of slips, trips, and falls by keeping the work area clear of excess equipment and cleaning up wet surfaces as soon as possible. In addition, the floor of every workroom shall be maintained in a clean and, so far as possible, a dry condition. Employees should avoid walking through/on wet and/or cluttered surfaces and be conscious of the fact the wet surfaces could be slippery and could cause injury. Spilled materials should be cleaned up immediately.

Sufficient illumination should be provided in all areas at all times. Employees should notify the responsible person (e.g., Principal–in-Charge, Project Manager, and/or Health and Safety Coordinator) of conditions where there is an absence of sufficient natural and/or permanent artificial light.

All employees are responsible for maintaining the work area(s) and in a clean and orderly manner, and for notifying the responsible person (e.g., Principal–in-Charge, Project Manager and/or Health and Safety Coordinator) of conditions beyond their control.

B3 Mechanical Hazards – Impact7G personnel shall not attempt to operate equipment they are not familiar with and/or are not equipped with protection devices (e.g., guards). Personnel shall familiarize themselves with the equipment being utilized on site and shall at a minimum, know how to stop or turn off the equipment.

B4 Traffic/Heavy Equipment Safety - Impact7G personnel should, under no circumstances, operate or ride on heavy equipment which is being used by a subcontractor. Site personnel will maintain a safe distance of at least 20 feet (6.5 meters) or more, depending on circumstances and directives, from all heavy equipment in operation. If activities warrant closer proximities to operating equipment, personnel will don brightly colored vests and a second person will stand watch to keep him/her out of the path of equipment while performing the required activity. Eye contact with the equipment operator will be maintained.

B5 Electrical Hazards – Electricity may pose a particular hazard to site workers due to the use of portable electrical equipment. If wiring or other electrical work is needed, a qualified electrician must perform it.

Properly ground all electrical equipment. Avoid standing in water when operating electrical equipment. Ground fault outlets or adapters shall be used for any electrical equipment. Apparatus, tools, equipment, and machinery will not be repaired while in operation.

Lockout/Tagout (LOTO) procedures will be implemented when necessary. If equipment must be connected by splicing wires, electrical work must be performed by a licensed and competent electrician.

B6 Fire and Explosion Hazards – The presence of petroleum and solvent-impacted material presents a potential fire hazard. Smoking and use of open flame will be prohibited. The use of non-sparking tools and equipment will be implemented if conditions warrant. Where the potential for fire exists, Impact7G will provide portable fire extinguishers. Where applicable, all fire extinguishers shall be mounted no higher and no lower than 4 feet (1.22 m) from the floor and/or shall be readily accessible for use, where applicable. All fire extinguishers shall be maintained as follows:

- Fully charged and in operable condition;
- Clean and free of defects; and
- Readily accessible at all times

B7 Acoustical Hazards – Hearing protection will be worn by all personnel operating or working within the vicinity of equipment when noise is sufficient to interfere with general conversation at a normal speaking volume; when noise levels exceed 85dBA; and/or when manufacturers' requirements indicate that its usage is mandatory. Personal hearing protectors, such as earplugs or earmuffs, may be used to reduce the amount of noise exposure while the above control measures are being evaluated or if such controls fail to reduce the exposure levels to below the PELs.

B8 Ventilation/Oxygen Deficiency Hazards – Impact7G personnel shall monitor the work area for oxygen deficiency hazards using monitoring devices that have been appropriately calibrated and are recommended for this specific use, as applicable. If direct air monitoring readings suggest an oxygen deficiency and/or the build-up of harmful substances, leave the area and contact your Project Manager. Implementation of corrective actions may include but not be limited to increasing work zone ventilation or evaluating alternatives (e.g., removing equipment that is generating combustion exhaust or venting the exhaust to the exterior of the building). However, work will not continue until the ventilation/oxygen deficiency hazard has been properly addressed, implemented, and verified.

B9 Heat Stress – Heat stress can be a significant hazard, especially for workers wearing protective clothing. Depending on the ambient conditions and the work being performed, heat stress can occur very rapidly, within as little as 15 minutes. Site personnel will be instructed in the identification of a heat-stress victim, the first-aid treatment procedures for the victim and the prevention of heat-stress incidents.

Workers will be encouraged to immediately report any heat-related problems that they experience or observe in fellow workers. Any worker exhibiting signs of heat stress and exhaustion should be made to rest in a cool location and drink plenty of water. Emergency help by a medical professional is required immediately for anyone exhibiting symptoms of heat stroke, such as red, dry skin, confusion, delirium, or unconsciousness. Heat stroke is a life-threatening condition that must be treated by a competent medical authority.

Heat Stress Prevention

Whenever possible or within the control of Impact7G, engineering controls should be utilized to protect workers from heat-related hazards. For example, isolation from the heat source, ventilation such as open windows, fans or other methods of creating air flow, and heat shieldings such as awnings or umbrellas. Appropriate work practices can also lessen the chances of heat-related hazards. Some of these include:

a. Water intake should be about equal to the amount of sweat produced (i.e., drinking 5-7 ounces of water every 15-20 minutes). Electrolyte fluids may also be necessary.
b. Whenever possible, gradual exposure to heat is preferred to allow the body's internal temperature to actuate to the working conditions.
c. Whenever possible, adjust the work schedule to reduce the risk of heat stress. For example, postpone nonessential or heavier work to the cooler part of the day and perform work in the shade if portable.
d. Rotate personnel to reduce the amount of time spent working in direct sun and heat.
e. Increase the number and/or duration of rest breaks, and whenever possible, rest break areas should be in a cool area and as close to the work area as is feasible.

Wear appropriate PPE when necessary, such as thermally conditioned clothing, self-contained air conditioning in a backpack, and plastic jackets/vests with pockets that can be filled with dry ice or ice. However, based on the type of work being done, where work is being performed, or other required PPE, these options may be prohibited or make the use of this PPE impossible or impractical.

Allocation of Work in a Work/Rest Cycle	Acclimatized				Action (Unacclimatized) Limit			
	Light	Moderate	Heavy	Very Heavy	Light	Moderate	Heavy	Very Heavy
75-100%	31.0 (87.8F)	28.0 (82.4F)	--	--	28.0 (82.4F)	25.0 (77F)	--	--
50-75%	31.0 (87.8F)	29.0 (84.2F)	27.5 (81.5)	--	28.5 (83.3F)	26.0 (78.8F)	24.0 (75.2F)	--
25-50%	32.0 (89.6F)	30.0 (86F)	29.0 (84.2F)	28.0 (82.4F)	29.5 (85.1F)	27.0 (80.6F)	25.5 (77.9)	24.5 (76.1F)
0-25%	32.5 (90.5F)	31.5 (88.7F)	30.5 (86.9F)	30.0 (86F)	30.0 (86F)	29.0 (84.2F)	28.0 (82.4F)	27.0 (80.6F)

B10 Cold Stress - The four Impact7G environmental conditions that cause cold-related stress are low temperatures, high/cool winds (wind chill), dampness, and cold water. One or any combination of these factors can cause cold-related hazards. Cold stress, including frostbite and hypothermia, can result in severe health effects.

A dangerous situation of rapid heat loss may arise for any individual exposed to high winds and cold temperatures. Major risk factors for cold-related stresses include:

- Wearing inadequate or wet clothing increases the effects of cold on the body.
- Taking certain drugs or medications such as alcohol, nicotine, caffeine, and medication that inhibits the body's response to the cold or impairs judgment.
- Having a cold or certain diseases, such as diabetes, heart, vascular, and thyroid problems, may make a person more susceptible to the winter elements.
- Being male increases a person's risk to cold-related stresses. Men experience far greater death rates due to cold exposure than women, perhaps due to inherent risk-taking activities, body-fat composition, or other physiological differences.
- Becoming exhausted or immobilized, especially due to injury or entrapment, may speed up the effects of cold weather.
- Aging -- the elderly are more vulnerable to the effects of harsh winter weather.

TABLE 2. Cooling Power or Wind on Exposed Flesh Expressed as Equivalent Temperature (under calm conditions)*

Estimated Wind Speed (in mph)	Actual Temperature Reading (°F)											
	50	40	30	20	10	0	−10	−20	−30	−40	−50	−60
	Equivalent Chill Temperature (°F)											
calm	50	40	30	20	10	0	−10	−20	−30	−40	−50	−60
5	48	37	27	16	6	−5	−15	−26	−36	−47	−57	−68
10	40	28	16	4	−9	−24	−33	−46	−58	−70	−83	−95
15	36	22	9	−5	−18	−32	−45	−58	−72	−85	−99	−112
20	32	18	4	−10	−25	−39	−53	−67	−82	−96	−110	−121
25	30	16	0	−15	−29	−44	−59	−74	−88	−104	−118	−133
30	28	13	−2	−18	−33	−48	−63	−79	−94	−109	−125	−140
35	27	11	−4	−20	−35	−51	−67	−82	−98	−113	−129	−145
40	26	10	−6	−21	−37	−53	−69	−85	−100	−116	−132	−148
(Wind speeds greater than 40 mph have little additional effect.)	LITTLE DANGER In < hr with dry skin. Maximum danger of false sense of security				INCREASING DANGER Danger from freezing of exposed flesh within one minute.				GREAT DANGER Flesh may freeze within 30 seconds.			
	Trenchfoot and immersion foot may occur at any point on this chart.											

*Developed by U.S. Army Research Institute of Environmental Medicine, Natick, MA.

Equivalent chilll temperature requiring dry clothing to maintain core body tempearture above 36°C (96.8°F) per cold stress TLV

Cold Stress Prevention

Engineering controls should be utilized whenever possible to protect workers from cold-related hazards. For example, on-site heat sources, heated shelters, work areas shielded from drafty or windy conditions, and the use of thermal insulating material on equipment handles. Effects arising from cold exposure will be minimized by the following control measures:

- Personnel will be trained to recognize cold stress symptoms.
- Field activities will be curtailed or halted if the equivalent chill temperature is below 20 F.
- As much as possible, work that exposes personnel to the cold will be done during the warmest hours of the day.
- Inactivity in cold conditions will be kept to a minimum.

- Frequent short breaks in warm, dry shelters will be taken.
- Vehicles will be equipped with supplies in case the vehicle becomes inoperable (e.g., a blanket, dry clothing, water, food, a shovel, etc.

The following PPE will be provided during work in cold environments:

- Workers will be provided with insulated dry clothing when the equivalent chill temperature is less the 30 F.
- Feet, hands, face, and head should be protected (40% of the body's heat can be lost when the head is exposed).
- Foot and hand wear may also need to be waterproof.
- Clothing should be layered so that adjustments can be made to changing environmental temperatures and conditions. For example, an outer layer to break the wind, a middle layer that will absorb sweat and retain insulation when wet, and an inner layer that allows ventilation.

B11 Insects, Snakes and Spiders - Care will be taken by all site workers to avoid stinging or biting insects such as ticks, spiders, bees, wasps, hornets, and yellow jackets. Workers allergic to any particular insect sting or bite should seek medical attention if stung or bitten and may need to carry emergency medicine prescribed by their doctor.

Care should always be taken to avoid these insects and increased vigilance is necessary during high infestation seasons, when opening protective casings of monitoring wells, and when walking through areas of heavy vegetation or areas known to be infested.

To minimize the chance of bites/stings:

- Wear appropriate PPE such as light-colored clothing so you can see insects, long pants tucked into boots, long sleeves when possible, a hat, and gloves if you are cutting brush or need to handle or move vegetation.
- Check your body and clothing for insects, shower after work and wash/dry clothes at as high temperature as possible.
- Don't swat at insects and don't eat in areas where there are insects.
- Avoid sweet smelling personal hygiene products and, unless contraindicated by the work being performed (e.g., sampling, data collection), wear EPA approved repellants such as those containing DEET.

Black Widow Spider

Brown Recluse Spider

Spider bites generally cause only localized reactions such as swelling, pain, and redness. However, bites from a Black Widow or Brown Recluse, or if you are allergic to spiders, can cause symptoms that are more serious.

First Aid for spider bites:

- Clean the bite area with soap and water and place a cold pack over the bite area to reduce swelling.
- Monitor for allergic reactions. If the victim has more than minor pain, or if nausea, vomiting, difficulty breathing, or swallowing occurs, medical attention should be sought immediately.

Tick

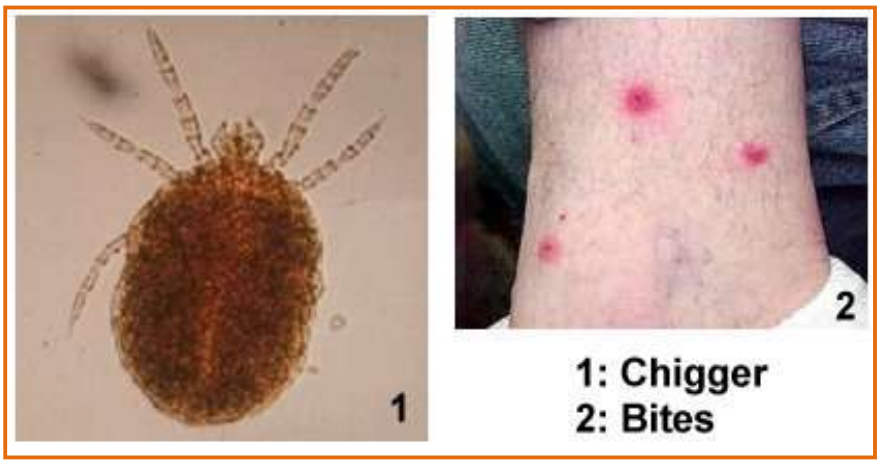
Removing a tick

Ticks are common, especially in the warmer weather months and may carry diseases such as Rocky Mountain Spotted Fever and Lyme disease.

First Aid for tick bites:

- Use a fine tipped tweezers, grasp tick firmly as close to skin as possible and pull the body away from skin. Avoid crushing the body and don't twist.
- If parts of the tick remain in the skin, don't be alarmed as the mouth will dislodge as skin sloughs off.
- Wash area with soap and water and apply antiseptic or antibiotic ointment to prevent infection.

- If unexplained symptoms develop such as severe headaches, fever, or rash within 10 days of the bite, seek medical attention.
- If possible, contain tick in an air tight container for identification purposes in the event of a serious reaction.

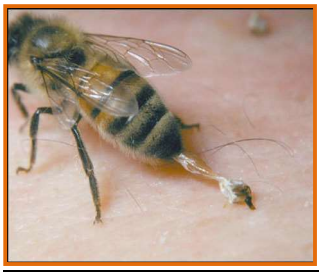


Chiggers are tiny, s-legged wingless organisms that grow up to become a type of mite. They are found in tall grass and weeds and their bites cause severe itching.

First Aid for chiggers:

- Reduce discomfort and prevent infection
- The affected area should be kept clean by washing with soap and water
- A topical hydrocortisone cream, antihistamine, or local anesthetic may be of value in reducing the itching
- The wounds should not be scratched, if possible
- If signs of infection occur, consult your physician

Wasp



Bee

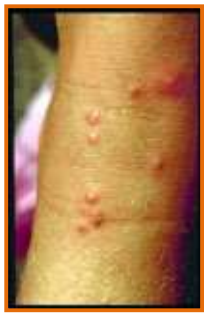
Bees and wasps belong to the phylum Arthropod family, and they are crucially important to the pollination of plants, specifically flowers, fruits, and vegetables. A sting from a bee or wasp will cause itching, irritation, redness and/or swelling at the sting site.

First Aid for bee stings:

- Remove the stinger as quickly as possible - venom continues to enter the skin from the stinger for 45 to 60 seconds following a sting – using a flat dull object, like a credit card. Slide the flat object in the opposite direction of the stinger to remove it from the skin.
- Wash the wound using soap and water
- Apply ice for swelling and pain
- A topical hydrocortisone cream, antihistamine, or local anesthetic may be of value in reducing itching
- If the sting occurs on the neck or mouth, seek medical attention immediately, swelling in these areas may cause suffocation

A small percentage of people are allergic to stings and a sting can be fatal, caused by a disruption to breathing and circulatory systems called anaphylactic shock. If the sting is followed by severe symptoms, seek medical attention immediately. Allergic people should never be alone for outdoor activities since help may be needed for prompt emergency treatment. Allergic people should have an identification bracelet as well as carry something like an "EpiPen" for immediate treatment for anaphylactic shock.





Fire ants are a variety of stinging ants with over 280 species worldwide. Typically, a colony produces large mounds in open areas, and feeds mostly on young plants, seeds, and insects. They nest in the soil, often near moist areas such as river banks and pond edges. Unlike other ants which bite and then spray acid on the wound, fire ants bite only to get a grip and then sting, injecting toxic alkaloid venom. This results in a painful stinging sensation, similar to what a fire burn feels like.

First Aid for fire ant bites:

- Move rapidly away from the nest
- Quickly remove or kill ants on skin and clothing to prevent further stings
- Wash the area gently with soap and water to rid the skin of any venom
- Place cool cloth or ice cloth on sites for 15 minutes, and to relieve pain, dab the area with calamine lotion, a topical (cortisone) or oral antihistamine (e.g. benadryl) to help with swelling
- Do not scratch the blister because this can lead to infection

- Allergic response is rare, but symptoms are difficulty breathing, light headedness, and weakness. Immediate medical attention is required

Snakes serve an important role as predators in the ecosystem, and help maintain populations of rodents and other prey.

First Aid for venomous snake bites:

- Wash and immobilize the injured area, keeping it lower than the heart if possible
- Seek medical attention immediately
- **DO NOT** apply ice, cut the wound, apply a tourniquet, or suck the bite
- Remain calm and try not to move the bitten body part
- Wash the bite with soap and water
- Remove jewelry or other items that may be affected by rapid swelling of affected body parts
- Try to identify the type of snake: note color, size, patterns, and markings
- The bite will be painful and have two distinct puncture wounds
- If venom is injected there will be burning and swelling
- ONLY FOR CORAL SNAKE BITES: apply a mild wrapping on the wound

Water Moccasin (aka cotton mouth)

Rattlesnake

Coral Snake

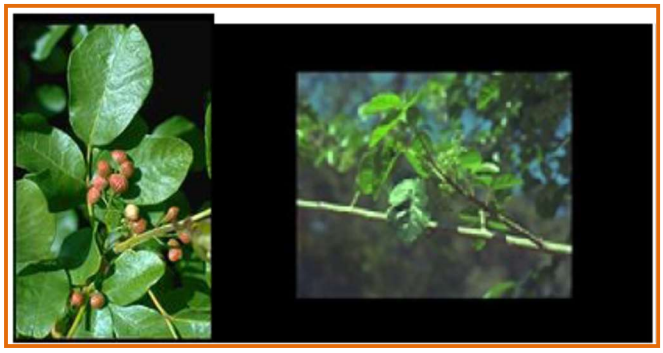
Copperhead

B12 Poisonous Plants – Plants poison on contact, through ingestion, or by absorption or inhalation. They cause painful skin irritations upon contact and can cause internal poisoning when eaten.


Poison Ivy


Poisonous Sumac

Giant Hogweed



First Aid for poisonous plants:

- Wash exposed areas with cold running water as soon as you can
- When possible, wash your clothing
- Relieve itching by taking cool showers and applying topical anti-itch medications or hydrocortisone
- The rash is often arranged in streaks or lines where you brushed against the plant
- In a few days, the blisters become crusted and take 10 days or longer to heal
- If the reaction is severe or worsens, seek medical attention

B13 Personal Safety - If it is deemed that a work site is in an area where an employee's personal safety may be at risk from potential criminal acts, wild animals, etc. the risks will be

evaluated and implementation of preventative measures will be taken to minimize the risk. Informational resources such as the Client, local law enforcement officials, Park or Wildlife Service, and Animal Control could be utilized to assess the risk and to ensure the safest possible work environment. For example, local law enforcement can be made present or make frequent drive-bys while work is being done, outside security can be hired, and work can occur only during certain times of the day or work may not proceed at all. Some general guidelines are provided here, but each situation is different and actions must be taken based on the specifics of each.

In areas of risk, employees will communicate via cell phones or 2-way radios, and will check-in at predetermined times throughout each workday. If employees do not call in to the Project Manager or designated representative, the team will be contacted, and if unsuccessful, local law enforcement will be notified.

If you see wild animals while driving, stay in your vehicle. Never get out for a photo or a closer look. Keep windows up and don't try to keep the animal from crossing a road with your vehicle. If you see a wild animal while on foot, never approach the animal. If the animal has not seen you, go back the way you came. Do NOT turn your back and run which could evoke their natural predator instinct. Instead, keep facing the animal and back away at a steady pace. Let it know you are human by talking in a low voice and waving your hands slowly. If you are near a car or building, get inside. In addition, in areas of higher risk (i.e., contacted officials have indicated that wild animals are a nuisance), employees may want to consider carrying "pepper spray".

If, while on the project site, and despite any precautions set forth, if an employee feels that their personal safety is at risk, they shall cease work, leave the work area and immediately report their concerns so that appropriate steps can be taken.

B14 Working Alone and Working in Isolated Areas - Site and Operations employees will assess the risk of working alone as outlined in Section 6 in this HASP. And whenever possible, will not work alone in isolated areas. If the isolated area involves hiking/walking into areas that are unmarked or if there is potential to become directionally disoriented (e.g., no trails, unmarked trails, forested or highly vegetated areas), employees will be trained on the use of a compass and trail/topography maps and if necessary, will take wilderness safety training. The employee will work with the Park/Wildlife service on what emergency planning if necessary (e.g., unexpected weather, animal attack, and search/rescue).

Communicating through cell phones or 2-Way Radios will be utilized whenever possible. Employees will check-in at predetermined times throughout each workday and as the risk rating increases, employees will check-in more frequently. If employees do not call in to the Project Manager or designated representative, the team will attempt to be contacted. If contacting the employee is unsuccessful, the appropriate authorities will be notified. In addition, and especially if communication is not possible during the day, the planned start and estimated finish times for the day will be communicated, and employees will check in at the beginning and end of the work day.

If employees will be moving from isolated area to isolated area, there will be established beginning and ending locations, planned start and estimated finish times, and planned routes that will be followed throughout the day. Employees will not deviate from this schedule without first contacting the appropriate personnel. It may also be necessary to notify the Client, law enforcement, or Park/Wildlife officials of these schedules.

Local authorities should be contacted about any hunting season that may be in session, and if it is possible that hunters may be present in the area in which Impact7G personnel will be working. If so, employees will wear brightly colored hardhats/hats and reflective vests, will not work before dusk, and work will end 30 minutes before dusk.

If this is not possible to complete work during daylight hours, employees will wear appropriate reflective apparel and have appropriate lighting, such as portable lighting, flashlights, or headlamps as appropriate for the activity being conducted. Personal security will be assessed and measures taken as discussed above if appropriate.

B15 Severe Weather

Severe weather conditions include high winds, electrical storms, and heavy rain. At a minimum, all work outdoors will cease during these events. When lightning is spotted, site personnel should use the following steps to avoid injury:

- Workers should note the flash-boom ratio (i.e., count the seconds after the lightning was seen until the thunder was heard).
- By counting the seconds between seeing lightning and hearing thunder and dividing by 5, you can estimate your distance from the storm (in miles). If the storm is 6 miles (9.6 kilometers) away or less (30 seconds between when lightning was seen and thunder was heard) workers must stop work and take shelter.
- If the storm is more than 6 miles (9.6 kilometers) away (greater than 30 seconds between lightning and thunder), the site supervisor should monitor the storm and be prepared to cease work if the storm approaches an unsafe distance. Since storms can travel at varying speeds and the amount of time it takes to cease and secure operations will also vary, so prudent judgment should be exercised when storms are in the vicinity and/or developing (e.g., darkening skies, increasing wind speeds, etc).
- Workers should not stay in exposed areas (outdoors on the ground, on a roof, in an aerial lift, on a steel truss, on an ungrounded steel structure, in a golf cart, un-sided building, etc.) after lightning has been witnessed. All personnel must move to a safe location.
- Workers should wait 30 minutes from the last sight of lightning or sound of thunder before returning to work.
- Those required to travel from one building to another during the 30-minute wait time should do so only by enclosed vehicle.
- Once the 30-minute wait time period has elapsed and no additional lightning or thunder has been seen or heard, individuals may resume normal work.

B16 Aboveground and Underground Utilities - Various forms of underground and aboveground utility lines or pipes (carrying water, wastewater, gas, and or electricity) may be encountered during work activities. Every effort shall be made to locate and mark underground utilities prior to the start of intrusive work. At a minimum, Impact7G will conduct a historical site review to develop a plot plan with the most up to date utility information, contact the appropriate One Call service (where available), contract a Private utility locating service (where available), and clear the critical zone around any intrusive location to 5 feet (1.3 m) in every direction. Please reference Section 6 of the site-specific HASP and SPI 27 Subsurface Clearance for more information.

Work involving machinery with high extensions (backhoes, etc.) will remain **at least** 10 feet (3.3 meters) from overhead power lines. As line voltage increases, your safe working distance will also increase. If overhead lines are present, call the utility company and find out what voltage is on the lines so the safe working distance can be calculated, or stay at least 28 feet (9m) from cables supported on wooden poles, and 50 feet (15m) from cables supported on metal poles.

Should any operations cause equipment to come into contact with utility lines, the appropriate authority will be notified immediately and an Incident Report will be completed. Work will be suspended until the appropriate actions for the particular situation can be taken.

B17 Material Handling (**Ergonomics**) - Proper lifting techniques such as keeping the back straight and legs bent, shall be utilized when lifting equipment. If the equipment cannot be lifted in this manner, it is too heavy to lift alone. Call other personnel, or use a mechanical device for lifting.

B18 Power Tools - Power tools can be hazardous when improperly used since these types of tools use an energy source: Electric, liquid fuel, hydraulic, pneumatic, and powder-actuated. The following precautions will be taken by employees to prevent injury:

- Power tools will always be operated within their design limitations.
- Eye protection, gloves and safety footwear are recommended during operation.
- Store tools in an appropriate dry location when not in use.
- Work only in well illuminated locations.
- Tools will not be carried by the cord or hose.
- Cords or hoses will not be yanked to disconnect it from the receptacle.
- Cords and hoses will be kept away from heat, oils, and sharp edges or any other source that could result in damage.
- Tools will be disconnected when not in use, before servicing, and when changing accessories such as blades, bits and cutters.
- Observers will be kept at a safe distance at all times from the work area.
- Tools will be maintained in a clean manner, and properly maintained in accordance with the manufacturer's guidelines.

- Ensure that proper shoes are worn and that the work area is kept clean to maintain proper footing and good balance.
- Ensure that proper apparel is worn. Loose clothing, ties, or jewelry can become caught in moving parts.
- Tools that are damaged will be removed from service immediately and tagged "Do Not Use".

B19 Vehicle Use – Work areas and site conditions must be considered when designating and selecting a vehicle for use. The vehicle shall be maintained in safe working order as required by the manufacturer. This would include a routine preventive maintenance schedule for servicing and checking of safety-related equipment. Special consideration should be taken when weather conditions reduce the safety and visibility while driving. Appropriate measures should be taken while driving during inclement weather including snow, icy, and/or wet conditions; high winds; hail, heavy rains; debris or other impairments to safe driving caused by natural weather.

B20 Seasonal Hunting Hazards – During recreational hunting seasons, field personnel will wear appropriate clothing, such as fluorescent orange Hi-Vis vests, so as to be visible to hunters and not blend in with the landscape. Field personnel should also use whistles, air horns and/or other means to make their presence known to hunters and wildlife alike. The schedule of the hunting season, if applicable, will be included as an addendum to this HASP in order to inform personnel of the type of game (e.g., deer, pheasant, duck, etc) that is being hunted and the type of weapon being used (e.g., bow & arrow, shotgun, single shot rifle, etc.). Be aware that even if "No Trespassing" and/or "No Hunting Allowed" signs are posted, trespassers and/or hunting may still be on site. At no point should field personnel or contractors confront trespassers.

Appendix C
Subsurface Clearance Field Checklist

Not Applicable

Appendix D
First Aid Guidance

D1 Purpose
The purpose of this Appendix is to establish the minimum first aid supplies, equipment and actions to properly respond to injuries.

D2 Scope
This program is applicable to all individuals while engaged in work at the project site.

D3 Responsibilities
- It is the responsibility of the Health & Safety Coordinator to ensure that first aid kits are provided and maintained.
- All employees are responsible for using first aid materials in a safe and responsible manner.
- The Health & Safety Director is responsible for corresponding with the Red Cross or an equivalent to keep employee training levels current.

D4 Planning
The Designated Site Supervisor will:
- Ensure that a minimum of one (1) employee, with a valid certificate, shall be present to render first aid at all times work is being performed if medical assistance is not available within 3-4 minutes.
- Ensure that provisions shall have been made prior to commencement of a project for prompt medical attention, including transportation, in case of serious injury.
- Ensure adequate first aid supplies and equipment are easily accessible when required.
- Ensure that in areas where 911 is not available, the telephone numbers of the physicians, hospitals, or ambulances to be used shall be conspicuously posted.

D5 Medical Response
All minor first aid is to be self-rendered. Because of the risks presented by certain bloodborne pathogens, no one is allowed to tend the minor injuries of another.

First aid providers are readily available to assist injured workers. In the absence of an infirmary, clinic, or hospital in near proximity to the workplace, a person or persons shall be available and adequately trained to render first aid.

First aid providers are certified. A person who has a valid certificate in first-aid training from the American Red Cross or equivalent that can be verified by documentary evidence, shall be available at the worksite to render first aid.

Employees authorized to render first aid will always observe universal precautions. (Universal Precautions means that the aid giver treats all bodily fluids as if they were contaminated).

If 911 is not available refer to the list of posted phone numbers for prearranged medical response providers. All Impact7G, Inc. authorized first responders shall have a cell phone as a means of

communications; otherwise handheld radios or telephones shall be used as a means of communication.

D6 Supplies and Equipment

First aid supplies are readily available. First aid supplies shall be easily accessible when required.

All first aid kits contain appropriate items determined to be adequate for the environment in which they are used and if on a construction site are stored in a weatherproof container with individual contents sealed from the manufacturer for each type of item.

First aid kits are inspected to ensure they are adequately stocked. The Health & Safety Coordinator should ensure the availability of adequate first aid supplies, and periodically reassess the demand for supplies and adjust their inventories. For longer duration projects, first aid kits shall be checked before being sent out to each job and at least weekly.

Emergency eyewashing equipment is readily available. Where the eyes or body of any person may be exposed to injurious corrosive materials, suitable facilities shall be provided within the work area.

D7 Transportation of Injured Employees

Services are available to transport injured workers to a health care facility. Proper equipment for prompt transportation of the injured person to a physician or hospital or a communication system for contacting necessary ambulance service shall be provided.

Examples of serious injuries that result in the injured being transported to a medical provider are those resulting in severe blood loss, possible permanent disfigurement, head trauma, spinal injuries, internal injuries and loss of consciousness. Keep in mind that the needs and wellbeing of the injured are the first priority.

Proper equipment for prompt transportation of the injured person to a physician or hospital or a communication system for contacting necessary ambulance service shall be provided.

Choices to consider include: private automobile, company vehicle, helicopter, EMS vehicles including medi-vac helicopters, or any other transportation that can provide safe transportation to the hospital or doctor's office in order to provide medical attention to the injured in the quickest manner without any additional complications or injuries to the injured employee.

Transportation needs must be preplanned and coordinated with the transportation provider prior to an incident requiring such service.

D8 Training

Volunteers or selected employees are trained by the American Red Cross or equivalent in CPR and first aid. Each of these trained and certified employees are equipped with protective gloves and other required supplies.

Appendix E
Emergency Information

Emergency Contact Information

Site Name: *Former YMCA Building*
Specific Location: *480 South 3rd Street, Clinton, Iowa 52732*

Table 1. Emergency Response Telephone Roster

Contact	Name	Office phone #	Mobile phone #
Local Fire Department	Joel Atkinson, Fire Chief	563.242.0125	[redacted]
Local Hospital	MercyOne	563.244.5555	
Local Police	Kevin Gyrion, Chief of Police	563.243.1455	
Spill Notification	Iowa DNR	515.725-8694	
Impact7G Principal	Mike Fisher	515.473.6256	319.551.1579
Impact7G Project Manager	Jon Reis	515.473.6256	515.231.3719
Impact7G Designated Site Supervisor	Leon Johnson	515.473.6256	515.201.8215
Health and Safety Coordinator	Matt Deutsch	515.473.6256	515.802.7466
Client (ECIA) Contact	Dawn Danielson		563-580-1976
Client (City of Clinton) Contact	Tammy Johnson	563-594-6730	563-212-2394
Contractor:			
(Other):			
Poison Control	[redacted]	800-222-1222	[redacted]

Potential Chemicals of Concern:

Potential contaminants that may be encountered during site operations include asbestos, lead (from lead-based paint), and mold. There is potential for asbestos fibers and lead in the air above applicable Permissible Exposure Limits (PELs) or Threshold Limit Values (TLVs) during the course of this cleanup project.

Route to Hospital:

Hospital name: *MercyOne Clinton Medical Center*

Hospital Address: *1410 N 4th Street, Clinton, Iowa 52732*

Hospital Phone Number: *1 + 563.244.5555*

Description of Route to Hospital

Describe Route to Hospital with Both Turn by Turn and Google maps:

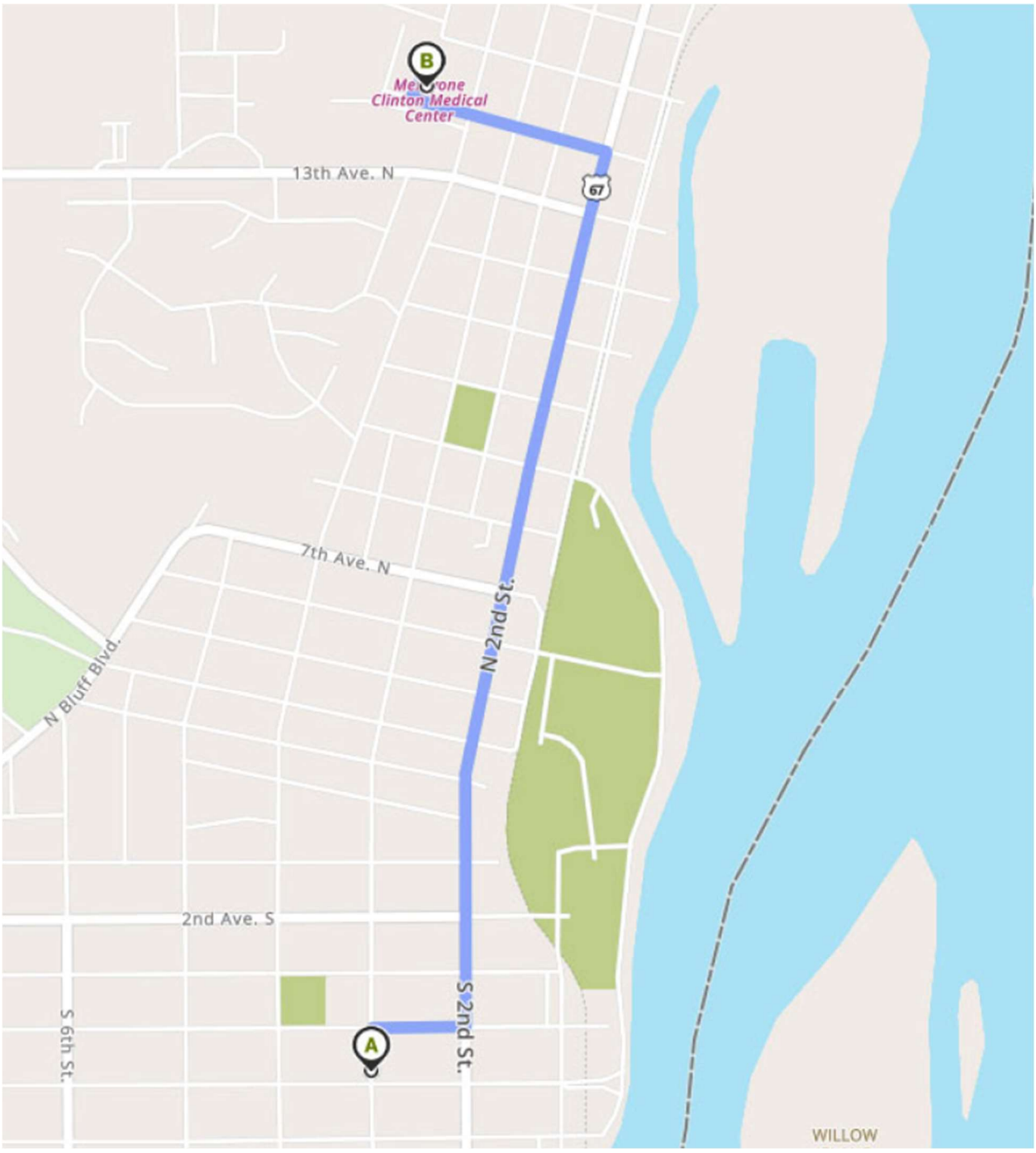
Work Site Name: *Former YMCA Building*

Work Site Address: *480 South 3rd Street, Clinton, Iowa 52732*

- *Head toward 4th Ave S on S 3rd St. (322 feet)*
- *Turn right onto 4th Ave S. (0.1 mi)*
- *Turn left onto S 2nd Street (US-67) (1.2 mi)*
- *Turn left onto 14th Ave N toward Hospital (0.3)*
- *Turn right (187 feet)*

End: MercyOne Clinton Medical Center is straight ahead.

Example Map: Map Diagram 1: Route to Hospital From Project Site



APPENDIX E

EMSL ANALYTICAL LABORATORY QUALITY ASSURANCE / QUALITY CONTROL

EMSL Analytical, Inc. Management

EMSL Analytical, Inc.

LABORATORY
QUALITY MANAGEMENT SYSTEM
(QMS) MANUAL

REVISION 26 – Dec. 15, 2023

For laboratory located at:

Lab specific Cover Pages can be found on E-link:
Quality Assurance>Quality Management System Manual>Lab Cover Pages

Approved by:

Laboratory Manager	Date
	12/15/2023
Nicholas Straccione Vice President of Quality Assurance	Date

Issued by: EMSL Analytical, Inc.
Corporate Headquarters
200 Route 130 North
Cinnaminson, NJ 08077
(800) 220-3675

Contains: QMS Manual Main Section

Mod A: Asbestos	Mod G: Food Sci.
Mod B: Env. Lead	Mod H: Molec. Biol.
Mod C: Env. Micro	Mod I: Materials Sci.
Mod D: IH	Mod K: Chemistry
Mod E: Radiochem	Mod L: Air Toxics
Mod F: Radon	

Authorized for use by Dr. Peter Frasca/President

COMPLIANCE and COMMITMENT AGREEMENT / SIGNATURE and INITIALS LOG

In executing this Agreement, I attest and confirm that I have read and understand the entire contents of this document. My signature represents that I agree to fully comply with, implement, and enforce all requirements, procedures, and protocols specified in these procedures set forth in this document and any supporting referenced materials or methodologies by the effective date. I acknowledge the proprietary nature of this document. Furthermore, I understand that this document is the most recent version and any revisions, modifications, additions, or amendments to this document will only be recognized and executed upon review, final approval, and reissue of this document by the Quality Assurance Department management.

Those individuals who have checked the column labeled "Lab Management Commitment" are further acknowledging they approve the document for use in their lab and are committed to enforcing the requirements stated herein. Those individuals holding positions of Laboratory, Department and/or Quality Manager, or who have been named to a position of authority for the purposes of state or independent accreditations shall mark this column.

After reviewing the main QMS Manual section and modules appropriate to the work you perform, sign, initial, date and check off those modules which you are acknowledging. **Print this page as many times as needed. A copy of this completed page shall be maintained as a Signature and Initials Log as per the requirements of Section 4.13.5 of this Manual.**

Print Name	*Signature*	*Initials*	*Lab Management Commitment*	*Date*	*Main Manual*	*A (Asb)*	*B (Lead)*	*C (Micro)*	*D (IH)*	*E (RadChem)*	*F (Radon)*	*G (Food)*	*H (MolecBiol)*	*I (MatSci)*	*K (Chem)*	*L (AirTox)*

QMS Manual Signatures/Initials Log, Page __ of __ (reprint page as necessary)

Table of Contents

PLEASE NOTE: This QMS Manual contains 86 pages of content, each page numbered as Page xx of 86. The initial six pages of the QMS Manual are uniquely identified using Roman numerals, as they contain information guiding the reader through the document.

Section 1.0: Scope

1.1 Scope of EMSL Quality Management System (QMS) Manual

Note: *Prior to Rev. 16 of this manual, the name of this manual was "EMSL Quality Assurance Manual." References to this term or the acronym (QAM) may appear on other management system documents but shall be read to reference this document. Out of date references will be updated as documents are revised.*

EMSL Analytical, Inc.'s commitment to providing quality services to our customers is embodied in EMSL's corporate policy on quality assurance (QA). The aims of the EMSL quality assurance program are to ensure the following:

- Quality, accuracy, and integrity of analytical results to minimize risk
- Conformance with analytical methodologies
- Conformance with corporate mandated QA/QC requirements
- Delivery of the highest quality of professional services and technical excellence to our customers
- Fulfillment of the requirements as set forth by of the American Industrial Hygiene Association Laboratory Accreditation Program (AIHA LAP, LLC), the National Voluntary Laboratory Accreditation Program (NVLAP), The NELAC Institute (TNI), A2LA, CALA, NYS ELAP, NJDEP, PALA, and other independent, state, and local accrediting authorities as relevant to the laboratories' qualifications. Test methods under which our laboratories perform accredited testing are listed on our certificates of accreditation found on the EMSL website – www.emsl.com.

To achieve these goals, this QMS Manual directs the implementation and maintenance of the quality management program, describes responsibilities and duties of personnel as related to quality, and establishes the required policies of the quality management system. This QMS Manual covers analytical services offered in the EMSL laboratories, Inc. (hereafter referred to as EMSL), which include asbestos, lead, environmental microbiology, industrial hygiene organics and inorganics, radon, food microbiology and chemistry, materials science, environmental chemistry metals, radiochemistry, and other developing service areas. General policies applicable to analytical areas are addressed in the main section of the QMS Manual, while policies, procedures and requirements for each specific service area are addressed in the program specific modules. These modules are organized as follows:

Module	Program Description
A	Asbestos
B	Environmental Lead
C	Environmental Microbiology
D	Industrial Hygiene
E	Radiochemistry
F	Radon
G	Food Microbiology and Chemistry
H	Molecular Biology (PCR)
I	Materials Science
K	Chemistry
L	Air Toxics

EMSL laboratories shall comply with the requirements detailed in this manual and the additional program

requirements specified in Modules A – L as applicable to the laboratory operations. This manual is posted to the EMSL E-link SharePoint site, and is accessible by all employees. Employees are responsible for being familiar with, and adhering to, its contents.

This manual is the property of EMSL and may not be used for any purposes other than those related to EMSL work. Under no circumstances, will this manual be removed from the laboratory facility, nor will any of its contents be disclosed to any outside entity unless prior approval has been granted by EMSL corporate management. Requests for copies of this manual must be made to the EMSL National Quality Assurance Department.

1.2 Quality Management System (QMS) Manual Maintenance and Update Procedures

As defined in the EMSL Control of Documents SOP (QA-SOP-301), the QMS Manual will be reviewed at least annually for continued suitability. Review will be conducted by the QA Department with assistance from national technical management and select others with appropriate knowledge and background in each area. Any revisions shall be reviewed and approved by the Vice President of Quality Assurance. Prior to publication, the QMS Manual revision will be authorized by the EMSL president. The revisions made to the QMS Manual are recorded in a Revision History in Section 6. A 'Notice from the Quality Assurance Department' may also be provided with the QMS Manual at distribution summarizing the additions and changes to the manual.

Section 2.0: Normative References

The EMSL's Quality Management System (QMS) has been developed to comply with the requirements of the following current references as well as those of several other state and local accrediting agencies:

- ISO/IEC 17025:2017
- The NELAC Institute (TNI) standards, 2016 (or latest revision)
- A2LA General Requirements: Accreditation of 17025 Laboratories (R101), November 2021 (or latest revision)
- AIHA LAP, LLC Accreditation Policies, June 2022 (or latest revision)
- NIST Handbook 150:2020, August 2020, NVLAP Procedures and General Requirements (or latest revision)
- PALA, Analytical Laboratory Accreditation Program
- CALA, Canadian Association for Laboratory Accreditation, Inc.
- Applicable State Quality Policies

Section 3.0: Terms and Definitions

See *Appendix A – Glossary*

Section 4.0 - Management Requirements

4.1 Organization

4.1.1 Quality Policy Statement

EMSL is committed to providing a high standard of service and producing dependable, accurate and technically defensible test results in order to best serve our customers. EMSL will avoid involvement in activities that would diminish confidence in its competence, impartiality, judgment, or operational integrity. Our experienced and qualified technical personnel are committed to providing data of the highest quality achievable.

The senior management of EMSL is committed to adopting the quality standards utilized by the various accrediting agencies and those requirements documented in the ISO/IEC 17025, TNI standards and PALA, and continually improving the management system efficiency. Management ensures scientific rigor and professionalism for our customers for the parameters specified in DR-12-CDA. The major goal of the laboratory and its personnel will be toward constant improvement in the quality management system, which has been designed with the purpose of ensuring consistent operations leading to quality data.

The senior management staff of EMSL acknowledges and accepts the responsibility for the commitment towards the quality of the data produced by the laboratory, and makes a commitment toward continual improvement of the final product and the management system. In doing so, management provides the laboratory manager and the Quality Assurance Department with full authority to accomplish this end. Management is committed to providing the necessary resources to provide high quality analytical data.

EMSL Analytical, Inc. is committed to address any complaints about the quality of the reported analytical results. Any complaint about the quality of report results may be referred to the accrediting body if such complaints cannot be resolved directly with the customer.

Personnel concerned with testing within the laboratory must familiarize themselves with the quality documentation, and implement the policies and procedures addressed in this manual.

Commitment to ISO Standard

Starting with corporate management and extending to regional and local laboratory management, EMSL is committed to ensuring that the standards documented in ISO/IEC 17025:2017 (or the most recent revision of the 17025 standard) are upheld in the applicable aspects of company affairs. The range of activities include, but are not limited to:

- Organization of management system in accordance with Option A of ISO 17025:2017
- Management system - definition, establishment, and maintenance
- Document control
- Review of requests for work (contracts, etc.)
- Subcontracting services/inter-laboratory exchange of samples
- Purchasing supplies
- Service to the customer
- Complaints
- Control of non-conforming work
- Corrective and preventative action
- Control of records
- Internal audits
- Management reviews
- Personnel qualifications
- Method validation
- Traceability
- Assuring quality
- Reporting results
- Risk management

By way of authority, it is corporate management that implements, maintains, and monitors compliance.

This statement is issued under the authority of company president, Peter Frasca, Ph.D.

4.1.2 Relevance of Personnel Activities and Communication by Management

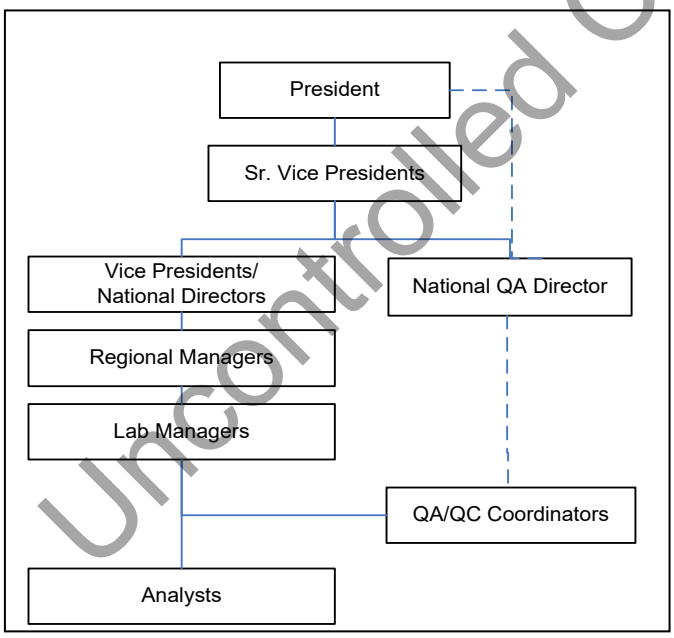
Management communicates to the staff the importance of their role in customer needs, regulatory requirements and involvement, to the achievement of the objectives of the management system through this QMS Manual, newsletters, management meetings and telephone and video conferences and periodic phone conversations.

Correspondence is also performed through the monthly quality control reports, the quarterly quality control reports, and the annual management review.

Management ensures employees are aware of their role in the achievement of the objectives of the quality management system by requiring employees to sign an acknowledgment of understanding of this QMS Manual, as well as relevant policies and procedures.

The management of EMSL Analytical, Inc. accepts legal responsibility for its actions associated with the analysis and reporting of samples in accordance with its Quality Management System.

4.1.3 General Organization Chart – Quality Management Structure



Individual Lab Organizational Charts are available on E-Link in Quality Assurance>QMS Manual>Org Charts.
Note: The terms 'Sr. Vice President,' 'Vice President,' 'National Director,' 'Regional Manager,' and 'Lab Manager,' wherever they appear in this document and its Modules shall be understood and read to mean 'Sr. Vice President(s),' 'Vice President(s),' 'National Director(s),' 'Regional Manager(s),' and 'Lab Managers(s),' where applicable.

4.1.4 Corporate Organization

The corporate headquarters of EMSL operates out of the Cinnaminson, New Jersey office location. The corporate headquarters oversee the laboratory operations located there, as well as the branch laboratory locations. Organizational charts for each laboratory are maintained by the corporate QA Department and are available on the company's intranet (E-link).

Corporate headquarters are responsible for the management of the company activities. These include:

- Fiscal management
- Personnel management
- Human resources
- Information technology (IT)
- Credit and collections
- Accounting
- Sales
- Customer service
- Contracts review
- Business development
- Quality assurance/quality control management systems
- Legal counsel
- Purchasing

The corporate laboratory and the branch laboratories perform the company's analytical services. They report to the corporate headquarters on quality control, productivity, staffing and marketing/sales matters.

4.1.4.1 EMSL Analytical, LA Testing, MPL Laboratories and Advanced MicroAnalytical

EMSL Analytical goes by three additional DBA names: LA Testing, operating in Southern California; MPL Laboratories, a GMP-microbial lab in Sparta, New Jersey; and Advanced MicroAnalytical, a materials testing lab in Salem, New Hampshire. The policies and procedures documented in this manual apply to all facilities, including those doing business as LA Testing and Advanced MicroAnalytical. MPL Laboratories operates under its own QMS Manual, and is not covered by this manual.

4.1.4.2 Products Division

EMSL also operates a products division which supplies environmental sampling equipment. No key personnel in this division have direct involvement or influence on the testing activities of our laboratories and, therefore, present no conflict of interest.

4.1.4.3 Roles of Administrative Support Groups

This section describes the basic role of the corporate administrative support groups in the laboratory organization. Administrative support consists of:

- Information technology
- Human resources
- Corporate counsel
- Accounting
- Credit/collection
- Sales and marketing
- Corporate customer service
- Purchasing

The departments of the support group are located in the corporate headquarters. Each department has defined roles which provide the laboratories with the support needed to maintain the business. Laboratory managers have direct access to employees of the individual departments in the administrative support group.

4.1.4.3.1 Information Technology (IT)

The IT Department is responsible for computer and technology services at EMSL including, but not limited to, servers, PCs, telecommunications, storage, security, web services, software licensing, repair, maintenance, support, and custom enhancement of EMSL's LIMS (Sample Master XP), LabConnect (report distribution engine) and all company databases. Requests for assistance are forwarded to IT through an e-mail help request system (itsupport@emsl.com). In addition, the IT Department is responsible for instructions for use of its products.

4.1.4.3.2 Human Resources

Human resource responsibilities are handled by EMSL's Human Resources Department. Responsibilities include, but are not limited to, employee recruitment and hiring, personnel record keeping, employee benefits and career development, as well as providing advice to laboratory management on topics such as employee discipline, conflicts of interest, and discrimination and harassment prevention.

4.1.4.3.3 Corporate Counsel

EMSL maintains an in-house corporate counsel. Corporate counsel advises EMSL corporate management on legal issues related to the business of EMSL.

4.1.4.3.4 Accounting

The Accounting Department has the fiduciary responsibility of ensuring the accuracy and timeliness of all accounting processes and financial reporting. This includes invoicing to customers, processing and payment of vendor bills, cash management, reconciliation of accounts, and satisfying financial reporting obligations to internal and external entities. The department ensures accounting transactions are recorded, flow through the general ledger, and are properly summarized to produce financial statements for management in accordance with Generally Accepted Accounting Principles (GAAP).

4.1.4.3.5 Credit/Collections

This is a sub-department within Accounting. The responsibility of this department is to act on the outstanding accounts receivable sub-ledger, which lists customers with outstanding invoices. Contacts are made in an effort to ensure outstanding debt is collected in a timely fashion. This department deposits daily cash receipts and applies customer payments to their accounts. It also reviews accounts in consideration for outside collection assistance.

4.1.4.3.6 Sales and Marketing

The Sales and Marketing Department develops new business for EMSL through advertising, marketing, and contacting potential customers. Each sales employee is assigned customers for whom they are responsible for negotiating contract terms. Marketing is responsible for the development of marketing materials including fliers, advertising, and informational materials distributed via the web and through the laboratories, as well as in-person through EMSL's participation in conferences and exhibitions.

4.1.4.3.7 Corporate Customer Service

The Corporate Customer Service team assists Marketing, Sales, and EMSL laboratories nationwide. Their current duties include, but are not limited to, answering incoming calls to the customer service extension, assisting customers who are seeking information on capabilities and technical questions, researching invoice discrepancies, finding, and sending

reports, assisting with LABConnect user issues, setting up LABConnect accounts, placing supply orders, and assisting with pricing inquiries.

4.1.4.3.8 Purchasing

The EMSL Purchasing Department is responsible for arranging for the procurement of supplies and services for the entire EMSL organization. Responsibilities include obtaining and reviewing suppliers for business-critical supplies and services, reviewing and approving service orders submitted by branch laboratories, and tracking performance of suppliers and service providers by being the main point of contact for complaints and supply/service problems. See § 4.6 for additional information.

4.1.5 Confidentiality, Ethics and Data Integrity Policy

4.1.5.1 Confidentiality (see also § 5.10.5)

It is understood that confidentiality and proprietary rights must be respected throughout the performance of services for any customer. Information will only be given to those for whom it is intended, and the proprietary rights of our customer shall be protected. EMSL does not place information related to our customers in the public domain. Data reports and/or other related information will not be given out to any person other than the customer, unless prior approval from the customer is received, or when EMSL is compelled to disclose records and/or information by law, subpoena, government entity, or other legal means. When the lab is contracted to notify the customer of the release of confidential information, it shall. Any information relayed to the laboratory by a third party (regulator, complainant, etc.) associated with the customer shall be kept confidential, unless agreed upon by the source.

This attention to confidentiality extends beyond the workplace. Employees, contractors, external assessors, and committee members shall be aware that revealing confidential information in a non-work social setting is still considered a breach of confidentiality requirements.

The laboratory manager is responsible for ensuring the sample results and related information is disseminated appropriately. In the event there is a question regarding applicability of confidentiality (including requests from government agencies or legal representatives), the vice president of quality assurance, national directors and/or vice presidents or Sr. vice presidents are to be consulted.

4.1.5.2 Ethics and Data Integrity Policies and Procedures

This section describes one of the key elements of this quality assurance program. A proper ethics and data integrity program establishes the principles which ensure the well-being of the company and its staff members. It presents the company values on honesty, integrity, excellence, and trust.

4.1.5.2.1 Ethics Policy

As a condition of hire, every employee (part-time or full-time, temporary, or permanent, including interns) is required to sign an acknowledgement of the Corporate Ethics Policy. The signed policy statement shall be maintained in the personnel files. This policy is as follows:

EMSL Analytical, Inc.
Corporate Ethics Statement

In order to comply with The NELAC Institute and ISO 17025 standards and to provide the highest level of proper, honest, reliable, legal, and ethical service to EMSL Analytical, Inc.'s customers, EMSL requires that each employee comply with the following Corporate Ethics Statement ("Ethics Statement"). This Ethics Statement mandates that each EMSL employee performs his/her jobs honestly, properly, ethically, and legally, and that each EMSL employee performs his/her assigned responsibilities with the utmost regard for the standards set forth in this Ethics Statement and in the EMSL Employee Handbook. Under no circumstances will any EMSL employee act dishonestly, unreliably, unethically, or unprofessionally while engaged in employment with EMSL. Without limiting what EMSL may consider acts that violate this Ethics Statement, examples of prohibited acts are as follows:

1) *Fabrication of data of any kind, including, but not limited to,*
   - *Reporting data for samples not analyzed*
   - *Quality control or customer results*
   - *Training records*
   - *Calibration measurements*
   - *Maintenance records*

2) *Intentional misuse of company resources, including but not limited to:*
   - *Changing documents without proper authorization or embezzling documentation (Manuals, Standard Operating Procedures, company generated forms)*
   - *Performing unauthorized services for personal use or for use by an EMSL competitor, or for any other non-EMSL purpose or use*
   - *Misuse of office resources (phone, fax, internet, etc.) for any non-EMSL purpose or use*

3) *Back-dating data*

4) *Misrepresenting or fabricating performance (e.g., sample productivity, billing)*

5) *Signing acknowledgements of policies or procedures (e.g., QMS Manual, SOPs, work instructions, policy statements) without having read, understood, and committed to their contents*

6) *Knowingly failing to follow said policies and procedures for any reason including, but not limited to, for the sake of productivity*

7) *Misrepresenting qualifications (e.g., experience, academic training, etc.)*

8) *Disclosing information in contravention to, or in disregard of, customer confidentiality agreements*

EMSL prohibits these and any other act that violates the Ethics Statement or the EMSL Employee Handbook. The officers, managers, and employees of EMSL will not condone, tolerate, encourage, or ignore any unprofessional, illegal, or unethical actions directed towards or impacting a person's work at EMSL, EMSL customers or potential customers, or a person's co-workers; or any act that violates the Ethics Statement or the Employee Handbook. In addition, no officers, managers, or employees of EMSL shall be offered, given or accept any encouragement, monetary or otherwise, to perform acts which violate the Ethics Statement or the Employee Handbook.

The management of EMSL strives to ensure laboratory employees (especially analysts) are not exposed to undue pressures such as:

- *Impossible time constraints (turnaround times)*
- *Customer influences that may affect analysis*
- *Pricing/marketing issues*
- *Productivity rates**

If employees feel they are exposed to any undue pressure, the situation should be brought to the attention of that staff member's immediate supervisor. If the supervisor is unable or unwilling to resolve the issue, or if the source of pressure originates with the supervisor and the staff member feels they cannot bring it to their attention, the situation may be reported to the Lab Manager or corporate management for review. These items may always be brought to the attention of the human resources department.

**NOTE: The corporate management of EMSL must monitor analyst's productivity rates as a normal course of business. Reasonable rates of analysis are used as guidelines to help determine analysts' ability. At no time are analysts given productivity goals that are unreasonable.*

Employees are required to report to managers located at EMSL branch offices, EMSL Corporate Officers/Managers or human resources department located in Cinnaminson, New Jersey, all acts by EMSL employees, managers or officers that may violate this Ethics Statement. The failure to report such actions may subject that person(s) to the punishments set forth below and in the Employee Handbook. Reporting unprofessional and/or unethical behavior will not negatively impact employment and will not jeopardize the employment status of any EMSL employee.

If an unfortunate event occurs where a customer or fellow employee asks a staff member to perform in an unethical manner, the situation will be brought to the attention of that staff member's immediate manager. If the cause of pressure comes from the immediate manager, or the immediate manager is unable to resolve the issue, the situation may be brought to the next level manager for resolution. At all times, an ethics issue may be brought to the human resources department or other corporate management by any staff member. Issues will be handled confidentially, whenever possible.

If a violation or potential violation of this ethics statement has been reported, it will be investigated by the laboratory manager and/or by corporate management. Investigations will be conducted confidentially until they are concluded. The findings shall be documented. Where customer data may have been affected, the customer shall be notified as soon as practical (no more than 15 days after close of investigation). These communications shall be documented in the integrity investigation records.

Depending on the findings of that investigation, any violation of the ethics statement may subject the offending employee to disciplinary or corrective action as outlined in this ethics statement or the Employee Manual. Following investigation, if it is determined that a violation has occurred, EMSL, in its sole discretion, may determine appropriate disciplinary or corrective action as outlined in the ethics statement or Employee Handbook, which may include:

- *Verbal warning*
- *Written warning*
- *Termination of employment*

In addition to the above, EMSL reserves all rights to take appropriate legal action when it deems necessary. Employees must also be aware that breaches of personal and legal data integrity may lead to civil liability/criminal prosecution and fines/punishment.

(end of Ethics Statement)

4.1.5.2.2 Ethics Committee

The Ethics Committee is a group of individuals selected from various departments to review potential ethical violations. Members of the group receive information from employees, customers, assessors, etc., and investigate the instance for validity. A lead person will be assigned, and additional members of the group, along with anyone else deemed necessary for investigation, will gather the information needed to decide whether or not the act in question was done with or without malicious intent. Should the committee decide the situation was unintentional, the matter is documented and filed on the secure QA drive, stating the findings. If an intentional ethical violation is determined, the committee will notify Human Resources, Legal Group and Senior Management of findings, with supporting documentation. The severity of the act will determine the disciplinary action taken, including possible termination. All documentation is filed in the secure QA drive.

4.1.5.2.3 Data Integrity

The data integrity policy is a portion of the ethics policy relating to fabrication of data and misrepresentation of results. EMSL complies with the TNI standard requirements addressing data integrity procedures as described below.

Ethics and Data Integrity Training

One of the objectives of the quality assurance program is to ensure the staff of EMSL is provided training in the aspects of ethics and data integrity as they pertain to corporate policy. The training is provided within three months of hiring, and annually thereafter. The goals of this training program are:

- To understand the responsibility to provide true and accurate information
- The understanding of the consequences of unethical conduct
- Provide direction to employees
- Define right and wrong (as it is job related)
- The understanding of the impact of our actions

Training will be provided in the form of required readings, staff meetings, workshops and/or corporate issued newsletters. Corporate management and the laboratory manager are responsible for ensuring this training is provided to the staff, and that records are maintained documenting the training.

Signed data integrity documentation: The ethics statement is signed by each employee as a condition of employment. In addition, a QMS Manual compliance disclosure form is executed by each employee (see *Compliance Disclosure* at beginning of this document). This compliance disclosure states that, “In executing this Compliance Disclosure, I attest and confirm that I have read and understand the entire contents of this document” (i.e., this manual).

Periodic Monitoring of Compliance - Methods of Monitoring Compliance May Include:

- Review of monthly and or quarterly quality control reports: Reports are submitted to the Quality Assurance Department for review. This review includes a check on integrity such as misrepresentation of data, falsification of

results, etc. Reports of review are completed and made part of the annual management review report.

- Monitoring of proficiency testing performance: Scores of PT samples are summarized in a report and reviewed by the QA Department, the national director and vice presidents
- Investigations initiated by a customer or internal complaint
- Internal audits
- Periodic submittal of blind samples by management
- Secondary data review

Confidential Reporting

As noted in the ethics agreement, issues that cannot be discussed directly with local lab management may always be directed to the corporate human resources department for review. Issues will be handled confidentially, whenever possible.

Data Integrity Investigations

When data integrity issues are reported, they will be reviewed by the party receiving the report. The issue shall be investigated as appropriate in order to determine its extent and impact, both potential and actual. Where detailed investigation is necessary, the person receiving the integrity complaint shall inform the vice president of quality assurance, or corporate QA manager, or human resources department to assist and review the investigation. Investigations shall be conducted in a confidential manner until they are completed. The investigation shall be documented including details on any notifications made to customers receiving affected data.

4.1.5.2.4 Impartiality

EMSL has reviewed laboratory activities and identified potential situations where impartiality can be affected:

- Financial
- Conflicts of interest
- Bias
- Prejudice
- Intimidation

The management staff and EMSL Quality Assurance personnel ensures impartiality through training, internal and external audits, peer review, ethics and integrity policies, conflict of interest, etc. Certain procedures are performed daily, while others are conducted annually; for example, annual data integrity and ethics training. As new situations present themselves, the management team reviews the potential conflict and brings the occurrence to the Human Resources department and Senior Management.

A more detailed description regarding how EMSL assesses impartiality can be found in QA-FM-10 Risk Assessment.

4.2 Management System

4.2.1 Program Objectives

The program described in this manual is designed to help plan and institute company policies and quality objectives throughout the laboratory facilities. This program is intended to provide procedures and policies, which provide:

- Development of company quality control programs
- Implementation of good laboratory technique
- Constant oversight of laboratory quality performance
- Establishment of training requirements
- Job descriptions of each employee delineating responsibilities
- Development and maintenance of internal quality audit program
- Use of appropriate analytical technology including review of current literature to capture recent applicable developments
- Proper documentation and quality review of analytical data
- A comfortable work atmosphere away from undue productivity pressures
- Maintenance of accreditation programs
- Assurance that national coherency is maintained through standardization of policies and procedures
- Control and maintenance of round robin programs
- Control of documents
- Respect for customer confidentiality
- Actions to address risks and opportunities

Quality policies and procedures are integrated into our daily work, and are constantly reviewed by national, regional and laboratory management and by the Quality Assurance Department.

The program is managed and maintained by the corporate QA Department.

4.2.2 Management System Review

The efficacy and appropriateness of the Management System is reviewed by the National QA Director and other management staff at least annually, as part of Annual Management Reviews. In addition, frequent periodic reviews are conducted in response to corrective and preventive actions. Per the EMSL document control program, documents which are part of the management system are reviewed at least once every three years, and the QMS Manual itself is reviewed annually. Revisions to the management system are discussed with technical and management personnel with the expertise to discuss the feasibility and acceptability of any requested changes.

4.2.3 Changes to the Quality Management System

The quality management system is designed to ensure the integrity of the system is maintained in the event any changes take place. If any changes to the management system are planned and implemented, the integrity of the management system will be maintained by senior management. Procedures include:

- Contingency plans
- Assignment of the same responsibility by multiple personnel (backups)
- Assignment of deputies or designated second person
- Implementation of procedural change
- Providing training if necessary for change

4.2.4 Departures from Quality Assurance Policies

Any departure from the procedures and policies as stated in this document must be reviewed by the Quality Assurance Department and corporate management prior to approval and effect. This review will include, at a minimum:

- Reason for deviation from policy and/or procedure
- Applicability of alternative policy and/or procedure
- Availability of resources
- For deviations of analytical procedures, assurance that data is reported with appropriate references and disclaimer on final reports affected by a policy and/or procedure change (if applicable)

A record of the review of the alternative procedure or policy is maintained as part of the project files.

No departures from the policies and procedures, as written in this document, are permitted without acceptance by the QA Director or corporate management.

4.2.5 Roles and Responsibilities of Technical and Quality Management

The roles and responsibilities of the technical and quality management of EMSL are described in the Personnel section of this manual (§ 5.2).

4.2.6 Addressing Risk and Opportunities

4.2.6.1 The policies and procedures in place, QMS Manual, SOPs, QA reports, Annual Management review, internal audits, test method assessments, corrective/ preventative action program, etc., ensure risk is limited during the activities of the laboratory. Each of the policies and procedures implemented are reviewed on a periodic basis by Technical Managers, along with the QA Department, to produce consistently high-quality data and reduce undesired outcomes.

4.2.6.1.1 Should any undesired outcomes arise, each case is evaluated on a case-by-case basis by supervisory personnel, along with the QA Department, through our non-conforming work policy and/or corrective action procedure.

4.2.6.1.2 Instances of questionable judgement are referred to the Ethics Committee. The committee researches the situation, and determines whether the act in question was intentional or accidental. Any intentional instances will result in disciplinary action that may result in termination. Other situations, deemed unintentional, can be addressed through corrective actions, training, or another form of correction.

4.2.6.2 EMSL management holds meetings with personnel on a weekly basis to discuss ongoing business opportunities, risk assessments, and continuous improvements that can be made. Upper Management is provided with information from the EMSL network, and the most appropriate course of action is determined based on the discussions at the meetings.

4.2.6.3 A more detailed description regarding how EMSL assesses risk can be found in QA-FM-10 Risk Assessment.

4.3 Document Control

EMSL document control procedures have been established to meet the requirements of ISO 17025 and the accreditation requirements of AIHA LAP, LLC; A2LA, The NELAC Institute (TNI), NVLAP, CALA and

state agencies. Procedures and policies apply to all EMSL laboratories. The program is overseen and administered by the Quality Assurance Department, including a designated Document Control Manager, who is the person mainly delegated to posting new and revised corporately approved documents on the E-Link SharePoint site, and sending out notifications when documents are added or revised.

The EMSL document control procedures are documented in the EMSL Controlled Documents SOP (QA-SOP-301), Document Master Lists SOP (QA-SOP-302) and related documents. EMSL controls documents to ensure the laboratories are performing analysis and reporting data following only the most up-to-date corporately approved EMSL policies and procedures. This program also establishes company-wide standardization and preserves company intellectual property. EMSL's document control SOPs referenced above covers the following topics in detail:

4.3.1 Structure of controlled document system
4.3.2 Required elements of a controlled document
4.3.3 Initiation, review, and approval of new or revised documents
4.3.4 Protection of controlled documents
4.3.5 Distribution of controlled documents by laboratory manager
4.3.6 Control of local documents and locally maintained copies
4.3.7 Retirement of obsolete documents
4.3.8 Periodic review of controlled documents
4.3.9 Amendments and revisions
4.3.10 Changes to LIMS final report templates

The list of corporately controlled documents is maintained in QA-FM-304 Corporate Master List of Controlled Documents. Each lab maintains a list of locally controlled documents in QA-FM-303 Local Master List of Controlled Documents. SOPs specific to cGMP are detailed in a locally controlled document, Cinnaminson cGMP Master List of Documents, available on Cinnaminson's local drive.

4.4 Review of Requests, Tenders and Contracts

4.4.1 General

EMSL services are generally offered as line-item tests which reference documented methodologies. Laboratory services are typically requested by the customer as "open order" requests. Samples may be delivered to the laboratory at any given time, without a firm documented arrangement. Analytical services are often performed on verbal contract. In these situations, our general terms and conditions apply. Management review procedures for open orders, verbal contracts and for the cases where a written contract is established are discussed in this section.

4.4.2 Procedures for Review of Contracts, Requests and Tenders

Requests, tenders, and contracts are three parts of the transaction process. Requests for service are made by the customer for a scope of work. The tender is the proposal from the lab to the customer, which could include clarifications of the work desired, proposal of turnaround time, and costs for the service. The contract is the actual agreement between customer and lab on finalized terms.

The customer's request for services may be made directly to the laboratory manager, corporate management, or sales staff. In any case, before the samples are accepted for analysis signifying acceptance of the contract, laboratory or corporate management must review the request. This review must cover:

- Requirements for analysis - method requested is a standard method (i.e., available on price list) and understood. Special handling procedures (if any) are noted.
- Customer's requirements for Laboratory Accreditation
- Applicability of the method requested - method is available and applicable for the sample type and result(s) will provide the customer with required information
- Technical capabilities- training, experience, and qualifications of the staff
- Understanding of the method(s) requested
- Equipment resources - equipment is available, in working order and calibrated
- Staff resources - number of personnel to perform the work and required QC is suitable
- Subcontracting - identification of outside services needed to support the request or contract (including other EMSL laboratories)

Under general circumstances, the status of the laboratory capabilities is well established. For example, technical ability and equipment resources are monitored with performance of QC analyses, proficiency testing and compliance with the QA policies documented in this manual (e.g., documentation of SOPs, training requirements, analytical specialist's qualifications, and calibration requirements). Applicability of method and staff resources is more subjective. It is the responsibility of the laboratory management to review the requests and ensure the laboratory (or laboratory to which the work will be subcontracted) can perform the services.

4.4.2.1 Documentation of Review

These reviews of customer requests are documented in a manner appropriate to the type of request. The majority of the work being received by EMSL is established as line item, open ended requests according to standard terms and conditions, or to prices which are negotiated with sales representatives ahead of time. Requests are generally made by the customer through the sales representative, corporate management, or laboratory management. Requests are reviewed and checked against the requirements listed above.

When work is received at the laboratory, the customer's COC defines the requested analysis and turnaround time. In addition, any requested deviations from standard terms and conditions or defined contractual requirements will be defined. If any clarification or modification of the request is necessary, the modified tender will be communicated to the customer and documented in writing, along with the customer's approval of these altered terms.

This review, and ultimately the acceptance of the work, is documented with the acceptance of the samples by the laboratory. The acceptance of a sample batch constitutes the review and acceptance of the request (or contract). The initials of the responsible laboratory staff member recorded on the internal chain of custody (in the 'sample accepted' box) documents the contract review.

Where standard terms and conditions are modified (e.g., special reporting requirements, non-standard pricing, modified methods, etc.), this shall be approved by a corporate sales representative. These approved contracts are maintained by the sales department and communicated to the laboratory as appropriate through special notes in SampleMaster. For more formal or complex contracts which involve review by the president or Sr. vice

president(s), documentation of review is evidenced with the signature of president or Sr. vice president on the contract.

4.4.2.2 Changes in Contracts, Requests and Tenders

If a laboratory is providing services under a written or verbal contract, that contract must be acceptable to both the laboratory and the customer. Any differences identified shall be resolved before the work begins. The customer shall be informed of any deviations to the contract or requests. Documentation of any pertinent discussions with the customer shall be documented.

Documentation of changes (or resolutions) is to be made as appropriate to the type of request. A simple notation on the chain of custody is sufficient for a change in turnaround time requirements, for example. More complex changes must be more formally recorded.

If a written contract needs to be amended after the commencement of the project, both the laboratory management and customer must agree to those amendments. These amendments must be documented.

4.4.3 Beginning New Work

The laboratory manager must not accept any new work without evaluating the current resources. This includes accreditation requirements, the availability of equipment and staffing. For example, a laboratory must not accept an increase in workload, if the laboratory staff is currently at capacity.

Any question regarding the capability of the laboratory to perform such new work must be brought to the attention of corporate management. The corporate management will either:

1) Provide the additional equipment and/or staff
2) Allocate work through the EMSL network
3) Reject the new work

4.4.4 New Technical Service

Prior to the implementation of any new technical service, corporate management performs a review. This review includes market applicability and availability of resources. The Sr. vice president(s) or the president must grant approval. The Sr. vice president or designated management personnel for the area being developed shall be notified of the expansion, and shall ensure standard operating procedures are written and quality control parameters are established for new methods.

4.5 Subcontracting of Tests

4.5.1 General

The EMSL subcontracting procedures are documented in the *EMSL Subcontract SOP (GEN-SOP-10)*. This SOP defines when a laboratory accepts samples to be subcontracted.

The network of EMSL laboratories provides the customer with a valuable resource. As per EMSL standard terms and conditions, EMSL reserves the right to subcontract samples to any EMSL branch lab, as long as the laboratory receiving samples holds equivalent relevant accreditations and scope of testing as the laboratory receiving the samples from the customer, and the customer is notified. By submitting samples for analysis, customers agree to these terms and conditions. In this way, samples may be shipped out for analysis to other EMSL laboratories when a laboratory is at workload capacity, turnaround time cannot be reached, or the laboratory temporarily does not have the analytical

capability (e.g., instrument is down, personnel are out). This flexibility is an added benefit to the customer, allowing drop-off of samples at any lab with the knowledge their requirements will be met.

When samples are subcontracted to an EMSL laboratory, a Sample Transfer Form or Standing Customer Agreement Form is completed electronically, or hard copy if necessary. These forms ensure the customer has agreed to the subcontract arrangements and is aware of the subcontractor's accreditation credentials, where applicable.

The laboratory receiving samples maintains responsibility for the subcontract lab's work except in those cases when the customer or regulatory authority specify which subcontractor is to be used, or when the receiving EMSL Lab is simply acting as a courier service (i.e., when they do not perform the analysis requested by the customer, or customer agrees beforehand that samples will be transferred).

In the event an outside, non-EMSL lab is required, the laboratory manager will ensure all testing is performed by qualified laboratories. Laboratories must subcontract only to outside laboratories that maintain accreditations appropriate for that analysis.

4.5.2 EMSL Courier Service

EMSL laboratories offer a courier service to customers that wish to drop off samples intended to be transferred to another EMSL laboratory for analysis. When a lab is acting as a courier, they are not seen to be part of the contract review for analytical process, and are not responsible for analytical results provided to the customer.

4.5.3 Selecting a Competent Subcontractor

Regardless of the situation, when subcontracting samples, the samples shall always be placed with a competent subcontractor. Where the customer specifically designates a laboratory to perform the analysis, this will override any other considerations and relieve the receiving laboratory of any responsibility for the selection.

In all other cases, the receiving laboratory shall select a laboratory which holds at least equivalent qualifications for the analysis. Relevant qualifications will depend on the needs of the customer, and should be determined prior to subcontracting. Where a laboratory is accredited for an analysis, the laboratory selected shall hold equivalent accreditations. If not accredited, it should be determined which accreditations are required by the customer and select a laboratory meeting those requirements.

Qualifications of EMSL laboratories are included in the "Laboratory Qualifications" pages on the EMSL website. The website includes copies of all accreditation certificates and scopes of accreditation, licenses, approval letters, etc., from 3rd party accreditors and regulators (e.g., state and federal departments).

If subcontracting to an external laboratory, the laboratory's qualifications shall be reviewed prior to selection. If the subcontract laboratory maintains accreditation for the analysis in question, a copy of their accreditation certificate shall be reviewed and kept on file. Where no accreditations are relevant to the analysis, information on laboratory personnel qualifications, quality system and proficiency testing participation may be requested at the user's discretion.

4.5.4 Customer Knowledge and Approval

As noted above, the EMSL standard terms and conditions reserves EMSL's option to transfer samples between EMSL branch laboratories with equivalent relevant qualifications. By submitting samples, customers agree to these terms, and accept a subcontracting arrangement with notification and

approval by the customer with the Sample Transfer Form or Standing Agreement Form. Unless otherwise documented on the chain of custody by specifying the lab to do the work, the transfer of samples may occur at the discretion of the laboratory manager as discussed in the EMSL Subcontracting SOP (GEN-SOP-10).

Under ordinary circumstances, the customer will be made aware of the laboratory and qualifications of the laboratory that will be performing the analysis at the time samples are submitted for analysis. In rare instances, a decision to subcontract may be made after the submission as a result of lab capacity, instrument problems, etc. In these cases, the laboratory will contact the customer to inform them the samples will be transferred. This communication will be documented in the customer correspondence logs or via e-mail. A Sample Transfer Form or Standing Agreement form is completed, documenting customer's approval.

In the case of outside subcontracting, the customer will be informed of the subcontract lab and their qualifications prior to sample submission. Unless the customer specifies the laboratory to be used, it is the lab manager and/or department manager's responsibility to select a competent laboratory for the work.

In any case, the test report submitted to the customer will make clear the location and identity of the laboratory which performed the work.

4.5.5 Responsibility to the Customer

The receiving laboratory (i.e., laboratory initially receiving the samples) is responsible to the customer for the work of any non-EMSL subcontractor, except in the case where the customer specifies which subcontractor is to be used.

In the case of subcontracting between EMSL laboratories, this responsibility is maintained regardless of whether the receiving laboratory is involved in the invoicing or direct reporting to the customer. Due to the corporate structure of EMSL, reporting is completed by the subcontracting lab, and invoicing is completed by the receiving lab, unless samples are relinquished. In this case, the samples are not considered to be subcontracted. Direct reporting from the analyzing laboratory ensures there is no confusion about the location at which the analysis was performed.

In all cases, the receiving laboratory remains the point of contact for the customer and will be involved in resolving disputes, arranging for reanalysis if requested, and generally acting as the responsible party for interacting with the subcontract laboratory.

4.5.6 Subcontract Register

As noted above, only competent laboratories shall be selected for subcontracting. Since EMSL laboratories may transfer samples to other EMSL laboratories with equivalent accreditations, the list of labs and qualifications on the EMSL website will be considered the registry of EMSL subcontract labs. This list is maintained and updated by the EMSL Corporate Quality Assurance Department.

In the case of outside laboratories used for subcontracting, a list of these labs shall be maintained in each branch laboratory that conducts external subcontracting, and these subcontractors shall be added to the EMSL Approved Vendor List and reviewed as per the EMSL vendor review process (see *QA-SOP-500: Evaluation of Suppliers and Service Providers*). In addition to the list, the information reviewed in making the determination of competence will be documented following the policies and procedures in QA-SOP-500.

4.5.7 Retention of Subcontracted Samples and Records

When samples are sent to another EMSL laboratory for analysis, the samples will be retained by the laboratory conducting the analysis, unless otherwise documented in project specific instructions. Technical records relating to the analysis (e.g., bench sheets, raw data, QC data) shall be retained by the analyzing lab, unless otherwise specified and documented.

When samples are subcontracted to an outside laboratory, the receiving laboratory shall ensure EMSL retention policies (for both samples and data) are communicated to the subcontracting lab, and samples are retained for the required period of time.

4.6 Purchasing Services and Supplies

4.6.1 General

The EMSL procedures for purchasing and evaluating of supplies and services that are critical to the analysis of samples are documented in two related SOPs:

QA-SOP-500: *Purchasing-Evaluation of Suppliers and Service Providers*
QA-SOP-501: *Purchasing-Receiving Supplies and Services*

These procedures help to ensure purchasing and vendor selection is consistent across all EMSL laboratories.

4.6.2 Purchasing

Prior to placing a purchase order for supplies or services, the laboratory manager shall refer to the EMSL List of Approved Vendors available on e-link. This list contains vendors for the following types of critical supplies and services:

- Laboratory equipment (consumable and permanent equipment)
- Subcontracted analytical work
- Proficiency testing providers
- Onsite services, such as balance calibration and repair
- Outside calibration services
- Reagents and standards

Approved vendors on the list have been evaluated by laboratory managers and the purchasing department on product/service quality, customer service, and delivery (see *QA-SOP-500*). New vendors will be added to the list after the Quality Assurance Department has verified the vendor has the necessary qualifications, and is then evaluated with the next annual evaluation survey. Any complaint regarding a vendor (e.g., defective product, poor customer service) will be communicated to the Purchasing Department, who will then investigate and help resolve the issue. Depending on the significance of the problem, a decision will be made between the national director, vice president, the Purchasing Department, and the Quality Assurance Department to discontinue use of the product, or place the vendor on probation.

Consumable supplies are to be purchased based on laboratory needs as determined by the laboratory manager. SOPs will indicate the specific grades and classes of consumable supply items to be used. Expendable materials intended for single use purposes such as microscope slides, plastic centrifuge tubes, etc., are not to be reused.

Selection of the appropriate grade of reagent(s) is designated in the reagent section of each analytical SOP, and in addition, may be specified by the laboratory manager in unusual circumstances. As a general practice, reagents will be of at least ACS reagent quality.

Reagents, reference standards and reference materials shall be purchased in accordance with the analytical needs of the laboratory as determined by the laboratory manager. Reference materials are crucial for ensuring traceability of results directly or indirectly tied to the quality and reliability of this material. Therefore, additional care must be taken to ensure qualified reference material providers are selected, and only grades of reference material that are fully accredited and NIST-traceable are purchased from qualified vendors. (See § 5.6.2 on more information on selecting reference material providers). Reference standards shall be NIST-traceable (where applicable) and include a certificate showing traceability. Reference materials and standard reagents shall be obtained from the vendor with a certificate of analysis (certificate must identify the lot number). These certificates shall be maintained in the laboratory files prior to initial use. If no certificate is received, laboratory shall contact the vendor.

For reference materials used in methods within the scope of ISO 17025 accreditations, reference materials shall be from a Reference Material Provider (RMP) accredited to ISO 17034:2016, and the product ordered shall be certified with a certificate bearing the Accredited RMP symbol.

Laboratory managers are to purchase reference materials and reagents in the smallest quantities practical to help reduce inventory. A reduced inventory will be used up more frequently, avoiding the possibility of having the standard stored in the laboratory past the expiration date.

Purchasing documents (e.g., order form submitted to purchasing via intranet, purchase order requests) shall contain technical details about the product or service being ordered. Prior to releasing to the vendor, these documents are reviewed for technical suitability by the laboratory management and/or the Purchasing Department. Most supplies are purchased through the EMSL 'Shopping Cart,' which is available on EMSL's intranet for placing purchase orders.

4.6.3 Approval of Service Providers

Outside services that are contracted and affect analytical testing, such as proficiency testing services, calibrations, repairs to equipment, adjustments to instrumentation, checks on performance, etc., require the vendor be accredited under the ISO 17025 standard, where applicable. Other considerations for the approval of providers (as per *QA-SOP-500*) include:

- Accreditation to appropriate standards (where relevant, e.g., ISO 17025, ISO 9001)
- Reputation in industry
- History of performance with EMSL
- Referrals

Services received must be documented and filed by the laboratory.

Note: When arranging calibrations with an external calibration provider, EMSL requirements for calibration certificates should be discussed with the provider at the time of contracting. See § 5.6.2 for requirements of a traceable calibration certificate.

4.6.4 Reception, Inspection and Acceptance of Reagents and Consumable Supplies

Procedures for the reception, inspection, acceptance, and storage of supplies are covered in QA-SOP-501. Generally, reagents and reference materials shall be verified against the product ordered, then dated and initialed, or a signature applied, with date received and expiration dates. Labels will also be dated and initialed, or a signature applied, when opened and/or when reagent mixtures are prepared. Materials shall be assigned an EMSL ID number and added to the Stock Standard and Reagent Log for the laboratory, along with required information.

4.6.4.1 Storage and Handling of Reagents, Reference Materials and Reference Standards

Reagents, reference materials and reference standards are to be stored in a manner which will conserve the purity and integrity. Reagents and reference materials are stored following manufacturer requirements (e.g., temperature, humidity). Care must be taken when handling reagents to avoid contamination or evaporation. Lids must be kept secure when not in use. Reference standards shall be stored according to manufacturer requirements.

All reagents shall be stored with bottle caps or stoppers securely sealed. If reagent materials have been spilled on the exterior of storage containers, containers should be wiped clean before being placed in storage. Storage cabinets shall be cleaned periodically to prevent deterioration. If storage cabinets show significant deterioration (e.g., rust) these shall be repaired or replaced to ensure their integrity.

General procedures for storage of reagents require the separation of incompatible materials. Organic solvents (e.g., acetone, THF, reagent alcohols) shall be maintained in a storage cabinet suitable for flammable materials (i.e., metal cabinet). Acids (nitric, hydrochloric, etc.) shall be stored separately from organic solvents in a cabinet away from them. Materials may be stored together when they are of similar classes that will not cause interferences or increase risk of cross contamination (e.g., hydrogen peroxide with acids).

4.6.4.2 Solution Preparation

Solutions prepared from neat materials shall be recorded on the *EMSL Standard Solution Prep Log* available on e-link. The log shall include a description of the solution, date of preparation, concentration and/or purity of solution, identification of parent material (i.e., the ID assigned on the *Stock Standards and Reagents Log*), preparer's initials, and expiration date. Solutions shall be labeled with the ID, ID number from preparation log, and expiration date (usually the expiration date of component materials which is closest to the date of preparation). Using preparation log and standards log, solutions shall be traceable back to parent material and certificates of analysis for that material.

4.6.4.3 Unique Identifier

For TNI labs: All containers of prepared standards, reference materials, and reagents shall bear a unique identifier and expiration date. When more than one container of a standard with the same lot number is received from a vendor, each container shall be labelled with a unique ID; for example, xxxA, xxxB, and xxxC. In the standard receipt log, one line entry for the standard may be made as xxx(A, B, C). This policy for labelling each container applies to standards and reagents prepared in-house as well.

4.7 Service to the Customer

Clear, continuous, and open communication between the laboratory and the customer is one of the keys to maintaining a successful, quality operation. Communication should be established prior to the start of any work. Information must be clearly understood between laboratory management and the customer. This information should include (but not be limited to):

- Type of analysis requested
- Turnaround times
- Expected deliverables (any requested changes to the standard report format)
- Sampling guidelines (media, recommended sample volume, etc.)
- Type of packaging for sample shipping

- Submission of final report (via fax, hard copy, mail, overnight shipment)

EMSL will cooperate with customer requests to monitor laboratory performance on their projects. Upon request, customers may be granted accompanied access to the laboratory to witness performance of testing or be provided with records (QC data, bench sheets, etc.) so long as doing so does not jeopardize the confidentiality of other customer information. Where a customer requests that we provide information on their project to an outside third party (their customer, for example), we must have written authority to do so. Text or email is acceptable.

Customer requests should be carefully considered and followed, as long as doing so is not detrimental to the business, integrity of the results, misleading, or in violation of any statutory, regulatory or accreditation requirements.

4.7.1 Documenting Customer Correspondence

Correspondence with customers shall be recorded by each EMSL laboratory in a manner fitting to the type of correspondence. Project related information may be recorded on the Chain of Custody forms for the project to ensure the information is available and associated with the project. Other correspondence may be manually recorded utilizing the Customer Correspondence Log template available on E-link, or commercially available bound phone message pads which are dated with initial and end dates, once full. Correspondence may also be recorded using electronic means when available to the laboratory (e.g., Outlook Journal feature, Maximizer, etc.). Regardless of how correspondence is recorded, the date of correspondence and initials of person making the entry is required. These records shall be maintained for 5 years, as per *QA-SOP-350: EMSL Record Control SOP,* or for the life of the project files, whichever is longer.

Customer complaints shall be documented utilizing the EMSL Complaint Resolution procedure (QA-SOP-600) and recorded on the Complaint Record form available from E-link. Where customer correspondence leads to corrective action, these corrective actions will be documented via the EMSL Corrective Action system (QA-SOP-200). When feedback is received via the web-based customer survey (rather than directly by the laboratory manager), the QA Department will forward this information to the laboratory manager for follow-up, as necessary.

4.7.2 Technical Support

EMSL provides quality assurance information and technical support to the customer to assure continued quality service. The support and information provided in relation to the work performed includes:

- Field sampling guides
- Availability of pertinent QC records
- Access to the Quality Assurance Department for technical assistance
- Security of data (confidentiality)
- Reasonable access to the relevant areas of the laboratory for the witnessing of analysis

EMSL also provides a variety of sampling equipment and procedures to support the customer's needs. Equipment is available such as sampling pumps, sampling cassettes and sampling media. Instructions are provided along with the equipment.

4.7.3 Customer Feedback Program

The EMSL customer feedback program includes:

- Continuous correspondence between customer and the customer service representatives
- Communication tools available on company website
- Direct contact with customer and Laboratory Manager
- Collecting comments offered by customers during seminars and conferences
- Periodic use of active solicitation of feedback such as through the use of customer survey

Summaries of feedback will be shared with laboratories in such a manner that customer confidentiality is maintained while providing the labs with feedback information. Ordinarily, this will be done in the Annual Management Review report.

4.7.4 Notice of Performance

The laboratory manager shall provide the customer with information as it relates to the performance of the analysis and turnaround time. The laboratory must notify the customer if:

- Analysis cannot be performed on time
- Integrity of the sample has been jeopardized (either by the laboratory or the customer)
- A discrepancy in the analysis has been found during QC analysis

4.7.5 Emergency Laboratory Closings

Where a laboratory's operating hours are affected by any emergency condition (e.g., weather events) the lab manager notifies the corporate Sr. vice president(s), the IT Department, and customers, where applicable. An intra-company email is broadcast with the information. Where possible, calls are re-directed to the corporate laboratory or other unaffected laboratory. The corporate customer service group and/or sales and marketing department representatives continue to contact customers as necessary.

4.8 Complaints

Complaints are considered any statement of dissatisfaction with the product or processes of the laboratory for which a reply is expected. Complaints may be received from any party, inside or outside of EMSL. They may be submitted in any form.

It is the policy of EMSL to take reasonable action to resolve complaints as quickly as possible. Whenever a complaint is received, it is investigated to determine whether the complaint is factually sound and whether resolution is within the control EMSL. If a complaint is not factually sound or EMSL is incapable of resolving the complaint (for example, the complaint is not about EMSL, or would require violating regulatory requirements), EMSL will follow-up with the complainant to ensure they are aware of why EMSL cannot resolve their complaint.

If a complaint is sound and capable of being fairly resolved, EMSL will take all reasonable actions to come to a resolution with the complainant that satisfies the complainant's needs, while not damaging or threatening the integrity of the laboratory, its personnel, or its results. EMSL's complaint resolution procedure is documented in QA-SOP-600 Complaint Resolution (QA-SOP-600-1 Complaint Resolution Overview is available for interested persons, upon request).

A complaint about the quality of reported results may be referred to the accrediting authorities who accredit the work being reported, if such complaints cannot be resolved directly with the customer.

4.8.1 Documentation of Customer Requested Re-analysis

There may be times when a customer will request re-analysis of samples.

4.8.1.1 Results Falling Within Quality Control Acceptance Limits

If the results from the re-analysis fall within the QC acceptance criteria, then the original report remains as the official report. The results should be communicated to the customer, this communication shall be documented, and the supporting data filed with the paperwork from the original analysis.

4.8.1.2 Results Falling Outside of Quality Control Acceptance Limits

If the results from the re-analysis fall outside of the acceptable QC range, and the original results have already been reported, the customer will be notified, and an amended report should be generated and submitted to the customer (See § 5.10.9). The discrepancy will need to be addressed with a corrective action report. All customer communication shall be documented, and the supporting data filed with the paperwork from the original analysis.

4.9 Control of Non-Conforming Testing

The control of non-conforming testing is addressed in detail the *EMSL SOP on Non-conformities and Corrective Actions* (QA-SOP-200). Non-conforming work can be identified by any person working in the laboratory, or brought to the attention of lab staff through an outside party (e.g., a complaint). Upon identification of any non-conforming work, it should immediately be documented using a *Non-Conformity/Corrective Action Record (CAR)* and forwarded to the laboratory or department manager for review. Any employee of EMSL may initiate a temporary work stoppage if it is believed non-conforming work will continue to be produced. The work stoppage shall be reported to the lab manager immediately. If the work stoppage is required for more than an hour, the lab manager must report the stoppage to corporate management.

The review of non-conforming work shall be documented on the CAR form and will include:

- An evaluation of the significance of the non-conforming work
- A determination of acceptability of non-conforming work
- An evaluation of whether the non-conforming work could recur, or whether it is a result of a failure to comply with EMSL policies or procedures

Remedial action will be taken immediately to correct non-conforming work based upon the level of risk evaluated by the lab. If a work stoppage was necessary, the lab or department manager will determine what action is necessary to begin work and document this on the CAR. Only the lab manager or corporate management has the authority to resume work once a stoppage is required.

If the evaluation determines the non-conforming work could recur, or is a result of a failure to comply with EMSL policies or procedures, formal corrective action is required. This shall be recorded on the form available on E-link according to QA-SOP-200 and § 4.11, below.

4.9.1 Notification of Non-Compliance

If a major deviation from policy or procedure is identified which significantly affects customer results, the customer shall be notified within 24 hours of confirmation of the deviation. Major non-conformities may be discovered during an internal audit, external audit, or a regular quality control review. In some cases, the report will require a disclaimer in order to ensure test results can be interpreted properly. Examples of major deviations may include (but are not limited to):

- Quality control reanalysis results outside acceptance limits which call into question test results

- Calibration measurements are outside acceptance limits and may have a negative impact on the results provided to customer
- Sample contamination is suspected (e.g., as a result of positive blanks)
- Failure to follow procedure as written resulting in possible erroneous results

For DOE associated projects:

- Clients must be notified within 15 business days of any potential deviations from policy or procedure that are identified, which may significantly affect customer results.
- The laboratory must report any instances of inappropriate and prohibited laboratory practices to the accrediting body within 15 business days of discovery. Lab will submit corrective actions to the accrediting body within 30 days of discovery of these occurrences.

4.10 Improvement

EMSL is committed to the continual improvement of the effectiveness of our quality system. As noted previously, the management system is reviewed annually as part of the annual management review, along with the continued efficacy of the quality policy and what progress was made on quality objectives. Management system documents are reviewed periodically and updated, as necessary. In addition, EMSL utilizes the feedback from customers, employees, and assessors in making changes to the management system in order to improve its efficiency. Other systems which are designed to provide feedback on both the design and implementation of the quality system include:

- Corrective and Preventive Action
- Internal Audit Program
- Customer Feedback Survey
- Monthly and Quarterly QC Reports

4.11 Corrective Action

This section briefly summarizes the procedures set forth in QA-SOP-200, which describes the mechanisms used to identify, prevent, and communicate conditions adverse to quality (a non-conformity), determine cause(s), initiate corrective action, document, and report the activities, and verify implementation of the corrective action.

A non-conformity is defined as any failure to meet stated requirements, whether these be technical (e.g., failure to meet internal statistically derived limits, use of wrong testing method), regulatory (e.g., state or federal requirements) or managerial requirements (e.g., corrective action procedures, log-in procedures).

Corrective actions serve as an indicator of the lab's performance. At the end of the year, these are reviewed, and a risk assessment can be conducted based on the type of corrective actions generated. For instance, if a lab has identified repeated training issues in the lab, then QA and management will work on a training program for the facility. This process is evaluated and recorded through the annual management review and the action items created from the document.

See the SOP for detailed procedures on how EMSL laboratories handle corrective actions.

4.11.1 Identification of Non-conformities

Non-conformities can be identified by anyone. Laboratory technical and support staff, internal and external auditors, and customers may all identify non-conformities in the laboratory's operation.

4.11.2 Documenting Non-conformities and Corrective Actions

Whenever a non-conformity is identified, the person who identified the non-conformity, or another responsible person, shall investigate. Corrective actions shall be taken when necessary, and shall be documented on the form available on E-link when appropriate, or if required by regulatory Standards. This form is used to document the non-conformity, the investigation of the non-conformity, and what actions (if any) were taken to resolve the non-conformity and prevent its recurrence. Its use is discussed in detail in the *Non-Conformities and Corrective Action SOP* (QA-SOP-200).

4.11.3 Evaluation of Non-conformities and Non-conforming Work

In order to evaluate the extent of effect a non-conformity may have on a result, the laboratory management will consider the following:

1) The significance of the nonconforming work
2) The acceptability of the non-conforming work (is it suitable for use?)
3) Whether customer notification is required
4) The most likely root cause(s) of the corrective actions
5) Whether it is necessary to stop work to prevent additional non-conforming work
6) Determine what is required to resume work (if work is stopped)

A stop work order may be given where a breach in the quality system jeopardizes analytical quality, or a failure in procedures presents an eminent safety concern.

4.11.4 Cause Analysis

Non-conformities must be handled in a manner which will provide a way to help ensure they are not repeated. This includes identification of the root cause(s) of the error, determination of corrective actions which will eliminate those root causes, and the initiation of those corrective actions. Identification of root cause(s) is one of the keys to corrective action and prevention. It helps identify the actual reason for the error. The *QA-SOP-200* contains a thorough discussion and guide to root cause analysis.

The investigation of the non-conformity will consist of a review of all steps leading up to the non-conforming condition or event. This may include review of QC data, sample tracking, data transcription, instrument calibration, training documentation, and discussion with personnel. See *QA-SOP-200* for additional details.

4.11.5 Selection and Implementation of Corrective Actions

Corrective actions are those actions which are taken to eliminate the root cause(s) of a non-conformity and prevent its recurrence. This should be contrasted with a remedial action, which is taken to eliminate the effects of a non-conformity (e.g., reissuing a corrected report is a remedial action, while improving the review process which allowed the faulty report may be a corrective action).

Corrective actions taken should be changes which will eliminate the deepest cause(s) possible and which are within the control of EMSL. The corrective action should be proportional to the severity of the non-conformity and the likelihood it will recur, and shall be documented and carried out within a reasonable time frame, so as to not jeopardize the quality of results. The investigation of the non-conformity includes an evaluation of the risk created from the situation, and an opportunity for improvement, to determine the appropriate plan to avoid recurrence.

The laboratory quality representative and/or laboratory's management personnel are responsible for ensuring corrective actions have been addressed in a timely manner. The lab's corrective action records must include proof of compliance with the Corrective Action Report. The laboratory quality

representative and/or laboratory management staff must indicate when corrective actions are complete.

4.11.6 Monitoring of Corrective Actions

Follow-up to corrective actions shall be scheduled and completed in order to determine whether the actions taken have been effective in preventing its recurrence. Follow-up actions shall be scheduled on a case-by-case basis as soon as practical, but far enough in the future so a recurrence might have had the opportunity to occur.

The follow-up shall indicate the corrective action has been satisfactorily completed, and will include a review of the effectiveness of the corrective action. The scheduled date for follow-up, date follow-up was conducted, and effectiveness of corrective action is documented on the form available on E-link.

The QA Department is responsible for following up on those corrective action reports submitted to the QA Department by the laboratory for further action.

4.11.7 Additional Audits

In some cases, a non-conformity may be cause to initiate an audit of related activities in order to: 1) help identify cause(s) of the error, 2) ensure no other areas are affected by the error, or 3) provide direction for preventative actions. For example, if a customer makes a complaint about a test result, an audit may be conducted involving:

- Review of calibration measurements and QC data associated with the analysis
- Check on analytical specialist qualifications
- Inspection of log-in procedures
- Review of other results that may be affected by the root cause(s) as determined

The audit can be 'free flowing' (no use of checklist), but must be documented.

4.12 Preventive Action

It is EMSL's intention to maintain an active program to prevent occurrences which require corrective actions, or where there is a trend in QC data or activities which may eventually result in an error. A proactive program is an important part of the objectives of this EMSL quality program. All staff members are encouraged to assist in identifying potential sources of non-conformities and to identify opportunities for improvement. EMSL's preventive action program is detailed in QA-SOP-250: *EMSL Preventive Action SOP.*

Preventive actions consist of the policies discussed in this QMS Manual. For example, the quality management system procedures and policies require:

- Analytical specialists satisfy training requirements
- Laboratories perform QC activities at required frequencies
- QC data is reported to the QA Department for review
- Management reports are submitted to corporate management
- Laboratories participate in proficiency testing programs
- Laboratories maintain accreditations from regulatory and other independent agencies

Preventive action measures also include those specific actions taken outside of the normal quality assurance/quality control activities. These actions are those opportunities for improvement associated with a potential non-conformity. This policy requires laboratory staff to attempt to identify potential non-

conformities, and apply actions which will prevent an occurrence. These actions are documented using the form located on E-link.

4.13 Control of Records

4.13.1 General

The EMSL control of records procedures are documented in the *EMSL Control of Records SOP (QA-SOP-350*). The SOP outlines the requirements of record maintenance, but each laboratory is responsible for the logistics of record control in their laboratory. Each laboratory is responsible for maintaining a *Records Management Log* (*QA-FM-350-1*) which documents where records are located and how they are indexed, accessed, and stored in the laboratory. General policies include:

- All laboratories will retain records of original observations in addition to derived information.
- All handwritten data shall be recorded using permanent ink.
- If a record contains a mistake that must be corrected, the mistake shall be single line crossed out and signed, initialed, and dated using indelible ink, and the correction made alongside.
- Records must never be corrected by erasing, deleting, or otherwise making the mistake illegible (e.g., use of correction fluid, correction tape, scratch-outs).
- Whenever a date is required to be entered by personnel on a document (i.e., COCs, internal COCs, reagent and standard logs, packing slips, etc.), the format used should be month/day/year.
- Records shall be retained in order to ensure sufficient information is maintained to allow for an audit trail. Therefore, records such as employee records, certificates of analysis for standards, calibration certificates, etc., shall be retained for the life of the activity to which they are related (e.g., until 5 years after an employee leaves, until 5 years after the standard is disposed of or completely used, until the next calibration is completed).
- The majority of records shall be retained for a minimum of 5 years or for the period of time established by relevant accrediting authorities or contract requirements (see *QA-SOP-350* for a list of exceptions to the 5-year hold time).
- Where records are removed from storage (e.g., archive boxes, file drawers) for any reason, the laboratory shall insert a Record Out Log card in place of the records, and record on the Log card the name of the person removing the file, the files removed, and the date removed. When replacing the file, the card shall be updated by noting “Replaced” and the date it was replaced in the file.
- Records shall be protected against fire, theft, loss, environmental deterioration, vermin, and, in the case of electronic records, electronic or magnetic sources.
- Records shall be disposed of in a manner that maintains customer confidentiality. Paper records containing customer information shall be shredded or incinerated before disposal. Electronic records shall be managed in such a way that access to backup files remains at least as restrictive as when on the EMSL servers. Specific means of destruction of records may vary from lab to lab and may include services such as a contracted shredding/incineration program by a professional archiving company (e.g., Iron Mountain), locally owned shredders within the lab, or by community shredding events.

- Electronic records are considered equivalent to paper records, and are to be maintained and controlled in an analogous manner. Backups of electronic records are to be protected according to the procedures in the Control of Records SOP (QA-SOP-350).
- All hardware and software necessary for the historic reconstruction of data must be maintained by the laboratory for the same period of time as the data produced.

4.13.2 Recording Analytical Information

Before beginning analysis of a batch of samples, the analytical specialist is responsible for checking to ensure the labels on the sample containers agree with the data recorded on the chain of custody for that sample. The analytical specialist is also responsible for checking (to the extent possible) the samples have been collected on appropriate sampling media. Any discrepancies are to be noted on the chain of custody and reported to the laboratory manager.

Data generated in the laboratory shall be recorded on preprinted analytical data worksheets or, where available, directly into the computer system via a Direct Data Entry (DDE) system (iL@b). Each analytical procedure has its own specific worksheet or iL@b module. Many of these worksheets, when used, are generated by the LIMS system at the time of log-in.

Observations, data, and hand calculations are recorded at the time they are made and are identifiable to the task. The analytical specialist is to ensure entries on all records are made legibly and using indelible ink. Corrections are made using a single line strikeout with the correct entry written in. Corrections are to be initialed and dated. Obliterating data using ink or correction fluid is prohibited.

Where iL@b DDE is available, data is recorded directly into the lab database. Any additional information recorded manually in hard copy shall be maintained along with the COC and ICOC in project records.

4.13.3 LIMS (SMXP/Element) Data and Security

SMXP/Element data is retained in a "live" redundant replicated instance of SQL Server 2014 Enterprise in a Master database for a minimum of 16 (SMXP) and 24 (Element) months. Data older than 16 or 24 months is migrated to an archive instance of SMXP/Element LIMS data. This production database contains analytical data for all local and remote company labs.

Although our computer equipment has proven to be reliable, unexpected problems do occasionally occur. Regarding EMSL Analytical, Inc. Computer Systems as one of the components of our Business Continuity and Disaster Recovery Plan, should EMSL experience an individual system and/or large-scale system outage, critical systems and data will fail-over to our disaster recovery systems. Critical systems include LIMS platforms; network and server infrastructure; phone systems; accounting; customer portal systems; e-mail; and customer service systems.

The process of restoring company systems to normal operations follows a tiered process prioritized to best support operational tasks. During the outage, recovery, and return to normal operations, department teams would continue to contact outside parties and perform manual processes, if needed.

All SMXP/Element data is replicated to a central SQL Server 2014 Enterprise database, which functions as the primary backup for the LIMS data. LIMS data is also copied (backed up) onto a backup disc subsystem nightly, and transferred to high density tapes which are relocated to secure, temperature controlled, fireproof vaults within Iron Mountain to prevent permanent data loss in the case of systems failure, accidents, or disasters. In most cases, duplicate equipment has been provided, so if

one computer experiences unexpected problems, a duplicate computer can be utilized while the other is being repaired.

More information on the backup and archiving of SMXP/Element data can be found in the *EMSL Control of Records SOP* (QA-SOP-350).

The security of the software is controlled by the corporate IT staff and the laboratory manager. Each computer user is assigned password protected rights and privileges specific to the tasks the user is allowed to perform. Access to all LIMS analytical related software is password protected on a user-by-user basis to ensure security. The IT staff is responsible for ensuring access to SMXP/Element is controlled, and assignments are held secure, using laboratory management approval.

The corporate IT staff is responsible for ensuring all computer systems, both hardware and software, are documented, inventoried, and adequate for use. All systems are operated in safe environments and maintained to ensure proper operation. The computer systems responsible for handling of analytical data have been set up to process data in a way that ensures data integrity with password specific approval assignments. Data integrity is also maintained by performance of daily tape backups as discussed in the *Control of Records SOP* (QA-SOP-350).

4.13.4 Electronic Record Retention Policies

Record retention policies for electronic records are analogous to policies for retention of non-electronic records maintained by EMSL laboratories. These policies are discussed fully in the *EMSL Control of Records SOP* (QA-SOP-350), including retention times and disposal.

All digital analytical records are permanently archived. The data is transferred to a disk-to-disk back-up system nightly, and once a week is transferred to high density tapes and transferred to Iron Mountain for storage. Access to these records is restricted and controlled by EMSL record policies and procedures. The record keeping system allows for the reconstruction of all activities required to produce an analytical result.

4.13.5 Signature and Initials Log

A log of the signatures and initials of laboratory staff is maintained with the Compliance and Commitment Agreement form found in this Manual. The information recorded includes

- Printed name
- Signature
- Initials (unique to laboratory; for duplicate initials, also use middle initial)
- Date of entry

This form helps identify the initials and/or signatures entered on laboratory documentation such as chain of custodies, analytical worksheets, final reports, etc.

4.13.6 Use of Electronic Signatures

Signatures are provided to the IT Department using *GEN-FM-901 Final Report Approval and Signature Sample*. Signatures are scanned, stored as an image, and forwarded back to the signatory via e-mail. The signatory maintains responsibility for the use of their signature. They may provide approval for its use through an e-mail or verbally. Documents are printed to PDF to secure signatures from alteration.

4.14 Internal Audits

An audit is an on-site, qualitative review of the various aspects of the total laboratory system. It represents an objective evaluation using an interactive program with respect to strengths, deficiencies, and potential areas of concern. Audits may also be performed remotely.

EMSL performs annual internal audits in laboratory facilities to verify work activities are being performed in full compliance with stated policies, established standard operating procedures, this quality assurance program, ISO 17025, TNI standards, and additional requirements as set forth by relevant accrediting authorities (e.g., AIHA LAP, LLC; NVLAP, A2LA, CALA). Audits will be conducted by laboratory management or by 3rd party personnel approved by the QA Department. Auditors and assistant auditors must complete the *QA-TC-700 Internal Auditor* training checklist.

The internal audit is scheduled by the Quality Assurance Department and covers aspects of the management system, including testing activities. Audit findings are recorded on an audit report, or on the *EMSL Internal Audit Checklist (QA-FM-700)* which is based on ISO 17025 requirements, with additions made for additional requirements of accrediting agencies. Non-conformities identified during the internal audit will be corrected and followed up according to EMSL corrective action process.

EMSL's internal audit procedures are located in the *EMSL Internal Audit Procedures SOP (QA-SOP-700).*

4.14.1 Test Method Assessments

As an added measure to evaluate methods and analysts, EMSL performs TMAs to ensure the laboratory is following the correct procedures, as set forth in EMSL SOPs. Test method assessments may be completed independently, or along with annual quality system audit.

In order to evaluate the performance of an analyst's compliance with method procedures, method specific assessments are performed every 3 years. PALA accredited labs are required to perform TMAs every 2 years. An assessor observes the analyst and evaluates every step of the method, from sample preparation to the reporting of results (QA-SOP-700).

4.15 Management Reviews

Management reviews are designed to provide the top management of EMSL with an overview of the performance of the management system and laboratory operations. They address the quality topics documented in the ISO 17025 and the TNI standard for each laboratory location, and include:

- The suitability of policies and procedures
- Reports from managerial and supervisory personnel
- The outcome of recent internal audits
- Corrective and preventive actions
- Assessments by external bodies
- Results of inter-laboratory comparisons or proficiency tests
- Changes in the volume and type of work
- Customer feedback
- Complaints
- Recommendations for improvement
- Review of quality policy objectives
- Status of previous management review action items and fulfillment of objectives
- Risk identification
- Effectiveness of improvements
- Changes to internal and external issues in laboratory
- Other relevant factors, such as quality control activities, resources, and staff training

During the first quarter of each year, the Quality Assurance Department, national directors, and vice presidents review labs for the previous calendar year.

The report shall be based on the recorded information and non-recorded observations made by the QA Department, national directors, vice presidents, outside accrediting agencies and customer feedback. It is a tool to ensure the laboratory activities comply with the procedures and policies of the quality assurance program, ensure the program's continued effectiveness, and to introduce any necessary changes or improvement.

Action items are created from the management review to address internal and external issues brought to management's attention. These items will include detailed objectives to be completed during the upcoming year, and a review of the past year's items identified to ensure completion. Improvements made as a result of the review are evaluated from year to year to verify effectiveness.

Follow-up on action items for improvement of laboratory activities identified in the management review is performed by corporate management, the QA Department, and EMSL branch laboratories. Those action items must be completed according to a reasonable schedule. Management Review procedures can be found in the *EMSL Annual Management Review SOP (QA-SOP-750).*

Section 5.0: Technical Requirements

5.1 General

This section discusses the general technical requirements of the EMSL management system which are applicable to lab operations. Specific and additional requirements for certain areas will be found in the program specific modules.

5.1.1 Selection of personnel is recorded in job requisition forms filed with the Human Resources Department.

5.2 Personnel

5.2.1 Laboratory Job Roles and Responsibilities

5.2.1.1 Scope

This section describes general laboratory job roles and responsibilities of the technical personnel in a basic laboratory operation of EMSL. It does not include specialized assignments or positions that may have been instituted for specific projects or special laboratory needs. It is possible that more than one of these job responsibilities is shared among one person. For example, an analytical specialist may also be assigned administrative support duties.

Minimum education and experience requirements are listed generally for each job role. Specific requirements for education, training and skills for specific positions are listed in each of the individual program modules where these are defined by outside agencies. Specific job titles/descriptions and responsibilities are maintained in personnel folders.

Roles discussed in this section include the responsibility to ensure compliance with the policies documented in this manual and the requirements of the quality standards including, but not limited to, ISO/IEC 17025, TNI, A2LA, AIHA LAP, LLC-specific requirements, NVLAP, CALA and state accreditation agencies where applicable.

5.2.1.2 Administrative Specialists

Job titles include: Administration, Administration Coordinators, Data Entry, Office Administrator, Administrative Assistant, Login

Administrative specialists report to the laboratory manager.

The minimum education and experience requirement is on the job training.

These are support positions for the laboratory including the analytical specialists. Responsibilities may include, but are not limited to, those listed below:

5.2.1.2.1 Sample Receipt Responsibilities

- Reviews paperwork for all incoming samples to ensure completeness and correctness
- Inspects samples to ensure sample integrity is retained and that packaging is not compromised, and informs the lab or department manager if there are any concerns noted regarding sample integrity
- Ensures laboratory has ability, capability, and capacity to analyze samples prior to log-in (with laboratory or department managers)
- Logs in all samples in a timely manner based on turnaround time
- Delivers incoming samples to the laboratory
- Ensures all samples are placed in the proper storage area to await analysis
- Informs the laboratory manager or analytical specialist of any special priorities regarding the samples

Administrative specialists with sample receipt responsibilities shall be aware of sample origin as it impacts regulatory requirements. The administrative specialist follows sample tracking protocols in handling samples, in particular, completing and verifying chain-of-custody forms as per EMSL *Sample Receiving and Chain of Custody SOP* (GEN-SOP-702).

Administrative specialists with receiving responsibilities are also responsible for ensuring proper sample numbering and labeling is performed, and sample information is transcribed correctly into the Laboratory Information Management System (LIMS) and onto applicable forms. The administrative specialist also ensures compliance with all relevant quality standards as related to job responsibilities.

5.2.1.2.2 Data Entry Responsibilities

- Generates analytical reports
- Enters data produced by the analytical specialists into the computer system for production of the final, customer-ready report
- Generates reports in the priority in which laboratory management staff assigns them
- Ensures the final report is prepared within the required time frames, and results are reported to the customer in a timely manner
- Reviews the information in the report and checks the data for any obvious errors
- Checks both technical and non-technical information, such as sample location, volume, and sample I.D. numbers for possible transcription

errors

- Reports any observations of erroneous or unusual data or apparent errors to the laboratory management
- Ensures compliance with all relevant quality standards as related to job responsibilities

The administrative specialist contributes to the achievement of EMSL quality objectives by ensuring they act as a professional interface between technical personnel and laboratory customers. Administrative specialists ensure samples are received with the appropriate paperwork, and data is transcribed accurately and in a manner which prevents questions about the integrity of laboratory data. They also ensure they record non-conformities as per the Corrective Action system, opportunities for improvement as per the Preventive Action system, and customer complaints as per the Complaint Resolution system, and reports these to the personnel authorized to handle these situations.

5.2.1.3 Technicians

Job titles include: Lab Technician, Prep Technician, Lab Prep Technician, Sorter

All technicians report directly to laboratory management.

Minimum education and experience requirements:

- In-house training documented by the EMSL qualifications checklist or SOP acknowledgement documentation

  Participation in ongoing training programs (in-house workshops, laboratory meetings, etc.)

Minimum requirements will vary depending on specific job title and responsibilities, and may include particular experience and/or education requirements as specified on job description posted.

A technician is responsible for non-administrative, non-analytical work performed in the laboratory. Assigned responsibilities may include preparation of samples, preparation of media or reagents, cleaning of glassware or equipment, transport of samples between administration and lab and ensuring proper storage, and performing calibrations or verifications of equipment. They are usually not involved in the analysis of customer samples, although they may act as analytical specialists in some areas, while remaining technicians in others.

The technician is responsible for maintaining any associated paperwork (e.g., logbooks, forms, notebooks) for the work performed in accordance with established laboratory procedures. He/she must ensure familiarity and compliance with all relevant quality standards as related to job responsibilities by reading and following EMSL policies and procedures which adopt these standards.

Technicians contribute to the EMSL quality objectives by ensuring they have read and understood all EMSL policies and procedures relevant to their job tasks, and follow SOPs in order to ensure integrity of samples and workflow are maintained. Technicians also ensure they record non-conformities as per the non-conformity/ Corrective Action system, possible

opportunities for improvement as per the Preventive Action system, and customer complaints as per the Complaint Resolution system, and report these to the attention to those personnel authorized to handle these situations.

Additionally, technicians contribute to the overall quality of EMSL final results by ensuring they avoid any actions which may call into question the integrity of their work.

5.2.1.4 Analytical Specialists

Job titles include: Analysts (including specialties, e.g., microscopist) and Scientists (including specialties, e.g., microbiologist, mycologist)

All analytical specialists report directly to laboratory management.

Minimum education and experience requirements:

- In-house training documented by the EMSL qualifications checklist
- Participation in ongoing training programs (in-house workshops, laboratory meetings, etc.)

Minimum requirements will vary depending on specific job title and responsibilities, and may include particular experience and/or education requirements as specified on job description posted.

The analytical specialist is responsible for performing calibrations of equipment, assigned analysis, and recording and maintaining analytical data according to established procedures including the Control of Records system. The analytical specialist must use good analytical technique and he/she must provide analytical results suitable for inclusion in a customer report.

The analytical specialist manages all work assigned and completes all paperwork in accordance with established laboratory procedures. The specialist reviews all paperwork for correctness and completeness and ensures that work progresses in a timely and productive manner.

The analytical specialist is responsible for performing required analysis on QC samples as directed by the laboratory management or designated quality representative, and for notifying the laboratory management or quality representative of any occurrence that could potentially affect the validity of an analytical result.

He/she must ensure familiarity and compliance with all relevant quality standards as related to job responsibilities by reading and following EMSL policies and procedures which adopt these standards.

The analytical specialist contributes to the EMSL quality objectives by ensuring they have read and understood all EMSL policies and procedures relevant to their job tasks, and follow all SOPs in order to ensure consistent and accurate analyses. The analytical specialist ensures all required QC functions of their job are performed in a timely manner, including calibration of equipment and analysis of QC samples at the required frequency. Analytical specialists also ensure they record non-conformities as per the Corrective Action system, possible opportunities for improvement as per the Preventive Action system, and customer complaints as per the Complaint Resolution system, and report these to the attention to those personnel authorized to handle these situations. Additionally, analytical specialists contribute to the

overall quality of EMSL final results by ensuring they avoid any actions which may call into question the integrity of their work.

For PALA accredited labs, only a PALA approved microbiologist can approve and send final reports.

5.2.1.5 Laboratory Quality Representatives

Job titles include: Quality Assurance Coordinator, Quality Coordinator, Quality Manager, Quality Officer, and Quality Associate (however named).

The laboratory quality representative works with the laboratory management (or regional manager if the laboratory quality representative is the laboratory manager) with direct reporting for quality responsibilities to a higher-level lab quality representative (e.g., a department quality coordinator reporting to the lab quality manager) or Vice President of Quality Assurance.

Minimum education and experience requirements:

- Basic understanding of EMSL QA/QC program (including statistical analysis)
- Participation in ongoing training programs (in-house workshops, laboratory meetings, etc.)

Minimum requirements will vary depending on specific job title and responsibilities, and may include particular experience and/or education requirements as specified on job description posted.

Laboratory quality responsibilities may be assigned to a single quality representative or to a group of quality representatives. In large labs, for instance, there may be a single quality manager who oversees quality representatives assigned to individual departments. Ultimate reporting responsibility is to the Corporate QA Department, specifically, the vice president of quality assurance.

The laboratory quality representative is responsible for ensuring all QA/QC procedures for which they are assigned responsibility are performed at the required frequencies for the laboratory or departments under their supervision. He/she collects and maintains all QC data for reporting to the laboratory manager.

He/she oversees the QA/QC program as assigned and is responsible for the laboratory's compliance with all standard policies as guided by the corporate quality assurance Director. An analytical specialist or laboratory manager may also function as the laboratory quality representative for a particular location.

The laboratory quality representative ensures the laboratory maintains compliance with the policies and procedures documented in this manual, and the requirements documented in all relevant quality standards listed in Section 2.0. The laboratory quality representative is responsible for reporting any non-compliance issues to the laboratory manager or, if necessary, directly to the Corporate QA Department.

The laboratory quality representative contributes to the EMSL quality objectives by ensuring quality management system requirements are being followed at all times and/or according to designated frequencies. The laboratory quality representative oversees the implementation of the system in their laboratory, and ensures it is consistently followed in such a manner that the

laboratory remains a coherent part of EMSL, and is not operating on its own set of policies and procedures. Quality representatives will oversee the quality reports being submitted to the Corporate QA Department to ensure they are generated on time, and that any problems reported have been handled and resolved in a manner which maintains the accuracy and integrity of laboratory data. They are responsible for designating qualified personnel (deputies) to assume temporary quality related responsibilities normally assigned in the event of absence.

5.2.1.6 Laboratory Management

Job titles include: Lab Director, Lab Manager, Technical Manager, Department Manager, Supervisor, Group Leader, Assistant Lab Manager, and Assistant Department Manager

Hierarchies of job positions make up the management team for a laboratory. In most branch laboratories, there is an individual who is designated a lab manager and is the technical head of that laboratory. Due to the diverse nature of services offered by EMSL, often a laboratory manager will be supported by other lab management positions, such as assistant managers, department managers, supervisors, group leaders, etc. In some cases, usually in larger laboratories, there may be multiple lab managers in charge of different aspects of the laboratory services.

Laboratory management personnel usually directly report to regional manager(s).

Minimum education and experience requirement for the lab management position is one (1) year of related analytical experience. Managers must also meet requirements specified in applicable regulatory standards.

The laboratory management position may be assigned various responsibilities depending on the role they serve within the laboratory. Lab and department managers will usually be responsible for technical decisions for the laboratory such as:

- Assuring requirements for laboratory equipment and supplies are met
- Resolution of analytical problems
- Development and implementation of training programs for analytical specialists
- Providing sufficient oversight of laboratory operations
- Review and approval of analytical results for release
- Development of new methodology and analysis
- For PALA accredited labs, only a PALA approved microbiologist can approve and send final reports. If the approved signatory is absent from the lab, final reports will not be approved or distributed.

Supervisors, group leaders, and assistant managers will be delegated some set of responsibilities over which they are responsible. Such duties may include supervising the workflow of the lab or a particular portion of the laboratory, overseeing a group of analysts and/or technicians, etc.

As a whole, laboratory management personnel are responsible for overall administration of laboratory operations. They ensure company policies are understood by all personnel, adequate supervision is provided to staff, work scheduling procedures adequately address customer needs, and are responsible for ensuring all customer complaints are resolved. They shall also approve all employee reviews and promotions, and provide regional or corporate

management with information regarding laboratory budgeting issues (e.g., purchase of equipment and supplies, expenses for out-of-house training, staffing requirements). The laboratory management staff shall ensure adequate supervision is provided for the laboratory technical personnel.

They are responsible for designating qualified personnel (deputies) to assume specific, temporary management responsibilities normally assigned to the laboratory management staff in the event of absence. The deputy is identified on the laboratory organization chart. For those single person laboratories, in the event the laboratory manager/analytical specialist/quality representative is absent, no analysis will be performed, and therefore the assignment of a deputy manager/quality representative is not applicable.

Laboratory management is also responsible for ensuring a comfortable working atmosphere, free from excessive pressures (including unreasonable productivity rates), for their laboratory employees. Laboratory management must ensure the policies and procedures of this quality management system are communicated to the laboratory staff.

Ultimately, laboratory management personnel are responsible for the data reported by the laboratory. He/she or approved designees review and approve the final customer reports for release to the customer. This responsibility includes the verification of the sample results which, include:

- Verification of sample number
- Correctness of sample result
- Check for typographical errors
- Completeness of chain of custody

Management personnel shall ensure any designees are fully capable of performing these reviews on their behalf. Management assigns designated personnel to perform the task of final review and approval following the *EMSL SOP for Final Report Approval and Electronic Signature* (GEN-SOP-901).

Management personnel or a designee shall ensure QA standards are established, understood, and administered. He/she is ultimately responsible for ensuring the QA program is conscientiously implemented. He/she reviews the QA program with the regional manager or national director to ensure completeness and effectiveness, and supports the local quality representatives, regional manager and/or the National Quality Assurance Department in carrying out the program by use of authority. Laboratory management is ultimately responsible for ensuring QC reports are submitted to the National QA Department in accordance with these QA program requirements.

Laboratory management personnel contribute to the EMSL quality objectives by ensuring the laboratory maintains compliance with the policies and procedures documented in this manual, and the requirements documented in relevant quality standards listed in Section 2.0. They oversee employee qualifications, ensuring they are properly qualified and trained prior to conducting analysis.

The management staff is ultimately responsible for the data reported from the laboratory. Management staff ensures non-conformities and complaints are resolved in a timely manner, leading to continual improvement at the laboratory.

In accredited labs, should the person identified with the accrediting body as the lab manager, technical director, technical manager, quality manager or quality assurance officer be absent for a period of time exceeding fifteen (15) consecutive calendar days, the laboratory shall designate another full-time staff member meeting the qualifications of said manager to temporarily perform this function. The Interim Manager shall also meet all the education and experience standards required of said manager, in order to function as Interim Manager.

If this absence exceeds twenty (20) consecutive business days, the appropriate accreditation body(ies) shall be notified in writing regarding how requirements will be met in the interim.

5.2.1.7 Regional Manager

The regional manager reports directly to the Vice President.

Minimum education and experience requirements:

- 2 years related analytical experience
- 1 year management experience

The regional manager assumes responsibility for the overall performance of two or more laboratory locations. He/she controls the analytical programs, reporting processes, general management and is accountable for the overall operational of the laboratories under authority.

The regional manager reports directly to the vice president and coordinates with the national director on technical issues, and initiates and controls operational policies in the areas of administrative and technical matters. The regional manager may also function as a laboratory manager.

The regional manager works closely with the National QA Department in developing and maintaining the QA program. He/she consults directly with the National QA Department regarding the effectiveness and applicability of the program, recommends needed changes, if any, and reports any problems with the program. The regional manager is responsible for ensuring annual technical QA/QC audits are performed at each of their laboratories.

The regional manager ensures the laboratory maintains compliance with the policies and procedures documented in this manual and the requirements documented in relevant quality standards.

The regional manager contributes to EMSL quality objectives by assisting laboratories in their implementation of the quality system, improving consistency across their laboratories. The input they provide to the National QA Department assists in the continual improvement of the quality system.

5.2.1.8 National Director/Vice President

The national director/vice president reports to the EMSL Sr. Vice Presidents.

Minimum educational/experience requirements:

- Associate of Science degree in related science
- 3 years related analytical experience
- 2 years management experience

The national director/vice president is responsible for the overall quality performance of the business service line they are responsible for, including the initiation, development, and maintenance of the quality management system. The national director/vice president advises the president and Sr. vice presidents on quality management system issues, and has the primary authority to ensure the integrity of the management system is maintained at all times, and initiates actions to prevent or minimize departures from the quality management system.

The national director/vice president ensures appropriate communication processes are established for implementation and effectiveness of the quality management system. He/she participates in the management review process and commits to continually improve the effectiveness of this system.

The national director/vice president provides input on decisions related to the status of laboratory certifications and accreditations.

The national director/vice president contributes to the quality objectives of the laboratory by ensuring the company maintains compliance with the policies and procedures documented in this manual, and the requirements documented in relevant quality standards.

As part of top laboratory management, the national director/vice president assists in setting the quality objectives of EMSL. In addition, the national director/vice president ensures these quality objectives are adequately communicated and understood by laboratory staff, and ensures they remain aware of the effectiveness of the EMSL quality system. The national director/vice president also contributes to the program by ensuring they are committed to the development, implementation, and continual improvement to the program. As part of top management, the national director/vice president shall ensure the integrity of the management system is maintained at all times when changes are made to laboratory operations.

5.2.1.9 National Quality Program Support Representatives

Titles include: Vice President of Quality Assurance, Quality Assurance Manager, Quality Assurance Specialist, Quality Assurance Coordinator, National [service area, i.e., asbestos] Manager.

The national quality program support representatives report to the vice president of quality assurance.

A minimum educational /experience requirement is 2 years related analytical experience.

The national quality program support representatives work under the direction of the vice president of quality assurance. They are responsible for providing support to the Quality Assurance Department, which includes:

- Participation in the development, implementation and maintenance of QA/QC policies and procedures
- Guidance to the laboratory operations on quality issues
- The monitoring and assurance of compliance with the QA plan
- Establishing and maintaining standardization throughout EMSL locations
- Processing accreditation applications and administration of documentation related to accreditation requirements

The national quality program support representatives provide reports of performance (frequency of report submittals and review of quality of reports) to the vice president of quality assurance, regional managers, national directors, and vice presidents.

The national quality program support representatives ensure the laboratory maintains compliance with the policies and procedures documented in this manual, and the requirements documented in relevant quality standards.

The national quality program support representatives contribute to the quality objectives by tracking whether quality control programs are being implemented at branch laboratories through the review of monthly and quarterly reports. This review of quality reports ensure QC is being properly documented and reviewed, thus improving the quality of data from all laboratories, and allowing corporate management to act when areas of concern are identified. The national quality program support representatives' participation in the annual management reviews includes feedback on individual lab performance and advice on areas for improvement.

5.2.1.10 Vice President of Quality Assurance (previously National Director of QA)

The vice president of quality assurance reports directly to the EMSL Sr. Vice Presidents. The vice president of quality assurance also has direct access to the EMSL President.

Minimum educational/experience requirements:

- 2 years related analytical experience
- 1 year management experience
- Course work on quality programs

The vice president of quality assurance has the authority to:

- Develop and implement quality assurance and quality control policies
- Implement change to ensure the effectiveness of the quality management program
- Participate in business decisions related to the development of additional service areas, accreditations, etc.
- Report non-conformities and breaches in ethics policies to senior corporate management
- Direct other departments in order to achieve the goals of the quality program
- Write and/or issue Standard Operating Procedures

The vice president of quality assurance director is responsible for establishing, implementing, and maintaining the entire QA program as described in this manual. He/she develops statistical protocols for data reduction and acceptance criteria. He/she defines requirements for submitting QC samples, controls results reporting policies, sets standards for analytical performance, and issues protocols for yearly on-site audits for the branch laboratories.

The vice president of quality assurance is also responsible for maintaining the QMS manual and all standard operating procedures (SOPs). He/she is responsible for conducting and/or establishing policies for QA audits, and setting the standards for laboratory practices. The vice president of quality assurance confers with the national directors, regional managers and/or the laboratory managers on QA policies, and supports the laboratory management and

laboratory quality representatives in the daily maintenance of the QC program. The vice president of quality assurance oversees laboratory accreditations including initial applications, maintenance of proficiency testing programs and responses to non-conformities identified during on site audits.

The vice president of quality assurance participates in the annual management review. The vice president of quality assurance also ensures the laboratory maintains compliance with all relevant quality standards.

The vice president of quality assurance assists top management in defining the EMSL quality objectives. As head of the quality unit, the vice president of quality assurance ultimately has oversight of the entire quality program of EMSL, and ensures the management systems meet the quality objectives.

The vice president of quality assurance is granted the authority by EMSL senior management to perform these tasks and ensures the EMSL quality management system is being implemented and followed at all times.

5.2.1.11 Senior Vice President - Technical Divisions

Titles include: Senior Vice President, laboratory services

The senior vice president (Sr. VP) is responsible for the overall quality performance of the entire company, including the initiation, development, and maintenance of the quality management system. The Sr. VP advises the president on quality program management issues, and has the ultimate authority to ensure the integrity of the management system is maintained at all times (including when changes are made) and initiates actions to prevent or minimize departures from the quality management system.

The Sr. VP ensures appropriate communication processes are established for implementation and effectiveness of the quality management system. He/she participates in the management review process and commits to continually improve the effectiveness of this system.

The Sr. VP makes all decisions related to the status of laboratory certifications and accreditations.

The Sr. VP contributes to the quality objectives of the laboratory by ensuring the company maintains compliance with the policies and procedures documented in this manual and the requirements documented in relevant quality standards.

As part of top laboratory management, the Sr. VP assists in setting the quality objectives of EMSL. In addition, the Sr. VP ensures these quality objectives are adequately communicated and understood by laboratory staff, and ensures they remain aware of the effectiveness of the EMSL quality system. The Sr. VP also contributes by ensuring they are committed to the development, implementation, and continual improvement of the laboratory quality system. As part of top management, the Sr. VP shall ensure the integrity of the management system is maintained at all times.

5.2.1.12 President

The president focuses and directs the path of the company and assumes complete responsibility for the success of the quality management system.

He provides the authority and approves the resources necessary to maintain compliance with the quality assurance program policies documented in this manual and applicable accreditation standards.

The president, as part of top laboratory management, assists in setting the quality objectives of EMSL, and issues the Quality Policy under which the company operates. The president contributes to the quality objectives by ensuring adequate resources to establish, maintain and improve the quality system of the laboratory, and by clearly communicating the company's commitment to its Quality Policy and quality system policies and procedures.

5.2.2 Training

5.2.2.1 Scope

This section describes the corporate procedures and policies of the EMSL training program. Additional requirements for training for each analytical methodology, if any, are discussed in the program modules. Details on documenting training for analytical specialists are available in the *Training on Analytical Methods SOP* (GEN-SOP-100) available on E-Link.

Analytical specialists must complete the EMSL training program in order to perform analysis independently and receive a completed Demonstration of Capability, authorizing the analyst to perform the methods listed on the certificate. All employees (full-time or part-time, permanent or temporary, including interns) must read the QMS manual and SOPs which are related to the work with which they will be responsible, ensure these are understood, and acknowledge the document, stating their commitment to follow the procedures and policies outlined therein.

Because the amount of training needed will vary based on the education, past experience and skills of the trainee, the requirements described in this section and the program-specific modules are considered minimums. Laboratory managers are responsible for ensuring appropriate training is provided to every analytical specialist, and they are completely competent, qualified, and signed off to perform analysis.

5.2.2.2 Identification of Training Needs and Goals of Training

The need and goals for training are determined by the laboratory manager or corporate management. Needs are identified considering:

- Cross training to increase laboratory productivity
- Decreasing trend in quality
- Change in type of work
- Change in requirements or procedure
- Addition of analytical services

The goals of training will differ based on the area of training. In general, training is intended to familiarize personnel with the policies and procedures of the laboratory, ensure personnel are aware of changes to policies and procedures, are knowledgeable and skilled in proper analytical and/or preparatory technique, and understand the theory underlying the work.

5.2.2.3 Types of Training

There are a variety of training programs offered. Documentation of these programs (certificates, training records, records of participation in training sessions, etc.) is considered the property of EMSL and not the trainees.

5.2.2.3.1 "In-House" Course

These are organized EMSL courses designed for a classroom setting (they can be scheduled in workshop type modules) with syllabus and course materials. These courses contain recommended contact hours. A certificate is issued which documents attendance.

Formal in-house courses are developed and implemented under the direction of corporate management. The trainer must follow the requirements of the EMSL training program and ensure all topics are covered according to the workshop outline or qualifications training checklist. The assignment of a trainer can be performed by laboratory management staff, regional manager, national director, QA manager, vice president or president. Capability will be determined based on knowledge, experience and demonstrated technical competence. The trainer must have a thorough and comprehensive understanding of the topics involved.

5.2.2.3.2 "On the Job" Technical Skills Training

This is training provided at the hands-on level. The amount of training time needed will vary for each method and for each trainee. If the training involves analytical procedures, the trainer must be a qualified analytical specialist with at least one (1) year of experience. Non-analytical procedures may be trained by any experienced EMSL employee with a thorough and comprehensive understanding of the topics involved.

5.2.2.3.3 "Out of House" Formal Training Courses

Under some circumstances, EMSL will provide staff members with formal, outside training. The certificate of training is maintained in the employee folder along with course outline. Courses will be selected based on applicability to job responsibilities. The qualifications of the course provider and instructor shall be reviewed prior to course approval. Contact hours vary based on the course.

5.2.2.4 Initial Training and Authorization of Analytical specialists

5.2.2.4.1 Training Checklist

Analytical specialists must satisfy theoretical and practical knowledge requirements in order to be authorized to independently analyze samples. Each EMSL program area utilizes a set of training checklist to document these requirements and track an analytical specialist's training. The EMSL training checklists are available on the E-link site and are referenced in the program specific modules.

The training checklist documents the aspects of the analytical specialist's training, from their understanding of the theory behind applicable concepts, to their ability to capably perform analysis of each method on which they are being trained. Specific requirements for each analysis are detailed in the QMS Manual Modules and the training checklists.

As training of an analytical specialist proceeds, the trainer and trainee sign and initial each item on the checklist as they are completed. There are a number of ways a new analytical specialist can satisfy the requirements presented in the training checklist.

The date the checklist is signed is the date on which the new analytical specialist demonstrated understanding or ability satisfying the requirement. This demonstration may be completed in a number of ways.

- The analytical specialist may receive training on the topic from a qualified trainer (an analytical specialist that has at least one year of experience and a completed DOC for the method being trained), and subsequent to the training, demonstrates their understanding and/or ability. Once the trainer is satisfied the analytical specialist has met the requirement, the trainer shall initial and date the training checklist for that requirement.
- Based on previous experience and training, a qualified trainer (as defined above) or the laboratory manager, may verify that knowledge or skills are already present through interviews and observed technique, and once satisfied the analytical specialist has met the requirement of the checklist, may initial and date the training checklist for that requirement without further training.

Note: Previous EMSL training policies allowed for a "qualifications statement" from the national director in lieu of a training checklist. This option was eliminated beginning with Revision 10 of this document. Analytical specialists must have each checklist item verified by laboratory manager or trainer and initialed on the checklist. "Qualification statements" issued prior to the removal of this option (Dec. 2008) will still be considered valid, and should remain a part of the analytical specialist's training records. Likewise, previous revisions of the training checklist are acceptable as it represents the state of training documentation at that time. Analytical specialist performance will have been demonstrated through acceptable QC analysis. However, if no training documentation exists, the current checklist should be used to document the current competency of the analytical specialist. Each item should be reviewed, and acceptable performance/knowledge documented by the analytical specialist and the department manager, or national director in the case of department managers.

Once all requirements of the training checklist have been completed and marked on the checklist by the analytical specialist and trainer, the laboratory manager signs off on the training checklist, stating the training of the analytical specialist has been completed.

Where no training checklist exists for a particular method, or if the checklist does not detail a method for initial demonstration of capability, an initial demonstration of capability shall be performed as per the method, or where the method does not specify, the method outlined in TNI Standard (2016) Sect. 1.6.2.2, or an equivalent method.

Frequency of Initial DOC

An initial DOC for each analyst shall be completed prior to a new method being introduced, or when there is a change in method or instrumentation. TNI also requires an initial DOC whenever an analytical specialist or the lab has not performed a method within the past twelve (12) months [six (6) months for AIHA LAP, LLC accredited laboratories]. This requirement shall be taken into account when considering accepting samples for a method that has not been performed in the past year.

Analytical specialists shall perform analysis with each method on QC samples at least once a year to maintain their capability with infrequently used methods.

5.2.2.4.2 Demonstration of Capability (DOC) Certificate

Following completion of the training checklist, the signed checklist is reviewed by the lab manager and regional manager, as needed.

EMSL utilizes a DOC certificate which is based on the sample provided in Appendix C of Section 5 of the 2016 TNI Standard. The form allows for the recording of all analyses for which demonstration has been completed for a particular analytical specialist.

The certificate is prepared by the lab manager, with assistance from the regional manager and/or QA Department, as needed, and signed by the department or lab manager, against the information provided by the laboratory manager on the training checklist, and supporting documentation for each matrix and method for which the analytical specialist is authorized to perform analysis. Each analyses type is listed, along with the date upon which Demonstration of Capability was completed. The date of the signature indicates the date upon which the information contained on the form was updated and confirmed, and the form issued by the lab manager or QA Department.

Once the DOC certificate is signed, the analytical specialist is authorized to perform work for those methods listed on the DOC certificate. (Note: When the analytical specialist being authorized is the laboratory manager, the DOC certificate shall be signed by either the regional manager or national director.)

The DOC certificate shall be revised whenever an analytical specialist completes a new demonstration of capability, or when their capability to perform the analysis changes. In such cases, the supporting material shall be sent to the laboratory designee, or the QA Department along with the most recent version of the DOC certificate. Once updated, the laboratory designee or QA Department will re-sign for re-affirmation of the information contained on the form. Thus, the dates of the signature always correspond to the date the certificate is issued, and the information contained therein is confirmed, not necessarily the date upon which specific demonstrations were completed.

5.2.2.4.3 Exception to Certification Form:

Where a method has been used in the laboratory since July 1999, and there have been no significant changes in instrumentation type, personnel or method, evidence of ongoing performance (see below) will be acceptable. The laboratory manager must have a record on file to demonstrate an initial DOC is not required.

5.2.2.4.4 Authorization to Perform Analysis

Analytical specialists must receive formal authorization to perform analysis. This is performed with the signature of the laboratory manager, regional manager, or national director and/or vice president of quality assurance on the qualifications/training checklists. These checklists are then followed up with the Demonstration of Capability certificate.

5.2.2.5 Ongoing Training and Continued Demonstration of Capability

5.2.2.5.1 Ongoing Training

Ongoing training of our staff is a very important piece of analytical quality. It provides an opportunity to sharpen skills and keep all employees up to date with the current procedures, techniques, regulations, etc.

Laboratory managers are to ensure ongoing training is provided to all employees on a consistent basis. The opportunity for ongoing training occurs in many different forms. The following list suggests a number of different types of ongoing training:

- Laboratory staff meetings – scheduled as needed, these can cover a variety of technical topics. There is no organized agenda and interaction between all attendees is encouraged (much like an open forum). Examples of topics could include technical subjects/analytical method updates, customer service issues, health and safety, etc. This training must be documented.
- Laboratory audits – the staff can consult with the auditor (of both internal and external audits) and ask questions to be advised on many topics.
- Workshops provided by professional organizations, regulatory agencies, or instrument/equipment vendors. If a certificate is not provided by the outside trainer, such as in a workshop, an open use training form is completed for each described topic covered during the training. A copy of this training record is maintained in the laboratory files.

5.2.2.5.2 Ongoing Demonstration of Capability

Continuous demonstration of capability by each analytical specialist is achieved through the QC reanalysis of samples by the same analytical specialist (intra-analyst), different analytical specialist (inter-analyst), inter-laboratory analysis, the analysis of standard reference samples/LCSs, and performance in proficiency testing programs. This is performed at a minimum of every 12 months, and is documented with:

- Copies of reports of individual analytical specialist's performance in proficiency testing programs (stored in employee training files)
- Copies of reports of individual analytical specialist's performance in round robin programs (stored in employee training files)
- Analytical quality control reports (QC results, standards analysis, etc.) generated during the course of analysis
- All target analytes shall be included in the DOC Study.

  ***Note**: This data is normally stored with the laboratory quality control data vs. in the individual analytical specialist's files.*

Whenever possible, inter-analyst QC should be performed by analytical specialists that have completed their training, and for whom certifications of demonstration have been completed.

When PT studies are used for ongoing demonstration of capabilities, only analytes that met PT acceptance criteria shall be used.

5.2.2.5.3 Recertification Statements

Every 12 months (or 6 months for lead methods within the scope of AIHA LAP, LLC ELLAP accreditation), the laboratory or department manager shall sign a Recertification Statement for each analytical specialist to document continued authorization to

perform analysis. If the laboratory/department manager is also authorized to perform analysis, the regional manager, national director, lab quality manager (if different), or designee shall review and sign the *Continuing Certification Statement* for the laboratory manager. The recertification statement will be attached to the original DOC certificate in the analytical specialist's folder.

5.2.2.6 New Manager Training

EMSL has created several video trainings describing the responsibilities a new manager must handle. Upon accepting a managerial position in an EMSL laboratory, the manager has approximately one to three months to view the training videos. After completion, a meeting will be conducted between the manager, QA, the Regional Manager, and or National Director/ Vice President, to discuss any questions the manager has related to their new responsibilities. GEN-TC-120 New Manager Training Checklist will then be approved and signed by the Regional Manager or other appropriate Corporate representative.

Supervisors and QA Representatives will view the applicable videos associated with their duties, and will follow the same process as above. These supervisory position employees have approximately six months to view the videos.

The QA Department will take note of new managers, and track their viewing of the video training sessions. Each month, the QA Department will contact the managers or supervisory personnel to address any questions they may have; this will also serve as a reminder to view their associated training videos to ensure completion.

5.2.2.7 Measurement of the Effectiveness of the Training Program

The effectiveness of our training program is evaluated using a number of identifiers. These include:

- Analytical specialist's performance in the quality control program (inter/intra analyst, analysis of standards, blanks)
- Performance in proficiency testing programs
- Evaluation of data generated in round robin programs
- Analysis of blind QC samples
- Performance at internal and external onsite site audits

The evaluation of any of these items may identify the need for additional training or modifications to the training program. Some examples of findings that may indicate training needs include:

- Poor performance in the quality control program
- Outliers reported in proficiency testing programs or round robin programs
- Findings noted during internal and external audits
- Feedback from laboratory staff self-identifying training needs
- Trends in non-conformities reported in the laboratory

5.2.2.8 Authorizations Log

Laboratory managers are responsible for authorizing lab personnel to perform critical tasks. This may be accomplished by utilizing a log which contains both technical tasks (preparation and analysis of samples), as well as any non-technical tasks which are critical to the operations of the laboratory (e.g., ordering supplies, discussing reports with customers, logging in samples). Alternatively, authorizations can be documented through Demonstration of Capabilities (DOCs), training records, job descriptions, and organizational charts.

The *Authorizations Log* spreadsheet and its "Instructions" tab is available on E-link.

5.2.2.9 Training and Personnel Files

Personnel and training files shall be maintained for all technical employees. Personnel files shall contain all general documentation associated with the employee. Training files shall include all files associated with the initial and ongoing training of the employee.

A completed personnel file must contain at a minimum:

- Resume/CV
- Signed Ethics Acknowledgment
- Diplomas for degreed employees (complete transcripts may also be used if showing graduation)
- Copies of any registrations/certifications held by analytical specialist

A completed training file must contain at a minimum:

- Training checklists for all analyses for which the analytical specialist is qualified
- Demonstration of Capability certificate (DOC) which lists all the methods the analytical specialist is authorized to perform
- Raw data supporting initial DOC for all analyses*
- Summaries of data reviewed to demonstrate ongoing capability*
- Misc. training records (certificates from classes taken and in-house training sheets)
- For Asbestos: NIOSH 582 training certificates
- For Lead: 4 independent runs for each matrix
- Results of performance on proficiency testing samples/round robin samples

*** Note:** Copies of raw data supporting the initial and ongoing demonstration of capability for the analytical specialist may be referenced in the personnel folder, instead of being included. Copies of the original raw data shall be maintained for the length of employment and for five (5) years after the end of employment. For ongoing demonstration of capability, summaries of data reviewed with references to the original data are sufficient in the training folders.

Files are to be maintained and updated by the laboratory manager.

5.2.3 Reporting of Significant Changes

Any changes in laboratory ownership, location (except for mobile and field operations laboratories), management, laboratory key personnel, or any other change that significantly affects the laboratory's capability, scope of accreditation, or ability to meet the policy

requirements, shall be reported in writing to the appropriate accrediting body within their required time frame. Any absence of personnel for an accredited body's required period, that impacts the laboratory's ability to perform its scope of testing, shall be reported to the appropriate accrediting body within their required time frame.

5.3 Accommodation and Environmental Conditions

5.3.1 General

EMSL is committed to ensuring laboratory facilities are appropriate for ensuring the correct performance of tests. For example, attention will be paid to energy sources, lighting and environmental conditions, and separation between neighboring areas in which there are incompatible tests.

Any specific technical requirements for a specific method are documented in the program specific modules of the QMS Manual, or in the specific technical SOPs. Examples of specific environmental conditions that may affect tests and will be documented in the modules or SOPs include sterility of work area, electromagnetic disturbances, temperature, and/or humidity, radiation, and vibration levels.

Where it is determined controlled environmental conditions are crucial for the performance of a test or the interpretation of results, the lab will monitor, control, and record these conditions as necessary (i.e., through the use of temperature logs, humidity logs, readings included on bench sheets, etc.).

Should a laboratory or department manager determine the facility must be modified to meet requirements, these requests will be sent to the President or Senior Vice President of Laboratory Services for approval.

Access to the laboratory beyond the receiving area is restricted to laboratory employees or contracted employees. If non-laboratory personnel wish to enter these areas, they shall be accompanied by authorized lab personnel. Applicable employees are provided keys or electronic fob keys by Management or Human Resources Department when hired, and must return keys when their employment ends.

The laboratory manager is responsible for ensuring good housekeeping practices are in place in the laboratory. This includes periodic wipes of areas prone to contamination, proper cleaning of lab glassware, disposal of disposable consumables following use, and general cleanliness of the laboratory facility, including non-analytical areas. Where specific procedures must be followed, these will be documented in the QMS Manual program specific modules or in analytical SOPs.

5.3.2 Contamination Management

This section describes reagent control and contamination management. Proper observance of these procedures is necessary to guarantee accuracy of results and the safety of laboratory staff members.

Contamination of samples, the laboratory environment and reagents used in analysis must be avoided to provide the highest quality, legally defensible data to our customers. In order to achieve this goal, laboratory staff must adhere to various preventative measures and use the testing procedures for contamination detection.

Contamination control is focused both on sources and on targets of contamination. Sources of contamination include samples and laboratory debris. Targets include things such as, samples, equipment (e.g., tools), supplies (e.g., microscope slides and reagents) and work areas.

Contamination control consists of 3 parts:

- Avoidance
- Detection
- Resolution

5.3.3 Contamination Avoidance

To avoid contamination, the following procedures must be followed:

- Maintain good housekeeping
- Clean all tools before and after preparing each sample
- Clean tool sets at the end of the workday
- Dispose of wipers after use; do not let them pile up during the workday
- Wipe all work surfaces before and after sample preparation. Surfaces include bench tops, slide trays, stereo microscope stage, and slide preparation surface.
- Control work areas
- Work only on clean surfaces

Only one active sample should be processed at each time. The sample containers are kept closed when not being processed. Inactive samples are stored in a suitable, out-of-the-way area. Target items (samples, reagents, and containers) are opened one at a time, as practical.

5.3.4 Detection of Contamination

Contamination control is verified by the evaluation of blank sample analysis and results of air/surface sampling.

5.3.4.1 Blank Analysis

The number of blank samples analyzed is specified in the quality control section in the appropriate SOP. This data is generated and tracked for the purposes of monitoring any possible contamination only, and is not to be used for statistical quality control.

5.3.4.2 Ambient Air Monitoring/Wipe Sampling

On a quarterly basis, or if there is a reason to suspect contamination, the laboratory is to perform ambient air monitoring and/or wipe sampling throughout the facility. This procedure not only helps to monitor possible sample contamination, but also provides data to evaluate any possible personnel exposure.

For air samples, a sampling pump is set up in a location that represents areas of most activity. The pump's rotameter must be calibrated against a primary standard, annually. Sampling is conducted according to the appropriate NIOSH, OSHA, or other published method as available. Flow rates, sampling times, media and all other parameters will be in accordance with appropriate methods and good scientific practice.

Specific sample volume, method of analysis, and acceptance criteria for the targeted compounds are listed in the individual modules.

Results of these samples are filed in the laboratory. If any result is above the contamination/exposure limit, the laboratory manager must immediately notify the Quality Assurance Department and/or the corporate health and safety officer. An investigation into

the source of contamination/exposure is performed, and a corrective action implemented. All actions are documented.

See the program specific modules for specific details on what quarterly contamination monitoring is required.

5.3.5 Resolution

If contamination is detected in any situation, the source of contamination must be traced, and the problem resolved to prevent reoccurrence. A Corrective Action Record (CAR) should be completed to document the analysis of the source of the contamination, as well as actions taken to resolve a contamination circumstance.

After corrective actions have been completed, and the contaminated areas have been cleaned, re-sampling and analysis shall be performed in order to ensure the contamination has been eliminated. A subsequent contamination check prior to the scheduled quarterly check may be warranted depending on source and/or type of contamination in order to ensure effectiveness of corrective actions.

5.4 Test Methods and Method Validation

5.4.1 General

Instructions or procedures for the activities affecting the quality of our analytical services shall be developed by management. This quality assurance program shall be used as a guideline for their development, use, and revision.

Technical standard operating procedures are documented in the SOP Manuals, located at each laboratory facility. These SOPs include step by step procedures for the preparation, analysis, and reporting of data.

Note: Not all methods written in our SOPs are applicable to all EMSL laboratories.

General and Administrative SOPs include, but may not be limited to:

- **EMSL Complaint Resolution SOP (QA-SOP-600)** – *Standard Operating Procedures for Complaint Handling and Resolution*
- **EMSL Corrective Action SOP (QA-SOP-200)** – *Standard Operating Procedures for Non-Conformities and Corrective Actions*
- **EMSL Preventive Action SOP** (**QA-SOP-250)** – *Standard Operating Procedure for Preventive Actions*
- **EMSL Final Report Approval and Electronic Signature SOP (GEN-SOP-901)** - *Procedures and Policy for Final Report Approval Using Electronic Signature*
- **EMSL Controlled Document SOP (QA-SOP-301)** – *Standard Operating Procedures for Document Control Program*
- **EMSL Document Master List SOP (QA-SOP-302)** – *Standard Operating Procedures for Maintaining Master Lists of Documents*
- **EMSL Control of Records SOP (QA-SOP-350)** – *Standard Operating Procedure for Control of Laboratory Records*
- **EMSL Internal Audit SOP (QA-SOP-700)** – *Standard Operating Procedure for Internal Quality Assurance Audits*

- **EMSL Annual Management Review SOP (QA-SOP-750)** – *Standard Operating Procedure for Annual Management Review Reporting*
- **Purchasing: Evaluation of Suppliers and Services SOP** (**QA-SOP-500**) – *Standard Operating Procedure addresses the evaluation and selection of suppliers and services critical to the analysis of samples*
- **Purchasing: Receiving Supplies and Services (QA-SOP-501)** – *Standard Operating Procedure addresses procedures for receiving and approving supplies and services for use upon receipt*
- **Prep and QC of Materials SOP-Micro (GEN-SOP-810)** – *Standard Operating Procedure for the receipt, preparation, handling, storage, quality control and disposal of consumables, kits, media, reagents, solutions, and standards used in Microbiology*
- **Safe Sample Handling Log-In Personnel (GEN-SOP-701)** – *Standard Operating Procedure covering the practices personnel shall use to prevent potential exposure to hazardous customer samples*
- **Sample Receiving and Chain of Custody SOP (GEN-SOP-702)** – *Standard Operating Procedure to track the custody of samples using the Chain of Custody form*
- **EMSL Method Validation SOP (GEN-SOP-310)** – *Standard Operating Procedure for Validation of Methods and Method Modifications*
- **EMSL Training on Analytical Methods SOP (GEN-SOP-100)** – *Standard Operating Procedure for Documentation of Training on Analytical Procedure*
- **EMSL Sample Transfer and Subcontracting SOP (GEN-SOP-10)** – *Standard Operating Procedure for the distribution of samples to other laboratories for analysis, including transfer of samples to other EMSL laboratories*
- **Amending Final Reports SOP (GEN-SOP-902)** – *Standard Operating Procedure to ensure all EMSL amended reports are appropriately and consistently identified as an amended report*
- **Analytical SOPs** – *Relevant analytical SOPs for each analytical method are found in the appropriate modules. These SOPs cover methodology for analytical procedures, calibrations, contamination checks, reporting procedures and quality control frequency.*

A list of the SOPs for each test method the laboratory is accredited for can be found on form 'List of Accredited Methods Validated by Use,' on EMSL's intranet. The link to each laboratory's list (located in individual laboratory folders) is https://elink.emsl.com/labs/default.aspx

The laboratory manager is responsible for ensuring the SOPs reflect the actual laboratory procedures. Managers are to submit suggestions for revisions to the vice president of quality assurance for review. The vice president of national quality assurance is responsible for controlling revisions and distribution of the SOPs. (See *Document Control and Control of Records* section of this manual.)

If analysis is performed using modifications to the EMSL SOP or the standard published methods, the final report will describe the modification in the report title or in the form of a disclaimer. See method SOPs for specific detail.

5.4.2 Selection of Method

EMSL always uses test methods which meet the requirements of its customers. Whenever published and widely accepted methods are available, these standard methods shall be reviewed and adopted when deemed appropriate. Where EMSL specific adjustments or modifications are necessary, these

shall be documented in the SOP for that method. Continued use of laboratory developed methods (vs. ASTM, for example) can be consistent with our policy of using standard methods when possible.

Methods shall be labeled as "Modified" if they are non-performance-based methods, and the changes to the methods are such that they alter the chemistry of the method, or change the determinative step of the SOP as compared to the approved method. Adjustments to the method which do not change the determinative step or chemistry shall be clearly stated in the SOP, or an addendum to the SOP which is referenced from the SOP itself. Reasons for the change, as well as any supporting data showing adjustments do not adversely affect the performance of the method, shall also be documented.

Most tests offered by EMSL are included on the standard chain of custody forms and selected by the customer by use of this form, or by documenting the test number selected on their own chain of custody. If a method is not selected by the customer, the laboratory shall communicate with the customer to determine which methods are most appropriate. If a customer selects an inappropriate method, they will be contacted immediately to determine the most appropriate method for their needs.

Where no standard methods are available, laboratory developed or modified standard methods may be used once they are appropriately validated, and once the laboratory confirms it can operate the procedure. The customer will always be made aware of the procedure to be used prior to testing.

5.4.3 Laboratory-Developed Methods

As noted above, where published standard methods are not available, EMSL will develop its own methods for an analysis, or modify existing methods to ensure they are appropriate for the test requested. Validation of these methods is discussed below. Development of new methods is a planned activity and assigned to personnel with appropriate expertise. The SOP will be reviewed and approved by the national director for that area of analysis.

5.4.4 Non-Standard Methods

5.4.4.1 Use of Non-Standard Methods

Before any non-standard method, including modified methods, is implemented, the customer (or other recipient) must be consulted on the new procedures. The customer should provide approval prior to beginning the work.

Non-standard analytical procedures must be written and validated. The method validation process should prove that the alternate method:

- Meets acceptable criteria for precision and accuracy (see validation section below)
- Meets or exceeds analytical sensitivities required by the customer
- Does not introduce uncontrolled or unknown biases, including matrix interferences

5.4.4.2 Departures from Standard Operating Procedures

Major departures from the EMSL standard operating procedures, whether technically adjustments or modifications, must go through a review by the national directors, regional managers, or quality assurance manager prior to use. Major departures include, but are not limited to:

- Different sample preparation procedures

- Use of alternative analytical instrumentation
- Use of additional or different reagents

Departures from standard operating procedures may be a result of a customer request. Review and documentation of major departures include:

- Reason for deviation from method
- Validation of procedure
- Applicability of alternative method
- Availability of needed resources (if applicable)
- Assurance data is reported with appropriate references and disclaimers (if applicable)
- Record of alternative procedure or policy is maintained as part of the corporate files

Where departures from standard operating procedures are not a result of a customer request, the laboratory must gain the customer's approval.

Validation of Non-Standard Methods or Departures from SOPs

A validation study must be performed before analysis is performed on customer samples for any non-standard method or departure from method. A validation study involves:

- Comparison against established methods (if available)
- Effects of deviation
- The assurance results are equal to or better than the original method (if original method exists)

The procedure used to validate a method also involves an ongoing process with continuous review of the QC data, including analysis of standards, inter/intra analyst reanalysis of samples, participation in round robin programs and proficiency testing programs.

Standard quality control acceptance criteria are applied to monitor performance of the method unless other QC criteria are established. If other criteria are used, they should follow general Good Laboratory Practice (GLP) guidelines.

5.4.5 Validation and Verification of Methods

The majority of the procedures utilized by EMSL laboratories are based on published methods issued through governmental regulatory agencies and independent standards organizations. These methods must be validated following the *EMSL Method Validation SOP* (GEN-SOP-310) to verify acceptable method performance. Validation must occur before performing analysis on customer samples.

TNI requires an initial DOC be conducted for each method and analytical specialist prior to using any method, and at any time there is a change in instrument type, personnel or method, or any time that a method has not been performed by the laboratory or analytical specialist in a twelve (12) month period.

In cases where a lab analyzes samples using a method that has been in use by the laboratory for at least one year prior to applying for TNI accreditation, and there have been no significant changes in

instrument type, personnel or method, the ongoing DOC shall be acceptable as an initial DOC. The laboratory shall have records on file to demonstrate an initial DOC is not required.

Methods used by EMSL are also continually validated through the review of QC analysis including analysis of known standards, inter/intra analyst reanalysis of samples, and participation in round robin programs and proficiency testing programs. When new services/methods are implemented in a laboratory location with newly trained analysts, a data review period will be set up by corporate QA and the National Director/Vice President of the related division. This process is created to ensure the data originating from the laboratory has the proper oversight to confirm its accuracy, and to provide any guidance necessary. During this time period, QA and the head of the related department will inform laboratory personnel of any issues/concerns discovered during the review. Once both the QA department and head of the related department are comfortable with the data, and a sufficient period of time for review has elapsed, the review period can end. The review period will be flexible, and the amount of data to review will be determined by QA and the head of the related department. A minimum data review period is one month, but is recommended to extend up to three months. The volume of data/reports reviewed is also based on the number of samples received, and can be adjusted as time progresses. For example, 50% of the data will be reviewed for the first month, 25% for the second month, and 10% for the third month, as long as no issues or concerns are detected.

5.4.5.1 **Verification of Methods**

When a new published method is implemented in a laboratory, a verification package shall be compiled. This package would include initial calibration of the instrument; proficiency tests (if available); a new demonstration of capability, if required; any quality control associated with the method; and other specific requirements written into the method, if applicable. Once the package is compiled, it is sent to the QA department for recording. When new method versions are released, the QA department or related head of the department will notify the laboratory if a method validation package is required.

5.4.6 Estimation of Uncertainty of Measurement

The QMS Manual program-specific modules and SOPs address the estimation of analytical uncertainty for each program area. EMSL's policy is to have a procedure for the reasonable estimation of analytical uncertainty for its quantitative tests.

EMSL's uncertainty procedures address only analytical uncertainty and do not account for contributors to uncertainty resulting from sampling procedures. Contributors are listed in the workbooks and/or the SOPs. Unless stated otherwise in the analytical procedure or QMS Manual Modules, EMSL uses measurands from repeated analysis of prepared standards over time as a basis for determining uncertainty for a test method (Type A approach). In general, replicate and/or duplicate quality control measurands are used to generate mean recoveries and standard deviations for the method over time. Using this mean recovery, each method will be evaluated upon request to determine the uncertainty and probable bias of the method. Expanded uncertainty will then be derived by multiplying the standard uncertainty by a k factor (i.e., the student t value at 95% confidence interval which is related to the degrees of freedom (v) of the data set used in the calculation (v=n-1)).

Uncertainty is determined using QC template Excel workbooks which have been designed to calculate sample results, chart control chart data for precision and accuracy of each run, and which calculate uncertainty data for each measurand. Instructions on the use of these workbooks can be found in the workbooks themselves. References to the proper workbooks can be found in the program specific QMS Manual Modules.

Each method (either in the SOP or in a separate document, such as an uncertainty worksheet) contains an evaluation of the sources of uncertainty, as well as the procedure for estimating uncertainty. Uncertainty will be reported if requested by the customer, when required by the analytical method, when necessary for interpretation of results, or when uncertainty affects compliance with a known specification limit. Even if not requested, all necessary data for evaluating uncertainty will be retained in the laboratory. When uncertainty is reported, it shall be reported in the same units as the measurand, and shall include the coverage factor and confidence interval used in the estimations. Bias will be reported separately where it exists and is uncorrected.

Uncertainty shall be re-estimated when changes to operations occur that could affect it, such as changes in instrumentation, modifications to methodology or technique, etc.

5.4.7 Control of Data

5.4.7.1 Continuous Data Validation

Data validation is a continuing process that takes place every time samples arrive at the laboratory and is carried through during log-in, analysis and final reporting. If any of the errors found during this proofing process are not traced back to transcription or analytical error, then the computer system is suspect and will be investigated. The processes that undergo this continuous validation include:

5.4.7.1.1 Sample Receiving

At completion of the log-in phase, the internal chain of custody and bench sheets appropriate to the analysis requested are produced by LIMS (SMXP or Element). Also at this time, an internal chain of custody is produced. This document summarizes the sample set with customer and sample information (including IDs), and generates a chain of custody log that is initialed and dated by everyone that handles the samples in the laboratory. The laboratory manager checks the accuracy of this information generated in LIMS.

Only labs and methods approved by corporate management for remote log-in may follow this process.

5.4.7.1.2 Sample Preparation

After log-in, the samples and all its corresponding paperwork are sent to the lab for preparation prior to analysis. Upon receipt, the prep person and/or analytical specialist initials the customer chain of custody confirming the requested analysis is being performed. At this stage too, any problems with the samples or paperwork are noted and brought to the attention of the laboratory manager.

5.4.7.1.3 Sample Analysis

After sample prep, the samples and all corresponding paperwork are sent to the analytical specialist. The analytical specialist initials the requested analytical method on the original chain of custody. At this stage, any problems with the paperwork (or samples) are documented on the sample paperwork and also brought to the attention of the laboratory manager. Upon completion of analysis, the analytical specialist dates and initials the internal chain of custody in the appropriate section.

The analytical process is obviously one of the most important stages in assuring data validity. The procedures taken to ensure the validity of the sample result include

calibration of equipment, formulation of method detection limits, instrument detection limits, determination of analytical specialist qualifications, instrument, and method precision and bias, etc., are very specific to the particular analysis being performed. Details of these procedures can be found in the SOPs for the various analyses.

5.4.7.1.4 Analytical Results Entry

iL@b is a custom module developed for the EMSL LIMS. It allows analytical specialists to input data directly into the lab database rather than relying on the added step of transcribing from paper bench sheets to the database, and does not utilize predefined default optical properties. iL@b is being rolled out gradually to all departments. Once approved by the analytical specialist, the data is available in the database for future review as discussed below, both as raw data and in the final report format.

For analyses not covered by iL@b, once sample analysis has been completed, all paperwork including field data sheets, field chain of custodies, internal chain of custodies, sample bench sheets, and any other paperwork generated to this point is sent to the data entry personnel. At this stage, results are transcribed from the bench sheets and instrument printouts into the LIMS (or Excel) reporting spreadsheet. Analytical results are entered either by personnel approved for data entry, or by the analytical specialists themselves. The software stores the analytical data, performs calculations, and generates the final report. The person performing the data entry would be aware of any error or unusual performance of the LIMS and would bring this to the attention of the laboratory manager.

This final report is reviewed by the laboratory manager (or designee) and approved before being forwarded to the customer. Chains of custody are copied and placed in the laboratory master files along with the analytical worksheets and raw data.

5.4.7.1.5 Proofing of Reports

After data entry, reports are sent to the laboratory manager or designee for review. The reports are reviewed for completeness and accuracy. A check on the quality control analysis performed in association with the results is also performed. This is also another point where transcription errors are caught and corrected. In addition, if the analytical data looks questionable for any reason, hand calculations are performed to verify results.

If errors are found, the report is returned to data entry for transcription error corrections or back to the lab if there are problems with the data. Where errors are determined to be a result of non-conformities in lab process, a corrective action will be initiated. Random errors, such as typographical errors, do not need to initiate corrective action unless they occur frequently, indicating a systematic problem which needs correction.

5.4.7.2 Computer Software

5.4.7.2.1 General

EMSL utilizes an automated Laboratory Information Management System (LIMS) to record, document, and assimilate pertinent field, laboratory, and administrative data. The LIMS system is referred to as SampleMaster XP (SMXP) or Promium Element.

The validation of the SMXP software, including final report templates, are performed by the corporate IT Department and the Quality Assurance Department and the SampleMaster Beta testing team, which consists of several EMSL Subject Matter experts.

The IT Department is responsible for maintaining updates and revisions and for tracking distribution. Release notes for each release of SMXP are prepared and distributed by the IT Department. A complete release history and historical release notes can be obtained from the IT Department at any time.

Validation of Element was conducted by Promium, and is maintained by Promium through routine service. New versions are tested at Promium, and implemented at EMSL, when available.

5.4.7.2.2 Validation of Computer Software and Data

Analytical data storage, processing, and reporting are facilitated through use of SMXP. SMXP software is run on Windows-based, PC computers. EMSL-developed Excel spreadsheets are used to track QC data, equipment calibrations, and environmental conditions. These spreadsheets are validated before being made available on E-link. The corporate IT staff are responsible for ensuring all computer systems, hardware, and software, are documented, inventoried and adequate for use. All systems are operated in safe environments and maintained to ensure proper operation. The computer systems responsible for handling of analytical data have been set up to process data in a way that ensures integrity.

Additional information on the EMSL Software Development Life Cycle, which includes the validation of LIMS software, can be found in the *General Guidelines for EMSL Information Technology* document found on E-link.

All computerized systems, especially the software used for data reporting, must be initially validated prior to use, and then subsequently periodically re-checked during the ongoing validation process.

All calculations and reporting performed by the software is implemented by the laboratory management, the corporate IT staff, or the QA manager. This coordination between the QA Department, laboratory management, and the IT Department allows the software to be reviewed and altered as necessary to comply with regulatory agencies and/or accrediting organizations requirements.

EMSL employs a system to periodically test and verify the software used for sample log-in and report generation is performing properly. To do this, a “dummy” set of samples has been created for each type of analysis the lab performs. Each set has a sufficient number of samples to be able to test as many variables as possible. Examples are:

- No volume
- Low volume / low sample weight
- High volume
- Low concentration
- High concentration
- None detected
- Overloaded sample

The "dummy" sample reports are proofread for accuracy of all text fields, and all results have been verified by hand calculation. The results of each periodic software validation are documented along with the date performed. If there is any discrepancy from the master that cannot be attributed to data entry error, the QA Department is notified, and corrective actions implemented.

5.5 Equipment

5.5.1 Local Equipment Inventory and Logbook

Each laboratory is required to maintain an inventory of all critical equipment in use at the laboratory. Since each laboratory's inventory varies according to size and scope of work performed at the laboratory, it is the responsibility of the lab manager to ensure this equipment inventory reflects actual equipment at that laboratory and includes wherever available, the manufacturer, model, serial number, date put into service and date taken out of service. This equipment inventory is maintained in the "Equipment Inventory" tab of *GEN-FM-450 Equipment Inventory and Maintenance Log*. The column indicating 'Date Taken Out of Service' on the "Equipment Inventory" tab refers to the date when non-functioning equipment was moved to storage in a lab, returned to EMSL's corporate office, or otherwise disposed of. For non-functioning equipment removed from the lab, the lab will add a copy of the "Equipment Inventory" tab, rename it "Out of Service Equip. Inventory," and list only equipment no longer present in the lab. On that tab, the lab will enter 'Returned to EMSL Corporate office' or 'Disposed of' in the 'Equipment Location' column.

In addition, a logbook shall be maintained for each piece of critical equipment in use at the laboratory. All maintenance, repairs, calibrations performed on the instrument shall be recorded, along with the identity of the equipment and software, mfg. name, type ID and serial number, and current location (if appropriate). For most labs, this is done within *GEN-FM-450 Equipment Inventory and Maintenance Log*. However, in some circumstances this will be maintained in a separate Equipment Log notebook. Labs are strongly encouraged to use the spreadsheet whenever possible. Each instrument service entry shall contain the following information:

- Date and time
- Initials of servicing individual (include if in-house or outside agency)
- Description of problem, evaluation of equipment and any data that may have been affected; notify client if necessary
- Maintenance element examined (note if any repairs or replacement of component were made); or, make the Certificate of Analysis available, detailing the equipment's service or repairs
- Description of equipment's acceptability to return to service and name of personnel approving; or, make the Certificate of Analysis available, detailing the equipment's acceptability, i.e., passing calibration, criteria, etc.
- Pertinent comment(s)

NOTE: All information from the items listed above may be entered into the Description of Problems and Action Taken sections of *GEN-FM-450 Equipment and Maintenance Log*.

5.5.2 Subcontracted or Leased Equipment

Any laboratory equipment which is to be used during analysis, other than EMSL equipment, (e.g., equipment borrowed/eased from an outside organization such as an academic institution), must undergo complete calibration, applicable start-up procedures and QC checks, as described in the laboratory SOP for the utilized instrument. These procedures must be performed prior to the start of

any sample analysis. All maintenance records, manuals, and performance records must be made available for review and approval by EMSL staff.

Records are to be maintained which include:

- Type of instrument subcontracted
- Date and purpose
- All raw QC data generated including calibration information

5.5.3 Instrument Calibration

Analytical instruments including GC, GC/MS, ICP/MS are calibrated following applicable SOPs, as per associated analytical method requirements, and also meeting regulatory Standards.

Accrediting authorities and standard published methods have specified the frequency and manner in which a laboratory must calibrate their support equipment (including thermometers, balances, weights, pipettes, etc.). For laboratories maintaining ISO 17025 accreditations (e.g., AIHA LAP, LLC; NVLAP, A2LA, TNI), calibrations of equipment used in accredited tests must be performed internally by trained personnel using approved accreditation procedures, or by an outside calibration firm accredited to the ISO/IEC 17025 standard. The calibration must be performed following the ISO standard.

Before being placed into service, or returned to service after repairs or modifications, the equipment and its software is calibrated and checked to establish it meets EMSL and method specifications. Thereafter, calibration schedules established in this QMS Manual and related program specific modules, as well as related SOPs shall be followed. Intermediate calibrations may be required, as necessary. All calibrations should be documented in *GEN-FM-450 Equipment Inventory and Maintenance Log.*

Labels shall be placed on all calibrated equipment and reference standards, where space permits, which include date of last calibration and date calibration is next due, along with any correction factor, where applicable. Where space does not permit the use of a label, a label shall be placed near the instrument or standard and shall be associated with the instrument by serial number or equipment ID.

Whenever calibration leads to a set of correction factor, these correction factors shall be referenced on the accreditation label or otherwise affixed to the equipment, and shall be included in any calculations for which the correction factor is relevant.

Specific analytical instrument calibration requirements are found in the appropriate program module or related SOPs. Requirements for the calibration of common support equipment are included below. Also see § 5.6 of this manual for requirements for calibration/verification of common Reference Standards.

Note: References to ***calibrations*** refer to EMSL internal procedures or those performed for EMSL by outside calibration providers. EMSL does not provide external calibration services to customers.

5.5.3.1 Balances

Balances shall be calibrated upon installation, then annually thereafter, by an outside 17025-accredited calibration provider.

Balances are verified in the laboratory to stated tolerances each day of use against working calibration weights traceable to NIST as per *GEN-SOP-410 Balance and Weights Calibration Verification.* Acceptance criteria are established in the SOP and included in *GEN-FM-410 Balance Calibration Verification Workbook,* which is used to record verification data.

Where verifications do not meet set acceptance criteria, the instrument shall be cleaned and re-checked. If verification still does not pass, instrument shall be taken out of service until it can be repaired.

5.5.3.2 Pipettes

Pipettes used for quantitative measurement shall be calibrated upon initial use, and verified quarterly thereafter, at a minimum. Pipettes may also be verified daily as described in *GEN-SOP-411 Pipette and Dispenser Verification and Calibration.* Measurements of dispensed weight are taken as per *GEN-SOP-411*, and results calculated using *GEN-FM-411 Pipette and Dispenser Verification.*

Acceptance criteria are established in *GEN-SOP-411 Pipette and Dispenser Verification and Calibration.* Where verification results are outside acceptance limits, the instrument shall be removed from service and adjusted or replaced, as appropriate. For adjustable pipettes, a failure at any check point requires the entire calibration to be repeated after adjustment.

Additional pipette, bottle top dispenser, and syringe verification or calibration forms are available for specific uses, including GEN-FM-411-1, GEN-FM-411-2, GEN-FM-412 and GEN-FM-413.

5.5.3.3 Working Thermometers/Thermocouples

All working thermometers shall be verified against a NIST-traceable reference thermometer (See § 5.6 below) following *GEN-SOP-401 Thermometer Calibration Verification.* Data shall be recorded on *GEN-FM-401 Thermometer Verification Calibration*. If deviations between the working and reference thermometers are within acceptable criteria range as defined by the SOP, the thermometer shall be labeled with the Correction Factor (CF) and use continued by applying the CF. If acceptance criterion is not met, the thermometer shall be immediately removed from use and repaired or replaced as appropriate.

NOTE: When recording results from Thermometers/Thermocouples for which a CF is necessary, the log where temperature is recorded shall make clear whether the CF has been applied. One approach is to record as Temp + CF (example: Instead of recording “31.8°C,” record as “32.0 - 0.2°C CF”).

5.5.3.4 Anemometer:

Thermal anemometer used for measuring laboratory hood flow shall be calibrated annually by an external service provider. The unit must have a valid NIST traceable ISO 17025 compliant calibration certificate.

5.5.4 Requirements for Calibration Certificates from External Calibration Services

When obtaining calibration services from an outside calibration service, it is crucial the calibration certificates received meet accreditation requirements. The following information must be present on the certificate, or if provided supplemental to the certificate, it shall be explicitly related to the certificate (e.g., by use of a calibration certificate number):

5.5.4.1 Evidence the measurements are traceable to NIST or an equivalent National Metrology Institute

5.5.4.2 The report or certificate shall be endorsed by the recognized AB's symbol (or otherwise make reference to accredited status by a specific, recognized AB) with an indication of the type of entity that is accredited.

5.5.4.3 An estimate of uncertainty for the measurements made

5.5.4.4 Date of calibration, reference standard ID, and due date for next calibration

Note: While many reports contain a "best" uncertainty capability for calibrations performed under ideal conditions in the lab [a Calibration and Measurement Capability (CMC)], this does not meet the requirement of uncertainty of measurement for the specific measurements being reported.

5.5.5 Equipment Maintenance

The laboratory manager, in cooperation with the corporate QA Department, shall determine whether an instrument is maintained and repaired in-house or by an outside service firm. Servicing will also be performed when a need has been identified by calibration or other QC checks. When special service is needed, the laboratory manager should notify the national director and corporate QA manager of the need and reasons for service.

Where regular maintenance schedules are necessary (spectrophotometric instrumentation, for example), the schedules are documented in the analytical SOP. The laboratory manager is responsible for ensuring maintenance schedules are met.

As noted above, all maintenance shall be recorded in *GEN-FM-450 Equipment Inventory and Maintenance Log,* or in a laboratory-assigned notebook. This record includes all minor and major equipment maintenance. Thorough maintenance records provide valuable information regarding the equipment, and can serve as a tool to aid in future repairs. Once the maintenance/repair is completed, the laboratory is responsible for entering a description detailing what maintenance or repair was performed, in order to close the entry. In addition, laboratory management must ensure all areas of the maintenance log are completed, including but not limited to software and firmware versions, date in and out of service, model and serial numbers, EMSL asset ID (if applicable), etc.

5.5.6 Equipment Handling, Transport and Storage

The management of major laboratory instrumentation is performed at the corporate level by the Department of Instrumentation and Planning. This department purchases, tracks and ships primary analytical instrumentation and a variety of support equipment.

5.5.6.1 Shipping

Equipment is assigned a serial number and inventoried. Packaging and shipping are handled internally for equipment which is relatively easy to handle such as optical microscopes, hot plates, etc. When microscopes are shipped, each microscope is placed into a Pelican case for safe handling. Each item of the microscope must be placed into its specific area in the case, to ensure no damage to the microscope, and to maintain the microscope's proper functionality.

A professional hauling service vendor may be used for large equipment (generally > 100 lbs.) such as TEMs, spectrophotometers and fume hoods, or where equipment is fragile.

Once equipment has been received by the laboratory, the instrumentation must undergo performance checks including:

- Calibrations

- IDL and MDL study (where applicable)
- Quality control checks

These performance checks may be completed by the laboratory manager and/or the Department of Instrumentation and Planning depending on the type of instrument and the ability of the laboratory manager. All checks must be documented electronically or in the laboratory equipment maintenance log.

Note: See also the analytical SOP for that test applicable to the specific instrumentation.

5.5.6.2 Storage

Laboratories are to adhere to the manufactures' requirements for the storage of instrumentation.

5.5.7 Equipment Serviced or Calibrated by an Outside Vendor

In the event any major equipment is sent out of house for repair, the laboratory manager will maintain a file documenting:

- Date of shipment
- Vendor information
- Service needed
- Date of return

This information is to be recorded on *GEN-FM-450 Equipment Inventory and Maintenance Log*.

The laboratory is responsible for ensuring all equipment is calibrated prior to placing back into service. Calibrations must meet the acceptance criteria established for that equipment.

For laboratories maintaining ISO 17025 accreditation, outside calibrations must be performed to ISO 17025 standards by a calibration laboratory accredited to ISO 17025. The certificate of calibration must indicate the calibration has been performed following the ISO standards.

5.5.8 Authorization to Operate Equipment

The laboratory manager is responsible for ensuring only authorized personnel operate the major laboratory instrumentation. Authorization is granted based on training and experience as detailed in each of the method sections. Authorization may be given to personnel through the completion of the qualifications checklist or verbally, depending upon type of instrumentation. For example, approval for operation of the transmission electron microscope or spectrophotometer is recorded on the training checklist for the test method, while the approval for an acetone vaporizer or water bath may be done verbally.

5.5.9 Instrument Manuals

The laboratory manager is responsible for maintaining and reviewing all instrument manuals pertaining to use, calibration and maintenance. Instrument manuals are to be made available to the analytical specialists. The laboratory manager is responsible to be informed of, and keep current with, all new releases of information on all equipment.

5.5.10 Defective Equipment

Analytical and support equipment found to be defective or performing poorly (out of calibration) is removed from operations until it can be repaired. The defective equipment is to be clearly labeled as "out of service." In PALA accredited labs, defective equipment must be subject to control of non-

compliant work. The laboratory manager is to investigate whether the defect has affected any reported analytical results.

5.5.11 Changes to Equipment Inventory

In the event equipment is replaced, this information is recorded on the equipment maintenance log.

5.6 Measurement Traceability

5.6.1 General

According to the International Vocabulary of Basic and General Terms in Metrology (VIM), traceability is the "property of the results of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparison, all having stated uncertainties." Any material used for calibration purposes in the laboratory must have its value traceable to NIST, if possible. Procedures have been developed following AIHA LAP, LLC's *Guidelines for Traceability*.

EMSL is committed to ensuring the traceability of data to national standards. This is accomplished by setting specific requirements, including:

- Use of Standard Reference Materials (SRMs) as certified and traceable to the National Institute of Standards and Technology (NIST). SRMs are used for QC analysis and training for achieving measurements of analytical specialists and overall laboratory accuracy. Certificates of analysis for SRMs must be on file in the laboratory before using the material.
- Calibration of instrumentation against NIST-traceable standards. Wherever possible, reference materials used in the calibration and verification of instruments shall be obtained from a recognized National Metrology Institute (NMI) (e.g., NIST), or a producer accredited to ISO 17034:2016 in combination with ISO 17025 calibration. For labs accredited to ISO 17025 by A2LA or AIHA LAP, LLC, the 17025-accrediting body of the producer shall also be an APLAC signatory (e.g., A2LA, ACLASS, and NVLAP).
- Analysis of consensus standards or proficiency testing samples where a qualified NIST-traceable reference material is not available
- Ensuring results are traceable to lots of consumables used in the prep and analysis of samples

5.6.2 Reference Standards and Reference Materials

EMSL strives for reference materials used by the laboratory to be traceable to certified reference materials or other well-categorized reference materials, where applicable. Reference materials shall be obtained from a vendor with a certificate of analysis which identifies the lot number. When selecting sources for reference material, sources should be from a national metrology institute or an accredited reference material provider (RMP) that conforms with ISO 17034:2016 in combination with ISO/IEC 17025, or *ILAC Guidelines for the Competence of Reference Material Producers, ILAC G12*. For laboratories accredited by AIHA LAP, LLC or A2LA, reference material providers must be selected which hold accreditations by accrediting bodies recognized directly or indirectly by ILAC. The two major North American accreditors of RMPs are A2LA and ACLASS. Accredited RMP lists can be found on their websites. Care must be taken when ordering standards to ensure the material ordered is under the RMP Accreditation. Accredited RMPs often have several classes of reference materials, with only one or two classes being compliant with ISO G34 guidelines. Certificates shall be endorsed with the ISO 17034:2016 RMP accreditation, when available. ISO 17025 accreditation symbols are insufficient for

reference materials under new ILAC guidelines, but are good intermediate quality signifiers when no ISO 17034:2016 compliant material is available.

Reference standards shall be NIST-traceable where applicable, and include a 17025 calibration certificate showing traceability and uncertainty of measurement in compliance with the requirements in § 5.5.4 above. The reference standards shall be with ±10% of the requested concentration, unless the method or other requirement is more stringent. Standards received within this tolerance are considered acceptable, and may be used without applying a correction factor. Should the standard be received outside the ±10% tolerance, a correction factor will be applied, or a new standard will be purchased. Recording the standard/reagent in the logbook is verification of review for the acceptance criteria. Certified reference materials received that are produced under ISO 17034 and/or NIST, do not require review, as they undergo strict testing and tolerance to meet method specifications. Reference standards of measurement (e.g., NIST traceable thermometer, calibrated weights) maintained by the laboratory should only be used for verification of calibrations, when possible.

Having multiple laboratory operations can facilitate the cost savings associated with the variety of standard materials required to check the performance of both instrument and analytical specialists. EMSL Analytical allocates and distributes these standard reference materials, where possible from 3 sources:

- The corporate laboratory facility
- The Quality Assurance Department
- The regional managers or national directors

In order to track the transfer of standards and reference materials between the original sources and the laboratory(ies), a chain of custody type form must be completed (see *EMSL Standard and Reference Material Traceability Form*). This form ensures traceability of measurements to a national standard and verification of measurements to reference samples. Reference materials are to be clearly labeled and stored as to maintain integrity.

As with equipment, specific procedures for which reference standards and reference materials are required are detailed in the QMS Manual program-specific modules and analytical procedures.

Reference materials shall be stored according to manufacturer recommendations. If no expiration date is included on the material, then a date shall be assigned that is appropriate for the material.

Common measurement standards and general policy requirements for verification/recertification are listed below:

5.6.2.1 Laboratory Working Weights:

Laboratory working weights used to verify balances and other equipment must be checked annually in-house using reference weights.

5.6.2.2 Reference Thermometer/Thermocouple:

The laboratory shall send at least one thermometer to an outside ISO 17025-accredited calibration service for calibration annually. Additional details regarding thermometer calibration frequency can be found in department-specific modules. This thermometer shall have readability (e.g., the smallest division which can be distinguished) at least as precise as the most precise temperature measuring instrument in the laboratory. Each temperature measuring instrument shall be verified to this Reference Thermometer at least every twelve

(12) months. See *GEN-SOP-401 Thermometer Calibration Verification* for additional requirements.

5.6.2.3 Stage Micrometers

Stage micrometers used in the verification of microscope performance as per the program specific QMS Manual modules and technical SOPs shall be calibrated prior to first use, and if damaged, by an ISO 17025-accredited calibration service. The calibration certificate shall meet the requirements of § 5.5.4 above. If a laboratory does not own its own calibrated Stage Micrometer, one can be loaned from the corporate QA Department upon request.

5.7 Sampling

With the exception of certain customers for whom EMSL performs wastewater sampling (see *GL-SOP-026*), EMSL does not conduct sampling for its customers. Sampling guides are available from the EMSL website for tests conducted by EMSL. Customers are instructed to ship samples in clearly labeled, non-breakable airtight containers, and to package such samples so as to minimize damage or change in condition of the samples. Samples shipped by air must be placed in containers that minimize jostling and damage. Samples should be packaged in non-static packaging, as applicable.

As EMSL is not present at the time of sampling, (except as noted above), we take no responsibility for the quality of the sampling performed or information provided (e.g., sampling method, identity of sampler, locations, times, or volumes). EMSL procedures cover only the analysis of the samples submitted. Any specific comments about sampling that the customer wishes to add to the report should be communicated on the chain of custody form, or in written correspondence to the lab.

Compliance samples may be rejected if it is determined they have been inappropriately sampled (e.g., improper volumes, containers, preservation, holding times). The customer is notified immediately if it is clear sampling has been performed incorrectly in such a manner as it may affect the analysis. Reports may contain disclaimers if the sampling may affect the analysis.

5.8 Handling of Test and Calibration Items

Rigorous sample tracking is fundamental to a QA program. The most thorough and complete analysis is useless if performed on the wrong sample.

The EMSL sample-tracking system is designed, to the extent that it is possible, to meet all litigation requirements. It is also designed to have redundancy safeguards wherever possible.

The procedures summarized below are described in greater detail in the *EMSL Sample Chain of Custody SOP* (GEN-SOP-702).

5.8.1 Chain of Custody

In order to ensure the integrity of any sample, records of its custody must be maintained throughout the sample collection in the field, acknowledgement of receipt, acceptance by the laboratory and analysis. The custody of the sample will be tracked via the completion of a chain of custody form.

With the exception of the sampling of wastewater for a select group of customers, EMSL Analytical, Inc. does not collect samples. Therefore, the chain of custody begins with the customer in the field, with the exception of TO-15 equipment, where the chain of custody begins with the preparation of the canisters and flow controllers. EMSL maintains chain of custody documents that customers are encouraged to use where they do not have their own form. Customers delivering samples without a chain of custody form will be required to complete a chain of custody prior to samples being logged-in

at the laboratory. EMSL takes possession of samples by signing the "Received" section of the chain of custody form. The chain of custody then accompanies the samples through the laboratory until analysis and final reporting is complete. Original chain of custody forms are returned to the customer with the final test report.

In those instances referenced above where EMSL collects wastewater samples for a customer, an EMSL chain of custody will be initiated by the collector in the field as per *SOP GL-026,* and submitted for testing with the samples.

In most instances, information provided by the customer related to samples is received through the chain of custody. Disclaimers are included in the report when the information received can affect the validity of the data. Typical disclaimers state EMSL does not accept responsibility for sample collection or analytical method limitations, and the results only relate to the materials received.

5.8.2 Sample Receipt

Upon receipt of samples, the administrative specialist will check for obvious signs the sample integrity has not been compromised. Any problems with the samples will be reported to the customer immediately. The customer chain of custody will be signed indicating samples have been received by the laboratory.

5.8.3 Sample Acceptance

Samples are not accepted for analysis until they have been received and reviewed by the analytical specialist or preparatory personnel. This review includes verification of receipt of all samples against the customer chain or custody. If samples are found to be unacceptable for analysis (see SOP for examples of reasons for unacceptability) this will be communicated to the customer immediately, and this communication and any resulting instructions recorded. Refer to GEN-SOP-702 Sample Receiving and Chain of Custody for more information.

5.8.4 Log-in and Internal Chain of Custody

Log-in of samples is accomplished by authorized personnel using the Laboratory Information Management System (SampleMaster XP (SMXP) or Element). It is at this point that unique order ID numbers and Sample ID numbers are assigned. This order number is physically attached to the sample batch and serves to identify the sample set throughout the analysis. This, in combination with the customer ID number, uniquely identifies each sample. An internal chain of custody is also generated at log-in which documents the handling of samples throughout the laboratory. See the EMSL *Sample Receiving and Chain of Custody SOP* (GEN-SOP-702) for additional details on log-in and internal chain of custody procedures.

5.8.5 Archival and Disposal of Samples

Once the analysis is complete and the analytical worksheet is signed, the analytical specialist stores any remaining portion of the sample in an appropriate storage area. All storage boxes are to be stored in a safe manner for the period indicated for that category of waste, in accordance with regulatory requirements. When a storage box is full, the month in which the samples were analyzed (or similar reference numbering system as appropriate for the operations, i.e., billing number), is marked on it. A new storage box replaces the old one, which is then stored until time of disposal. All samples will be stored so as to provide protection from any possible contamination or loss of integrity.

Any specific storage requirements are documented in the analytical SOPs or in the QMS Manual program-specific modules. Default retention times for samples are established in the program-specific Modules in this manual.

Upon request, samples will be returned to the customer.

5.9 Assuring the Quality of Test and Calibration Results

Laboratory performance will be determined by use of results from the following sources:

- Results from intra-lab and inter-lab testing
- Performance in on-site assessments from accrediting agencies
- Performance in proficiency testing programs
- Completion of internal quality audits
- Continued analysis of standard and reference materials traceable to third party programs
- Quality control reanalysis
- Calibration measurements

Quality control is performed continuously throughout the course of laboratory operations regardless of laboratory productivity, and is made part of the normal course of laboratory sample analysis. Frequency and volume of QC analysis is based on regulatory requirements and good laboratory practice. The frequency of QC analysis must be consistent and reflect the sample volume at any given time.

Performance criteria will be maintained for both individual analytical specialists and for the entire laboratory. The standards for acceptance criteria, frequency and volume are documented in the program modules.

5.9.1 Quality Control Program and Review

The overall quality control program is established and overseen by the Vice President of QA and national directors in order to ensure each EMSL laboratory produces quality data. Each branch laboratory's QA program is implemented and managed by the laboratory quality representative for that location. This process ensures fulfillment of our commitment to our customers, that our data is legally defensible, and that all personnel perform their responsibilities properly.

In addition to the review of quality control data for final report approval, the overall QC performance of the laboratory shall be reviewed on a regular basis in accordance with regulatory agency requirements. Specific quality control procedures are detailed in the program modules.

In general, QC analysis represents at least 10% of all analysis performed. QC analysis will entail inter-analyst reanalysis, intra-analyst reanalysis, intra-laboratory reanalysis, analysis of reference standards and blanks at the frequencies required by the analytical method and/or program specific QMS Manual Modules.

Where a specific percentage of QC is required, the lab manager or lab quality representative must ensure this is considered the minimum percentage of QC performed. If QC is to be performed with each run, even if the run is smaller than the maximum allowed run-size, QC shall be performed with the run. If the maximum allowed run size is exceeded, the required QC shall be increased accordingly to maintain the required percentage. Where a specific number of samples between QC is not specified, the lab shall strive to conduct QC in as real-time as possible, and should be completed prior to the reporting of analytical results for samples used for QC. The intent of percentage requirements is to suggest an approximate frequency at which QC should be performed. Likewise, QC results should be reviewed in real-time and prior to reporting of results, in order to identify potential problems without calling into question associated samples.

The laboratory manager or designee reviews the quality assurance data on a monthly basis (minimum). If the quality control analyses are within control limits, the results will be cleared for reporting. As long as those statistics are deemed acceptable, customer reports will continue to be processed.

If the difference between duplicate analyses exceeds statistically derived control limits, the laboratory manager and the analytical specialist will review the sample data and resolve the differences. A detailed corrective action report recording all activity is submitted to the QA manager. (See "Control of non-conforming work" and "Corrective action" sections of this manual.)

The quality review also includes a check on verification checks of the instruments and/or analysts (standards). Measurements are checked against the acceptance criteria. If any measurement is out of compliance, the laboratory manager is responsible for investigating the cause(s) and initiating a corrective action.

In cases where analytical specialists are transferred temporarily to another laboratory, QC data produced by that analytical specialist will be associated with the laboratory at which the data was produced for purposes of determining percentages of QC analysis performed. Likewise, inter-analyst data produced by that analytical specialist will be associated with the lab at which it was produced. The analytical specialist's CV from their original lab shall be utilized when applicable.

However, a transfer analytical specialist's QC data will also be associated with the analytical specialist for purposes of determining on-going capability. A copy of the data may be held by the analytical specialist and placed in their ongoing training records at their home lab. This may include intra-analyst samples as well as analysis of known samples or PT/RR results.

5.9.2 Quarterly Report

The person responsible for overseeing the QA in the lab (i.e., laboratory quality representative or laboratory manager) completes a report every quarter for the laboratory manager. In the cases where the laboratory manager is the laboratory quality representative, the report is written for the national director or corporate QA manager. These reports are designed to express concerns, address needs, and report any major changes to management. They are ultimately submitted to the corporate QA Department for review.

Format shall include the following topics:

- Summary of quality control data (e.g., QC reanalysis that may have been out of control limits and the corrective action)
- Uncertainty measurements – Sr for Micro; CV for PCM asbestos
- Summary of the number of corrective actions initiated and closed along with detail on any major issues (CAR/PAR workbook attached to report)
- Summary of preventative actions (CAR/PAR workbook attached to report)
- Calibration/Instrument maintenance; dates of any quarterly, semi-annual, or annual equipment calibrations and any non-routine maintenance performed
- Equipment issues; summary of any outstanding equipment issues
- Summary of quarterly contamination monitoring
- Customer problems
- Safety issues and results of safety audits
- Report of findings from any internal audits or external audits conducted during quarter
- Results of proficiency testing and/or round robin analysis
- Summary of staffing issues or changes
- Risk identification, improvements, and internal/external issues

- Miscellaneous
- Review of corporate website to ensure lab accreditations, open hours, etc. are accurate

5.9.3 Proficiency Testing Programs

Laboratories participating in proficiency testing (PT) programs will ensure the analysis is performed using the same sample tracking procedures and analytical methodology, and is analyzed by the same analytical specialist(s) as under normal, customer sample conditions. At no time is there inter-laboratory exchange of proficiency samples.

- Asbestos
    - NVLAP – for PLM bulk and TEM airborne asbestos analysis
    - AIHA LAP, LLC-IHPAT
    - New York State ELAP – for asbestos in air, bulk, and water
- Env. Micro
    - AIHA LAP, LLC-EMPAT – for environmental microbiology
    - NYS ELAP – water microbiology
    - ERA – microbiology
    - CDC Elite for Legionella
    - Wisconsin State Laboratory of Hygiene for Cryptosporidium and Giardia
    - Sigma Aldrich for Legionella
- Env. Lead
    - ERA – Environmental lead
    - NYS ELAP – Lead (wipes, paint, soil, air)
    - AIHA LAP, LLC-ELPAT Lead (wipes, paint, soil, air)
- IH/Chem
    - IHPAT, organics, metals, silica
    - NYS ELAP – non-potable water chemistry
    - ERA – TO-15, organics, inorganics
    - WASP – for formaldehyde
- Food
    - API for Food Micro and Food Chemistry
- Radiochemistry/Radon
    - Bowser-Morner – for radon
    - ERA – for radiochemistry
- Materials Science
    - ASTM for Carbon and Alloy Steel (Materials Science)

Samples with instructions and accompanying report sheets are distributed to the appropriate laboratory staff or designee. The samples are incorporated into the normal sample load and analyzed as a normal customer sample, on a rotating basis, between qualified analysts. Results are calculated and reported on the supplied forms. The result forms are double-checked against the raw data for data entry transcription or omission errors.

Records of proficiency testing analysis are to be completed and maintained in a separate laboratory PT file. This data may also be maintained for each participating analytical specialist in his or her personal training file.

PT samples are scheduled, analyzed, reviewed, and reported similar to customer samples.

Note, for Asbestos only: For laboratories with multiple analysts, only one analyst analyzes the PT sample. Once the results are reported and the scored results are received from the PT provider, all qualified analytical specialists shall analyze the proficiency samples. Results from all analytical specialists are reviewed by the laboratory manager and compared to the official results.

The data is reported using the appropriate format and method. Data may be reported by mail, fax or by the internet, depending on the requirements. If email results are required, the instructions given by the submitting agency are followed. Copies of confirmation of "data sent and received" are placed in the file with the data. The laboratory manager is responsible for submitting the scored results from each PT round to the Quality Assurance Department, where they are tracked for trends and evaluated against acceptance limits.

Whenever a laboratory reports an outlier on a proficiency testing round, a Corrective Action shall be initiated to review the root cause(s) of the outlier. As this is equivalent to reporting incorrect results to a customer, a PT outlier should be treated accordingly. This process shall be completed within thirty (30) days of receipt of results.

The laboratory must maintain Proficiency status, "P," for all parameters tested and reported. If the laboratory becomes non-proficient, this will be indicated in the report to the laboratory containing the results of a given study. The lab manager, lab quality representative or designee shall investigate the reasons for the poor performance. A corrective action plan will be developed by the QA manager and the lab manager. The plan will be written by the laboratory manager, who will submit the plan to QA manager for review. The plan will include all actions that will be taken (along with a timetable) to bring the quality of data to an acceptable level. Once the plan is acceptable, this should be forwarded to the corporate quality assurance manager for review and approval.

All records for proficiency samples are kept in files for each analytical specialist, along with the scored results.

Several accreditation bodies (ABs) require that, as a condition of accreditation, results from proficiency testing (PT) programs used as a demonstration of competency for methods for which the laboratory is accredited be reported to the AB on a regular basis. EMSL authorizes the release of proficiency testing results from the proficiency testing provider to its various accrediting authorities whenever such disclosures are required. When possible, standing authorizations are granted. The QA Department is responsible for ensuring the distribution of proficiency testing results to outside agencies when requested or required. See *GEN-SOP-851 3rd Party PT Reporting* for current requirements. A list of ABs that require PT results be forwarded on receipt is included in the SOP, along with details on how results should be reported.

In addition, for food accreditations, A2LA requires form F237 be submitted with the application specifying the four-year testing plan for accredited food tests.

Where commercial proficiency testing programs are not available, proficiency is obtained by:

- Participation in a round robin program, and/or
- A minimum of 20 QC data points are obtained initially to determine upper and lower control limits at three standard deviations. Program shall offer at least 2 rounds per year, separated by a six-month time period. Each set of samples must include 4 blind spikes.

5.9.4 EMSL Round Robin Programs

Periodically, the Quality Assurance Department, national directors and/or technical division VPs, will provide a company-wide round robin program. Samples are to be analyzed by all active analytical specialists. The laboratory manager is to submit results of all analytical specialists who participated in the round to the Quality Assurance Department, where all results will be scored and graphed using standard deviation statistics.

The laboratory manager is responsible for ensuring any results falling outside of the control limits be investigated, and a corrective action report completed.

5.9.5 Infrequent Analysis

In cases where a laboratory may receive few or infrequent samples for which they hold accreditation programs, they must maintain analysts' skills and proficiency, and continue to follow the procedures for proficiency testing and participation in RR programs.

5.9.6 Trend Analysis

QC data is charted over time in order to evaluate analyst and laboratory performance. This data shall be reviewed by the laboratory and/or the Quality Assurance Department. Statistically relevant trends should trigger an evaluation.

Items being monitored:

- Failures exceeding the Control Limits (3s)
- Two consecutive points above or below the Warning Limits (2s)
- Seven (7) consecutive data points on either side of the mean
- Seven consecutive points moving in the same direction

Trend analysis shall be documented along with conclusions. If any actions are taken as a result, these may be documented as preventive actions unless a failure has occurred. Failures should be documented as a corrective action. Trend evaluations shall be included in quality reports submitted to the laboratory manager and corporate Quality Assurance Department, where appropriate.

5.10 Reporting the Results

The customer report is, ultimately, our "final product." This report reflects on our standard of quality. This section describes EMSL corporate policy on the procedures, policies, and formats for reporting analytical data. Additional, test specific requirements are listed in the program modules.

5.10.1 Test reports

Each final report will have at a minimum the following information:

- Laboratory identification and address
- Name and address of customer
- Date of receipt by laboratory (or original chain of custody attached)
- Unique sample IDs
- Description of sample (or original chain of custody attached)
- Identification and description of test procedures performed
- Results of testing and analysis
- Sample preparation date (where applicable)
- Analysis date, and time (if holding time is <72 hours)
- Any deviations or additions to test specifications
- Name and signature of responsible person (laboratory manager or designee)
- Any applicable disclaimers and statements (See specific SOPs)

- Notification of any deviations from the test method
- An estimation of uncertainty when requested by customer, required in the analytical SOP, or when necessary for the interpretation of data
- For reports issued under NVLAP, a statement that the report must not be used by the customer to claim product certification, approval, or endorsement by NVLAP, NIST, or any agency of the federal government
- For PALA accredited labs, including the following: Title; unique ID number on report; page numeration, including end point; units of measure; disclaimer stating report relates only to samples tested and not reproduced; and date of sampling
- Information on any analyses that had been subcontracted (attach subcontract lab's report)

The signature of the analytical specialist is not made a part of the final report unless requested by the customer. Analytical specialists accept responsibility for the data generated by entering the data electronically, or signing the worksheets where applicable.

Any modifications to the methods cited on the report will include all applicable comments and disclaimers as issued by the QA manager.

When by written agreement any of these items are excluded from the final report, a copy of the written agreement shall be maintained in the laboratory, and all information not reported shall be readily available upon request. Where requests to remove required disclaimers are received, the laboratory should consult with the QA Department or national directors prior to proceeding, since these are in many cases designed to protect EMSL by qualifying results.

5.10.1.1 Use of Significant Figures

Where stated, results are to be reported to the amount of significant figures prescribed by the analytical method or accrediting agency. In the absence of a method requirement for significant figures, the value reported can be based on either significant figures, or decimal places, in order to report values that show significant detail to comply with various regulatory requirements and accommodate sensitivity requests/requirements.

5.10.1.2 Reference to Accreditation

Each accreditation agency sets its own requirements for use of its symbol on customer reports. Likewise, additional requirements may be set for references made to accreditation. EMSL adheres to policies of the accrediting authorities. NVLAP Policies are found in Handbook 150:2020 (August 2020), specifically Annex A, NVLAP accreditation, and Annex E, Accredited Laboratory Combined ILAC MRA Mark. PALA accredited laboratories reference accreditation is based on PALA requirements in document DR-12-SCA-01. EMSL's general policies can be found in § 5.11, below.

5.10.1.3 Listing of Accreditation/Required Statements (See also § 5.11, below)

Laboratory accreditation is presented on the report with a reference to the agency, followed by the Lab ID code (such as: NVLAP Lab Code 000000-0) or via the use of approved accredited laboratory symbol.

The citation of the accreditation will not be used in a manner which misrepresents a laboratory's accreditation status. Citation of accreditation will be provided for the type of analytical test applicable to that accreditation only. If a particular analysis is performed which is not covered by an accreditation program, the report contains no reference to that

accreditation agency or contains the statement, "This report contains data that are (is) not covered by the XXXX accreditation." If a final report contains a combination of data for both accredited and non-accredited analysis, the non-accredited tests will be marked as such.

Reference to an accreditation by an applicant laboratory that has not yet achieved accreditation shall include a statement accurately reflecting the laboratory's status. Certificates of accreditation (applicable to the analysis) may be made part of the report if requested by the customer.

The title of the approval signatory shall appear on the final report that displays the accreditation.

In the rare cases where the analysis (or part of the analysis) has been subcontracted, the report will clearly state the data had been subcontracted. The report will include the statement "This report contains data that were produced under subcontract by Laboratory X." If the subcontract laboratory is accredited, the report will cite the accreditation agency and the Lab's ID code.

5.10.1.4 Proficiency Testing

Ambiguous reference to a Proficiency Testing Program (PAT) must be avoided. For example, listing of a PAT Identification number must be clearly identified with a statement such as *"EMSL XXXX (location) Participates in the AIHA LAP, LLC Proficiency Analytical Testing (PAT) Program for Asbestos: ID #123546"* to avoid inappropriate representation of full accreditation.

5.10.1.5 Statement on Quality Control Results – ELLAP AIHA LAP, LLC Requirement

For those laboratories which maintain the ELLAP AIHA LAP, LLC certification, final reports will state: "The QC data associated with the sample results included in this report meet the recovery and precision requirements established by AIHA LAP, LLC unless specifically indicated otherwise."

5.10.1.6 Suspension of Accreditation

In the unlikely event a laboratory's accreditation is revoked or suspended, reference (symbol and lab code number) to the accreditation and the scope of accreditation will be removed from all applicable documentation until accreditation is reinstated. Documentation includes:

- Final reports
- Marketing materials such as brochures, mailers, etc.
- EMSL website

In addition, at the discretion of the laboratory manager, national director and QA Department, samples may be subcontracted to a laboratory with equivalent accreditations.

In the case of AIHA LAP, LLC ELLAP matrix suspensions, the laboratory shall inform AIHA LAP, LLC in writing within ten (10) business days, of procedures for any samples that are received by the laboratory for analysis in the suspended FoT(s) until accreditation is restored.

5.10.1.7 Reporting to Governing Agencies (Notification of Compliance Reports)

At the request of the customer, EMSL can report analytical results directly to a compliance agency (state water authority, state environmental department, etc.). Results can be submitted on the agency's specialized forms, if requested. In these cases, the original EMSL report must also be submitted.

5.10.2 Final Report Approval

Final customer reports are released only after the data has been reviewed by an approved reviewer. In almost all cases, the review is independent and performed by a qualified individual other than the analytical specialist (some exceptions are listed below). This review is documented with the initials of the reviewer on the "Screened" line on the Internal Chain of Custody form. This review includes:

Quality Control Review

Quality control analysis performed for that specific batch of customer sample is compared against acceptance criteria.

Note: Our quality control program is designed to comply with the requirement of state, federal and independent accrediting authorities' policy for reanalysis. Specific batch QC requirements are specified in the Program Specific QMS Manual Modules and/or Method SOPs. For percentage-based QC requirements, the quality control samples may or may not include samples associated with the set of results being approved for reporting.

In addition to QC review, analytical data is reported with confidence based on compliance with this QA program. The quality of the data reported is ensured through the procedures and policies as documented in this manual, including:

- Delineation of responsibility
- Compliance with analytical standard operating procedures
- Following calibration protocols
- Fulfillment of the required amount of quality control analysis
- Satisfaction of training requirements

Review of Data

- Raw data (e.g., from bench sheets, prep logs, printouts from instrumentation) and the information on the chain of custody are reviewed for correctness and compared against the typed information on the final report to check for any transcription errors.
- Date derived from calculations will be reviewed to ensure they appear correct based on the recorded data (this may be a brief overview).
- Where appropriate, correlations between data will be reviewed to ensure the sensibility of the data.

Appropriate Methodology

The review also verifies the correct methodology was performed on the samples. This is done by checking on the customer's request as documented on the chain of custody, as well as any supplemental conversations with customer as recorded in laboratory records (if any).

5.10.2.1 Approved Signatories

An approved signatory is responsible for the technical content of the report, and is the person to be contacted by the accrediting authorities or customers in case of questions or problems with the report. Signatories shall be persons with responsibility, authority and technical capability for the results provided. Technical capability is defined as having the aptitude for understanding the analysis and ability to recognize an error. It does not mean the approval signatory must be an approved analytical specialist. For PALA accredited labs, a PALA approved microbiologist is an approved signatory.

The Quality Assurance Department, regional manager or national director can qualify the laboratory manager as an approved EMSL signatory. (See *GEN-FM-901 Final Report Approval and Signature Sample.*)

The laboratory manager may assign designated personnel to perform the task of final review and approval. This designation must be clearly documented (See *GEN-FM-901 Final Report Approval and Signature Sample.*)

Exceptions to Peer Review Requirement

5.10.2.1.1 All AIHA LAP, LLC and/or NLLAP* accredited analysis must be independently reviewed before it is released to the customer. No exceptions can be applied to work done under the AIHA LAP, LLC and/or NLLAP* accreditation. If work must be released prior to independent review, it must be marked "Preliminary" as per § 5.10.7 below.

***NOTE:** National Lead Laboratory Accreditation Program (NLLAP) is an EPA program which provides a list of accredited environmental lead laboratories. AIHA LAP, LLC and A2LA are both recognized NLLAP accrediting bodies. In addition, as of the time of this publication, Perry Johnson Lab Accreditation, Inc. (PJLA), ANSI-ASQ National Accreditation Board/ACLASS, and Laboratory Accreditation Bureau (L-A-B) are also recognized as NLLAP accreditation bodies. The most recent list of accrediting bodies can be found on the NLLAP website:

http://www2.epa.gov/lead/national-lead-laboratory-accreditation-program-nllap

5.10.2.1.2 For analysis not covered by AIHA LAP, LLC/NLLAP accreditations, an independent review shall always be performed, except under the specific circumstances identified below. In all other cases, work being reported prior to customers prior to independent review must be marked as "Preliminary" as per § 5.10.7, below.

5.10.2.1.3 Only in the following circumstances can a report be issued as Final without a second independent review being performed. In these circumstances, the report shall be reviewed by the original analytical specialist prior to release. Whenever an exception is being applied, the number of the exception which appears below shall be documented next to the "Screened" line of the Internal Chain of Custody to document the circumstances.

(1) Non-AIHA LAP, LLC analysis performed outside of a laboratory's regular business hours (i.e., 8-5 M-F) when a reviewer is not available to review work before the TAT.
(2) Non-AIHA LAP, LLC analysis performed during a laboratory's regular business hours when a reviewer is not available to review work before the TAT due to extended leave.

5.10.3 Opinions and Interpretations

EMSL generally discourages statements of opinions and interpretations on reports; however, a specialized report which contains results and interpretations as to whether the results are in or outside criteria is available. Any statement included in the test report shall be reviewed by the manager, QA,

or upper management team prior to release. The source of the decision rule or interpretation will be cited, when applicable.

Specialized statements included on test reports are communicated to the customer either by phone or email prior to the report being sent. These types of statements are related to samples that have non-typical components to the analysis, and prompt the lab to communicate the situation with the customer before the report is sent. The communication with the customer is documented through email or a phone call, and noted on the internal COC.

5.10.4 Testing Obtained from Subcontractors

When a test report contains results obtained from a subcontractor, these will be clearly identified. This can be done either by scanning in the subcontracted report stating which laboratory performed the work, or by entering the data into Sample Master, commenting who completed the analysis. See the *EMSL Subcontract SOP* (GEN-SOP-010) for detailed procedures.

5.10.5 Confidential Transmission of Results

All EMSL employees have signed confidentiality agreement on file. Customer confidentiality is maintained when results are reported.

There are a number of forms of result transmission used by EMSL. These include:

1) Fax through Sample Master – A fax cover sheet is automatically included with the transmission. The fax cover sheet includes the standard confidentiality statement, *"This information may contain privileged and confidential information and is solely for the use of the sender's intended recipient(s). If you receive this information in error, please notify the sender and delete all copies."*

2) Email through SampleMaster – The confidentiality statement is (automatically) included in the body of the e-mail, *"This email may contain privileged and confidential information and is solely for the use of the sender's intended recipient(s). If you received this email in error, please notify the sender by reply email and delete all copies and attachments. Thank you."*

3) Manual fax – The cover page and report are printed through SampleMaster and manually faxed to the customer. The cover page includes the confidentiality statement, *"This information may contain privileged and confidential information and is solely for the use of the sender's intended recipient(s). If you receive this information in error, please notify the sender and delete all copies."* Note: Evidence of transmittal (fax receipt or email record) is to be retained and will serve as a formal record of receipt.

4) Use of LabConnect – The user must agree to the terms before using this service. The agreement includes the statement: *"The results available on this site are provided as a matter of service and convenience for customers of EMSL. They are intended for use only by authorized parties and are confidential in nature. It is the responsibility of our customers to maintain and update their user accounts to ensure that no unauthorized access is allowed by its employees. If you are not an authorized user, do not attempt to enter. While the results have been verified for accuracy against our analytical reports, they are not intended as a substitute for a hard copy or approved electronic report. Please contact your Account Representative if you have any questions regarding the available information.*" The user is prompted to check *"I accept the legal conditions above" or "I do not accept the legal conditions above."*

5) Mail (US Postal Service) – The front of the mailing envelope includes a statement, *"The information contained in this correspondence may contain privileged and confidential information and is solely for*

the use of the sender's intended recipient. If you received this correspondence in error, please notify EMSL Analytical and return to sender."

5.10.6 Verbal Results

Where it is necessary to provide verbal results, it is EMSL policy to discuss analytical methodology and results only. Results are provided 'verbatim' by giving sample number and concentration only. Under no circumstances are results given as fail, pass, meeting acceptance criteria, etc. Interpretation of results is the responsibility of the customer. A note to the file must be made each time verbal results are given (note on the chain of custody and/or the customer communication log).

5.10.7 Preliminary Reports

Corporate policy discourages the issue of draft or preliminary data (for example, results that have not yet gone through a quality control review). However, there are circumstances where this may be unavoidable as a result of turnaround time issues, staffing situations, etc. If the laboratory manager chooses to provide preliminary data, the report is not signed and will clearly state "preliminary results."

A report is defined as 'preliminary' when it has not been reviewed following the procedures in § 5.10.2.1.2, above.

A final, signed report must eventually be provided to the customer. If any changes are made between the preliminary and final reports, the customer is notified with a statement on the final report, or by verbal contact. Verbal notifications must be recorded in writing on the internal chain of custody and/or in the customer correspondence log.

5.10.8 Exported Data

Exported data is provided in a variety of formats, (generally PDF format) depending on the specific needs of our customers. Export formats for data deliverables are implemented and controlled by the corporate IT staff, which has the flexibility to implement new export formats as required. Final, signed customer reports are to be submitted in addition to delivery by email or CD. Electronically delivered data is not intended to replace hard copy results unless otherwise requested by a customer. In this way, exported data can be verified. Electronically transmitted results meet the requirements of the QA policies as documented in this manual.

5.10.9 Amendments to Test Reports

In the event of any change to the final report after issue, the amended report must indicate the report is revised, the date of the revision and the reason for the amendment. The revisions must include the original reference number. A statement indicating the report is amended, the date and time of amended and original reports, and an amendment reason code, is included in the report footer for all amended reports. Customers must be informed immediately of the changes.

The laboratory sample set is not re-logged into the LIMS program. Tracking is done with the laboratory files, which include a printout of the original and amended report. When amendments to the final report result from a non-conformity, a corrective action form will be completed and filed by appropriate personnel following the EMSL Non-Conformities and Corrective Action SOP (QA-SOP-200).

Changes requiring an amended report include, but are not limited to:

- Errors in sample results
- A typographical error (sample location, sample volume, sample ID, etc.) that impacts the final results

- Reports issued to incorrect customer
- Changes requested by customer

5.11 Use of Accreditation Symbols and/or References to Accreditation in Advertising and Customer Reports

EMSL has defined the requirements for referencing accreditation in reports, advertising, and promotional materials in the *EMSL Referencing Accreditation – Advertising Policy SOP* (QA-SOP-310). This procedure has been developed based on the requirements *of ISO/IEC 17025:2017, A2LA – P101*, *NVLAP* Handbook 150:2020 (August 2020**),** *AIHA LAP, LLC Policy Module,* among others.

Section 6.0: Revision History

Rev. 20	12/15/2017
Rev. 20.1	10/02/2018
Rev. 21	12/17/2018
Rev. 22	12/13/2019
Rev. 23	12/16/2020
Rev. 24	12/17/2021
Rev. 25	12/21/2022

Rev. #	Rev. Date	Changes in this Revision
26	12/15/2023	Added Appendix C to cross reference the QMS Manual to ISO 17025:2017 sections Removed reference to MDDELCC in Section 1.1 Updated national director of quality assurance to vice president of quality assurance throughout Noted EMSL does not place information related to our customers in the public domain in Section 4.1.5.1 Added cGMP Cinnaminson local SOP master list information in Section 4.3 Added 'however named' to clarify quality representative job titles in Section 5.2.1.5 Added language emphasizing the DOC lists all methods analyst is authorized to perform in Sections 5.2.2.1, and 5.2.2.9 Revised title for Section 5.4.5 to include 'and verification' and added requirement for QA and head of department data review when new services/methods are implemented in lab with newly trained analysts Added Section 5.4.5.1 to require verification package when new published methods are implemented in lab Added requirements to update GEN-FM-450 when differentiating between out of service equipment present or removed from the lab in Section 5.5.1 Revised to all checks must be documented electronically or in the log in Section 5.5.6.1 Added CAR/PAR workbook to be attached to report; corporate website reviewed for lab accuracy to quarterly report requirements in Section 5.9.2

APPENDIX A: Glossary

ACS – American Chemical Society

Accuracy – The closeness of a measured result to a known, theoretical or target value. This should be distinguished from "Precision" below.

AHERA – Asbestos Hazard Emergency Response Act

AIHA LAP, LLC – American Industrial Hygiene Association Laboratory Accreditation Program

Alternative Method (procedure) – A major modification to standard methods and EMSL Standard Operating Procedures

Amended Report (see also revised report) – A report which reflects a change or correction to an original report

Analyte – A substance, organism, physical parameter, property, or chemical constituent(s) for which an environmental sample is being analyzed

Analytical Sensitivity – The lowest concentration that can be detected by the method, based upon the amount or portion of sample analyzed (e.g., for methods involving a count = 1 raw count per amount or portion of sample analyzed, calculated, and expressed in the final reporting units)

Analytical Worksheet (Bench Sheet) – The form used by the analytical specialist to collect the raw analytical data during analysis

Bench Sheet – (see "**Analytical Worksheet**")

Branch Laboratory – All EMSL laboratories excluding those located at 200 Route 130 North, Cinnaminson, NJ 08077

CALA – Canadian Association for Laboratory Accreditation

Chain of Custody (COC) – An unbroken trail of accountability that ensures the physical security of samples, data, and records

Chemical Hygiene Plan – A program which defines the work practices and procedures to ensure that employees of EMSL Analytical are protected from health hazards associated with hazardous chemicals with which they may work or be exposed. EMSL's chemical hygiene plan also includes its Biosafety Guide.

Coefficient of Variation (CV) – Standard deviation divided by the mean. Note: The Relative Standard Deviation (RSD) is the absolute value of the coefficient of variation.

Consensus Standards – Samples with values assigned based on a statistically significant number of repetitive analyses

Corporate Management – Staff members which include the Company President, Vice Presidents, QA Manager, National Directors, MIS Manager, Controller, Collection Manager and Equipment Manager

Culturable – Capable of, or fit for, being cultivated (antonym: non-culturable)

> **Note:** Prior to Revision 10 of this document the terms Viable/Non-viable were used in place of Culturable/Non-culturable. This terminology may still occur in some documents published prior to the date of publication of Revision 10.

Customer – Any person or entity that receives products or services from EMSL

Demonstration of Capability – A procedure to establish the ability of the analyst to perform analyses with acceptable accuracy and precision

Detection Limit – The minimum result, which can be reliably discriminated from a blank with a predetermined confidence level; also used as Method Detection Limit

Document (*noun*) – A written policy, procedure, instruction, form, template, etc., which is revision sensitive. If an outdated revision is used it could cause the wrong process to be followed (e.g., not all required information is included on a previous revision of a form template). Contrast with "Record" below.

EMSL Environmental Laboratories – Laboratory facilities/locations performing the analysis for the analytical programs including asbestos, environmental lead, environmental microbiology, various IH parameters (organics, metals, etc.) and environmental chemistry parameters (metals, organics, inorganics, wet chemistry)

Integrity – Sound, honest, true

Inter-analyst/lab – Re-analysis of the same sample by a different analyst/lab

Intra-analyst/lab – Re-analysis of the same sample by the same analyst/lab

Limits of Quantitation (LOC) – The minimum levels, concentrations, or quantities of a target variable (e.g., target analyte) that can be reported with a specified degree of confidence; also used as Reporting Level

Lot – A definite amount of material produced during a single manufacturing cycle, and intended to have uniform character and quality

Measurand – The quantity intended to be measured. This varies depending on the test, and takes into account the type of substance carrying the quantity.

Measurement Uncertainty – The uncertainty (or range of dispersion) of a measurement resulting from random and systematic errors in each step of the measurement process. Where a systematic bias exists and is not corrected for, it should be reported separately.

Method Detection Limit (MDL)/Detection Limit (DL) – The minimum measured concentration of a substance that can be reported with 99% confidence the measured concentration is distinguishable from method blank results

Method Validation – See *Validation, Methods*

NIST – National Institute of Standards and Technology

NLLAP — National Lead Laboratory Accreditation Program

NMI – National Metrology/Measurement Institute (e.g., NIST)

Non-conformity – A deficiency, error, or a lack of compliance with the procedures or policies documented in this manual

Non-Standard Method – An analytical procedure, which is developed in-house, or a significant modification to a published procedure which requires validation prior to being introduced into the laboratory. See also *Standard Method*.

NVLAP – National Voluntary Laboratory Accreditation Program

NYS ELAP – New York State Environmental Laboratory Approval Program

Precision – Closeness of repeated measurements to one another. This should be distinguished from "Accuracy" above.

Proficiency Testing (PT) – As systematic program in which one or more standardized samples is analyzed by one or more laboratories to determine the capability of each participant

Program Module – Sections of this QMS Manual which address analytical method specific requirements (e.g., asbestos, lead, microbiology, IH organics and IH inorganics)

Quality Assurance (QA) – The total integrated program for assuring reliably of the measurement and monitoring of data

Quality Assurance Department – The QA Department is headed by the Quality Assurance Director. The Department minimally consists of the QA Manager and Document Control Manager, but may also include other EMSL staff members or outside consultants assigned to special projects or teams as assigned.

QAM – Quality Assurance Manager

Quality Control (QC) – The routine application of procedures for obtaining prescribed standards of performance in the monitoring and measurement process

Quality Management System – A set of policies, processes and procedures required for planning and execution

Quality Management System (QMS) Manual – This manual and related program modules; previously named "Quality Assurance Manual" or "QAM" prior to Revision 16. Older references in other management system documents to the "Quality Assurance Manual" or "QAM" refer to this document.

Reagents – A substance reacting with another substance. Lab reagents are compounds such as hydrochloric acid used in the analysis.

Reanalysis – A second analysis of the same sample (see also inter or intra)

Record (noun) – A written record of events which are not revision sensitive. Data records related to analytical activities should form an unbroken trail between sample receipt and reporting, including records of custody, prep and analytical steps, customer correspondence, equipment used, calibration records of that instrument, etc. Records are controlled as per the *EMSL Control of Records SOP* (QA-SOP-350). Contrast with a "Document" defined above. A form template is a document (revision sensitive); once information is entered on form, the completed form is considered a record (cannot be revised, only corrected, as per SOP).

Reference Materials – General term used to describe samples which have a known value. These could include standards, proficiency testing samples and consensus standards.

Reference Material Provider (RMP) – EMSL requires that for tests accredited by AIHA LAP, LLC or A2LA, all reference materials purchased after January 1, 2013 be purchased from ISO 17034:2016 accredited RMPs. A2LA and ACLASS both accredit to the ISO 17034:2016 guideline.

Reference Method (to be used to determine the extent of method validation in Modules 3-7) – A reference method is a published method issued by an organization generally recognized as competent to do so. (When the ISO language refers to a 'standard method,' that term is equivalent to 'reference method.') When a laboratory is required to analyze by a specified method due to a regulatory requirement, the analyte/method combination is recognized as a reference method. If there is not a regulatory requirement for the analyte/method combination, the analyte/method combination is recognized as a reference method if it can be analyzed by another reference method of the same matrix and technology.

Relative Standard Deviation (Sr, **S_r**, or **RSD)** – See "Coefficient of Variation" above

Reference Weights – Set of weights which are used only to calibrate working weights in the laboratory. They may also be used for periodic calibrations of other equipment, but not on a routine basis (e.g., for daily balance verifications). Reference weights shall be calibrated at least every five (5) years. Extra care shall be taken to maintain the integrity of the standard.

Reporting Limit/LOQ– The lowest concentration of analyte in a sample that can be reported with a defined, reproducible level of certainty. This value is based on the low standard used for instrument calibration. For environmental lead analyses, the reporting limit must be at least twice the MDL/DL.

Revised Report (see also amended report) – A report which reflects a change or correction to an original report

Round Robin – An exchange of samples with other laboratories; may be 2 or more

RPD – Relative Percent Difference; calculated as $RPD = \frac{|R1 - R2|}{R} \times 100$

Where: R1-R2 = difference in two values
R = average of the two values

SRM – Standard Reference Material

Standards – Samples (materials) of known concentrations

Standard Methods – Methods published by regulatory agencies such as EPA, NIOSH, OSHA, State agencies. Also includes methods developed by recognized scientific agencies and/or individual groups, such as ASTM and Chatfield. If a method is significantly modified (e.g., changes to the method which may affect the principle of analysis), it shall no longer be considered Standard and shall be validated as a non-standard method.

Standard Operating Procedure – A written document that details the method of an operation, analysis, or action whose techniques and procedures are thoroughly prescribed, and which is accepted as the method for performing certain routine or repetitive tasks

Sub-facility – Term used in association with the NVLAP program. A sub-facility is considered an extension of the Main Facility (Cinnaminson, NJ). It receives technical direction and quality management from the Main Facility.

Traceability – A process whereby the result from a measuring instrument (or a material measure) can be compared, in one or more stages, with a national or international standard for the measurand in question

Validation, Method – Planned process which must be completed prior to adoption of a new method by which the method's performance criteria are determined and documented. Performance criteria may include accuracy, precision, linearity, LOQ, LOD, and/or ruggedness.

Verification, Equipment – Process whereby equipment is checked against acceptance criteria to ensure that it is operating properly. Generally, a routine scheduled check performed by the laboratory.

Verification, Methods – A process whereby a laboratory verifies that it can perform a standard method or previously validated method within acceptable criteria at the location, and with analytical specialists and equipment at the location at which verification is performed

Working Weights – A set of weights which are used during routine measurements and verifications in the laboratory. Working weights shall be calibrated annually in-house using a set of reference weights as defined above, or by an outside vendor if lab does not have a set of in-house reference weights.

APPENDIX B: Personal Conflict of Interest Statement

It is the policy of EMSL Analytical, Inc. (hereafter, "EMSL") that all employees avoid any conflict between their personal interests and those of EMSL. A conflict of interest is defined as any relationship between an Employee and another entity that may impair the objectivity of the Employee in performing their work. In order to avoid such situations, it is crucial that any *potential** conflict of interest is reported to EMSL Human Resources. A report of any potential conflict of interest, even where none actually exists, protects the employees and EMSL by ensuring transparency.

The participation of the Employee or a member of the Employee's immediate family in the following activities may be considered to be a conflict of interest:

- Holding a controlling interest in, or accepting free or discounted goods from any organization that does, or is seeking to do business with EMSL, by any employee who is in a position to directly or indirectly influence either EMSL's decision to do business, or the terms upon which business would be done with such organization. A "Controlling Interest" means that through ownership (i.e., stockholder, partner, sole owner) or position (i.e., director, officer, trustee) the individual has the capacity to control the actions of the organization in question.
- Holding an interest in an organization that competes with EMSL. There is no conflict of interest if one owns diversified mutual funds, money market funds and/or other diversified investments where the individual does not control the choice of specific investments.
- Being employed by (including as a consultant) or serving on the board of any organization which does, or is seeking to do, business with EMSL or which competes with EMSL. There is no conflict if Employee family members are employed by, but cannot influence the relationship between an organization and EMSL.
- Profiting personally from any organization seeking to do business with EMSL (except as noted above).
- Performing services for another employee similar to the services provided by the Employee to EMSL, on or off EMSL property, without the express prior permission of Dr. Frasca, President of EMSL, which may or may not be granted.
- Employees may not accept gifts from vendors or customers of a value greater than $50.00.

It is the Employee's responsibility to report any actual, potential, or apparent conflict of interest that may exist between the Employee or their immediate family and EMSL. In the absence of a report, violations of the principles and standards contained in this policy statement may subject the Employee to discipline, up to and including termination of employment. This report can be made in writing and appended to this form.

Employees who become aware of an actual or potential conflict of interest as defined above are responsible for and authorized to confidentially report the conflict to the Human Resources Department immediately, not to exceed 3 business days from recognizing the conflict.

Conflict of interest situations will be reviewed by Human Resources and/or Senior Management. Dr. Frasca, in his capacity as President of EMSL, retains sole discretion to determine appropriate actions to alleviate an actual conflict.

My signature below is evidence that I have read and understand the policy stated above, and declare that no unreported potential conflict of interest exists between me, my immediate family, and EMSL.

_____	_____
Printed Name	Signature
	_____
	Date

**Reports of potential or apparent conflicts do not automatically trigger any actions other than review. Each case will be considered case-by-case based on facts. In most cases, no action is necessary other than ensuring the relevant details are on record in order to defend both Employee and EMSL from future potential accusations of improper practices.*

APPENDIX C: Cross Reference EMSL QMS Manual to ISO 17025:2017

EMSL QMS Manual and Related Modules	ISO/IEC 17025:2017
Section 1.0	**1.0 Scope**
Section 2.0	**2.0 Normative references**
Appendix A - Glossary	**3.0 Terms and definitions**
Section 4.0 Management requirements	**4.0 General requirements**
Section 4.1.5.2.4	4.1 Impartiality
Section 4.1.5	4.2 Confidentiality
Section 4.1	**5.0 Structural requirements**
	6.0 Resource requirements
Section 5.1	6.1 General
Section 5.2	6.2 Personnel
Section 5.3	6.3 Facilities and environmental conditions
Section 5.5	6.4 Equipment
Section 5.6	6.5 Metrological traceability
Section 4.6	6.6 Externally provided products and services
	7.0 Process requirements
Section 4.4	7.1 Review of requests, tenders and contracts
	7.2 Selection, verification and validation of methods
Section 5.4.2	7.2.1 Selection and verification of methods
Section 5.4.5	7.2.2 Validation of methods
Section 5.7	7.3 Sampling
Section 5.9	7.4 Handling of test or calibration items
Section 4.13	7.5 Technical records
Section 5.4.6	7.6 Evaluation of measurement uncertainty
Section 5.9	7.7 Ensuring the validating of results
Section 5.10	7.8 Reporting of results
Section 5.10	7.8.1 General
Section 5.10.1	7.8.2 Common requirements for reports
Section 5.10.1	7.8.3 Specific requirements for test reports
Section 5.8	7.8.4 Specific requirements for calibration certificates
Section 5.7	7.8.5 Reporting sampling-specific requirements
Section 5.10.3	7.8.6 Reporting statements of conformity
Section 5.10.3	7.8.7 Reporting opinions and interpretations
Section 5.10.9	7.8.8 Amendments to reports
Section 4.8	7.9 Complaints
Section 4.9	7.10 Non-conforming work
Section 5.4.7	7.11 Control of data and information management
	8.0 Management system requirements
	8.1 Options (8.1.1 General; 8.1.2 Opt. A; 8.1.3 Opt. B-N/A to EMSL)
Section 4.2	8.2 Management system documentation
Section 4.3	8.3 Control of management system documents
Section 4.13	8.4 Control of records
Section 4.2.6	8.5 Actions to address risks and opportunities
Section 4.10	8.6 Improvement
Section 4.11	8.7 Corrective actions
Section 4.14	8.8 Internal audits
Section 4.15	8.9 Management reviews

APPENDIX F
ACTIVITY SUMMARY FORMS/FIELD SHEETS

PRE-CLEANING RECORD

Building Name: _____ Asbestos Program Manager: _____

Address: _____ Date: _____

DATE	AREA	TECHNIQUE	SUPERVISOR	INITIAL

WORK AREA DAILY LOG

Building Owner		Total Drive Time	
Project & Address		Date	
Abatement Company			

Abatement Contractors

Names	Accredited		Accreditation Number	Project		Containment	
	Yes	No		Start	Finish	Start	Finish
	X						

Impact7G Personnel

Names	Accredited		Accreditation Number	Project		Containment	
	Yes	No		Start	Finish	Start	Finish
	X						

WORK AREA DAILY LOG

Building Owner		Total Drive Time	
Project & Address		Date	
Abatement Company			

Workers are wearing? Half-face Full-face Tyvek Suits Boots Gloves Hard Hats Glasses Fall Protection

Material removed: XX

Location of removal: XX

Is there a decontamination unit? Yes 1-cell 3-cell No N/A **Is the decon unit attached?** Yes No N/A

Is the containment under negative pressure? Yes No N/A **Manometer Reading:**

Are they performing the proper glovebag removal techniques? Yes No N/A

Are asbestos warning signs posted? Yes No **Is barrier tape in use?** Yes No

Water Source: Garden hose Garden sprayer Other

Is the asbestos waste being: Double-bagged in 6-mil poly Double-wrapped in 6-mil poly Placed in barrels

Are DOT, waste generator and OSHA labels attached? Yes No N/A

A visual inspection performed? Yes No N/A **Did the inspection pass?** Yes No N/A

Visual inspection area(s): REMOVE IF NOT USED

Clearance samples running? Yes No N/A **Type of clearance sample?** PCM TEM

Clearance sample area(s): REMOVE IF NOT USED

DAILY FIELD REPORT (DFR):

IMPACT7G

AIR MONITORING FORM

CLIENT NAME		**SAMPLED BY**		**ANALYZED BY**	
PROJECT NAME		**SAMPLE DATE**		**ANALYSIS DATE**	
FLOWMETER NUMBER		**TYPED BY**		**ANALYSIS ENTERED BY**	

Sample #	**TIME**		**FLOW**		**SAMPLE TYPE**		**DESCRIPTION**			**Fibers**	**Fields**
	Begin	**End**	**Begin**	**End**			**Location 1 / Person**	**Location 2**	**During**		
	FIELD BLANK										
	FIELD BLANK										
					Pre STEL PCM	A P TEM					
					Pre STEL PCM	A P TEM					
					Pre STEL PCM	A P TEM					
					Pre STEL PCM	A P TEM					
					Pre STEL PCM	A P TEM					
					Pre STEL PCM	A P TEM					
					Pre STEL PCM	A P TEM					
					Pre STEL PCM	A P TEM					
					Pre STEL PCM	A P TEM					
					Pre STEL PCM	A P TEM					
					Pre STEL PCM	A P TEM					
					Pre STEL PCM	A P TEM					
	QUALITY CONTROL – 10% REPLICATE ANALYSIS SAMPLE										

CERTIFICATION OF VISUAL INSPECTION

BUILDING NAME _____

ADDRESS _____

Form Reset

ABATEMENT COMPANY _____

The contractor and industrial hygienist hereby certify that they have visually inspected the work area (all surfaces including pipes, beams, ledges, walls, ceiling and floor, decontamination unit, sheet plastic, etc.) and have found no dust, debris, or residue to the best of their knowledge.

DATE	REMOVAL AREA	MATERIALS REMOVED	SUPERVISOR NAME & SIGNATURE	HYGIENIST NAME & SIGNATURE
			Print	Print
			Signature	Signature
			Print	Print
			Signature	Signature
			Print	Print
			Signature	Signature
			Print	Print
			Signature	Signature

NOTES:

Form Reset

Client Name:			Project Address:			Date:		Page #
Start Time:	:	Private ☐	Comercial ☐	School ☐	# of Stories: _____	# of Structures: _____		
End Time:	:	House	Garage	Basement	Shed	Scanned	Photos Uploaded	Total Pages
Total Time:		Inspector Code			Full ACM ☐	Limited ACM ☐	Miscellaneous Bulk ☐	
Limitations								

Sample#	Material	Color	Floor	Location	Est Qty	Notes

Reliquished By: _____ Date: ____/____/_____ Time: ____:____

Received By: _____Date: ____/____/_____ Time: ____:____

APPENDIX G
STANDARD OPERATION PROCEDURES

Standard Operation Procedure – Asbestos PCM Air Sampling

General: The scope of this Standard Operating Procedure (SOP) is to address general requirements associated with **Air Sampling for Phase Contrast Microscopy (PCM) Analysis.**

Background: Asbestos is a naturally occurring mineral. One of its main characteristics is as a health risk as a known carcinogen. Most air sampling projects that Impact7G completes are associated with renovation or demolition projects. The objective is to capture and quantify the amount of airborne asbestos fibers in the air and to assess whether levels present suggest an elevated fiber concentration. The analytical technique is specific for fibers. Phase contrast is a fiber counting technique that excludes non-fibrous particles from the analysis.

Equipment:

1. Sampler: field monitor, 25-mm, three-piece cassette with 50-mm electrically conductive extension cowl and cellulose ester filter, 0.45 to 1.2 µm pore size and back up pad. (0.80 µm pore size filters are recommended for PCM analysis and 0.45 µm pore size filters are recommended for TEM analysis).
2. Personal or area sampling pumps.
3. Wire, multi-stranded, 22-gauge; 1”, hose clamp to attach wire to cassette.
4. Flexible tubing, 6-mm bore.
5. Pump calibration: Stopwatch and bubble tube/burette, electronic meter, or rotameter. (Please note the use of a rotameter is an industry standard and not part of the NIOSH 7400 method).

Procedure:

1. Charge the pumps completely before beginning.
2. To reduce contamination and to hold the cassette tightly together, seal the point where the base and cowl of each cassette meet, with a gel band or tape.
3. Connect each pump to a calibration cassette with an appropriate length of 6-mm bore plastic tubing.
4. Select an appropriate flow rate for the situation being monitored. The sampling flow rate must be between 0.5 and 5.0 L/min for personal sampling and is commonly set between 1 and 2 L/min. Always choose a flow rate that will not produce overloaded filters.
5. Calibrate each sampling pump before and after sampling with a calibration cassette in-line (Note: This calibration cassette should be from the same lot of cassettes used for sampling). Use a primary standard (e.g. bubble burette) to calibrate each pump or a secondary standard such as a rotameter. If possible, calibrate at the sampling site.
6. Connect each pump to the base of each sampling cassette with flexible tubing. Remove the end cap of each cassette and take each air sample open face. Assure that each sample cassette is held open side down in the employee’s breathing zone during sampling. The distance from the nose/mouth of the employee to the cassette should be about 10 cm. Secure the cassette on the collar or lapel of the employee using spring clips or other similar devices.
7. A suggested minimum air volume when sampling to determine TWA compliance is 25 L. For Excursion Limit (30 min sampling time) evaluations, a minimum air volume of 48 L is recommended.

8. The most significant problem when sampling for asbestos is overloading the filter with non-asbestos dust. Suggested maximum air sample volumes for specific environments are:

Environment	Air Volume (L)
Asbestos removal operations (visible dust)	100 - 200
Asbestos removal operations (little dust)	100 - 400
Office environments	400 - 2,400

Note: Do not overload the filter with dust. High levels of non-fibrous dust particles may obscure fibers on the filter and lower the count or make counting impossible. If more than about 25 to 30% of the field area is obscured with dust, the result may be biased low. Smaller air volumes may be necessary when there is excessive non-asbestos dust in the air. While sampling, observe the filter with a small flashlight. If there is a visible layer of dust on the filter, stop sampling, remove and seal the cassette, and replace with a new sampling assembly. The total dust loading should not exceed 1 mg.

9. Blank samples are used to determine if any contamination has occurred during sample handling. Prepare two blanks for the first 1 to 20 samples. For sets containing greater than 20 samples, prepare blanks as 10% of the samples. Handle blank samples in the same manner as air samples with one exception: Do not draw any air through the blank samples. Open the blank cassette in the place where the sample cassettes are mounted on the employee. Hold it open for about 30 seconds. Close and seal the cassette appropriately. Store blanks for shipment with the sample cassettes.
10. Immediately after sampling, close and seal each cassette with the base and plastic plugs. Do not touch or puncture the filter membrane, as this will invalidate the analysis.
11. Attach a seal around each cassette in such a way as to secure the end cap plug and base plug. Tape the ends of the seal together since the seal is not long enough to be wrapped end-to-end. Also wrap tape around the cassette at each joint to keep the seal secure.

Shipping

1. Ship samples with conductive cowl attached in a rigid container with packing material to prevent jostling or damage. Do not use untreated polystyrene foam in shipping container because electrostatic forces may cause fiber loss from sample filter.
2. To avoid the possibility of sample contamination, always ship bulk samples in separate mailing containers.

Standard Operation Procedure – Asbestos Containing Materials Inspection

General: The scope of this Standard Operating Procedure (SOP) is to address general requirements associated with **Asbestos Containing Materials (ACM) Inspections**.

Background: Asbestos is a naturally occurring mineral. One of its main characteristics is as a health risk as a known carcinogen. The majority of the ACM Inspections that Impact7G completes are associated with renovation or demolition projects. The overall purpose of these inspections is to minimize the potential release of asbestos fibers into the environment and thus minimize the risk of exposure. Another reason why the ACM Inspection process is important is that it is a "deliverable," a service that we provide a client. Often our ACM Inspection report will be utilized by the client or other firms for project specifications, bidding purposes, and/or abatement. Therefore, the accuracy and dependability of our inspection is crucial.

Procedure:

1. Review existing project information
    a. Review the available information for the project / property and confirm its accuracy
        i. Purpose of project – demolition, renovation, etc.
        ii. Address, GPS Coordinates.
        iii. Owner information.
        iv. Type of property (industrial, commercial, residential).
        v. Blueprints, building drawings, engineering drawings, etc.
        vi. Occupancy (difference between discreet or destructive sampling).
        vii. Utilities (if they are functioning requires an added level of safety).
        viii. Security (could determine the hours you're allowed to sample).
        ix. Previous sampling events.
        x. Completed work and/or updates or the building.
        xi. Discuss the sampling scheme (ASTM, OSHA, EPA, etc.).
        xii. Verify timeline / due date.
2. Certification
    a. Almost every level of asbestos work requires a certification.
    b. Some states have more stringent standards and require their own certification (i.e. MN).
    c. Some states, such as Iowa, allow reciprocity.
    d. Inspectors are taught how to safely collect samples of suspect ACM.

3. Sampling
    a. Discreet
        i. Typical chosen sampling type when the building is still occupied
        ii. Samples are collected from discreet, low visibility areas of the building
            1. Above drop ceilings, behind doors, in corners, closets, beneath rugs, etc.
        iii. Owner may require sampling locations to be patched.

iv. Roofing samples are only collected at the owner's direction, otherwise an opinion is based on the building records and available information concerning maintenance and updates.
v. Conclusions are based on available sampling data, construction records, and sometimes assumptions.

b. Destructive
    i. Typical chosen sampling type when the building is to be renovated or demolished.
    ii. Samples are collected via a safe "punch and grab" method
        1. Allows for a more thorough inspection of the building without worrying about low visibility areas.
    iii. Samples of every building component and material should be collected, unless an area is determined to be unsafe.
    iv. Conclusions are based on available sampling data and assumptions are reserved only for the unsafe areas.
c. Safety
    i. Impact7G provides employees with satisfactory personal protective equipment (PPE).

4. ACM Inspection Process
    a. Check supplies, sampling equipment, and PPE prior to leaving the office.
    b. Print an assessor's map prior to leaving the office (if a site map is not provided by client).
    c. Coordinate arrival at the site with the owner.
    d. If present, ask the owner about any safety issues and the utilities.
    e. Perform a quick survey of the building to identify any potential safety concerns and complete a building layout map (tip: in commercial buildings, fire escape route maps are an easy way to complete the map).
    f. Identify each of the homogenous areas/materials/components.
    g. Sample each building material in accordance with training.
    h. Label each sample.
    i. Mark the location where the sample was collected on the building. layout/sampling location map.
    j. Repeat the process for each floor of the building.
    k. Sample the exterior components, including the roof, separately from the interior.
    l. Log each sample onto the Chain of Custody and submit the samples for analysis per the appropriate turnaround time as directed by the Project Manager.

FIELD SAMPLING GUIDE
(ASBESTOS & OTHER FIBERS BY PCM-NIOSH 7400)

The following field sampling guide is designed for use as a reference for the field consultant. It summarizes procedures and techniques for the sampling of asbestos and other fibers by PCM (following NIOSH 7400) as they impact the analytical procedures.

For additional information on field sampling equipment, field health and safety, certain regulatory requirements for field sampling , sampling strategies and data interpretation, refer to the appropriate documented methodology and/or regulatory agency.

Matrix	Method	Collection Media	Receommended Volume	Detection Limit	Blanks
Air	NIOSH 7400	.45 Cellulose ester membrane, 25mm; conductive cowl on cassette	400-1800 liters @ flow rate 2-10 L/Min	7 f/mm^2 (0.002f/cc with 1200 liters sample volume	Unsampled cassette 2 or 10% of total samples submitted (whichever is greater)

There are a variety of field conditions which can effect the analytical process. These include:

SAMPLE OVERLOAD

Macroscopically (observed in the field)

if > 50% of the filter surface is covered with particles, the filter may be to overloaded to count and will bias the measured fiber concentration.

Microscopically (observed through the microscope)

if 1/6 of the sample field of view is covered by a agglomerate, the microscopist must reject the field of veiw.

FIELD SAMPLING GUIDE
(ASBESTOS IN BULK MATERIALS BY PLM)

Interim Method for the Determination of Asbestos in Bulk Insulation Samples EPA600/M4-82-020.
NY State PLM Methods for Identifying and Quantitating Asbestos in Bulk Materials ELAP 198.1

The following field sampling guide is designed for use as a reference for the field consultant. It summarizes procedures and techniques for the sampling of asbestos for analysis using polarized light microscopy as they impact the analytical procedures.

For additional information on field sampling equipment, field health and safety, regulatory requirements for field sampling , sampling strategies and data interpretation, refer to the appropriate documented methodology and/or regulatory agency.

Matrix	Method	Collection Type	Receommended Volume	Detection Limit	Blanks
Bulk	EPA/600/R-93/116	Grab	Size representative of material of interest. For example: Floor tiles, roofing material – 3 to 4 in2 Ceiling tiles, loose fill insulation - 1 in3 Mastics, paints – enough to represent the material being tested	1%	N/A

Samples should be placed in a 'zip lock' bag.

There are a variety of field conditions which can effect the analytical process. These include:

- Sample wet Non homogeneity
- Layers Soil
- Sample amount

APPENDIX H

NIOSH 7400

ASBESTOS and OTHER FIBERS by PCM 7400

FORMULA: Various MW: Various CAS: see Synonyms RTECS: Various

METHOD: 7400, Issue 2 **EVALUATION: FULL** **Issue 1: Rev. 3 on 15 May 1989**
Issue 2: 15 August 1994

OSHA: 0.1 asbestos fiber (> 5 µm long)/cc; 1 f/cc, 30 min excursion; carcinogen
MSHA: 2 asbestos fibers/cc
NIOSH: 0.1 f/cc (fibers > 5 µm long), 400 L; carcinogen
ACGIH: 0.2 f/cc crocidolite; 0.5 f/cc amosite; 2 f/cc chrysotile and other asbestos; carcinogen

PROPERTIES: solid, fibrous, crystalline, anisotropic

SYNONYMS [CAS #]: actinolite [77536-66-4] or ferroactinolite [15669-07-5]; amosite [12172-73-5]; anthophyllite [77536-67-5]; chrysotile [12001-29-5]; serpentine [18786-24-8]; crocidolite [12001-28-4]; tremolite [77536-68-6]; amphibole asbestos [1332-21-4]; refractory ceramic fibers [142844-00-6]; fibrous glass

SAMPLING

SAMPLER: FILTER (0.45- to 1.2-µm cellulose ester membrane, 25-mm; conductive cowl on cassette)

FLOW RATE*: 0.5 to 16 L/min

VOL-MIN*: 400 L @ 0.1 fiber/cc
-MAX*: (step 4, sampling)

*Adjust to give 100 to 1300 fiber/mm^2

SHIPMENT: routine (pack to reduce shock)

SAMPLE STABILITY: stable

BLANKS: 2 to 10 field blanks per set

ACCURACY

RANGE STUDIED: 80 to 100 fibers counted

BIAS: see EVALUATION OF METHOD

OVERALL PRECISION ($\hat{S}_{rT}$): 0.115 to 0.13 [1]

ACCURACY: see EVALUATION OF METHOD

MEASUREMENT

TECHNIQUE: LIGHT MICROSCOPY, PHASE CONTRAST

ANALYTE: fibers (manual count)

SAMPLE PREPARATION: acetone - collapse/triacetin - immersion method [2]

COUNTING RULES: described in previous version of this method as "A" rules [1,3]

EQUIPMENT:
1. positive phase-contrast microscope
2. Walton-Beckett graticule (100-µm field of view) Type G-22
3. phase-shift test slide (HSE/NPL)

CALIBRATION: HSE/NPL test slide

RANGE: 100 to 1300 fibers/mm^2 filter area

ESTIMATED LOD: 7 fibers/mm^2 filter area

PRECISION ($\bar{S}_r$): 0.10 to 0.12 [1]; see EVALUATION OF METHOD

APPLICABILITY: The quantitative working range is 0.04 to 0.5 fiber/cc for a 1000-L air sample. The LOD depends on sample volume and quantity of interfering dust, and is <0.01 fiber/cc for atmospheres free of interferences. The method gives an index of airborne fibers. It is primarily used for estimating asbestos concentrations, though PCM does not differentiate between asbestos and other fibers. Use this method in conjunction with electron microscopy (e.g., Method 7402) for assistance in identification of fibers. Fibers < ca. 0.25 µm diameter will not be detected by this method [4]. This method may be used for other materials such as fibrous glass by using alternate counting rules (see Appendix C).

INTERFERENCES: If the method is used to detect a specific type of fiber, any other airborne fiber may interfere since all particles meeting the counting criteria are counted. Chain-like particles may appear fibrous. High levels of non-fibrous dust particles may obscure fibers in the field of view and increase the detection limit.

OTHER METHODS: This revision replaces Method 7400, Revision #3 (dated 5/15/89).

REAGENTS:

1. Acetone,* reagent grade.
2. Triacetin (glycerol triacetate), reagent grade.

*See SPECIAL PRECAUTIONS.

EQUIPMENT:

1. Sampler: field monitor, 25-mm, three-piece cassette with ca. 50-mm electrically conductive extension cowl and cellulose ester filter, 0.45- to 1.2-µm pore size, and backup pad.
   NOTE 1: Analyze representative filters for fiber background before use to check for clarity and background. Discard the filter lot if mean is ≥ 5 fibers per 100 graticule fields. These are defined as laboratory blanks. Manufacturer-provided quality assurance checks on filter blanks are normally adequate as long as field blanks are analyzed as described below.
   NOTE 2: The electrically conductive extension cowl reduces electrostatic effects. Ground the cowl when possible during sampling.
   NOTE 3: Use 0.8-µm pore size filters for personal sampling. The 0.45-µm filters are recommended for sampling when performing TEM analysis on the same samples. However, their higher pressure drop precludes their use with personal sampling pumps.
   NOTE 4: Other cassettes have been proposed that exhibit improved uniformity of fiber deposit on the filter surface, e.g., bellmouthed sampler (Envirometrics, Charleston, SC). These may be used if shown to give measured concentrations equivalent to sampler indicated above for the application.
2. Personal sampling pump, battery or line-powered vacuum, of sufficient capacity to meet flow-rate requirements (see step 4 for flow rate), with flexible connecting tubing.
3. Wire, multi-stranded, 22-gauge; 1″ hose clamp to attach wire to cassette.
4. Tape, shrink- or adhesive-.
5. Slides, glass, frosted-end, pre-cleaned, 25- × 75-mm.
6. Cover slips, 22- × 22-mm, No. 1½, unless otherwise specified by microscope manufacturer.
7. Lacquer or nail polish.
8. Knife, #10 surgical steel, curved blade.
9. Tweezers.

EQUIPMENT (continued):

10. Acetone flash vaporization system for clearing filters on glass slides (see ref. [5] for specifications or see manufacturer's instructions for equivalent devices).
11. Micropipets or syringes, 5-µL and 100- to 500-µL.
12. Microscope, positive phase (dark) contrast, with green or blue filter, adjustable field iris, 8 to 10× eyepiece, and 40 to 45× phase objective (total magnification ca. 400×); numerical aperture = 0.65 to 0.75.
13. Graticule, Walton-Beckett type with 100-µm diameter circular field (area = 0.00785 mm^2) at the specimen plane (Type G-22). Available from Optometrics USA, P.O. Box 699, Ayer, MA 01432 [phone (508)-772-1700], and McCrone Accessories and Components, 850 Pasquinelli Drive, Westmont, IL 60559 [phone (312) 887-7100].
    NOTE: The graticule is custom-made for each microscope. (see APPENDIX A for the custom-ordering procedure).
14. HSE/NPL phase contrast test slide, Mark II. Available from Optometrics USA (address above).
15. Telescope, ocular phase-ring centering.
16. Stage micrometer (0.01-mm divisions).

SPECIAL PRECAUTIONS: Acetone is extremely flammable. Take precautions not to ignite it. Heating of acetone in volumes greater than 1 mL must be done in a ventilated laboratory fume hood using a flameless, spark-free heat source.

SAMPLING:

1. Calibrate each personal sampling pump with a representative sampler in line.
2. To reduce contamination and to hold the cassette tightly together, seal the crease between the cassette base and the cowl with a shrink band or light colored adhesive tape. For personal sampling, fasten the (uncapped) open-face cassette to the worker's lapel. The open face should be oriented downward.
    NOTE: The cowl should be electrically grounded during area sampling, especially under conditions of low relative humidity. Use a hose clamp to secure one end of the wire (Equipment, Item 3) to the monitor's cowl. Connect the other end to an earth ground (i.e., cold water pipe).
3. Submit at least two field blanks (or 10% of the total samples, whichever is greater) for each set of samples. Handle field blanks in a manner representative of actual handling of associated samples in the set. Open field blank cassettes at the same time as other cassettes just prior to sampling. Store top covers and cassettes in a clean area (e.g., a closed bag or box) with the top covers from the sampling cassettes during the sampling period.
4. Sample at 0.5 L/min or greater [6]. Adjust sampling flow rate, Q (L/min), and time, t (min), to produce a fiber density, E, of 100 to 1300 fibers/mm^2 (3.85×10^4 to 5×10^5 fibers per 25-mm filter with effective

collection area A_c = 385 mm^2) for optimum accuracy. These variables are related to the action level (one-half the current standard), *L* (fibers/cc), of the fibrous aerosol being sampled by:

$$t = \frac{A_c \times E}{Q \times L \times 10^3}.$$

NOTE 1: The purpose of adjusting sampling times is to obtain optimum fiber loading on the filter. The collection efficiency does not appear to be a function of flow rate in the range of 0.5 to 16 L/min for asbestos fibers [7]. Relatively large diameter fibers (>3 µm) may exhibit significant aspiration loss and inlet deposition. A sampling rate of 1 to 4 L/min for 8 h is appropriate in atmospheres containing ca. 0.1 fiber/cc in the absence of significant amounts of non-asbestos dust. Dusty atmospheres require smaller sample volumes (≤400 L) to obtain countable samples. In such cases take short, consecutive samples and average the results over the total collection time. For documenting episodic exposures, use high flow rates (7 to 16 L/min) over shorter sampling times. In relatively clean atmospheres, where targeted fiber concentrations are much less than 0.1 fiber/cc, use larger sample volumes (3000 to 10000 L) to achieve quantifiable loadings. Take care, however, not to overload the filter with background dust. If ≥50% of the filter surface is covered with particles, the filter may be too overloaded to count and will bias the measured fiber concentration.

NOTE 2: OSHA regulations specify a minimum sampling volume of 48 L for an excursion measurement, and a maximum sampling rate of 2.5 L/min [3].

5. At the end of sampling, replace top cover and end plugs.
6. Ship samples with conductive cowl attached in a rigid container with packing material to prevent jostling or damage.
   NOTE: Do not use untreated polystyrene foam in shipping container because electrostatic forces may cause fiber loss from sample filter.

SAMPLE PREPARATION:

NOTE 1: The object is to produce samples with a smooth (non-grainy) background in a medium with refractive index ≤ 1.46. This method collapses the filter for easier focusing and produces permanent (1–10 years) mounts which are useful for quality control and interlaboratory comparison. The aluminum "hot block" or similar flash vaporization techniques may be used outside the laboratory [2]. Other mounting techniques meeting the above criteria may also be used (e.g., the laboratory fume hood procedure for generating acetone vapor as described in Method 7400—revision of 5/15/85, or the non-permanent field mounting technique used in P&CAM 239 [3,7–9]). Unless the effective filtration area is known, determine the area and record the information referenced against the sample ID number [1,9–11].

NOTE 2: Excessive water in the acetone may slow the clearing of the filter, causing material to be washed off the surface of the filter. Also, filters that have been exposed to high humidities prior to clearing may have a grainy background.

7. Ensure that the glass slides and cover slips are free of dust and fibers.
8. Adjust the rheostat to heat the "hot block" to ca. 70 °C [2].
   NOTE: If the "hot block" is not used in a fume hood, it must rest on a ceramic plate and be isolated from any surface susceptible to heat damage.
9. Mount a wedge cut from the sample filter on a clean glass slide.
   a. Cut wedges of ca. 25% of the filter area with a curved-blade surgical steel knife using a rocking motion to prevent tearing. Place wedge, dust side up, on slide.
      NOTE: Static electricity will usually keep the wedge on the slide.
   b. Insert slide with wedge into the receiving slot at base of "hot block". Immediately place tip of a micropipet containing ca. 250 µL acetone (use the minimum volume needed to consistently clear the filter sections) into the inlet port of the PTFE cap on top of the "hot block" and inject the

acetone into the vaporization chamber with a slow, steady pressure on the plunger button while holding pipet firmly in place. After waiting 3 to 5 s for the filter to clear, remove pipet and slide from their ports.

CAUTION: Although the volume of acetone used is small, use safety precautions. Work in a well-ventilated area (e.g., laboratory fume hood). Take care not to ignite the acetone. Continuous use of this device in an unventilated space may produce explosive acetone vapor concentrations.

c. Using the 5-µL micropipet, immediately place 3.0 to 3.5 µL triacetin on the wedge. Gently lower a clean cover slip onto the wedge at a slight angle to reduce bubble formation. Avoid excess pressure and movement of the cover glass.

NOTE: If too many bubbles form or the amount of triacetin is insufficient, the cover slip may become detached within a few hours. If excessive triacetin remains at the edge of the filter under the cover slip, fiber migration may occur.

d. Mark the outline of the filter segment with a glass marking pen to aid in microscopic evaluation.

e. Glue the edges of the cover slip to the slide using lacquer or nail polish [12]. Counting may proceed immediately after clearing and mounting are completed.

NOTE: If clearing is slow, warm the slide on a hotplate (surface temperature 50 °C) for up to 15 min to hasten clearing. Heat carefully to prevent gas bubble formation.

CALIBRATION AND QUALITY CONTROL:

10. Microscope adjustments. Follow the manufacturer's instructions. At least once daily use the telescope ocular (or Bertrand lens, for some microscopes) supplied by the manufacturer to ensure that the phase rings (annular diaphragm and phase-shifting elements) are concentric. With each microscope, keep a logbook in which to record the dates of microscope cleanings and major servicing.

    a. Each time a sample is examined, do the following:

        (1) Adjust the light source for even illumination across the field of view at the condenser iris. Use Kohler illumination, if available. With some microscopes, the illumination may have to be set up with bright field optics rather than phase contract optics.

        (2) Focus on the particulate material to be examined.

        (3) Make sure that the field iris is in focus, centered on the sample, and open only enough to fully illuminate the field of view.

    b. Check the phase-shift detection limit of the microscope periodically for each analyst/microscope combination:

        (1) Center the HSE/NPL phase-contrast test slide under the phase objective.

        (2) Bring the blocks of grooved lines into focus in the graticule area.

        NOTE: The slide contains seven blocks of grooves (ca. 20 grooves per block) in descending order of visibility. For asbestos counting, the microscope optics must completely resolve the grooved lines in block 3 although they may appear somewhat faint, and the grooved lines in blocks 6 and 7 must be invisible when centered in the graticule area. Blocks 4 and 5 must be at least partially visible but may vary slightly in visibility between microscopes. A microscope which fails to meet these requirements has resolution either too low or too high for fiber counting.

        (3) If image quality deteriorates, clean the microscope optics. If the problem persists, consult the microscope manufacturer.

11. Document the laboratory's precision for each counter for replicate fiber counts.

    a. Maintain as part of the laboratory quality assurance program a set of reference slides to be used on a daily basis [13]. These slides should consist of filter preparations including a range of loadings and background dust levels from a variety of sources including both field and reference samples (e.g., PAT, AAR, commercial samples). The Quality Assurance Officer should maintain custody of the reference slides and should supply each counter with a minimum of one reference

slide per workday. Change the labels on the reference slides periodically so that the counter does not become familiar with the samples.

b. From blind repeat counts on reference slides, estimate the laboratory intra- and intercounter precision. Obtain separate values of relative standard deviation (S_r) for each sample matrix analyzed in each of the following ranges: 5 to 20 fibers in 100 graticule fields, >20 to 50 fibers in 100 graticule fields, and >50 to 100 fibers in 100 graticule fields. Maintain control charts for each of these data files.

NOTE: Certain sample matrices (e.g., asbestos cement) have been shown to give poor precision [9].

12. Prepare and count field blanks along with the field samples. Report counts on each field blank.

NOTE 1: The identity of blank filters should be unknown to the counter until all counts have been completed.

NOTE 2: If a field blank yields greater than 7 fibers per 100 graticule fields, report possible contamination of the samples.

13. Perform blind recounts by the same counter on 10% of filters counted (slides relabeled by a person other than the counter). Use the following test to determine whether a pair of counts by the same counter on the same filter should be rejected because of possible bias: Discard the sample if the absolute value of the difference between the square roots of the two counts (in fiber/mm^2) exceeds $2.77XS_r'$ where X = average of the square roots of the two fiber counts (in fiber/mm^2) and $S_r' = S_r / 2$ where S_r is the intracounter relative standard deviation for the appropriate count range (in fibers) determined in step 11. For more complete discussions see reference [13].

NOTE 1: Since fiber counting is the measurement of randomly placed fibers which may be described by a Poisson distribution, a square root transformation of the fiber count data will result in approximately normally distributed data [13].

NOTE 2: If a pair of counts is rejected by this test, recount the remaining samples in the set and test the new counts against the first counts. Discard all rejected paired counts. It is not necessary to use this statistic on blank counts.

14. The analyst is a critical part of this analytical procedure. Care must be taken to provide a non-stressful and comfortable environment for fiber counting. An ergonomically designed chair should be used, with the microscope eyepiece situated at a comfortable height for viewing. External lighting should be set at a level similar to the illumination level in the microscope to reduce eye fatigue. In addition, counters should take 10- to 20-minute breaks from the microscope every one or two hours to limit fatigue [14]. During these breaks, both eye and upper back/neck exercises should be performed to relieve strain.
15. All laboratories engaged in asbestos counting should participate in a proficiency testing program such as the AIHA-NIOSH Proficiency Analytical Testing (PAT) Program for asbestos and routinely exchange field samples with other laboratories to compare performance of counters.

MEASUREMENT:

16. Center the slide on the stage of the calibrated microscope under the objective lens. Focus the microscope on the plane of the filter.
17. Adjust the microscope (Step 10).

NOTE: Calibration with the HSE/NPL test slide determines the minimum detectable fiber diameter (ca. 0.25 µm) [4].

18. Counting rules: (same as P&CAM 239 rules [1,10,11]: see examples in APPENDIX B).

a. Count any fiber longer than 5 µm which lies entirely within the graticule area.
   (1) Count only fibers longer than 5 µm. Measure length of curved fibers along the curve.
   (2) Count only fibers with a length-to-width ratio equal to or greater than 3:1.

b. For fibers which cross the boundary of the graticule field:
   (1) Count as ½ fiber any fiber with only one end lying within the graticule area, provided that the fiber meets the criteria of rule a above.

(2) Do not count any fiber which crosses the graticule boundary more than once.
(3) Reject and do not count all other fibers.

c. Count bundles of fibers as one fiber unless individual fibers can be identified by observing both ends of a fiber.
d. Count enough graticule fields to yield 100 fibers. Count a minimum of 20 fields. Stop at 100 graticule fields regardless of count.

19. Start counting from the tip of the filter wedge and progress along a radial line to the outer edge. Shift up or down on the filter, and continue in the reverse direction. Select graticule fields randomly by looking away from the eyepiece briefly while advancing the mechanical stage. Ensure that, as a minimum, each analysis covers one radial line from the filter center to the outer edge of the filter. When an agglomerate or bubble covers ca. 1/6 or more of the graticule field, reject the graticule field and select another. Do not report rejected graticule fields in the total number counted.

NOTE 1: When counting a graticule field, continuously scan a range of focal planes by moving the fine focus knob to detect very fine fibers which have become embedded in the filter. The small-diameter fibers will be very faint but are an important contribution to the total count. A minimum counting time of 15 s per field is appropriate for accurate counting.

NOTE 2: This method does not allow for differentiation of fibers based on morphology. Although some experienced counters are capable of selectively counting only fibers which appear to be asbestiform, there is presently no accepted method for ensuring uniformity of judgment between laboratories. It is, therefore, incumbent upon all laboratories using this method to report total fiber counts. If serious contamination from non-asbestos fibers occurs in samples, other techniques such as transmission electron microscopy must be used to identify the asbestos fiber fraction present in the sample (see NIOSH Method 7402). In some cases (i.e., for fibers with diameters >1 µm), polarized light microscopy (as in NIOSH Method 7403) may be used to identify and eliminate interfering non-crystalline fibers [15].

NOTE 3: Do not count at edges where filter was cut. Move in at least 1 mm from the edge.

NOTE 4: Under certain conditions, electrostatic charge may affect the sampling of fibers. These electrostatic effects are most likely to occur when the relative humidity is low (below 20%), and when sampling is performed near the source of aerosol. The result is that deposition of fibers on the filter is reduced, especially near the edge of the filter. If such a pattern is noted during fiber counting, choose fields as close to the center of the filter as possible [5].

NOTE 5: Counts are to be recorded on a data sheet that provides, as a minimum, spaces on which to record the counts for each field, filter identification number, analyst's name, date, total fibers counted, total fields counted, average count, fiber density, and commentary. Average count is calculated by dividing the total fiber count by the number of fields observed. Fiber density (fibers/mm^2) is defined as the average count (fibers/field) divided by the field (graticule) area (mm^2/field).

CALCULATIONS AND REPORTING OF RESULTS

20. Calculate and report fiber density on the filter, E (fibers/mm^2), by dividing the average fiber count per graticule field, F / n_f, minus the mean field blank count per graticule field, B / n_b, by the graticule field area, A_f (approx. 0.00785 mm^2):

$$E = \frac{(F/n_f - B/n_b)}{A_f}, \text{ fibers/mm}^2.$$

NOTE: Fiber counts above 1300 fibers/mm^2 and fiber counts from samples with >50% of filter area covered with particulate should be reported as "uncountable" or "probably biased." Other fiber counts outside the 100–1300 fiber/mm^2 range should be reported as having "greater than optimal variability" and as being "probably biased."

21. Calculate and report the concentration, C (fibers/cc), of fibers in the air volume sampled, V (L), using the effective collection area of the filter, A_c (approx. 385 mm^2 for a 25-mm filter):

$$C = \frac{EA_c}{V \times 10^3}.$$

NOTE: Periodically check and adjust the value of A_c, if necessary.

22. Report intralaboratory and interlaboratory relative standard deviations (from Step 11) with each set of results.
    NOTE: Precision depends on the total number of fibers counted [1,16]. Relative standard deviation is documented in references [1,15–17] for fiber counts up to 100 fibers in 100 graticule fields. Comparability of interlaboratory results is discussed below. As a first approximation, use 213% above and 49% below the count as the upper and lower confidence limits for fiber counts greater than 20 (Figure 1).

EVALUATION OF METHOD:

Method Revisions:

This method is a revision of P&CAM 239 [10]. A summary of the revisions is as follows:

1. Sampling:
   The change from a 37-mm to a 25-mm filter improves sensitivity for similar air volumes. The change in flow rates allows for 2-m^3 full-shift samples to be taken, providing that the filter is not overloaded with non-fibrous particulates. The collection efficiency of the sampler is not a function of flow rate in the range 0.5 to 16 L/min [10].
2. Sample preparation technique:
   The acetone vapor-triacetin preparation technique is a faster, more permanent mounting technique than the dimethyl phthalate/diethyl oxalate method of P&CAM 239 [2,4,10]. The aluminum "hot block" technique minimizes the amount of acetone needed to prepare each sample.
3. Measurement:
   a. The Walton-Beckett graticule standardizes the area observed [14,18,19].
   b. The HSE/NPL test slide standardizes microscope optics for sensitivity to fiber diameter [4,14].
   c. Because of past inaccuracies associated with low fiber counts, the minimum recommended loading has been increased to 100 fibers/mm^2 filter area (a total of 78.5 fibers counted in 100 fields, each with field area = 0.00785 mm^2.) Lower levels generally result in an overestimate of the fiber count when compared to results in the recommended analytical range [20]. The recommended loadings should yield intracounter S_r in the range of 0.10 to 0.17 [21–23].

Interlaboratory Comparability:

An international collaborative study involved 16 laboratories using prepared slides from the asbestos cement, milling, mining, textile, and friction material industries [9]. The relative standard deviations (S_r) varied with sample type and laboratory. The ranges were:

Rules	Intralaboratory S_r	Interlaboratory S_r	Overall S_r
AIA (NIOSH A Rules)*	0.12 to 0.40	0.27 to 0.85	0.46
Modified CRS (NIOSH B Rules)†	0.11 to 0.29	0.20 to 0.35	0.25

*Under AIA rules, only fibers having a diameter less than 3 µm are counted and fibers attached to particles larger than 3 µm are not counted. NIOSH A Rules are otherwise similar to the AIA rules.
†See Appendix C.

A NIOSH study conducted using field samples of asbestos gave intralaboratory S_r in the range 0.17 to 0.25 and an interlaboratory S_r of 0.45 [21]. This agrees well with other recent studies [9,14,16].

At this time, there is no independent means for assessing the overall accuracy of this method. One measure of reliability is to estimate how well the count for a single sample agrees with the mean count from a large number of laboratories. The following discussion indicates how this estimation can be carried out based on measurements of the interlaboratory variability, as well as showing how the results of this method relate to the theoretically attainable counting precision and to measured intra- and interlaboratory S_r. (NOTE: The following discussion does not include bias estimates and should not be taken to indicate that lightly loaded samples are as accurate as properly loaded ones).

Theoretically, the process of counting randomly (Poisson) distributed fibers on a filter surface will give an S_r that depends on the number, N, of fibers counted:

$$S_r = 1/N^{1/2}.$$

Thus S_r is 0.1 for 100 fibers and 0.32 for 10 fibers counted. The actual S_r found in a number of studies is greater than these theoretical numbers [17,19–21].

An additional component of variability comes primarily from subjective interlaboratory differences. In a study of ten counters in a continuing sample exchange program, Ogden [15] found this subjective component of intralaboratory S_r to be approximately 0.2 and estimated the overall S_r by the term:

$$\frac{[N + (0.2 \times N)^2]^{1/2}}{N}.$$

Ogden found that the 90% confidence interval of the individual intralaboratory counts in relation to the means were +2 S_r and −1.5 S_r. In this program, one sample out of ten was a quality control sample. For laboratories not engaged in an intensive quality assurance program, the subjective component of variability can be higher.

In a study of field sample results in 46 laboratories, the Asbestos Information Association also found that the variability had both a constant component and one that depended on the fiber count [14]. These results gave a subjective interlaboratory component of S_r (on the same basis as Ogden's) for field samples of ca. 0.45. A similar value was obtained for 12 laboratories analyzing a set of 24 field samples [21]. This value falls slightly above the range of S_r (0.25 to 0.42 for 1984–85) found for 80 reference laboratories in the NIOSH PAT program for laboratory-generated samples [17].

A number of factors influence S_r for a given laboratory, such as that laboratory's actual counting performance and the type of samples being analyzed. In the absence of other information, such as from an interlaboratory quality assurance program using field samples, the value for the subjective component of variability is chosen as 0.45. It is hoped that the laboratories will carry out the recommended interlaboratory quality assurance programs to improve their performance and thus reduce the S_r.

The above relative standard deviations apply when the population mean has been determined. It is more useful, however, for laboratories to estimate the 90% confidence interval on the mean count from a single sample fiber count (Figure 1). These curves assume similar shapes of the count distribution for interlaboratory and intralaboratory results [16].

For example, if a sample yields a count of 24 fibers, Figure 1 indicates that the mean interlaboratory count will fall within the range of 227% above and 52% below that value 90% of the time. We can apply these percentages directly to the air concentrations as well. If, for instance, this sample (24 fibers counted) represented a 500-L volume, then the measured concentration is 0.02 fibers/mL (assuming 100 fields counted, 25-mm filter, 0.00785 mm^2 counting field area). If this same sample were counted by

a group of laboratories, there is a 90% probability that the mean would fall between 0.01 and 0.08 fiber/mL. These limits should be reported in any comparison of results between laboratories.

Note that the S_r of 0.45 used to derive Figure 1 is used as an estimate for a random group of laboratories. If several laboratories belonging to a quality assurance group can show that their interlaboratory S_r is smaller, then it is more correct to use that smaller S_r. However, the estimated S_r of 0.45 is to be used in the absence of such information. Note also that it has been found that S_r can be higher for certain types of samples, such as asbestos cement [9].

Quite often the estimated airborne concentration from an asbestos analysis is used to compare to a regulatory standard. For instance, if one is trying to show compliance with an 0.5 fiber/mL standard using a single sample on which 100 fibers have been counted, then Figure 1 indicates that the 0.5 fiber/mL standard must be 213% higher than the measured air concentration. This indicates that if one measures a fiber concentration of 0.16 fiber/mL (100 fibers counted), then the mean fiber count by a group of laboratories (of which the compliance laboratory might be one) has a 95% chance of being less than 0.5 fibers/mL; i.e., $0.16 + 2.13 \times 0.16 = 0.5$.

It can be seen from Figure 1 that the Poisson component of the variability is not very important unless the number of fibers counted is small. Therefore, a further approximation is to simply use +213% and −49% as the upper and lower confidence values of the mean for a 100-fiber count.

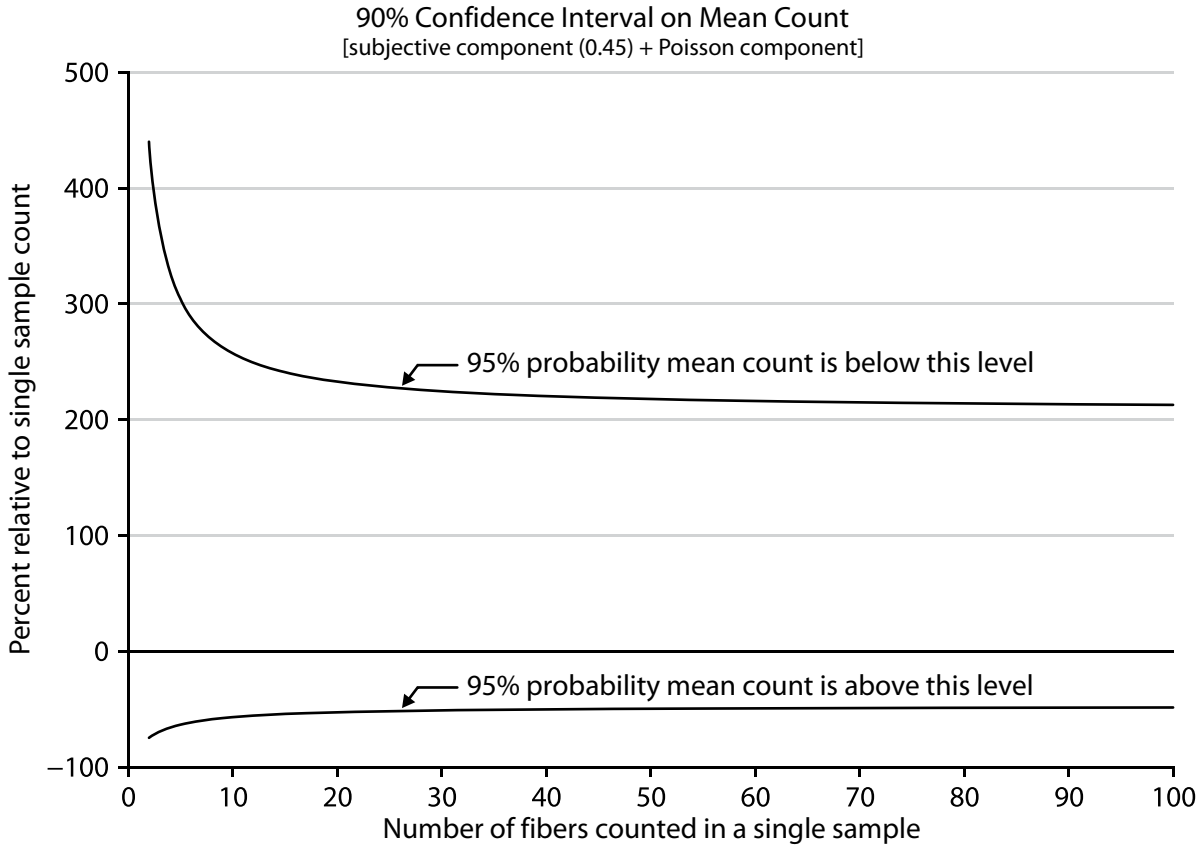


Figure 1. Interlaboratory precision of fiber counts.

The curves in Figure 1 are defined by the following equations:

$$U_{CL} = \frac{2X + 2.25 + [(2.25 + 2X)^2 - 4(1 - 2.25S_r^2)X^2]^{½}}{2(1 - 2.25S_r^2)} \text{ and}$$

$$L_{CL} = \frac{2X + 4 - [(4 + 2X)^2 - 4(1 - 4S_r^2)X^2]^{½}}{2(1 - 4S_r^2)},$$

where S_r = subjective interlaboratory relative standard deviation, which is close to the total interlaboratory S_r when approximately 100 fibers are counted,
X = total fibers counted on sample,
L_{CL} = lower 95% confidence limit, and
U_{CL} = upper 95% confidence limit.

Note that the range between these two limits represents 90% of the total range.

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APPENDIX A. CALIBRATION OF THE WALTON-BECKETT GRATICULE

Before ordering the Walton-Beckett graticule, the following calibration must be done to obtain a counting area (*D*) 100 µm in diameter at the image plane. The diameter, d_c (mm), of the circular counting area and the disc diameter must be specified when ordering the graticule.

1. Insert any available graticule into the eyepiece and focus so that the graticule lines are sharp and clear.
2. Set the appropriate interpupillary distance and, if applicable, reset the binocular head adjustment so that the magnification remains constant.
3. Install the 40 to 45× phase objective.
4. Place a stage micrometer on the microscope object stage and focus the microscope on the graduated lines.
5. Measure the magnified grid length of the graticule, L_o (µm), using the stage micrometer.
6. Remove the graticule from the microscope and measure its actual grid length, L_a (mm). This can best be accomplished by using a stage fitted with verniers.
7. Calculate the circle diameter, d_c (mm), for the Walton-Beckett graticule:

$$d_c = \frac{L_a}{L_o} \times D.$$

   Example: If L_o = 112 µm, L_a = 4.5 mm, and D = 100 µm, then d_c = 4.02 mm.
8. Check the field diameter, *D* (acceptable range 100 µm ± 2 µm) with a stage micrometer upon receipt of the graticule from the manufacturer. Determine field area (acceptable range 0.00754 mm^2 to 0.00817 mm^2).

APPENDIX B. COMPARISON OF COUNTING RULES

Figure 2 shows a Walton-Beckett graticule as seen through the microscope. The rules will be discussed as they apply to the labeled objects in the figure.

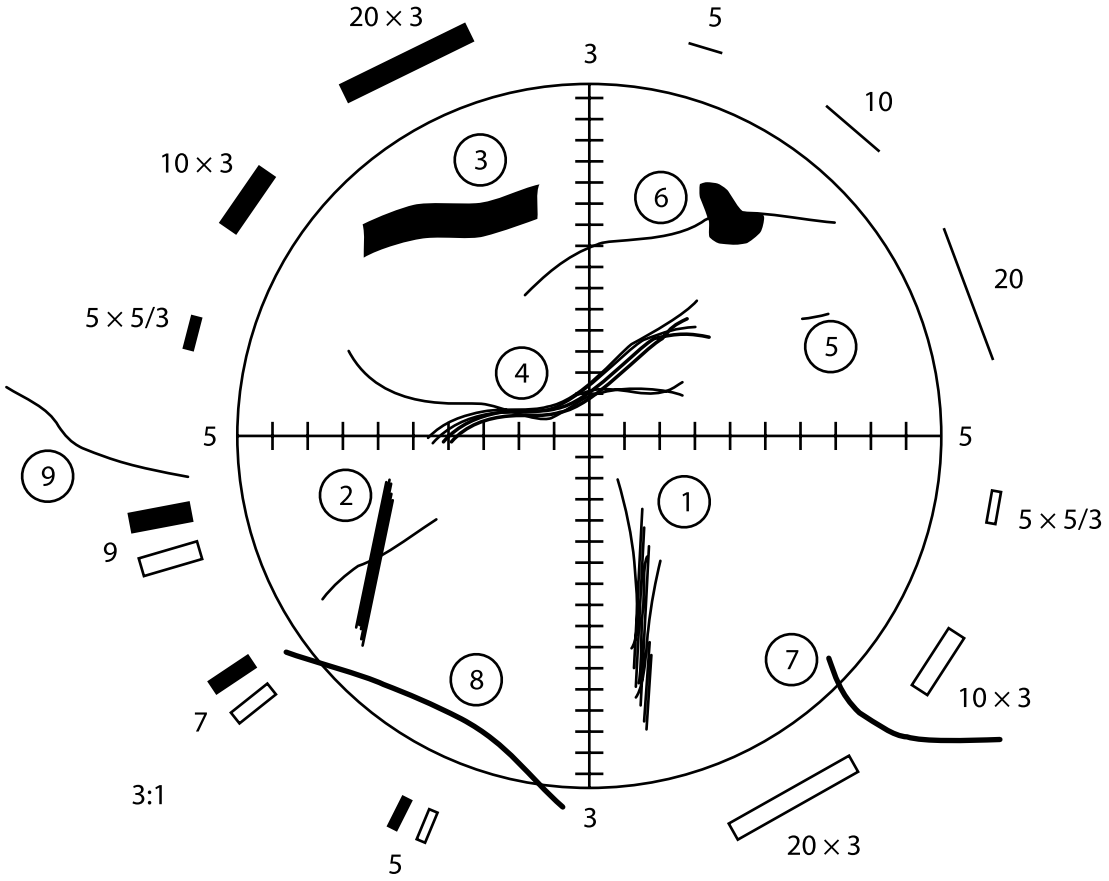

Figure 2. Walton-Beckett graticule with fibers.

These rules are sometimes referred to as the "A" rules:

Object	Count	Discussion
1	1 fiber	Optically observable asbestos fibers are actually bundles of fine fibrils. If the fibrils seem to be from the same bundle, the object is counted as a single fiber. Note, however, that all objects meeting length and aspect ratio criteria are counted whether or not they appear to be asbestos.
2	2 fibers	If fibers meeting the length and aspect ratio criteria (length >5 µm and length-to-width ratio > 3 to 1) overlap, but do not seem to be part of the same bundle, they are counted as separate fibers.
3	1 fiber	Although the object has a relatively large diameter (>3 µm), it is counted as fiber under the rules. There is no upper limit on the fiber diameter in the counting rules. Note that fiber width is measured at the widest compact section of the object.
4	1 fiber	Although long fine fibrils may extend from the body of a fiber, these fibrils are considered part of the fiber if they seem to have originally been part of the bundle.
5	Do not count	If the object is ≤ 5 µm long, it is not counted.
6	1 fiber	A fiber partially obscured by a particle is counted as one fiber. If the fiber ends emanating from a particle do not seem to be from the same fiber and each end meets the length and aspect ratio criteria, they are counted as separate fibers.
7	½ fiber	A fiber which crosses into the graticule area one time is counted as ½ fiber.
8	Do not count	Ignore fibers that cross the graticulate boundary more than once.
9	Do not count	Ignore fibers that lie outside the graticule boundary.

APPENDIX C. ALTERNATE COUNTING RULES FOR NON-ASBESTOS FIBERS

Other counting rules may be more appropriate for measurement of specific non-asbestos fiber types, such as fibrous glass. These include the "B" rules given below (from NIOSH Method 7400, Revision #2, dated 8/15/87), the World Health Organization reference method for man-made mineral fiber [24], and the NIOSH fibrous glass criteria document method [25]. The upper diameter limit in these methods prevents measurements of non-thoracic fibers. It is important to note that the aspect ratio limits included in these methods vary. NIOSH recommends the use of the 3:1 aspect ratio in counting fibers.

It is emphasized that hybridization of different sets of counting rules is not permitted. Report specifically which set of counting rules are used with the analytical results.

"B" Counting Rules

1. Count only *ends* of fibers. Each fiber must be longer than 5 µm and less than 3 µm diameter.
2. Count only ends of fibers with a length-to-width ratio equal to or greater than 5:1.
3. Count each fiber end which falls within the graticule area as one end, provided that the fiber meets rules 1 and 2 above. Add split ends to the count as appropriate if the split fiber segment also meets the criteria of rules 1 and 2 above.
4. Count visibly free ends which meet rules 1 and 2 above when the fiber appears to be attached to another particle, regardless of the size of the other particle. Count the end of a fiber obscured by another particle if the particle covering the fiber end is less than 3 µm in diameter.

5. Count free ends of fibers emanating from large clumps and bundles up to a maximum of 10 ends (5 fibers), provided that each segment meets rules 1 and 2 above.
6. Count enough graticule fields to yield 200 ends. Count a minimum of 20 graticule fields. Stop at 100 graticule fields, regardless of count.
7. Divide total end count by 2 to yield fiber count.

APPENDIX D. EQUIVALENT LIMITS OF DETECTION AND QUANTITATION

	Fiber density on filter*		Fiber concentration in air, f/cc	
	Fibers per 100 fields	Fibers/mm^2	400-L air sample	1000-L air sample
	200	255	0.25	0.10
	100	127	0.125	0.05
LOQ	80.0	102	0.10	0.04
	50	64	0.0625	0.025
	25	32	0.03	0.0125
	20	25	0.025	0.010
	10	12.7	0.0125	0.005
	8	10.2	0.010	0.004
LOD	5.5	7	0.00675	0.0027

*Assumes 385 mm^2 effective filter collection area, and field area = 0.00785 mm^2, for relatively "clean" (little particulate aside from fibers) filters.