Remedial Action Plan

Redwood Road Dump Pilot Phase Development: VCP Site C121

Approximately 1850 West Indiana Avenue

Salt Lake City, Salt Lake County, Utah

June 21, 2023

Terracon Project No. 61227342_2

Prepared for:

Salt Lake City Corporation

Salt Lake City, Utah

Prepared by:

Terracon Consultants, Inc.

Midvale, Utah

June 21, 2023

Utah Department of Environmental Quality
Division of Environmental Response and Remediation
195 North 1950 West
Salt Lake City, Utah 84116

Attn: Mr. Chris Howell
P: (801) 536-4092
E: cjhowell@utah.gov

Re: Remedial Action Plan
Redwood Road Dump VCP Site C121
Approximately 1850 West Indiana Avenue, Salt Lake City, Utah
Terracon Project No. 61227342

Dear Mr. Howell:

Terracon Consultants, Inc. (Terracon), has prepared this Remedial Action Plan to address environmental impacts identified at the Site referenced above. Terracon prepared the RAP on behalf of Salt Lake City Corporation to address redevelopment of the Site.

Should you have any questions or require additional information, please do not hesitate to contact our office.

Sincerely,
Terracon Consultants, Inc.

Nancy Saunders
Project Manager

Amy Austin
Authorized Project Reviewer

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APPENDICES

Appendix A

1.0 INTRODUCTION

Terracon Consultants, Inc. (Terracon), has prepared this Remedial Action Plan (RAP) at the request of Salt Lake City Corporation (SLCC) to address environmental impacts identified at the property located at 1850 West Indiana Avenue, Salt Lake City, Utah (**Exhibit 1; Appendix A**). The Site is an approximately 8-acre parcel of land within an approximately 45-acre parcel owned by SLCC. The property was enrolled into the Voluntary Cleanup Program (VCP) to address the environmental impacts prior to redevelopment of the Site. The VCP is implemented by the Utah Department of Environmental Quality (UDEQ) Division of Environmental Response and Remediation (DERR) for the UDEQ. The Site has been issued VCP Site ID C121.

1.1 Proposed Redevelopment of the Site

SLCC seeks to redevelop the property as a tiny home development to serve the City's unsheltered population. This would consist of numerous tiny homes, a medical clinic, and two public buildings. SLCC plans to lease the property to The Other Side Academy (TOSA), who will construct and operate the Tiny Homes Village (TOSV). The proposed development plan is shown on **Exhibit 2**.

1.2 Background

The Site is identified as parcel No. 15101010010000, and addressed as 1850 West Indiana Avenue, Salt Lake City, Utah, and consists of 8.057 acres. It was formerly included in a larger parent parcel of approximately 45 acres (the parent parcel). The Site is undeveloped land, with the exception of a 160 ft by 160 ft asphalt pad at the south end of the property used by SLCC as part of their green waste processing operation. The legal description provided by the Salt Lake County Assessor is presented on **Exhibit 3**.

The Site is located to the east of the Redwood Road Dump Comprehensive Environmental Response, Compensation, and Liability Act (CERCLIS) facility (Facility ID UTD980961502), an historical municipal landfill that accepted waste from 1923 to 1962. The CERCLIS facility boundaries are approximately 1800 West to 2200 West and 500 South to Indiana Avenue. In the late 1970s, the landfill was bisected by the construction of Interstate 215 (I-215), creating a West Pile and an East Pile. **Exhibit 4** shows the East and West Piles and the VCP Site boundaries. Since the development of I-215, Salt Lake City has used portions of the East Pile and surrounding land for processing green waste; however, municipal dumping stopped in the 1960s.

1.3 Public Notice

Public Notice is required prior to conducting remedial work at the Site. The Public Notice will be published for two consecutive days in the local newspaper and mailed and/or hand-delivered to

adjacent landowners and will provide 30 calendar days for public comments to be submitted. A copy of the Public Notice is provided in **Appendix B**.

2.0 ENVIRONMENTAL ASSESSMENT

2.1 Site Investigations

From 2021 through 2022, Terracon, on behalf of The Other Side Academy (TOSA), investigated the Site and the larger 45-acre parent parcel to evaluate potential impacts that could affect development of a proposed tiny home village. Documents detailing these investigations have been submitted to the DERR and are contained in the Administrative Record. The locations of samples that have been collected within or near the boundaries of the Site during these investigations are shown on **Exhibit 5**.

Most recently, Terracon completed a Site Characterization study and subsequent Supplemental Site Characterization study on behalf of SLCC as part of the VCP process. The results of these investigations are presented in the Site Characterization Report (March 9, 2023) and Supplemental Site Characterization Report (June 5, 2023).

2.1.1 Previous Investigations

The Redwood Road Dump CERCLIS facility has been investigated by the DERR or its predecessor, Bureau of Solid and Hazardous Waste (BSHW). In addition, a study was conducted in 1977 by Dr. David W. Eckhoff on behalf of the Utah Department of Transportation (UDOT), prior to the construction of I-215. A limited number of samples were collected for these various investigations. Only one groundwater sample point, monitoring well MW-06, and one soil sample, both located at the southeast corner of the Site, are located within the VCP Site area.

These studies identified concentrations of benzo(a)pyrene above regulatory screening levels in non-native soils on the West Pile and arsenic in groundwater at concentrations above the Environmental Protection Agency (EPA) Maximum Contaminant Level (MCL) in wells located on the parent parcel. Well MW-06, located at the southeast corner of the VCP Site area and considered a “background” well, reported an arsenic concentration of 0.012 milligrams per liter (mg/L), just above the MCL of 0.010 mg/L. The soil sample RD-SO-02, considered a background location for soil, reported arsenic at 10.8 milligrams per kilogram (mg/kg).

In 2018 the EPA issued a No Further Action (NFA) designation for the parent parcel. The decision rationale was the lack of on-site residents, schools, or daycares located within 200 feet of the property; the lack of downgradient wells used for drinking water within four miles of the property, and downgradient contaminants in surface water and sediments could not be attributed to the landfill due to potential upstream sources of contamination. The NFA decision is appropriate for

the historical landfill areas. The VCP Site is being addressed separately since municipal landfilling was limited to the western portion of the parent parcel and did not occur within the Site boundaries.

2.2 Summary of Site Impacts

Terracon has completed three investigations on the VCP Site and two additional investigations that included the VCP Site area as well as the parent parcel. Native soils and non-native fill materials were analyzed for semi-volatile organic compounds (SVOCs), including polycyclic aromatic hydrocarbons (PAHs), volatile organic compounds (VOCs), RCRA 8 Metals (arsenic, barium, cadmium, chromium, lead, mercury, nickel, and silver), pesticides, polychlorinated biphenols (PCBs), and dioxins. Groundwater samples were analyzed for SVOCs, including PAHs and 1,4-Dioxane, VOCs, RCRA 8 Metals, hexavalent chromium, pesticides, PCBs, and Per and Polyfluorinated Substances (PFAS). Soil gas samples were analyzed for VOCs and methane.

Results for soil and fill samples were compared to the Environmental Protection Agency (EPA) Regional Screening Levels (RSLs), with the exception of arsenic. Arsenic concentrations were compared to the site-specific background concentration established by UDEQ of 10.8 milligrams per kilogram (mg/kg) in their 1991 investigation. Groundwater sample results were compared to EPA MCLs where established or Tap Water Screening Levels if MCLs are not available. Soil gas samples were compared to EPA Vapor Intrusion Screening Levels (VISLs).

2.3 Contaminants of Concern and Cleanup Levels

The following contaminants of concern (COC) have been identified at the VCP Site based on their presence above EPA and UDEQ cleanup levels. The cleanup level for each COC is included in the table.

Contaminant of Concern	Affected Media	Cleanup Level
Benzo(a)pyrene	Fill	0.11 mg/kg [1]
Arsenic	Fill	10.8 mg/kg [2]
Cadmium	Fill	7.1 mg/kg [1]
Arsenic	Native Soil	10.8 mg/kg [2]
Arsenic	Groundwater	0.010 mg/L [3]
Hexavalent chromium	Groundwater	0.0000035 mg/L [4]
1,4-dioxane	Groundwater	0.00046 mg/L [4]
Perfluorooctanesulfonic acid (PFOS)	Groundwater	40 ng/L [4]
Perfluorooctanoic acid (PFOA)	Groundwater	60 ng/L [4]
Chloroform	Soil Gas	4.07 µg/m^3 [5]

1 EPA's May 2023 Regional Screening Levels (RSLs) for residential soil using a Target Cancer Risk of one in a million and a non-cancer Hazard Quotient of 1.
2 Utah DEQ Background Concentration.
3 EPA's May 2023 Maximum Contaminant Level for Drinking Water.
4 EPA's May 2023 Tap Water Screening Level for Drinking Water.
5 Target Soil Gas Concentrations (TSGC)=U.S. Environmental Protection Agency's (EPA's) Vapor Intrusion Screening Levels (VISLs) for Target Indoor Air Concentration using Target Cancer Risk=1E-06. Hazard Quotient=1; downloaded from the EPA's Vapor Intrusion Screening Level Calculator website 01/19/2023.

Although not identified at the Site, methane is a common product of decomposition of organic matter at landfill sites. Soil gas sampling targeting methane has been conducted within the Site boundaries and surrounding area to evaluate its potential as a contaminant. The EPA has not established a Vapor Intrusion Screening Level (VISL) for methane but the general industry practice is to use an action level of 5 percent of the Lower Explosive Limit (LEL), due to its explosive characteristic. The LEL for methane is 5 percent, which is equivalent to 50,000 parts per million by volume (ppmv). Therefore, an action of 5 percent of 50,000 ppmv is 2,500 ppmv. As a precaution, methane will remain a potential concern at the site. The proposed remedy to address its potential presence, along with chloroform, the other soil gas contaminant identified at the Site, is a vapor intrusion mitigation system, described in Section 4.2.

The sections below provide a summary of the impacts identified at the Site where a contaminant exceeded an applicable screening level.

2.3.1 Non-Native Fill Material

The results of investigations reported the presence of non-native fill material over much of the parent parcel and over approximately one-half of the VCP Site. **Exhibit 6** shows an estimate of the areal extent and depth of fill within the Site. The fill has been observed to consist primarily of silts, combined with limited amounts of green waste, and sporadically with construction waste such as concrete and brick fragments. In an area of approximately 0.4 acres along the northeast Site boundary, observations indicated debris from the east-adjoining Alvie Carter Trust property

encroached onto Salt Lake City property. In this location, fill material contained debris that included lumber, concrete, brick, melted plastic, and metal, to a depth ranging from approximately 1 to 3.5 feet. Although most of this material has been removed, a portion of it remains onsite.

Non-native fill material sampled during the Site Characterization reported the presence of the PAH benzo(a)pyrene in three locations at concentrations above the Residential RSL of 0.11 mg/kg: TP-36 in the approximate center of the Site (0.134 mg/kg), TP-40 on the east side of the Site (0.47 mg/kg), and from shallow materials (0-6 inches from the surface) collected from TP-37, just north of the asphalt pad.

Cadmium was reported in two fill samples at the Site at concentrations above the Residential RSL of 7.1 mg/kg: TP-138 (13.6 mg/kg) and TP-140 (8.42 mg/kg). These were duplicate Quality Assurance/Quality Control (QA/QC) samples collected from test pits TP-38 and TP-40, respectively, and the presence of cadmium in the duplicate samples indicates it is likely present in the non-native fill materials in exceedance of the Residential RSL at these locations.

Arsenic was reported in fill samples at concentrations above the UDEQ established background concentration of 10.8 mg/kg at TP-33 (13.2 mg/kg), TP-138 (blind duplicate of TP-38 {15.9 mg/kg}), TP-140 (blind duplicate of TP-40 {12.2 mg/kg}) and TP-42 (15.1 mg/kg). **Exhibit 7** shows the locations where a screening level was exceeded in fill.

Subsequent samples collected during the Supplemental Site Characterization defined the extent of impacted fill material in these locations, with the exception of TP-36, TP-37, and TP-40. In addition, a blind duplicate sample, TP-142E-10, reported benzo(a)pyrene above the screening level. The extent of impacts at TP-36, TP-37, TP-40 and TP-42E will be determined by collecting confirmation samples during excavation and is discussed in further detail in Section 4.1.1.

2.3.2 Native Soil

Samples collected from native soil beneath non-native fill materials at the Site have not reported concentrations of contaminants above cleanup levels except for arsenic. Arsenic was reported above the background level of 10.8 mg/kg in native soils in TP-40 (20.9 mg/kg) in the Alvie Carter Trust area, and in the samples collected from the North Ditch, ND-4 (18.1 mg/kg) and ND-5 (13.3 mg/kg), as shown on **Exhibit 7**.

2.3.3 Groundwater

Dissolved arsenic was reported in all five monitoring wells installed at the Site at concentrations above the EPA MCL of 0.01 mg/L. The compound 1,4-dioxane was detected in two of the wells from the Site at concentrations above the EPA Tap Water Screening Level of 0.00046 mg/L: TOSA MW01 (0.00198 ug/L) and TOSA MW03 (0.000872 ug/L). Several PFAS compounds were reported in samples from all five wells. Of these compounds, Perfluorooctanoic acid (PFOA) and Perfluorooctanesulfonic acid (PFOS) exceeded the EPA Tap Water Screening Levels of 60

nanograms per liter (ng/L) and 40 ng/L, respectively. Hexavalent chromium was reported in TOSA MW01 at 0.000207 mg/L, which is above the EPA Tap Water Screening Level of 0.0000035 mg/L. **Exhibits 8, 9, 10**, and **11** show where contaminants in groundwater exceed a screening level.

2.3.4 Soil Gas

Chloroform was reported in the soil gas samples SG-8 and SG-9 at 8.4 and 73 micrograms per cubic meter (ug/m^3), respectively. These concentrations exceed the EPA VISL of 4.07 ug/m^3 for Residential properties. In addition, the sample from SG-9 exceeded the VISL of 17.8 mg/m^3 for Commercial properties. **Exhibit 12** shows the locations of the soil gas samples that exceed a screening level.

Methane in soil gas has been evaluated in previous investigations. EPA has not established a VISL for methane; however, the Lower Explosive Limit (LEL) is used to evaluate the physical hazard posed by methane, due to its explosive characteristic. The LEL for methane is 5 percent which is equivalent to 50,000 parts per million by volume (ppmv). The soil gas sample from SG-3, collected approximately 60 feet west of the VCP Site area, reported a methane concentration of 23,000 ppmv which is approximately one half of the LEL. Methane has not been detected above laboratory detection limits in soil gas samples within the Site; however, as noted in Section 2.3, due to its explosive characteristic, methane is considered a potential concern as a precaution.

2.4 Site Conceptual Model

Using data obtained from the previous investigations discussed above, Terracon developed a Conceptual Site Model (CSM), to evaluate the site-specific risks associated with the COCs at the Site based on the source(s) of contamination, the release mechanism(s), potential routes of exposure (ROE), representative concentrations of contaminants of concern (COC), and receptors (i.e., property occupants and employees of the social enterprises and medical facilities). A graphical representation of the CSM is presented as **Exhibit 13** (**Appendix A**). Screening levels used for the evaluation are discussed above in Section 2.3.

2.4.1 Sources and Affected Media

Sources of contamination are the impacted fill material, the native soils along the north ditch with elevated arsenic levels, groundwater, and soil gas. Contaminants in fill material apparently originated offsite and were transported to the site with the fill material. The arsenic that is present above background levels in the native soils along the north ditch presumably originated in the runoff from the north ditch. Groundwater impacts are presumed to have migrated from offsite sources, specifically the adjacent landfill as well as unspecified surrounding industrial properties. Soil gas impacts appear to be limited to chloroform. It is likely chloroform is generated when chlorinated water comes in contact with organic materials. Chlorinated water could be leaking from the sewer line that trends along the western site boundary or other culinary or sewer lines in the vicinity.

2.4.2 Routes of Exposure and Receptors

The proposed future development will bring construction workers to the Site as well as future residents and clients of the proposed onsite service providers. The following routes of exposure were evaluated to identify if complete pathways for construction workers, future residents, and future employees and clients exist at the Site.

Soil Routes of Exposure: Ingestion, inhalation of dust particulates, and dermal contact with soil are the routes of exposure that may exist. Construction workers could be exposed during site preparations such as grubbing and grading and excavations for utilities. As long as areas of impacted fill and native soils remain on the Site this is considered a complete exposure pathway. As impacted fill and arsenic-impacted native soils will be removed during this phase, future use of the Site will not present an exposure pathway for either commercial users or residents. As such, exposure via soils and fill is not a complete exposure pathway in future use scenarios.

Groundwater Routes of Exposure: Ingestion and dermal contact are the routes of exposure considered for the construction worker scenario. If groundwater is encountered during development and dewatering is necessary to proceed with construction, this exposure pathway would be complete. Once the development is finished, institutional controls will be employed to prevent future residents and commercial users from accessing groundwater. This interrupts the groundwater exposure pathway for future users.

Soil Vapor Routes of Exposure: Chloroform has been detected in soil gas samples at the Site at concentrations that exceed residential screening levels, and in one case, the commercial screening level. Soil gas is a concern in enclosed spaces and as such, there is no exposure pathway for the construction worker. The RAP includes the use of vapor intrusion mitigation controls beneath occupied buildings. This engineering control will prevent a complete exposure pathway for future users of the Site.

3.0 REMEDIAL ACTION PLAN OBJECTIVE

The overall objective of the RAP is to remove or control the potential exposure risks posed by the presence of benzo(a)pyrene, arsenic and cadmium in fill materials and arsenic in native soils, control exposure to groundwater, and mitigate chloroform in soil gas as the Site is developed for residential and commercial use.

The remedial action plan designed for the Site will consist of the following components:

- Excavation, removal, and proper disposal of debris identified on the east side of the property originating from the adjoining property (Alvie Carter Trust property).
- Removal of non-native fill material and native soils exceeding Residential RSLs for benzo(a)pyrene and cadmium and the background concentration for arsenic.
- Vapor intrusion mitigation for all residential and commercial structures.

- Evaluation of stormwater run-off as well as debris and sediment transfer originating from the east-adjoining property.
- Implementation of institutional and engineering controls to limit exposure and manage any impacts remaining on the Site post remediation.
- Implementation of a groundwater monitoring program to continue evaluation of groundwater impacts reported at the Site.

These combined components will ensure the safety of construction workers during development and prevent exposure to future residents from the existing impacts reported at the Site as well as from potential hazards from surrounding industrial properties that may impact the Site in the future.

4.0 REMEDIAL APPROACH

The following sections detail the implementation of the remedial approach designed for the Site.

4.1 Fill Material and Soil Excavation Procedures

The proposed development plan requires removal of all non-native fill material from beneath buildings, roadways, and parking lots, as it does not meet geotechnical requirements for development. Fill material and soils exceeding a cleanup level will be excavated and transported to a properly permitted facility for disposal. Excavation and removal of impacted materials will be performed prior to transferring non-impacted fill to the west-adjoining property. Fill materials and soils that do not exceed a cleanup level will be excavated and stockpiled on the west-adjoining property owned by SLCC, with the permission of SLCC. As this procedure will not disturb the cap that has been placed on the historical dump, and the material qualifies for unrestricted use, the placement of non-impacted fill material at this location is appropriate.

4.1.1 Non-Native Fill Material: Exceeding Cleanup Levels

Six areas of fill material reporting exceedance of a COC have been identified as shown on **Exhibit 7**. The extent of impacts was defined in TP-33 and TP-38. These areas will be excavated to the total depth of fill and to the top of the native soil.

At the locations of TP-36, TP-37, TP-40, and TP-42, the extent of impacted fill was not fully defined in each cardinal direction. Where the impacted fill was defined by an analytical sample, excavation will proceed to that boundary. In the direction where a boundary was not defined and the previous wall sample failed, initial excavation will be stepped out an additional 5 feet in the direction of the wall that failed: TP 36 in the north direction, TP-37 in the east and south directions, and TP-42 in the east direction. At the location of TP-40, the samples failed in the north, east, and southeast directions. Samples could not be collected in the west direction due to standing water.

Exhibit 14 shows where the extent of impacts has been defined and the areas and directions where a wall sample failed, requiring excavation to step out farther in a particular direction. **Table 1** (**Appendix C**) lists the anticipated confirmation samples and corresponding sample analytes, as well as the samples that were already collected to define the extent of impacted fill. Note that the step-out distances shown in the table are estimates as the final step-out distance will be determined based on analytical results. The actual step-out distance for each sample will be recorded with the sample name.

Where the extent of impacts has not previously been defined and additional excavation is required, confirmation samples will be collected from those walls. A composite sample will be collected from the vertical profile of fill in each new wall of the excavation. If an extent of excavation sample reports a COC above a screening level, the excavation will proceed an additional 3 to 5 feet in the direction of the wall sample that failed. This process will be repeated until the extent of excavation wall samples do not report a concentration of a COC that exceeds a cleanup level.

When the excavations have been extended to the necessary dimensions to remove all impacted materials, confirmation samples will be collected from the floor of each excavation. Floor confirmation samples consisting of a 5-point composite sample will be collected at a rate of one sample not-to-exceed 2,500 square feet. The samples will be submitted for analysis of the contaminants associated with that test pit, as shown in **Table 1.**

4.1.2 Native Soils: Exceeding Arsenic Background Concentration

Soil samples collected along the North Ditch reported arsenic at concentrations slightly elevated with respect to the background concentration of 10.8 mg/kg. The initial excavation will proceed by digging a swath that extends approximately 10 feet on each side of the ditch alignment to a depth of one foot below grade.

As the excavation of native soils along the North Ditch proceeds, confirmation samples will be collected along each wall of the excavation. Confirmation samples will consist of material collected from the vertical profile at a rate not to exceed one sample per 50 linear feet. The floor of the excavation will be sampled at a rate of one 5-point composite sample not-to-exceed 2,500 square feet.

If an extent of excavation sample reports a COC above a screening level, the excavation will proceed an additional 3 to 5 feet in the direction of the wall sample that failed and an additional 6-inches for the floor. This process will be repeated until the extent of excavation wall and floor samples do not report a concentration of a COC that exceeds a cleanup level.

4.1.3 Non-Native Fill Material: Below Cleanup Levels

Once excavation and removal of all fill and soil exceeding a screening level has been completed, fill material that did not report an exceedance of a screening level will be transferred to the west-adjoining parent parcel alongside the east and south sides of the historical dump.

To ensure the fill material transferred to the adjoining property meets the unrestricted land use screening levels, the material will be stockpiled on visqueen and composite samples will be collected for laboratory analysis. One 10-point composite sample will be collected from stockpiled fill at a rate not-to-exceed 10,000 cubic yards of material. Samples will be submitted for laboratory analyses for benzo(a)pyrene, cadmium, and arsenic.

4.1.4 Asphalt Pad Removal

Soils and fill material beneath the asphalt pad have not been evaluated. The asphalt pad will be removed during the excavation of impacted soils and a test pit will be excavated in the approximate center of the area. Two soil samples will be collected: one sample from surface soils to 12 inches below ground surface and one from 12 inches below the ground surface to the native soil interface. **Table 1** (**Appendix C**) lists the sample details.

4.1.5 Confirmation Sampling Analytical Program

Table 1 (**Appendix C**), details the proposed sampling strategy, selected analytes, and laboratory analytical methods. The sample analytes have been selected based on the COCs reported in the Site characterization investigations. Only those contaminants that have been reported above a cleanup level will be selected as analytes. Confirmation sampling will include collection of Quality Control samples in accordance with the project Quality Assurance Project Plan (**QAPP, Appendix D**) and submitted to the analytical laboratory requesting a Level 3 or equivalent data package including a case narrative.

4.2 Vapor Intrusion Mitigation

Design of future Site structures will include standard industry practices and controls for mitigation of potential vapor intrusion and will be based on site-specific soil gas data. This may include either building design (such as thickened concrete slabs), elevated units that will not be in contact with the ground, or a passive vapor intrusion mitigation system (VIMS) installed below the floor slabs. If elevated units are constructed at the site, the space between the unit and the ground surface will remain open to ensure there is adequate ventilation and vapors do not accumulate beneath the structures.

The VIMS design will specify minimum standards such as vapor barrier material and thickness, type of venting materials, substrate bedding material, and utility penetration sealing methods and will be stamped by a Utah-licensed Professional Engineer. The VIMS will be installed according

to manufacturer's specifications by a qualified contractor and installation will be observed by a knowledgeable third party to verify adherence to the design.

The final vapor mitigation measures used at the Site and verification of installation by a qualified contractor will be documented in the Remediation Completion Report.

4.3 Prevention of Impacts to Site Via Stormwater Runoff, Debris, and Sediment Migration

The potential exists for new impacts to occur if stormwater, debris, and sediment, are allowed to migrate onto the Site from offsite sources. To prevent the migration of these media onto the Site, the final Site grade will be at an elevation that is equal to or higher than adjoining properties. Additionally, fencing will be utilized along the east and south property boundaries to assist with inhibiting migration of potentially impacted media.

4.4 Utility Installation

Impacts to groundwater have been documented at the site in the form of arsenic, 1,4-dioxane, hexavalent chromium, and PFAS compounds. In order to ensure these compounds do not enter the culinary water system during times of significant precipitation where the groundwater table is higher than normal, piping used for culinary water will be impervious to chemicals. This will likely consist of HDPE piping with welded joints. The specifications for the proposed piping will be included in the RAP implementation report.

4.5 Consideration of Groundwater Impacts

As impacts to groundwater have been documented, a groundwater monitoring plan will be implemented to establish seasonal groundwater trends over time and to confirm that institutional controls restricting access to groundwater will remain protective of residential land use. Details of the groundwater monitoring plan are outlined in Section 7.4.

Culinary water lines will be protected from infiltration of contaminants by the selection of impervious piping materials. An Environmental Covenant will prohibit access to groundwater.

5.0 QUALITY ASSURANCE/QUALITY CONTROL

Sampling will be conducted according to the Standard Operating Procedures (SOPs) provided in the QAPP (**Appendix D**). Quality control for the sampling program will include using standardized sample collection and handling methods, documenting pertinent field information, keeping chain-of-custody records, and collecting quality control samples (i.e., field duplicate samples and Agency split samples). For this sampling activity, field duplicate samples will be collected at a rate of 10 percent of the sample load. Agency split samples will be collected at the discretion of the VCP.

6.0 CONSTRUCTION MANAGEMENT

6.1 Site Access Control

The General Contractor will be required to maintain strict access control to and from the Site at all times. The boundaries of the entire Site are to be fenced and points of ingress and egress are to be designated and controlled.

Once development is complete, the temporary fencing will be replaced with permanent fencing along the eastern Site boundary and around the residential areas, as shown in **Exhibit 2**. This will restrict Site access to residents and authorized guests, in accordance with the development's stated objective of providing safe, supportive housing, as well as preventing access to the adjoining landfill.

6.2 Haul Roads and Equipment Decontamination

The initial phase of construction will consist of excavating impacted materials and disposing of them off-site at an approved facility. During excavation of impacted material, the entrance and exit points of the property where equipment and dump trucks will enter and leave the property will be constructed with a temporary gravel base and/or rip rap. The exit point will have a rumble strip to help remove soil from the equipment and dump trucks. For construction equipment (dump trucks, front-end loaders, track hoes, etc.), visible soil and debris will be brushed from the equipment prior to leaving the Site. Trucks hauling impacted soil and entering public roads will be tarped. For hand tools, visible soil and debris will be brushed from the tools prior to them leaving the Site. Equipment or tool washing, using either water or a water and mild detergent mixture, may be permitted if wash water controls have been established that will inhibit run-off of wash water and/or sediment from the decontamination area.

In the event soil track-out occurs, the streets will be swept using street cleaning equipment and/or hand tools. When possible, the area will be lightly wet before cleaning to reduce fugitive dust during sweeping activities. It is not anticipated that wash water controls will be required; however, if deemed necessary, the control measures will be developed and implemented in consultation with the DERR.

Once excavation of impacted material is complete, all subsequent activities can be conducted following general construction standards. Best management practices for eliminating track-out, fugitive dust emissions, and stormwater runoff will be maintained.

6.3 Special Training Requirements

Field personnel involved in the remediation activities will have up-to-date Occupational Safety and Health Administration (OSHA) 40-hour Hazardous Waste Operations and Emergency Response (HAZWOPER) training, including an up-to-date 8-hour refresher course as required by

OSHA. This will typically include equipment operators involved in removing impacted fill and soil and Terracon staff directing excavation activities and collecting confirmation samples. If groundwater is encountered during construction, workers involved in groundwater handling will also be required to have HAZWOPER training. Once impacted materials have been segregated and disposed of the HAZWOPER training requirement will no longer be applicable.

All site workers that could come into contact with impacted materials will receive training about the specific hazards of the contaminants of concern, and how to minimize exposures to those contaminants through the use of engineering controls, work practices, personal hygiene, and personal protective equipment. This information is intended to meet the requirements in the OSHA Hazard Communication Standard (29 CFR 1910.1200(h)(1) for training relative to new chemical hazards in their work area for which employees have not previously received training. All contractors on the site will be responsible for including the information in a site-specific health and safety plan and its implementation.

6.4 Storm Water Control and Fugitive Emissions

The General Contractor will be required to prepare a Storm Water Pollution Prevention Plan (SWPPP), as required by Salt Lake City's Stormwater Quality Program, and a Fugitive Dust Control Plan (FDCP), as required by UDEQ, Department of Air Quality (DAQ) prior to initiating excavation activities. Implementation of the FDCP will be monitored by Terracon to ensure that appropriate dust suppression measures are implemented during impacted soil removal and there is no visible dust leaving the Site.

6.5 Construction Dewatering

Construction dewatering may be required to facilitate site development needs. The General Contractor will obtain the necessary permits through UDEQ, Division of Water Quality (DWQ). The management of the water may include a lined evaporation pond placed at the southeast portion of the VCP Site. If construction dewatering plans include an onsite containment pond, a construction plan will be submitted separately to DWQ and SLCC for review and approval. All construction dewatering practices will be addressed in consultation with SLCC, DERR and DWQ prior to implementation.

6.6 Excavation Activities near Existing Sewer Line

A sanitary storm sewer line trends roughly south to north along the approximate western boundary of the VCP Site at a depth of approximately 16 feet below grade (**Exhibit 5**). Based on sample results, areas of impacted fill on the Site have not been identified within the buffer zone with the exception of TP-37. At this location, impacts were limited to the upper 6 inches of surface material and proposed shallow soil removal is not anticipated to affect the sewer line.

Non-impacted fill material is present within the 30-foot buffer zone, as shown on **Exhibit 6**. Excavation will be conducted in accordance with SLCC Public Utility Department requirements for working within the buffer zone.

7.0 SITE MANAGEMENT

7.1 Prevention of Migration of Contaminants from Off-site Sources

To diminish or prevent potential migration of surface water, debris, and sediment, originating from the east-adjoining industrial property, SLCC will evaluate the stormwater run-off and debris and sediment migration patterns from this property by conducting a visual inspection of the property. If the potential for migration onto the VCP Site is observed, action will be taken to divert or mitigate migration such as grading the eastern boundary of the Site to an elevation that is higher than or equal to the east-adjoining property. In addition, SLCC is evaluating storm water runoff practices in the vicinity and will enforce existing rules under the Utah Pollutant Discharge Elimination System (UPDES) to prevent the migration of chemicals onto the VCP Site.

7.2 Surface Water Management

Surface water has been observed at the Site during the spring months. If its presence impedes construction, it may be relocated to a different location within the VCP Site. Management of surface water will be performed in accordance with local and state regulations. In the event that a different engineering solution is desired, SLCC, TOSA, DERR, and DWQ will coordinate on a suitable alternative.

7.3 VIMS Inspections

If the installation of a passive VIMS is the remedy selected to address the potential for vapor intrusion into buildings, sub-slab work that is conducted once the VIMS is in place, such as repositioning of drains or other utilities, may damage the membrane component of the system. If this occurs, the membrane must be repaired according to manufacturer's specifications. Details of the required VIMS inspections and maintenance will be a component of the Site Management Plan.

7.4 Groundwater Monitoring Plan

Once development of the Site has been completed, a groundwater monitoring plan will be implemented. A network of four monitoring wells will be used to conduct sampling on a quarterly basis for two years to document concentrations of arsenic, hexavalent chromium, 1,4-dioxane, and PFAS compounds in at groundwater the Site, as well as the water level and direction of flow. The locations of the monitoring wells to be used will be developed in coordination with DERR. DWQ will be consulted on monitoring well placement if a water containment pond is constructed on the site (Construction Dewatering; Section 6.5).

After the initial eight quarters of sampling are completed, SLCC will review the stability of the groundwater contamination. Based on the findings, SLCC may petition the DERR to adjust the groundwater monitoring plan if groundwater conditions are stable and the remedial approach for groundwater is protective of the land use. The groundwater monitoring plan will be included as an attachment to the Site Management Plan.

8.0 CONTINGENCY PLANS

8.1 Encapsulation of Soils

It is the intent of the RAP that all impacted material be removed from the Site. However, in the event that removal of all impacted material is not practicable, SLCC will work with DERR to determine if the material can be encapsulated onsite. This will be accomplished by placing the material beneath hard scaping, such as asphalt or concrete, beneath at least 1.5 feet of clean fill, or creation of a repository. A geotextile or fabric marker barrier will be placed at the bottom of the repository and at the top of the impacted soil interval to delineate the boundaries. Repositories will be positioned such that the bottom of the impacted soil layer is above the seasonal high water level mark. The location and elevation of any repositories created at the Site will be documented in the Site Management Plan.

8.2 Segregation / Characterization of Previously Unidentified Potentially Contaminated Soil

If at any point during excavation of soils at the Site, suspect soils are encountered that have not been previously characterized they will be segregated and evaluated. Soils exhibiting evidence of impacts by visual, olfactory evidence and/or field screening results above 10 parts per million (ppm), as determined by headspace analysis techniques using a photoionization detector (PID), that was not previously identified will be excavated and stockpiled on impervious surface or polyethylene sheeting, covered with polyethylene sheeting at the end of each day, and characterized by laboratory analyses. Stockpiled suspect soil will be sampled at a frequency of one 5-point composite sample per 100 cubic yards of stockpiled soil.

The soil may be analyzed for one or more of the following parameters to characterize the impact and use in disposal characterization:

- VOCs by EPA Method 8260
- Total Petroleum Hydrocarbons (TPH) by EPA Method 8015 or 8260
- RCRA Metals by EPA Methods 6020 and 7471
- PAHs by EPA Method 8270

If impacted soils are encountered that report concentrations of contaminants above a cleanup level, samples may be collected at the extent of excavation to document concentrations of impacts

remaining in soils. If significant soil impacts are identified on-site, Terracon and the DERR may revise the Site's sampling design to further delineate impacted areas. If impacted soils are to be left in-place, the location of the impacted interval will be surveyed and included in the final report to document the location.

8.3 Potential Asbestos Containing Materials

Due to the proximity of the Site to the historical municipal landfill, the potential for the discovery of asbestos-containing materials (ACMs) during Site development exists. A Utah certified Asbestos Inspector will be on-site to visually observe for the presence of potential ACM from excavations that encounter municipal landfill debris. If potential ACM is observed, work will be halted in the area and DERR will be notified. All sampling and ACM abatement will be completed in compliance with the Division of Air Quality (DAQ) Asbestos rules.

8.4 Municipal Landfill Debris

Municipal landfill material, if encountered, will be removed from the Site. If required, to prevent odors emanating from the material prior to removal from the Site, clean cover material will be placed over the debris on a temporary basis.

8.5 Unidentified Environmental Concerns

In the event that unidentified environmental concerns are identified during excavation or other construction activities, work will stop in the area of the concern until SLCC, TOSA, Terracon, and regulatory agency personnel determine an appropriate course of action.

9.0 POST REMEDIATION DOCUMENTATION AND REPORTING

9.1 Remediation Completion Report

A Remediation Completion Report will be generated to document the remedial activities conducted at the Site. The report will document the location and results of all sampling conducted at the Site, the extent of excavations, the location of impacted materials remaining at the Site, if any, and the final disposition of any impacted soils removed from the Site. The report will include any deviations from the RAP. The report will also include a data quality discussion for all confirmation samples collected during the RAP implementation and will provide documentation of offsite material disposition, such as weigh tickets for materials disposed of at the landfill or an estimated volume of material transported to the west-adjoining landfill.

9.2 Environmental Covenant and Site Management Plan

The use of Institutional Controls and Engineering Controls will be used to restrict access to groundwater and any impacted material that may remain on Site. SLCC will enter into an

Environmental Covenant (EC) with the DERR that outlines the continuing obligations and activity and use limitations associated with any impacted material remaining at the Site.

The EC will reference a Site Management Plan (SMP) that will define any future Site management requirements which may include activity and use limitations, and/or site inspection and reporting requirements. The Site Management Plan will include guidance for inspection and maintenance of the VIMS systems and details of the groundwater monitoring program.

10.0 PROJECT SCHEDULE

Development of the Site is anticipated to commence July 2023. The initial phase will be removal of impacted material. Approximately one month has been set aside for this task. Grading and site preparations will begin after impacted material removal and are anticipated to take one and one-half months. Approximately eight months have been set aside for construction of the tiny homes, community facilities, and the retail and clinic buildings, bringing the final phase of construction to be completed in June 2024

Soil excavation and disposal activities will be documented in a report to be prepared within 60 days of completion of soil excavation activities. Documentation of vapor mitigation activities will be prepared in a separate report within 60 days of completion of building construction activities.

Building occupancy will be allowed after the remedial approaches are implemented and DERR verifies the site is safe for residential use.

11.0 REFERENCES

Eckhoff 1977, *Preliminary Investigations Disposition of Garbage Materials in Abandoned Landfill,* Dr. David W. Eckhoff, July 1977.

UDEQ 1992. *Analytical Results Report Redwood Road Dump*, Utah Department of Environmental Quality, Division of Environmental Response and Remediation, January 14, 1992.

UDEQ 1995. *Site Inspection Prioritization, Redwood Road Dump Site*, Utah Department of Environmental Quality, Division of Environmental Response and Remediation, September 28, 1995.

UDEQ 2011. *Site Re-Assessment (SRA) Report, Redwood Road Dump*, Utah Department of Environmental Quality, Division of Environmental Response and Remediation, July 11, 2011.

UDEQ 2017. *Expanded Site Investigation (ESI) Analytical Results Report (ARR), Redwood Road Dump*, Utah Department of Environmental Quality, Division of Environmental Response and Remediation, December 14, 2017.

Terracon 2021a. *Limited Site Investigation, Proposed TOSA Village on Indiana Avenue, 1850 West Indiana Avenue, Salt Lake City, Utah.* July 1, 2021.

Terracon 2021b. *Supplemental Limited Site Investigation, Proposed TOSA Village on Indiana Avenue, 1850 West Indiana Avenue, Salt Lake City, Utah.* August 26, 2021.

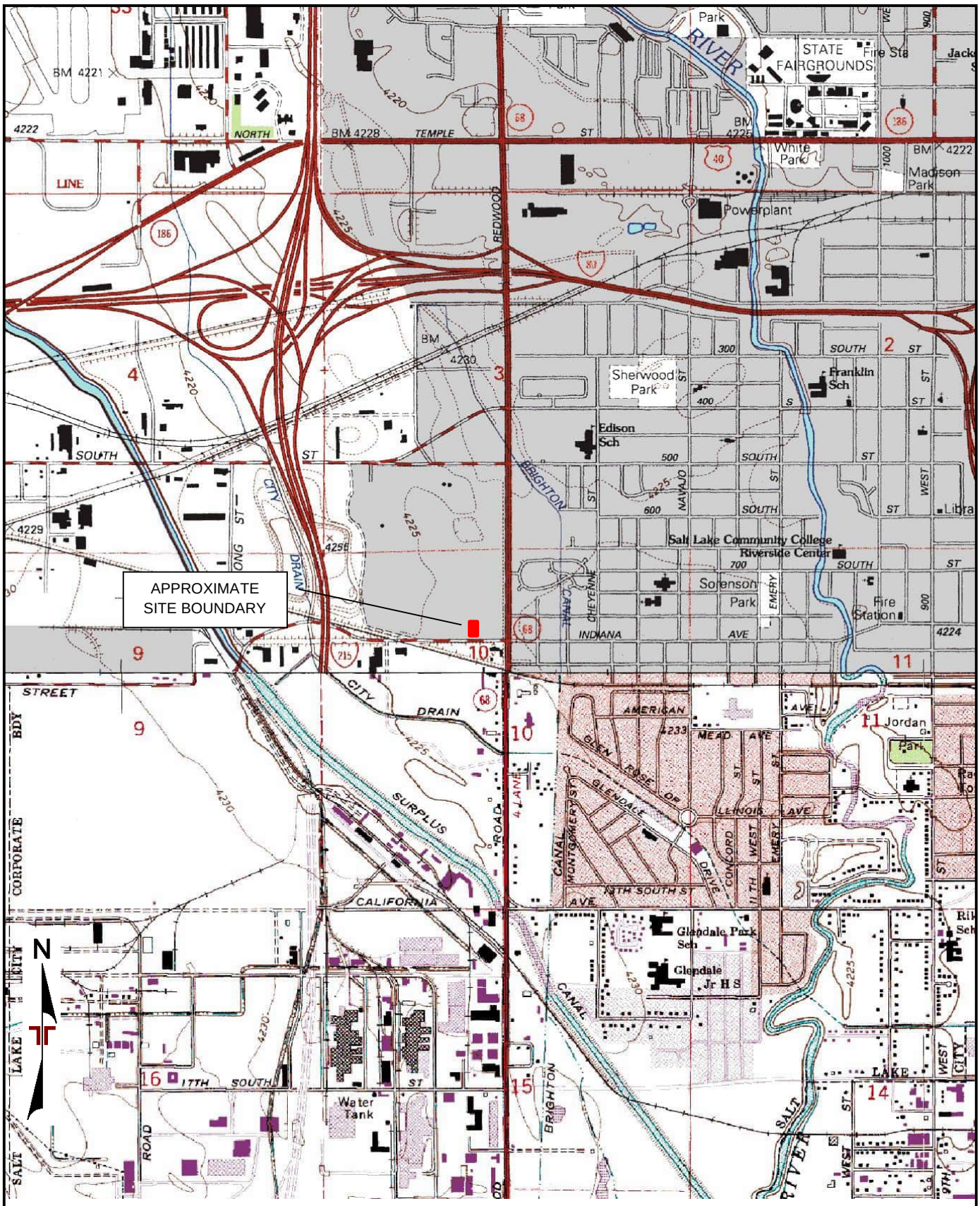
Terracon 2022. *Limited Site Investigation, Proposed TOSA Village Pilot Phase, 1850 West Indiana Avenue, Salt Lake City, Utah.* March 2, 2022.

Terracon 2023a. *Site Characterization Report, Redwood Road Dump Pilot Phase Development, VCP Site C121, 1850 West Indiana Avenue, Salt Lake City, Utah.* March 9, 2023.

Terracon 2023b. *Supplemental Site Characterization Report, Redwood Road Dump Pilot Phase Development, VCP Site C121, 1850 West Indiana Avenue, Salt Lake City, Utah.* March 30, 2023.

Utah Department of Environmental Quality, Division of Environmental Response and Remediation (DERR) 2022. *Voluntary Cleanup Program Remedial Action Plan Guidelines.*

APPENDIX A
Exhibits



TOPOGRAPHIC MAP IMAGE COURTESY OF THE U.S. GEOLOGICAL SURVEY
QUADRANGLES INCLUDE: SALT LAKE CITY NORTH, UT (1/1/1998) and SALT LAKE CITY SOUTH, UT (1/1/1999).

Project Manager:	NS
Drawn by:	NS
Checked by:	AA
Approved by:	AA

Project No.	61227342
Scale:	1"=2,000'
File Name:	Ex 1
Date:	9/22

Terracon
6949 S High Tech Dr Ste 100
Midvale, UT 84047-3707

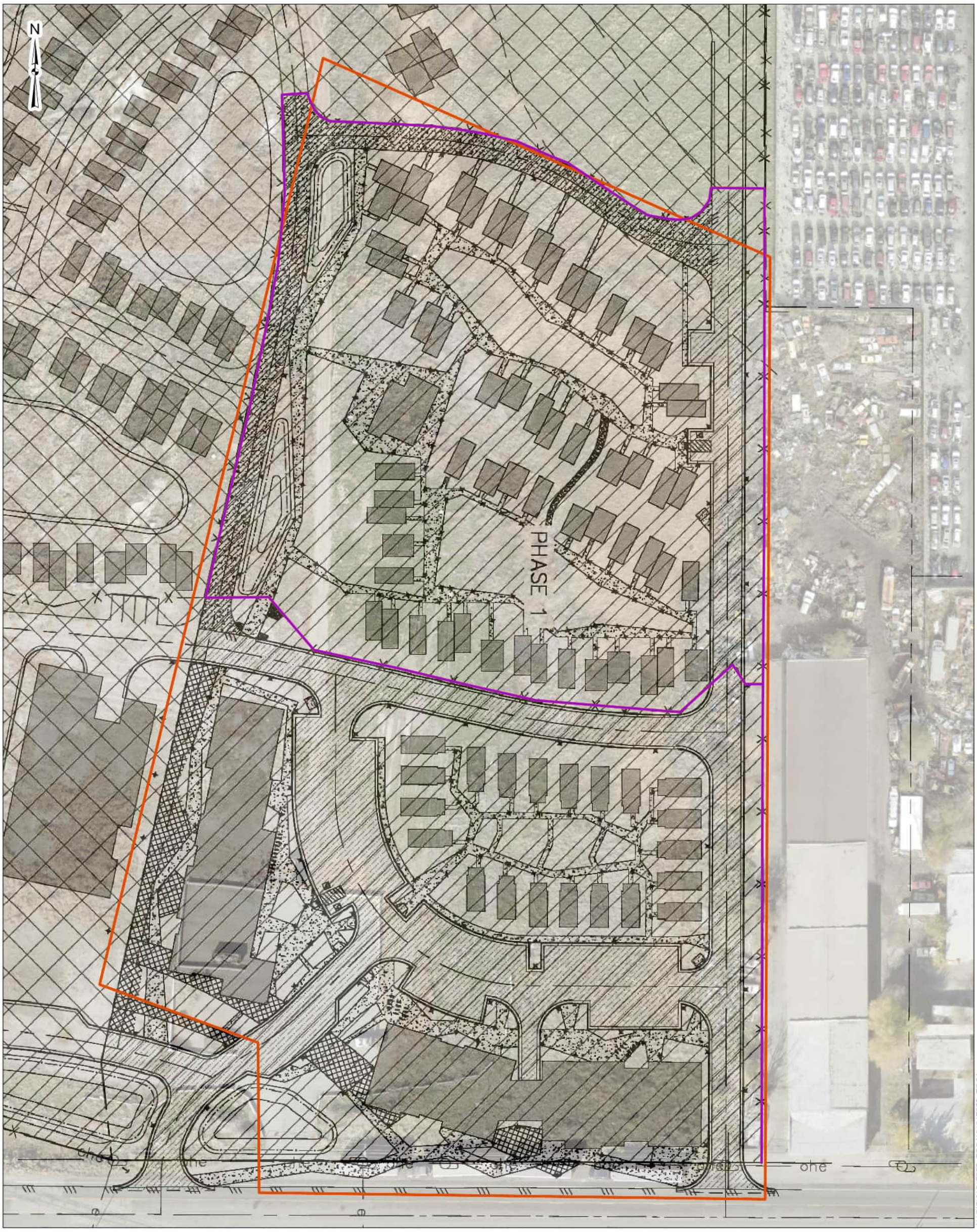
TOPOGRAPHIC MAP

Redwood Road Dump VCP Site C121

1850 West Indiana Avenue
Salt Lake City, UT

Exhibit

1



Project No.:	61227342
Date:	Apr 2023
Drawn By:	AST
Reviewed By:	NMS

Terracon
6949 S High Tech Dr
Midvale, UT
PH. 801-545-8500 terracon.com

Site Diagram with VCP Site Boundaries

Redwood Road Dump VCP Site C121
1850 West Indiana Avenue
Salt Lake City, Utah

Exhibit

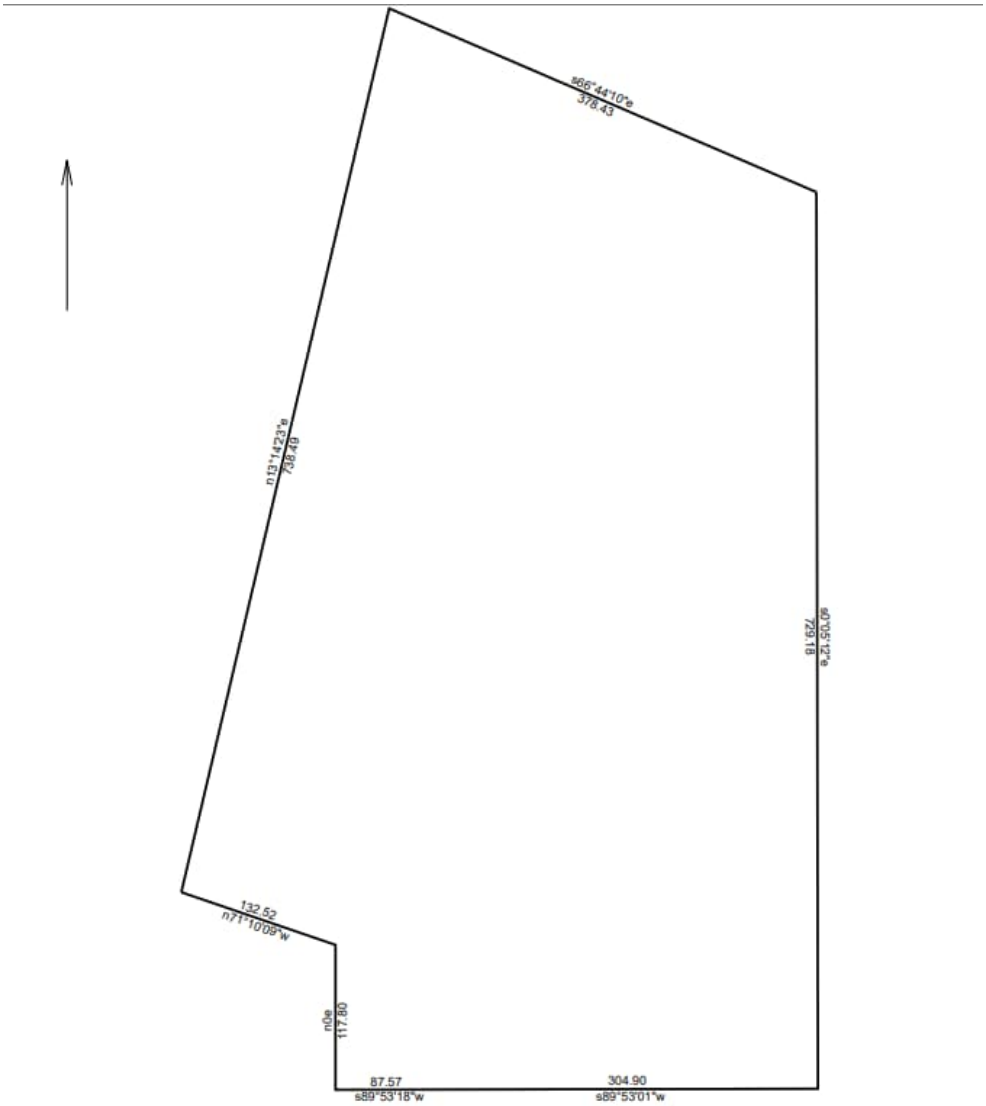
2

N:\GIS\61217255_TOSA\61217255_TOSA.aprx

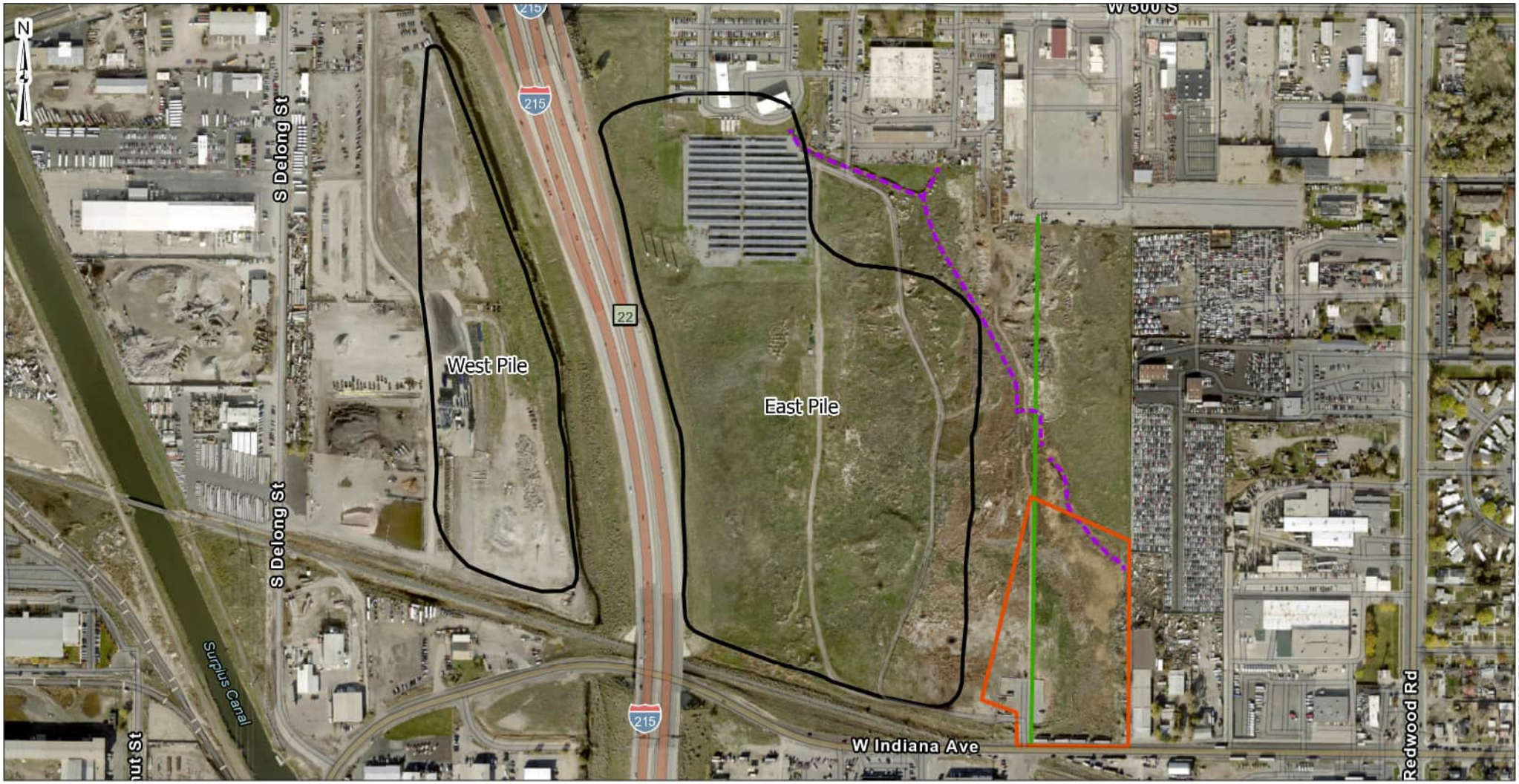
N

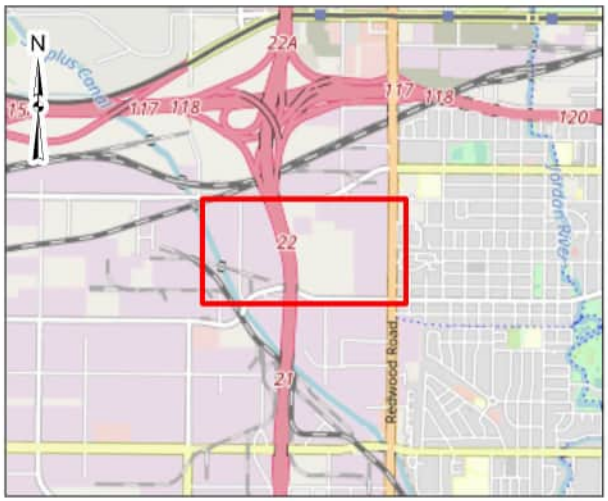
Redwood Road Dump VCP Site C121 Boundary Description

A property located in the Northwest Quarter of Section 10, Township I South, Range 1 West, Salt Lake Base and Meridian, more particularly described as follows: Beginning at a point located483.50 feet North 00°01’30” West along the west line of said Section 3, and 1651.04 feet North 89°52’50” East and South 00°05’12” East 1070.61 feet; Said point being the Point of Beginning from the Salt Lake County Survey monument found marking the southwest corner of said Section 3; thence South 00°05’12” East 729.18 feet to the northerly right-of-way line of Indiana Avenue; thence South 89°53’01” West 304.90 feet; thence South 89°53’18” West 87.57 feet, along said right-ofway line; thence North 00°00’00” East 117.80 feet; thence North 71°10’09” West 132.52 feet; thence North 13°14’23” East 738.49 feet; thence South 66°44’10” East 378.43 feet; to the Point of Beginning. Containing 8.057 acres.



Project Manager: ns	Project No. 61227342	Terracon 6949 S High Tech Dr Ste 100 Midvale, UT 84047-3707	LEGAL DESCRIPTION & SITE BOUNDARY Redwood Road Dump VCP Site C121 1850 West Indiana Avenue Salt Lake City, UT	Exhibit 3
Drawn by: ns	Scale: AS SHOWN			
Checked by: aa	File Name: Ex 3			
Approved by: aa	Date: 9/2022			





Sewer Line

Approximate North Ditch Alignment

VCP Site Boundary

Approximate CERCLIS landfilled area*

Feet

0 250 500 1,000

DATA SOURCES:
ESRI - Basemaps

* Boundaries of east and west landfill piles, as depicted in "Site Inspection Prioritization, Redwood Road Dump Site" UDEQ, 1995.

Project No.:	61227342
Date:	Jan 2023
Drawn By:	AST
Reviewed By:	NAS

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Midvale, UT
PH. 801-545-8500 terracon.com

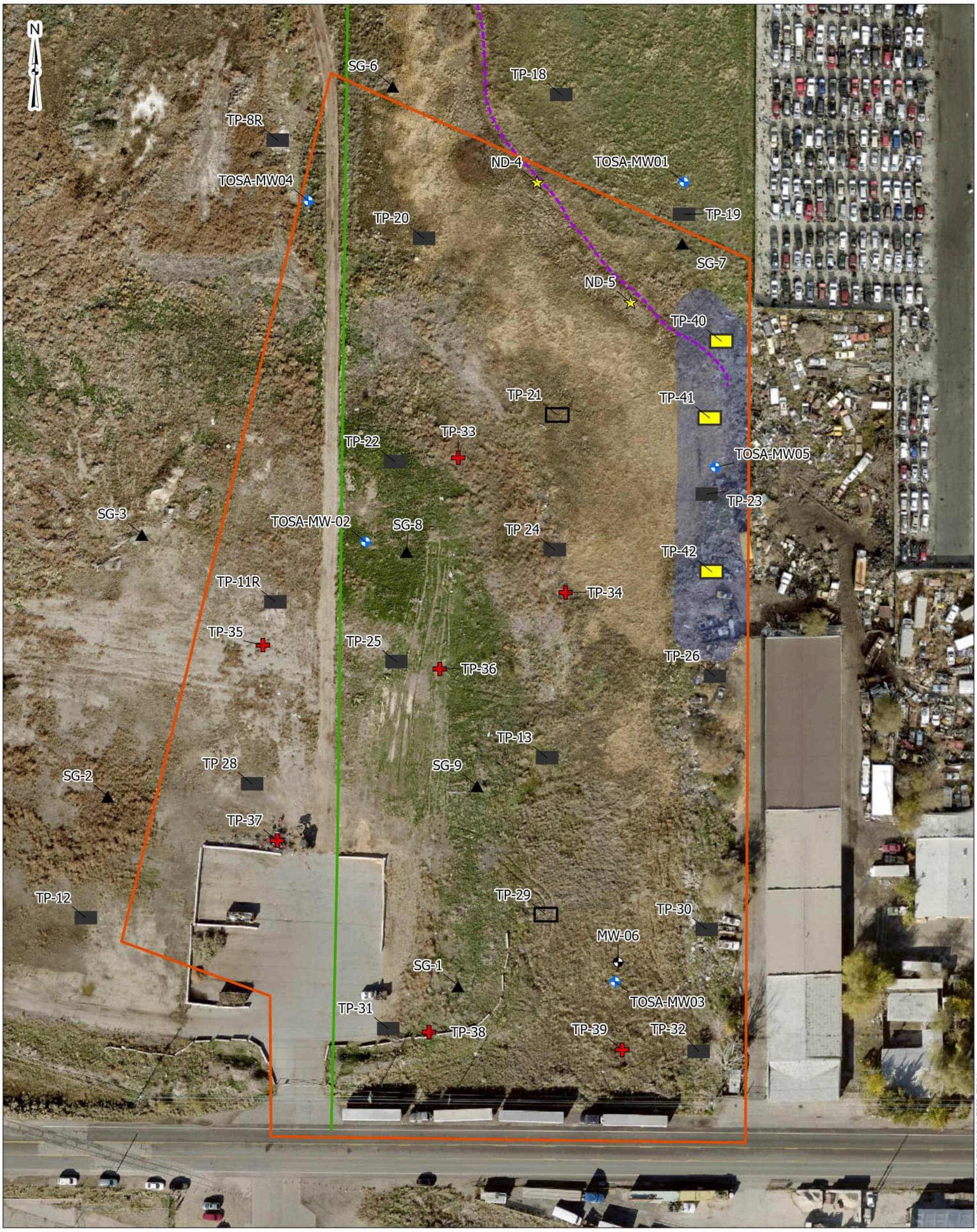
VCP Site and Dump Site Boundaries

Redwood Road Dump VCP Site C121

1850 West Indiana Avenue
Salt Lake City, Utah

Exhibit

4



VCP Site Boundary

Alvie Carter Trust (ACT) area and burn pit

Approximate North Ditch Alignment

Sewer Line

VCP Site Characterization Sample Location

Monitoring Well

Fill Sample

North Ditch Sample

Test Pit

Previous Sample Locations

Monitoring Well

Previous Investigation Test Pit

Test Pit for Observation Only

Previous Investigation Soil Gas Sample

Feet

0 50 100 200

Project No.:	61227342
Date:	Mar 2023
Drawn By:	AST
Reviewed By:	NMS

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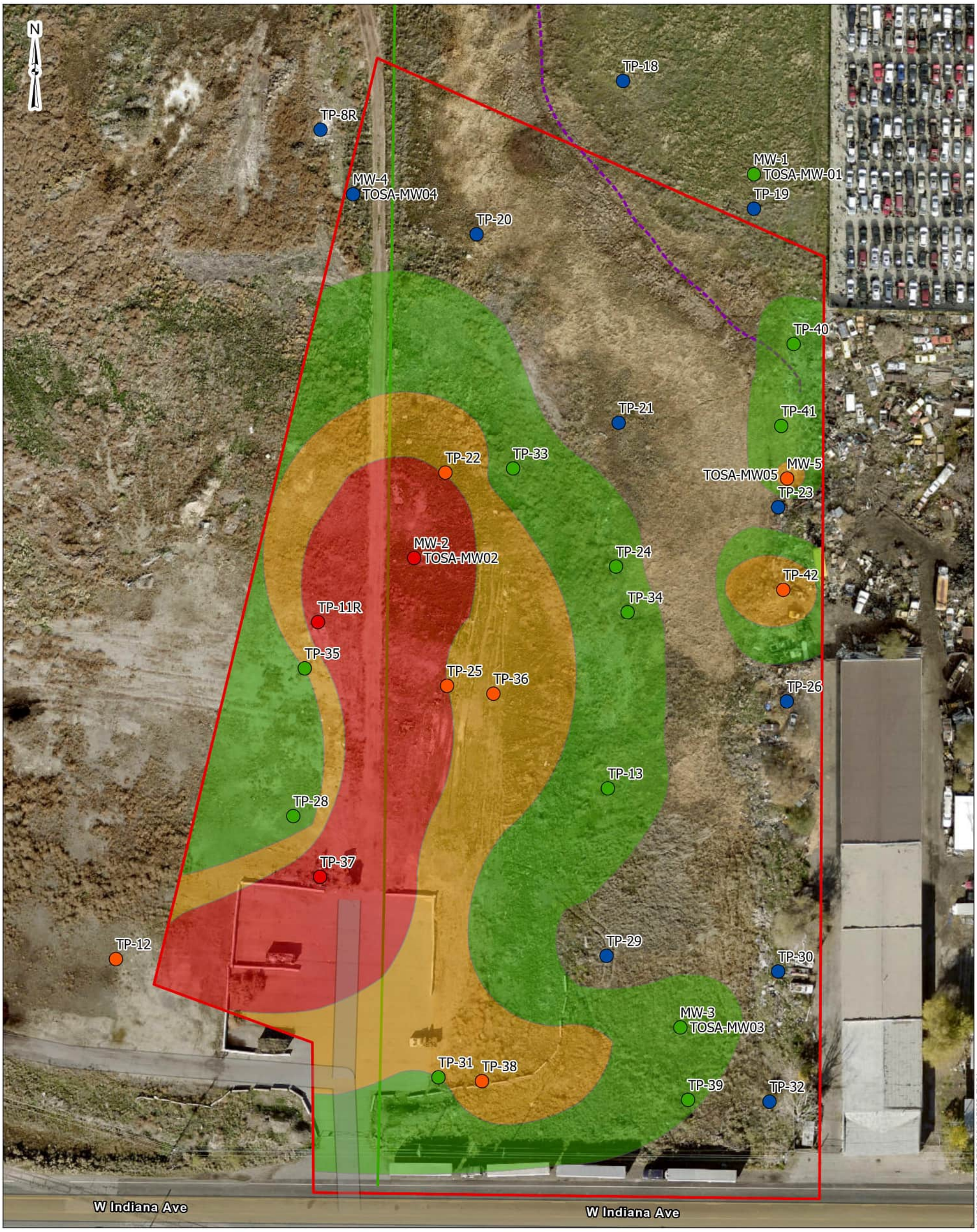
PH. 801-545-8500 terracon.com

Site Diagram with Sample Location and Site Features

Redwood Road Dump VCP Site C121
1850 West Indiana Avenue
Salt Lake City, Utah

Exhibit

5



VCP Site Boundary

Approximate North Ditch Alignment

Sewer Line

Sample Location with Fill Thickness (ft)

- No Fill Observed
- 1-3 ft
- 3-5 ft
- 5+ ft

Approximate Extent of Fill

- 1-3 ft
- 3-5 ft
- 5+ ft

Feet

0 50 100 200

Project No.:	61227342
Date:	Dec 2022
Drawn By:	AST
Reviewed By:	NMS

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Approximate Extent of Fill

Redwood Road Dump VCP Site C121

1850 West Indiana Avenue
Salt Lake City, Utah

Exhibit

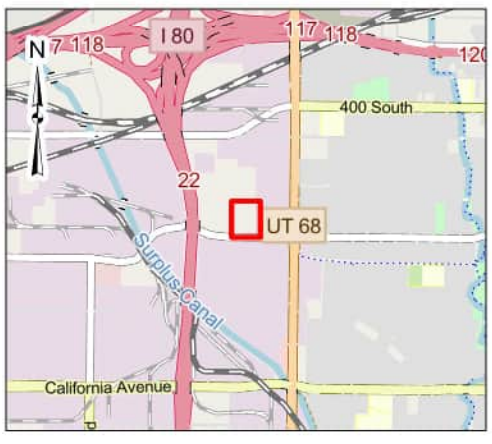
6

- Sample Location
- Alvie Carter Trust (ACT) area and burn pit
- Approximate North Ditch Alignment
- Sewer Line
- VCP Site Boundary

Soil/Fill Exceedances

- Exceeds Background Arsenic Concentration
- Exceeds Cadmium Residential RSL
- Exceeds PAH Residentail RSL

Feet
0 50 100 200



Project No.:	61227342
Date:	Mar 2023
Drawn By:	AST
Reviewed By:	NMS

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Screening Level Exceedances in Soil/Fill

Redwood Road Dump VCP Site C121
1850 West Indiana Avenue
Salt Lake City, Utah

Exhibit

7

N:\GIS\61217255_TOSA\61217255_TOSA.aprx

Monitoring Well with Arsenic Concentration (mg/l)

Approximate North Ditch Alignment

Sewer Line

VCP Site Boundary

Arsenic Exceedances in Groundwater

Exceeds MCL

Feet

0 50 100 200

Project No.:	61227342
Date:	Jan 2023
Drawn By:	AST
Reviewed By:	NMS

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Arsenic Exceedances in Groundwater

Redwood Road Dump VCP Site C121

1850 West Indiana Avenue
Salt Lake City, Utah

Exhibit

8

N:\GIS\61217255_TOSA\61217255_TOSA.aprx

TOSA-MW04
0.000436

TOSA-MW-01
0.00198

TOSA-MW05
<0.0004

TOSA-MW02
0.000432

TOSA-MW03
0.000872

W Indiana Ave

W Indiana Ave

N:\GIS\61217255_TOSA\61217255_TOSA.aprx

Monitoring Well with 1,4-Dioxane Concentrations (mg/l)

Approximate North Ditch Alignment

Sewer Line

VCP Site Boundary

1,4-Dioxane Exceedances in Groundwater

Exceeds Tapwater RSL

Feet
0 50 100 200

Project No.:	61227342
Date:	Jan 2023
Drawn By:	AST
Reviewed By:	NMS

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1,4-Dioxane Exceedances in Groundwater

Redwood Road Dump VCP Site C121

1850 West Indiana Avenue
Salt Lake City, Utah

Exhibit

9

TOSA-MW04
85.9*

TOSA-MW-01
2.27

TOSA-MW05
47.3

TOSA-MW02
216

TOSA-MW03
14.3

W Indiana Ave

W Indiana Ave

N:\GIS\61217255_TOSA\61217255_TOSA.aprx

Monitoring Well with PFOA Concentrations (ng/L)

Approximate North Ditch Alignment

Sewer Line

VCP Site Boundary

PFOA Exceedances in Groundwater

Exceeds Tapwater RSL

* Result is from MW40, duplicate of MW04.

Feet
0 50 100 200

Project No.:	61227342
Date:	Jan 2023
Drawn By:	AST
Reviewed By:	NMS

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PFOA Exceedances in Groundwater	Exhibit
Redwood Road Dump VCP Site C121 1850 West Indiana Avenue Salt Lake City, Utah	10

TOSA-MW04
NA

TOSA-MW-01
0.000207

TOSA-MW05
NA

TOSA-MW02
<0.00500

TOSA-MW03
<0.00500

N:\GIS\61217255_TOSA\61217255_TOSA.aprx

Monitoring Well with Hexavalent Chromium Concentration (mg/l)

Approximate North Ditch Alignment

Sewer Line

VCP Site Boundary

Hexavalent Chromium Exceedances in Groundwater

Exceeds Tapwater Screening Level

NA - Not Analyzed

Feet
0 50 100 200

Project No.:	61227342
Date:	Jun 2023
Drawn By:	AST
Reviewed By:	NMS

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Midvale, UT
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Hexavalent Chromium Exceedances in Groundwater

Redwood Road Dump VCP Site C121
1850 West Indiana Avenue
Salt Lake City, Utah

Exhibit

11

Soil Gas Sample with Chloroform Concentrations (ug/m3)

Approximate North Ditch Alignment

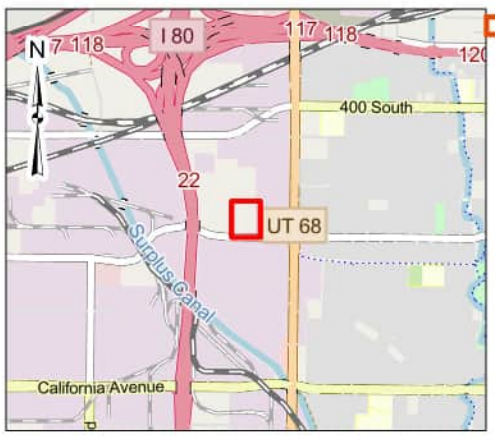
Sewer Line

VCP Site Boundary

Chloroform Exceedances in Soil Gas

Exceeds Residential RSL

Exceeds Commercial RSL



Feet

0 50 100 200

Project No.:	61227342
Date:	Jan 2023
Drawn By:	AST
Reviewed By:	NMS

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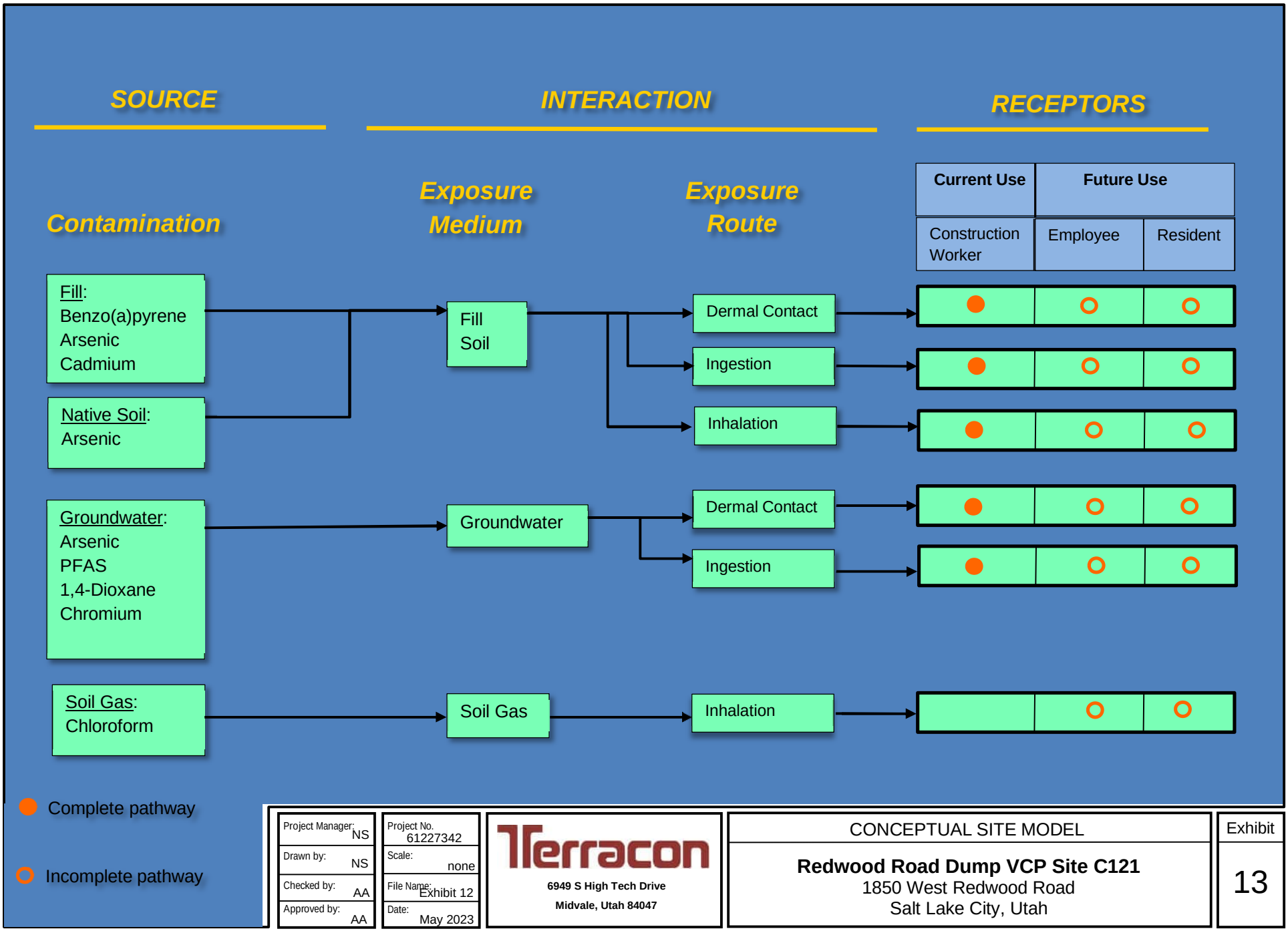
PH. 801-545-8500 terracon.com

Chloroform Exceedances in Soil Gas	Exhibit
Redwood Road Dump VCP Site C121 1850 West Indiana Avenue Salt Lake City, Utah	12

N:\GIS\61217255_TOSA\61217255_TOSA.aprx



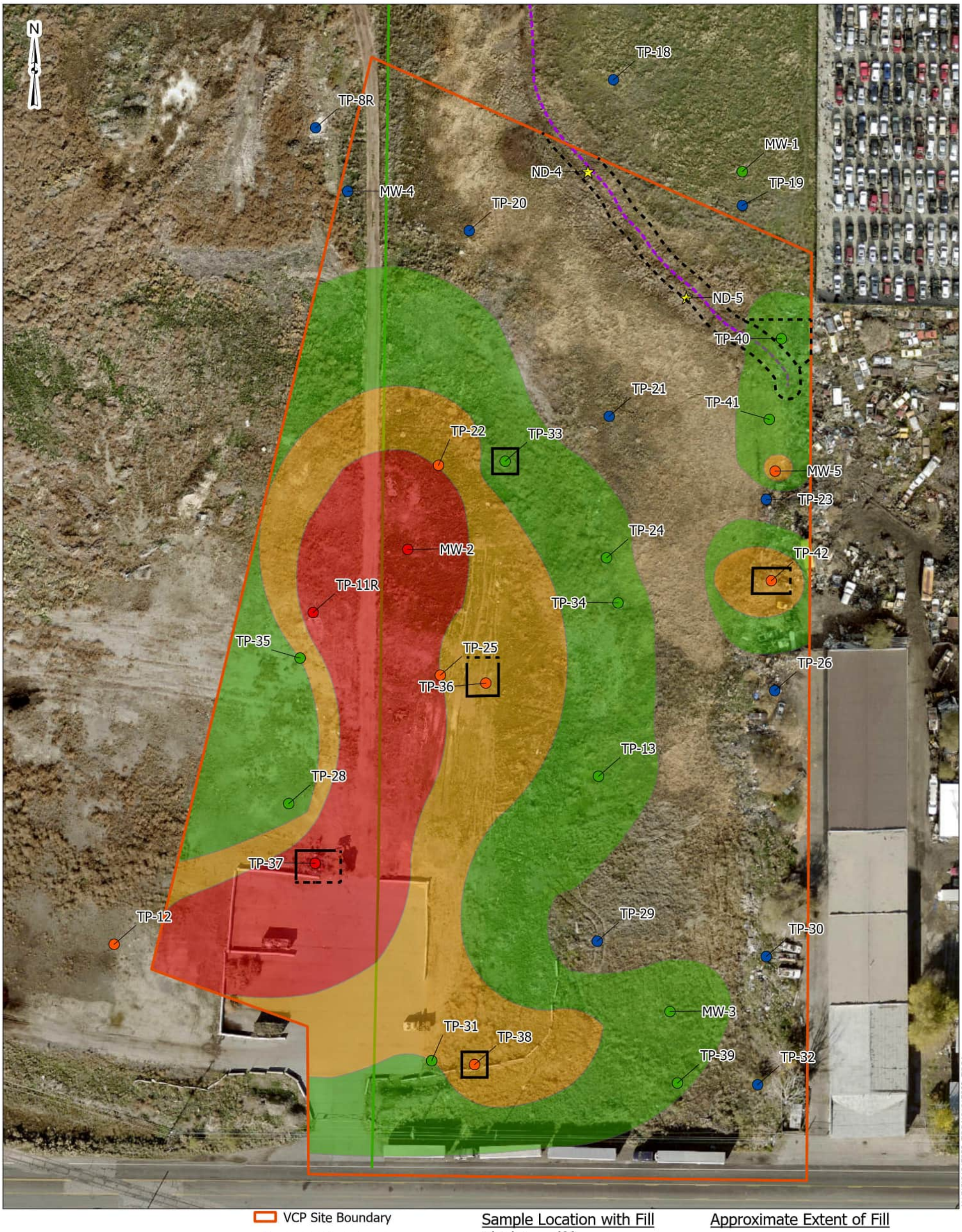
Project Manager:	NS
Drawn by:	NS
Checked by:	AA
Approved by:	AA
Project No.	61227342
Scale:	none
File Name:	Exhibit 12
Date:	May 2023

Terracon
6949 S High Tech Drive
Midvale, Utah 84047

CONCEPTUAL SITE MODEL

Redwood Road Dump VCP Site C121
1850 West Redwood Road
Salt Lake City, Utah

Exhibit
13



VCP Site Boundary

North Ditch Sample

Approximate North Ditch Alignment

Sewer Line

Estimated area where Regulatory Screening Level Exceeded in Fill

Additional Excavation Required: Excavation to Advance in 5-Foot Step-outs Until "Clean" Sample Obtained

Sample Location with Fill Thickness (ft)

- No Fill Observed
- 1-3 ft
- 3-5 ft
- 5+ ft

Approximate Extent of Fill

- 1-3 ft
- 3-5 ft
- 5+ ft

Feet

0 50 100 200

Project No.:	61227342
Date:	Jun 2023
Drawn By:	AST
Reviewed By:	NMS

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Midvale, UT

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Exceedance Extent and Additional Excavation

Redwood Road Dump VCP Site C121
1850 West Indiana Avenue
Salt Lake City, Utah

Exhibit

14

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APPENDIX B
Public Notice

Public Notice

30-Day Comment Period

Redwood Road Dump, VCP Site C121

Investigations have identified environmental impacts exceeding a residential screening level at the property located at 1850 West Indiana Avenue, Salt Lake City, Salt Lake County, Utah. Fill material was reported to exceed the Environmental Protection Agency (EPA) Residential Screening Level (RSL) for cadmium and benzo(a)pyrene, and a localized area of native soil was reported to exceed the Utah Department of Environmental Quality (UDEQ) background level for arsenic. Groundwater was reported to exceed EPA Maximum Contaminant Levels (MCLs) for arsenic and an EPA Tap Water Screening Level for 1-4 dioxane, hexavalent chromium, perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS). Chloroform was reported to exceed an EPA Vapor Intrusion Screening Level (VISL).

The owner of the Site, Salt Lake City Corporation (SLCC, The City), has enrolled the property in the UDEQ Division of Environmental Response and Remediation's (DERR's) Voluntary Cleanup Program (VCP) in order to properly address the impacts prior to Site redevelopment. The property will be developed as a tiny home village to consist of numerous tiny homes, a medical clinic, and two public buildings. The City plans to lease the property to The Other Side Academy (TOSA), who will construct and operate the Tiny Homes Village (TOSV).

SLCC has worked with the DERR to develop a Remedial Action Plan that will address all impacts identified on the Site. Site work is anticipated to start in the summer of 2023. The initial phase will be removal of impacted material. Approximately one month has been set aside for this task. Grading and site preparations will begin after impacted material removal and are anticipated to take one and one-half months. Approximately eight months have been set aside for construction of the tiny homes, community facilities, and the retail and clinic buildings, bringing the final phase of construction to be completed in June 2024. Groundwater will be managed through institutional controls consisting of an Environmental Covenant restricting access to groundwater. A groundwater monitoring program will be established once development is complete. The potential for vapor intrusion will be managed using standard vapor intrusion mitigation practices.

Following completion of remediation activities, a Site Management Plan will be generated to define the site management, monitoring, and inspection requirements, continuing obligations, activity and use limitations, and reporting requirements. Engineering controls and institutional controls will be incorporated at the Site to ensure continued protection of human health and the environment.

Additional information is available on SLCC's website (https://www.slc.gov/sustainability/tosv-environmental/). The Remedial Action Plan may be viewed, and comments on the plan received, at the Utah DEQ/DERR offices at the address below. The Public Comment period will commence on June 23, 2023 and comments will be received through July 23, 2023.

Please send comments to:

Chris Howell, Project Manager
Voluntary Cleanup/Brownfields Section
Division of Environmental Response and Remediation
Utah Department of Environmental Quality
P. O. Box 144840, 195 North 1950 West, 1st Floor
Salt Lake City, Utah 84114-4840
cjhowell@utah.gov
(385) 391-8140

APPENDIX C
Table

Table 1 - Excavation Extent and Confirmation Samples

Redwood Road Dump VCP Site C121
1850 West Indiana Ave, Salt Lake City, Utah
Terracon Project No. 61227342_6.2

Area of Interest	Estimated Thickness of Impacted Material	Excavation Extent	Estimated Volume of Impacted Material (cubic yards)	Proposed Confirmation Sample[1]	Confirmation Soil Analytical[2]		
					Arsenic	Cadmium	Benzo(a) pyrene
Test Pits							
TP-33N-10	1 ft	Extent Defined	22	Extent Defined			
TP-33E-10	2 ft	Extent Defined					
TP-33S-10	1 ft	Extent Defined					
TP-33W-10	1 ft	Extent Defined					
Estimated Floor Area (square ft)			400	TP-33 Floor	X		
TP-36E-10	4 ft	Extent Defined	North extent to be determined	Extent Defined			
TP-36S-10	2.5 ft	Extent Defined		Extent Defined			
TP-36W-15	4 ft	Extent Defined		Extent Defined			
TP-36N-20	4 ft	Additional Excavation Required		TP-36N-20			X
Estimated Floor Area (square ft)			750	TP-36 Floor			X
TP-37N-10	6"	Extent Defined	East and South extent to be determined	Extent Defined			
TP-37W-15	6"	Extent Defined		Extent Defined			
TP-37S-15	6"	Additional Excavation Required		TP-37S-15			X
TP-37E-20	6"	Additional Excavation Required		TP-37E-20			X
Estimated Floor Area (square ft)			875	TP-37 Floor			X
TP-38N-10	3 ft	Extent Defined	37	TP-38N-10			
TP-38E-10	2.5 ft	Extent Defined		TP-38E-10			
TP-38S-10	2.5 ft	Extent Defined		TP-38S-10			
TP-38W-10	2.5 ft	Extent Defined		TP-38W-10			
Estimated Floor Area (square ft)			400	TP-38 Floor	X	X	
TP-40N-15	1 ft	Additional Excavation Required	North, East, South, West Extent to be determined	TP-40N-20		X	X
TP-40E-15	2 ft	Additional Excavation Required		TP-40E-20	X	X	X
TP-40SE-15	1 ft	Additional Excavation Required		TP-40S-20	X		X
TP-40W-10	1 ft	Additional Excavation Required		TP-40W-20	X	X	X
Estimated Floor Area (square ft)			750	TP-40 Floor	X	X	X
TP-42N-10	2.5 ft	Extent Defined	East Extent to be determined	Extent Defined			
TP-42E-10	2 ft	Additional Excavation Required		TP-42E-15			X
TP-42S-10	2.5 ft	Extent Defined		Extent Defined			
TP-42W-15	3.5 ft	Extent Defined		Extent Defined			
Estimated Floor Area (square ft)			500	TP-42 Floor	X		X
Asphalt Pad							
Asphalt Pad	0-1 ft	Initial Characterization	Not determined	AP 0-1 ft	X	X	X
Asphalt Pad	Not Defined	TBD		TBD	X	X	X
Estimated Floor Area (square ft)			TBD	AP Floor	X	X	X
North Ditch							
ND-4, ND-5	0-1 ft	Additional Excavation Required	Not determined	ND-W-#	X		
Estimated Floor Area (square ft)			TBD	ND-Floor-#	X		

Notes:

[1]Proposed step-out distance to be determined based on sample results. *TBD - Actual sample depth determined in the field.

[2]Analytical Methods:

Benzo(a)pyrene: EPA Method 8270 SIM. Arsenic and Cadmium: EPA Method 6010B.

TBD - To be determined based on sample results.

QA/QC Samples will be collected as defined in the QAPP and determined in the field.

APPENDIX D
Quality Assurance Project Plan (QAPP)

QUALITY ASSURANCE PROJECT PLAN

Redwood Road Dump Pilot Phase Project

VCP Site C121

Salt Lake City, Utah

October 17, 2022

Terracon Project No. 61227342

Prepared for:
Salt Lake City Corporation, Department of Sustainability

Prepared by:
Terracon Consultants, Inc.
Salt Lake City, Utah

GROUP A PROJECT MANAGEMENT

A1 Title and Approval Sheet

Project Title:
Redwood Road Dump Pilot Phase Project Quality Assurance Project Plan
VCP Site C121
Salt Lake City, Utah

Terracon Consultant Project Manager

Signature _____ Date _____

Nancy Saunders.
Printed Name

Terracon Consultant Authorized Project Reviewer

Signature _____ Date _____

Amy Findley
Printed Name

N:\Projects\2022\61227342\Working Files\DRAFTS (Proposal-Reports-Communications)\61227342 Redwood Road Dump Pilot Ph QAPP.docx

A2 Table of Contents

EXHIBIT

TABLES

APPENDICES

A2.1 Acronym List

CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act, as Amended
DERR	Division of Environmental Response and Remediation
DL	laboratory reporting limit a.k.a. practicable quantification limit
DQI	Data Quality Indicators
DQO	Data Quality Objectives
EDD	Electronic Data Deliverable
ESA	Environmental Site Assessment
ESC	ESC Laboratories
HASP	Health and Safety Plan
LCS	Laboratory Control Sample
LFB	Laboratory Fortified Blank
LIMS	Laboratory Information Management System
LRL	Laboratory Reporting Limit
MCL	Maximum Contaminant Level
mg/kg	milligrams per kilogram (or parts per million)
mg/L	milligrams per liter (or parts per million)
µg/kg	micrograms per kilogram (or parts per billion)
µg/L	micrograms per liter (or parts per billion)
MS	Matrix Spike
MSD	Matrix Spike Duplicate
NELAP	National Environmental Laboratory Accreditation Program
OSHA	Occupational Safety and Health Act
PARCCS	Precision, Accuracy, Representativeness, Completeness, Comparability, and Sensitivity
ppb	parts per billion (in µg/kg or µg/L)
ppm	parts per million (in mg/kg or mg/L)
PR	Percent Recovery
PS	Performance Standard
QA	Quality Assurance
QAPP	Quality Assurance Project Plan
QC	Quality Control
RSL	Regional Screening Level
SAP	Sampling and Analysis Plan
SLCC	Salt Lake City Corporation
TOC	Table of Contents
UDEQ	Utah Department of Environmental Quality
US EPA	United States Environmental Protection Agency

A3 Distribution List

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(385) 418-4803
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Andrew Turner, P.G.
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6949 South High Tech Drive
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Email: andrew.turner@terracon.com

Environmental Laboratory: Chemtech-Ford Analytical
Jen Osborne, Laboratory Quality Assurance Director
9632 500 West
Sandy, Utah 84070
Phone: (801) 262-7299
Email: josborn@esclabsciences.com

A4 Project/Task Organization

This Quality Assurance Project Plan (QAPP) provides guidelines for the acquisition, analysis, and validation of data collected for the Redwood Road Dump Pilot Phase Project. The property is enrolled in the Utah Department of Environmental Quality (UDEQ) Voluntary Cleanup Program and is registered as VCP Site C121. Following is a brief description and identification of key personnel involved in conducting investigations at this site.

Salt Lake City Corporation Project Manager

The property is owned by the Salt Lake City Corporation (SLCC). The Owner's Project Manager is the central point of contact approving VCP activities and problem resolution and is the primary point of contact with the Consultant Project Manager regarding administrative and technical issues associated with this project. The Owner's Project Manager for this project is:

Catherine Wyffels
Air Quality & Environmental Program Manager
Salt Lake City Corporation, Department of Sustainability
451 South State Street, Room 148
Salt Lake City, UT 84115-5470
(385) 418-4803
Email: Catherine.Wyffels@SLCgov.com

Consultant Project Manager

The Consultant Project Manager is the central point of contact directing VCP activities and problem resolution and will have responsibility for overseeing the activities associated with the sampling activities. This person will be in direct contact with the Owner's Project Manager and with the UDEQ Project Manager. This person will be responsible for the preparation and maintenance of the QAPP, for distribution of the most current version of the QAPP to the individuals identified in the **DISTRIBUTION LIST**, preparing and/or overseeing preparation of Site Characterization Work Plans (SCWPs) for individual investigations, and for overall management of the field investigation portion of the project. The Consultant Project Manager will coordinate closely with the Consultant Quality Assurance/Quality Control (QA/QC) Officer and provide oversight during the field activities with routine visits to the jobsite(s). Additional responsibilities include scheduling, subcontractor procurement, cost accounting and reporting, identification of potential problems and development of contingency plans to respond to the identified problems. The Consultant Project Manager for this project is:

Nancy Saunders
Consultant Project Manager
Terracon Consultants, Inc.
6949 South High Tech Drive
Midvale, UT 84047
Phone: (801) 746-5473
Email: nancy.saunders@terracon.com

Consultant QA/QC Officer

The Consultant QA/QC Officer for this project will act as an independent advisor to the Consultant Project Manager and will oversee project activities as necessary. This role will include providing surveillance level oversight, laboratory performance evaluation, and data quality validation with QA/QC reviews of all data included in final reports. The Consultant QA/QC Officer for this project is:

Andrew Turner, P.G.
Consultant QA/QC Officer
Terracon Consultants, Inc.
6949 South High Tech Drive
Midvale, UT 84047
Phone: (385) 388-7028
Email: andrew.turner@terracon.com

UDEQ Project Manager

The UDEQ Project Manager will assist and support the review of the QAPP, SAPs, and other reports generated under the VCP project. The UDEQ will remain a technical resource for the field activities and reporting throughout the course of the project. The UDEQ Project Manager for this project is:

Chris Howell, P.G.
Utah Department of Environmental Quality
Division of Environmental Response and Remediation
P.O. Box 144840
Salt Lake City, UT 84114-4840
(801) 385-391-8140
Email: jcjhowell@utah.gov

Environmental Laboratory: Chemtech Ford Analytical Laboratories

Samples of environmental media that are collected during the course of this project will be analyzed by Chemtech Ford Analytical Laboratories. Chemtech Ford is responsible for providing reliable and high-quality analytical data, using the quality systems detailed in its Quality Manual (**Appendix B**). The Quality Assurance Director for Chemtech Ford is responsible for managing

the implementation, monitoring, and development of the laboratory's Quality Assurance Systems as well as overseeing laboratory safety, waste management, internal and external audits, and new method implementation. The Environmental Laboratory and Quality Assurance Director is:

Chemtech-Ford Inc.
Jenn Osborn, Laboratory Director of Quality
9632 South 500 West
Sandy, Utah 84070
Phone: (801) 262-7299
Email: josborn@esclabsciences.com

Environmental Laboratory: Eurofins EMLab P&K Analytical Testing Laboratories (EMLab P&K)
Samples of potential asbestos-containing building materials (ACBM), if collected, will be analyzed by EMLab P&K. A copy of EMLab P&K's Quality Assurance Manual is provided in **Appendix B**. The Environmental Laboratory and Quality Assurance Director is:

Eurofins EMLab P&K Analytical Testing Laboratories
Claudia Palermo, Laboratory Quality Manager
1501 W. Knudsen Drive
Phoenix, Arizona 85027
Phone: (856) 334-1001 x 102
Email: claudia.palermo@et.eurofinsus.com

A5 Problem Definition/Background

The site is located at approximately 1850 West Indiana Avenue, Salt Lake City, Utah (**Exhibit 1**). It was formerly included in the Redwood Road Dump CERCLA facility (Facility ID UTD980961502); however, the current Pilot Phase Project area is comprised of 8 acres which are situated east of the area that was formerly landfilled.

Previous investigations of the larger parent parcel and the current Pilot Phase portion have indicated there have been minimal impacts from landfilling and other industrial uses of the site and nearby properties. Soil impacts have not been observed, with the exception of minor amounts of debris in the upper 5 feet in soils in some locations. Groundwater impacts appear limited to dissolved arsenic. In addition, a sample from one groundwater monitoring well at the site reported perfluorooctanesulfonic acid (PFOS) in excess of the health advisory level of 70 ng/L. The source of these impacts is likely the landfill on the parent parcel which appears to be upgradient of the Site.

Chloroform may pose a potential for vapor intrusion into future buildings on the northern portion of the Site based on soil gas analytical results. Additionally, methane appears to be present at elevated levels farther west of the Site, on the parent parcel. The source of the methane was not specifically identified, but likely includes both landfill materials and natural sources.

The UDEQ VCP has indicated that additional site characterization is needed to provide data on current site conditions, to characterize the nature of the overlying fill material so that proper disposal methods during site development can be determined, and to evaluate impacts from the east-adjoining Alvie Carter Trust (ACT) property junk yard observed during a site visit. In correspondence dated September 1, 2022, the DERR requested a Site Characterization Workplan (SCWP) for additional investigation and a QAPP to guide all investigations at the Site.

A5.1 Regulatory Standards and Criteria

Regulatory standards will be the current Environmental Protection Agency (EPA) regulatory guidance and standards.

- Soil sample results will be compared to the most recently published EPA Regional Screening Levels (RSL) for residential and industrial use scenarios.

- Groundwater sample results will be compared to the most recently published EPA Maximum Contaminant Levels (MCLs) for drinking water. If an MCL is not established for an analyte, the results will be screened against the EPA RSL for tapwater. Note that MCLs have been published for five PFAS compounds.

- Samples of suspect ACBM will be analyzed and compared to regulatory guidance and standards at U.S. EPA 40 CFR Part 60 Subpart M (Asbestos NESHAP) and Utah Department of Environmental Quality, Division of Air Quality standards at UAC R307-801.

A6 Project / Task Description and Schedule

The objectives of sampling at the Site are to:

- Identify and document concentrations of COCs in groundwater and, if COC concentrations are identified in groundwater that exceed Cleanup Levels, properly address management of groundwater.

- Evaluate the potential for other COCs in the ACT area where junk yard debris has encroached onto the site and evidence of burning was recently observed. Further characterization of soils and groundwater in this area is warranted.

- Document concentrations of COCs in soil. Where present, proper handling of those soils will be specified in the RAP.

A Site Characterization Work Plan (SCWP) will be developed for the Phase II Assessment to be conducted on the site. The SCWP will detail the contaminants of concern, sampling locations, and sampling rationale.

The SCWP will include a detailed map of proposed sampling locations, as well as resource and time constraints.

A7 Quality Objectives and Criteria for Measurement Data

A7.1 Data Quality Objectives

Data Quality Objectives (DQOs) are quantitative and qualitative statements that specify the quality of data required to support the objectives of an investigation. DQOs are generated through the DQO Process, as shown in Guidance on Systematic Planning Using the Data Quality Objectives Process (QA/G-4) (EPA; February, 2006).

A7.2 Measurement Performance Criteria

Table 1 provides measurement performance criteria, which are Data Quality Indicators (DQIs) expressed in terms of precision, accuracy, representativeness, comparability, completeness, and sensitivity (PARCCS). The DQIs provide verifiable measurement criteria to assess data quality. Following is a brief definition of the PARCCS parameters, including bias.

Precision	The measure of agreement among repeated measurements of the same property under identical, or substantially similar conditions; calculated as either the range or as the standard deviation. Precision may also be expressed as a percentage of the mean of the measurements, such as relative range or relative standard deviation (coefficient of variation).
Bias	The systematic or persistent distortion of a measurement process that causes errors in one direction. Use reference materials or analyze spiked matrix samples.
Accuracy	A measure of the overall agreement of a measurement to a known value; includes a combination of random error (precision) and systematic error (bias) components of both sampling and analytical operations.
Representativeness	A qualitative term that expresses “the degree to which data accurately and precisely represent a characteristic of a population, parameter variations at a sampling point, a process condition, or an environmental condition.” (ANSI/ASQC 1995)
Comparability	A qualitative term that expresses the measure of confidence that one data set can be compared to another and can be combined for the decision(s) to be made.

Completeness	A measure of the amount of valid data needed to be obtained from a measurement system.
Sensitivity	The capability of a method or instrument to discriminate between measurement responses representing different levels of the variable of interest.

The Consultant QA/QC Officer will evaluate the PARCCS parameters in terms of the DQIs presented in **Table 1**. Precision will be evaluated on the basis of relative percent difference (RPD) as a measure of reproducibility between LCS/LCSD pairs and MS/MSD pairs (analytical precision), and between field samples and field duplicate samples (field precision). Bias and Accuracy will be evaluated through a review of the method blanks, LCS/LCSD, and MS/MSD summaries provided by the laboratory. Method blank analyte concentrations are expected to be below laboratory reporting limits, while LCS/LCSD and MS/MSD pairs are expected to be within the laboratory/method standards. Representativeness will be ensured by use of appropriate sampling locations, collection and preservation methods (including sample holding times), and analytical procedures according to the approved SAPs. Comparability will be ensured through the use of standardized sampling procedures in accordance with the approved SAP and QAPP, use of standardized and approved laboratory analytical methods, and reporting the analytical results in appropriate and consistent units. Completeness is the ratio of valid measurements to the number of planned measurements, expressed as a percentage, and the completeness goal for the project is 90%. The level of sensitivity must be such that the laboratory reporting limits are sufficiently low as to allow identification of analyzed constituent concentrations that are above applicable regulatory screening levels.

Environmental samples submitted for laboratory analyses will be considered definitive, consistent with EPA Superfund Data Categories (EPA; September 1993). Analytical results will be evaluated using current EPA RSLs, MCLs, and VISLs, as appropriate. Results for asbestos samples, if collected, will be compared to EPA 40 CFR Part 60 Subpart M (Asbestos NESHAP) and Utah Department of Environmental Quality, Division of Air Quality standards (UAC R307-801). As such, the level of data sensitivity is required to result in laboratory reporting limits (practical quantitation limits or PQLs) that are below the regulatory screening levels listed above.

Certification and validation requirements apply to the laboratories. Regularly scheduled analyses of known duplicates, standards, and spiked samples are a routine aspect of data reduction, validation, and reporting procedures for the laboratory. The laboratory, which is associated with the National Environmental Laboratory Accreditation Program (NELAP), will verify the reliability and credibility of the analytical results. Additionally, the laboratory reporting limits need to be lower than the screening levels for each of the analytes analyzed. A copy of the laboratories' Quality Assurance Manuals (QAM) with the laboratory reporting levels is provided in **Appendix A**.

A8 Special Training Requirements

The Occupational Safety and Health Administration (OSHA) 40-hour Hazardous Waste Operations and Emergency Response (HAZWOPER) training, including an up-to-date 8-hour refresher course as required by OSHA, is required for field personnel. Initial 40-hour HAZWOPER "live" training is provided by reputable training providers in the local community, and annual refreshers are provided either by "live" training or via online courses approved by Terracon's Corporate Safety and Health Manager. The Consultant Project Manager will ensure that training/certification requirements are satisfied for all field personnel prior to their entry to any project site where investigation activities are conducted. Documentation (training certificates) of HAZWOPER and refresher training is maintained by Terracon's Corporate Safety and Health Manager in employees' confidential medical surveillance/environmental training files. In addition, Terracon's environmental project managers (or designees) are responsible for conducting site-specific safety briefings prior to beginning all Terracon hazardous waste site projects. Terracon will prepare a site-specific Health and Safety Plan (HASP) prior to mobilizing to the site to identify specific hazards that may be encountered during all phases of the field work. Terracon will also require any onsite subcontractors (e.g., drillers) to provide documentation of current HAZWOPER certification prior to mobilization. In addition, Terracon personnel that collect samples of potential asbestos-containing material will be Certified Asbestos Building Inspectors as required by Utah Division of Air Quality rules at UAC R307-801.

A9 Documentation and Records

The data collected during any assessments will be summarized in reports documenting the investigation procedures and results, along with supporting maps, figures, and data summary tables. Appendices will include appended data for analyses, including laboratory QA/QC evaluation, chain of custody documentation, and field forms. The reports will include discussion and general recommendations for identified conditions that must be considered in planning for future redevelopment, as applicable.

Field personnel will maintain a field log to record pertinent activities associated with sampling activities. Photographic documentation will also be recorded in the field log, as will documentation of any field problems and corrective measures taken. Additional field documents will include sketch maps, field forms, borehole logs, and chain of custody records.

Labels generated by the laboratory will be affixed to sample containers and completed by field personnel. The labels will identify sample numbers, dates and times collected, and requested analyses. Chain of custody records will be maintained for all samples from the time of collection through the time of submittal to the laboratory for analysis.

Electronic project documents (including but not limited to word processing files, spreadsheets, laboratory analytical reports, project photographs, and CAD/GIS files) will be stored for a minimum of five years in an electronic project folder on a local server hard drive in the Terracon office that

is backed up automatically on a daily basis to a separate file server hard drive at Terracon's corporate office in Olathe, Kansas. In addition, analytical reports and chain-of-custody records will be maintained indefinitely on the analytical laboratory's LIMS database, and made available via the laboratory's secured online data access system.

Samples will be submitted to the laboratory using standard turnaround times unless alternate turnaround times are requested on chain of custody records for individual sample sets. It is anticipated that Chemtech Ford and EMLab (if required) will be used for analyses. If another laboratory performs analyses, it must meet the following criteria and submit QA/QC documentation for approval as described above:

- Demonstrated ability to achieve the required detection limits;
- Certified by the State of Utah for the specific analyses;
- Ability to meet the project's analytical QC requirements, which includes a laboratory method blank, laboratory control sample, matrix spike and matrix spike duplicate performed on one of the project's samples, chromatograms, and narrative report of QC results and any corrective actions required; and
- Follows an internal QA/QC Program.

Details of the laboratory QA/QC Programs are presented in **Appendix B**.

GROUP B MEASUREMENT/DATA ACQUISITION

B1 Sampling Process Design

A SCWP will be developed for each Phase II ESA investigation. Regulatory and historical data available for the Site, a visual inspection of the property, and any identified issues will be used to develop the SCWP. The SCWP will be reviewed and approved by the DERR prior to implementation. The sample results will be used to evaluate whether concentrations of COCs are above or below Cleanup Levels established in the RAP.

B2 Sampling Methods Requirements

Samples will be collected following applicable Terracon Standard Operating Procedures (SOPs) included in **Appendix B**. The SOPs include lists of equipment needed for each SOP, and were developed in general accordance with *Guidance for Preparing Standard Operating Procedures (SOPs) (QA/G-6)* (U.S. EPA, April 2007). If problems develop in the field during implementation of an SOP, field personnel will contact the Consultant Project Manager and Consultant QA/QC Officer for information on appropriate corrective action, and the problem and corrective action will be documented in the field log book.

B3 Sample Handling, Preservation and Custody Requirements

Samples will be identified, labeled, preserved, and handled following **SOP 20**, which includes chain of custody and documentation procedures. An example sample label and chain of custody form are included as attachments to **SOP 20**.

Required sample containers, sample volumes, sample holding times, and sample preservation methods for a variety of analytical parameters including those that are likely to be used in the proposed assessment are summarized in the work plans and are presented here in **Table 2**. The primary analytical parameters anticipated for the assessments include, but are not limited to, the following: volatile organic compounds (VOCs; EPA Method 8260); semi-volatile organic compounds (SVOCs; EPA Method 8270); metals (EPA Methods 6010//6020/7470/7471); polychlorinated biphenols (PCBs; EPA Method 8082); Dioxins / Furans (EPA Method 1613), per- and polyfluoroalkyl substances (PFASEPA Method 537, modified), and 1,4-dioxane (EPA Method 8260 SIM). Soil gas samples, if collected, will be analyzed for VOCs using EPA Method TO-15.

Samples will be placed into the appropriate laboratory-provided container immediately after collection. The container will remain in the sight of the sampler or will be locked in a secured area until the samples are transported under chain of custody protocols for delivery to the laboratory.

B4 Analytical Methods Requirements

All analytical methods will follow standard EPA procedures as outlined in Test Methods for Evaluating Solid Wastes - Physical/Chemical Methods (SW-846) as updated. Please refer to SW-846 and the laboratory QM's (**Appendix B**) for analytical SOPs and information regarding analytical equipment, instrumentation, performance criteria, corrective action procedures and documentation, sample disposal, and method validation information and procedures for nonstandard methods. Laboratory turnaround times needed will be specified on chain of custody records for each sample set.

B5 Quality Control Requirements

B5.1 Definitive Data

To ensure that high quality, reliable data are consistently collected, and that data are comparable to previous investigations, QA procedures will be followed throughout the investigation. Quality assurance procedures include using the data quality objectives, following SOPs, and collecting and analyzing field and laboratory QC samples.

QC samples collected in the field will be preserved, handled, and transported in an identical manner as the environmental samples. QC samples will include the following:

- Field duplicates
- Field/Equipment blanks (if applicable for individual sites)

- Trip blanks (if applicable for individual sites)
- Matrix spikes and matrix spike duplicates (MS/MSDs)
- Laboratory method blanks
- Laboratory control samples (LCS)

Quality control samples are briefly described below.

Field Duplicate Samples. To evaluate sampling and laboratory precision, field duplicate samples may be collected at a rate of 10 percent, or as specified in the work plan. One sample set will be labeled with the correct sample identification, while the other will be labeled with a false or "blind" sample identification. If the detected analytes in the field sample and its duplicate are less than 5 times the laboratory reporting limit (LRL) and the difference between the reported concentration in the sample and the reported concentration in the duplicate is less than or equal to the LRL value (for aqueous samples) or less than twice the LRL (for soil/solid samples), the samples will be considered within control. If the difference is greater than the LRL value, the data will be flagged and evaluated by the Consultant QA/QC Officer.

The relative percent difference (RPD) between detected analytes in the field sample and its duplicate are calculated when the reported concentrations for the sample and duplicate are greater than or equal to 5 times the LRL. The RPD is calculated to evaluate precision using the following equation.

$$RPD = \frac{X_1 - X_2}{\left(\frac{X_1 + X_2}{2}\right)} x100$$

Where X_1 and X_2 are the reported concentrations of the samples being evaluated.

The target RPD values for samples and their duplicates will be ±25% (for aqueous samples) and ±50% (for solid samples, due to greater sample heterogeneity). If samples exceed the target RPD values, the data will be flagged and evaluated by the Consultant QA/QC Officer. The samples may be used on a conditional basis if sample heterogeneity or matrix interference appears to be the cause of the high RPD value.

Field/Equipment Blank. Field equipment blanks may be collected, as specified in the SCWP. Acceptance criteria will be analyte concentrations less than the LRLs. If above the LRLs, the data will be flagged and evaluated by the Consultant QA/QC Officer. The Consultant QA/QC Officer will review the sampling procedures and equipment to determine if contaminants could have been introduced by the sampling methodology. When necessary, the results will be discussed with the Agencies, laboratory personnel, and/or appropriate regulatory officials to determine if the data are acceptable or should be rejected.

Trip Blanks. Trip blanks will apply only when a work plan includes collection of samples to be analyzed for volatile organic compounds (VOCs) and PFAS, and will be used to evaluate whether external VOCs from bottle handling and analytical processes, independent of the field sampling processes, are contaminating the samples. Trip blanks will be prepared by the laboratory with

analyte-free water prior to the sampling event, kept with the investigative samples throughout the sampling event, and returned to the laboratory with the other samples for analysis. One trip blank will typically be used and analyzed per VOC sample shipment where soil and groundwater sample analyses will include VOCs; and one trip blank will typically be used and analyzed per PFAS sample shipment.

Matrix Spike (MS) and Matrix Spike Duplicate (MSD) Samples. Samples for MS/MSD analyses will be selected by the laboratory from the sample set at random and split in the laboratory. The MS/MSD samples will be spiked in the laboratory with target analytes prior to extraction or analysis, according to the laboratory's SOPs, and then analyzed for the same compounds as the environmental samples. Each MS/MSD will be evaluated for Percent Recovery (PR). If the data meets the PR criteria, the MS/MSD will be evaluated for RPD according to the equation presented above.

Percent Recovery = $\frac{X_s - X_i}{SC} x100$

Where X_s = concentration measured in spiked sample
X_i = concentration measured prior to spiking, and
SC = spike concentration

The PR acceptance criteria for MS/MSD samples will vary by sample medium, analyte, and analytical method, and may be either method defaults or laboratory-derived. Laboratory RPD acceptance criteria also vary by sample medium, analyte, and analytical method, and are specified in the Chemtech Ford QM (**Appendix B**). Each laboratory report will include quality control summaries with PR results and comparison against PR acceptance criteria for each sample medium, analyte, and analytical method for that sample set. If data fail to meet the acceptance criteria, the Consultant QA/QC Officer will evaluate the data with the laboratory to determine potential causes of failure, such as matrix interference or sample heterogeneity. Data may be flagged or invalidated based on discussions with the laboratory.

Laboratory Method Blanks. Method blank samples will be prepared by the laboratory and analyzed with each analytical batch for each method. A method blank consists of laboratory-grade deionized water or solid that is processed through all of the analytical steps required by a method, including sample extraction, preparation, and analysis. Laboratory method blank samples are used to identify contamination originating in the laboratory, such as laboratory water, reagents, sample preparation steps, and instrument contamination. Method blank samples aid in distinguishing low-level field contamination from laboratory contamination. Method blank samples will be run with each batch of samples (20 or fewer samples per batch). If analytes are detected in the method blank, the laboratory will correct problems as per their SOPs.

Laboratory Control Samples (LCS). Laboratory control samples are used to evaluate laboratory accuracy in the absence of matrix interference. A laboratory control sample is composed of laboratory-grade deionized water or clean solid that is spiked with target analytes according to the laboratory's SOPs prior to extraction or analysis. The percent recovery of the spiked compounds is calculated and compared to established QC limits using the following formula.

Percent Recovery = $\frac{X_S}{SC} x 100$ Where X_S = concentration measured in spiked sample, and SC = spike concentration

Acceptance criteria for the LCS will vary by sample medium, analyte, and analytical method; may be either method defaults or laboratory-derived; and are compared against PR results in the laboratory quality control summaries provided as part of each laboratory report. If the LCS is out of control, the laboratory will correct problems in accordance with its standard operating procedures.

Holding Times. Holding times are used to evaluate the representativeness of the environmental samples. Holding time is the period following sample collection when a sample is considered representative of the environmental conditions. The holding time for each analysis will be compared to the method-specific holding times. Samples held beyond their holding time prior to analysis will be rejected.

B5.2 Non-definitive data

Non-definitive data utilized to support decisions may include field soil screening measurements and observations, physical observations, and groundwater field parameter measurements. Non-definitive data will be collected following Terracon SOPs **(Appendix A)**. The QC documentation for non-definitive data is not as rigorous as requirements for definitive data.

B6 Equipment Testing, Inspection, and Maintenance Requirements

Testing, inspection, and maintenance of sampling equipment and field instrumentation will be performed by Terracon field personnel prior to each day's field use and in accordance with the procedures and schedules in the manufacturers' specifications. A supply of appropriate spare parts and batteries will be maintained with each instrument in its transport case, along with instrument calibration supplies. Any identified deficiencies will be documented in the field log book, along with any corrective actions (e.g., spare parts replacement and instrument re-testing) and effectiveness of corrective actions.

Each laboratory conducts its own equipment testing, inspections, maintenance, and record keeping of the laboratory equipment as detailed in the laboratory QMs provided in **Appendix B**.

B7 Instrument/Equipment Calibration and Frequency

B7.1 Field Instruments

Field instruments will be calibrated daily or in accordance with manufacturers' specifications by Terracon field personnel, using National Institute of Standards and Technology (NIST) standards or equivalent. Calibration deficiencies, if any, will be documented in the field log book along with their resolution (e.g., spare parts replacement and re-calibration).

B7.2 Laboratory Instruments

The laboratories QM and SOPs meet all State of Utah, The NELAC Institute, and EPA method protocols necessary to produce legally and defensible analytical data, as indicated in the Utah Environmental Laboratory Certification Program (ELCP) document. Certification also applies to instrument calibration, reference material, standards traceability, data validation, and all other aspects of the QAM.

In the event of a negative audit finding or any other circumstance, which raises doubt concerning the laboratory's competence or compliance with required procedures, the laboratory ensures that those areas of concern are quickly investigated. A resolution of the situation is promptly sought and, where necessary, recalibration and retesting is conducted. Records of events and corrective actions taken by the laboratory to resolve issues and to prevent further occurrences are maintained.

B8 Inspection/Acceptance Requirements for Supplies and Consumables

Sample containers and other dedicated consumables will meet EPA criteria for cleaning procedures required for low-level chemical analysis. Sample containers will have Level II certification provided by the manufacturer, in accordance with pre-cleaning criteria established by EPA in "*Specifications and Guidelines for Obtaining Contaminant-Free Sample Containers*." The certificates of cleanliness are maintained by the container suppliers and can be obtained upon request using the container batch and lot numbers. Sample containers and sample preservatives (where applicable) will be provided by the laboratory. The containers shall be pre-preserved by the laboratory, if required. In addition, the laboratory will supply the laboratory-grade deionized water and PFAS-free water for the field and equipment blanks. The laboratory-grade deionized water may be prepared by the laboratory in-house, but the laboratory must have a routine procedure in place to analyze the water to ensure the deionized water's quality. New disposable nitrile sampling gloves will be used during collection of samples and will be discarded after collection of each sample. If soil gas testing is required, Summa canisters will be batch-certified by the laboratory. New disposable water filters (if required), bailers, and/or tubing will be used to collect groundwater samples and will be discarded after use. Prior to use, the materials provided by the laboratory or other suppliers will be inspected visually for signs of tampering, contamination, or damage. No evidence of tampering, contamination, or damage will be acceptable. The field team leader will be responsible for the inspection. Reserves of field supplies and consumables are stored and maintained in Terracon's secured storage warehouse and used as needed by field personnel for each day's field activities, and the reserves of consumables are re-ordered/replenished as needed by Terracon staff.

B9 Data Acquisition of Non-direct Measurements

Additional data may be collected and used for site characterization following SOPs. QA procedures will be followed throughout the investigation. External sources of existing data may

also be used (for example, computer databases or regulatory files of previously investigated sites); such information will be used only for reference. This type of data will be considered non-definitive for the purpose of assessing selected sites, unless the data was collected following an Agency-approved work plan, evaluated following a QAPP that meets or exceeds the requirements provided in this QAPP, validated, and deemed definitive.

B10 Data Management

The results of each investigation will be compiled and detailed in a report. Please refer to Section A9 for information pertaining to documentation that will be generated during the course of the project, and storage requirements for these records.

Data will be processed using commercially available word processing, spreadsheet, and/or database programs. During transcription of field measurements, each entry will be double-checked immediately after each transcription from field log books and forms. Example forms for typical field data collection are included in **Appendix A**. To minimize potential errors in laboratory data transcription, the use of electronic data deliverables (EDDs) will be maximized during data entry to summary tables and databases. The control mechanism to detect and correct possible errors in data transcription, reduction, reporting, and data entry to forms, reports, and databases will be the senior peer review of documents by the Consultant Project Manager and Consultant QA/QC Officer. Data will be stored electronically, both on a local server hard drive (subject to daily backup on a separate file server at Terracon's corporate office in Olathe, KS) and on the laboratory's LIMS database system, and can be retrieved via the local server and via the laboratory's secured online data access system. Please refer to **Appendix B** for information relating to procedures used and individuals responsible for laboratory data processing, transmittal, storage/archival, and hardware/software configurations.

GROUP C ASSESSMENT/OVERSIGHT

C1 Assessment Activities

Assessment and oversight activities will be conducted by the Consultant QA/QC Officer. There will be three primary activities conducted by the Consultant QA/QC Officer:

1) Surveillance Level Oversight

The Consultant Project Manager will coordinate the investigation, with independent oversight by the Consultant QA/QC Officer. Both of these individuals will have authority to stop work in the event of unsafe work conditions or deviation from SOPs. In the event of unsafe work conditions, field personnel will also have authority to stop work and will immediately contact the Consultant Project Manager for resolution. Any deviations from the QAPP will be addressed immediately to ensure the quality of the data. Surveillance level oversight will be conducted throughout the duration of field activities.

2) Performance Evaluations

The Consultant QA/QC Officer will verify that the laboratory certifications and methods are current and approved by the NELAP, prior to the initiation of field sampling.

3) Data Quality Validation Summary

Within approximately one week of receipt of analytical data sets from the laboratory, the Consultant Project Manager will perform an initial review of the data, followed by a data validation review by the Consultant QA/QC Officer to determine whether DQOs were met and evaluate the overall usability of the data. The results of these data validation reviews will be communicated to the Consultant Project Manager, who will immediately notify the laboratory if any need for corrective actions is identified. In this case, the laboratory will be required to perform and verify any corrective actions taken, which will then be documented in an amended laboratory report identifying the corrective actions taken and any resulting changes to the analytical results. In addition, the data validation reviews will form the basis for development of data validation summaries for inclusion with the final site investigation reports.

C2 Reports to Management

Data validation summaries will be included as part of the final reports detailing the investigations. In the event that laboratory corrective actions are required, the Consultant Project Manager will notify Salt Lake County, and final reports will include copies of both the original and amended laboratory reports. In the event that field corrective actions are required, the problem and corrective action will be recorded in the field log book, and will also be documented in the final report. Copies of the final reports detailing the investigations will be sent to all parties listed in **Section A3 Distribution List**.

GROUP D DATA VALIDATION AND USABILITY

D1 Data Review

Following receipt of the laboratory analytical results and initial review by the Consultant Project Manager, the data will be forwarded to the Consultant QA/QC Officer for review which will include initial screening to evaluate whether any of the data is flagged or if laboratory control limits were not met. Upon acceptance of the data from the laboratory, the data will be validated. The data validation process evaluates whether the specific requirements for an intended use have been fulfilled and ensures that the results conform to the users' needs.

D2 Validation and Verification Methods

All laboratory data will be subject to internal reduction and validation by the laboratory prior to external release of the data, as detailed in the laboratory's QM (Section 5.4) in **Appendix B**.

Following receipt of data released by the laboratory, additional data validation and verification will be conducted by the Consultant QA/QC Officer, using the criteria described in **Section B5.1** and **Table 3**, and including review of chain of custody and laboratory log-in records. Data will be reviewed as it is received throughout the project. Each laboratory data set will be provided by the

laboratory as a Level III data package which will include the final analytical report with qualifiers where necessary; chain of custody records; and results for method blanks, MS/MSD analyses with control limits; LCS summary with control limits; reporting limits listed on all reports; surrogate recoveries for GC and GC/MS analyses; initial and continuing calibration information; and instrument blank performance.

Laboratory QC issues will be addressed by communication between the Consultant QA/QC Officer and laboratory personnel. Problems identified in sample collection, handling, preservation, and documentation will be addressed with the Consultant Project Manager and field staff.

Any deviations from the QA goals will be evaluated in terms of their effect on data usability. The degree of sample deviation beyond the acceptance limit will be evaluated for its potential effect on data usability, contribution to the quality of the reduced and analyzed data, and on decision-making for the project.

D3 Reconciliation with User Requirements

Following the validation of field and laboratory data, all data and information will be reconciled with the project objectives to assess the overall success of sampling activities. Qualitative DQOs will be reviewed through a narrative discussion of the results to including limitations, if any, on data use due to uncertainties posed by any flagged data or elevated laboratory reporting limits. If such uncertainties result in significant hindrances to data usability, practical follow up actions (for example, limited resampling) may be recommended as warranted.

GROUP E REFERENCES

U.S. Environmental Protection Agency. *Guidance for Preparing Standard Operating Procedures (SOPs) (QA/G-6)*. EPA/600/B-07/001, April, 2007.

U.S. Environmental Protection Agency. *Data Quality Assessment: A Reviewer's Guide (QA/G-9R)*. EPA/240/B-06/003, February, 2006.

U.S. Environmental Protection Agency. *Data Quality Assessment: Statistical Tools for Practitioners (QA/G-9S)*. EPA/240/B-06/002, February, 2006.

U.S. Environmental Protection Agency. *Guidance for Quality Assurance Project Plans (QA/G-5)*. EPA/240/R-02/009, December, 2002.

U.S. Environmental Protection Agency. *Guidance on Systematic Planning Using the Data Quality Objectives Process (QA/G-4)*. EPA/240/B-06/001, February, 2006.

U.S. Environmental Protection Agency. *Data Quality Objectives Process for Superfund – Interim Final Guidance.* Pub. No. 9355-9-01, September, 1993.

U.S. Environmental Protection Agency. *Regional Screening Levels (RSLs)*. www.epa.gov/risk/regional-screening-levels-rsls

U.S. Environmental Protection Agency. National Primary Drinking Water Regulations. www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations

Table 1
Data Quality Indicators (DQIs)

Parameter	QC Program	Evaluation Criteria	Summary of QA/QC Goals
Precision	Field Duplicate Pairs	RPD[a]	RPDs will be less than ± 25% (aqueous samples) and ± 50% (solid samples) when detected concentrations are ≥ 5x the LRL. When detected concentrations are <5x the LRL and the difference between the reported concentrations is less than or equal to the LRL value (for aqueous samples) or less than twice the LRL (for soil/solid samples), the samples will be considered within control.
Bias	Laboratory Control Sample	Percent Recovery[b]	LCS percent recoveries will vary by sample medium, analyte, and method, and may be either method defaults or laboratory-derived.
	Matrix Spike/Matrix Spike Duplicate (MS/MSD)	Percent Recovery[b] RPD[a]	MS/MSD percent recoveries and RPDs will vary by sample medium, analyte, and method, and may be either method defaults or laboratory-derived.
Accuracy[c]	Method Blanks	LRL	Less than LRL
	Equipment Blanks	LRL	Less than LRL
Representativeness	Standard Operating Procedures (SOPs)	Qualitative determination of SOP adherence	All samples collected following SOPs
	Holding Times	Holding Times	All samples analyzed within holding times
	Field/Equipment Blanks	LRL	Less than LRL
Comparability	Units of Measure	Metric Units	100% of sample results reported in same units
	Analytical Methods	Approved Methods	100% of samples analyzed using approved methods
	Standardized Sampling	Qualitative determination of SOP adherence	All samples collected following SOPs
	QC Samples 10% Field Duplicates 10% Field Blanks Lab QA	 Verify Verify Verify	 100% compliance 100% compliance 100% compliance
Completeness	Complete Sampling	Percent Valid Data	90% or more of the planned measurements are valid
Sensitivity	Sample analyses	LRL	100% of LRLs are less than Performance Standards

a: RPD = $\frac{X_1 - X_2}{\left(\frac{X_1 + X_2}{2}\right)} x100$; where X_1 and X_2 are the reported concentrations of the samples being evaluated.

b: Percent Recovery = $\frac{X_s - X_i}{SC} x100$; where X_s = concentration measured in spiked sample, X_i = concentration measured prior to spiking, and SC = spike concentration.

c: Instrument calibration, reference material, standards traceability, and data validation will follow ESC's Standard Operating Procedures.

LRL - Laboratory Reporting Limit
RPD - Relative Percent Difference
SOP - Standard Operating Procedure

Table 2
Method Summary

Parameter	Matrix	Analytical Method	Laboratory Method Detection Limit (MDL)	Container	Volume	Preservative	Temp	Maximum Holding Time (days)
Asbestos	Building Material	EPA Methods: 600/M4-82-020 and 600/R-93/116	<1%	NA	NA	NA	NA	NA
VOCs	Soil	SW-846 8260	0.002 - 0.12 mg/kg	4 oz glass	1	NA	4 deg C*	14
VOCs (including 1,4-dioxane)	Groundwater	SW-846 8260	0.2 - 40 ug/L	40 ml liter	3	HCL	4 deg C*	14
SVOCs	Soil	SW-846 8270	0.01 - 0.1 mg/kg	4 oz glass[1]	1	NA	4 deg C*	14
SVOCs	Groundwater	SW-846 8270	0.5 - 4 ug/L	60 ml amber glass	4	NA	4 deg C*	7
Barium, Cadmium, Chromium, Silver	Soil	SW-846 6010	0.271 mg/kg	4 oz glass[1]	1	NA	NA	180
Arsenic, Lead, Selenium	Soil	SW-846 6010	2.71 mg/kg	4 oz glass[1]	1	NA	NA	180
Mercury	Soil	SW-846 7471	0.03 mg/kg	4 oz glass[1]	1	NA	NA	28
Dissolved Metals	Groundwater	SW-846 6020	0.0005 mg/L	250 ml plastic[2]	1	HNO_3	NA	180
Dissolved Metals - Mercury	Groundwater	SW-846 7470	0.0002 mg/L	250 ml plastic[2]	1	HNO_3	NA	28
PFAS	Groundwater	537 Mod	20 ng/L	1 L amber glass	1	NA	4 deg C*	28
TDS	Groundwater	SM 2540 C	20 mg/L	1 L plastic	1	NA	4 deg C*	7
PCBs	Soil	8082	2 ug/L	4 oz glass[1]	1	NA	4 deg C*	7
Dioxins/furans	Soil	8290	0.196 - 4.14 ng/kg	4 oz glass	1	NA	4 deg C*	365

[1]glass - may be combined with other analyses

[2]combined with other dissolved metals analyses and filtered in the field

L = liter; mg = milligrams; ug = micrograms; ng = nanograms; oz - ounce

HCL = hydrochloric acid; HNO3 - nitric acid

NA - Not Applicable / Not Required

*if samples are delivered to the laboratory on the day of collection, they must be placed on ice but it is not necessary to reach 4 deg C.

Table 3
Data Validation and Verification Methods

Data Validation and Verification Requirements	Data Validation and Verification Methods
■ Samples were collected as per scheduled locations and frequency.	■ Comparison with Site Characterization Work Plan.
■ Sample collection and handling followed specific procedures (i.e., relevant SOPs and chain of custody procedures).	■ Review of field notes, sampling logs and COCs. ■ Surveillance-level oversight of field procedures to maximize consistency in field.
■ Appropriate analytical methods were used, and internal laboratory calibration checks were performed according to the method-specified protocol.	■ Review of analytical methods and case narratives provided with laboratory reports. ■ Maintain documentation of communications with laboratory regarding problems or corrective actions.
■ Required holding times and laboratory reporting limits were met.	■ Comparison with specified holding times and LRLs.
■ Recovery acceptance limits for field and laboratory QC samples (MS/MSD, LCS, and method blanks) were met.	■ Comparison with specified acceptance limits. ■ Comparison with Data Quality Indicators.
■ Appropriate steps were taken to ensure the accuracy of data reduction, including reducing data transfer errors in the preparation of summary data tables and maps.	■ Maintaining a permanent file of hard copies of laboratory analytical reports. ■ Minimizing retyping of data. ■ Double-checking values entered into database, tables, and maps against laboratory reports.

APPENDIX A

Relevant Standard Operating Procedures (SOPs) and Field Forms

SOP 1

Soil Sampling and Logging

Introduction

This SOP describes the procedures for properly collecting, handling, and logging soil samples (when required). Method-specific sampling techniques are presented in the following SOPs:

SOP 2	Surface Soil Sampling
SOP 4	Test Pit and Excavation Soil Sampling
SOP 5	Direct-push Drilling Sampling
SOP 13	Field Instrument Calibration
SOP 17	Equipment Decontamination
SOP 20	Sample Handling and Documentation

Equipment

Equipment needs will vary, depending on the sample collection or drilling method. Refer to the appropriate SOP listed above for method-specific equipment needs.

Procedures

Non-Sleeved Grab Samples

Immediately upon receiving the sample, either from the split spoon or backhoe bucket, the material will be screened with the appropriate direct reading instrument, such as a PID or XRF, and the reading will be recorded on the log form or in the field notebook. The portion of the sample collected for chemical analysis will be transferred immediately into the appropriate sample container using decontaminated equipment, new wooden tongue depressors, or by hand wearing new disposable chemical-resistant gloves. Avoid gravels and rock fragments when filling soil sample containers. If the sample is to be analyzed for volatile organics, the container will be completely filled with soil to minimize headspace. The container will be labeled appropriately following SOP 20 and immediately stored in an iced cooler to maintain a temperature of 4° Celsius.

Grab Samples Using Sleeves (auger drilling methodology)

When sampling for volatile compounds, the sample will be kept in the brass or plastic sleeves, and the sleeves will be handled with chemical-resistant gloves. The sample will be screened with the direct reading instrument by exposing the end of one sample tube to the instrument probe. The sample sleeve selected for chemical analysis will be packaged immediately by covering each end of the sleeve with Teflon™ tape and sealed with plastic caps. The sample sleeve will be labeled as described above and immediately stored in an iced cooler to maintain a temperature of 4° Celsius.

Grab Samples Using Sleeves (Direct-push drilling methodology)

The sample sleeve will be cut and the sleeves will be handled with chemical-resistant gloves. The sample will be screened with the direct reading instrument by removing a portion of the sleeve, exposing the soil to the instrument probe. The soil sample selected for chemical analysis will be packaged immediately into laboratory-supplied soil jars, labeled as described above, and immediately stored in an iced cooler to maintain a temperature of 4° Celsius.

Composite Soil Samples

Composite samples will be prepared by placing equal amounts of soil in a stainless steel bowl or a clean plastic bag using a stainless steel spoon or by hand wearing new chemical-resistant gloves. The sample will be homogenized with a stainless steel spoon or gloved hand. The homogenized soil will be packaged in a laboratory-supplied sample container, labeled appropriately, and placed in an iced cooler to maintain a temperature of 4° Celsius. Note that samples for VOC analysis will not be composited.

Soil Logging

When a detailed log of soils is required by the Sampling and Analysis Plan, soil will be logged following the procedures outlined below. The level of detail for soil logging will depend on the Data Quality Objectives and intended use of the log information. A description of visual soil characteristics will be recorded for all soil samples. The soil description may include the following information (in the order listed below):

- Soil type according to unified soil classification system
- Color according to the Munsell color chart
- Grain size and roundness
- Percentage fines, sands, and gravels
- Presence of interbedding, and number and thickness of layers
- Description of odors, staining, or sheen
- Density or stiffness
- Relative moisture content

A description of soil types and various field tests for soil classification is given at the end of this SOP.

The following information will be recorded in the appropriate spaces provided on the sample log form:

- Depth of all drive samples;
- Sample interval submitted for laboratory analysis;
- Meter reading from direct-reading instrument (if applicable);
- Contacts between soil types.

In addition to logging soils, the geologist will record the occurrence of first water and the approximate static water level within each borehole. The reference point for all subsurface measurements will be included on all boring logs (i.e., feet below ground surface).

Decontamination

Strict decontamination procedures, as outlined in SOP 17, will be used to prevent cross-contamination of samples. Decontamination will be performed on non-disposable sampling equipment, including drilling equipment (e.g., auger barrel, split spoon) and hand tools (e.g., shovels, hand augers, etc.

When possible, samples will be collected using disposable equipment to avoid the need for decontamination.

Unified Soil Classification System (when required)

The following is an overview of classifying soil according to the USC system. The distinction between soil types is based on the percentage of fine vs. coarse material in a sample. This is easily done in a laboratory but involves a lot of guesswork in the field. The key is to be consistent. If you are fortunate enough to have samples submitted to a geotechnical lab for sieve analysis, check your field classifications against the laboratory results. This will help you estimate percentages in the field.

1) Distinguishing Coarse-grained from Fine-grained Soils:
   A) Determine if material is predominantly coarse grained (sand or gravel) or fine grained (silt or clay). Coarse-grained materials are those with more than 50% retained on a No. 200 sieve (very fine-grained sand or larger).

   B) If coarse-grained, determine if it is predominantly sand or gravel. Be aware that in the USCS system, pea gravel-size particles are considered "very coarse grained sand."

   C) Further classify material based on the amount of fines present. Roughly, no or very little fines is a SP or GP classification; slight amount of fines is a GP-GM or a SP-SM classification; much fines is a GM or SM classification. The following chart shows the breakdown for these classifications.

Classification of Coarse-grained Sands
>50% larger than No. 200 sieve

Percentage Fines	Soil Name	USC Designation
<5% Fines	Gravel	GP or GW[1]
	Sand	SP or SW[1]
5-12% Fines	Gravel with Silt or Clay	GP-GM or GP-GC
	Sand with Silt or Clay	SP-SM or SP-SC
>12%	Silty or Clayey Gravel	GM or GC
	Silty or Clayey Sand	SM or SC

[1] - The designation SW or GW means well sorted -not well graded (confusing for geologists). This is a condition not normally found in natural depositional environments and usually indicates engineered fill. Do not use this classification unless you think the material is specifically graded-engineered fill.

   D) If material is fine grained, determine if any coarse-grained materials are present. Note that all fine-grained materials have the same USC designation. Therefore, you must use both the name and the designation to adequately describe the soil. Use the following chart to classify fine-grained materials.

Classification of Fine-grained Soils
>50% passing No. 200 sieve

Percentage Coarse	Soil Name	USC Designation
<15% Coarse	Silt	ML, MH
	Clay	CL, CH
15-29% Coarse	Silt w/Coarse	ML, MH
	Clay w/Coarse	CL, CH
>29% Coarse	Sandy Silt	ML, MH
	Gravelly Silt	ML, MH
	Sandy Clay	CL, CH
	Gravelly Clay	CL, CH

2) Classification of Fine-grained Soils

A) Distinguish clay from silt. The following are field tests for determining if a material is clay or silt.

1) Dilatency (reaction to shaking)
Remove course-grained materials. Prepare a pat of moist soil with a volume of about 1/2 cubic inch. Add enough water if necessary to make the soil soft but not sticky. Place the pat in the open palm of one hand and shake horizontally, striking vigorously against the other hand several times. A clean fine-grained sand will rapidly show water on the surface and become glossy. When squeezed between fingers, the gloss disappears from the surface, the pat stiffens and finally cracks or crumbles. A very plastic clay will show little reaction to shaking and squeezing; an inorganic silt will react somewhere in between.

2) Dry strength (crushing characteristics)
After removing coarse-grained particles, mold a pat of soil to a 1/2-inch cube, adding water, if necessary. Allow to dry completely. Test the strength of the dry cube by crushing between fingers. The dry strength increases with increasing plasticity, with a plastic clay having high dry strength. An inorganic silt and silty fine-grained sands are similar. Fine sand feels gritty where silt has a smooth, flour-like feel.

3) Toughness (consistency near plastic limit)
The worm test: roll soil into a rope (or worm). A clay can usually be rolled to 1/8-inch diameter before it breaks.

B) CH vs. CL and MH vs. ML

C) Additional Characteristics

1) Relative Density (coarse-grained material)

Blows per foot	Relative Density
<4	very loose
4 - 10	loose
10 - 30	medium dense
30 - 50	dense
> 50	very dense

2) Consistency (fine-grained material)

Blows per foot	Consistency	Field Test
0 - 2	very soft	easily penetrated several inches with fist
2 - 4	soft	easily penetrated several inches with thumb
4 - 8	medium stiff	penetrated several inches by thumb with moderate effort
8 - 15	stiff	readily indented by thumb but penetrated only with great effort
15 - 30	very stiff	readily indented by thumbnail
> 30	hard	indented with difficulty by thumb nail

3) Relative Moisture

Moisture is measured relative to its optimum water content for compaction. Use the following descriptions:

Relative Moisture	Field Test
Dry	does not contain water.
Slightly Moist	damp, will not hold together.
Moist	soil will reach its maximum compaction under pressure.
Wet	contains excess moisture for compaction.
Saturated	below the water table.

SOP 2

Surface Soil Sampling

Introduction

This SOP describes the procedures for sampling surface soils from ground surface to 12 inches below ground surface. Samples may be collected with decontaminated hand tools.

Equipment

- Hand tools (e.g., shovels, spoons, etc.)
- Sample driver apparatus
  - Drive barrel
  - Brass sleeves
  - Rod and slide hammer
- Teflon™ tape and end caps to seal brass sleeves
- Laboratory-supplied sample containers if not using brass sleeves
- Decontamination Supplies
  - Buckets
  - Alconox Detergent
  - Distilled water
  - Scrub brush
- Direct Reading Instrument (PID and/or XRF)
- Tape Measure
- Log Forms/Field Notebook

Preliminaries

Soil sample locations will be determined from the project-specific work plan. If necessary, concrete coring will be arranged before mobilizing to the field.

Procedures

Soil will be collected and placed into laboratory-supplied sample containers with decontaminated hand tools or with a gloved hand. Coarse-grained soils, such as gravel and rock fragments, will be avoided whenever possible. To prevent loss of volatiles, soil will be packed tightly inside the sample container to minimize headspace.

If soil samples are being collected with a sample driver, brass sleeves will be placed inside the sample barrel and the sampler will be driven to the desired depth with the slide hammer. After the sample barrel is retrieved, the brass sleeves will be removed and the ends of each sleeve will be covered with Teflon™ tape and sealed with plastic caps.

Samples will be labeled appropriately and immediately stored in an iced cooler to maintain a temperature of 4° Celsius. The sample depths and locations will be measured and documented in the field notebook with the soil description.

SOP 4

Test Pit/Excavation Soil Sampling

Introduction

This SOP describes the equipment and procedures for collecting soil samples from test pits and excavations. Samples may be collected from the backhoe bucket or from the excavation wall, provided the excavation meets safe entry requirements.

Equipment

- Hand tools (e.g., shovels, spoons, etc.)
- Sample containers
- Decontamination supplies
  - Buckets
  - Alconox detergent
  - Distilled water
  - Scrub brush
- Direct reading instrument
- Tape measure
- Log forms/field notebook
- Laboratory-supplied sample containers

Preliminaries

Sample locations will be determined using the project-specific work plan. Arrangements will be made for the location of underground utilities using Blue Stakes. When necessary, a private locating service will be used for utilities that are not covered by Blue Stakes.

Procedures for Sampling from Backhoe Bucket

Soil within the backhoe bucket will be screened with the appropriate direct reading instrument and readings will be recorded in the field notebook. Soil samples selected for laboratory analysis will be collected from the backhoe bucket, taking care to avoid sloughed material and avoiding material that has been in direct contact with the backhoe bucket. Samples will be packed in laboratory-supplied containers to minimize headspace. Each sample will be labeled following SOP 20.

Procedures for Sampling Directly from Pit Wall (less than 5 feet deep)

A fresh surface will be scraped from the pit wall using decontaminated hand tools. The soil on the pit wall will be screened with a direct reading instrument and the reading will be recorded in the field notebook. A soil sample will be collected by either pushing a brass sleeve into the wall of the excavation, or by removing material with decontaminated hand tools or gloved hand and packing it into the sample container. To prevent loss of volatiles, the brass sleeve or sample jar should be packed full so that no headspace is present. Each sample will be labeled following SOP 20.

Decontamination

Strict decontamination procedures, as outlined in SOP 17, will be used to prevent cross-contamination of samples. Decontamination will be performed on non-disposable sampling equipment, including drilling equipment (e.g., auger barrel, split spoon) and hand tools (e.g., shovels, hand augers, etc.

SOP 5

Direct-push Drilling Sampling

Introduction

Direct-push drilling equipment will be used to advance shallow soil borings (generally 30 feet or less) to collect soil and groundwater samples and for sites where access restrictions prevent mobilization of a larger drill rig. Standard operating procedures for direct-push soil and groundwater sampling are described below.

Preliminaries

Direct-push drilling sample locations will be marked or staked in the field and coordinated with the Terracon project manager and, if necessary, the client's project manager. Blue Stakes utility clearance will be requested for each boring location prior to direct-push sampling. Borings will be located at least two feet from marked underground utilities.

All sampling equipment will be decontaminated according to SOP 17 prior to initiating drilling activities. This equipment includes all direct-push drill rods, samplers, and hand tools.

Direct-push Drilling Equipment and Procedures

Soil borings will be advanced and sampled using a hydraulic hammer mounted to a truck, van, three-wheeler, or small tractor. Each borehole will be started by hydraulically hammering steel drill rod with a disposable pointed steel end point into the ground. The borehole will be advanced in regular increments, available in varying lengths from 2 to 5-feet, by adding sections of flush-threaded drill rod to the drill stem already in the ground. No lubricants or additives will be used while advancing direct-push borings.

Soil Sampling Equipment

The following equipment will used to conduct soil sampling:

- Direct-push core samplers (supplied by the drilling contractor)
- New polybuterate sample liners (supplied by the drilling contractor)
- New sample liner end caps (supplied by the drilling contractor)
- Chemical-resistant gloves
- Appropriate personal protection equipment according to the HASP
- Sealable plastic bags
- Sample labels
- Laboratory-supplied glass soil sample jars and labels (optional)
- Stainless steel putty knife
- Stainless steel bowl and spoon
- Photoionization detector (PID)
- Cooler and ice
- Munsell color chart, if required
- Unified Soil Classification System (USCS) chart, if required

Soil Sampling

Samples will be collected as specified in the site-specific sampling plan. At a minimum, soil samples will be collected at regular intervals if lithologic information is needed. Each soil sample will be collected in a drill rod sampler lined with a clear polybuterate sample sleeve. The sampler will be attached to the drill rod, lowered to the sample interval, opened, and then hydraulically hammered into the subsurface.

Soil samples for laboratory analyses can be collected directly in the samples' sleeves or may be transferred from the sleeves to laboratory-supplied sample containers using decontaminated hand tools or by hand wearing new chemical-resistant gloves.

Soil Sampling Using the Driller's Sample Sleeves

The polybuterate sleeves may be used as sample containers, using the following procedure. After the sampler has been retrieved from the borehole, the sample shoe will be removed from the sampler and the soil contents will be sealed in a plastic bag for headspace analysis. If the sample shoe is empty, a small amount of soil will be removed from the portion of the liner immediately above the sample shoe. The soil will be allowed to equilibrate in the plastic bag for approximately 15 minutes. The headspace vapors inside the bag will be measured by pushing the PID tip through one side of the plastic bag into the headspace of the bag. The maximum PID reading over a 30-second interval will be recorded at the corresponding depth on the soil-boring log. Following headspace sample collection, soil will be removed from each end of the polybuterate liner for soil classification. If recovery is poor, the headspace sample will be used for soil classification after the headspace reading has been measured and recorded on the boring log. The polybuterate liner will be trimmed flush on each side to minimize headspace, and each end will be covered with Teflon tape. Each end of the liner will then be sealed tightly with polybuterate end caps. The sample will be labeled and immediately placed in an iced cooler to maintain a temperature of 4°C.

In general, the sample liner associated with the highest headspace reading will be submitted for VOC and semi-VOC analysis. If headspace readings are zero for all samples, odors, soil staining, and clay-rich (high sorption) lithology will be used as selection criteria.

Soil Sampling Using Laboratory-Supplied Soil Jars

The sample sleeve will be cut and the sleeves will be handled with chemical-resistant gloves. The sample will be screened with the direct reading instrument by removing a portion of the sleeve, exposing the soil to the instrument probe. The soil sample selected for chemical analysis will be packaged immediately into laboratory-supplied soil jars, labeled as described above, and immediately stored in an iced cooler to maintain a temperature of 4° Celsius.

Sample Selection Criteria for Laboratory Analysis

In general, the sample liner associated with the highest headspace reading will be submitted for VOC and semi-VOC analysis. If headspace readings are zero for all samples, odors, soil staining, and clay-rich (high sorption) lithology will be used as selection criteria.

Groundwater Sampling

To facilitate the collection of groundwater samples at sites where the water table is penetrated, a temporary well point will be installed in the direct-push borehole. After the water table has been encountered, the borehole will be advanced at least three more feet to ensure adequate sample volume. The well point may consist of either a three-foot long stainless steel screen drill rod attachment or slotted PVC screened in a similar interval. New tubing and well screens will be used for each well point. A peristaltic pump will be attached to the tubing to obtain groundwater samples by the following analyte order in the appropriate laboratory-supplied pre-preserved sample containers:

1) VOCs and BTEXN
2) Semi-VOCs
3) Total Petroleum Hydrocarbons
4) Oil and Grease
5) Filtered metals

Groundwater samples collected for dissolved metals analysis may be field filtered using in-line filters attached to the outlet tubing of the peristaltic pump or with Nalgene™ hand-pump filters.

The sample will be labeled and immediately placed in an iced cooler to maintain a temperature of 4°C.

Boring Abandonment

After all soil and groundwater samples have been collected, each soil boring will be backfilled with granular bentonite. Borings that were drilled through asphalt or concrete will be backfilled with granular bentonite to within six inches of the ground surface and the asphalt and concrete cores will be restored.

Demobilization

After the equipment has been rigged down and loaded, the site will be cleaned and restored as close to its original condition as possible. All sampling equipment will be decontaminated prior to mobilizing to the next direct-push drilling sample location.

SOP 9A–SOIL GAS SAMPLING

Introduction

This SOP describes the equipment, criteria, and procedures that will be used to collect samples from soil gas probes. Some deviations from this SOP may be necessary because of site-specific conditions. This SOP applies to soil gas probes installed up to 5 feet below the ground surface (bgs).

Equipment

Below is a checklist of equipment for conducting soil gas probe sampling:

- Direct Reading Instrument (e.g., MGD-2002 gas meter for helium))
- Necessary fittings to complete the sample train;
- Log Forms
- Batch-certified clean Summa® canisters, using new Teflon® tubing and flow regulator to be supplied by the laboratory;
- Peristaltic pump for evacuating the tubing and filling Tedlar bags with helium for leak detection testing.

Procedures

Summa Canister Sampling

Soil vapor samples will be collected in laboratory-supplied, batch-certified clean Summa® canisters, using new Teflon® tubing and a flow regulator that will restrict flow to no more than 200 mL per minute.

In order to ensure the soil vapors collected are representative of subsurface pore spaces, the soil probe and attached tubing will be evacuated of three volumes of the vapor point annulus and attached Teflon®-lined or Tygon® tubing prior to sampling. The sample train will be constructed in a manner that allows for annulus purging and sample collection without disconnecting the sample train. The canister will be connected to the sampling port using dedicated Teflon®-lined or Tygon® sample tubing connected to a sample train.

Leak detection will be conducted using two separate methods. First, a shut-in test will be conducted on the sample train after it is fully assembled. Shut-in tests involve pulling a vacuum on the sample train and monitoring the vacuum on an inline vacuum gauge. If the sample train holds vacuum, the sample train will be deemed to be airtight. The second test measures the integrity of the sample train by introducing helium gas in the vicinity of the sample train while a vacuum is being applied. Air from the vapor point and tubing will be purged and collected in a new Tedlar bag. While the purging occurs, the sample point and sample train are placed under a shroud that is filled with 15-20% helium by volume. The helium percentage in the shroud is monitored with a MGD-2002 gas meter. The purged air collected in the Tedlar bag is then tested with the gas meter. If the purged air contains less than 5% of the shroud's helium content, the sample train will be deemed to be airtight. This process is repeated three times to ensure the sample train's integrity and to purge the appropriate three volumes of air from the vapor point annulus through the entire sample train.

Once purging has been completed, open the Summa canister valve. The flow rate for the Summa canister will vary, depending upon desired results (e.g., for comparison to PELs or TLVs). Once sampling is complete, close the valve of the canister and disconnect the tubing. Document the flow rate, the time the canister's regulator was opened, and the time the canister's regulator was closed. The Summa canister should not be completely filled (i.e. the valve should be shut when the vacuum gauge reads between 2 to 4 inches of Hg). Document the vacuum gauge reading.

Mark the sample canister with the sample identification, date and time of collection, and the sampler's initials. Document all of the sampling methodologies used in the project field log form.

SOP 10B

Monitoring Well Design and Installation (using direct-push drilling)

Introduction

This SOP describes procedures for the drilling and installation of shallow monitoring wells within the unconfined water table aquifer using direct-push drilling equipment. Site-specific conditions may warrant deviating from these standard designs. Field personnel should consult with the project manager and the work plan before deviating from the basic design.

Well Design

The typical well design to be used is intended to provide water samples of the upper 5-10 feet of the water-bearing zone. The well screens will be 10-feet long and will be set so that the top of the screen is at least two feet above the highest-observed water level.

Casing and Screen Materials

In general, well materials will be 1-inch to 2-inch-diameter, schedule 40, flush-threaded, PVC. All joints will be flush-threaded. The perforated zone will be constructed from machine slotted 0.010-inch or 0.020-inch slot screen. A six-inch long sump (silt trap) will be placed at the bottom of the screen. Depending on site conditions, well materials can vary, including different diameter casings, different schedule ratings for the PVC, etc.

Sand Pack

The sand pack material will be a commercially packaged, inert, non-carbonate, well rounded, sieved, product of clean, silica sand. In general, a sand of 16-40 to 10-20 mesh should be used with 0.020-inch slot well screen. The sand pack will be placed from the bottom of the boring up to 1 foot above the top of the screened section.

Bentonite Seal

A bentonite seal will be installed in the annulus above the sand pack to prevent grout from infiltrating into the screen and sand pack zone. Bentonite chips may be used for the seal if it is placed above the water table. Pellets should be used below the water table, as they have a higher density than the chips and will settle through the water better.

Annular Seal

Shallow wells (less than 20 feet of annulus above the bentonite seal) can be sealed with bentonite chips, which are hydrated in place with potable water. Wells that have a longer annular space should be sealed with a cement grout mix.

Drilling and Installation Methods

Drilling Equipment

Boreholes for monitoring wells will be installed using direct-push drilling equipment unless field conditions dictate otherwise. The inside diameter of the rods should be at least 1 inch larger than the outside diameter of the well casing to allow room for a filter pack and grout seal to be installed through the rods.

Borehole Drilling

The borehole for the well casing will be drilled using direct-push rods. No lubricants, circulating fluid, drilling muds, or other additives will be used during drilling.

During drilling, native soil samples will be retrieved in clear polybuterate sleeves within the direct-push rods. The collected samples will be logged per the sampling work plan requirements, which may include soil type (Unified Soil Classification), moisture, and color. Selected samples may be submitted for chemical and physical analysis if called for in the work plan.

Once the borehole has been drilled to the desired depth, the subcontractor will prepare to install the well. The drill rods will remain in the ground to ensure stability of the borehole during well construction.

Well Casing Installation

Clean chemical-resistant gloves will be worn by drilling personnel while handling the well screen and casing. All lengths of well casing and screen will be measured and recorded in the field log book prior to well installation.

Filter Pack Installation

The filter sand pack will be installed by slowly pouring silica sand through the direct-push rods as they are slowly removed from the borehole. By this procedure, the rods act as a tremie pipe and will prevent sand from bridging inside the rods. The level of sand pack inside the annular space will be continuously monitored. As the rods are pulled upward, the sand settles out through the bottom and additional sand pack will be added at the surface. By adding sand pack this way, the borehole will remain open and free from cave-ins, and the well casing will remain centered within the sand pack and the borehole.

Bentonite Seal Installation

After the appropriate amount of sand pack has been added and its depth verified, the remaining annulus will be sealed with bentonite. Once the desired thickness of bentonite is in place, the bentonite will be allowed to settle for approximately 30 minutes. The thickness of the bentonite seal will be verified and subsequently hydrated using potable water.

Flush-Mount Completion

After the grout has cured, the PVC well casing will be cut so that it is approximately three inches below the ground surface. The top of the PVC well casing will be sealed with a locking expandable well cap, or PVC cap, and an 8-inch flush-mount well vault will be installed at the surface with cement. The cement surface surrounding the vault cover will be slightly mounded to cause surface water to drain away from the well so that the well vault will not fill with water.

SOP 12

Groundwater Monitoring Well Sampling

Introduction

This SOP describes the equipment, criteria, and procedures that will be used to sample groundwater monitoring wells. Some deviations from this SOP may be necessary because of site-specific conditions.

Equipment

Below is a checklist of equipment for conducting groundwater sampling:

- Tools for opening well covers
- Keys to wells
- Water-level indicators
  - Dual-phase (if free product is suspected)
  - Single phase
- Positive displacement pump
- pH, conductivity, and temperature meters
- Standards for pH calibration
- In-line filters for metals samples
- Chemical resistant gloves
- Laboratory-supplied sample containers
- Iced cooler
- Field Notebook
- Chain of custody form
- Appropriate personal protection equipment according to HASP
- Photoionization detector (optional)
- Drum(s) for purge water containment
- Drum labels
- Permanent marker

Preliminaries

All equipment will be decontaminated as described in SOP 17 prior to initiating sampling. Equipment requiring calibration will be calibrated following manufacturer's recommendations prior to initiating sampling. If a well pump will be used, the operating condition of well pump will be checked prior to field mobilization.

Procedures

Upon arriving at each groundwater monitoring well, the well vault cover will be removed and the wellhead will be examined. Any signs of tampering will be recorded in the field logbook. The lock and well cap will then be removed from the well casing and depth to water and total depth will be measured.

Well Evacuation

To obtain a groundwater sample representative of natural aquifer conditions, at least three casing volumes will be evacuated from the well using a positive displacement pump, disposable bailer, peristaltic pump with new tubing, or other equipment per the sampling work plan. Non-disposable equipment will be decontaminated prior to use as described in SOP 17. Evacuated groundwater will be poured into a graduated 5-gallon bucket to keep track of the purge volume. If purge water cannot be discharged at the site, when the graduated bucket is full, the contents will be transferred into a 55-gallon drum. If the well does not recharge fast enough to permit the removal of three casing volumes, the well will be pumped dry and sampled as soon as it has sufficiently recharged.

Casing Volume Calculation

The well casing volume will be calculated to determine the purge volume required to obtain a groundwater sample representative of natural aquifer conditions. The following procedure will be used to calculate the total purge volume. Using the top of the north side of the inner well casing as a reference point, the depth to water (DTW) and total depth (TD) of the well will be measured using a water-level probe. The height of the water column will then be calculated by subtracting the depth to water from the total depth of the well (TD - DTW). Equation (1) below is used to calculate volume constants for wells with various casing sizes.

$$\text{Well Casing Volume} = \pi\,(\text{Casing Radius})^2\,(7.48\ \text{gal/ft}^3) \qquad (1)$$

where Casing Radius = the radius of the well casing in feet
$7.48\ \text{gal/ft}^3$ = volume conversion constant
π = constant = 3.14

For a 2-inch diameter well casing:
Casing Volume = (TD-DTW feet) (0.16 gallons/foot)
Total Purge Volume = Casing Volume x 3

For a 4-inch diameter well casing:
Casing Volume = (TD-DTW feet) (0.65 gallons/foot)
Total Purge Volume = Casing Volume x 3

Stabilization Parameters

If required by the sampling work plan, groundwater stabilization parameters pH, temperature, and specific conductivity can be monitored during well purging to verify when the aquifer has stabilized and groundwater sampling can commence. Stabilization parameters will be measured at least four times; once every casing volume and immediately before sampling. All stabilization parameter measurements will be recorded in the field log book. The following guidelines are acceptable ranges for stabilization parameters:

- pH readings are consistently within 0.2 pH units;
- temperature is within 0.5˚C of the last reading;
- conductivity is within 10 percent of the last reading.

Groundwater Sample Collection

A complete set of laboratory-supplied sample containers will be prepared and labeled prior to collecting groundwater samples. A disposable bailer or low-flow peristaltic pump will be used to obtain groundwater samples by the following analyte order in the appropriate pre-preserved sample containers:

1) PFAS
2) VOCs;
3) Semi-VOCs;
4) Filtered metals

All 40-milliliter containers will be filled so that no headspace is present in the container after the lid has been fastened. Groundwater samples collected for dissolved metals analysis may be field filtered using inline filters attached to the outlet tubing of a peristaltic pump or with a Nalgene™ hand-pump filter press. The labels for each groundwater sample will be double-checked and immediately placed in an iced cooler to maintain a temperature of 4˚C.

Purge Water Containment and Disposal

If required by the sampling work plan, purge water can be contained in labeled 55-gallon drums and stored onsite. At a minimum, drum labels will contain the following information:

- Site Identification
- Monitoring Well Identification
- Volume (Gallons) of Purge Water
- Terracon
- Terracon Project Manager (Name)
  6949 South High Tech Drive
  Midvale, UT 84047
  801-545-8500

The final disposition of the purge water will depend on groundwater analytical results and contract specifications.

Decontamination

All sampling equipment will be decontaminated according to SOP 17 before initiating sampling. If more than one well will be sampled, sampling equipment must also be decontaminated between wells.

Demobilization

After well sampling has been completed and all equipment has been decontaminated, each well will be capped and secured. Damaged equipment will be noted in the field logbook and labeled on the instrument.

SOP 12A Monitoring Well Sampling Using Low-flow Methods

Introduction

This SOP describes the equipment, criteria, and procedures that will be used to sample groundwater monitoring wells using low-flow (micropurging) methods. Some deviations from this SOP may be necessary because of site-specific conditions. Well sampling should be completed at least 24 hours after the wells have been developed.

Equipment

Below is a checklist of equipment for conducting groundwater sampling:

- Tools for opening well covers
- Keys to wells
- Water-level indicators
  - Dual-phase (if free product is suspected)
  - Single phase
- Low-flow micropurge pump
- Hydrolab with flow-through cell
- Standards for Hydrolab calibration
- In-line filters for metals samples
- Chemical-resistant gloves
- Laboratory-supplied sample containers
- Iced cooler
- Field notebook
- Chain-of-custody form
- Appropriate personal protection equipment according to HASP
- Photoionization detector (optional)
- Drum(s) and label(s) for purge water containment (if specified in Work Plan)
- Permanent marker

Preliminaries

All equipment will be decontaminated as described in SOP 17 prior to mobilizing to the site. All equipment requiring calibration will be calibrated at the equipment warehouse prior to mobilizing to the field. The operating condition of pump will be checked prior to field mobilization.

Upon arriving at each groundwater monitoring well, the well vault cover will be removed and the wellhead will be examined. Any signs of tampering will be recorded in the field log book. The lock and well cap will then be removed from the well casing and depth to water and total depth will be measured.

Equipment

The wells will be evacuated with a low-flow micropurge pump. New tubing will be used for each well. Stabilization parameters will be measured in line with a Hydrolab flow-through cell (or

equivalent instrumentation). The meter will be calibrated according to manufacturer's specifications.

Purging Procedures

- Measure depth to water and total depth of each well
- Calculate one volume of the screened or open interval as performed in the following example:

  10 foot screen, 2-inch well diameter = 10 feet x 0.1632 gal/foot = 1.632 gal

  1.63 gal x 3.785 liters/gal = 6.17 liters or 6.17 liters x 1,000 mL/liter = 6171 mL

- Calculate the time required to purge one well volume, assuming a purge rate of 200 mL/min:

  6171 mL ÷ 200 mL/min = 30.85 minutes to purge one volume

Calculating the purge volume will be helpful in determining when stability of the water-borne constituents can be expected.

- Lower pump to the mid-point of the screened interval.
- Inflate packer (if used) just above top of screen to isolate the screened interval.
- Begin to purge well. USEPA recommends a purge rate of 200 to 300 mL/min. Actual purge rates will be site-specific. If the packer is not used, the purge rate should not exceed the recharge rate (i.e., no drawdown in static water level).
- Measure water quality parameters specified in the Work Plan (pH, temperature, turbidity, conductivity, , and dissolved oxygen) with a flow-through cell at 3 to 5 minute intervals. These parameters should begin to stabilize at one-half the screened area volume.
- Once the above-mentioned parameters have stabilized within 10% over three readings, sampling can begin.

Sampling Procedures

Using the well purging pump already in place, the sample will be collected out of the pump discharge line. The sampling rate can be maintained at 200 mL/min for collecting samples for metals analysis. The flow-through cell will be disconnected or bypassed during sample collection.

If analyzing for dissolved metals, the samples will be collected through an in-line, disposable, 0.45-micron pore filter.

Purge Water Disposal

Purge water will be thin-spread on the ground, either in the area around the well or on asphalt or concrete. .

Decontamination

All sampling equipment will be decontaminated according to SOP 17 before mobilizing to the site. If more than one well will be sampled, sampling equipment must be decontaminated between wells.

Demobilization

After well sampling has been completed and all equipment has been decontaminated, each well will be capped and secured. Damaged equipment will be noted in the field logbook and labeled on the instrument.

SOP 13

Groundwater Monitoring Well Sampling - perfluoroalkyl substances (PFAS)

Introduction

This SOP describes the equipment, criteria, and procedures that will be used to sample groundwater monitoring wells for PFAS compounds. These analytes require special sampling and handling methods. Terracon will employ the "Clean Hands – Dirty Hands" protocol, developed by the US EPA for sampling low level metals and can be used for other contaminants that are analyzed in the parts per trillion range. Some deviations from this SOP may be necessary because of site-specific conditions.

Equipment

In addition to the equipment listed in SOP 12, Groundwater Monitoring Well Sampling, the following is a list of specific equipment for use when sampling for PFAS.

ITEMS TO BRING:

- High-density polyethylene (HDPE) tubing
- Clothing - 100% cotton (no use of dryer sheets)

ITEMS THAT CANNOT BE BROUGHT TO SITE:

- Rain gear
- Non-cotton fabrics
- food
- Anything marked as waterproof (ie notebook, Gore-tex boots)
- Aluminum foil
- Teflon-coated containers or lids
- Sunscreen
- Insect repellent
- Personal care products

Preliminaries

All equipment will be decontaminated as described in SOP 17 prior to initiating sampling. Equipment requiring calibration will be calibrated following manufacturer's recommendations prior to initiating sampling. If a well pump will be used, the operating condition of well pump will be checked prior to field mobilization.

Step-by-step Procedures

Clean Hands (CH) / Dirt Hands (DH)

1. Before arriving onsite
    a. Wash water level probe
    b. Wash hands then put on nitrile gloves
    c. Put ice in Ziploc bags then into coolers
2. Arrive onsite, Prep
    a. Put on gloves – DH opens outer glove bag for CH, CH opens inner bag and removes gloves

3. Equipment blank before sample first well
    a. DH opens outer bag with sample tubing
    b. CH opens inner bag with sample tubing, holds segment of tubing for DH to cut
    c. DH connects tubing to pump
    d. DH2 opens cooler, removes bag with sample bottles, opens outer sample bottle bag
    e. CH opens inner sample bottle bag, removes bottles
    f. DH1 turns on pump
    g. CH collects sample. Hold lids or keep in inner sample bag (do not place on ground)
4. Gauges well: DH gauge using deconned WLM and records info on groundwater sampling form
5. To Purge Well:
    a. DH stages pump next to well
    b. DH opens outer bag with HDPE tubing
    c. CH opens inner bag with sample tubing
    d. CH handles tubing, puts down well (touching nothing but tubing), holds tubing for DH to cut
    e. DH cuts tubing
    f. DH sets up water quality meter – probe in bucket, not connected to tubing
    g. DH turns on pump, purges water into bucket, records readings on sample form
6. To Sample PFAS sample:
    a. DH opens cooler, removes bag with sample bottles
    b. DH opens outer sample bottle bag
    c. CH opens inner sample bottle bag, removes bottles
    d. CH collects sample, touching nothing but sample tubing and sample bottles. Hold lids or keep in inner sample bag (do not place on ground)
    e. CH fills out label on sample bottles
    f. CH puts sample bottles in inner sample bag and zips bag closed
    g. DH closes outer bag, opens cooler, places sample in cooler
7. Field Blank – follow sampling protocol. Only CH touch sample bottles and pours PFAS free water
8. Fill remaining sample containers; CH/DH not applicable

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SOP 14

Field Instrument Calibration

Introduction

This SOP describes the procedures for the use and calibration of the most commonly used field instruments. The use and calibration procedures are provided for the following field instruments:

- Photoionization detector/organic vapor monitor (PID/OVM)
- X-Ray Fluorescence (XRF) Multi-element Analyzer

Photoionization Detector

- Photoionization detector meter and filter screen
- Isobutylene span gas (100 ppm) and gas sample bag

Calibration Procedures

Calibration procedures will be performed, as specified by the manufacturer, each day prior to use.

SOP 17

Equipment Decontamination

In order to reduce the risk of cross-contamination or transferring contaminants from areas of known contamination to known clean areas, decontamination of personnel and equipment is required. The decontamination procedures shall be established for each site based on the degree of hazard associated with the site and the amount of contact with hazardous materials resulting from site work. Final decontamination procedures shall be reviewed and approved by the Site Safety and Health Manager and included in the site-specific Health and Safety Plan (HASP). This procedure contains general decontamination protocols, suitable for most sites, although decontamination procedures will be reviewed on a site-by-site, contaminant-by-contaminant basis. Spent decontamination fluids will generally be considered non-hazardous waste and disposed accordingly, dependent on contaminant types present at a given site.

Decontamination Guidelines

Terracon uses a four-step decontamination procedure described below:

Step 1 Gross Contaminant Removal
This step consists of a removing gross materials by gloved hand and then scrubbing using a detergent solution and water and a stiff brush. Scrubbing will continue until visible contaminants are removed. The water will be changed as necessary, daily at a minimum.

Step 2 Alconox Wash
An Alconox wash will be prepared by mixing 1 to 1-½ tablespoons of Alconox per gallon of warm water. The water will be changed as necessary, daily at a minimum.

Step 3 Clear Water Rinse
A rinse with clear potable water. This water will be changed as necessary to ensure its purity, daily at a minimum.

Step 4 Distilled Water Rinse
Unused distilled water will be used as a final rinse for all decontamination procedures. The water may be poured or sprayed.

Decontamination Blanks to document the decontamination procedures will be collected if required in the sampling work plan.

SOP 20

Sample Handling and Documentation

Introduction

This SOP describes procedures to follow once soil, sediment, or water samples are collected to ensure that the samples are handled properly and that appropriate documentation is completed.

Sample Handling

Chemical resistant gloves will be worn during collection and initial handling of all samples. All samples will be promptly placed in an iced cooler to maintain a temperature of 4°C. Typically, samples selected for chemical analysis are delivered at the end of each day to the analytical laboratory. If they are not submitted to the laboratory on the same day collected, they will be stored in a refrigerator in a locked sample storage room at Terracon's office until transport and delivery to the laboratory in an iced cooler. Upon receipt of the samples, the laboratory will record the internal temperature of the sample transport coolers on the chain of custody record.

Documentation

Sample Identification and Labeling

Samples will be labeled following the specific labeling requirements set forth in the sampling plan or using labeling methods that identify the area from which they were collected and the depth.

Each sample sleeve or sample container will be immediately labeled with the following information:

- Project number
- Sample identification
- Sample depth
- Date and time collected
- Analyses requested
- Filtered or unfiltered (for water samples)

This information will also be recorded in the field notebook. An example sample label is provided as an attachment to this SOP

Chain of Custody

Chain of custody documentation will begin in the field for each sample submitted to the laboratory and will be maintained by laboratory personnel. Samples will remain in the possession of the sampler at all times, or in a locked facility until delivery to the analytical laboratory. A chain of custody form will be completed and will accompany each sample cooler to the analytical laboratory. An example chain of custody form is provided as an attachment to this SOP.

Field Book

Terracon field personnel will maintain a field log book to record all field activities. The field logbook will be a weather-resistant bound survey-type field book. All data generated during the project and any comments or other notes will be entered directly into the field logbook.

Example Sample Label:

Prepared by Environmental Science Corp.

Project: ______________________

Proj #: ______________________

Sample Location/ID: ______________________

Analysis Reqd: ______________________

____

Date: ____________ Time: ____________

Example Chain of Custody Form:

CHAIN OF CUSTODY - SAMPLE SUBMITTAL FORM

COMPANY: ______________________

ADDRESS: ______________________

CITY/STATE/ZIP: ______________________

PHONE #: ______________________

CONTACT: ______________________

EMAIL: ______________________

PROJECT: ______________________

PO Number: ______________________

INVOICE EMAIL ADDRESS: ______________________

RUSH Due Date:

*Expedited turnaround subject to additional charge

QC Level

1 2 2+ 3 3+

CHEMTECH-FORD LABORATORIES

Chemtech-Ford Laboratories
9632 South 500 West
Sandy, UT 84070
Phone: 801-262-7299
www.chemtechford.com

Sample condition	
Custody Seal	Correct Containers
Container Intact	Sufficient Sample Volume
COC/Labels Agree	Headspace Present (VOC)
Received on Ice	Temperature Blank
	Received within Holding Time

Delivery Method	
UPS	USPS
FedEx	Chemtech-Ford Courier
Walk-in	Customer Courier

Lab Use Only	CLIENT SAMPLE INFORMATION				TESTS REQUESTED		
	LOCATION / IDENTIFICATION	DATE	TIME	MATRIX	E. Coli/Coliform (Absent/Present)	E. Coli/Coliform (Enumerated)	HPC
	1.						
	2.						
	3.						
	4.						
	5.						
	6.						
	7.						
	8.						
	9.						
	10.						
				Bottle type			
				Lot #			

Sampled by: [print]	Sampled by: [signature]	ON ICE NOT ON ICE Temp (C°):
Special Instructions:		Samples received outside the EPA recommended temperature range of 0-6 C° may be rejected.

Relinquished by: [signature]	Date/Time	Received by: [signature]	Date/Time
Relinquished by: [signature]	Date/Time	Received by: [signature]	Date/Time
Relinquished by: [signature]	Date/Time	Received by: [signature]	Date/Time

Payment Terms are net 30 days OAC. 1.5% interest charge per month (18% per annum). Client agrees to pay collection costs and attorney's fees.

APPENDIX B

Laboratory Quality Assurance Manuals

Chemtech-Ford, Inc.
9632 South 500 West
Sandy, UT 84070
(801) 262-7299

Vice President of Quality: Paul Ellingson

Quality Manager: Ron Fuller

Laboratory Director: Dave Gayer

Date of Issue: October 1, 2017

Controlled Copy #: QM-27

Dave Gayer, Laboratory Director

Paul Ellingson, Vice President

Ron Fuller, QA Officer

Quality Manual

This Quality Manual meets the requirements of ISO 17025, ISO 9001, and TNI. This Quality Manual is confidential and assigned as outlined below.

Original Document: Quality Manager

☐ Controlled Copy
☒ Uncontrolled Copy

All employees have access to a controlled version through Quality Manager, or through the Chemtech-Ford intranet. Printed copies are not considered controlled documents.

Companies whose Quality Systems are defined by this document are:

Chemtech-Ford Laboratories
9632 South 500 West
Sandy, UT 84070
801.262.7299

Timpview Analytical Laboratories
1384 West 130 South
Orem, UT 84058
801.229.2272

This Quality Manual has been approved for use by affiliate laboratories of Chemtech-Ford, Inc.

Table of Contents

Introduction

Purpose

This Quality Manual contains all the requirements that our laboratory uses to demonstrate our quality management system, technical competence, and valid results.

Section 4 specifies how we demonstrate sound management and maintain client satisfaction.

Section 5 specifies how we demonstrate technical competence in our laboratory.

In addition, this Quality Manual outlines how we meet:

- ISO 17025
- ISO 9001
- TNI

All personnel are to take an active role in establishing, implementing, and maintaining our quality management program. We do not separate quality from our daily business. Quality is integrated into every facet of the decision-making process in the management of our laboratory and the science that we practice.

It is the policy of Chemtech-Ford, Inc. and its employees to perform their duties in a consistently legal and ethical manner. A professionally high level of ethical behavior is characterized by, but not limited to, dealing honestly and forthrightly with all clients and co-workers, maintaining data integrity, the open and timely treatment of inaccurate, invalid, or misreported analytical data, and abiding by all pertinent rules, regulations, company policies, and standard operating procedures.

Chemtech-Ford, Inc. encourages its employees to demonstrate consistently ethical and professional behavior by implementing programs consonant with that purpose. These programs, generally, include:

1) a thorough training program for new employees and continuing seminars throughout employment which reflect Chemtech-Ford, Inc.'s commitment to integrity and quality control and which present specific ways to honor that commitment

2) a comprehensive documentation program for all facets of laboratory operation, which allows ready reconstruction of any quality process

3) a program of continual evaluation, both internally and externally, with required levels of quality acceptance

4) a management monitoring system which routinely evaluates the overall performance of the laboratory.

This Quality Manual summarizes the policies and procedures employed by Chemtech-Ford, Inc. It is the purpose of these policies and procedures to maintain the highest level of integrity and ethical behavior in all aspects of laboratory work.

Distribution List

The approved version of this manual is available to all employees through Quality Manager and/or Chemtech-Ford Laboratories intranet. All printed copies are uncontrolled.

In the event that a controlled copy of this manual is necessary, the Quality Manager will maintain a distribution list.

1. Scope

This Quality Manual facilitates:

- Recognition of technical competence for standardized methods, non-routine methods, and laboratory-developed methods we perform
- Inspection and product certification capabilities and/or services we provide
- Total quality for our administrative and technical systems
- Audits by clients, regulatory authorities and accreditation bodies
- Meeting the requirements of ISO 17025, ISO 9001, and TNI
- Client satisfaction

Chemtech-Ford Laboratories displays all Fields of Accreditation on our website.

2. Normative References

Reference List

ISO/IEC 17000, Conformity assessment – Vocabulary and general principles

VIM, International vocabulary of basic and general terms in metrology, issued by BIPM, IEC, IFCC, ISO, IUPAC, IUPAP and OIML.

ISO 9001:2000 – Quality Management Systems – Fundamentals and vocabulary.

ISO/IEC 17025:2005 – General Requirements for the Competence of Testing and Calibration Laboratories.

TNI Standard, Volume 1, 2009 NELAC Standard.

Cross-references

This manual is numerically aligned with the international standard ISO 17025. Furthermore, each section cross-references the ISO 9001 standard.

For ease of use, each section starts with a brief summation of what the section addresses and a listing of the quality terminology and key words.

3. Terms and Definitions

For the purposes of this manual, the following documents and their corresponding definitions apply: ISO/IEC 17000; ISO/IEC Guide 30; ISO Council Committee on Conformity Assessment (CASCO); ISO 9000; ISO 5725-1; ISO 17025; TNI 2009 Standard; AOAC; and International Vocabulary of Basic and General Terms in Metrology (VIM).

Accreditation – formal recognition of a laboratory by an independent science-based organization that the laboratory is competent to perform specific tests.

4.1 Organization

Section Synopsis

This section tells you our laboratory has:

1. Appointed a Quality Manager
2. Organized the workforce to achieve quality
3. Provided adequate resources to ensure quality

Key Words

Quality Manager
Organizational Chart
Authority
Resources
Confidential Information
Proprietary Rights
Responsibilities
Conflict of Interest

Cross-references

ISO 17025:2005 Section 4.1
ISO 9001:2000 Section 4.1, 5.1, 5.3, 5.4.1, 5.5.1, 5.5.2, 5.5.3, 6.1, 6.2.1, 6.2.2, 6.3.1, 7.1, 7.5.4

4.1.1 Legal Identification / Registration

Chemtech-Ford, Inc.
9632 South 500 West.
Sandy, UT 84070
(801)262-7299
(866)792-0093

4.1.2 Laboratory Requirements

The work area of Chemtech-Ford, Inc has been organized to satisfy the needs of the customer and regulatory authorities and to meet the international standards TNI, ISO 17025 and ISO 9001. Chemtech-Ford, Inc. is composed of the following work areas:

President/CEO/Vice Presidents
Lab Director
QA/QC Department
Customer Service Department
Receiving/Shipping Department
Organics Lab
Inorganics Lab
Microbiology Lab
Metals Lab

4.1.3 Scope of Management System

The management system covers activities all of the laboratory's facilities. The fields of activities include:

Environmental Sample Testing
Medical Device Testing
Nutraceutical Product Testing
Specialty Testing

The laboratory's scope of tests is listed in the current Price List.

4.1.5 Organization

A) Management and Technical Personnel

Policy:

The laboratory managerial and technical personnel, irrespective of other responsibilities, have the necessary authority and resources needed to meet the mandates assigned to their areas.

Details:
Responsibilities are detailed in 5.2.5

Departures from the organizational and management policies in this manual can only be approved by a Vice President.

Departures from quality management system procedures can only be approved by a Vice President or the Quality Manager.

Departures from test methods or technical standard operating procedures (SOPs) can only be approved by the Quality Manager and/or the Laboratory Director.

See also section 5.2.

B) Conflict of Interest

Policy:
Management and personnel are to be free from any undue internal and external commercial, financial and other pressures that may adversely affect the quality of their work. The integrity of test results is the responsibility of all personnel. Management ensures that employees are never instructed or forced to alter or falsify data. Chemtech-Ford Laboratories performs annual data integrity training. A review of the undue pressure policy is part of this training.

Details:
The following list provides some guidelines on how employees avoid conflict of interest situations. Employees shall not:

- falsify records, prepare fraudulent reports, or make false claims

- seek or use privileged or confidential company information, or data from any customer, for any purpose beyond the scope of employment
- conduct non-laboratory business on laboratory time, or use company facilities or equipment to conduct outside interests in business, unless prior approval has been obtained
- solicit business on their own behalf (rather than the laboratory) from a customer
- be employed by, or affiliated with, organizations whose products or services compete with laboratory products or services
- have employment that negatively affects or interferes with their performance of laboratory duties
- compete with the laboratory in the purchase, sale, or leasing of property or goods
- allow association, family, or friends to influence business decisions to their benefit. Decisions must be made on a strictly business basis, always in the best interest of the laboratory
- make any decision that provides gains or benefits to the employee and/or others
- have personal financial dealings with an individual or company that does business with the laboratory which might influence decisions made on the laboratory's behalf

Firm adherence to this code of values forms the foundation of our credibility. Personnel involved in dishonest activities are subject to a range of disciplinary action including dismissal.

C) Customer Confidentiality

Policy:
It is the policy of our laboratory to protect the confidential information and proprietary rights of our customer including the electronic storage and transmission of results.

Details and Procedures:
All employees sign a Confidentiality Agreement. The signed agreement is retained in each employee's Human Resources file.

Test results are only released to the customer. Release to someone other than the customer requires the express permission of the customer, except when the situation contravenes State or Federal Legislation and the results must be provided to the appropriate agency. The release of test results to anyone other than the customer requires the permission of management. Laboratory reports are reviewed for accuracy prior to release.

D) Operational Integrity

Policy:
The laboratory will avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment, or operational integrity.

Details and Procedures:
To ensure confidence in laboratory operations a formal quality assurance program is implemented. Technical competence is ensured through commercial performance testing studies and data formatted in DOCs (Demonstration of Competency) reports. Impartiality is assessed through audits and approvals. Judgment is ensured through the hiring of qualified personnel and by continuously refining, upgrading, and improving his or her skills. Operational integrity is reviewed by management on a regular basis at management review meetings to ensure continued suitability and effectiveness of laboratory policies and procedures. Any problems are acted on immediately through corrective action procedures.

E) Organizational Structure

Policy:
The organization and management structure of the laboratory and the relationships between management, technical operations, support services, and the quality management system is defined through the aid of an organizational chart.

Details:
The most current organizational structure is contained within Quality Manager. The organizational structure is reviewed at regular intervals (at least two times per calendar year).

F) Responsibility and Authority

The responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the tests and/or calibrations is defined in section 5.2.5

G) Laboratory Supervision

Policy:

Adequate supervision is provided in each area of the laboratory for all testing and calibration personnel, including trainees, by persons familiar with the methods and procedures.

Details:
Adequate supervision is ensured through designated supervisors as well as through documentation such as this Quality Manual, test methods and SOPs. Initial and ongoing training for regular personnel is required. The successful completion of analyses in the commercial PT study program, and/or DOC studies are evidence of successful and continued training.

H) Technical Management

Policy:
A technical manager is assigned to each major work area of the laboratory. They have overall responsibility for the technical operations and the provision of resources needed to ensure the required quality of laboratory operations.

Details:
While the technical manager may at times delegate duties to other personnel, the technical manager is responsible for the work produced in his area of the laboratory, and is accountable for any nonconforming activities.

I) Quality Manager

Policy:
The Quality Manager is appointed by the highest level of management. The Quality Manager, who, irrespective of other duties and responsibilities, has defined responsibility and authority for ensuring that the management system related to quality is implemented and followed. The Quality Manager has direct access to the highest level of management where decisions are taken on laboratory policy or resources.

Details:
This statement notifies all laboratory personnel that the Quality Manager is authorized by senior management and the President to administer all activities relating to the Chemtech-Ford Laboratories quality system. A formal announcement to the laboratory and appropriate certification/regulatory authorities will be made if a change is made to the person filling this position.

J) Managerial Substitutions

Policy:
Deputies for key personnel are appointed to fulfill the key personnel's duties in their absence.

Details:
In the absence of the Lab Director, the Quality Manager or Deputy Lab Director will assume his/her responsibilities.

In the absence of the Quality Manager, the Lab Director will assume his/her responsibilities.

In the absence of the Laboratory Supervisor, the Lab Director, Deputy Lab Director and/or Quality Manager will assume his/her responsibilities.

Management is responsible for ensuring that current and/or increased workload requirements are met. This includes making adjustments as a result of employee absence. Only fully trained employees are utilized to fulfill the duties of personnel who are absent. Evidence of a DOC for each specific analysis must be recorded prior to allowing the employee to perform any testing in the laboratory. If sufficient human resources are not available, management will identify the best possible solution to meet operational requirements.

K) Awareness

Policy:
Management ensures that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system.

Details:
Supervisors review the details of each employee's job description with the appropriate employee and how the overall Quality Policy Statement (Section 4.2.2) relates to their activities to achieve the objectives of the management system.

4.1.6 Communication Processes

Policy:
Top management ensures that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system.

Details:
Management meetings are held regularly. Assignments and important communications are made in this meeting. The appropriate manager communicates the assignment or communication to their direct reports. These meetings are documented and follow-up activities are recorded.

Revision History

Changes from Revision 26
Modified section 4.1.3 to include all of the facilities of the company rather than just the main facility.

4.2 Management System

Section Synopsis

This section tells you that our Management System (or Quality Management System) is based on:

1. A well-defined quality policy statement
2. Say what you do through documentation
3. Do what you say following your documentation
4. Record what you did

Key Words

Establish, Implement, and Maintain
Policies, Systems, Processes, Programs, Procedures, Instructions
Communicate, Understand
Quality Policy Statement
Quality Manual
SOP
Test Method

Cross-references

ISO 17025:2005 Section 4.2

ISO 9001:2000 Section 4.1, 4.2.1, 4.2.2, 5.1, 5.3, 5.4.1, 5.4.2, 5.5.1, 5.5.2, 6.2.1, 7.1

4.2.1 Policies and Procedures

Policy:
The Quality Management System is established, implemented, and maintained by management. It is applicable to all the fields of testing and activities in which the laboratory is involved and undertakes. All policies, systems, programs, procedures and instructions are documented to the extent necessary to enable the laboratory to assure the quality of results generated. These documents are communicated to, understood by, available to, and implemented by the appropriate personnel.

Details:
The purpose of our Quality Management System is to ensure that all services and products satisfy the customer's requirements and have been designed, tested, and delivered under controlled conditions.

The effectiveness of the Quality Management System is assessed in several ways:

- by a program of planned internal audits, covering all aspects of the operation of the quality management system
- by regular management reviews of the suitability and effectiveness of the quality management system
- by analysis of potential and actual problems as shown by customer complaints and supplier and subcontractor assessments
- by other methods approved from time to time by the appropriate authority.

This Quality Manual and associated documents (including procedures) and records serve as the quality plan for the laboratory. Other documents and records may include:

- standard operating procedures (SOPs)
- quality control plans in test methods
- organizational charts
- proposals
- project management schemes
- Equipment manuals
- Reference methods
- Regulations
- Accreditation standards
- Software

4.2.2 Quality Policy Statement

Policy:
The policies and objectives for laboratory operations are documented in this Quality Manual. The overall objectives are set out in the Quality Policy Statement and reviewed during management review. The Quality Policy Statement is issued under the authority of the Senior Management on the effective date.

Quality Policy Statement:
To ensure accurate and timely analytical services and to continuously meet or exceed the stated or implied expectations of our customers through day-to-day interactions.

Effective Date: February 15, 2016

a) *Management commitment to good professional practice and quality of services provided to the customer*: tests and calibrations are always carried out in accordance with stated standardized methods and customers' requirements. Requests to perform tests that may jeopardize an objective result or have a low validity are rejected, or the laboratory's concerns are noted in the certificate of analysis.

b) *Standards of service include*:
- Customer Satisfaction
- Accuracy
- Timeliness
- Compliance with applicable standards and procedures

Excellence in the workplace is promoted by providing all employees with the knowledge, training, and tools necessary to allow for the completion of accurate and timely work.

c) *Purpose of management system related to quality*: to manage our business by meeting the needs of our customers and the requirements of the applicable standards and procedures.

d) *Personnel*: familiarize them with quality documentation and implement the policies and procedures in their work.

e) Management is committed to complying with the applicable standards and regulations (e.g. TNI, ISO, OGWDW etc.) and to continually improve the effectiveness of the management system: the objective of this Quality Manual is to document the compliant policies and associated procedures that are integrated into our daily activities. Continual improvements are established, implemented, and locked into the management system.

Additional objectives include:

- to establish the level of the laboratory's performance
- to make test method changes to improve performance
- to participate in proficiency testing or quality evaluation programs with peer laboratories
- to ensure that all personnel are trained to a level of familiarity with the quality management system appropriate to the individual's degree of responsibility
- to improve and validate laboratory methodologies by participation in method validation collaborative tests
- to establish and report on quality savings

4.2.3 Commitment to the Management System

Policy:
Top management is committed to the development and implementation of the management system and continually improving its effectiveness.

Details:
The results of the management system are regularly reviewed during management review (see Section 4.15) and continual improvements are made as outlined in Section 4.10 – Improvements.

4.2.4 Communication of Requirements

Policy:
Top management communicates to the organization the importance of meeting customer requirements as well as statutory and regulatory requirements.

Details:
In general, the underlying message in all oral and written management communications involves meeting the aforementioned requirements. Meeting customer requirements ensures that ongoing business relationships secure the contracts that keep everyone employed. Meeting statutory and regulatory requirements ensures that laboratory operations will not be disrupted and the organization can continue to meet customer needs.

4.2.5 Quality Manual

Policy:
This Quality Manual outlines the structure of the documentation used in the quality management system. This Quality Manual makes reference to supporting procedures including technical procedures and is maintained up to date.

Details:
This quality management system is structured in three tiers of documentation. The tiers are as follows:
I. Quality Manual
II. Standard Operating Procedures and Test Methods
III. Records

For most customers, this Quality Manual and the associated documents form a general Quality Plan. If necessary, specific Quality Plans will be prepared on a 'per-customer' basis. These Quality Plans will modify the general requirements stated in the Manual and associated documents.

All of the above documents are controlled documents. Not all quality system documents and procedures are maintained in this manual, rather some are referenced and located in other documents. The following records and directive documents are contained or referenced in the Quality Manual:

- organizational chart (section 4.1.5.E)
- identification of resources and management review (section 4.15.1)
- job descriptions (section 5.2.4)
- statistical techniques (section 5.9)
- test reports (section 4.13.2 and 5.10)
- identification of the laboratory's approved signatures (section 5.10.2)

- laboratory's scope of tests (section 4.1.3)
- equipment inventory and records (sections 5.5.4 and 5.5.5)
- calibration status indicators (section 5.5.8)
- reference standards inventory (section 5.6.3)
- verification records (section 5.9)
- quality control plan / criteria for workmanship (section 5.4.1)
- corrective action records (section 4.11)
- preventive action records (section 4.12)
- customer complaint records (section 4.8.1)
- audit schedule and records (section 4.14.3)
- procurement and subcontracting records (sections 4.6 and 4.5.4)
- training records (section 5.2.5)
- master list of documentation (section 4.3.2)
- confidentiality agreements (section 4.1.5 C)
- contract review (section 4.4.2)
- validation of test methods (section 5.4.5)
- facility floor plan (section 5.3.1)

4.2.6 Change Management

The roles and responsibilities for change management are outlined in QSP 4-2-6.

4.2.7 Technical Management and the Quality Manager

The roles and responsibilities for technical management and the Quality Manager are outlined in section 5.2.5 of this manual.

Technical management ensures that section 5 of this manual is implemented and maintained. The Quality Manager ensures that section 4 of this manual is implemented and maintained.

4.2.8 Maintenance

Policy and Details:
Top management ensures that the integrity of the management system is maintained when changes to the management system are planned and implemented.

Revision History

Changes from Revision 24

Revision 25 is a significant revision with numerous additions, deletions and corrections. These are not all documented in the revision history, rather all persons on the distribution list are required to read the entire document.

4.3 Document Control

Section Synopsis

This section tells you that Document Control involves:

1. Writing good procedures
2. Getting them to the users
3. Keeping procedures good

Key Words

Controlled Document
Master List
Unique Identification
Revise
Revision Number
Effective Date
Review and Approval
Obsolete
Archive
Hand-written changes

Cross-references

ISO 17025:2005 Section 4.3

ISO 9001:2000 Section 4.2.1, 4.2.3, 4.2.4

4.3.1 Policies and Procedures

Policy:
The SOP# QSP 4-3-1 is used to control all quality management system documents (internally generated and from external sources). These include documents of external origin, such as regulations, standards, other normative documents, test and/or calibration methods, as well as drawings, specifications, instructions, and manuals.

Details:
Document means any information or instructions including policy statements, procedures, specifications, charts, text books, posters, notices, memoranda, software, drawings, and plans. These may be in various media, whether hard copy or electronic and they may be digital, analog, photographic or written.

The documents to be controlled include:
- Quality Manual
- Standard Operating Procedures and test methods
- Forms
- Standards
- Software manuals
- Reference methods and manuals
- Equipment manuals
- Applicable regulations/statutes

The control of data related to testing and calibration is covered in section 5.4.7. The control of records is covered in section 4.13.

4.3.2 Document Approval and Issue

4.3.2.1 Review / Approval / Master List

Policy and Details:
All documents issued to personnel in the laboratory as part of the quality management system are reviewed and approved for use by authorized personnel prior to issue (i.e., reviewed by personnel knowledgeable in the documented activity and then approved by management). A master list can be obtained by viewing the lists located on the Chemtech Quality Manager and the SOP database for performance based methods, or intranet under the SOP section. The categories are divided by folders. Each folder has a hyperlinked list

of the SOPs. A listing of document revision is posted on the announcement area of the Chemtech Document Archive tab. A revision history is maintained. Documents are formally reviewed periodically to ensure their continuing suitability.

4.3.2.2 Availability and Obsolete Documents

Policy and Details:
The master list shows the current status of all controlled documents. The master list document is organized with the following information:

- Document Title
- Effective Date
- Revision Number
- Method Reference (if applicable)
- Date of last review

Controlled documents are approved before issue.

The SOP# QSP 4-3-1 for document control ensures that:

- authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed
- documents are periodically reviewed and where necessary revised to ensure continuing suitability and compliance with applicable requirements
- invalid or obsolete documents are promptly removed from all points of issue or use to assure against unintended use
- obsolete documents retained for either legal or knowledge preservation purposes are suitably marked (i.e., “INACTIVE" and dated) and/or archived appropriately.

4.3.2.3 Identification

Policy and Details:
All quality management system documentation is identified by:

- date of issue and/or revision number
- page numbering
- total number of pages (e.g., page 5 of 5)
- issuing authority (i.e., reviewer approval)

4.3.3 Document Changes

4.3.3.1 Review / Approval

Policy:
Changes to documents are reviewed and approved by the same function (i.e., personnel or position) that performed the original review.

Details:
Developments in policies and procedures require documents to be changed from time to time. Changes to documents receive the same level of review and approval as the originals.

The Quality Manual is reviewed annually by the Quality Manager. Records are kept of this review.

Test methods and SOPs are reviewed on a biennial basis. Procedures for this are outlined in SOP# QSP 4-3-1.

Obsolete documents are withdrawn, but are retained for archive purposes and clearly labeled as obsolete.

4.3.3.2 Identification of Changes

Policy:
The nature of document changes is identified in the document.

Details:
As outlined in SOP# QSP 4-3-1.

In general, the nature of changes is identified in the document by changing the font color to blue. Revision history is recorded at the end of the document.

4.3.3.3 Amendments by Hand

Policy and Details:
Hand-written amendments to documents are permitted only by those personnel authorized to do so (see section 4.1.5 A). Amendments are clearly marked, initialed, and dated. A revised document is formally re-issued at the time of the annual review. For further details refer to SOP# QSP 4-3-1.

4.3.3.4 Computerized Documents

Policy and Details:
The SOP# QSP 4-3-1 details how changes in documents maintained in computerized systems are made and controlled.

Revision History

Changes from Revision 24

None

4.4 Review of Requests, Tenders, and Contracts

Section Synopsis

This section tells you that you must:

1. Clearly understand customer requirements

Key Words

Requirements
Subcontractor
Request
Tender
Contract
Review

Cross-references

ISO 17025:2005 Section 4.4

ISO 9001:2000 Section 5.2, 6.1, 7.2.1, 7.2.2, 7.2.3

4.4.1 Policies and Procedures

Policy:
Prior to the commencement of any services that fall within the scope of this Quality System, Chemtech-Ford will ensure that the scope of the work is clearly defined and that the objectives of the project can be met. In some cases, the requests are formalized through a statement of work and signed contract. Other cases require less formalized contracts. In all instances Chemtech-Ford formalizes a contract between the laboratory and the client. The lab ensures that:

a) the customer requirements including the methods to be used are adequately defined, documented and understood (see section 5.4.2)
b) the laboratory has the capability and resources to meet the requirements
c) the appropriate test method is selected and capable of meeting the customer's requirements (see section 5.4.2)

When practicable, any differences between the request or tender and the contract are resolved before any work commences. Each contract must be acceptable by both the laboratory and the customer.

Details:
The review of capability establishes that the laboratory possesses the necessary physical, personnel, and information resources, and that the laboratory's personnel have the skills and expertise necessary for the performance of the tests in question. The review may also encompass results of earlier participation in inter-laboratory comparisons or proficiency testing and/or the running of trial test using samples or items of known value in order to determine uncertainties of measurement, limits of detection, and confidence limits.

Some contracts are formalized through a bidding process, RFP etc. Some contracts are less formal. When a formal process initiates the work, the specifications of the project are agreed upon and programed into the LIMS. When appropriate contracts are signed by necessary parties.

All work orders at Chemtech-Ford Laboratories are considered contracts between the lab and the customer. After logging the sample(s) into the LIMS and after a login review is performed by the lab, a login summary of requested analyses is submitted to the customer for their review. The customer is informed of tests to be performed including test method, subcontracted work, conditions of samples upon receipt and any other anomaly that might have an adverse effect on the results of the analyses. The customer is requested to review the work order for accuracy and note any discrepancies to the lab in a

timely manner. If the customer does not reply in a timely manner, Chemtech-Ford Laboratories proceeds with the work. For some analyses, the lab is required to start work immediately (e.g. short holding times or rush analyses). The customer has the ability to stop this work as needed.

The contract review ensures that each customer's requirements are adequately defined and documented in a timely manner. This should ensure that any order, once accepted, can be completed without delay, and that the customer's requirements including delivery date, technical specification can be met.

Typical types of contracts include:

- approved service quotations
- confidentiality agreements
- non-disclosure agreements
- sample submission requests
- memorandum of agreement
- memorandum of understanding
- research proposals and contracts
- verbal orders (oral agreements)
- activity plans

4.4.2 Records of Review

Policy:
Records of request, tender and contract review, including significant changes, are maintained. Records of pertinent discussions with a customer relating to the customer's requirements or the work during the period of execution of the contract are also maintained.

Details:
Records of request is made by the client via chain-of-custody. Alternative requests may also be made through other mechanisms (e.g. email). In the event that an alternative mechanism besides the chain-of-custody is used for a request, such documentation is retained. After samples have been entered into the LIMS and reviewed for correctness, a summary of the requested work is sent to the client via email to verify the accuracy of their request compared to Chemtech-Ford Laboratories interpretation of the request. Chemtech-Ford Laboratories assumes that the request is accurate unless the client

informs us otherwise. If there is a discrepancy, the change is noted and documented in the LIMS or chain-of-custody.

Other work may demand more complex and formalized contract review. These contracts are maintained by Chemtech-Ford Laboratories and the client. Formal contracts should be stored in the project in LIMS. The LIMS project can be customized for most of the project requirements such as pricing, analyte lists, reporting limits, QC limits, report format, report recipients, etc.

When a formal contract is entered into between the lab and the client, the appropriate lab member of management must sign the contract (usually the Vice President or their designee). The person responsible for managing the project ensures that all of the aspects of the project can be met. That person coordinates the project plan and execution of the project with the appropriate laboratory staff. They also communicate any problems meeting the client objectives to the client and will advise the lab how to proceed.

4.4.3 Review of Subcontracted Work

Policy:
Request, tender, and contract review also includes work that is subcontracted by the laboratory.

Details:
Subcontractor laboratories are reviewed as described in section 4.5. Performance based methods developed by Chemtech-Ford Laboratories are not subcontracted.

4.4.4 Notification of Customer

Policy and Details:
Customers are informed of deviations from the contract. This is typically communicated to the customer prior to the performing the deviation.

4.4.5 Contract Amendment

Policy and Details:

If a contract needs to be amended after the work has commenced, the same contract review process is repeated and any amendments are communicated to all affected personnel.

Revision History

Changes from Revision 24
Revision 25 is a significant revision with numerous additions, deletions and corrections. These are not all documented in the revision history, rather all persons on the distribution list are required to read the entire document.

4.5 Subcontracting of Tests and Calibrations

Section Synopsis

This section tells you that we must:

1. Know what tests and calibrations need to be done by another laboratory
2. Check out the other laboratories

Key Words

Competence
Register of Subcontractors
Assessment

Cross-references

ISO 17025:2005 Section 4.5

ISO 9001:2000 Section 7.2.3, 7.4.1, 7.4.3, 8.2.4

4.5.1 Subcontractor Competence

Policy:
Performance based methods developed by Chemtech-Ford Laboratories are not subcontracted unless directed by the client. Work that must be subcontracted is done so to a technically competent laboratory due to:

- unforeseen circumstances
- workload
- project specifications/requirements
- contracts requiring some extra technical expertise

Details:
The subcontracted laboratory demonstrates technical competence by possession or receipt of one or more of the following:

- recognized technical accreditation (e.g. TNI, ISO, EPA etc.)
- satisfactory performance of appropriate quality control check samples, certified reference material, in-house reference material or replicate analysis
- audit of the subcontractor's quality management system by our auditors

It is the responsibility of the Quality Manager to assess and approve the competence level of subcontractor laboratories. The approved subcontract laboratories are maintained in Quality Manager.

4.5.2 Customer Approval

Policy:
Customers are advised of work (or any portion thereof) that is being subcontracted to another laboratory and their approval is obtained (preferably in writing).

Details:
Customers are advised of subcontracted work through the contracting process (see 4.4).

4.5.3 Assurance of Subcontractor Competence

Policy:
If the laboratory selects the subcontracted lab, then the laboratory is responsible to the customer for the subcontractor's work. Technical competence of subcontractor

laboratories is demonstrated through various records including accreditation records from the laboratories Accreditation Body. There may be circumstances where the customer specifies which subcontractor is to be used. In such cases we may not be able to demonstrate the competence of the subcontractor and therefore are not responsible for the results.

Details:
Records of subcontractor competence can include, but are not limited to, the following:
- accreditation certificates or documentation
- registration certificates
- check sample results
- audit results
- approval by the Quality Manager
- approval by the client

4.5.4 Subcontractor Register

Policy:
A register of all subcontractors performing tests and calibrations is maintained in Quality Manager or within the project records.

Details:
The approved register of subcontractors is maintained by the applicable Accreditation Body or in the project records.

Revision History

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Revision 25 is a significant revision with numerous additions, deletions and corrections. These are not all documented in the revision history, rather all persons on the distribution list are required to read the entire document.

4.6 Purchasing Services and Supplies

Section Synopsis

This section tells you that we must:

1. Know what we want
2. Check out our suppliers

Key Words

Selection
Verify
Specifications
History

Cross-references

ISO 17025:2005 Section 4.6

ISO 9001:2000 Section 6.3.1, 7.4, 7.5.5, 8.2.4

4.6.1 Policies and Procedures

Policy:
The SOP# QSP 4-6-1 is used to select and purchase services and supplies. The SOP# QSP 4-6-1 is used for procurement, reception, and storage of supplies.

Details:
Consumable materials are stored according to the appropriate test method, SOP, or work instruction.

4.6.2 Specifications

Policy:
Only services and supplies of the required quality are used. These quality requirements are detailed in laboratory SOPs under the "*Equipment and Supplies"* and "*Reagents and Standards"* sections and will identify the appropriate minimum specifications when necessary.

Details:
Packing slips are checked against package content labels and matched with the Purchase Order if accepted. Once accepted, the packing slip is dated and initialed as evidence of compliance. Certificates of analysis (COA) are scanned and maintained on file in the LIMS or other appropriate area after the COA is checked to ensure the received item meets minimum specifications.

Chemicals are purchased with manufacturer's certificates where possible. Uncertified chemicals are purchased from ISO 9000 registered companies. Whatever the source, the laboratory verifies the quality of the standards by comparing the new batch of standards to the old. Due regard is paid to the manufacturer's recommendations on storage and shelf life.

Reagents are generally purchased from manufacturers who have a quality management system based on ISO 9000. The grade of any reagent used (including water) is stated in the method together with guidance on any particular precautions to be observed in its preparation or use.

Where no independent assurance of the quality of procured goods or services is available or the supplier's evidence is insufficient the laboratory ensures that purchased goods and

services comply with specified requirements. Where possible and practical the laboratory ensures that goods are inspected, calibrated, or are otherwise in compliance with any standard specification relevant to the calibrations or tests concerned.

4.6.3 Purchasing Documents

Policy:
Purchasing requests are recorded on the Purchase Order form and contain data describing the product ordered. The Purchase Order is reviewed and approved for technical content prior to release.

Details:
The description may include type, class, grade, precise identification, specifications, drawings, inspection instructions, other technical data including approval of test results, quality required and quality management system standard under which they were produced.

The completion of the Purchase Order is the responsibility of the originator or supervisor. Either reviews the Purchase Order for accuracy and approve the technical content prior to release with their signature and the date.

4.6.4 Approved Suppliers

Policy:
Suppliers of critical services are evaluated and approved before use. An approved supplier list is maintained.

Details:
Audits or tender evaluation is conducted to qualify suppliers of critical services prior to use. The criteria for evaluation may include, but is not limited to the following:

- references
- accreditation
- formal recognition

The records are maintained by purchasing personnel.

Revision History

Changes from Revision 24

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4.7 Service to the Customer

Section Synopsis

This section tells you that we must:

1. Facilitate clarification of the customer's request
2. Give customer access to relevant testing area
3. Maintain customer contact
4. Inform customer of delays or deviations
5. Utilize customer surveys

Key Words

Clarification
Deviations
Delays
Customer Satisfaction Survey

Cross-references

ISO 17025:2005 Section 4.7

ISO 9001:2000 Section 6.1, 7.2.1, 7.2.3, 7.4.3, 7.5.1

4.7.1 Service

Policy:
Customer requests are clarified for the customers or their representatives. Furthermore, the customer or their representative will be afforded the right to monitor the performance of the laboratory in relation to the work performed, provided that the laboratory ensures confidentiality to other customers.

Details and Procedures:
Service to the customer includes:

- Affording the customer or the customer's representative reasonable access to relevant areas of the laboratory for the witnessing of work performed for the customer; it is understood that such access should not conflict with rules of confidentiality of work for other customers or with safety.

- Maintaining of open contacts. The customer values advice and guidance in technical matters, and opinions and interpretations based on results. Contact with the customer, especially in large assignments, should be maintained throughout the work. The laboratory should inform the customer of any delays or major deviations in the performance of the tests.

4.7.2 Feedback

Policy and Details:
The laboratory seeks feedback from the customer. Positive and negative feedback can be obtained passively through ongoing communications with the customer (e.g., review of test reports with customers) or actively through customer satisfaction surveys. The feedback is used to improve the quality management system, testing activities, and customer service.

One mechanism Chemtech-Ford Laboratories has established is a database that allows for the entry of customer feedback (both positive and negative). The database categorizes each item of feedback. When a laboratory representative receives feedback from a client or other interested party, this should be reported in the database. When feedback requires an action this is documented and assigned to the appropriate team member for review.

Other mechanisms are in place to review customer feedback. During weekly management meetings, customer feedback is reviewed (positive and negative).

Revision History

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4.8 Complaints

Section Synopsis

This section tells you that you must:

1. Maintain records of Complaints
2. Maintain records of Corrective Action

Key Words

Resolving
Investigation
Corrective Action
Follow-up Verification

Cross-references

ISO 17025:2005 Section 4.8

ISO 9001:2000 Section 7.2.3

4.8.1 Policies and Procedures

Policy:
The SOP# QSP 4-8-1 is used for resolving complaints received from customers or other parties. Records are maintained of all complaints and follow-up.

Details:
Records of complaints include the following information:

- description of the complaint
- investigation
- corrective action (if necessary)
- solution notes and date
- follow-up verification
- issuance level

See also section 4.11.

Revision History

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4.9 Control of Nonconforming Testing and Calibration Work

Section Synopsis

This section tells you that you must:

1. Stop testing when nonconforming work is identified
2. Determine what is causing nonconforming work

Key Words

Nonconforming
Root Cause

Cross-references

ISO 17025:2005 Section 4.9

ISO 9001:2000 Section 5.5.1, 7.4.3, 7.5.1, 8.2.4, 8.3, 8.5.3

4.9.1 Procedures to Control Nonconforming Work

Policy:
The SOP# QSP 4-9-1 is used to control any aspect of testing and/or calibration work, or the results of this work, when they do not conform with the test methods or the agreed requirements of the customer.

Details:
The procedure ensures that:

- Responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of test reports as necessary) are defined and taken into consideration when nonconforming work is identified
- an evaluation of the significance of the nonconforming work is made
- correction is taken immediately, together with any decision about the acceptability of the nonconforming work
- where necessary, the customer is notified and the work is recalled
- the responsibility for authorizing the resumption of work is defined

Identification of nonconforming work or problems with the quality management system or with testing activities can occur at various locations within the quality management system and technical operations such as:

- customer complaints
- quality control
- instrument calibration
- checking of consumable materials
- staff observations or supervision
- test report checking
- management reviews
- internal or external audits

4.9.2 Root Cause Analysis

Policy:
Where evaluation indicates that nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, the corrective action procedures given in 4.11 are followed to identify the root cause(s) of the problem and to eliminate this (these) cause(s). All notes, discoveries, and actions

taken by participating personnel are to be reflected on the corrective action form. The QM directs this process and retains all documentation within the appropriate files for future reference. These corrective action documents will be stored for five years.

Details:
The SOP# QSP 4-11-1 outlines the recording of the root cause analysis for investigating nonconforming work.

Situations warranting corrective action investigation include:
- failure to comply with test method including all applicable procedures necessary to ensure the integrity and representative nature of the sample
- presentation of uncertain knowledge as to compliance with test methods including all applicable procedures necessary to ensure the integrity and representative nature of the sample
- failure or suspected failure in method performance as demonstrated by results provided by quality control samples
- lack of relevant evidence provided by quality audit, proficiency testing, or customer feedback
- lack of relevant evidence provided by data validation
- neglect to check the inherent property of the sample that compromises the testing

Revision History

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4.10 Improvements

Section Synopsis

This section tells you that you must:

1. Review procedures for improvements
2. Continually implement improvements

Key Words

Continually
Effectiveness
Analysis of data

Cross-references

ISO 17025:2005 Section 4.10

ISO 9001:2000 Section 6.1, 8.1, 8.2.1, 8.4, 8.5.1

4.10.1 Policies and Procedures

Policy:
The laboratory continually improves the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions, and management review.

Details:
The laboratory has implemented a continual improvement philosophy within the management system. Every employee in the laboratory is encouraged to suggest new ideas for improving services, processes, systems, productivity, and the working environment.

Opportunities for improvement of operations and processes are identified by managers on a continual basis from ongoing feedback on operations and through management reviews. Opportunities for improvement of services are identified by anyone within the organization including Sales, and Marketing.

Inputs for improvement opportunities may be obtained from the following sources:
- customer satisfaction surveys and any other customer feedback
- market research and analysis
- employees, suppliers, and other interested parties
- internal and external audits of the management system
- records of service nonconformities
- data from process and service characteristics and their trends

Opportunities for improvement may also be identified on a special project basis. The following are listed only as examples:
- improving usefulness of bench space
- reducing excessive inspection/testing
- reducing excessive handling and storage
- reducing test/calibration failures

Opportunities for improvement from daily feedback on operational performance (i.e., internal audits, customer feedback, test/calibration failures) are evaluated by the Technical or Quality Manager. Typically, they are implemented through the corrective and preventive action system.

Opportunities for improvement from analysis of longer-term data and trends are evaluated and implemented through the management review process. They are prioritized with respect to their relevance for achieving quality objectives. When opportunities for improvement are no longer supported by the current policy and objectives, management will establish new quality objectives, and possibly change the policy. The process for this evaluation is described in Section 4.15. Longer-term improvement projects are initiated through the management review process, as well as the corrective and preventive action system.

Service improvement opportunities are evaluated by management. They are implemented through the supervisor of the laboratory who ensures that the improvements are validated as outlined in Section 4.12 of this manual and appropriate level of quality control is performed on an ongoing basis.

Revision History

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4.11 Corrective Action

Section Synopsis

This section tells you that you must:

1. Identify problems
2. Determine why the problem occurred
3. Fix the cause of the problem
4. Verify that your changes worked

Key Words

CAR
Root Cause
Monitor
Audit
Nonconforming work

Cross-references

ISO 17025:2005 Section 4.11
ISO 9001:2000 Section 5.5.1, 5.5.2, 8.1, 8.2.2, 8.2.3, 8.4, 8.5.2, 8.5.3

4.11.1 General

Policy:
The SOP# QSP 4-11-1 is utilized for implementing corrective action when nonconforming work or departures from policies and procedures in the quality management system or technical operations have been identified. The procedure requires that appropriate authority be designated for the implementation of corrective actions and includes cause analysis, selection and implementation of corrective action, and monitoring of actions.

Details:
Problems with the quality management system or technical operations of the laboratory may be identified through a variety of activities, such as control of nonconforming work, internal or external audits, management reviews, feed-back from customers, or staff observations.

Corrective action investigations are documented and required changes to operational procedures are implemented. The corrective action request (CAR), investigation and resolution are recorded in the CAR database.

4.11.2 Cause Analysis

Policy:
Corrective action always begins with an investigation to determine root cause(s) of the problem (see SOP# QSP 4-11-1).

Details:
Potential causes of the problem could include customer requirements, the samples, sample specifications, methods and procedures (see 4.11.6), personnel skills and training, consumable materials, or equipment and its calibration.

4.11.3 Selection and Implementation of Corrective Actions

Policy and Details:
After determining the cause(s) of the problem, potential corrective actions are identified. The most likely action(s) (this includes practical and/or reasonable) are selected and implemented to eliminate the problem and to prevent recurrence. It should be noted that

any corrective actions taken to eliminate the cause(s) of nonconformities or other departures are to a degree appropriate to address the magnitude of the problem and commensurate with the risks encountered (Note – in plain language, this means determine whether the benefit outweighs the cost). Controls are applied to prevent recurrence. The laboratory documents and implements the required changes resulting from corrective action investigations.

4.11.4 Monitoring of Corrective Action

Policy:
After implementing the corrective action(s), the laboratory monitors the results to ensure that the actions taken have been effective in overcoming the problems originally identified.

Details:
Monitoring is assigned to an appropriate individual such as the originator of the CAR or the originator's manager. Changes resulting from corrective action are documented.

4.11.5 Additional Audits

Policy:
Where the identification of nonconformities or departures casts doubts on compliance of policies, procedures, regulations, international quality standards, the appropriate areas of activity are promptly audited in accordance with section 4.14.

Details:
Special audits follow the implementation of corrective actions to confirm their effectiveness. A special audit is only necessary when a serious issue or risk to the business is identified. Special audits are carried out by trained and qualified personnel who are [whenever resources permit] independent of the activity to be audited. See section 4.14 for more details.

4.11.6 Responsibility

Policy:
Analytical data routinely generated by the laboratory is evaluated to determine acceptability, including precision and accuracy. Laboratory analyst and supervisors are responsible for evaluating QC in comparison to acceptance criteria.
Details:
When data falls outside of the established control limits or acceptance limits for a given method (as defined by the SOP), that information is evaluated and appropriate action taken. If a problem is discovered that could merit corrective action, the person that discovers the problem should discuss with the Quality Manager the need to initiate a formal corrective action. All Chemtech-Ford Laboratories employees can recommend corrective action. If it is determined that the problem merits corrective action, the Quality Manager will initiate the corrective action.

Revision History

Changes from Revision 24

None

4.12 Preventive Action

Section Synopsis

This section tells you that you must:

1. Identify potential problems
2. Determine why the problem could occur
3. Fix the cause of the potential problem
4. Verify that your changes worked

Key Words

PAR
Potential Nonconformity
Action Plan

Cross-references

ISO 17025:2005 Section 4.12

ISO 9001:2000 Section 4.2.4, 6.3.1, 8.4, 8.5.1, 8.5.2, 8.5.3

4.12.1 Preventative Action Identification

Policy:
Opportunities for needed improvement and potential sources of nonconformities, either technical or with the quality management system shall be identified. If action is required, action plans are developed, implemented and monitored, to reduce the likelihood of occurrence of such nonconformities and to take advantage of the improvement opportunities.

Details:

Records of preventive action include the following information:

- details of potential nonconformities
- investigation
- preventive action
- follow-up verification

4.12.2 Preventive Action Plans

Policy:
The preventive action procedure includes the initiation of such actions and application of controls to ensure that they are effective.

Details:
Preventive action may result from the review of operational procedures and analysis of data. Analysis of data includes trend analysis, analysis of proficiency testing results, and risk analysis.

Preventive actions can be designated and documented in the Corrective Action database or in management meeting notes or other approved laboratory mechanism for recording/monitoring preventive actions.

Revision History

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4.13 Control of Records

Section Synopsis

This section tells you that you must:

1. Identify the records to be kept
2. Keep identified records in a useful state
3. Destroy records when they are no longer needed

Key Words

Collection
Indexing
Access
Storage
Maintenance
Disposition
Legible
Traceable
Retrievable
Secure

Cross-references

ISO 17025:2005 Section 4.13

ISO 9001:2000 Section 4.2.4, 6.3, 6.4, 7.1, 7.5.1, 7.5.2, 7.5.3, 8.1, 8.2.2, 8.2.3, 8.2.4

4.13.1 General

4.13.1.1 Procedures

Policy:
The SOP# QSP 4-13-1 is used to identify, collect, index, access, file, store, maintain, protect, backup, and dispose quality and technical records. Quality records include reports from internal audits and management reviews as well as corrective and preventive action records.

Details:
Records are available to demonstrate conformance to requirements and effective operation of the Quality Management System. Quality records from suppliers are also controlled.

All records, including test reports, are safely stored and held secure (either electronically or physically), and in confidence to the customer. Records are maintained in the designated archival area for five (5) years.

4.13.1.2 Record Integrity

Policy:
All records are to be legible and shall be retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss.

Details:
The retention times for records are generally set at five (5) years. Records may be in the form of any type of media, such as hard copy or electronic media.

4.13.1.3 Record Security

Policy:
All records are held secure and in confidence.

Details:
Access to records is secured through locked rooms, filing cabinets, passwords.

4.13.1.4 Record Backup

Policy:
The SOP# QSP 4-13-1 is followed to protect and backup data/records held on computers at all times and to prevent unauthorized access to or amendment of data/records on computers.

Details:
Data is password protected.

Backups ensure integrity and availability of data/information in the event of a system/power failure.

4.13.2 Technical Records

4.13.2.1 Record Information

Policy:
Original observations, calculations, derived data and sufficient information to establish an audit trail, calibration records, personnel records and a copy of each test report issued are retained for five (5) years.

The records for each test or calibration shall contain sufficient information to facilitate, if possible, identification of factors affecting the test uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original. The records include the identity of personnel responsible for sampling, performing of each test and/or calibration and checking of results.

Details:
Technical records are accumulations of data (see 5.4.7) and information that result from carrying out tests and/or calibrations and which indicate whether specified quality or process parameters are achieved. They may include forms, contracts, work sheets, work

books, note books, instrument printouts, magnetic media, check sheets, work notes, control graphs, test reports, calibration certificates, customer's notes, papers and feedback, and test reports to customers.

The records for each test contain sufficient information to permit its repetition. Records include:

- date of sampling
- sample receipt
- sample handling, storage, and disposal
- identification of personnel
- analyst proficiency
- equipment identification and performance
- calibration records
- media performance, where appropriate
- test organism batch # or lot #, where appropriate
- results
- reports (mailed, emailed, or faxed)
- review

Note – the above records may be stored in separate locations. They are cross-referenced for easy retrieval.

4.13.2.2 Recording

Policy:
Observations, data, and calculations are clearly and permanently recorded and identifiable to the specific job at the time they are made.

Details:
Handwritten records must be legible and made with indelible ink immediately after an observation, after data is collected and/or after calculations are made.

4.13.2.3 Corrections to Records

Policy:
Changes to test data are made so as not to obscure or delete the previous data entry.

Details:
Mistakes are crossed out with a single line, initialed, dated and the correct value entered alongside. Mistakes are not erased, made illegible, or deleted. All alterations to records are signed or initialed by the person making the correction. In the case of computer-collected data, similar measures are taken to avoid loss or change of original data.

4.13.2.4 Transfer of records

Policy:
Records will be maintained or transferred in the event that a laboratory transfers ownership or goes out of business.

Details:
In the event that the laboratory changes ownership, all records will be transferred to the new owners. The new owner(s) will then be given the responsibility of maintaining the records.

If the laboratory goes out of business, all hard copy and electronic records will be maintained by the ownership group at the time of the dissolution of the company for a period of 5 years.

Revision History

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4.14 Internal Audits

Section Synopsis

This section tells you that:

1. Trained internal auditors examine your internal operations for quality
2. Auditors report the results to those in charge
3. You must correct any areas that need fixing

Key Words

Schedule
Elements
Independent
Nonconformity
CAR

Cross-references

ISO 17025:2005 Section 4.14

ISO 9001:2000 Section 8.1, 8.2.2, 8.2.3

4.14.1 Internal Audit Program

Policy:
The internal audit program involves periodic audits conducted according to a predetermined schedule for each year. Each year different aspects of the Quality System are evaluated. The schedule is reviewed during the managerial review. All elements of the management system including the testing activities are covered on a regular basis. These audits are performed to verify operations continue to comply with the requirements of this Quality Manual and are effective.

Details:
The tracking of internal audit results is maintained in Quality Manager. The frequency is also maintained in Quality Manager. The Quality Manual, test procedures, and laboratory results are verified for compliance. It is the responsibility of the Quality Manager to plan and organize audits as required by the schedule and requested by management. Audits are carried out by trained and qualified personnel who are [wherever resources permit] independent of the activity to be audited. Personnel are not to audit their own activities except when it can be demonstrated that an effective audit will be carried out (see also 4.11.5). Audits are performed through the aid of a checklist prepared in advance to minimize the possibility of overlooking any details during the audit. The results of the internal audit are maintained and accessible.

Generally, the types of audits include:
- quality management system
- technical methods
- products, services, and reports

4.14.2 Corrective Action

Policy:
When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of test or calibration results, timely corrective action is taken and customers are notified if investigations show that laboratory results may have been affected.

Details:
Nonconformities that can be resolved easily are to be corrected immediately, ideally during the audit. Records are made on the audit checklist. Nonconformities that require a

more involved resolution are recorded on a CAR and resolved as described in section 4.11.

Corrective actions and customer notifications must be kept on record for each audit deviation that casts doubt as described in this section.

4.14.3 Records and Management

Policy:
Records are made of the activity being audited, the audit findings, and corrective actions that arise. Management ensures that corrective actions are discharged within an appropriate and agreed timeline.

Details:
A report is prepared by the auditors and distributed to those audited and/or the area manager/supervisor within an appropriate and agreed timeline. The audit report may include the following sections, as appropriate:

- audit objective and scope
- area or section audited
- personnel involved – auditors and auditees
- date of audit
- reference documents
- observations including nonconformities and commendations
- opening and closing meetings
- recommendations
- audit report distribution

The appropriate manager is responsible for ensuring that corrective actions are sufficiently recorded. Follow-up is performed by the auditor and recorded when corrective action is complete and deemed effective. The audit records are kept in the laboratory.

4.14.4 Follow-up Audits

Policy:
Follow-up audits are performed to verify and record the implementation and effectiveness of the corrective action taken.

Details:
The follow-up audit is performed at a mutually acceptable time between the area implementing corrective action and the auditor. This time is determined when the CAR is issued.

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4.15 Management Reviews

Section Synopsis

This section tells you that management must:

1. Periodically review technical competence and customer satisfaction
2. Keep records of reviews
3. Ensure follow-up is executed
4. Measure progress

Key Words

Supervisor Reports
Audit Reports
CAR / PAR
Proficiency Results
Customer Satisfaction Survey
Resources

Cross-references

ISO 17025:2005 Section 4.15

ISO 9001:2000 Section 5.1, 5.4.2, 5.6, 6.2.1, 7.1, 8.5.1

4.15.1 Review of Quality Management System and Testing

Policy:
Top management periodically (at least annually) and in accordance with a predetermined schedule and SOP# QSP 4-15-1, conduct a review of the laboratory's quality management system and testing and/or calibration activities to ensure their continuing suitability and effectiveness and to introduce any necessary changes or improvements.

Details:
The review takes account of:

- suitability of policies and procedures (including the Quality Policy outlined in this manual)
- 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 undertaken
- feedback from customers, including complaints and customer satisfaction surveys
- recommendations for improvement
- other relevant factors, such as quality control activities, resources and personnel training

A minimum period for conducting a management review is once a year. Results of the review feed into the laboratory planning system and include goals, objectives and action plans for the coming year.

A management review can be supplemented by consideration of related subjects at regular management meetings.

4.15.2 Findings, Actions, and Records

Policy and Details:
Findings from management reviews and the actions that arise are recorded in the minutes of the meeting. Management will ensure that the actions are discharged within an appropriate and agreed upon timeline.

Revision History

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5.1 General

Section Synopsis

This section informs you that:

1. Many factors contribute to the correctness and reliability of tests and/or calibrations
2. The laboratory must account for these factors

Key Words

Correctness
Reliability
Uncertainty

Cross-references

ISO 17025:2005 Section 5.1

ISO 9001:2000 Section 7.1, 7.5.1

5.1.1 Correctness and Reliability

Policy and Details:
Correctness and reliability of the tests and/or calibrations performed have many contributing factors including:

- Human factors (see section 5.2)
- Accommodation and environmental conditions (see section 5.3)
- Test and calibration methods and method validation (see section 5.4)
- Equipment (see section 5.5)
- Measurement traceability (see section 5.6)

5.1.2 Measurement Uncertainty

Policy:
When developing test and calibration methods and procedures, total measurement uncertainty must be accounted for in the training and qualification of personnel, and in the selection and calibration of equipment.

Details:
The extent to which the factors contribute to total measurement uncertainty differs between tests, matrices, methodologies.

See section 5.4.6 for more details.

Revision History

Changes from Revision 24
Revision 25 is a significant revision with numerous additions, deletions and corrections. These are not all documented in the revision history, rather all persons on the distribution list are required to read the entire document.

5.2 Personnel

Section Synopsis

This section tells you that management:

1. Analyzes training needs
2. Provides training to employees for them to do their jobs
3. Qualifies people performing specific tasks

Key Words

Competence
Qualification
Authorize
Training Needs
Job Description
Registry of Skills

Cross-references

ISO 17025:2005 Section 5.2

ISO 9001:2000 Section 5.5.1, 6.2.1, 6.2.2, 7.5.1, 7.5.2

5.2.1 Competence and Qualification

Policy:
Management ensures the competency of all employees including specific equipment operators, those performing tests and/or calibrations, those evaluating results and signing test reports. Appropriate supervision is provided for employees undergoing training. Personnel performing specific tasks are qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.

In addition, personnel responsible for the opinions and interpretations included in test reports also have:

- Relevant knowledge of the technology used in the performance of analyses, materials, products tested, or the way they are used or intended to be used and of the defects or degradation that may occur during sampling, analysis, or use.
- Knowledge of the general requirements expressed in the legislation and standards.
- An understanding of the significance of deviations found with regard to the normal use of the items, materials, or products concerned.

Details:
Management defines the minimum levels of qualification and experience necessary for all posts within the laboratory. The educational and experience requirements for various laboratory positions are listed in the following sections:

5.2.1.1 Laboratory Director – The minimum requirements for the technical director are:

Bachelor's degree in the chemical, environmental, biological sciences, physical sciences or engineering with at least twenty-four (24) college semester credit hours in chemistry and at least two (2) years of experience in the environmental analysis of representative inorganic and organic analytes for which the Chemtech-Ford Laboratories seeks or maintains accreditation. A master's or doctoral degree in one of the above disciplines may be substituted for one (1) year of experience.

For microbiological analyses the technical manager must have a minimum of an associate's degree with at least four (4) college semester credit hours in general microbiology when the laboratory is engaged in microbiological analysis limited to fecal coliform, total coliform, E. coli and standard plate count. In

addition, the person shall have one (1) year of experience in microbiological analyses.

If the laboratory maintains a scope beyond fecal coliform, total coliform, E. coli and standard plate count, then the technical director must have a bachelor's degree in microbiology, biology, chemistry, environmental sciences, physical sciences or engineering with a minimum of sixteen (16) college semester credit hours in general microbiology and biology and at least two (2) years of experience in the environmental analysis of representative analytes for which the laboratory seeks or maintains accreditation. A master's or doctoral degree in one of the above disciplines may be substituted for one (1) year of experience.

5.2.1.2 Quality Manager - The minimum requirements for the quality manager are:

Bachelor's degree and 2 years of experience in environmental laboratory analysis/operation or an associate's degree and 4 years of experience in environmental laboratory analysis/operation. Understanding of quality systems including QA/QC. Understanding of laboratory operations. Strong communication skills including to work with a variety of staff and management

5.2.1.3 Supervisor - The minimum requirements for a laboratory supervisor are:

A bachelor's degree plus one-year work experience in a certified environmental laboratory or in a laboratory that the prospective supervisor demonstrates as one that substantially meets equivalent quality standards for a certified laboratory; or

An associate's degree in the biological, chemical, or physical sciences from an institution of higher education, plus four years work experience in a certified laboratory or in a laboratory that the prospective supervisor demonstrates as one that substantially meets equivalent quality standards for a certified laboratory.

The supervisor must demonstrate competency to supervise testing in the areas over which they supervise.

5.2.1.4 Technical Employees - The minimum requirements for technical laboratory employees vary as to position and job requirements. The education requirements

differ based on the job assignments. In general, the requirements are:

A bachelors degree in the biological, chemical, or physical sciences from an institution of higher education; or

An associates degree in the biological, chemical, or physical sciences from an institution of higher education; or

A high school degree.

Continued competence is monitored through the use of blind performance evaluation samples and Demonstrations of Competency. Where this is not achieved, the need to retrain personnel is considered. Where a method or technique is not in regular use, verification of personnel performance before they undertake tests, may be necessary.

5.2.2 Training Policies and Procedures

Policy:
Management will formulate the goals with respect to the education and the skills of the laboratory personnel. The training program is relevant to the present and anticipated tasks of the laboratory. SOP# QSP 5-2-1 is utilized to identify training needs and providing the necessary training for personnel.

Details:
The skills and knowledge are defined in the job description for each job function as described in section 5.2.1. Management compares the job description to the skills and knowledge of the new incumbent to determine the training needs.

5.2.2.1 QA Program - Chemtech-Ford, Inc. provides easy access to controlled copies of this "quality assurance program" as written within this document for all employees of this laboratory.

5.2.2.2 Training Files - Chemtech-Ford, Inc. maintains training files for all employees involved with data generation and reduction. The training files contain the following sub-files:

- Job description (minimum qualifications, experience, and skills defined).

- Analytical qualification documentation "Demonstrations of Capability," (DOC's). DOCs are neither appropriate nor required for the analyses of Odor, Color, and Paint Filter Test. Also alternatively, duplicate checks of capability are performed for Dissolved Oxygen, Flashpoint, and all microbiological analyses.
- Training attendance sheets.
- SOP reading documentation.
- Certificates, degrees, etc.
- Signed "Ethics Statement."

Training in the laboratory must include all methods or parts of methods and techniques that personnel are asked to perform. Minimally, the analyst must demonstrate competency through observation by management and verification using replicate and/or check samples. For technicians who perform only parts of the method, confirmation of competency may be verified by observation only. Re-verification of all personnel must be performed annually on all methods or techniques pertinent to their job description by use of blind performance evaluation samples and/or Demonstrations of Competency tests.

5.2.3 Employees

Policy:
Competent permanent or contractual employees are employed in the laboratory. The technical manager ensures that contractual, additional technical employees, and key support personnel are supervised and work in accordance to the policies and procedures of this Quality Manual.

Details:
Testing must be either performed or supervised by an experienced person qualified by the experience and/or degree level requirements from section 5.2.1.

5.2.4 Job Descriptions

Policy:
Current job descriptions for managerial, technical and key support personnel involved in tests and/or calibrations are maintained centrally in the administration area of the laboratory.

Details:
Minimum contents of job descriptions include:
- The duty of performing tests.
- The act of planning tests and evaluation of results.
- The responsibility of developing and validating new methods as / when requested.
- Expertise and experience.
- Qualifications and training programs.
- Managerial duties.

5.2.5 Key Personnel and Responsibilities

Policy:
Chemtech-Ford, Inc. complies with the managerial staff requirements as identified and required by "Utah Rule R444-14-8."

Details:
Key Personnel include the following listed positions:

5.2.5.1 Authority and Interrelationships – The laboratory has designated the following lines of authority:
- CEO
- President – Reports to CEO
- Executive Vice President reports to President
- Vice President, Quality Manager, Laboratory Director report to Executive Vice President
- Deputy Lab Director report to Lab Director
- Section Manager reports to Lab Director or Deputy Lab Director
- Team Leader reports to Section Manager
- Analysts & Technicians report to Team Leader

These lines of authority may have exceptions (e.g. there may not be a Team Leader and the analyst/technician may report to a Section Manager. The organizational chart is reviewed and updated (as needed) at least semi-annually (or more frequently as needed).

5.2.5.2 Laboratory Director - The Laboratory Director is responsible for the administrative oversight and overall technical operation of the laboratory. The laboratory director will:

- Define minimum qualifications, experience, and skills necessary for all technical employees.

- Ensure and document through an annual competency check that each technical employee demonstrates initial and on-going proficiency for the tests performed by that employee.

- Review the Quality Managers audit findings and document such reviews.

- Oversee laboratory technical and support staff.

- Review and approve all new and existing analytical procedures.

- Review and approve all deviations from normal analytical protocols.

- Review external and internal quality control audits and all other relative documentation/information.

- Perform final review and approval of new laboratory projects including reports and documents.

- Nominate deputies in case of temporary absence. Unless otherwise specified, the QM or deputy Lab Director will serve as acting laboratory director in the director's absence.

- Review laboratory resources and capabilities prior to accepting new non-routine project work that may affect or adversely tax the present capacity of the laboratory.

- Ensure that subcontracted laboratories are capable and appropriately certified for analytical work sent to them.

5.2.5.3 Quality Manager (QM) - The QM reports directly to the executive team. The QM has the responsibility for the quality system and its implementation (See Section 6 of the QM). The Quality Assurance Officer will:

- Have direct access to the highest level of management at which decisions are taken on laboratory policy and resources, and to the laboratory director.

- Serve as the focal point for quality assurance and oversee and review quality control data.

- Have functions independent from laboratory operations for which he or she has quality assurance oversight.

- Have documented training or experience in quality assurance procedures and be knowledgeable in the quality assurance requirements of Utah Rule R444-14; also be knowledgeable in the quality systems.

- Have knowledge of the approved methods used by the laboratory in order to accurately evaluate laboratory performance.

- Objectively evaluate data and objectively perform assessments without undue influence.

- Oversee all quality aspects of sample handling, testing, and report generation.

- Schedule, oversee, and be responsible for reviews of the entire technical operation of the laboratory. This includes conducting annual technical audits.

- Arrange, when available, analytical participation in inter-laboratory comparisons and proficiency testing programs. For purposes of qualifying for and maintaining accreditation, the QM shall arrange for participation in an external proficiency test program according to Utah Rule R-444-14 and as identified in the Quality Systems of NELAP.

- Notify laboratory management of deficiencies in the quality system and monitor corrective actions (ensure managers review all corrective actions initiating from their areas of concern, using corrective action reports as references during QA training meetings).

- Serve as the back-up to the Laboratory Director in the absence of the Laboratory Director.

5.2.5.4 Laboratory Area Supervisors - These managers are responsible for the day-to-day operation of the laboratory. Their responsibilities include:

- Supervise all technical and non-technical employees.
- Be responsible for the production and quality of all data reported by the laboratory.
- Review and approve analytical data generated within the area.
- Develop and submit new methods and operating procedures for approval by the Laboratory Director.
- Evaluate instrument and personnel needs.
- Ensure that all samples are accepted, analyzed, and reported in accordance with laboratory SOPs.

5.2.5.5Technical Staff - Technical personnel, generally, are responsible for the routine receipt, analysis and reporting of all laboratory samples. The technical staff will:

- Report directly to the assigned supervisor.
- Perform duties in accordance to laboratory policy and procedures.
- Read, understand, and follow the Quality Manual and all appropriate SOPs.

5.2.6 Laboratory Organizational Chart

The official organizational structure is contained in Quality Manager.

5.2.7 Staff Management Policies

Policy:

Management authorizes specific personnel to perform particular types of testing, to issue test reports, to give opinions and interpretations and to operate particular types of equipment. Records of the relevant competence, educational and professional qualifications, training, skills and experience of all technical personnel and contracted personnel are maintained. This information is readily available and includes the date on which authorization and/or competence was confirmed and the criteria on which the authorization is based and the confirming authority.

Details:

5.2.7.1 Confidentiality

Each employee shall read, understand, and acknowledge that the analytical work performed in the laboratory demands a high degree of confidentiality. In a practical sense, this has to do with the potential communication of laboratory procedures and analytical results to clients, regulatory agencies, and other interested parties. All employees should understand that **analytical data legally belongs to the client who contracted such work**.

5.2.7.1.1 Telephone Correspondence

A request for analytical results via telephone should be verified by requesting the name of the requestor (and as applicable the phone number, FAX number, e-mail address, or mailing address) before releasing data. It should be clear that the contracting client is the same as the client requesting the data. **For any data request from a client other than the contracting client, the contracting client must approve its use by the requesting client before release.** Such permission must be documented (requestor, contracting client, date and time of request, staff member taking request) and placed in the client data file.

5.2.7.1.2 E-mail and FAX Correspondence

Similar guidelines to 5.2.7.1.1 apply to requests for results transmitted by e-mail or FAX. Chemtech-Ford, Inc. will keep electronic records of e-mail/FAX requests and reports for 5 years.

5.2.7.1.3 "In-Person" Requests

Similar guidelines to 5.2.7.1 apply to clients who appear at the laboratory in person and request analytical data or other laboratory documentation. Copies of such reports or documentation may be released only after determining that the requestor is the contracting party, or has written permission from the contracting party to release the data.

5.2.7.1.4 Statement of Confidentiality

Each employee shall sign a Confidentiality Agreement, which describes the understanding of such laboratory confidentiality and acknowledges the penalties for failing to follow established laboratory procedures regarding confidentiality.

5.2.7.2 Improper, Unethical, and Illegal Actions

It is the policy of Chemtech-Ford, Inc. and its employees to perform their duties in a consistently legal and ethical manner. A high level of ethical behavior is characterized by, but not limited to, dealing honestly and forthrightly with all clients and co-workers, maintaining data integrity, open and timely treatment of inaccurate, invalid, or misreported analytical data, and abiding by all pertinent rules, regulations, company policies, and standard operating procedures.

Deliberate violations of such behavior will result in disciplinary action up to and including termination, the consequences of which could additionally lead to direct liability and legal action against the responsible individual.

It is the responsibility of each Chemtech-Ford, Inc. employee to report any observed violation of this policy. This observation may result from a visual or studied review of protocol, generated data, or reported information. Laboratory management will review the evidence of any such reported violation; confirmation that such a violation occurred will result in severe disciplinary action, up to and including termination and possible legal action.

Serious violations of Chemtech-Ford, Inc.'s ethical policy include, but are not limited to, the following:

- Changing a reported value in the LIMS database without proper support of documentation;
- Intentionally misrepresenting data generated by instrument or calculation;
- Recording invalid or otherwise altered data to make the analysis conform to "expected" levels;
- Recording invalid or otherwise altered data at someone else's suggestion or insistence;
- Recording invalid or otherwise altered data to satisfy quality assurance acceptance criteria;
- Manually integrating chromatographic data to satisfy quality assurance acceptance criteria;
- Withholding information that was noted during sample receipt or analysis;
- Purposefully destroying a sample prior to the completion of analysis; and
- Willfully circumventing the sample disposal Standard Operating Procedure.

Each Chemtech-Ford, Inc. employee is required to participate in a training session within two weeks of employment. The training will include Chemtech-Ford's ethical policies, examples of unethical behaviors, and penalties for non-compliance. The new employee will be required to sign an attestation statement as a condition of employment which will again define Chemtech-Ford's policies and penalties.

Each year, or more frequently if needed, each Chemtech-Ford, Inc. employee is required to attend ethical training to review company policies and penalties. At the conclusion of the training, each employee will be required to sign an attestation called an Ethical Attestation Statement that summarizes the employee's ethical and legal responsibilities. This Statement acknowledges that penalties exist for deliberately violating this policy.

In order to promote an atmosphere of integrity, management will reiterate at routine staff meetings the importance of reporting discovered errors and the insistence that such reporting will not necessarily result in personal punishment, even though the company may suffer financially.

Furthermore, management will institute internal proficiency testing (blind and double blind samples) where applicable; QC meetings whose emphasis is on

appropriate and inappropriate laboratory technique and instrument/data manipulation will be held routinely to address this topic.

5.2.7.2 Manual Integration

In keeping with Chemtech-Ford's policy of producing data of the highest possible quality, integrations performed in the laboratory must be generated by fully calibrated instruments and not altered in an unsubstantiated manner.

Improper manual integrations performed for the purposes of meeting quality control criteria or any other reason are not allowed. Such unsubstantiated integrations are subject to possible disciplinary action by laboratory management.

If a manual integration is necessary, the integration produced after manual integration shall both be labeled and present in the raw data package. The intent is to demonstrate the results of the integration are appropriate and according to good laboratory practices. It is recommended that a short explanation be provided if an unusual integration has to be made (e.g. for unusual tailing due to matrix effect).

All manual integrations are subject to strict scrutiny to ensure that they are performed appropriately. Analysts are advised that they must be prepared at any time to defend a manual integration. When there is a question to the validity of the manual integration by the analyst, then they should discuss the integration with their supervisor. Supervisors should regularly review the manual integrations of employees.

Manual integrations are noted in the raw data package. Typically, these are denoted by an "m" next to the integrated area or concentration.

5.2.7.3 Undue Pressure

An appropriate working atmosphere will be provided at Chemtech-Ford, Inc. so that all employees will be free from any commercial, financial, or other undue pressures, which might adversely affect the quality of their work.

If a Chemtech-Ford, Inc. employee feels that his or her work has been affected by undue pressure of any sort, the following recourses are available:

5.2.7.3.1 The employee may report the source of the pressure(s) affecting lab performance to his or her supervisor, or to the laboratory director or owner if the employee believes notifying the supervisor will be ineffective or problematic; and/or

5.2.7.3.2 The employee may generate a Corrective Action Form. This form will specify those requests, behaviors, or other pressures, which adversely affect the quality of the employee's work. The form will then follow normal review channels through the laboratory in order to be resolved.

5.2.7.4 Validation of Employee Qualifications

It is the responsibility of Chemtech-Ford, Inc. management to ensure that all employees have demonstrated capability in the activities for which they have been hired and are responsible. This includes verification that a potential employee possesses all of the technical, organizational, and communication skills prior to employment; and that, once hired, each employee continues to upgrade his knowledge and skills.

Each new employee is required to read, sign, and understand a comprehensive employment documents provided at time of employment. These documents verify the position's required skills as well as educating the employee in all aspects of the company's operations and policies. This documents include, but are not limited to containing:

- An attestation that all educational qualifications and technical and communication skills requirements have been fulfilled and reviewed by management.
- A Confidentiality Agreement.
- An Ethics Statement.
- A Harassment Prevention Policy.
- An attestation that the employee has read, acknowledged, and understood the Chemtech-Ford, Inc. Quality Manual.
- An attestation that the employee has read, understood, and agreed to perform the most recent version(s) of the test method(s) for which the employee is responsible.

- Demonstrations of Capability for all technical competencies required.
- An explanation of the Chemtech-Ford, Inc. Laboratory Information Management System (LIMS) and its functions.

New employees are apprised of all laboratory security systems and the Training Files to be kept by each employee.

Specialized training sessions will be routinely held to 1) review current policies and procedures; 2) institute new policies and procedures; 3) review particular technical skills, Quality Assurance topics, or corrective actions; and 4) institute cross training. These training sessions/courses will be documented in each employee's training file.

Prior to the initiation and acceptance of test results from an employee on any test method, satisfactory demonstration of capability is required.
Following the completion of all capability demonstration work, the initial analytical work of any new employee will be carefully reviewed for accuracy, thoroughness, and timeliness by the laboratory supervisor. Correct and accurate entry of data into the LIMS will also be monitored. Once the supervisor is satisfied of the technical competency of the new employee, a less rigorous review of the employee's skills and generated data will be required.

Records are held in Quality Manager.

Revision History

Changes from Revision 24
Revision 25 is a significant revision with numerous additions, deletions and corrections. These are not all documented in the revision history, rather all persons on the distribution list are required to read the entire document.

5.3 Accommodation and Environmental Conditions

Section Synopsis

This section tells you:

1. That laboratory facilities are suitable for attaining correct performance of tests and calibrations
2. Critical environmental conditions are monitored, controlled and recorded
3. Incompatible activities are separated
4. Access to laboratories is controlled
5. Good housekeeping is practiced

Key Words

Incompatible activities
Prevent cross-contamination
Controlled access

Cross-references

ISO 17025:2005 Section 5.3

ISO 9001:2000 Section 6.3, 6.4, 7.1, 7.5.1, 7.5.2, 7.6, 8.2.3

5.3.1 Facility

Policy:
Laboratory facilities shall be appropriate to allow for the proper performance of analytical testing. This may include, but not limited to, energy sources, lighting, heating, ventilation and any other environmental conditions.

Appropriate care is taken to ensure that the environment does not invalidate the results or adversely affect the required quality of any measurement. The technical requirements for accommodation and environmental conditions that can affect the results of tests and calibrations are documented.

Details:
This section deals with the test areas in the laboratory and premises for support such as sample receipt and storage. Central laboratory supplies and services, such as water purification systems, air supply, vacuum source, and sample storage, are appropriate to facilitate proper performance of tests.

5.3.2 Monitoring

Policy:
Critical environmental conditions are monitored, controlled and recorded as required by the relevant specifications, methods, and procedures or where they may influence the quality of the results. Tests and calibrations are stopped when the environmental conditions jeopardize the results of the tests and/or calibrations.

Details:
Laboratories are ventilated to reduce the levels of contamination, lower humidity, and control temperature. Laboratories' test areas are air-conditioned and the temperature is 20-25 °C.

Bench tops and floors are made of impervious, smooth easily cleaned materials. There is at least two linear meters workspace per analyst while working. Walls and ceilings are made of materials that are smooth and easily cleaned.

5.3.3 Separation of Incompatible Activities

Policy:
Effective separation between neighboring areas is made when the activities are incompatible. Measures are taken to prevent cross-contamination.

Details:
Reference materials and certified reference materials must be kept separated from samples (log-in and storage). Sample log-in and storage must be segregated, ideally in a separate area from the testing laboratory, and include proper sanitation to exclude the possibility of cross-contamination. Segregation of activities is achieved through time and space allocations.

5.3.4 Controlled Access

Policy:
Access to and use of areas affecting quality of the tests is defined and controlled.

Details:
Access to the laboratory is restricted to authorized personnel only. The authorized personnel are made aware of the following items:

- the intended use of the area
- the restrictions imposed on working within such areas
- the reasons for imposing the restrictions

5.3.4.1 *Sample Receiving* - The sample receiving area is designed to be independent of the other laboratory areas. The sample receiving area is designed with a convenient access from the out-of-doors. This access is controlled allowing security of the laboratory and sample storage. The sample receiving area may also be used for preparing and shipping of containers to clients.

5.3.4.2 *Volatiles Laboratory* - The volatiles laboratory is located within a climate controlled area away from the main laboratory in order to eliminate solvent cross-contamination from other areas of the laboratory. As with the main laboratory, access to this building is limited to authorized personnel only. All GC/MS volatiles work is performed in this area.

5.3.4.3 *Inorganic Chemistry Laboratory* - The inorganic chemistry laboratory occupies the largest of the lab area within the building. The area consists of a centrally located spacious rooms equipped with several large benches for analytical work. Conventional wet techniques such as gravimetric, colorimetric, titrimetric are performed here. Several fume hoods are located within the rooms to provide ease of sample preparation.

5.3.4.4 *Wet Chemistry Laboratory* - This laboratory is adjacent to the inorganic chemistry laboratory and contains the necessary equipment required to perform various wet chemistries (e.g., BOD, COD, and TSS).

5.3.4.5 *Metals Laboratory* - The metals analysis laboratory contains all of the metals analytical equipment. However, samples are prepared for metals analysis in the inorganic laboratory, thus reducing the possibility of instrument contamination. The metals laboratory is designed for ICP, ICP/MS, and Hg cold-vapor instrumentation.

5.3.4.6 *GC and Semi-Volatile GC/MS Laboratory* - The preparation lab contains standard fume hoods and ample bench space for sample extraction. The GC and Semi-volatile GC/MS instrument laboratory has several benches with GC and GC/MS instrumentation and supplies.

5.3.4.7 *Microbiology Laboratory* - The microbiology laboratory is a separate room that is climate-controlled with ample bench space on which to perform the required analytical procedures. The laboratory contains its own supplies and storage facilities for ease of analysis and for prevention of contamination.

5.3.4.8 *Sample Storage* - Samples remaining in the sample analysis stream are located within their respective holding areas (refrigerators, etc.) until required analyses have been complete. Additional post-analysis storage for metals-preserved sample bottles is accomplished via storage shelves located within the metals laboratory. All other inorganic/organic samples are kept for a maximum of three months (following data reporting) in refrigerated storage throughout the laboratory.

5.3.5 Good Housekeeping

Policy:
Measures are taken to ensure good housekeeping in the laboratory. Special procedures are followed when necessary.

Details:
Controlled use of cleaning and pest control materials is exercised. The laboratory complies with the local health and safety requirements.

Revision History

Changes from Revision 25
Section 5.4.5.3 Title edited for grammar.

5.4 Test Methods and Method Validation

Section Synopsis

This section tells you:

1. Preference is given to the use of a standard method when selecting procedures
2. All methods must be validated before use
3. Measurement uncertainty is estimated
4. Data is controlled

Key Words

Standard Methods
Laboratory-Developed Methods
Non-standardized Methods
Validation
Uncertainty of Measurement
Data Checks

Cross-references

ISO 17025:2005 Section 5.4

ISO 9001:2000 Section 4.2.1, 4.2.3, 6.1, 6.3, 6.4, 7.1, 7.2.1, 7.2.2, 7.3, 7.4.3, 7.5.1, 7.5.2, 7.6, 8.1, 8.2.3, 8.2.4

5.4.1 General

Policy:
Methods and procedures used for all tests and/or calibrations are appropriate as per:

- sampling, handling, transport, storage, and preparation of items to be tested and/or calibrated
- an estimation of the measurement of uncertainty as well as statistical techniques for analysis of test and/or calibration data where appropriate

Instructions on the use and operation of all relevant equipment and on the handling and preparation of items for testing and/or calibration are available. All instructions, standards, manuals and reference data relevant to the work of the laboratory are maintained current and readily available to personnel. Deviation from test and calibration methods must be documented, technically justified, authorized, and accepted by the customer.

Details:
There are SOPs for sample handling, storage, preparation of test items, QA/QC procedures (media QC, incubation times and temperatures, equipment calibration and maintenance, process control QC), and standards for approving / rejecting results. These may be combined with or separate from the method. The content of an environmental (TNI) test method should include:

- Applicable Matrices
- Detection Limit
- Method Scope
- Method Summary
- Definitions
- Interferences
- Safety
- Equipment and Supplies
- Reagents and Standards
- Sample Collection, Preservation, Shipment and Storage
- Quality Control
- Calibration and Standardization
- Procedure
- Calculations
- Method Performance
- Changes to the Approved Method
- Data Assessment and Acceptance Criteria

- Corrective Action & Contingencies for Out of Control Data
- Pollution Prevention and Waste Management
- References
- Editorial Changes to SOP
- Appendices

International, national, or regional standards or other recognized specifications that contain sufficient and concise information on how to perform the tests and/or calibrations are not necessarily supplemented or rewritten as an internal procedure when they are written in a way that can be used as published by laboratory staff. Consideration may need to be given to providing additional documentation for optional steps in the method.

5.4.2 Selection of Methods

Policy:
Test and/or calibration methods, including methods for sampling, meet the needs of the customer and are appropriate for the tests and/or calibrations it undertakes. Preference is given to reference methods published as international, national, or regional standards. The laboratory ensures that the latest edition of a standard is used unless it is not appropriate or possible to do so. When necessary, the standard is supplemented with additional details to ensure consistent application.

Details:
Methods that have been published either in international, national, or regional standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer are selected when the customer does not specify the method to be used. Methods may be adopted from but are not limited to the following sources: EPA, Standard Methods, USP, AOAC, FDA BAM, USDA FSIS & AMS, APHA SMEDP, APHA, AWWA, WEF, NELAC, TNI, Compendium of Methods for the Microbiological Examination of Foods, ISO, ICMSF, National Food Processors, American Association of Cereal Chemists, Association of Dressing and Sauces, Health Canada, Environmental Protection Agency, OIE, and ASTM.

The ability of the laboratory to achieve satisfactory performance against documented performance characteristics is verified before samples are analyzed.

Laboratory-developed methods or methods adopted by the laboratory may also be used if they are appropriate for the intended use and if they are validated. The customer is

informed as to the method chosen. The laboratory confirms that it can properly operate standardized methods before introducing the tests or calibrations. If the standardized method changes, the confirmation is repeated.

The customer is informed when the method proposed by the customer is considered to be inappropriate or out of date.

5.4.3 Laboratory-Developed Methods

Policy:
Introduction of test and calibration methods developed internally is a planned activity and is assigned to qualified personnel equipped with adequate resources. Plans are updated as development proceeds and ensures effective communication among all personnel involved.

Details:
Methods developed in-house are validated and authorized before use. Where available, Certified Reference Materials (CRMs) are used to determine any systemic bias, or where possible results are compared with other techniques, preferably based on different principles of analysis. As applicable, determination of uncertainty is part of this validation process and is essential for ongoing quality control.

5.4.4 Non-Standard Methods

Policy:
Utilization of non-standard methods is subject to agreement with the customer and includes a clear specification of the customer's requirements and the purpose of the test. The developed method is validated appropriately before use.

Details:
Discussion and agreement for the use of non-standard methods is recorded as part of contract review procedures (see section 4.4).

All non-standard and new tests are validated for their intended purpose. Qualitative test methods must be validated to demonstrate estimated sensitivity and specificity, relative accuracy to official methods (if appropriate), positive and negative deviation, limit of detection, matrix effect, repeatability, and reproducibility.

Quantitative test methods are validated to demonstrate specificity, sensitivity, relative accuracy, positive and negative deviation, repeatability, reproducibility, and limit of determination.

For new methods where procedures are developing rapidly, especially for emergency situations, it may be necessary to circumvent normal validation procedures. Minimally, this must be a demonstrated recovery in replicate.

New test and/or calibration methods are documented prior to providing test and/or calibration results to customers and contain at least the following information:

- appropriate identification
- scope
- description of the type of item to be tested or calibrated
- parameters or quantities to be determined
- apparatus and equipment, including technical performance requirements
- reference standards and reference materials required
- environmental conditions required and any stabilization period needed
- description of the procedure, including:
  - affixing identification marks, handling, transporting, storing and preparing of items
  - ensuring checks are made before the work is started
  - checking that the equipment is working properly and, where required, calibrating and adjusting the equipment before each use
  - listing method of recording the observations and results
  - indicating any safety measures to be observed
- criteria and/or requirements for approval/rejection (quality control plan)
- data to be recorded and method of analysis and presentation
- uncertainty or procedure for estimating uncertainty

5.4.5 Validation of Methods

5.4.5.1 Performance Characteristics

Policy:
Validation of a method establishes, by systematic laboratory studies, that the performance characteristics of the method meet the specifications related to the intended use of the test results.

Details:
The performance characteristics of a validation plan includes, as applicable:

- selectivity and specificity
- range
- linearity
- sensitivity
- limit of detection
- limit of quantitation
- accuracy
- precision
- reporting limit
- repeatability
- reproducibility
- recovery
- confirmation techniques
- criteria for the number of samples tested to validate method as per defined scope of method
- action levels where defined by regulation
- quality control incorporating statistics as applicable

Performance characteristics that are selected take into account the intended use of the method, whether for screening, confirmatory analysis, or quantitation.

The design, verification of the method and documentation procedures for validation are planned and conducted by qualified personnel, equipped with adequate resources.

This section lists a few acceptable validation procedures. The choice of the procedure depends on the extent of the deviation from the published method.

Validation of methodology is a value judgment in which the performance parameters of the method are compared with the requirements for the test data. A prerequisite for a valid method is that data produced by the method must attain a state of statistical control. Such a state is obtained when the mean value of a large number of individual values tends to approach a limiting value called the limiting mean.

Methods may be validated by one or more alternative procedures. Some of these procedures are described below. Apparent differences can be analyzed statistically to

confirm their significance. In all cases, the reasons for choosing one or more alternatives must be documented.

- analysis of standard reference materials (SRM) that are identical or almost identical to the test samples
- in the absence of suitable SRMs, analysis of reference materials that are similar in all respect to the test samples; the use and validity of this reference material must be documented
- using an alternative method to measure the same parameter provides a very high level of confidence if results are confirmed
- recovery studies by the addition of a known concentration of the parameter of interest to some of the replicates being measured

The parameters to be determined include:

- the scope of the method and any known interference
- detection limit
- the range of concentration where the method is valid
- precision and bias

Judgment is required to determine if some or all of the above is required. Requirements will depend largely on the extent of deviation from the original method.

Developments in methodology and techniques require methods to be changed from time to time. The difference in performance between revised and obsolete methods is established so that it is possible to compare old and new data.

Where a change in method involves only minor adjustments, such as sample size, or different reagents, the amended method is validated and the changes brought to the attention of the accreditation body at the next accreditation audit. Where the proposed change involves technology or methodology, the laboratory seeks the approval of the accreditation body.

Records are kept on all validation activities. The records include any of the performance characteristics chosen, reference procedures or guidance documents followed to validate the method or custom validation procedure, and a final confirmation (memo to file) that the method validation results are acceptable for continued use of the method. An example statement would be “This serves as record that the validation of the XYZ Test Method has been approved for use by [name and title of approver]”.

5.4.5.2 Fit for Use

Policy:
The laboratory validates non-standardized methods, laboratory-designed/developed methods, standardized methods used outside their intended range, and amplifications of standard methods to confirm that the methods are fit for the intended use. The validation is as extensive as is necessary to meet the needs in the given application or field of application (may include procedures for sampling, handling, and transportation). The laboratory records the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.

Details and Procedure:
Validation records are kept as in section 5.4.5.1. Included in these records is the validation procedure. The procedure used for the validation is likely to vary between different methods. Therefore, the procedures included in the laboratory records are not as detailed as a typical SOP, but are sufficient enough to re-create how the method was validated.

The techniques used for the determination of the performance of a method, are one of, or a combination of, the following:

- calibration using reference standards or reference materials
- comparison of results achieved with other methods
- inter-laboratory comparisons
- systematic assessment of the factors influencing the result
- assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience.

When changes are made in the validated non-standard method, the influence of such changes carried out is documented and if appropriate a new validation is performed.

5.4.5.3 Customer's Needs

Policy:
The range and accuracy of the values obtainable from validated methods (e.g., the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object) as assessed for the intended use is relevant to the customer's needs.

Details:
Validation includes the specification of the requirements, determination of the characteristics of the methods, the comparison of the requirements with the values of the characteristics of the method, and a statement on the validity.

As method development proceeds, regular review is required to verify that the needs of the customer are still being fulfilled. Changing requirements requiring modifications to the development plan are approved and authorized.

Validation is always a balance between costs, risks, and technical possibilities.

5.4.6 Uncertainty of Measurement

5.4.6.1 Calibration

Policy:
Physical, chemical, and biological standards are calibrated or characterized by qualified subcontractors.

Details and Procedures:
Repeatability and reproducibility data are components of measurement uncertainty and are determined as a first step towards producing estimates of this parameter. The uncertainty of measurement may be made available on the certificate of analysis or calibration certificate from a subcontractor.

Note – in-house calibrations include procedures for uncertainty of measurement estimates where practicable.

5.4.6.2 Testing

Policy:
The SOP# QSP 5-4-1 is utilized to estimate uncertainties of measurement in testing, except when the test methods preclude such rigorous calculations. In certain cases, it is not possible to undertake metrologically and statistically valid estimations of uncertainty of measurement. In these cases, the laboratory attempts to identify all the components of uncertainty and make the best possible estimation, and ensure that the form of reporting does not give an exaggerated impression of accuracy. Reasonable estimation is based on

knowledge of the performance of the method and on the measurement scope and makes use of previous experience and validation data.

Details:
The degree of rigor needed in an estimation of uncertainty of measurement depends on factors such as:

- requirement of the test method
- requirement by the customer
- if there are narrow limits on which decisions on conformity to a specification are based

In cases where a well-recognized test method specifies limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results, the laboratory is considered to have satisfied the estimation uncertainty of measurement by following the reporting instructions (see section 5.10).

5.4.6.3 Uncertainty Components

Policy:
When estimating the uncertainty of measurement, all uncertainty components that are of importance in the given situation are taken into account using accepted methods of analysis.

Details:
Sources contributing to the uncertainty include, but are not necessarily limited to, the reference standards and reference materials used, methods and equipment used, the environmental conditions, the item being tested or calibrated and the operator.

The predicted long-term behavior of the tested and/or calibrated item is normally not taken into account when estimating the measurement uncertainty.

For further information, see ISO 5725 and the Guide to Expression of Uncertainty in Measurement.

5.4.7 Control of Data

5.4.7.1 Calculations and Data Transfers

Policy:
Calculations and data transfers are subject to appropriate checks in a systematic manner.

Details:
Test data are approved through the following arrangements by the QM, supervisor, lab director, peer etc.:

- checks to determine accuracy of calculations, conversions, and data transfers
- checks for transcription errors, omissions, and mistakes
- checks to determine consistency with normal or expected values

For those analyses where manual data reduction is required, it is performed according to the instructions provided in the test method or SOP.

5.4.7.2 Computers and Automated Equipment

Policy:
When computers or automated equipment are used for the acquisition, processing, manipulation, recording, reporting, storage or retrieval of test or calibration data, the laboratory ensures that:

- computer software developed by the user is documented in sufficient detail and suitably validated or otherwise checked as being adequate for use
- procedures are established and implemented for protecting the integrity of data; such procedures include, but are not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission, and data processing (see section 4.13.1.4)
- computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data
- data is securely maintained by preventing unauthorized access to, and unauthorized amendment of, computer records

Details and Procedures:

Data generated using computer software programs that are interfaced directly to instruments incorporates all dilutions and calculations, thereby eliminating the need for manual data reduction.

Commercially developed software in general use within its designed application range may be considered sufficiently validated. Laboratory software configuration / modifications are validated as outlined in SOP# QSP 5-5-1.

It is the **stated goal** of Chemtech-Ford Laboratories to meet the requirement for Electronic records, electronic signatures, and handwritten signatures executed to electronic records as defined by 21 CFR. Part 11 (Docket No. 92NO251) RIN0910-AA29; Federal Register: March 20, 1997, Volume 62, Number 54), Rules and Regulations, pages 13429-13466. Chemtech-Ford is not now fully compliant, but records of compliance evaluation are maintained and can be inspected upon request.

For details of the requirement see:

http://www.fda.gov/ora/compliance_ref/part11/

Revision History

Changes from Revision 24
Revision 25 is a significant revision with numerous additions, deletions and corrections. These are not all documented in the revision history, rather all persons on the distribution list are required to read the entire document.

5.5 Equipment

Section Synopsis

This section tells you to:

1. Identify information needs for accept / reject decisions
2. Install equipment capable of providing that information
3. Use the equipment in the proper environment
4. Periodically check the equipment calibration

Key Words

Required Equipment and Accuracy
Authorized Personnel
Unique Identification
Inventory
Maintenance
Procedures
Out of Service
Calibration Status
Re-verification
Checks
Correction Factors
Safeguards against Adjustment

Cross-references

ISO 17025:2005 Section 5.5

ISO 9001:2000 Section 4.2.1, 4.2.3, 5.1, 6.2.2, 6.3.1, 7.1, 7.4, 7.5.1, 7.5.2, 7.5.3, 7.6, 8.1, 8.2.3, 8.2.4

5.5.1 Required Equipment

Policy:
The laboratory is furnished with all items for sampling, measurement and test equipment required for the correct performance of the tests and/or calibrations (including sampling, preparation of test and/or calibration items, processing and analysis of test and/or calibration data). When equipment is used outside the laboratory's permanent control, it ensures that the requirements of this Quality Manual are met.

Details:
Equipment is used in an environment appropriate to its proper performance. All equipment required by a test is described in each method, including the equipment's tolerances.

A current list of equipment is maintained in Quality Manager.

5.5.2 Required Accuracy

Policy:
Equipment and software used for testing, calibration and sampling are capable of achieving the accuracy required and comply with specifications relevant to the tests and/or calibrations concerned. Calibration programs are established for key quantities or values of the instruments where these properties have a significant effect on the results. When received, equipment, including that used for sampling, is checked to establish that it meets the laboratory's specification requirements, complies with the relevant standard specifications, and is checked and/or calibrated in accordance with section 5.6 before use.

Details:
The procedures for checking newly received equipment are as determined by manufacturers' specification and/or those determined by the laboratory during procurement.

5.5.3 Authorized Personnel

Policy:
Equipment is operated by authorized personnel. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) are readily available for use by the appropriate laboratory personnel.

Details:
Access to laboratory equipment is controlled to ensure that only authorized personnel use equipment.

5.5.4 Unique Identification

Policy:
Each item of equipment used for testing and calibration is uniquely identified when practicable.

Details:
Measuring and testing equipment is uniquely identified. Typical identification includes instrument type, make, model, serial number or other unique markings. Measuring and testing equipment includes any instrument that could affect the quality of test results. Components that can be interchanged between various instruments are tracked in equipment logbooks but are not assigned individual identification.

5.5.5 Inventory and Maintenance Records

Policy:
Records are maintained for each item of equipment significant to the tests and/or calibrations performed. The records include the following:

- identity of the item of equipment (and its software)
- manufacturer's name, type identification, and serial number and/or other unique identification
- Date received (if available)
- Date placed into service (if available)
- checks that equipment complies with the specification (see section 5.5.2)
- current location, where appropriate
- the manufacturer's instructions, if available, or reference to their location
- dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and due date of next calibration
- maintenance carried out to date and the maintenance plan (includes calibration)
- damage, malfunction, modification or repair to the equipment
- Analysts initials

Details:
A database is used to capture the above inventory information. The above information related to service and maintenance is kept in Quality Manager. Other information recorded may include:

- date received and date placed in service
- condition when received (e.g., new, used, refurbished)
- dates and results of calibration and/or verification and date of next calibration and/or verification
- performance history, where appropriate (e.g., response time, drift, noise level)

5.5.6 Equipment Procedures

Policy:
The SOP# QSP 5-5-1 is utilized as an established plan for safe handling, transport, storage, use and maintenance (including calibration) of measuring equipment, and appropriate use of correction factors to ensure proper functioning and in order to prevent contamination or deterioration.

Note – additional procedures may be necessary when measuring equipment is used outside the permanent laboratory for tests, calibrations, or sampling (currently not applicable at our laboratory).

Details and Procedures:
The procedures for each piece of measuring equipment are located in the appropriate room where the equipment is located. These procedures detail any information for safe handling, transport, storage, use, and maintenance of measuring equipment.

5.5.7 Out of Service Equipment

Policy:
Equipment that has either been subjected to overloading or mishandling, or gives suspect results, or has been shown to be defective or outside specified limits, is taken out of service, clearly marked, and appropriately stored until it has been repaired and shown by calibration or test to perform correctly.

Details:
Routine testing work is completely discontinued on equipment that even shows minor nonconformances. Not only do we do this for ethical reasons in support of our customer, but minor nonconformances are often indicative of major breakdowns in expensive equipment. These breakdowns need to be avoided wherever possible.

Out of service equipment is clearly marked as outlined in section 5.5.8.

The laboratory examines the effect of the defect or departure from specified limits on previous test and/or calibrations and institutes the “Control of Nonconforming Work” procedure as outlined in section 4.9.

5.5.8 Calibration Status

Policy:
Equipment requiring calibration is labeled to indicate the calibration status and/or operational status and the date when re-calibration is due when appropriate.

Details:
Calibration labels have a write-on surface and a pressure sensitive adhesive. The areas that are filled out include the person who performed the calibration, the date it was performed, the date it is due for re-calibration, and the equipment's identification number.

CALIBRATION
BY_____DATE_____
DUE_____ID#_____

Measuring equipment that has failed calibration or is deemed out of service is labeled with one of the following labels:

CALIBRATION VOID

DO NOT USE

OUT OF SERVICE

DO NOT USE

A piece of equipment that is not calibrated or checked is labeled with the following label:

5.5.9 Return to Service

FOR REFERENCE ONLY

Policy:
When equipment goes outside the direct control of the laboratory for a period, the laboratory ensures that the function and calibration status of the equipment are checked and validated and shown to be satisfactory before the equipment is returned to service.

Details and Procedures:
The procedures used to check and ensure that the function and calibration status of the equipment are satisfactory before the equipment is returned to service are outlined in the

manufacturer's equipment manual. Any additional quality control checks are outlined in the "Quality Control Plan" section of the appropriate test method.

5.5.10 Periodic Checks

Policy:
When intermediate checks are needed to maintain confidence in the calibration status of equipment, these checks are carried out periodically according to defined procedure.

Details and Procedures:
As stated in section 5.5.6, the procedures for each piece of measuring equipment are available on the laboratory computer network. SOP# QSP 5-5-1 outlines a general maintenance plan for equipment and includes various checks. Internal quality control checks are specified in individual test methods that are located in the appropriate laboratory areas thereby providing procedures for intermediate checks.

5.5.11 Correction Factors

Policy
Calibrations that give rise to a set of correction factors are updated along with all copies of this data (e.g., in computer software).

Details and Procedures:
The updating of correction factors, including all copies, is assured by following the appropriate test method or SOP. It is the responsibility of the QM to ensure that all copies are updated.

5.5.12 Safeguards against Adjustments

Policy:
Test and calibration equipment, including hardware and software, are safeguarded from adjustments that invalidate test and/or calibration results/status.

Details:
Safeguards against adjustment for laboratory equipment include:
- detailed SOPs and manufacturer's manuals on the operation of the equipment

- policies permitting only fully trained and competent personnel to operate equipment
- access to the laboratory is restricted to authorized personnel

Safeguards against adjustment for software includes:
- password protection for important files and packages
- access to the laboratory is restricted to authorized personnel
- An electronic audit trail is maintained on for the changes made in the LIMS software

Revision History

Changes from Revision 24
Revision 25 is a significant revision with numerous additions, deletions and corrections. These are not all documented in the revision history, rather all persons on the distribution list are required to read the entire document.

5.6 Measurement Traceability

Section Synopsis

This section tells you:

1. Measurements are traceable to SI units (when applicable)
2. Reference Standards and Reference Materials are used

Key Words

Systemèm International
Reference Standard
Reference Material
Traceability

Cross-references

ISO 17025:2005 Section 5.6

ISO 9001:2000 Section 6.3.1, 7.1, 7.5.1, 7.6

5.6.1 General

Policy:
Test and/or calibration equipment for subsidiary measurements (e.g., for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration, or sampling are calibrated before being put into service. All measurement and test equipment having an effect on the accuracy or validity of tests is calibrated and/or verified before being put into service. As mentioned in section 5.5, the SOP# QSP 5-5-1 outlines an established program for the maintenance of equipment and includes calibration.

Details:
The program includes a system for selecting, using, calibrating, checking, controlling, and maintaining:

- measurement standards
- reference standards used as measurement standards
- measuring and test equipment used to perform tests and calibrations

Procedures are documented where appropriate. All measurements that play a defining role in testing accuracy are based directly or indirectly on reference standards, reference materials, certified reference materials, or other standards or materials having appropriate traceability.

Records are maintained in the LIMS for each standard. These records include, as applicable:

- supplier, grade, lot number, and concentration
- dates of preparation or verification
- measurement of weights, volumes, time intervals, temperatures, and pressures and related calculations
- relevant processes (e.g., pH adjustment, sterilization)
- verification results
- identification of personnel involved

Reagents prepared in the laboratory are labelled to identify substance, strength, solvent (where not water), and date of preparation and/or expiry. The person responsible for the preparation of the reagent is identified either from the label or from records.]

5.6.2 Specific Requirements

5.6.2.1 Calibration

Policy:
The program for calibration equipment is designed and operated to ensure that calibration measurements are traceable to the System International (SI) units of measurement.

Details:
Traceability of measurement is assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability. The calibration certificates issued by these laboratories show that there is a link to a primary standard or to a natural constant realizing the SI unit by an unbroken chain of calibrations. The calibration certificates contain the measurement results including the measurement uncertainty and/or a statement of compliance with an identified metrological specification (see also section 5.10.4.2).

Calibration laboratories accredited to ISO 17025 are considered competent to provide the appropriate calibration services.

Traceability to SI units of measurement may be achieved by reference to an appropriate primary standard or by reference to a natural constant the value of which, in terms of the relevant SI unit, is known.

The term “identified metrological specification” means that it must be clear from the calibration certificate against which specification the measurements have been compared with, by including the specification or by giving an unambiguous reference to the specification.

When the terms “international standard” or “national standard” are used in connection with traceability, it is assumed that these standards fulfil the properties of primary standards for the realization of SI units.

Maintain certificates of all reference standards, measuring equipment, or certified reference material used in ensuring traceability. Where traceability to national standards of measurement is not applicable, the laboratory provides satisfactory evidence of correlation

of results, for example by participation in a suitable program of inter-laboratory comparisons or proficiency testing.

Reference standards, such as thermometers and weights, are traceable to a national or international standard (e.g., NIST).

5.6.2.1.1 Instrument Performance Evaluation

5.6.2.1.1.1 General calibration of laboratory instruments falls into two categories: 1) calibration which is conducted on a routine basis as part of the analytical procedure prior to each use; and 2) periodic, scheduled calibration of instruments and gauges against known standards to ensure the continuing precision and accuracy of such instruments.

5.6.2.1.1.2 All instrumentation must be demonstrably calibrated and evaluated for appropriateness before analysis is initiated. Divergence from acceptable benchmark criteria requires correction before analyses may be performed. The instrument performance evaluation material may be a standard spiked into the solvent used for analysis, but it is not extracted as if it were a sample.

5.6.2.1.2 Calibration

5.6.2.1.2.1 Generally, as applicable to the method, calibration curves are established for each parameter using known concentrations of standards. At least three different concentrations in non-interfering matrices, that span the range of expected sample values are analyzed and plotted. Generally, a correlation coefficient of better than 0.995 constitutes an acceptable calibration.

5.6.2.1.2.2 Method-specific calibration requirements are included in individual SOPs. In this case, the analytical method will take precedence.

5.6.2.1.3 Continuing Calibration

5.6.2.1.3.1 Prior to use each day, the initial calibration must be verified. Typically, one of the mid-point calibration standards are analyzed and the results are compared to the expected results. If the results fall within the method acceptance limits, then analysis can proceed. If the results are not within the acceptance limits, then the problem must be corrected prior to analysis of samples. Some methods require that samples be bracketed by valid opening and closing

calibration standards. When bracketing is required, only results between valid calibration verification standards can be used.

5.6.2.1.3.2 Reportable analytical results are those within the calibration range of the parameter. In general, values above the highest standard are not reported. The lowest reportable value is the MRL. Instrumental calibration will be verified either initially and during sample analysis or at a rate that the established method requires. The continuing calibration (may be substituted by the check standard) is made with standards independent from that used for instrumental calibration. The calibration check must agree within established limits with the calibration or the instrument is re-celebrated. Continuing calibration standards must agree within established limits of calibration. If not, the cause of the discrepancy is identified, corrected, and documented.

5.6.2.1.4 Initial Calibration Verification (ICV)

5.6.2.1.4.1 An ICV is a well-characterized material that is run, at a minimum, with each calibration. The material, which is obtained from a documented second source. In order to assess the performance of the method, the ICV is run in the same manner as the other calibration standards. If the results are not within acceptable limits, the source of the problem is evaluated. Continual failure indicates there is a problem with the system, the ICV standard or the calibration standards. Prior to analysis, the ICV must pass method criteria. A calibration check solution or sample material should be analyzed at least each day of analysis to demonstrate that calibration and standardization of instrumentation is within acceptable limits.

5.6.2.1.5 Calibration Policy

5.6.2.1.5.1 The calibration policies and procedures set forth in this section apply to all instruments requiring scheduled calibrations against traceable standards, including: analytical and test equipment in the laboratory, flow rate (e.g., rotometers), volume (e.g., dry gas meters), temperature measurement equipment, balances, weights, thermometers, pH meters, SRM's, etc.

5.6.2.1.5.1.1 The standards used in the laboratory measurement system will be calibrated against higher-level, primary standards having certified accuracy. NIST or other equivalently-recognized standardization will certify these higher-level standards.

5.6.2.1.5.3 Calibration standard reagents purchased from commercial vendors will be required to have a certificate of analysis. Whenever a certified, calibration standard is available from NIST, commercial vendors will be required to establish traceability of the certificate of analysis to the certified standard.

5.6.2.2 Testing

5.6.2.2.1 Uncertainty

Policy:
The requirements given in section 5.6.2.1 apply to measuring and test equipment with measuring functions used, unless it has been established that the associated calibration uncertainty contributes little to the total uncertainty of the test result. When this situation arises, the laboratory ensures that equipment used can provide the accuracy of measurement needed.

Details:
The extent to which the requirements in section 5.6.2.1 are followed depends on the relative contribution of calibration uncertainty to the total uncertainty. If calibration is the dominant factor, the requirements are strictly followed. If, however, calibration is not one of the major contributors to the total uncertainty, other ways for providing confidence may be used, as given in section 5.6.2.2.2.

5.6.2.2.2 Traceability

Policy:
Where traceability to SI units of measurement is not possible and/or not relevant, other means for providing confidence in the results are applied such as:

- the use of suitable reference materials certified to give a reliable characterization of the material
- mutual-consent standards or methods which are clearly specified and agreed upon by all parties concerned
- participation in a suitable program of inter-laboratory comparisons or proficiency testing

Details:
Reliable characterization involves an estimate of recovery.

The laboratory participates in proficiency testing and/or check sample programs. The list of programs is maintained by the Quality Manager.

5.6.3 Reference Standards and Reference Materials

5.6.3.1 Reference Standards

Policy:
The SOP# QSP 5-6-1 outlines the program for the calibration of reference standards. Reference standards are obtained or calibrated by a body that can provide traceability as described in section 5.6.2.1. Such reference standards of measurement held by the laboratory are used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated.

Details:
Reference standards are obtained from ISO certified vendors], if applicable.

5.6.3.2 Reference Materials

Policy:
Where possible, reference materials are traceable to SI units of measurement, or to certified reference materials. Internal reference materials are checked as far as is technically and economically practicable.

Details:
Reference materials, including calibration standards, used in chemical measurement are prepared so that the point of measurement is similar or equivalent to that of the samples. The matrix, prior to the addition of the analyte does not have a detectable concentration of the analyte. Reagents used in the preparation of reference materials, including calibration standards are of certified purity.

5.6.3.3 Intermediate Checks

Policy:
Checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards and reference materials are carried out according to defined procedures and schedules.

Details and Procedures:
The control check standards used to verify the accuracy of all the other standards are prepared independently from all the other standards used to establish the original calibration. These control check standards are preferably prepared from a separate lot # or source. It is the responsibility of the Quality Manager to establish and maintain the individual schedule for each SOP and/or test method. In some cases, where the first two source standards agree but the results are called into question, then it may be appropriate to obtain an additional source for verifications.

5.6.3.4 Transport and Storage

Policy:
The SOP# QSP 5-6-1 outlines safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity.

Revision History

Changes from Revision 24
Revision 25 is a significant revision with numerous additions, deletions and corrections. These are not all documented in the revision history, rather all persons on the distribution list are required to read the entire document.

5.7 Sampling

Section Synopsis

This section tells you:

1. There must be a sampling plan and procedure
2. Appropriate records of sampling are kept
3. Deviations, additions, and exclusions from the plan or procedure are recorded

Key Words

Sampling Plan and Procedure
Deviation, Addition, or Exclusion

Cross-references

ISO 17025:2005 Section 5.7

ISO 9001:2000 Section 4.2.4, 7.5.1

5.7.1 Sampling Plan and Procedures

Chemtech-Ford, Inc. Does not currently perform sampling.

Revision History

Changes from Revision 24
Revision 25 is a significant revision with numerous additions, deletions and corrections. These are not all documented in the revision history, rather all persons on the distribution list are required to read the entire document.

5.8 Handling of Test and Calibration Items

Section Synopsis

This section tells you to:

1. Keep samples in good condition.

Key Words

Identification
Receipt
Protection

Cross-references

ISO 17025:2005 Section 5.8

ISO 9001:2000 Section 6.3, 6.4, 7.1, 7.4.3, 7.5, 8.2.4

5.8.1 Procedures

Policy:
The SOP# QSP 5-8-1 outlines the procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of test and/or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and the interests of the laboratory and the customer.

Details:
Samples, reagents, and standards are stored so as to ensure their integrity by preventing against deterioration, contamination, and loss of identity. It is recognized that this is a general statement, but details are elaborated upon in SOP# QSP 5-8-1.

5.8.2 Identification of Test and/or Calibration Items

Policy:
Test and/or calibration items are systematically identified as they arrive at the laboratory. The identification is retained throughout the life of the item in the laboratory. The system is designed and operated so as to ensure that items cannot be confused physically, or when referred to in records or other documents. The system accommodates a sub-division of groups of items and the transfer of items within and from the laboratory when appropriate.

Details:
Sample labelling indicates the unique identification and conforms to applicable legal requirements. The laboratory has established and documents a system for appropriate chain-of-custody.

5.8.3 Receipt

Policy:
Upon receipt of the test or calibration item, any abnormalities or departures from normal or specified conditions, as described in the relevant test or calibration method, are recorded. When there is any doubt as to the suitability of an item for test or calibration, or when an item does not conform to the description provided, or the test or calibration required is not specified in sufficient detail, the laboratory consults the customer for further instructions before proceeding and keeps a record of the discussion.

The Chemtech-Ford sample acceptance policy is detailed in document QSP 5-8-3.

Details:
Conform to applicable regulations or contractual arrangements. The condition of sample may include or relate to damage, quantity, preparation, packaging, or temperature. Preparation may include addition of chemical preservative, removal of moisture, isolation of portion of sample to be tested, homogenization, or subsampling.

Procedures are in place to document that the elapsed time between sampling and testing does not exceed test method specifications (holding time) once the sample is received in the laboratory.

5.8.4 Protection

Policy:
The SOP# QSP 5-8-1 outlines the procedures and appropriate facilities for avoiding deterioration, loss or damage to the test or calibration item during storage, handling and preparation and testing; instructions provided with the item are followed. When items have to be stored or conditioned under specified environmental conditions, these conditions are maintained, monitored, and recorded. Where a test item is to be held secure (e.g., for reasons of record, safety or value, or to enable complementary test and/or calibrations to be performed later), the laboratory has arrangements for storage and security that protect the condition and integrity of the secured item concerned.

Details:
A sampling procedure and information on storage and transport of samples, including all information that may influence the test or calibration result, is provided to those responsible for taking and transporting the samples.

The laboratory establishes whether the sample has received all necessary preparation or whether the customer requires preparation to be undertaken or arranged by the laboratory. Proper requirements for packaging, environmental conditions, and separation from incompatible materials are observed. Where samples have to be stored or conditioned under specific conditions, these conditions are maintained, monitored, and recorded, where necessary.

Where a sample, or portion of a sample, is to be held secure (e.g., for reasons of record, safety, or value, or to enable check tests to be performed later), the laboratory has storage and security arrangements that protect the condition and integrity of the sample.

Revision History

Changes from Revision 24
Revision 25 is a significant revision with numerous additions, deletions and corrections. These are not all documented in the revision history, rather all persons on the distribution list are required to read the entire document.

5.9 Assuring the Quality of Test Results

Section Synopsis

This section tells you:

1. That results are monitored
2. There is a plan for monitoring

Key Words

Internal Quality Control
Statistical Techniques
Inter-laboratory Comparisons
Proficiency Testing
Certified Reference Materials
Secondary Reference Material
Replicates
Re-testing
Correlation

Cross-references

ISO 17025:2005 Section 5.9

ISO 9001:2000 Section 6.3, 6.4, 7.1, 7.2.1, 7.2.2, 7.3, 7.4.3, 7.5.1, 7.5.2, 7.5.3, 7.5.5, 8.1, 8.2.3, 8.2.4, 8.4

5.9.1 Quality Control / Quality Assurance

Policy:
Quality control procedures are utilized to monitor the validity of test and/or calibration results. These procedures are for each test method utilized in the laboratory. The resulting data are recorded so that trends are detectable (and where practicable, statistical techniques are applied to the reviewing of the results). This monitoring is planned and reviewed and may include, but not limited to, the following:

- regular use of certified reference materials and/or internal quality control using secondary reference materials
- participation in inter-laboratory comparisons or proficiency testing programs
- replicate tests or calibrations using the same or different methods
- re-testing or re-calibration of retained items
- correlation of results for different characteristics of an item

Details:
The methods utilized from the above list will be appropriate for the type and volume of the work undertaken. Records are maintained of assurance activities and any actions taken.

As a guide, for routine analyses the level of internal quality control is typically 5% of the sample throughput. For more complex procedures, 20% is not unusual and on occasions even 50% may be required. For analyses performed infrequently, a full system validation is performed on each occasion. This may typically involve the use of a reference material containing a certified or known concentration of analyte, followed by replicate analyses of the sample and spiked sample. For analyses undertaken more frequently, systematic quality control procedures incorporating the use of control charts and check samples are implemented. These procedures are documented in the "Quality Control Plan" of each test method.

Proficiency testing helps to highlight not only repeatability and reproducibility performance between laboratories, but also systematic errors such as bias. It is important to monitor proficiency testing results as a means of checking quality assurance and take action as necessary.

The QM maintains a list of all the current proficiency testing programs the laboratory participates in, monitors the results, and notifies the appropriate personnel of both problematic and successful results.

Technical personnel use certified reference materials and reference materials to evaluate test performance on a daily basis and include daily process control checks. These data are used to evaluate the validity of the test results.

Replicate tests may be used if suitable reference material is available. These materials and proficiency test materials are available for improving repeatability.

Re-testing of test items is performed occasionally at the discretion of the supervisor or when test results seem anomalous.

5.9.1.1 Quality Control Procedures

The determination of precision and accuracy is an important analytical tool in evaluating the quality of generated data. Precision is defined as the ability to reproduce a value within defined limits. Accuracy is defined as producing the correct answer. Different methods are employed to measure each of these parameters.

5.9.1.1.1 ***Precision*** - Utilizing duplicate samples and comparing their respective results is the primary method for the analysis of precision. However, it has no bearing on accuracy. A result may be precise and inaccurate at the same time. One duplicate sample is analyzed for each matrix type and method, and for each sample batch, or for each sample batch containing 20 samples, whichever is less. The relative percent difference (RPD) for each component is then calculated and compared to the acceptance limits for the matrix and method.

5.9.1.1.2 ***Accuracy*** - Utilizing matrix-matched standards of known concentration and comparing them to the analyte of interest is the primary method for measuring accuracy. Participation in independent Performance Evaluation (PE) studies is also utilized to monitor accuracy of data in the laboratory.

5.9.1.1.3 ***Reproducibility*** - The tracking of reproducibility ensures that analyses performed at different times or by different individuals may be acceptably reproduced. This demonstrates that the method, instrumentation, and analytical technique are resilient enough to reproduce results within a specified range over time.

5.9.1.2 Quality Control Samples

The quality control principles contained in this section will be implemented consistently, dependent upon the type of analysis to be performed and any

associated, specific requirements of such analysis. In addition, the analyst is to use his/her best judgment to evaluate the use of additional QC bracketing samples which have a difficult matrix, react differently, or have distinctive client or reporting requirements. The additional QC can take the form of additional spikes, standards, and/or SRM's. Sufficient QC should be performed to insure that the analyst has performed due diligence with regard to QC while analyzing the sample.

5.9.1.2.1 ***Matrix Spike and Matrix Spike Duplicate*** - Matrix spikes are employed to monitor recoveries and maintain extraction and/or concentration techniques at acceptable levels. Compounds of interest are added to samples prior to extraction and analysis. Compound recoveries and reproducibility are then compared with tables of acceptance for each method. The established acceptance ranges are contained in each method SOP.

5.9.1.2.1.1 This QC procedure provides information about the effect of the sample matrix on the analyte in question. Generally, a ratio of one spike sample for each ten samples for drinking water and for each twenty samples for RCRA and wastewater analyzed must be maintained. In the event that an analytical run will have less than ten samples one spike shall accompany the batch. The method SOP should be consulted to determine the proper frequency. Solutions used to fortify samples should, when possible, be made from a source other than that from which the calibration standards are made. Percent recovery of matrix spikes is determined using the following:

Percent Recovery = (SSR-SR)/SA x 100

Where:
SSR = Spiked Sample Result
SR = Sample Result
SA = Spike Added

5.9.1.2.1.2 **Spike Recoveries** - Percent spike recoveries range between $\pm$3 standard deviations (SD) of the historical percent recoveries when method-specified criteria are not available. It is recognized that this will not always be achievable due to matrix effects. In that case, the data will be reported and an explanation made concerning the problem.

5.9.1.2.1.3 **Laboratory matrix spikes and matrix spike duplicates** must be prepared and analyzed for each ten samples for drinking water and for each twenty

samples for RCRA and wastewater analyses. This procedure provides information regarding the precision of an analysis. (These sample types are not always possible due to the type of analysis, for example pH.) The relative difference between duplicate measurements is assessed using the following equation:

Relative Percent Difference (RPD) = $|D_1-D_2|/ ((D_1 + D_2)/2) \times 100$

Where:

D_1 = Sample Value

D_2 = Duplicate Sample Value

5.9.1.2.2 ***Laboratory Control Spikes*** - Compounds of interest are added to reagent blank samples prior to extraction and analysis, as required by each method SOP. Compound recoveries and reproducibility are then compared with tables of acceptance for each method.

5.9.1.2.3 ***Duplicates and Spike Duplicates*** - Both routine sample analysis and spiked samples are run in duplicate at a prescribed frequency. The relative percent difference between duplicate sample analysis or duplicate spike analysis must range between $\pm$ 2 standard deviations (SD) of historical relative percent difference (RPD), when method-specified criteria are not available. It is recognized that this will not always be achievable due to matrix effects. If a matrix effect is confirmed, the data will be reported and an explanation concerning the problem will be noted on the final report.

5.9.1.2.4 ***Surrogates*** - Surrogate spike compounds of interest are added to each sample prior to extraction and analysis. Compound recoveries and reproducibility are then compared with tables of acceptance for each method.

5.9.1.2.5 ***Method and Reagent Blanks*** - Method blanks must be prepared with each batch of samples and analyzed to ensure that sample contamination has not occurred. If blank analyses do not fall within acceptable limits, as noted in the method specific SOP, a modification of method reagents or cleaning of glassware may need to be implemented before further analysis is attempted. In addition to method blanks, reagent blanks shall be prepared whenever the lot number of a reagent used in the analysis has changed.

5.9.1.2.6 ***Internal Standards*** - Internal standards will be prepared from a solution containing a known amount of analyte and will be traceable to a certified reference solution. Internal standard levels spiked into the sample for analysis

will be according to method SOP protocol. During analysis, internal standard intensities will be monitored and compared to the intensities established in the calibration blank. In general, intensities should be within 60 – 135% of the original response in the calibration blank, or as otherwise specified in the method SOP.

5.9.1.2.7 ***Quality Control Check Samples*** - Quality control check samples will be prepared from a solution containing a known amount of analyte and will be traceable to a certified reference solution. These solutions will be prepared from a solution that is "second source" in difference from the calibration standards/tuning standards. These solutions will be used to verify the stability of the analytical curve established for the current analytical run.

5.9.1.2.7.1 After calibration and calibration verification, continued calibration blanks (CCB) and continued calibration verification samples (CCV) will typically be analyzed after every 10 samples and at the end of every analytical run. Control limits during analysis of these solutions will be subject to the QA protocol as defined by the method SOP.

5.9.1.2.7.2 Quality control check samples will be used to verify the efficacy of the sample preparation procedure via the analyses of preparation blanks (PB) and laboratory control samples (LCS) derived from a certified reagent traceable to a certified reference material or solution. Laboratory control samples must agree within $\pm$ 2 standard deviations of the historical data base or no greater than $\pm$ 20 percent of the true value. Where method specific ranges exist, they may be used.

5.9.1.2.8 ***Calibration Standards*** - Calibration Standards will be prepared from a solution containing a known amount of analyte and will be traceable to a certified reference solution. Calibration standards will be prepared from a solution that is "second source;" that is, different from the continued calibration verification (CCV) solution.

These solutions are to be utilized for the calibration/tuning of analytical instruments at the beginning of an analytical run and to be used for tuning frequency as required by the method SOP protocol. These solutions are also used to evaluate method MDL's and effective quantitative ranges (linearity).

When required, these samples will be analyzed as samples with control limits as required by the method QA SOP protocol. Selection of appropriate

formulae to reduce raw data to final results is included in the method analyte SOP

5.9.1.3 Other Quality Control Measures

5.9.1.3.1 **Control charts** can be produced by analyte for the evaluation of QA/QC data. The charts are produced by the LIMS software.

5.9.1.4 Out-of-Control Situations

On occasion, a quality control sample may fail; i.e., the recovery for one or more specific analytes may lie outside the acceptable range (creating an "out-of-control" situation). This failure may or may not affect the acceptability of the analytical run and the quality of associated generated data. Quality control guidelines, contained in Chemtech-Ford, Inc.'s Data Validation and Acceptance Procedure, have been established to be used in the evaluation of out-of-control data for each analytical SOP

5.9.2 Correction and Prevention

Policy and Details:
Quality control data are analyzed and, where they are found to be outside pre-defined criteria, planned action is taken to correct and to prevent incorrect results from being reported.

Revision History

Changes from Revision 24
Revision 25 is a significant revision with numerous additions, deletions and corrections. These are not all documented in the revision history, rather all persons on the distribution list are required to read the entire document.

5.10 Reporting of Results

Section Synopsis

This section tells you:

1. What needs to be on a report
2. How to handle amendments to reports

Key Words

Specific Information
Required Information
Interpretation
Opinion
Subcontractor
Electronic Transmission of Results
Format
Amendments

Cross-references

ISO 17025:2005 Section 5.10
ISO 9001:2000 Section 6.1, 6.3.1, 7.1, 7.2.1, 7.2.2, 7.4.3, 7.5.1, 7.5.4, 7.5.5, 8.2.4

5.10.1 General

Policy:
The results of each test, or series of tests are reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test methods.

The results are reported, normally in a test report and include all the information requested by the customer and necessary for the interpretation of the test results and all information required by the method used. This information may include what is outlined in section 5.10.2, 5.10.3 and 5.10.4.

Details:
Test reports are issued as either hard copy or by electronic data transfer.

5.10.2 Test reports and certificates

Policy:
Test reports include the following information, as appropriate:

- a title (e.g., " Certificate of Analysis")
- name and address of laboratory, and location where tests were carried out if different from the address of the laboratory
- Unique identification of the test report, and on each page an identification in order to ensure that the page is recognized as a part of the test report
- name and address of the customer
- identification of the method used
- Description, condition, and unambiguous identification of the item(s) tested.
- date of receipt of test items (where this is critical to the validity and application of the results) and date(s) of performance of the analysis
- reference to sampling procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results
- test results with, where appropriate, units of measurement
- the name(s), function(s) and signature(s) or equivalent of person(s) authorizing the test report
- where relevant, a statement to the effect that the results relate only to the items tested

Details:
Signing authority for test reports is the responsibility of the Lab Director. Records for individuals with signing authority for test reports are approved by the Quality Manager and maintained by same.

Analytical reports include the individual page number and total number of report pages (Page 3 of 16).

A statement is included specifying that the test report is not to be reproduced except in full, without written approval of the laboratory. Data reported to the customer contains the appropriate significant digits for each test method. Low level data are identified as being below specified limits and are flagged with a 'J' flag indicating a value found between the MDL and MRL.

5.10.3 Test Reports

5.10.3.1

Policy and Details:
In addition to the requirements listed in section 5.10.2, test reports include the following, where necessary for the interpretation of results:

- deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions
- where relevant, a statement of compliance/non-compliance with requirements and/or specifications
- where applicable, a statement on the estimated uncertainty of measurement of the test result; information on uncertainty is needed in test reports when it is relevant to the validity or application of the test results, when a customer's instruction so requires, or when uncertainty affects compliance to a specification limit
- where appropriate and needed opinions and interpretations (see section 5.10.5)
- additional information required by specific methods, customers, or groups of customers

5.10.3.2

Policy and Details:
In addition to the requirements listed in sections 5.10.2 and 5.10.3.1, test reports containing the results of sampling include the following, where necessary for the interpretation of test results:

- date of sampling
- unambiguous identification of substance, matrix, material or product sampled (including name of manufacturer and lot number as appropriate)
- location of sampling
- reference to sampling plan and procedures used
- details of any environmental condition during sampling that may affect the interpretation of the test results
- any standard or other specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification concerned

5.10.4 Calibration Certificates

5.10.4.1

Policy:
The testing laboratory does not issue calibration certificates. However, the laboratory often receives calibration services from a calibration laboratory and needs to be familiar with the information on a calibration certificate.

Details:
In addition to the requirements listed in 5.10.2, the calibration certificate could include the following, where necessary for the interpretation of calibration results:

- the conditions (e.g., environmental) under which the calibrations were made that have an influence on the measurement results
- the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof
- evidence that the measurements are traceable (see 5.6.2.1.1)

5.10.4.2

Policy:
This section is not applicable to a testing laboratory.

5.10.4.3

Policy:
This section is not applicable to a testing laboratory.

5.10.4.4

Policy:
A calibration certificate (or calibration label) shall not contain any recommendation on the calibration interval except where this has been agreed with the customer or it is to be used by the laboratory itself.

5.10.5 Opinions and Interpretations

Policy:
When opinions and interpretations are included in the test report, the basis upon which the opinions and interpretations have been made is documented. Opinions and interpretations are clearly marked as such in the test report.

Note - Opinions and interpretations should not be confused with inspections and product certifications as intended in ISO/IEC 17020 and ISO/IEC Guide 65.

Details:
Opinions and interpretations included in a test report may comprise, but not be limited to the following:

- opinion on conformity of the results with requirements
- fulfilment of contractual requirements
- recommendations on how to use the results
- guidance to be used for improvements

In many cases it is appropriate to communicate the opinions and interpretations by direct dialogue with the customer.

5.10.6 Testing and Calibration Results Obtained from Subcontractors

Policy and Details:
Test reports containing the results of tests performed by subcontractors are clearly identified for the subcontracted results. The subcontractor reports the results either in writing or electronically to our laboratory.

5.10.7 Electronic Transmission of Results

Policy:
In the case of transmission of test results by telephone, facsimile or other electronic or electromagnetic means, the requirements of the policies and procedures of this Quality Manual continue to apply (see also 5.2.7.1.2).

Details:
Signatures are recorded on file at the laboratory. Clients may request a hardcopy example of signatures.

5.10.8 Format of Reports

Policy:
The format of reports is designed to accommodate each type of test carried out and to minimize the possibility of misunderstanding or misuse.

Details:
The layout of the test report is such that the presentation of the test data facilitates ease of assimilation by the reader.

5.10.9 Amendments to Reports

Policy:
Material amendments to a test report after issue are made only in the form of a further document, or data transfer, which includes the statement "Amended Report". Such amendments meet all the requirements in this Quality Manual.

Details:
When it is necessary to issue a complete new test report, it is uniquely identified and contains a reference to the original that it replaces. A narrative accompanies the amended report which details the changes in the report as well as justifications for the change. Details for producing an amended report are located in document QSP-5-10-9.

Revision History

Changes from Revision 24
Revision 25 is a significant revision with numerous additions, deletions and corrections. These are not all documented in the revision history, rather all persons on the distribution list are required to read the entire document.

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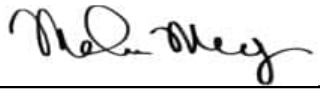
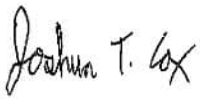


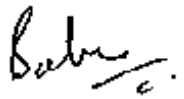
West Cluster Leader – Malcolm Moody — 10/1/2020 Date

Central Cluster Leader – Kamash Pillai — 10/1/2020 Date



Aerotech Cluster Leader – Joshua Cox — 10/2/2020 Date

Technical Director – Michael Berg (Deputy for East Cluster Leader) — 10/2/2020 Date



South Cluster Leader – Balu Krishnan — 10/2/2020 Date

Quality Assurance Manager - Urooj Sagheer — 10/1/2020 Date

Quality Assurance Manager - Dan Shelby — 10/1/2020 Date

Senior Quality Assurance Manager - Claudia Palermo — 10/2/2020 Date

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3.0 INTRODUCTION, SCOPE AND APPLICABILITY

3.1 Introduction and Compliance References

Eurofins EMLab P&K's Quality Assurance (QA) Manual is a document prepared to define the overall policies, organization objectives and functional responsibilities for achieving Eurofins EMLab P&K's data quality goals. Governing SOPs are in place within the organization to ensure the proper execution of this QA Manual (refer to Appendix 1). This manual and referenced documents are required reading for all personnel within the Eurofins EMLab P&K network, which is comprised of two legal entities, EMLab P&K, LLC and Aerotech Laboratories, Inc.

The laboratory is a team of people who work together to serve the health and environmental needs of society through science and technology. The Eurofins EMLab P&K network of laboratories maintains a local perspective in its scope of services and client relations and maintains a national perspective in terms of quality.

The QA Manual has been prepared to assure compliance with The NELAC Institute (TNI) Standard, dated 2009 and 2016; ISO/IEC Guide 17025:2005 and 2017. Policies and procedures listed in Appendix 1 are compliant with the National Divisional Support Center (NDSC) Quality Management Plan (QMP) for Eurofins TestAmerica; Eurofins EMLab P&K and the various accreditation and certification programs which are held by the laboratory to support environmental work (Appendix 2).
Refer to Appendix 3 for a list of additional references for which this QA Manual is compliant.

3.2 Terms and Definitions

A Quality Assurance Program is a company-wide system designed to ensure that data produced by the laboratory conforms to the standards set by state and/or federal regulations (i.e. CA-ELAP, TCEQ, NYS DOH, etc.), as well as applicable accrediting bodies. The program functions at the local management level through company goals, from guidance at the executive management level, and at the analytical level through Standard Operating Procedures (SOPs) and quality control. Our program is designed to minimize systematic error, encourage constructive, documented problem solving, and provide a framework for continuous improvement within the organization.

Refer to Appendix 4 for the Glossary/Acronyms.

3.3 Scope / Fields of Testing

The laboratory analyzes a broad range of environmental and industrial samples. Sample matrices vary, but are not limited to, air, potable and non-potable waters, bulks, wipes, swabs, dust, soils, etc. The Quality Assurance Program contains specific procedures and methods to test samples of differing matrices for chemical, physical and biological parameters. The Program also contains guidelines on maintaining documentation of analytical processes, reviewing results, servicing clients and tracking samples through the laboratory. The technical and service requirements of all analytical requests are thoroughly evaluated before commitments are made to accept the work. Measurements are made using published reference methods or methods developed and validated by the laboratory.

The methods covered by this manual include the most frequently requested methodologies needed to provide analytical services in the United States and its territories. The specific list of test methods used by the laboratory can be found in LabServe, under the services list. Additional information, such as facility specific scopes of accreditation, may be found on the Eurofins EMLab P&K, LLC website.

The approach of this manual is to define the minimum level of quality assurance and quality control necessary to meet these requirements. All methods performed by the laboratory shall meet these criteria as appropriate. In some instances, quality assurance project plans (QAPPs), project specific data quality objectives (DQOs) or local regulations may require criteria other than those contained in this manual. In these cases, the laboratory will abide by the requested criteria following review and acceptance of the requirements by the Cluster Leader and the Quality Assurance (QA) Manager. In some cases, QAPPs and DQOs may specify less stringent requirements. The Cluster Leader and the QA Manager must determine if it is in the lab's best interest to follow the less stringent requirements.

3.4 Management of the Manual

3.4.1 Review Process

Eurofins National Divisional Support Center (NDSC) which houses the Quality Assurance leadership team for Eurofins Environment Testing America. NDSC QA will assure that the template remains in compliance with Section 3.1. This manual itself is reviewed annually by Cluster Leaders and Quality Assurance Managers, to assure that it reflects current practices and meets the requirements of the laboratory's clients and regulators as well as the QMP. Occasionally, the manual may need changes in order to meet new or changing regulations and operations. The QA Manager will review the changes in the normal course of business and incorporate changes into revised sections of the document. All updates will be reviewed by the Cluster Leaders and Quality Assurance Managers. The laboratory updates and approves such changes according to our Document Control & Updating procedures (refer to SOP No. EM-QA-S-2059).

4.0 MANAGEMENT REQUIREMENTS

4.1 Overview

Eurofins EMLab P&K, LLC is a is a business unit of Eurofins Environment Testing America Built Environment The laboratory's operational and support staff have the day-to-day independent operational authority under the direction of the Eurofins Built Environment Laboratory President, Business Unit Manager, and Cluster Leaders and is supported by the NDSC QA team. The laboratory operational and support staff work under the direction of the Cluster Leaders. The organizational chart of the management staff are presented in Figure 4-1. Individual departmental staff lists are maintained in the laboratory's internal intranet.

4.2 Selection of Personnel

Where individual facility updates, changes or goals necessitate, hiring or transfer of personnel either into new or existing roles is driven by cluster leaders. Once defined as a need, all aspects of the hiring process at Eurofins EMLab P&K are managed via the Eurofins US Recruitment

team. All position requests are submitted to the Eurofins US Recruitment team for coordination and planning of position details (requirements, location, salary, etc.). The process includes the review and setting of timelines, selection of posting sites, and defining recruitment team and hiring manager responsibilities associated with the available position.

4.3 Roles and Responsibilities

In order for the Quality Assurance Program to function properly, all members of the staff must clearly understand and meet their individual responsibilities as they relate to the quality program. The responsibility for quality resides with every employee of the laboratory. All employees have access to the QA Manual, are trained to this manual, and are responsible for upholding the standards therein. Each person carries out his/her daily tasks impartially and in a manner consistent with the goals and in accordance with the procedures in this manual and the laboratory's SOPs. The following descriptions briefly define each role in its relationship to the Quality Assurance Program.

4.3.1 Vice President of Quality and Environmental Health and Safety (VP-QA/EHS)

The Vice President (VP) of QA/EHS reports directly to Eurofins Environment Testing America Chief Operating Officer (COO). With the aid of the NDSC Quality Team Members, Business Unit Managers, Laboratory Directors, the VP-QA/EHS has the responsibility for the establishment, general overview and maintenance of the Quality Assurance and EH&S Programs within Eurofins Environment Testing America. Additional responsibilities include:

- Review of QA/QC and EHS aspects of NDSC Official Document, national projects and expansions or changes in services.
- Work with various organizations outside of the laboratory to further the development of quality standards and represent the laboratory at various trade meetings.
- Prepare monthly reports for quality and EH&S metrics across the environmental testing laboratories and a summary of any quality and EH&S related initiatives and issues.
- With the assistance of the Executive Management, and the EHS Managers, maintenance and implementation of the Eurofins Environment Testing America Environmental, Health and Safety Program.

4.3.2 Quality Directors

There are four (4) Quality Directors within NDSC that report directly to the VP-QA/EHS. These Quality Directors have oversight of the general overview and maintenance of the QA Program within the Eurofins Environment Testing America laboratories. Supported tasks include:

- Monitors laboratory internal audit findings;
- Identifies common laboratory weaknesses and monitors corrective action closures.
- Develops NDSC quality guidance documents and management tools for ensuring and improving compliance;
- Monitors and communicates DoD/DoE requirements;
- Monitors and communicates regulatory and certification requirements;
- Training and OnBoarding
- Laboratory assessments, mentoring, and interventions

- Track/drive root cause investigations and corrective action plans
- Builds knowledge base for preventive actions

4.3.3 Quality Information Manager

The Quality Information works directly with the NDSC Quality Directors and EHS Managers; and reports directly to the VP-QA/EHS. The Quality Information Manager is responsible for the management of:

- NDSC Official Documents
- TALS/LIMS Certification Module Data
- Company's Intranet website
- Company's Regulatory Limits Database
- Subcontract laboratory and approved vendor information
- Internal and External client support for various company groups (e.g., Client Services, EH&S, Legal, IT, Sales) for both quality and operational functions
- Communicate regulatory information and lists

4.3.4 Environmental Health and Safety (EH&S) Managers

There are 3 EH&S Managers within NDSC that report directly to the VP-QA/EHS. These EH&S Managers have oversight of the general overview and maintenance of the EH&S Program within the Eurofins Environment Testing America laboratories. Supported tasks include:

- Consolidation and tracking all safety and health-related information and reports for the company, and managing compliance activities for Eurofins Environment Testing America locations.
- Coordination/preparation of the Environmental, Health and Safety Manual Template that is used by each laboratory to prepare its own laboratory-specific Safety Manual/ CHP.
- Preparation of information and training materials for laboratory EHS Coordinators.
- Assistance in the coordination of employee exposure and medical monitoring programs to insure compliance with applicable safety and health regulations.
- Serving as Department of Transportation (D.O.T.) focal point and providing technical assistance to location management.
- Serving as Hazardous Waste Management main contact and providing technical assistance to location management.

4.3.5 Ethics and Compliance Officers (ECOs)

The NDSC VP-QA/EHS and Corporate Counsel are designated Each ECO acts as a back-up to the other ECO and both are involved when data investigations occur. Each ECO has a direct line of communication to the entire executive management personnel and lab management staff.
The ECOs monitor and audit procedures to determine compliance with policies and to make recommendations for policy enhancements to the President, COO, Laboratory Director or other appropriate individuals within the laboratory. The ECO will assist the laboratory QA Manager in the coordination of internal auditing of ethical policy related activities and processes within the laboratory, in conjunction with the laboratory's regular internal auditing function.

The ECOs will also participate in investigations of alleged violations of policies and work with the appropriate internal departments to investigate misconduct, remedy the situation, and prevent recurrence of any such activity.

4.3.6 Business Unit Manager

The Business Unit Manager is responsible for the overall quality, safety, financial, technical, human resource and service performance of the network of Eurofins EMLab P&K laboratories and reports to their business unit President. The Business Unit Manager provides the resources necessary to implement and maintain an effective and comprehensive Quality Assurance and Data Integrity Program. Provides support to the laboratory management of all clusters and is responsible for the overall performance and viability of the lab's profitability. The GM is also responsible for generating positive operating margin and growing revenues for the company at the business unit level by supporting business and market strategy plans. Responsibilities include, but are not limited to:

- Manages labs in accordance with business plan and analyzes financial performance to meet the business objectives.
- Monitors progress of business units toward objectives and key performance indicators (KPI's) to improve financial performance, customer service and revenue growth daily. Ensures that personnel are free from any commercial, financial and other undue pressures which might adversely affect the quality of their work.
- Provides weekly and monthly reports to management to ensure that goals and objectives are being achieved and to recognize opportunities for development.
- Conducts supervisory responsibilities with direct reports to foster and maintain strong staff performance.
- Prepares annual capital and operating budgets for business units yearly to meet financial goals and objectives.
- Responsible for establishing new business developments and additive growth to meet financial objectives.
- Facilitates local and company-wide initiatives and activities weekly to promote cooperation and consistency across their group and the company.
- Communicates with employees daily concerning objectives, company direction and expectations to create a positive work environment and improve staff performance.
- Supports all company policies and procedures daily to ensure compliance with standard operating procedures (SOP's).
- Meets with clients on a regular basis to evaluate lab performance and respond to changing customer requirements
- Reviews audit findings and ensures corrective actions are taken as needed to maintain compliance.
- Assists laboratory management personnel with operational issues including contract negotiations, sales and service issues, customer relations, and key proposals in order to ensure smooth operating systems and meet customer needs.
- Participates in corporate and group lab meetings to support key Eurofins TestAmerica initiatives and provide supervision at remote facilities.

4.3.7 Cluster Leader

The Cluster Leaders are responsible for maintaining positive operating margin to the company at the laboratory level and for meeting and exceeding the annual budget. The Cluster Leaders are responsible for overseeing operations personnel of the Eurofins EMLab P&K, LLC laboratories in their individual cluster, and providing guidance and direction as needed. Eurofins EMLab P&K, LLC's laboratories are grouped in clusters, as defined in organization charts, Figure 4-1. These positions represent the analytical departments in corporate planning and implementation of policies. This includes assuring the quality of all processes through training and placement of departmental personnel in key roles and coordination of department activities with other corporate departments and assuring the smooth flow of work on a daily basis. The Cluster Leader directly or indirectly manages their client service personnel who are the contacts for clients regarding analytical services and advice. The Cluster Leader will work closely with the Business Unit Manager in monitoring, reviewing and directing laboratory personnel, including through the individual Laboratory Managers and Supervisors. The Cluster Leaders are also responsible for implementing the safety policies for their facilities. Responsibilities include but are not limited to:

- Overall responsibility for the operation of the analytical laboratories in their cluster
- Coordinates and supervises all activities related to Eurofins EMLab P&K, LLC analytical processes Manages the laboratory to provide positive operating margin for the company and meet annual budgetary goals.
- Approves of all laboratory purchases including capital spending approvals to support the business plan and maintain profitability.
- Ensures that all analysts and supervisors have the appropriate education and training to properly carry out the duties assigned to them and ensures that this training has been documented. Works with Eurofins Environment Testing Human Resources for hiring of new personnel.
- Ensures that personnel are free from any commercial, financial and other undue pressures which might adversely affect the quality of their work.
- Ensures company human resource policies are adhered to and maintained.
- Ensures that sufficient numbers of qualified personnel are employed to supervise and perform the work of the laboratory. Assesses laboratory capacity and workload.
- Ensures that appropriate corrective actions are taken to address analyses identified as requiring such actions by internal and external performance or procedural audits.
- Communicates facility specific goals and objectives to employees.
- Reviews and approves all SOPs prior to their implementation and ensures all approved SOPs are implemented and adhered to.
- Pursues and maintains appropriate laboratory certification and contract approvals. Supports ISO 17025 requirements.
- Maintains positive customer relationships through direct interaction with customers, as needed.
- Ensures client specific reporting and quality control requirements are met.
- Contributes to the continuous improvement of the laboratory operations.
- Maintains an awareness of technical developments and regulatory requirements.
- Represents analytical services in corporate planning and vision
- Develops new and alternate analytical services
- Performs periodic reviews of their direct staff and oversees evaluation of analyst and/or laboratory technician performance and provides written feedback regarding performance

- Reviews analytical methods on an biennial basis
- Ensures that the EHS program is enforced and the EHS Manual is implemented in the facilities under their control
- Can act as a Technical Manager or NVLAP Approved Signatory if approved by respective regulatory agency.
- This individual may serve as report signatory.

Departmental Relations

- Reports directly to the Business Unit Manager.
- Works directly with the Quality Assurance Manager to ensure accuracy and precision of all analytical results
- Works with Facility Managers and personnel to coordinate implementation of company policies

Qualifications (Minimum)

- An earned life science degree, minimally at the baccalaureate level and a minimum of two years of full time equivalent documented relevant environmental microbiological work experience (mycological and/or bacteriological) and/or an earned physical or biological science degree, minimally at the baccalaureate level.
- The individual must be familiar with indoor air quality, bacteriological sampling and analytical methodology.

4.3.8 Senior Quality Assurance (QA) Manager

The Senior Quality Assurance (QA) Manager, in addition to all the responsibilities of a QA Manager (Section 4.2.4), is also responsible for managing the QA Managers or Quality Coordinators of assigned laboratories. The Senior QA Manager oversees the assigned laboratories to ensure that these labs have implemented an effective quality management system and that the labs drive continuous improvement. This includes identifying or developing quality management tools and training quality staff in the implementation of quality management systems, techniques and tools. The Senior QA Manager reports directly to the General Manager. In addition to those responsibilities listed in Section 4.2.4, responsibilities of the Senior QA Manager include, but are not limited to:

- Act as the QA representative and a representative of senior management in client meetings, regulatory meetings, open forums for discussing regulation changes, etc.
- Generate and submit monthly QA reports for the Management team to keep the team informed of the QA activities
- Provide the necessary support to drive and lead the initiative in making improvements to different processes/functions/procedures within the Quality Assurance program by closely working with other QA Managers, Operations, IT and the Management team
- Assist Business Unit Manager in QA personnel decisions including: staffing, hiring, evaluations, and disciplinary actions as requested.
- Supervise and coordinate the activities of the QA staff at assigned laboratories. Serve as a resource to all laboratory personnel on QA issues.
- Captains the QA team to enable communication and to distribute duties and responsibilities.

4.3.9 Quality Assurance (QA) Manager

The QA Manager has responsibility and authority to ensure the continuous implementation of the quality system. The QA Manager reports directly to the Senior Quality Assurance Manager. This position is able to evaluate data objectively and perform assessments without outside (e.g., managerial) influence. The NDSC Team may be used as a resource in dealing with regulatory requirements, certifications and other quality assurance related items. The Senior QA Manager directs the activities of the QA Managers to accomplish specific responsibilities, which include, but are not limited to:

- Serves as the focal point for QA/QC in the laboratory.
- Have functions independent from laboratory operations for which he/she has quality assurance oversight.
- Have documented training and/or experience in QA/QC procedures and the laboratory's Quality System.
- Arrange for or conducting internal audits on quality systems and the technical operation
- Implements and oversees the Eurofins EMLab P&K, LLC Quality Assurance program for the main laboratories and satellite laboratories (microlabs).
- Maintains and updates the Quality Assurance Manual.
- Maintains all quality control statistical data and other quality control documentation.
- Annually audits the Quality Assurance program, reporting procedures, and other documentation for each assigned facility.
- Works with supervisors to review, develop, and implement appropriate QA steps throughout process flow to ensure high quality of work and reasonable documentation.
- Assesses and implements requirements for current ISO/IEC 17025:2017, AIHA-LAP, LLC EMLAP, IHLAP, and NVLAP accreditation, along with any other accreditations, such as state specific accreditations/certifications (i.e. CA-ELAP, NY-ELAP, etc.).
- Responsible for ensuring that the laboratory is compliant to the current ISO/IEC 17025 standard, the AIHA-LAP, LLC, the NVLAP accreditation policies, and additional accreditations as they apply.
- Produces the monthly quality assurance report
- Responsible for training in Quality Assurance department.
- Maintains and controls all Quality Assurance documents and records.
- Researches and obtains new accreditations/licensing as required.
- Maintains regional facility accreditations/licensing and proficiency testing programs.
- Notifying laboratory management of non-conformances in the quality system and ensuring corrective action is taken. Procedures that do not meet the standards set forth in the QAM or laboratory SOPs shall be investigated following procedures outlined in Section 12 and if deemed necessary may be temporarily suspended during the investigation.
- Communication to the relevant regulatory authorities when there are management or facility changes that impact the laboratory.
- Monitoring and evaluating laboratory accreditations, certifications, and licenses; scheduling proficiency testing samples, where applicable.
- Monitoring and communicating regulatory changes that may affect the laboratory to management.
- Training and advising the laboratory staff on quality assurance/quality control procedures that are pertinent to their daily activities.

- The laboratory QA Manager will maintain records of all ethics-related training, including the type and proof of attendance.
- Maintain, improve, and evaluate the corrective action database and the corrective and preventive action systems.
- Objectively monitor standards of performance in quality control and quality assurance without outside (e.g., managerial) influence.
- Ensuring Communication & monitoring standards of performance to ensure that systems are in place to produce the level of quality as defined in this document.
- Evaluation of the thoroughness and effectiveness of training.

Qualifications (Minimum)

- A baccalaureate degree in an applicable basic or applied science and have at least one year of non-academic analytical experience.
- Quality Assurance Manager shall have documented training in statistics or laboratory quality assurance/quality control.
- Have documented training and/or experience in QA/QC procedures and the laboratory's Quality System.
- Have a general knowledge of the analytical test methods for which data audit/review is performed (and/or having the means of getting this information when needed).

4.3.10 Quality Assurance (QA) Assistant / Environmental Health and Safety Coordinator

The combined role of Quality Assurance Assistant / Environmental Health and Safety Coordinator holds dual responsibilities within the Quality Assurance team and the EH&S program for Eurofins EMLab P&K and reports directly to the Senior Quality Assurance Manager. The role of Quality Assurance Assistant includes assisting Quality Assurance Managers in the maintenance and continual improvement of the Quality Management System for the environmental microbiology, asbestos, lead, and radon programs. The role of Environmental Health and Safety Coordinator (EHSC) is responsible for administering the EH&S program across all Eurofins EMLab P&K locations, and working with facility management and local safety committee teams to provide a safe, healthy working environment and maintain regulatory compliance with local, state, and federal laws. The EH&S Coordinator role enforces environmental, health, and safety policies and procedures. Responsibilities include, but are not limited to:

QA Assistant Role:

- Assist QA Managers with data entry and QC reporting
- Assisting QA Managers with document control, including tracking and assignment of reviews
- Assisting QA Managers in maintaining the laboratory's reference data, preparation of certification applications
- Assisting with maintenance of training records for all employees
- Assist with maintenance of technical records including SOPs, QC records, laboratory data, etc.
- Performs additional tasks as needed and directed by Quality Assurance Manager.
- May perform customer service requests for Project Management staff, supply SOP's, certification information, etc.

EHS Coordinator Role:

- Works with facility management and local safety committee members to ensure facility compliance with the EH&S Manual and applicable policies/procedures.
- Works with laboratory management and corporate EH&S to ensure all Eurofins EMLab P&K facilities are monitored for unsafe conditions, acts, and potential hazards, proper personal protective equipment is available and used, and personnel are properly trained in its use.
- Completes monthly and annual EH&S reports, both internal and external.
- Investigates accidents, incidents, and near misses and identifies root causes, and works with management to eliminate those root causes. Completes accident investigation and reporting in reporting suite.
- Works with facility management to ensure that routine facility inspections for compliance with health, safety and environmental regulations and procedures are completed at each facility.
- Works with facility management to ensure that safety equipment checks are completed at each location to ensure proper working order and sufficient inventory.
- Plans, delivers and tracks completion of monthly refresher and general awareness training sessions and compliance training, including new employee EH&S orientation.
- Participates in and conducts routine EH&S committee meetings.
- Conducts annual EH&S audits for Eurofins EMLab P&K

Qualifications (Minimum)

- A high school diploma or GED and documented on-the-job experience training and experience in general laboratory quality assurance/quality control.

4.3.11 Laboratory Manager

The Laboratory Manager, where applicable, is responsible for overseeing facility specific analytical operations. The Facility Manager will work closely with the Cluster Leader in monitoring, reviewing and directing laboratory work, analytical quality, and overall capacity evaluations. Responsibilities include, but are not limited to:

- Overall responsibility for the operation of the analytical laboratory
- Coordinates and supervises all activities related to Eurofins EMLab P&K, LLC analytical processes
- Implements any Corrective Actions in the laboratory regarding analytical procedures or processes.
- Oversees training programs, if applicable
- Provides assistance with Quality Assurance SOPs for the facility – through the Cluster Leader – and ensures their implementation so that the facility is operated in a compliant manner that allows it to produce defensible data.
- Responsible for ensuring that the laboratory is compliant to the current ISO/IEC 17025 standard, the AIHA-LAP, LLC accreditation policies, the NVLAP accreditation policies, and additional accreditations as they apply.
- Interfaces with analysts to assure that quality analytical data is provided to clients and on – time delivery dates are met.
- Ensures that the employee health and safety procedures are implemented and followed to maintain facility operations that are compliant with appropriate policies and regulations.
- Maintains positive customer relationships through direct interaction with customers, as needed.

- Ensures client specific reporting and quality control requirements are met.
- Can act as the Technical Manager or NVLAP Approved Signatory if approved by respective regulatory agency.
- This individual may serve as report signatory.

Departmental Relations

- Reports directly to the Cluster Leader.
- Works directly with the Quality Assurance Manager to ensure accuracy and precision of all analytical results.
- Works with Cluster Leaders to coordinate implementation of company policies.
- Works with facility personnel staff to implement company policies.

Qualifications (Minimum)

- An earned life science degree, minimally at the baccalaureate level and a minimum of two years of full time equivalent documented relevant environmental microbiological work experience (mycological and/or bacteriological) and/or an earned physical or biological science degree, minimally at the baccalaureate level.
- The individual must be familiar with indoor air quality, bacteriological sampling and analytical methodology.

4.3.12 Technical Manager or Designee

Technical Manager Qualifications

- An earned science degree, minimally at the baccalaureate level, with a minimum of one year of relevant laboratory experience, three months of which must be full time equivalent documented environmental work experience applicable to analyses performed (i.e. mycological and/or bacteriological microbiology, asbestos fibers by PCM, lead analyses).
- The individual must be experienced in the selection and use of bioaerosol, surface, fluid and raw material sampling methods and in sample processing for the quantification and identification of mesophilic and thermophilic bacteria, and mesophilic, xerophilic, hydrophilic and thermotolerant fungi (molds and yeasts) isolated by those methods, as applicable.
- The individual must be experienced in the sampling methods and sample processing for the quantification of asbestos and other fibers by PCM analysis, as applicable.
- The individual must be experienced in the sampling methods and sample processing for the quantification of lead, as applicable to AIHA-LAP, LLC ELLAP.
- The technical manager or their designee shall be responsible for all technical operations and shall be available to address technical issues for laboratory staff and customers concerning analyses, as applicable.
- This individual may serve as report signatory.
- The individual must be present on-site at least 20 hours per week, or 50% of the laboratory working hours (whichever is greater) to address technical issues for laboratory staff and clients.

4.3.13 Senior Analyst

Senior analysts may oversee other departmental analyses, such as mycology and/or bacteriology. Senior Analysts will provide leadership to analytical and support staff. A Senior Analyst is responsible for providing high quality analyses and excellent client service. Senior analysts may also oversee asbestos, allergen and other analytical testing done in the laboratory. Responsibilities may include, but are not limited to:

- May supervise and coordinate laboratory work flow and analyses

- Performs analysis
- May train new analysts
- Maintains client relations and technical support when applicable
- Assists in research and development of new analytical services as required
- Assists the QA manager in development, implementation and data collection of QA processes for analytical services
- Performs independent data reviews for other analyst's work

Departmental Relations

- Reports to the Cluster Leader or Facility Manager.
- Implements and performs mycological, bacteriological, asbestos and other analytical training as required by the Cluster Leader
- Supports other Supervisors, Facility Managers or Cluster Leader when necessary
- Can act as the facility Technical Manager or NVLAP Approved Signatory if approved by respective regulatory agency.

Qualifications (Minimum)

Environmental Microbiology Laboratory Program (Fungi and Bacteria)

- An earned science degree, minimally at the baccalaureate level and a minimum of three years of full time equivalent documented environmental microbiological work experience (mycological and/or bacteriological).

Industrial Hygiene Laboratory Accreditation Program (PCM Asbestos)

- An earned physical or biological science degree, minimally at the baccalaureate level and a minimum of three years relevant nonacademic analytical chemistry experience. A minimum of two years' experience must be in asbestos analyses. The remaining one year can be substituted for work experience.
- Completion of NIOSH 582 (or equivalent) training course for PCM analyses.

National Voluntary Laboratory Accreditation Program (PLM Asbestos)

- Understand polarized light microscopy and its application to crystalline materials sufficiently to conduct analyses. That they understand what the various optical properties are, how they are measured or observed in the microscope, and how the data are used to form a conclusion about the identity of the component, (e.g., an analyst using central and/or annular focal screening (dispersion staining) to measure refractive index must be able to explain what produces the observed color and how that color is used to determine refractive index) Analysts are competent with the polarized light microscope, Can properly align the microscope and identify all of the crucial parts.
- Completion of McCrone (or equivalent) training course for PLM analyses if deemed necessary.

4.3.14 Analyst

Analysts perform a range of analyses based upon specific area of responsibility, including but not limited to, aerobiological, environmental, asbestos and drinking water samples. Analysts are responsible for high quality analyses and excellent client service. Responsibilities may include, but are not limited to:

- Analyzes samples for fungal and/or bacterial parameters
- Identify macrofungi and microfungi
- Analyzes samples for bacterial parameters, including drinking waters for coliforms and *E. coli*
- Process and prepare samples for analysis Analyze samples for asbestos
- Analyze samples for allergens

- Digest and analyze samples for lead analysis.
- Accurately records and reports analytical data
- Performs specific tasks related to Quality Control
- Maintains analytical quality control records
- Performs regular analysis of reference materials and other quality control samples
- Performs independent data reviews for other analysts' work

Departmental Relations

- Reports to Cluster Leader, or Facility Manager.
- Works with management and support staff for optimal teamwork
- Works with project management staff to clarify technical matters.
- Can act as the facility Technical Manager and NVLAP Approved Signatory if approved by respective regulatory agency

Qualifications (Minimum)

- Environmental Microbiology Laboratory Program (Fungi and Bacteria)
- A bachelor's degree in physical or biological science and documented on-the-job training as an analyst trainee under the supervision of a Senior Analyst.
- Industrial Hygiene Laboratory Accreditation Program (Asbestos)
- A bachelor's degree in a physical or biological science, and a minimum of one year relevant nonacademic analytical chemistry experience.
- Completion of training courses for PCM analyses.

Environmental Lead Laboratory Accreditation Program (ELLAP)

- A bachelor's degree in physical or biological science and one month of documented on-the-job training as an analyst trainee under the supervision of a Senior Analyst.
- National Voluntary Laboratory Accreditation Program (PLM Asbestos)
- Understand polarized light microscopy and its application to crystalline materials sufficiently to conduct analyses. That they understand what the various optical properties are, how they are measured or observed in the microscope, and how the data are used to form a conclusion about the identity of the component, (e.g., an analyst using central and/or annular focal screening (dispersion staining) to measure refractive index must be able to explain what produces the observed color and how that color is used to determine refractive index). Analysts are competent with the polarized light microscope, and can properly align the microscope and identify all of the crucial parts.
- Completion of McCrone (or equivalent) training course for PLM analyses if deemed necessary.

4.3.15 Laboratory Technician/Assistant

Laboratory technicians and assistants prepare bioaerosol and microbial samples for fungal and bacteriological analysis. Receive samples and complete required paperwork for processing and analysis of samples, where applicable. Responsibilities may include, but are not limited to:

- Prepares bioaerosol and microbial samples for fungal and bacterial analysis
- Cultures fungi and bacteria from environmental samples for analysis
- Works with a variety of sampling media for optimal results
- Analyzes samples for fungal parameters
- Identify macrofungi and microfungi
- Analyzes samples for bacterial parameters, including drinking waters for coliforms and *E. coli*
- Analyze water samples for analysis

- Analyze samples for asbestos
- Analyze samples for allergens
- Digest and analyze samples for lead analysis.
- Accurately enters and reports analytical data
- Performs specific tasks related to Quality Control
- Performs required Quality Control procedures
- Maintenance of laboratory supplies, equipment, and routine lab reagents
- Prepare samples for ELISA analysis and perform ELISA analysis

Departmental Relations

- Reports to Cluster Leader or Facility manager
- Work with analysts to complete samples by required deadlines
- Work with log-in and receiving supervisors to control flow of work through the laboratory.
- Can act as the NVLAP Approved Signatory if approved by respective regulatory agency.

Qualifications (Minimum)

Environmental Microbiology Laboratory Program (Fungi and Bacteria)

- A high school diploma or GED and documented on-the-job training as an analyst trainee under the supervision of a Senior Analyst.

Environmental Lead Laboratory Accreditation Program (ELLAP)

- A high school diploma or GED and documented on-the-job training as an analyst trainee under the supervision of a Senior Analyst.

National Voluntary Laboratory Accreditation Program (PLM Asbestos)

- Understand polarized light microscopy and its application to crystalline materials sufficiently to conduct analyses. That they understand what the various optical properties are, how they are measured or observed in the microscope, and how the data are used to form a conclusion about the identity of the component, (e.g., an analyst using central and/or annular focal screening (dispersion staining) to measure refractive index must be able to explain what produces the observed color and how that color is used to determine refractive index); b) analysts are competent with the polarized light microscope, Can properly align the microscope and identify all of the crucial parts.
- Completion of McCrone (or equivalent) training course for PLM analyses if deemed necessary.

4.3.16 Project Manager (PM)

Members of the laboratory Client Services/Project Management Group are responsible for organizing and managing client projects. Clients are assigned a project manager who serves as their primary contact at the laboratory. It is the PM's responsibility to act as the client advocate by communicating client requirements to laboratory personnel and ensuring that clients provide complete information needed by the laboratory to meet those requirements – including all verbal communications. The PM reports to the Cluster Leader and serves as the interface between the laboratory's technical departments and the laboratory's clients. With the overall goal of total client satisfaction, the functions of this position are outlined below:

- Scheduling sample submissions, sample container orders and sample pick-up via the laboratory courier service.
- Confirming certification status
- Coordinating and communicating turnaround time (TAT) requirements for high priority samples/projects.
- Answering common technical questions, facilitating problem resolution and coordinating technical details with the laboratory staff.

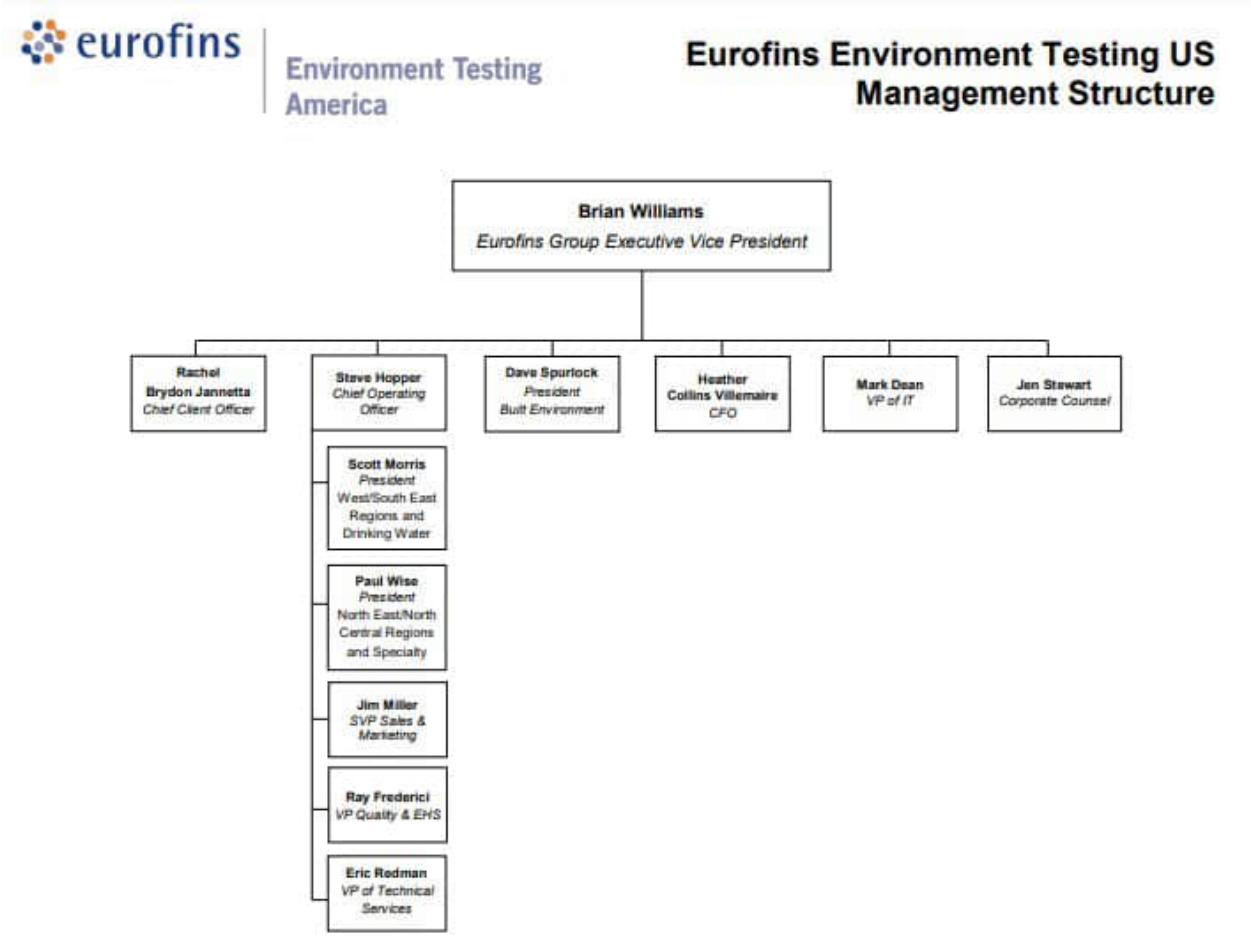
- Responsible to ensure that clients receive the proper sampling supplies.
- Accountable for response to client inquiries concerning sample status.
- Responsible for assistance to clients regarding the resolution of problems concerning COC.
- Ensuring that client specifications, when known, are met by communicating project and quality assurance requirements to the laboratory.
- Notifying the supervisors of incoming projects and sample delivery schedules.
- Responsible for discussing with client any project-related problems, resolving service issues, and coordinating technical details with the laboratory staff.
- Responsible for staff familiarization with specific quotes, sample log-in review, and final report completeness.
- Monitor the status of all data projects in-house to ensure timely and accurate delivery of reports.
- Inform clients of data project-related problems and resolve service issues.
- Coordinate requests for sample containers and other services (data packages).

4.4 Business Continuity and Contingency Plans

Various policies and practices are in place to address continuity of business and contingency plans to ensure continued operations or minimal disruption in operations should unplanned events (natural disasters, unexpected management changes, etc.) occur. Deputies are identified for all key management personnel. Deputies would temporarily fill a role if the primary is absent for more than 15 consecutive calendar days. The deputies must meet the same qualifications as the primary person should they be required to take on the responsibilities. The QA Manager communicates to the relevant regulatory authorities when there are management or facility changes that impact the laboratory. Changes in the technical director must be communicated within a period of time and in the manner dictated by each regulatory authority.

The Eurofins EMLab P&K Deputy List, document EM-QA-R-7794, defines who assumes the responsibilities of key personnel in their absence for the western region and the eastern region respectively.

Figure 4-1. Corporate and Laboratory Organization Charts



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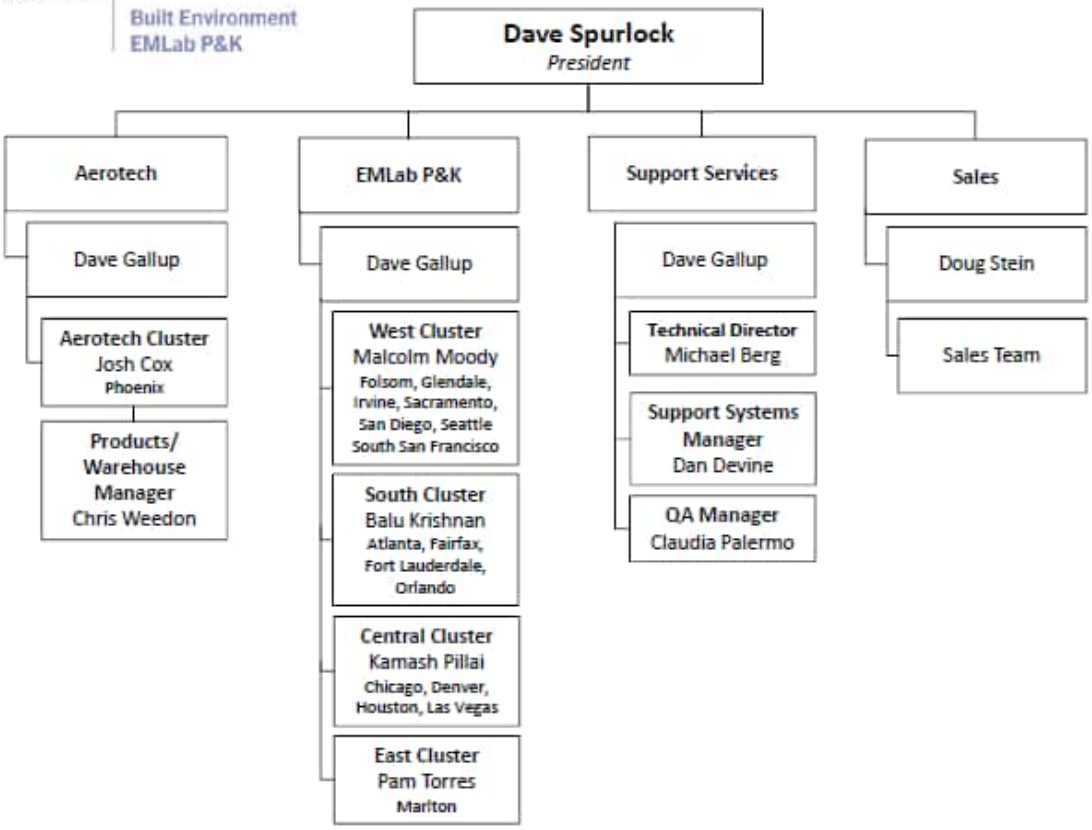

5.0 PERSONNEL

5.1 Overview

The laboratory's management believes that its highly qualified and professional staff is the single most important aspect in assuring a high level of data quality and service. The staff consists of professionals and support personnel.

All personnel must demonstrate competence in the areas where they have responsibility. Any staff that is undergoing training shall have appropriate supervision until they have demonstrated their ability to perform their job function on their own. Staff shall be qualified for their tasks based on appropriate education, training, experience and/or demonstrated skills as required.

The laboratory employs sufficient personnel with the necessary education, training, technical knowledge and experience for their assigned responsibilities. Personnel may perform laboratory activities in more than one facility as directed by Cluster Leaders. Authorized analysts may be employed across more than one facility as needed to meet operational and personnel needs, Where personnel are deployed to a secondary facility, records are to be maintained detailing the dual facility assignments, anticipated timeframe of assignment, and organizational charts must reflect the use of dual location analysts where long term arrangements are in place (greater than 15 business days).

All personnel are responsible for complying with all QA/QC requirements that pertain to the laboratory and their area of responsibility. Each staff member must have a combination of experience and education to adequately demonstrate a specific knowledge of their particular area of responsibility. Technical staff must also have a general knowledge of lab operations, test methods, QA/QC procedures and records management.

Laboratory management is responsible for formulating goals for lab staff with respect to education, training and skills and ensuring that the laboratory has a policy and procedures for identifying training needs and providing training of personnel. The training shall be relevant to the present and anticipated responsibilities of the lab staff.

The laboratory only uses personnel that are employed by or under contract to, the laboratory. Contracted personnel, when used, must meet competency standards of the laboratory and work in accordance to the laboratory's quality system.

5.2 Education and Experience Requirements for Technical Personnel

The laboratory makes every effort to hire analytical staffs that possess a college degree (AA, BA, BS) in an applied science with some biology in the curriculum. Exceptions can be made based upon the individual's experience and ability to learn. Selection of qualified candidates for laboratory employment begins with documentation of minimum education, training, and experience prerequisites needed to perform the prescribed task. Minimum education and training requirements for laboratory employees are outlined in job descriptions maintained by Eurofins Environment Testing America Human Resources.

Experience and specialized training are occasionally accepted in lieu of a college degree (basic lab skills such as using a balance, colony counting, aseptic or quantitation techniques, etc., are also considered).

As a general rule for analytical staff, refer to Table 5-1:

Table 5-1. Analytical Staff Education and Experience Requirements

Specialty	Education	Experience
Sample Processing	H.S. Diploma or GED	On the job training (OJT)
Laboratory Technician / Assistant	H.S. Diploma or GED	One year of documented on-the-job training as an analyst trainee under the supervision of a Senior Analyst. For fungal air direct exam (spore trap) and/or lead, analysts are required to undergo six months of documented on-the-job training as a spore trap analyst trainee under the supervision of a Senior Analyst.
Laboratory Technician / Assistant (PLM Asbestos)	H.S. Diploma or GED Completion of McCrone (or equivalent) training course for PLM analysis if deemed necessary.	Understand polarized light microscopy and its application to crystalline materials sufficiently to conduct analyses. That they understand what the various optical properties are, how they are measured or observed in the microscope, and how the data are used to form a conclusion about the identity of the component, (e.g., an analyst using central and/or annular focal screening (dispersion staining) to measure refractive index must be able to explain what produces the observed color and how that color is used to determine refractive index). Analysts are competent with the polarized light microscope, and can properly align the microscope and identify all of the crucial parts. Completion of McCrone (or equivalent) training course for PLM analysis if deemed necessary.

Specialty	Education	Experience
Senior Analyst – Mycology/Bacteriology	An earned science degree, minimally at the baccalaureate level.	Minimum of three years of full time equivalent documented environmental microbiological work experience (mycological or bacteriological)
Senior Analyst – PCM Asbestos	An earned physical or biological science degree, minimally at the baccalaureate. Level. Completion of NIOSH 582 (or equivalent) training course for PCM analyses.	A minimum of three years relevant nonacademic analytical chemistry experience. A minimum of two years' experience must be in asbestos analyses. The remaining one year can be substituted for work experience.
Senior Analyst – PLM Asbestos	A bachelor's degree in physical or biological science. Completion of McCrone (or equivalent) training course for PLM analysis if deemed necessary.	Understand polarized light microscopy and its application to crystalline materials sufficiently to conduct analyses. That they understand what the various optical properties are, how they are measured or observed in the microscope, and how the data are used to form a conclusion about the identity of the component, (e.g., an analyst using central and/or annular focal screening (dispersion staining) to measure refractive index must be able to explain what produces the observed color and how that color is used to determine refractive index) Analysts are competent with the polarized light microscope. Can properly align the microscope and identify all crucial parts.
Analyst (Fungi/Bacteria)	A bachelor's degree in physical or biological science.	Six months of documented on-the-job training as an analyst trainee under the supervision of a Senior Analyst (For fungal air direct exam (spore trap), analysts are required to undergo three months of documented on-the-job training as a spore trap analyst trainee under the supervision of a Senior Analyst.)
Analyst (PCM Asbestos)	A bachelor's degree in a physical or biological science. Completion of training course for PCM analysis.	A minimum of one year relevant nonacademic analytical chemistry experience.

Specialty	Education	Experience
Analyst (PLM Asbestos)	A bachelor's degree in physical or biological science. Completion of McCrone (or equivalent) training course for PLM analysis if deemed necessary.	Understand polarized light microscopy and its application to crystalline materials sufficiently to conduct analyses. That they understand what the various optical properties are, how they are measured or observed in the microscope, and how the data are used to form a conclusion about the identity of the component, (e.g., an analyst using central and/or annular focal screening (dispersion staining) to measure refractive index must be able to explain what produces the observed color and how that color is used to determine refractive index). Analysts are competent with the polarized light microscope, and can properly align the microscope and identify all of the crucial parts.
Analyst (Lead)	A bachelor's degree in physical or biological science.	One month of documented on-the-job training as an analyst trainee under the supervision of a Senior Analyst.
Technical Managers	An earned science degree, minimally at the baccalaureate level. (For bacteria/fungi: The individual must be experienced in the selection and use of bioaerosol, surface, fluid and raw material sampling methods and in sample processing for the quantification and identification of mesophilic and thermophilic bacteria, and mesophilic, xerophilic, hydrophilic and thermotolerant fungi (molds and yeasts) isolated by those methods.)	A minimum of one year of relevant laboratory experience, three months of which must be full time equivalent documented environmental microbiological work experience (mycological and/or bacteriological).

When an analyst does not meet these requirements, they can perform a task under the direct supervision of a qualified analyst, peer reviewer or Technical Manager, and are considered an analyst in training. The person supervising an analyst in training is accountable for the quality of the analytical data and must review and approve data and associated corrective actions.

5.3 Training

The laboratory is committed to furthering the professional and technical development of employees at all levels.

Orientation to the laboratory's policies and procedures, in-house method training, and employee attendance at outside training courses and conferences all contribute toward employee proficiency. Below are examples of various areas of required employee training:

Table 5-2. Examples of Required Training

Required Training	Time Frame	Employee Type
Environmental Health & Safety	Prior to lab work	All
Ethics – New Hires	1 week of hire	All
Ethics – Comprehensive	60 days of hire	All
Data Integrity	60 days of hire	Technical and PMs
Quality Assurance	90 days of hire	All
Ethics – Comprehensive Refresher	Annually	All
Initial Demonstration of Capability (DOC)	Prior to unsupervised method performance	Technical

The laboratory maintains records of relevant authorization/competence, education, professional qualifications, training, skills and experience of technical personnel (including contracted personnel) as well as the date that approval/authorization was given. These records are kept on file at the laboratory. Authorizations are applicable across the Eurofins EMLab P&K network of laboratories for shared procedures. Also refer to "Demonstration of Capability" in Section 19.

The training of technical staff is kept up to date by:

- Each employee must have documentation in their training file that they have read, understood and agreed to follow the most recent version of the laboratory QA Manual and SOPs in their area of responsibility. This documentation is updated as SOPs are updated.
- Documentation from any training courses or workshops on specific equipment, analytical techniques or other relevant topics.
- Documentation of proficiency (refer to Section 19).
- An Ethics Agreement signed by each staff member (renewed each year) and evidence of annual ethics training.
- A Confidentiality Agreement signed by each staff member signed at the time of employment.
- Human Resources maintains documentation and attestation forms on employment status and records; benefit programs; timekeeping/payroll; and employee conduct (e.g., ethics violations). This information is maintained in the employee's secured personnel file.

Evidence of successful training could include such items as:

- Adequate documentation of training within operational areas, including one-on-one technical training for individual technologies, and particularly for people cross-trained.
- Analysts knowledge to refer to QA Manual for quality issues.
- Analysts following SOPs, i.e., practice matches SOPs.

- Analysts regularly communicate to supervisors and QA if SOPs need revision, rather than waiting for auditors to find problems.

Further details of the, laboratory's training program are described in the Laboratory Training SOP (EM-AD-S-1646, General Training).

5.4 Data Integrity and Ethics Training Program

The laboratory's Ethics and Data Integrity Program is discussed in Section 7.2. Employees are trained as to the legal and environmental repercussions that result from data misrepresentation. Key topics covered in the presentation include:

- Organizational mission and its relationship to the critical need for honesty and full disclosure in all analytical reporting.
- Ethics Policy
- How and when to report ethical/data integrity issues. Confidential reporting.
- Record keeping.
- Discussion regarding data integrity procedures.
- Specific examples of breaches of ethical behavior (e.g. peak shaving, altering data or computer clocks, improper macros, etc., accepting/offering kickbacks, illegal accounting practices, unfair competition/collusion)
- Internal monitoring. Investigations and data recalls.
- Consequences for infractions including potential for immediate termination, debarment, or criminal prosecution.
- Importance of proper written narration / data qualification by the analyst and project manager with respect to those cases where the data may still be usable but are in one sense or another partially deficient.

Additionally, a data integrity hotline (1-800-736-9407) is maintained by The NDSC.

6.0 ACCOMMODATIONS AND ENVIRONMENTAL CONDITIONS

6.1 Overview

Each Eurofins EMLab P&K laboratory is a secure laboratory facility with controlled access and designed to accommodate an efficient workflow and to provide a safe and comfortable work environment for employees. All visitors sign in and are escorted by laboratory personnel. Access is controlled by various measures.

Each laboratory is equipped with structural safety features. Each employee is familiar with the location, use, and capabilities of general and specialized safety features associated with their workplace. The laboratory provides and requires the use of protective equipment including safety glasses, protective clothing, gloves, etc., OSHA and other regulatory agency guidelines regarding required amounts of bench and fume hood space, lighting, ventilation (temperature and humidity controlled), access, and safety equipment are met or exceeded.

Traffic flow through sample preparation and analysis areas is minimized to reduce the likelihood of contamination. Adequate floor space and bench top area is provided to allow unencumbered sample preparation and analysis space. Sufficient space is also provided for storage of reagents and media, glassware, and portable equipment. Ample space is also provided for refrigerated sample storage before analysis and archival storage of samples after analysis. Laboratory HVAC and deionized water systems are designed to minimize potential trace contaminants.

The laboratory is separated into specific areas for sample receiving, sample preparation, microbiological sample analysis, asbestos sample analysis, lead sample analysis, and administrative functions.

6.2 Environment

Laboratory accommodation, test areas, energy sources, and lighting are adequate to facilitate proper performance of tests. Each facility is equipped with heating, ventilation, and air conditioning (HVAC) systems appropriate to the needs of environmental testing performed at this laboratory. The environment in which these activities are undertaken does not invalidate the results or adversely affect the required accuracy of any measurements.

Each laboratory provides for the effective monitoring, control and recording of environmental conditions that may affect the results of environmental tests as required by the relevant specifications, methods, and procedures. Such environmental conditions include temperature of in use equipment and within the laboratory, where applicable. Monitoring also includes environmental monitoring for airborne molds, bacterial contaminants, surface lead and total airborne fibers, including asbestos, which is performed on a predetermined schedule per facility.

When any of the method or regulatory required environmental conditions change to a point where they may adversely affect test results, analytical testing will be discontinued until the environmental conditions are returned to the required levels.

Environmental conditions of the facility housing the computer network and Labserve are regulated to protect against raw data loss.

When the laboratory performs laboratory activities at sites or facilities outside its permanent control, it shall ensure that the requirements related to facilities and environmental conditions of this document are met.

Specific requirements for facility and environmental conditions, as well as periodic monitoring of conditions, are given in the Environmental Health & Safety Manual plus each laboratory's Facility Addendum. Procedures and requirements for routine environmental monitoring are found in EM-HS-S-1585.

6.3 Work Areas

There is effective separation between neighboring areas when the activities therein are incompatible with each other. Examples include:

- Microbiological culture handling and sample incubation areas.
- Asbestos sample handling and preparation of reagents.
- Chemical handling areas, including reagent preparation and waste disposal areas.

Access to and use of all areas affecting the quality of analytical testing is defined and controlled by secure access to the laboratory building as described below in the Building Security section.

Adequate measures are taken to ensure good housekeeping in each laboratory and to ensure that any contamination does not adversely affect data quality. These measures include regular cleaning to control dirt and dust within the laboratory. Work areas are available to ensure an unencumbered work area. Work areas include:

- Access and entryways to the laboratory.
- Sample receipt areas.
- Sample storage areas.
- Chemical and waste storage areas.
- Data handling and storage areas.
- Sample processing areas.
- Sample analysis areas.

Refer to the following documents and procedures for specific requirements for microbiological laboratory facility requirements.

- Standard Methods, 20th Ed., 9020B, Sec. 2
- TNI V1M5, 1.7.3.7.a
- CW-E-M-001, Eurofins TestAmerica Environmental Health and Safety Manual, Section 16
- EM-HS-S-1639, Housekeeping and Decontamination
- EM-HS-S-1286, Procedure for the Retention and Disposal of Samples

6.4 Responding to Emergencies

Employees must be aware of procedures to respond to all emergencies that might occur in the workplace. Employees must be familiar with the location and proper operation of all emergency equipment, evacuation routes and designated assembly areas for all areas where they work. Refer to the NDSC EH&S Manual Document No. CW-E-M-001. Sec. 7 and the laboratory's local EH&S addendum for complete details. These documents provide direction for situations where normal operations of the laboratory are not possible (e.g., electrical failures, heating/air conditioning failures, fire/building evacuation, computer failures, hazardous material spills, injury to employees, pandemic flu, disruption of phone service, etc.)

In the event that the building or information technology (IT) systems would be severely challenged, a designated disaster recovery team, which includes Facility Management, Maintenance, Safety, Laboratory/Executive Management, Public Relations, IT, QA and other applicable personnel depending on the scope of the disaster, would assemble at a designated area to assess the situation and formulate a plan.

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6.5 Building Security

Building keys and/or key fobs are distributed to employees as necessary.

Visitors to the laboratory sign in and out in a visitor's logbook. A visitor is defined as any person who visits the laboratory who is not an employee of the laboratory. In addition to signing into the laboratory, the Environmental Health and Safety policies require the completion of specific EH &S forms by all visitors and vendors. Visitors (with the exception of company employees) are escorted by laboratory personnel at all times, or the location of the visitor is noted in the visitor's logbook.

7.0 QUALITY SYSTEM

7.1 Quality Policy Statement

The Quality Policy statement gives employees clear requirements for the production of analytical data. As an organization, all personnel are committed to high quality professional practice, testing and data, and service to our clients.

We strive to provide the highest quality data achievable by:

- Reading and understanding all of the quality documents applicable to each position and implementing the process in our work.
- Following all recordkeeping requirements; describing clearly and accurately all activities performed; recording "real time" as the task is carried out; understanding that it is never acceptable to "back date" entries and should additional information be required at a later date, the actual date and by whom the notation is made must be documented.
- Ensuring data integrity through the completeness, consistency, impartiality and accuracy of the data generated. Data is attributable, legible, contemporaneously recorded, original or a true copy, and accurate (ALCOA). This applies to manual paper documentation and electronic records.
- Providing accountability and traceability for each sample analyzed through proper sample handling, labeling, preparation, instrument calibration/qualification/validation, analysis, and reporting; establishing an audit trail (the who, what, when, and why) that identifies date, time, analyst, instrument used, instrument conditions, quality control samples (where appropriate and/or required by the method), and associated standard material.
- Emphasizing a total quality management process which provides impartiality, accuracy, and strict compliance with agency regulations and client requirements, giving the highest degree of confidence; understanding that meeting the requirements of the next employee in the work flow process is just as important as meeting the needs of the external client.
- Providing thorough documentation and explanation to qualify reported data that may not meet all requirements and specifications, but is still of use to the client; understanding this occurs only after discussion with the client on the data limitations and acceptability of this approach.
- Responding immediately to indications of questionable data, out-of-specification occurrences, equipment malfunctions, and other types of laboratory problems, with investigation and applicable corrective action; documenting these activities completely, including the reasons for the decisions made.

- ❖ Providing a work environment that ensures accessibility to all levels of management and encourages questions and expression of concerns on quality issues to management. Eurofins recognizes that the implementation of a quality assurance program requires management's commitment and support as well as the involvement of the entire staff
- ❖ Continually improve systems and manage risk to support quality improvement efforts in laboratory, administrative and managerial activities

7.2 Ethics and Data Integrity

Eurofins Environment Testing America is committed to ensuring the integrity of its data and meeting the quality needs of its clients. The laboratory operates our Ethics and Data Integrity program under the guidance of Eurofin's Key Guidance Document (KGD). The elements of our Ethics and Data Integrity Program include:

- An Ethics Policy (NDS Document No. CW-L-P-004) and Employee Ethics Statements.
- Ethics and Compliance Officer/s (ECOs).
- A Training Program.
- Self-governance through disciplinary action for violations.
- A confidential mechanism for anonymously reporting alleged misconduct and a means for conducting internal investigations of all alleged misconduct. (NDSC Document No. CW-L-S-002).
- Procedures and guidance for recalling data if necessary (NDSC Document No. CW-Q-S-005).
- Effective external and internal monitoring system that includes procedures for internal audits (Section 17).
- Produce results, which are accurate and include QA/QC information that meets client pre-defined Data Quality Objectives (DQOs).
- Present services in a confidential, honest and forthright manner.
- Provide employees with guidelines and an understanding of the Ethical and Quality Standards of our Industry.
- Provide procedures and guidance to ensure the impartiality and confidentiality of all data and customer information.
- Operate our facilities in a manner that protects the environment and the health and safety of employees and the public.
- Obey all pertinent federal, state and local laws and regulations and encourage other members of our industry to do the same.
- Educate clients as to the extent and kinds of services available.
- Assert competency only for work for which adequate personnel and equipment are available and for which adequate preparation has been made.
- Promote the status of environmental laboratories, their employees, and the value of services rendered by them.

7.3 Quality System Documentation

The laboratory's Quality System is communicated through a variety of documents.

- Quality Assurance Manual – Eurofins EMLab P&K has one quality assurance manual to address the quality management system applicable to all Eurofins EMLab P&K facilities.NDSC Official Documents – Each laboratory may use the Guidance (instructional use) documents at their discretion. Template documents are process documents that the laboratory's need to implement locally by using the document as is or as an outline to define their internal practices that meet the minimum requirements of the template. Required documents need to be implemented as is and listed in the laboratory's document control list.
- Key Guidance Documents (KGDs) - Documents compiled at the Group Service Centre (GSC) level by Functional Leaders (document owners) aimed at providing specific Eurofins groups of employees with guidelines necessary for the good conduct of their respective work.
- Laboratory SOPs and Policies– General and Technical
- Laboratory QA/QC Policy Memorandums

7.3.1 Order of Precedence

In the event of a conflict or discrepancy between policies, the order of precedence is as follows:

- Quality Management Plan (QMP)
- NDSC Guidance Documents
- KGDs
- Laboratory Quality Assurance Manual (QAM)
- Laboratory SOPs and Policies
- Other (Work Instructions (WI), memos, flow charts, etc.)

NOTE: The laboratory has the responsibility and authority to operate in compliance with regulatory requirements of the jurisdiction in which the work is performed. Where the QMP conflicts with those regulatory requirements, the regulatory requirements of the jurisdiction shall hold primacy. The laboratory's QA Manual shall take precedence over the QMP in those cases.

7.4 QA/QC Objectives for the Measurement of Data

Quality Assurance (QA) is responsible for developing planned activities whose purpose is to provide assurance to all levels of management that a quality program is in place within the laboratory, and that it is functioning in an effective manner that is consistent with the requirements of NELAP, ISO 17025, and any other regulatory agencies (i.e., states) in which the laboratory maintains accreditation.
Quality Control (QC) is generally understood to be limited to the analyses of samples and to be synonymous with the term *"analytical quality control"*. QC refers to the routine application of statistically based procedures to evaluate and control the accuracy of results from analytical measurements. The QC program includes procedures for estimating and controlling precision and bias and for determining reporting limits.

Request for Proposals (RFPs) and Quality Assurance Project Plans (QAPP) provide a mechanism for the client and the laboratory to discuss the data quality objectives in order to ensure that analytical services closely correspond to client needs. In order to ensure the ability

of the laboratory to meet the Data Quality Objectives (DQOs) specified in the QAPP, clients are advised to allow time for the laboratory to review the QAPP before being finalized. The client is responsible for developing the QAPP; however, the laboratory will provide support to the client for developing the sections of the QAPP that concern laboratory activities.

Historically, laboratories have described their QC objectives in terms of precision, accuracy, representativeness, comparability, completeness, selectivity and sensitivity (PARCCSS).

7.4.1 Precision

The objective is to meet the performance for precision demonstrated for the methods on similar samples and to meet data quality objectives (DQOs) of the EPA and/or other regulatory programs. Precision is defined as the degree of reproducibility of measurements under a given set of analytical conditions (exclusive of field sampling variability). Precision is documented on the basis of replicate analysis, usually duplicate or matrix spike (MS) duplicate samples.

7.4.2 Accuracy

The objective is to meet the performance for accuracy demonstrated for the methods on similar samples and to meet data quality objectives (DQOs) of the EPA and/or other regulatory programs. Accuracy is defined as the degree of bias in a measurement system. Accuracy may be documented through the use of laboratory control samples (LCS) and/or MS. A statement of accuracy is expressed as an interval of acceptance recovery about the mean recovery.

7.4.3 Representativeness

The objective is to provide data which is representative of the sampled medium. Representativeness is defined as the degree to which data represent a characteristic of a population or set of samples and is a measurement of both analytical and field sampling precision. The representativeness of the analytical data is a function of the procedures used in procuring and processing the samples. The representativeness can be documented by the relative percent difference between separately procured, but otherwise identical samples or sample aliquots.

The representativeness of the data from the sampling sites depends on both the sampling procedures and the analytical procedures. Refer to laboratory SOPs for subsampling and homogenization techniques appropriate to the analytical method.

7.4.4 Comparability

The objective is to provide analytical data for which the accuracy, precision, representativeness, and reporting limit statistics are similar to these quality indicators generated by other laboratories for similar samples, and data generated by the laboratory over time.

Comparability objective is documented by inter-laboratory studies carried out by regulatory agencies or carried out for specific projects or contracts, by comparison of periodically generated statements of accuracy, precision, and reporting limits with those of other laboratories.

7.4.5 Completeness

The completeness objective for data is 90% (or as specified by a particular project), expressed as the ratio of the valid data to the total data over the course of the project. Data will be

considered valid if they are adequate for their intended use. Data usability will be defined in a QAPP, project scope, or regulatory requirement. Data validation is the process for reviewing data to determine its usability and completeness. If the completeness objective is not met, actions will be taken internally and with the data user to improve performance. This may take the form of an audit to evaluate the methodology and procedures as possible sources for the difficulty or may result in a recommendation to use a different method.

7.4.6 Selectivity

Selectivity is defined as the capability of a test method or instrument to respond to a target substance or constituent in the presence of non-target substances. Target analytes are separated from non-target constituents and subsequently identified/detected through one or more of the following, depending on the analytical method: extractions (separation), digestions (separation), interelement corrections (separation), use of matrix modifiers (separation), specific retention times (separation and identification), confirmations with different columns or detectors (separation and identification), specific wavelengths (identification), specific mass spectra (identification), and specific electrodes (separation and identification).

7.4.7 Sensitivity

Sensitivity refers to the amount of analyte necessary to produce a detector response that can be reliably detected (above the Method Detection Limit) or quantified (above the Reporting Limit).

7.5 Criteria for Quality Indicators

The laboratory maintains a *Quality Control Criteria Summary that contains tables* that summarize the precision and accuracy acceptability limits for performed analyses (EM-QA-R-5730). This summary includes an effective date, is updated each time new limits are generated, and are managed by the laboratory's QA department. Unless otherwise noted, limits within these tables are laboratory generated. Some acceptability limits are derived from US EPA methods when they are required. Where US EPA method limits are not required, the laboratory has developed limits from evaluation of data from similar matrices. Criteria for development of control limits is contained in EM-AD-S-3548, Selection and Validation of Analytical Methods.

7.6 Statistical Quality Control

Statistically-derived precision and accuracy limits are required by selected methods (such as NIOSH 7400) and programs (such as the AIHA-LAP, LLC Laboratory Accreditation Program). The laboratory routinely utilizes statistically-derived limits to evaluate method performance and determine when corrective action is appropriate. The current limits in the laboratory are entered into the Laboratory Information Management System (LIMS), also referenced as LabServe. An archive of all limits used within the laboratory is maintained within the LIMS/LabServe and Bugzilla records. If a method defines the QC limits, the method limits are used.

If a method requires the generation of historical limits, the lab develops such limits from recent data in the QC database of LIMS/LabServe following the guidelines described in Section 24. All calculations and limits are documented and dated when approved and effective. On occasion, a client requests contract-specified limits for a specific project.

Current QC limits are entered and maintained in the LIMS/LabServe analyte database. As sample results and the related QC are entered into LIMS/LabServe, the sample QC values are compared with the limits in LIMS/LabServe to determine if they are within the acceptable range. The analyst then evaluates if the sample needs to be re-analyzed.

7.6.1 QC Charts

All QC analyses (duplicates, replicates, daily references) including data reviews, must be completed prior to release of results to clients**.** When QC analysis cannot be completed on the same day, the results must be qualified with a report comment.

Proficiency Testing results, and data from additional QC analyses may be used in determining analyst accuracy and precision, where applicable, for demonstration of continuing capability. If proficiency testing problems arise, the analysts will be asked to review the samples again to determine the source of error. If necessary, corrective actions will be implemented as determined by Quality Assurance, the facility manager and/or the Cluster Leader based on the nature of the problems.

Asbestos-PLM (Document EM-AS-S-1267)
Quality Control Requirements include duplicate analysis, Monthly Reference Sample, and Proficiency testing.

- Replicate and duplicate analyses are performed to evaluate the precision of a particular analysis. The routine analysis portion is processed through the laboratory in a normal manner. After the analysis has been completed, LabServe automated programming triggers the selection of 5% of the completed bulk samples for replicate analysis and 5% for duplicate analysis, based upon service, analyst and batch. The primary data along with the replicate and duplicate data will be statistically analyzed and control limits will be determined for the analyses (also automated by Labserve).
- Proficiency Testing results and data from additional QC analyses may be used in determining analyst accuracy and precision, where applicable, for demonstration of continuing capability. If proficiency testing problems arise, the analysts will be asked to review the samples again to determine the source of error. If necessary, corrective actions will be implemented as determined by Quality Assurance, the facility manager and/or the Cluster Leader based on the nature of the problems.

Asbestos - PCM (Document EM-AS-S-1260)

- Microscopes must be adjusted at least once a day, per analyst. Also, the phase-shift detection limit of the microscope must be checked weekly using the HSE/NPL phase-contrast test slide.
- Quality Control Requirements include duplicate analysis at the rate of 10%, Daily Reference Sample, Round Robin and Proficiency testing.
- The Reference Sample Quality Control Analysis (PCM) is performed by each analyst per day of analysis to evaluate the precision and accuracy of each analyst for fiber identification. The goal of performing Daily Reference Sample Quality Control Analysis is for continuous improvement. The samples for the Daily Reference Sample Quality Control Analysis consist of reference permanent slides, each of which contains varying asbestos or non-asbestos fiber. Each analyst will analyze a randomly selected slide for each day, recording their

results for the fiber counts. The identification by each analyst will be compared with the known standard through LabServe QC criteria automation. Any discrepancies in data comparison trigger an automated failure task for the analyst, who will be required to review the slide again to determine the source of error, and document any associated corrective actions.

- Biannual ongoing demonstration of analyst proficiency using Proficiency Analytical Testing (PAT) samples is required.

Training of Analysts (Document EM-AD-S-1646 and EM-AS-S-1261)

- All new analysts will receive documented training on Eurofins EMLab P&K, LLC analysis and sample preparation procedures as it relates to their individual job functions. The extent and duration of the training will depend on the level of education and experience of the trainee as outlined in Documents EM-AD-S-1646 and EM-AS-S-1261.
- All analytical training will include, but not be limited to, maintaining documentation of the training procedures and duration, a list of criteria documenting that the required steps involved have been addressed during the training, testing using reference materials where available, comparison of trainee results against analyst results, and providing the trainee with training documents and reference texts.
- Analysts and technicians will be authorized to perform a specific task and operate specific instruments once the applicable Training Acknowledgment and Authorization forms have been completed and signed by the trainee and trainer and all related data, reviews, and records have been submitted to Quality Assurance for final review and inclusion in analyst training records.

Analysis of Unknown Samples and Reference Materials

- Where applicable to job responsibilities, analysts will analyze unknown bacterial and/or fungal organisms at least monthly to ensure the consistency of identification. Selection of organisms will be made randomly from laboratory stock cultures.
- Where applicable to job responsibilities, analysts will analyze unknown samples for asbestos identification and quantitation.
- Documentation of the analyses will be maintained by the Quality Assurance department.
- Reference Materials
- Eurofins EMLab P&K, LLC maintains a library of reference materials that are accessible to all analysts. Each facility is responsible for maintaining an individual list of reference texts which are maintained in LabServe.
- Eurofins EMLab P&K, LLC maintains a library of cultures and reference slides. EMPAT and other microbiological reference materials are grown and analyzed by the laboratory on a routine basis.
- Asbestos reference samples such as NIST SRM #1866 and SRM #1867, or equivalent, are also maintained in applicable laboratories, if available.
- The laboratory retains and utilizes proficiency testing materials for use as in-house instructional materials. The proficiency test results are used to verify accuracy and precision for each analyst and to judge the analysts' overall performance. Proficiency test results are used for inter-analyst comparisons and entered into the laboratory’s management system

records. The laboratory determines precision on the qualitative and quantitative analyses of samples by: repeatability - repeat analyses by the same analyst; -comparison of results from multiple slide mounts of the same material; reproducibility - analysis of samples by multiple analysts if possible (single analyst laboratories require more interlaboratory data); and interlaboratory analysis - analysis of samples by other laboratories. The laboratory also determines the accuracy of the qualitative and quantitative analyses of samples by: analysis of proficiency testing materials; analysis of standards either prepared in-house or purchased; and analysis of samples using independent methods (e.g., XRD, gravimetric, etc.).

- When analyzing QC samples (duplicates, replicates) or reference samples, analysts must complete the analysis and enter the results into Labserve or record them on appropriate data sheets, without any assistance from or discussions with other analysts.
- Analysts should not edit the result they reported in Labserve or recorded on appropriate data sheets.

Demonstration of Capability: (Document EM-AD-S-1646)

Semi-annual demonstrations of capability may be accomplished by successful completion of:

- duplicate analyses;
- replicate analyses;
- daily reference analyses and
- proficiency testing samples.
- Acceptable performance criteria for Ongoing Demonstrations of competency are based on the performance characteristics for the method, established either from the data collected from the analysis of QC check samples, those already promulgated by the method, those set by an outside provider or an error rate of ≤1% for Asbestos PLM, and ≤5% for other analyses over a six month period.
- For example, if an analyst is qualified to perform bacterial analyses and is required to participate in the AIHA EMPAT Bacterial Culturable Proficiency Testing program, the acceptable performance for their Ongoing Demonstration of Competency would be a score of ≥85%, which is set by the provider

7.7 Quality System Metrics

In addition to the QC parameters discussed above, the entire Quality System is evaluated on a monthly basis through the use of specific metrics (refer to Section 18). These metrics are used to drive continuous improvement in the laboratory's Quality System.

8.0 DOCUMENT CONTROL

8.1 Overview

The QA Department is responsible for the control of documents used in the laboratory to ensure that approved, up-to-date documents are in circulation and out-of-date (obsolete) documents are archived or destroyed. The following documents, at a minimum, must be controlled:

- Laboratory Quality Assurance Manual
- Laboratory Standard Operating Procedures (SOP)
- Laboratory Policies
- Work Instructions and Forms
- NDSC Documents[1]
- KGDs[1]

[1]Includes locally implemented documents that are document controlled within the laboratory's document control system. The NDSC and/or KGD documents are only considered controlled when they are read on the intranet site. Printed copies are considered uncontrolled unless the laboratory physically distributes them as controlled documents. A detailed description of the procedure for issuing, authorizing, controlling, distributing, and archiving NDSC Official Documents is found in Document CW-Q-S-001, NDSC Document Control and Archiving. The laboratory's internal document control procedure is defined in SOP No. EM-QA-S-2059. All documents that are part of the Eurofins EMLab P&K quality assurance system, either internally generated or external are controlled through the Eurofins EMLab P&K LabServe Document Control system. The formal distribution of documents to Eurofins EMLab P&K employees is conducted through a companywide electronic release of revisions in LabServe. All users with log in credentials are afforded access to current revisions of released documents through the LabServe Document control module.

The laboratory QA Department also maintains access to various references and document sources integral to the operation of the laboratory. This includes reference methods and regulations. Instrument manuals (hard or electronic copies) are also maintained by the laboratory.

The laboratory maintains control of records for raw analytical data and supporting records such as audit reports and responses, logbooks, standard logs, training files, MDL studies, Proficiency Testing (PT) studies, certifications and related correspondence, and corrective action reports *(however named)*. Raw analytical data consists of bound logbooks, instrument printouts, any other notes, magnetic media, electronic data, and final reports.

8.2 Document Approval and Issue

The pertinent elements of the document control system include a unique document title and number, pagination, the total number of pages of the item or an 'end of document' page, the effective date, revision number, and the laboratory's name. The QA personnel are responsible for the maintenance of this system.

Controlled documents are authorized by the QA Department and Regional Laboratory Directors. In some cases, the document owner and/or facility technical managers/approved signatories, may be asked to review controlled documents prior to release. In order to develop a new document, a document owner/author submits an electronic draft to the QA Department for

suggestions, review, and approval before use. Upon approval, QA personnel add the identifying version information to the document and retain that document as the official document on file. That document is then electronically registered and distributed to applicable facilities via LabServe Document Control. Changes to documents stored electronically will be strictly controlled by the LabServe document control system. Handwritten changes to SOPs are not allowed.

The QA Department maintains a list of the official versions of controlled documents. A Master List of Eurofins EMLab P&K Controlled Documents is maintained in LabServe and can be accessed by all employees using the “My Docs" tab on the LabServe home page.

Quality System Policies and Procedures will be reviewed at a minimum of every two years and revised as appropriate. Changes to documents occur when a procedural change warrants.

8.3 Procedures for Document Control Policy

For changes to the QA Manual, and all other quality documents, refer to SOP No. EM-QA-S-2059. Uncontrolled copies must not be used within the laboratory. Printing of Eurofins EMLab P&K SOPs is not permissible unless strictly and exclusively used for review or training purposes. Any document printed for this purpose must be labeled as “UNCONTROLLED” or “OBSOLETE” to indicate it is not a controlled copy. Any official document printed for these purposes must be discarded/shredded immediately following completion of review or training. Previous revisions are removed from general access points and stored within the LabServe Document Control module, and are not accessible to lab personnel. Current electronic copies are stored within LabServe Document Control and are accessible to personnel via the “MyDocs” link after logging in with individual system credentials.

For changes to SOPs, refer to SOP No. EM-QA-S-2059, Document Control and Control of Records.

Forms, worksheets, work instructions and information are organized by department in the LabServe Document Control module. The procedure for the care of these documents is in SOP EM-QA-S-2059.

8.4 Obsolete Documents

All invalid or obsolete documents are removed, or otherwise prevented from unintended use. The laboratory has specific procedures as described above to accomplish this. In general, obsolete documents are removed from general access points in LabServe Document Control. A copy of the obsolete document is archived within LabServe Document Control according to SOP No. EM-QA-S-2059.

9.0 SERVICE TO THE CLIENT

9.1 Overview

The laboratory has established procedures for the review of work requests and contracts, oral or written. The procedures include evaluation of the laboratory's capability and resources to meet the contract's requirements within the requested time period. All requirements, including the methods to be used, must be adequately defined, documented and understood. For many environmental sampling and analysis programs, testing design is site or program specific and does not necessarily fit into a standard laboratory service or product. It is the laboratory's intent to provide both standard and customized environmental laboratory services to our clients.

A thorough review of technical and QC requirements contained in contracts is performed to ensure project success. The appropriateness of requested methods, and the lab's capability to perform them must be established. Projects, proposals, and contracts are reviewed for adequately defined requirements and the laboratory's capability to meet those requirements. Alternate test methods that are capable of meeting the clients' requirements may be proposed by the lab. A review of the lab's capability to analyze non-routine analytes is also part of this review process.

All projects, proposals and contracts are reviewed for the client's requirements in terms of compound lists, test methodology requested, sensitivity (detection and reporting levels), accuracy, and precision requirements (% Recovery and RPD). The reviewer ensures that the laboratory's test methods are suitable to achieve these requirements and that the laboratory holds the appropriate certifications and approvals to perform the work. The laboratory and any potential subcontract laboratories must be certified, as required, for all proposed tests.

Electronic or hard copy deliverable requirements are evaluated against the laboratory's capacity for production of the documentation.

If the laboratory cannot provide all services but intends to subcontract such services, whether to another Eurofins facility on the same LIMS or to an outside firm, this will be documented and discussed with the client prior to contract approval. (Refer to Section 10 for Subcontracting Procedures.)

The laboratory informs the client of the results of the review if it indicates any potential conflict, non-conformance, lack of accreditation, or inability of the lab to complete the work satisfactorily. Any discrepancy between the client's requirements and the laboratory's capability to meet those requirements is resolved in writing before acceptance of the contract. It is necessary that the contract be acceptable to both the laboratory and the client. Amendments initiated by the client and/or Eurofins EMLab P&K are documented in writing.

All contracts, QAPPs, Sampling and Analysis Plans (SAPs), contract amendments, and documented communications become part of the project record.

The same contract review process used for the initial review is repeated when there are amendments to the original contract by the client, and the participating personnel are informed of the changes.

9.2 Review Sequence and Key Personnel

Appropriate personnel will review the work request at each stage of evaluation.

For routine projects and other simple tasks, a review of standard COC submissions by the receiving and log in staff is considered adequate. The receiving and log in staff confirm that the laboratory has any required certifications, that it can meet the clients' data quality and reporting requirements and that the lab has the capacity to meet the clients turn around needs. Routine project submission reviews are performed according to SOP No. EM-SM-S-1288, Sample Receiving, and EM-SM-S-1993, Sample Log-In.

For new, complex or large projects, the proposed contract is given to the Regional Account Manager or Project Manager, who will decide which lab will receive the work based on the scope of work and other requirements, including certification, testing methodology, and available capacity to perform the work. The contract review process is outlined in NDSC Document No. CA-L-P-002**,** Contract Compliance Policy.

This review encompasses all facets of the operation. The scope of work is distributed to the appropriate personnel, as needed based on scope of contract, to evaluate all of the requirements shown above (not necessarily in the order below)**:**

- Contract Administrator
- Laboratory Project Manager
- Laboratory Cluster Leaders and/or Technical Managers
- Account Executives
- Quality Managers
- Laboratory Environmental Health and Safety Managers/Directors
- The Laboratory Director reviews the formal laboratory quote and makes final acceptance for their facility.

The Sales Director, Contract Administrator, Account Executive or Proposal Coordinator then submits the final proposal to the client.

In the event that one of the above personnel is not available to review the contract, his or her back-up will fulfill the review requirements.

9.3 Balancing Laboratory Capacity and Workload

Evaluating laboratory capacity to perform specific projects is the responsibility of the Business Unit Manager, Cluster Leaders, Facility Managers, and Client Services. Many analysts are cross-trained to perform a variety of tests, and there is redundant equipment available in case of malfunctions. This minimizes the need to evaluate small and medium size projects against capacity available to complete them. Large and complex projects are reviewed against capacity estimates before bids are submitted to ensure that the client's analysis schedule is met. Regularly scheduled meetings are held between laboratory management, PMs, Client Services and QA personnel to review progress with current projects, as well as special requirements of new work scheduled for the laboratory. Laboratory capacity and backlog is tracked on a continuous basis using information from the Laboratory Sample Information System (LIMS) including turnaround time, and work in-house.

9.4 Documentation

Copies of all signed and/approved contracts are maintained within LabServe account records.

Appropriate records are maintained for every contract or work request. All stages of the contract review process are documented and include records of any significant changes.

The contract will be distributed to and maintained by the appropriate sales/marketing personnel and the Account Executive. A copy of the contract and formal quote will be filed with the laboratory PM and the Laboratory Director.

Records are maintained of pertinent discussions with a client relating to the client's requirements or the results of the work during the period of execution of the contract. The PM keeps a phone log of conversations with the client.

9.4.1 Project-Specific Quality Planning

Communication of contract specific technical and QC criteria is an essential activity in ensuring the success of site specific testing programs. To achieve this goal, a PM is assigned to each client. It is the PM's responsibility to ensure that project-specific technical and QC requirements are effectively evaluated and communicated to the laboratory personnel before and during the project. QA department involvement may be needed to assist in the evaluation of custom QC requirements.

PM's are the primary client contact and they ensure resources are available to meet project requirements, they coordinate opportunities and work with laboratory management and supervisory staff to ensure available resources are sufficient to perform work for the client's project.

Prior to work on a new project, the dissemination of project information and/or project opening meetings may occur to discuss schedules and unique aspects of the project. Items to be discussed may include the project technical profile, turnaround times, holding times, methods, analyte lists, reporting limits, deliverables, sample hazards, or other special requirements. The PM introduces new project information to maximize production and client satisfaction, while maintaining quality.Project notes may be associated with each sample batch as a reminder upon sample receipt and analytical processing.

Any change that may occur within an active project is agreed upon between the client/regulatory agency and the PM/laboratory. These changes (e.g., use of a non-standard method or modification of a method) and approvals must be documented prior to implementation. Documentation pertains to any document (e.g., letter, e-mail, variance, contract addendum), which has been signed by both parties.

Such changes are also communicated to the laboratory either during operations meetings or via LabServe project tasks. Such changes are updated to the project notes and are introduced to the managers at these meetings. The laboratory staff is then introduced to the modified requirements via the PM or the individual laboratory Technical Manager. After the modification is implemented into the laboratory process, documentation of the modification is made in the case narrative of the data report(s), where applicable.

The laboratory strongly encourages client visits to the laboratory and for formal/informal information sharing session with employees in order to effectively communicate ongoing client needs as well as project specific details for customized testing programs.

9.5 Special Services

The laboratory cooperates with clients and their representatives to monitor the laboratory's performance in relation to work performed for the client. It is the laboratory's goal to meet all client requirements in addition to statutory and regulatory requirements. The laboratory has procedures to ensure confidentiality to clients (Section 15 and 25).

The laboratory's standard procedures for reporting data are described in Section 25. Special services are also available and provided upon request. These services include:

- Reasonable access for our clients or their representatives to the relevant areas of the laboratory for the witnessing of tests performed for the client.
- Assisting client-specified third party data validators as specified in the client's contract.
- Supplemental information pertaining to the analysis of their samples. Note: An additional charge may apply for additional data/information that was not requested prior to the time of sample analysis or previously agreed upon.

When the client requests a statement of conformity to a specification or standard based on the analysis performed by the laboratory (e.g., pass/fail, in-tolerance/out-of-tolerance), the decision rule shall be clearly defined. Unless inherent in the requested specification or standard, the decision rule selected shall be communicated to the client. Associated reporting requirements are addressed in Section 25.2.18.

9.6 Client Communication

PMs are the primary communication link to the clients. They shall inform their clients of any delays in project completion as well as any non-conformances in either sample receipt or sample analysis. Project management will maintain ongoing client communication throughout the entire client project.

Technical Managers and/or Regional Laboratory Directors are available to discuss any technical questions or concerns that the client may have.

9.7 Reporting

The laboratory works with our clients to produce any special communication reports required by the contract.

9.8 Client Surveys

The laboratory assesses both positive and negative client feedback. The results are used to improve overall laboratory quality and client service. Eurofins Sales and Marketing teams periodically develop lab and client specific surveys to assess client satisfaction.

When a complaint is received, we determine, to the best of our ability, the extent of the issue and what data is in question. The person receiving the complaint documents this information

and promptly forwards it to the appropriate management personnel where the work in question was performed. If a data reporting error is discovered, the final report and/or data must be regenerated with the correct value(s).

The person receiving the complaint is responsible for entering client concerns into Labserve via the task system, ensuring that concerns selections are marked. In some cases, an ICAT is initiated to address and document the situation. While an individual issue may not warrant a formal investigation, QA monitors these issues for potential trends and will issue an ICAT if a trend is evident.

10.0 SUBCONTRACTING OF TESTS

10.1 Overview

For the purpose of this quality manual, the phrase subcontract laboratory refers to a laboratory external to the Eurofins EMLab P&K. The phrase “work sharing” refers to internal transfers of samples between the Eurofins EMLab P&K laboratories. The term outsourcing refers to the act of subcontracting tests.

When contracting with our clients, the laboratory makes commitments regarding the services to be performed and the data quality for the results to be generated. When the need arises to outsource testing for our clients because project scope, changes in laboratory capabilities, capacity, or unforeseen circumstances, we must be assured that the subcontractors or work sharing laboratories understand the requirements and will meet the same commitments we have made to the client. Refer to Eurofins EMLab P&K’s Sample Receiving SOP (EM-SM-S-1288) for Subcontracting Procedures and the Work Sharing Process.

When outsourcing analytical services, the laboratory will assure, to the extent necessary, that the subcontract or work sharing laboratory maintains a program consistent with the requirements of this document, the requirements specified in the current ISO/IEC 17025 and/or the client’s Quality Assurance Project Plan (QAPP). All QC guidelines specific to the client’s analytical program are transmitted to the subcontractor and agreed upon before sending the samples to the subcontract facility. Additionally, work requiring accreditation will be placed with an appropriately accredited laboratory. The laboratory performing the subcontracted work will be identified in the final report, as will non-TNI accredited work where required.

Project Managers (PMs) or other responsible Client Service members, for the Export Lab (i.e., the Eurofins EMLab P&K laboratory that transfers samples to another laboratory) are responsible for obtaining client approval prior to subcontracting any samples. The laboratory will advise the client of a subcontract arrangement in writing and when possible approval from the client shall be obtained and retained in the project folder. Standard Eurofins EMLab P&K Terms & Conditions include the flexibility to work-share samples within the Eurofins EMLab P&K laboratories. Therefore, additional advance notification to clients for intra-laboratory work-shares is not necessary unless specifically required by a client contract. Unless the client has specified a particular location where Eurofins EMLab P&K, LLC is to perform its services, Eurofins EMLab P&K, LLC may perform services for the client at any laboratory in its network provided that for the samples being work-shared, the receiving lab has the same requested services on its Scope of Accreditation as the lab to which the samples were originally sent. Before samples are work-shared, Eurofins EMLab P&K, LLC will advise the client of the arrangement in writing by

requesting a Transfer Approval/Disapproval Agreement to be completed by the client. These agreements will be kept on file for future use. Every attempt will be made to gain the client's approval in writing using the Transfer Approval/Disapproval Agreement. If the client does not respond to the approval request, Eurofins EMLab P&K, LLC retains the right, at its discretion, to work-share services ordered by the client to another Eurofins EMLab P&K, LLC laboratory or other laboratories.

Note: In addition to the client, some regulating agencies (e.g., USDA) or contracts require notification prior to placing such work**.**

10.2 Qualifying and Monitoring Subcontractors

Whenever a PM or Regional Account Manager becomes aware of a client requirement or laboratory need where samples must be outsourced to another laboratory, the other laboratory(s) shall be selected based on the following:

- Subcontractors specified by the client - In these circumstances, the client assumes responsibility for the quality of the data generated from the use of a subcontractor.
- Subcontractors reviewed by Eurofins EMLab P&K – Firms which have been reviewed by the company and are known to meet standards for accreditations (e.g., AIHA-LAP, LLC, NVLAP, State specific accreditations, TNI, etc.); technical specifications; legal and financial information.

A listing of vendors is available on the Eurofins Environment Testing TestAmerica intranet site.

All Eurofins EMLab P&K laboratories are pre-qualified for work sharing provided they hold the appropriate accreditations and can adhere to the project/program requirements. Client approval is not necessary unless specifically required by the contract. In these cases, the client must provide acknowledgement that the samples can be sent to that facility (an e-mail is sufficient documentation or if acknowledgement is verbal, the date, time, and name of person providing acknowledgement must be documented). The originating laboratory is responsible for communicating all technical, quality, and deliverable requirements as well as other contract needs. (NDSC Document No. CA-C-S-001, Work Sharing Process).

Eurofins EMLab P&K, LLC will be held responsible for data produced as a result of subcontracting of work, except in the case where the client or a regulatory authority specifies which subcontractor is to be used.

Prior to submitting samples to subcontractors the samples may be logged into the LIMS/LabServe and assigned a Eurofins EMLab Project ID number. A Chain of Custody (COC) must be signed to document transfer to the subcontracting laboratory. All data reported from a subcontractor shall list the name of the laboratory performing the analysis. A copy of the COC must be part of the report sent to Eurofins EMLab P&K, LLC after completion of the analysis by the subcontractor.

10.2.1 When the potential sub-contract laboratory has not been previously approved, RAMs or PMs may nominate a laboratory as a subcontractor based on need. The decision to nominate a laboratory must be approved by the Business Unit Manager or Cluster Leader. The Business Unit Manager or Cluster Leader requests that the QA Manager or PM begin the process of

approving the subcontract laboratory as outlined in NDSC Document No. CW-L-S-004, Subcontracting Procedures.

Once the appropriate accreditation and legal information is received by the laboratory, it is evaluated for acceptability and forwarded to the NDSC Quality Information Manager (QIM) for review. After the NDSC QIM reviews the documents for completeness, the information is forwarded to the Finance Department for formal signature and contracting with the laboratory. The approved vendor will be added to the approved subcontractor list on the intranet site, and the finance group is concurrently notified.

The client will assume responsibility for the quality of the data generated from the use of a subcontractor they have requested the lab to use. The qualified subcontractors on the intranet site are known to meet minimal standards. Eurofins EMLab P&K does not certify laboratories. The subcontractors on our approved list can only be recommended to the extent that we would use them.

10.3 Oversight and Reporting

The status and performance of qualified subcontractors will be monitored by NDSC, and includes an annual review process (see NDSC Document No. CW-L-S-004). Any problems identified will be brought to the attention of NDSC and/or Procurement personnel.

- Complaints shall be investigated. Documentation of the complaint, investigation, and corrective action will be maintained in the subcontractor's file on the intranet site. Complaints are posted using the Vendor Performance Report.
- Information shall be updated on the intranet when new information is received from the subcontracted laboratories.
- Subcontractors in good standing will be retained on the intranet listing. Client Services personnel will notify all Eurofins EMLab P&K laboratories, NDSC, and Corporate Contracts if any laboratory requires removal from the intranet site. This notification will be posted on the intranet site and e-mailed to all Client Services Personnel, Cluster Leaders, QA Managers, and Sales Personnel.

Prior to initially sending samples to the subcontracted laboratory, the PM confirms their certification status to determine if it's current and scope-inclusive. The information is documented within the project records.

10.3.1 All subcontracted samples must be accompanied by a Eurofins EMLab P&K Chain of Custody (COC). A copy of the original COC sent by the client must be available in LIMS for all samples workshared within Eurofins EMLab P&K. Client COCs are only forwarded to external subcontractors when samples are shipped directly from the project site to the subcontractor lab. Under routine circumstances, client COCs are not provided to external subcontractors.

Through communication with the subcontracted laboratory, the PM monitors the status of the subcontracted analyses, facilitates successful execution of the work, and ensures the timeliness and completeness of the analytical report.

Non-TNI accredited work must be identified in the subcontractor's report as appropriate. If TNI accreditation is not required, the report does not need to include this information.

Reports submitted from subcontractor laboratories are not altered and are included in their original form in the final project report. This clearly identifies the data as being produced by a subcontractor facility. If subcontract laboratory data is incorporated into the laboratory's EDD (i.e., imported), the report must explicitly indicate which lab produced the data for which methods and samples.

Note: The results submitted by a Eurofins EMLab P&K work sharing laboratory may be transferred electronically and the results reported by the Eurofins EMLab P&K work sharing lab are identified on the final report. The report must explicitly indicate which lab produced the data for which methods and samples. The final report must include a copy of the completed COC for all work sharing reports.

10.4 Contingency Planning

The full qualification of a subcontractor may be waived to meet emergency needs. This decision and justification must be documented in the project files, and the 'Purchase Order Terms And Conditions For Subcontracted Laboratory Services' must be sent with the samples and COC.

In the event this provision is utilized, the laboratory (e.g., PM) will be required to verify and document the applicable accreditations of the subcontractor. All other quality and accreditation requirements will still be applicable, but the subcontractor need not have signed a subcontract agreement with Eurofins EMLab P&K at this time.

The use of any emergency subcontractor will require the PM to complete a ~~JDE~~ New Vendor Add Form in order to process payment to the vendor and add them to LIMS/LabServe. This form requires the user to define the subcontractor's category/s of testing and the reason for testing.

10.4 Use of NELAP and A2LA Logo

It is not laboratory policy to use these logos on any company letterhead, including analytical reports.

11.0 PURCHASING SERVICES AND SUPPLIES

11.1 Overview

Evaluation and selection of suppliers and vendors is performed, in part, on the basis of the quality of their products, their ability to meet the demand for their products on a continuous and short term basis, the overall quality of their services, their past history, and competitive pricing. This is achieved through evaluation of objective evidence of quality furnished by the supplier, which can include certificates of analysis, recommendations, and proof of historical compliance with similar programs for other clients. To ensure that quality critical consumables and equipment conform to specified requirements, which may affect quality, all purchases from

specific vendors are approved by a member of the supervisory or management staff. Capital expenditures are made in accordance with Eurofins TestAmerica's Fixed Asset Acquisition, Retention and Safeguarding SOP No. CW-F-S-007.

Contracts will be signed in accordance with the laboratory's authorization matrix, or refer to NDSC Document No. CW-F-P-002. Request for Proposals (RFP's) will be issued where more information is required from the potential vendors than just price. Process details are available in NDSC Document No. CW-F-P-004, Guidance on Procurement and Contracts Policy. RFP's allow the laboratory to determine if a vendor is capable of meeting requirements such as supplying all of the Eurofins TestAmerica facilities, meeting required quality standards and adhering to necessary ethical and environmental standards. The RFP process also allows potential vendors to outline any additional capabilities they may offer.

11.2 Glassware

Glassware used for volumetric measurements must be Class A or verified for accuracy according to laboratory procedure. Pyrex (or equivalent) glass should be used where possible. For safety purposes, thick-wall glassware should be used where available.

11.3 Reagents, Standards & Supplies

Purchasing guidelines for equipment, consumables, and reagents must meet the requirements of the specific method and testing procedures for which they are being purchased.

11.3.1 Purchasing

Chemical reagents, solvents, glassware, and general supplies are ordered as needed to maintain sufficient quantities on hand. Materials used in the analytical process must be of a known quality. The wide variety of materials and reagents available makes it advisable to specify recommendations for the name, brand, and grade of materials to be used in any determination. This information is contained in the method SOP. Requests for reagents, standards, or supplies are directed to facility managers, Cluster Leaders, or designee. For labs using on-site consignment, analyst may check the item out of the on-site consignment system that contains items approved for laboratory use.

11.3.2 Receiving

It is the responsibility of the facility manager, or designee, to receive the shipment. It is the responsibility of the receiving personnel to document the date materials were received. Once the ordered reagents or materials are received, the receiver compares the information on the label or packaging to the original order to ensure that the purchase meets the quality level specified. This is documented through the addition of the received date and initials to the information present on the packing slip. All reagents and media received by the laboratory for internal use must be dated and initialed upon receipt, and assigned an expiration date if one is not assigned by the manufacturer. All items are to be stored according to manufacturer's instructions and SDS requirements. The Certification of Analysis and other Quality Control records for specific medium and reagent lots supplied by the vendors are maintained at each facility. (Supply Receiving and Distribution East, Document EM-MR-S-1209, and Supply Receiving and Distribution West, Document EM-MR-S-7350)

Materials may not be released for use in the laboratory until they have been inspected, verified as suitable for use, and the inspection/verification has been documented. Materials which are found to not meet expected requirements and level of quality either at receiving or upon initial use, are to be set aside for return to the vendor. Facility managers, or designees, are to be notified of any negative trend noted in quality of vendor materials for further evaluation and vendor replacement as needed. Trends are reported immediately by the laboratory staff to the Purchasing Group.

The Purchasing Group will work through the appropriate channels to gather the information required to clearly identify the problem and will contact the vendor to report the problem and to make any necessary arrangements for exchange, return authorization, credit, etc.

Any media or reagents generated by the laboratory must follow the prescribed procedure for quality control checking prior to use in analysis. **I**n-house generated standards or reagents must complete quality control checks, before being used in the processing of samples. All standards and reagents produced by the laboratory are produced with a description of content, preparer's initials, manufacturer and lot number of parent material, pH (if applicable), assigned lot numbers and expiration dates.

All standards used to calibrate instruments or measuring devices must be traceable to the NIST, or equivalent national or international standard.

Safety Data Sheets (SDSs) are available online through the Company's intranet website. Anyone may review these for relevant information on the safe handling and emergency precautions of on-site chemicals.

11.3.3 Specifications

Methods used in the laboratory specify the grade of reagent that must be used in the procedure. If the quality of the reagent is not specified, analytical reagent grade will be used. It is the responsibility of the analyst to check the procedure carefully for the suitability of grade of reagent.

Reagents, media, and chemicals must not be used past the manufacturer's expiration date and must not be used past the expiration time noted in a method SOP. If expiration dates or recommended retest dates are not provided, the laboratory may contact the manufacturer to determine an expiration date. If no recommended expiration is available, the laboratory will assume a 5 year expiration from date of manufacture.

Wherever possible, standards must be traceable to national or international standards of measurement or to national or international reference materials. Records to that effect are available to the user.

Where applicable, compressed gases in use are checked for pressure and secure positioning daily. To prevent a tank from going to dryness, or introducing potential impurities, the pressure should be closely watched as it decreases to approximately 15% of the original reading, at which point it should be replaced. For example, a standard sized laboratory gas cylinder containing 3,000 psig of gas should be replaced when it drops to approximately 500 psig. The

quality of the gases must meet method or manufacturer specification or be of a grade that does not cause any analytical interference.

Water used in the preparation of samples, standards or reagents must meet the applicable water quality requirements noted in individual method SOPs.

The laboratory may purchase reagent grade (or other similar quality) water for use in the laboratory. This water must be certified clean by the supplier for all target analytes or otherwise verified by the laboratory prior to use. This verification is documented.

Purchased bottleware used for sampling must be certified clean and the certificates must be maintained. If uncertified sampling bottleware is purchased, all lots must be verified clean prior to use. This verification must be maintained. (Reference SOPs EM-MR-S-1209 and EM-MR-S-7350.)

11.3.4 Storage

Reagent and chemical storage is important from the aspects of both integrity and safety. Light-sensitive reagents may be stored in brown-glass containers. Storage conditions are per the NDSC Environmental Health & Safety Manual Document No. CW-E-M-001, the local laboratory EH&S manual addendum and method SOPs or manufacturer instructions.

11.4 Purchase of Equipment / Instruments / Software

When a new piece of equipment is needed, either for additional capacity or for replacing inoperable equipment, the analyst or supervisor makes a supply request to the Facility Manager, Cluster Leader, or the Business Unit Manager. If they agree with the request, the procedures outlined in NDSC Document No. CA-T-P-001, Qualified Products List, are followed. A decision is made as to which piece of equipment can best satisfy the requirements. The appropriate written requests are completed and purchasing places the order.

Upon receipt of a new or used piece of equipment, an identification name is assigned and added to the equipment list. Its capability is assessed to determine if it is adequate or not for the specific application. For instruments, a calibration curve is generated, followed by MDLs, Demonstration of Capabilities (DOCs), and other relevant criteria (refer to Section 19). For software, its operation must be deemed reliable and evidence of instrument verification must be retained by the QA Department. Software certificates supplied by the vendors are filed with the QA Department. The manufacturer's operation manual is retained locally at each facility.

11.5 Services

Service to analytical instruments (except analytical balances) is performed on an as needed basis. Routine preventative maintenance is discussed in Section 20. The need for service is determined by analysts and/or Technical Managers. The service providers that perform the services are approved by the Facility Manager.

Analytical balances are serviced and calibrated annually in accordance with SOP EM-EQ-S-1584. The calibration and maintenance services are performed on-site, and the balances are returned to use immediately following successful calibration. Calibration certificates are filed for reference. If the calibration was unsuccessful, the balance is immediately removed from service and segregated pending either further maintenance or disposal.

Calibration services for support equipment such as thermometers, weight sets, autopipettors, etc., are obtained from vendors with current and valid ISO/IEC 17025 accreditation for calibration of the specific piece of equipment. Prior to utilizing the vendor's services, the vendor's accreditation status is verified. Once the equipment has been calibrated, the calibration certificates are reviewed by the QA department, and documentation of the review is filed with the calibration certificates. The equipment is then returned to service within the laboratory.

11.6 Suppliers

The laboratory selects vendors through a competitive proposal / bid process, strategic business alliances or negotiated vendor partnerships (contracts). This process is defined in the NDSC Procurement & Contracts Policy (Document No. CW-F-P-004). The level of control used in the selection process is dependent on the anticipated spending amount and the potential impact on the laboratory's business. Vendors that provide test and measuring equipment, solvents, standards, certified containers, instrument related service contracts or subcontract laboratory services shall be subject to more rigorous controls than vendors that provide off-the-shelf items of defined quality that meet the end use requirements. The purchasing system includes all suppliers/vendors that have been approved for use.

Evaluation of suppliers is accomplished by ensuring the supplier ships the product or material ordered and that the material is of the appropriate quality. This is documented by signing off on packing slips or other supply receipt documents. The purchasing documents contain the data that adequately describe the services and supplies ordered.

Any issues of vendor performance are to be reported immediately by the laboratory staff to thePurchasing Group by completing a Vendor Performance Report.

The Purchasing Group will work through the appropriate channels to gather the information required to clearly identify the problem and will contact the vendor to report the problem and to make any necessary arrangements for exchange, return authorization, credit, etc.

Suppliers are subject to re-evaluation, as deemed appropriate, through the use of Vendor Performance Reports used to summarize and review to determine corrective action necessary, or service improvements required by vendors

The laboratory has access to a listing of all approved suppliers of critical consumables, supplies and services. This information is provided through the purchasing system.

11.6.1 New Vendor Procedure

Laboratory employees who wish to request the addition of a new vendor must complete a Vendor Add Request Form.

New vendors are evaluated based upon criteria appropriate to the products or services provided as well as their ability to provide those products and services at a competitive cost. Vendors are also evaluated to determine if there are ethical reasons or potential conflicts of interest with laboratory employees that would make it prohibitive to do business with them as well as their

financial stability. The QA Department and/or the Cluster Leaders and Business Unit Manager are consulted with vendor and product selection that have an impact on quality.

12.0 COMPLAINTS

12.1 Overview

The laboratory considers an effective client complaint handling processes to be of significant business and strategic value. Listening to and documenting client concerns captures client knowledge that enables our operations to continually improve processes and client satisfaction. An effective client complaint handling process also provides assurance to the data user that the laboratory will stand behind its data, service obligations and products.

A client complaint is any expression of dissatisfaction with any aspect of our business services (e.g., communications, responsiveness, data, reports, invoicing and other functions) expressed by any party, whether received verbally or in written form. Client inquiries, complaints or noted discrepancies are documented, communicated to management, and addressed promptly and thoroughly.

The laboratory has procedures for addressing both external and internal complaints with the goal of providing satisfactory resolution to complaints in a timely and professional manner.

The nature of the complaint is identified, documented and investigated, and an appropriate action is determined and taken. In cases where a client complaint indicates that an established policy or procedure was not followed, the QA Department must evaluate whether a special audit must be conducted to assist in resolving the issue. A written confirmation or letter to the client, outlining the issue and response taken is recommended as part of the overall action taken.

The process of complaint resolution and documentation utilizes the procedures outlined in Section 12 (Corrective Actions) and is documented following EM-CS-S-1709, Resolving Client Concerns and Soliciting Client Feedback, and/or EM-QA-S-3553, Root Cause and Corrective Actions, as applicable.

12.2 External Complaints

An employee that receives a complaint initiates the complaint resolution process by first documenting the complaint according to (EM-CS-S-1709).

Complaints fall into two categories: correctable and non-correctable. An example of a correctable complaint would be one where a report re-issue would resolve the complaint. An example of a non-correctable complaint would be one where a client complains that their data was repeatedly late. Non-correctable complaints should be reviewed for preventive action measures to reduce the likelihood of future occurrence and mitigation of client impact.

The general steps in the complaint handling process are:

- Receiving and documenting complaints
- Acknowledging receipt of complaint, whenever possible

- Complaint investigation and service recovery
- Process improvement

The laboratory shall inform the initiator of the complaint of the results of the investigation and the corrective action taken, if any.

12.3Internal Complaints

Internal complaints include, but are not limited to: errors and non-conformances, training issues, internal audit findings, and deviations from methods. Corrective actions may be initiated by any staff member who observes a nonconformance and shall follow the procedures outlined in Section 12. In addition, Executive Management, Sales and Marketing and IT may initiate a complaint by contacting the laboratory or through the corrective action system described in Section 14.

12.4Management Review

The number and nature of client complaints is reported by the QA Manager to the Laboratory Director and Quality Director in the QA Monthly report. Monitoring and addressing the overall level and nature of client complaints and the effectiveness of the solutions is part of the Annual Management Systems Review (Section 18).

13.0 CONTROL OF NON-CONFORMING WORK

13.1Overview

When data discrepancies are discovered or deviations and departures from laboratory SOPs, policies and/or client requests have occurred, corrective action is taken immediately. First, the laboratory evaluates the significance of the nonconforming work. Then, a corrective action plan is initiated based on the outcome of the evaluation. If it is determined that the nonconforming work is an isolated incident, the plan could be as simple as adding a qualifier / report comment to the final results and/or making a notation in the project log. If it is determined that the nonconforming work is a systematic or improper practices issue, the corrective action plan could include a more in depth investigation and a possible suspension of an analytical method. In all cases, the actions taken are documented using the laboratory's corrective action system (refer to Section 12).

Due to the frequently unique nature of environmental samples, sometimes departures from documented policies and procedures are needed. When an analyst encounters such a situation, the problem is presented to the supervisor for resolution. (this may be done via LabServe task system.) The supervisor may elect to discuss it with the Technical Manager or have a representative contact the client to decide on a logical course of action. Once an approach is agreed upon, it must be documented via the LabServe project task system. This information can then be supplied to the client in the form of a report comment, where applicable.

Project Management may encounter situations where a client may request that a special procedure be applied to a sample that is not standard lab practice. Based on a technical evaluation, the lab may accept or opt to reject the request based on technical or ethical merit. An example might be the need to report an analyte that the lab does not normally report. The

lab would not have validated the method for this compound following the procedures in Section 19. The client may request that the compound be reported based only on the calibration. Such a request would need to be approved by the QA Manager and the Cluster Leader, documented and included in the project record. Deviations **must** also be noted on the final report with a statement that the analyte is not reported in compliance with the analytical method requirements and the reason. Data being reported to a non-TNI state would need to note the change made to how the method is normally run.

13.2Responsibilities and Authorities

Under certain circumstances, the Cluster Leader, a Technical Manager, or a member of the QA team may authorize departures from documented procedures or policies. The departures may be a result of procedural changes due to the nature of the sample; a one-time procedure for a client; QC failures with insufficient sample to reanalyze, etc. In most cases, the client will be informed of the departure prior to the reporting of the data. Any departures must be well documented using the laboratory's corrective action procedures. This information may also be documented in logbooks and/or data review checklists as appropriate**.** Any impacted data must be referenced in a case narrative and/or flagged with an appropriate data qualifier.

Any misrepresentation or possible misrepresentation of analytical data discovered by any laboratory staff member must be reported to facility Senior Management within 24-hours. The Senior Management staff is comprised of the Business Unit Manager,Cluster Leader, the QA Manager, and the Facility/Technical Managers. The reporting of issues involving alleged violations of the company's Data Integrity or Manual Integration procedures must be conveyed to an ECO (e.g., the VP-QA/EHS) and the laboratory's Quality Manager within 24 hours of discovery.

Whether an inaccurate result was reported due to calculation or quantitation errors, data entry errors, improper practices, or failure to follow SOPs, the data must be evaluated to determine the possible effect.

The Business Unit Manager, Cluster Leader, QA Manager, ECOs, VP of Operations and the Quality Directors have the authority and responsibility to halt work, withhold final reports, or suspend an analysis for due cause as well as authorize the resumption of work.

13.3Evaluation of Significance and Actions Taken

For each nonconforming issue reported, an evaluation of its significance and the level of management involvement needed is made. This includes reviewing its impact on the final data, whether or not it is an isolated or systematic issue, and how it relates to any special client requirements.

The NDSC Document entitled Data Recalls (CW-Q-S-005) is the procedure to be followed when it is discovered that erroneous or biased data may have been reported to clients or regulatory agencies.

The NDSC Document entitled Internal Investigations (CW-L-S-002) is the procedure to be followed for investigation and correction of situations involved alleged incidents of misconduct or violation of the company's ethics policy.

Laboratory level decisions are documented and approved using the laboratory's standard nonconformance/corrective action reporting in lieu of the data recall determination form contained in NDSC Document No. CW-Q-S-005.

13.4 Prevention of Nonconforming Work

If it is determined that the nonconforming work could recur, further corrective actions must be made following the laboratory's corrective action system. Periodically as defined by the laboratory's preventive action schedule, the QA Department evaluates non-conformances to determine if any nonconforming work has been repeated multiple times. If so, the laboratory's corrective action process may be followed.

13.5 Method Suspension / Restriction (Stop Work Procedures)

In some cases, it may be necessary to suspend/restrict the use of a method or target analyte which constitutes significant risk and/or liability to the laboratory. Suspension/restriction procedures can be initiated by any of the persons noted in Section 13.2, Paragraph 5.

Prior to suspension/restriction, confidentiality will be respected, and the problem with the required corrective and preventive action will be stated in writing and presented to the Cluster Leader.

The Cluster Leader shall arrange for the appropriate personnel to meet with the QA Manager as needed. This meeting shall be held to confirm that there is a problem, that suspension/restriction of the method is required and will be concluded with a discussion of the steps necessary to bring the method/target or test fully back on line. In some cases, that may not be necessary if all appropriate personnel have already agreed there is a problem and there is agreement on the steps needed to bring the method, target or test fully back on line. The QA Manager will also initiate a corrective action report as described in Section 12 if one has not already been started. A copy of any meeting notes and agreed upon steps should be e-mailed by the laboratory to their Business Unit President, Business Unit Manager, and VP-QA & EHS . This e-mail acts as notification of the incident.

After suspension/restriction, the lab will hold all reports to clients pending review. No faxing, mailing or distributing through electronic means may occur. The report must not be posted for viewing on the internet. It is the responsibility of the Laboratory Director to hold all reporting and to notify all relevant laboratory personnel regarding the suspension/restriction (e.g., Project Management, Log-in, etc.). Clients will NOT generally be notified at this time. Analysis may proceed in some instances depending on the non-conformance issue.

Within 72 hours, the QA Manager will determine if compliance is now met and reports can be released, OR determine the plan of action to bring work into compliance, and release work. A team, with all principals involved (e.g., Cluster Leader, Facility/Technical Manager, QA Manager) can devise a start-up plan to cover all steps from client notification through compliance and release of reports. Project Management and the Directors of Client Services and Sales and Marketing must be notified if clients must be notified or if the suspension/restriction affects the laboratory's ability to accept work. The QA Manager must approve start-up or elimination of any restrictions after all corrective action is complete.

14.0 CORRECTIVE ACTION

14.1Overview

A major component of the laboratory's Quality Assurance (QA) Program is the problem investigation and feedback mechanism designed to keep the laboratory staff informed on quality related issues and to provide insight to problem resolution. When nonconforming work or departures from policies and procedures in the quality system or technical operations are identified, the corrective action procedure provides a systematic approach to assess the issues, restore the laboratory's system integrity, and prevent reoccurrence. Eurofins EMLab P&K employs two systems to manage non-conformances. Issues suspected of being systematic in nature and for which root cause analysis and a formal Corrective Action Report (CAR) are documented in the Incident Corrective Action Tracking (ICAT) database. Routine batch non-conformances, events that are understood to be isolated in nature, are documented in the LabServe task system.

14.2General

Problems within the quality system or within analytical operations may be discovered in a variety of ways, such as QC sample failures, internal or external audits, proficiency testing (PT) performance, client complaints, staff observation, etc.

The purpose of a corrective action system is to:

- Identify non-conformance events and assign responsibility for investigating.
- Resolve non-conformance events and assign responsibility for any required corrective action.
- Identify systematic problems before they become serious.
- Identify and track client complaints and provide resolution.

14.2.1 LabServe Task System - is used to document the following types of corrective actions:

- Deviations from an established procedure or SOP
- QC outside of limits
- Isolated reporting / calculation errors
- Client complaints

14.2.2 Corrective Actions Documented In the ICAT Database

- Internal and external audit findings
- Failed or unacceptable PT results
- Identified poor process or method performance trends
- Issues found while reviewing tasks that warrant further investigation
- Systematic reporting / calculation errors
- Data recall investigations
- Questionable trends that are found in the review of NCMs.
- Client complaints

- Excessive revised reports
- Health and Safety violations

The ICAT database is used to document background information, track the results of corrective action investigations and root cause analysis, and to provide reports of corrective action plans.

14.3Closed Loop Corrective Action Process

Any employee in the company can initiate a corrective action. There are four main components to a closed-loop corrective action process once an issue has been identified: Cause Analysis, Selection and Implementation of Corrective Actions (both short and long term), Monitoring of the Corrective Actions, and Follow-up.

14.3.1 Cause Analysis

- Upon discovery of a non-conformance event, the event must be defined and documented. A LabServe task or entry into the ICAT system must be initiated, someone is assigned to investigate the issue and the event is investigated for cause. Table 12-1 provides some general guidelines on determining responsibility for assessment.
- The cause analysis step is the key to the process as a long term corrective action cannot be determined until the cause is determined.
- If the cause is not readily obvious, the Technical Manager, Laboratory Director, or QA Manager (or QA designee) is consulted.

14.3.2 Selection and Implementation of Corrective Actions

- Where corrective action is needed, the laboratory shall identify potential corrective actions. The action(s) most likely to eliminate the problem and prevent recurrence are selected and implemented. Responsibility for implementation is assigned.
- The laboratory must additionally consider potential risks and opportunities in the development and implementation of corrective actions. Where any identified risk and/or opportunity needs to be updated as a result of a nonconformity, this shall be performed and documented during the planning of the corrective action.
- Corrective actions shall be to a degree appropriate to the magnitude of the problem identified through the cause analysis.
- Whatever corrective action is determined to be appropriate, the laboratory shall document and implement the changes. This documentation may be recorded within the context of the originating nonconformity and using the applicable tool (QA-zilla, iCat, LabServe task, etc.)

14.3.3 Root Cause Analysis

Root Cause Analysis is a class of problem solving (investigative) methods aimed at identifying the basic or causal factor(s) that underlie variation in performance or the occurrence of a significant failure. The root cause may be buried under seemingly innocuous events, many steps preceding the perceived failure. At first glance, the immediate response is typically directed at a symptom and not the cause. Typically, root cause analysis would be best with three or more incidents to triangulate a weakness. NDSC Document Root Cause Analysis (No. CA-Q-S-009) provides guidance on this, as well as Eurofins EMLab P&K SOP, Conducting

Root Cause Investigations and Implementing Corrective Actions,(Document EM-QA-S-3553)describe the procedure.

Systematically analyze and document the root causes of the more significant problems that are reported. Identify, track, and implement the corrective actions required to reduce the likelihood of recurrence of significant incidents. Trend the root cause data from these incidents to identify root causes that, when corrected, can lead to dramatic improvements in performance by eliminating entire classes of problems.

Identify the one event associated with problem and ask why this event occurred. Brainstorm the root causes of failures; for example, by asking why events occurred or conditions existed; and then why the cause occurred consecutive times until you get to the root cause. For each of these sub events or causes, ask why it occurred. Repeat the process for the other events associated with the incident.

Root cause analysis does not mean the investigation is over. Look at technique or other systems outside the normal indicators. Often creative thinking will find root causes that ordinarily would be missed and continue to plague the laboratory or operation.

14.3.4 Monitoring of the Corrective Actions

- The Cluster Leader, Facility Manager and/or Technical Manager and QA Manager are responsible to ensure that the corrective action taken was effective.
- Ineffective actions are documented and re-evaluated until acceptable resolution is achieved. Technical Managers are accountable to the Laboratory Director to ensure final acceptable resolution is achieved and documented appropriately.
- The QA Manager reviews monthly ICAT records for trends. Highlights are included in the QA monthly report (refer to Section 18). If a significant trend develops that adversely affects quality, an audit of the area is performed and corrective action implemented.
- Any out-of-control situations that are not addressed acceptably at the laboratory level may be reported to the NDSC Quality Director by the QA Manager, indicating the nature of the out-of-control situation and problems encountered in solving the situation.

14.3.5 Follow-up Audits

- Follow-up audits may be initiated by the QA Manager and shall be performed as soon as possible when the identification of a nonconformance casts doubt on the laboratory's compliance with its own policies and procedures, or on its compliance with state or federal requirements.
- These audits often follow the implementation of the corrective actions to verify effectiveness. An additional audit would only be necessary when a critical issue or risk to business is discovered.

(Also refer to Section 17.1.4, Special Audits.)

14.4Technical Corrective Actions

In addition to providing acceptance criteria and specific protocols for technical corrective actions in the method SOPs, the laboratory has general procedures to be followed to determine when

departures from the documented policies and procedures and quality control have occurred (refer to Section 13). The documentation of these procedures is through the use of a LabServe task or record in the ICAT system.

Table 14-1 includes examples of general technical corrective actions. For specific criteria and corrective actions, refer to the analytical methods or specific method SOPs. The laboratory may also maintain Work Instructions on these items that are available upon request.

Table 14-1 provides some general guidelines for identifying the individual(s) responsible for assessing each QC type and initiating corrective action. The table also provides general guidance on how a data set should be treated if associated QC measurements are unacceptable. Specific procedures are included in Method SOPs, Work Instructions, QAM Sections 19 and 20. All corrective actions are reviewed monthly, at a minimum, by the QA Manager and highlights are included in the QA monthly report.

To the extent possible, samples shall be reported only if all quality control measures are acceptable. If the non-conformance does not impair the usability of the results, data will be reported with an appropriate data qualifier. Where sample results may be impaired, the Project Manager is notified by a LabServe task and appropriate corrective action (e.g., reanalysis) is taken and documented**.**

14.5Basic Corrections

When mistakes occur in records, each mistake shall be crossed-out, [not obliterated (e.g. no white-out)], and the correct value entered alongside. All such corrections shall be initialed (or signed) and dated by the person making the correction. In the case of records stored electronically, the original uncorrected file must be maintained intact and a second corrected file is created. This same process applies to adding additional information to a record. All additions made later than the initial must also be initialed (or signed) and dated. When corrections are due to reasons other than obvious transcription errors, the reason for the corrections (or additions) shall also be documented.

Table 14-1. Example – General Corrective Action Procedures

QC Activity ***(Individual Responsible for Initiation/Assessment)***	**Acceptance Criteria**	**Recommended Corrective Action**
Initial Instrument Blank *(Analyst)*	- Instrument response < MDL.	- Prepare another blank. - If same response, determine cause of contamination: reagents, environment, instrument equipment failure, etc..

QC Activity *(Individual Responsible for Initiation/Assessment)*	Acceptance Criteria	Recommended Corrective Action
Initial Calibration Standards *(Analyst, Technical Manager(s))*	- Correlation coefficient > 0.99 or standard concentration value. - % Recovery within acceptance range. - See details in Method SOP.	- Reanalyze standards. - If still unacceptable, remake standards and recalibrate instrument.
Independent Calibration Verification (Second Source) *(Analyst, Technical Manager(s))*	- % Recovery within control limits.	- Remake and reanalyze standard. - If still unacceptable, then remake calibration standards or use new primary standards and recalibrate instrument.
Continuing Calibration Standards *(Analyst, Data Reviewer)*	% Recovery within control limits.	- Reanalyze standard. - If still unacceptable, then recalibrate and rerun affected samples.
Matrix Spike / Matrix Spike Duplicate (MS/MSD) *(Analyst, Data Reviewer)*	- % Recovery within limits documented in ***(state where limits are maintained)***.	- If the acceptance criteria for duplicates or matrix spikes are not met because of matrix interferences, the acceptance of the analytical batch is determined by the validity of the LCS. - If the LCS is within acceptable limits the batch is acceptable. - The results of the duplicates, matrix spikes and the LCS are reported with the data set. - For matrix spike or duplicate results outside criteria the data for that sample shall be reported with qualifiers.
Laboratory Control Sample (LCS) *(Analyst, Data Reviewer)*	- % Recovery within limits specified in ***(state where limits are maintained).***	- Batch must be re-prepared and re-analyzed. This includes any allowable marginal exceedance. When not using marginal exceedances, the following exceptions apply: 1) when the acceptance criteria for the positive control are exceeded high (i.e., high bias) and there are associated samples that are non-detects, then those non-detects may be reported with data qualifying codes; 2) when the acceptance criteria for the positive control are exceeded low (i.e., low bias), those sample results may be reported if they exceed a maximum regulatory limit/decision level with data qualifying codes. **Note:** If there is insufficient sample or the holding time cannot be met, contact client and report with flags.

QC Activity *(Individual Responsible for Initiation/Assessment)*	Acceptance Criteria	Recommended Corrective Action
Method Blank (MB) *(Analyst, Data Reviewer)*	< Reporting Limit	- Reanalyze blank. - If still positive, determine source of contamination. If necessary, reprocess (i.e. digest or extract) entire sample batch. Report blank results. - Qualify the result(s) if the concentration of a targeted analyte in the MB is at or above the reporting limit AND is > 1/10 of the amount measured in the sample.
Proficiency Testing (PT) Samples *(QA Manager, Technical Manager(s))*	- Criteria supplied by PT Supplier.	- Any failures or warnings must be investigated for cause. Failures may result in the need to repeat a PT sample to show the problem is corrected.
Daily References *(QA Manager(s), Analysts)*	SOP EM-QA-S-1194, Quality Control for Sample Analysis SOP EM-QA-S-1259, Quality Control for Asbestos Analysis Reference EM-QA-R-5730, Quality Control Criteria Summary	- Any failures or warnings must be investigated for cause. Failures may result in the need to repeat sample analysis to show the problem is corrected.
Duplicate Samples *(QA Manager(s), Analysts)*	SOP EM-QA-S-1194, Quality Control for Sample Analysis SOP EM-QA-S-1259, Quality Control for Asbestos Analysis Reference EM-QA-R-5730, Quality Control Criteria Summary	- Any failures or warnings must be investigated for cause. Failures may result in the need to repeat sample analysis to show the problem is corrected.
Replicate Samples *(QA Manager(s), Analysts)*	SOP EM-QA-S-1194, Quality Control for Sample Analysis SOP EM-QA-S-1259, Quality Control for Asbestos Analysis Reference EM-QA-R-5730, Quality Control Criteria Summary	- Any failures or warnings must be investigated for cause. Failures may result in the need to repeat sample analysis to show the problem is corrected.
Internal / External Audits *(QA Manager, Technical Manager(s), Laboratory Director)*	- Defined in Quality System documentation such as SOPs, QAM, etc..	- Non-conformances must be investigated through CAR system and necessary corrections must be made.

QC Activity *(Individual Responsible for Initiation/Assessment)*	Acceptance Criteria	Recommended Corrective Action
Reporting / Calculation Errors (Depends on issue – possible individuals include: Analysts, Data Reviewers, Project Managers, Technical Managers, QA Manager, Corporate QA, Corporate Management)	- NDSC Document No. CW-Q-S-005, Data Recall	- Corrective action is determined by type of error. Follow the procedures in NDSC Document No. CW-L-S-002 or EM-QA-S-3533.
Client Complaints *(Project Managers, Lab Director/Manager, Sales and Marketing)*	-	- Corrective action is determined by the type of complaint. For example, a complaint regarding an incorrect address on a report will result in the report being corrected and then follow-up must be performed on the reasons the address was incorrect (e.g., database needs to be updated).
QA Monthly Report (Refer to Section 16 for an example) (QA Manager, Lab Director/Manager, *Technical Manager(s)*)	- QAM, SOPs.	- Corrective action is determined by the type of issue. For example, CARs for the month are reviewed and possible trends are investigated.
Health and Safety Violation (Safety Officer, Lab Director/Manager, *Technical Manager(s)*)	- Environmental Health and Safety (EHS) Manual.	- Non-conformance is investigated and corrected through CAR system.

15.0 PREVENTIVE ACTION / IMPROVEMENT

15.1 Overview

The laboratory's preventive action programs improve or eliminate potential causes of nonconforming product and/or nonconformance to the quality system. This preventive action process is a proactive and continuous process of improvement activities that can be initiated through feedback from clients, employees, business providers, and affiliates. The QA Department has the overall responsibility to ensure that the preventive action process is in place, and that relevant information on actions is submitted for management review. (EM-QA-S-7577, Continuous Improvement and Preventive Actions.)

Dedicating resources to an effective preventive action system emphasizes the laboratory's commitment to its QA Program. It is beneficial to identify and address negative trends before they develop into complaints, problems and corrective actions. Additionally, the laboratory continually strives to improve customer service and client satisfaction through continuous improvements to laboratory systems.

Opportunities for improvement may be discovered through any of the following:

- review of the monthly QA Metrics Report,
- trending Labserve tasks or iCAT corrective actions,
- review of control charts and QC results,
- trending proficiency testing (PT) results,
- performance of management system reviews,
- trending client complaints,
- review of processing operations, or
- staff observations.

The monthly Management Systems Metrics Report shows performance indicators in all areas of the laboratory and quality system. These areas include revised reports, corrective actions, audit findings, internal auditing and data authenticity audits, client complaints, PT samples, holding time violations, SOPs, ethics training, etc. The metrics report is reviewed monthly by the laboratory management, NDSC QA Team, Local and Executive Management. These metrics are used in evaluating the management and quality system performance on an ongoing basis and provide a tool for identifying areas for improvement.

Items identified as continuous improvement opportunities to the management system may be issued as goals from the annual management systems review, recommendations from internal audits, white papers, Lessons Learned, Technical Services audit report, Technical Best Practices, or as Executive or management initiatives.

The laboratory's corrective action process is integral to implementation of preventive actions. A critical piece of the corrective action process is the implementation of actions to prevent further occurrence of a non-compliance event. Historical review of corrective action and non-conformances provides a valuable mechanism for identifying preventive action opportunities.

15.1.1 The following elements are part of a preventive action/process improvement system:

- Identification of an opportunity for preventive action or process improvement.
- Process for the preventive action or improvement.
- Define the measurements of the effectiveness of the process once undertaken.
- Execution of the preventive action or improvement.
- Evaluation of the plan using the defined measurements.

- Verification of the effectiveness of the preventive action or improvement.
- Close-Out by documenting any permanent changes to the Quality System as a result of the Preventive Action or Process Improvement. Documentation of Preventive Action/process Improvement is incorporated into the monthly QA reports, corrective action process and management review.

15.1.2 Any preventive actions/process improvement undertaken or attempted shall be taken into account during the annual Management Systems Review (Section 16). A highly detailed report is not required; however, a summary of successes and failures within the preventive action program is sufficient to provide management with a measurement for evaluation.

16.0 CONTROL OF RECORDS

The laboratory maintains a records management system appropriate to its needs and that complies with applicable standards or regulations as required. The system produces unequivocal, accurate records that document all laboratory activities. The laboratory retains all original observations, calculations and derived data, calibration records and a copy of the analytical report for a minimum of five years after it has been issued. Exceptions for programs with longer retention requirements are discussed in Section 14.1.2.

16.1 Overview

The laboratory has established procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records. A record index is listed in Table 16-1. More detailed information on retention of specific records is provided in EM-QA-S-2059, Document Control and Control of Records. Quality records are maintained by the QA department in a database, which is backed up as part of the regular laboratory backup. Records are of two types; either electronic or hard copy paper formats depending on whether the record is computer or hand generated (some records may be in both formats). Technical records are maintained by local facility management. Laboratory technical records are maintained by IT.

Table 16-1. Record Index[1]

	Record Types [1]:	**Retention Time:**
Technical Records	- Raw Data - Logbooks[2] - Standards - Certificates - Analytical Records - MDLs/IDLs/DOCs - Lab Reports	5 Years from analytical report issue*

	Record Types [1]:	**Retention Time:**
Official Documents	- Quality Assurance Manual (QAM) - Work Instructions - Policies - SOPs - Policy Memorandums - Manuals - Published Methods	Indefinitely
QA Records	- Certifications - Method and Software Validation / Verification Data	Indefinitely
QA Records	- Internal & External Audits/Responses - Corrective/Preventive Actions - Management Reviews - Data Investigation	5 Years from archival* **Data Investigation:** 5 years or the life of the affected raw data storage whichever is greater (beyond 5 years if ongoing project or pending investigation)
Project Records	- Sample Receipt & COC Documents - Contracts and Amendments - Correspondence - QAPP - SAP - Telephone Logbooks - Lab Reports	5 Years from analytical report issue*
Administrative Records	Financial and Business Operations	Refer to NDSC Document No. CW-L-WI-001
	EH&S Manual, Permits	Indefinitely
	Disposal Records	Indefinitely
	Employee Handbook	Indefinitely
	Personnel files, Employee Signature & Initials, Administrative Training Records (e.g., Ethics)	Refer to HR Manual
	Administrative Policies	Indefinitely
	Technical Training Records	7 years
	Legal Records	Indefinitely
	HR Records	Refer to NDSC Document No. CW-L-WI-001
	IT Records	Refer to NDSC Document No. CW-L-WI-001
	Corporate Governance Records	Refer to NDSC Document No. CW-L-WI-001
	Sales & Marketing	5 years
	Real Estate	Indefinitely

[1] Record Types encompass hardcopy and electronic records.
[2] Examples of Logbook types: Maintenance, Instrument Run, Preparation (standard and samples), Standard and Reagent Receipt, Archiving, Balance Calibration, Temperature (hardcopy or electronic records).
* Exceptions listed in Table 14-2.

16.1.1 All records are stored and retained in such a way that they are secure and readily retrievable at the laboratory facility or main regional facility that provides a suitable environment to prevent damage or deterioration and to prevent loss. All records shall be protected against fire, theft, loss, environmental deterioration, and vermin. In the case of electronic records, electronic or magnetic sources, storage media are protected from deterioration caused by magnetic fields and/or electronic deterioration.

Access to the data is limited to laboratory and company employees and shall be documented with an access log**.** Records archived off-site are stored in a secure location where a record is maintained of any entry into the storage facility. Whether on-site or off-site storage is used, logs are maintained in each storage box to note removal and return of records. Retention of records are maintained on-site at the laboratory for at least 1 month after their generation and moved offsite for the remainder of the required storage time. Records are maintained for a minimum of five years unless otherwise specified by a client or regulatory requirement.

For raw data and project records, record retention shall be calculated from the date the project report is issued. For other records, such as NDSC and or KGD, Controlled Documents, QA, or Administrative Records, the retention time is calculated from the date the record is formally retired. Records related to the programs listed in Table 16-2 have lengthier retention requirements and are subject to the requirements in Section 16.1.3.

16.2 Programs with Longer Retention Requirements

Some regulatory programs have longer record retention requirements than the standard record retention time. These are detailed in Table 16-2 with their retention requirements. In these cases, the longer retention requirement is enacted. If special instructions exist such that client data cannot be destroyed prior to notification of the client, the container or box containing that data is marked as to who to contact for authorization prior to destroying the data.

Table 16-2. Example: Special Record Retention Requirements

Program	**[1]Retention Requirement**
Drinking Water – All States	10 years (lab reports and raw data)
AIHA-LAP ELLAP (Lead)	5 years (project records) (quality control laboratory records required to support retained data and associated reporting for AIHA-LAP ELLAP (lead) will be maintained for a minimum of 6 years)
NYS DOH	5 years (quality control laboratory records required to support retained data and associated reporting for NYS DOH will be maintained for a minimum of 6 years)
OSHA	30 years

[1]Note: Extended retention requirements must be noted with the archive documents or addressed in facility-specific records retention procedures.

16.2.1 The laboratory has procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records. All analytical data is maintained as hard copy or in a secure readable electronic format. For analytical reports that are maintained as copies in PDF format, refer to Section 19.13.1 for more information.

16.2.2 The record keeping system allows for historical reconstruction of all laboratory activities that produced the analytical data, as well as rapid recovery of historical data (Records stored off

site should be accessible within 2 days of a request for such records). The history of the sample from when the laboratory took possession of the samples must be readily understood through the documentation. This shall include inter-laboratory transfers of samples.

- The records include the identity of personnel involved in sampling, sample receipt, preparation, or testing. All analytical work contains the initials (at least) of the personnel involved. The laboratory's copy of the COC is stored in chronological order. The chain of custody would indicate the name of the sampler. If any sampling notes are provided with a work order, they are kept with this package.

- All information relating to the laboratory facilities' equipment, analytical test methods, and related laboratory activities, such as sample receipt, sample preparation, or data verification are documented.

- The record keeping system facilitates the retrieval of all working files and archived records for inspection and verification purposes (e.g., set format for naming electronic files, set format for what is included with a given analytical data set. Instrument data is stored sequentially by instrument. A given day's analyses are maintained in the order of the analysis. Run logs are maintained for each instrument or method; a copy of each day's run log or instrument sequence is stored with the data to aid in re-constructing an analytical sequence. Where an analysis is performed without an instrument, bound logbooks or bench sheets are used to record and file data, where applicable and not part of LabServe direct entry. Standard and reagent information is recorded in logbooks or entered into LabServe for each method as required.

- Changes to hardcopy records shall follow the procedures outlined in Section 12 and 19. Changes to electronic records in LabServe or instrument data are recorded in audit trails.

- The reason for a signature or initials on a document is clearly indicated in the records such as "sampled by," "prepared by," "reviewed by", or "analyzed by".

- All generated data except those that are generated by automated data collection systems, are recorded directly, promptly and legibly in permanent dark ink.

- Hard copy data may be scanned into PDF format for record storage as long as the scanning process can be verified in order to ensure that no data is lost and the data files and storage media must be tested to verify the laboratory's ability to retrieve the information prior to the destruction of the hard copy that was scanned.

- Also refer to Section 19.13.1 'Computer and Electronic Data Related Requirements'**.**

16.3Technical and Analytical Records

16.3.1 The laboratory retains records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each analytical report issued, for a minimum of five years unless otherwise specified by a client or regulatory requirement. The records for each analysis shall contain sufficient information to enable the analysis to be repeated under conditions as close as possible to the original. The records shall include the identity of laboratory personnel responsible for the subsampling,

performance of each analysis and reviewing results.

16.3.2 Observations, data and calculations are recorded real-time and are identifiable to the specific task.

16.3.3 Changes to hardcopy records shall follow the procedures outlined in Section 12 and 19. Changes to electronic records in LabServe or instrument data are recorded in audit trails.

The essential information to be associated with analysis, such as strip charts, tabular printouts, computer data files, analytical notebooks, and run logs, include:

- laboratory sample ID code**;**
- Date of analysis; time of analysis is also required if the holding time is seventy-two (72) hours or less, or when time critical steps are included in the analysis (e.g., drying times, incubations, etc.); instrumental analyses have the date and time of analysis recorded as part of their general operations. Where a time critical step exists in an analysis, location for such a time is included as part of the documentation in a specific logbook or on a benchsheet.
- Instrumentation identification and instrument operating conditions/parameters. Operating conditions/parameters are typically recorded in instrument maintenance logs where available.
- analysis type**;**
- all manual calculations and manual integrations**;**
- analyst's or operator's initials/signature**;**
- sample preparation including cleanup, sample processing/dilution/plating, incubation periods or subculture, ID codes, volumes, weights, instrument printouts, meter readings, calculations, reagents**;**
- test results**;**
- standard and reagent origin, receipt, preparation, and use**;**
- calibration criteria, frequency and acceptance criteria**;**
- data and statistical calculations, review, confirmation, interpretation, assessment and reporting conventions**;**
- quality control protocols and assessment**;**
- electronic data security, software documentation and verification, software and hardware audits, backups, and records of any changes to automated data entries; and
- Method performance criteria including expected quality control requirements. These are indicated both in LabServe and on specific analytical report formats**.**

16.3.4 All logbooks used during receipt, preparation, storage, analysis, and reporting of samples or monitoring of support equipment shall undergo a periodic, documented supervisory or peer review.

16.4Laboratory Support Activities

In addition to documenting all the above-mentioned activities, the following are retained QA records and project records (previous discussions in this section relate where and how these data are stored):

- all original raw data, whether hard copy or electronic, for calibrations, samples and quality control measures, including analysts' work sheets and data output records (chromatograms, strip charts, and other instrument response readout records)**;**
- a written description or reference to the specific test method used which includes a description of the specific computational steps used to translate parametric observations into a reportable analytical value**;**
- copies of final reports**;**
- archived SOPs**;**
- correspondence relating to laboratory activities for a specific project**;**
- all corrective action reports, audits and audit responses**;**
- proficiency test results and raw data; and
- results of data review, verification, and crosschecking procedures

16.4.1 Sample Handling Records

Records of all procedures to which a sample is subjected while in the possession of the laboratory are maintained. These include but are not limited to records pertaining to:

- sample preservation including appropriateness of sample container and compliance with holding time requirement;
- sample identification, receipt, acceptance or rejection and login;
- sample storage and tracking including shipping receipts, sample transmittal / COC forms; and
- procedures for the receipt and retention of samples, including all provisions necessary to protect the integrity of samples.

16.5 Administrative Records

The laboratory also maintains the administrative records in either electronic or hard copy form. Refer to Table 14-1.

16.6 Records Management, Storage and Disposal

All records (including those pertaining to test equipment), certificates and reports are safely stored, held secure and in confidence to the client. Certification related records are available upon request.

All information necessary for the historical reconstruction of data is maintained by the laboratory. Records that are stored only on electronic media must be supported by the hardware and software necessary for their retrieval.

Records that are stored or generated by computers or personal computers have hard copy, write-protected backup copies, or an electronic audit trail controlling access**.**

The laboratory has a record management system (a.k.a., document control) for control of laboratory notebooks, instrument logbooks, standards logbooks, and records for data reduction, validation, storage and reporting. Records are considered archived when noted as such in the records management system (a.k.a., document control.)

16.6.1 Transfer of Ownership

In the event that the laboratory transfers ownership or goes out of business, the laboratory shall ensure that the records are maintained or transferred according to client's instructions. Upon ownership transfer, record retention requirements shall be addressed in the ownership transfer agreement and the responsibility for maintaining archives is clearly established. In addition, in cases of bankruptcy, appropriate regulatory and state legal requirements concerning laboratory records must be followed. In the event of the closure of the laboratory, all records will revert to the control of the NDSC. Should the entire company cease to exist, as much notice as possible will be given to clients and the accrediting bodies who have worked with the laboratory during the previous 5 years of such action.

16.6.2 Records Disposal

Records are removed from the archive and destroyed after 5 years unless otherwise specified by a client or regulatory requirement. On a project specific or program basis, clients may need to be notified prior to record destruction. Records are destroyed in a manner that ensures their confidentiality such as shredding, mutilation or incineration. (Refer to Tables 16-1 and 16-2).

Electronic copies of records must be destroyed by erasure or physically damaging off-line storage media so no records can be read.

If a third party records management company is hired to dispose of records, a "Certificate of Destruction" is required.

17.0 AUDITS

17.1Internal Audits

Internal audits are performed to verify that laboratory operations comply with the requirements of the lab's quality system and with the external quality programs under which the laboratory operates. Audits are planned and organized by the QA staff. Personnel conducting the audits should be independent of the area being evaluated. Auditors will have sufficient authority, access to work areas, and organizational freedom necessary to observe all activities affecting quality and to report the assessments to laboratory management and**,** when requested**,** to Executive management.

Audits are conducted and documented as described in the NDSC Document on performing Internal Auditing, No. CW-Q-S-003. The types and frequency of routine internal audits are

described in Table 15-1. Special or ad hoc assessments may be conducted as needed under the direction of the QA staff.

Table 17-1. Types of Internal Audits and Frequency

Description	Performed by	Frequency
Quality Systems Audits	QA Department, QA approved designee, or NDSC QA	All areas of the laboratory annually
Method Audits QA Technical Audits	Joint responsibility: a) QA Manager or designee b) Technical Manager or Designee (Refer to NDSC Document No. CW-Q-S-003)	QA Technical Audits Frequency: 50% of methods annually
SOP Method Compliance	Joint responsibility: a) QA Manager or designee b) Technical Manager or Designee (Refer to CW-Q-S-003)	SOP Compliance Review Frequency: • Every 2 years • 100% of SOPs annually (DoD/DOE Labs)
Special	QA Department or Designee	Surveillance or spot checks performed as needed, e.g., to confirm corrective actions from other audits.
Performance Testing	Analysts with QA oversight	Two successful per year for each TNI-field of testing or as dictated by regulatory requirements

17.1.1 Annual Quality Systems Audit

An annual quality systems audit is required to ensure compliance to analytical methods and SOPs, Eurofins Data Integrity and Ethics Policies (See Section 7.2), TNI quality systems, AIHA-LA LLC quality systems, NIST NVLAP quality systems, client and state requirements, and the effectiveness of the internal controls of the analytical process, including but not limited to data review, quality controls, preventive action and corrective action. The completeness of earlier corrective actions is assessed for effectiveness & sustainability. The audit is divided into sections for each operating or support area of the lab, and each section is comprehensive for a given area. The area audits may be performed on a rotating schedule throughout the year to ensure adequate coverage of all areas. This schedule may change as situations in the laboratory warrant.

17.1.2 QA Technical Audits

QA technical audits assess data authenticity and analyst integrity. These audits are based on client projects, associated sample delivery groups, and the methods performed. Reported results are compared to raw data to verify the authenticity of results. The validity of calibrations and QC results are compared to data qualifiers, footnotes, and report comments. Manual calculations are checked. QA technical audits will include all methods within a two-year period.

17.1.3 SOP Method Compliance

Compliance of all SOPs with the source methods and compliance of the operational groups with the SOPs will be assessed by the Technical Manager or qualified designee at least every two years.

17.1.4 Special Audits

Special audits are conducted on an as needed basis, generally as a follow up to specific issues such as client complaints, corrective actions, PT results, data audits, system audits, validation comments, regulatory audits or suspected ethical improprieties. Special audits are focused on a specific issue, and report format, distribution, and timeframes are designed to address the nature of the issue.

17.1.5 Performance Testing

Eurofins EMLab P&K, LLC participates in external proficiency testing programs consistent with the requirements outlined by the Laboratory's accreditation, licensing, or registration bodies, and at the frequency required to remain compliant with such programs. The laboratory generally participates in the following types of PT studies, where applicable and/or required by external accreditation, licensing, or registration bodies: AIHA-PAT LLC (EMLAP, IHLAP), NIST NVLAP Bulk Asbestos, Legionella proficiency testing, potable and non-potable water, etc.

It is Eurofins policy that PT samples be treated as typical samples in the production process. Furthermore, where PT samples present special or unique problems, in the regular production process they may need to be treated differently, as would any special or unique request submitted by any client. The QA Manager must be consulted and in agreement with any decisions made to treat a PT sample differently due to some special circumstance.

When the analysis includes subjective analyst evaluation (e.g., microscopic identification and/or quantitation), all analysts, including those in sub-facilities, are required to participate in proficiency testing, with each analyst separately analyzing, recording, and reporting test results. All proficiency testing samples are to be analyzed by the receiving facility. Transfer to alternate laboratory is prohibited, as is discussion of proficiency round details with other facilities prior to completion of a round. Where a facility employs analysts who perform analyses across more than one facility, these analysts are restricted to participation in one facility's proficiency testing, and any discussion of details with personnel outside of the analyst's participation location is strictly prohibited.

Written investigations for unacceptable PT results are required. In some cases it may be necessary for blind QC samples to be submitted to the laboratory to show a return to control.

17.2External Audits

External audits are performed when accrediting and/or certifying agencies or clients conduct on-site inspections or submit performance testing samples for analysis. It is Eurofins policy to cooperate fully with regulatory authorities and clients. The laboratory makes every effort to provide the auditors with access to personnel, documentation, and assistance. Laboratory supervisors are responsible for providing corrective actions to the QA Manager who coordinates

the response. Audit responses are due in the time allotted by the client or agency performing the audit.

The laboratory cooperates with clients and their representatives to monitor the laboratory's performance in relation to work performed for the client. The client may only view data and systems related directly to the client's work. All efforts are made to keep other client information confidential.

17.2.1 Confidential Business Information (CBI) Considerations

During on-site audits, auditors may come into possession of information claimed as business confidential. A business confidentiality claim is defined as "a claim or allegation that business information is entitled to confidential treatment for reasons of business confidentiality or a request for a determination that such information is entitled to such treatment." When information is claimed as business confidential, the laboratory must place on (or attach to) the information at the time it is submitted to the auditor, a cover sheet, stamped or typed legend or other suitable form of notice, employing language such as "trade secret", "proprietary" or "company confidential". Confidential portions of documents otherwise non-confidential must be clearly identified. CBI may be purged of references to client identity by the responsible laboratory official at the time of removal from the laboratory. However, sample identifiers may not be obscured from the information. Additional information regarding CBI can be found in within the 2009 TNI standards.

17.3 Audit Findings

Audit findings are documented using the corrective action process and database (see Section 12). The laboratory's corrective action responses may include action plans that could not be completed within a predefined timeframe. In these instances, a completion date must be set and agreed to by operations management and the QA Manager.

Developing and implementing corrective actions to findings is the responsibility of the Cluster Leader and/or Facility Manager where the finding originated. Findings that are not corrected by specified due dates are reported monthly to management in the QA monthly report.

If any audit finding casts doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test results, the laboratory shall take timely corrective action, and shall notify clients in writing if the investigations show that the laboratory results have been affected. Once corrective action is implemented, a follow-up audit is scheduled to ensure that the problem has been corrected.

Clients must be notified promptly in writing of any event such as the identification of defective measuring or test equipment that casts doubt on the validity of results given in any test report or amendment to a test report. The investigation must begin within 24 hours of discovery of the problem and all efforts are made to notify the client within two weeks after the completion of the investigation.

18.0 MANAGEMENT REVIEWS

18.1 Quality Assurance Report

The QA Department is responsible for preparing a comprehensive monthly metrics report to Management to keep them apprised of current quality issues. This report fosters communication, review, and refinement of the QA system to evaluate the suitability of policies and procedures to meet both regulatory and laboratory quality objectives.

The NDSC QA team compiles information from all of the Environment Testing laboratories monthly metrics reports for the Executive Management team. This report includes notable information and concerns regarding the laboratories QA program and a listing of new regulations that may potentially impact the laboratories.

18.2 Annual Management Review

The Laboratory Management team (Cluster Leader, Facility Managers/Technical Manager, QA Manager) conducts a review annually of its quality systems to ensure its continuing suitability and effectiveness in meeting client and regulatory requirements and to introduce any necessary changes or improvements. It will also provide a platform for defining goals, objectives and action items that feed into the laboratory planning system. The LabServe review consists of examining any audits, complaints or concerns that have been raised through the year that are related to LabServe. The laboratory will summarize any critical findings that cannot be solved by the lab and report them to Corporate IT.

This management systems review (NDSC Document No. CW-Q-S-004 and Work Instruction No. CW-Q-WI-003) uses information generated during the preceding year to assess the “big picture” by ensuring that routine actions taken and reviewed on a monthly basis are not components of larger systematic concerns. The monthly review should keep the quality systems current and effective, therefore, the annual review is a formal senior management process to review specific existing documentation. Significant issues from the following documentation are compiled or summarized by the QA Manager prior to the review meeting:

- Matters arising from the previous annual review.
- Prior Monthly QA Reports issues.
- Laboratory QA Metrics.
- Review of report reissue requests.
- Review of client feedback and complaints.
- Issues arising from any prior management or staff meetings.
- Minutes from prior senior lab management meetings. Issues that may be raised from these meetings include:
    - Adequacy of staff, equipment and facility resources.
    - Adequacy of policies and procedures.
    - Future plans for resources and testing capability and capacity.
- The annual internal double blind PT program sample performance (if performed),
- Compliance to the Ethics Policy and Data Integrity Plan. Including any evidence/incidents of inappropriate actions or vulnerabilities related to data Integrity.

- Evaluation of overall risk, including risks to impartiality, confidentiality, reporting statements of conformity, and nonconforming work.

A report is generated by the QA Manager and management. The report is distributed to the Business Unit Manager, Cluster Leader, Facility/Technical Manager, and QA Manager. The report includes, but is not limited to:

- The date of the review and the names and titles of participants.
- A reference to the existing data quality related documents and topics that were reviewed.
- Quality system or operational changes or improvements that will be made as a result of the review [e.g., an implementation schedule including assigned responsibilities for the changes (Action Table)].

Changes to the quality systems requiring update to the laboratory QA Manual shall be included in the next revision of the QA Manual.

18.3 Potential Integrity Related Managerial Reviews

Potential integrity issues (data or business related) must be handled and reviewed in a confidential manner until such time as a follow-up evaluation, full investigation, or other appropriate actions have been completed and issues clarified. NDSC Internal Investigations Document shall be followed (NDSC Document No. CW-L-S-002). All investigations that result in finding of inappropriate activity are documented and include any disciplinary actions involved, corrective actions taken, and all appropriate notifications of clients.

Eurofins Built Testing President, Business Unit Manager, Cluster Leader, and NDSC Team are informed of any current data integrity or data recall investigations via the monthly metrics report.

19.0 **TEST METHODS AND METHOD VALIDATION**

19.1 Overview

The laboratory uses methods that are appropriate to meet our clients' requirements and that are within the scope of the laboratory's capabilities. These include sampling, handling, transport, storage and preparation of samples, and, where appropriate, an estimation of the measurement of uncertainty as well as statistical techniques for analysis of environmental data.

Instructions are available in the laboratory for the operation of equipment as well as for the handling and preparation of samples. All instructions, Standard Operating Procedures (SOPs), reference methods and manuals relevant to the working of the laboratory are readily available to all staff. Deviations from published methods are documented (with justification) in the laboratory's approved SOPs. SOPs are submitted to clients for review at their request. Significant deviations from published methods require client approval and regulatory approval where applicable.

19.2 Standard Operating Procedures (SOPS)

The laboratory maintains SOPs that accurately reflect all phases of the laboratory such as assessing data integrity, corrective actions, handling customer complaints as well as all analytical methods and sampling procedures. Where method SOPs are derived from the most recently promulgated/approved, published methods and are specifically adapted to the laboratory facility. Modifications or clarifications to published methods are clearly noted in the SOPs. All SOPs are controlled in the laboratory.

- All SOPs contain a revision number, effective date, and appropriate approval signatures. Controlled copies are available to all staff.
- Procedures for writing an SOP are incorporated by reference to SOP EM-QA-S-2059, Document Control and Control of Records.
- SOPs are reviewed at a minimum of every 2 years (annually for Drinking Water and DoD/DOE SOPs), and where necessary, revised to ensure continuing suitability and compliance with applicable requirements.

19.3 Laboratory Methods Manual

For each test method, the laboratory shall have available the published referenced method as well as the laboratory developed SOP.

Note: If more stringent standards or requirements are included in a mandated test method or regulation than those specified in this manual, the laboratory shall demonstrate that such requirements are met. If it is not clear which requirements are more stringent, the standard from the method or regulation is to be followed. Any exceptions or deviations from the referenced methods or regulations are noted in the specific analytical SOP.

The laboratory maintains an SOP Index for both technical and non-technical SOPs. Technical SOPs are maintained to describe a specific test method. Non-technical SOPs are maintained to describe functions and processes not related to a specific test method.

19.4 Selection of Methods

Since numerous methods and analytical techniques are available, continued communication between the client and laboratory is imperative to assure the correct methods are utilized. Once client methodology requirements are established, this and other pertinent information is summarized by the Project Manager. These mechanisms ensure that the proper analytical methods are applied when the samples arrive for log-in. For non-routine analytical services (e.g., special matrices, non-routine compound lists), the method of choice is selected based on client needs and available technology. The methods selected should be capable of measuring the specific parameter of interest, in the concentration range of interest, and with the required precision and accuracy.

19.4.1 Sources of Methods

Routine analytical services are performed using both in-house developed methodology and standard EPA-approved methodology. In some cases, modification of standard approved

methods may be necessary to provide accurate analyses of particularly complex matrices. When the use of specific methods for sample analysis is mandated through project or regulatory requirements, only those methods shall be used.

When clients do not specify the method to be used or methods are not required, the methods used will be clearly validated and documented in an SOP and available to clients and/or the end user of the data. Refer to Appendix 3 for a list of the currently accepted U.S. EPA analytical method references used by the laboratory.

The laboratory reviews updated versions to all the aforementioned references for adaptation based upon capabilities, instrumentation, etc., and implements them as appropriate. As such, the laboratory strives to perform only the latest versions of each approved method as regulations allow or require.

Other reference procedures for non-routine analyses may include methods established by specific states (e.g., Underground Storage Tank methods), ASTM or equipment manufacturers. Sample type, source, and the governing regulatory agency requiring the analysis will determine the method utilized.

The laboratory shall inform the client when a method proposed by the client may be inappropriate or out of date. After the client has been informed, and they wish to proceed contrary to the laboratory's recommendation, it will be documented.

19.4.1.1 Client Supplied Methods

Most of the client-supplied method requirements presented to us involve achieving specific quality control criteria, limits of quantitation (LOQ), and/or method detection limits (MDL) using standard EPA methods. These requirements are communicated to the appropriate technical groups prior to the project start up. Each technical group evaluates the scope of work and the requirements to ensure the criteria can be met using the standard EPA method. The data is monitored to ensure the criteria are met throughout the project. The PM notifies the client if there is a more appropriate method available or if the client's criteria cannot be achieved on a certain sample matrix (i.e., due to matrix or dilutions).

Occasionally, we are asked to transfer a non-standardized method from a client into our lab or to develop a new method, when one is not available. In the case of a method transfer, we set up the client's method and perform some initial evaluation. After the initial evaluation, we may make recommendations on how to improve method performance. If the method appears to be adequate, we determine linearity, specificity, precision, accuracy, MDL, and LOQ by performing calibrations, analyzing method blanks, and carrying out method detection limit and IDOC studies.

In the case of method development, we work with the client and/or data user to determine the level of validation required ensuring that the method meets its intended purpose. In addition to the elements above, we also determine standard and sample stability and robustness depending on the scope of the project. Typically, a standard operating procedure is written and submitted to the client with the results of the validation. These steps are completed prior to analysis of field samples. Data related to the setup of the method are archived.

19.4.1.2 Procedural Deviations

Analysts are required to follow a documented method for all tests performed; and any deviations from analytical methods must be documented, approved, and justified in an appropriate and consistent manner. We classify method deviations as either being a planned deviation or an unplanned deviation. In general, the following information is captured to document both types of situations:

- Description of the situation
- Reason or justification for the deviation
- Impact the deviation had on the testing
- Signature/date of analyst performing the test (may also be LabServe user identification and timestamp)
- Signature/date of QA and Laboratory management approving the deviation (may also be LabServe user identification and timestamp)
- Signature/date of client approval, if necessary (may also be electronic communication from client)

Deviations to written procedures are documented in raw data records, LabServe Task System, or through ICAT. All types of documentation require management and QA review and approval.

19.4.2 Demonstration of Capability

Before the laboratory may institute a new method and begin reporting results, the laboratory shall confirm that it can properly operate the method. In general, this demonstration does not test the performance of the method in real world samples, but in an applicable and available clean matrix sample. If the method is for the testing of analytes that are not conducive to spiking, demonstration of capability may be performed on quality control samples.

A demonstration of capability (DOC, Lab SOP # EM-AD-S-1646) is performed whenever there is a change in instrument type (e.g., new instrumentation), matrix, method or personnel (e.g., analyst has not performed the test within the last 12 months).

Note: The laboratory shall have a DOC for all analytes included in the methods that the laboratory performs, and proficiency DOCs for each analyst shall include all analytes that the laboratory routinely performs. Addition of non-routine analytes does not require new DOCs for all analysts if those analysts are already qualified for routine analytes tested using identical chemistry and instrument conditions.

The initial demonstration of capability must be thoroughly documented and approved by the Facility Manager, Technical Manager (where appropriate), and QA Manager prior to independently analyzing client samples. All associated documentation must be retained in accordance with the laboratory's archiving procedures.

The laboratory must have an approved SOP, demonstrate satisfactory performance, and conduct an MDL study (when applicable). There may be other requirements as stated within the published method or regulations (e.g., retention time window study).

Note: In some instances, a situation may arise where a client requests that an unusual analyte be reported using a method where this analyte is not normally reported. If the analyte is being reported for regulatory purposes, the method must meet all procedures outlined within this QA Manual (SOP, MDL, and Demonstration of Capability). If the client states that the information is not for regulatory purposes, the result may be reported as long as the following criteria are met:

- The client request is documented and the lab informs the client of its procedure for working with unusual compounds. The final report must be footnoted: *Reporting Limit based on the low standard of the calibration curve.*

19.4.3 Initial Demonstration of Capability (IDOC) Procedures

19.1.1.1 All analysts and technicians are required to demonstrate their ability to produce reliable results before they perform analysis without direct supervision and document on an Initial Demonstration of Capability (IDOC) form. This form is to be completed by the QA Manager and maintained as part of the employee's training record. (SOP EM-AD-S-1646). The Initial Demonstration of Capability (IDOC) form is to be completed per procedure/analysis prep.

19.1.1.2 Training timeframes and minimum sample counts are defined by analysis type and are applicable to initial training. A list of training requirements may be found in the General Training SOP, EM-AD-S-1646. Where training requirements are undefined, a detailed training plan is required.

19.1.1.3 Where an analyst has previous documented training, and has met the required timeframe and minimum sample count for same/like analytical methods, the timeframe and noted sample count will not be required. Sample training in these situations require development of a training plan with an appropriate timeframe and appropriate number of minimum samples.

19.1.1.4 An authorization statement (refer to Figure 19-1 as an example shall be used to document the completion of each initial demonstration of capability.) A copy of the authorization is archived in the analyst's training folder.

19.5 Laboratory Developed Methods and Non-Standard Methods

Eurofins EMLab P&K employs the use of in-house developed methods as well as published reference methods. Any new method developed by the laboratory must be fully defined in an SOP and validated by qualified personnel with adequate resources to perform the method. Method specifications and the relation to client requirements must be clearly conveyed to the client if the method is a non-standard method (not a published or routinely accepted method). The client must also be in agreement to the use of the non-standard method.

19.6 Validation of Methods

Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.

All non-standard methods, laboratory designed/developed methods, standard methods used outside of their scope, and major modifications to published methods must be validated to confirm they are fit for their intended use. The validation will be as extensive as necessary to meet the needs of the given application. The results are documented with the validation procedure used and contain a statement as to the fitness for use.

19.6.1 Method Validation and Verification Activities for All New Methods

While method validation can take various courses, the following activities can be required as part of method validation. Method validation records are designated QC records and are archived accordingly.

When changes are made to any validated methods, the influence of such changes shall be documented and, if appropriate, a new validation shall be performed.

19.6.1.1 Determination of Method Selectivity – Method selectivity is the demonstrated ability to discriminate the analyte(s) of interest from other compounds in the specific matrix or matrices from other analytes or interference. In some cases to achieve the required selectivity for an analyte, a confirmation analysis is required as part of the method.

19.6.1.2 Determination of Method Sensitivity – Sensitivity can be both estimated and demonstrated. Whether a study is required to estimate sensitivity depends on the level of method development required when applying a particular measurement system to a specific set of samples. Detection limit studies are conducted as described in Section 19.7 below. Where other protocols for estimations and/or demonstrations of sensitivity are required by regulation or client agreement, these shall be followed.

19.6.1.3 Relationship of Limit of Detection (LOD) to the Limit of Quantitation (LOQ) – An important characteristic of expression of sensitivity is the distinction between the LOD and the LOQ. The LOD is the minimum level at which the presence of an analyte can be reliably concluded. The LOQ is the minimum concentration of analyte that can be quantitatively determined with acceptable precision and bias, equivalent to the laboratory's routine reporting limit (RL). For most instrumental measurement systems, there is a region where semi-quantitative data is generated around the LOD (both above and below the estimated MDL or LOD) and below the LOQ. In this region, detection of an analyte may be confirmed but quantification of the analyte is unreliable within the accuracy and precision guidelines of the measurement system. When an analyte is detected below the LOQ, and the presence of the analyte is confirmed by meeting the qualitative identification criteria for the analyte, the analyte can be reliably reported, but the amount of the analyte can only be estimated. If data is to be reported in this region, it must be done so with a qualification that denotes the semi-quantitative nature of the result.

19.6.1.4 Determination of Interferences – A determination that the method is free from interferences in a blank matrix is performed.

19.6.1.5 Determination of Range – Where appropriate to the method, the quantitation range is determined by comparison of the response of an analyte in a curve to established or targeted criteria. Generally the upper quantitation limit is defined by highest acceptable calibration concentration. The lower quantitation limit or QL cannot be lower than the lowest non-zero calibration level, and can be constrained by required levels of bias and precision.

19.6.1.6 Determination of Accuracy and Precision – Accuracy and precision studies are generally performed using replicate analyses, with a resulting percent recovery and measure of reproducibility (standard deviation, relative standard deviation) calculated and measured against a set of target criteria.

19.6.1.7 Documentation of Method – The method is formally documented in an SOP. If the method is a minor modification of a standard laboratory method that is already documented in an SOP, an SOP Attachment describing the specific differences in the new method is acceptable in place of a separate SOP.

19.6.1.8 Continued Demonstration of Method Performance – Continued demonstration of method performance is addressed in the SOP. Continued demonstration of method performance is generally accomplished by batch specific QC samples such as LCS, method blanks or PT samples.

19.7 Method Detection Limits (MDL) / Limits of Detection (LOD)

The MDL is the minimum measured quantity of a substance that can be reported with 99% confidence that the concentration is distinguishable from method blank results, consistent with 40CFR Part 136 Appendix B, August, 2017. The MDL is equivalent to the TNI LOD, and is also equivalent to the DoD/DOE Quality Systems Manual (QSM) DL. The working or final MDL is the higher of the MDL value determined from spikes (MDLs) and the MDL value determined from blanks (MDLb). An initial MDL study shall be performed during the method validation process and when the method is altered in a way that can reasonably be expected to change its sensitivity. On-going data are collected during each quarter in which samples are being analyzed. At least once every 13 months the MDLs and MDLb are re-calculated and re-evaluated using data collected during the preceding period. Refer to the laboratory's SOP No. EM-AD-S-3548 for details on the laboratory's method validation process.

19.8 Verification of Detection Limits

If it is found during the re-evaluation of detection limit results that more than 5% of the spiked samples do not return positive numeric results that meet all method qualitative identification criteria, then then spiking level shall be increased and the initial MDL study pre-performed at the new spiking concentration.

19.9 Instrument Detection Limits (IDL)

The IDL is sometimes used to assess the reasonableness of the MDL or in some cases required by the analytical method or program requirements. IDLs are most commonly used in metals analyses but may be useful in demonstration of instrument performance in other areas.

IDLs are calculated to determine an instrument's sensitivity independent of any preparation method. IDLs are calculated either using 7 replicate spike analyses, like MDL but without sample preparation, or by the analysis of 10 instrument blanks and calculating 3 x the absolute value of the standard deviation.

19.10 Limit of Quantitation

The LOQ shall be at a concentration equivalent to the lowest calibration standard concentration, with the exception of methods using a single-point calibration, and shall be greater than the

MDL. The LOQ is verified by preparing and analyzing spikes at concentrations 1-2 times the selected LOQ, employing the complete analytical process.

When the laboratory establishes a quantitation limit, it must be initially verified by the analysis of a low level standard or QC sample at 1-2 times the reporting limit and annually thereafter. The annual requirement is waived for methods that have an annually verified MDL. The laboratory will comply with any regulatory requirements.

19.11 Estimation of Uncertainty of Measurement

19.11.1 Uncertainty is "a parameter associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand" (as defined by the International Vocabulary of Basic and General Terms in Metrology, ISO Geneva, 1993, ISBN 92-67-10175-1). Knowledge of the uncertainty of a measurement provides additional confidence in a result's validity. Its value accounts for all the factors which could possibly affect the result, such as adequacy of analyte definition, sampling, matrix effects and interferences, climatic conditions, variances in weights, volumes, and standards, analytical procedure, and random variation. Some national accreditation organizations require the use of an "expanded uncertainty" defined as the range within which the value of the measurand is believed to lie within at least a 95% confidence level with the coverage factor k=2.

19.11.2 Uncertainty is not error. Error is a single value (i.e., the difference between the true result and the measured result). On environmental samples, the true result is never known. The measurement is the sum of the unknown true value and the unknown error. Unknown error is a combination of systematic error, or bias, and random error. Bias varies predictably, constantly, and independently from the number of measurements. Random error is unpredictable, assumed to be Gaussian in distribution, and reducible by increasing the number of measurements.

19.11.3 The minimum uncertainty associated with results generated by the laboratory can be determined by using the Laboratory Control Sample (LCS) accuracy range for a given analyte. The LCS limits are used to assess the performance of the measurement system since they take into consideration all of the laboratory variables associated with a given test over time (except for variability associated with the sampling and the variability due to matrix effects). The percent recovery of the LCS is compared either to the method-required LCS accuracy limits or to the statistical, historical, in-house LCS accuracy limits.

19.11.4 To calculate the uncertainty for the specific result reported, refer to SOP EM-QA-S-1960.

19.11.5 In the case where a well-recognized test method specifies limits to the values of major sources of uncertainty of measurement (e.g., 524.2, 525, etc.) and specifies the form of presentation of calculated results, no further discussion of uncertainty is required.

19.12 Sample Reanalysis Guidelines

Because there is a certain level of uncertainty with any analytical measurement, a sample re-preparation (where appropriate) and subsequent analysis (hereafter referred to as 'reanalysis') may result in either a higher or lower value from an initial sample analysis. There are also

variables that may be present (e.g., sample homogeneity, analyte precipitation over time, etc.) that may affect the results of a reanalysis. Based on the above comments, the laboratory will reanalyze samples at a client's request with the following caveats. Client specific Contractual Terms & Conditions for reanalysis protocols may supersede the following items.

- If the reanalysis does not agree (as defined above) with the original result, then the laboratory will investigate the discrepancy and reanalyze the sample a third time for confirmation if sufficient sample is available.

- Any potential charges related to reanalysis are discussed in the contract terms and conditions or discussed at the time of the request. The client will typically be charged for reanalysis unless it is determined that the lab was in error.

- Due to the potential for increased variability, reanalysis may not be applicable to Non-homogenous, Encore, and Sodium Bisulfate preserved samples. See the Area Supervisor or Laboratory Director if unsure.

19.13 Control of Data

The laboratory has policies and procedures in place to ensure the authenticity, integrity, and accuracy of the analytical data generated by the laboratory.

19.13.1 Computer and Electronic Data Related Requirements

The three basic objectives of our computer security procedures and policies are shown below.
The laboratory is currently using the Eurofins EMLab P&K LabServe system, a proprietary in-house developed LIMS system. It is referred to as LabServe for the remainder of this section. Labserve utilizes a Microsoft SQL database which is an industry standard relational database platform.

19.13.1.1 Maintain the Database Integrity – Assurance that data is reliable and accurate through data verification (review) procedures, password-protecting access, anti-virus protection, data change requirements, as well as an internal LIMS permissions procedure.

- LIMS Database Integrity is achieved through data input validation, internal user controls, documentation of system failures and corrective actions taken, and data change requirements.
- Spreadsheets and other software developed in-house must be verified with documentation through hand calculations prior to use. Cells containing calculations must be lock-protected and controlled.
- Instrument hardware and software adjustments are safeguarded through maintenance logs, audit trails and controlled access.
- Custom built software applications, as well as significantly modified off the shelf software, are validated for performing accurate mathematical calculations and transposition of non-numerical information. Whenever the computer software is edited or changed, the computation and transposition processes are revalidated using a computerized test suite in the potentially affected areas prior to the software being used to gather or report data. Data are checked for the following processes:

  - Data accuracy during data collection and storage
  - Data integrity and confidentiality during data storage
  - Integrity of data following electronic transmission to clients
- All software validations and associated process checks are to be fully documented within the Bugzilla system. All supporting spreadsheets, documents, etc. are to be attached to the validation record within Bugzilla.

19.13.1.2 Ensure Information Availability – Protection against loss of information or service is ensured through scheduled back-ups, stable file server network architecture, secure storage of media, line filter, Uninterruptible Power Supply (UPS), and maintaining older versions of software as revisions are implemented.

19.13.1.3 Maintain Confidentiality – Ensure data confidentiality through physical access controls such as password protection or website access approval when electronically transmitting data.

19.13.2 Data Reduction

The complexity of the data reduction depends on the analytical method and the number of discrete operations involved (e.g., extractions, dilutions, instrument readings and concentrations). The analyst calculates the final results from the raw data or uses appropriate computer programs to assist in the calculation of final reportable values.

Analytical results are reduced to appropriate concentration units specified by the analytical method, taking into account factors such as dilution, sample weight or volume, etc. Blank correction will be applied only when required by the method or per manufacturer's indication; otherwise, it should not be performed. Calculations are independently verified by appropriate laboratory staff. Calculations and data reduction steps for various methods are summarized in the respective analytical SOPs or program requirements.

19.13.2.1 All raw data must be retained with the project folder, computer file (if appropriate), and/or appropriate log. All criteria pertinent to the method must be recorded. The documentation is recorded at the time observations or calculations are made and must be signed or initialed/dated (month/day/year). It must be easily identifiable who performed which tasks if multiple people were involved.

19.13.2.2 Detection and reporting limits for analyses are unique to the method being performed. Detection and reporting limits are defined within the respective analytical procedures, where applicable. They are also listed on final reports, where applicable.

19.13.2.3 Due to the nature of biological data the number of significant figures that are used for interpretation should generally be one or two. Therefore data generated by the laboratory is reported with a maximum of two significant figures, unless the use of additional significant figures is warranted by specific analytical reporting requirements.

19.13.2.4 For those methods that do not have an instrument printout or an instrumental output compatible with the LabServe System, the raw results and dilution factors are entered directly into LabServe by the analyst, and the software calculates the final result for the analytical report. LabServe has a defined significant figure criterion for each analyte.

19.13.2.5 The laboratory strives to import data directly from instruments or calculation spreadsheets to ensure that the reported data are free from transcription and calculation errors. For those analyses with an instrumental output compatible with LabServe, the raw results and dilution factors are transferred into LabServe electronically after reviewing the quantitation report, and removing unrequested or poor spectrally-matched compounds. The analyst prints a copy of what has been entered to check for errors. This printout and the instrument's printout of calibrations, concentrations, retention times, chromatograms, and mass spectra, if applicable, are retained with the data file. The data file is stored in a monthly folder on the instrument computer; periodically, this file is transferred to the server and, eventually, to a tape file.

19.13.3 Logbook / Worksheet Use Guidelines

Logbooks and worksheets are filled out 'real time' and have enough information on them to trace the events of the applicable analysis/task. (e.g. calibrations, standards, analyst, sample ID, date, time on short holding time tests, temperatures when applicable, calculations are traceable, etc.)

- Corrections are made following the procedures outlined in Section 12.
- Logbooks are controlled by the QA department. A record is maintained of all logbooks in the lab.
- Unused portions of pages must be "Z"'d out, signed and dated.
- Worksheets are created with the approval of the Regional Manager and QA Manager at the facility. The QA Manager controls all worksheets following the procedures in Section 6.

19.13.4 Review / Verification Procedures

Review procedures are outlined in several SOPs (e.g. Sample Receiving (EM-SM-S-1288), Sample Log In (EM-SM-S-1993), Technical Report Review and Release Procedures (EM-SM-S-1637) to ensure that reported data are free from calculation and transcription errors, that QC parameters have been reviewed and evaluated before data is reported. The general review concepts are discussed below, more specific information can be found in the SOPs.

19.13.4.1 Log-In Review - The data review process starts at the sample receipt stage. Sample control personnel review chain-of-custody forms and project instructions from the project management group. This is the basis of the sample information and analytical instructions entered into LabServe. The log-in instructions are reviewed by the personnel entering the information, and a second level review is conducted by the project management staff.

19.13.4.2 First Level Data Review - The next level of data review occurs with the analysts. As data are generated, analysts review their work to ensure that the results meet project and SOP requirements. First level reviews include inspection of all raw data (e.g., raw data sheets, logs, etc.), evaluation of calibration/calibration verification data in the day's analytical run, evaluation of QC data, and reliability of sample results. The analyst transfers data not already directly entered into LabServe, data qualifiers are added as needed. All first level reviews are documented.

19.13.4.3 Second Level Data Review – All analytical data are subject to review by a second qualified analyst or supervisor. Second level reviews include inspection of all raw data including 100% of data associated with any changes made by the primary analyst. The second review also includes evaluation of QC data, reliability of sample results, qualifiers, and project tasks. Manual calculations are checked in second level review. All second level reviews are documented.

Issues that deem further review include the following:

- QC data are outside the specified control limits for accuracy and precision
- Reviewed sample data does not match with reported results
- Unusual detection limit changes are observed
- Samples having unusually high results
- Samples exceeding a known regulatory limit
- Raw data indicating some type of contamination or poor technique
- Transcription errors
- Results outside of calibration range

19.13.4.4 Unacceptable analytical results may require reanalysis of the samples. Any problems are brought to the attention of the Laboratory Director, Project Manager, Quality Manager, Technical Manager, or Supervisor for further investigation. Corrective action is initiated whenever necessary.

19.13.4.5 The review process includes, but is not limited to, verifying that the COC is followed, report comments are present where necessary, comments are appropriate, and project specific requirements are met.

20.0 EQUIPMENT and CALIBRATIONS

20.1 Overview

The laboratory purchases the most technically advanced analytical instrumentation for sample analyses. Instrumentation is purchased on the basis of accuracy, dependability, efficiency and sensitivity. Each laboratory is furnished with all items of sampling, preparation, analytical testing and measurement equipment necessary to correctly perform the tests for which the laboratory has capabilities. Each piece of equipment is capable of achieving the required accuracy and complies with specifications relevant to the method being performed. Before being placed into use, the equipment (including sampling equipment) is calibrated and checked to establish that it meets its intended specification. The calibration routines for analytical instruments establish the range of quantitation. Calibration procedures are specified in SOP EM-EQ-S-1584. A list of available laboratory instrumentation, per facility, is maintained by Quality Assurance in QA server folders.

Equipment is only operated by authorized and trained personnel. Manufacturer’s instructions for equipment use are readily accessible to all appropriate laboratory personnel.

20.2 Preventive Maintenance

The laboratory follows a well-defined maintenance program to ensure proper equipment operation and to prevent the failure of laboratory equipment or instrumentation during use. This program of preventive maintenance helps to avoid delays due to instrument failure.

Routine preventive maintenance procedures and frequency, such as cleaning and replacements, should be performed according to the procedures outlined in the manufacturer's manual. Qualified personnel must also perform maintenance when there is evidence of degradation of peak resolution, a shift in the calibration curve, loss of sensitivity, or failure to continually meet one of the quality control criteria.

Scheduled routine maintenance is defined in SOP EM-EQ-S-1584. It is the responsibility of each Facility Manager and/or designee to ensure that instrument maintenance logs are kept for all equipment in his/her facility. Preventative maintenance procedures are outlined in EM-EQ-S-1584 and may also be outlined in analytical SOPs or instrument manuals. (Note: for some equipment, the log used to monitor performance is also the maintenance log. Multiple pieces of equipment may share the same log as long as it is clear as to which instrument is associated with an entry.)

Instrument maintenance logs are controlled and are used to document instrument problems, instrument repair and maintenance activities. Maintenance logs shall be kept for all major pieces of equipment. Instrument maintenance logs may also be used to specify instrument parameters.

- Documentation must include all major maintenance activities such as contracted preventive maintenance and service and in-house activities such as the replacement of electrical components, lamps, tubing, valves, columns, detectors, cleaning and adjustments.
- Each entry in the instrument log includes the analyst's initials, the date, a detailed description of the problem (or maintenance needed/scheduled), a detailed explanation of the solution or maintenance performed, and a verification that the equipment is functioning properly (state what was used to determine a return to control. e.g. instrument recalibrated on ‘date’ with acceptable verification, etc.) must also be documented in the instrument records.
- When maintenance or repair is performed by an outside agency, service receipts detailing the service performed are to be maintained as part of facility equipment records.

If an instrument requires repair (subjected to overloading or mishandling), gives suspect results, or otherwise has shown to be defective or outside of specified limits it shall be taken out of operation and tagged as out-of-service or otherwise isolated until such a time as the repairs have been made and the instrument can be demonstrated as operational by calibration and/or verification or other test to demonstrate acceptable performance. The laboratory shall examine the effect of this defect on previous analyses.

In the event of equipment malfunction that cannot be resolved, service shall be obtained from the instrument vendor manufacturer, or qualified service technician, if such a service can be tendered. If on-site service is unavailable, arrangements shall be made to have the instrument shipped back to the manufacturer for repair. Back up instruments, which have been approved, for the analysis shall perform the analysis normally carried out by the malfunctioning instrument. If the back-up is not available and the analysis cannot be carried out within the needed timeframe, the samples shall be subcontracted.

At a minimum, if an instrument is sent out for service or transferred to another facility, it must be verified as functional upon return or repair prior to return to lab operations.

20.3 Support Equipment

This section applies to all devices that may not be the actual test instrument, but are necessary to support laboratory operations. These include but are not limited to: balances, ovens, refrigerators, freezers, incubators, water baths, temperature measuring devices, and volumetric dispensing devices if quantitative results are dependent on their accuracy, as in standard preparation and dispensing or dilution into a specified volume. All raw data records associated with the support equipment are retained to document instrument performance. Additional information and requirements may be found in SOP EM-EQ-S-1584.

20.3.1 Weights and Balances

The accuracy of the balances used in the laboratory is checked every working day, before use. All balances are placed on stable counter tops.

Each balance is checked prior to initial serviceable use with at least two certified ASTM type 1 weights spanning its range of use (weights that have been calibrated to ASTM type 1 weights may also be used for daily verification). ASTM type 1 weights used only for calibration of other weights (and no other purpose) are inspected for corrosion, damage or nicks at least annually and if no damage is observed, they are calibrated at least every 5 years by an outside calibration laboratory. Any weights (including ASTM Type 1) used for daily balance checks or other purposes are recalibrated/recertified every two years to NIST standards (this may be done internally if laboratory maintains “calibration only” ASTM type 1 weights).
All balances are serviced annually by a qualified service representative, who supplies the laboratory with a certificate that identifies traceability of the calibration to the NIST standards.

All of this information is recorded in logs, and the recalibration/recertification certificates are kept on file.

20.3.2 pH, Conductivity, and Turbidity Meters

The pH meters used in the laboratory are accurate to ± 0.1 pH units, and have a scale readability of at least 0.05 pH units. The meters automatically compensate for the temperature, and are calibrated with at least two working range buffer solutions before each use.

Conductivity meters are also calibrated before each use with a known standard to demonstrate the meters do not exceed an error of 1% or one umhos/cm.

Turbidity meters are also calibrated before each use. All of this information is documented in logs.

Consult pH, Conductivity, and Turbidity SOPs for further information.

20.3.3 Thermometers

All thermometers are calibrated on an annual basis with a NIST-traceable thermometer.

- If the temperature measuring device is used over a range of 10°C or less, then a single point verification within the range of use is acceptable;
- If the temperature measuring device is used over a range of greater than 10°C, then the verification must bracket the range of use.

IR thermometers and digital thermometers are calibrated every 6 months, (or quarterly where required by external accrediting bodies).

The NIST reference thermometer is recalibrated every five years (unless thermometer has been exposed to temperature extremes or apparent separation of internal liquid) by an approved outside service and the provided certificate of traceability is kept on file. The NIST thermometer(s) have increments of 1 degree (0.5 degree or less increments are required for drinking water microbiological laboratories), and have ranges applicable to method and certification requirements. The NIST traceable thermometer is used for no other purpose than to calibrate other thermometers.

All of this information is documented in logs. Monitoring method-specific temperatures, including incubators, heating blocks, water baths, and ovens, is documented in equipment-specific logs. More information on this subject can be found in the *Calibration and Maintenance of Lab Equipment* SOP, EM-EQ-S-1584.

20.3.4 Refrigerators/Freezer Units, Water baths, Ovens and Incubators

The temperatures of all refrigerator units and freezers used for sample and standard storage are monitored each working day, at minimum. Temperatures are recorded twice daily, with a minimum 4 hours between readings for days in use.

Ovens, water baths and incubators are monitored on days of use.

All of this equipment has a unique identification number, and is assigned a thermometer for monitoring.

Sample storage refrigerator temperatures are kept between 2ºC and 8 ºC.

Specific temperature settings/ranges for other refrigerators, ovens, water baths, and incubators can be found in method specific SOPs.

All of this information is documented in Daily Temperature Logs and/or electronic data logger records.

20.3.5 Autopipettors, Dilutors, and Syringes

Mechanical volumetric dispensing devices are given unique identification numbers and the delivery volumes are verified, at a minimum, on a monthly basis. Monthly pipette verification and annual calibration procedures are found in SOP EM-EQ-S-1584.

For those dispensers that are not used for analytical measurements, a label can be applied to the device stating that it is not calibrated and not for use in analysis. Any device not regularly verified cannot be used for any quantitative measurements.

20.3.6 Autoclaves

Each autoclave requires routine maintenance and cleaning to ensure functionality of the unit. Process controls are in place daily, weekly, and quarterly to ensure that the unit is performing as required with respect to time, temperature and sterilization requirements. Details of required maintenance can be found in manufacturer manuals as well as SOP Autoclave Operation and Maintenance SOP, EM-EQ-S-1198.

20.3.7 Microscopes

The routine maintenance of microscopes is outlined in Document EM-EQ-S-1586 "Routine Maintenance of Microscopes". Microscope Ocular Micrometers are calibrated annually with an NIST traceable micrometer per Document EM-EQ-S-1588 "Ocular Micrometer Calibration". Records of the maintenance and ocular micrometer calibrations are maintained as part of the Quality System documentation.

For those microscopes used in PCM analysis, routine maintenance and alignment requirements are outlined with the analytical Document EM-AS-S-1260 "PCM Analysis for Asbestos and Other Fibers".

For those microscopes used in Asbestos PLM analysis, routine maintenance and alignment requirements are outlined with the analytical Document EM-AS-S-1267 "Sample Preparation and Analysis for Asbestos Fibers by Polarized Light Microscopy (PLM)".

20.3.8 Ventilation and Decontamination

Class II Biosafety hoods are certified on an annual basis by a NSF accredited field certifier to ensure that the hoods are functioning according to the specifications outlined in NSF Standard 49 and the Chapter 13 of the ASHRAE Applications Notebook (1999). The records for the hood calibration are maintained at each facility.

All other Biohazard hoods, including Class I with HEPA filter used for asbestos, are certified on an annual basis by an ISO/IEC 17025:2017 accredited vendor.

Hoods used for asbestos analyses must operate at a minimum 75 fpm or they shall not be used for asbestos work.

20.4 Instrument Calibrations

Calibration of analytical instrumentation is essential to the production of quality data. Strict calibration procedures are followed for each method. These procedures are designed to determine and document the method detection limits, the working range of the analytical instrumentation and any fluctuations that may occur from day to day.

Sufficient raw data records are retained to allow an outside party to reconstruct all facets of the initial calibration. Records contain, but are not limited to, the following: calibration date, method, instrument, analyst(s) initials or signatures, analysis date, analytes, concentration, response,

and type of calibration (Avg RF, curve, or other calculations that may be used to reduce instrument responses to concentration.)

Sample results must be quantitated from the initial calibration and may not be quantitated from any continuing instrument calibration verification unless otherwise required by regulation, method or program.

If the initial calibration results are outside of the acceptance criteria, corrective action is performed and any affected samples are reanalyzed if possible. If the reanalysis is not possible, any data associated with an unacceptable initial calibration will be reported with appropriate data qualifiers (refer to Section 12).

Note: Instruments are calibrated initially and as needed after that and at least annually.

20.4.1 Calibration Standards

Calibration standards are prepared using the procedures indicated in the Reagents and Standards section of the determinative method SOP. If a reference method does not specify the number of calibration standards, a minimum of 3 calibration points will be used.

Standards for instrument calibration are obtained from a variety of sources. All standards are traceable to national or international standards of measurement, or to national or international standard reference materials.

The lowest concentration calibration standard that is analyzed during an initial calibration must be at or below the stated reporting limit for the method based on the final volume of extract (or sample).
The other concentrations define the working range of the instrument/method or correspond to the expected range of concentrations found in actual samples that are also within the working range of the instrument/method. Results of samples not bracketed by initial instrument calibration standards (within calibration range to at least the same number of significant figures used to report the data) must be reported as having less certainty, e.g., defined qualifiers or flags (additional information may be included in the case narrative).

All initial calibrations are verified with a standard obtained from a second source and traceable to a national standard, when available (or vendor certified different lot if a second source is not available). For unique situations, such as air analysis where no other source or lot is available, a standard made by a different analyst at a different time or a different preparation would be considered a second source. This verification occurs immediately after the calibration curve has been analyzed, and before the analysis of any samples.

20.4.1.1 Calibration Verification

The calibration relationship established during the initial calibration must be verified initially and at least daily as specified in the laboratory method SOPs in accordance with the referenced analytical methods and in the 2009 and 2016 TNI Standard. The process of calibration verification applies to both external standard and internal standard calibration techniques, as well as to linear and non-linear calibration models. Initial calibration verification (ICV) is with a standard source secondary (second source standard) to the calibration standards, but

continuing calibration verifications (CCV) may use the same source standards as the calibration curve.

Note: The process of calibration verification referred to here is fundamentally different from the approach called "calibration" in some methods. As described in those methods, the calibration factors or response factors calculated during calibration are used to update the calibration factors or response factors used for sample quantitation. This approach, while employed in other EPA programs, amounts to a daily single-point calibration.

All target analytes and surrogates, including those reported as non-detects, must be included in periodic calibration verifications for purposes of retention time confirmation and to demonstrate that calibration verification criteria are being met, i.e., RPD, per 2009 and 2016 TNI Std. EL-V1M4 Sec. 1.7.2.

All samples must be bracketed by periodic analyses of standards that meet the QC acceptance criteria (e.g., calibration and retention time). The frequency is found in the determinative methods or SOPs.

Note: If an internal standard calibration is being used then bracketing calibration verification standards are not required, only daily verifications are needed. The results from these verification standards must meet the calibration verification criteria and the retention time criteria (if applicable).

Generally, the calibrations must be verified by an ICV analyzed immediately following initial calibration and before sample analysis. The ICV may be used as the first bracketing CCV, if criteria for both are met.

A continuing instrument calibration verification (CCV) is generally analyzed at the beginning of each 12-hour analytical shift during which samples are analyzed. The 12-hour analytical shift begins with the injection of the calibration verification standard (or the MS tuning standard in MS methods). The shift ends after the completion of the analysis of the last sample, QC, or standard that can be injected within 12-hours of the beginning of the shift. For methods that have quantitation by external calibration models, a CCV is analyzed at the end of each analytical sequence. Some methods have more frequent CCV requirements. See specific SOPs. Most inorganic methods require the CCV to be analyzed after ever 10 samples or injections, including matrix or batch QC samples.

Note: If an internal standard calibration is being used (e.g., GCMS) then bracketing standards are not required, only daily verifications are needed, except as specified by program or method requirements.

If the results of a CCV are outside the established acceptance criteria and analysis of a second consecutive (and immediate) CCV fails to produce results within acceptance criteria, corrective action shall be performed. Once corrective actions have been completed and documented, the laboratory shall demonstrate acceptable instrument / method performance by analyzing two consecutive CCVs, or a new initial instrument calibration shall be performed.

Sample analyses and reporting of data may not occur or continue until the analytical system is calibrated or calibration verified. However, data associated with an unacceptable calibration

verification may be fully useable reported based upon discussion and approval of the client under the following special conditions:

a). when the acceptance criteria for the CCV are exceeded high (i.e., high bias) and the associated samples within the batch are non-detects, then those non-detects may be reported case narrative comment explaining the high bias. Otherwise the samples affected by the unacceptable CCV shall be re-analyzed after a new calibration curve has been established, evaluated and accepted; or

b). when the acceptance criteria for the CCV are exceeded low (i.e., low bias), those sample results may be reported if they exceed a maximum regulatory limit/decision level. Otherwise the samples affected by the unacceptable CCV shall be re-analyzed after a new calibration curve has been established, evaluated and accepted.

Samples reported by the 2 conditions identified above will be appropriately flagged.

20.4.1.2 Verification of Linear and Non-Linear Calibrations

Calibration verification for calibrations involves the calculation of the percent drift or the percent difference of the instrument response between the initial calibration and each subsequent analysis of the verification standard. (These calculations are available in the laboratory method SOPs.) Verification standards are evaluated based on the % Difference from the average CF or RF of the initial calibration or based on % Drift or % Recovery if a linear or quadratic curve is used.

Regardless of whether a linear or non-linear calibration model is used, if initial verification criterion is not met, then no sample analyses may take place until the calibration has been verified or a new initial calibration is performed that meets the specifications listed in the method SOPs. If the calibration cannot be verified after the analysis of a single verification standard, then adjust the instrument operating conditions and/or perform instrument maintenance, and analyze another aliquot of the verification standard. If the calibration cannot be verified with the second standard, then a new initial calibration is performed.

- When the acceptance criteria for the calibration verification are exceeded high, i.e., high bias, and there are associated samples that are non-detects, then those non-detects may be reported. Otherwise, the samples affected by the unacceptable calibration verification shall be reanalyzed after a new calibration curve has been established, evaluated and accepted.

- When the acceptance criteria for the calibration verification are exceeded low, i.e., low bias, those sample results may be reported if they exceed a maximum regulatory limit/decision level. Otherwise, the samples affected by the unacceptable verification shall be reanalyzed after a new calibration curve has been established, evaluated and accepted. Alternatively, a reporting limit standard may be analyzed to demonstrate that the laboratory can still support non-detects at their reporting limit.

21.0 MEASUREMENT TRACEABILITY

21.1 Overview

Traceability of measurements shall be assured using a system of documentation, calibration, and analysis of reference standards. Laboratory equipment that are peripheral to analysis and whose calibration is not necessarily documented in a test method analysis or by analysis of a reference standard shall be subject to ongoing certifications of accuracy. At a minimum, these must include procedures for checking specifications of ancillary equipment: balances, thermometers, temperature, Deionized (DI) and Reverse Osmosis (RO) water systems, automatic pipettes and other volumetric measuring devices. (Refer to Section 20.3). With the exception of Class A Glassware and glass microliter syringes, quarterly accuracy checks (at minimum) are performed for all mechanical volumetric devices. Wherever possible, subsidiary or peripheral equipment is checked against standard equipment or standards that are traceable to national or international standards. Class A Glassware and glass microliter syringes should be routinely inspected for chips, acid etching or deformity (e.g., bent needle). If the Class A glassware or syringe is suspect, the accuracy of the glassware will be assessed prior to use.

All reusable glassware and plasticware that is used in the analysis of samples must be cleaned, and where appropriate, sterilized according to Document EM-EQ-S-5810 "Glassware Cleaning". All glassware shall be inspected for cracks and chips before each time it is used. If cracks or chips are found, the glassware shall not be used and shall be repaired or discarded.

21.2 NIST-Traceable Weights and Thermometers

Reference standards of measurement shall be used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated.

For NIST-traceable weights and thermometers, the laboratory requires that all calibrations be conducted by a calibration laboratory accredited by A2LA, NVLAP (National Voluntary Laboratory Accreditation Program), or another accreditation organization that is a signatory to a MRA (Mutual Recognition Arrangement) of one or more of the following cooperations – ILAC (International Laboratory Accreditation Cooperation) or APLAC (Asia–Pacific Laboratory Accreditation Cooperation). A calibration certificate and scope of accreditation is kept on file at the laboratory.

21.3 Reference Standards / Materials

Reference standards/materials, where commercially available, are traceable to certified reference materials. Commercially prepared reference standards, to the extent available, are purchased from vendors that are accredited to ISO Guide 34 and ISO/IEC Guide 17025:2017. All reference standards from commercial vendors shall be accompanied with a certificate that includes at least the following information:

- Manufacturer
- Analytes or parameters calibrated
- Identification or lot number
- Calibration method
- Concentration with associated uncertainties

- Purity

If a standard cannot be purchased from a vendor that supplies a Certificate of Analysis, the purity of the standard is documented by analysis. The receipt of all reference standards must be documented. Reference standards are labeled with a unique ID and expiration date. All documentation received with the reference standard is retained as a QC record and references the unique ID.

All reference, primary and working standards/materials, whether commercially purchased or laboratory prepared, must be checked regularly to ensure that the variability of the standard or material from the true value does not exceed method requirements. The accuracy of calibration standards is checked by comparison with a standard from a second source. In cases where a second standard manufacturer is not available, a vendor certified different lot is acceptable for use as a second source. For unique situations, such as air analysis where no other source or lot is available, a standard made by a different analyst would be considered a second source. The appropriate Quality Control (QC) criteria for specific standards are defined in laboratory SOPs. In most cases, the analysis of an Initial Calibration Verification (ICV) or LCS (where there is no sample preparation) is used as the second source confirmation. These checks are generally performed as an integral part of the analysis method (e.g. calibration checks, laboratory control samples).

All standards and materials must be stored and handled according to method or manufacturer's requirements in order to prevent contamination or deterioration. Refer to the Environmental Health & Safety Manual or laboratory SOPs. For safety requirements, please refer to method SOPs and the laboratory's Environmental Health and Safety Manual.

Standards and reference materials shall not be used after their expiration dates unless their reliability is verified by the laboratory and their use is approved by the Quality Assurance Manager. The laboratory must have documented contingency procedures for re-verifying expired standards.

21.4 Documentation and Labeling of Standards, Reagents, and Reference Materials

Reagents must be at a minimum the purity required in the test method. The date of reagent receipt and the expiration date are documented.

All manufacturer or vendor supplied Certificate of Analysis or Purity must be retained, stored appropriately, and readily available for use and inspection. These records are maintained on-site with each facility's current QA/QC records. Records must be kept of the date of receipt and date of expiration of standards, reagents and reference materials. In addition, records of preparation of laboratory standards, reagents, and reference materials must be retained, stored appropriately, and be readily available for use and inspection. For detailed information on documentation and labeling, please refer to facility Supply Receiving and Distribution SOPs.

Wherever possible, cultures purchased for use as control or reference cultures and inclusion in laboratory stock must be obtained from external sources traceable to Guide 34 such as, but not limited to, American Type Culture Collection (ATCC), Hardy Diagnostics and other commercially available traceable culture catalogs. It is not permissible to retain AIHA-EMPAT proficiency

testing rounds for inclusion in stock culture collections due to licensing agreements in place with AIHA-PAT, LLC.
All standards, reagents, and reference materials must be labeled in an unambiguous manner.
Records are maintained for standard and reference material preparation. These records show the traceability to purchased stocks or neat compounds. These records also include method of preparation, date of preparation, expiration date and preparer's name or initials. Preparation procedures are provided in the Method SOPs.

Commercial materials purchased for preparation of calibration solutions, spike solutions, etc.., are usually accompanied with an assay certificate or the purity is noted on the label. If the assay purity is 96% or better, the weight provided by the vendor may be used without correction. If the assay purity is less than 96% a correction will be made to concentrations applied to solutions prepared from the stock commercial material. Blended gas standard cylinders use a nominal concentration if the certified value is within +/-15%, otherwise the certified values is used for the canister concentration.

21.4.1 All standards, reagents, and reference materials must be labeled in an unambiguous manner.

Records are maintained for standard and reference material preparation. These records show the traceability to purchased stocks or neat compounds. These records also include method of preparation, date of preparation, expiration date and preparer's name or initials. Preparation procedures are provided in the Method SOPs.

21.4.2 All standards, reagents, and reference materials must be clearly labeled with a minimum of the following information:

- Lot number
- Expiration Date (include prep date for reagents)
- Standard ID
- Special Health/Safety warnings if applicable

Records must also be maintained of the date of receipt for commercially purchased items or date of preparation for laboratory prepared items. Special Health/Safety warnings must also be available to the analyst. This information is maintained on-site with each facility's current QA/QC records.

21.4.3 In addition, the following information may be helpful:

- Date opened (for multi-use containers, if applicable)
- Description of standard (if different from manufacturer's label or if standard was prepared in the laboratory)
- Recommended Storage Conditions
- Concentration (if applicable)
- Initials of analyst preparing standard or opening container

All containers of prepared reagents must include an expiration date and an ID number to trace back to preparation.

Procedures for preparation of reagents can be found in the Method SOPs.

Standard ID numbers must be traceable through associated logbooks, worksheets and preparation/analytical batch records.

All reagents and standards must be stored in accordance to the following priority: 1) with the manufacturer's recommendations; 2) with requirements in the specific analytical methods as specified in the laboratory SOP.

22.0 SAMPLING

22.1 Overview

Eurofins EMLab P&K, LLC does not offer sampling services. Rare exceptions have been made upon high profile client request. Such requests are to include client specified sampling plans and are reviewed and approved on a case by case basis by the General Manager and Cluster Leader. Such requests and dictated protocols are documented as part of the client account records. Clients of the laboratory are supplied, upon request, with Eurofins EMLab P&K, LLC Chain of Custody (COC) forms, and written information regarding the use of sampling devices and sampling procedures. Clients may also obtain these materials and a detailed list of sampling procedures from the Eurofins EMLab P&K, LLC internet site.

22.2 Sampling Containers

The laboratory offers clean sampling containers for use by clients. These containers are obtained from reputable container manufacturers. Certificates of cleanliness for bottles and preservatives are provided by the supplier and are maintained at the laboratory. Alternatively, the certificates may be maintained by the supplier and available to the laboratory on-line. Internally, a representative sample from new lots of sample containers are checked for sterility and records maintained per lot.

22.2.1 Preservatives

Upon request, preservatives are provided to the client in pre-cleaned sampling containers. In some cases containers may be purchased pre-preserved from the container supplier. Whether prepared by the laboratory or bought pre-preserved, the grades of the preservatives are at a minimum:

- Sodium Thiosulfate – ACS Grade or equivalent

22.3 Definition of Holding Time

The date and time of sampling documented on the COC form establishes the day and time zero. As a general rule, when the maximum allowable holding time is expressed in days (e.g., 14 days, 28 days), the holding time is based on calendar day measured. Holding times expressed in hours (e.g., 6 hours, 24 hours, etc.) are measured from date and time zero. Holding times for analysis include any necessary reanalysis. However, there are some programs that determine

holding time compliance based on the date and specific time of analysis compared to the time of sampling regardless of how long the holding time is.

22.4 Sampling Containers, Preservation Requirements, Holding Times

The preservation and holding time criteria specified in the laboratory SOPs are derived from the source documents for the methods. If method required holding times or preservation requirements are not met, the reports will be qualified using a report comment. As soon as possible or “ASAP” is an EPA designation for tests for which rapid analysis is advised, but for which neither EPA nor the laboratory have a basis for a holding time.

22.5 Sample Aliquots / Subsampling

Taking a representative sub-sample from a container is necessary to ensure that the analytical results are representative of the sample collected in the field. The size of the sample container, the quantity of sample fitted within the container, and the homogeneity of the sample need consideration when sub-sampling for sample preparation. It is the laboratory’s responsibility to take a representative subsample or aliquot of the sample provided for analysis.

Analysts should handle each sample as if it is potentially dangerous. At a minimum, safety glasses (where applicable), gloves, and lab coats must be worn when preparing aliquots for analysis.

Only open asbestos samples in appropriate HEPA filtered hoods with a minimum flow rate of 75 fpm.

Guidelines on taking sample aliquots & subsampling are located in individual method SOPs.

23.0 HANDLING OF SAMPLES

Sample management procedures at the laboratory ensure that sample integrity and custody are maintained and documented from sampling/receipt through disposal.

Consider every sample as potentially dangerous. Handle samples in manner that reduces the potential of contamination to others and the laboratory environment.

Wipe every surface involved in the processing of samples with disinfectant after working with the samples.

Do not leave the lids off of plates at any time, and if necessary reseal plates with parafilm after analysis.

It is every employee's responsibility to report any safety concerns or incidence of non-compliance to supervisors, quality assurance officer, safety coordinator, or corporate management.

23.1 Chain of Custody (COC)

The COC form is the written documented history of any sample and is initiated when bottles are sent to the field, or at the time of sampling. This form is completed by the sampling personnel

and accompanies the samples to the laboratory where it is received and stored under the laboratory's custody. The purpose of the COC form is to provide a legal written record of the handling of samples from the time of collection until they are received at the laboratory. It also serves as the primary written request for analyses from the client to the laboratory. The COC form acts as a purchase order for analytical services when no other contractual agreement is in effect. An example of a COC form may be found in Figure 23-1.

23.1.1 Field Documentation

When the sampling personnel deliver the samples directly to Eurofins EMLab P&K personnel, the samples are stored in a cooler with ice, as applicable, and remain solely in the possession of the client's field technician until the samples are delivered to the laboratory personnel. The sample collector must assure that each container is in his/her physical possession or in his/her view at all times, or stored in such a place and manner to preclude tampering. The field technician relinquishes the samples in writing on the COC form to the sample control personnel at the laboratory or to a Eurofins courier. When sampling personnel deliver the samples through a common carrier (Fed-Ex, UPS), the CoC relinquished date/time is completed by the field personnel and samples are released to the carrier. Samples are only considered to be received by the laboratory when personnel at the fixed laboratory facility have physical contact with the samples.

Note: Independent couriers are not required to sign the COC form. The COC is usually kept in the sealed sample cooler. The receipt from the courier is stored in log-in by date; it lists all receipts each date.

23.1.2 Legal / Evidentiary Chain-of-Custody

If samples are identified for legal/evidentiary purposes on the COC, standard COC and sample handling procedures apply. Eurofins EMLab P&K does not provide internal chain of custody.

23.2 Sample Receipt

Samples are received at the laboratory by designated sample receiving personnel and a unique laboratory project identification number is assigned. Each sample container shall be assigned a unique sample identification number that is cross-referenced to the client identification number such that traceability of test samples is unambiguous and documented. Each sample container is affixed with a durable sample identification label. Sample acceptance, receipt, tracking and storage procedures are detailed in SOP EM-SM-S-1288, and summarized in the following sections.

23.2.1 Laboratory Receipt

The integrity of all samples received is checked during the Sample Receipt process outlined in Document EM-SM-S-1288 "Sample Receipt" prior to sample Log-in. It is the duty of the individual receiving the samples to ensure that the samples received are intact and not compromised in any fashion. The sample acceptance policy to be used as a guideline for assessing the integrity of received samples is contained within Document EM-SM-S-1288 "Sample Receiving".

During sample receipt and log in, the receiving staff separates the individual analysis types into bins and makes copies of the original COC for each bin as needed. The types of analyses, the number of samples received for each analysis, the type of sample and the requested turnaround time are recorded into the database. Any missing or extra samples received are recorded on the original COC and into the database. If any of the previous information is missing or incomplete, the information is documented into the database and the client is contacted. Samples are categorized by projects and analysis types into individual bins and queued for the Log-in process. The laboratory maintains a sample storage area that protects the samples from deterioration, loss, damage or from unauthorized access.

Whenever a compromised sample is encountered, the information is documented in LabServe (Report Comments, Project Log, Project Tasks, Log-in Field or Account Details). The client must be contacted and at the very least, if possible, a message left to inform the client of the situation. If, at the client's request, a compromised sample is analyzed, a qualifying statement must be submitted with the written report describing that the integrity of the results are potentially compromised and that the interpretation of the data is left to the client. Clients are informed on the condition of the sample in the final report. A record of pertinent discussions with clients must be maintained in LabServe (for example in the account details, project logs, tasks, etc.).

23.2.1.1 Unique Sample Identification

All samples that are processed through the laboratory receive a unique sample identification to ensure that there can be no confusion regarding the identity of such samples at any time. This system includes identification for all samples.

The laboratory assigns a unique identification (e.g., Sample ID) code to each sample container received at the laboratory.

23.3 Sample Acceptance Policy

The laboratory has a written sample acceptance policy noted in Document EM-SM-S-1288 "Sample Receipt" (Example in Figure 23-2) that clearly outlines the circumstances under which samples shall be accepted or rejected. These include, but are not limited to:

- sample holding times must be adhered to (Sampling Guide);
- all samples submitted must have a Chain of Custody (COC), or an equivalent sample request, to be received by the laboratory;
- samples are checked for unique identifiers on each sample and that the number of samples matches the information on the COC;
- proper sample containers with adequate volume for the analysis (Sampling Guide) and necessary QC;
- samples must be preserved according to the requirements of the requested analytical method (Sampling Guide);
- the project manager will be notified if any sample is received in damaged condition.

Data from samples which do not meet these criteria are flagged and the nature of the variation from policy is defined.

23.3.1 After inspecting the samples, the sample receiving personnel sign and date the COC form, make any necessary notes of the samples' conditions and store them in appropriate refrigerators or storage locations, as needed.

23.3.2 Any deviations from these checks that question the suitability of the sample for analysis, or incomplete documentation as to the tests required will be resolved by consultation with the client. If the sample acceptance policy criteria are not met, the laboratory shall either:

- Retain all correspondence and/or records of communications with the client regarding the disposition of rejected samples, or
- Fully document any decision to proceed with sample analysis that does not meet sample acceptance criteria.

Once sample acceptance is verified, the samples are logged into the LIMS/LabServe according SOP No. EM-SM-S-1993. and assigned an Eurofins EMLab P&K, LLC Project Number and unique laboratory identifiers for each sample in the project.

All client information, project information, analysis requests, sample identifier information, sample descriptions and miscellaneous notes are entered into the database. The information logged into the database is checked against the information on the original COC and Project Log before the samples are sent to a Receiving and Log- in Quality Control check.

In an effort to meet the needs of the client, Eurofins EMLab P&K, LLC offers the client the ability to log samples in via the internet. Clients enter Chain of Custody (COC) information into the internet log-in screen and then print a COC form which is sent with the samples to the laboratory.
Upon receipt of the samples at the laboratory the COCs are signed by the receiving laboratory staff and the information logged in by the clients is compared with the samples received and the information on the printed client produced COC. Additional information regarding Sample Log In via the internet can be found in SOP EM-SM-S-1993.

23.4 Sample Storage

In order to avoid deterioration, contamination or damage to a sample during storage and handling, from the time of receipt until all analyses are complete, samples are stored in refrigerators, freezers or protected locations suitable for the sample matrix. Samples are never to be stored with reagents, standards or materials that may create contamination.

Access to the laboratory is controlled such that sample storage need not be locked at all times unless a project specifically demands it. Samples are accessible to laboratory personnel only. Visitors to the laboratory are prohibited from entering the refrigerator and laboratory areas unless accompanied by an employee of Eurofins.

23.5 Hazardous Samples and Foreign Soils

To minimize exposure to personnel and to avoid potential accidents, hazardous and foreign soil samples are stored in an isolated area designated for hazardous waste only. For any sample that is known to be hazardous at the time of receipt or, if after completion of analysis the result exceeds the acceptable regulatory levels, a Hazardous Sample Notice must be completed by the analyst. This form may be completed by Sample Control, Project Managers, or analysts and must be attached to the report. The sample itself is clearly marked with a red stamp, stamped on the sample label reading “HAZARDOUS” or “FOREIGN SOIL” and placed in a colored and/or marked bag to easily identify the sample. The date, log number, lab sample number, and the result or brief description of the hazard are all written on the Hazardous & Foreign Soil Sample Notice. A copy of the form must be included with the original COC and Work Order and the original must be given to the Sample Control Custodian. Analysts will notify Sample Control of any sample determined to be hazardous after completion of analysis by completing a Hazardous Sample Notice. All hazardous samples are either returned to the client or disposed of appropriately through a hazardous waste disposal firm that lab-packs all hazardous samples and removes them from the laboratory. Foreign soil samples are sent out for incineration by a USDA-approved waste disposal facility.

23.6 Sample Shipping

In the event that the laboratory needs to ship samples, the samples are placed in a cooler with enough ice where necessary to ensure the samples remain within required temperature range for desired analysis during transit. The samples are carefully surrounded by packing material to avoid breakage (yet maintain appropriate temperature where necessary). The chain-of-custody form is signed by the sample control technician and included in the shipment. Samples are generally shipped overnight express or hand-delivered by a Eurofins TestAmerica courier to maintain sample integrity. All personnel involved with shipping and receiving samples must be trained to maintain the proper chain-of-custody documentation and to keep the samples intact and on ice, where necessary. The Environmental, Health and Safety Manual contains additional shipping requirements.

23.7 Sample Disposal

Samples should be retained for a minimum of 30 days after the project report is sent, however, provisions may be made for earlier disposal of samples once the holding time is exceeded. Some samples are required to be held for longer periods based on regulatory or client requirements (e.g., 60 days after project report is sent). The laboratory must follow the longer sample retention requirements where required by regulation or client agreement. Several possibilities for sample disposal exist: the sample may be consumed completely during analysis, the sample may be returned to the customer or location of sampling for disposal, or the sample may be disposed of in accordance with the laboratory’s waste disposal procedures (SOP EM-HS-S-1286). All procedures in the laboratory’s Environmental Health and Safety Manual are followed during disposal. Samples are normally maintained in the laboratory no longer than one month from receipt unless otherwise requested. Unused portions of samples found or suspected to be hazardous according to state or federal guidelines may be returned to the client upon completion of the analytical work.

Figure 23-1 . Example: Sample Acceptance Policy

All incoming work will be evaluated against the criteria listed below and found with SOP EM-SM-S-1288. Where applicable, data from any samples that do not meet the criteria listed below will be noted on the laboratory report defining the nature and substance of the variation. In addition the client will be notified ASAP after the receipt of the samples.

Per State and/or Federal Regulation, the client is responsible to ensure that samples are shipped in accordance with DOT/IATA requirements, and that radioactive materials may only be delivered to licensed facilities. Any samples containing (or suspected to contain) Source, Byproduct, or Special Nuclear Material as defined by 10 CFR should be delivered directly to facilities licensed to handle such radioactive material. Natural material or ores containing naturally occurring radionuclides may be delivered to any Eurofins facility or courier as long as the activity concentration of the material does not exceed 270 pCi/g alpha or 2700 pCi/g beta (49 CFR Part 173).

Samples received are expected to display the following features:

- Sealed correctly to eliminate cross contamination.
- Clearly discernible markings and identifications.
- Packing materials sufficient to appropriate to eliminate the risk of damage during delivery.
- Sample volume/amount must meet minimum and maximum amount requirements for each analysis, if applicable.
- Lead wipes must meet ASTM E1792 criteria.
- Culture media within expiration dates and lot numbers clearly identified on the plate.
- Asbestos PCM cassettes should not be packaged in Styrofoam and should be separated from PLM samples.
- Bacteriology samples, where a state certification is applicable, should only be shipped to labs holding that certification and should meet the analysis' temperature and holding time requirements.

Samples will be placed on the Project Manager will contact the client if any of the following are observed:

- Leakage from a sample.
- Water intrusion into a sample.
- Physical damage to a sample due to improper packaging during transport.
- Breaking or otherwise discernible compromise to the integrity of the sample.
- Illegible, ambiguous, or missing sample identification information.
- Sample volume/amount does not meet minimum and maximum amount requirements for each analysis, if applicable.
- Lead wipes do not meet the ASTM E1792 criteria.
- Culture media that is expired, dried, or detached from the culture plate.
- Asbestos PCM cassettes packaged in Styrofoam or with asbestos bulk samples.
- Bacteriology samples submitted for an analysis for which state certification is not held at the laboratory of receipt, and/or not adhering to the temperature and hold time requirements

Sample and hold time requirements vary per method. These can be found in SOP EM-SM-S-1288.

Eurofins EMLab P&K will make every effort to analyze samples within the regulatory holding time. Samples must be received in the laboratory with enough time to perform the sample analysis. Except for short holding time samples (< 48hr HT) sample must be received with at least 48 hrs (2 working days) remaining on the holding time for us to ensure analysis.

24.0 ASSURING THE QUALITY OF TEST RESULTS

24.1 Overview

In order to assure our clients of the validity of their data, the laboratory continuously evaluates the quality of the analytical process. The analytical process is controlled not only by instrument calibration as discussed in Section 20, but also by routine process quality control measurements (e.g. Blanks, Laboratory Control Samples (LCS), Matrix Spikes (MS), duplicates (DUP), replicates (REP), daily reference slides, and routine quality control checks). These quality control checks are performed as required by the method or regulations to assess precision and accuracy. Quality control samples are to be treated in the exact same manner as the associated field samples being tested. In addition to the routine process quality control samples, Proficiency Testing (PT) Samples (concentrations unknown to laboratory) are analyzed to help ensure laboratory performance.

24.2 Controls

Sample preparation or pre-treatment is commonly required before analysis. Typical preparation steps vary per method and may include homogenization, drying, acid digestion filter concentration, heat treatment, acid treatment, dilution, centrifugation, etc.. During these pre-treatment steps, samples are arranged into discreet manageable groups referred to as preparation (prep) batches, where applicable. Prep batches provide a means to control variability in sample treatment. Control samples are added to each prep batch to monitor method performance and are processed through the entire analytical procedure with investigative/field samples.

Quality Control Requirements include, but are not limited to, duplicate analysis, replicate analysis, daily reference analysis, round robin and proficiency testing as applicable to the method being performed. Quality control requirements, acceptance criteria, frequency and required trending practices are outlined in Document EM-QA-S-1994, Quality Control for Sample Analysis, Document EM-QA-S-1259, Quality Control for Asbestos Analysis, or within method specific documents.

A Quality Control and Acceptance Criteria Summary is available as Document EM-QA-R-5730.

24.3 Negative Controls

Table 24-1. Example – Negative Controls

Control Type	Details
Negative Control (NC)	are used to assess preparation and analysis for possible contamination during the preparation and processing steps.
	The specific frequency of use for method blanks during the analytical sequence is defined in the specific standard operating procedure for each analysis. Generally it is 1 per day of analysis.
	The method blank is prepared from a clean matrix similar to that of the associated samples that is free from target analytes (e.g., Reagent water, Ottawa sand, glass beads, etc.) and is processed along with and under the same conditions as the associated samples. The method blank goes through all of the steps of the process (including as necessary: filtration, clean-ups, etc.).
	Reanalyze or qualify associated sample results when the concentration of a targeted analyte in the blank is at or above the reporting limit as established by the method or by regulation, AND is greater than 1/10 of the amount measured in the sample.

Table 24-1. Example – Negative Controls

Control Type	Details
Calibration Blanks	are prepared and analyzed along with calibration standards where applicable. They are prepared using the same reagents that are used to prepare the standards. In some analyses the calibration blank may be included in the calibration curve.
Instrument Blanks	are blank reagents or reagent water that may be processed during an analytical sequence in order to assess contamination in the analytical system. In general, instrument blanks are used to differentiate between contamination caused by the analytical system and that caused by the sample handling or sample prep process. Instrument blanks may also be inserted throughout the analytical sequence to minimize the effect of carryover from samples with high analyte content.
Field Blanks [1]	are sometimes used for specific projects by the field samplers.

[1] When known, these field QC samples should not be selected for matrix QC as it does not provide information on the behavior of the target compounds in the field samples. Usually, the client sample ID will provide information to identify the field blanks with labels such as "FB", "EB", or "TB."

Evaluation criteria and corrective action for these controls are defined in the specific standard operating procedure for each analysis.

24.3.1 Negative Controls for Microbiological Methods – Microbiological Methods utilize a variety of negative controls throughout the process to ensure that false positive results are not obtained. These controls are critical to the validity of the microbiological analyses. Details of required negative controls are located within in each method SOP.

Table 24-2. Examples of Negative Controls for Microbiology

Control Type	Details
Sterility Checks (Media)	are analyzed for each lot of pre-prepared media, ready-to-use media and for each batch of medium prepared by the laboratory.
Sterility checks (Sample Containers)	are performed on at least one container per lot of purchased, pre-sterilized containers. If containers are prepared and sterilized by the laboratory, one container per sterilization batch is checked. Container sterility checks are performed using non-selective growth media.
Sterility Checks (Dilution Water)	are performed on each batch of dilution water prepared by the laboratory and on each batch of pre-prepared dilution water.
Sterility Checks (Filters)	are also performed on at least one filter from each new lot of membrane filters using non-selective growth media.

Negative culture controls demonstrate that a media does not support the growth of non-target organisms and ensures that there is not an atypical positive reaction from the target organisms. Prior to the first use of the media, each lot of pre-prepared selective media or batch of laboratory prepared selective media is analyzed with at least one known negative culture control as appropriate to the method.

24.4Positive Controls

Each regulatory program and each method within those programs specify the control samples that are prepared and/or analyzed with a specific batch

Note that frequency of control samples vary with specific regulatory, methodology and project specific criteria. Complete details on method control samples are as listed in each analytical SOP.

Cultures for quality control testing of media and for use as reference organisms are stored appropriately based on procedural requirements. Details can be found in EM-AD-S-5745.

24.4.1 Controls for Microbiological Methods

Laboratory produced media and reagents are checked against quality control organisms, where applicable, and for sterility according to media type recipes/instructions prior to use in analytical procedures. Documentation for the quality control of media and reagents are kept on file. Quality Control records for media produced by outside vendors are kept on file.

24.5Acceptance Criteria (Control Limits)

As mandated by the test method and regulation, each individual QC sample (daily reference, duplicate, replicate, positive control, negative control, etc.) is evaluated against the control limits published in the test method. Where there are no established acceptance criteria, the laboratory calculates in-house control limits with the use of control charts or, in some cases, utilizes client project specific control limits. When this occurs, the regulatory or project limits will supersede the laboratory's in-house limits.

Note: For methods, analytes and matrices with very limited data (e.g., unusual matrices not analyzed often), interim limits are established using available data or by analogy to similar methods or matrices.

Once control limits have been established, they are verified, reviewed, and updated if necessary on a biennial basis unless the method requires more frequent updating. Control limits are established per method (as opposed to per instrument) regardless of the number of instruments utilized.

Laboratory generated % Recovery acceptance (control) limits are generally established by taking $\pm$ 3 Standard Deviations (99% confidence level) from the average recovery of a minimum of 20-30 data points (more points are preferred).

- Regardless of the calculated limit, the limit should be no tighter than the Calibration Verification (ICV/CCV) where applicable. (Unless the analytical method specifies a tighter limit).

- In-house limits cannot be any wider than those mandated in a regulated analytical method. Client or contract required control limits are evaluated against the laboratory's statistically derived control limits to determine if the data quality objectives (DQOs) can be achieved. If

laboratory control limits are not consistent with DQOs, then alternatives must be considered, such as method improvements or use of an alternate analytical method.

24.5.1 The lab must be able to generate a current listing of their control limits and track when the updates are performed. In addition, the laboratory must be able to recreate historical control limits.

24.5.2 A LCS that is within the acceptance criteria establishes that the analytical system is in control and is used to validate the process. Samples that are analyzed with an LCS with recoveries outside of the acceptance limits may be determined as out of control and should be reanalyzed if possible. If reanalysis is not possible, then the results for all affected analytes for samples within the same batch must be qualified when reported. The internal corrective action process (see Section 12) is also initiated if an LCS exceeds the acceptance limits. Sample results may be qualified and reported without reanalysis if:

- The analyte results are below the reporting limit and the LCS is above the upper control limit.

- If the analytical results are above the relevant regulatory limit and the LCS is below the lower control limit.

24.5.3 If the MS/MSDs do not meet acceptance limits, the MS/MSD and the associated spiked sample is reported with a qualifier for those analytes that do not meet limits. If obvious preparation errors are suspected, or if requested by the client, unacceptable MS/MSDs are reprocessed and reanalyzed to prove matrix interference. A more detailed discussion of acceptance criteria and corrective action can be found in the lab's method SOPs and in Section 12.

24.6 Additional Procedures to Assure Quality Control

The laboratory has written and approved method SOPs to assure the accuracy of the test method including calibration (see Section 20), use of certified reference materials (see Section 21) and use of PT samples (see Section 15).

A discussion regarding MDLs, Limit of Detection (LOD) and Limit of Quantitation (LOQ) can be found in Section 19.

- Use of formulae to reduce data is discussed in the method SOPs and in Section 20.
- Selection of appropriate reagents and standards is included in Section 9 and 21.
- A discussion on selectivity of the test is included in Section 5.
- Constant and consistent test conditions are discussed in Section 18.
- The laboratories sample acceptance policy is included in Section 23.

25.0 REPORTING RESULTS

25.1 Overview

The results of each test are reported accurately, clearly, unambiguously, and objectively in accordance with State and Federal regulations as well as client requirements. Analytical results are issued in a format that is intended to satisfy customer and laboratory accreditation requirements as well as provide the end user with the information needed to properly evaluate the results. Where there is conflict between client requests and laboratory ethics or regulatory requirements, the laboratory's ethical and legal requirements are paramount, and the laboratory will work with the client during project set up to develop an acceptable solution. Refer to Section 9.

A variety of report formats are available to meet specific needs.

In cases where a client asks for simplified reports, there must be a written request from the client. There still must be enough information that would show any analyses that were out of conformance (QC out of limits) and there should be a reference to a full report that is made available to the client. Review of reported data is included in Section 19.

25.2 Test Reports

Analytical results are reported in a format that is satisfactory to the client and meets all requirements of applicable accrediting authorities and agencies. A variety of report formats are available to meet specific needs. Data results are predominantly made available to clients directly through electronic means. Eurofins EMLab P&K, LLC additionally offers hard copy reporting by special client request only. At a minimum, the standard laboratory report shall contain the following information:

25.2.1 A report title (e.g., Analytical Report)

25.2.2 The cover page shall include the laboratory name, address and telephone number.

25.2.3 A unique identification of the report (e.g., Eurofins EMLab P&K Project #) and on each page an identification in order to ensure the page is recognized as part of the report and a clear identification of the end.

Note: Page numbers of report are represented as page # of ##. Where the first number is the page number and the second is the total number of pages.

25.2.4 A copy of the chain of custody (COC).

- Any COCs involved with Subcontracting are included.

25.2.5 The name and address of client and a project name/number, if applicable.

25.2.6 Description and unambiguous identification of the tested sample(s) including the client identification code.

25.2.7 Date of receipt of sample, date and time of collection, and date(s) of test preparation and performance, and time of preparation or analysis if the required holding time for either activity is less than or equal to 72 hours.

25.2.8 Date reported or date of revision, if applicable.

25.2.9 Method of analysis including method code (EPA, Standard Methods, etc.).

25.2.10 Reporting limits, where applicable

25.2.11 Method detection limits (if requested)

25.2.12 Definition of Data qualifiers and reporting acronyms (e.g. ND).

25.2.13 Sample results.

25.2.14 Condition of samples at receipt.

25.2.15 A statement to the effect that the results relate only to the items tested and the sample as received by the laboratory, except when information is provided by the client. When data is provided by the client there shall be a clear identification of it, and a disclaimer shall be put in the report when the client supplied data can affect the validity of the test.

25.2.16 A statement that the report shall not be reproduced except in full, without prior express written approval by the laboratory.

25.2.17 A signature and title of the person(s) accepting responsibility for the content of the report and date of issue.

25.2.18 When TNI accreditation is required, the lab shall certify that the test results meet all requirements of TNI or provide reasons and/or justification if they do not.

25.2.19 Appropriate laboratory certification number for the state of origin of the sample, if applicable.

25.2.20 If only part of the report is provided to the client (client requests some results before all of it is complete), it must be clearly indicated on the report (e.g., preliminary report). A complete report must be sent once all of the work has been completed.

25.2.21 Any non- Eurofins EMLab P&K subcontracted analysis results are provided as a separate report on the official letterhead of the subcontractor. All Eurofins TestAmerica subcontracting is clearly identified on the report as to which laboratory performed a specific analysis.

Note: Refer to Eurofins EMLab P&K SOP EM-QA-2059 for details on internally applying electronic signatures of approval.

25.2.22 Electronic Data Deliverables (EDDs)

EDDs are routinely offered as part of Eurofins Eurofins EMLab P&K's services in addition to the test report as described in Section 25.2. When NELAP accreditation is required and both a test report and EDD are provided to the client, the official version of the test report will be the combined information of the report and the EDD. Eurofins EMLab P&K offers a variety of EDD formats including Excel and custom files.

EDD specifications are submitted to the IT department by the PM for review and undergo the contract review process. Once the facility has committed to providing data in a specific electronic format, the coding of the format may need to be performed. This coding is documented and validated. The validation of the code is retained by the IT staff coding the EDD.

EDDs shall be subject to a review to ensure their accuracy and completeness. If EDD generation is automated, review may be reduced to periodic screening if the laboratory can demonstrate that it can routinely generate that EDD without errors. Any revisions to the EDD format must be reviewed until it is demonstrated that it can routinely be generated without errors. If the EDD can be reproduced accurately and if all subsequent EDDs can be produced error-free, each EDD does not necessarily require a review.

25.3 Supplemental Information for Test

The lab identifies any unacceptable QC analyses or any other unusual circumstances or observations such as environmental conditions and any non-standard conditions that may have affected the quality of a result. This is typically in the form of a footnote or a qualifier and/or a report comment explaining the discrepancy in the front of the report.

Numeric results with values outside of the calibration range, either high or low are qualified as estimated.

Where quality system requirements are not met, a statement of compliance/non-compliance with requirements and/or specifications is required, including identification of test results derived from any sample that did not meet TNI sample acceptance requirements such as improper container, holding time, or temperature.

Where applicable, a statement on the estimated uncertainty of measurements; information on uncertainty is needed when a client's instructions so require.

When, as requested by the client and agreed to by Eurofins EMLab P&K, the report includes a statement of conformity to specification or standard (see Special Services, Section 7.4), the report shall clearly identify:

- to which results the statement applies,
- which specifications, standard or parts thereof are met or not, and
- the decision rule that was applied (unless the decision rule is inherent in the requested specification or standard, taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule.

Opinions and Interpretations - The test report contains objective information, and generally does not contain subjective information such as opinions and interpretations. If such information is required by the client, the Laboratory Director will determine if a response can be prepared. If so, the Laboratory Director will designate the appropriate member of the management team to prepare a response. The response will be fully documented, and reviewed by the Laboratory Director, before release to the client. There may be additional fees charged to the client at this time, as this is a non-routine function of the laboratory.

Note: Review of data deliverable packages for submittal to regulatory authorities requires responses to non-conforming data concerning potential impact on data quality. This necessitates a limited scope of interpretation, and this work is performed by the QA Department. This is the only form of “interpretation” of data that is routinely performed by the laboratory.

When opinions or interpretations are included in the report, the laboratory provides an explanation as to the basis upon which the opinions and interpretations have been made. Opinions and interpretations are clearly noted as such and where applicable, a comment should be added suggesting that the client verify the opinion or interpretation with their regulator.

25.4 Environmental Testing Obtained From Subcontractors

If the laboratory is not able to provide the client the requested analysis, the samples would be subcontracted following the procedures outlined in the Eurofins EMLab P&K SOP on Subcontracting (SOP No. EM-SM-S-1288).

Data reported from analyses performed by a subcontractor laboratory are clearly identified as such on the analytical report provided to the client. Results from a subcontract laboratory outside of Eurofins EMLab P&K are reported to the client on the subcontract laboratory’s original report stationary and the report includes any accompanying documentation.

25.5 Client Confidentiality

The laboratory will ensure the highest standards of quality and integrity of the data and services provided to our clients.

The laboratory is responsible for maintaining in confidence all client information obtained or created. In situations involving the transmission of environmental test results by telephone, facsimile or other electronic means, client confidentiality must be maintained.

The laboratory will not intentionally divulge to any person (other than the client or any other person designated by the client in writing) any information regarding the services provided by the laboratory or any information disclosed to the laboratory by the client. Furthermore, information known to be potentially endangering to national security or an entity’s proprietary rights will not be released.

Should it be necessary to place any client information in a public domain, the customer shall be informed in advance, unless the client already provides the same information publically and/or has agreed to the release by the laboratory.

Information about the client obtained from sources other than the client (e.g., complainant, regulators) shall be confidential between client and the laboratory. The source of this

information shall be confidential to the laboratory and shall not be shared with the client, unless agreed by the source.

Note: This shall not apply to the extent that the information is required to be disclosed by the laboratory under the compulsion of legal process. The laboratory will, to the extent feasible, provide reasonable notice to the client before disclosing the information.

Note: Authorized representatives of an accrediting authority are permitted to make copies of any analyses or records relevant to the accreditation process, and copies may be removed from the laboratory for purposes of assessment.

25.5.1 Report deliverable formats are discussed with each new client. If a client requests that reports be faxed or e-mailed, the reports are to meet all requirements of this document, including cover letter.

25.6 Format of Reports

The format of reports is designed to accommodate each type of environmental test carried out and to minimize the possibility of misunderstanding or misuse.

25.7 Amendments to Test Reports

Corrections, additions, or deletions to reports are only made when justification arises through supplemental documentation. Justification is documented using the laboratory's corrective action system (refer to Section 12).

The revised report is retained in the LIMS/LabServe, under the "Deliverables" section of the project details page. The original report is maintained in the LIMS/LabServe, under the "Reports" section of the project details page. The revised report will have the word "revised" or "amended" on the report cover page and a unique report ID in LabServe. The "Delivery" section of the project details page in the LIMS/LabServe provides a delivery record of reports and packages.

When the report is re-issued, a notation of "revised report" is placed on the cover/signature page of the report with a brief explanation of reason for the re-issue._

25.8 Policies on Client Requests for Amendments

25.8.1 Policy on Data Omissions or Reporting Limit Increases

Fundamentally, our policy is simply to not omit previously reported results (including data qualifiers) or to not raise reporting limits and report sample results as ND. This policy has few exceptions. Exceptions are:

- Laboratory error.
- Sample identification is indeterminate (confusion between COC and sample labels).

- An incorrect analysis (not analyte) was requested (e.g., COC lists 8315 but client wanted 8310). A written request for the change is required.
- Incorrect limits reported based on regulatory requirements.
- The requested change has absolutely *no possible* impact on the interpretation of the analytical results and there is *no possibility* of the change being interpreted as misrepresentation by anyone inside or outside of our company.

25.8.2 Multiple Reports

Eurofins EMLab P&K does not issue multiple reports for the same work order where there is different information on each report (this does not refer to copies of the same report) unless required to meet regulatory needs and approved by QA.

26.0 ACCREDITATION AND LOGO ADVERTISING POLICY

26.1 Eurofins EMLab P&K, LLC strives to comply with the advertising and logo requirements of all external licensing/accrediting bodies. As such, the accreditation and logo advertising polices of all external licensing/accrediting bodies (i.e. NIST NVLAP, AIHA-LAP, LLC EMLAP and ELLAP, IHLAP, TCEQ, and NYS DOH programs etc.) must be reviewed and all conditions adhered to prior to use in advertising and/or reporting.

26.1.1 When the external licensing/accrediting bodies term is used to reference a laboratory's accredited status, it shall be accompanied by the external licensing/accrediting bodies lab code, where applicable.

26.1.2 The logos are on the Eurofins EMLab P&K website and some marketing material and not used on reports.

26.1.3 A test report bearing the term and/or symbol shall include a statement that the report must not be used by the client to claim product certification, approval, or endorsement by any external licensing/accrediting bodies or agency of the U.S. Government.

26.1.4 A laboratory shall not use the terms certified or registered when referencing its accreditations or conformance to current ISO/IEC 17025 requirements. The correct term is accredited.

26.1.5 When an accredited laboratory uses the term and/or symbol in a contract or proposal, the laboratory shall reference its current accreditation status and provide a copy of, or link to its scope of accreditation.

26.1.6 The external licensing/accrediting body's symbol shall stand by itself and shall not be combined with any other logo, symbol, or graphic.

26.1.7 All use of external licensing/accrediting body logos and accreditation information in advertising or otherwise distributed material must be pre-approved by the management

team (Cluster Leaders and Quality Assurance) to ensure adherence to the advertising and logo requirements of all external licensing/accrediting bodies, as noted in 26.1 above.

27.0 REVISION HISTORY

27.1 For access and review of previous Quality Assurance Manual revisions, contact Quality Assurance.

27.2 Revision 10, December 2015

27.2.1 Updated laboratory information for Chicago, Florida and South San Francisco, Added laboratory information for Atlanta (cover page).

27.2.2 Updated Technical Mangers for Irvine, South San Francisco, Sacramento, Seattle and Las Vegas. Added Technical Manager for Atlanta. (cover page).

27.2.3 Added responsibility for resumption of work for a stop work directive. (section 2.1.8 and 9.4).

27.2.4 Updated analytical method review frequency to biennially in the QA Manager job description (section 3.3.2)

27.2.5 Removed reference to “Lean Manager” in Project Manager job description (section 3.5.3).

27.2.6 Replaced term AIHA with AIHA-LAP, LLC throughout the document.

27.2.7 Corrected NVLAP acronym (section 3.6.4, 3.7.4 and 3.8.4).

27.2.8 Updated glassware washing requirements to “reusable” glassware (section 4.9)

27.2.9 Switched assigning the unique laboratory identification n umber from sample receipt procedure to login procedure (sections 5.3 and 5.4).

27.2.10 Removed records and control chats from controlled document section to records. (section 7.0 and 7.4)

27.2.11 Updated procedure for obsolete documents (section 7.15)

27.2.12 Added a monthly minimum requirement for QC blind recounts (section 8.2).

27.2.13 Added option for non-proficiency testing data for use in creating demonstrations of capability (section 12.4)

27.2.14 Updated requirements for PLM round robin analysis, (section 12.5.3).

27.2.15 Updated requirements for asbestos environmental monitoring (section 13.0)

27.2.16 Updated South San Francisco floor plan

27.2.17 Revised Organizational chart format to remove names (section 19.5).

27.3Revision 11, November 2016

27.3.1 Updated contact information for western region QA Manager on cover page.

27.3.2 Updated Las Vegas laboratory address on cover page.

27.3.3 Updated Technical Mangers for Irvine and, Sacramento on cover page.

27.3.4 Added Atlanta AIHA-LAP, LLC Laboratory ID number and removed "approved signatory" from Technical Managers signature on cover page

27.3.5 Moved statement marked in 1.1.1 to 1.1.2

27.3.6 Added statement that QA Manual confirms to CQMP in section 1.1.2.

27.3.7 Added reference to scopes of accreditation and added lead as an analytical technique in section 1.2.1

27.3.8 Added "NYS DOH" to sections 2.1.1 and 16.1

27.3.9 Added job description for ELLAP Technical Manager and updated job description for Analyst and Laboratory Technician in sections 3.7.2.g, 3.7.4.c.i, 3.8.2.j and 3.11.

27.3.10 Changed "calibration" to "verification" in section 4.4.2

27.3.11 Updated section 4.8.2 to reflect current annual schedule for non-BSC hood calibrations

27.3.12 Added suggested addition of COC under "contract review" in section 6.2.1

27.3.13 Added reference to EMLab P&K signature policy CA-I-P-002 in section 7.3.3

27.3.14 Updated record retention policy for all documents relating to AIHA_LAP, LLC ELLAP and NYS-DOH in section 7.4.2

27.3.15 Updated record retention policy for training documents relating to AIHA_LAP, LLC ELLAP and NYS-DOH in section 7.4.3

27.3.16 Updated computer back-up storage policy in section 7.5.6

27.3.17 Added requirement for client notification of where client data has been affected must be made within two weeks of completing investigation in section 9.4.1

27.3.18 Added requirement for environmental monitoring for lead to section 13.1.1

27.3.19 Updated the accreditation logo and name policy in section 16.0.

27.3.20 Replaced "QAzilla" with "corrective action request" in sections referencing work out of spec or corrective actions, etc.

27.4 Revision 12, March 2017

27.4.1 Updated Western and Central Regional Director name on cover page.

27.4.2 Updated EMLAP, IHLAP and ELLAP Technical Manager requirements.

27.4.3 Added that reporting limits are listed on final reports where applicable in section 5.11

27.4.4 Added if available to the requirement for NIST reference materials in section 12.8.2.c.

27.5 Revision 13, May 2018

27.5.1 QA Manual template conversion from EMLab P&K template to TestAmerica corporate template/structure.

27.5.2 Addition of lab manager role in personnel section

27.5.3 Addition of notification requirements for laboratory changes.

27.6 Revision 14, September 2018

27.6.1 Revision updates to address changes related to ISO 17025:2017 updates

27.6.2 Restoration of “Accreditation and Logo Advertising Policy”

27.7 Revision 15, September 2019

27.7.1 Revision updates to address rebranding to Eurofins TestAmerica and Eurofins EMLab P&K

27.7.2 Removal of Technical Manager approval requirements for annual QA Manual revision in Sec. 3.4.1.

27.7.3 Sec. 18.2 - Added paragraph 6 regarding the requirement concerning management of environmental conditions when work is being performed offsite.

27.7.4 Sec. 20.3.1, Correction to working weight verification schedule.

27.7.5 Updated Table 20-1 to reflect updated calibration frequency for biological safety cabinets.

27.7.6 Updated Org charts, Figure 4-1

27.7.7 Updated Revision History section to reflect and support technical record retention period.

27.8 Revision 16, October 2020

27.8.1 Revision updates to address continued rebranding, and updating references to ‘corporate’ as “NDSC’

27.8.2 Revisions to address changes to NDSC QAM template guidance, including section re-organization, table relocations to appendices.

27.8.3 Revisions to update Org Charts.

27.8.4 Removal of floor plans.

27.8.5 Added Section 4.1.1, Selection of Personnel

27.8.6 Addition of Section 4.3.10 for combined QA Assistant / EHSC role

27.8.7 Revisions to address deployment of personnel in additional network facilities, Sections 5.1, 5.3, and 17.1.5.

27.8.8 Revisions to address risks and opportunities in Section 14.3.2

27.8.9 Revisions to clarify processes for vendor/supplier evaluations, purchasing.

27.8.10 Revisions to include policy on deployment of analysts across network facilities, as well as related policies on PT participation.

27.8.11 Update to Client Confidentiality, Section 25.5 to include notification for information in public domains.

27.8.12 Reference QAzilla # 11048 for revision/approval process details.

Appendix 1.

List of Governing Documents applicable to the QA Manual

(NDSC, KDG and Laboratory SOPs and Policies)

NDSC Doc. No.	Title
CA-C-S-001	Work Sharing Process
CA-I-P-002	Electronic Reporting and Signature Policy
CA-L-P-002	Contract Compliance Policy
CA-Q-M-002	Corporate Quality Management Plan
CA-Q-S-001	Acid and Solvent Lot Testing and Approval Program
CA-Q-S-002	Manual Integrations-
CA-Q-S-006	Detection and Quantitation Limits
CA-Q-S-009	Root Cause Analysis
CA-T-P-001	Qualified Products List
CW-E-M-001	Corporate Environmental Health & Safety Manual
CW-F-P-002	Company-Wide Authorization Matrix
CW-F-P-004	Procurement and Contracts Policy
CW-F-S-007	Fixed Asset Acquisition, Retention and Safeguarding
CW-I-M-001	IT Change Control Procedure Manual
CW-L-P-001	Records Retention Policy
CW-L-P-004	Ethics Policy
CW-L-S-002	Internal Investigation
CW-Q-S-001	Corporate Document Control and Archiving
CW-Q-S-002	Writing a Standard Operating Procedure (SOPs)
CW-Q-S-003	Internal Auditing
CW-Q-S-004	Management Systems Review
CW-Q-S-005	Data Recall Process
CW-Q-S-001	Corporate Document Control and Archiving

Referenced Laboratory SOPs

Eurofins EMLab P&K Doc. No.	Title
EM-QA-S-2059	Document Control & Updating (Document Control and Control of Records, Sec. 3.4.1)
EM-CS-S-1709	Complaint Resolution (Resolving Client Concerns and Soliciting Client Feedback, Sec .10.1)
EM-QA-S-2059	Data Scanning (Document Control and Control of Records – Sec. 14.1.4)
EM-AD-S-1646 EM-AD-S-1261	Lab Training (General Training, Asbestos Analysis Training, Sec. 17.3)
EM-QA-S-2059	Writing SOPs (Document Control and Control of Records, Sec. 19.2)
EM-AD-S-1646 EM-AD-S-3548 EM-AD-S-1619	DOCs (General Training, Selection and Validation of Analytical Methods, Nonstandard Methods for Analysis Sec. 19.4.2)
EM-QA-S-1994 EM-QA-S-1259	MDLs (Quality Control for Sample Analysis, Quality Control for Asbestos Analysis, Sec. 19.7)
EM-AD-S-1601 EM-AD-S-1884	MI (Laboratory Service Management, QAzilla and LabServe Enhancement Procedure, Sec. 19.14.1)
EM-SM-S-1288 EM-SM-S-1993	Sample Receipt / Login, etc… (Sample Receiving, Sample Log In, Sec. 23.2.1.3)

Appendix 2.

Laboratory Certifications, Accreditations, Validations

Eurofins EMLab P&K maintains accreditations, certifications, and approvals with numerous state and national entities. Programs vary but may include on-site audits, reciprocal agreements with another entity, performance testing evaluations, review of the QA Manual, Standard Operating Procedures, Method Detection Limits, training records, etc. Details of accreditation/ certification/licensing, including accredited parameter lists are available for each program at www.emlab.com under "Accreditations".

Appendix 3.

References used to prepare the QA Manual

The QAM has been prepared to be consistent with the requirements of the following documents:

- ANSI/ASQC, E4-1994, "Specifications and Guidelines for Quality Management Systems for Environmental Data Collection and Environmental Technology Programs" (American National Standard, January 5, 1995, or most recent version)
- "EPA Requirements for Quality Management Programs" (QA/R-2) (EPA/240/B-01/002, May 31, 2006).
- EPA 600/4-79-019, *Handbook for Analytical Quality Control in Water and Wastewater Laboratories,* EPA, March 1979.
- *Test Methods for Evaluating Solid Waste Physical/Chemical Methods (SW846), Third Edition, September 1986, Final Update I, July 1992, Final Update IIA, August 1993, Final Update II, September 1994; Final Update IIB, January 1995; Final Update III, December 1996; Final Update IV, January 2008; Final Update V, August 2015.*
- Federal Register, 40 CFR Parts 136, 141, 172, 173, 178, 179 and 261.
- *Manual for the Certification of Laboratories Analyzing Drinking Water (EPA 815-R-05-004, January 2005) (DW labs only)*
- APHA, *Standard Methods for* the Examination of Water and Wastewater, 18th Edition, 19th, 20th, 21st, 22nd and on-line Editions.
- Marine Protection, Research, and Sanctuaries Act (MPRSA).
- Toxic Substances Control Act (TSCA).
- AIHA-LAP, LLC Accreditation Policy Modules,Rev 14
- NIST NVLAP Handbooks 150, Procedures and General Requirements (2020) and 150-3, Bulk Asbestos Analysis (2018-07)

Appendix 4.

Glossary/Acronyms (EL-V1M2 Sec. 3.1)

Glossary:

Acceptance Criteria: Specified limits placed on characteristics of an item, process, or service defined in requirement documents. (ASQC)

Accreditation: The process by which an agency or organization evaluates and recognizes a laboratory as meeting certain predetermined qualifications or standards, thereby accrediting the laboratory.

Accuracy: The degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components which are due to sampling and analytical operations; a data quality indicator. (QAMS)

Analyst: The designated individual who performs the "hands-on" analytical methods and associated techniques and who is the one responsible for applying required laboratory practices and other pertinent quality controls to meet the required level of quality.

Analytical Uncertainty: A subset of Measurement Uncertainty that includes all laboratory activities performed as part of the analysis. (TNI)

Anomaly: A condition or event, other than a non-conformance, that may affect the quality of the data, whether in the laboratory's control or not.

Asbestos Definitions

- Limit of Quantitation: The Limit of Quantitation is 1%.
- Less than One Percent (<1%): When the Laboratory reports a value of <1% using Calibrated Visual Area Estimation, this indicates that asbestos is present in an amount between trace and 0.99%, but cannot be accurately quantified at that level unless a 400 Point Count is performed.
- Non-Detected (ND): The Laboratory reports "Non-Detected" when the laboratory homogenizes the sample in some way or analyzes a sufficient number of sub-samples to obtain a representative analysis whereby no asbestos fibers have been detected in any sub-sample preparations
- Trace: When reporting the results of asbestos analyses using Calibrated Visual Area Estimation that are below the Laboratory's Limit of Quantitation, the Laboratory does not refer to or use the term "Trace"; the Laboratory reports the results as <1%. However, on occasion, samples can contain a "Trace" amount of asbestos. The term "Trace" means that asbestos was found to be present in the sample, but at a level below the minimum concentration needed to quantify at the reporting limit of 0.25% via a 400 Point Count (performed only by client request).

Assessment: The evaluation process used to measure or establish the performance, effectiveness, and conformance of an organization and/or its systems to defined criteria (to the standards and requirements of laboratory accreditation). (TNI)

Audit: A systematic and independent examination of facilities, equipment, personnel, training, procedures, record-keeping, data validation, data management, and reporting aspects of a system to determine whether QA/QC and technical activities are being conducted as planned and whether these activities will effectively achieve quality objectives. (TNI)

Batch: Environmental samples that are prepared and/or analyzed together with the same process and personnel, using the same lot(s) of reagents. A **preparation batch** is composed of one (1) to twenty (20) environmental samples of the same quality systems matrix, meeting the above mentioned criteria and with a maximum time between the start of processing of the first and last sample in the batch to be twenty-four (24) hours. An **analytical batch** is composed of prepared environmental samples (extracts, digestates or concentrates) which are analyzed together as a group. An analytical batch can include

prepared samples originating from various quality system matrices and can exceed twenty (20) samples. (TNI)

Bias: The systematic or persistent distortion of a measurement process, which causes errors in one direction (i.e., the expected sample measurement is different from the sample's true value). (TNI)

Blank: A sample that has not been exposed to the analyzed sample stream in order to monitor contamination during sampling, transport, storage or analysis. The blank is subjected to the usual analytical and measurement process to establish a zero baseline or background value and is sometimes used to adjust or correct routine analytical results. (ASQC)

Calibration: A set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards. (TNI)

1) In calibration of support equipment the values realized by standards are established through the use of reference standards that are traceable to the International System of Units (SI).

2) In calibration according to methods, the values realized by standards are typically established through the use of Reference Materials that are either purchased by the laboratory with a certificate of analysis or purity, or prepared by the laboratory using support equipment that has been calibrated or verified to meet specifications.

Calibration Curve: The mathematical relationship between the known values, such as concentrations, of a series of calibration standards and their instrument response. (TNI)

Calibration Standard: A substance or reference material used to calibrate an instrument (QAMS)

Certified Reference Material (CRM): A reference material accompanied by a certificate, having a value, measurement uncertainty, and stated metrological traceability chain to a national metrology institute. (TNI)

Chain of Custody (COC) Form: Record that documents the possession of the samples from the time of collection to receipt in the laboratory. This record generally includes: the number and types of containers; the mode of collection; the collector; time of collection; preservation; and requested analyses. (TNI)

Compromised Samples: Those samples which are improperly sampled, insufficiently documented (chain of custody and other sample records and/or labels), improperly preserved, collected in improper containers, or exceeding holding times when delivered to a laboratory. Under normal conditions, compromised samples are not analyzed. If emergency situation require analysis, the results must be appropriately qualified.

Confidential Business Information (CBI): Information that an organization designates as having the potential of providing a competitor with inappropriate insight into its management, operation or products. TNI and its representatives agree to safeguard identified CBI and to maintain all information identified as such in full confidentiality.

Confirmation: Verification of the identity of a component through the use of an approach with a different scientific principle from the original method. These may include, but are not limited to Second Column Confirmation; Alternate wavelength; Derivatization; Mass spectral interpretation; Alternative detectors or Additional Cleanup procedures. (TNI)

Conformance: An affirmative indication or judgment that a product or service has met the requirements of the relevant specifications, contract, or regulation; also the state of meeting the requirements. (ANSI/ASQC E4-1994)

Correction: Actions necessary to correct or repair analysis specific non-conformances. The acceptance criteria for method specific QC and protocols as well as the associated corrective actions. The analyst will most frequently be the one to identify the need for this action as a result of calibration checks and QC sample analysis**.** No significant action is taken to change behavior, process or procedure.

Corrective Action: The action taken to eliminate the causes of an existing nonconformity, defect or other undesirable situation in order to prevent recurrence. (ISO 8402)

Daily Reference: A reference sample with a known or accepted quantity of analyte(s) of interest used as a daily calibration standard to verify accuracy.

Data Audit: A qualitative and quantitative evaluation of the documentation and procedures associated with environmental measurements to verify that the resulting data re of acceptable quality (i.e., that they meet specified acceptance criteria).

Data Reduction: The process of transforming the number of data items by arithmetic or statistical calculations, standard curves, and concentration factors, and collation into a more useable form. (TNI)

Deficiency/ Non-conformance: An unauthorized deviation from acceptable procedures or practices, or a defect in an item (ASQC), whether in the laboratory's control or not.

Demonstration of Capability: A procedure to establish the ability of the analyst to generate analytical results of acceptable accuracy and precision. (TNI)

Document Control: The act of ensuring that documents (and revisions thereto) are proposed, reviewed for accuracy, approved for release by authorized personnel, distributed properly, and controlled to ensure use of the correct version at the location where the prescribed activity if performed. (ASQC)

Duplicate Analyses: The analyses or measurements of the variable of interest performed identically on two subsamples of the same sample. The results from duplicate analyses are used to evaluate analytical or measurement precision but not the precision of sampling, preservation or storage internal to the laboratory. (EPA-QAD)

Equipment Blank: Sample of analyte-free media which has been used to rinse common sampling equipment to check effectiveness of decontamination procedures.

External Standard Calibration: Calibrations for methods that do not utilize internal standards to compensate for changes in instrument conditions.

Field Blank: Blank prepared in the field by filing a clean container with pure de-ionized water and appropriate preservative, if any, for the specific sampling activity being undertaken (EPA OSWER)

Field of Accreditation: Those matrix, technology/method, and analyte combinations for which the accreditation body offers accreditation.

Holding Times: The maximum time that samples may be held prior to analyses and still be considered valid or not compromised. (40 CFR Part 136)

Internal Standard: A known amount of standard added to a test portion of a sample as a reference for evaluating and controlling the precision and bias of the applied analytical test method. (TNI)

Internal Standard Calibration: Calibrations for methods that utilize internal standards to compensate for changes in instrument conditions.

Instrument Blank: A clean sample (e.g., distilled water) processed through the instrumental steps of the measurement process; used to determine instrument contamination. (EPA-QAD)

Instrument Detection Limit (IDL): The minimum amount of a substance that can be measured with a specified degree of confidence that the amount is greater than zero using a specific instrument. The IDL is associated with the instrumental portion of a specific method only, and sample preparation steps are not considered in its derivation. The IDL is a statistical estimation at a specified confidence interval of the concentration at which the relative uncertainty is ± 100%. The IDL represents a range where qualitative detection occurs on a specific instrument. Quantitative results are not produced in this range.

Laboratory Control Sample (however named, such as laboratory fortified blank, spiked blank, or QC check sample): A sample matrix, free from the analytes of interest, spiked with verified known amounts of analytes or a material containing known and verified amounts of analytes, taken through all preparation and analysis steps of the procedure unless otherwise noted in a reference method. It is generally used to establish intra-laboratory or analyst specific precision and bias or to assess the performance of all or a portion of the measurement system.

An LCS shall be prepared at a minimum of 1 per batch of 20 or less samples per matrix type per sample extraction or preparation method except for analytes for which spiking solutions are not available such as total suspended solids, total dissolved solids, total volatile solids, total solids, pH, color, odor, temperature, dissolved oxygen or turbidity. The results of these samples shall be used to determine batch acceptance.

Least Squares Regression (1st Order Curve): The least squares regression is a mathematical calculation of a straight line over two axes. The y axis represents the instrument response (or Response ratio) of a standard or sample and the x axis represents the concentration. The regression calculation will generate a correlation coefficient (r) that is a measure of the "goodness of fit" of the regression line to the data. A value of 1.00 indicates a perfect fit. In order to be used for quantitative purposes, r must be greater than or equal to 0.99 for organics and 0.995 for inorganics.

Limit(s) of Detection (LOD) [a.k.a., Method Detection Limit (MDL)]: The MDL is the minimum measured quantity of a substance that can be reported with 99% confidence that the concentration is distinguishable from method blank results, consistent with 40CFR Part 136 Appendix B, August, 2017.

Limit(s) of Quantitation (LOQ) [a.k.a., Reporting Limit]: The minimum levels, concentrations, or quantities of a target variable (e.g., target analyte) that can be reported with a specified degree of confidence.

(QS) Matrix: The component or substrate that contains the analyte of interest. For purposes of batch and QC requirement determinations, the following matrix distinctions shall be used:

Aqueous: Any aqueous sample excluded from the definition of Drinking Water or Saline/Estuarine. Includes surface water, groundwater effluents, and TCLP or other extracts.
Drinking Water: Any aqueous sample that has been designated as a potable or potential potable water source.
Saline/Estuarine: Any aqueous sample from an ocean or estuary, or other salt water source such as the Great Salt Lake.
Non-Aqueous Liquid: Any organic liquid with <15% settleable solids.
Biological Tissue: Any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origin.
Solids: Includes soils, sediments, sludges, and other matrices with >15% settleable solids.
Chemical Waste: A product or by-product of an industrial process that results in a matrix not previously defined.

Air & Emissions: Whole gas or vapor samples including those contained in flexible or rigid wall containers and the extracted concentrated analytes of interest from a gas or vapor that are collected with a sorbant tube, impinger solution, filter, or other device. (TNI)

Matrix Spike (spiked sample or fortified sample): A sample prepared, taken through all sample preparation and analytical steps of the procedure unless otherwise noted in a referenced method, by adding a known amount of target analyte to a specified amount of sample for which an independent test result of target analyte concentration is available. Matrix spikes are used, for example, to determine the effect of the matrix on a method's recovery efficiency.

Matrix Spike Duplicate (spiked sample or fortified sample duplicate): A replicate matrix spike prepared and analyzed to obtain a measure of the precision of the recovery for each analyte.

Method Blank: A sample of a matrix similar to the batch of associated samples (when available) that is free from the analytes of interest and is processed simultaneously with and under the same conditions as samples through all steps of the analytical procedures, and in which no target analytes or interferences are present at concentrations that impact the analytical results for sample analyses.

Method Detection Limit: See Limit of Detection (LOD)-

Negative Control: Measures taken to ensure that a test, its components, or the environment do not cause undesired effects, or produce incorrect test results.

Non-conformance: An indication, judgment, or state of not having met the requirements of the relevant specifications, contract, or regulation.

Observation: A record of phenomena that (1) may assist in evaluation of the sample data; (2) may be of importance to the project manager and/or the client, and yet not at the time of the observation have any known effect on quality.

Performance Audit: The routine comparison of independently obtained qualitative and quantitative measurement system data with routinely obtained data in order to evaluate the proficiency of an analyst or laboratory.

Positive Control: Measures taken to ensure that a test and/or its components are working properly and producing correct or expected results from positive test subjects.

Precision: The degree to which a set of observations or measurements of the same property, obtained under similar conditions, conform to themselves; a data quality indicator. Precision is usually expressed as standard deviation, variance or range, in either absolute or relative terms. (TNI)

Preservation: Any conditions under which a sample must be kept in order to maintain chemical and/or biological integrity prior to analysis. (TNI)

Proficiency Testing: A means of evaluating a laboratory's performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by an external source. (TNI)

Proficiency Testing Program: The aggregate of providing rigorously controlled and standardized environmental samples to a laboratory for analysis, reporting of results, statistical evaluation of the results and the collective demographics and results summary of all participating laboratories. (TNI)

Proficiency Test Sample (PT): A sample, the composition of which is unknown to the laboratory and is provided to test whether the laboratory can produce analytical results within specified acceptance criteria. (TNI)

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

Quality Assurance [Project] Plan (QAPP): A formal document describing the detailed quality control procedures by which the quality requirements defined for the data and decisions pertaining to a specific project are to be achieved. (EAP-QAD)

Quality Control: The overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer; operational techniques and activities that are used to fulfill requirements for quality; also the system of activities and checks used to ensure that measurement systems are maintained within prescribed limits, providing protection against “out of control” conditions and ensuring that the results are of acceptable quality. (TNI)

Quality Control Sample: A sample used to assess the performance of all or a portion of the measurement system. One of any number of samples, such as Certified Reference Materials, a quality system matrix fortified by spiking, or actual samples fortified by spiking, intended to demonstrate that a measurement system or activity is in control. (TNI)

Quality Manual: A document stating the management policies, objectives, principles, organizational structure and authority, responsibilities, accountability, and implementation of an agency, organization, or laboratory, to ensure the quality of its product and the utility of its product to its users. (TNI)

Quality System: A structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required QA and QC activities. (TNI)

Raw Data: The documentation generated during sampling and analysis. This documentation includes, but is not limited to, field notes, electronic data, magnetic tapes, untabulated sample results, QC sample results, print outs of chromatograms, instrument outputs, and handwritten records. (TNI)

Record Retention: The systematic collection, indexing and storing of documented information under secure conditions.

Reference Material: Material or substance one or more properties of which are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials. (TNI)

Reference Standard: Standard used for the calibration of working measurement standards in a given organization or a given location. (TNI)

Sampling: Activity related to obtaining a representative sample of the object of conformity assessment, according to a procedure.

Second Order Polynomial Curve (Quadratic): The 2nd order curves are a mathematical calculation of a slightly curved line over two axis. The y axis represents the instrument response (or Response ratio) of a standard or sample and the x axis represents the concentration. The 2nd order regression will generate a

coefficient of determination (COD or r^2) that is a measure of the "goodness of fit" of the quadratic curvature the data. A value of 1.00 indicates a perfect fit. In order to be used for quantitative purposes, r^2 must be greater than or equal to 0.99.

Selectivity: The ability to analyze, distinguish, and determine a specific analyte or parameter from another component that may be a potential interferent or that may behave similarly to the target analyte or parameter within the measurement system. (TNI)

Sensitivity: The capability of a method or instrument to discriminate between measurement responses representing different levels (e.g., concentrations) of a variable of interest. (TNI)

Spike: A known mass of target analyte added to a blank, sample or sub-sample; used to determine recovery efficiency or for other quality control purposes.

Standard: The document describing the elements of laboratory accreditation that has been developed and established within the consensus principles of standard setting and meets the approval requirements of standard adoption organizations procedures and policies. (TNI)

Standard Operating Procedures (SOPs): A written document which details the method for an operation, analysis, or action, with thoroughly prescribed techniques and steps. SOPs are officially approved as the methods for performing certain routine or repetitive tasks. (TNI)

Storage Blank: A blank matrix stored with field samples of a similar matrix (volatiles only) that measures storage contribution to any source of contamination.

Systems Audit (also Technical Systems Audit): A thorough, systematic, qualitative on-site assessment of the facilities, equipment, personnel, training, procedures, record keeping, data validation, data management, and reporting aspects of a total measurement system. (EPA-QAD)

Technical Manager: A member of the staff of an environmental laboratory who exercises actual day-to-day supervision of laboratory operations for the appropriate fields of accreditation and reporting of results

Technology: A specific arrangement of analytical instruments, detection systems, and/or preparation techniques.

Traceability: The ability to trace the history, application, or location of an entity by means of recorded identifications. In a calibration sense, traceability relates measuring equipment to national or international standards, primary standards, basic physical constants or properties, or reference materials. In a data collection sense, it relates calculations and data generated throughout the project back to the requirements for the quality of the project. (TNI)

Trip Blank: A blank matrix placed in a sealed container at the laboratory that is shipped, held unopened in the field, and returned to the laboratory in the shipping container with the field samples.

Uncertainty: A parameter associated with the result of a measurement that characterizes the dispersion of the value that could reasonably be attributed to the measured value.

Acronyms:

AIHA-LAP, LLC – AIHA Laboratory Accreditation Programs, LLC
CAR – Corrective Action Report
CCV – Continuing Calibration Verification
CF – Calibration Factor
CFR – Code of Federal Regulations

COC – Chain of Custody
DOC – Demonstration of Capability
DQO – Data Quality Objectives
DUP - Duplicate
EHS – Environment, Health and Safety
ELLAP (AIHA-LAP, LLC) - Environmental Lead Laboratory Accreditation Program
EMLAP (AIHA-LAP, LLC) – Environmental Microbiology Laboratory Accreditation Program
EPA – Environmental Protection Agency
GC - Gas Chromatography
GC/MS - Gas Chromatography/Mass Spectrometry
HPLC - High Performance Liquid Chromatography
ICP - Inductively Coupled Plasma Atomic Emission Spectroscopy
ICP/MS – ICP/Mass Spectrometry
ICV – Initial Calibration Verification
IDL – Instrument Detection Limit
IH – Industrial Hygiene
IHLAP (AIHA-LAP, LLC) – Industrial Hygiene Laboratory Accreditation Program
IS – Internal Standard
LCS – Laboratory Control Sample
LCSD – Laboratory Control Sample Duplicate
LIMS – Laboratory Information Management System
LOD – Limit of Detection
LOQ – Limit of Quantitation
MDL – Method Detection Limit
MDLCK – MDL Check Standard
MDLV – MDL Verification Check Standard
MRL – Method Reporting Limit Check Standard
MS – Matrix Spike
MSD – Matrix Spike Duplicate
NYS DOH – New York State Department of Health
SDS - Safety Data Sheet
NELAP - National Environmental Laboratory Accreditation Program
NIST NVLAP – National Institute of Standards and Technology National Voluntary Laboratory Accreditation Program
TCEQ – Texas Commission of Environmental Quality
TNI – The NELAC Institute
QAM – Quality Assurance Manual
QA/QC – Quality Assurance / Quality Control
QAPP – Quality Assurance Project Plan
REP – Replicate
RF – Response Factor
RPD – Relative Percent Difference
RSD – Relative Standard Deviation
SD – Standard Deviation
SOP – Standard Operating Procedure
TAT – Turn-Around-Time
VOA – Volatiles
VOC – Volatile Organic Compound