Attachment 4

Environmental Monitoring Sampling & Analysis Plans

Groundwater Sampling & Analysis Plan

POST CLOSURE GROUNDWDATER SAMPLING & ANALYSIS PLAN

WOODLAND MEADOWS NORTH
MID 000 810 408

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Golder Associates

Table of Contents

Table of Contents-continued

List of Tables

List of Figures

List of Appendices

1.0 INTRODUCTION

This document presents the Post Closure Groundwater Sampling and Analysis Plan (SAP) for the Woodland Meadows North Hazardous Waste Landfill (WMNL), located in Canton Township, Wayne County, Michigan. The SAP was prepared on behalf of the site owner/operator by Golder Associates Inc. of Farmington Hills, Michigan, and has been developed to meet detection monitoring requirements of applicable local, State and Federal regulations.

The objectives and protocol included within the SAP meet the performance requirements of 40 CFR 264.97(d) and R299.9611 of Part 111, Act 451, Hazardous Waste Management, of the Natural Resources and Environmental Protection Act, 1994 PA 451, as amended (Part 111).

1.1 Purpose and Scope

The purpose of this SAP is to provide a means for early detection of a potential release to groundwater in accordance with applicable Act 451, Part 111 rules. This SAP details the design of the monitoring system for the WMNL, presents procedures for monitoring groundwater chemistry and establishes sampling parameters and frequencies for detection monitoring. This SAP serves as a guidance document for personnel performing site monitoring during post closure monitoring at the facility.

Included within this SAP are: descriptions of the hydrogeologic setting of the site; the proposed monitoring well network and the basis for its configuration; leachate and surface water monitoring locations; monitoring frequencies; monitoring parameters; sampling and analysis procedures; and a discussion of statistical methodology/approach. The proposed groundwater monitoring program is based on the hydrogeologic characteristics of the site and surrounding area and the potential influence of the landfill on the local hydrogeologic system.

Also included with this SAP is a provision for reducing monitoring frequency consistent with the United States Environmental Protection Agency (USEPA) Memorandum dated December 15, 2016 and titled, *Guidelines for Evaluating the Post closure Care Period for Hazardous Waste Disposal Facilities under Subtitle C of RCRA,* issued by the Office of Resource Conservation and Recovery and as approved by MDEQ in a May 24, 2017 meeting with WMNL regarding the new 10-year Post Closure Care (PCC) license. The USEPA guidance was published to clarify the requirements outlined in 40 CFR 264.117.

1.2 Site Location

The WMNL is located in Canton Township, Wayne County, Michigan. WMNL is a closed landfill located in Section 36, Township 2 South, Range 8 East, in Wayne County, Michigan. The site is bound to the east by Hannan Road, to the south by the Conrail Railroad track and the closed Woodland Meadows South Landfill, and to the west by Lotz Road. Figure 1, Site Location Map, depicts the general location and approximate areal extent of the WMNL, referenced to nearby roads and topography.

1.3 Facility Description

The WMNL disposal facility became operational in 1974. In 1975, Michigan Waste Systems, Inc. began operating the landfill on a 57-acre parcel of land. Later that same year, WMNL was expanded, with the appropriate regulatory approval, to encompass the 97-acre site as shown on Figure 1. Approximately 61 acres of the 97-acre site were eventually landfilled. The remaining 36 acres remain undeveloped. The site was used for the co-disposal of municipal and industrial waste and was operated under the RCRA Interim Status Standard from November 1980 until March 1983. Hazardous waste disposal activities at the site were terminated in January 1983. The facility continued to receive non-hazardous wastes until March 1983. Closure of the WMNL included construction of a minimum 5-foot thick compacted clay cover. Final closure was certified by Waste Management in November 1985, and approved by the Michigan Department of Natural Resources (MDNR) on September 30, 1992.

Figure 2, Site Plan and Monitoring Well Location Map depicts the site layout as well as buildings and other features along with the location of the site monitoring wells.

2.0 SITE GEOLOGY & HYDROGEOLOGIC CONDITIONS

The following portions of this section present a detailed review of the site (i.e., local) and regional hydrogeologic conditions at, and surrounding, the site. The local site and regional hydrogeologic characterization are based on past investigations and studies conducted by various entities.

2.1 Hydrogeologic Setting

WMNL is located within a relatively flat-lying glacial till plain. The regional geologic setting includes glacial drift deposits overlying sedimentary bedrock. The bedrock in the region consists of highly variable sedimentary sequences of Devonian age limestone, dolomite, and shale. Bedrock is overlain by tens to hundreds of feet of glacial deposits from at least four major glacial events in the Late Pleistocene Epoch.

The predominant glacial unit underlying the site is relatively homogeneous silty clay till that typically extends from ground surface to a depth of approximately 70 feet. Lenses and seams of sand and silt have been encountered within or at the bottom of the silty clay till. These lenticular deposits range in thickness from less than an inch to over 30 feet.

The silty clay till is underlain by a stratum of very dense, coarser-textured basal (lodgement) till. The basal till overlies bedrock at a depth of about 100 feet below ground surface. The gradation of the basal till varies from sand with some silt and some gravel to hard gray clay and silt with some fine to coarse sand and some gravel. The basal till was likely deposited beneath advancing glaciers as they overrode the underlying bedrock. These glaciers scoured and picked up both bedrock fragments and glacial deposits as they advanced. The resulting basal till is highly over-consolidated and of variable texture. Cobbles and boulders are occasionally present within the basal till. Although the majority of the basal till is a low permeability cohesive clay and silt, stringers and seams of silt, sand, or gravel are present.

The basal till unit is considered the uppermost water bearing unit and the primary pathway for horizontal groundwater flow. A north-south oriented groundwater divide exists within the basal till. Historically, horizontal groundwater flow within the basal till is towards the north, northeast, and northwest beneath the site.

Surface runoff at the site is collected in a perimeter ditch that flows to the Bell Drain, which bounds the eastern margin of the site. The Bell Drain flows northeast and eventually discharges to the Lower River Rouge.

The hydrogeologic monitoring system at the WMNL consists of 12 groundwater monitoring wells and two piezometers, GA-46W and GA-51, which are used for static water level measurements only. These wells are installed in laterally discontinuous sand lenses present within the silty clay or basal till, which overlies the bedrock at the site. Table 1, Groundwater Monitoring System, presents the pertinent well construction

information for each of the on-site monitoring wells. It is noted that monitoring well E7A has replaced monitoring well MW-7AR for future sampling events as approved by MDEQ.

2.2 Groundwater Flow

Groundwater flow is present under confined conditions and can be described as a function of the aquifer permeability, hydraulic gradient, porosity, and local recharge conditions. Golder calculated groundwater elevations based on water levels measured during November 2016, and the top of the surveyed well casing elevations. The water level data obtained during November 2016 for the WMNL have been used to develop Figure 3, Groundwater Elevation Contour Map Basal Till – May 2017. As shown on Figure 3, the general direction of groundwater flow is toward the north-northwest across the WMNL, consistent with historic findings.

Figure 4, Groundwater Elevation Contour Map Sand Lens – May 2017, shows a groundwater contour map based on water level data from the wells that represent the "sand lens unit" at the site. The map suggests a groundwater elevation pattern similar to that for the basal till, with groundwater flow generally to the north-northwest. Because the "sand lens unit" is laterally discontinuous, groundwater within the sand lenses flow consistent with the low permeability tills that encase them. This hydrogeologic condition is verified by the direction of groundwater flow to the north-northwest being generally consistent between monitoring events.

2.3 Groundwater Flow Velocity

Groundwater flow velocity at the site was calculated using a derivation of Darcy's Law. Specifically,

$$V = \frac{K * i}{n_e}$$

Where:

$V =$ Groundwater flow velocity $\left(\frac{feet}{day}\right)$

$K =$ Average Permeability of the aquifer $\left(\frac{feet}{day}\right)$

$i =$ Horizontal hydraulic gradient $\left(\frac{feet}{feet}\right)$

$n_e =$ Effective porosity

Based on aquifer performance tests previously conducted at the site, the average hydraulic conductivity of the groundwater flow system is approximately 0.0085 foot/day. Groundwater flow velocity has been calculated across the site at flow path "A" on Figure 3. The table below summarizes the details of our calculations, using the determined hydraulic gradients, an assumed effective porosity of 20 percent (based on silt content) and the average hydraulic conductivity for the respective unit. The groundwater flow velocity at the site is approximately 0.0005 foot/day (0.19 foot/year).

Groundwater Flow Velocity Calculations (November 2016)					
Flow Path	Hydraulic Gradient (I) (feet/feet)	Average Hydraulic Conductivity (K) (feet/day)	Assumed Effective Porosity (n_e)	Calculated Groundwater Flow Velocity (feet/day)	Calculated Groundwater Flow Velocity (feet/year)
A	0.0124	0.0085	0.20	0.0005	0.19

Note: Horizontal hydraulic gradients November 2016 monitoring event were along a flow path oriented perpendicular to the potentiometric contours. The average horizontal hydraulic gradient was calculated between contour lines.

2.4 Time of Travel

The estimated transport time of potential leachate in the groundwater is dependent on the following variables:

- Chemical composition of the permeant (leachate)
- Hydraulic conductivity of the aquifer
- Horizontal distance of the leachate source to the receptors
- Hydraulic gradient
- Permeability of soils underlying the landfill

For this analysis, transport time will be predicted assuming:

- Darcy's Law is valid
- Homogeneous isotropic, saturated soil state
- The current water table regime will remain relatively constant in the future

The above assumptions present a very conservative assessment of the travel time to a potential receptor. Two further assumptions provide the greatest influence in this conservative assessment.

First is the selection of the receptor as a hypothetical drinking water well, located 100 feet from the waste limits (just beyond the facility property line), as the closest point of exposure (POE) (i.e., note that closest existing drinking water well is more than 1,600 feet sidegradient of site). The time of travel calculation presented in the table below is for this hypothetical downgradient drinking water well located 100 feet beyond the facility property boundary. Other drinking water sources are considerably further downgradient from the waste limits and are typically located in different, hydraulically separate groundwater regimes. In general, drinking water is in the area of the WMNL is from municipal sources and not private water wells.

Second is the conservative assumption that the calculated time of travel to the hypothetical drinking water well ignores travel time through the underlying low permeability till units (i.e., no travel time is assumed through the tills underlying the landfill). Based on these two highly conservative assumptions, the estimated travel time for a potential contaminant to migrate from the waste unit boundary to the hypothetical downgradient drinking water well is approximately 526 years (see table below) when calculated using the groundwater velocity reported above for the November 2016 monitoring event. An added degree of conservatism in this calculation is realized when considering no account was made for natural attenuation processes such as sorption, which is a prevalent characteristic of the underling till units.

Time of Travel Calculation (Hypothetical Drinking Water Well Located 100 feet from Site Property Boundary			
Calculated Groundwater Flow Velocity (feet/year)	**Distance to Receptor**		**Years Required to Pass through to Receptor**
0.19	Hypothetical Drinking water well Located just beyond property boundary	100 feet	526 years

2.5 Surface Water Hydrology

Surface water from the Bell Drain is collected from S02U (upstream) and S01D (downstream) of the WMNL. Results of surface water sampling are qualitatively compared upstream to downstream to identify evidence of surface water quality deterioration as water flows past the site.

3.0 POST CLOSURE DETECTION MONITORING PROGRAM

This SAP was developed in accordance with 40 CFR 264 and R299.9612. It describes the monitoring well network, monitoring parameters, and sampling frequency for monitoring in accordance with these regulations. Based on communication between WMNL and MDEQ dated March 4, 2014, an Addendum to Environmental Monitoring Plan Selection of Indicator Parameters (a.k.a., secondary Indicators), Monitoring Well Selection & Proposed Statistical Update was submitted for the facility. The selected inorganic indicator parameters have been retained for routine detection monitoring at WMNL

3.1 Groundwater Detection Monitoring System

The hydrogeologic monitoring system at the WMNL consists of 12 groundwater monitoring wells and two piezometers, GA-46W and GA-51, which are used for static water level measurements only. The wells are installed in sand lenses within the glacial till or in the basal till itself, which overlies the bedrock at the site. Table 1 presents the pertinent well information for each of the on-site monitoring wells. The number, spacing, and depth of the groundwater monitoring wells were selected based on characterization of the site-specific hydrogeologic conditions, which are described in previous hydrogeologic studies completed in conjunction with the requirements of 40 CFR 264 Subpart F and Part 111.

The proposed monitoring well network is listed on Table 1. The approximate locations of the wells in the monitoring program are illustrated on Figure 2. The monitoring system consists of groundwater monitoring wells screened in both the Upper Sand Lens Unit and the Basal Till Aquifer. Copies of the groundwater monitoring well logs are included in Appendix A, Monitoring Well Logs. The monitoring well network provides representative upgradient and downgradient coverage of the site. The monitoring wells are positioned at locations most likely to provide early detection of a potential landfill release to groundwater.

3.2 Groundwater Monitoring Frequency

Based on the hydrogeologic information presented above, Golder has evaluated the monitoring frequency in consideration of the following:

a. Lithology of the aquifer and unsaturated zone
b. Hydraulic conductivity of the aquifer and unsaturated zone
c. Groundwater flow rates
d. Time of travel from landfill property boundary to downgradient drinking water well (receptor)
e. Resource value of the aquifer

In addition, site-specific information including the site compliance monitoring history, VOC detection history for the groundwater, site-specific leachate data, and other-site specific data have been reviewed to supplement the items listed above.

Site hydrogeologic data indicate that, an alternate sampling frequency is appropriate for WMNL during the extended post closure care period based on: (1) hydrogeology, (2) hydraulic conductivity of the saturated and unsaturated zone, (3) groundwater flow velocity, (4) groundwater travel times and travel distance, and (5) groundwater monitoring results.

Review of the site Hydrogeologic data indicates that the slow movement of groundwater within the uppermost aquifer, the low permeability of the compacted clay liner, and the resulting time of travel to the closest receptor are consistent with conditions that support an alternate monitoring frequency while maintaining appropriate environmental protection. Because of the low-permeability of liner materials and t slow rate of groundwater flow, reducing monitoring requirements to annual for the inorganic and VOC parameters is appropriate.

The sampling frequency and the constituents that will be analyzed for the detection monitoring program are listed on Table 2, Groundwater Monitoring Parameters. These parameters were determined based on historic groundwater monitoring at the site and are representative of the previously accepted waste streams as well as the historical monitoring program at the site. As described herein, groundwater monitoring will be conducted annually.

3.3 Sampling & Analytical Requirements for New/Replacement Monitoring Wells

Should it become necessary to install a replacement monitoring well, an appropriate number of groundwater samples must be collected to establish a statistically valid background population for each of the proposed monitoring parameters. Each well requires a minimum of four independent background samples to establish background; however, eight independent samples provide better statistical power and are recommended. Since the wells on site have been sampled for many years, existing wells have adequate background. If a replacement well is installed, four new independent background samples will be collected and the data will be statistically compared (using a Mann-Whitney or equivalent test) with the historical data from the well that was replaced. If the data from the replacement well are statistically similar to the well requiring replacement, the data from the replacement well will be merged with the historical data and the statistical analysis will be performed on the entire data set. If the data from the replacement well are statistically different, then a total of eight background data points will be collected prior to the performance of statistical analysis.

Background groundwater samples will be required from any *new* monitoring well installed starting with the earliest quarterly sampling event after installation. The groundwater samples will be analyzed for the inorganic indicator parameters identified on Table 2, unless an alternate parameter list is requested by the MDEQ. Based on the slow movement of groundwater flow, we anticipate, eight independent samples will be obtained on a semi-annual sampling schedule until a minimum of eight

independent samples are collected from each new well. Following the initial two year period, the statistical plan will be updated to include the new well(s). After background has been established, the sampling program for the new wells will revert to the schedule listed on Table 2.

4.0 LEACHATE COLLECTION SYSTEM MONITORING

The following sections outline the monitoring to be followed for primary leachate system monitoring. Actual sampling methodologies are included in Section 6.0 of this document.

4.1 Leachate Monitoring

In addition to groundwater monitoring, the WMNL has a leachate collection system that is sampled annually at the leachate collection tank, designated as WMNMH-1. The location of the tank is shown on Figure 2. Leachate monitoring data will be submitted in the annual report. Leachate data will be evaluated and reported in the *Evaluation of Post-Closure Care* (EPCC) report, which is part of the process that will be implemented for evaluating the post-closure care period through a performance based functional stability analysis. The purpose of this analysis is to demonstrate that site-specific conditions adequately minimize risk (or do not pose an unacceptable risk) to human health and the environment to justify ending post closure care, or if the performance-based criteria determines additional monitoring is needed to protect human health and the environment, recommended maintenance and monitoring activities can be proposed.

The volume of liquid evacuated from the landfill is recorded, at a minimum, on a monthly basis and included in the Operating Record. Evacuated liquids are removed, transferred to holding tanks, and properly disposed.

4.2 Leachate Monitoring Parameters

Leachate will be monitored for chemical parameters in accordance with Part 111 and the sites post closure operating license. The annual leachate monitoring parameters are presented on Table 3, Leachate Monitoring Parameters.

5.0 SURFACE WATER MONITORING

Surface water samples are to be collected annually from two locations in Bell Drain, which runs along the east side of the landfill. Surface water from the Bell Drain is collected from S02U (upstream) and S01D (downstream) of the WMNL. The surface water monitoring parameters are listed in Table 4, Surface Water Monitoring Parameters. Results of surface water sampling are compared qualitative upstream to downstream to identify evidence of surface water quality deterioration as water flows past the site. Figure 2 includes the surface water sampling locations. Section 6.4 of this report includes sampling methods associated with surface water. Similarly, sample handling and shipment, as well as QA/QC procedures, are described in Section 6.4. Section 7.0 includes laboratory practices for surface water.

6.0 FIELD SAMPLING PROCEDURES

Water quality sampling of the WMNL monitoring system will be performed in accordance with the provisions of Part 111 and EPA Document SW-846, which is incorporated into this document by reference. The field sampling procedures detailed below are designed to be protective of human health and the environment. Upon approval of this SAP, that includes the sampling and analysis information, the MDEQ Director will be notified that the plan has been placed in the site's operating record.

6.1 Groundwater Sampling

The following sections include the steps to be followed by the field sampling crew.

6.1.1 Determination of Static Water Level

In accordance with general sampling standards, a full round of static water level measurements (depth to water from top of casing) will be recorded using a water level measurement instrument, accurate to 0.01-feet prior to sampling. A complete round of water level measurements will be recorded prior to initiation of pre-sample purging at any well to avoid temporal variations. Measurements will be made from the top of the casing, with the elevation of all casings in the monitoring well systems related to a permanent survey mark using United States Geological Survey datum. Recorded water level data will be used by WMNL to establish groundwater flow rate and direction each time groundwater is sampled.

6.1.2 EVALUATION OF GROUNDWATER FLOW RATE & DIRECTION

Static water levels will be collected annually during each groundwater sampling event. These data will be collected in accordance with Section 6.1.1 of this Plan during each routine groundwater monitoring event. These measurements will be used to calculate piezometric elevations, which will be used to generate groundwater elevation contours maps. Estimated groundwater flow velocity and direction will be determined based on the information provided on the piezometric surface contour maps and be included in the text of the report.

6.1.3 Well Evacuation

Groundwater samples will be collected to be as representative of the site's groundwater quality as possible. To obtain samples that are representative of the groundwater, monitoring wells will be purged and sampled using dedicated monitoring devices. Samples will be collected immediately after purging, or within 24 hours, if a well is pumped dry during purging. Well purging is typically performed utilizing dedicated bladder pumps. In the event of an equipment failure, disposable sampling equipment may be used.

Groundwater purged from the well can be discharged onto the ground away from the well unless there is known contamination. If there is known contamination, the purge water must be containerized and disposed

properly. Purged groundwater will not be allowed to re-enter the well or the well protective casing nor should there be ponding of the water around the well.

6.1.4 Micro-Purge (Low Flow) Sampling Techniques

Growing research demonstrates that the use of low-flow sampling devices, left in place or dedicated to each monitor well, can greatly reduce the volume of water that must be purged from a well before representative samples can be collected. This principle is based on the premise that water flowing through the well screen results in sufficient exchange of water to provide representative samples without removing overlying standing water (Robin and Gillham 1987; Kearl et al. 1992; Powell and Puls, 1993). The practice of low-rate/low-volume purging is referred to as micro-purge sampling.

Although the traditional well purging technique may be adequate for sampling, WMN plans to employ micro-purge sampling (i.e., low-flow sampling) for the collection of groundwater. Traditional well purging methods are not recommended because more representative samples can be obtained with the micro-purge technique. Any changes to the sampling technique will be presented to MDEQ for approval and comment prior to implementation.

The following paragraphs describes measuring and documenting the field parameters and well purging techniques specific to low flow sampling.

6.1.4.1 Field Parameters Measurements with SmarTroll

InSitu Instruments' SmarTroll (or similar) will be used to record field parameters, facilitate report preparation, and provide confidence in the equilibration process. The following steps are followed during low flow purging techniques:

- Field measurements of pH, specific conductance, temperature, turbidity, DO, and ORP must be recorded during well purging.
- Turbidity measurements may be made with a separate instrument using water collected after it discharges from the flow-through cell.
- Inspect the flow-through cell regularly to assure that particulates are not building up within the device and possibly interfering with the measurements.
- If the cell needs to be cleaned while purging a well, continue purging while disconnecting the cell and cleaning it. Then re-attach the cell and continue recording the parameter values.
- Verify that no air is trapped within the flow-through cell and that the probes are fully submerged at all times.
- For low-flow purging, field measurements must be recorded every 3 to 5 minutes and purging will continue until the measurements stabilize.
- In the event of a malfunctional SmarTroll, other water quality devices may be temporarily used to record periodic measurements until pH, specific conductance, temperature, and dissolved oxygen (DO), have stabilized.

6.1.4.2 Parameter Stabilization Criteria

Low-flow (minimal drawdown) groundwater sampling procedures will be used for purging and sampling monitoring wells that will sustain a pumping rate of at least 100 milliliters per minute (ml/min) without purging dry. During purging the goal is to avoid excessive drawdown within the well and minimize disturbance of the water column. Field water quality parameters recorded during purging will be used as criteria to determine when purging has been completed.

Most wells are screened with the top-of-screen below the static water level in the well. In these wells (1) the water level in the well must not be drawn down below the top of scree, and (2) stabilization of the water column will be considered achieved when three consecutive water level measurements vary by 0.3 foot or less at a pumping rate of no less than 100 ml/min.

If the static (pre-pumping) water level is below the top-of-screen, the water level must not be drawn down below the top of pump where it can be accurately measured.

Field water quality parameters (temperature, pH, turbidity, conductivity, dissolved oxygen and oxidation reduction potential) will be measured but not all will be used for determining stabilization. Stabilization will be considered achieved and purging will be considered complete when three consecutive measurements of each field parameter vary within the following limits:

- 0.1 standard units for pH
- 5% for specific conductance
- 0.2 Mg/L or 10% for DO > 0.5 mg/l (whichever is greater). Where DO < 0.5 mg/l, no stabilization criteria apply.
- Turbidity measurements less than 5 NTU (The goal when sampling is to attain a turbidity of less than 5 NTU; however, samples may be collected where turbidity is greater than 5 NTU and the other stabilization criteria described above are met.)
- Temperature and ORP – record only, no stabilization criteria

6.1.5 Wells that Purge Dry

If a monitoring well is purged dry when pumped at a rate of 100 milliliters/minute or less or if low-flow minimum purge passive sampling is unsuccessful, it must be allowed to recover before collecting samples. Where wells purge dry, field parameter stabilization requirements do not apply. When a well purges dry:

- Document the date and time for both well evacuation and sample collection.
- Evacuate the well until it yields little or no water.
- Record the total volume of water removed.
- Allow the well to recover no more than 24 hours before collecting samples.
- Record the water level again before sampling to document the amount of recovery in the well.

- Sample in the following order (as applicable):
- Organics
- Inorganics
- Metals
- Record field parameters after collecting the samples for laboratory analysis.

If recharge is insufficient to fill all necessary sample bottles, samplers will note this, contact the Project Manager, and fill as many sample bottles as possible. Allow the well to recover another 24 hours and fill the remaining sample containers.

6.1.6 Field Measurements

Measurements of pH, temperature, and conductivity will be taken during purging to verify stabilization of parameters as described above before sample collection. The final measurement will be reported as the sample measurement.

6.1.7 Field Forms

Field activities will be documented by the field sampling personnel using Field Information Logs. The individual Field Information Logs will be completed by the field personnel performing the field sampling and physical parameter monitoring activities. The specific information that is required for documentation is both listed on the form and described in previous sections of this SAP. Field Information Logs will be signed by the appropriate individual(s) performing the field task and a copy will be filed in the site records. An example Field Information Log is included in Appendix B, Field Information Forms & Chain-of-Custody. Use of a different form does not constitute a deviation from this SAP.

6.1.8 Sample Collection

Groundwater samples will be collected using dedicated bladder pumps or portable ProActive pumps. Groundwater samples will be collected by experienced personnel who have thoroughly reviewed this monitoring plan and are familiar with the sampling procedures. Samples will be collected with only inert non-reactive sampling equipment, with care taken to avoid cross-contamination. Samples will be transferred directly from the sampling system to the appropriate container. The wells will be sampled in an upgradient to downgradient order based on historical data gathered from the site. Also, wherever applicable, wells with known contamination will be sampled last to preclude cross-contamination.

6.1.9 Sample Preservation

Groundwater samples will be collected in the designated size and type of containers required for specific parameters, as specified in the laboratory's QA Manual. A copy of the current laboratory's manual is included in Appendix C, Laboratory QA/QC Manual. Sample containers will be filled in such a manner as not to lose any preservative chemicals from the containers, and in the case of VOAs, to prevent air from being trapped in the vials after filling.

6.1.10 Field Filtration

Samples to be tested for dissolved metals will be field filtered. Samples will be filtered through a clean disposable in-line 0.45 micron membrane filter into the appropriate sample vessel, containing the specified preservative for metals analysis. Filtering will occur immediately during sample extraction. The sample will then be stored at a temperature approximately 4°C for transportation to a laboratory for analysis, pursuant to US EPA SW-846 protocols.

6.1.11 Chain-of-Custody Forms

Copies of the Chain-of-Custody forms will be filed in the Operating Record after the laboratory has returned the forms with the analytical results. A copy of an example Chain-of-Custody form for the current laboratory is included in Appendix B. Use of a different Chain-of-Custody form does not constitute a deviation from this SAP.

6.1.12 Sample Shipment

Groundwater samples will be preserved as previously described, stored in appropriate containers, and labeled. Samples will be cooled to approximately 4°C and transported to the laboratory for analysis. Groundwater and surface water samples will not be stored/transported in the same cooler(s) as leachate samples.

6.1.13 Well Maintenance

Wells are to be visible throughout the year, be clearly labeled, securely capped, properly vented, and covered with locking protective casings. MDEQ will be notified before replacing or performing significant repairs to any monitoring well. Minor repairs, such as repairing or replacing protective casings or surface seals, and dedicated pumps may be performed as part of routine maintenance.

6.2 Leachate Collection System Sampling

Sampling protocols used for sampling the leachate at the site are the same as those presented for Groundwater Sampling, Section 6.1, with the following differences:

- Static water level determination is not required or recommended for leachate sampling.
- Excess liquids obtained during sampling will be returned to the leachate system.
- Leachate samples will be preserved as previously described, stored in appropriate containers, and labeled. Samples will be cooled to approximately 4°C and transported to the laboratory for analysis. Leachate samples will not be field filtered or stored in the same cooler as groundwater samples or surface water.
- Blanks are not collected during leachate sampling.

6.3 Surface Water Sampling Methods

Field procedures used for sampling the surface and subsurface waters are the same as presented above in Section 6.1, Groundwater Sampling, with the following differences:

- Grab samples will be collected utilizing a decontaminated surface water sampling device.
- Samples will be collected from the upstream and downstream surface water monitoring locations. Samples will be collected from the flowing segments of the stream, and transferred to the appropriate sample containers.
- Blanks are not associated/collected with surface water sampling.

Surface water samples will be preserved as previously described, stored in appropriate containers, and labeled. Samples will be cooled to approximately 4°C and transported to the laboratory for analysis. Surface water samples will not be stored in the same coolers as leachate samples.

6.4 Monitoring Well Installation & Development

Generally, monitoring wells will be installed and constructed using the procedures described herein. The MDEQ will be notified prior to new monitoring well installation, replacement, and/or significant repair activities and when documentation of the procedures specified in the following sections are placed in the operating record. Specific well locations and installation depths and any other planned modifications to the well installation procedures described in this SAP will also be provided to MDEQ in advance for review and approval.

Drilling and sampling equipment will be steam-cleaned before arrival at the site and between each soil boring and monitoring well installation. Soil sampling tools will be properly cleaned before each boring and thoroughly rinsed with potable water between uses. Monitoring well casing and screens will be properly handled and decontaminated prior to installation.

Monitoring wells will generally be constructed with 2-inch diameter, 5-foot long PVC screens (or as otherwise appropriate and in concurrence with the MDEQ Hazardous Waste Geologist) and 2-inch diameter PVC riser pipe. As indicated above, the groundwater monitoring wells will be installed through hollow-stem augers before their removal from the borehole. The annular space around the monitoring well screen will be backfilled with a washed sand filter pack at a size able to be retained by the screen to a minimum of 3 feet above the top of the well screen.

A minimum 2-foot thick bentonite seal will be placed above the filter pack and the well will be developed. Well development will be complete by alternately, and repeatedly, pumping and surging the well until relatively clear and turbid free water is observed coming from the borehole. During development, the field parameters of temperature, pH and specific conductance will be recorded until stabilization has been achieved in accordance with prescribed tolerances.

Following development, the remainder of the annular space within the borehole will be tremie backfilled under low pressure with a high-solids, pH neutral, slurry grout made of a bentonite/cement mixture, as the augers are extracted from the borehole. Care will be taken to prevent the slurry from migrating into the filter pack material.

Wells will be completed approximately 2.5 feet above the ground surface and secured inside a lockable protective casing. The protective casing will be locked and clearly labeled for identification purposes. Each protective casing will be set with a thick concrete pad approximately 2 feet in diameter. Weep holes will be drilled in the protective casing and the annular space between the well casing and protective casing will be filled with pea stone of sufficient size to prevent loss through the weep hole.

6.5 Monitoring Well Decommissioning

Monitoring well decommissioning will be completed under the full-time observation of qualified personnel. Prior to undertaking well decommissioning, including wells that are decommissioned in place (see below), the MDEQ will be notified and details regarding wells and decommissioning procedures will be provided.

Where appropriate, hollow-stem augers will be used to overdrill the existing monitoring well casing and remove the annular seal materials. If possible, the groundwater monitoring well casing and screen will be removed through the inside of the hollow-stem augers. If the casing cannot be extracted through the inside of the augers, attempts will be made to remove the well and the augers together. The borehole will then be re-entered with the hollow-stem augers to ensure that the well casing and annular seal materials have been removed. The borehole will then be tremie-grouted with a thick bentonite mixture, or equivalent, from the bottom of the borehole to the ground surface as the augers are extracted. The grout mixture will be prepared in accordance with manufacturer's specifications.

In areas where restricted access precludes the use of a drill rig to extract the well casing, and/or the area is outside a designated landfill cell, the well casing may be filled with grout from the bottom up utilizing low pressure tremie methods and cut below ground surface. In this situation, a work plan for in-situ well decommissioning procedures will be submitted to the MDEQ on a case by case basis.

7.0 LABORATORY ANALYSIS

This section describes the procedures for completing laboratory analysis of the samples collected as part of this SAP.

7.1 Analytical Methods & Reporting Limits

Analytical methods and reporting limits appropriate for the analysis will be used at WMNL. The selected methods support the prescribed reporting limits for the monitoring parameters. Analytical methods used and referenced for meeting environmental testing requirements evolve over time due to changes in technology, prescribed updates, additions to published methodology and when regulations change to require reference to different methods. In many instances, there are also equivalent methods for the same analyte published by different authorities on methods development; e.g., the USEPA Office of Water, USEPA Office of Solids Waste, Standard Methods for the Examination of Water and Wastewater, or American Society for Testing and Materials (ASTM) and Operational Memorandum GEN-8, dated December 22, 2006.

Where an approved analytical method is updated (for example, from SW-846 Revision 3 to SW-846 Revision 4), or substituted by law (such as 40 CFR 136, the Method Update Rule) the use of the updated/substituted analytical method is considered acceptable unless MDEQ explicitly prohibits the use of the updated/substituted method.

7.2 Program Quality Assurance/Quality Control Procedures

The QA/QC procedures for the monitoring program will be provided via utilization of field forms and Chain-of-Custody forms. When necessary, trip blanks and field blanks may be analyzed. Laboratory QA/QC procedures will also be performed and documented. A copy of the laboratory QA/QC plan is included in Appendix C.

7.2.1 Trip Blanks

Trip blanks, prepared at the laboratory, are samples of organic-free water (e.g., deionized) prepared in VOA vials with preservative appropriate for a volatile organic carbon (VOC) sampling. The trip blanks remain with the sample bottles while in transit to the site, during sampling, and during the return trip to the laboratory. Trip blank sample bottles are not opened at any time during this process. Upon return to the laboratory, trip blanks are analyzed for VOC parameters using the same procedures and methods that are used for the collected field samples. When analyzed, trip blank results will be reported in the laboratory results and provide QA that samples have not been affected by the laboratory or during sampling and transport of field collected samples back to the laboratory.

7.2.2 Field Blanks

Field blanks may be prepared on occasion for QA purposes to evaluate sampling team performance. Field blanks are prepared at the sampling site by the sampling team. The field blank is prepared by pouring deionized water into sample bottles at the location of one of the wells in the sampling program, and leaving the container open during sampling. The well at which the field blank is prepared is identified on the Field Information Form. The purpose of the field blank is to detect any contamination which might be introduced into the groundwater samples through the ambient air. Once field blanks are collected, they are handled and shipped in the same manner as the rest of the samples.

For dedicated or disposable sampling equipment requiring no filtration or in-line filtration, the deionized water is exposed to the air, transferred to the field blank bottles, and the proper preservative is added as required. If the analyses for the field blank would normally be filter and required filtration is not done in-line, the deionized water is exposed to the air, poured into pre-filtration bottles, filtered (as required), and placed in the field blank bottles. The proper preservative is then added as required.

When prepared, field blank results will be reported in the laboratory reports as separate samples, using the designations FB-(well #) as their sample point designation.

7.3 Statistical Analysis Plan

The groundwater monitoring data will be statistically analyzed using the statistical approach presented in Appendix D, Statistical Plan. This Plan was developed by Dr. Robert Gibbons, Professor of Biostatistics and Psychiatry, University of Illinois at Chicago and upon review of *Statistical Analysis of Ground-Water Monitoring Data at RCRA Facilities, Interim Final Guidance,* published by the Office of Solid Waste Management Division of the EPA (1989, 1992). Updates to the statistical plan take into consideration, *Statistical Analysis of Ground-Water Monitoring Data at RCRA Facilities, Unified Guidance* (USEPA 2009).

Since development of the statistical plan for WMNL, statistical analysis has been performed on an intrawell basis. In general, intrawell statistical methods (comparing a well's compliance sampling results to its own background history) are typically more environmentally sensitive for detection monitoring at landfill facilities since the statistical uncertainty that often occurs from spatial variability is eliminated, especially where groundwater flow is slow such as at WMNL. The absence of significant trends, VOC detections, and the slow movement of groundwater at WMNL supports the use of intrawell comparisons. An intrawell monitoring system will provide an indication of background groundwater quality that is as representative, or more representative, than that provided by upgradient wells. This is achieved by utilizing downgradient wells, which eliminates natural spatial variability inherent between upgradient and downgradient groundwater chemistry. This spatial component of variability comprises a significant portion (about two-thirds) of the total variability accounted for by the statistical methodology.

The statistical analysis program for inorganic parameters will be based on combined Shewhart-CUSUM control charts at each detection monitoring well. For those constituents that are detected at least once, but less than 25% of the time in background, a nonparametric prediction limit will be computed.

7.3.1 Background Groundwater Monitoring

As described above, intrawell monitoring does not require background monitoring at upgradient wells because the water chemistry of a well is compared to itself over time. However, upgradient well(s) are useful for detecting any potential off-site influences on the monitoring network. Intrawell monitoring requires a minimum of four sampling events per well prior to implementation of statistics. However, a total of eight background events per well is generally preferred and recommended in the statistical literature. For the purposes of this plan, each detection monitoring well will require eight background samples for the secondary parameters, to improve the sensitivity of the statistical method(s) being used, and to account for seasonal or other causes of temporal variability.

7.3.2 Statistical Power

The EPA guidance document entitled, *Statistical Analysis of Ground-Water Monitoring Data at RCRA Facilities, Unified Guidance* (USEPA 2009) recommends that the selected statistical method for multiple constituent comparisons provide a site-wide false positive rate of 5% or less while maintaining a statistical power (1 minus the false negative rate) from the EPA reference power curve (correlating to a statistical power of >55% for a 3-sigma release and >80% for a 4-sigma release). If this cannot be achieved through a parameter or monitoring point reduction, then options available within the statistical program may be implemented, if necessary. Adjustments to the control chart factor (for intrawell control charts) and verification resampling options, or the use of normal prediction limits may be implemented to achieve the statistical standards recommended by USEPA (2009).

7.3.3 Determination of a Statistically Significant Increase (Verification Resampling)

In the event that a groundwater analytical result shows an initial statistical exceedance following appropriate quality control checks, resampling will be performed to determine if the initial exceedance is statistically significant (i.e. represent a statistically significant increase above background, or a SSI). A pass 1-of-1 resampling strategy will be used when determining an SSI of the offending parameter(s). If an initial statistical exceedance is observed, an independent resample will be collected to determine whether the initial statistical exceedance is verified. If the initial finding is not verified by resampling, the passing resampled value will replace the initial finding. Should the resample confirm the initial exceedance and an SSI is determined, an additional quadruplicate resampling will then be performed to reconfirm the SSI. Should quadruplicate resampling be performed, samples will be collected via low flow sampling techniques and will be collected consecutively during a single sampling event.

If two or more of the four replicate samples exceed the control limit, then an SSI will be reconfirmed. If one or fewer of the replicate samples are above the control limit, the SSI is considered unconfirmed and the average value of the four replicate samples will replace the initial finding. If the quadruplicate results confirm a SSI, the results will be evaluated to determine if the SSI is an artifact of the laboratory or sampling procedure, or from another source.

7.3.4 Alternate Source Demonstration

If a natural or non-landfill source is suspected for the SSI, an alternate source demonstration may be submitted to MDEQ with a request to remain in detection monitoring for review and approval. The *Unified Guidance* provides a suggested framework and recommendations for the statistical analysis of groundwater monitoring at RCRA facilities to determine whether groundwater has been impacted by a hazardous constituent. If an alternate source demonstration is considered and developed, WMN will evaluate the data following standard methods presented in the *Unified Guidance (2009).* It is noted that the *Unified Guidance* draws upon the experience gained in the last decade in implementing the RCRA Subtitle C groundwater monitoring programs and new research that has emerged since earlier Agency guidance.

7.3.5 Corrective Action Monitoring

In the event that the MDEQ determines that a successful alternative source demonstration cannot be made, MDEQ may require the initiation of compliance monitoring or corrective action per 40 CFR 264.99 and R299.9629 or through conditions outlined in the post closure operating license.

8.0 DATA EVALUATION, REPORTING & RECORD KEEPING

Prior to the submittal of a monitoring report, several data evaluation, reporting, and record keeping tasks will be implemented. The following sections describe the evaluation, reporting and record keeping procedures that are followed upon receipt of the analytical report.

8.1 Data Evaluation

Each analytical report will undergo the two levels of data evaluation described below.

8.1.1 Initial QA/QC Checks

Before the data are submitted for statistical analysis, they will be evaluated by examining the quality control data accompanying the data report from the laboratory. Relevant quality control data include measures of accuracy (percent recovery), precision (relative percent difference, RPD), and sample contamination (blank determinations). Data that fail any of these checks will be flagged for further evaluation. A Data Quality Review (DQR) from the laboratory may be initiated for any anomalous data.

8.1.2 Data Validation

Upon completion of the QA/QC review procedures, assuming any anomalous results are not due to laboratory or other error, the data will be submitted for statistical analysis as described in preceding sections of this SAP.

8.2 Data Reporting

Following receipt of the groundwater analytical results from the laboratory, WMNL will conduct the statistical analysis described above. The results of these analyses will be submitted to the Waste and Hazardous Materials Division (WHMD) of the MDEQ within 60 days after the completion of the sampling event. A copy of the report will be placed in the facility's Operating Record.

The report will include a brief description of the methodologies used during groundwater sample collection, a discussion of the statistical evaluation, analytical results, chain-of-custody, water level measurements, groundwater flow rates, direction and hydraulic gradients, copies of field sampling records and a groundwater elevation contour map for the site.

8.3 Data Record Keeping Requirements

Copies of monitoring data collected in accordance with this SAP will be maintained in the facility operating record. Each set of monitoring data will be submitted to the MDEQ within ninety (60) days of the sampling event.

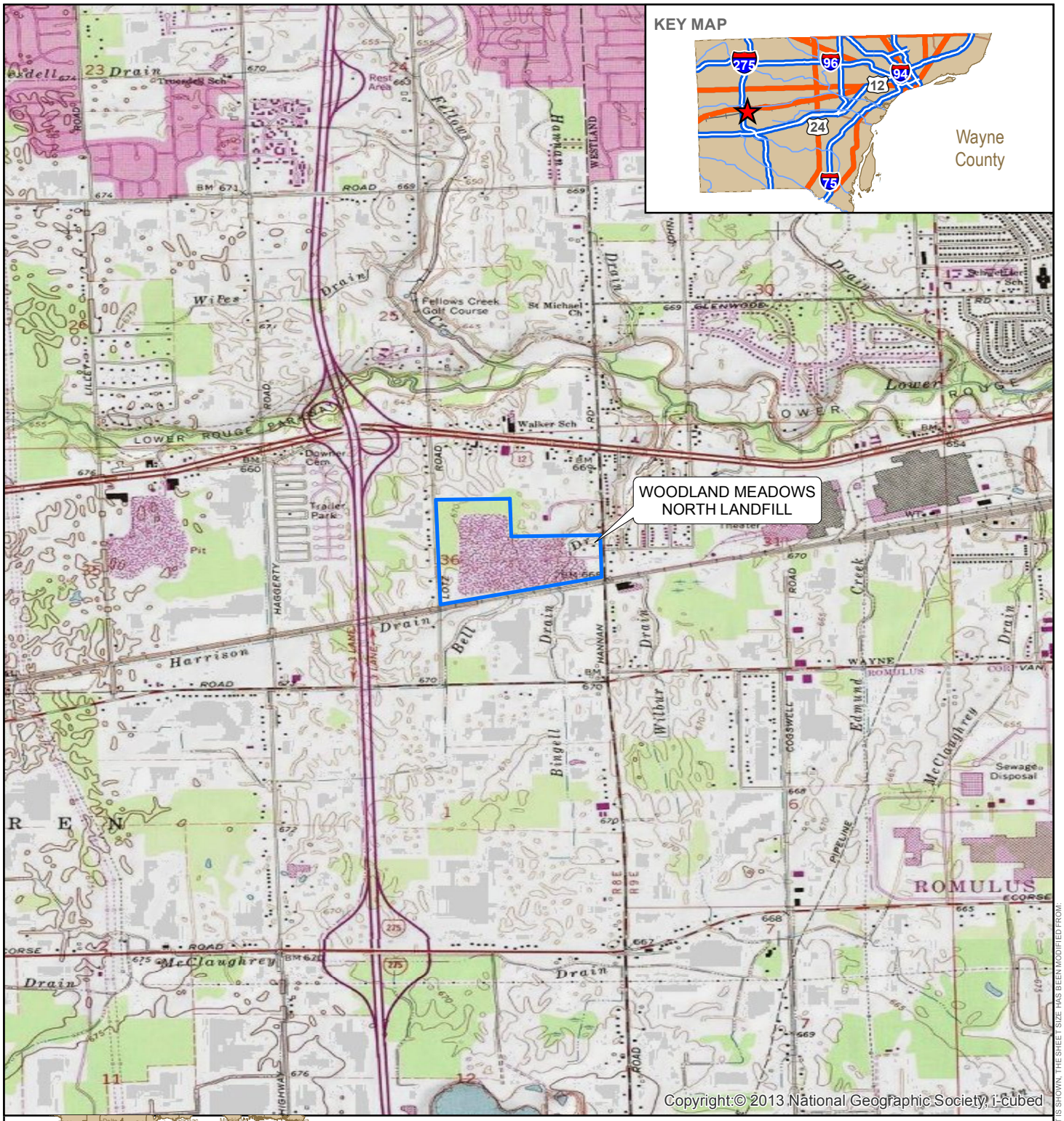
9.0 COMPLIANCE WITH 40 CFR 264 AND R299.9611/9612

This SAP has been prepared in compliance with applicable Act 451, Part 111 rules by a professional geologist at Golder Associates Inc., of Farmington Hills, Michigan. References to the appropriate Part 111, Act 451 Rules are incorporated throughout this document. Documentation of MDEQ approval of this SAP will be placed in the site operating record within 14 days of the issuance of the approval.

Dawn L. Prell, CPG — Date: 8/11/2017

Sean C. Paulsen, PG — Date: 8/11/2017

FIGURES



CLIENT
WASTE MANAGEMENT

PROJECT
WOODLAND MEADOWS NORTH LANDFILL
CANTON TOWNSHIP, MICHIGAN

TITLE
SITE LOCATION MAP

CONSULTANT
Golder Associates

YYYY-MM-DD	2014-04-11
PREPARED	JLL
DESIGN	DP
REVIEW	dlp
APPROVED	scp

PROJECT 140-2828 | CONSULTANT | Rev. | FIGURE 1

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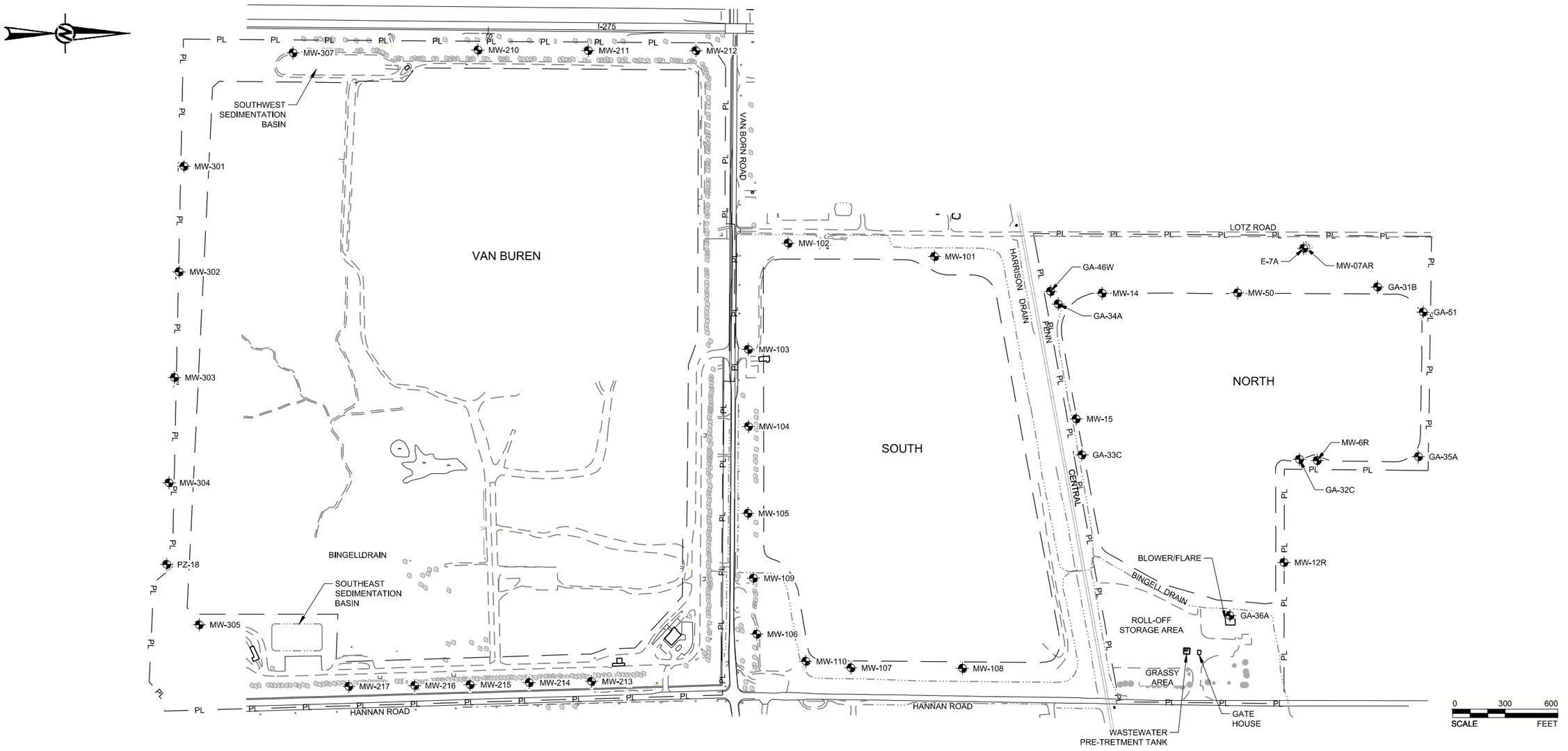

LEGEND

PL	PROPERTY BOUNDARY
	SOLID WASTE BOUNDARY
MW-XX	MONITORING WELL LOCATION

NOTE

BASE MAP TAKEN FROM NTH CONSULTANTS, LTD.

CLIENT
WASTE MANAGEMENT
WOODLAND MEADOWS NORTH
CANTON TOWNSHIP, MICHIGAN

PROJECT
2017 GROUNDWATER SAMPLING & ANALYSIS PLAN

TITLE
SITE PLAN AND MONITORING WELL LOCATION MAP

CONSULTANT
Golder Associates

YYYY-MM-DD	2017-05-02
PREPARED	DJC
DESIGN	DLP
REVIEW	dlp
APPROVED	scp

PROJECT No.	CONTROL	Rev.	FIGURE
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1 in

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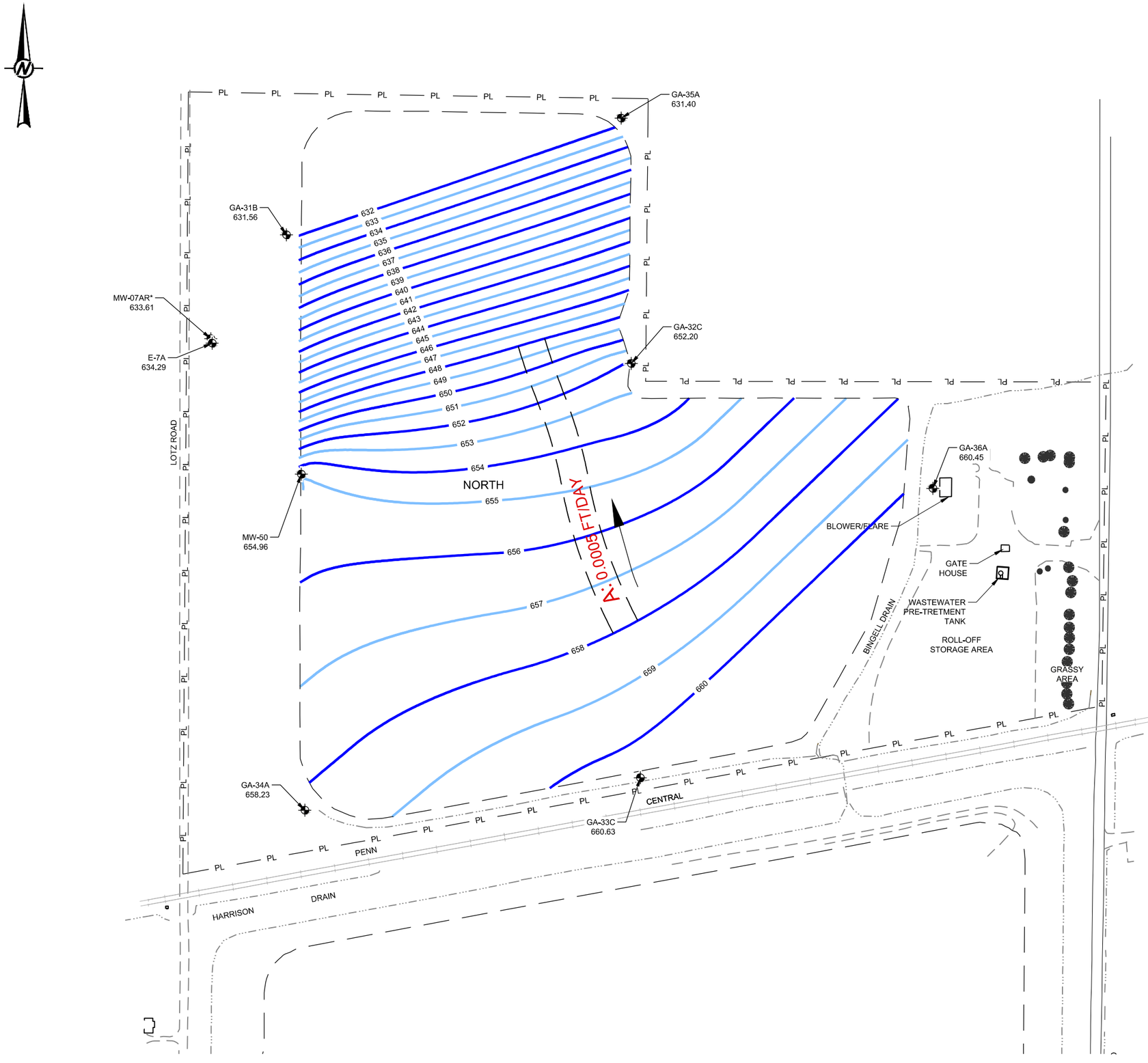

LEGEND

PL	PROPERTY BOUNDARY
	SOLID WASTE BOUNDARY
GA-XX XXX.XX	GROUNDWATER MONITORING WELL (BASAL TILL) WITH GROUNDWATER ELEVATION
658 / 659	GROUNDWATER CONTOUR

FLOW RATE: A: 0.0005 FT/DAY

NOTE

BASE MAP TAKEN FROM NTH CONSULTANTS, LTD.

0 150 300
SCALE FEET

CLIENT
WASTE MANAGEMENT
WOODLAND MEADOWS NORTH
CANTON TOWNSHIP, MICHIGAN

PROJECT
2017 SEMI-ANNUAL GROUNDWATER MONITORING

TITLE
GROUNDWATER ELEVATION CONTOUR MAP
BASIL TILL
MAY 2017

CONSULTANT
Golder Associates

YYYY-MM-DD	2017-06-26
PREPARED	DJC
DESIGN	DK
REVIEW	dlp
APPROVED	scp

PROJECT No.	CONTROL	Rev.	FIGURE
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IF THIS MEASUREMENT DOES NOT MATCH WHAT IS SHOWN, THE SHEET SIZE HAS BEEN MODIFIED FROM: ANSI B

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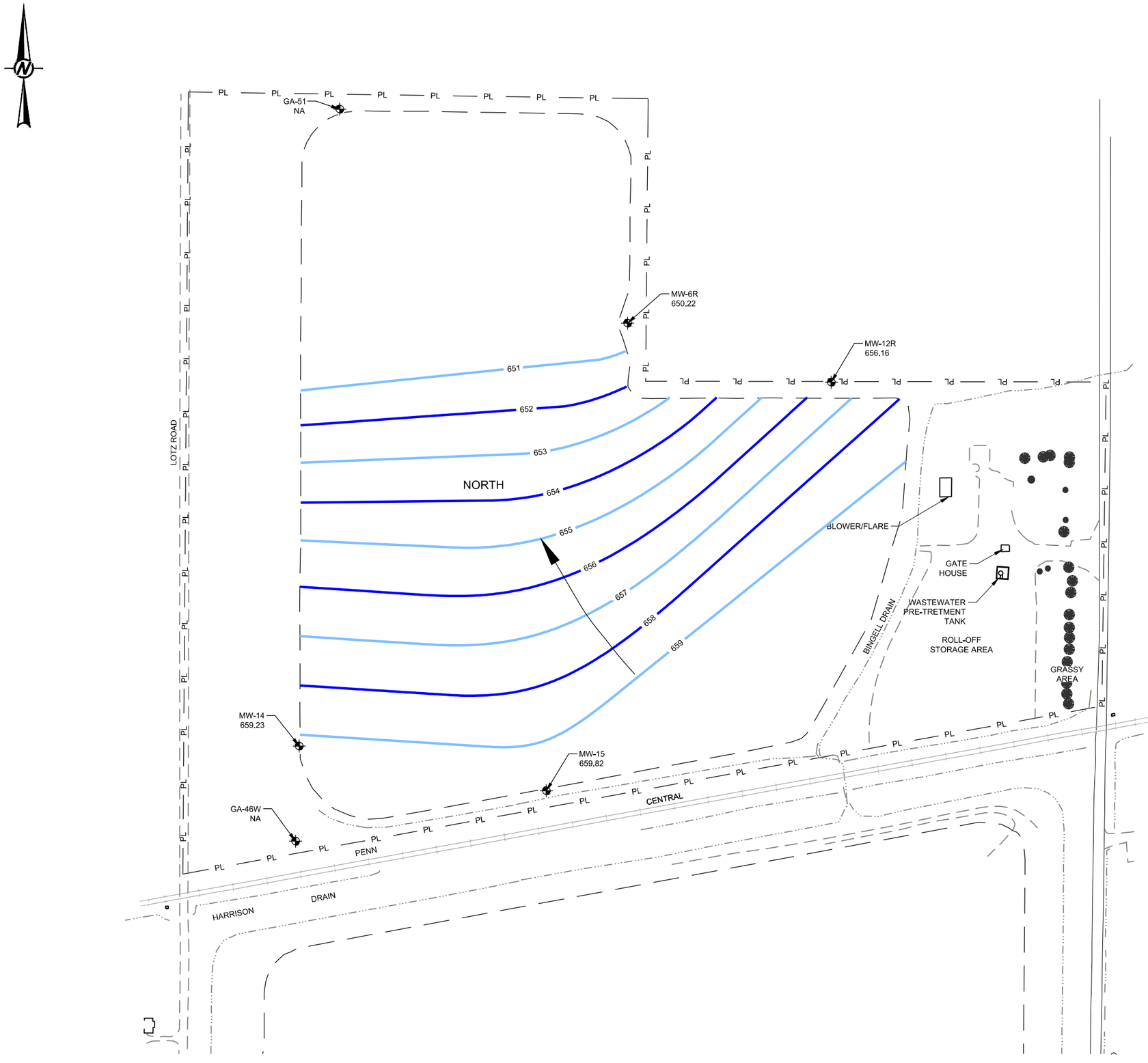

LEGEND

PL	PROPERTY BOUNDARY
	SOLID WASTE BOUNDARY
GA-XX XXX.XX	GROUNDWATER MONITORING WELL (BASAL TILL) WITH GROUNDWATER ELEVATION
658 659	GROUNDWATER CONTOUR
	IMPLIED DIRECTION OF GROUNDWATER FLOW

NOTE

BASE MAP TAKEN FROM NTH CONSULTANTS, LTD.

0 150 300
SCALE FEET

CLIENT
WASTE MANAGEMENT
WOODLAND MEADOWS NORTH
CANTON TOWNSHIP, MICHIGAN

PROJECT
2017 SEMI-ANNUAL GROUNDWATER MONITORING

TITLE
GROUNDWATER ELEVATION CONTOUR MAP
SAND LENS
MAY 2017

CONSULTANT
Golder Associates

YYYY-MM-DD	2017-06-26
PREPARED	DJC
DESIGN	DK
REVIEW	dlp
APPROVED	scp

PROJECT No.	CONTROL	Rev.	FIGURE
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TABLES

TABLE 1.
GROUNDWATER MONITORING SYSTEM
Woodland Meadows North
Wayne, Michigan

WELL IDENTIFICATION	FORMATION MONITORED	TOP OF CASING ELEVATION[2] (ft)	SCREEN TIP ELEVATION (ft)	SCREEN LENGTH (ft)	WELL CASING/ SCREEN MATERIALS	DATE INSTALLED
MW-6R	sand lense	674.04	613.90	5.0	2" PVC&Stainless/Stainless	06/1989
MW-12R	sand lense	671.24	611.40	5.0	2" PVC&Stainless/Stainless	06/1989
MW-14	sand lense	675.00	626.30	5.0	2" PVC&Stainless/Stainless	06/1989
MW-15	sand lense	672.03	629.90	3.0	2" PVC&Stainless/Stainless	06/1989
GA-31B	basal till	672.51	588.30	5.0	2" PVC/PVC	07/1985
GA-32C	basal till	673.18	585.60	5.0	2" PVC/PVC	07/1985
GA-33C	basal till	668.45	583.40	5.0	2" PVC/PVC	08/1985
GA-34A	basal till	673.35	592.30	5.0	2" PVC/PVC	08/1985
GA-35A	basal till	669.51	585.80	5.0	2" PVC/PVC	07/1985
GA-36A	basal till	667.77	568.80	5.0	2" PVC/PVC	08/1985
GA-46W[1]	sand lense	674.18	617.30	10.0	4" PVC/PVC	03/1986
MW-50	basal till/rock	674.48	570.60	5.0	2" PVC&Stainless/Stainless	07/1994
GA-51[1]	sand lense	676.56	597.90	5.0	2" PVC&Stainless/Stainless	07/1994
E7A	sand lense	673.20	609.21	5.0	2" PVC/PVC	01/1980

Notes:

[1] - Piezometers used for static water level measurements only.

[2] - Top of casing elevations from survey on November 18, 2004.

TABLE 2.
GROUNDWATER MONITORING PARAMETERS
Woodland Meadows North
Wayne, Michigan

Field Parameters: COMMON NAME	Method Code	CAS Number	RL	Units	Annual Monitoring
Temperature, Field	Field Sampling	STL00246	0.001	Celsius	Field Only
pH, Field	Field Sampling	STL00199	0.001	SU	Field Only
Specific Conductance, Field	Field Sampling	STL00244	0.001	umhos/cm	Field Only
Primary Indicator Parameters: COMMON NAME	**Method Code**	**CAS Number**	**RL**	**Units**	**Annual Monitoring**
1,1,1,2-Tetrachloroethane	8260C	630-20-6	1.0	ug/L	X
1,1,1-Trichloroethane	8260C	71-55-6	1.0	ug/L	X
1,1,2,2-Tetrachloroethane	8260C	79-34-5	1.0	ug/L	X
1,1,2-Trichloroethane	8260C	79-00-5	1.0	ug/L	X
1,1-Dichloroethane	8260C	75-34-3	1.0	ug/L	X
1,1-Dichloroethene	8260C	75-35-4	1.0	ug/L	X
1,2,3-Trichloropropane	8260C	96-18-4	1.0	ug/L	X
1,2-Dibromo-3-Chloropropane	8260C	96-12-8	5.0	ug/L	X
1,2-Dibromoethane	8260C	106-93-4	1.0	ug/L	X
1,2-Dichlorobenzene	8260C	95-50-1	1.0	ug/L	X
1,2-Dichloroethane	8260C	107-06-2	1.0	ug/L	X
1,2-Dichloropropane	8260C	78-87-5	1.0	ug/L	X
1,4-Dichlorobenzene	8260C	106-46-7	1.0	ug/L	X
2-Butanone	8260C	78-93-3	10.0	ug/L	X
2-Hexanone	8260C	591-78-6	5.0	ug/L	X
4-Methyl-2-pentanone	8260C	108-10-1	5.0	ug/L	X
Acetone	8260C	67-64-1	25.0	ug/L	X
Acrylonitrile	8260C	107-13-1	5.0	ug/L	X
Benzene	8260C	71-43-2	1.0	ug/L	X
Bromochloromethane	8260C	74-97-5	1.0	ug/L	X
Bromodichloromethane	8260C	75-27-4	1.0	ug/L	X
Bromoform	8260C	75-25-2	1.0	ug/L	X
Bromomethane	8260C	74-83-9	5.0	ug/L	X
Carbon disulfide	8260C	75-15-0	5.0	ug/L	X
Carbon tetrachloride	8260C	56-23-5	1.0	ug/L	X
Chlorobenzene	8260C	108-90-7	1.0	ug/L	X
Chloroethane	8260C	75-00-3	5.0	ug/L	X
Chloroform	8260C	67-66-3	1.0	ug/L	X
Chloromethane	8260C	74-87-3	5.0	ug/L	X
cis-1,2-Dichloroethene	8260C	156-59-2	1.0	ug/L	X
cis-1,3-Dichloropropene	8260C	10061-01-5	1.0	ug/L	X
Dibromochloromethane	8260C	124-48-1	1.0	ug/L	X
Dibromomethane	8260C	74-95-3	1.0	ug/L	X
Ethylbenzene	8260C	100-41-4	1.0	ug/L	X
Iodomethane	8260C	74-88-4	1.0	ug/L	X
Methylene Chloride	8260C	75-09-2	5.0	ug/L	X

TABLE 2.
GROUNDWATER MONITORING PARAMETERS
Woodland Meadows North
Wayne, Michigan

Primary Indicator Parameters: COMMON NAME	Method Code	CAS Number	RL	Units	Annual Monitoring
Styrene	8260C	100-42-5	1.0	ug/L	X
Tetrachloroethene	8260C	127-18-4	1.0	ug/L	X
Toluene	8260C	108-88-3	1.0	ug/L	X
trans-1,2-Dichloroethene	8260C	156-60-5	1.0	ug/L	X
trans-1,3-Dichloropropene	8260C	10061-02-6	1.0	ug/L	X
trans-1,4-Dichloro-2-butene	8260C	110-57-6	2.1	ug/L	X
Trichloroethene	8260C	79-01-6	1.0	ug/L	X
Trichlorofluoromethane	8260C	75-69-4	5.0	ug/L	X
Vinyl acetate	8260C	108-05-4	5.0	ug/L	X
Vinyl chloride	8260C	75-01-4	5.0	ug/L	X
Xylenes, Total	8260C	1330-20-7	3.0	ug/L	X
Secondary Inorganic Indicator Parameters: COMMON NAME	**Method Code**	**CAS Number**	**RL**	**Units**	**Annual Monitoring**
Alkalinity, Bicarbonate	310.2	STL00138	10	mg/L	X
Iron, Dissolved	6010C	7439-89-6	0.05	mg/L	X
Ammonia as N	350.1	7664-41-7	0.02	mg/L as N	X
Sodium, Dissolved	6010C	7440-23-5	1.0	mg/L	X
Zinc, Dissolved	6020A	7440-66-6	0.01	mg/L	X

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TABLE 3.
LEACHATE MONITORING PARAMETERS
Woodland Meadows North
Wayne, Michigan

Field Parameters Common Name	Method Code	CAS Number	RL	Units	Annual Monitoring
Temperature, Field	FieldSampling	STL00246	0.001	Celsius	X
pH, Field	FieldSampling	STL00199	0.001	SU	X
Specific Conductance, Field	FieldSampling	STL00244	0.001	umhos/cm	X
VOCs/SVOCs Common Name	**Method Code**	**CAS Number**	**RL**	**Units**	**Annual Monitoring**
1,1,1,2-Tetrachloroethane	8260C	630-20-6	1.0	ug/L	X
1,1,1-Trichloroethane	8260C	71-55-6	1.0	ug/L	X
1,1,2,2-Tetrachloroethane	8260C	79-34-5	1.0	ug/L	X
1,1,2-Trichloroethane	8260C	79-00-5	1.0	ug/L	X
1,1-Dichloroethane	8260C	75-34-3	1.0	ug/L	X
1,1-Dichloroethene	8260C	75-35-4	1.0	ug/L	X
1,2,3-Trichloropropane	8260C	96-18-4	1.0	ug/L	X
1,2-Dibromo-3-Chloropropane	8260C	96-12-8	5.0	ug/L	X
1,2-Dibromoethane	8260C	106-93-4	1.0	ug/L	X
1,2-Dichlorobenzene	8260C	95-50-1	1.0	ug/L	X
1,2-Dichloroethane	8260C	107-06-2	1.0	ug/L	X
1,2-Dichloropropane	8260C	78-87-5	1.0	ug/L	X
1,4-Dichlorobenzene	8260C	106-46-7	1.0	ug/L	X
2-Butanone	8260C	78-93-3	10.0	ug/L	X
2-Hexanone	8260C	591-78-6	5.0	ug/L	X
4-Methyl-2-pentanone	8260C	108-10-1	5.0	ug/L	X
Acetone	8260C	67-64-1	25.0	ug/L	X
Acrylonitrile	8260C	107-13-1	5.0	ug/L	X
Benzene	8260C	71-43-2	1.0	ug/L	X
Bromochloromethane	8260C	74-97-5	1.0	ug/L	X
Bromodichloromethane	8260C	75-27-4	1.0	ug/L	X
Bromoform	8260C	75-25-2	1.0	ug/L	X
Bromomethane	8260C	74-83-9	5.0	ug/L	X
Carbon disulfide	8260C	75-15-0	5.0	ug/L	X
Carbon tetrachloride	8260C	56-23-5	1.0	ug/L	X
Chlorobenzene	8260C	108-90-7	1.0	ug/L	X
Chloroethane	8260C	75-00-3	5.0	ug/L	X
Chloroform	8260C	67-66-3	1.0	ug/L	X
Chloromethane	8260C	74-87-3	5.0	ug/L	X
cis-1,2-Dichloroethene	8260C	156-59-2	1.0	ug/L	X
cis-1,3-Dichloropropene	8260C	10061-01-5	1.0	ug/L	X
Dibromomethane	8260C	74-95-3	1.0	ug/L	X
Ethylbenzene	8260C	100-41-4	1.0	ug/L	X
Iodomethane	8260C	74-88-4	1.0	ug/L	X
Methylene Chloride	8260C	75-09-2	5.0	ug/L	X
Styrene	8260C	100-42-5	1.0	ug/L	X
Tetrachloroethene	8260C	127-18-4	1.0	ug/L	X
Toluene	8260C	108-88-3	1.0	ug/L	X
trans-1,2-Dichloroethene	8260C	156-60-5	1.0	ug/L	X

TABLE 3.
LEACHATE MONITORING PARAMETERS
Woodland Meadows North
Wayne, Michigan

VOCs/SVOCs Common Name	Method Code	CAS Number	RL	Units	Annual Monitoring
trans-1,3-Dichloropropene	8260C	10061-02-6	1.0	ug/L	X
trans-1,4-Dichloro-2-butene	8260C	110-57-6	2.1	ug/L	X
Trichloroethene	8260C	79-01-6	1.0	ug/L	X
Trichlorofluoromethane	8260C	75-69-4	5.0	ug/L	X
Vinyl acetate	8260C	108-05-4	1.0	ug/L	X
Vinyl chloride	8260C	75-01-4	5.0	ug/L	X
Xylenes, Total	8260C	1330-20-7	3.0	ug/L	X
1,2,4-Trichlorobenzene	8270D	120-82-1	10.0	ug/L	X
1,2-Dichlorobenzene	8270D	95-50-1	10.0	ug/L	X
1,3-Dichlorobenzene	8270D	541-73-1	10.0	ug/L	X
1,4-Dichlorobenzene	8270D	106-46-7	10.0	ug/L	X
2,4,5-Trichlorophenol	8270D	95-95-4	10.0	ug/L	X
2,4,6-Trichlorophenol	8270D	88-06-2	10.0	ug/L	X
2,4-Dichlorophenol	8270D	120-83-2	10.0	ug/L	X
2,4-Dimethylphenol	8270D	105-67-9	10.0	ug/L	X
2,4-Dinitrophenol	8270D	51-28-5	50.0	ug/L	X
2,4-Dinitrotoluene	8270D	121-14-2	10.0	ug/L	X
2,6-Dinitrotoluene	8270D	606-20-2	10.0	ug/L	X
2-Chloronaphthalene	8270D	91-58-7	10.0	ug/L	X
2-Chlorophenol	8270D	95-57-8	10.0	ug/L	X
2-Methylnaphthalene	8270D	91-57-6	10.0	ug/L	X
2-Methylphenol	8270D	95-48-7	10.0	ug/L	X
2-Nitroaniline	8270D	88-74-4	50.0	ug/L	X
2-Nitrophenol	8270D	88-75-5	10.0	ug/L	X
3,3'-Dichlorobenzidine	8270D	91-94-1	20.0	ug/L	X
3-Methylphenol	8270D	108-39-4	10.0	ug/L	X
3-Nitroaniline	8270D	99-09-2	50.0	ug/L	X
4,6-Dinitro-2-methylphenol	8270D	534-52-1	50.0	ug/L	X
4-Bromophenyl phenyl ether	8270D	101-55-3	10.0	ug/L	X
4-Chloro-3-methylphenol	8270D	59-50-7	10.0	ug/L	X
4-Chloroaniline	8270D	106-47-8	10.0	ug/L	X
4-Chlorophenyl phenyl ether	8270D	7005-72-3	10.0	ug/L	X
4-Methylphenol	8270D	106-44-5	10.0	ug/L	X
4-Nitroaniline	8270D	100-01-6	50.0	ug/L	X
4-Nitrophenol	8270D	100-02-7	50.0	ug/L	X
Acenaphthene	8270D	83-32-9	10.0	ug/L	X
Acenaphthylene	8270D	208-96-8	10.0	ug/L	X
Anthracene	8270D	120-12-7	10.0	ug/L	X
Benzidine	8270D	92-87-5	80.0	ug/L	X
Benzo[a]anthracene	8270D	56-55-3	10.0	ug/L	X
Benzo[a]pyrene	8270D	50-32-8	10.0	ug/L	X
Benzo[b]fluoranthene	8270D	205-99-2	10.0	ug/L	X
Benzo[g,h,i]perylene	8270D	191-24-2	10.0	ug/L	X
Benzo[k]fluoranthene	8270D	207-08-9	10.0	ug/L	X
Benzoic acid	8270D	65-85-0	100.0	ug/L	X

TABLE 3.
LEACHATE MONITORING PARAMETERS
Woodland Meadows North
Wayne, Michigan

VOCs/SVOCs Common Name	Method Code	CAS Number	RL	Units	Annual Monitoring
Benzyl alcohol	8270D	100-51-6	20.0	ug/L	X
bis (2-chloroisopropyl) ether	8270D	108-60-1	10.0	ug/L	X
Bis(2-chloroethoxy)methane	8270D	111-91-1	10.0	ug/L	X
Bis(2-chloroethyl)ether	8270D	111-44-4	10.0	ug/L	X
Bis(2-ethylhexyl) phthalate	8270D	117-81-7	10.0	ug/L	X
Butyl benzyl phthalate	8270D	85-68-7	10.0	ug/L	X
Chrysene	8270D	218-01-9	10.0	ug/L	X
Dibenz(a,h)anthracene	8270D	53-70-3	10.0	ug/L	X
Dibenzofuran	8270D	132-64-9	10.0	ug/L	X
Diethyl phthalate	8270D	84-66-2	10.0	ug/L	X
Dimethyl phthalate	8270D	131-11-3	10.0	ug/L	X
Di-n-butyl phthalate	8270D	84-74-2	10.0	ug/L	X
Di-n-octyl phthalate	8270D	117-84-0	10.0	ug/L	X
Fluoranthene	8270D	206-44-0	10.0	ug/L	X
Fluorene	8270D	86-73-7	10.0	ug/L	X
Hexachlorobenzene	8270D	118-74-1	10.0	ug/L	X
Hexachlorobutadiene	8270D	87-68-3	10.0	ug/L	X
Hexachlorocyclopentadiene	8270D	77-47-4	24.0	ug/L	X
Hexachloroethane	8270D	67-72-1	10.0	ug/L	X
Indeno[1,2,3-cd]pyrene	8270D	193-39-5	10.0	ug/L	X
Isophorone	8270D	78-59-1	10.0	ug/L	X
Naphthalene	8270D	91-20-3	10.0	ug/L	X
Nitrobenzene	8270D	98-95-3	10.0	ug/L	X
Pentachlorophenol	8270D	87-86-5	50.0	ug/L	X
Phenanthrene	8270D	85-01-8	10.0	ug/L	X
Phenol	8270D	108-95-2	10.0	ug/L	X
Pyrene	8270D	129-00-0	10.0	ug/L	X
Total Metals Common Name	**Method Code**	**CAS Number**	**RL**	**Units**	**Annual Monitoring**
Arsenic-total	6020A	7440-38-2	0.002	mg/L	X
Barium-total	6010C	7440-39-3	0.02	mg/L	X
Beryllium-total	6010C	7440-41-7	0.005	mg/L	X
Cadmium-total	6010C	7440-43-9	0.005	mg/L	X
Calcium-total	6010C	7440-70-2	1.0	mg/L	X
Chromium	6010C	7440-47-3	0.02	mg/L	X
Cobalt-total	6010C	7440-48-4	0.02	mg/L	X
Copper-total	6010C	7440-50-8	0.02	mg/L	X
Cyanide, total	335.4	57-12-5	0.02	mg/L	X
Iron-total	6010C	7439-89-6	0.02	mg/L	X
Lead-total	6010C	7439-92-1	0.04	mg/L	X
Magnesium-total	6010C	7439-95-4	1.0	mg/L	X
Mercury	7470A	7439-97-6	0.0002	mg/L	X
Nickel-total	6010C	7440-02-0	0.02	mg/L	X
Selenium-total	6020A	7782-49-2	0.002	mg/L	X
Silver-total	6010C	7440-22-4	0.01	mg/L	X

TABLE 3.
LEACHATE MONITORING PARAMETERS
Woodland Meadows North
Wayne, Michigan

Total Metals Common Name	Method Code	CAS Number	RL	Units	Annual Monitoring
Tin-total	6010C	7440-31-5	0.5	mg/L	X
Vanadium-total	6010C	7440-62-2	0.02	mg/L	X
Zinc-total	6020A	7440-66-6	0.01	mg/L	X
General Chemistry Common Name	**Method Code**	**CAS Number**	**RL**	**Units**	**Annual Monitoring**
Alkalinity, bicarbonate (as caco3)	310.2	STL00138	10.0	mg/L	X
Alkalinity, carbonate (as caco3)	310.2	STL00154	10.0	mg/L	X
Biochemical oxygen demand	SM 5210B	STL00311	2.0	mg/L	X
Chemical Oxygen Demand	410.4	STL00070	10.0	mg/L	X
Chloride	SM4500_Cl_E	16887-00-6	1.0	mg/L	X
Nitrogen, ammonia	350.1	7664-41-7	0.2	mg/L as N	X
Sodium-total	6010C	7440-23-5	1.0	mg/L	X
Total Dissolved Solids	2540C_Calcd	STL00242	20.0	mg/L	X
Total Suspended Solids	2540D	STL00161	5.0	mg/L	X
Sulfate	D516	14808-79-8	5.0	mg/L	X

TABLE 4.
SURFACE WATER MONITORING PARAMETERS SCHEDULE
Woodland Meadows North
Wayne, Michigan

Field Parameters: Common Name	Method Code	CAS Number	RL	Units	Annual Monitoring
Temperature, Field	FieldSampling	STL00246	0.001	Celsius	X
pH, Field	FieldSampling	STL00199	0.001	SU	X
Oxygen, Dissolved	FieldSampling	STL00082	0.001	mg/L	X
Specific Conductance, Field	FieldSampling	STL00244	0.001	umhos/cm	X
Indicator Parameters: Common Name	**Method Code**	**CAS Number**	**RL**	**Units**	**Annual Monitoring**
Nitrite as N	353.2_Nitrite	14797-65-0	0.05	mg/L as N	X
Nitrogen, Nitrate	Nitrate_Calc	14797-55-8	0.05	mg/L as N	X
Nitrate Nitrite as N	353.2	STL00217	0.05	mg/L as N	X
Total Phosphorus	4500_P_E	7723-14-0	0.02	mg/L as P	X
Total Dissolved Solids	2540C_Calcd	STL00242	10.0	mg/L	X
Biochemical Oxygen Demand	5210B	STL00311	2.0	mg/L	X
Chloride	SM4110B_28D	16887-00-6	0.5	mg/L	X
Iron, Total	7439-89-6	6010C	0.02	mg/L	X
Total Suspended Solids	2540D	STL00161	5.0	mg/L	X
Sulfate	SM4110B_28D	14808-79-8	2.0	mg/L	X

APPENDIX A

MONITORING WELL LOGS

PROJECT No.: 1402828 / 0003
CLIENT: WM-Woodland Meadows
PROJECT: Groundwater Monitoring
LOCATION: Wayne, Michigan
N: 4952.100 E: 7426.900
Survey Provided by: McNeely & Lincoln Associates, Inc., Dated 8-19-2014

RECORD OF MONITORING WELL E-7A

BORING DATE: January 1980
DRILLING CONTRACTOR: N/A

SHEET 1 OF 1
DATUM: Site Specific

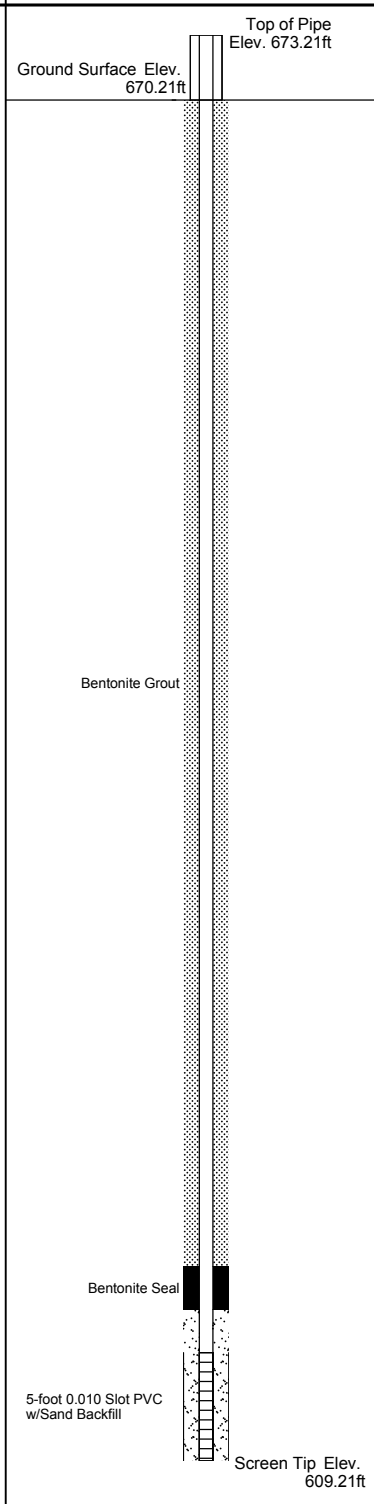
DEPTH SCALE FEET	DRILLING RIG / DRILLING METHOD	SOIL PROFILE: DESCRIPTION	STRATA PLOT	ELEV. / DEPTH (ft)	SAMPLES: NUMBER	TYPE	BLOWS/ft	ELEVATION FEET
0	Hollow Stem Auger			670.21				670
		(CL) SILTY CLAY, SILTY CLAY		0.00				
10								660
20								650
30								640
40				631.21				630
		(SM) SILTY SAND, SILTY SAND		41.00				
				627.21				
		(CL) SILTY CLAY, SILTY CLAY		45.00				
50								620
60				613.21				
		(SM) SILTY SAND, SILTY SAND		59.00				
				610.21				610
		(CL) SILTY CLAY, SILTY CLAY		609.21				
		End of Monitoring Well.		63.00				

HYDRAULIC CONDUCTIVITY, k, cm/s
10^{-6} 10^{-5} 10^{-4} 10^{-3}
WATER CONTENT PERCENT
Wp W Wl
10 20 30 40

ADDITIONAL LAB. TESTING

INSTALLATION AND GROUNDWATER OBSERVATIONS

E-7A



DOWN HOLE DEPTH SCALE
1 inch to 8.9 feet

Golder Associates

SOIL CLASSIFICATION SYSTEM: GACS

CHECKED: dlp

Figure:

National IM Server:GINT_GAL_TEMPLATE_PREVIEW Unique Project ID: Output Form:WIXOM_ENV (WIP) DPrell 9/10/14

Golder No. 893-2197

Well No. MW-6R

Boring No. X-Ref: MW-6R

MONITOR WELL CONSTRUCTION SUMMARY

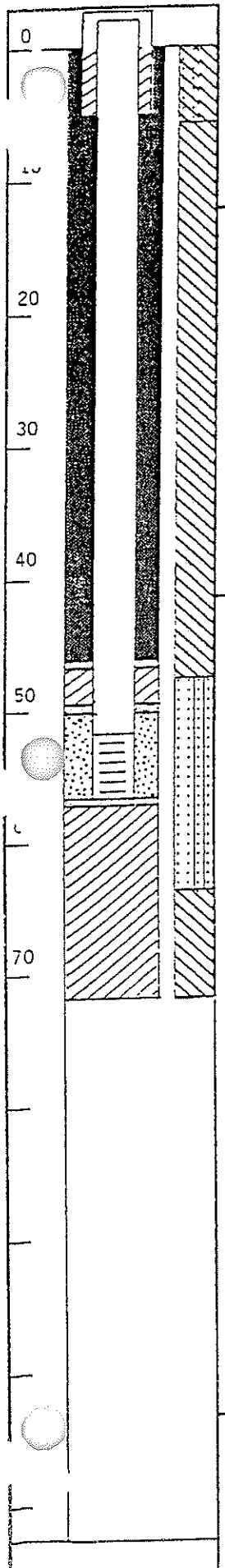
Survey Coords: 5030N; 8633E

Elevation Ground Level 670.92

Top of Casing 673.87 (PVC)

SITE NAME Woodland Meadows North Landfill

SUPERVISED BY K. Repola



Drilling Summary:

Total Depth 71.0 ft.
Borehole Diameter 8.25 in.
Casing Stick-up Height: 2.95 ft.
Driller McDowell & Associates
Ferndale, Michigan

Rig CME 55
Bit(s) 0 - 71.0 ft. HSA

Drilling Fluid None

Protective Casing Gold 4-in. Anodized Alum.

Construction Time Log:

Task	Start Date	Start Time	Finish Date	Finish Time
Drilling HSA	6-9	1300	6-9	1630
	6-12	0803	6-12	1135
Geophys.Logging:				
Casing:				
Filter Placement:	6-12	1530	6-12	1607
Cementing: *	6-13	0811	6-13	1030
Development:	6-16	1030	6-16	1430
*Volclay Grout				

Well Design & Specifications

Basis: Geologic Log X Geophysical Log ____

Casing String (s): C = Casing S = Screen.

Depth			String(s)	Elevation	
+3.0	-	47.0	C1	673.89	623.92
47.0	-	52.0	C2	623.92	618.92
52.0	-	57.0	S1	618.92	613.92
	-				-
	-				-

Casing: C1 2-inch schedule 40 PVC flush joint, teflon taped

C2 2-inch stainless steel riser

Screen: S1 2-inch 0.020 wire wrapped stainless steel

S2

Filter Pack: #200 ottowa sand 45.5-46.0 ft., 49.0-50.0 ft., 57.0-57.5 ft., #3 quartz sand 50.0-57.0 ft.

Grout Seal:

Bentonite Seal: Bentonite pellets 46.0-49.0 ft., 57.5-71.0 ft., volclay grout 5.0-45.5 ft.

Well Development:

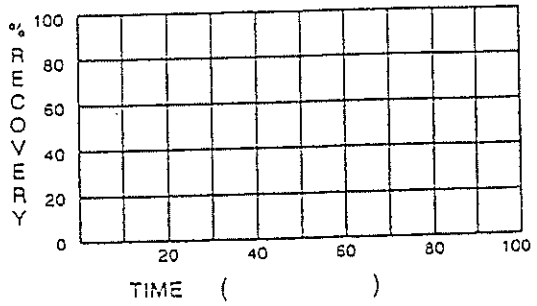
Developed for 4.0 hours using Geo-Guard pump. Produced 85 gallons water at 0.25-0.33 gpm. (0.30 gpm average)

Stabilization Test Data:

Time	pH	Spec. Cond.	Temp (C)
1045	8.77	369	10
1145	8.88	401	10
1250	8.81	451	10
1345	8.73	474	12
1415	8.59	493	11

Recovery Data: (See Appendix E)

Q= S_o=



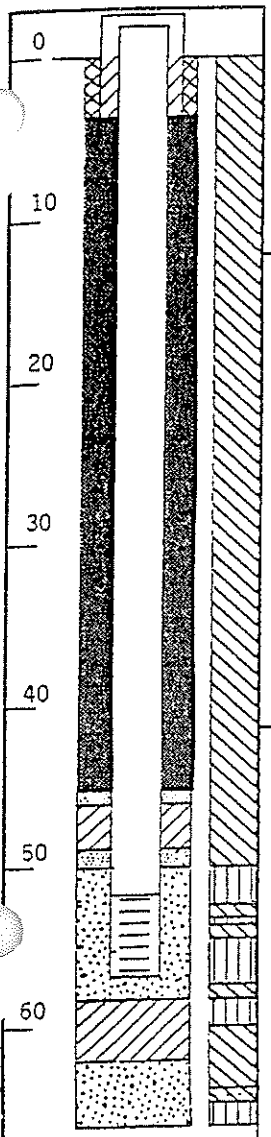
Comments:

Golder No. 893-2197

Well No. MW-12R

Boring No. X-Ref: MW-12R

MONITOR WELL CONSTRUCTION SUMMARY



Survey Coords: 4840N; 9213E

Elevation Ground Level 668.09

Top of Casing 671.05 (PVC)

SITE NAME Woodland Meadows North Landfill

Drilling Summary:

Total Depth 66.3 ft.
Borehole Diameter 8.25 in.
Casing Stick-up Height: 2.96 ft.
Driller McDowell & Associates
Ferndale, Michigan
J. Jones
Rig CME 55
Bit(s) 0 - 66.3 ft. HSA

Drilling Fluid None

Protective Casing Gold 4-in. Anodized Alum.

Construction Time Log:

Task	Start Date	Start Time	Finish Date	Finish Time
Drilling HSA	6-2	1500	6-2	1730
	6-3	0840	6-3	1100
Geophys. Logging:				
Casing:				
Filter Placement:	6-3	1215	6-3	1420
Cementing:	6-3	1040	6-3	1130
Development:	6-15	1330	6-15	1745

Well Design & Specifications

Basis: Geologic Log X Geophysical Log ___

Casing String (s): C = Casing S = Screen.

Depth		String(s)	Elevation	
+2.96	46.7	C1	671.05	621.39
46.7	51.7	C2	621.39	616.39
51.7	56.7	S1	616.39	611.39

Casing: C1 2-inch schedule 40 PVC flush joint, teflon taped

C2 2-inch stainless steel riser

Screen: S1 2-inch 0.020-slot wire wrapped stainless steel

S2

Filter Pack: #200 ottowa sand49.0-50.0 ft., 45.0-46.0 ft., #3 quartz 62.0-66.3 ft., 58.0 50.0 ft.

Grout Seal:

Bentonite Seal: Bentonite pellets 58.0-62.0 ft., 49.0-46.0 ft., volclay grout 5.0-45.0 ft.

Well Development:

Developed for 4.25 hours using Geo-Guard pump. Produced approximately 64 gallons at 0.25 gpm.

Stabilization Test Data:

Time	pH	Spec. Cond.	Temp (C)
1405	8.80	580	9.5
1505	8.32	686	12.0
1605	8.33	740	12.0
1705	8.53	777	13.5
1725	8.60	780	13.0

Recovery Data:

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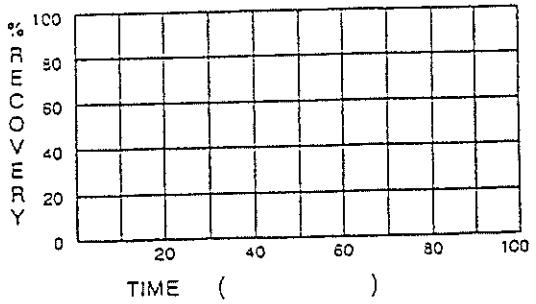


SUPERVISED BY K. Repola

Comments:

Golder No. 893-2197

Well No. MW-14

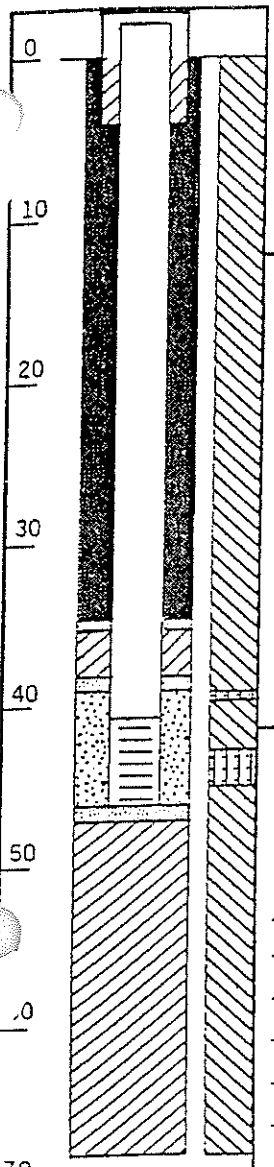
Boring No. X-Ref: MW-14

MONITOR WELL CONSTRUCTION SUMMARY

Survey Coords: 3805N; 7682E

Elevation Ground Level 671.82

Top of Casing 674.70 (PVC)



Drilling Summary:

Total Depth 67.0 ft.
Borehole Diameter 8.25 in.
Casing Stick-up Height: 2.88 ft.
Driller McDowell & Associates
Ferndale, Michigan

Rig CME 55
Bit(s) 0 - 67.0 ft. HSA

Drilling Fluid

Protective Casing Gold 4-in. Anodized Alum.

Construction Time Log:

Task	Start Date	Start Time	Finish Date	Finish Time
Drilling HSA	6-26	1111	6-26	1710
	6-27	0830	6-27	1030
Geophys. Logging:				
Casing:				
Filter Placement:	6-27	1400	6-27	1530
Cementing: *	6-27	1610	6-27	1645
Development:	6-29	1010	6-29	1415
*Volclay Grout				

Well Design & Specifications

Basis: Geologic Log X Geophysical Log ____
Casing String (s): C = Casing S = Screen.

Depth			String(s)	Elevation		
+2.9	-	35.5	C1	674.70	-	636.32
35.5	-	40.5	C2	636.32	-	631.32
40.5	-	45.5	S1	631.32	-	626.32
	-				-	
	-				-	

Casing: C1 2-inch schedule 40 PVC flush joint teflon taped
C2 2-inch stainless steel riser

Screen: S1 2-inch 0.020 wire wrapped stainless steel
S2

Filter Pack: #200 ottawa sand 34.0-34.5 ft., 37.5-38.5 ft., 45.5-46.0 ft., #3 quartz sand 38.5-45.5 ft.

Grout Seal:

Bentonite Seal: Bentonite chips 34.5-37.5 ft. 46.0-67.0 ft., Volclay grout 5.0-34.0 ft.

Well Development:

Developed for 4.1 hours using Geo-Guard pump. Produced approximately 45 gallons at an average rate of 0.186 gpm.

Stabilization Test Data:

Time	pH	Spec. Cond.	Temp (C)
1030	7.00	542	12.0
1130	8.13	939	14.0
1230	7.19	949	14.5
1330	7.12	960	14.5
1400	7.38	943	14.5

Recovery Data: (See Appendix E)

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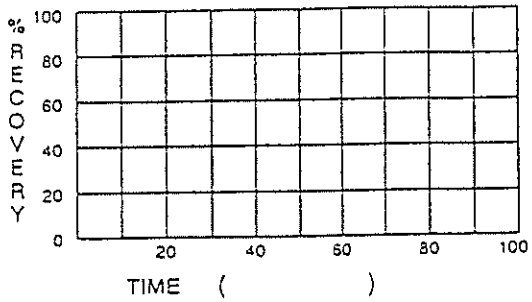
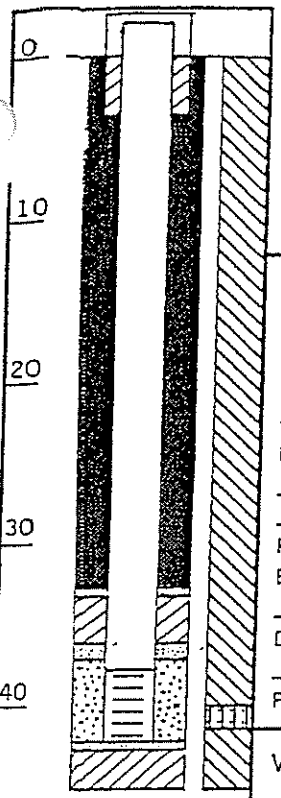


Comments:

SITE NAME Woodland Meadows North Landfill

SUPERVISED BY K. Repola

Golder No. 893-2197



Well No. MW-15

Boring No. X-Ref: MW-15

MONITOR WELL CONSTRUCTION SUMMARY

Survey Coords: 3658N; 8396E

Elevation Ground Level 668.85

Top of Casing 671.73 (PVC)

SITE NAME Woodland Meadows North Landfill

Drilling Summary:

Total Depth 45.0 ft.
Borehole Diameter 8.25 in.
Casing Stick-up Height: 2.88 ft.
Driller McDowell & Associates
Ferndale, Michigan
J. Jones
Rig CME 55
Bit(s) 0 - 45.0 ft. HSA
Drilling Fluid
Protective Casing Gold 4-in. Anodized Alum.

Construction Time Log:

Task	Start Date	Start Time	Finish Date	Finish Time
Drilling HSA	6-8	0800	6-8	1200
Geophys.Logging:				
Casing:				
Filter Placement:	6-8	1355	6-8	1431
Cementing: *	6-8	1530	6-8	1631
Development:	6-20	1135	6-20	1535
*Volclay Grout				

Well Design & Specifications

Basis: Geologic Log X Geophysical Log ____
Casing String (s): C = Casing S = Screen.

Depth	String(s)	Elevation
+2.9 - 34.0	C1	671.73 - 634.85
34.0 - 39.0	C2	634.85 - 629.85
39.0 - 42.0	S1	629.85 - 626.85
-		-
-		-

Casing: C1 2-inch schedule 40 PVC flush joint teflon taped
C2 2-inch stainless steel riser
Screen: S1 2-inch 0.020 wire wrapped stainless steel
S2
Filter Pack: #200 ottawa sand 32.5-33.0 ft., 36.0-37.0 ft., 42.0-42.5 ft., #3 quartz sand 37.0-42.0 ft.
Grout Seal:
Bentonite Seal: Bentonite chips 33.0-36.0 ft 42.5-45.0 ft., Volclay grout 5.0-32.5 ft.

Well Development:

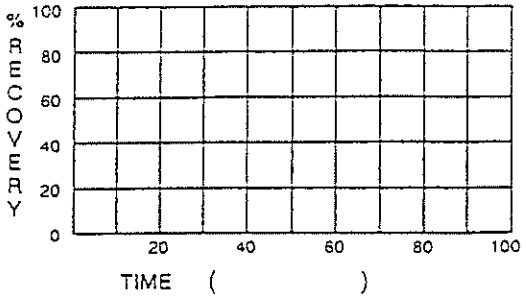
Developed for 4.0 hours using Geo-Guard pump. Produced 42.5 gallons at 0.14-0.33 gpm. (0.17 gpm average)

Stabilization Test Data:

Time	pH	Spec. Cond.	Temp (C)
1410	7.03	865	13
1440	7.40	655	13
1510	7.61	684	13.5
1530	7.53	667	13.5

Recovery Data: (See Appendix E)

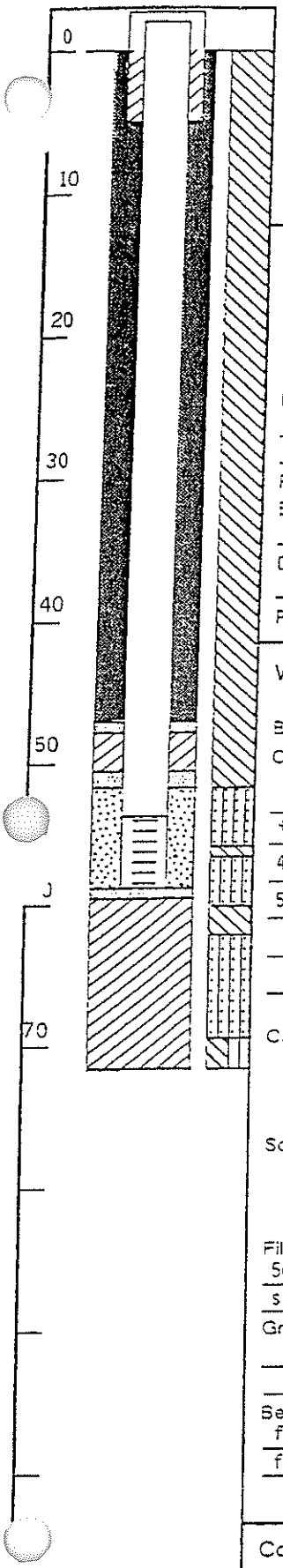
Q= S_o=



SUPERVISED BY K. Repola

Comments:

Golder No. 893-2197



Well No. MW-24R

Boring No. X-Ref: MW-24R

MONITOR WELL CONSTRUCTION SUMMARY

Survey Coords: 4216N; 9822E

Elevation Ground Level 671.02

Top of Casing 673.94 (PVC)

SITE NAME Woodland Meadows North Landfill

Drilling Summary:

Total Depth 71.0 ft.
Borehole Diameter 8.25 in.
Casing Stick-up Height: 2.92 ft.
Driller McDowell & Associates
Ferndale, Michigan
J. Jones
Rig CME 55
Bit(s) 0 - 71.0 ft. HSA

Drilling Fluid None

Protective Casing Gold 4-in. Anodized Alum.

Construction Time Log:

Task	Start Date	Start Time	Finish Date	Finish Time
Drilling HSA	6-28	1210	6-28	1750
	6-29	0730	6-29	0945
Geophys. Logging:				
Casing:				
Filter Placement:	6-29	1225	6-29	1315
Cementing: *	6-29	1430	6-29	1530
Development:	7-3	0935	7-3	1500
*Volclay Grout				

Well Design & Specifications

Basis: Geologic Log X Geophysical Log ____
Casing String (s): C = Casing S = Screen.

Depth	String(s)	Elevation
+2.9 - 48.5	C1	673.94_622.52
48.5 - 53.5	C2	622.52_617.52
53.5 - 58.5	S1	617.52_612.52
____ - ____		____ - ____
____ - ____		____ - ____

Casing: C1 2-inch schedule 40 PVC flush joint, teflon taped
C2 2-inch stainless steel riser

Screen: S1 2-inch 0.020 stainless steel
S2

Filter Pack: #200 ottawa sand 47.0-47.5 ft., 50.5-51.5 ft., 58.5-59.0 ft., #3 quartz sand 51.5-58.5 ft.

Grout Seal:

Bentonite Seal: Bentonite pellets 47.5-50.5 ft., 59.0-71.0 ft., Volclay grout 5.0-47.0 ft.

Well Development:

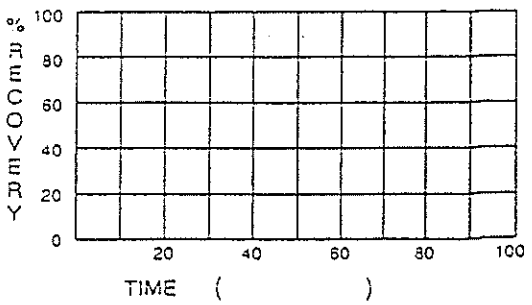
Developed for 5.5 hours using Geo-Guard pump. Produced approximately 82.5 gallons at average rate of 0.25 gpm.

Stabilization Test Data:

Time	pH	Spec. Cond.	Temp (C)
0950	7.60	484	13.5
1140	7.06	653	13.5
1240	7.08	768	14.0
1340	7.10	801	15.0
1440	7.32	833	15.0

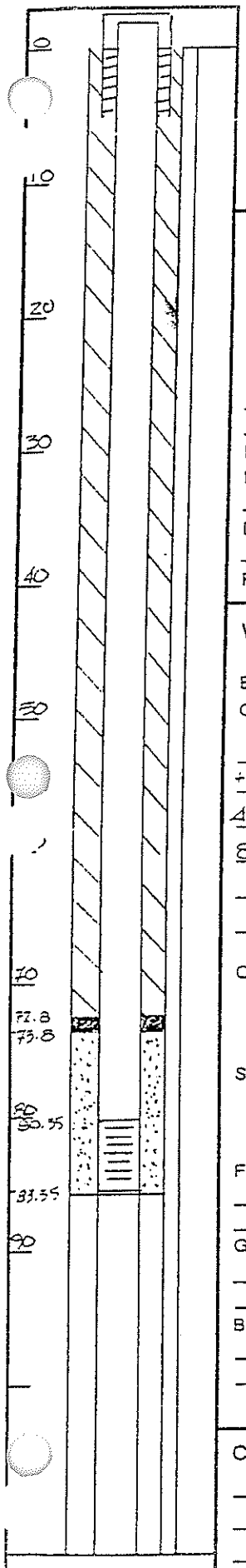
Recovery Data: (See Appendix E)

Q= S_o=



SUPERVISED BY K. Repola

Comments:



Well No. GA-31B

Boring No. X-Ref: GA-31B

MONITOR WELL CONSTRUCTION SUMMARY

Survey Coords: _____

Elevation Ground Level 671.3

Top of Casing 673.29

Drilling Summary:

Total Depth 85.35

Borehole Diameter 7.0 IN.

Casing Stick-up Height: 1.99 FT.

Driller MATECO

Rig CME 550

Bit(s) _____

Drilling Fluid NONE

Protective Casing 4-IN. STEEL

Construction Time Log:

Task	Start Date	Start Time	Finish Date	Finish Time
Drilling	7-85	NA	7-85	NA
Geophys. Logging:	NA.			
Casing:				
Filter Placement:		NA		
Cementing:	7-85	[illegible]	7-85	NA
Development:	NA	NA	NA	NA

Well Design & Specifications

Basis: Geologic Log X Geophysical Log ____

Casing String (s): C = Casing S = Screen.

Depth	String(s)	Elevation
+1.99 - 48.01	C1	____ - ____
48.01 - 80.35	C2	____ - ____
80.35 - 85.35	S1	____ - ____
____ - ____		____ - ____
____ - ____		____ - ____

Casing: C1 2-IN SCHEDULE 40 PVC FLUSH JOINT, TEFLON

C2 TAPED.

Screen: S1 2-IN 0.010 WIRE WRAPPED PVC

S2 _____

Filter Pack: SAND 73.8 - 85.35 FT

Grout Seal: BENTONITE SLURRY 0 - 72.8 FT.

Bentonite Seal: BENTONITE PELLETS 72.8 - 73.8 FT.

Well Development:

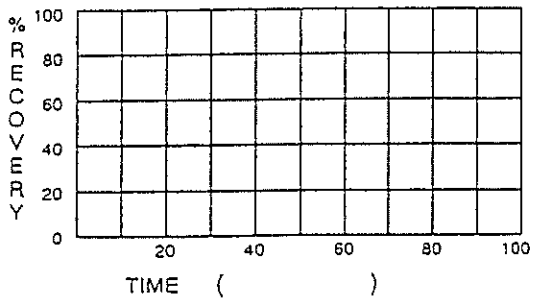
NA

Stabilization Test Data:

Time	pH	Spec. Cond.	Temp (C)

Recovery Data:

Q= S_o=



Comments: THIS WELL CONSTRUCTION SUMMARY HAS BEEN RECONSTRUCTED FROM EXISTING DATA. GEOLOGIC INFORMATION IS FOUND ON GA-31A BOEING LOG

SITE NAME _____

SUPERVISED BY _____

PIEZOMETER INSTALLATION LOG

JOB NO 853-3172 PROJECT WMI/WOODLAND/MI WELL NO GA-32C SHEET 1 OF 1
GA INSP S. REESE DRILLING METHOD HOLLOW STEM AUGER GROUND ELEV 670.93 WATER DEPTH 662.4
WEATHER SUNNY DRILLING COMPANY MATECO DATE/TIME 10/23/85
TEMP WARM DRILL RIG CME 550 DRILLER S. REMPALSKI STARTED 0715 / 7-26-85 COMPLETED 1500 / 7-26-85
(TIME / DATE) (TIME / DATE)

MATERIALS INVENTORY

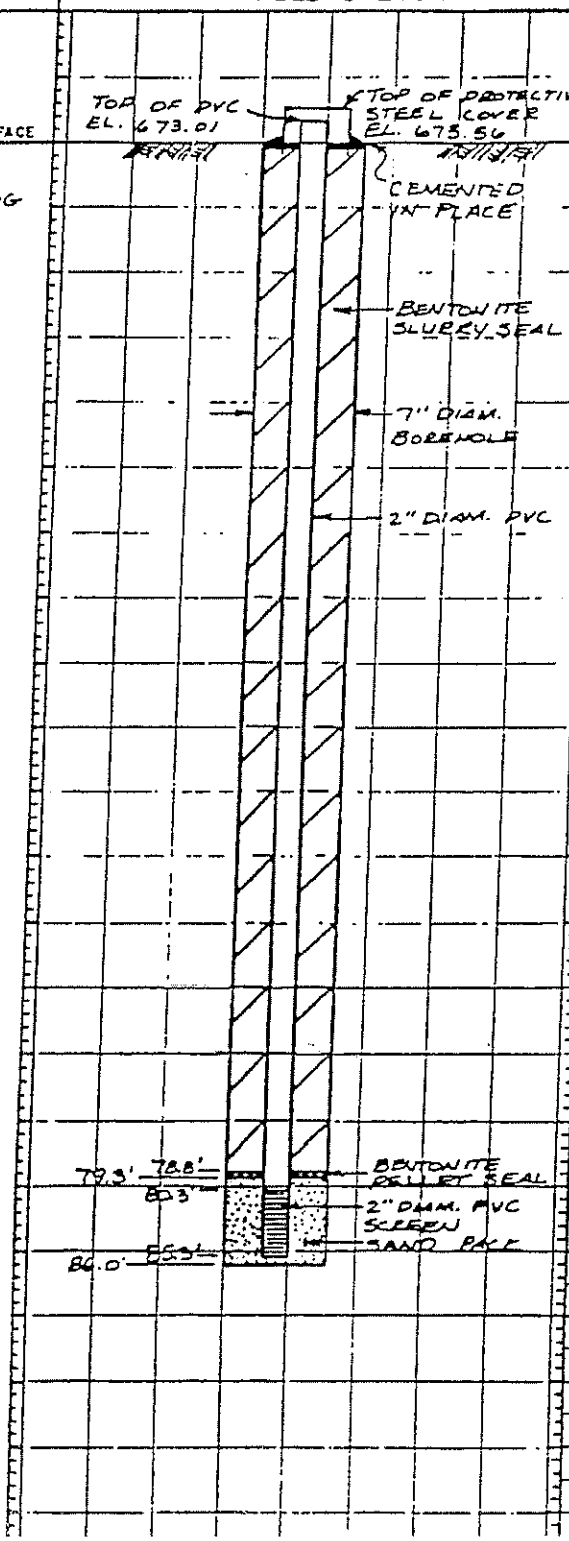
WELL CASING 2 in dia 82.5 ft
CASING TYPE PVC
JOINT TYPE FLUSH COUPLED-TEFLON TAPED
GROUT QUANTITY —
GROUT TYPE BENTONITE SLURRY

WELL SCREEN 2 in dia 5 ft
SCREEN TYPE JOHNSON WELL SCREEN PVC
SLOT SIZE 0.010
CENTRALIZERS —
DRILLING MUD TYPE —

BENTONITE SEAL BENTONITE PELLETS
INSTALLATION METHOD HAND POURED
FILTER PACK QTY 6.7 FT
FILTER PACK TYPE SAND
INSTALLATION METHOD HAND POURED

ELEV/DEPTH	SOIL/ROCK DESCRIPTION
(670.9)	GROUND SURFACE
0.0	
	SEE BORING LOG GA-32A FOR SOIL/ROCK DESCRIPTION
10.0	
20.0	
30.0	
40.0	
50.0	
60.0	
70.0	
80.0	
(580.3) 90.0	

WELL SKETCH



INSTALLATION NOTES

BENTONITE SLURRY: 0'-78.8'
TOP OF BENT. PELLETS: 78.8'
TOP OF SAND: 79.3'
TOP OF SCREEN: 80.3'
BOTTOM OF SCREEN: 85.3'

NOTE: ALL PVC WAS STEAM CLEANED PRIOR TO USE

WELL DEVELOPMENT NOTES

EVAC. WELL WITH STAINLESS STEEL BAILER ON 8-4-85.
EVAC. WELL WITH NITR. GAS ON 9-19-85.
EVAC. WELL WITH NITR. GAS ON 9-20-85.
EVAC. WELL WITH NITR. GAS ON 9-25-85.

PIEZOMETER INSTALLATION LOG

JOB NO 853-3172 PROJECT WMI/WOODLAND/MI WELL NO GA-33C SHEET 1 OF 1
GA INSP S. REESE DRILLING METHOD HOLLOW STEM AUGER GROUND ELEV 666.24 WATER DEPTH 661.2
WEATHER SUNNY DRILLING COMPANY MATECO DATE/TIME 10/2/85
TEMP WARM DRILL RIG CME 550 DRILLER S REMPALSKI STARTED 1300 / 8-21-85 COMPLETED 1900 / 8-28-85
(TIME / DATE) (TIME / DATE)

MATERIALS INVENTORY

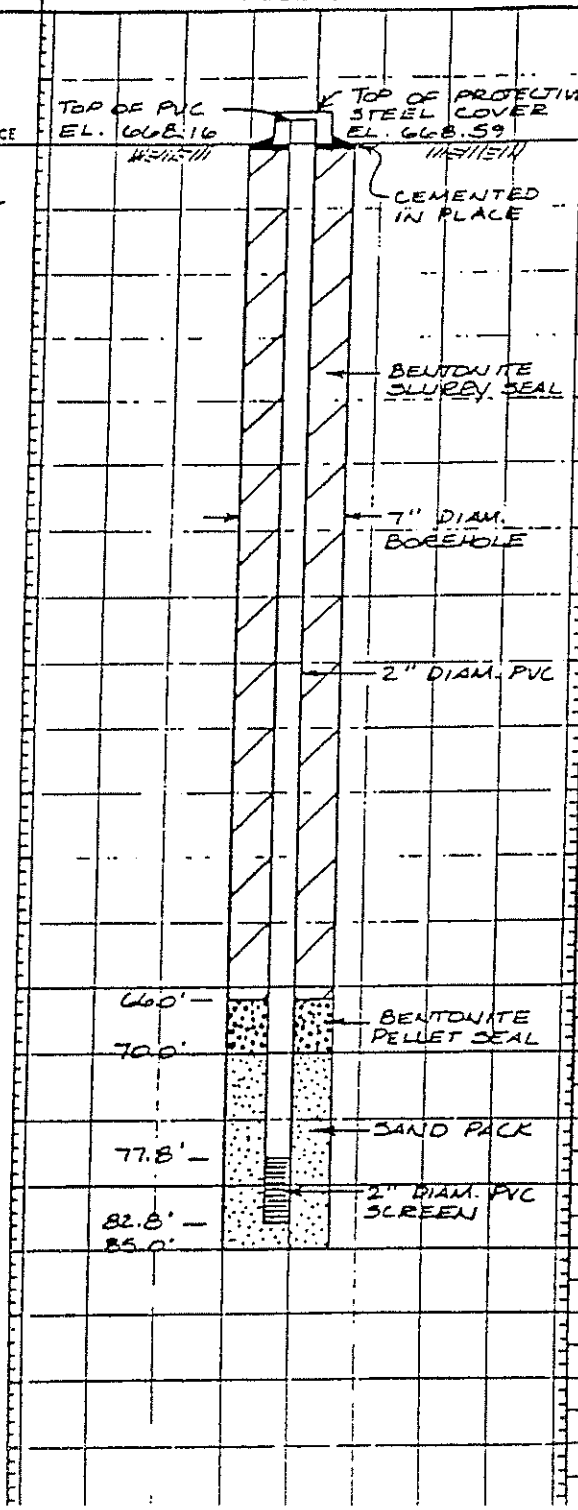
WELL CASING 2 in dia 79.8 ft
CASING TYPE PVC
JOINT TYPE FLUSH COUPLED-TEFLON TAPED
GROUT QUANTITY —
GROUT TYPE BENTONITE SLURRY

WELL SCREEN 2 in dia 5 ft
SCREEN TYPE JOHNSON WELL SCREEN PVC
SLOT SIZE 0.010
CENTRALIZERS —
DRILLING MUD TYPE —

BENTONITE SEAL BENTONITE PELLETS
INSTALLATION METHOD HAND POURED
FILTER PACK QTY 15.0 FT
FILTER PACK TYPE SAND
INSTALLATION METHOD HAND POURED

ELEV./DEPTH	SOIL/ROCK DESCRIPTION
(666.2)	GROUND SURFACE
0.0	SEE BORING LOG GA-33A FOR SOIL/ROCK DESCRIPTION
10.0	
20.0	
30.0	
40.0	
50.0	
60.0	
70.0	
80.0	
(576.2) 90.0	

WELL SKETCH



INSTALLATION NOTES

BENTONITE SLURRY: 0'-66.0'
TOP OF BENT. PELLETS: 66.0'
TOP OF SAND: 70.0'
TOP OF SCREEN: 77.8'
BOTTOM OF SCREEN: 82.8'

NOTE: ALL PVC WAS STEAM CLEANED PRIOR TO USE

WELL DEVELOPMENT NOTES

EVAC WELL WITH NITR.
GAS ON 9-19-85.
EVAC. WELL WITH NITR.
GAS ON 9-20-85.
EVAC. WELL WITH NITR.
GAS ON 9-23-85.
EVAC. WELL WITH NITR.
GAS ON 9-25-85.

PIEZOMETER INSTALLATION LOG

JOB NO 853-3172 PROJECT WMI/WOODLAND/MI WELL NO GA-34A SHEET 1 OF 1
GA INSP S. REESE DRILLING METHOD HOLLOW STEM AUGER GROUND ELEV 671.31 WATER DEPTH 666.9
WEATHER SUNNY DRILLING COMPANY MATECO DATE/TIME 10/23/85
TEMP WARM DRILL RIG CME 550 DRILLER S REMPALSKI STARTED 1630/8-1-85 (TIME / DATE) COMPLETED 2100/8-1-85 (TIME / DATE)

MATERIALS INVENTORY

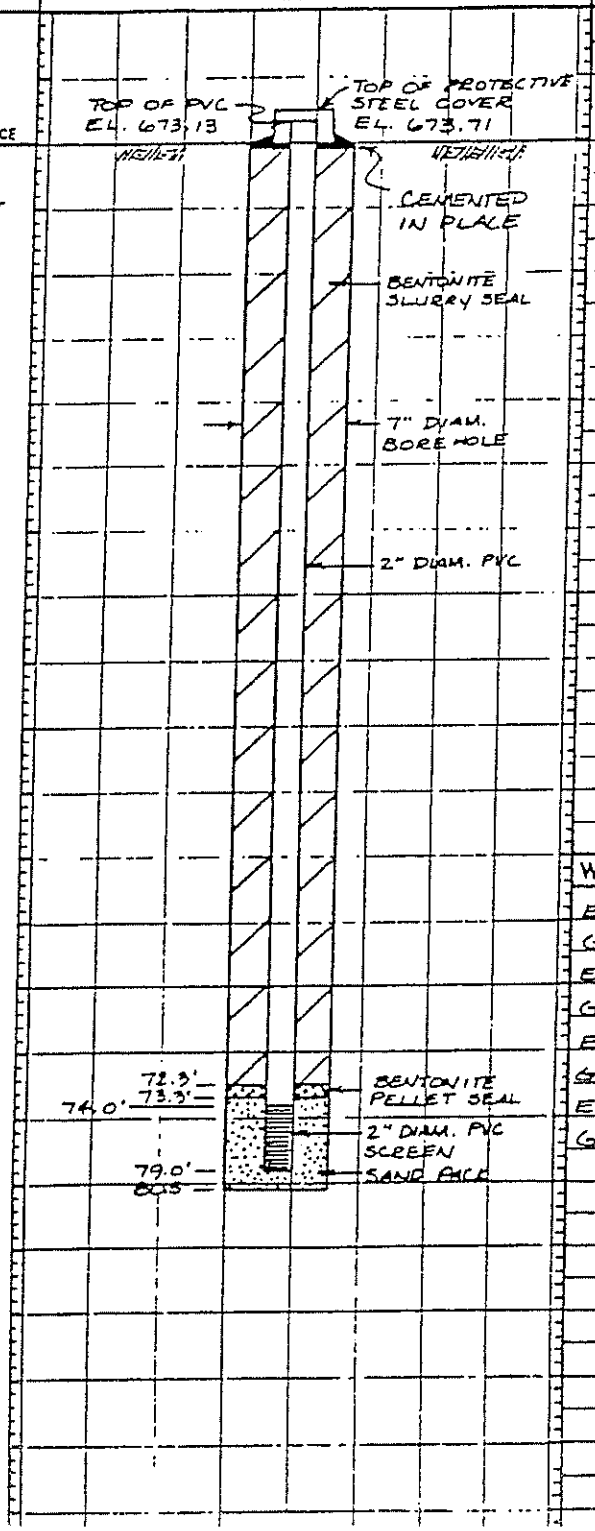
WELL CASING 2 in dia 75.8 ft
CASING TYPE PVC
JOINT TYPE FLUSH COUPLED-TEFLON TAPED
GROUT QUANTITY —
GROUT TYPE BENTONITE SLURRY

WELL SCREEN 2 in dia 5 ft
SCREEN TYPE JOHNSON WELL SCREEN PVC
SLOT SIZE 0.010
CENTRALIZERS —
DRILLING MUD TYPE —

BENTONITE SEAL BENTONITE PELLETS
INSTALLATION METHOD HAND POURED
FILTER PACK QTY 7.2 FT.
FILTER PACK TYPE SAND
INSTALLATION METHOD HAND POURED

ELEV/DEPTH	SOIL/ROCK DESCRIPTION
(671.3)	GROUND SURFACE
0.0	SEE BORING LOG GA-34A FOR SOIL/ROCK DESCRIPTION
10.0	
20.0	
30.0	
40.0	
50.0	
60.0	
70.0	
(591.3) 80.0	

WELL SKETCH



INSTALLATION NOTES

BENTONITE SLURRY: 0'-72.3'
TOP OF BENT. PELLETS: 72.3'
TOP OF SAND: 73.3'
TOP OF SCREEN: 74.0'
BOTTOM OF SCREEN: 79.0'

NOTE: ALL PVC WAS STEAM CLEANED PRIOR TO USE

WELL DEVELOPMENT NOTES

EVAC. WELL WITH NITR.
GAS ON 9-18-85.
EVAC. WELL WITH NITR.
GAS ON 9-19-85.
EVAC. WELL WITH NITR.
GAS ON 9-21-85.
EVAC. WELL WITH NITR.
GAS ON 9-25-85.

PIEZOMETER INSTALLATION LOG

JOB NO 853-3172 PROJECT WMI/WOODLAND/MI WELL NO GA-35A SHEET 1 OF 1
GA REP P. INGRAM DRILLING METHOD HOLLOW STEM AUGER GROUND ELEV 667.18 WATER DEPTH 653.6
WEATHER CLEAR DRILLING COMPANY MATECO DATE/TIME 10/23/85
TEMP 85° DRILL RIG CME 550 DRILLER S. REMPALSKI STARTED 1200/7-3-85 COMPLETED 1320/7-11-85
(TIME / DATE) (TIME / DATE)

MATERIALS INVENTORY

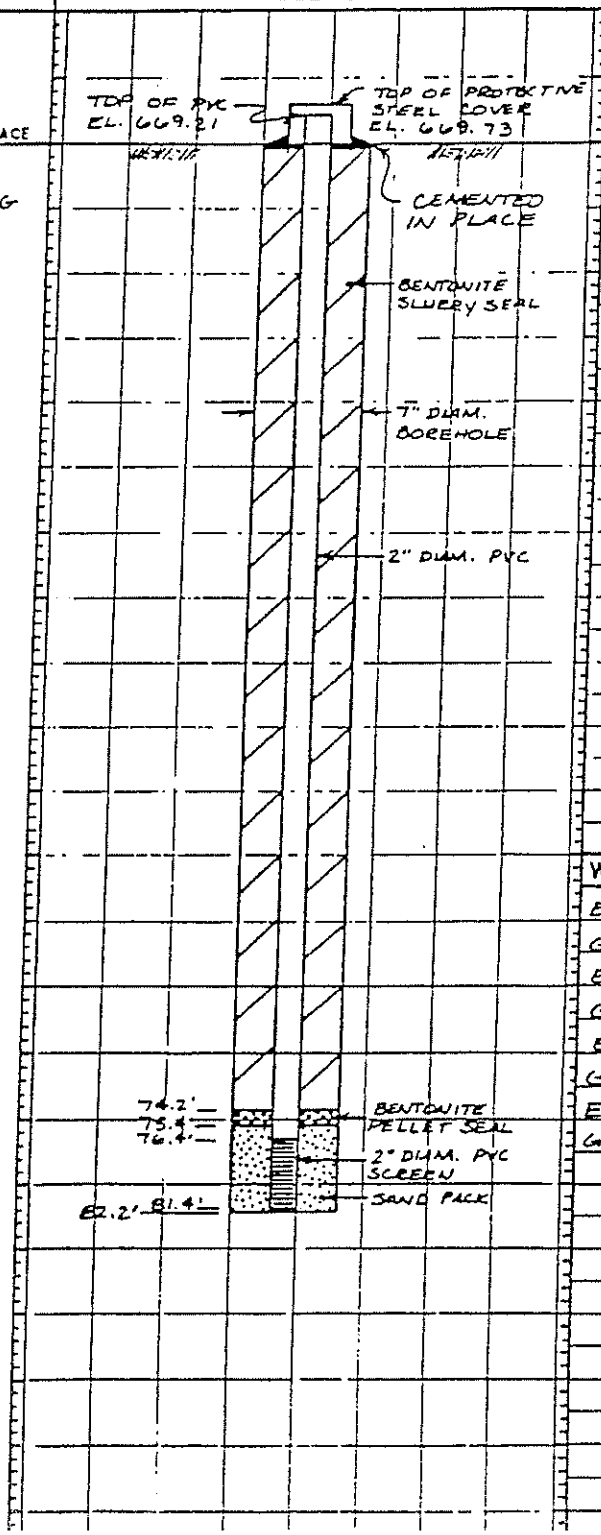
WELL CASING 2 in dia 78.4 ft
CASING TYPE PVC
JOINT TYPE FLUSH COUPLED-TEFLON TAPED
GROUT QUANTITY —
GROUT TYPE BENTONITE SLURRY

WELL SCREEN 2 in dia 5 ft
SCREEN TYPE JOHNSON WELL SCREEN PVC
SLOT SIZE 0.010
CENTRALIZERS —
DRILLING MUD TYPE —

BENTONITE SEAL BENTONITE PELLETS
INSTALLATION METHOD HAND POURED
FILTER PACK QTY 6.8 FT
FILTER PACK TYPE SAND
INSTALLATION METHOD HAND POURED

ELEV./DEPTH	SOIL/ROCK DESCRIPTION
(667.2) 0.0	GROUND SURFACE
	SEE BORING LOG GA-35A FOR SOIL/ROCK DESCRIPTION
10.0	
20.0	
30.0	
40.0	
50.0	
60.0	
70.0	
(587.2) 80.0	

WELL SKETCH



INSTALLATION NOTES

BENTONITE SLURRY: 0'-74.2'
TOP OF BENT. PELLETS: 74.2'
TOP OF SAND: 75.4'
TOP OF SCREEN: 76.4'
BOTTOM OF SCREEN: 81.8'

NOTE: ALL PVC WAS STEAM CLEANED PRIOR TO USE

WELL DEVELOPMENT NOTES

EVAC. WELL WITH NITR. GAS ON 9-18-85.
EVAC. WELL WITH NITR. GAS ON 9-19-85.
EVAC. WELL WITH NITR. GAS ON 9-20-85.
EVAC. WELL WITH NITR. GAS ON 9-25-85.

PIEZOMETER INSTALLATION LOG

JOB NO 853-3172 PROJECT WMI/WOODLAND/MI WELL NO GA-36A SHEET 1 OF 1
S.A. INSP S. REESE DRILLING METHOD HOLLOW STEM AUGER GROUND ELEV 665.65 WATER DEPTH 660.9
WEATHER SUNNY DRILLING COMPANY MATECO DATE/TIME 10/29/85
TEMP HOT DRILL RIG CME 550 DRILLER S. REMPALSKI STARTED 0951 / 8-8-85 (TIME / DATE) COMPLETED 1500 / 8-8-85 (TIME / DATE)

MATERIALS INVENTORY

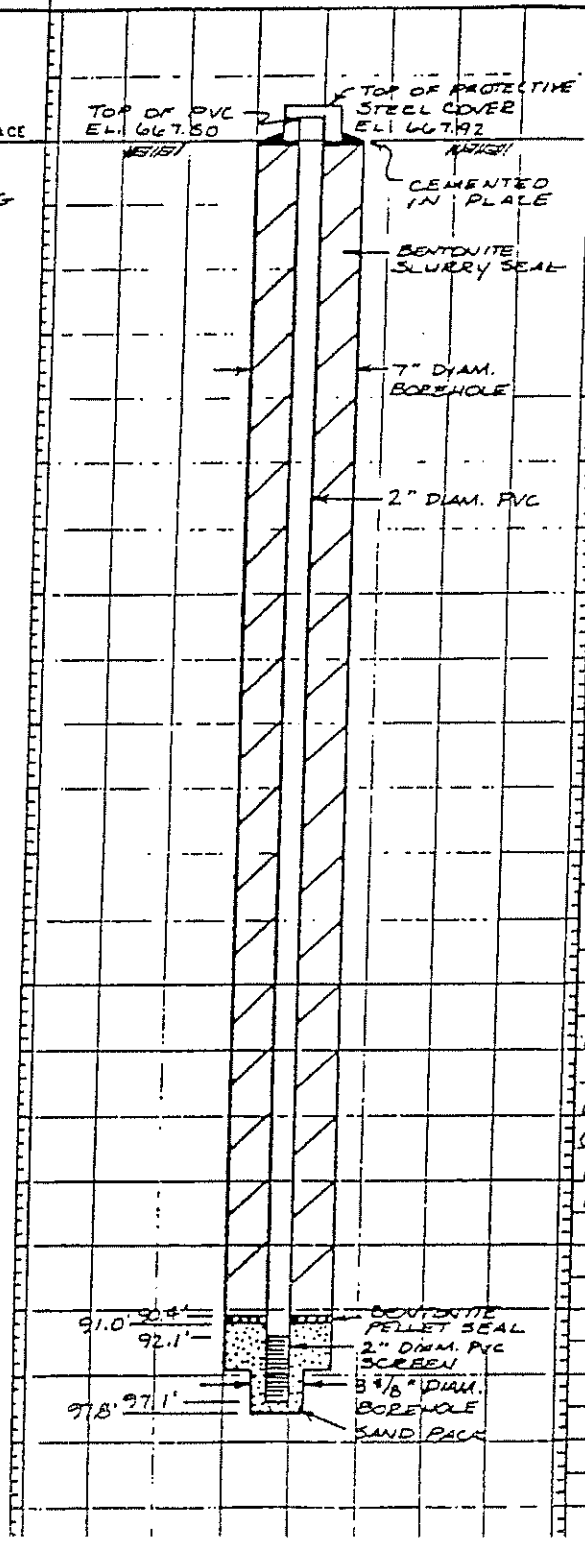
WELL CASING 2 in dia 93.9 ft
CASING TYPE PVC
JOINT TYPE FLUSH COUPLED-TEFLON TAPED
GROUT QUANTITY —
GROUT TYPE BENTONITE SLURRY

WELL SCREEN 2 in dia 5 ft
SCREEN TYPE JOHNSON WELL SCREEN PVC
SLOT SIZE 0.010
CENTRALIZERS —
DRILLING MUD TYPE —

BENTONITE SEAL BENTONITE PELLETS
INSTALLATION METHOD HAND POURED
FILTER PACK QTY 6.8 FT
FILTER PACK TYPE SAND
INSTALLATION METHOD HAND POURED

ELEV./DEPTH	SOIL/ROCK DESCRIPTION
(665.7)	GROUND SURFACE
0.0	SEE BORING LOG GA-36A FOR SOIL/ROCK DESCRIPTION
10.0	
20.0	
30.0	
40.0	
50.0	
60.0	
70.0	
80.0	
90.0	
(565.7) 100.0	

WELL SKETCH



INSTALLATION NOTES

BENTONITE SLURRY: 0'-90.4'
TOP OF BENT. PELLETS: 90.4'
TOP OF SAND: 91.0'
TOP OF SCREEN: 92.1'
BOTTOM OF SCREEN: 97.1'

NOTE: ALL PVC WAS STEAM CLEANED PRIOR TO USE

WELL DEVELOPMENT NOTES

EVAC. WELL WITH AIR.
GAS ON 9-18-85.
EVAC. WELL WITH NITR.
GAS ON 9-19-85
EVAC. WELL WITH NITR.
GAS ON 9-20-85.
EVAC. WELL WITH NITR.
GAS ON 9-21-85.
EVAC. WELL WITH NITR.
GAS ON 9-25-85.

MONITORING WELL INSTALLATION LOG

JOB NO 863-2009 PROJECT WMI Woodland II / MI WELL NO GA-46W SHEET 1 OF 1
GA INSP G. Auberlin DRILLING METHOD Hollow Stem Auger / Rotary wash GROUND ELEV 672.00 WATER DEPTH 12.4' *
WEATHER Overcast DRILLING COMPANY Matteco Drilling * from PVC. DATE 3-6-86
TEMP. 5/16°F DRILL RIG CME 550 DRILLER S. Lemanski STARTED 3-17-86 COMPLETED 3-25-86

MATERIALS INVENTORY

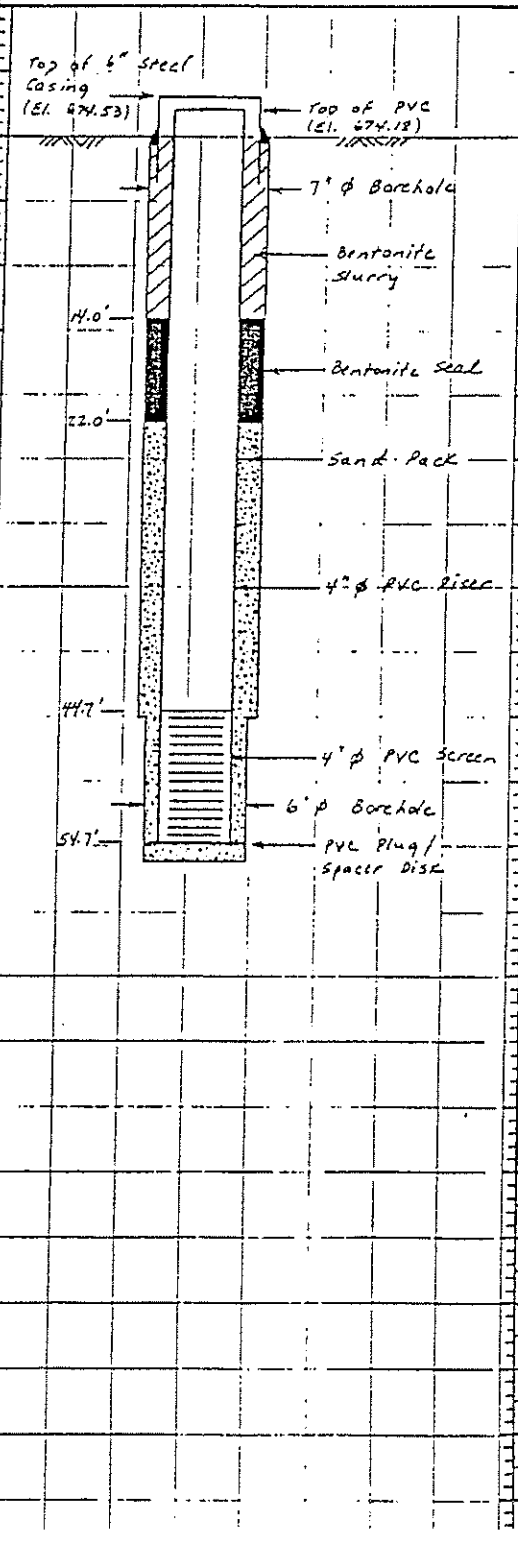
WELL CASING 4.03 in. dia. 46.9 Lf
CASING TYPE Johnson PVC Riser
JOINT TYPE Flush Coupled (Teflon Taped)
GROUT QUANTITY —
GROUT TYPE Bentonite Slurry

WELL SCREEN 4.00 in. dia. 10.0 Lf
SCREEN TYPE Johnson PVC well Screen
SLOT SIZE 0.010 inch
CENTRALIZERS PVC Spacer Disk
DRILLING MUD TYPE Quick Gel

BENTONITE SEAL Bentonite Chips
INSTALLATION METHOD Hand Poured
FILTER PACK QTY —
FILTER PACK TYPE Medium to Coarse Sand
INSTALLATION METHOD Hand Poured

ELEV./DEPTH	SOIL/ROCK DESCRIPTION
672.00	GROUND SURFACE
0.0	See boring log GA-46W for soil descriptions.
10.0	
20.0	
30.0	
40.0	
50.0	
615.8	
56.2	

WELL SKETCH



INSTALLATION NOTES

Top of Bentonite Seal: 14.0'
Top of Sand: 22.0'
Top of Screen: 44.7'
Bottom of Screen: 54.7'

Bentonite Slurry: 0'-14.0'
(6" S.D. steel casing cemented in place)

Note: All PVC was steam cleaned prior to use

WELL DEVELOPMENT NOTES

Submersible pump intake was set ≈ 40' below the ground surface and pumped for about 5 hours at an average discharge of ≈ 1 gpm on 3-5-86.

Well No. MW-50

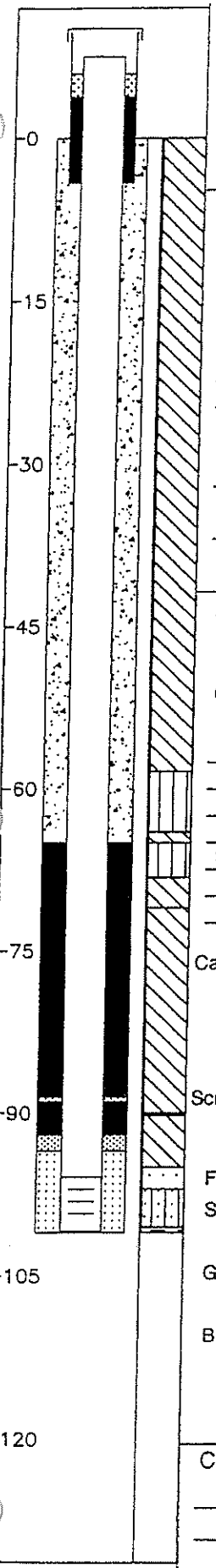
Boring No. X-Ref: MW-50

MONITORING WELL CONSTRUCTION SUMMARY

Survey Coords: Northing: 4575 ft. Easting: 7680 ft.

Elevation Ground Level 671.5 ft. NGVD

Top of PVC Casing 674.30 ft. NGVD



Not to Scale

Drilling Summary:

Total Depth 101.0 ft.

Borehole Diameter (0.0-74.0') 10.25";(74.0-101.0') 3.875"

Casing Stickup Height 2.80 ft.

Driller Rau Drilling, Bay City, MI

Rig CME 75

Bit(s) 6 1/4" ID Auger Bit and 3 7/8" Tricone Bit

Drilling Fluid Water from 74.0-101.0'

Protective Casing 4x4" square by 7.5' Anodized Aluminum

Construction Time log:

Task	Start Date	Start Time	Finish Date	Finish Time
Drilling	7/26/94	13:00	7/28/94	17:00
Geophys.Logging				
Casing:	7/29/94	9:30	7/29/94	9:50
Filter Placement:	7/29/94	10:25	7/29/94	10:45
Cementing:	7/29/94	11:15	7/29/94	12:15
Development	8/1/94	14:30	8/2/94	20:50
Bentonite Seal	7/29/94	10:45	7/29/93	11:15

Well Design & Specifications

Basis: Geologic Log X Geophysical Log

Casing string(s): C = Casing S = Screen

Depth			String(s)	Elevation		
+ 2.80	-	90.90	C1	674.30	-	580.52
4.00	-	74.00	C2	667.46	-	597.46
90.90	-	95.90	C3	580.56	-	575.56
95.90	-	100.90	S1	575.56	-	570.56
	-				-	
	-				-	

Casing: C1 2" ID Schedule 40 Flush Threaded PVC Riser with O-Rings

C2 4" ID Schedule 40 Flush Threaded PVC Surface Casing

C3 2" ID Stainless Steel Flush Threaded Riser

Screen: S1 2" ID Stainless Steel 0.010" Wire Wrap, Flush Threaded, with Welded Bottom Cap

Filter Sand: #100 Silica Sand (88.5-89.0' & 92.0-93.5')

Sand Pack: #7 Global Drilling Silica Sand (93.5-101.0')

Grout Seal: Cement/Bentonite Grout (0.0-65.0') Volclay/Bentonite Grout (65.0-88.5')

Bentonite Seal: Enviroplug Medium Bentonite Chips (89.0-92.0')

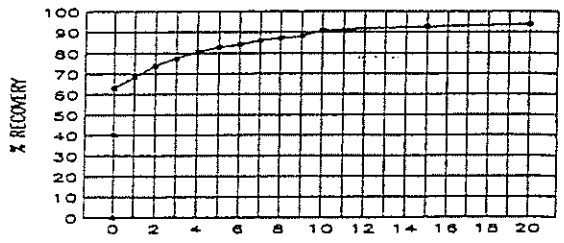
Well Development

Bailed about 40 gals. from well. Purged well with Grundfos pump and removed about 280 gals., water clear after purging about 55 gals.

Stabilization Test Data:

Time	pH	Spec. Cond.	Temp (°C)
18:49	9.31	1201	18.1
19:51	8.61	1383	16.1
20:35	8.55	1380	14.7
20:40	8.51	1383	15.5
20:45	8.54	1385	14.6

Recovery Data:



Comments:

Supervised by B. Tilton

Job Number 913-2402.007

Site WMNA/NORTH LANDFILL/MI

File Name 2402MW50

Well No. GA-51

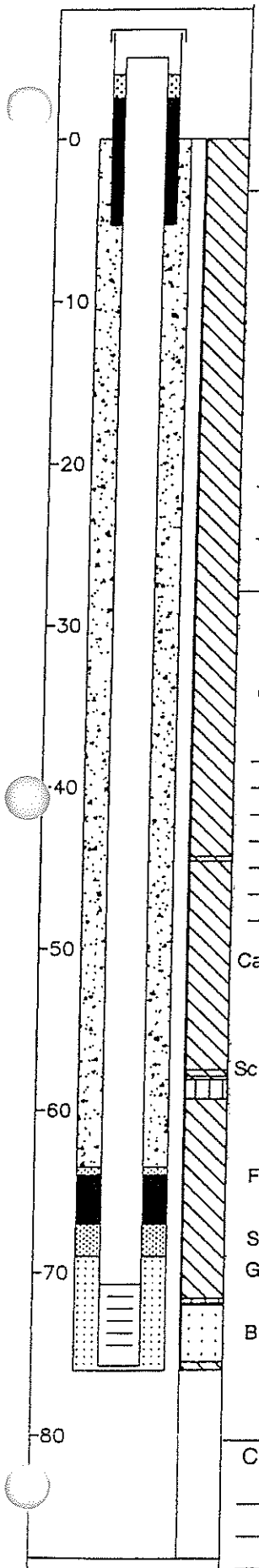
Boring No. X-Ref: GA-51

MONITORING WELL CONSTRUCTION SUMMARY

Survey Coords: Northing: 5631 ft. Easting: 7789 ft.

Elevation Ground Level 673.6 ft. NGVD

Top of PVC Casing 676.39 ft. NGVD



Not to Scale

Drilling Summary:

Total Depth 76.0 ft.
Borehole Diameter 8.25"
Casing Stickup Height 2.79 ft.
Driller Rau Drilling
Bay City, MI

Rig CME 75
Bit(s) 4 1/4" ID Auger Bit

Drilling Fluid None

Protective Casing 4x4" square by 7.5' Anodized Aluminum

Construction Time log:

Task	Start Date	Start Time	Finish Date	Finish Time
Drilling	7/29/94	16:15	7/30/94	15:00
Geophys.Logging				
Casing:	7/30/94	15:30	7/30/94	15:45
Filter Placement:	7/30/94	15:45	7/30/94	16:15
Cementing:	7/30/94	16:30	7/30/94	18:00
Development	8/1/94	14:30	8/3/94	11:30
Bentonite Seal	7/30/94	16:15	7/30/94	16:30

Well Design & Specifications

Basis: Geologic Log X Geophysical Log

Casing string(s): C = Casing S = Screen

Depth			String(s)	Elevation		
+ 2.79	-	65.70	C1	676.39	-	607.86
65.70	-	70.70	C2	607.86	-	602.86
70.70	-	75.70	S1	602.86	-	597.86
	-				-	
	-				-	
	-				-	

Casing: C1 2" ID Schedule 40 Flush Threaded PVC with O-Rings

C2 2" ID Stainless Steel Flush Threaded Riser

Screen: S1 2" ID Stainless Steel 0.010" Wire Wrap, Flush Threaded, with Welded Bottom Cap

Filter Sand: #100 Silica Sand (67.0-69.0' & 63.5-64.0')

Sand Pack: #7 Global Drilling Silica Sand (69.0-76.0')

Grout Seal: Cement/Bentonite Grout (0.0-63.5')

Bentonite Seal: Enviroplug Medium Bentonite Chips (64.0'-67.0')

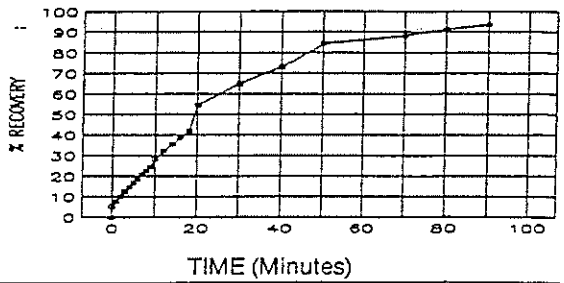
Well Development

Bailed about 25 gals. from well. Well repeatedly pumped dry and allowed to recharge numerous times over 16 hours. At end of development, water light brown to milky in color.

Stabilization Test Data:

Time	pH	Spec. Cond.	Temp (°C)
10:13	9.31	424	21.2
10:19	9.33	382	16.2
10:23	9.3	382	16.2
10:26	9.28	386	16.2

Recovery Data:



Comments:

Supervised by B. Tilton Site WMNA/NORTH LANDFILL/MI

Job Number 913-2402.007 File Name 2402MW51

APPENDIX B

FIELD INFORMATION LOGS & CHAIN OF CUSTODY FORM

FIELD INFORMATION FORM

WASTE MANAGEMENT

Site Name: _____ Site No.: _____ Sample Point: _____ Sample ID

This Waste Management Field Information Form is Required
This form is to be completed, in addition to any State Forms. The Field Form is submitted along with the Chain of Custody Forms that accompany the sample containers (i.e. with the cooler that is returned to the laboratory).

Laboratory Use Only/Lab ID: _____

PURGE INFO

PURGE DATE (MM DD YY)	PURGE TIME (2400 Hr Clock)	ELAPSED HRS (hrs:min)	WATER VOL IN CASING (Gallons)	ACTUAL VOL PURGED (Gallons)	WELL VOLs PURGED

Note: For Passive Sampling, replace "Water Vol in Casing" and "Well Vols Purged" w/ Water Vol in Tubing/Flow Cell and Tubing/Flow Cell Vols Purged. Mark changes, record field data, below.

PURGE/SAMPLE EQUIPMENT

Purging and Sampling Equipment ... Dedicated: Y or N

Filter Device: Y or N 0.45 µ or _____ µ (circle or fill in)

Purging Device: _____ Sampling Device: _____ X-Other: _____

A- Submersible Pump, B-Peristaltic Pump, C-QED Bladder Pump, D-Bailer, E-Piston Pump, F-Dipper/Bottle

Filter Type: _____ A-In-line Disposable, B-Pressure, C-Vacuum, X-Other _____

Sample Tube Type: _____ A-Teflon, B-Stainless Steel, C-PVC, D-Polypropylene, X-Other: _____

WELL DATA

Well Elevation (at TOC): _____ (ft/msl) Depth to Water (DTW) (from TOC): _____ (ft) Groundwater Elevation (site datum, from TOC): _____ (ft/msl)

Total Well Depth (from TOC): _____ (ft) Stick Up (from ground elevation): _____ (ft) Casing ID: _____ (in) Casing Material: _____

Note: Total Well Depth, Stick Up, Casing Id, etc. are optional and can be from historical data, unless required by Site/Permit. Well Elevation, DTW, and Groundwater Elevation must be current.

STABILIZATION DATA (Optional)

Sample Time (2400 Hr Clock)	Rate/Unit _____	pH (std)	Conductance (SC/EC) (µmhos/cm @ 25 °C)	Temp. (°C)	Turbidity (ntu)	D.O. (mg/L - ppm)	eH/ORP (mV)	DTW (ft)
1st								
2nd								
3rd								
4th								
Suggested range for 3 consec. readings or note Permit/State requirements:		+/- 0.2	+/- 3%	--	--	+/- 10%	+/- 25 mV	Stabilize

Stabilization Data Fields are Optional *(i.e. complete stabilization readings for parameters required by WM, Site, or State). These fields can be used where four (4) field measurements are required by State/Permit/Site. If a Data Logger or other Electronic format is used, fill in final readings below and submit electronic data separately to Site. If more fields above are needed, use separate sheet or form.*

FIELD DATA

SAMPLE DATE (MM DD YY)	pH (std)	CONDUCTANCE (umhos/cm @ 25°C)	TEMP. (°C)	TURBIDITY (ntu)	DO (mg/L-ppm)	eH/ORP (mV)	Other: _____ Units _____

Final Field Readings are required *(i.e. record field measurements, final stabilized readings, passive sample readings before sampling for all field parameters required by State/Permit/Site.*

FIELD COMMENTS

Sample Appearance: _____ Odor: _____ Color: _____ Other: _____

Weather Conditions (required daily, or as conditions change): Direction/Speed: _____ Outlook: _____ Precipitation: Y or N

Specific Comments (including purge/well volume calculations if required): _____

I certify that sampling procedures were in accordance with applicable EPA, State, and WM protocols (if more than one sampler, all should sign):

Date	Name	Signature	Company
___/___/___			
___/___/___			

DISTRIBUTION: WHITE/ORIGINAL - Stays with Sample, YELLOW - Returned to Client, PINK - Field Copy

[redacted]

Chain of Custody Record

WASTE MANAGEMENT

OMA-4124 0797

Client	Project Manager	Date	Chain of Custody Number 23899
Address	Telephone Number (Area Code)/Fax Number	Lab Number	Page ____ of ____
City / State / Zip Code	Site Contact	Lab Contact	Analysis (Attach list if more space is needed)
Project Name	Carrier/Waybill Number		
Contract/Purchase Order/Quote No.	Matrix / Containers & Preservatives		Special Instructions/ Conditions of Receipt

Sample I.D. No. and Description (Containers for each sample may be combined on one line)	Date	Time	Matrix: Aqueous	Sed.	Soil	Containers & Preservatives: Unpres.	H_2SO_4	HNO3	HCl	NaOH	ZnAc/NaOH	

Possible Hazard Identification

☐ Non-Hazard ☐ Flammable ☐ Skin Irritant ☐ Poison B ☐ Unknown

Sample Disposal

☐ Return To Client ☐ Disposal By Lab ☐ Archive For _____ Months (A fee may be assessed if samples are retained longer than 3 months)

Turn Around Time Required

☐ 24 Hours ☐ 48 Hours ☐ 7 Days ☐ 14 Days ☐ 21 Days ☐ Other_____

QC Requirements (Specify)

1. Relinquished By	Date	Time	1. Received By	Date	Time
2. Relinquished By	Date	Time	2. Received By	Date	Time
3. Relinquished By	Date	Time	3. Received By	Date	Time

Comments

APPENDIX C

LABORATORY QA/QC MANUAL

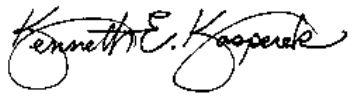
Cover Page:

Quality Assurance Manual

TestAmerica Buffalo
10 Hazelwood Drive
Amherst, New York 14228
716.504.9800
716.691.7991

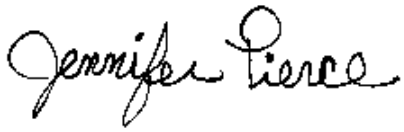
www.testamericainc.com

Title Page:
Quality Assurance Manual
Approval Signatures



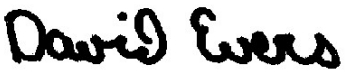
Laboratory Director – Kene' Kasperek — 4/3/2015 Date

Quality Assurance Manager - Brad Prinzi — 4/3/2015 Date



Inorganic Operations Manager – Jennifer Pierce — 4/3/2015 Date

Organic Operations Manager – Michelle Freeman — 4/3/2015 Date



Organic Preparation Manager – David Evers — 4/3/2015 Date

Wet Chemistry Manager – James Rojecki — 4/3/2015 Date

GC Semivolatiles / Volatiles Manager – Gary Rudz — 4/3/2015 Date

Metals Manager – Todd Brandt — 4/3/2015 Date

GC/MS Semivolatiles – Jason Michalek — 4/3/2015 Date

Facilities Manager – Ken Kinecki — 4/3/2015 Date

SECTION 2

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF APPENDICES

REFERENCED CORPORATE SOPs AND POLICIES

SOP / Policy Reference	Title
CA-I-P-002	Electronic Reporting and Signature Policy
CA-L-P-002	Contract Compliance Policy
CA-L-S-002	Subcontracting Procedures
CA-Q-M-002	Corporate Quality Management Plan
CA-Q-S-001	Solvent and Acid Lot Testing and Approval
CA-Q-S-002	Acceptable Manual Integration Practices
CA-Q-S-006	Detection Limits
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	Capital Expenditure, Controlled Purchase Requests and Fixed Asset Capitalization
CW-L-P-004	Ethics Policy
CW-L-S-002	Internal Investigation of Potential Data Discrepancies and Determination for Data Recall
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
CA-Q-S-004	Method Compliance & Data Authenticity Audits

REFERENCED LABORATORY SOPs

SOP Reference	Title
BF-GP-001	Calibration of Autopipettes and Repipetters
BF-GP-002	Support Equipment: Maintenance, Record Keeping and Corrective Actions
BF-GP-005	Sample Homogenization and Subsampling
BF-GP-012	Technical Data Review
BF-GP-013	Manual Integration
BF-GP-015	Record Storage and Retention
BF-GP-018	Strict Internal Chain or Custody

BF-GP-019	Standard Traceability and Preparation
BF-GP-020	Thermometer Calibration
BF-PM-001	Project Information Requirements
BF-PM-003	Bottle Order Set-up
BF-PM-005	Correctness of Analysis
BF-QA-001	Determination of Method Detection Limits
BF-QA-002	Quality Control Limits
BF-QA-003	Procedure for Writing, Reviewing and Revising Controlled Documents
BF-QA-004	Laboratory Personnel Training
BF-QA-005	Preventative and Corrective Action
BF-QA-006	Data Quality Review
BF-SR-001	Cooler Shipping - Bottle Kits and Samples
BF-SR-002	Receipt of Analytical Samples

SECTION 3

INTRODUCTION, SCOPE AND APPLICABILITY

3.1 INTRODUCTION AND COMPLIANCE REFERENCES

TestAmerica Buffalo's Quality Assurance Manual (QAM) is a document prepared to define the overall policies, organization objectives and functional responsibilities for achieving TestAmerica's data quality goals. The laboratory maintains a local perspective in its scope of services and client relations and maintains a national perspective in terms of quality.

The QAM has been prepared to assure compliance with 2003 National Environmental Laboratory Accreditation Conference (NELAC) standards, The NELAC Institute (TNI) Standard, dated 2009, Volume 1 Modules 2 and 4, and ISO/IEC Guide 17025(E) In addition, the policies and procedures outlined in this manual are compliant with TestAmerica's Corporate Management Plan (CQMP) and the various accreditation and certification programs listed in Appendix 3. The CQMP provides a summary of TestAmerica's quality and data integrity system. It contains requirements and general guidelines under which all TestAmerica facilities shall conduct their operations.

The QAM has been prepared to be consistent with the requirements of the following documents:

- EPA 600/4-88/039, *Methods for the Determination of Organic Compounds in Drinking Water,* EPA, Revised July 1991.
- EPA 600/R-95/131, *Methods for the Determination of Organic Compounds in Drinking Water,* Supplement III, EPA, August 1995.
- 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 II A, August 1993, Final Update II, September 1994; Final Update IIB, January 1995; Final Update III, December 1996; Final Update IV, January 2008.
- Federal Register, 40 CFR Parts 136, 141, 172, 173, 178, 179 and 261. New York State Analytical Services Protocol, July 2005
- Manual for the Certification of Laboratories Analyzing Drinking Water (EPA 815-R-05-004, January 2005).
- Statement of Work for Inorganics & Organics Analysis, SOM and ISM, current versions, USEPA Contract Laboratory Program Multi-media, Multi-concentration.
- APHA, *Standard Methods for the Examination of Water and Wastewater,* 18th Edition, 19th, 20th, and on-line Editions. 21st.
- *U.S. Department of Energy* Order 414.1B, *Quality Assurance*, Approved April 29, 2004.
- *U.S. Department of Energy* Order 414.1C, *Quality Assurance*, June 17, 2005.
- *U.S. Department of Energy*, *Quality Systems for Analytical Services*, Revision 3.6, November 2010.
- Toxic Substances Control Act (TSCA).

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. The program functions at the management level through company goals and management policies, and at the analytical level through Standard Operating Procedures (SOPs) and quality control. The TestAmerica 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 2 for the Glossary/Acronyms.

3.3 SCOPE / FIELDS OF TESTING

The laboratory analyzes a broad range of environmental and industrial samples every month. Sample matrices vary among air, drinking water, effluent water, groundwater, hazardous waste, sludge and soils. 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 Section 19.0. 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 Laboratory Director/Manager and the Quality Assurance (QA) Manager. In some cases, QAPPs and DQOs may specify less stringent requirements. The Laboratory Director/Manager 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

The template on which this manual is based is reviewed annually by Corporate Quality Management Personnel to assure that it remains in compliance with Section 3.1. The manual itself is reviewed every two years by senior laboratory management to assure that it reflects current practices and meets the requirements of the laboratory's clients and regulators as well as the CQMP. 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 senior laboratory management staff. The laboratory updates and approves such changes according to our Document Control & updating procedures (refer to BF-QA-003)

SECTION 4

MANAGEMENT REQUIREMENTS

4.1 OVERVIEW

TestAmerica Buffalo is a local operating unit of TestAmerica Laboratories, Inc. The organizational structure, responsibilities and authorities of the corporate staff of TestAmerica Laboratories, Inc. are presented in the CQMP. The laboratory has day-to-day independent operational authority overseen by corporate officers (e.g., Chief Executive Officer, Executive VP Operations, Corporate Quality, etc.). The laboratory operational and support staff work under the direction of the Laboratory Director. The organizational structure for both Corporate & TestAmerica Buffalo is presented in Figure 4-1.

4.2 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 following descriptions briefly define each role in its relationship to the Quality Assurance Program.

4.2.1 Additional Requirements for Laboratories

The responsibility for quality resides with every employee of the laboratory. All employees have access to the QAM, are trained to this manual and are responsible for upholding the standards therein. Each person carries out his/her daily tasks in a manner consistent with the goals and in accordance with the procedures in this manual and the laboratory's SOPs. Role descriptions for corporate personnel are defined in the CQMP. This manual is specific to the operations of TestAmerica's Buffalo laboratory.

4.2.2 Laboratory Director

TestAmerica Buffalo's Laboratory Director is responsible for the overall quality, safety, financial, technical, human resource and service performance of the whole laboratory and reports to their respective GM. The Laboratory Director provides the resources necessary to implement and maintain an effective and comprehensive Quality Assurance and Data Integrity Program.

The Laboratory Director has the authority to affect those policies and procedures to ensure that only data of the highest level of excellence are produced. As such, the Laboratory Director is responsible for maintaining a working environment which encourages open, constructive problem solving and continuous improvement.

Specific responsibilities include, but are not limited to:

- Provides one or more department managers for the appropriate fields of testing. If the Department Manager is absent for a period of time exceeding 15 consecutive calendar

days, the Laboratory Director must designate another full time staff member meeting the qualifications of the Department Manager to temporarily perform this function. If the absence exceeds 65 consecutive calendar days, the primary NELAC accrediting authority must be notified in writing.

- 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.
- Ensures that personnel are free from any commercial, financial and other undue pressures which might adversely affect the quality of their work.
- Ensures TestAmerica's 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.
- Ensures that appropriate corrective actions are taken to address analyses identified as requiring such actions by internal and external performance or procedural audits. Procedures that do not meet the standards set forth in the QAM or laboratory SOPs may be temporarily suspended by the Laboratory Director.
- 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.
- Ensures client specific reporting and quality control requirements are met.
- Leads the management team, consisting of the QA Manager, the Technical Manager, and the Operations Manager as direct reports.

4.2.2 Quality Assurance (QA) Manager or Designee

The QA manager has responsibility and authority to ensure the continuous implementation of the quality system.

The QA Manager reports directly to the Laboratory Director and their Corporate Quality Director. This position is able to evaluate data objectively and perform assessments without outside (i.e., managerial) influence. Corporate QA may be used as a resource in dealing with regulatory requirements, certifications and other quality assurance related items. The QA Manager directs the activities of the QA department to accomplish specific responsibilities, which include, but are not limited to:

- Serves as the focal point for QA/QC in the laboratory.
- Having functions independent from laboratory operations for which he/she has quality assurance oversight.
- Maintaining and updating the QAM.

- Monitoring and evaluating laboratory certifications; scheduling proficiency testing samples.
- 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.
- Have documented training and/or experience in QA/QC procedures and the laboratory's Quality System.
- Having 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).
- Arranging for or conducting internal audits on quality systems, data authenticity and the technical operation.
- 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 and preventive action systems.
- Notifying laboratory management of deficiencies 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.
- Objectively monitor standards of performance in quality control and quality assurance without outside (e.g., managerial) influence.
- Coordinating of document control of SOPs, MDLs, control limits, and miscellaneous forms and information.
- Review a subset of all final data reports for internal consistency.
- Review of external audit reports and data validation requests.
- Follow-up with audits to ensure client QAPP requirements are met.
- Establishment of reporting schedule and preparation of various quality reports for the Laboratory Director, clients and/or Corporate QA.
- Development of suggestions and recommendations to improve quality systems.
- Research of current state and federal requirements and guidelines.
- Leads the QA team to enable communication and to distribute duties and responsibilities.
- Ensuring Communication & monitoring standards of performance to ensure that systems are in place to produce the level of quality as defined in this document.
- Notifying laboratory management of deficiencies 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 are temporarily suspended following the procedures outlined in Section 12.

- Evaluation of the thoroughness and effectiveness of training.
- Compliance with ISO 17025.

4.2.3 Technical Manager or Designee

The Technical Manager(s) report(s) directly to the Laboratory Director. He/she is accountable for all analyses and analysts under their experienced supervision. The scope of responsibility ranges from the new-hire process and existing technology through the ongoing training and development programs for existing analysts and new instrumentation. Specific responsibilities include, but are not limited to:

- Exercises day-to-day supervision of laboratory operations for the appropriate field of accreditation and reporting of results. Coordinating, writing, and reviewing preparation of all test methods, i. e., SOPs, with regard to quality, integrity, regulatory and optimum and efficient production techniques, and subsequent analyst training and interpretation of the SOPs for implementation and unusual project samples. He/she insures that the SOPs are properly managed and adhered to at the bench. He/she develops standard costing of SOPs to include supplies, labor, overhead, and capacity (design vs. demonstrated versus first-run yield) utilization.
- Reviewing and approving, with input from the QA Manager, proposals from marketing, in accordance with an established procedure for the review of requests and contracts. This procedure addresses the adequate definition of methods to be used for analysis and any limitations, the laboratory's capability and resources, the client's expectations. Differences are resolved before the contract is signed and work begins. A system documenting any significant changes is maintained, as well as pertinent discussions with the client regarding their requirements or the results of the analyses during the performance of the contract. All work subcontracted by the laboratory must be approved by the client. Any deviations from the contract must be disclosed to the client. Once the work has begun, any amendments to the contract must be discussed with the client and so documented.
- Monitoring the validity of the analyses performed and data generated in the laboratory. This activity begins with reviewing and supporting all new business contracts, insuring data quality, analyzing internal and external non-conformances to identify root cause issues and implementing the resulting corrective and preventive actions, facilitating the data review process (training, development, and accountability at the bench), and providing technical and troubleshooting expertise on routine and unusual or complex problems.
- Providing training and development programs to applicable laboratory staff as new hires and, subsequently, on a scheduled basis. Training includes instruction on calculations, instrumentation management to include troubleshooting and preventive maintenance.

- Enhancing efficiency and improving quality through technical advances and improved LIMS utilization. Capital forecasting and instrument life cycle planning for second generation methods and instruments as well as asset inventory management.
- Coordinating sample management from "cradle to grave," insuring that no time is lost in locating samples.
- Scheduling all QA/QC-related requirements for compliance, e.g., MDLs, etc..
- Captains department personnel to communicate quality, technical, personnel, and instrumental issues for a consistent team approach.
- Coordinates audit responses with the QA Manager.

4.2.4 Operations Manager

The Operations Manager manages and directs the analytical production sections of the laboratory. He/She reports directly to the Laboratory Director. He/She assists the Technical Manager in determining the most efficient instrument utilization. More specifically, he/she:

- Evaluates the level of internal/external non-conformances for all departments.
- Continuously evaluates production capacity and improves capacity utilization.
- Continuously evaluates turnaround time and addresses any problems that may hinder meeting the required and committed turnaround time from the various departments.
- Develops and improves the training of all analysts in cooperation with the Technical Manager and QA Manager and in compliance with regulatory requirements.
- Is responsible for efficient utilization of supplies.
- Constantly monitors and modifies the processing of samples through the departments.
- Fully supports the quality system and, if called upon in the absence of the QA Manager, serves as his substitute in the interim.

4.2.5 Department Managers

Department Managers report to the Operations Manager. The Department Managers serve as the technical experts on assigned projects, provide technical liaison, assist in resolving any technical issues within the area of their expertise; and implement established policies and procedures to assist the Operations Manager in achieving section goals. Each one is responsible to:

- Ensure that analysts in their department adhere to applicable SOPs and the QA Manual. They perform frequent SOP and QA Manual review to determine if analysts are in compliance and if new, modified, and optimized measures are feasible and should be added to these documents.
- With regard to analysts, participates in the selection, training, and development of performance objectives and standards of performance, appraisal (measurement of objectives), scheduling, counseling, discipline, and motivation of analysts and documents these activities in accordance with systems developed by the QA and Human Resources

Departments. They evaluate staffing sufficiency and overtime needs. Training consists of familiarization with SOP, QC, Safety, and computer systems.

- Encourage the development of analysts to become cross-trained in various methods and/or operate multiple instruments efficiently while performing maintenance and documentation, self-supervise, and function as a department team.
- Provide guidance to analysts in resolving problems encountered daily during sample prep/analysis in conjunction with the Technical Manager, Operations Manager, and/or QA Manager. Each is responsible for 100% of the data review and documentation, non-conformance and CPAR issues, the timely and accurate completion of performance evaluation samples and MDLs, for his department.
- Ensure all logbooks are maintained, current, and properly labeled or archived.
- Report all non-conformance conditions to the QA Manager, Technical Manager, Operations Manager, and/or Laboratory Director.
- Ensure that preventive maintenance is performed on instrumentation as detailed in the QA Manual or SOPs. He is responsible for developing and implementing a system for preventive maintenance, troubleshooting, and repairing or arranging for repair of instruments.
- Maintain adequate and valid inventory of reagents, standards, spare parts, and other relevant resources required to perform daily analysis.
- Achieve optimum turnaround time on analyses and compliance with holding times.
- Conduct efficiency and cost control evaluations on an ongoing basis to determine optimization of labor, supplies, overtime, first-run yield, capacity (designed vs. demonstrated), second- and third-generation production techniques/instruments, and long-term needs for budgetary planning.
- Develop, implement, and enhance calibration programs.
- Provide written responses to external and internal audit issues.

4.2.6 Hazardous Waste Coordinator

The Hazardous Waste Coordinator reports directly to the Laboratory Director. The duties consist of:

- Staying current with the hazardous waste regulations.
- Continuing training on hazardous waste issues.
- Reviewing and updating annually the Hazardous Waste Contingency Plan in the Environmental Health & Safety Manual.
- Auditing the staff with regard to compliance with the Hazardous Waste Contingency Plan.
- Contacting the hazardous waste subcontractors for review of procedures and opportunities for minimization of waste.

4.2.7 Environmental Health & Safety Coordinator

The Environmental Health and Safety Coordinator reports to the Laboratory Director and ensures that systems are maintained for the safe operation of the laboratory. The Safety Officer is responsible to:

- Conduct ongoing, necessary safety training and conduct new employee safety orientation.
- Assist in developing and maintaining the Chemical Hygiene/Safety Manual.
- Administer dispersal of all Safety Data Sheet (SDS) information.
- Perform regular chemical hygiene and housekeeping instruction.
- Give instruction on proper labeling and practice.
- Serve as chairman of the laboratory safety committee.
- Provide and train personnel on protective equipment.
- Oversee the inspection and maintenance of general safety equipment – fire extinguishers, safety showers, eyewash fountains, etc. and ensure prompt repairs as needed.
- Supervise and schedule fire drills and emergency evacuation drills.
- Determine what initial and subsequent exposure monitoring, if necessary to determine potential employee exposure to chemicals used in the laboratory.
- When determined necessary, conduct exposure monitoring assessments.
- Determine when a complaint of possible over-exposure is “reasonable” and should be referred for medical consultation.
- Assist in the internal and external coordination of the medical consultation/monitoring program conducted by TestAmerica’s medical consultants.

4.2.8 Laboratory Analysts

Laboratory analysts are responsible for conducting analysis and performing all tasks assigned to them by the group leader or supervisor. The responsibilities of the analysts are listed below:

- Perform analyses by adhering to analytical and quality control protocols prescribed by current SOPs, this QA Manual, and project-specific plans honestly, accurately, timely, safely, and in the most cost-effective manner.
- Document standard and sample preparation, instrument calibration and maintenance, data calculations, sample matrix effects, and any observed non-conformance on worklists, benchsheets, lab notebooks and/or the Non-Conformance Database.
- Report all non-conformance situations, instrument problems, matrix problems and QC failures, which might affect the reliability of the data, to their supervisor, the Technical Manager, and/or the QA Manager or member of QA staff.
- Perform 100% review of the data generated prior to entering and submitting for secondary level review.

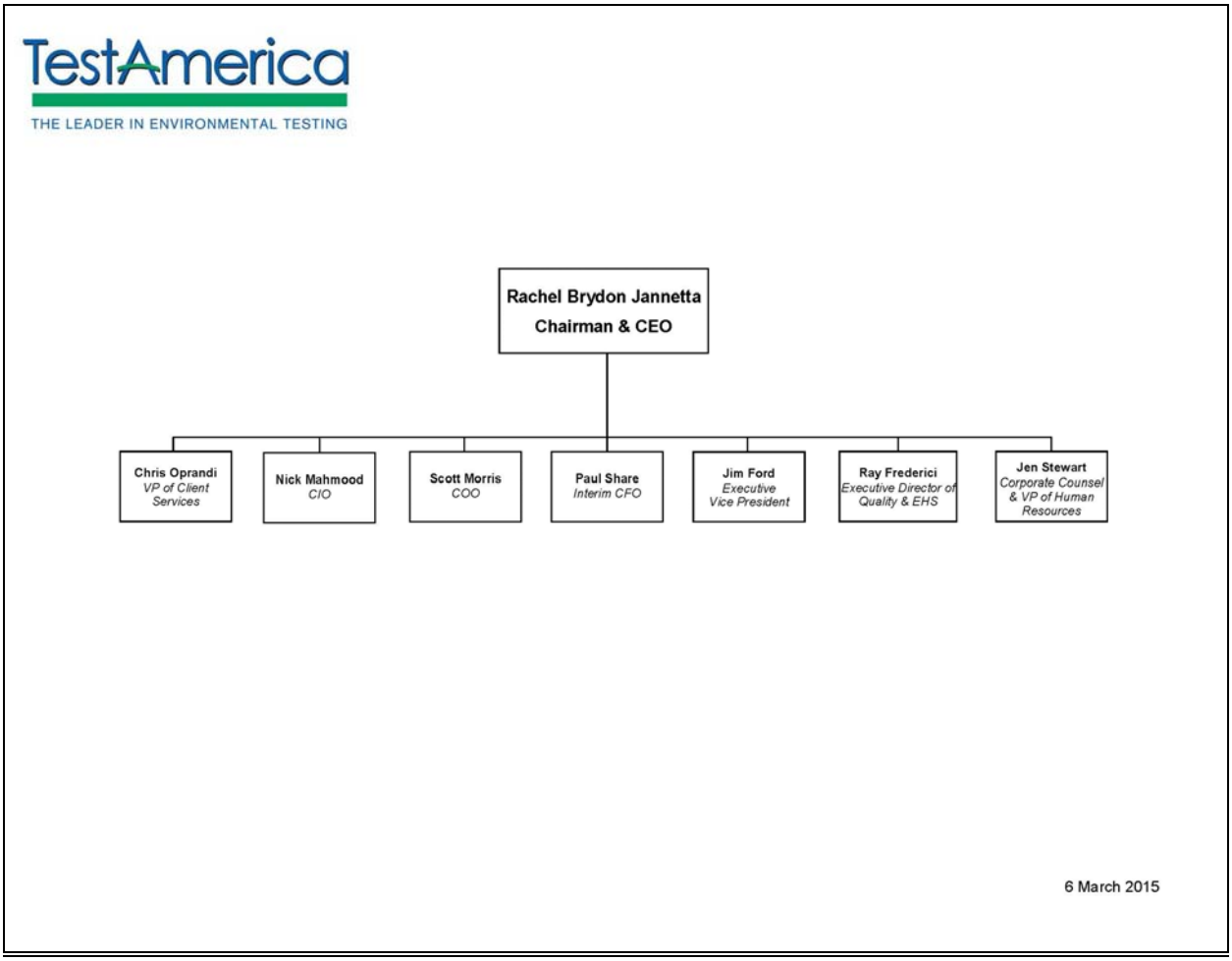
- Suggest method improvements to their supervisor, the Technical Manager, and the QA Manager. These improvements, if approved, will be incorporated. Ideas for the optimum performance of their assigned area, for example, through the proper cleaning and maintenance of the assigned instruments and equipment, are encouraged.
- Work cohesively as a team in their department to achieve the goals of accurate results, optimum turnaround time, cost effectiveness, cleanliness, complete documentation, and personal knowledge of environmental analysis.

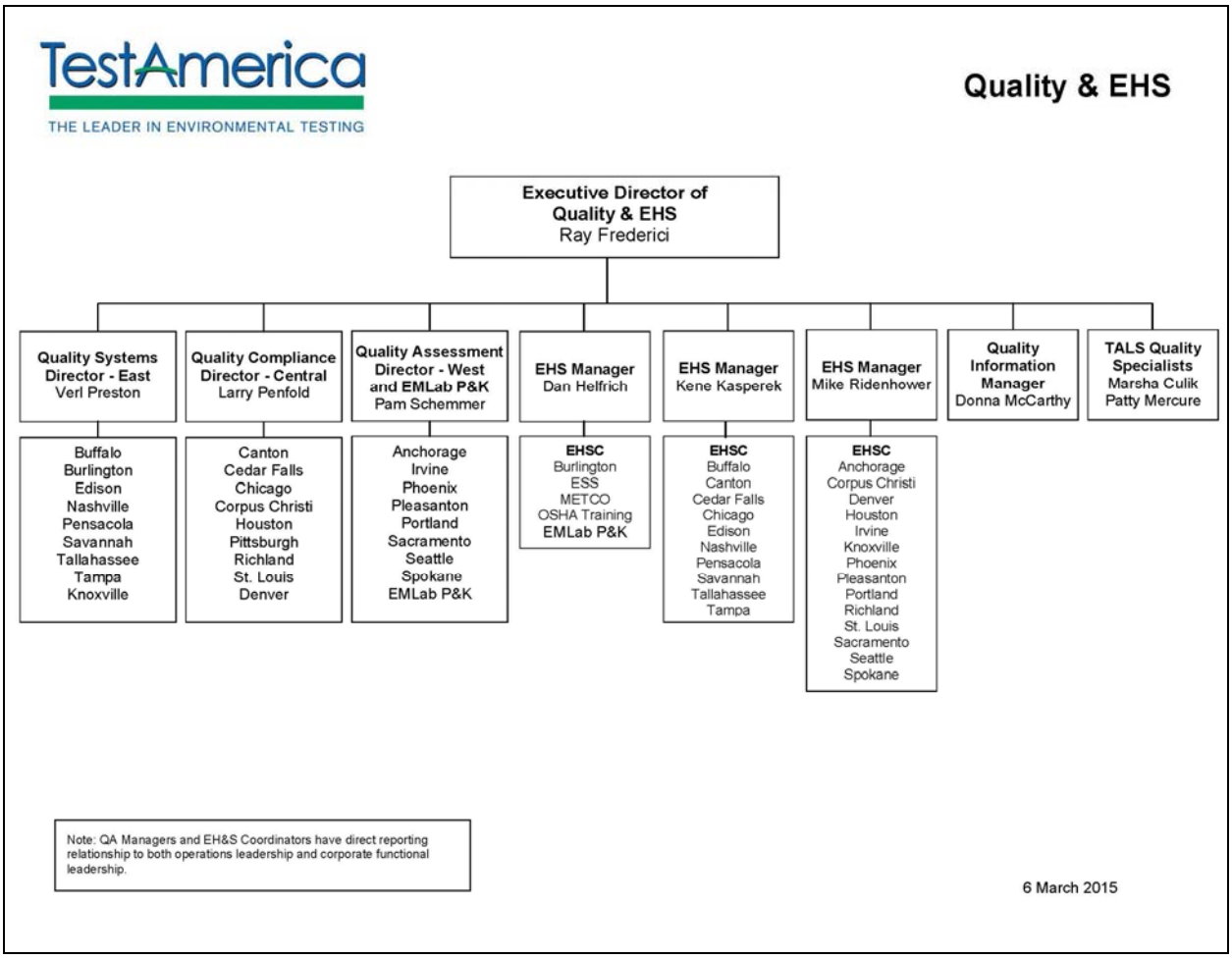
4.3 DEPUTIES

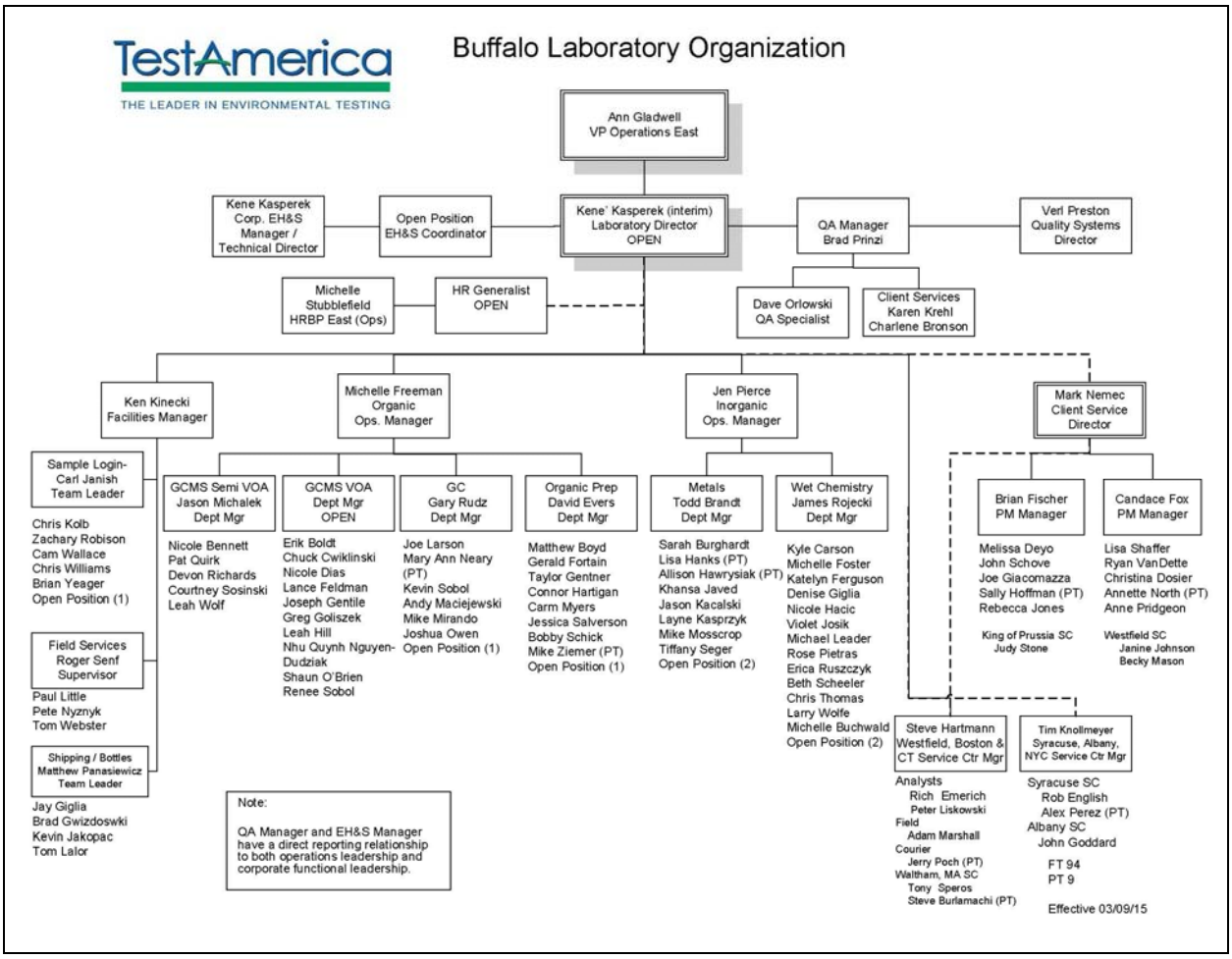
The following table defines who assumes the responsibilities of key personnel in their absence:

Key Personnel	Deputy	Comment
Laboratory Director	Operations Manager (1) Technical Manager (2)	
QA Manager	QA Specialist (1) Operations Manager (2)	
Technical Manager	Laboratory Director (1) Operations Manager (2)	
Operations Manager	Department Manager (1) Department Manager (2)	Selected based on availability
Manager of Project Management	Project Manager (1) Client Services Director (2)	Selected based on availability
Project Manager	Project Manager (1) Project Management Asst. (2)	(1) 2° team PM (2) Team PMA
Organic Department Manager	Analyst (1) Analyst (2)	Selected based on department, experience and availability
Inorganic Department Manager	Analyst (1) Analyst (2)	Selected based on department, experience and availability
Data Validation / Data Packaging Manager	Data Validation Specialist Data Packaging Specialist	Selected based on department and availability
EHS Coordinator	Laboratory Director (1) EHS Manager (2)	
Sample Management Manager	Sample Custodian (1) EHS Coordinator (2)	
Bottle Preparation / Shipping Manager	Bottle Prep Technician (1) Sample Mng't Manager (2)	

Figure 4-1.
Corporate and Laboratory Organization Charts




TestAmerica
THE LEADER IN ENVIRONMENTAL TESTING
Quality & EHS
Executive Director of Quality & EHS
Ray Frederici
Quality Systems Director - East
Verl Preston
Quality Compliance Director - Central
Larry Penfold
Quality Assessment Director - West and EMLab P&K
Pam Schemmer
EHS Manager
Dan Helfrich
EHS Manager
Kene Kasperek
EHS Manager
Mike Ridenhower
Quality Information Manager
Donna McCarthy
TALS Quality Specialists
Marsha Culik
Patty Mercure
Buffalo
Burlington
Edison
Nashville
Pensacola
Savannah
Tallahassee
Tampa
Knoxville
Canton
Cedar Falls
Chicago
Corpus Christi
Houston
Pittsburgh
Richland
St. Louis
Denver
Anchorage
Irvine
Phoenix
Pleasanton
Portland
Sacramento
Seattle
Spokane
EMLab P&K
EHSC
Burlington
ESS
METCO
OSHA Training
EMLab P&K
EHSC
Buffalo
Canton
Cedar Falls
Chicago
Edison
Nashville
Pensacola
Savannah
Tallahassee
Tampa
EHSC
Anchorage
Corpus Christi
Denver
Houston
Irvine
Knoxville
Phoenix
Pleasanton
Portland
Richland
St. Louis
Sacramento
Seattle
Spokane
Note: QA Managers and EH&S Coordinators have direct reporting relationship to both operations leadership and corporate functional leadership.
6 March 2015


TestAmerica
THE LEADER IN ENVIRONMENTAL TESTING
Buffalo Laboratory Organization
Ann Gladwell
VP Operations East
Kene Kasperek
Corp. EH&S Manager / Technical Director
Open Position
EH&S Coordinator
Kene' Kasperek (interim)
Laboratory Director
OPEN
QA Manager
Brad Prinzi
Verl Preston
Quality Systems Director
Michelle Stubblefield
HRBP East (Ops)
HR Generalist
OPEN
Dave Orlowski
QA Specialist
Client Services
Karen Krehl
Charlene Bronson
Ken Kinecki
Facilities Manager
Michelle Freeman
Organic Ops. Manager
Jen Pierce
Inorganic Ops. Manager
Mark Nemec
Client Service Director
Sample Login-
Carl Janish
Team Leader
Chris Kolb
Zachary Robison
Cam Wallace
Chris Williams
Brian Yeager
Open Position (1)
GCMS Semi VOA
Jason Michalek
Dept Mgr
Nicole Bennett
Pat Quirk
Devon Richards
Courtney Sosinski
Leah Wolf
GCMS VOA
Dept Mgr
OPEN
Erik Boldt
Chuck Cwiklinski
Nicole Dias
Lance Feldman
Joseph Gentile
Greg Goliszek
Leah Hill
Nhu Quynh Nguyen-Dudziak
Shaun O'Brien
Renee Sobol
GC
Gary Rudz
Dept Mgr
Joe Larson
Mary Ann Neary (PT)
Kevin Sobol
Andy Maciejewski
Mike Mirando
Joshua Owen
Open Position (1)
Organic Prep
David Evers
Dept Mgr
Matthew Boyd
Gerald Fortain
Taylor Gentner
Connor Hartigan
Carm Myers
Jessica Salverson
Bobby Schick
Mike Ziemer (PT)
Open Position (1)
Metals
Todd Brandt
Dept Mgr
Sarah Burghardt
Lisa Hanks (PT)
Allison Hawrysiak (PT)
Khansa Javed
Jason Kacalski
Layne Kasprzyk
Mike Mosscrop
Tiffany Seger
Open Position (2)
Wet Chemistry
James Rojecki
Dept Mgr
Kyle Carson
Michelle Foster
Katelyn Ferguson
Denise Giglia
Nicole Hacic
Violet Josik
Michael Leader
Rose Pietras
Erica Ruszczyk
Beth Scheeler
Chris Thomas
Larry Wolfe
Michelle Buchwald
Open Position (2)
Brian Fischer
PM Manager
Melissa Deyo
John Schove
Joe Giacomazza
Sally Hoffman (PT)
Rebecca Jones
King of Prussia SC
Judy Stone
Candace Fox
PM Manager
Lisa Shaffer
Ryan VanDette
Christina Dosier
Annette North (PT)
Anne Pridgeon
Westfield SC
Janine Johnson
Becky Mason
Field Services
Roger Senf
Supervisor
Paul Little
Pete Nyznyk
Tom Webster
Shipping / Bottles
Matthew Panasiewicz
Team Leader
Jay Giglia
Brad Gwizdoswki
Kevin Jakopac
Tom Lalor
Note:
QA Manager and EH&S Manager have a direct reporting relationship to both operations leadership and corporate functional leadership.
Steve Hartmann
Westfield, Boston & CT Service Ctr Mgr
Analysts
Rich Emerich
Peter Liskowski
Field
Adam Marshall
Courier
Jerry Poch (PT)
Waltham, MA SC
Tony Speros
Steve Burlamachi (PT)
Tim Knollmeyer
Syracuse, Albany, NYC Service Ctr Mgr
Syracuse SC
Rob English
Alex Perez (PT)
Albany SC
John Goddard
FT 94
PT 9
Effective 03/09/15

SECTION 5

QUALITY SYSTEM

5.1 QUALITY POLICY STATEMENT

It is TestAmerica's Policy to:

- Provide data of known quality to its clients by adhering to approved methodologies, regulatory requirements and the QA/QC protocols.
- Effectively manage all aspects of the laboratory and business operations by the highest ethical standards.
- Continually improve systems and provide support to quality improvement efforts in laboratory, administrative and managerial activities. TestAmerica recognizes that the implementation of a quality assurance program requires management's commitment and support as well as the involvement of the entire staff.
- Provide clients with the highest level of professionalism and the best service practices in the industry.
- To comply with the NELAC Standards (2003), ISO/IEC 17025:2005(E) International Standard, the 2009 TNI Standard and to continually improve the effectiveness of the management system.

Every staff member at the laboratory plays an integral part in quality assurance and is held responsible and accountable for the quality of their work. It is, therefore, required that all laboratory personnel are trained and agree to comply with applicable procedures and requirements established by this document.

5.2 ETHICS AND DATA INTEGRITY

TestAmerica is committed to ensuring the integrity of its data and meeting the quality needs of its clients. The 7 elements of TestAmerica's Ethics and Data Integrity Program include:

- An Ethics Policy (Corporate Policy No. CW-L-P-004) and Employee Ethics Statements.
- Ethics and Compliance Officers (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. (Corporate SOP No. CW-L-S-002)
- Procedures and guidance for recalling data if necessary (Corporate SOP No. CW-L-S-002).

- Effective external and internal monitoring system that includes procedures for internal audits (Section 15).
- 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.
- 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.

5.3 QUALITY SYSTEM DOCUMENTATION

The laboratory's Quality System is communicated through a variety of documents:

- Quality Assurance Manual – Each laboratory has a lab specific quality assurance manual.
- Corporate SOPs and Policies - Corporate SOPs and Policies are developed for use by all relevant laboratories. They are incorporated into the laboratories normal SOP distribution, training and tracking system. Corporate SOPs may be general or technical.
- Work Instructions - A subset of procedural steps, tasks or forms associated with an operation of a management system (e.g., checklists, preformatted bench sheets, forms).
- Laboratory SOPs – General and Technical
- Laboratory QA/QC Policy Memorandums

5.3.1 Order of Precedence

In the event of a conflict or discrepancy between policies, the order of precedence is as follows:

- Corporate Quality Management Plan (CQMP)
- Corporate SOPs and Policies
- Laboratory QA/QC Policy Memorandum
- 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 CQMP conflicts with those regulatory requirements, the regulatory requirements of the jurisdiction shall hold primacy. The laboratory's QAM shall take precedence over the CQMP in those cases.

5.4 QA/QC OBJECTIVES FOR THE MEASUREMENT OF DATA

Quality Assurance (QA) and Quality Control (QC) are activities undertaken to achieve the goal of producing data that accurately characterize the sites or materials that have been sampled. Quality Assurance is generally understood to be more comprehensive than Quality Control. Quality Assurance can be defined as the integrated system of activities that ensures that a product or service meets defined standards.

Quality Control 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. The client is responsible for developing the QAPP. 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. Additionally, 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).

5.4.1 Precision

The laboratory objective for precision is to meet the performance for precision demonstrated for the methods on similar samples and to meet data quality objectives 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.

5.4.2 Accuracy

The laboratory objective for accuracy is to meet the performance for accuracy demonstrated for the methods on similar samples and to meet data quality objectives 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.

5.4.3 Representativeness

The laboratory objective for representativeness 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. The laboratory may provide guidance to the client regarding proper sampling and handling methods in order to assure the integrity of the samples.

5.4.4 Comparability

The comparability 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.

The 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.

5.4.5 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.

5.4.6 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), specific electrodes (separation and identification), etc..

5.4.7 Sensitivity

Sensitivity refers to the amount of analyte necessary to produce a detector response that can be reliably detected (Method Detection Limit) or quantified (Reporting Limit).

5.5 CRITERIA FOR QUALITY INDICATORS

The laboratory maintains Quality Control Limit Data in their LIMS system. A summary report is generated from LIMS to check the precision and accuracy acceptability limits for performed analyses on request. The summary report is generated and is managed by the laboratory's QA department. 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 are contained in Section 24.

5.6 STATISTICAL QUALITY CONTROL

Statistically-derived precision and accuracy limits are required by selected methods (such as SW-846) and programs [such as the Ohio Voluntary Action Plan (VAP)]. The laboratory routinely utilizes statistically-derived limits to evaluate method performance and determine when corrective action is appropriate. The procedure for determining the statistical limits may be found in SOP BF-QA-002, Quality Control Limits. The analysts are instructed to use the current limits in the laboratory (dated and approved the QA Manager) and entered into the Laboratory Information Management System (LIMS). The Quality Assurance department maintains an archive of all limits used within the laboratory through date sensitive tables within the LIMs System. 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 the LIMS 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.

Surrogate recoveries are determined for a specific time period as defined above. The resulting ranges are entered in LIMS.

Current QC limits are entered and maintained in the LIMS analyte database. As sample results and the related QC are entered into LIMS, the sample QC values are compared with the limits in LIMS to determine if they are within the acceptable range. The analyst then evaluates if the sample needs to be rerun or re-extracted/rerun or if a comment should be added to the report explaining the reason for the QC outlier.

5.6.1 QC Charts

The QA Manager periodically evaluates these to determine if adjustments need to be made or for corrective actions to methods (SOP No. BF-QA-002). All findings are documented and kept on file.

5.7 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 16). These metrics are used to drive continuous improvement in the laboratory's Quality System.

SECTION 6

DOCUMENT CONTROL

6.1 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
- Corporate Policies and Procedures distributed outside the intranet

Corporate Quality posts Corporate Manuals, SOPs, Policies, Work Instructions, White Papers and Training Materials on the company intranet site. These Corporate 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 corporate documents is found in Corporate SOP No. CW-Q-S-001, Corporate Document Control and Archiving. The laboratory's internal document control procedure is defined in SOP No. BF-QA-003.

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 notices. Raw analytical data consists of bound logbooks, instrument printouts, any other notes, magnetic media, electronic data and final reports.

6.2 DOCUMENT APPROVAL AND ISSUE

The pertinent elements of a document control system for each document 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 Quality personnel are responsible for the maintenance of the system.

Controlled documents are authorized by the QA Department. In order to develop a new document, a Department Manager submits an electronic draft to the QA Department for

suggestions 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 provided to all applicable operational units. Controlled documents are identified as such and records of their distribution are kept by the QA Department. Document control may be achieved by either electronic or hardcopy distribution.

The QA Department maintains a list of the official versions of controlled documents.

Quality System Policies and Procedures will be reviewed at a minimum of every two years for the majority of procedures. Exceptions include review every 1 year for Drinking Water programs and the Kentucky CWA program. Changes to documents occur when a procedural change warrants.

6.3 PROCEDURES FOR DOCUMENT CONTROL POLICY

For changes to the QA Manual, refer to SOP No. BF-QA-003, “Writing, Reviewing and Revising Controlled Documents”. Uncontrolled copies must not be used within the laboratory. Previous revisions and back-up data are stored by the QA department. A controlled electronic copy of the current version is maintained on the laboratory Intranet site and is available to all personnel.

For changes to SOPs, refer to SOP No. BF-QA-003, “Writing, Reviewing and Revising Controlled Documents”.

Forms, worksheets, work instructions and information are organized by department and are maintained electronically by QA. There is a table of contents. As revisions are required, a new version number and revision date is assigned. Controlled electronic copies are made available on a public server for laboratory staff to access.

6.4 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 collected from employees according to distribution lists and are marked obsolete on the cover or destroyed. At least one copy of the obsolete document is archived according to SOP No. BF-GP-015.

SECTION 7

SERVICE TO THE CLIENT

7.1 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.

The laboratory must determine if it has the necessary physical, personnel and information resources to meet the contract, and if the personnel have the expertise needed to perform the testing requested. Each proposal is checked for its impact on the capacity of the laboratory's equipment and personnel. As part of the review, the proposed turnaround time will be checked for feasibility.

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 TestAmerica facility or to an outside firm, this will be documented and discussed with the client prior to contract approval. (Refer to Section 8 for Subcontracting Procedures.)

The laboratory informs the client of the results of the review if it indicates any potential conflict, deficiency, 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 TestAmerica, 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.

7.2 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 by the Project Manager (PM) is considered adequate. The PM confirms 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. It is recommended that, where there is a sales person assigned to the account, an attempt should be made to contact that sales person to inform them of the incoming samples.

For new, complex or large projects, the proposed contract is given to the Client Relations Manager or Proposal Team, 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 TestAmerica's Corporate SOP 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):

- Contact Administrator
- VP of Operations
- Laboratory Project Manager
- Laboratory and/or Corporate Technical Managers
- Corporate Information Technology Managers/Directors
- Regional and/or National Account representatives
- Laboratory and/or Corporate Quality
- Laboratory and/or Corporate 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.

The Contracts Department maintains copies of all signed contracts. The Project Managers at the TestAmerica Buffalo facility also maintains copies of these documents.

7.3 DOCUMENTATION

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.

7.3.1 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. The PM is the first point of contact for the 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. Specific information related to project planning may be found in SOP BF-PM-001, Project Information Requirements.

PM's are the primary client contact and they ensure resources are available to meet project requirements. Although PM's do not have direct reports or staff in production, they coordinate opportunities and work with laboratory management staff to ensure available resources are sufficient to perform work for the client's project. Project management is positioned between the client and laboratory resources.

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 projects to the laboratory staff through project kick-off meetings or to the management staff during production meetings. These meetings provide direction to the laboratory staff in order to maximize production and client satisfaction, while maintaining quality. In addition, project notes may be associated with each sample batch as a reminder upon sample receipt and analytical processing.

During the project, 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 during production meetings. 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 Department Manager.

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.

7.4 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.
- Assist 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.

7.5 CLIENT COMMUNICATION

Project managers 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/Designees are available to discuss any technical questions or concerns that the client may have.

7.6 REPORTING

The laboratory works with our clients to produce any special communication reports required by the contract.

7.7 CLIENT SURVEYS

The laboratory assesses both positive and negative client feedback. The results are used to improve overall laboratory quality and client service.

TestAmerica's Sales and Marketing teams periodically develops lab and client specific surveys to assess client satisfaction.

SECTION 8

SUBCONTRACTING OF TESTS

8.1 OVERVIEW

For the purpose of this quality manual, the phrase subcontract laboratory refers to a laboratory external to the TestAmerica laboratories. The phrase “work sharing” refers to internal transfers of samples between the TestAmerica 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 TestAmerica’s Corporate SOP’s on Subcontracting Procedures (CA-L-S-002).

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 TNI/ISO 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), Client Service Managers (CSM), or Account Executives (AE) for the Export Lab (TestAmerica 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 or work sharing arrangement in writing and when possible approval from the client shall be retained in the project folder. Standard TestAmerica Terms & Conditions include the flexibility to subcontract samples within the TestAmerica laboratories. Therefore, additional advance notification to clients for intra-laboratory subcontracting is not necessary unless specifically required by a client contract.

Note: In addition to the client, some regulating agencies, such as the Department of Energy and the USDA, may require notification prior to placing such work**.**

Approval may be documented through reference in a quote / contract or e-mail correspondence.

8.2 QUALIFYING AND MONITORING SUBCONTRACTORS

Whenever a PM, Account Executive (AE) or Client Service Manager (CSM) 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:

- The first priority is to attempt to place the work in a qualified TestAmerica laboratory;
- Firms specified by the client for the task (Documentation that a subcontractor was designated by the client must be maintained with the project file. This documentation can be
- as simple as placing a copy of an e-mail from the client in the project folder);
- Firms listed as pre-qualified and currently under a subcontract with TestAmerica. A listing of all approved subcontracting laboratories is available on the TestAmerica intranet site. Supporting documentation is maintained by corporate offices and by the TestAmerica laboratory originally requesting approval of the subcontract lab. Verify necessary accreditation, where applicable (e.g. on the subcontractors TNI, A2LA accreditation or State certification.
- Firms identified in accordance with the company's Small Business Subcontracting program as small, women-owned, veteran-owned and/or minority-owned businesses;
- TNI or A2LA accredited laboratories.
- In addition, the firm must hold the appropriate certification to perform the work required.

All TestAmerica laboratories are pre-qualified for work-sharing provided they hold the appropriate accreditations, can adhere to the project/program requirements, and the client approved sending samples to that laboratory. 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.

When the potential sub-contract laboratory has not been previously approved, Account Executives or PMs may nominate a laboratory as a subcontractor based on need. The decision to nominate a laboratory must be approved by the Laboratory Director. The Laboratory Director requests that the QA Manager/Designee begin the process of approving the subcontract laboratory as outlined in Corporate SOP No. CA-L-S-002, Subcontracting Procedures. 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).

8.2.1 Once the appropriate accreditation and legal information is received by the laboratory, it is evaluated for acceptability (where applicable) and forwarded to the Corporate Quality Information Manager (QIM) for review. Once all documents are reviewed for completeness, the Corporate QIM will forward the documents to the Purchasing Manager 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 for JD Edwards.

8.2.2 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. TestAmerica does not certify laboratories. The subcontractor is on our approved list and can only be recommended to the extent that we would use them.

8.2.3 The status and performance of qualified subcontractors will be monitored periodically by the Corporate Contracts and/or Quality Departments. Any problems identified will be brought to the attention of TestAmerica's Corporate Finance or Corporate Quality 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 (Form No. CW-F-WI-009)**.**
- 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. The QA Manager will notify all TestAmerica laboratories and Corporate Quality 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 Laboratory Directors/Managers, QA Managers and Sales Personnel.

8.3 OVERSIGHT AND REPORTING

The PM must request that the selected subcontractor be presented with a subcontract, if one is not already executed between the laboratory and the subcontractor. The subcontract must include terms which flow down the requirements of our clients, either in the subcontract itself or through the mechanism of work orders relating to individual projects. A standard subcontract and the Lab Subcontractor Vendor Package (posted on the intranet) can be used to accomplish this, and the Corporate Counsel can tailor the document or assist with negotiations, if needed. The PM (or AE or CSM, etc.) responsible for the project must advise and obtain client consent to the subcontract as appropriate, and provide the scope of work to ensure that the proper requirements are made a part of the subcontract and are made known to the subcontractor.

Prior to 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 on a Subcontract Laboratory Certification Verification Form (Figure 8-1) and the form is retained in the project folder. For TestAmerica laboratories, certifications can be viewed on the company TotalAccess Database.

The Sample Control department is responsible for ensuring compliance with QA requirements and applicable shipping regulations when shipping samples to a subcontracted laboratory.

All subcontracted samples must be accompanied by a TestAmerica Chain of Custody (COC). A copy of the original COC sent by the client must also be included with all samples workshared

within TestAmerica. 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, facilities 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 are incorporated into the laboratories EDD (i.e. imported), the report must explicitly indicate which lab produced the data for which methods and samples.

Note: The results submitted by TestAmerica work sharing laboratory may be transferred electronically and the results reported by the TestAmerica 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.

8.4 CONTINGENCY PLANNING

The Laboratory Director may waive the full qualification of a subcontractor process temporarily to meet emergency needs; however, this decision & 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 Chain-of-Custody. 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 with TestAmerica at this time. . The comprehensive approval process must then be initiated within 30 calendar days of subcontracting.

Figure 8-1 Subcontracting Laboratory Approval Form (Initial / Renewal)

SUBCONTRACTING LABORATORY APPROVAL

Reference: Section 8 – Quality Assurance Manual

Date: _____
Laboratory: _____
Address: _____
_____
Contact and e-mail address: _____
Phone: Direct _____ Fax _____

Requested Item[3]	Date Received	Reviewed/ Accepted	Date
1. Copy of State Certification[1]			
2. Insurance Certificate			
3. USDA Soil Permit			
4. Description of Ethics Program[3]			
5. QA Manual[3]			
6. Most Recent (and relevant) 2 Sets of WP/WS Reports with Corrective Action Response[1,3]			
7. State Audit with Corrective Action Response (or NELAC or A2LA Audit)[3]			
8. Sample Report[3]			
9. SOQ or Summary list of Technical Staff and Qualifications [3]			
10. SOPs for Methods to Be Loadshifted[2,3]			
11. For DoD Work: Statement that Lab quality system complies with QSM.			
12. For DoD Work: Approved by specific DoD Component laboratory approval process.			

1 - Required when emergency procedures are implemented.
2 - Some labs may not submit copies due to internal policies. In these cases, a copy of the first page and signature page of the SOP is acceptable. This requirement may also be fulfilled by supplying a table of SOPs with effective dates.
3 – If the laboratory has NELAC accreditation, Item #s 4 through 10 are not required.

On Site Audit Planned: YES NO If yes, Date Completed: _____ By Whom: _____

Comments: _____

Lab Acceptable for Subcontracting Work: YES NO Limitations: _____

QA Manager (Signature): _____ Date: _____

□ Forwarded to Contract Coordinator, by: _____ Date: _____

SECTION 9

PURCHASING SERVICES AND SUPPLIES

9.1 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 TestAmerica's Capital Expenditure, Controlled Purchase Requests and Fixed Asset Capitalization, SOP No. CW-F-S-007.

Contracts will be signed in accordance with TestAmerica's Company-Wide Authorization Matrix Policy, Policy 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 TestAmerica's Corporate Procurement and Contracts Policy (Policy No. CW-F-P-004). RFP's allow TestAmerica to determine if a vendor is capable of meeting requirements such as supplying all of the 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.

9.2 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.

9.3 REAGENTS, STANDARDS & SUPPLIES

Purchasing guidelines for equipment and reagents must meet the requirements of the specific method and testing procedures for which they are being purchased. Solvents and acids are pre-tested in accordance with TestAmerica's Corporate SOP on Solvent & Acid Lot Testing & Approval, SOP No. CA-Q-S-001 and TestAmerica Buffalo SOP on Solvent Purity, SOP BF-OP-013.

9.3.1 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. Purchase requisitions are

placed into the J.D. Edwards system by designated departmental personnel. The listing of items available in the J.D. Edwards system has been approved for use by the corporate purchasing staff. Each purchase requisition receives final approval by the laboratory Operations Manager or purchasing coordinator before the order is submitted.

The analyst may also check the item out of the on-site consignment system that contains items approved for laboratory use.

9.3.2 Receiving

It is the responsibility of the purchasing manager/designee to receive the shipment. It is the responsibility of the department that ordered the materials to date the material when received. Once the ordered reagents or materials are received, the department that submitted the order compares the information on the label or packaging to the original order to ensure that the purchase meets quality level specified. 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.

9.3.3 Specifications

Methods in use 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.

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 are not provided, the laboratory may contact the manufacturer to determine an expiration date.

The laboratory assumes a five year expiration date on inorganic dry chemicals and solvents unless noted otherwise by the manufacturer or by the reference source method. Chemicals/solvents should not be used past the manufacturer's or SOP expiration date unless 'verified' (refer to item 3 listed below).

- An expiration date cannot not be extended if the dry chemical/solvent is discolored or appears otherwise physically degraded, the dry chemical/solvent must be discarded.

- Expiration dates can be extended if the dry chemical/solvent is found to be satisfactory based on acceptable performance of quality control samples (Continuing Calibration Verification (CCV), Blanks, Laboratory Control Sample (LCS), etc.).

- If the dry chemical/solvent is used for the preparation of standards, the expiration dates can be extended 6 months if the dry chemical/solvent is compared to an unexpired independent source in performing the method and the performance of the dry chemical/solvent is found to be satisfactory. The comparison must show that the dry chemical meets CCV limits. The comparison studies are maintained along with the calibration raw data for which the reagent was used.

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.

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 standards or reagents must have a specific conductivity of less than 1- umho/cm (or specific resistivity of greater than 1.0 megohm-cm) at 25^{o}C. The specific conductivity is checked and recorded daily. If the water's specific conductivity is greater than the specified limit, the Facility Manager and appropriate Department Managers/Supervisors must be notified immediately in order to notify all departments, decide on cessation (based on intended use) of activities, and make arrangements for correction.

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.

Standard lots are verified before first time use if the laboratory switches manufacturers or has historically had a problem with the type of standard.

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.

Records of manufacturer's certification and traceability statements are maintained in the LIMS system, files or binders in each laboratory section. These records include date of receipt, lot number (when applicable), and expiration date (when applicable). Incorporation of the item into the record indicates that the analyst has compared the new certificate with the previous one for the same purpose and that no difference is noted, unless approved and so documented by the Technical Manager or QA Manager.

9.3.4 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 Corporate Environmental Health & Safety Manual (Corp. DOC No. CW-E-M-001) and method SOPs or manufacturer instructions.

9.4 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 Technical Manager and/or the Laboratory Director. If they agree with the request the procedures outlined in TestAmerica's Corporate Policy No. CA-T-P-001, Qualified Products List, is 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. IT must also be notified so that they can synchronize the instrument for back-ups. 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 IT Department or QA Department. Software certificates supplied by the vendors are filed with the LIMS Administrator. The manufacturer's operation manual is retained at the bench.

9.5 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 Department Managers. The service providers that perform the services are approved by the Department Managers, Operations Manager and/or Technical Manager.

9.6 SUPPLIERS

TestAmerica selects vendors through a competitive proposal / bid process, strategic business alliances or negotiated vendor partnerships (contracts). This process is defined in the Procurements & Contracts Policy (Policy 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 TestAmerica 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 JD Edwards 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 the Corporate Purchasing Group by completing a Vendor Performance Report.

The Corporate 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.

As deemed appropriate, the Vendor Performance Reports will be summarized and reviewed 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 JD Edwards purchasing system.

9.6.1 New Vendor Procedure

TestAmerica employees who wish to request the addition of a new vendor must complete a J.D. Edwards Vendor Add Request Form (available on the intranet site).

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 TestAmerica employees that would make it prohibitive to do business with them as well as their financial stability. The QA Department and/or the Technical Manager are consulted with vendor and product selection that have an impact on quality.

SECTION 10

COMPLAINTS

10.1 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 with 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 in the laboratory SOP related Corrective Action (BF-QA-005).

10.2 EXTERNAL COMPLAINTS

An employee that receives a complaint initiates the complaint resolution process by first documenting the complaint according to BF-QA-005.

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 likely hood of future occurrence and mitigation of client impact.

The general steps in the complaint handling process are:

- Receiving and Documenting Complaints
- 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.

10.3 INTERNAL 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 13. In addition, Corporate Management, Sales and Marketing and Information Technology (IT) may initiate a complaint by contacting the laboratory or through the corrective action system described in Section 12.

10.4 MANAGEMENT REVIEW

The number and nature of client complaints is reported by the QA Manager to the laboratory 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 Review (Section 16)

SECTION 11

CONTROL OF NON-CONFORMING WORK

11.1 OVERVIEW

When data discrepancies are discovered or deviations and departures from laboratory standard procedures, 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 to the final results and/or making a notation in the case narrative. 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 department manager for resolution. The department manager may elect to discuss it with the Technical Manager, QA Manager or have a representative contact the client to decide on a logical course of action. Once an approach is agreed upon, the analyst documents it using the laboratory's non-conformance and corrective action system described in Section 12. This information can then be supplied to the client in the form of a footnote or a case narrative with the report.

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 a compound 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 Laboratory Director, Technical Manager, Operations Manager or QA Manager, documented and included in the project folder. Deviations must also be noted on the final report with a statement that the compound is not reported in compliance with the analytical method requirements and the reason.

11.2 RESPONSIBILITIES AND AUTHORITIES

TestAmerica's Corporate SOP entitled Internal Investigation of Potential Data Discrepancies and Determination for Data Recall (SOP No. CW-L-S-002) outlines the general procedures for the reporting and investigation of data discrepancies and alleged incidents of misconduct or violations of TestAmerica's data integrity policies as well as the policies and procedures related to the determination of the potential need to recall data.

Under certain circumstances the Laboratory Director, the Technical Manager, the Operations Manager or a member of the QA team may exceptionally 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 non-conformance and corrective action procedures described in Section 12. This information may also need to 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 laboratory management within 24-hours. The Senior Management staff is comprised of the Laboratory Director, Technical Manager, and QA Manager. Suspected misrepresentation issues may also be reported to any member of the corporate staff as identified in Ethics Policy, CA-L-P-001. The data integrity hotline (1-800-736-9407) may also be used. The reporting of issues involving alleged violations of the company's Data Integrity or Manual Integration procedures must be conveyed to an Ethics and Compliance Officer (ECO), Director of Quality & EHS and the laboratory's Quality Director 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 Laboratory Director, QA Manager, ECOs, Corporate Quality, Executive 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.

11.3 EVALUATION 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.

TestAmerica's Corporate Data Investigation & Recall Procedure (SOP No. CW-L-S-002 distinguishes between situations when it would be appropriate for laboratory management to make the decision on the need for client notification (written or verbal) and data recall (report revision) and when the decision must be made with the assistance of the ECO's and Corporate Management. 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 TestAmerica's Corporate SOP No. CW-L-S-002.

11.4 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.

11.5 METHOD SUSPENSION/RESTRICTION (STOP WORK PROCEDURES)

In some cases it may be necessary to suspend/restrict the use of a method or target compound which constitutes significant risk and/or liability to the laboratory. Suspension/restriction procedures can be initiated by any of the persons noted in Section 11.2, 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 Laboratory Director.

The Laboratory Director 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 faxed or e-mailed by the laboratory to the appropriate VP of Operations and member of Corporate QA. This fax/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 (i.e., 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 (Laboratory Director, Technical Manager, Operations Manager, QA Manager, Department 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. This approval is given by final signature on the completed corrective action report.

SECTION 12

CORRECTIVE ACTION

12.1 OVERVIEW

A major component of TestAmerica'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. Corrective actions are documented using Non-Conformance Memo (NCM) and Corrective Action Reports (CAR) (refer to Figure 12-1).

12.2 GENERAL

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

12.2.1 Non-Conformance Memo (NCM) - is used to document the following types of corrective actions:

- Deviations from an established procedure or SOP
- QC outside of limits (non matrix related)
- Isolated reporting / calculation errors
- Client complaints
- Project Management concerns regarding specific analytical results
- Discrepancies in materials / goods received vs. manufacturer packing slips.

12.2.2 Corrective Action Report (CAR) - is used to document the following types of corrective actions:

- Questionable trends that are found in the monthly review of NCMs.
- Issues found while reviewing NCMs that warrant further investigation.
- Internal and External Audit Findings

- Failed or Unacceptable PT results.
- Corrective actions that cross multiple departments in the laboratory.
- Systematic Reporting / Calculation Errors
- Client complaints
- Data recall investigations
- Identified poor process or method performance trends
- Excessive revised reports

This will provide background documentation to enable root cause analysis and preventive action.

12.3 CLOSED 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.

12.3.1 Cause Analysis

- Upon discovery of a non-conformance event, the event must be defined and documented. A NCM or CAR 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 Department Manager, Operations Manager, Technical Manager, or QA Manager (or QA designee) is consulted.

12.3.2 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.
- 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. The NCM or CAR is used for this documentation.

12.3.3 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.

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 5 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.

12.3.4 Monitoring of the Corrective Actions

- The Department Manager, Operations 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. Department Managers and the Operations Manager are accountable to the Laboratory Director to ensure final acceptable resolution is achieved and documented appropriately.
- Each NCM is entered into the Laboratory Information Management System (LIMS) and each CAR is entered into a spreadsheet (Figure 12-1) for tracking and trending purposes for review to aid in ensuring that the corrective actions have taken effect.
- The QA Manager reviews monthly NCMs and CARs for trends. Highlights are included in the QA monthly report (refer to Section 16). 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 Corporate Quality Director by the QA Manager, indicating the nature of the out-of-control situation and problems encountered in solving the situation.

12.3.5 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 15.1.4, Special Audits)

12.4 TECHNICAL 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 11). The documentation of these procedures is through the use of a NCM or CAR.

Table 12-1 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 12-1 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 deficiency does not impair the usability of the results, data will be reported with an appropriate data qualifier and/or the deficiency will be noted in the case narrative. Where sample results may be impaired, the Project Manager is notified by an NCM and appropriate corrective action (e.g., reanalysis) is taken and documented**.**

12.5 BASIC 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.

Figure 12-1.
Example – Corrective Action Notice

TestAmerica Buffalo

Corrective Action Summary

#	Source	Type	Audit Organization	Dept.	Method	Repeat Finding?	Category	Finding, Deficiency, Area Needing Improvement or Recommended Action	Laboratory Investigation Summary	Root Cause of Deficiency	Laboratory Corrective Action Plan	Resp. Person	Date Opened	Response Due	CA Due Date	Date Lab Closed	Follow up notes	Follow Up Date	Follow-up Closed By
1																			
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Table 12-1.

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.
Initial Calibration Standards *(Analyst, Department Manager)*	- 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, Department Manager)*	- % 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 LIMs.	- 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 the data for that sample shall be reported with qualifiers.

QC Activity *(Individual Responsible for Initiation/Assessment)*	Acceptance Criteria	Recommended Corrective Action
Laboratory Control Sample (LCS) *(Analyst, Data Reviewer)*	- % Recovery within limits specified in LIMs.	- 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.
Surrogates *(Analyst, Data Reviewer)*	- % Recovery within limits of method or within three standard deviations of the historical mean.	- Individual sample must be repeated. Place comment in LIMS. - Surrogate results outside criteria shall be reported with qualifiers.
Method Blank (MB) *(Analyst, Data Reviewer)*	< Reporting Limit [1]	- 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, Department Manager)*	- 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.

QC Activity *(Individual Responsible for Initiation/Assessment)*	Acceptance Criteria	Recommended Corrective Action
Internal / External Audits *(QA Manager, Department Manager, Operations Manager, Technical Manager, 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.
Reporting / Calculation Errors *(Depends on issue – possible individuals include: Analysts, Data Reviewers, Project Managers, Department Manager, QA Manager, Corporate QA, Corporate Management)*	- SOP CW-L-S-002, Internal Investigation of Potential Data Discrepancies and Determination for Data Recall.	- Corrective action is determined by type of error. Follow the procedures in SOP CW-L-S-002.
Client Complaints *(Project Managers, Lab Director, Sales and Marketing, QA Manager)*	-	- 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 17 for an example) *(QA Manager, Lab Director, Operations Manager Department Managers)*	- 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 *(EH&S Coordinator, Lab Director, Operations Manager, Department Manager)*	- Environmental Health and Safety (EHS) Manual.	- Non-conformance is investigated and corrected through EH&S office.

Note: 1. Except as noted below for certain compounds, the method blank should be below the reporting limit. Concentrations up to five times the reporting limit will be allowed for the

ubiquitous laboratory and reagent contaminants: methylene chloride, acetone, 2-butanone and phthalates provided they appear in similar levels in the reagent blank and samples. This allowance presumes that the reporting limit is significantly below any regulatory limit to which the data are to be compared and that blank subtraction will not occur. For benzene and ethylene dibromide (EDB) and the other analytes for which regulatory limits are extremely close to the detection limit, the method blank must be below the method detection limit.

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SECTION 13.0

PREVENTIVE ACTION / IMPROVEMENT

13.1 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.

Dedicating resources to an effective preventive action system emphasizes the laboratory's commitment to its Quality 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 during management system reviews, review of monthly QA Metrics Report, evaluation of internal or external audits, results & evaluations of proficiency testing (PT) performance, review of control charts and QC results, data analysis & review processing operations, client complaints, staff observation, etc.

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 be the laboratory management, Corporate QA and TestAmerica's Executive Committee. 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, Lesson Learned, Technical Services audit report, Technical Best Practices, or as Corporate 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.

13.1.1 The following elements are part of a preventive action system/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 improvment.
- 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

13.1.2 Any Preventive Actions/Process Improvements undertaken or attempted shall be taken into account during the Annual Management Systems Review (Section 17). A highly detailed report is not required; however a summary of success and failure within the preventive action program is sufficient to provide management with a measurement for evaluation.

13.2 MANAGEMENT OF CHANGE

The Management of Change process is designed to manage significant events and changes that occur within the laboratory. Through these procedures, the potential risks inherent with a new event or change are identified and evaluated. The risks are minimized or eliminated through pre-planning and the development of preventive measures. The types of changes covered under this system include: Facility Changes, Major Accreditation Changes, Addition or Deletion to Division's Capabilities or Instrumentation, Key Personnel Changes, Laboratory Information Management System (LIMS) changes.

SECTION 14.0

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. TestAmerica Buffalo SOP BF-GP-015, Record Storage and Retention specify additional storage, archiving and retention procedures.

14.1 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 14-1. Quality records are maintained by the QA department in a database which is backed up as past 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). Hardcopy technical records are maintained by the Laboratory Director and the QA Department while electronic technical records are maintained by the IT Administrator.

Table 14-1. 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*
Official Documents	- Quality Assurance Manual (QAM) - Work Instructions - Policies - Policy Memorandums - SOPs - Manuals	5 Years from document retirement date*
QA Records	- Internal & External Audits/Responses - Certifications - Corrective/Preventive Actions - Management Reviews - Method & Software Validation / Verification Data - 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)

	Record Types [1]:	Retention Time:
Project Records	- Sample Receipt & COC Documentation - Contracts and Amendments - Correspondence - QAPP -SAP - Telephone Logbooks - Lab Reports	5 Years from analytical report issue*
Administrative Records	Finance and Accounting	10 years
	EH&S Manual, Permits	7 years
	Disposal Records	Indefinitely
	Employee Handbook	Indefinitely
	Personnel files, Employee Signature & Initials, Administrative Training Records (e.g., Ethics)	All HR docs have different retention times: Refer to HR Manual
	Administrative Policies Technical Training Records	7 years

[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.

14.1.1 All records are stored and retained according to BF-GP-015 and in such a way that they are secure and readily retrievable at the laboratory facility that provides a suitable environment to prevent damage or deterioration and to prevent loss. Records are maintained for a minimum of five years unless other wise specified by a client or regulatory requirement. 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.

If records are archived off-site they are to be stored in a secure location where a record is maintained of any entry into the storage facility.

For raw data and project records, record retention shall be calculated from the date the project report is issued. For other records, such as 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 14-2 have lengthier retention requirements and are subject to the requirements in Section 14.1.3.

14.1.2 Programs with Longer Retention Requirements

Some regulatory programs have longer record retention requirements than the standard record retention time. These are detailed in Table 14-2 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. Specific Information related to archival of data for greater than 5 years may be found in TestAmerica Buffalo SOP BF-GP-015.

Table 14-2. Special Record Retention Requirements

Program	[1]Retention Requirement
Drinking Water – All States	5 years (project records) 10 years-Radiochemistry (project records)
Drinking Water Lead and Copper Rule	12 years (project records)
Commonwealth of MA – All environmental data 310 CMR 42.14	10 years
FIFRA – 40 CFR Part 160	Retain for life of research or marketing permit for pesticides regulated by EPA
Housing and Urban Development (HUD) Environmental Lead Testing	10 years
Alaska	10 years
Louisiana – All	10 years
Michigan Department of Environmental Quality – all environmental data	10 years
Navy Facilities Engineering Service Center (NFESC)	5 years
NY Potable Water NYCRR Part 55-2	10 years
TSCA - 40 CFR Part 792	10 years after publication of final test rule or negotiated test agreement

[1]Note: Extended retention requirements are noted with the archive documents or addressed in TestAmerica Buffalo facility-specific records retention procedure BF-GP-015.

14.1.3 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. TestAmerica Buffalo SOP BF-GP-015 also contains specific information for archival of scanned data.

14.1.4 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 (any records stored off site should be accessible within 2 business 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 and/or extracts.

- 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 chain of custody is stored with the project file and the Job Number in TALS. 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. Calibration data for a given sequence are maintained in the order of the analysis. Sample data are stored on a job number basis in the project file or as part of the daily batch or sequence. 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, bench sheets or excel spreadsheets are used to record and file data. Standard and reagent information is recorded in logbooks or on the raw data for each method as required.

- Changes to hardcopy records shall follow the procedures outlined in Section 13 and 20. Changes to electronic records in LIMS 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. The procedure for this verification can be found in TestAmerica SOP BF-GP-015.

- Also refer to Section 19.14.1 'Computer and Electronic Data Related Requirements'**.**

14.2 TECHNICAL AND ANALYTICAL RECORDS

14.2.1 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 sampling, performance of each analysis and reviewing of results.

14.2.2 Observations, data and calculations are recorded real-time.

14.2.3 Changes to hardcopy records shall follow the procedures outlined in Section 13 and 20. Changes to electronic records in LIMS 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 bench sheet.
- Instrumentation identification and instrument operating conditions/parameters. Operating conditions/parameters are typically recorded in the method specific SOPs, in the instrument method detail records or the instrument maintenance logs where available.
- analysis type**;**
- all manual calculations and manual integrations**;**
- analyst's or operator's initials/signature**;**
- sample preparation including cleanup, separation protocols, incubation periods, ID codes, volumes, weights, instrument printouts, meter readings, temperatures, 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.
- Method performance criteria including expected quality control requirements. These are indicated both in the LIMS and on specific analytical report formats**.**

14.3 LABORATORY 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

14.3.1 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.

14.4 ADMINISTRATIVE RECORDS

The laboratory also maintains the administrative records in either electronic or hard copy form. Refer to Table 14-1.

14.5 RECORDS MANAGEMENT, STORAGE AND DISPOSAL

14.5.1 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.

14.5.2 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.

14.5.3 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**.**

14.5.4 The laboratory has a record management system (also known as document control) for control of laboratory notebooks, instrument logbooks, standards logbooks, and records for data reduction, validation, storage and reporting. Laboratory notebooks are issued on a per instrument or analysis basis, and are numbered sequentially as they are issued. No instrument or analysis has more than one active notebook at a time, so all data are recorded sequentially within a series of sequential notebooks. Bench sheets and raw data sequence files are filed sequentially by date. Standard and reagent information is maintained in LIMS and logbooks which are maintained on a departmental basis and are numbered sequentially as they are issued or as they are archived by QA.

14.5.5 Records are considered archived when noted as such in the records management system (also known as document control). Access to archived hard-copy information is documented with an access log and in/out records is used to note data that is removed and returned.

14.5.6 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 corporate headquarters. 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.

14.5.7 Records Disposal

14.5.7.1 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 14-1 and 14-2).

14.5.7.2 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**.**

SECTION 15

AUDITS

15.1 INTERNAL 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 corporate management.

Audits are conducted and documented as described in the TestAmerica Corporate SOP on performing Internal Auditing, SOP No. CA-Q-S-004. 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 15-1. Types of Internal Audits and Frequency

Description	Performed by	Frequency
Quality Systems Audits	QA Department, QA approved designee or Corporate QA	All areas of the laboratory annually
Method Audits	Joint responsibility: a) QA Manager or designee b) Technical Manager or Designee (Refer to CA-Q-S-003)	Methods Audits Frequency: All methods are reviewed annually 50% of methods receive a QA Technical Audit 50% of methods receive a SOP Method Compliance Audit
Special	QA Department or Designee	Surveillance or spot checks performed as needed to monitor specific issues
Performance Testing	Coordinated by Corporate QA	Two successful per year for each TNI -NELAC field of testing or as dictated by regulatory requirements

15.1.1 Annual Quality Systems Audit

An annual quality systems audit is required to ensure compliance to analytical methods and SOPs, TestAmerica's Data Integrity and Ethics Policies, TNI 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.

15.1.2 QA Technical Audits

QA technical 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 case narratives. Documentation is assessed by examining run logs and records of manual integrations. Manual calculations are checked. Where possible, Chrom AuditMiner is used to identify unusual manipulations of the data deserving closer scrutiny. QA technical audits will include all methods within a two-year period.

15.1.3 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. It is also recommended that the work of each newly hired analyst assessed within 3 months of working independently, (e.g., completion of method IDOC). In addition, as analysts add methods to their capabilities, (new IDOC) reviews of the analyst work products will be performed within 3 months of completing the documented training.

15.1.4 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.

15.1.5 Performance Testing

The laboratory participates semi-annually in performance audits conducted through the analysis of PT samples provided by a third party. The laboratory generally participates in the following types of PT studies: Drinking Water, Non-potable Water, Soil, and Air.

It is TestAmerica's 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.

Written responses to 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.

15.2 EXTERNAL AUDITS

External audits are performed when certifying agencies or clients conduct on-site inspections or submit performance testing samples for analysis. It is TestAmerica's 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 for any deficiencies discovered during an external audit. Audit responses are due in the time allotted by the client or agency performing the audit. When requested, a copy of the audit report and the labs corrective action plan will be forwarded to Corporate Quality.

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.

15.2.1 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.

15.3 AUDIT FINDINGS

Audit findings are documented using the corrective action process and database. The laboratory's corrective action responses for both types of audits may include action plans that could not be completed within a predefined timeframe. In these instances, a completion date must set and agreed to by operations management and the QA Manager.

Developing and implementing corrective actions to findings is the responsibility of the Department Manager where the finding originated. Findings that are not corrected by specified due dates are reported monthly to management in the QA monthly report. . When requested, a copy of the audit report and the labs corrective action plan will be forwarded to Corporate Quality.

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.

SECTION 16

MANAGEMENT REVIEWS

16.1 QUALITY ASSURANCE REPORT

A comprehensive QA Report shall be prepared each month by the laboratory's QA Department and forwarded to the Laboratory Director, Technical Managers, their Quality Director as well as the VP of Operations. All aspects of the QA system are reviewed to evaluate the suitability of policies and procedures. During the course of the year, the Laboratory Director, General Manager or Corporate QA may request that additional information be added to the report.

On a monthly basis, Corporate QA compiles information from all the monthly laboratory reports. The Corporate Quality Director prepares a report that includes a compilation of all metrics and notable information and concerns regarding the QA programs within the laboratories. The report also includes a listing of new regulations that may potentially impact the laboratories. This report is presented to the Senior Management Team and VPs of Operations.

16.2 ANNUAL MANAGEMENT REVIEW

The senior lab management team (Laboratory Director, Technical Manager, Operations Manager, and QA Manager) conducts a review annually of its quality systems and LIMS 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. Corporate Operations and Corporate QA personnel may be included in this meeting at the discretion of the Laboratory Director. The LIMS review consists of examining any audits, complaints or concerns that have been raised through the year that are related to the LIMS. The laboratory will summarize any critical findings that can not be solved by the lab and report them to Corporate IT.

This management systems review (Corporate SOP No. CA-Q-S-004 & Work Instruction No. CA-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.

A report is generated by the QA Manager and management. The report is distributed to the appropriate VP of Operations and the Quality Director. 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.

Changes to the quality systems requiring update to the laboratory QA Manual shall be included in the next revision of the QA Manual.

16.3 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. The TestAmerica Corporate Data Investigation/ Recall SOP shall be followed (SOP 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.

TestAmerica's CEO, VP of Quality, Technical & Operations Support, VP of Client and Technical Services, VPs of Operations and Quality Directors receive a monthly report from the Exec. Director of Quality & EHS summarizing any current data integrity or data recall investigations. The VPs of Operations are also made aware of progress on these issues for their specific labs.

SECTION 17

PERSONNEL

17.1 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 as outlined in the organization chart in Figure 4-1.

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.

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.

17.2 EDUCATION AND EXPERIENCE REQUIREMENTS FOR TECHNICAL PERSONNEL

The laboratory makes every effort to hire analytical staff that possesses a college degree (AA, BA, BS) in an applied science with some chemistry 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 TestAmerica employees are outlined in job descriptions and are generally summarized for analytical staff in the table below.

The laboratory maintains job descriptions for all personnel who manage, perform or verify work affecting the quality of the environmental testing the laboratory performs. Job Descriptions are

located in the TestAmerica intranet site's Human Resources web-page (Also see Section 4 for position descriptions/responsibilities).

Experience and specialized training are occasionally accepted in lieu of a college degree (basic lab skills such as using a balance, pipette, quantitation techniques, etc. are also considered).

As a general rule for analytical staff:

Specialty	Education	Experience
Extractions, Digestions, some electrode methods (pH, DO, Redox, etc.), or Titrimetric and Gravimetric Analyses	H.S. Diploma	On the job training (OJT)
CVAA, Single component or short list Chromatography (e.g., Fuels, BTEX-GC, IC)	A college degree in an applied science or 2 years of college and at least 1 year of college chemistry	Or 2 years prior analytical experience is required
ICP, ICPMS, Long List or complex chromatography (e.g., Pesticides, PCB, Herbicides, HPLC, etc.), GCMS	A college degree in an applied science or 2 years of college chemistry	or 5 years of prior analytical experience
Spectra Interpretation	A college degree in an applied science or 2 years of college chemistry	And 2 years relevant experience Or 5 years of prior analytical experience
Technical Managers/Department Managers – **General**	Bachelors Degree in an applied science or engineering with 24 semester hours in chemistry An advanced (MS, PhD.) degree may substitute for one year of experience	And 2 years experience in environmental analysis of representative analytes for which they will oversee

When an analyst does not meet these requirements, they can perform a task under the direct supervision of a qualified analyst, peer reviewer or Department 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.

17.3 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:

Required Training	Time Frame	Employee Type
Environmental Health & Safety	Prior to lab work	All
Ethics – New Hires	1 week of hire	All
Ethics - Comprehensive	90 days of hire	All
Data Integrity	30 days of hire	Technical and PMs
Quality Assurance	90 days of hire	All
Ethics – 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. 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 are maintained in their training file.
- Documentation of proficiency (refer to Section 20).
- 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.
- The Human Resource office maintains documentation and attestation forms on employment status & records; benefit programs; timekeeping/payroll; and employee conduct (e.g., ethics violations). This information is maintained in the employee's secured personnel file.

Further details of the laboratory's training program are described in TestAmerica Buffalo SOP BF-QA-004, Laboratory Personnel Training.

17.4 DATA INTEGRITY AND ETHICS TRAINING PROGRAM

Establishing and maintaining a high ethical standard is an important element of a Quality System. Ethics and data integrity training is integral to the success of TestAmerica and is provided for each employee at TestAmerica. It is a formal part of the initial employee orientation within 1 week of hire followed by technical data integrity training within 30 days, comprehensive

training within 90 days, and an annual refresher for all employees. Senior management at each facility performs the ethics training for their staff.

In order to ensure that all personnel understand the importance TestAmerica places on maintaining high ethical standards at all times; TestAmerica has established a Corporate Ethics Policy No. CW-L-P-004 and an Ethics Statement. All initial and annual training is documented by signature on the signed Ethics demonstrating that the employee has participated in the training and understands their obligations related to ethical behavior and data integrity.

Violations of this Ethics Policy will not be tolerated. Employees who violate this policy will be subject to disciplinary actions up to and including termination. Criminal violations may also be referred to the Government for prosecution. In addition, such actions could jeopardize TestAmerica's ability to do work on Government contracts, and for that reason, TestAmerica has a Zero Tolerance approach to such violations.

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 TestAmerica and administered by the Corporate Quality Department.

SECTION 18

ACCOMMODATIONS AND ENVIRONMENTAL CONDITIONS

18.1 OVERVIEW

TestAmerica Buffalo is a 32,000 ft^2 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.

The 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 field operations, bottle kit preparation, sample receiving, sample preparation, volatile organic sample analysis, non-volatile organic sample analysis, inorganic sample analysis and administrative functions.

18.2 ENVIRONMENT

Laboratory accommodation, test areas, energy sources, lighting are adequate to facilitate proper performance of tests. The 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.

The 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 humidity, voltage, temperature, and vibration levels in the laboratory. Key equipment has been provided with back-up power supply in the event of a power outage.

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 LIMS are regulated to protect against raw data loss.

18.3 WORK AREAS

There is effective separation between neighboring areas when the activities therein are incompatible with each other. Examples include:

- Volatile organic chemical handling areas, including sample preparation and waste disposal, and volatile organic chemical analysis 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 the 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.

18.4 FLOOR PLAN

A floor plan can be found in Appendix 1.

18.5 BUILDING SECURITY

Building pass cards and alarm codes are distributed to all facility employees.

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. [The reason for this is that it is important to know who is in the building in case of a safety emergency. The visitors logbook is used to ensure that everyone got out of the building safely.] In addition to signing into the laboratory, the Environmental, Health and Safety Manual contains requirements for visitors and

vendors. There are specific safety forms that must be reviewed and signed. 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.

SECTION 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. The 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 TestAmerica's Corporate SOP CW-Q-S-002, Writing a Standard Operating Procedure (SOP) and Laboratory SOP BF-QA-003, Procedure for Writing, Reviewing and Revising Controlled Quality Documents (QAM, SOP, etc)
- SOPs are reviewed at a minimum of every 2 years (annually for Drinking Water 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, etc.), 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 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.

19.4.1.1 The analytical methods used by the laboratory are those currently accepted and approved by the U. S. EPA and the state or territory from which the samples were collected. Reference methods include:

- *Method 1664, Revision A: N-Hexane Extractable Material (HEM; Oil and Grease) and Silica Gel Treated N-Hexane Extractable Material (SGT-HEM); Non-polar Material) by Extraction and Gravimetry, EPA-821-R-98-002, February 1999*
- *Compendium of Methods for the Determination of Toxic Organic Compounds in Ambient Air, US EPA, January 1996.*
- *Guidelines Establishing Test Procedures for the Analysis of Pollutants Under the Clean Water Act; Analysis and Sampling Procedures; 40CFR Part 136 as amended by Method Update Rule; May 18, 2012*
- *Methods for Chemical Analysis of Water and Wastes, EPA 600 (4-79-020), 1983.*
- *Methods for the Determination of Inorganic Substances in Environmental Samples, EPA-600/R-93/100, August 1993.*
- *Methods for the Determination of Metals in Environmental Samples, EPA/600/4-91/010, June 1991. Supplement I: EPA-600/R-94/111, May 1994.*

- *Methods for the Determination of Organic Compounds in Drinking Water, EPA-600/4-88-039, December 1988, Revised, July 1991, Supplement I, EPA-600-4-90-020, July 1990, Supplement II, EPA-600/R-92-129, August 1992. Supplement III EPA/600/R-95/131 - August 1995 (EPA 500 Series) (EPA 500 Series methods)*
- *Technical Notes on Drinking Water Methods, EPA-600/R94-173, October 1994*
- *NIOSH Manual of Analytical Methods, 4th ed., August 1994.*
- *Statement of Work for Inorganics & Organics Analysis, SOM and ISM, current versions, USEPA Contract Laboratory Program Multi-media, Multi-concentration.*
- *Standard Methods for the Examination of Water and Wastewater, 18th/19th /20th / 21st/ 22nd/on-line edition; Eaton, A.D. Clesceri, L.S. Greenberg, A.E. Eds; American Water Works Association, Water Pollution Control Federation, American Public Health Association: Washington, D.C.*
- *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.*
- *Annual Book of ASTM Standards, American Society for Testing & Materials (ASTM), Philadelphia, PA.*
- *National Status and Trends Program, National Oceanographic and Atmospheric Administration, Volume I-IV, 1985-1994.*
- *Manual for the Certification of Laboratories Analyzing Drinking Water (EPA 815-R-05-004, January 2005)* ***(DW labs only)***
- *Code of Federal Regulations (CFR) 40, Parts 136, 141, 172, 173, 178, 179 and 261*
- *New York State DEC Analytical Services Protocol, 2005*
- *New York State DOH Methods Manual*
- *Massachusetts Contingency Plan 310 CMR 40, April 25, 2014*
- *Connecticut Reasonable Confidence Protocol, July 2006*

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.

19.4.2 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.

19.4.2.1 A demonstration of capability (BF-QA-004) is performed whenever there is a significant change in instrument type (e.g., new instrumentation), method or personnel.

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.

19.4.2.2 The initial demonstration of capability must be thoroughly documented and approved by the Operations Manager/Designee and QA Manager prior to independently analyzing client samples. All associated documentation must be retained in accordance with the laboratories archiving procedures.

19.4.2.3 The laboratory must have an approved SOP, demonstrate satisfactory performance, and conduct a method detection limit study (when applicable). There may be other requirements as stated within the published method or regulations (i.e., 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 instrument is calibrated for the analyte to be reported using the criteria for the method and ICV/CCV criteria are met (unless an ICV/CCV is not required by the method or criteria are per project DQOs).
- The laboratory's nominal or default reporting limit (RL) is equal to the quantitation limit (QL), must be at or above the lowest non-zero standard in the calibration curve and must be reliably determined. Project RLs are client specified reporting levels which may be higher than the QL. Results reported below the QL must be qualified as estimated values. Also see Section 19.6.1.3, Relationship of Limit of Detection (LOD) to Quantitation Limit (QL).

- 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

Procedures for generation of IDOCs are detailed below and in laboratory SOP BF-QA-004, Laboratory Personnel Training.

19.4.3.1 The spiking standard used must be prepared independently from those used in instrument calibration.

19.4.3.2 The analyte(s) shall be diluted in a volume of clean matrix sufficient to prepare four aliquots at the concentration specified by a method or the laboratory SOP.

19.4.3.3 At least four aliquots shall be prepared (including any applicable clean-up procedures) and analyzed according to the test method (either concurrently or over a period of days).

19.4.3.4 Using all of the results, calculate the mean recovery in the appropriate reporting units and the standard deviations for each parameter of interest.

19.4.3.5 When it is not possible to determine the mean and standard deviations, such as for presence, absence and logarithmic values, the laboratory will assess performance against criteria described in the Method SOP.

19.4.3.6 Compare the information obtained above to the corresponding acceptance criteria for precision and accuracy in the test method (if applicable) or in laboratory generated acceptance criteria (LCS or interim criteria) if there is no mandatory criteria established. If any one of the parameters do not meet the acceptance criteria, the performance is unacceptable for that parameter.

19.4.3.7 When one or more of the tested parameters fail at least one of the acceptance criteria, the analyst must proceed according to either option listed below:

- Locate and correct the source of the problem and repeat the test for all parameters of interest beginning with 19.4.3.3 above.
- Beginning with 19.4.3.3 above, repeat the test for all parameters that failed to meet criteria. Repeated failure, however, will confirm a general problem with the measurement system. If this occurs, locate and correct the source of the problem and repeat the test for all compounds of interest beginning with 20.4.3.1 above.

Note: Results of successive LCS analyses can be used to fulfill the DOC requirement.

A certification statement (see Figure 19-1) shall be used to document the completion of each initial demonstration of capability. A copy of the certification is archived in the analyst's training folder.

19.5 LABORATORY DEVELOPED METHODS AND NON-STANDARD 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.

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. Where estimations and/or demonstrations of sensitivity are required by regulation or client agreement, such as the procedure in 40 CFR Part 136 Appendix B, under the Clean Water Act, these shall be followed.

19.6.1.3 Relationship of Limit of Detection (LOD) to the Quantitation Limit (QL)

An important characteristic of expression of sensitivity is the difference in the LOD and the QL. The LOD is the minimum level at which the presence of an analyte can be reliably concluded. The QL is the minimum concentration of analyte that can be quantitatively determined with acceptable precision and bias. 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 QL. 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 QL, 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)

Method detection limits (MDL) are initially determined in accordance with 40 CFR Part 136, Appendix B or alternatively by other technically acceptable practices that have been accepted by regulators. MDL is also sometimes referred to as Limit of Detection (LOD). The MDL theoretically represents the concentration level for each analyte within a method at which the Analyst is 99% confident that the true value is not zero. The MDL is determined for each analyte initially during the method validation process and updated as required in the analytical methods, whenever there is a significant change in the procedure or equipment, or based on project specific requirements (refer to 19.7.10). Generally the analyst prepares at least seven replicates of solution spiked at one to five times the estimated method detection limit (most often at the lowest standard in the calibration curve) into the applicable matrix with all the analytes of interest. Each

of these aliquots is extracted (including any applicable clean-up procedures) and analyzed in the same manner as the samples. Where possible, the seven replicates should be analyzed over 2-4 days to provide a more realistic MDL. To allow for some flexibility, this low level standard may be analyzed every batch or every week or some other frequency rather than doing the study all at once. In addition, a larger number of data points may be used if the appropriate t-value multiplier is used.

Refer to the Corporate SOP No. CA-Q-S-006 or the laboratory's SOP No. BF-QA-001 for details on the laboratory's MDL process.

19.8 INSTRUMENT DETECTION LIMITS (IDL)

19.8.1 The IDL is sometimes used to assess the reasonableness of the MDLs or in some cases required by the analytical method or program requirements. IDLs are most used in metals analyses but may be useful in demonstration of instrument performance in other areas.

19.8.2 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. (For CLP procedures, the IDL is determined using the standard deviation of 7 replicate spike analyses on each of 3 non-consecutive days.)

19.8.3 If IDL is > than the MDL, it may be used as the reported MDL.

19.9 VERIFICATION OF DETECTION AND REPORTING LIMITS

19.9.1 Once an MDL is established, it must be verified, on each instrument, by analyzing a quality control sample (prepared as a sample) at no more than 3 times the calculated MDL for single analyte analyses (e.g. most wet chemistry methods, CVAA, etc.) and no more than 4 times the calculated MDL for multiple analyte methods (e.g. GC, GCMS, ICP, etc.). The analytes must be qualitatively identified or see section 20.7.9 for other options. This verification does not apply to methods that are not readily spiked (e.g. pH, turbidity, etc.) or where the lab does not report to the MDL. If the MDL does not verify, then the lab will not report to the MDL, or redevelop their MDL or use the level where qualitative identification is established. MDLs must be verified at least annually.

19.9.2 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 the reporting limit and annually thereafter. The annual requirement is waved for methods that have an annually verified MDL. The laboratory will comply with any regulatory requirement.

19.10 RETENTION TIME WINDOWS

Most organic analyses and some inorganic analyses use chromatography techniques for qualitative and quantitative determinations. For every chromatography analysis each analyte will have a specific time of elution from the column to the detector. This is known as the analyte's retention time. The variance in the expected time of elution is defined as the retention time

window. As the key to analyte identification in chromatography, retention time windows must be established on every column for every analyte used for that method. These records are kept with the files associated with an instrument for later quantitation of the analytes. Complete details are available in the laboratory's SOPs.

19.11 EVALUATION OF SELECTIVITY

The laboratory evaluates selectivity by following the checks within the applicable analytical methods, which include mass spectral tuning, second column confirmation, ICP interelement interference checks, chromatography retention time windows, sample blanks, and specific electrode response factors.

19.12 ESTIMATION OF UNCERTAINTY OF MEASUREMENT

19.12.1 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": 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.

19.12.2 Uncertainty is not error. Error is a single value, 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.

19.12.3 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.

19.12.4 To calculate the uncertainty for the specific result reported, multiply the result by the decimal of the lower end of the LCS range percent value for the lower end of the uncertainty range, and multiply the result by the decimal of the upper end of the LCS range percent value for the upper end of the uncertainty range. These calculated values represent uncertainties at approximately the 99% confidence level with a coverage factor of k = 3. As an example, for a reported result of 1.0 mg/L with an LCS recovery range of 50 to 150%, the estimated uncertainty in the result would be 1.0 ±0.5 mg/L.

19.12.5 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.

19.13 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.

- Homogenous samples: If a reanalysis agrees with the original result to within the RPD limits for MS/MSD or Duplicate analyses, or within $\pm$ 1 reporting limit for samples $\leq$ 5x the reporting limit, the original analysis will be reported. At the client's request, both results may be reported on the same report but not on two separate reports.

- 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 Department Supervisor or Laboratory Director/Manager if unsure.

19.14 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.

19.14.1 Computer and Electronic Data Related Requirements

The three basic objectives of our computer security procedures and policies are shown below. The laboratory is currently running the 'TALS Data System' which is a LIMs system that has been highly customized to meet the needs of the laboratory. It is referred to as LIMS for the remainder of this section. The LIMS utilizes a SQL server which is an industry standard relational database platform. It is referred to as Database for the remainder of this section.

19.14.1.1 Maintain the Database Integrity

Assurance that data is reliable and accurate through data verification (review) procedures, password-protecting access, anti-virus protection, and data change requirements, as well as an internal LIMS permissions procedure.

- LIMS Database Integrity is achieved through data input validation, internal user controls, 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.

19.14.1.2 Ensure Information Availability

Protection against loss of information or service is ensured through scheduled back-ups, stable file server network architecture, storage of media, line filter, Uninterruptible Power Supply (UPS), and maintaining older versions of software as revisions are implemented.

19.14.1.3 Maintain Confidentiality

Ensure data confidentiality through physical access controls such as password protection or website access approval, when electronically transmitting data.

19.14.2 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.

For manual data entry, e.g., Wet Chemistry, the data is reduced by the analyst and then verified by the Department Manager or alternate analyst prior to updating the data in LIMS. The data review sheets, or any other type of applicable documents, are signed by both the analyst and alternate reviewer to confirm the accuracy of the manual entry(s).

Manual integration of peaks will be documented and reviewed and the raw data will be flagged in accordance with the TestAmerica Corporate SOP CA-Q-S-002, *Acceptable Manual Integration Practices*.

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.

19.14.2.1 All raw data must be retained in the project job folder, computer file, and/or run 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.

19.14.2.2 In general, concentration results are reported in milligrams per liter (mg/l) or micrograms per liter (µg/l) for liquids and milligrams per kilogram (mg/kg) or micrograms per kilogram (µg/kg) for solids. For values greater than 10,000 mg/l, results can be reported in percent, i.e., 10,000 mg/l = 1%. Units are defined in each lab SOP.

19.14.2.3 In reporting, the analyst or the instrument output records the raw data result using values of known certainty plus one uncertain digit. If final calculations are performed external to LIMS, the results should be entered in LIMS with at least three significant figures. In general, final inorganic results are reported to 2 significant figures for values less than 10 and 3 significant figures for values greater than 10 on the final report. Organic results are generally reported to 1 significant figure for values less than 10 and 2 significant figures for values greater than 10 on the final report. The number of significant figures may be adjusted based on client or project requirements.

19.14.2.4 For those methods that do not have an instrument printout, an instrumental output or a calculation spreadsheet upload compatible with the LIMS System, the final results and dilution factors are entered directly into LIMS by the analyst, and the software formats the final result for the analytical report. LIMS has a defined significant figure criterion for each analyte.

19.14.2.5 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 the LIMS, the raw results and dilution factors are transferred into LIMS 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 automatically transferred to the network server and, eventually, to a back-up tape file.

19.14.3 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 Technical Manager/QA Manager at the facility. The QA Manager controls all worksheets following the procedures in Section 6.

19.14.4 Review / Verification Procedures

Review procedures are out lined in several laboratory SOPs (e.g. BF-SR-002, "Receipt of Analytical Samples", BF-GP-012, "Technical Data Review", and BF-PM-001, "Project Information Requirements") 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 laboratory also has an SOP discussing Manual Integrations to ensure the authenticity of the data (BF-GP-013, Manual Integration). The general review concepts are discussed below, more specific information can be found in the SOPs.

19.14.4.1 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 the LIMS. The log-in instructions are reviewed by the personnel entering the information, and a second level review is conducted by the project management staff.

19.14.4.2 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., instrument output for continuous analyzers, chromatograms, spectra, and manual integrations), 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 into LIMS, data qualifiers are added as needed. All first level reviews are documented.

19.14.4.3 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 (e.g., instrument output, chromatograms, and spectra) including 100% of data associated with any changes made by the primary analyst, such as manual integrations or reassignment of peaks to different analytes, or elimination of false negative analytes. The second review also includes evaluation of initial calibration/calibration verification data in the day's analytical run, evaluation of QC data, reliability of sample results, qualifiers and NCM narratives. 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
- Inconsistent peak integration
- Transcription errors
- Results outside of calibration range

19.14.4.4 Unacceptable analytical results may require reanalysis of the samples. Any problems are brought to the attention of the Laboratory Director, Project Manager, Quality Director/Manager, Technical Manger, or Supervisor for further investigation. Corrective action is initiated whenever necessary.

19.14.4.5 The results are then entered or directly transferred into the computer database and a hard copy (or .pdf) is printed for the client.

19.14.4.6 As a final review prior to the release of the report, the Project Manager reviews the results for appropriateness and completeness. This review and approval ensures that client requirements have been met and that the final report has been properly completed. The process includes, but is not limited to, verifying that chemical relationships are evaluated, COC is followed, cover letters/ narratives are present, flags are appropriate, and project specific requirements are met.

19.14.4.7 Any project that requires a data package is subject to a tertiary data review for transcription errors and acceptable quality control requirements. The Project Manager then signs the final report and creates the invoice. When complete, the report is issued to the client.

19.14.5 Manual Integrations

Computerized data systems provide the analyst with the ability to re-integrate raw instrument data in order to optimize the interpretation of the data. Though manual integration of data is an invaluable tool for resolving variations in instrument performance and some sample matrix problems, when used improperly, this technique would make unacceptable data appear to meet quality control acceptance limits. Improper re-integrations lead to legally indefensible data, a poor reputation, or possible laboratory decertification. Because guidelines for re-integration of data are not provided in the methods and most methods were written prior to widespread implementation of computerized data systems, the laboratory trains all analytical staff on proper manual integration techniques using SOP CA-Q-S-002 as the guidelines**.**

19.14.5.1 The analyst must adjust baseline or the area of a peak in some situations, for example when two compounds are not adequately resolved or when a peak shoulder

needs to be separated from the peak of interest. The analyst must use professional judgment and common sense to determine when manual integrating is required. Analysts are encouraged to ask for assistance from a senior analyst or manager when in doubt.

19.14.5.2 Analysts shall not increase or decrease peak areas for the sole purpose of achieving acceptable QC recoveries that would have otherwise been unacceptable. The intentional recording or reporting of incorrect information (or the intentional omission of correct information) is against company principles and policy and is grounds for immediate termination.

19.14.5.3 Client samples, performance evaluation samples, and quality control samples are all treated equally when determining whether or not a peak area or baseline should be manually adjusted.

19.14.5.4 All manual integrations receive a second level review. Manual integrations must be indicated on an expanded scale “after” chromatograms such that the integration performed can be easily evaluated during data review. Expanded scale “before” chromatograms are also required for all manual integrations on QC parameters (calibrations, calibration verifications, laboratory control samples, internal standards, surrogates, etc.) unless the laboratory has another documented corporate approved procedure in place that can demonstrate an active process for detection and deterrence of improper integration practices.

Figure 19-1.
Example - Demonstration of Capability Documentation

TestAmerica
THE LEADER IN ENVIRONMENTAL TESTING

BF-QA-DOC-004
DOC Cert. Statement
Rev.0 2/27/13

TESTAMERICA LABORATORIES, INC.

TRAINING & DEMONSTRATION OF CAPABILITY CERTIFICATION STATEMENT

Employee: _____ Page ____ of ____

Method Number: _____ Date: _____

Parameters or Analytes: _____

Initial Demonstration of Capability: ☐

SOP Number: _____ Revision # _____ Date Read _____

Trained By: _____

Date training began: _____ Date training completed: _____

Continued Demonstration of Capability: ☐

SOP Number: _____ Revision # _____ Date Read _____

I CERTIFY that I have read, understand and agree to use the SOP identified above. I have also submitted data associated with the demonstration of capability.

_____ _____
Employee Signature Date

We, the undersigned, CERTIFY that:

1. The analyst identified above, using the cited test method(s), which is in use at this facility for the analyses of samples under the National Environmental Laboratory Accreditation Program, have met the Demonstration of Capability.

2. The test method(s) was performed by the analyst(s) identified on this certification.

3. A copy of the test method(s) and the laboratory-specific Sops are available for all personnel on-site.

4. The data associated with the demonstration capability are true, accurate, complete and self-explanatory.

5. All raw data (including a copy of this certification form) necessary to reconstruct and validate these analyses have been retained at this facility, and that the associated information is well organized and available for review by authorized assessors.

_____ _____ _____
Operations Manager Signature Date

_____ _____ _____
Quality Assurance Manager Signature Date

SECTION 20

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 laboratory SOPs. A list of laboratory equipment and instrumentation is presented in Table 20-1.

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

20.2.1 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.

20.2.2 Routine preventive maintenance procedures and frequency, such as lubrication, 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.

20.2.3 Table 20-2 lists examples of scheduled routine maintenance. It is the responsibility of each Department Manager to ensure that instrument maintenance logs are kept for all equipment in his/her department. Preventative maintenance procedures 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.)

20.2.4 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.

20.2.4.1 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.

20.2.4.2 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. CCV run on *'date'* was acceptable, or instrument recalibrated on 'date' with acceptable verification, etc.) must also be documented in the instrumentation records.

20.2.4.3 When maintenance or repair is performed by an outside agency, service receipts detailing the service performed can be affixed into the logbooks adjacent to pages describing the maintenance performed. This stapled in page must be signed across the page entered and the logbook so that it is clear that a page is missing if only half a signature is found in the logbook.

20.2.5 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

20.2.6 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 recalibrated and the laboratory MDL verified (using an MDLV) 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, field sampling devices, 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. Laboratory SOPs BF-GP-001,"Calibration of Autopipettes and Repipetters" and BF-GP-002, "Support Equipment: Maintenance, Record Keeping and Corrective Actions of Analytical Balances, Temperature Control Devises and Reagent Water" provide additional detail on the monitoring and record keeping for support equipment.

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 annually 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 and Conductivity, and Turbidity SOPs for further information.

20.3.3 Thermometers

All reusable thermometers are calibrated on an annual basis with a NIST-traceable thermometer at temperatures bracketing the range of use. Disposable thermometers are discarded upon expiration and replaced with newly purchased thermometers. IR thermometers should be calibrated over the full range of use, including ambient, iced (4 degrees) and frozen (0 to -5 degrees), per the Drinking Water Manual. The IR thermometers are verified daily and calibrated quarterly. Digital probes and thermocouples are calibrated quarterly.

The NIST Mercury 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 digital thermometer is recalibrated every one year (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 logbooks. Monitoring method-specific temperatures, including incubators, heating blocks, water baths, and ovens, is documented in method-specific logbooks. More information on this subject can be found in the laboratory SOP BF-GP-020, "Thermometer Calibration".

20.3.4 Refrigerators/Freezer Units, Waterbaths, Ovens and Incubators

The temperatures of all refrigerator units and freezers used for sample and standard storage are monitored each working day.

Ovens, waterbaths and incubators are monitored on days of use.

All of this equipment has a unique identification number, and is assigned a unique thermometer for monitoring.

Sample storage refrigerator temperatures are kept between > 0ºC and ≤ 6 ºC.

Specific temperature settings/ranges for other refrigerators, ovens waterbaths, and incubators can be found in method specific SOPs.

All of this information is documented in Daily Temperature Logbooks and method-specific logbooks.

20.3.5 Autopipettors, Dilutors, and Syringes

Mechanical volumetric dispensing devices including burettes (except Class A Glassware and Glass microliter syringes) are given unique identification numbers and the delivery volumes are verified gravimetrically at a minimum on a quarterly basis.

For those dispensers that are not used for analytical measurements, a label is applied to the device stating that it is not calibrated. Any device not regularly verified can not be used for any quantitative measurements.

Micro-syringes are purchased from Hamilton Company. Each syringe is traceable to NIST. The laboratory keeps on file an "Accuracy and Precision Statement of Conformance" from Hamilton attesting established accuracy.

20.3.6 Field Sampling Devices (Isco Auto Samplers)

Each Auto Sampler (ISCO) is assigned a unique identification number in order to keep track of the calibration. This number is also recorded on the sampling documentation.

The Auto Sampler is calibrated monthly (or if not utilized monthly, immediately prior to its usage) by setting the sample volume to 100ml and recording the volume received. The results are filed

in a logbook/binder. The Auto Sampler is programmed to run three (3) cycles and each of the three cycles is measured into a graduated cylinder to verify 100ml are received.

If the RSD (Relative Standard Deviation) between the 3 cycles is greater than 10%, the procedure is repeated and if the result is still greater than 10%, then the Auto Sampler is taken out of service until it is repaired and calibration verification criteria can be met. The results of this check are kept in a logbook/binder.

Additional calibration and use information is detailed in laboratory SOP BF-FS-006, "Calibration of Field Meter".

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, 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 (exception being ICP and ICP/MS methods) will be used.

20.4.1.1 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.

20.4.1.2 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).

20.4.1.3 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). The exceptions to these rules are methods where the referenced method does not specify two or more standards.

20.4.1.4 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 would be considered a second source. This verification occurs immediately after the calibration curve has been analyzed, and before the analysis of any samples.

20.4.2 Calibration Verification

The calibration relationship established during the initial calibration must be verified at least daily as specified in the laboratory method SOPs in accordance with the referenced analytical methods and NELAC (2003) standard, Section 5.5.5.10. 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 is with a standard source secondary (second source standard) to the calibration standards, but continuing calibration verifications may use the same source standards as the calibration curve.

Note: The process of calibration verification referred to 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 NELAC (2003) Standard, Section 5.5.5.10 and 2009 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 (basically GCMS) then bracketing 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 initial calibrations must be verified at the beginning of each 12-hour analytical shift during which samples are analyzed. (Some methods may specify more or less frequent verifications). 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.

A continuing instrument calibration verification (CCV) must be repeated at the beginning and, for methods that have quantitation by external calibration models, at the end of each analytical batch. 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 (basically GCMS) then bracketing 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).

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 & 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 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 with a footnote or case narrative 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.

20.4.2.1 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.

20.5 TENTATIVELY IDENTIFIED COMPOUNDS (TICS) – GC/MS ANALYSIS

For samples containing components not associated with the calibration standards, a library search may be made for the purpose of tentative identification. The necessity to perform this type of identification will be determined by the purpose of the analyses being conducted. Data system library search routines should not use normalization routines that would misrepresent the library or unknown spectra when compared to each other.

Note: If the TIC compound is not part of the client target analyte list but is calibrated by the laboratory and is both qualitatively and/or quantitatively identifiable, it should not be reported as a TIC. If the compound is reported on the same form as true TICs, it should be qualified and/or narrated that the reported compound is qualitatively and quantitatively (if verification in control) reported compared to a known standard that is in control (where applicable).

For example, the RCRA permit or waste delisting requirements may require the reporting of non-target analytes. Only after visual comparison of sample spectra with the nearest library searches may the analyst assign a tentative identification. See laboratory SOP's BF-MB-005 and BF-MV-007 for guidelines for making tentative identifications

Note:
For general reporting if TICs are requested, the ten (10), largest non-target analyte peaks whose area count exceeds 10% of the nearest internal standard will be termed “Tentatively Identified Compounds” (TICs). More or fewer TICs may be identified based on client requirements.

20.6 GC/MS TUNING

Prior to any GCMS analytical sequence, including calibration, the instrument parameters for the tune and subsequent sample analyses within that sequence must be set.

Prior to tuning/auto-tuning the mass spec, the parameters may be adjusted within the specifications set by the manufacturer or the analytical method. These generally don't need any adjustment but it may be required based on the current instrument performance. If the tune verification does not pass it may be necessary to clean the source or perform additional maintenance. Any maintenance is documented in the maintenance log.

Table 20-1. Laboratory Equipment and Instrumentation – TestAmerica Buffalo

TestAmerica
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TestAmerica Buffalo Instrument List

Equipment/ Instrument	Manufacturer	Model Number	Serial Number	Year Put into Service	Condition When Received
GC/MS Instrumentation	Agilent	5975	US83110163	2013	good
GC/MS Instrumentation	Agilent	5973	US02450141	2013	good
GC/MS Instrumentation	Agilent	5975	CN10833020	2009	good
GC/MS Instrumentation	Agilent	5975	US80838844	2008	good
GC/MS Instrumentation	Agilent	5973	US44621446	2005	good
GC/MS Instrumentation	Agilent	5973	US52420646	2005	good
GC/MS Instrumentation	Agilent	5973	US41720721	2004	good
GC/MS Instrumentation	Agilent	5973	US35120354	2004	good
GC/MS Instrumentation	Agilent	5973	US41720707	2004	good
GC/MS Instrumentation	Agilent	5973	US10241053	2003	good
GC/MS Instrumentation	Agilent	5973	US30965634	2003	good
GC/MS Instrumentation	Agilent	5973	US03965692	2003	good
GC/MS Instrumentation	Agilent	5973	US05060076	2001	good
GC/MS Instrumentation	Agilent	5973	US05060084	2001	good
GC/MS Instrumentation	Agilent	5973	US03950346	2001	good
GC/MS Instrumentation	Agilent	5973	US82321636	2001	good
GC Instrumentation	Perkin Elmer	Clarus 608 dual uECD	680S10042901	2012	good
GC Instrumentation	Perkin Elmer	Clarus 600 dual FID	665S10020401	2012	good
GC Instrumentation	Agilent	6890 dual uECD	CN10520009	2005	good
GC Instrumentation	Agilent	6890 dual uECD	CN10520010	2005	good
GC Instrumentation	Agilent	6890 dual uECD	CN10448015	2005	good
GC Instrumentation	Hewlett Packard	5890II dual ECD	3336A53126	1994	good
GC Instrumentation	Hewlett Packard	5890II dual ECD	3336A63465	1994	good
GC Instrumentation	Hewlett Packard	5890II dual ECD	3336A53464	1994	good
GC Instrumentation	Hewlett Packard	5890II dual ECD	3336A53463	1994	good
GC Instrumentation	Hewlett Packard	5890II dual ECD	3336A54409	1994	good
GC Instrumentation	Hewlett Packard	5890II dual ECD	3336A54408	1994	good
GC Instrumentation	Hewlett Packard	5890II FID/FID	3115A34892	1994	good
GC Instrumentation	Hewlett Packard	5890II PID/FID	3336A60622	1994	good
GC Instrumentation	Hewlett Packard	5890II Hall/PID	3235A54089	1994	good
GC Instrumentation	Hewlett Packard	5890II PID/FID	3336A53465	1994	good
GC Instrumentation	Hewlett Packard	5890II dual FID	3336A53727	1994	good
GC Instrumentation	Hewlett Packard	5890II dual ECD	3310A47661	1993	good
GC Instrumentation	Hewlett Packard	5890II dual ECD	3336A53325	1993	good

Rev. 11-2014

Page 1 of 4

TestAmerica
THE LEADER IN ENVIRONMENTAL TESTING

GC Instrumentation	Hewlett Packard	5890II PID/FID	3133A37157	1993	good
GC Instrumentation	Hewlett Packard	5890II dual ECD	3203A42206	1992	good
GC Instrumentation	Hewlett Packard	5890II dual FID	3019A28433	1991	good
GC Instrumentation	Hewlett Packard	5890II Hall/PID	3121A35782	1990	good
Metals Instrumentation	Perkin Elmer	Elan 9000 ICP-MS	P0230202	2002	good
Metals Instrumentation	Leeman	PS200 II	HG9045	2000	good
Metals Instrumentation	Leeman	PS200 II	HG0033	2000	good
Metals Instrumentation	Thermo	ICAP 6000 Duo	ICP-20094603	2010	good
Metals Instrumentation	Thermo	ICAP 6000 Duo	ICP-20094602	2010	good
Water Quality Instrumentation	Metrohm	IC Model 881	4111	2013	good
Water Quality Instrumentation	Konelab	Aqua20	SEA032	2009	good
Water Quality Instrumentation	Flash Point Analyzer	HFP 339	Herzog	2007	good
Water Quality Instrumentation	OI	Carbon Analyzer Model 1030	A54TB0578P	2006	good
Water Quality Instrumentation	OI	Carbon Analyzer Model 1030	E616130020E	2006	good
Water Quality Instrumentation	Thermo	ECA 1200 TOX	2006.0373	2006	good
Water Quality Instrumentation	Horizon	Speed Vap	03-0415	2005	good
Water Quality Instrumentation	Konelab	20XT	E3719731	2005	good
Water Quality Instrumentation	Thermo	ECA 1200 TOX	2004.901	2004	good
Water Quality Instrumentation	Dionex	Ion Chromatograph #DX-120	20126	2004	good
Water Quality Instrumentation	Konelab	20	S5019455	2004	good
Water Quality Instrumentation	Glastron	CN Midi-distillation	2502	2003	good
Water Quality Instrumentation	Glastron	Phenol Midi-distillation	2069	2003	good
Water Quality Instrumentation	Glastron	Phenol Midi-distillation	2053	2003	good
Water Quality Instrumentation	Labtronics	BOD Autoanalyzer	270H3XB531	2004	good
Water Quality Instrumentation	Mantech	BOD Autoanalyzer	MT-184-216	2014	good
Water Quality Instrumentation	ManTech	PC Titrator	MS-OK2-607	2003	good
Water Quality Instrumentation	HACH	Spectrophotometer #DR/2500	30200004886	2003	good
Water Quality Instrumentation	Dionex	Ion Chromatograph #DX-120	2060196	2002	good

TestAmerica
THE LEADER IN ENVIRONMENTAL TESTING

Water Quality Instrumentation	Spectronic	Genesis 4001/4	3SGC199091	2000	good
Water Quality Instrumentation	Lachat	Quickchem 8000 Autoanalyzer	A83000-1527	2000	good
Water Quality Instrumentation	Lachat	Quickchem 8500 Autoanalyzer	40300001665	2014	good
Water Quality Instrumentation	Lachat	Quickchem 8000 Autoanalyzer	A83000-1439	1999	good
Water Quality Instrumentation	Dionex	Ion Chromatograph #DX-120	99010157	1999	good
Water Quality Instrumentation	Dionex	Ion Chromatograph #DX-120	99110569	1999	good
Water Quality Instrumentation	BOD chamber		Revco	1994	good
Sample Preparation Equipment	CEM	Microwave MARS	MD3978	2013	good
Sample Preparation Equipment	Gilson	Fractionator Model GX-274	40579	2013	good
Sample Preparation Equipment	TurboVap	II	TV0529N12427	2006	good
Sample Preparation Equipment	TurboVap	II	TV0529N12428	2006	good
Sample Preparation Equipment	TurboVap	II	TV9445N5816	1996	good
Sample Preparation Equipment	TurboVap	II	TV9427N4133	1996	good
Sample Preparation Equipment	TurboVap	II	TV944N5819	1996	good
Sample Preparation Equipment	TurboVap	II	TV944N5820	1996	good
Sample Preparation Equipment	TurboVap	II	TV0024N9623	2000	good
Sample Preparation Equipment	TurboVap	II	TV0022N9604	2000	good
Sample Preparation Equipment	TurboVap	II	TV0312N11592	2003	good
Sample Preparation Equipment	TurboVap	II	TV0312N11591	2003	good
Sample Preparation Equipment	Organomation	Rot-X-Tractor	16902	1999	good
Sample Preparation Equipment	Organomation	Rot-X-Tractor	16907	1999	good
Sample Preparation Equipment	Organomation	Rot-X-Tractor	16913	1999	good
Sample Preparation Equipment	Heat Systems	Sonicator #XL-2020	G1647/C5659	1994	good
Sample Preparation Equipment	Heat Systems	Sonicator #XL-2020	G2665/C5674	1994	good
Sample Preparation Equipment	Heat Systems	Sonicator #XL-2020	G2620/C5660	1994	good
Sample Preparation Equipment	Heat Systems	Sonicator #XL-2020	G2245/C6328	1995	good

Sample Preparation Equipment	Heat Systems	Sonicator #XL-2020	G2621/C6733	1995	good
Sample Preparation Equipment	Heat Systems	Sonicator #XL-2020	G2713/C6732	1995	good
Sample Preparation Equipment	Heat Systems	Sonicator #XL-2020	G1643/C6837	1995	good
Sample Preparation Equipment	Heat Systems	Sonicator #XL-2020	G2742/C6842	1995	good

Table 20-2.

Schedule of Routine Maintenance

Instrument	Procedure	Frequency
Leeman Mercury Analyzer	Check tubing for wear Fill rinse tank with 10% HCl Change dryer tube Fill reductant bottle with 10% Stannous Chloride	Daily Daily As Needed Daily
ICP & ICP/MS	Check pump tubing Check liquid argon supply Check fluid level in waste container Check re-circulator levels Clean or replace filters Check torch Check sample spray chamber for debris Clean and align nebulizer Change pump oil Change Cones Change printer cartridge Replace pump tubing	Daily Daily Daily Monthly As required Daily Monthly Monthly Monthly As required As required As required
UV-Vis Spectrophotometer	Clean ambient flow cell Precision check/alignment of flow cell Wavelength verification check	As required As required Annually
Auto Analyzers	Clean sampler Check all tubing Clean inside of colorimeter Clean pump well and pump rollers Clean wash fluid receptacle Oil rollers/chains/side rails Clean optics and cells	Daily Daily Daily Quarterly Weekly Weekly Quarterly

Instrument	Procedure	Frequency
Agilent GC/MS	Pump oil-level check Pump oil changing Analyzer bake-out Analyzer cleaning Resolution adjustment COMPUTER SYSTEM AND PRINTER: Air filter cleaning Change data system air filter Printer head carriage lubrication Paper sprocket cleaning Drive belt lubrication	Monthly Annually As required As required As required As required As required As required As required As required
Gas Chromatograph	Compare standard response to previous day or since last initial calibration Check carrier gas flow rate in column Check temp. of detector, inlet, column oven Septum replacement Glass wool replacement Check system for gas leaks with SNOOP Check for loose/frayed power wires and insulation Bake injector/column Change/remove sections of guard column Replace connectors/liners Change/replace column(s)	Daily Daily via use of known compound retention Daily As required As required W/cylinder change as required As Required As Required As Required As Required As Required
Electron Capture Detector (ECD)	Detector wipe test (Ni-63) Detector cleaning	Semi-annually As required
Flame Ionization Detector (FID)	Detector cleaning	As required
Photoionization Detector (PID)	Change O-rings Clean lamp window	As required As required
HPLC	Change guard columns Change lamps Change pump seals Replace tubing Change fuses in power supply Filter all samples and solvents Change autosampler rotor/stator	As required As required Semi-annually or as required As required As required Daily As required

Instrument	Procedure	Frequency
Vacuum Pumps/ Air Compressor	Drained Belts checked Lubricated	Weekly Monthly Semi-annually
Centrifuge	Check brushes and bearings	Every 6 months or as needed

Table 20-3.

Periodic Calibration

Instrument	Type of Calibration/ Number of Standards	Frequency	Acceptance Limits	Corrective Action
Analytical Balance	Accuracy determined using "S" NIST traceable weights. Minimum of 2 standards bracketing the weight of interest. Inspected and calibrated by A2LA accredited person annually.	Daily, when used Annual	± 0.2%	Clean, check level, insure lack of drafts, and that unit is warmed up, recheck. If fails, call service.
Top Loading Balance	Accuracy determined using "S" NIST traceable. Minimum of 2 standards bracketing the weight of interest. Inspected and calibrated by A2LA accredited person annually.	Daily, when used Annual	± 0.5%	Clean. Replace.
NIST Certified Weights	Accuracy determined by accredited weights and measurement laboratory.	1 year	As per certificate.	Replace.
NIST-Traceable Thermometer-Mercury	Accuracy determined by accredited measurement laboratory.	3 years	As per certificate.	Replace.
NIST-Traceable Thermometer-Digital	Accuracy determined by accredited measurement laboratory.	1 year	As per certificate	Replace.
Thermometer	Against NIST-traceable thermometer	Yearly at appropriate temperature range for intended use	± 1.2°C	Replace
Minimum-Maximum Thermometers	Against NIST-traceable thermometer	Yearly	± 1.5°C	Replace

Instrument	Type of Calibration/ Number of Standards	Frequency	Acceptance Limits	Corrective Action
InfraRed Temperature Guns	Against NIST-traceable thermometer Accuracy determined by accredited measurement laboratory.	Daily at appropriate temperature range for intended use. Annual	± 1.5°C	Repair/replace
Dial-type Thermometers	Against NIST-traceable thermometer	Quarterly at appropriate temperature range for intended use.	± 1.5°C	Replace
Refrigerator	Temperature checked using NIST-traceable thermometer.	Daily. If out of range, check again in two hours.	0-6°C	Adjust. Repair. While waiting for repair, seal door, attach "Out of Service" sign, move items to functional unit. Notify supervisor.
Freezer	Temperature checked using NIST-traceable thermometer	Daily. If out of range, check again in two hours.	(-10)-(-20)°C	Adjust. Repair. While waiting for repair, seal door, attach "Out of Service" sign, move items to functional unit. Notify supervisor.
Oven	Temperature checked using NIST-traceable thermometer.	When in use.	104 ± 1°C (drying) 180 ± 2°C (TDS)	Adjust. Replace.
Water Bath	Temperature checked using NIST-traceable thermometer.	When in use.	± 2°C	Adjust. Replace.
Volumetric Dispensing Devices (Eppendorf ® pipette, automatic dilutor or dispensing devices)	One delivery by weight. Using DI water or solvent of use, dispense into tared vessel. Record weight with device ID number. Calibrate using 4 replicate gravimetric measurements	Each day of use Quarterly	± 2% Calculate accuracy by dividing weight by stated volume times 100 for percent.	Adjust. Replace.

Instrument	Type of Calibration/ Number of Standards	Frequency	Acceptance Limits	Corrective Action
Glass Microliter Syringes	None	Accuracy must be initially demonstrated if syringe was not received with a certificate attesting to established accuracy.	± 1%	Not applicable.
Deionized Water	Check in-line conductivity meter on system with conductivity meter in Inorganics Department.	Daily	<1.0 µmho at 25°C	Record on log. Report discrepancies to QA Manager, Operations Manager or Technical Manager.

SECTION 21

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 are performed for all mechanical volumetric devices. For certain programs Microsyringes are verified semi-annually or disposed of after 6 months of use. 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.

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 certificate and scope of accreditation is kept on file at the laboratory.

The calibration report or certificate submitted to ***TestAmerica Buffalo*** contains, in a well designed format, a traceability statement, the conditions under which the calibrations were made in the context of any potential influence, a compliance statement with an identified metrological specification and the pertinent clauses, a clearly identified record of the quantities and functional test results before and after re-calibration, and no recommendation on the calibration interval. Opinions and interpretations of results are presented along with the basis upon which they were made and identified as such. The report may be submitted by facsimile or other electronic means as long as the requirements of the International Standard are achieved. If significant amendments are made to a calibration certificate, a supplemental certificate for the serial-number-specified piece of equipment is so identified. When a new certificate is offered, it uniquely identifies and references the one it replaces. All calibration reports are filed in the QA Office.

An external certified service engineer services laboratory balances on an annual basis. This service is documented on each balance with a signed and dated certification sticker. Balance calibrations are checked each day of use. All mercury thermometers are calibrated annually against a traceable reference thermometer. Temperature readings of ovens, refrigerators, and incubators are checked on each day of use.

21.3 REFERENCE STANDARDS / MATERIALS

Reference standards/materials, where commercially available, are traceable to certified reference materials. Commercially prepared standard materials are purchased from vendors accredited by ISO Guide 34 and ISO/IEC Guide 17025. 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 Standard Identification Number and expiration date. All documentation received with the reference standard is retained as a QC record and references the Standard Identification Number.

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 Corporate Environmental Health & Safety Manual or laboratory SOPs. Method specific information may also be found in the laboratory method SOPs in the "Standards and Reagents" sections. For safety requirements, please refer to method SOPs and the laboratory 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. The lots for most of the common solvents and acids are tested for acceptability prior to company wide purchase. Refer to SOP No. CA-Q-S-001, Solvent and Acid Lot Testing and Approval.

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 by each department in bound or electronic folders. 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 laboratory SOP BF-GP-019, “Standard Traceability and Preparation” and also to the method specific 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. Standards are logged into the laboratory department’s chemical history log and are assigned a unique identification number. Preparation of working standards or reagents prepared from the stock is documented in the laboratory Department’s Standard Preparation Log. The following information is typically recorded:

- Standard ID
- Description of Standard
- Department
- Preparer’s name
- Final volume and number of vials prepared
- Solvent type and lot number
- Preparation Date

- Expiration Date
- Standard source type (stock or daughter)
- Standard type (spike, surrogate, other)
- Parent standard ID (if applicable)
- Parent Standard Analyte Concentration (if applicable)
- Parent Standard Amount used (if applicable)
- Component Analytes
- Final concentration of each analyte
- Comment section

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:

- Expiration Date
- Standard ID from LIMS.
- 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 in the LIMS system.

21.4.3 In addition, the following information may be helpful:

- Date of receipt for commercially purchased items or date of preparation for laboratory prepared items
- 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 SOPs.

SECTION 22.0

SAMPLING

22.1 OVERVIEW

The laboratory provides sampling services. Sampling procedures are described in the following SOPs:

BF-FS-001	Chain of Custody Documentation
BF-FS-003	Groundwater Sampling Field Data Collection
BF-FS-004	Equipment Decontamination
BF-FS-005	Groundwater/Surface Water Sampling
BF-FS-006	Calibration of Field Meter
BF-FS-007	Low Flow Sampling Procedures
BF-FS-008	Surface and Subsurface Soil/Sediment Sampling

22.2 SAMPLING CONTAINERS

The laboratory offers clean sampling containers for use by clients. These containers are obtained from reputable container manufacturers and meet EPA specifications as required. 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 online.

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:

- Hydrochloric Acid – Reagent ACS (Certified VOA Free) or equivalent
- Methanol – Purge and Trap grade
- Nitric Acid – Instra-Analyzed or equivalent
- Sodium Bisulfate – ACS Grade or equivalent
- Sodium Hydroxide – Instra-Analyzed or equivalent
- Sulfuric Acid – Instra-Analyzed or equivalent
- Sodium Thiosulfate – ACS Grade or equivalent

22.3 DEFINITION OF HOLDING TIME

The date and time of sampling documented on the chain-of-custody (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. These programs will be addressed on a case-by-case basis.

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, this info is in the SOP or preservation requirements are not met, the reports will be qualified using a flag, footnote or case narrative. 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, gloves, and lab coats must be worn when preparing aliquots for analysis.

The following information provides general guidance for homogenization and subsampling. For laboratory specific procedures refer to SOP BF-GP-005, "Sample Homogenization and Subsampling".

SECTION 23

HANDLING OF SAMPLES

Sample management procedures at the laboratory ensure that sample integrity and custody are maintained and documented from sampling/receipt through disposal.

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

The information the sampler needs to provide at the time of sampling on the container label is:

- Sample identification
- Date and time
- Preservative

During the sampling process, the COC form is completed and must be legible (see Figure 23-1). This form includes information such as:

- Client name, address, phone number and fax number (if available)
- Project name and/or number
- The sample identification
- Date, time and location of sampling
- Sample collectors name
- The matrix description
- The container description
- The total number of each type of container
- Preservatives used
- Analysis requested
- Requested turnaround time (TAT)
- Any special instructions
- Purchase Order number or billing information (e.g. quote number) if available
- The date and time that each person received or relinquished the sample(s), including their signed name.

When the sampling personnel deliver the samples directly to TestAmerica 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. 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 TestAmerica 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 lab 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 shipping documents are retained with the project files.

23.1.2 Legal / Evidentiary Chain-of-Custody

If samples are identified for legal/evidentiary purposes on the COC or in the project notes, sample management will initiate Strict Chain of Custody procedures as defined in SOP BF-GP-018, "Strict 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 summarized in the following sections.

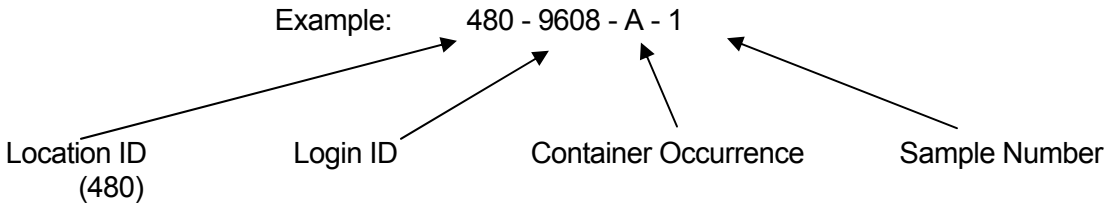
23.2.1 Laboratory Receipt

When samples arrive at the laboratory, sample receiving personnel inspect the coolers and samples. The integrity of each sample must be determined by comparing sample labels or tags with the COC and by visual checks of the container for possible damage. Any non-conformance, irregularity, or compromised sample receipt must be documented on the Sample Login Form – and brought to the immediate attention of the client. The COC, shipping documents, documentation of any non-conformance, irregularity, or compromised sample receipt, record of client contact, and resulting instructions become part of the project record.

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 anytime. This system includes identification for all samples, subsamples and subsequent extracts and/or digestates.

The laboratory assigns a unique identification (e.g., Sample ID) code to each sample container received at the laboratory. This Primary ID is made up of the following information (consisting of 4 components):



The above example states that TestAmerica Buffalo Laboratory (Location 480). Login ID is 9608 (unique to a particular client/job occurrence). The container code indicates it is the first container ("A") of Sample #1.

If the primary container goes through a prep step that creates a "new" container, then the new container is considered secondary and gets another ID. An example of this being a client sample in a 1-Liter amber bottle is sent through a Liquid/Liquid Extraction and an extraction vial is created from this step. The vial would be a SECONDARY container. The secondary ID has 5 components.

Example: XXX - 9608 - A - 1 - **A** ← **Secondary Container Occurrence**

Example: 220-9608-A-1-A, would indicate the PRIMARY container listed above that went through a step that created the 1st occurrence of a Secondary container.

With this system, a client sample can literally be tracked throughout the laboratory in every step from receipt to disposal.

23.3 SAMPLE ACCEPTANCE POLICY

The laboratory has a written sample acceptance policy (Figure 23-2) that clearly outlines the circumstances under which samples shall be accepted or rejected. These include:

- a COC filled out completely;
- samples must be properly labeled;
- 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);

- sample holding times must be adhered to (Sampling Guide);
- every sample cooler is given a radiation screen with a standardized Radiation Monitor (Monitor 4 model). This screen has no analytical repercussions; it is just a gross screen for employee safety purposes. Contact TestAmerica Buffalo's Technical Manager, Environmental Health and Safety Coordinator or Sample Control Manager immediately if screening indicates radioactivity in excess of 0.02 mR/hr.;
- 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.

23.3.2 Any deviations from these checks described in Section 23.1.1.1 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 according SOP No. BF-SR-002.

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. Aqueous samples designated for metals analysis are stored at ambient temperature. In addition, samples to be analyzed for volatile organic parameters are stored in separate refrigerators designated for volatile organic parameters only. Samples are never to be stored with reagents, standards or materials that may create contamination.

To ensure the integrity of the samples during storage, refrigerator blanks are maintained in the volatile sample refrigerators and analyzed at a minimum of every two weeks.

Analysts and technicians provide a request form to the cooler custodian who then retrieves the requested samples. In the absence of the cooler custodian, the analysts may personally retrieve the sample containers allocated to their analysis from the designated refrigerator. The samples are placed on carts, transported the analytical area and analyzed. Following analysis

the remaining sample is returned to the refrigerator from which it originally came. All unused portions of samples are returned to the secure sample control area. All samples are kept in the refrigerators for two to four weeks after analysis, which meets or exceeds most sample holding times. After two to four weeks the samples are moved to dry room temperature, sample archive area where they are retained a minimum of 2 weeks after the final report has been issued to the client at which time disposal occurs. Special arrangements may be made to store samples for longer periods of time. Extended archival periods allow additional metal analyses to be performed on the archived sample and assists clients in dealing with legal matters or regulatory issues.

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 TestAmerica.

23.5 HAZARDOUS SAMPLES AND FOREIGN SOILS

To minimize exposure to personnel and to avoid potential accidents, samples which are known or suspected to be hazardous are segregated and a notification is issued to all laboratory personnel.
All hazardous samples are either returned to the client or disposed of appropriately through a hazardous waste disposal firm. All soil samples, including foreign soil samples are heat treated or incinerated in accordance with USDA permit requirements and are transported / disposed by USEPA approved facilities.

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.

23.6 SAMPLE SHIPPING

In the event that the laboratory needs to ship samples, the samples are placed in a cooler with enough ice to ensure the samples remain just above freezing and at or below 6.0°C during transit. The samples are carefully surrounded by packing material to avoid breakage (yet maintain appropriate temperature). For sample shipments which include water/solid volatile organic analyses (see Note), a trip blank is enclosed when required by method specifications or state or regulatory programs. The chain-of-custody form is signed by the sample control technician and attached to the shipping paperwork. Samples are generally shipped overnight express or hand-delivered by a 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. The Environmental, Health and Safety Manual contains additional shipping requirements.

Note: If a client does not request trip blank analysis on the COC or other paperwork, the laboratory will analyze the trip blanks that were supplied.

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: BF-WM-001, "Waste Management".) All procedures in the laboratory Environmental, Health and Safety Manual are followed during disposal. Samples are normally maintained in the laboratory no longer than six weeks 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.

If a sample is part of a known litigation, the affected legal authority, sample data user, and/or submitter of the sample may request to participate in the decision about the sample's disposal. All documentation and correspondence concerning the disposal decision process must be kept on file. Pertinent information includes the date of disposal and nature of disposal (such as sample depletion, hazardous waste facility disposal, and return to client). All disposal of sample containers is accomplished through incineration. A Waste Disposal Record should be completed.

Figure 23-1.

Example: Chain of Custody (COC)

[redacted]

Chain of Custody Record

Temperature on Receipt _____

Drinking Water? Yes☐ No☐

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TAL-4124 (1007)

Client	Project Manager	Date	Chain of Custody Number 193232
Address	Telephone Number (Area Code)/Fax Number	Lab Number	Page _____ of _____
City / State / Zip Code	Site Contact / Lab Contact	Analysis (Attach list if more space is needed)	Special Instructions/ Conditions of Receipt
Project Name and Location (State)	Carrier/Waybill Number		
Contract/Purchase Order/Quote No.	Matrix / Containers & Preservatives		

Sample I.D. No. and Description (Containers for each sample may be combined on one line)	Date	Time	Air	Aqueous	Sed.	Soil	Unpres.	H2SO4	HNO3	HCl	NaOH	ZnAc/ NaOH

Possible Hazard Identification
☐ Non-Hazard ☐ Flammable ☐ Skin Irritant ☐ Poison B ☐ Unknown

Sample Disposal
☐ Return To Client ☐ Disposal By Lab ☐ Archive For _____ Months
(A fee may be assessed if samples are retained longer than 1 month)

Turn Around Time Required
☐ 24 Hours ☐ 48 Hours ☐ 7 Days ☐ 14 Days ☐ 21 Days ☐ Other _____

QC Requirements (Specify)

1. Relinquished By	Date	Time	1. Received By	Date	Time
2. Relinquished By	Date	Time	2. Received By	Date	Time
3. Relinquished By	Date	Time	3. Received By	Date	Time

Comments

DISTRIBUTION: WHITE - Returned to Client with Report; CANARY - Stays with the Sample; PINK - Field Copy

Figure 23-2.

Example: Sample Acceptance Policy

All incoming work will be evaluated against the criteria listed below. 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 either by telephone, fax or e-mail ASAP after the receipt of the samples.

1) Samples must arrive with labels intact with a Chain of Custody filled out completely. The following information must be recorded.
   - *Client name, address, phone number and fax number (if available)*
   - *Project name and/or number*
   - *The sample identification*
   - *Date, time and location of sampling*
   - *The collectors name*
   - *The matrix description*
   - *The container description*
   - *The total number of each type of container*
   - *Preservatives used*
   - *Analysis requested*
   - *Requested turnaround time (TAT)*
   - *Any special instructions*
   - *Purchase Order number or billing information (e.g. quote number) if available*
   - *The date and time that each person received or relinquished the sample(s), including their signed name.*
   - ***The date and time of receipt must be recorded between the last person to relinquish the samples and the person who receives the samples in the lab, and they must be exactly the same.***
   - **Information must be legible**

2) Every sample cooler is given a radiation screen with a standardized Radiation Monitor (Monitor 4 model). This screen has no analytical repercussions; it is just a gross screen for employee safety purposes. Contact TestAmerica Buffalo's Technical Manager, Environmental Health and Safety Coordinator or Sample Control Manager immediately if screening indicates radioactivity in excess of 0.02 mR/hr.

3) 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 TestAmerica 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).

4) Samples must be properly labeled.
   - Use durable labels (labels provided by TestAmerica are preferred)
   - Include a unique identification number
   - Include sampling date and time & sampler ID
   - Include preservative used.
   - Use indelible ink
   - **Information must be legible**

5) Proper sample containers with adequate volume for the analysis and necessary QC are required for each analysis requested.

6) Samples must be preserved according to the requirements of the requested analytical method. See lab Sampling Guide.
   Note: Samples that are hand delivered to the laboratory immediately after collection may not have had time to cool sufficiently. In this case the samples will be considered acceptable as long as there is evidence that the chilling process has begun (arrival on ice).

   - Chemical preservation (pH) will be verified prior to analysis and documented, either in sample control or at the analyst's level. The project manager will be notified immediately if there is a discrepancy. If analyses will still be performed, all affected results will be flagged to indicate improper preservation.

   - For Volatile Organic analyses in drinking water (Method 524.2). Residual chlorine must be neutralized prior to preservation. If there is prior knowledge that the samples are not chlorinated, state it on the COC and use the VOA vials pre-preserved with HCl. The following are other options for a sampler and laboratory where the presence of chlorine is not known:
     - 1. Test for residual chlorine in the field prior to sampling.
       - If no chlorine is present, the samples are to be preserved using HCl as usual.
       - If chlorine is present, add either ascorbic acid or sodium thiosulfate prior to adding HCl.
     - 2. Use VOA vials pre-preserved with sodium thiosulfate or ascorbic acid and add HCl after filling the VOA vial with the sample.
   - **FOR WATER SAMPLES TESTED FOR CYANIDE – for NPDES samples by Standard Methods or EPA 335**
     - In the Field: Samples are to be tested for Sulfide using lead acetate paper prior to the addition of Sodium Hydroxide (NaOH). If sulfide is present, the sample must be treated with Cadmium Chloride and filtered prior to the addition of NaOH.

       - If the sulfide test and treatment is not performed in the field, the lab will test the samples for sulfide using lead acetate paper at the time of receipt and if sulfide is present in the sample, the client will be notified and given the option of retaking the sample and treating in the field per the method requirements

or the laboratory can analyze the samples as delivered and qualify the results in the final report.

- It is the responsibility of the client to notify the laboratory if thiosulfate, sulfite, or thiocyanate are known or suspected to be present in the sample. This notification may be on the chain of custody. The samples may need to be subcontracted to a laboratory that performs a UV digestion. If the lab does not perform the UV digestion on samples that contain these compounds, the results must be qualified in the final report.

- The laboratory must test the sample for oxidizing agents (e.g. Chlorine) prior to analysis and treat according to the methods prior to distillation. (ascorbic acid or sodium arsenite are the preferred choice).

7) Sample Holding Times

- TestAmerica 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 to ensure analysis.

- Analyses that are designated as “field” analyses (Odor, pH, Dissolved Oxygen, Disinfectant Residual; a.k.a. Residual Chlorine, and Redox Potential) should be analyzed ASAP by the field sampler prior to delivering to the lab (within 15 minutes). However, if the analyses are to be performed in the laboratory, TestAmerica will make every effort to analyze the samples within 24 hours from receipt of the samples in the testing laboratory. Samples for “field” analyses received after 4:00 pm on Friday or on the weekend will be analyzed no later than the next business day after receipt (Monday unless a holiday). Samples will remain refrigerated and sealed until the time of analysis.

8) All samples submitted for Volatile Organic analyses must have a Trip Blank submitted at the same time. TestAmerica will supply this blank with the bottle order.

9) The project manager will be notified if any sample is received in damaged condition. TestAmerica will request that a sample be resubmitted for analysis.

10) Recommendations for packing samples for shipment.

- Pack samples in Ice rather than “Blue” ice packs.

- Soil samples should be placed in plastic zip-lock bags. The containers often have dirt around the top and do not seal very well and are prone to intrusion from the water from melted ice.

- Water samples would be best if wrapped with bubble-wrap or paper (newspaper, or paper towels work) and then placed in plastic zip-lock bags.

- Fill extra cooler space with bubble wrap.

Figure 23-3.
Example: Cooler Receipt Form

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6/10/2013

SAMPLE LOGIN

Project_____Event _____

Analysis Groups_____

TAT ____ # SAMPLES: _____ TRIP BLANK? Y/N ___ #/date _____

Custody Seal Intact Y/N NONE Rad Check <0.02 mR/hr Y/N

Residual Chlorine Check Y/N/ NA Pres Checked Y/N/NA

Workshare/Subcontract Y/N Lab_____ _____ SO/ICOC #_____

Received out of hold: Samples _____Analysis_____

Checklist/NCM's_____

Temperature(s) #of coolers_____ IR Gun 1 2 3

RUSH **TIME CRITICAL**

Section 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), surrogates, Internal Standards (IS)). 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 include homogenization, grinding, solvent extraction, sonication, acid digestion, distillation, reflux, evaporation, drying and ashing. During these pre-treatment steps, samples are arranged into discreet manageable groups referred to as preparation (prep) batches. 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.

24.3 NEGATIVE CONTROLS

Table 24-1.

Control Type	Details
Method Blank (MB)	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 for each batch of samples; not to exceed 20 environmental samples.
	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.
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.

Table 24-1.

Control Type	Details
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.
Trip Blank [1]	Are required to be submitted by the client with each shipment of samples requiring aqueous and solid volatiles analyses (or as specified in the client's project plan) Additionally, trip blanks may be prepared and analyzed for volatile analysis of air samples, when required by the client. A trip blank may be purchased (certified clean) or is prepared by the laboratory by filling a clean container with pure deionized water that has been purged to remove any volatile compounds. Appropriate preservatives are also added to the container. The trip blank is sent with the bottle order and is intended to reflect the environment that the containers are subjected to throughout shipping and handling and help identify possible sources if contamination is found. The field sampler returns the trip blank in the cooler with the field samples.
Field Blanks [1]	Are sometimes used for specific projects by the field samplers. A field blank prepared in the field by filling a clean container with pure reagent water and appropriate preservative, if any, for the specific sampling activity being undertaken. (EPA OSWER)
Equipment Blanks [1]	Are also sometimes created in the field for specific projects. An equipment blank is a sample of analyte-free media which has been used to rinse common sampling equipment to check effectiveness of decontamination procedures. (NELAC)
Holding Blanks	also referred to as refrigerator or freezer blanks, are used to monitor the sample storage units for volatile organic compounds during the storage of VOA samples in the laboratory

[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.

24.4 POSITIVE CONTROLS

Control samples (e.g., QC indicators) are analyzed with each batch of samples to evaluate data based upon (1) Method Performance (Laboratory Control Sample (LCS) or Blank Spike (BS)), which entails both the preparation and measurement steps; and (2) Matrix Effects (Matrix Spike (MS) (Matrix spikes are not applicable to air) or Sample Duplicate (MD, DUP), which evaluates field sampling accuracy, precision, representativeness, interferences, and the effect of the matrix on the method performed. 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.

24.4.1 Method Performance Control - Laboratory Control Sample (LCS)

24.4.1.1 The LCS measures the accuracy of the method in a blank matrix and assesses method performance independent of potential field sample matrix affects in a laboratory batch.

24.4.1.2 The LCS is prepared from a clean matrix similar to that of the associated samples that is free from target analytes (for example: Reagent water, Ottawa sand, glass beads, etc.) and is processed along with and under the same conditions as the associated samples. The LCS is spiked with verified known amounts of analytes or is made of a material containing known and verified amounts of analytes, taken through all preparation and analysis steps along with the field samples. Where there is no preparation taken for an analysis (such as in aqueous volatiles), or when all samples and standards undergo the same preparation and analysis process (such as Phosphorus), a calibration verification standard may be reported as the LCS. In some instances where there is no practical clean solid matrix available, aqueous LCS's may be processed for solid matrices; final results may be calculated as mg/kg or ug/kg, assuming 100% solids and a weight equivalent to the aliquot used for the corresponding field samples, to facilitate comparison with the field samples.

24.4.1.3 Certified pre-made reference material purchased from a NIST/A2LA accredited vendor may also be used for the LCS when the material represents the sample matrix or the analyte is not easily spiked (e.g. solid matrix LCS for metals, TDS, etc.).

24.4.1.4 The specific frequency of use for LCS during the analytical sequence is defined in the specific standard operating procedure for each analysis. It is generally 1 for each batch of samples; not to exceed 20 environmental samples.

24.4.1.5 If the mandated or requested test method, or project requirements, do not specify the spiking components, the laboratory shall spike all reportable components to be reported in the Laboratory Control Sample (and Matrix Spike) where applicable (e.g. no spike of pH). In order to meet this requirement, TestAmerica Buffalo spikes with the Corporate Standard Standards primary mix for each analysis. However, in cases where the components interfere with accurate assessment (such as simultaneously spiking chlordane, toxaphene and PCBs in Method 608), the test method has an extremely long list of components or components are incompatible, at a minimum, a representative number of the listed components (see below) shall be used to control the test method. The selected components of each spiking mix shall represent all chemistries, elution patterns and masses, permit specified analytes and other client requested components. However, the laboratory shall ensure that all reported components are used in the spike mixture within a two-year time period.

24.4.1.5.1 For methods that have 1-10 target analytes, spike all components.

24.4.1.5.2 For methods that include 11-20 target analytes, spike at least 10 or 80%, whichever is greater.

24.4.1.5.3 For methods with more than 20 target analytes, spike at least 16 components.

24.4.1.5.4 Exception: Due to analyte incompatibility in pesticides, Toxaphene and Chlordane are only spiked at client request based on specific project needs.

24.4.1.5.5 Exception: Due to analyte incompatibility between the various PCB aroclors, aroclors 1016 and 1260 are used for spiking as they cover the range of all of the aroclors. Specific aroclors may be used by request on a project specific basis.

24.5 SAMPLE MATRIX CONTROLS

Table 24-5. Sample Matrix Control

Control Type	Details	
Matrix Spikes (MS)	Use	Used to assess the effect sample matrix of the spiked sample has on the precision and accuracy of the results generated by the method used;
	Typical Frequency [1]	At a minimum, with each matrix-specific batch of samples processed, an MS is carried through the complete analytical procedure. Unless specified by the client, samples used for spiking are randomly selected and rotated between different client projects. If the mandated or requested test method does not specify the spiking components, the laboratory shall spike all reportable components to be reported in the Laboratory Control Sample and Matrix Spike. Refer to the method SOP for complete details
	Description	Essentially a sample fortified with a known amount of the test analyte(s).
Surrogate	Use	Measures method performance to sample matrix (organics only).
	Typical Frequency [1]	Are added to all samples, standards, and blanks, for all organic chromatography methods except when the matrix precludes its use or when a surrogate is not available. The recovery of the surrogates is compared to the acceptance limits for the specific method. Poor surrogate recovery may indicate a problem with sample composition and shall be reported, with data qualifiers, to the client whose sample produced poor recovery.
	Description	Are similar to matrix spikes except the analytes are compounds with properties that mimic the analyte of interest and are unlikely to be found in environment samples.
Duplicates[2]	Use	For a measure of analytical precision, with each matrix-specific batch of samples processed, a matrix duplicate (MD or DUP) sample, matrix spike duplicate (MSD), or LCS duplicate (LCSD) is carried through the complete analytical procedure.
	Typical Frequency [1]	Duplicate samples are usually analyzed with methods that do not require matrix spike analysis.
	Description	Performed by analyzing two aliquots of the same field sample independently or an additional LCS.
Internal Standards	Use	Are spiked into all environmental and quality control samples (including the initial calibration standards) to monitor the qualitative aspect of organic and some inorganic analytical measurements.
	Typical Frequency [1]	All organic and ICP methods as required by the analytical method.
	Description	Used to correct for matrix effects and to help troubleshoot variability in analytical response and are assessed after data acquisition. Possible sources of poor internal standard response are sample matrix, poor analytical technique or instrument performance.

[1] See the specific analytical SOP for type and frequency of sample matrix control samples.

[2] LCSD's are normally not performed except when regulatory agencies or client specifications require them. The recoveries for the spiked duplicate samples must meet the same laboratory established recovery limits as the accuracy QC samples. If an LCSD is analyzed both the LCS and LCSD must meet the same recovery criteria and be included in the final report. The precision measurement is reported as "Relative Percent Difference" (RPD). Poor precision between duplicates (except LCS/LCSD) may indicate non-homogeneous matrix or sampling.

24.6 ACCEPTANCE CRITERIA (CONTROL LIMITS)

24.6.1 As mandated by the test method and regulation, each individual analyte in the LCS, MS, or Surrogate Spike 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.

24.6.2 Once control limits have been established, they are verified, reviewed, and updated if necessary on an annual 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.

24.6.3 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).

24.6.3.1 Regardless of the calculated limit, the limit should be no tighter than the Calibration Verification (ICV/CCV). (Unless the analytical method specifies a tighter limit).

24.6.3.2 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.

24.6.3.3 The lowest acceptable recovery limit will be 10% (the analyte must be detectable). Exception: The lowest acceptable recovery limit for Benzidine will be 5% and the analyte must be detectable.

24.6.3.4 The maximum acceptable recovery limit will be 150%.

24.6.3.5 The maximum acceptable RPD limit will be 35% for waters and 40% for soils. The minimum RPD limit is 10%.

24.6.3.6 If either the high or low end of the control limit changes by $\leq$ 5% from previous, the data points are inspected and, using professional judgment, the limits may be left unchanged if there is no affect on laboratory ability to meet the existing limits.

24.6.4 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. This process is outline in BF-QA-002.

24.6.4.1 The control limits are maintained in the laboratory LIMs system. The limits for each analyte/method/matrix combination are assigned effective and expiration dates. The QA department is able to query the LIMs system and print an active list of control limits based on this database. The most current laboratory limits (based on the effective/expiration dates) are reflected on the laboratory worksheets and final reports unless superseded by project specific limits.

24.6.5 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 13) is also initiated if an LCS exceeds the acceptance limits. Sample results may be qualified and reported without reanalysis if:

24.6.5.1 The analyte results are below the reporting limit and the LCS is above the upper control limit.

24.6.5.2 If the analytical results are above the relevant regulatory limit and the LCS is below the lower control limit.

24.6.6 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.

24.6.7 If a surrogate standard falls outside the acceptance limits, if there is not obvious chromatographic matrix interference, reanalyze the sample to confirm a possible matrix effect. If the recoveries confirm or there was obvious chromatographic interference, results are reported from the original analysis and a qualifier is added. If the reanalysis meets surrogate recovery criteria, the second run is reported (or both are reported if requested by the client). Under certain circumstances, where all of the samples are from the same location and share similar chromatography, the reanalysis may be performed on a single sample rather than all of the samples and if the surrogate meets the recovery criteria in the reanalysis, all of the affected samples would require reanalysis.

24.7 ADDITIONAL PROCEDURES TO ASSURE QUALITY CONTROL

24.7.1 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.

24.7.2 A discussion regarding MDLs, Limit of Detection (LOD) and Limit of Quantitation (LOQ) can be found in Section 19.

24.7.3 Use of formulae to reduce data is discussed in the method SOPs and in Section 20.

24.7.4 Selection of appropriate reagents and standards is included in Section 9 and 22.

24.7.5 A discussion on selectivity of the test is included in Section 5.

24.7.6 Constant and consistent test conditions are discussed in Section 19.

24.7.7 The laboratories sample acceptance policy is included in Section 23.

SECTION 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. A variety of report formats are available to meet specific needs. 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 7.

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. The report is printed on laboratory letterhead, reviewed, and signed by the appropriate project manager. At a minimum, the standard laboratory report shall contain the following information:

25.2.1 A report title (e.g. Analytical Report) with a "sample results" column header.

25.2.2 Each report cover page is printed on company letterhead which includes the laboratory name, address and telephone number.

25.2.3 A unique identification of the report (e.g. job number) 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 # / ##. 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 Client project manager or other contact

25.2.7 Description and unambiguous identification of the tested sample(s) including the client identification code.

25.2.8 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.

25.2.9 Date reported or date of revision, if applicable.

25.2.10 Method of analysis including method code (EPA, Standard Methods, etc).

25.2.11 Practical quantitation limits or client reporting limit.

25.2.12 Method detection limits (if requested)

25.2.13 Definition of Data qualifiers and reporting acronyms (e.g. ND).

25.2.14 Sample results.

25.2.15 QC data consisting of method blank, surrogate, LCS, and MS/MSD recoveries and control limits (if requested).

25.2.16 Condition of samples at receipt including temperature. This may be accomplished in a narrative or by attaching sample login sheets (Refer to Sec. 25.2.4 – Item 3 regarding additional addenda). Sample temperatures are recorded in the report case narrative and on the COC. Deviations from normal conditions (e.g., preservation, breakage) are recorded in the report case narrative.

25.2.17 A statement expressing the validity of the results, that the source methodology was followed and all results were reviewed for error.

25.2.18 A statement to the effect that the results relate only to the items tested and the sample as received by the laboratory.

25.2.19 A statement that the report shall not be reproduced except in full, without prior express written approval by the laboratory coordinator.

25.2.20 A signature and title of the person(s) accepting responsibility for the content of the report and date of issue. Signatories are appointed by the Lab Director.

25.2.21 When NELAC accreditation is required, the lab shall certify that the test results meet all requirements of NELAC or provide reasons and/or justification if they do not.

25.2.22 The laboratory includes a cover letter.

25.2.23 Where applicable, a narrative to the report that explains the issue(s) and corrective action(s) taken in the event that a specific accreditation or certification requirement was not met.

25.2.24 When Soil samples are analyzed, a specific identification as to whether soils are reported on a "wet weight" or "dry weight" basis.

25.2.25 Appropriate laboratory certification number for the state of origin of the sample if applicable.

25.2.26 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, partial report). A complete report must be sent once all of the work has been completed.

25.2.27 Any non-TestAmerica subcontracted analysis results are provided as an addendum to the report on the official letterhead of the subcontractor. All TestAmerica subcontracting is clearly identified on the report as to which laboratory performed a specific analysis.

25.2.28 Certification Summary report, where required, will document that unless otherwise noted, all analytes tested and reported by the laboratory were covered by the noted certifications.

25.3 REPORTING LEVEL OR REPORT TYPE

TestAmerica Buffalo offers four levels of quality control reporting. Each level, in addition to its own specific requirements, contains all the information provided in the preceding level. The packages provide the following information in addition to the information described above:

- Level I is a report with the features described in Section 25.2 above.
- Level II is a Level I report plus summary information, including results for the method blank, percent recovery for laboratory control samples and matrix spike samples, and the RPD values for all MSD and sample duplicate analyses.
- Level III contains all the information supplied in Level II, but presented on CLP-like summary forms, and relevant calibration information. A Level II report is not included, unless specifically requested. No raw data is provided.
- Level IV is the same as Level III with the addition of all raw supporting data.

In addition to the various levels of QC packaging, the laboratory also provides reports in diskette deliverable form. Initial reports may be provided to clients by facsimile. All faxed reports are followed by hardcopy. Procedures used to ensure client confidentiality are outlined in Section 26.7.

25.3.1 Electronic Data Deliverables (EDDs)

EDDs are routinely offered as part of TestAmerica'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 . TestAmerica Buffalo offers a variety of EDD formats including Environmental Restoration Information Management System (ERPIMS), Excel, Dbase, GISKEY, and Text 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.

25.4 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 narrative explaining the discrepancy in the front of the report

25.4.1 Numeric results with values outside of the calibration range, either high or low are qualified as 'estimated'.

25.4.2 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.

25.4.3 Where applicable, a statement on the estimated uncertainty of measurements; information on uncertainty is needed when a client's instructions so require.

25.4.4 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.

25.5 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 Section 8.

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 TestAmerica are reported to the client on the subcontract laboratory's original report stationary and the report includes any accompanying documentation.

25.6 CLIENT CONFIDENTIALITY

In situations involving the transmission of environmental test results by telephone, facsimile or other electronic means, client confidentiality must be maintained.

TestAmerica 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 TestAmerica or any information disclosed to TestAmerica by the Client. Furthermore, information known to be potentially endangering to national security or an entity's proprietary rights will not be released.

Note: This shall not apply to the extent that the information is required to be disclosed by TestAmerica under the compulsion of legal process. TestAmerica 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.

25.6.1 Report deliverable formats are discussed with each new client. If a client requests that reports be faxed or e-mailed, the reports are faxed with a cover sheet or e-mailed with the following note that includes a confidentiality statement similar to the following:

This material is intended only for the use of the individual(s) or entity to whom it is addressed, and may contain information that is privileged and confidential. It is our policy that facsimiles are intended for and should be used for business purposes only. If you are not the intended recipient, or the employee or agent responsible for delivering this material to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this

25.7 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.

25.8 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 on the Archive data server, as is the original report. The revised report is stored in the Archive data server under the sample number followed by "R". The revised report will have the word "revised" appended to the cover letter.

When the report is re-issued, a notation of "revised" is placed on the cover/signature page of the report. A brief explanation of reason for the re-issue is included in the report case narrative.

25.9 POLICIES ON CLIENT REQUESTS FOR AMENDMENTS

25.9.1 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.

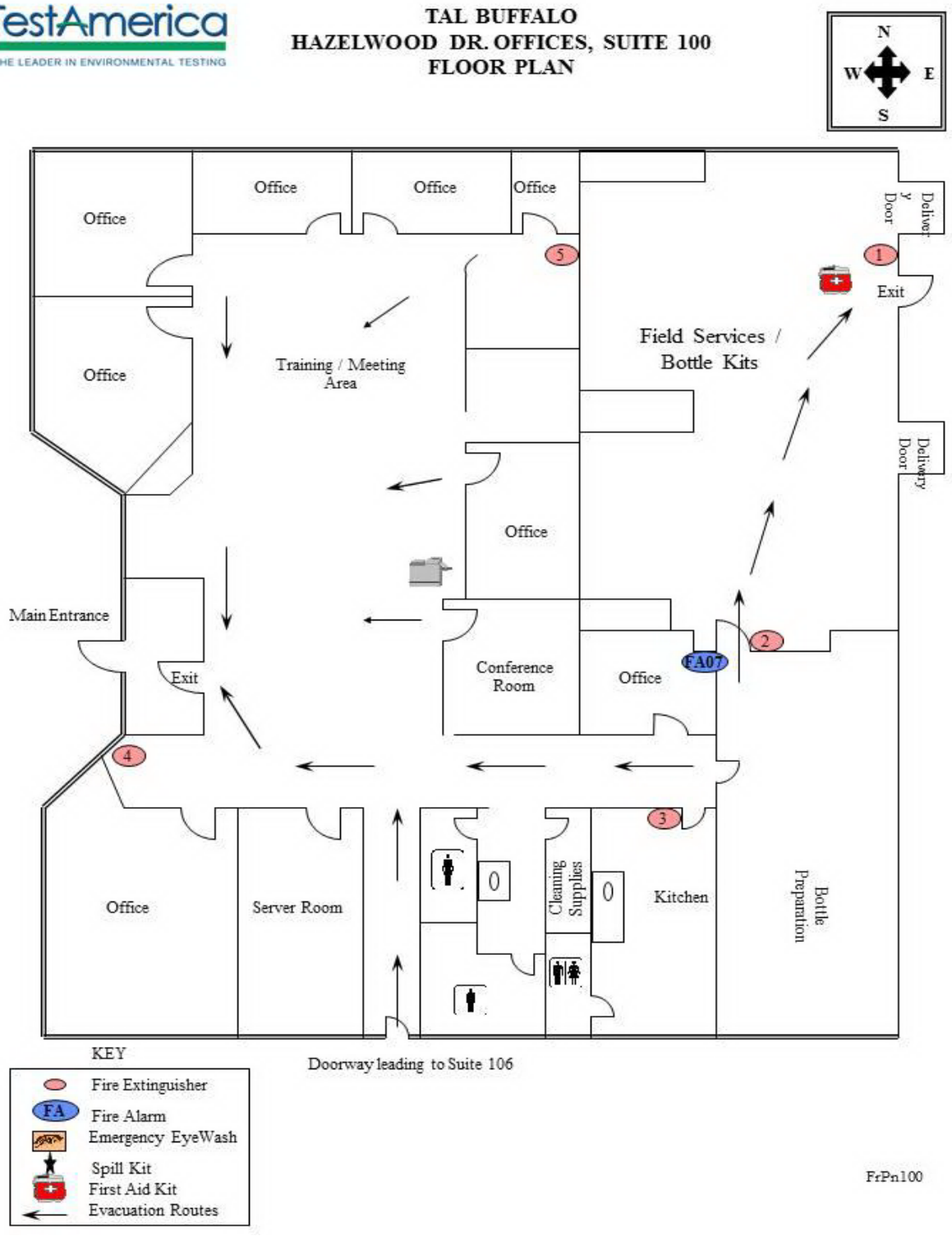
25.9.2 Multiple Reports

TestAmerica does not issue multiple reports for the same workorder 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.

Appendix 1.

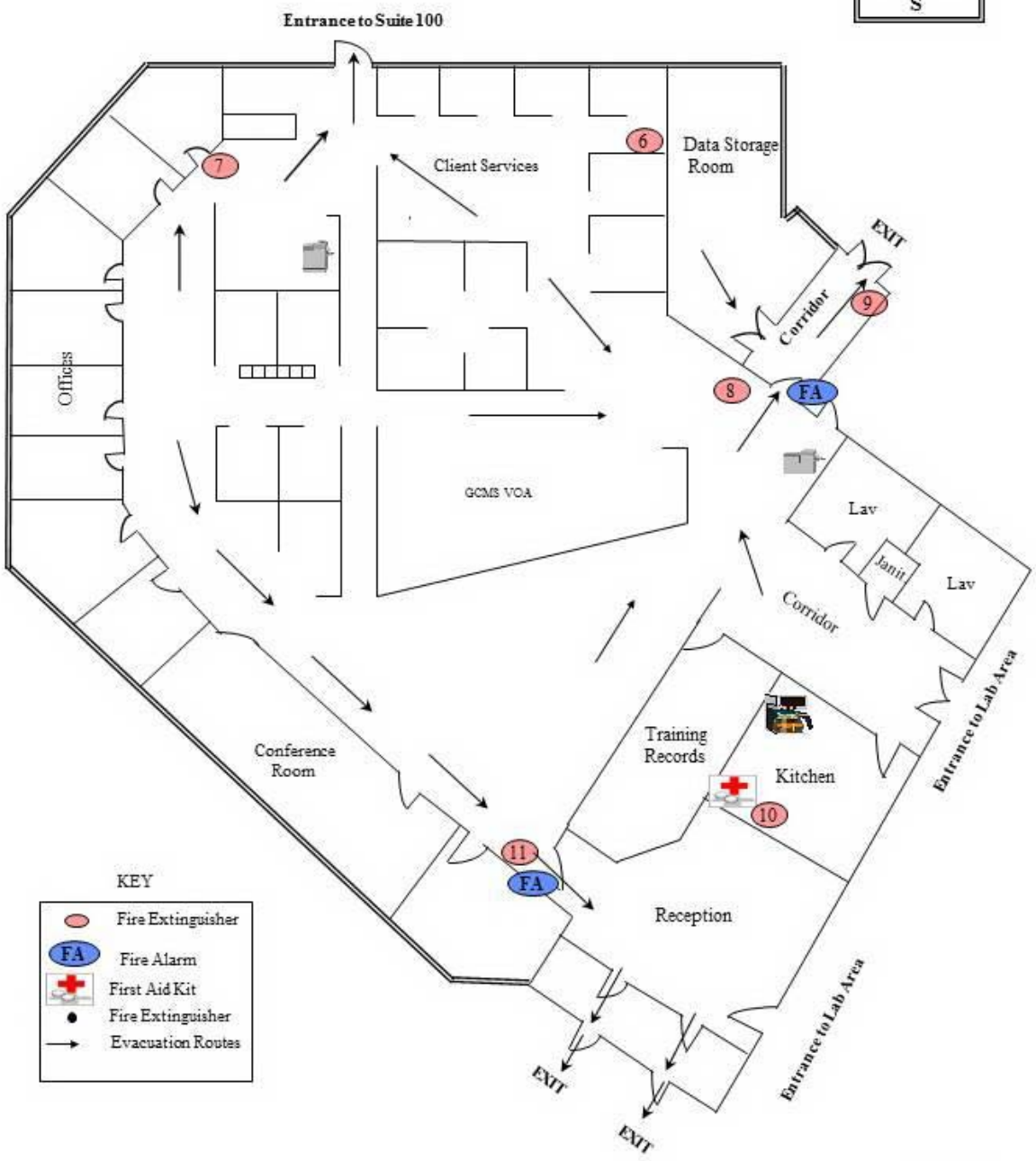
TestAmerica
THE LEADER IN ENVIRONMENTAL TESTING

TAL BUFFALO
HAZELWOOD DR. OFFICES, SUITE 100
FLOOR PLAN



TestAmerica
THE LEADER IN ENVIRONMENTAL TESTING

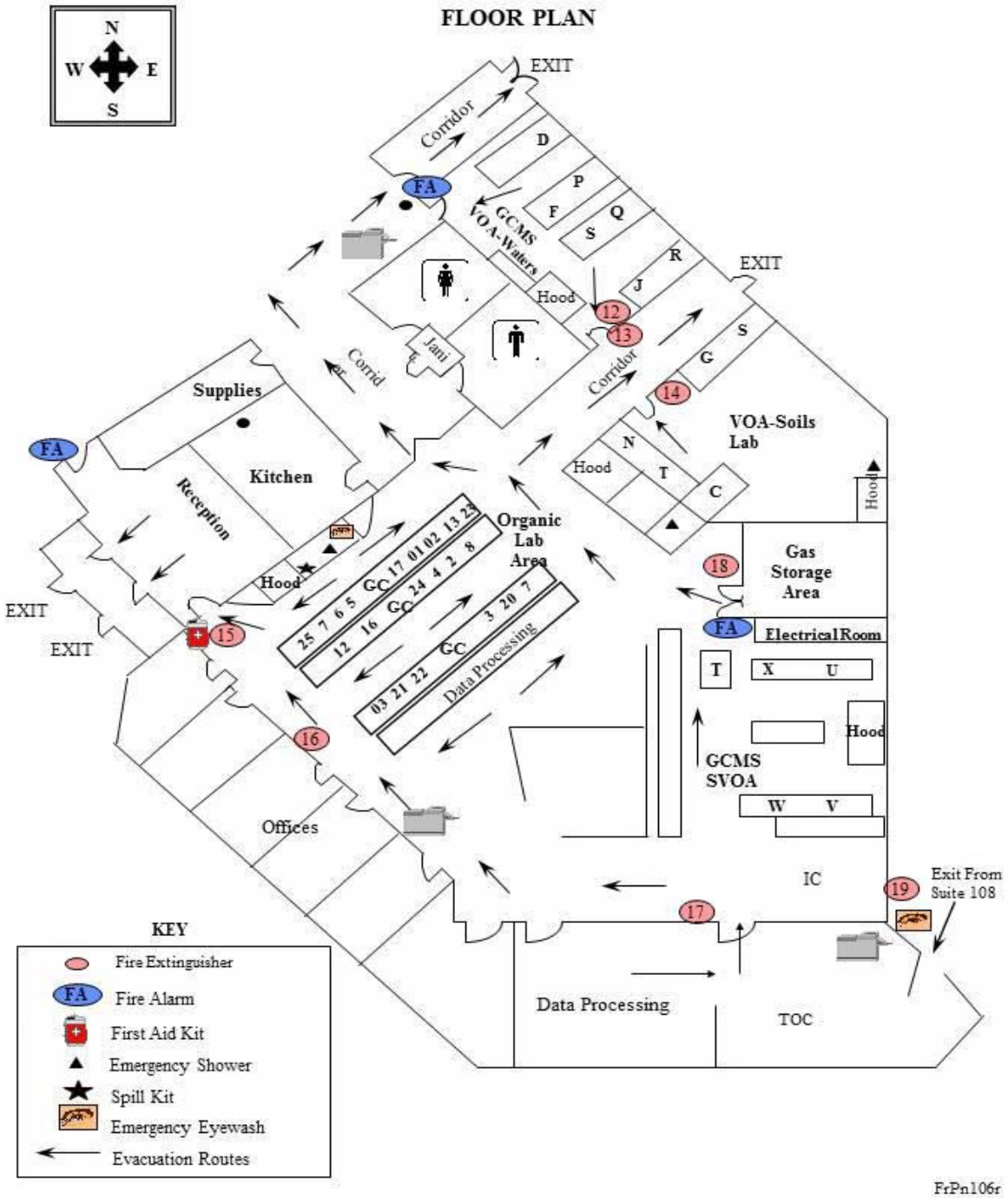
TAL BUFFALO
HAZELWOOD DR. OFFICES, SUITE 106
CLIENT SERVICES/REPORT PREP
FLOOR PLAN



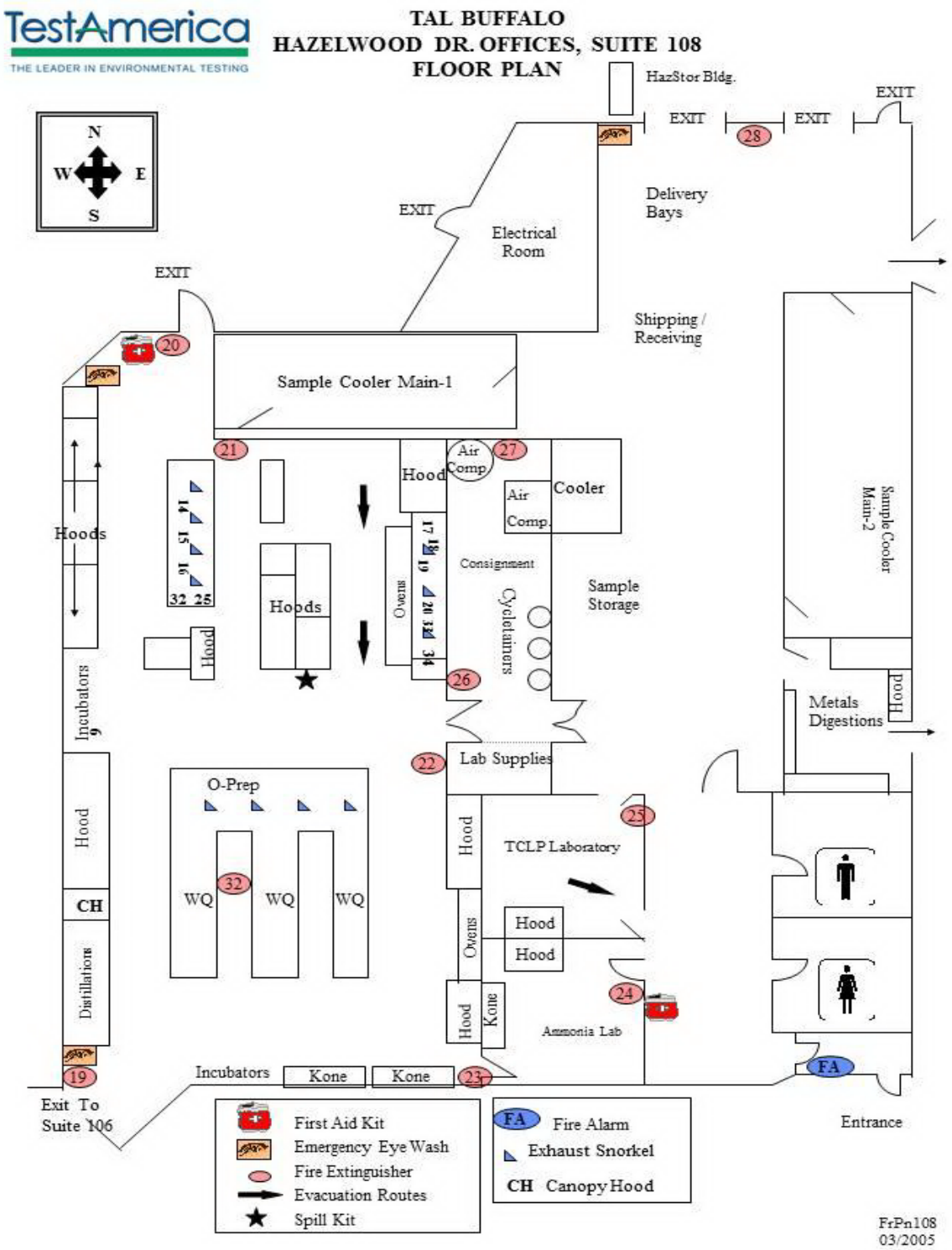
FrP1106L
3/2005

TestAmerica
THE LEADER IN ENVIRONMENTAL TESTING

TAL BUFFALO
HAZELWOOD DR. NY OFFICES, SUITE 106
LABORATORY AREA
FLOOR PLAN



FrPn106r
03/2005


TestAmerica
THE LEADER IN ENVIRONMENTAL TESTING
TAL BUFFALO
HAZELWOOD DR. OFFICES, SUITE 108
FLOOR PLAN
N
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E
S
HazStor Bldg.
EXIT
EXIT
EXIT
EXIT
28
Delivery Bays
Electrical Room
EXIT
Shipping / Receiving
20
Sample Cooler Main-1
21
Hood
Air Comp
27
Air Comp.
Cooler
Hoods
Hoods
Hood
Ovens
Consignment
Cycletainers
Sample Storage
Sample Cooler Main-2
26
Hood
Metals Digestions
Incubators
22
Lab Supplies
O-Prep
WQ
32
WQ
WQ
Hood
25
TCLP Laboratory
Hood
Hood
Ovens
CH
Distillations
Hood
Kone
24
Ammonia Lab
19
Incubators
Kone
Kone
23
FA
Exit To Suite 106
Entrance
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Evacuation Routes
Spill Kit
FA Fire Alarm
Exhaust Snorkel
CH Canopy Hood
FrPn108
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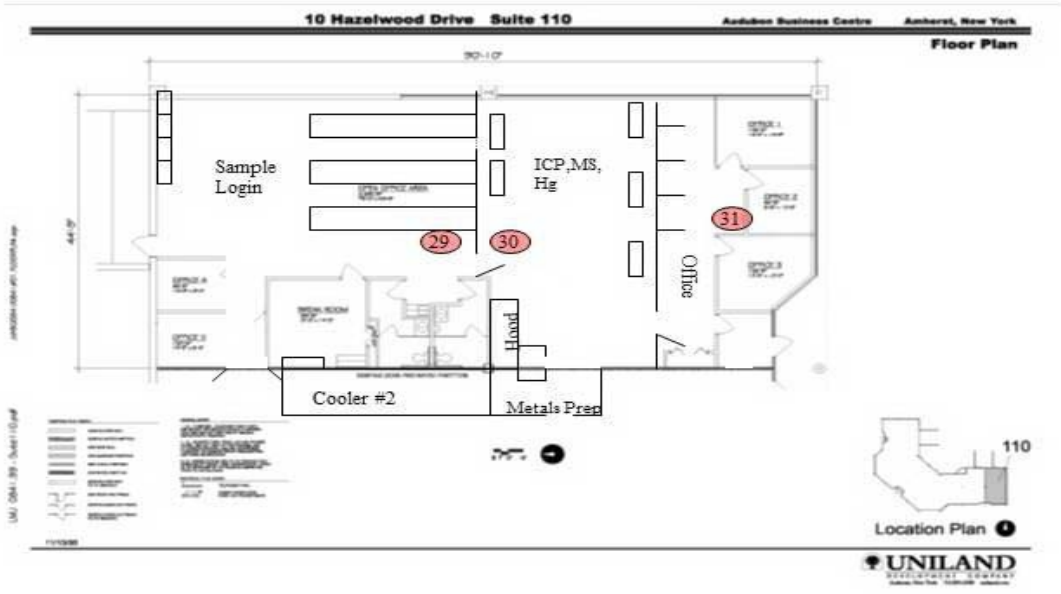
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Floor Plan
Sample Login
ICP,MS, Hg
29
30
31
Office
Hood
Cooler #2
Metals Prep
110
Location Plan
UNILAND

Appendix 2. Glossary/Acronyms

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. In the context of the National Environmental Laboratory Accreditation Program (NELAP), this process is a voluntary one. (TNI)

Accrediting Authority: The Territorial, State, or Federal Agency having responsibility and accountability for environmental laboratory accreditation and which grants accreditation (TNI)

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. (TNI)

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 deficiency, that may affect the quality of the data, whether in the laboratory's control or not.

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 which 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 to 20 environmental samples of the same 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 24 hours. An analytical batch is composed of prepared environmental samples (extracts, digestates or concentrates) and /or those samples not requiring preparation, which are analyzed together as a group using the same calibration curve or factor. An analytical batch can include samples originating from various environmental matrices and can exceed 20 samples. (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. (TNI)

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. NELAC and its representatives agree to safeguarding 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
Derivitization
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)

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)

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). (TNI)

Data Reduction: The process of transforming the number of data items by arithmetic or statistical calculations, standard curves, concentration factors, etc., and collation into a more useable form. (TNI)

Deficiency: 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. (TNI)

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)]: A laboratory's estimate of the minimum amount of an analyte in a given matrix that an analytical process can reliably detect in their facility. (TNI)

LOD Verification [a.k.a., MDL Verification]: A processed QC sample in the matrix of interest, spiked with the analyte at no more than 3X the LOD for single analyte tests and 4X the LOD for multiple analyte tests and processed through the entire analytical procedure.

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. (TNI)

(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 matrix or Saline/Estuarine source. 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. (NELAC)

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. (TNI)

Method Detection Limit: The minimum concentration of a substance (an analyte) that can be measured and reported with 99% confidence that the analyte concentration is greater than zero and is determined from analysis of a sample in a given matrix containing the analyte. (40 CFR Part 136, Appendix B)

Negative Control: Measures taken to ensure that a test, its components, or the environment do not cause undesired effects, or produce incorrect test results. (TNI)

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. (TNI)

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. (TNI)

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. (NELAC)

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) [2.1]

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 analyst/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. (NELAC)

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 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 NELAC 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 and which is accepted as the method 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.

Surrogate: A substance with properties that mimic the analyte of interest. It is unlikely to be found in environment samples and is added to them for quality control purposes.

Surrogate compounds must be added to all samples, standards, and blanks, for all organic chromatography methods except when the matrix precludes its use or when a surrogate is not

available. Poor surrogate recovery may indicate a problem with sample composition and shall be reported to the client whose sample produced poor recovery. (QAMS)

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)

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:

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
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
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
NELAP - National Environmental Laboratory Accreditation Program
PT – Performance Testing
NELAC – The NELAC Institute
QAM – Quality Assurance Manual
QA/QC – Quality Assurance / Quality Control
QAPP – Quality Assurance Project Plan
RF – Response Factor
RPD – Relative Percent Difference
RSD – Relative Standard Deviation
SD – Standard Deviation
SDS - Safety Data Sheet
SOP: Standard Operating Procedure
TAT – Turn-Around-Time
VOA – Volatiles
VOC – Volatile Organic Compound

Appendix 3. Laboratory Certifications, Accreditations, Validations

TestAmerica Buffalo maintains certifications, accreditations, certifications, and validations 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. At the time of this QA Manual revision, the laboratory has accreditation/certification/licensing with the following organizations:

State	*Program*	*Cert # / Lab ID*
Arkansas	*CWA, RCRA, SOIL*	*88-0686*
California*	*NELAP CWA, RCRA*	*01169CA*
Connecticut	*SDWA, CWA, RCRA, SOIL*	*PH-0568*
Florida*	*NELAP CWA, RCRA*	*E87672*
Georgia*	*SDWA,NELAP CWA, RCRA*	*956*
Illinois*	*NELAP SDWA, CWA, RCRA*	*200003*
Iowa	*SW/CS*	*374*
Kansas*	*NELAP SDWA, CWA, RCRA*	*E-10187*
Kentucky	*SDWA, CWA*	*90029*
Kentucky UST	*UST*	*30*
Louisiana*	*NELAP CWA, RCRA*	*2031*
Maine	*SDWA, CWA*	*NY0044*
Maryland	*SDWA*	*294*
Massachusetts	*SDWA, CWA*	*M-NY044*
Michigan	*SDWA*	*9937*
Minnesota	*SDWA,CWA, RCRA*	*036-999-337*
New Hampshire Primary*	*NELAP SDWA, CWA, RECRA*	*2973*
New Hampshire Secondary*	*NELAP SDWA, CWA, RECRA*	*2337*
New Jersey*	*NELAP,SDWA, CWA, RCRA,*	*NY455*
New York*	*NELAP, AIR, SDWA, CWA, RCRA*	*10026*
North Dakota	*CWA, RCRA*	*R-176*
Oklahoma	*CWA, RCRA*	*9421*
Oregon*	*CWA,RCRA*	*NY200003*
Pennsylvania*	*NELAP CWA,RCRA*	*68-00281*
Rhode Island	*SDWA, CWA*	*LAO00328*
Tennessee	*SDWA*	*02970*
Texas*	*NELAP CWA, RCRA*	*T104704412-08-TX*
USDA	*FOREIGN SOIL PERMIT*	*S-41579*
Virginia	*SDWA*	*278*
Washington*	*NELAP CWA,RCRA*	*C1677*
Wisconsin	*CWA, RCRA*	*998310390*
West Virginia	*CWA,RCRA*	*252*

The certificates and accredited parameter lists are available for each State/Program at www.testamericainc.com under Analytical Services Search – Certifications.

APPENDIX D

STATISTICAL PLAN

Statistical Methods for Ground-Water Monitoring at the Woodland Meadows - North Landfill

Prepared

by

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February 2001

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Executive Summary

This report has two specific aims. First to describe a general intra-well statistical strategy for ground-water detection monitoring that is applicable at the Woodland Meadows - North Landfill and second, to apply this methodology to existing data at the facility. The methodology is first described in considerable detail, appropriately referenced to both the scientific literature and USEPA regulation and guidance and then applied to existing data at the facility.

The methods described here are based on the new ASTM standard D6312-98 (formerly PS 64-96) *Developing Appropriate Statistical Approaches for Ground-Water Detection Monitoring Programs* written by Dr. Robert Gibbons (University of Illinois) , Dr. Kirk Cameron (statistical consultant to USEPA) and Jim Brown (USEPA).

Intra-well comparisons revealed no statistically significant exceedance for any well or constituent. No VOCs have been detected since 1993. In light of these results we propose to perform intra-well comparisons using combined Shewhart-CUSUM control charts for routine detection monitoring at this facility. At this point, background should be fixed for a period of two years and reupdated at that time for all wells that have not exhibited a verified exceedance. This process will continue for the life of the facility. Once eight background samples are available for those wells and constituents with fewer than eight background samples, control limits should be computed and added to the monitoring program.

Table of Contents

F. Results of Application at the Woodland Meadows - North Landfill

1. Monitoring Well Network
2. Intra-well comparisons
3. Statistical Power
4. VOCs
5. Summary

Some Relevant Literature

Overview

In the context of ground-water monitoring at waste disposal facilities, legislation has required statistical methods as the basis for investigating potential environmental impact due to waste disposal facility operation. Owner/Operators must perform a statistical analysis on a quarterly or semi-annual basis. A statistical test is performed on each of many constituents (*i.e.*, 10 to 50) for each of many wells (5 to 100 or more). The result is potentially hundreds, and in some cases, a thousand or more statistical comparisons performed on each monitoring event. Even if the false positive rate for a single test is small (*e.g.*, 1%), the possibility of failing at least one test on any monitoring event is virtually guaranteed. This assumes you have done the correct statistic in the first place.

In the following sections, a statistical plan is developed that includes: an effective verification resampling plan, and selection of appropriate statistical methods (*e.g.*, parametric and nonparametric prediction limits and control charts for intra-well comparison) that detect contamination when it is present and do not falsely conclude that the site is contaminated. Statistical significance of contamination detection cannot be properly determined without verification resampling. It is noted from the information presented herein that the final statistical detection monitoring plan cannot be fully specified until background samples for the required list of indicator constituents are available. In general, it is unwise to perform statistical computations on any less than eight background samples. This may be four quarterly samples in each of two upgradient wells, or eight samples taken in each well where intra-well comparisons are to be performed. To take any fewer samples will lead to high false negative rates due to the large size of the prediction limit (*i.e.*, with four samples and three degrees of freedom, the uncertainty in the true mean and standard deviation (μ and σ) given the sample based estimates ($\bar{x}$ and s) is enormous, resulting in extremely high prediction limits). Conversely, with only a few background measurements, our knowledge of the true sampling variability, distributional form and detection frequency may be completely inaccurate leading to a high false positive rate.

It is noted that when justified, intra-well comparisons are always more powerful than their inter-well counterparts because they completely eliminate the spatial component of variability. Due to the absence of spatial variabil-

ity, the uncertainty in measured concentrations is decreased making intra-well comparisons more sensitive to real releases (*i.e.*, lower false negative rate) and false positive results due to spatial variability are completely eliminated.

The following provides an outline of the general intra-well statistical procedure for ground-water monitoring under the Subtitle D regulation, which is also described in the flowchart at the end of this report.

A. Detection Monitoring

1. Intra-well Comparisons

   (a) For those facilities that either

      i. Have no definable gradient,

      ii. Have no existing contamination from an on-site-off-site landfill or other source,

      iii. Have too few upgradient wells to meaningfully characterize spatial variability (*e.g.*, a site with one upgradient well or a facility in which upgradient water quality is not representative of downgradient water quality),

      iv. Satisfy specific hydrogeological criteria (*e.g.*, slow moving ground-water zones, no access to upgradient ground water, inappropriate ground-water migration pathways) as defined by a ground-water professional,

   compute intra-well comparisons using combined Shewhart-CUSUM control charts (40CFR 258.53(h)(3)).

   (b) For those wells and constituents that fail upgradient versus downgradient comparisons, compute combined Shewhart-CUSUM control charts. If no VOCs or hazardous metals are detected and no trend is detected in other indicator constituents, use intra-well comparisons for detection monitoring of those wells and constituents.

   (c) If data are all non-detects after 13 quarterly sampling events, use PQL as statistical decision limit (40CFR 258.53(h)(5)). Thirteen samples provides a 99% confidence nonparametric prediction limit with one resample (40CFR 258.53(h)(1) and USEPA 1992 section 5.2.3). Note that 99% confidence is equivalent to a 1% false positive

rate, and pertains to a single comparison (*i.e.*, well and constituent) and not the site-wide error rate (*i.e.*, all wells and constituents) that is set to 5%.

(d) If detection frequency is greater than zero (*i.e.*, the constituent is detected in at least one background sample) but less than 25% set control limit to the largest of at least 13 background samples.

(e) As an alternative to (c) and (d) compute a Poisson prediction limit following collection of at least 4 background samples (USEPA 1992 section 2.2.4). Since the mean and variance of the Poisson distribution are the same, the Poisson prediction limit is defined even there is no variability (*e.g.*, even if then constituent is never detected in background). In this case, the quantification limits are used in place of the measurements and the Poisson prediction limit can be computed directly.

2. Verification Resampling

(a) Verification resampling is an integral part of the statistical methodology (USEPA 1992 section 5).

(b) Without verification resampling much larger prediction limits would be required to obtain a site-wide false positive rate of 5%. The resulting false negative rate would be dramatically increased.

(c) Verification resampling allows sequential application of a much smaller prediction limit, therefore minimizing both false positive and false negative rates.

(d) A statistically significant exceedance is not declared and should not be reported until the results of the verification resample are known. The probability of an initial exceedance is much higher than 5% for the site as a whole.

(e) Note that requiring passage of two verification resamples (*e.g.*, in the state of California regulation) will lead to higher false negative rates because larger prediction limits are required to achieve a site-wide false positive rate of 5% than for a single verification resample; hence, the preferred method is one verification resample. Also note that for nonparametric limits, requiring passage of two verification

resamples may result in need for a larger number of background samples than are typically available (see Gibbons, 1994).

3. False Positives and False Negative Rates

   (a) Conduct simulation study based on current monitoring network, constituents, detection frequencies, and distributional form of each monitoring constituent (USEPA 1992 Appendix B).

   (b) Project frequency of verification resamples and false assessments for site as a whole for each monitoring event based on the results of the simulation study.

   (c) As a general guideline, we require a site-wide false positive rate of 5% and a false negative rate of approximately 5% for differences on the order of 3 to 4 standard deviation units (see USEPA 1992 Appendix B). Note that following USEPA we simulate the most conservative case of a release that effects a single constituent in a single downgradient well. In practice, multiple constituents in multiple wells will be impacted, therefore, the actual false negative rates will be considerably smaller than estimates obtained via simulation.

4. Use of MDLs and PQLs in Ground-Water Monitoring

   (a) MDLs indicate that the analyte is present in the sample with confidence.

   (b) PQLs indicate that the true quantitative value of the analyte is close to the measured value.

   (c) For analytes with estimated concentration exceeding the MDL but not the PQL, it can only be concluded that the true concentration is greater than zero - there is no way of knowing the actual concentration.

   (d) If the laboratory-specific MDL for a given compound is 3 μg/l, and the PQL for the same compound is 6 μg/l, then a detection of that compound at 4 μg/l could actually represent a true concentration of anywhere between 0 and 6 μg/l. The true concentration may well be *less than* the MDL (see Currie 1968, Hubaux and Vos, 1970 and Gibbons 1994).

(e) Comparison of such a value to a maximum contaminant level (MCL), or any other concentration limit, is not meaningful unless the concentration is larger than the PQL.

(f) Verification resampling applies to this case as well.

B. Assessment or Corrective Action Monitoring

1. Comparison to Background

(a) Define background for any Appendix II compounds detected (*i.e.*, a minimum of four background samples 40CFR 258.55(b)).

(b) Compute appropriate prediction limit based on distributional tests and detection frequency as previously described, based on upgradient data or historical data from each well (40CFR 258.55(e)).

(c) Compare any Appendix II constituent concentrations found to the background prediction limit. If all values are below the prediction limit for two consecutive sampling events return to detection monitoring (40CFR 258.55(e)).

(d) In Corrective Action (required if background is exceeded) use same statistic until background is achieved for three years. (40CFR 258.58(e)(2)). Use Sen's test to evaluate trends (declining) to demonstrate effectiveness of corrective action.

2. Comparison to a Standard

(a) If a maximum contaminant level (MCL) or alternate concentration limit (ACL) is used, and the ACL or MCL is greater than the background prediction limit, then new concentrations in the assessment or corrective action wells should be compared to the standard (*i.e.*, ACL or MCL) using the lower 95% confidence limit (LCL) for assessment monitoring or the upper 95% confidence limit (UCL) for corrective action. We use the LCL in assessment monitoring because we are testing the null hypothesis of no difference between the true ground-water concentration and the regulatory standard (USEPA, 1992). By contrast, in corrective action we are concerned with demonstrating that the true concentration is less

than the regulatory standard due to the positive effects of the remediation, and we therefore use the UCL. The LCL or UCL should be computed from at least the last available four measurements. If only four measurements are available, a normal UCL/LCL should be used imputing the DL/2 for the nondetects. If eight or more measurements are used, tests of distributional form and statistical adjustment for nondetects (*e.g.*, Aitchison's method) can be used and corresponding normal, lognormal or nonparametric UCLs or LCLs should be used depending on results of distributional testing.

(b) In the case of anthropogenic compounds such as VOCs, if the standard is less than the PQL, then the standard becomes the PQL, since no smaller value can be quantified.

(c) Use Sen's test to evaluate trends (both increasing and decreasing) to demonstrate the effectiveness of corrective action.

C. Implementation

1. The computer program used to implement the detection monitoring plan will encompass all aspects of the previously presented statistical decision tree.

2. The program will be automatic with respect to selection of statistical methods based on the decision tree and all wells and analytes will be input as a complete file and analyzed on the basis of a single instruction. Cumbersome programs such as GRITS/STAT which require extensive user input for analysis of each well and constituent individually will be avoided.

3. Once the program is configured no further statistical decisions, choices or selections will be made so that it can be run by someone with or without adequate statistical background to make these decisions.

4. The program will have a graphical user interface that allows the user to communicate the data format and to add new data to an existing database rather than requiring a complete new database each quarter.

5. The computer program DUMPStat (Downgradient Upgradient Monitoring Program Statistics) distributed by Discerning Systems, Vancouver CA is the only existing program that provides these features.

D. Technical Details

The purpose of this section is to provide a description of the specific statistical methods used in DUMPStat, which is the computer program that will be used in performing the routine statistical analysis of detection monitoring data at the facility. Please note, however, that specific recommendations for any given facility require an interdisciplinary site-specific study that encompasses knowledge of the facility, it's hydrogeology, geochemistry, and study of the false positive and false negative error rates that will result. In general, the appropriate statistical methods are available in DUMPStat, however the program must be properly configured for each site to insure that the methods are properly implemented. Performing a correct statistical analysis, such as nonparametric prediction limits, in the wrong situation (*e.g.*, when there are too few background measurements) can lead to disaster. It is for this reason that DUMPStat's simulation capabilities are so important. In the following, the general DUMPStat algorithm is described.

1. Intra-Well Comparisons

   One particularly good method for computing intra-well comparisons is the combined Shewhart-CUSUM control chart (USEPA 1992 section 6.1). The method is sensitive to both gradual and rapid releases and is also useful as a method of detecting "trends" in data. Note that this method should be used on wells unaffected by the landfill. There are several approaches to implementing the method and in the following one useful way is described as well as discussion of some statistical properties.

   (a) Assumptions

   The combined Shewhart-CUSUM control chart procedure assumes that the data are *independent* and *normally* distributed with a *fixed* mean μ and constant variance σ^2. The most important assumption is independence, and as a result wells should be sampled *no more* frequently than quarterly. In some cases, where ground-water moves

relatively quickly, it may be possible to accelerate background sampling to eight samples in a single year; however, this should only be done to establish background and not for routine monitoring. The assumption of normality is somewhat less of a concern, and if problematic, natural log or square root transformation of the observed data should be adequate for most practical applications. For this method, nondetects can be replaced by the quantification limit (or median quantification limit if there are variable quantification limits) without serious consequence. This procedure should *only* be applied to those constituents that are quantified at least in 25% of all samples, otherwise, σ^2 is not adequately defined.

(b) Nondetects

i. For those well and constituent combinations in which the detection frequency is less than 25%, we will provide graphical display of these data until a sufficient number of measurements are available to provide 99% confidence (*i.e.*, 1% false positive rate) for an individual well and constituent using a nonparametric prediction limit (see Table 1), which in this context is the maximum quantified value out of the n historical measurements. As previously discussed this amounts to 13 background samples for 1 resample, 8 background samples for pass 1 of 2 resamples and 18 background samples for pass 2 of 2 resamples. It should be obvious that if nonparametric prediction limits are to be used for intra-well comparisons of rarely detected constituents, two verification resamples will often be required and failure will only be indicated if *both* measurements exceed the limit (*i.e.*, the maximum of the first 8 samples).

ii. For those cases in which the detection frequency is greater than or equal to 25%, DUMPStat substitutes the median quantification limit for the nondetects. In this way, changes in quantification limits do not appear to be significant trends.

iii. If nothing is quantified in 8, 13 or 18 independent samples (depending on resampling strategy), DUMPStat uses the quantification limit as the control limit.

iv. As in the previously described inter-well comparisons, DUMPStat provides optional use of Poisson prediction limits as an

alternative to nonparametric prediction limits for rarely quantified constituents (*i.e.*, less than 25% detects). Poisson prediction limits can be computed after 8 background measurements regardless of detection frequency.

(c) Procedure

i. DUMPStat requires that at least 8 historical independent samples are available to provide reliable estimates of the mean μ and standard deviation σ, of the constituent's concentration in each well.

ii. DUMPStat selects the three Shewhart-CUSUM parameters h (the value against which the cumulative sum will be compared), k (a parameter related to the displacement that should be quickly detected), and SCL (the upper Shewhart limit which is the number of standard deviation units for an immediate release). Lucas (1982) and Starks (1988) suggest that $k = 1$, $h = 5$, and $SCL = 4.5$ are most appropriate for ground-water monitoring applications. This sentiment is echoed by USEPA in their interim final guidance document *Statistical analysis of ground-water monitoring data at RCRA facilities* (April, 1989). Also see USEPA 1992 section 6.1. For ease of application, however, we have selected $h = SCL = 4.5$, which is slightly more conservative than the value of $h = 5$ suggested by USEPA.

iii. Denote the new measurement at time-point t_i as x_i.

iv. Compute the standardized value z_i

$$z_i = \frac{x_i - \bar{x}}{s}$$

where $\bar{x}$ and s are the mean and standard deviation of the at least 8 historical measurements for that well and constituent (collected in a period of no less than one year).

v. At each time period, t_i, compute the cumulative sum S_i, as

$$S_i = \max\left[0, (z_i - k) + S_{i-1}\right]$$

where max[A, B] is the maximum of A and B, starting with $S_0 = 0$.

vi. Plot the values of S_i (y-axis) versus t_i (x-axis) on a time chart. Declare an "out-of-control" situation on sampling period t_i if

for the first time, $S_i \geq h$ or $z_i \geq SCL$. Any such designation, however, must be verified on the next round of sampling, before further investigation is indicated.

vii. The reader should note that unlike prediction limits which provide a fixed confidence level (*e.g.*, 95%) for a given number of future comparisons, control charts do not provide explicit confidence levels, and do not adjust for the number of future comparisons. The selection of $h = SCL = 4.5$ and $k = 1$ is based on USEPA's own review of the literature and simulations (see Lucas, 1982; Starks, 1988; and USEPA, 1989). USEPA indicates that these values "allow a displacement of two standard deviations to be detected quickly." Since 1.96 standard deviation units corresponds to 95% confidence on a normal distribution, we can have approximately 95% confidence for this method as well.

viii. In terms of plotting the results, it is more intuitive to plot values in their original metric (*e.g.*, μg/l) rather than in standard deviation units. In this case $h = SCL = \bar{x} + 4.5s$ and the S_i are converted to the concentration metric by the transformation $S_i * s + \bar{x}$, noting that when normalized (*i.e.*, in standard deviation units) $\bar{x} = 0$ and $s = 1$ so that $h = SCL = 4.5$ and $S_i * 1 + 0 = S_i$.

ix. When $n \geq 12$ Starks (1988) and USEPA (1992) suggest that $k = .75$, and $h = SCL = 4.0$ provide more conservative control limits and this approach is now used in DUMPStat.

(d) Outliers

i. From time to time, inconsistently large or small values (outliers) can be observed due to sampling, laboratory, transportation, transcription errors, or even by chance alone. The verification resampling procedure that we have proposed will tremendously reduce the probability of concluding that an impact has occurred if such an anomalous value is obtained for any of these reasons. However, nothing has eliminated the chance that such errors might be included in the historical measurements for a particular well and constituent. If such erroneous values (either too high or too low) are included in the historical database, the

result would be an artificial increase in the magnitude of the control limit, and a corresponding increase in the false negative rate of the statistical test (*i.e.*, conclude that there is no site impact when in fact there is).

ii. To remove the possibility of this type of error, the historical data are screened for each well and constituent for the existence of outliers (USEPA 1992 section 6.2) using the well known method described by Dixon (*Biometrics,* 1953, **9**, 74-89). These outlying data points are indicated on the control charts (using a different symbol), but are excluded from the measurements that are used to compute the background mean and standard deviation. In the future, new measurements that turn out to be outliers, in that they exceed the control limit, will be dealt with by verification resampling in downgradient wells only.

iii. This same outlier detection algorithm is applied to each upgradient well and constituent to screen outliers for inter-well comparisons as well.

(e) Existing Trends

If contamination is pre-existing, trends will often be observed in the background database from which the mean and variance are computed. This will lead to upward biased estimates and grossly inflated control limits. To remove this possibility, we first screen the background data for each well and constituent for trend using Sen's (1986) nonparametric estimate of trend. Confidence limits for this trend estimate are given by Gilbert (1987). A significant trend is one in which the 99% lower confidence bound is greater than zero. In this way, even pre-existing trends in the background dataset will be detected.

(f) A Note on Verification Sampling

i. It should be noted that when a new monitoring value is an outlier, perhaps due to a transcription error, sampling error, or analytical error, the Shewhart and CUSUM portions of the control chart are affected quite differently. The Shewhart portion of the control chart compares each individual new measurement to the control limit, therefore, the next monitoring event measurement constitutes an independent verification of the original

result. In contrast, however, the CUSUM procedure incorporates *all* historical values in the computation, therefore, the effect of the outlier will be present for both the initial and verification sample; hence the statistical test will be invalid.

ii. For example, assume $\bar{x} = 50$, and $s = 10$. On quarter 1 the new monitoring value is 50, so $z = (50 - 50)/10 = 0$ and $S_i = \max[0, (z - 1) + 0] = 0$. On quarter 2, a sampling error occurs and the reported value is 200, yielding $z = (200 - 50)/10 = 15$ and $S_i = \max[0, (15 - 1) + 0] = 14$, which is considerably larger than 4.5; hence an initial exceedance is recorded. On the next round of sampling, the previous result is not confirmed, because the result is back to 50. Inspection of the CUSUM, however, yields $z = (50 - 50)/10 = 0$ and $S_i = \max[0, (0 - 1) + 14] = 13$, which would be taken as a confirmation of the exceedance, when in fact, no such confirmation was observed. For this reason, the verification must *replace* the suspected result in order to have an unbiased confirmation.

(g) Updating the Control Chart

i. As monitoring continues and the process is shown to be in control, the background mean and variance should be updated periodically to incorporate these new data. Every year or two, all new data that are *in control* should be pooled with the initial samples and $\bar{x}$ and s recomputed. These new values of $\bar{x}$ and s will then be used in constructing future control charts. This updating process should continue for the life of the facility and/or monitoring program (USEPA 1992 section 6.2).

ii. DUMPStat allows the user to update background by changing the time window menu option. This option sets a window of time for which background summary statistics are computed. Changing the maximum date will incorporate new data into the background limit estimate. Note that this time window applies to computing background for both inter-well and intra-well comparisons.

(h) An Alternative Based on Prediction Limits

i. An alternative approach to intra-well comparisons involves com-

putation of well-specific prediction limits. Prediction limits are somewhat more sensitive to immediate releases but less sensitive to gradual releases than the combined Shewhart-CUSUM control charts. Prediction limits are also less robust to deviations from distributional assumptions.

ii. As an alternative to combined Shewhart-CUSUM control charts DUMPStat can compute normal prediction limits as described in the previous section on inter-well comparisons.

iii. For detection frequencies greater than or equal to 25%, nondetects are replaced with the median quantification limit. For detection frequencies less than 25%, either nonparametric or Poisson prediction limits are computed depending on what option the user has selected (*i.e.*, rare-event statistic window).

2. Comparison to a Standard

   (a) For assessment or corrective action, it is often required that samples from a potentially impacted well be compared to a ground-water quality protection standard such as an MCL or ACL. DUMPStat's assessment/corrective action monitoring module provides tabular and graphical display of this comparison based on tests of increasing and decreasing trend and comparison of the standard to the lower (assessment) or upper (corrective action) 95% normal confidence limit applied to the last four independent samples.

   (b) The 95% lower confidence limit for the mean of the last four measurements is computed as

   $$\bar{x} - t_{[3,.05]}\frac{s}{2} .$$

   (c) The 95% upper confidence limit for the mean of the last four measurements is computed as

   $$\bar{x} + t_{[3,.05]}\frac{s}{2} .$$

   (d) Nondetects are replaced by one-half of the quantification limit since with only four measurements, more sophisticated statistical adjustments are not appropriate. Note that one half of the quantification

limit is used here because some regulatory standards may be set at the quantification limit.

TABLE 1

PROBABILITY THAT THE FIRST SAMPLE OR THE VERIFICATION RESAMPLE WILL BE BELOW THE MAXIMUM OF n BACKGROUND MEASUREMENTS AT EACH OF k MONITORING WELLS FOR A SINGLE CONSTITUENT

Previous	Number of Monitoring Wells (k)														
n	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
4	.933	.881	.838	.802	.771	.744	.720	.698	.679	.661	.645	.630	.617	.604	.592
5	.952	.913	.879	.849	.823	.800	.779	.760	.742	.726	.711	.697	.684	.672	.661
6	.964	.933	.906	.882	.860	.840	.822	.805	.789	.774	.761	.748	.736	.725	.714
7	.972	.947	.925	.905	.886	.869	.853	.838	.825	.812	.799	.788	.777	.766	.757
8	.978	.958	.939	.922	.906	.891	.878	.864	.852	.841	.830	.819	.809	.800	.791
9	.982	.965	.949	.935	.921	.908	.896	.885	.874	.864	.854	.844	.835	.827	.818
10	.985	.971	.957	.945	.933	.922	.911	.901	.891	.882	.873	.865	.857	.849	.841
11	.987	.975	.964	.953	.942	.933	.923	.914	.906	.897	.889	.882	.874	.867	.860
12	.989	.979	.969	.959	.950	.941	.933	.925	.917	.910	.902	.896	.889	.882	.876
13	.990	.981	.973	.964	.956	.948	.941	.934	.927	.920	.914	.907	.901	.895	.889
14	.992	.984	.976	.969	.961	.954	.948	.941	.935	.929	.923	.917	.912	.906	.901
15	.993	.986	.979	.972	.966	.959	.953	.947	.942	.936	.931	.926	.920	.915	.910
16	.993	.987	.981	.975	.969	.964	.958	.953	.948	.943	.938	.933	.928	.923	.919
17	.994	.988	.983	.978	.972	.967	.962	.957	.953	.948	.943	.939	.935	.930	.926
18	.995	.990	.985	.980	.975	.970	.966	.961	.957	.953	.949	.944	.940	.937	.933
19	.995	.991	.986	.982	.977	.973	.969	.965	.961	.957	.953	.949	.946	.942	.938
20	.996	.991	.987	.983	.979	.975	.972	.968	.964	.960	.957	.953	.950	.947	.943
25	.997	.994	.992	.989	.986	.984	.981	.978	.976	.973	.971	.968	.966	.964	.961
30	.998	.996	.994	.992	.990	.988	.986	.984	.983	.981	.979	.977	.975	.974	.972
35	.998	.997	.996	.994	.993	.991	.990	.988	.987	.986	.984	.983	.981	.980	.979
40	.999	.998	.997	.995	.994	.993	.992	.991	.990	.989	.988	.987	.985	.984	.983
45	.999	.998	.997	.996	.995	.995	.994	.993	.992	.991	.990	.989	.988	.987	.987
50	.999	.998	.998	.997	.996	.996	.995	.994	.993	.993	.992	.991	.990	.990	.989
60	.999	.999	.998	.998	.997	.997	.996	.996	.995	.995	.994	.994	.993	.993	.992
70	1.00	.999	.999	.998	.998	.998	.997	.997	.997	.996	.996	.995	.995	.995	.994
80	1.00	.999	.999	.999	.998	.998	.998	.998	.997	.997	.997	.996	.996	.996	.996
90	1.00	1.00	.999	.999	.999	.999	.998	.998	.998	.998	.997	.997	.997	.997	.996
100	1.00	1.00	.999	.999	.999	.999	.999	.998	.998	.998	.998	.998	.997	.997	.997

Previous	Number of Monitoring Wells (k)														
n	20	25	30	35	40	45	50	55	60	65	70	75	80	90	100
4	.542	.504	.474	.449	.428	.410	.394	.380	.367	.356	.345	.336	.327	.312	.299
5	.612	.574	.543	.517	.495	.476	.459	.443	.430	.417	.406	.396	.386	.369	.355
6	.668	.631	.600	.574	.552	.532	.514	.499	.484	.472	.460	.449	.439	.420	.405
7	.713	.678	.648	.623	.600	.580	.563	.547	.532	.519	.507	.496	.485	.466	.450
8	.750	.717	.688	.664	.642	.622	.605	.589	.574	.561	.549	.537	.527	.507	.490
9	.781	.750	.723	.699	.678	.659	.642	.626	.612	.598	.586	.574	.564	.544	.527
10	.807	.777	.752	.729	.709	.691	.674	.659	.644	.631	.619	.608	.597	.578	.560
11	.828	.801	.777	.755	.736	.718	.702	.687	.674	.661	.649	.638	.627	.608	.590
12	.847	.821	.799	.778	.760	.743	.727	.713	.700	.687	.675	.664	.654	.635	.618
13	.862	.839	.817	.798	.781	.764	.750	.736	.723	.711	.699	.689	.678	.660	.643
14	.876	.854	.834	.816	.799	.784	.769	.756	.744	.732	.721	.710	.701	.682	.666
15	.888	.867	.848	.831	.815	.801	.787	.774	.762	.751	.740	.730	.721	.703	.686
16	.898	.879	.861	.845	.830	.816	.803	.791	.779	.768	.758	.748	.739	.722	.706
17	.907	.889	.872	.857	.843	.830	.817	.806	.794	.784	.774	.765	.756	.739	.723
18	.914	.898	.882	.868	.855	.842	.830	.819	.808	.798	.789	.780	.771	.754	.739
19	.921	.906	.891	.878	.865	.853	.842	.831	.821	.811	.802	.793	.785	.769	.754
20	.928	.913	.899	.886	.874	.863	.852	.842	.832	.823	.814	.806	.798	.782	.768
25	.950	.939	.929	.919	.910	.901	.892	.884	.876	.869	.862	.855	.848	.835	.823
30	.963	.955	.947	.940	.932	.925	.919	.912	.906	.900	.894	.888	.882	.872	.861
35	.972	.966	.959	.954	.948	.942	.937	.931	.926	.921	.916	.911	.907	.898	.889
40	.978	.973	.968	.963	.958	.954	.949	.945	.941	.936	.932	.928	.924	.917	.909
45	.982	.978	.974	.970	.966	.962	.959	.955	.951	.948	.944	.941	.938	.931	.925
50	.985	.982	.979	.975	.972	.969	.966	.963	.959	.956	.954	.951	.948	.942	.937
60	.990	.987	.985	.982	.980	.978	.975	.973	.971	.968	.966	.964	.962	.958	.954
70	.992	.990	.989	.987	.985	.983	.981	.980	.978	.976	.974	.973	.971	.968	.965
80	.994	.993	.991	.990	.988	.987	.986	.984	.983	.981	.980	.979	.977	.975	.972
90	.995	.994	.993	.992	.991	.990	.988	.987	.986	.985	.984	.983	.982	.980	.978
100	.996	.995	.994	.993	.992	.991	.991	.990	.989	.988	.987	.986	.985	.983	.982

E. Some Methods to be Avoided

In the following sections some statistical methods that should be avoided are described.

1. Analysis of Variance - ANOVA

   Application of ANOVA procedures to ground-water detection monitoring programs, both parametric and nonparametric is inadvisable for the following reasons.

   (a) Univariate ANOVA procedures do not adjust for multiple comparisons due to multiple constituents which can be devastating to the site-wide false positive rate) As such, a site with 10 indicator constituents will have a 40% chance of failing at least one on every monitoring event (USEPA 1992 section 5.2.1).

   (b) ANOVA is more sensitive to spatial variability than contamination. Spatial variability effects mean concentrations but typically not the variance, hence small yet consistent differences will achieve statistical significance. In contrast, contamination effects both variability and mean concentration, therefore a much larger effect is required to achieve statistical significance. In fact, application of ANOVA methods to pre-disposal ground-water monitoring data can result in statistically significant differences between upgradient and downgradient wells, despite the fact that there is no waste in between. The reasons for this are: (a) The overall F-statistic tests the null hypothesis of no differences among any of the wells regardless of gradient (*i.e.*, it will be significant if two downgradient wells are different), and (b) The distribution of the mean of 4 measurements (*i.e.*, four measurements collected from the same well within a six month period) is normal with mean μ and variance $\sigma^2/4$ whereas the distribution of each of the individual measurements is normal with mean μ and variance σ^2. This means that the standard deviation of the mean of four measurements is one-half the size of the standard deviation of the individual measurements themselves. As a result, small but consistent geochemical differences that are invariably observed naturally across a waste disposal facility will be

attributed to contamination. To make matters worse, since there are far more downgradient than upgradient wells at these facilities, spatial variation has a far greater chance of occurrence downgradient than upgradient further increasing the likelihood of falsely concluding that contamination is present. While spatial variation is also a problem for prediction limits and tolerance limits for single future measurements, it is not nearly as severe a problem as for ANOVA since the distribution of the individual measurement is considered and not the more restrictive distribution of the sample mean.

(c) Nonparametric ANOVA is often presented by USEPA as if it protects the user from all of the weaknesses of its parametric counterpart. This is *not* the case. Both methods assume identical distributions for the analyte in *all* monitoring wells. The only difference is that the parametric ANOVA assumes that the distribution is normal and the nonparametric ANOVA is indifferent to what the distribution is. Both parametric and nonparametric ANOVA assume homogeneity of variance, a condition that almost never occurs in practice. This is not a weakness of methods for single future samples (*i.e.*, prediction and tolerance limits) since the variance estimates rely solely on the background data. Why would anyone want to use downgradient data from an existing site (which could be affected by the site) to characterize natural variability? Yet this is exactly what the ANOVA does. Furthermore, ANOVA is not a good statistical technique for detecting a narrow plume that might effect only one of 10 or 20 monitoring wells (USEPA 1992 section 5.2.1).

(d) ANOVA requires the pooling of downgradient data. Specifically, USEPA has suggested that four samples per semi-annual monitoring event be collected (*i.e.*, eight samples per year). As such, on average, it will never most rapidly detect a release, since only a subset of the required four semi-annual samples will be affected by a site impact. This heterogeneity will decrease the mean concentration and dramatically increase the variance for the affected well thereby limiting the ability of the statistical test to detect contamination when it occurs. This is not true for tolerance limits, predic-

tion limits and control charts, which can and *should* be applied to individual measurements. USEPA may like ANOVA because it will appear to be more powerful than prediction and tolerance limits for single future values. The increased power, however, is only realized when all four measurements from a single well are equally affected by the site impact which on average will only occur 25% of the time (*i.e.*, if four semi-annual sampling events are evenly spaced, all four will be impacted by a new release only one in four times). For these reasons, when applied to ground-water detection monitoring, ANOVA will maximize both false positive and false negative rates, and double the cost of monitoring (*i.e.*, ANOVA requires four samples per semi-annual event or eight per year versus a maximum of four quarterly samples per year for prediction or tolerance limits that test each new individual measurement).

To illustrate, consider the data in Table 2 which were obtained from a facility in which no disposal of waste has yet occurred (see Gibbons, 1994 *NSWMA WasteTech Conference Proceedings*, Charleston SC, 1/14/94).

TABLE 2

Raw Data for All Detection Monitoring
Wells and Constituents (mg/l)
This Landfill has no Garbage in it

Well	Event	TOC	TKN	COD	ALK
MW01	1	5.2000	.8000	44.0000	58.0000
MW01	2	6.8500	.9000	13.0000	49.0000
MW01	3	4.1500	.5000	13.0000	40.0000
MW01	4	15.1500	.5000	40.0000	42.0000
MW02	1	1.6000	1.6000	11.0000	59.0000
MW02	2	6.2500	.3000	10.0000	82.0000
MW02	3	1.4500	.7000	10.0000	54.0000
MW02	4	1.0000	.2000	13.0000	51.0000
MW03	1	1.0000	1.8000	28.0000	39.0000
MW03	2	1.9500	.4000	10.0000	70.0000
MW03	3	1.5000	.3000	11.0000	42.0000
MW03	4	4.8000	.5000	26.0000	42.0000
MW04	1	4.1500	1.5000	41.0000	54.0000
MW04	2	1.0000	.3000	10.0000	40.0000
MW04	3	1.9500	.3000	24.0000	32.0000
MW04	4	1.2500	.4000	45.0000	28.0000
MW05	1	2.1500	.6000	39.0000	51.0000
MW05	2	1.0000	.4000	26.0000	55.0000
MW05	3	19.6000	.3000	31.0000	60.0000
MW05	4	1.0000	.2000	48.0000	52.0000
MW06	1	1.4000	.8000	22.0000	118.0000
MW06	2	1.0000	.2000	23.0000	66.0000
MW06	3	1.5000	.5000	25.0000	59.0000
MW06	4	20.5500	.4000	28.0000	63.0000
P14	1	2.0500	.2000	10.0000	79.0000
P14	2	1.0500	.3000	10.0000	96.0000
P14	3	5.1000	.5000	10.0000	89.0000

Results of applying both parametric and nonparametric ANOVA to these predisposal data yielded an effect that approached significance for Chemical Oxygen Demand (COD) ($p < .072$ parametric and $p < .066$ nonparametric) and a significant difference for Alkalinity (ALK) ($p < .002$ parametric and $p < .009$ nonparametric). In terms of individual comparisons, significantly increased COD levels were found for well MW05 ($p < .026$) and significantly increased ALK was found for wells MW06 ($p < .026$) and P14 ($p < .003$) relative to upgradient wells. Of course, these

results represent false positives due to spatial variability, since there is no garbage. What is perhaps most remarkable, however, is the absence of any significant results for TOC, where some of the values are as much as 20 times higher than the others. The reason, of course, is that these extreme values tremendously increase the within-well variance estimate, rendering the ANOVA powerless to detect any differences regardless of magnitude. This is yet another testimonial to why it is environmentally negligent to average measurements from downgradient monitoring wells, a problem that is inherent to ANOVA-type analyses when applied to dynamic ground-water quality measurements. The elevated TOC data are clearly inconsistent with chance expectations and should be investigated. In this case, however, they are likely due to insects getting into the wells since this greenfield facility is in the middle of the Mohave desert.

2. Cochran's Approximation to the Behrens Fisher t-test

   Although no longer required, for years the USEPA RCRA regulation was based on application of the Cochran's approximation to the Behrens Fisher (CABF) t- test. The test was incorrectly implemented by requiring that four quarterly upgradient samples from a single well and single samples from a minimum of three downgradient wells each be divided into four aliquots and treated as if there were $4n$ independent measurements. The net result was that every hazardous waste disposal facility regulated under RCRA was declared "leaking." As an illustration consider the data in Table 3.

TABLE 3

Illustration of pH Data Used in Computing the CABF t-test

Date	Replicate				Average
	1	2	3	4	
Background					
11/81	7.77	7.76	7.78	7.78	7.77
2/82	7.74	7.80	7.82	7.85	7.80
5/82	7.40	7.40	7.40	7.40	7.40
8/82	7.50	7.50	7.50	7.50	7.50
$\bar{X}_B$		7.62			7.62
SD_B		0.18			0.20
N_B		16			4
Monitoring					
9/83	7.39	7.40	7.38	7.42	7.40
$\bar{X}_B$		7.40			7.40
SD_B		0.02			
N_B		4			1

Note that the aliquots are almost perfectly correlated and add virtually no independent information yet they are assumed to be completely independent by the statistic. The CABF t-test is computed as

$$t = \frac{\bar{X}_B - \bar{X}_M}{\sqrt{\frac{S_B^2}{N_B} + \frac{S_M^2}{N_M}}} = \frac{7.62 - 7.40}{\sqrt{\frac{.032}{16} + \frac{.0004}{4}}} = \frac{.22}{.05} = 4.82 \, .$$

The associated probability of this test statistic is 1 in 10,000 indicating that the chance that the new monitoring measurement came from the same population as the background measurements is 1 in 10,000. Note that in fact, the mean concentration of the four aliquots for the new monitoring measurement is identical to one of the four mean values for background, suggesting that intuitively the probability is closer to 1 in

4 rather than 1 in 10,000. Averaging the aliquots, which should have never been split in the first place, yields the statistic

$$t = \frac{\bar{X}_B - \bar{X}_M}{S_B\sqrt{\frac{1}{N_B}+1}} = \frac{7.62 - 7.40}{.20\sqrt{\frac{1}{4}+1}} = \frac{.22}{.22} = 1.0$$

which has an associated probability of 1 in 2. Had the sample size been increased to $N_B = 20$ the probability would have decreased to 1 in 3. It took U.S. EPA six years to recognize this flaw and to change this regulation (see USEPA 1988).

3. Control of False Positive Rate by Constituent

   Site-wide false positive and false negative rates are more important than choice of statistic, nonetheless, certain statistics make it impossible to control the site-wide false positive rate because the rate is controlled separately for each constituent (*e.g.*, parametric and nonparametric ANOVA - see USEPA 1992 section 5.2.1). The only important false positive rate is the one which includes all monitoring wells and all constituents, since any single exceedance can trigger an assessment. This criterion impacts greatly on the selection of statistical method. These error rates are dependent on the number of wells, number of constituents, number of background measurements, type of comparison (*i.e.*, intra-well versus inter-well), distributional form of the constituents, detection frequency of the constituents and the individual comparison false positive rate of the statistic being used. Invariably, this leads to a problem in interval estimation the solution of which is typically a prediction limit that incorporates the effects of verification resampling as well as multiple comparisons introduced by both multiple monitoring wells and multiple monitoring constituents.

4. Restriction of Background Samples

   Certain states have interpreted the Subtitle D regulation as indicating that background be confined to the first four samples collected in a day or a semi-annual monitoring event or a year. The first approach (*i.e.*, four samples in a day violates the assumption of independence and confounds day to day temporal and seasonal variability with potential contamination. As an analogy, consider setting limits on yearly ambient

temperatures in Chicago by taking four temperature readings on July 4th. Say the temperature varied between 75 and 85 degrees on that day yielding a prediction interval from 70 to 90 degrees. As I write this, the temperature in Chicago is -20 degrees. Something is clearly amiss. In the second example of restricting background to the first four events taken in 6 months, the measurements may be independent if ground water flows fast enough, but seasonal variability is confounded with contamination. The net result is that comparisons of background water quality in the summer may not be representative of point of compliance water quality in the winter (*e.g.*, disposal of road salts increasing conductivity in the winter). In the third example in which background is restricted to the first four quarterly measurements, independence is typically not an issue and background versus point of compliance monitoring well comparisons are not confounded with season. However, as previously pointed out in the site-specific illustration, restriction of background to only four samples dramatically increases the size of the statistical prediction limit thereby increasing the false negative rate of the test (*i.e.*, the prediction limit is over five standard deviation units above the background mean concentration). The reason for this is that the uncertainty in the true mean concentration covers the majority of the normal distribution. As such we could obtain virtually any mean and standard deviation by chance alone. If by chance the values are low, false positive results will occur. If by chance the values are high, false negative results will occur. By increasing the background sample size, uncertainty in the sample based mean and standard deviation decrease as does the size of the prediction limit, therefore both false positive and false negative rates are minimized. Furthermore, use of statistical outlier detection procedures applied to the background data will remove the possibility of spurious background results falsely inflating the size of the prediction limit.

F. Results of Application at the Woodland Meadows - North Landfill

In the following, results of site-specific analysis of the existing monitoring program are described.

1. Monitoring Well Network

   A list of upgradient and downgradient monitoring wells are provided in the following Table.

Current Upgradient and Downgradient Monitoring Wells

Upgradient	Downgradient
None	MW-6R
	MW-7R
	MW-12R
	MW-14
	MW-15
	MW-24R
	MW-46W
	MW-50
	GA-31B
	GA-32C
	GA-33C
	GA-34A
	GA-35A
	GA-36A

Note that for this site we have selected intra-well comparisons because of the presence of a ground-water divide within the site boundary, such that there is no upgradient area that can be used as a proper background.

A list of the constituents used in the analysis is provided in the following Table.

Constituents used in the Analysis

Constituent
Sodium
Potassium
Calcium
Magnesium
Iron
Ammonia Nitrogen
Total Phenolics
Sulfate
Alkalinity (bicarbonate)
Chloride
Total Cyanide
Appendix I VOCs

2. Intra-well Comparisons

In general, given (1) the presence of spatial variability, (2) the absence of any detected volatile organic compounds (which are present in large concentrations in the facility's leachate) and (3) the absence of any significant trend in historical concentrations, intra-well comparisons are the method of choice. Combined Shewhart-CUSUM control charts are displayed graphically for all wells and constituents in Appendix A. Summary statistics and intermediate computations are displayed in Table 1 of Appendix A.

In terms of statistical specifications, background was defined as all data from 1998 through 2000. These more recent data were used as a background to eliminate trends in the data produced by changes in groundwater quality induced by a drastic lowering of the head in the aquifer caused by a nearby construction de-watering project. By going back to the begining of 1998, we have a sufficient background sample size for a meaningful statistical analysis for most constituents. There are fewer than eight background measurements available for a few wells and constituents. In these cases, additional background data should be obtained prior to running statistics. Until sufficient data are available (*i.e.*, a minimum of eight samples per well), data for these wells and constituents should be displayed graphically.

A control chart factor of 5.0 in conjunction with a pass 1 of 2 resampling plan was required to produce a site-wide false positive rate of less than 10% (see Gibbons, 1999). For constituents with detection frequencies less than 25%, nonparametric prediction limits were used. Given the pass 1 of 2 resampling plan, the nonparametric prediction limit provides 99% confidence with eight background samples.

All wells and constituents were automatically tested for trend using Sen's nonparametric test prior to analysis. Very gradual trends were noted for bicarbonate in well GA-32C, chloride in well MW-14, iron in well MW-6R, and for potassium in well GA-34A. No exceedances of control limits were found.

3. Statistical Power

   Statistical power curves for the facility-wide false positive and false negative rates are presented at the end of the Appendix. For intra-well comparisons the false positive rate is 8% and the test becomes sensitive to 3 standard deviation unit increases over background (*i.e.*, power of 80%).

4. VOCs

   Historical detections of all Appendix I VOCs are displayed at the end of the Appendix. No VOCs have been recently detected.

5. Summary

Intra-well comparisons revealed no statistically significant exceedance for any well or constituent. No VOCs have been detected since 1993. In light of these results we propose to perform intra-well comparisons using combined Shewhart-CUSUM control charts for routine detection monitoring at this facility. At this point, background should be fixed for a period of two years and reupdated at that time for all wells that have not exhibited a verified exceedance. This process will continue for the life of the facility. Once eight background samples are available for those wells and constituents with fewer than eight background samples, control limits should be computed and added to the monitoring program.

Some Relevant Literature

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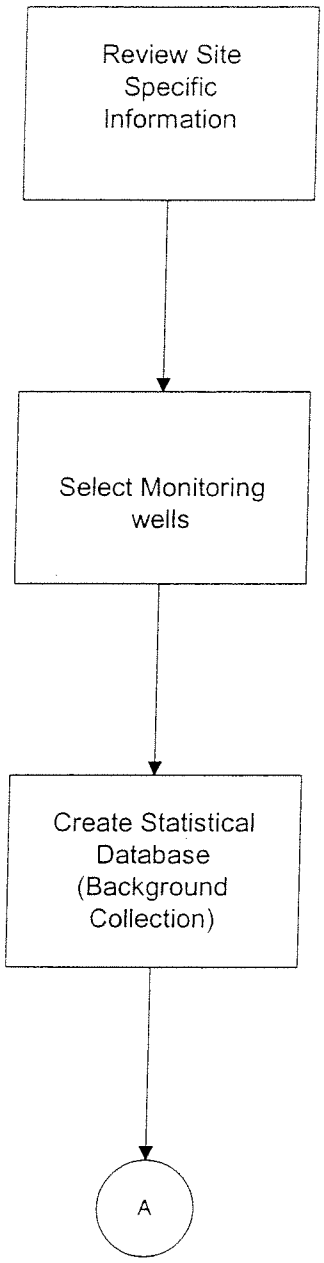
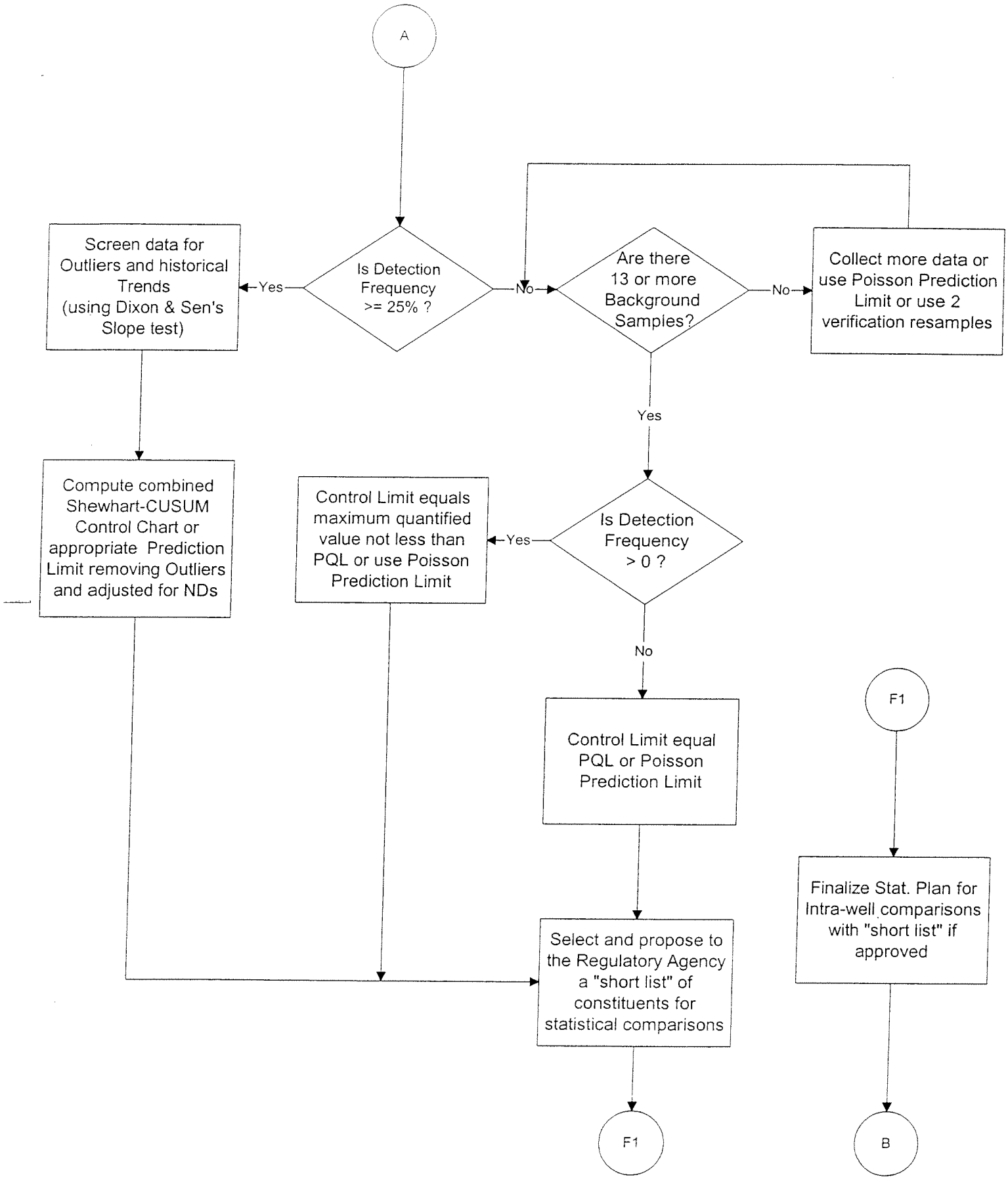
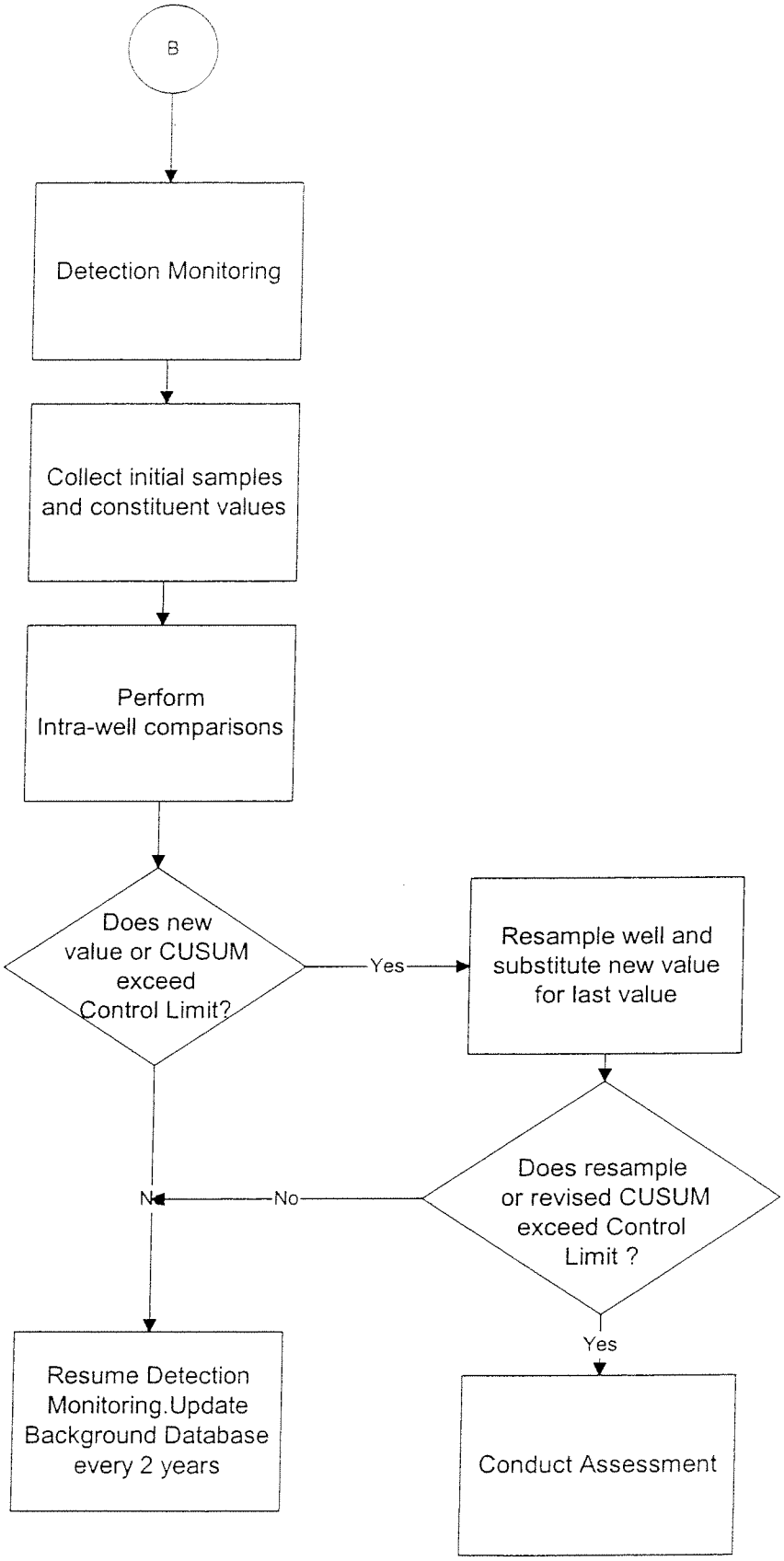
Development of an Intra-well Statistical Detection Monitoring Plan




A
Is Detection Frequency >= 25% ?
Yes
No
Screen data for Outliers and historical Trends (using Dixon & Sen's Slope test)
Are there 13 or more Background Samples?
No
Collect more data or use Poisson Prediction Limit or use 2 verification resamples
Yes
Compute combined Shewhart-CUSUM Control Chart or appropriate Prediction Limit removing Outliers and adjusted for NDs
Is Detection Frequency > 0 ?
Yes
Control Limit equals maximum quantified value not less than PQL or use Poisson Prediction Limit
No
Control Limit equal PQL or Poisson Prediction Limit
Select and propose to the Regulatory Agency a "short list" of constituents for statistical comparisons
F1
F1
Finalize Stat. Plan for Intra-well comparisons with "short list" if approved
B


B
Detection Monitoring
Collect initial samples and constituent values
Perform Intra-well comparisons
Does new value or CUSUM exceed Control Limit?
Yes
Resample well and substitute new value for last value
Does resample or revised CUSUM exceed Control Limit ?
No
Yes
Resume Detection Monitoring.Update Background Database every 2 years
Conduct Assessment