

Variance from Classification as a Waste Application

AMG Vanadium LLC
Zanesville, Ohio

U.S. EPA ID No. OHR000212902
November 1, 2019, Rev. 0

PUBLIC VERSION
(ORC 3704.08; OAC 3745-49-03)



Prepared by:



Cover Letter

Cover Letter



November 1, 2019

Director of Ohio EPA
Attn: Brad Mitchell
Ohio EPA – Division of Environmental Response and Revitalization
50 West Town Street, Suite 700
Columbus, Ohio 43215

**RE: Application for a Variance from Classification as a Waste, AMG Vanadium LLC,
Zanesville, Ohio, EPA ID No. OHR000212902**

**PUBLIC VERSION
(ORC 3704.08; OAC 3745-49-03)**

Dear Brad:

AMG Vanadium LLC ("AMG") has facilities located at 60790 Southgate Road in Cambridge, Ohio and 3400 East Pointe Drive in Zanesville, Ohio. AMG is a catalyst reclaimer and produces ferrous and non-ferrous metal products. AMG utilizes secondary materials, including Reclaimed Catalyst, as raw materials in its manufacturing process for the production of Roasted Catalyst, Ferrovan[®] (a ferrovanadium alloy), FeNiMoly[®] (an iron nickel molybdenum alloy), Revan[™] (a synthetic slag for steel manufacturing) and saleable Process Residuals. AMG's Cambridge Facility maintains a Variance from Classification as a Waste ("Variance"). The Variance exempts from the definition of solid waste K171 and K172 at the Cambridge Facility. Provided herein is an Application for a Variance to exempt from the definition of solid waste K171 and K172 at the Zanesville Facility.

It should be noted that there is a great deal of technical knowledge associated with AMG's process, that if acquired by others could do great damage to AMG's economic model. AMG is also sharing information related to its contracting process that could damage the Company if released. AMG therefore requests that the discussions of these processes and contracts are handled as highly confidential trade secrets and confidential business information. Confidential information within this coverletter and attached Application is identified as such.

Applicability per OAC 3745-50-24(C)

AMG has determined its applicability for this Variance based on the following factors:

- a. The degree of processing the material has undergone and the degree of further processing that is required:¹
- i. The metals of interest to the Applicant are vanadium, nickel and molybdenum. Some or all of these occur in crude oils and oil sands at parts per million levels, with the exact concentration dependent on the oil source.
 - ii. The metals are partially reclaimed from the oil during the upgrading or refining process so that they are present at the percent level in the catalyst. The catalyst is then substantially partially reclaimed outside of the refining process to reclaim crude oil producing Reclaimed Catalyst. The Reclaimed Catalyst will be shipped to the Zanesville Facility for further reclamation.² Once at the Zanesville Facility, the Reclaimed Catalyst will be reclaimed further in Applicant's proprietary process as the raw material to produce the products Roasted Catalyst, Ferrovan[®], FeNiMoly[®], and Revan[™].³
 - iii. Reclaimed Catalyst will be delivered to the Zanesville Facility primarily in bulk railcars or truck. This material will then, as demand requires, be transported to storage areas in a Raw Material Storage Building (RMSB) by heavy equipment, or transported directly to the Roaster feed hoppers without prior storage in a RMSB. The Reclaimed Catalyst may also be loaded into a truck or railcar for transport to the Cambridge Facility for further reclamation. Once in the Roaster feed hoppers, the Reclaimed Catalyst will be transferred to the Roaster by enclosed conveyor, where it is roasted. The roasting process is primarily to convert the metal sulfides in the Reclaimed Catalyst to metal oxides and to reduce the amount of carbon in the material. The Roasted Catalyst will exit the bottom of the Roaster where it may be screened to remove oversize material. The Roasted Catalyst may be transported by enclosed conveyor to the silo system that blends feed for the electric arc furnaces (EAFs), discharged to an enclosed truck for transport to the Cambridge facility for further reclamation, discharged to an enclosed truck for transport to the EAF Feed Building for later loading into the silo system, or packaged for sale. The Roasted Catalyst will be sold as a Product or blended with other raw materials for processing in the EAFs. The blended material will be transferred to the furnace room and then fed through the furnace feed hoppers to the EAFs for

¹ AMG will require specific proof of the degree of processing the material has undergone prior to executing any contract with a potential new source of Reclaimed Catalyst.

² Reclaimed Catalyst will be processed through a Roaster to convert metallic sulfides to metallic oxides. The Roasted Catalyst will no longer exhibit the properties of Reclaimed Catalyst having been both chemically and physically changed.

³ The refineries perform an oil recovery step whereby they recover valuable oil product prior to shipping the Catalyst to AMG for further reclamation.

the melting process. The EAFs will generate ferrovanadium alloy, Ferrovan[®], as the major product as well as two co-products; Revan[™], which will be sold as a metallurgical slag for steelmaking, and FeNiMoly[®], which will be sold based on its metal content. Intermediate product Slag will also be generated, which will be re-processed through the EAFs into one of these three Products or can be sold.

- b. The value of the material after it has been reclaimed:
 - i. The Reclaimed Catalyst is of significant economic value due to its vanadium, nickel and molybdenum content. The Applicant enters into long term contractual purchase agreements with suppliers to ensure its supply of this raw material feedstock. Applicant will purchase the Reclaimed Catalyst based upon the market price of the vanadium, nickel and molybdenum contained in the catalyst.
 - ii. The Applicant will further process the catalyst to produce four Products. As demonstrated by the Cambridge Facility, three of the Products are used in the iron and steelmaking industry. Ferrovan[®] is a ferro-vanadium alloy that is used to make steel stronger which can result in lighter structural steel components. FeNiMoly[®] alloy is used to make stainless steel. Revan[™] is used as a fluxing agent in the steelmaking industry. The Roasted Catalyst is utilized as a raw material for its metal value and can be processed or sold for the purpose of metals reclamation.
 - iii. The significant economic value of the Roasted Catalyst, Ferrovan[®], FeNiMoly[®] and Revan[™] will be determined by market conditions and in the case of the ferroalloys, the content of vanadium, nickel and molybdenum contained within them. The value of these metals has risen with increased global demand and a shortage of vanadium bearing raw materials. Applicant is the last domestic source of ferrous and non-ferrous vanadium products available to the American steel industry.
- c. The degree to which the Reclaimed Catalyst is like an analogous raw material:
 - i. The Reclaimed Catalyst is valuable to the Applicant for its vanadium, nickel, and/or molybdenum content with vanadium being of primary interest to the Applicant. The Reclaimed Catalyst is a viable substitute for vanadium containing ore. Vanadium containing ore deposits contain less than 1 percent vanadium pentoxide (approximately 0.5 percent vanadium) and are often much lower. The vanadium content of the Reclaimed Catalyst will vary but will typically be greater than 1.5 percent vanadium and often between 7 and 10 percent.

- ii. There are no domestic sources of vanadium bearing ore, although uranium ore bodies located in Utah and Colorado do contain vanadium at approximately 0.75 percent. The most extensive ore sources are located in South Africa, Brazil, Russia and China.
- d. The extent to which an end market for the Reclaimed Catalyst is guaranteed:
 - i. The end market for the Reclaimed Catalyst is guaranteed as Applicant requires the Reclaimed Catalyst to produce its valuable Products. Applicant enters into long term contractual purchase agreements with petroleum refineries to ensure a continuous supply of Reclaimed Catalyst.
 - ii. Applicant's Products have a guaranteed saleable market as demonstrated by its sales history, known customers, and expanding demand for Applicant's final products Reclaimed Catalyst, Ferrovan[®], FeNiMoly[®] and Revan[™].
 - iii. As demonstrated by the Cambridge Facility, Applicant's products are sold for use in the metals industry including, but not limited to, the steelmaking industry. Ferrovan[®] is an iron and vanadium alloy that is used to make steel stronger allowing for production of lighter structural components. FeNiMoly[®] is an alloy used to make stainless steel. Revan[™] is used as a fluxing agent in the steelmaking industry. Roasted Catalyst is a metal bearing feedstock that is reclaimed for its metals value.
- e. The extent to which the reclaimed material is handled to minimize loss:
 - i. The Application includes narrative information and attachments regarding the management and processing of Reclaimed Catalyst and other materials.⁴ To ensure the proper handling of Reclaimed Catalyst and other materials, the Applicant will maintain and implement the following: Contingency Plan, Inspection Program, Training Program, site security, and safety plan. Proper handling of Reclaimed Catalyst and other materials will also be ensured through the Applicant's procedures related to the use and management of containers and operation of a RMSB.

⁴ Reclaimed Catalyst is a valuable raw material for the Applicant and is, therefore, handled to minimize loss. AMG purchases this Raw Material based upon the market price of the vanadium, nickel and molybdenum contained. The current market price (which is subject to significant market fluctuation) of vanadium is over \$15 per pound. AMG has invested over \$75,000,000 in buildings, grounds and equipment at its Cambridge Facility to support the responsible management of Reclaimed Catalyst as a raw material. The Zanesville Facility is of similar design and represents an investment of approximately \$300,000,000. At the Zanesville facility, like the Cambridge Facility, Reclaimed and Roasted Catalyst will be contained in enclosed conveyors, covered transport or in buildings in order to minimize loss.

- ii. Site security will be achieved through procedures that include fencing, gates, signage, access keycards, and a security guard that will be present twenty-four (24) hours per day.
- iii. The Training Program ensures that all personnel involved with the handling of Reclaimed Catalyst and other materials receive initial and periodic classroom instruction and on-the-job training such that duties are performed correctly. The Training Program also includes various health and safety aspects.
- iv. The Inspection Program consists of a procedural system for the inspection of communications and alarm systems, fire protection equipment, spill control equipment, and decontamination equipment. The Inspection Program is also meant to determine the malfunction or deterioration of equipment and structures, operator errors, and discharges of Reclaimed Catalyst and other materials that could pose a threat to human health and the environment.
- v. The Contingency Plan is designed to minimize hazards to human health and the environment from emergencies which include fires, explosions, severe weather, floods, power outages, or releases of Reclaimed Catalyst and other materials.

AMG believes its current compliance with these factors at the Cambridge Facility and future compliance with these factors at the Zanesville Facility adequately demonstrates that the K171/172 catalyst ceases being a waste once it is Accepted at Facility for further reclamation and processing.

AMG Contract Information Requested by Ohio EPA
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****Information redacted****

Process Residual Information Requested by Ohio EPA

AMG makes every effort to establish sales outlets for each of its Process Residuals which has resulted in over 99% conversion of incoming raw material to saleable goods at the Cambridge Facility. A similar conversion rate is anticipated for the Zanesville Facility.

LimeAdd™ is a commercially valuable Product and is used to solidify sludges generated by the oil and gas industry, prior to disposal of the sludges. Samples of LimeAdd™ will be collected daily when the Circulating Dry Scrubber (CDS) is operating. From these samples a composite will be generated at least quarterly and tested using the Toxicity Characteristic Leachate Procedure

("TCLP") for metals. At the Cambridge Facility, LimeAdd™ consistently passes TCLP. LimeAdd™ has, in AMG's history, been sent to a landfill; however, infrequently since the customer base has been established.

Dust to be generated from the secondary EAF baghouse will be a commercially valuable Product for solidifying oil and gas sludges. Each lot of secondary EAF baghouse dust will be TCLP tested for metals, which at the Cambridge Facility has occasionally failed. If the material fails TCLP, the lot of it will be disposed as hazardous waste. Lots that pass TCLP will be sold for commercial use.

Dust to be collected in the cyclone serving the primary EAF has commercial value for its metals content and will typically be recycled into AMG's process. Periodically, AMG may sell or dispose some of the dust. In these circumstances, the lots will be TCLP tested for metals. If the material fails TCLP, the lot will be recycled on-site or disposed as hazardous waste. Lots that pass TCLP may be sold for commercial use (typically for the same uses as Secondary EAF baghouse dust) or disposed as non-hazardous waste.

Free Liquid, which includes Free Oil that readily separates from the Reclaimed Catalyst, at the Zanesville Facility will be collected from a RMSB and sent to third party oil recyclers. TCLP testing has been performed on similar material at the Cambridge facility and it consistently passes.

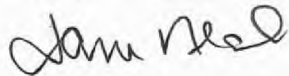
The secondary EAF will generate calcium-aluminate slag, which AMG will market as Revan™. Samples of Revan™ will be collected daily when the melting process is in operation. From these samples, a composite will be generated and tested at least quarterly using TCLP for metals, which Revan™ consistently passes at the Cambridge Facility. Revan™ has not been disposed at the Cambridge Facility.

Additional information and discussion regarding AMG's Process Residuals is provided within the enclosed Variance renewal application.

If you have any questions or require additional information, please contact Jane Neal of AMG at 740-435-4608.

I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations.

Respectfully Submitted,



Jane Neal
Senior Vice President

Attachments

cc: Emily Deshaies, Ohio EPA SEDO
Nick Petruzzi, Cox-Colvin & Associates, Inc.
David Edelstein, Vorys

COVER LETTER SUPPLEMENTAL INFORMATION

Redacted

PUBLIC VERSION
(ORC 3704.08; OAC 3745-49-03)

Master Table of Contents and Definitions

Master Table of Contents
and Definitions.

Variance Application – Master Table of Contents
PUBLIC VERSION
(ORC 3704.08; OAC 3745-49-03)

Coverletter (Public Version Redacted)

Supplemental Information (Public Version Redacted)

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Variance Renewal Application – Definitions

Unless otherwise stated, all terms used in this Variance shall have the same meaning as defined in ORC Chapter 3734 and the rules promulgated thereunder. Whenever the terms listed below are used in this Variance, the following definitions shall apply:

- a. “Accepted at Facility” shall mean that time when Reclaimed Catalyst is within the Facility security fence.
- b. “Applicant” shall mean AMG Vanadium LLC.
- c. “Application” shall mean the responses to the criteria listed in OAC rule 3745-50-24(C) and supporting documents for a Variance submitted by Applicant on November 2, 2019.
- d. “Baghouse Dust or Cyclone Dust” is a Process Residual that is generated from the electric arc furnaces and collected in a baghouse or cyclone.
- e. “Cambridge Facility” shall mean the metals reclamation site at 60790 Southgate Road in Cambridge, Ohio 43725 and all contiguous, land, and structures used for storing and processing Reclaimed Catalyst or storing Roasted Catalyst.
- f. “Circulating Dry Scrubber” or “CDS” is a Flue Gas Desulfurization (FGD) unit that utilized dry hydrated lime to react with acid gases, specifically sulfur dioxide (SO₂) in the combined offgas from the Roaster and Primary Electric Arc Furnace (Primary EAF). The product of the reaction of the hydrated lime and acid gases is LimeAdd™.
- g. “EAF Feed Building” is a building at the Facility where Roasted Catalyst is stored or blended prior to processing in the electric arc furnaces. Reclaimed Catalyst is not placed in the EAF Feed Building.
- h. “Emergency Spill” is defined as any on-site release of Reclaimed Catalyst that could result in or pose an imminent danger which requires prompt action to mitigate or minimize the impact of the incident on human health or the environment; or any release that Applicant is required to report to Ohio EPA’s Spill Hotline or the National Response Center.
- i. “Facility” or “Zanesville Facility” or “Company” shall mean the metals reclamation site at 3400 East Pointe Drive in Zanesville, Ohio and all contiguous, land, and structures used for storing and processing Reclaimed Catalyst or storing Roasted Catalyst.

- j. “Free Liquid” means liquids which readily separate from the solid portion of a material under ambient temperature and pressure. Free Oil that runs off from Reclaimed Catalyst is considered Free Liquid.
- k. “Free Oil” means the residual oil that coats the Reclaimed Catalyst until the Reclaimed Catalyst is processed through the Roaster.
- l. “Incidental Spill” is a release of Reclaimed Catalyst that may occur within the Facility boundaries and which does not pose an imminent danger to human health and the environment.
- m. “K171/K172” means spent hydrotreating or hydrorefining catalyst from petroleum refining operations that is classified as a hazardous waste under Ohio EPA’s hazardous waste rules.
- n. “LimeAdd™” is a Process Residual that is generated in the Circulating Dry Scrubber baghouse when lime is allowed to react with sulfur dioxide in the flue gas desulfurization unit. It consists of calcium sulfite, calcium sulfate, unreacted lime, and flyash.
- o. “Products” shall include but not be limited to Roasted Catalyst, calcium aluminate additive (Revan™), slabs containing iron, nickel and molybdenum (FeNiMoly®) and ferrovanadium alloy (FeroVan®).
- p. “Process Residuals” are not listed hazardous waste K171 or K172 and means those secondary materials generated from the processing and management of Reclaimed Catalyst and Roasted Catalyst including but is not limited to LimeAdd™, EAF Cyclone Dust, EAF Baghouse Dust, Free Liquid, Slag, water that has come in contact with Reclaimed Catalyst or other Process Residuals, and vehicle wash water.
- q. “Railcar Unloading Area” consists of the following units: railcar conveyor systems, railcar canopy and gangway, containment and conveyor area pad, truck pan system, truck loading pad, roll-off box or truck, double-walled above ground storage tank for Free Liquid, and optional storm water oil/water separator.
- r. “Raw Material Storage Building” or “RMSB” is a containment building as defined in OAC rule 3745-50-10 at the Facility where Reclaimed Catalyst is stored and/or blended prior to processing in the Roaster.
- s. “Reclaimed Catalyst” means K171/K172 containing vanadium, nickel, and/or molybdenum that has been Accepted at the Facility and has been reclaimed to recover crude oil prior to the catalyst being shipped to the Applicant for further metals recovery.

- t. “Roasted Catalyst” means the Reclaimed Catalyst that has been processed through a Roaster and is further processed as a raw material to reclaim its metal values.
- u. “Roaster” for the purposes of inspections means the roaster feed hoppers, conveyor systems, roaster, Circulating Dry Scrubber and baghouse, and LimeAdd™ silo.
- v. “Slag” is a Process Residual that is generated in the electric arc furnaces, along with Products.

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Attachment 1

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Attachment 2

Use and Management of Containers

Attachment 2
Containers

Attachment 2
Use and Management of Containers
Revision 0

November 1, 2019

Submitted to:

AMG Vanadium LLC
3400 East Pointe Drive
Zanesville, Ohio 43701
EPA ID No. OHR000212902

Submitted by:

Cox-Colvin & Associates, Inc.
7750 Corporate Blvd.
Plain City, Ohio 43064
(614) 526-2040



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I.0 Use and Management of Containers

This attachment describes the use and management of regulated waste storage containers at the Facility.

I.1 Condition of Containers

Reclaimed Catalyst is typically delivered to the Facility primarily in bulk railcars or truck and stored in bulk. However, Reclaimed Catalyst may also be delivered, containerized as non-bulk, by either rail or road and in these instances would be received in 55-gallon drums (steel construction, 95% usable volume), up to 30-yd³ steel roll-off containers (steel construction, dimensions approximately 2 yd by 10 yd by 1.5 yd high, approximately 90% usable volume), 4-yd³ flow bins (steel construction, dimensions approximately 2yd by 2yd by 1 yd high, 90% usable volume) or 2.3-yd³ super sacks (woven polypropylene construction, dimensions approximately 1.3 yd by 1.3 yd by 1.3 yd high, 100% usable volume). Other types of containers not specifically identified herein may also be received and utilized. In the instances of container delivery, the material would be weighed and staged for less than 48 hours prior to being transferred into a RMSB or other designated area for container storage.

In receiving Reclaimed Catalyst, the Company utilizes standard receiving procedures that satisfy ISO 9001 quality requirements, ISO 14001 environmental requirements, and OHSAS 18001 safety requirements. These procedures are included in the Waste Analysis Plan (Attachment 7).

Containers received in all shipments of Reclaimed Catalyst will be inspected upon arrival at the Facility. If a container holding Reclaimed Catalyst outside of a RMSB is not in good condition (e.g., severe rusting, apparent structural defects, etc.) or if it begins to leak, the Company will transfer the waste to a container that is in good condition or manage the waste in some other manner. All containers at the Facility which are not empty and are used to store Reclaimed Catalyst outside of a RMSB will be inspected as indicated in the inspection matrix presented in Attachment 5.

I.2 Container Storage Areas

Depending on the disposition of the material, containers may be stored at various designated areas, including a RMSB.

RMSB #4 is approximately 50,900 ft² and consists of wet and dry storage that may be used for storing containers or bulk piles of Reclaimed Catalyst and other materials received or

generated by the Company. Construction details of RMSB #4 are described in Attachment 3. Future RMSB #5 is approximately 50,900 ft² and consists of wet and dry storage that may be used for storing containers or bulk piles of Reclaimed Catalyst and other materials received or generated by the Company

Any liquid that accumulates within a RMSB will be identified per the Inspection Program (Attachment 5) and collected to prevent overflow of the collection system. The liquid would be pumped into drums, totes, tanks, or other containers or solidifying agent would be added to the pad itself and solidified material would be removed from the pad. In either case, the liquid or solidified material would be incorporated into the manufacturing process for the production of ferrovanadium alloy. Alternatively, accumulated liquid may be disposed or recycled offsite. Analysis, if necessary, would be performed according to the Waste Analysis Plan (Attachment 7).

Maximum design capacity for container storage within RMSB #4 is 6,600 cubic yards. Maximum design capacity for container storage within future RMSB #5 is 6,600 cubic yards. Containers include, but are not limited to, a combination of super sacks, drums, flow bins, and rolloff boxes.

I.3 Staging Areas

Containers shipped via truck would be unloaded and staged in a RMSB or other designated unloading area pending sampling and acceptance of the Reclaimed Catalyst. The containers would then be moved to a specified location within a RMSB or other designated area.

I.4 Less than 90 Day Storage Areas

The Company may designate one or more less than 90 day storage areas. The hazardous wastes placed in these areas are stored for less than 90 days. In most cases the hazardous wastes stored at these locations will be free of liquids, since they have been processed at very high temperatures.

I.5 Compatibility of Waste with Containers

Drums, roll-off containers, and flow bins used to store hazardous waste will be constructed of carbon steel or stainless steel. Carbon steel and stainless steel are compatible with the waste and have been shown to work well for the intended purpose so liners are not required, although they may be used. Other types of containers, if used, would be assessed for compatibility with the waste on a case by case basis and based on the manufacturer's recommendations. These may need to be lined or treated, dependent on the exact chemical composition of the waste. Containers of Reclaimed Catalyst stored outside of a RMSB will

be required to be in sufficiently good condition to avoid leakage, irrespective of whether they are new, used or reconditioned.

I.6 Management of Containers

Containers of Reclaimed Catalyst stored outside of a RMSB will remain closed or covered at all times except when it is necessary to add or remove, transfer, or obtain samples. Such containers will not be opened, handled, or stored in a manner that may rupture the container or cause it to leak.

All containers containing Reclaimed Catalyst will be properly labeled. If outside of a RMSB, roll off boxes will be closed with a tarp; drums covered with a lid; totes kept closed; super sacks tied closed; and other metal boxes covered with a custom-made closure. Other types of containers may be accepted and utilized, which are not specifically identified herein.

Roll-off containers are moved throughout the Facility using a specialized truck designed for this purpose. Drums, flow bins, and super sacks can be moved throughout the Facility on pallets using a forklift or individually using other equipment such as a backhoe, skid loader, lift truck, or front end loader. Containers of Reclaimed Catalyst must be covered when moved about the Facility or when being used for storage if outside of a RMSB.

The Company will maintain adequate aisle space to allow for inspection of all Reclaimed Catalyst containers and the unobstructed movement of emergency personnel, fire protection equipment, spill control equipment, and decontamination equipment. A minimum of 3 feet will be maintained between rows of Reclaimed Catalyst containers.

Containers will be emptied of Reclaimed Catalyst prior to rinsing or disposal. Once empty, pursuant to the RCRA definition described below, any residue or rinsate within the container can be considered non-regulated for RCRA purposes. Continual care must be taken, however, to prevent uncontrolled sudden releases of waste constituents to the environment. Such releases will continue to be subject to provisions of the other environmental statutes such as RQ determination and discharge limitation. In accordance with OAC 3745-51-07, a container that has held hazardous waste is considered empty if it meets the following criteria:

- All material has been removed that can be removed using the practices commonly employed to remove materials from that type of container (e.g., pouring, pumping, tipping, etc.).
- No more than 1 inch of residue remains on the bottom of the container or inner liner.

- No more than 3 percent by weight of the total capacity of the container remains in the container or inner liner if the container is less than or equal to 110 gallons in size.
- No more than 0.3 percent by weight of the total capacity of the container remains in the container or inner liner if the container is greater than 110 gallons in size.

Table 2-1 presents a summary of the RCRA definition as it relates to empty containers.

TABLE 1. RCRA DEFINITION OF AN EMPTY CONTAINER

Type of Container	Total Capacity* (lb)	Residual Material That Can Remain in an Empty Container (lb)
30-yd ³ roll-off container	60,000	180
55-gal drum	500	16
4-yd ³ flow bin	8,000	24
2.3-yd ³ super sack	4,600	13.8

*Total container capacities are approximate. Actual capacities are dependent on the density of the material stored in the container. Other container types not specifically identified above may be utilized.

I.7 Inspection of Containers

Containers holding Reclaimed Catalyst will be inspected as necessary for deterioration or damage, labeling and closure. Spare containers will be readily available to accept Reclaimed Catalyst from damaged containers. Any container of Reclaimed Catalyst stored outside of a RMSB that is found to be in poor or suspect condition will be immediately taken out of service and the waste transferred to a container in good condition. The defective container will be destroyed or disposed of in a suitable manner. Inspection will be completed by personnel trained in accordance with the Training Program presented in Attachment 6.

I.8 Containment System

Free Liquid may be present in containerized material at the Facility that has not been subject to thermal treatment; therefore, RMSBs are equipped with a dual containment system. The design and operation of the containment system is described in Attachment 3.

The Roaster operates at temperatures in excess of 1500 degrees Fahrenheit. After roasting, the chemical and physical properties of the Reclaimed Catalyst have changed, sulfur and carbon have been significantly reduced and moisture has been reduced to 1 percent or less, basically generating dry pellets.

I.9 Special Requirements for Ignitable, Reactive, or Incompatible Reclaimed Catalyst

Containers used to store ignitable or reactive Reclaimed Catalyst will be located at least 50 feet from any property line. Incompatible Reclaimed Catalyst will not be placed in the same container or placed in an unwashed container that previously held an incompatible waste. A storage container holding a Reclaimed Catalyst that is incompatible with any other waste will be separated from the other material or protected by means of a dike, berm, wall, or other device. All Reclaimed Catalyst accepted by the Company are compatible; therefore, no special precautions are needed for incompatible waste.

The Company takes the following precautions to prevent accidental ignition or reaction of ignitable or reactive Reclaimed Catalyst. This Reclaimed Catalyst shall be separated and protected from sources of ignition or reaction including but not limited to: open flames, smoking, cutting and welding, hot surfaces, frictional heat, sparks (static, electrical, or mechanical), spontaneous ignition (e.g., from heat-producing chemical reactions), and radiant heat. In this way reactions which generate extreme heat or pressure, fire or explosion or violent reaction is avoided. Reclaimed Catalyst will not produce uncontrolled mists, fumes, dusts or gases in sufficient quantities to threaten human health or the environment or pose a risk of fire or explosion. This information is detailed in the Company's Hot Work Permit Procedure.

While ignitable or reactive Reclaimed Catalyst is being handled, the Company shall confine smoking and open flame to specially designated locations. "No Smoking" signs shall be conspicuously placed wherever there is a hazard from ignitable or reactive Reclaimed Catalyst. These signs are posted at the Railcar Unloading Area on conveyors that transport Reclaimed Catalyst and at RMSBs.

In addition, portable fire extinguishers are located throughout the Facility (see the Contingency Plan, Attachment 8) to be used if necessary. Once Reclaimed Catalyst has been roasted, oxidation is essentially complete, so the materials are neither pyrophoric nor flammable.

I.10 Removal and Decontamination

Removal and decontamination procedures associated with RMSBs will be performed in accordance with the Company's Removal and Decontamination Plan in Attachment 4.

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Attachment 3

Containment Building

Attachment 3
Containment Building

**Attachment 3
Containment Building
Revision 0**

November 1, 2019

Submitted to:

AMG Vanadium LLC
3400 East Pointe Drive
Zanesville, Ohio 43701
EPA ID No. OHR000212902

Submitted by:

Cox-Colvin & Associates, Inc.
7750 Corporate Blvd.
Plain City, Ohio 43064
(614) 526-2040



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3-1	Raw Material Storage Building #4 General Layout
3-2	Raw Material Storage Building #4 Dual Containment System Cross Section
A2.0	Raw Material Storage Building #4 Design Drawing
EC1.0	Raw Material Storage Building #4 Design Drawing
EC2.0	Raw Material Storage Building #4 Design Drawing
S1.0	Raw Material Storage Building #4 Design Drawing

Appendices

A	Certifications for Raw Material Storage Building #4 [forthcoming after construction]
B	Liner Inspection and Testing Records for Raw Material Storage Building #4 on CD [forthcoming after construction]

I.0 Containment Building

There is one containment building (RMSB #4) and one future containment building (RMSB #5) at the Facility, where Reclaimed Catalyst and other materials are stored in bulk piles prior to being processed. In addition to bulk piles, various containers which contain Reclaimed Catalyst may also be stored in a RMSB (see Attachment 2 for a description of containers). RMSBs not used to serve as a secondary containment system for tanks placed within the buildings so the requirements of OAC 3745-55-93 do not apply. Design and construction details, inspection, and removal and decontamination of RMSBs are discussed below.

I.1 RMSB #4 Design and Construction

RMSB #4 is located to the east of the Roaster and the Main Mill Building that houses the electric arc furnaces. The design and construction of RMSB #4 meets the requirements of OAC 3745-205-101 for containment and storage of both wet and dry materials. The footprint of RMSB #4 is approximately 35,000 ft² with a total design storage capacity of approximately 6,600 yd³. In general, the floor plan includes five storage bin areas. RMSB #4 also has a dual containment system that includes a primary and secondary liner. The dual containment system was placed upon a foundation capable of providing support to the liners and resistance to pressure gradients above and below the liners to prevent failure due to settlement, compression, or uplift. A Free Liquid drainage layer and collection system was installed immediately above each liner, and is designed, constructed, maintained, and operated to collect and remove Free Liquid and to function without clogging throughout the operational life of RMSB #4. The design and construction of RMSB #4 is described below, with references to Figures 3-1, 3-2, A2.0, EC1.0, EC2.0, and S1.0, as appropriate.

Reclaimed Catalyst unloaded from bulk railcars is transported by covered heavy equipment to RMSB #4 through the equipment entrance door or loaded directly into covered trucks for transport to the Cambridge Facility. The Reclaimed Catalyst may also be delivered from offsite to RMSB #4 by covered truck through the equipment entrance door. This Reclaimed Catalyst is then, as demand requires, transported by heavy equipment to the storage bins in RMSB #4. Alternatively, the Reclaimed Catalyst may be transported directly to the Roaster Feed Hoppers, located in RMSB #4. Reclaimed Catalyst is loaded into the Roaster Feed Hoppers via heavy equipment. The Reclaimed Catalyst is delivered to the Roaster from the Roaster Feed Hoppers via enclosed conveyor. Figures 3-1 and A2.0 provide details of the floor plan in RMSB #4.

RMSB #4 is completely enclosed with a floor, walls, and a roof to prevent exposure to precipitation, wind, and run-on as per the requirements of OAC 3745-205-101. All interior floor and walls (termed “abuse walls”) that will be in contact with Reclaimed Catalyst and other materials are of enough strength to support the waste contents and any personnel and

heavy equipment that operate within the building. The interior walls will prevent failure due to pressure gradients, settlement, compression, uplift, physical contact with the Reclaimed Catalyst and other materials, climatic conditions, and the stresses of daily operation. All surfaces that will be in contact with Reclaimed Catalyst and other materials are chemically compatible, consisting of concrete or steel. RMSB #4 will be operated in a fashion that assures that Reclaimed Catalyst and other materials will not come into contact with doors or exterior walls that are not designed to support or prevent the release of Reclaimed Catalyst and other materials. There are no windows incorporated into RMSB #4. All doors are of standard, rather than lightweight construction, therefore no exception to the structural strength requirement is required. Incompatible materials will not be placed in RMSB #4 if they could cause the containment system to leak, corrode, or otherwise fail. The exterior walls and roof of the building are constructed with a metal siding. The roof is sloped 1:12+/-, which prohibits an accumulation of precipitation that could enter the building. RMSB #4 also contains a total of six louvers on the east and west walls and six roof exhaust fans. The cumulative capacity of the exhaust fans is capable of providing approximately six air exchanges per hour. The floor of RMSB #4 is sloped away from any building openings and has a 4-inch containment curb is utilized along the entire perimeter of the building (including man doors and the equipment entrance door).

The structural foundation of RMSB #4 was constructed by using steel piles and concrete and steel piers (Figure S1.0). Three hundred eight nine +/- steel piles (i.e., micropiles) with a design capacity of 190 kips compression were driven to bedrock and extend upwards approximately 8 inches into the concrete structural mat. The steel piles are spaced evenly in rows and columns approximately ten feet apart throughout most of the building. In addition to the steel piles, concrete and steel piers were utilized to stabilize the perimeter of building. A 30-inch thick structural mat ("No. 1" on Figure 3-2) and 1-foot 10-inch thick abuse walls are cast in place over the steel piles and concrete and steel piers using concrete and steel reinforcement. The abuse walls provide containment for the Reclaimed Catalyst in the storage bin areas. Each storage bin area consists of abuse walls on three sides and is open to a central aisle through the building to allow heavy equipment to transfer the Reclaimed Catalyst. The central aisle is contained by the perimeter abuse wall on the north end of the building. The exterior building walls and perimeter abuse walls are roughly six feet apart, providing an aisle around the perimeter of the building.

A 60-mil HDPE liner was installed directly on top of the concrete structural mat to serve as the secondary liner in the dual liner system ("No. 2" on Figure 3-2). A 350-mil geonet drainage layer was placed directly above the secondary liner, to provide drainage to a port for the secondary liner ("No. 3" on Figure 3-2). Another layer of 60-mil HDPE liner was installed over the drainage layer to serve as the primary liner ("No. 4" on Figure 3-2). A 350-mil geonet drainage layer was placed directly above the primary liner, to provide drainage to a port for the primary liner ("No. 5" on Figure 3-2). A 12-inch thick aggregate subgrade layer was then placed on top of the primary drainage layer ("No. 6" on Figure 3-2). The purpose of the aggregate is to provide drainage to detection ports for the primary

liner and to provide subgrade for the concrete surface floor slab. The 8-inch thick concrete surface layer with steel reinforcement (“No. 7” on Figure 3-2) was placed above the aggregate layer. Per manufacturer specifications, the 350-mil primary and secondary geonet drainage layers have a transmissivity of approximately $6 \times 10^{-3} \text{ m}^2/\text{sec}$.

The primary and secondary liners were anchored/welded to the concrete perimeter foundation walls above the structural concrete mat. Edges of the sections of the primary and secondary liner panels are overlapped and the seams were heat sealed in place by a hot iron welder. During and immediately after installation of the primary and secondary liners, all materials used to construct the dual liner system were inspected and horizontal sections tested for uniformity, tight seams, damage, and imperfections. The results of these inspections and tests indicate that all liner materials were in good condition and that the final construction of the dual liner system met required specifications. Following construction, inspection and testing records will be included on CD in Appendix B.

Any Free Liquids present in RMSB #4 are collected by two Free Liquid drainage layer and collection systems. The upper Free Liquid drainage layer and collection system includes, but is not limited to, a drainage port, and upper liner. The lower Free Liquid drainage layer and collection system includes, but is not limited to, a drainage port and a lower liner. The primary and secondary liners are sloped to direct liquids toward the drainage ports. The drainage ports are located at the southern end of the central aisle (Figure EC1.0). Each drainage port consists of an 8-inch HDPE riser pipe that has a HDPE plate fusion welded to the top of the concrete structural mat. Free Liquids drain into the riser pipes that each transition to an 8-inch lateral HDPE pipe that is sloped to the south and penetrate through the concrete wall into the pit of the Roaster Feed Hoppers. The pipe penetrations are sealed. Within the pit, each 8-inch HDPE pipe connects to a separate 4-inch galvanized steel pipe that runs along the north and east concrete walls. The galvanized pipes are sloped to allow Free Liquids to gravity drain into two 150-gal steel tanks that are located on the chemical-resistant coated concrete floor of the pit. Each tank is equipped with a level gauge, leak detection gauge, and audible high level alarm. Each tank contains a submersible pump that connects to a single 2-inch galvanized pipe that conveys Free Liquids to a 2,000-gal double walled steel tank outside the southeast corner of RMSB #4. The 2,000-gal tank is above grade and includes a level switch, continuous level sensor, overflow bowl with drain, and camlock fittings to remove tank contents. Conveyance of Free Liquids from the drainage ports to the tanks is shown on Figure EC2.0.

Free Liquids on the sloped concrete surface layer of RMSB #4 are directed to and collected by two sumps (Figures 3-1 and EC1.0). Details of the sump and the drainage pattern for Free Liquids on the concrete surface layer are shown on Figure EC1.0.

The presence and removal of Free Liquids within the sumps and accumulation tanks will be determined on a schedule per the Inspection Program (Attachment 5). The Free Liquids will be pumped out of the sumps and accumulation tanks into drums, totes or other

containers or tanks. Additionally, a solidifying agent may be added to the concrete surface itself and solidified material would be removed from the concrete surface. In either case, the Free Liquid or solidified material would be incorporated into the manufacturing process. Alternatively, accumulated Free Liquid may be recycled offsite or disposed of offsite. Analysis, if necessary, would be performed according to the Waste Analysis Plan (Attachment 7).

I.1.1 RMSB #4 Certification

Following construction, the certifications associated with RMSB #4 will be provided in Appendix A.

I.2 RMSB #5 (Future) Design and Construction

Future RMSB #5 is anticipated to be approximately 35,000 ft² and have a maximum capacity of 6,600 cubic yards. This subsection and other applicable sections of the Application will be updated when design drawings of future RMSB #5 are available and the Company defines the specific use of future RMSB #5 with respect to facility operations.

I.3 Inspection of RMSBs

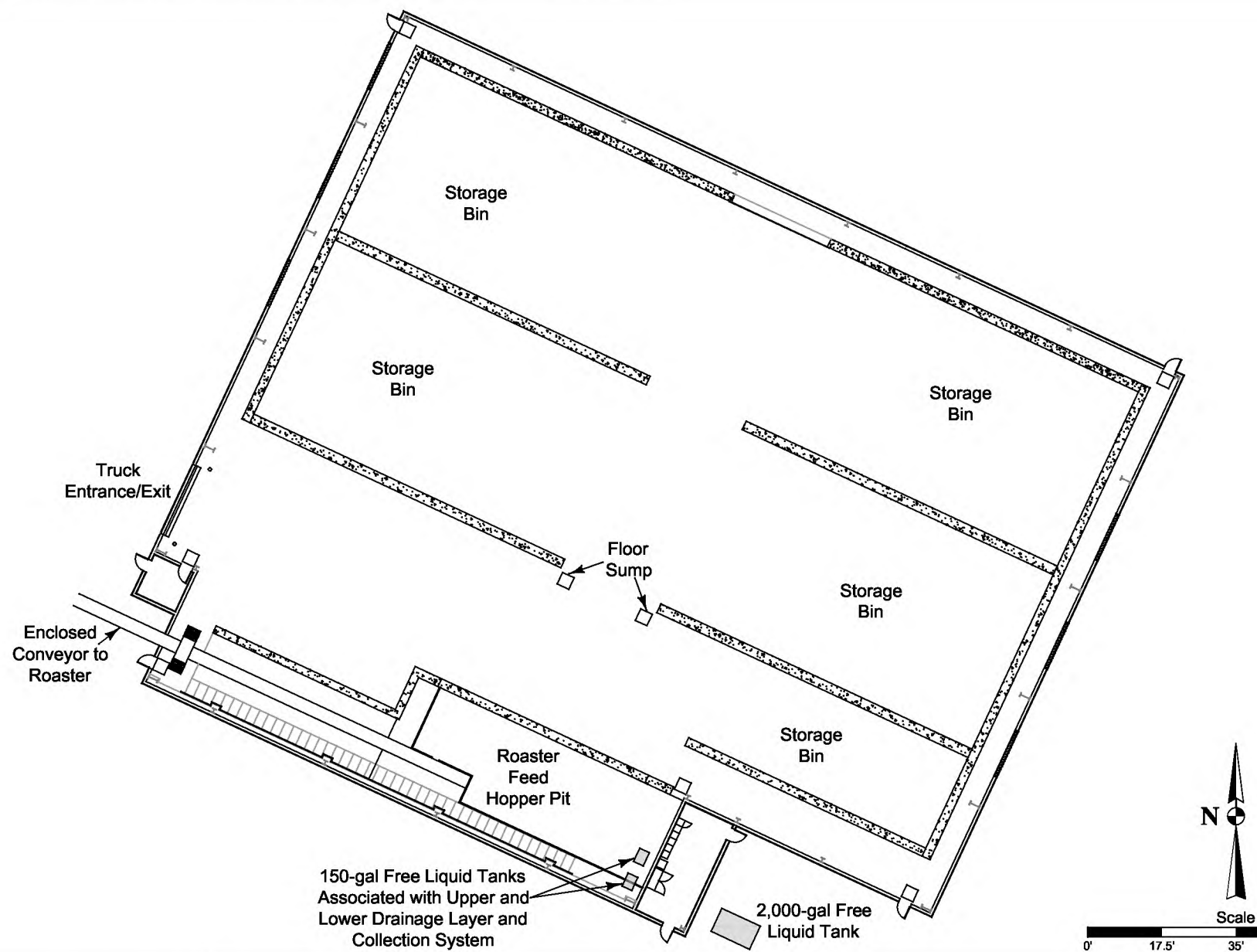
The Company performs inspections to maintain compliance with the requirements of OAC 3745-205-101(C)(1), 3745-205-101(C)(2), and 3745-205-101(C)(4). Inspections are performed in accordance with the Company's Inspection Program (Attachment 5).

I.4 Removal and Decontamination Associated with RMSBs

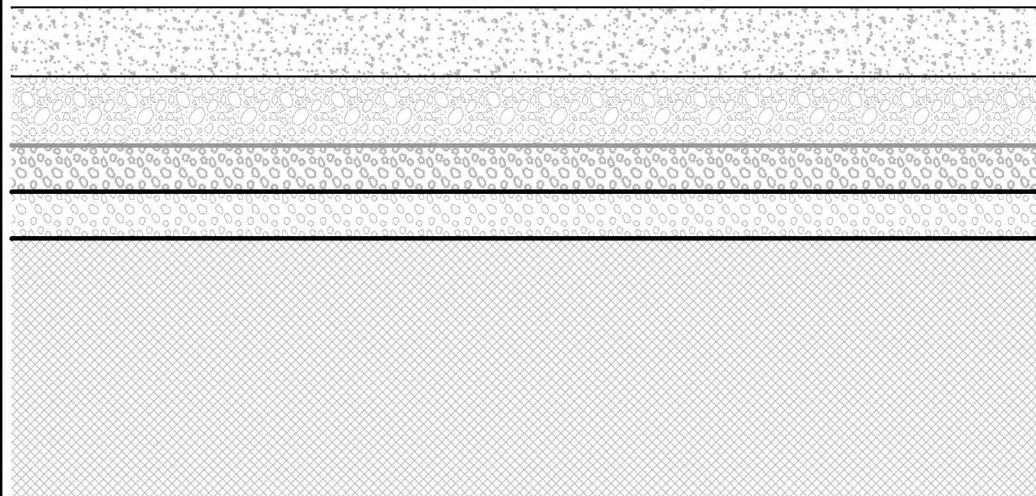
Removal and decontamination procedures associated with RMSBs will be performed in accordance with the Company's Removal and Decontamination Plan in Attachment 4.

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Figures



Surface



No. 7. - Concrete Surface Layer with Steel Reinforcement (8 in.)

No. 6. - Aggregate Subgrade Drainage Layer (12 in.)

No. 5. - Drainage Layer (350 mil)

No. 4. - Primary Liner (60 mil HDPE)

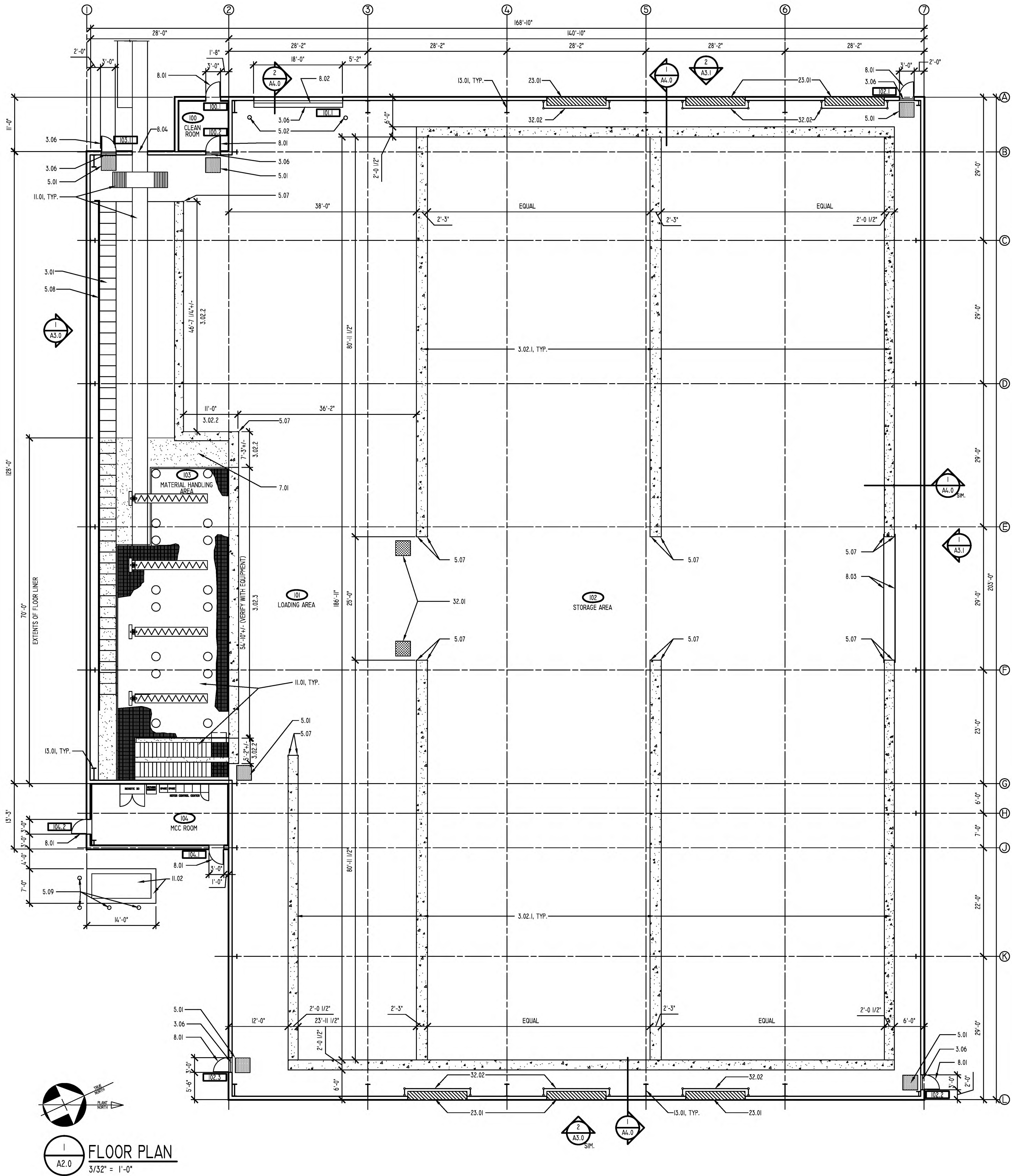
No. 3. - Drainage Layer (350 mil)

No. 2. - Secondary Liner (60 mil HDPE)

No. 1. - Concrete Structural Mat (30 in.)

Native Soil and Structural Piers/Piles

Note: Drawing Not to Scale.



TYPICAL NOTES:	
<ul style="list-style-type: none">CONTRACTOR SHALL FIELD VERIFY ALL EXISTING CONDITIONS AND DIMENSIONS BEFORE PROCEEDING WITH WORK.ALL DIMENSIONS ARE TO FACE OF CONCRETE, MASONRY, STRUCTURE LINE, OR CENTERLINE OF COLUMNS.FOLLOW ALL MANUFACTURERS INSTRUCTIONS & SPECIFICATIONS FOR INSTALLATION UNLESS OTHERWISE INSTRUCTED BY THE ARCHITECT.CONTRACTOR TO PROVIDE CLEAN, COMPACTED BACKFILL IN ALL EXCAVATED AREAS. BLEND NEW FINISH GRADES WITH UNDISTURBED AREAS.ALL EXTERIOR CONCRETE TO BE BROOM FINISH UNLESS NOTED OTHERWISE.CONTRACTOR TO COORDINATE WITH ALL TRADES FOR CLEARANCE REQUIREMENTS, BLOCKING, BRACING, ETC.COORDINATE ALL WORK WITH OWNER'S OPERATIONS.COORDINATE WITH O.U.P.S. PRIOR TO EXCAVATION.REFERENCE ELEVATION 100'-0" EQUALS SITE ELEVATION 888'-8.1" TYP.	
P.E.M.B. NOTES:	
<ul style="list-style-type: none">G.C. TO COORDINATE WITH P.E.M.B. MANUFACTURER. G.C. TO ENSURE THAT THE REQUIRED BUILDING CLEAR HEIGHTS ARE MAINTAINED AS PER ROOF PLAN ON SHEET A2.1. EAVE HEIGHTS MAY VARY.PRIOR TO PLACING ABUSE WALLS, G.C. TO COORDINATE WITH P.E.M.B. MANUFACTURER TO ENSURE SUFFICIENT CLEARANCE FOR A PERSON WITH A WHEELBARROW TO MANEUVER BETWEEN P.E.M.B. FRAMING AND ABUSE WALLS. REFER TO REFERENCE DIMENSIONS ON DETAIL 1/AA.0.	
CODED NOTES:	
<ul style="list-style-type: none">NOT ALL THE MATERIALS LISTED HERE ARE NECESSARILY USED ON THIS SHEET.	
3.00 CONCRETE	
3.01	CONCRETE STAIR BUILT IN TO FLOOR SLAB FOR EQUIPMENT ACCESS, REFER TO STRUCTURAL DRAWINGS.
3.02.1	CONCRETE ABUSE WALL, 12'-0" A.F.F. MIN. (VARIES). REFER TO STRUCTURAL DRAWINGS.
3.02.2	CONCRETE ABUSE WALL, 3'-6" A.F.F. MIN. (VARIES). REFER TO STRUCTURAL DRAWINGS.
3.02.3	CONCRETE ABUSE WALL, 3'-2" A.F.F. (VARIES - VERIFY WITH EQUIPMENT). REFER TO STRUCTURAL DRAWINGS.
3.03	STRUCTURAL MAT SLAB - SEE STRUCTURAL DRAWINGS.
3.04	WEAR SLAB - SEE STRUCTURAL DRAWINGS.
3.05	CONCRETE CURB FOR CONTAINMENT AROUND ENTIRE EXTERIOR PERIMETER - SEE STRUCTURAL DRAWINGS FOR ADDITIONAL INFORMATION.
3.06	CONCRETE CURB FOR CONTAINMENT AT ALL DOORS - CONCRETE CURBS AT RAMP AND ALL DOORS ARE TO TIE IN TO PERIMETER CURB SEE STRUCTURAL DRAWINGS.
5.00 METALS	
5.01	GRATED DECONTAMINATION AREA - SEE STRUCTURAL
5.02	6" DIA. INTERIOR CONCRETE FILLED PIPE BOLLARDS, SEE DETAIL 3/AA.0. PAINT YELLOW PRIME PLUS (2) FINISH COATS).
5.03	STRUCTURAL PILE - SEE STRUCTURAL DRAWINGS
5.04	12"x12"x3/8" STEEL PLATE (EMBEDDED)
5.05	(4) 1/2" DIA. X 6" STUDS WELDED TO PLATE
5.06	(2) #4.5 (2'-0" LONG) EACH WAY AT EMBEDDED PLATE
5.07	STEEL END GUARDS, SEE STRUCTURAL DRAWINGS
5.08	1-1/4" OUTSIDE DIAMETER HANDRAIL, MOUNT 36" A.F.F. TO TOP OF RAIL
5.09	9" DIA. EXTERIOR BOLLARDS FOR TANK PROTECTION, REFER TO CONTAINMENT DRAWINGS. PAINT YELLOW (PRIME PLUS (2) FINISH COATS).
7.00 THERMAL AND MOISTURE PROTECTION	
7.01	RHINO EXTREME II-50 GTS FLOOR LINER, EXTEND UNDER ALL EQUIPMENT, STAIRS ETC. AND 24" MIN. UP ALL PERIMETER WALLS. TOUCH-UP AS REQUIRED AFTER EQUIPMENT INSTALLATION.
7.02	WATERTOP - SEE STRUCTURAL
7.03	WATERPROOFING ON OUTSIDE FACE OF ALL FOUNDATION WALLS BELOW GRADE, TYP.
8.00 DOORS & WINDOWS	
8.01	3'-0" x 7'-0" MAN DOOR
8.02	18'-0" x 20'-0" OVERHEAD DOOR
8.03	OPENING COVER STRUCTURE, REFER TO STRUCTURAL DRAWINGS.
8.04	OPENING IN P.E.M.B. WALL FOR CONVEYOR, CONFORM WITH EQUIPMENT.
11.00 EQUIPMENT	
11.01	MATERIAL HANDLING EQUIPMENT INCLUDING ACCESS STAIRS AND PLATFORMS UNDER SEPARATE CONTRACT.
11.02	OVERFLOW TANK ON CONCRETE PAD, SEE CONTAINMENT AND STRUCTURAL DRAWINGS FOR ADDITIONAL INFORMATION.
13.00 SPECIAL CONSTRUCTION (P.E.M.B. - REFER TO P.E.M.B. DRAWINGS)	
13.01	P.E.M.B. STRUCTURAL STEEL
13.02	P.E.M.B. GUTTER AND DOWNSPOUT
13.03	P.E.M.B. WALL PANELS
13.04	P.E.M.B. STANDING SEAM ROOF PANELS
13.05	P.E.M.B. CLOSURE
13.06	P.E.M.B. FACED INSULATION
13.07	P.E.M.B. ROOF PURLINS
13.08	P.E.M.B. WALL GIRTS
23.00 HEATING, VENTILATION AND AIR CONDITIONING	
23.01	H.V.A.C. EQUIPMENT, SEE H.V.A.C. DRAWINGS.
26.00 ELECTRICAL	
26.01	LIGHT FIXTURES, SEE ELECTRICAL DRAWINGS.
32.00 EXTERIOR IMPROVEMENTS	
32.01	CONTAINMENT SYSTEM, SEE CONTAINMENT DRAWINGS
32.02	9'-0" HIGH CUSTOM GALVANIZED CHAIN LINK FENCE FOR PEDESTRIAN PROTECTION FROM HVAC UNITS. PROVIDE ACCESS PANELS AS REQUIRED SUBMIT SHOP DRAWINGS FOR APPROVAL.

DOOR SCHEDULE					
NO.	SIZE	TYPE	FRAME		REMARKS
			ELEV	TYPE	
100.1	3'-0"x 7'-0"x 1/4"	HMTL		PEMB	1,2,3,4,5,6
100.2	3'-0"x 7'-0"x 1/4"	HMTL		PEMB	1,2,3,4,5,6
101.1	18'-0"x 20'-0"	OH DOOR		PEMB	BY OH DOOR MAN.
102.1	3'-0"x 7'-0"x 1/4"	HMTL		PEMB	1,2,3,4,5,6
102.2	3'-0"x 7'-0"x 1/4"	HMTL		PEMB	1,2,3,4,5,6
102.3	3'-0"x 7'-0"x 1/4"	HMTL		PEMB	1,2,3,4,5,6
103.1	3'-0"x 7'-0"x 1/4"	HMTL		PEMB	1,2,3,4,5,6
104.1	3'-0"x 7'-0"x 1/4"	HMTL		PEMB	1,2,3,4,5,6
104.2	3'-0"x 7'-0"x 1/4"	HMTL		PEMB	1,2,3,4,5,6
ALL EGRESS DOORS SHALL BE READILY OPENABLE FROM THE SIDE FROM WHICH EGRESS IS TO BE MADE WITHOUT THE USE OF A KEY OR SPECIAL KNOWLEDGE OR EFFORT.					
HARDWARE LIST (NOTE: SEE SCHEDULE FOR LOCATION)					
1.	1 1/2 PAIR NRP HINGES	5.	WEATHER STRIPPING AND SWEEP STRIP		
2.	CLOSER	6.	PANIC HARDWARE:		
3.	SILENCERS		VON DUPRIN 98L EXIT SERIES OR EQUAL. 992L-BE		
4.	THRESHOLD		OUTSIDE TRIM		
REMARKS					
1. DOOR AND FRAME PROVIDED BY P.E.M.B. MANUFACTURER. HARDWARE PROVIDED BY G.C.					

PROJECT
AMG Vanadium
Raw Material Storage Building

ISSUED:
08/23/2019 BASIC ENGINEERING
10/16/2019 DETAILED ENGINEERING

PROJECT NO.
1829

DRAWN:
ZPS

CHECKED:
MAB/RWW

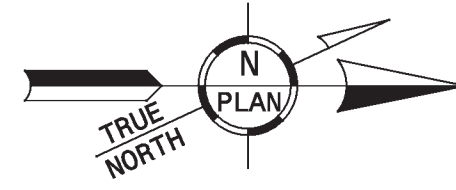
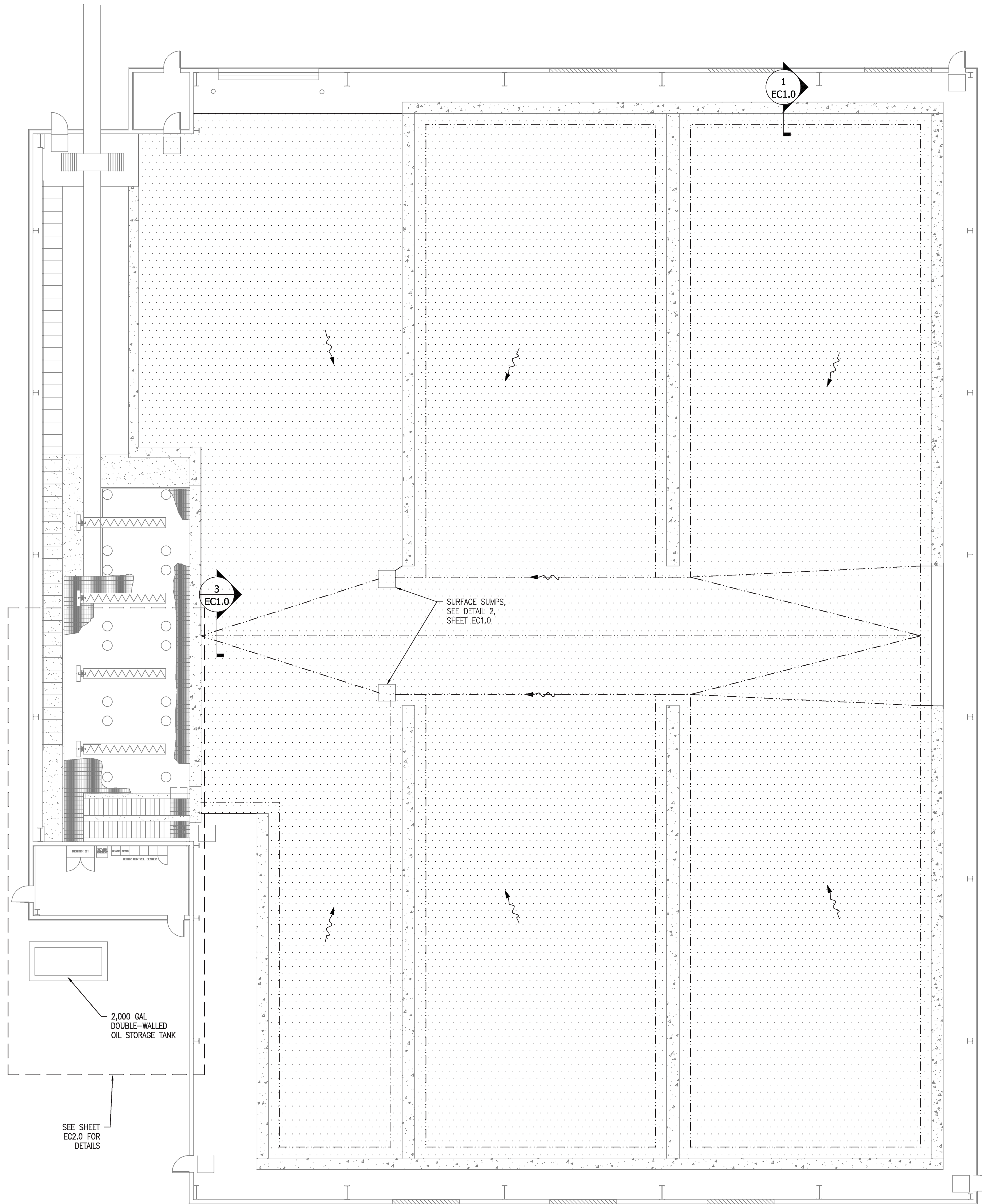
SHEET NAME
FLOOR PLAN

A2.0

STATE OF OHIO
RONALD D. VAN WEY II
JULY 11 1986
REGISTERED ARCHITECT

0124
V2 ARCHITECTS
903 Steubenville Ave.
Cambridge, OH 43725

Copyright © 2019 V2 ARCHITECTS
RON VAN WEY II LIC. #9856
EXPIRATION DATE: 12/31/2019



0 5 10 20
SCALE IN FEET

LEGEND

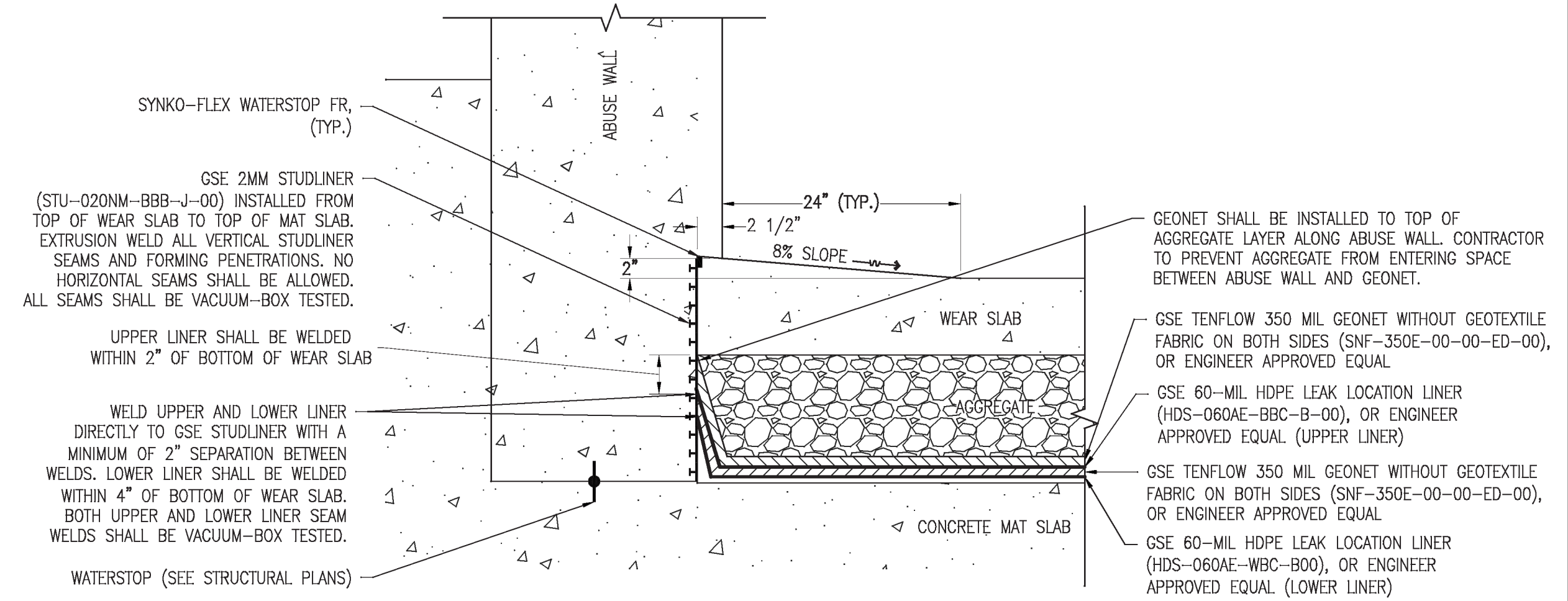
- PROPOSED GRADE BREAK
- PROPOSED AERIAL LIMITS OF CONTAINMENT
- PROPOSED DIRECTION OF SLOPE

NOTES:

- SEE STRUCTURAL AND MECHANICAL PLANS FOR ALL FOUNDATION, ABUSE WALL, AND CONCRETE SLAB REINFORCEMENT, ELEVATIONS, DIMENSIONS, AND DETAILS.
- CONTRACTOR TO USE PRE-FORMED LINER PIECES AT ALL INSIDE AND OUTSIDE CORNERS. PRE-FORMED LINER PIECES SHALL BE FABRICATED OUT OF THE SAME MATERIAL AS THE LINER.
- ENSURE POSITIVE DRAINAGE AROUND ENDS OF ALL ABUSE WALLS.

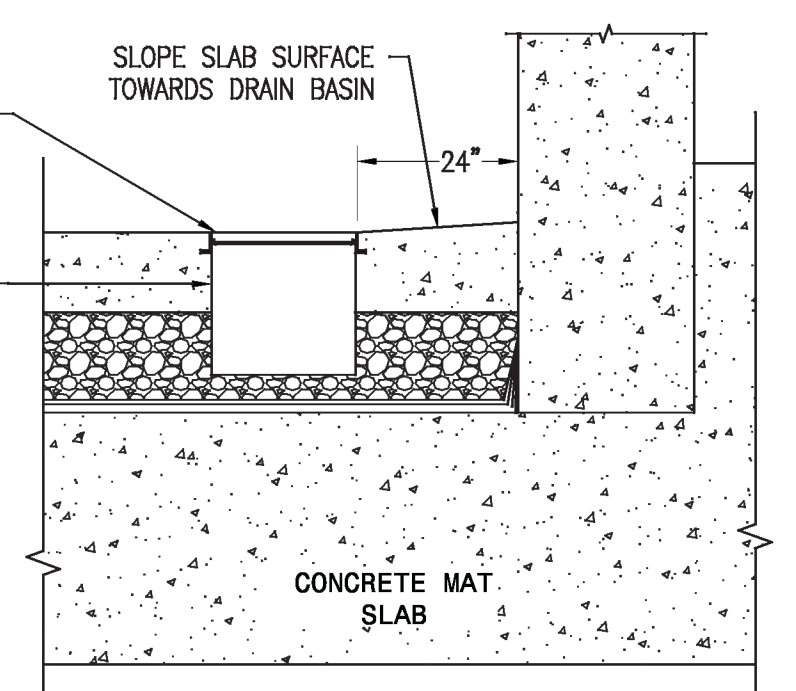
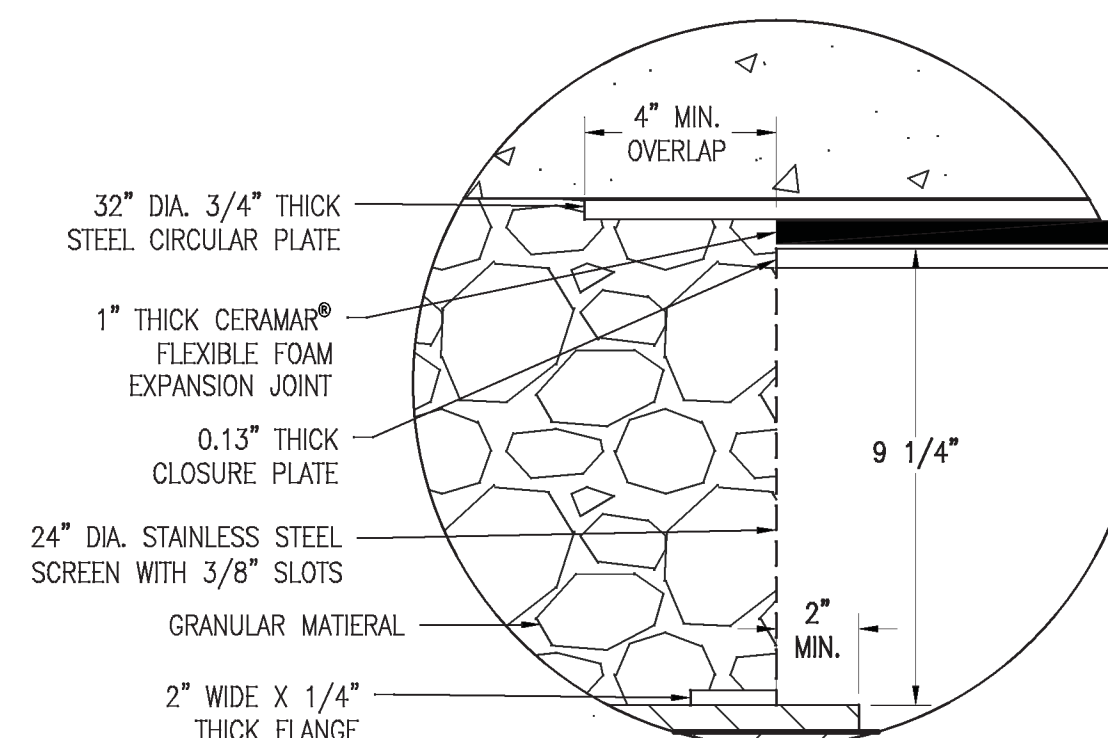
PRE-CONSTRUCTION NOTICE

THESE PLANS HAVE BEEN PREPARED USING THE MOST ACCURATE INFORMATION AND DATA AVAILABLE AT THE TIME OF PREPARATION. FIELD CONDITIONS MAY BE ENCOUNTERED DURING CONSTRUCTION THAT MAY NOT HAVE BEEN ANTICIPATED, AND AS SUCH, THESE PLANS SHOULD BE USED ONLY AS A CONSTRUCTION CONTROL REFERENCE (I.E. NOT A PRECISE CONSTRUCTION DOCUMENT). MODIFICATIONS TO THE DESIGN AS SHOWN MAY BE REQUIRED BASED ON FIELD CONDITIONS ENCOUNTERED AT THE TIME OF CONSTRUCTION. IN ANY EVENT, THE ENGINEERING OBJECTIVES OF THE DESIGN SHALL BE MET. IF SUCH MODIFICATIONS ARE APPROPRIATE AND APPROVED BY THE ENGINEER, THE MEASUREMENTS AND DETAILS OF SUCH IMPROVEMENTS SHALL BE MADE A PART OF THE CONSTRUCTION OBSERVATION RECORD.



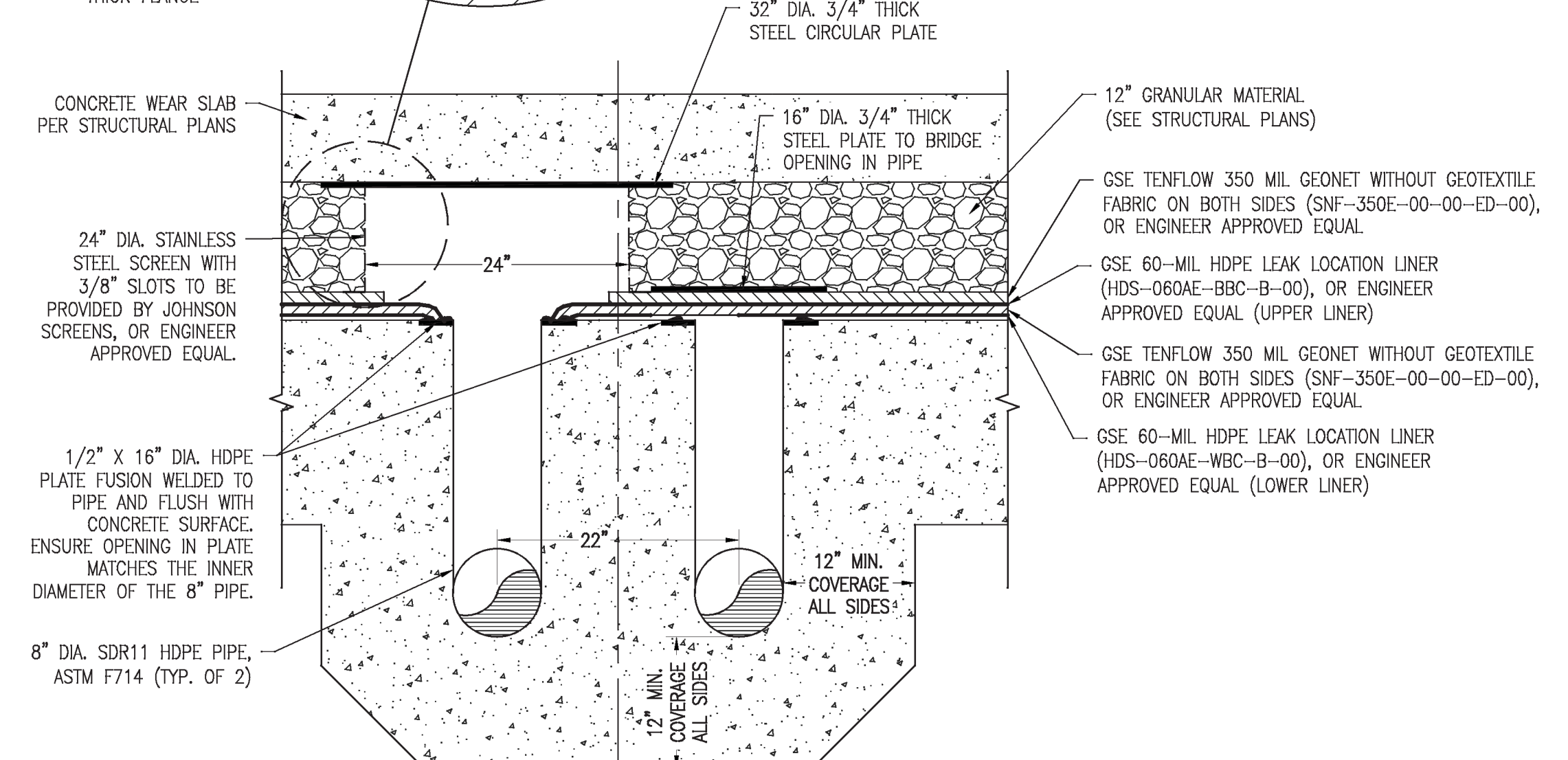
1 TYPICAL SECTION

SCALE: N.T.S.



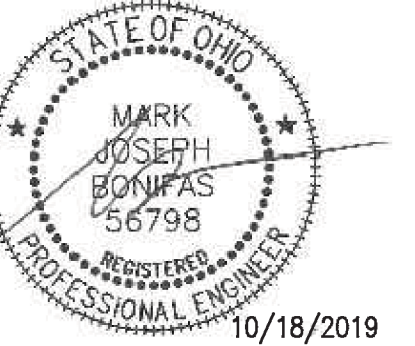
2 SURFACE SUMP DETAILS

SCALE: N.T.S.



3 DUAL LINER DRAINAGE PORTS

SCALE: N.T.S.



V2 ARCHITECTS
903 Steubenville Ave.
Cambridge, OH 43725

PROJECT
AMG Vanadium
Raw Material Storage Building
3400 East Pointe Drive
Zanesville, OH 43701

ISSUED:
08/23/2019 BASIC ENGINEERING
10/18/2019 DETAILED ENGINEERING

PROJECT NO.
1829

DRAWN:
DWS

CHECKED:
MJB

SHEET NAME
CONTAINMENT PLAN

EC1.0

PROJECT

08/23/2019 BASIC ENGINEERING
10/19/2019 DETAILED ENGINEERING08/23/2019 B
10/18/2019 D

1829

DWS

DRAWN:

CONTAINMENT DETAILS

EC2.0

THESE PLANS HAVE BEEN PREPARED USING THE MOST ACCURATE INFORMATION AND DATA AVAILABLE AT THE TIME OF PREPARATION. FIELD CONDITIONS MAY BE ENCOUNTERED DURING CONSTRUCTION THAT MAY NOT HAVE BEEN ANTICIPATED, AND AS SUCH, THESE PLANS SHOULD BE USED ONLY AS A CONSTRUCTION CONTROL REFERENCE (I.E. NOT A PRECISE CONSTRUCTION DOCUMENT). ANY VARIATIONS TO THE DESIGN AS SHOWN MAY BE REQUESTED BASED ON FIELD CONDITIONS ENCOUNTERED AT THE TIME OF CONSTRUCTION. IN ANY EVENT, THE ENGINEERING OBJECTIVES OF THE DESIGN SHALL BE MET. IF SUCH MODIFICATIONS ARE APPROPRIATE AND APPROVED BY THE ENGINEER, THE MEASUREMENTS AND DETAILS OF SUCH IMPROVEMENTS SHALL BE MADE A PART OF THE CONSTRUCTION OBSERVATION RECORD.

SEE STRUCTURAL AND MECHANICAL PLANS FOR ALL FOUNDATION, ABUSE WALL, AND CONCRETE SLAB REINFORCEMENT, ELEVATIONS, DIMENSIONS, AND DETAILS. ARCHITECTURAL F.F. ELEVATION 100' = 888' STEEL ELEVATION.

2. THE TWO USED OIL TANKS FOR STORAGE OF COLLECTED OIL FROM THE UPPER AND LOWER LINERS SHALL BE IDENTICAL. EACH TANK SHALL BE A 150 GALLON, STEEL SINGLE-WALLED, OPEN-TOP TANK, PROVIDED BY HIGHLAND TANK (OR ENGINEER APPROVED EQUAL) WITH THE FOLLOWING CHARACTERISTICS:

- 12 GA SHELL AND 12 GA HEAD
- 3"-2" DIAMETER AND 2"-7" HIGH
- 2" WIDE BY 1/4" THICK STEEL RING AROUND TOP OF TANK TO REINFORCE
- 12" WIDE STEEL CROSS-BEAM ACROSS CENTER OF TANK FOR MOUNTING PUMP AND SENSORS

3. EQUIPPED WITH SIEMENS SITRANS PROBE LVL240 ULTRASONIC LEVEL PROBE WITH FMS 200 UNIVERSAL PUMP BRACKET

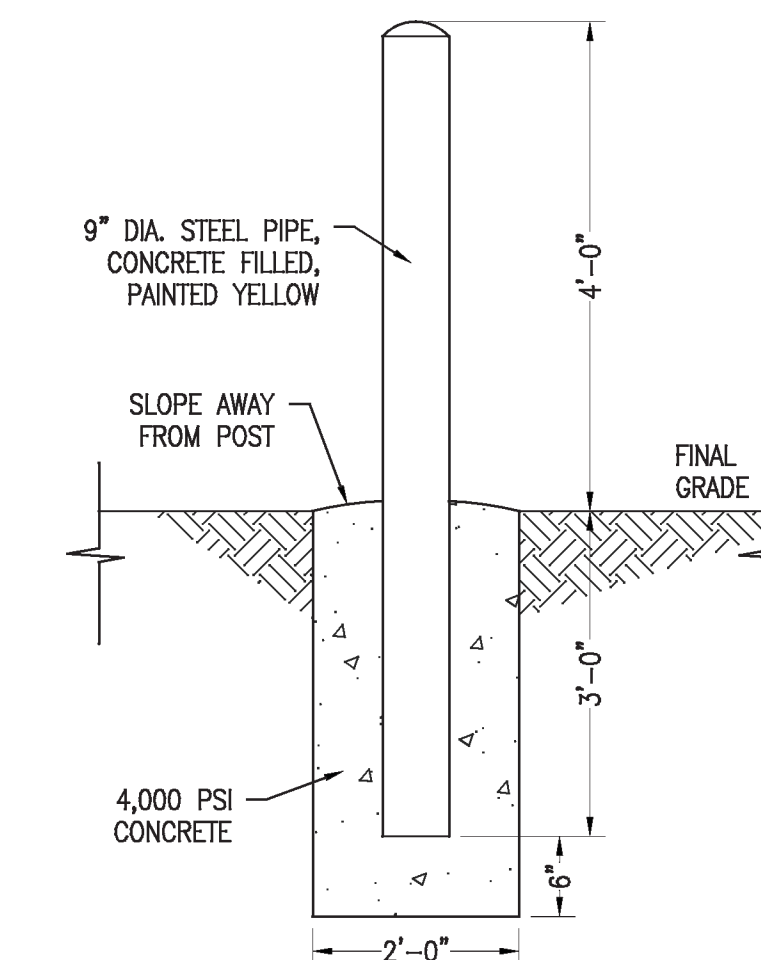
4. EQUIPPED WITH SIEMENS SITRANS LVL200 VIBRATING LEVEL SWITCH WITH WELDED SOCKET FOR SIDE FLUSH MOUNT AT 90% TANK HEIGHT

3. THE 2,000 GALLON STEEL DOUBLE-WALLED, OIL STORAGE TANK SHALL BE PROVIDED BY HIGHLAND TANK (OR ENGINEER-APPROVED EQUAL) WITH THE FOLLOWING CHARACTERISTICS:

- 7 GA INNER SHELL AND 10 GA OUTER SHELL
- 5'-4" DIAMETER AND 12'-0" LONG
- WHITE POLYURETHANE EXTERIOR COATING
- THREE 2" NPT THREADED OPENINGS ON TOP
- TWO 2" INTERNAL PIPES EXTENDING TO BOTTOM OF TANK AND 10" FROM BOTTOM OF TANK, RESPECTIVELY
- SADDLE-TYPE SUPPORTS, SEAL WELDED TO TANK
- CLOCK GAUGE
- POP-UP LEAK GAUGE
- TWO 2" MALE THREAD X MALE QUICK CONNECT FITTINGS
- TWO 3.5 GALLON COATED CARBON OVERFILL BOWL WITH DRAIN FOR 2" FITTING
- EQUIPPED WITH SIEMENS SITRANS PROBE LVL240 ULTRASONIC LEVEL PROBE
- EQUIPPED WITH SIEMENS SITRANS LVL200 VIBRATING LEVEL SWITCH INSTALLED AT 2" FLANGE ON TOP OF TANK, EXTEND LEVEL SWITCH TO 90% TANK VOLUME LEVEL

4. POWER AND CONTROLS FOR THE PUMPS, FLOW METERS, LEVEL SENSORS, AND LEVEL SWITCHES TO BE COORDINATED WITH OWNER AND BUILDING ELECTRICAL. THE PROPOSED MONITORING AND CONTROLS SCHEME IS AS FOLLOWS:

- BOTH 150-GAL TANKS WILL BE EQUIPPED WITH CONTINUOUS LEVEL MONITORING DEVICES WITH 4-20mA SIGNALS.
- BOTH 150-GAL TANKS WILL BE EQUIPPED WITH HIGH LEVEL SWITCHES THAT WILL SEND A HIGH LEVEL SIGNAL TO THE BUILDING'S CONTROL PANEL WHEN LIQUID IN THE TANK REACHES 90% OF THE TANK VOLUME.
- THE 150-GAL TANKS WILL BE EMPTIED BY MANUALLY ACTIVATING THE DIAPHRAGM PUMPS. THE HIGH LEVEL SIGNALS WILL ONLY BE USED TO NOTIFY PLANT PERSONNEL OF THE HIGH LEVEL CONDITIONS IN THE TANKS.
- BOTH DISCHARGE LINES FROM EACH 150-GAL TANK WILL BE EQUIPPED WITH CONTINUOUS FLOW MONITORING DEVICES, WHICH WILL HAVE LOCAL DISPLAYS AND SEND 4-20mA SIGNALS TO THE BUILDING'S CONTROL PANEL.
- THE 2,000 GAL TANK WILL BE EQUIPPED WITH A CONTINUOUS LEVEL MONITORING DEVICE WITH A 4-20mA SIGNAL.
- THE 2,000 GAL TANK WILL BE EQUIPPED WITH A LEVEL SWITCH THAT WILL ACTIVATE WHEN THE LIQUID LEVEL IN THE TANK REACHES 90% OF THE TANK VOLUME. IF THE HIGH LEVEL SWITCH IS ACTIVATED, A SIGNAL WILL SHUT OFF POWER TO BOTH PUMPS, INDICATE THE HIGH LEVEL STATUS TO THE PLANT PERSONNEL REMOTELY, AND ACTIVATE A LOCAL ALARM LIGHT NEAR THE 150-GAL TANKS IN THE HOPPER PIT.
- THE 2,000 GAL TANK IS EQUIPPED WITH TWO QUICK CONNECT FITTINGS AND WILL BE EMPTIED MANUALLY USING VACUUM TRUCKS EQUIPPED WITH THEIR OWN PUMPS.



Appendix A
Certifications for Raw Material Storage
Building #4
[Forthcoming After Construction]

Appendix B

Liner Inspection and Testing Records for Raw Material Storage Building #4 on CD

[Forthcoming After Construction]

Attachment 4

Attachment 4
RDP

Removal and Decontamination Plan

Attachment 4 Removal and Decontamination Plan Revision 0

November 1, 2019

Submitted to:

AMG Vanadium LLC
3400 East Pointe Drive
Zanesville, Ohio 43701
EPA ID No. OHR000212902

Submitted by:

Cox-Colvin & Associates, Inc.
7750 Corporate Blvd.
Plain City, Ohio 43064
(614) 526-2040



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1.0 Introduction

AMG Vanadium LLC (referred to as the “Company”) Zanesville Facility (referred to as the “Facility”) accepts Reclaimed Catalyst and produces ferrous and non-ferrous metal Products. If manufacturing operations were to cease at the Facility, RMSBs would undergo removal and decontamination procedures as required by this plan.

2.0 Facility and Unit-Specific Descriptions

A general description of the Facility is provided below. Unit-specific descriptions of RMSBs is also presented.

2.1 Facility Description

The Facility is located at 3400 East Pointe Drive in Zanesville, Ohio. The property encompasses approximately 163 acres, of which approximately 27 acres is used for industrial manufacturing and contains numerous buildings and paved access areas. A site location map on a United States Geological Survey (USGS) topographic quadrangle (Figure 4-1) shows the location of the Facility in relation to the surrounding area. Figure 4-2 provides a Facility layout showing the Facility property boundary and manufacturing area.

The Facility has standard industrial classification (SIC) codes of 3313 (electrometallurgical products) and 3341 (secondary smelting and refining) and North American Industrial Classification System (NAICS) codes of 331110 (iron and steel mills and ferroalloy manufacturing) and 331492 (secondary smelting, refining, and alloying of nonferrous metal). The Facility produces ferrous and non-ferrous metal products.

2.2 Environmental Setting

The Facility is located within a semi-rural area of Muskingum County. Within and surrounding the facility are drastic changes in elevation, which is typical of the western Appalachian foothills. Thick deposits of outwash, ranging from approximately 50 to 80 ft thick, are present within the area. The Lower Mercer Limestone (Pottsville Group, Middle Pennsylvanian) is the uppermost underlying bedrock unit at and near the Facility. The southern portion of the Facility is wooded and slopes steeply to the south. An unnamed perennial stream extends along the southern portion of the property at the base of the steep slope and flows west approximately 0.8 miles where it discharges to the Muskingum River. Several smaller ephemeral and intermittent streams, ponds, and

wetlands are also present onsite. The Facility is located outside of the 100-year floodplain.

From the 1950s to 1970s, portions of the property were strip mined for coal, after which, reclamation was performed by filling with mine spoil and fill soil. Therefore, limited topsoil is present at the Facility, below which consists of mine spoils (crushed shale, sandstone, limestone, siltstone, and coal) as well as intermixed fill consisting of silt, sand, and clay. Based on exploratory borings completed at the Facility, the mine spoils and fill extend to or slightly above the top of bedrock. Bedrock is encountered as shallow as one foot below ground surface near the southern portions of the property, to greater than 70 feet below ground surface within the central portions of the property.

Due to the heterogeneous presence and composition of mine spoil and fill, groundwater is encountered at various depths throughout the property within this unconsolidated material. Regionally, a prolific sand and gravel aquifer is present beneath the Muskingum River floodplain. Although the Facility is located within the drainage basin of the Muskingum River, it is located well beyond the Muskingum River floodplain. As such, it is believed that the only contiguous groundwater unit beneath the site that has a regional expanse is within the limestone bedrock. Information obtained from the Ohio Department of Natural Resources suggest that bedrock groundwater yield in this portion of the county is only a few gallons per minute.

2.3 Waste Generation and Management

A complete description of Facility processes and activities is beyond the scope of this RDP. Therefore, only those processes and activities that routinely generate or utilize Reclaimed Catalyst are briefly described below, along with the management of those materials. It should be understood that only RMSBs are subject to this RDP and not any of the other units discussed below.

Reclaimed Catalyst is transported to the Facility as a K171/K172 hazardous waste. However, upon being Accepted at the Facility, an Ohio EPA-issued Variance from Classification as a Waste (Variance) exempts from the definition of solid waste K171 and K172 hazardous waste. If necessary, the Reclaimed Catalyst, as well as other materials received and generated by Facility operations, are stored in a RMSB (Figure 4-2). The specific properties of the Reclaimed Catalyst that led to their being listed as a hazardous waste are ignitability and toxicity (40 CFR 261.32). As identified in 40 CFR 268.40, there are several hazardous constituents associated with K171/172. Some materials produced or generated by the Facility, if disposed, may be characteristic for cadmium (D006), chromium (D007), and/or selenium (D010). The list of hazardous waste codes applicable to RMSBs and this RDP are K171 and K172.

2.4 RMSB #4

RMSB #4 is located to the east of the Roaster and the Main Mill Building that houses the electric arc furnaces. The design and construction of RMSB #4 meets the requirements of OAC 3745-205-101 for containment and storage of both wet and dry materials. The footprint of RMSB #4 is approximately 35,000 ft² with a total design storage capacity of approximately 6,600 yd³. In general, the floor plan includes five storage bin areas (Figure 4-3). RMSB #4 also has a dual containment system that includes a primary and secondary liner. The dual containment system was placed upon a foundation capable of providing support to the liners and resistance to pressure gradients above and below the liners to prevent failure due to settlement, compression, or uplift. A Free Liquid drainage layer and collection system was installed immediately above each liner, and is designed, constructed, maintained, and operated to collect and remove Free Liquid and to function without clogging throughout the operational life of RMSB #4.

Reclaimed Catalyst unloaded from bulk railcars is transported by covered heavy equipment to RMSB #4 through the equipment entrance door or loaded directly into covered trucks for transport to the Cambridge Facility. The Reclaimed Catalyst may also be delivered from offsite to RMSB #4 by covered truck through the equipment entrance door. This Reclaimed Catalyst is then, as demand requires, transported by heavy equipment to the storage bins in RMSB #4. Alternatively, the Reclaimed Catalyst may be transported directly to the Roaster Feed Hoppers, located in RMSB #4. Reclaimed Catalyst is loaded into the Roaster Feed Hoppers via heavy equipment. The Reclaimed Catalyst is delivered to the Roaster from the Roaster Feed Hoppers via enclosed conveyor.

RMSB #4 is completely enclosed with a floor, walls, and a roof to prevent exposure to precipitation, wind, and run-on as per the requirements of OAC 3745-205-101. All interior floor and walls (termed “abuse walls”) that will be in contact with Reclaimed Catalyst and other materials are of enough strength to support the waste contents and any personnel and heavy equipment that operate within the building. The interior walls will prevent failure due to pressure gradients, settlement, compression, uplift, physical contact with the Reclaimed Catalyst and other materials, climatic conditions, and the stresses of daily operation. All surfaces that will be in contact with Reclaimed Catalyst and other materials are chemically compatible, consisting of concrete or steel. RMSB #4 will be operated in a fashion that assures that Reclaimed Catalyst and other materials will not come into contact with doors or exterior walls that are not designed to support or prevent the release of Reclaimed Catalyst and other materials. There are no windows incorporated into RMSB #4. All doors are of standard, rather than lightweight construction, therefore no exception to the structural strength requirement is required. Incompatible materials will not be placed in RMSB #4 if they could cause the containment system to leak, corrode, or otherwise fail. The exterior walls and roof of the building are constructed with a metal siding. The roof is sloped 1:12+/-, which prohibits an

accumulation of precipitation that could enter the building. RMSB #4 also contains a total of six louvers on the east and west walls and six roof exhaust fans. The cumulative capacity of the exhaust fans is capable of providing approximately six air exchanges per hour. The floor of RMSB #4 is sloped away from any building openings and has a 4-inch containment curb is utilized along the entire perimeter of the building (including man doors and the equipment entrance door).

The structural foundation of RMSB #4 was constructed by using steel piles and concrete and steel piers. Three hundred eight nine +/- steel piles (i.e., micropiles) with a design capacity of 190 kips compression were driven to bedrock and extend upwards approximately 8 inches into the concrete structural mat. The steel piles are spaced evenly in rows and columns approximately ten feet apart throughout most of the building. In addition to the steel piles, concrete and steel piers were utilized to stabilize the perimeter of building. A 30-inch thick structural mat and 1-foot 10-inch thick abuse walls are cast in place over the steel piles and concrete and steel piers using concrete and steel reinforcement. The abuse walls provide containment for the Reclaimed Catalyst in the storage bin areas. Each storage bin area consists of abuse walls on three sides and is open to a central aisle through the building to allow heavy equipment to transfer the Reclaimed Catalyst. The central aisle is contained by the perimeter abuse wall on the north end of the building. The exterior building walls and perimeter abuse walls are roughly six feet apart, providing an aisle around the perimeter of the building.

Any Free Liquids present in RMSB #4 are collected by two Free Liquid drainage layer and collection systems. The upper Free Liquid drainage layer and collection system includes, but is not limited to, a drainage port, and upper liner. The lower Free Liquid drainage layer and collection system includes, but is not limited to, a drainage port and a lower liner. A cross section of the dual containment system is provided on Figure 4-4.

The primary and secondary liners are sloped to direct liquids toward two drainage ports that are sloped to the south and penetrate through the concrete wall into the pit of the Roaster Feed Hoppers. The pipe penetrations are sealed. Within the pit, each HDPE pipe connects to a separate galvanized steel pipe that runs along the north and east concrete walls. The galvanized pipes are sloped to allow Free Liquids to gravity drain into two 150-gal steel tanks that are located on the chemical-resistant coated concrete floor of the pit. Each tank is equipped with a level gauge, leak detection gauge, and audible high level alarm. Each tank contains a submersible pump that connects to a single 2-inch galvanized pipe that conveys Free Liquids to a 2,000-gal double walled steel tank outside the southeast corner of RMSB #4. The 2,000-gal tank is above grade and includes a level switch, continuous level sensor, overflow bowl with drain, and camlock fittings to remove tank contents.

Free Liquids on the sloped concrete surface layer of RMSB #4 are directed to and collected

by two sumps (Figure 4-3). The Free Liquids will be pumped out of the sumps and accumulation tanks into drums, totes or other containers or tanks. Additionally, a solidifying agent may be added to the concrete surface itself and solidified material would be removed from the concrete surface. In either case, the Free Liquid or solidified material would be incorporated into the manufacturing process. Alternatively, accumulated Free Liquid may be recycled offsite or disposed of offsite.

RMSB #4 will be used for storage of Reclaimed Catalyst and other materials. A summary of hazardous constituents associated with Reclaimed Catalyst and other materials that could be stored in RMSB #4 is provided in Table 4-1. As a conservative approach, it is assumed that the approximate allowed mass of Reclaimed Catalyst within RMSB #4 at the time removal and decontamination procedures begin, represents the approximate mass associated with financial assurance required by the Variance (maximum 6,600 cy³ equivalent to approximately 6,930 tons). A construction design drawing for RMSB #4 is provided as Figure A2.0. Additional details regarding the construction of RMSB #4 can be found in Attachment 3 of the Facility's Variance Application.

2.5 RMSB #5 (Future)

Future RMSB #5 is anticipated to be approximately 35,000 ft² and have a maximum capacity of 6,600 cubic yards (equivalent to approximately 6,930 tons). This subsection and other applicable sections of the Application will be updated when design drawings of future RMSB #5 are available and the Company defines the specific use of future RMSB #5 with respect to facility operations.

3.0 Removal and Decontamination Performance Standard

The removal and decontamination performance standard for a RMSB will:

- minimize the need for further maintenance; and
- control, minimize, or eliminate, to the extent necessary to protect human health and the environment, escape of hazardous waste constituents, leachate, contaminated runoff, or hazardous waste decomposition products to the ground or surface waters or atmosphere.

To achieve the above removal and decontamination performance standard for a RMSB, Reclaimed Catalyst will be removed and surfaces will be decontaminated. Physical extraction methods (e.g., high pressure steam or water sprays) will be conducted as part of decontamination. Performance-based physical extraction methods may be used in lieu of sampling and analysis to demonstrate a structure has been adequately decontaminated. As

such, the removal and decontamination performance standard will be achieved by completing decontamination procedures. The portion of the definition of a “clean debris surface” (defined in the Table of OAC 3745-270-45) that pertains to waste removal will be used to determine the adequacy of decontamination efforts. Specifically, Reclaimed Catalyst and waste may be present in cracks, crevices, and pits, provided that the Reclaimed Catalyst and waste is present in less than five percent of each square inch of surface area.

The procedure for removal of Reclaimed Catalyst and decontamination of a RMSB is described in Section 4.0. Achieving the removal and decontamination performance standard for a RMSB will achieve an unrestricted use. Use restriction and other ongoing obligations for a RMSB will only become necessary in the event that all Reclaimed Catalyst cannot be practicably removed.

4.0 Removal and Decontamination Procedures

Removal and decontamination procedures for a RMSB are described in the following subsections. If unexpected event(s) occur during implementation of removal and decontamination procedures that require modification of this RDP, an amended RDP will be submitted to Ohio EPA within 30 days of the unexpected event(s) for approval. The Facility will not continue with additional activities at a RMSB until approval of the amended RDP by Ohio EPA.

4.1 Reclaimed Catalyst and Waste Removal

It will conservatively be assumed that the maximum allowed mass of Reclaimed Catalyst (approximately 13,860 tons) will be present on-site and within RMSBs at the time of removal and decontamination procedures. Although other wastes may be present within a RMSB at that time and count toward the capacity, it will be assumed for simplicity that the 13,860 tons consists entirely of Reclaimed Catalyst. It is anticipated that the Facility will process the Reclaimed Catalyst through the Roaster and possibly electric arc furnaces. Alternatively, the Facility may sell the Reclaimed Catalyst as it is considered a valuable commodity. This RDP assumes that all 13,860 tons of Reclaimed Catalyst will require off-site disposal or recycling.

Gross solid contamination will be removed from floor, wall, and equipment surfaces with a high efficiency particulate air (HEPA) vacuum system. Dedicated equipment within a RMSB will be HEPA vacuumed in the areas where Reclaimed Catalyst residuals would likely accumulate. Equipment may be initially brushed clean of any Reclaimed Catalyst residuals prior to the use of the HEPA vacuum system. Gross solid contamination

removed by the HEPA vacuum system and any brushes utilized will be contained for subsequent off-site transportation and disposal.

4.2 Integrity Evaluation

Prior to beginning decontamination activities, a RMSB will be inspected for physical signs of structural integrity breakdown by a professional engineer registered in the State of Ohio. This effort will include evaluation of visual observations noted on recent inspection logs. Any conditions that could potentially lead to loss of decontamination liquid will also be identified. The inspection will involve visual examination of all cracks, seals covering expansion joints, and floor to wall seams. A secondary high intensity lighting system may be necessary to create the proper inspection conditions for a complete evaluation. All locations where cracks, seals, and seams are of sufficient size to accumulate Reclaimed Catalyst will be re-vacuumed. All visible cracks will be caulked flush to the floor surface with a product that is compatible with the Reclaimed Catalyst and also with the high-pressure/temperature water and cleaner to be used during the decontamination procedure. If the integrity evaluation suggests that a release could have potentially occurred, the RDP will be amended, if necessary, to include additional investigation activities.

4.3 Decontamination Procedure

Prior to the initiation of decontamination procedures, the floor of a RMSB will be modified such that they will serve as decontamination pads, with containment curbing in all appropriate areas. This will be accomplished by constructing roll-over curbing in the doorways (as necessary) to a minimum height of approximately four inches. The curbing will be constructed of concrete, wood, or other suitable material. Joints and/or abutments to existing curbing will be sealed with an appropriate caulk. Any access ports associated with the dual containment system will also be temporarily sealed during decontamination activities.

After the repairs to floor cracks (Section 4.2), curbing is installed (and fully cured if concrete is utilized), and access ports temporarily sealed, dedicated equipment within a RMSB will be decontaminated using a triple wash/rinse procedure. Equipment will likely include one or more front end loaders, Reclaimed Catalyst transport trucks, totes, and 55-gallon steel drums. The wash step will consist of scrubbing surfaces with Simple Green® Industrial Cleaner/Degreaser (or equivalent) and new brushes/brooms (which may be attached to equipment). Simple Green® Industrial Cleaner/Degreaser was selected as the wash detergent for all surfaces based on the manufacturer's wide range of material compatibility and intended uses, including removal of various types of gross contamination and oils. Once the wash step is complete, the surfaces will be rinsed with

potable water that is heated to approximately 170° F using a high pressure steam cleaner. This wash/rinse process will be completed a total of three times. Liquids will be controlled and collected using new floor squeegees, new sump pumps, and/or a vacuum truck. Any solids loosened from the surfaces will be collected with the liquids. For the front end loaders and other heavy equipment operated in a RMSB, surfaces to be triple washed/rinsed will include the beds/buckets, axles, wheel wells, tires, and rims. Once the triple rinse is completed, all equipment will be moved out of a RMSB away from the activities. Equipment will remain with the Facility or will be sold.

The floor and walls of a RMSB which have contacted Reclaimed Catalyst or wastes will be decontaminated using the same triple wash/rinse procedure as described above. Following the triple wash/rinse, a verification inspection will be performed to ensure that decontamination has met the definition of a clean debris surface as presented in Section 3.0. It is assumed that approximately 8,000 gallons of wash/rinse liquids will be generated.

5.0 Waste Characterization and Management

Wastes generated from removal and decontamination procedures will be adequately contained within RMSBs. Wastes that are anticipated to be generated from removal and decontamination procedures include the following:

- 13,860 tons of Reclaimed Catalyst;
- 200 tons of solids consisting of materials that cannot be processed or sold; contamination removed by the HEPA vacuum system; empty totes and drums; and brushes, brooms, squeegees, and personal protective equipment; and
- 16,000 gallons of wash/rinse liquids from decontamination procedures (including any slurried solids).

Although it is anticipated that the 13,860 tons of Reclaimed Catalyst will be processed onsite, it is conservatively assumed that it will be disposed or recycled off-site. The Facility also anticipates that the solids and liquids will be disposed of as hazardous waste. To properly characterize these waste streams, representative samples of the solids and liquids will be submitted to a laboratory for analysis of K171/K172 parameters found in 40 CFR 268.40. A summary of analytical methods, practical quantitation limits, holding times, containers, and preservation is provided in Tables 4-2 and 4-3 for liquids and solids, respectively. The TCLP extraction method (1311) only applies to solids. However, both the liquids and solids will be analyzed for the TCLP parameters and compared to the corresponding regulatory limits. Waste management and documentation will be performed in accordance with the requirements of OAC 3745-52. Packaging and

transportation of hazardous wastes will be performed in accordance with applicable Department of Transportation (DOT) regulations.

6.0 Air Emissions and Wastewater

The HEPA vacuum system that will be utilized to remove contamination from surfaces during the waste removal process will limit dust generation during subsequent removal and decontamination procedures. For wash/rinse procedures, limited air emissions may be generated, primarily consisting of water vapors/mist. However, any water vapors/mists should be contained within a RMSB. It is anticipated that air permitting associated with removal and decontamination procedures will not be necessary. Liquids generated from removal and decontamination procedures will either be transported off-site for appropriate disposal or discharged to a publicly owned treatment works (POTW). If discharged to a POTW, appropriate authorization will be obtained from the POTW.

7.0 Health, Safety, and Site Control

Prior to implementation of removal and decontamination activities, a Health and Safety Plan (HASP) will be prepared in accordance with applicable requirements of 29 CFR 1910. Existing Facility standard operating procedures (SOPs) may be used to supplement the HASP. The HASP and SOPs will address the health and safety of all personnel and subcontractors performing the work, and will specify, at a minimum, the following information:

- appropriate levels of personal protective equipment based on the nature of hazards to be encountered;
- environmental monitoring methods (if necessary);
- contingency plans to deal with emergencies and accidental exposures;
- an emergency contact list;
- work areas subject to the closure-related health and safety requirements; and
- personnel decontamination procedures and methods, and proper disposal or decontamination of equipment used during closure activities.

8.0 Oversight and Certification

Following completion of removal and decontamination procedures, as outlined in Section 4.0, a certification report will be completed by an independent professional engineer

registered in the State of Ohio. The certification report will be submitted to the Director of Ohio EPA with 60 days of completing removal and decontamination procedures. The professional engineer or his/her representative will be present during all critical activities, including:

- integrity evaluation; and
- decontamination procedures.

The professional engineer or his/her representative will not need to be present during removal of Reclaimed Catalyst, as verification of removal will be completed during the integrity evaluation. Ohio EPA will be notified a minimum of five working days prior to the above critical activities. At a minimum, the certification report will include the following information:

- a copy or reference of the approved RDP;
- copies of applicable Ohio EPA and Facility correspondence;
- a description of removal and decontamination procedures;
- the volume of waste generated and removed;
- analytical results of waste characterization;
- documentation that the removal and decontamination performance standards defined in the approved RDP have been achieved;
- documentation indicating the amount of Reclaimed Catalyst processed or sold following the start of removal and decontamination procedures;
- shipping manifests associated with the disposal of wastes; and
- a certification statement [in accordance with OAC 3745-50-42(D)] signed by the owner/operator and the independent registered professional engineer.

9.0 Cost Estimate and Financial Assurance

A written cost estimate to implement removal and decontamination procedures associated with the RMSBs will be prepared and a mechanism for financial assurance (including liability requirements) will be established as required by the Variance. This RDP assumes the maximum allowed mass of Reclaimed Catalyst (approximately 13,860 tons) will be present on-site and within the RMSBs at the time of removal and decontamination procedures. However, the quantity of material stored shall not exceed that used as the basis for the cost estimate and financial assurance.

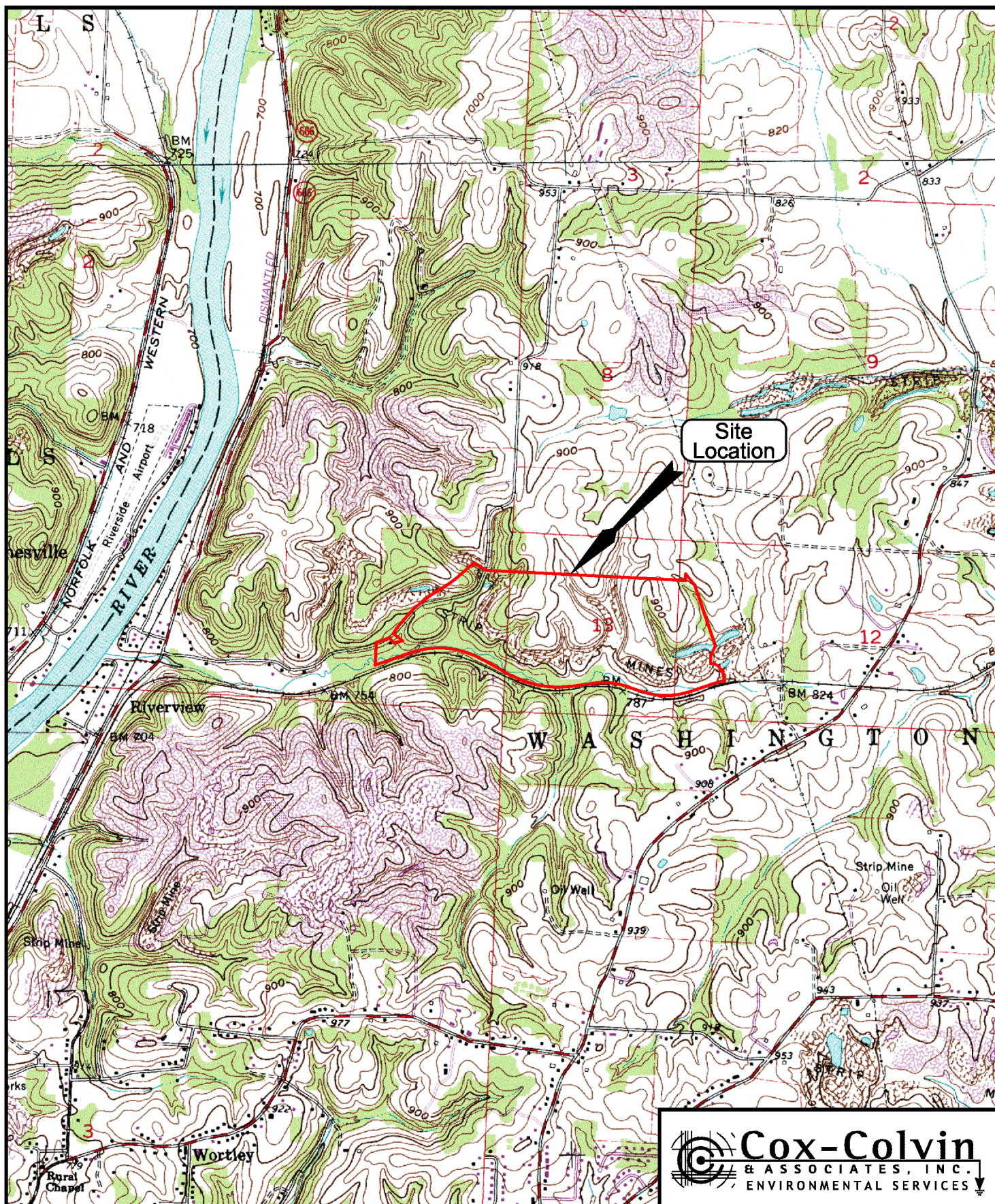
10.0 Schedule

The Facility will notify the Director of the Ohio EPA in writing at least 45 days prior to beginning any removal and decontamination procedures. The procedures will begin no later than 30 days after the date a RMSB receives the known final volume of Reclaimed Catalyst. An anticipated schedule is provided below.

- start (0 days elapsed) – final receipt of Reclaimed Catalyst; begin removal and decontamination procedures with depletion/processing of Reclaimed Catalyst
- 90 days (90 days elapsed) – complete depletion/processing of Reclaimed Catalyst and continue removal and decontamination procedures
- 90 days (180 days elapsed) – complete removal and decontamination procedures; begin to prepare certification
- 60 days (240 days elapsed) – complete and submit certification

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Figures



Cox-Colvin
 & ASSOCIATES, INC.
 ENVIRONMENTAL SERVICES

Scale 1:24,000
 0' 1000' 2000' 3000' 4000' 5000'

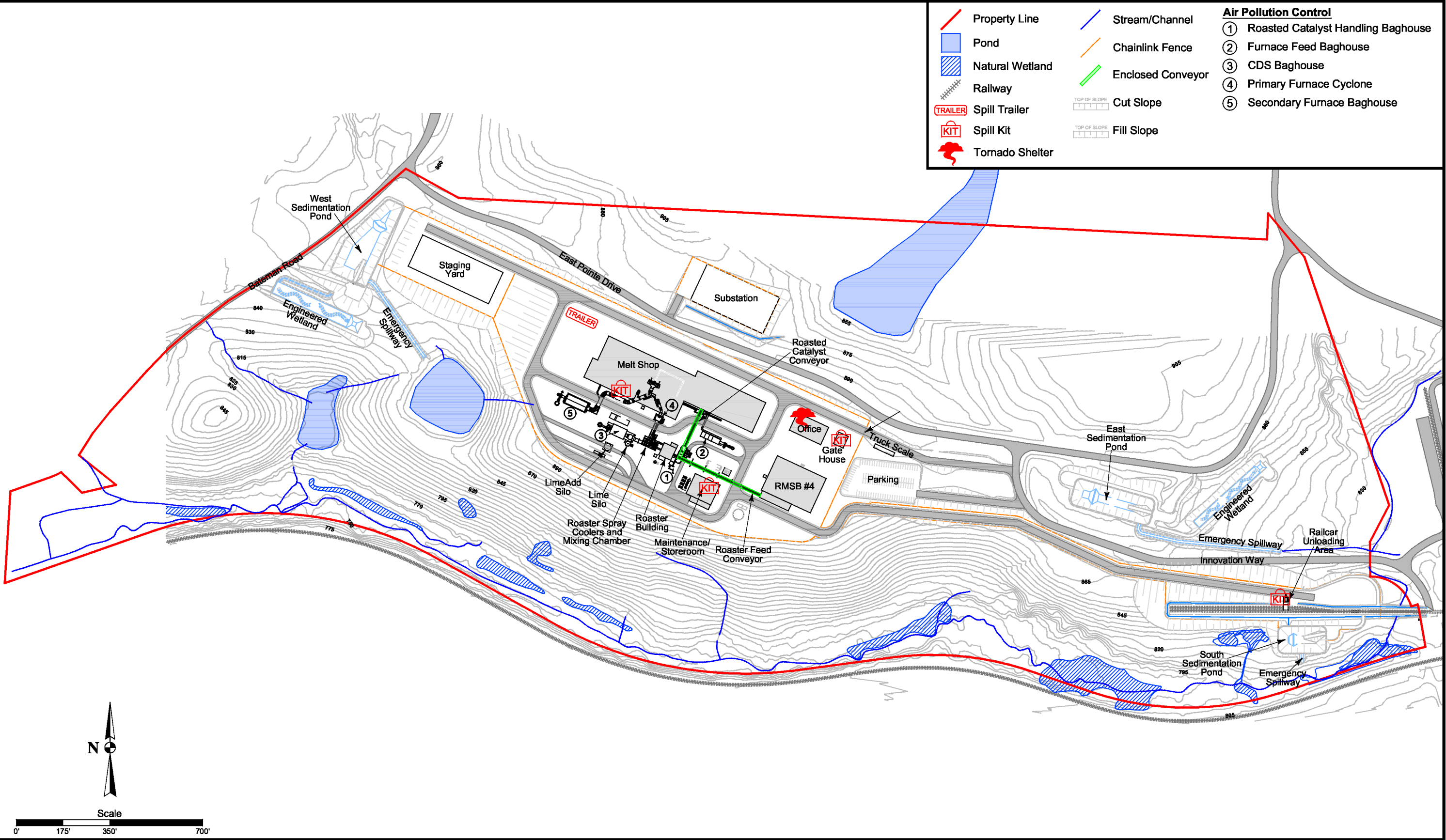


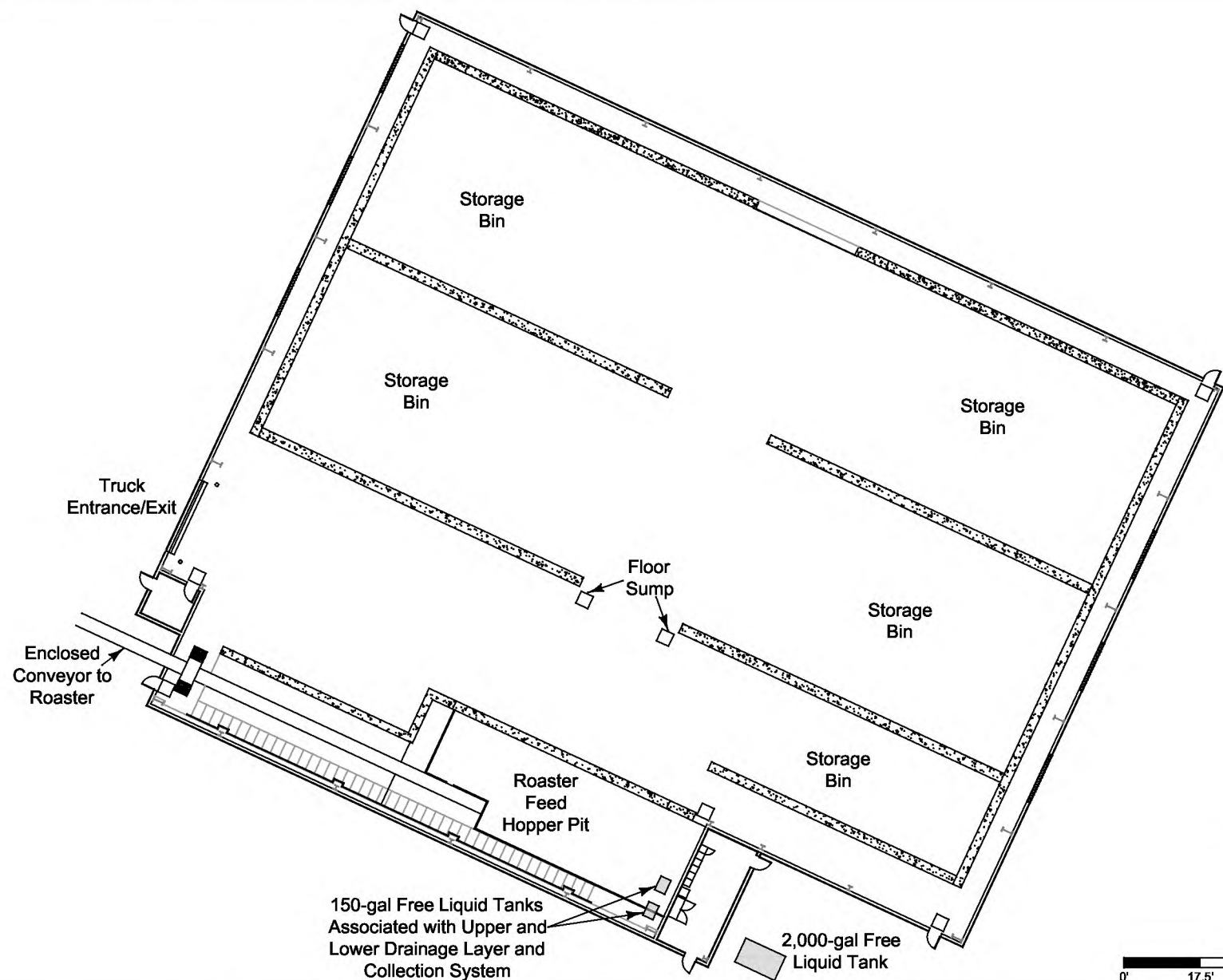
Figure 4-1

Site Location Map,
 AMG Vanadium LLC,
 Zanesville, Ohio

Revision 0

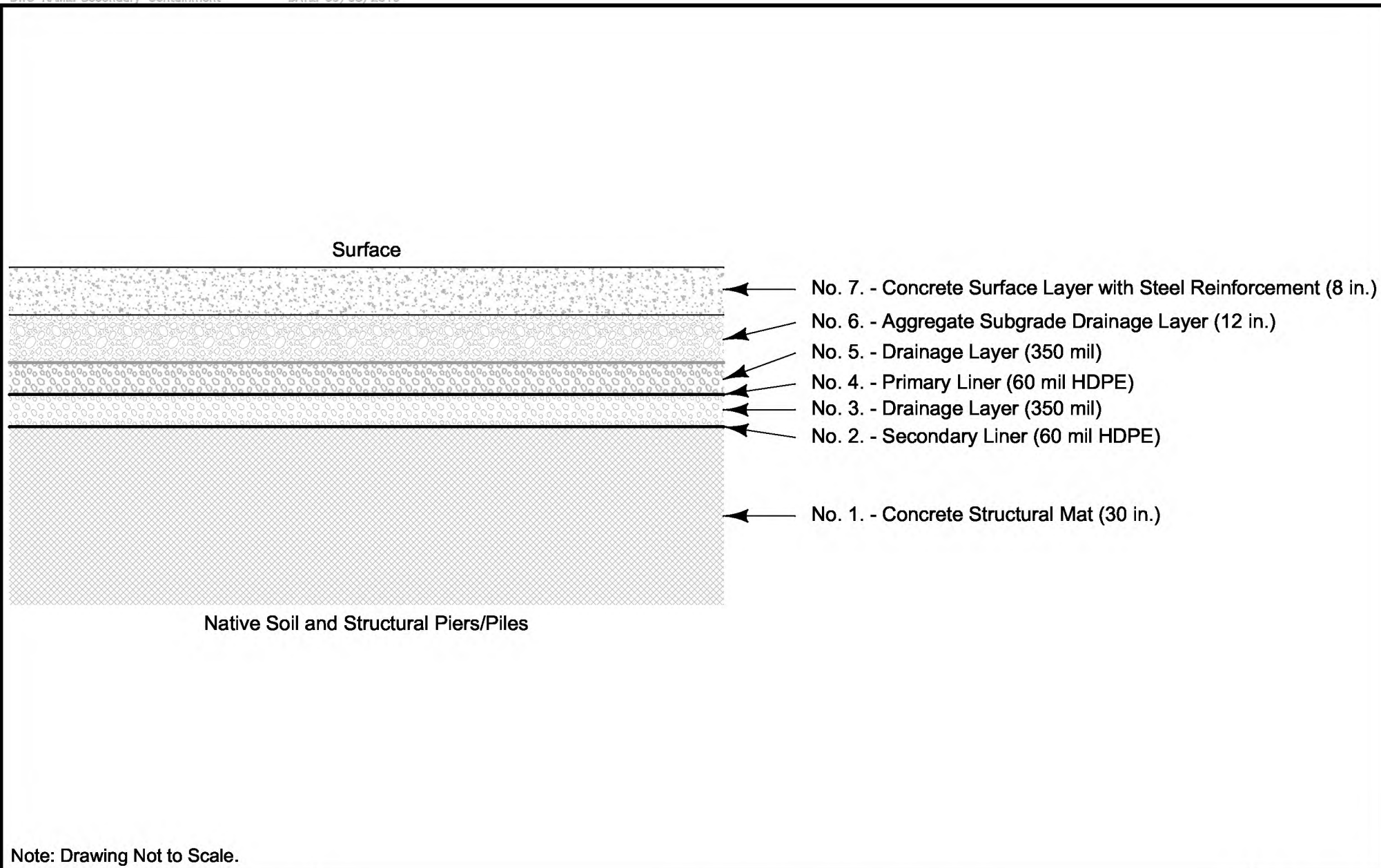
Source: 7.5 Minute Series Quadrangle
 Adamsville, Ohio (1962, Photorevised 1987)
 Zanesville East, Ohio (1961, Photorevised 1987)

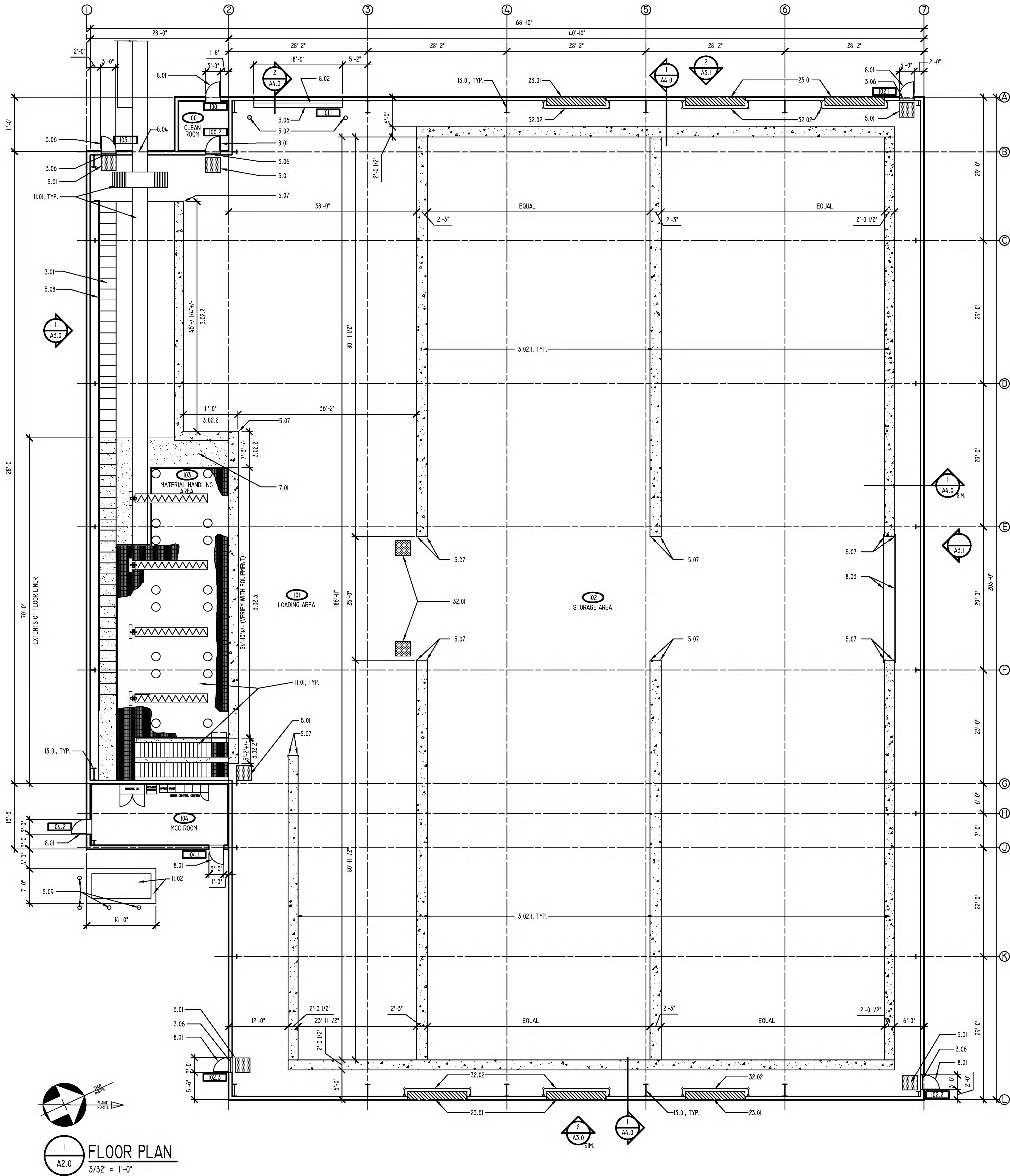




Scale

0' 17.5' 35' 70'





FLOOR PLAN
3/32" = 1'-0"

TYPICAL NOTES:	
<ul style="list-style-type: none">CONTRACTOR SHALL FIELD VERIFY ALL EXISTING CONDITIONS AND DIMENSIONS BEFORE PROCEEDING WITH WORK.ALL DIMENSIONS ARE TO FACE OF CONCRETE, MASONRY, STRUCTURE LINE, OR CENTERLINE OF COLUMNS.FOLLOW ALL MANUFACTURER'S INSTRUCTIONS & SPECIFICATIONS FOR INSTALLATION UNLESS OTHERWISE INSTRUCTED BY THE ARCHITECT.CONTRACTOR TO PROVIDE CLEAN, COMPACTED BACKFILL IN ALL EXCAVATED AREAS. BLEND NEW FINISH GRADES WITH UNDISTURBED AREAS.ALL EXTERIOR CONCRETE TO BE BROOM FINISH UNLESS NOTED OTHERWISE.CONTRACTOR TO COORDINATE WITH ALL TRADES FOR CLEARANCE REQUIREMENTS, BLOCKING, BRACING, ETC.COORDINATE ALL WORK WITH OWNER'S OPERATIONS.COORDINATE WITH O.U.P.S. PRIOR TO EXCAVATION.REFERENCE ELEVATION 100'-0" EQUALS SITE ELEVATION 888'-8.1" TYP.	
P.E.M.B. NOTES:	
<ul style="list-style-type: none">G.C. TO COORDINATE WITH P.E.M.B. MANUFACTURER. G.C. TO ENSURE THAT THE REQUIRED BUILDING CLEAR HEIGHTS ARE MAINTAINED AS PER ROOF PLAN ON SHEET A2.1. EAVE HEIGHTS MAY VARY.PRIOR TO PLACING ABUSE WALLS, G.C. TO COORDINATE WITH P.E.M.B. MANUFACTURER TO ENSURE SUFFICIENT CLEARANCE FOR A PERSON WITH A WHEELBARROW TO MANEUVER BETWEEN P.E.M.B. FRAMING AND ABUSE WALLS. REFER TO REFERENCE DIMENSIONS ON DETAIL 1/AA.0.	
CODED NOTES:	
<ul style="list-style-type: none">NOT ALL THE MATERIALS LISTED HERE ARE NECESSARILY USED ON THIS SHEET.	
3.00 CONCRETE	
3.01	CONCRETE STAIR BUILT IN TO FLOOR SLAB FOR EQUIPMENT ACCESS, REFER TO STRUCTURAL DRAWINGS.
3.02.1	CONCRETE ABUSE WALL, 12'-0" A.F.F. MIN. (VARIES). REFER TO STRUCTURAL DRAWINGS.
3.02.2	CONCRETE ABUSE WALL, 3'-6" A.F.F. MIN. (VARIES). REFER TO STRUCTURAL DRAWINGS.
3.02.3	CONCRETE ABUSE WALL, 3'-2" A.F.F. (VARIES - VERIFY WITH EQUIPMENT). REFER TO STRUCTURAL DRAWINGS.
3.03	STRUCTURAL MAT SLAB - SEE STRUCTURAL DRAWINGS.
3.04	WEAR SLAB - SEE STRUCTURAL DRAWINGS.
3.05	CONCRETE CURB FOR CONTAINMENT AROUND ENTIRE EXTERIOR PERIMETER - SEE STRUCTURAL DRAWINGS FOR ADDITIONAL INFORMATION.
3.06	CONCRETE CURB FOR CONTAINMENT AT ALL DOORS - CONCRETE CURBS AT RAMP AND ALL DOORS ARE TO TIE IN TO PERIMETER CURB SEE STRUCTURAL DRAWINGS.
5.00 METALS	
5.01	GRATED DECONTAMINATION AREA - SEE STRUCTURAL
5.02	6" DIA. INTERIOR CONCRETE FILLED PIPE BOLLARDS, SEE DETAIL 3/AA.0. PAINT YELLOW PRIME PLUS (2) FINISH COATS.
5.03	STRUCTURAL PILE - SEE STRUCTURAL DRAWINGS
5.04	12"x12"x3/8" STEEL PLATE (EMBEDDED)
5.05	(4) 1/2" DIA. X 6" STUDS WELDED TO PLATE
5.06	(2) #4.5 (2'-0" LONG) EACH WAY AT EMBEDDED PLATE
5.07	STEEL END GUARDS, SEE STRUCTURAL DRAWINGS
5.08	1-1/4" OUTSIDE DIAMETER HANDRAIL, MOUNT 36" A.F.F. TO TOP OF RAIL
5.09	9" DIA. EXTERIOR BOLLARDS FOR TANK PROTECTION, REFER TO CONTAINMENT DRAWINGS. PAINT YELLOW (PRIME PLUS (2) FINISH COATS).
7.00 THERMAL AND MOISTURE PROTECTION	
7.01	RHINO EXTREME II-50 GTS FLOOR LINER, EXTEND UNDER ALL EQUIPMENT, STAIRS ETC. AND 24" MIN. UP ALL PERIMETER WALLS. TOUCH-UP AS REQUIRED AFTER EQUIPMENT INSTALLATION.
7.02	WATERTOP - SEE STRUCTURAL
7.03	WATERPROOFING ON OUTSIDE FACE OF ALL FOUNDATION WALLS BELOW GRADE, TYP.
8.00 DOORS & WINDOWS	
8.01	3'-0" x 7'-0" MAN DOOR
8.02	18'-0" x 20'-0" OVERHEAD DOOR
8.03	OPENING COVER STRUCTURE, REFER TO STRUCTURAL DRAWINGS.
8.04	OPENING IN P.E.M.B. WALL FOR CONVEYOR, CONFORM WITH EQUIPMENT.
11.00 EQUIPMENT	
11.01	MATERIAL HANDLING EQUIPMENT INCLUDING ACCESS STAIRS AND PLATFORMS UNDER SEPARATE CONTRACT.
11.02	OVERFLOW TANK ON CONCRETE PAD, SEE CONTAINMENT AND STRUCTURAL DRAWINGS FOR ADDITIONAL INFORMATION.
13.00 SPECIAL CONSTRUCTION (P.E.M.B. - REFER TO P.E.M.B. DRAWINGS)	
13.01	P.E.M.B. STRUCTURAL STEEL
13.02	P.E.M.B. GUTTER AND DOWNSPOUT
13.03	P.E.M.B. WALL PANELS
13.04	P.E.M.B. STANDING SEAM ROOF PANELS
13.05	P.E.M.B. CLOSURE
13.06	P.E.M.B. FACED INSULATION
13.07	P.E.M.B. ROOF PURLINS
13.08	P.E.M.B. WALL GIRTS
23.00 HEATING, VENTILATION AND AIR CONDITIONING	
23.01	H.V.A.C. EQUIPMENT, SEE H.V.A.C. DRAWINGS.
26.00 ELECTRICAL	
26.01	LIGHT FIXTURES, SEE ELECTRICAL DRAWINGS.
32.00 EXTERIOR IMPROVEMENTS	
32.01	CONTAINMENT SYSTEM, SEE CONTAINMENT DRAWINGS
32.02	9'-0" HIGH CUSTOM GALVANIZED CHAIN LINK FENCE FOR PEDESTRIAN PROTECTION FROM HVAC UNITS. PROVIDE ACCESS PANELS AS REQUIRED. SUBMIT SHOP DRAWINGS FOR APPROVAL.

DOOR SCHEDULE					
NO.	SIZE	TYPE	FRAME		REMARKS
			ELEV	TYPE	
100.1	3'-0"x 7'-0"x 1/4"	HMTL		PEMB	1,2,3,4,5,6
100.2	3'-0"x 7'-0"x 1/4"	HMTL		PEMB	1,2,3,4,5,6
101.1	18'-0"x 20'-0"	OH DOOR		PEMB	BY OH DOOR MAN.
102.1	3'-0"x 7'-0"x 1/4"	HMTL		PEMB	1,2,3,4,5,6
102.2	3'-0"x 7'-0"x 1/4"	HMTL		PEMB	1,2,3,4,5,6
102.3	3'-0"x 7'-0"x 1/4"	HMTL		PEMB	1,2,3,4,5,6
103.1	3'-0"x 7'-0"x 1/4"	HMTL		PEMB	1,2,3,4,5,6
104.1	3'-0"x 7'-0"x 1/4"	HMTL		PEMB	1,2,3,4,5,6
104.2	3'-0"x 7'-0"x 1/4"	HMTL		PEMB	1,2,3,4,5,6
ALL EGRESS DOORS SHALL BE READILY OPENABLE FROM THE SIDE FROM WHICH EGRESS IS TO BE MADE WITHOUT THE USE OF A KEY OR SPECIAL KNOWLEDGE OR EFFORT.					
HARDWARE LIST (NOTE: SEE SCHEDULE FOR LOCATION)					
1.	1 1/2 PAIR NRP HINGES	5.	WEATHER STRIPPING AND SWEEP STRIP		
2.	CLOSER	6.	PANIC HARDWARE:		
3.	SILENCERS		VON DUPRIN 98L EXIT SERIES OR EQUAL. 992L-BE		
4.	THRESHOLD		OUTSIDE TRIM		
REMARKS					
1. DOOR AND FRAME PROVIDED BY P.E.M.B. MANUFACTURER. HARDWARE PROVIDED BY G.C.					

STATE OF OHIO
RONALD D. VAN WEY II
JULY 11, 1985
REGISTERED ARCHITECT

0124

V 2 ARCHITECTS
903 Steubenville Ave.
Cambridge, OH 43725

PROJECT
AMG Vanadium
Raw Material Storage Building
3400 East Pointe Drive
Zanesville, OH 43701

ISSUED:
08/23/2019 BASIC ENGINEERING
10/16/2019 DETAILED ENGINEERING

PROJECT NO.
1829

DRAWN:
ZPS

CHECKED:
MAB/RWW

SHEET NAME
FLOOR PLAN

A2.0

Tables

Table 4-1. Summary of Hazardous Constituents that Could be Associated with Reclaimed Catalyst and Other Materials Potentially Stored in a RMSB, AMG Vanadium LLC, Zanesville, Ohio

Revision 0

K171 Hazardous Constituents*	
Constituent	CAS #
Benzo(a)anthracene	56-55-3
Benzene	71-43-2
Chrysene	218-01-9
Ethyl benzene	100-41-4
Naphthalene	91-20-3
Phenanthrene	81-05-8
Pyrene	129-00-0
Toluene (Methyl Benzene)	108-88-3
Xylene(s) (Total)	1330-20-7
Arsenic	7740-38-2
Nickel	7440-02-0
Vanadium	7440-62-2
Reactive sulfides	NA
K172 Hazardous Constituents*	
Constituent	CAS #
Antimony	7440-36-0
Benzene	71-43-2
Ethyl benzene	100-41-4
Toluene (Methyl Benzene)	108-88-3
Xylene(s) (Total)	1330-20-7
Arsenic	7740-38-2
Nickel	7440-02-0
Vanadium	7440-62-2
Reactive sulfides	NA

NA Not Applicable

*based on regulated hazardous constituents identified in 40 CRF 268.40

K:\CCA\PROJECTS\AMG Zanesville\Variance Application 2019\Att 4 RDP\Table 4-1.xlsx]Sheet1

Table 4-2. Summary of Laboratory Methods, Practical Quantitation Limits, Holding Times, Preservatives, and Sampling Containers for Totals Analysis of Liquids, AMG Vanadium LLC, Zanesville, Ohio

Revision 0

Parameter	Method	PQL	Units	Holding Time	Container	Preservative
Benzo(a)anthracene	8270C	0.2	ug/L	40 days	2 x 1-L glass amber	Cool 4°C
Benzene	8260B	1.0	ug/L	14 days	3 x 40 ml glass vials	HCl, Cool 4°C
Chrysene	8270C	0.2	ug/L	40 days	2 x 1-L glass amber	Cool 4°C
Ethyl benzene	8260B	1.0	ug/L	14 days	3 x 40 ml glass vials	HCl, Cool 4°C
Naphthalene	8270C	0.2	ug/L	40 days	2 x 1-L glass amber	Cool 4°C
Phenanthrene	8270C	0.2	ug/L	40 days	2 x 1-L glass amber	Cool 4°C
Pyrene	8270C	0.2	ug/L	40 days	2 x 1-L glass amber	Cool 4°C
Toluene (Methyl Benzene)	8260B	1.0	ug/L	14 days	3 x 40 ml glass vials	HCl, Cool 4°C
Xylene(s) (Total)	8260B	2.0	ug/L	14 days	3 x 40 ml glass vials	HCl, Cool 4°C
Antimony	6020	0.002	mg/L	6 months	500 ml poly	HNO ₃ , Cool 4°C
Arsenic	6020	0.005	mg/L	6 months	500 ml poly	HNO ₃ , Cool 4°C
Nickel	6020	0.002	mg/L	6 months	500 ml poly	HNO ₃ , Cool 4°C
Vanadium	6020	0.005	mg/L	6 months	500 ml poly	HNO ₃ , Cool 4°C
Sulfide	9034	0.003	mg/L	7 days	500 ml poly	Zn Acetate, NaOH, Cool 4°C

PQL - Practical Quantitation Limit

ug/L - micrograms per liter

mg/L - milligrams per liter

SW846 Method 8260B: VOCs by Gas Chromatography/Mass Spectrometry (GC/MS), Revision 2, December 1996.

SW846 Method 8270C: Semivolatile Organic Compounds by Gas Chromatography/Mass Spectrometry (GC/MS), Revision 3, December 1996.

SW 846 Method 6020: Inductively Coupled Argon Plasma - Mass Spectrometry, Revision 0, September 1994.

SW846 Method 9034 : Titrimetric Procedure for Acid-Soluble and Acid-Insoluble Sulfides, Revision 0, July 1992.

PQLs are periodically updated by the laboratory and subject to change.

K:\CCA\PROJECTS\AMG Zanesville\Variance Application 2019\Att 4 RDP\[Table 4-2.xlsx]Sheet1

Table 4-3. Summary of Laboratory Methods, Practical Quantitation Limits, Holding Times, Preservatives, and Sampling Containers for Totals and TCLP Analysis of Solids, AMG Vanadium LLC, Zanesville, Ohio

Revision 0

Parameter	Analysis Type	Method	PQL	Units	Holding Time	Container	Preservative
Benzo(a)anthracene	Total	8270C	6.67	ug/kg	40 days	8 oz glass	Cool 4°C
Benzene	Total	8260B	5	ug/kg	14 days	8 oz glass	Cool 4°C
Chrysene	Total	8270C	6.67	ug/kg	40 days	8 oz glass	Cool 4°C
Ethyl benzene	Total	8260B	5	ug/kg	14 days	8 oz glass	Cool 4°C
Naphthalene	Total	8270C	6.67	ug/kg	40 days	8 oz glass	Cool 4°C
Phenanthrene	Total	8270C	6.67	ug/kg	40 days	8 oz glass	Cool 4°C
Pyrene	Total	8270C	6.67	ug/kg	40 days	8 oz glass	Cool 4°C
Toluene (Methyl Benzene)	Total	8260B	5	ug/kg	14 days	8 oz glass	Cool 4°C
Xylene(s) (Total)	Total	8260B	10	ug/kg	14 days	8 oz glass	Cool 4°C
Antimony	Total	6020	0.4	mg/kg	6 months	8 oz glass	Cool 4°C
Arsenic	Total	6020	1	mg/kg	6 months	8 oz glass	Cool 4°C
Nickel	Total	6020	0.4	mg/kg	6 months	8 oz glass	Cool 4°C
Vanadium	Total	6020	1	mg/kg	6 months	8 oz glass	Cool 4°C
Sulfide	Total	9034	30	mg/kg	7 days	8 oz glass	Cool 4°C
Benzene	TCLP	1311/8260B	0.025	mg/L	14 days TCLP ext, 14 days analysis	8 oz glass	Cool 4°C
Arsenic	TCLP	1311/6020	0.005	mg/L	6 months TCLP ext, 6 months analysis	8 oz glass	Cool 4°C

PQL - Practical Quantitation Limit

ug/kg - micrograms per kilogram

mg/kg - milligrams per kilogram

mg/L - milligrams per liter

SW846 Method 1311: Toxicity Characteristic Leaching Procedure, Revision 0, July 1992.

SW846 Method 8260B: VOCs by Gas Chromatography/Mass Spectrometry (GC/MS), Revision 2, December 1996.

SW846 Method 8270C: Semivolatile Organic Compounds by Gas Chromatography/Mass Spectrometry (GC/MS), Revision 3, December 1996.

SW846 Method 6020: Inductively Coupled Argon Plasma - Mass Spectrometry, Revision 0, September 1994.

SW846 Method 9034: Titrimetric Procedure for Acid-Soluble and Acid-Insoluble Sulfides, Revision 0, December 1996.

PQLs are periodically updated by the laboratory and subject to change.

K:\CCA\PROJECTS\AMG Zanesville\Variance Application 2019\Att 4 RDP\Table 4-3.xlsx]Sheet1

Attachment 5

Inspection Program

Attachment 5
Inspection Program

**Attachment 5
Inspection Program
Revision 0**

November 1, 2019

Submitted to:

AMG Vanadium LLC
3400 East Pointe Drive
Zanesville, Ohio 43701
EPA ID No. OHR000212902

Submitted by:

Cox-Colvin & Associates, Inc.
7750 Corporate Blvd.
Plain City, Ohio 43064
(614) 526-2040



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Tables

5-1	Inspection Matrix
-----	-------------------

I.0 Introduction

This attachment describes the proceduralized system that the Company uses to perform inspections of communications or alarm systems, fire protection equipment, spill control equipment, and decontamination equipment to maintain compliance with applicable Ohio environmental regulations. The inspection program presented in this attachment also will determine the malfunction and/or deterioration of equipment, operator errors, and discharges that may be causing, or have the potential to cause, release of Reclaimed Catalyst that could pose a threat to human health and the environment. Unit-specific requirements for the operation of a containment building is also addressed.

I.1 Amendment of the Plan

AMG's inspection program is a living program which will be continually reviewed and updated, if necessary, to improve practices and reflect the current environmental legislation, respond to notices of deficiency and violations and meet current business needs.

2.0 Inspection Procedures and Forms

Inspection procedures and forms are referenced throughout this document, which are change controlled and require an internal approval process when any changes are made. The actual inspection procedures and forms have been purposely excluded from this document to provide the Company with flexibility to update without the need for a formal modification in instances when inspection frequencies or scope are increased or appearance/format change. For each area of inspection discussed in the following sections, the minimum points of inspection are summarized in Table 5-1. The minimum elements included in the inspection procedures and/or forms are:

- The location(s) and area(s) that the inspection apply;
- Frequency of inspection;
- Personnel to notify;
- Procedures for completing the inspection form;
- Description of actions required for each inspection step;
- Procedures for or corrective action taken;
- Date, time, and person conducting the inspection; Personal protective equipment required during the inspection; and
- Potential hazards and problems that may be encountered.

2.1 Roaster

The Company operates a Roaster that is equipped with flue gas desulfurization unit (FGD) in the form of a Circulating Dry Scrubber (CDS) and fabric filter dust collection (baghouse). The Roaster is used to precondition the Reclaimed Catalyst prior to its incorporation into a furnace blend or being sold for metals reclamation. The CDS is used to control sulfur dioxide emissions from both the Roaster and Primary EAF and the baghouse is used to control particulate emissions from the CDS. For the purpose of inspection, the CDS will be included in the Roaster inspections.

2.1.1 Roaster Inspection

The Roasters inspection procedure and the results form are both change controlled documents that must go through an approval process when any changes are made. They are maintained in the Company's document control system. Minimum points of inspection are summarized in Table 5-1.

2.2 RMSBs

The design, construction, and operation of RMSBs is described in Attachment 3.

2.2.1 RMSB Inspection

RMSB inspection procedures and forms are change controlled documents that must go through an approval process when any changes are made. They are maintained in the Company's document control system. Minimum points of inspection are summarized in Table 5-1.

2.2.2 RMSB Visible Emissions Inspection

The visible fugitive emissions inspection (including Method 22) procedures and forms are change controlled documents that must go through an approval process when any changes are made. They are maintained in the Company's document control system. In addition, a policy for closed doors is implemented to reduce the generation of fugitive emissions. Minimum points of inspection are summarized in Table 5-1.

2.2.3 Tracking Reduction Procedure

The tracking reduction procedure and form includes both an in-building decontamination and a post exit check for effectiveness. Specific information is included regarding:

- Exiting a RMSB;
- Exiting the Baghouse Roll Off Enclosures;
- Exiting the LimeAdd™ Silo enclosure; and
- Inspecting vehicle for compliance once they have left these areas.

These are change controlled documents that must go through an approval process when any changes are made. They are maintained in the Company's document control system. Minimum points of inspection are summarized in Table 5-1.

2.2.4 Personnel Decontamination Procedure

The personnel decontamination procedure is designed to ensure pedestrian traffic exiting areas where Reclaimed Catalyst is utilized does not remove these materials from the building. This is a change-controlled document that must go through an approval process when any changes are made. It is maintained in the Company's document control system. Minimum points of inspection are summarized in Table 5-1.

2.3 Railcar Unloading Area Inspection

The Railcar Unloading Area is used to unload reclaimed catalyst from railcars. The Railcar Unloading Area inspection is detailed in a procedure and the results noted on a form. These are both change controlled documents that must go through an approval process when any changes are made. They are maintained in the Company's document control system. Minimum points of inspection are summarized in Table 5-1.

2.4 Fire Extinguisher Inspection

Fire extinguishers maintained in the areas where Reclaimed Catalyst or wastes are stored are inspected. All fire extinguishers are maintained in line with OSHA regulations. The RCRA fire extinguisher inspection is detailed in a procedure and the results noted on a form. These are both change controlled documents that must go through an approval process when any changes are made. They are maintained in the Company's document control system. Minimum points of inspection are summarized in Table 5-1.

2.5 Safety & Emergency Equipment Inspection

Safety and Emergency Equipment is maintained in the areas where Reclaimed Catalyst or waste are stored are inspected. The Safety and Emergency Equipment Inspection is detailed in a procedure and the results noted on a form. These are both change controlled documents that must go through an approval process when any changes are made. They are maintained in the Company's document control system. Minimum points of inspection are summarized in Table 5-1.

2.6 Security Inspection

The Security of the site is inspected on a routine basis. This inspection, a combination of audit and physical checks, is detailed in a procedure and the results noted on a form. These are both change controlled documents that must go through an approval process when any changes are made. They are maintained in the Company's document control system. Minimum points of inspection are summarized in Table 5-1.

2.7 Inspection Matrix

An inspection matrix, which includes frequencies and the minimum points of inspection, is provided as Table 5-1.

K:\CCA\PROJECTS\AMG Zanesville\Variance Application 2019\Att 5 Inspections\Attachment 5 Rev 0.docx

Table

Table 5-1. Inspection Matrix, AMG Vanadium LLC, Zanesville, Ohio

Revision 0

Inspection	Unit/Area	Responsible Person	Frequency	Minimum Points of Inspection	
Roaster Inspection	Roaster	Roaster Foreman	Daily	<ul style="list-style-type: none">• Feed Conveyors and Pad Spills• LimeAdd Silo Spills/Releases• LimeAdd/Roaster Feed Spill Control Equipment Available• Ground Floor Doors and Housekeeping	<ul style="list-style-type: none">• ECT Area Spills/Releases/Containment• CDS Area Spills/Releases/Containment• Baghouse Area Spills/Releases/Tracking• Stack Condensate Drain Spills/Releases
Raw Material Storage Buildings	RMSBs	Environmental Specialist	At Least Once Every 7 Days	<ul style="list-style-type: none">• Integrity of Primary Barrier• Evidence of Releases from Exterior Walls• Sump Port Observations (Daily)• Level in Accumulation Tanks	<ul style="list-style-type: none">• Tracking• Evidence of Precipitation Entering• Roaster Feed Hoppers Integrity/Spills
Fugitive Emissions Inspection	RMSBs	Roaster Foreman	Daily	<ul style="list-style-type: none">• Visible Emissions Present• Normal/Abnormal Operations	<ul style="list-style-type: none">• Color and Duration of Emissions
Fugitive Emissions Method 22	RMSBs	Environmental Specialist	Monthly	<ul style="list-style-type: none">• Weather Conditions• Observation Information	<ul style="list-style-type: none">• Observer Position
Tracking Reduction Procedure	RMSBs, LimeAdd Silo, Baghouses	Equipment Operators	As Required	<ul style="list-style-type: none">• Mobile Vehicle/Equipment ID and Operator• Equipment Used for Cleaning (if applicable)	<ul style="list-style-type: none">• Cleaning Required
Security Inspection	General	Yard Supervisor	Monthly	<ul style="list-style-type: none">• Perimeter Fencing and Gates Intact and Locked• Gate Intercom Operation• Automatic Gate Operation	<ul style="list-style-type: none">• Fence Warning Signage Present• Truck and Visitor Log Check• In-plant Warning Signage Present
Fire Extinguisher Inspection	Roaster, RMSBs, Railcar Unloading Area	Environmental Specialist	Monthly	<ul style="list-style-type: none">• Extinguishers Present• 1-Year Tag and Sign	<ul style="list-style-type: none">• Clean and Usable Condition
Safety and Emergency Equipment Inspection	Roaster and RMSBs	Environmental Specialist	Weekly	<ul style="list-style-type: none">• SCBAs Availability and Condition• Operation of Eyewash Stations• PPE Inventory Adequate• Emergency Fire Pump Availability	<ul style="list-style-type: none">• Emergency Lighting Availability• Spill Cleanup Equipment Availability• Emergency Power Supply Availability• Emergency PPE Availability
Personnel Decontamination Procedure	RMSBs	Person Exiting Building	As Required	<ul style="list-style-type: none">• Procedure Only, Inspection Not Applicable	
Railcar Unloading Inspection	Railcar Unloading Area	Yard Supervisor	Daily	<ul style="list-style-type: none">• Number of Railcars Onsite and Offsite• Trackpan Contents/Condition• Railcar Placarding• Loading Area Spills/Condition	<ul style="list-style-type: none">• General Leaks/Spills• Screw Auger and Unloading Conveyors Spills/Condition• Sump Contents/Condition• Free Liquid Tanks/Containers per SPCC Plan
Closed Door Policy	RMSBs and Baghouses	Person Exiting Building	As Required	<ul style="list-style-type: none">• Policy Only, Inspection Not Applicable	

Notes:
Daily frequency is Sunday through Saturday when in use, regardless of facility operation schedule
Weekly frequency is at least once Sunday through Saturday
Refer to actual inspection procedure and log (internal documents) for additional information on points of inspection

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Attachment 6

Training Program

Attachment 6
Training Program

**Attachment 6
Training Program
Revision 0**

November 1, 2019

Submitted to:

AMG Vanadium LLC
3400 East Pointe Drive
Zanesville, Ohio 43701
EPA ID No. OHR000212902

Submitted by:

Cox-Colvin & Associates, Inc.
7750 Corporate Blvd.
Plain City, Ohio 43064
(614) 526-2040



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A	Training Outlines
B	Training Matrix
C	Job Descriptions

1.0 Introduction

AMG Vanadium LLC (“AMG” or “The Company”) has implemented a training program to ensure that all existing and future Facility personnel will successfully complete training that will consist of classroom instruction, computer based, or on-the-job training. This training will ensure that all Facility personnel are able to respond effectively and appropriately to emergency situations by familiarizing them with the implementation of the Contingency Plan (Attachment 8), emergency procedures, emergency equipment, and emergency systems. The training program will also teach each employee (pursuant to their job functions) how to perform their duties in a way that ensures the Facility’s compliance with all applicable regulations. An overview of this program is provided in the following subsections.

The training program is directed by the Environmental Manager, a person trained in Reclaimed Catalyst management procedures, or by suitably qualified external trainers.

2.0 General Training Program

Components of the general training program include Contingency Plan training, regulated waste training, process training, supervisor training, and annual refresher training. Each of these components is discussed below¹. Supplemental information is provided in Appendices A, B, and C.

2.1 Contingency Plan Training

All current Facility employees, all future employees, and all contract employees that may be on site for an extended period, will undergo training to ensure that they are aware of what actions they must take in the event that an emergency situation occurs and the Contingency Plan is implemented. AMG will review with each employee those parts of the plan that the employee must know to protect the employee in the event of an emergency. Because various personnel have different potential for exposure to emergency situations, or have different responsibilities for implementing the Contingency Plan, the Contingency Plan training is divided into two levels, as discussed in the following paragraphs.

2.1.1 Level I Contingency Plan Training

Anyone entering the site to perform activities that will not expose them to the dangers inherent to Facility operations or to Reclaimed Catalyst will be required to undergo Level I Contingency Plan training. This is the most basic level of emergency plan training and

¹ If equivalent training is provided at the Cambridge Facility, it will satisfy the training requirement of the Zanesville Facility.

will instruct personnel how to recognize emergency signals and what evacuation procedures they would need to know in the event of an emergency at the Facility. A synopsis of the emergency and evacuation procedures from the Contingency Plan will be made available to personnel and all personnel will be required to sign the training log indicating that they have been made aware of, and understand the emergency plan procedures.

2.1.2 Level II Contingency Plan Training

Facility personnel working in and around areas where typical Facility operations take place or in areas where Reclaimed Catalyst is present, will undergo Level II Contingency Plan training. This level of training will instruct personnel on all aspects of implementing the Contingency Plan, including how to perform their job functions properly and how to respond effectively to emergencies by familiarizing them to emergency procedures, emergency equipment, and emergency systems, including:

- Procedures for using, inspecting, repairing, and replacing Facility emergency and monitoring equipment;
- Communication or alarm systems;
- Response to fires or explosions; and
- Shut down of operations.

AMG will apprise employees of the fire hazards of the Reclaimed Catalyst and processes to which they are exposed. AMG will review with each employee upon initial assignment those parts of the fire prevention and Facility evacuation plans within the Contingency Plan that the employees must know to protect themselves in the event of an emergency. AMG will review the plan with each employee covered by the plan at the following times:

- Initially when the plan is developed or a new employee is hired;
- Whenever the employee's responsibilities or designated actions under the plan change; and
- Whenever the plan is changed.

2.2 Reclaimed Catalyst Training

Additional and continuing training will include instruction that teaches Facility personnel general Reclaimed Catalyst handling procedures. All Facility personnel involved in the handling of Reclaimed Catalyst will receive instruction on how to perform their job functions in a way that ensures the Facility's compliance with the requirements of OAC 3745-54-16.

All employees (such as, but not limited to, equipment operators, general laborers, and others) that are exposed to hazardous substances, health hazards, or safety hazards will receive training before they are permitted to engage in Facility operations. Employees will not be permitted to participate in Reclaimed Catalyst activities until they have been trained to a level required by their job function and responsibility. The training will cover the following:

- The names of personnel and alternates responsible for site health and safety;
- Safety, health, and other hazards present at the site;
- Use of personal protective equipment;
- Work practices that minimize risks from hazards;
- Safe use of engineering controls and equipment on the site;
- Medical surveillance requirements, including recognition of symptoms and signs that might indicate overexposure to hazards; and
- The emergency and control procedures outlined in the Contingency Plan.
- The training is designed to satisfy the requirements of Ohio EPA (i.e., RCRA), Occupational Safety and Health Administration (i.e., HAZWOPER), and Department of Transportation (i.e., Hazardous Materials) concurrently.

The training program includes instruction that teaches employees Reclaimed Catalyst management procedures (including Contingency Plan implementation as discussed previously) relevant to the positions in which they are employed.

2.3 Process Training

Each employee presently involved in operating a process, and each employee before being involved in operating a newly assigned process, will be trained in an overview of the process and in the operating procedures. The training will include emphasis on the specific safety and health hazards, emergency operations including shutdown, and safe work practices applicable to the employee's job tasks. In lieu of initial training for those employees already involved in operating a process, AMG may certify in writing that the employee has the required knowledge, skills, and abilities to safely carry out the duties and responsibilities as specified in the operating procedures.

AMG will document that each employee involved in operating a process has received and understood the training required by this paragraph. AMG will maintain a record that contains the identity of the employee, the date of training, and the means used to verify that the employee understood the training.

2.4 Supervisor Training

Any Facility personnel that supervise or manage personnel involved in handling Reclaimed Catalyst will be required to complete appropriate training. This will include at a minimum, Level II Contingency Plan training and Reclaimed Catalyst training. Personnel will not be permitted to supervise Reclaimed Catalyst operations until they have been trained to a level required by their job function or level of responsibility. In some cases, some process training may be appropriate for personnel in supervisory positions.

2.5 Refresher Training

Annual review of the Reclaimed Catalyst training program is performed with applicable employees. For employees that are required to have Level II Contingency Plan training, this review will take the form of monthly safety training supplemented by additional training if necessary. For employees that are required to have Level I Contingency Plan training, this review is less formal and includes a simple review of evacuation and emergency response procedures on an annual basis.

3.0 Personnel Documentation

The following documents and records will be kept on file at the Facility:

- The job title for each position at the Facility involving Reclaimed Catalyst operations and the up-to-date name of the employee filling each position;
- A written job description for each position involved with Reclaimed Catalyst operations. This description will include the requisite skill, education or other qualifications, and duties of employees assigned to each position;
- A written description of the type and amount of introductory and continuing training that will be given to each employee filling a position related to Reclaimed Catalyst management; and
- Records documenting that the required training or job experience has been given to, and successfully completed by, Facility personnel.

4.0 Record Keeping

Training records on current personnel will be kept until closure of the Facility. Training records for former personnel will be kept for a minimum of three years from the employee's last day at the Facility. Training records will accompany personnel transferred within the Company.

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Appendix A

Training Outlines

Outline of Introductory and Continuing Training Programsⁱ

Contingency Plan Level 1	
Scope	All employees that perform activities that do not expose them to the dangers inherent to facility operations or to Reclaimed Catalyst. And do not supervise employees that require Reclaimed Catalyst training.
Duration	30 minutes
Description	Review contingency plan. Employee will know how to recognize emergency signals, know when to evacuate, and know the location of the Rally Point. Also handling of Universal Waste

Contingency Plan Level 2	
Scope	All employees that perform activities that expose them to the dangers inherent to facility operations or to Reclaimed Catalyst. Or supervise employees that require Reclaimed Catalyst training.
Duration	2 hours
Description	Review contingency plan. Employee will know how to recognize emergency signals, know when to evacuate, and know the location of the Rally Point. Will also know how to use, inspect, repair and replace monitoring and emergency equipment, how to use the communication and alarm systems, how to respond to fires and/or explosions, and how to shut down operations and equipment they are responsible for.

Reclaimed Catalyst Training	
Scope	Any employee that interacts with the Reclaimed Catalyst. Any employee that supervises an employee required to have Reclaimed Catalyst training
Duration	24 hours
Description	<p>This training satisfies the requirements of Ohio EPA, OSHA, DOT, and ODH concurrently. The course will cover at minimum the following:</p> <ul style="list-style-type: none"> • The names of personnel and alternates responsible for the site health and safety • Safety, health, and other hazards present at the site • Use of personal protective equipment • Work practices that minimize risks from hazards • Safe use of engineering controls and equipment on the site • Medical surveillance requirements, including recognition of symptoms and signs that might indicate overexposure to hazards • Response to ground water contamination or other unintentional release of material • Emergency shutdown of equipment • The emergency and control procedures outlined in the Contingency Plan

Process Training	
Scope	All production employees
Duration	2-3 weeks
Description	On-the-job training to instruct employee how to perform position specific tasks. Topics include; review of written policies, procedures and job-safety-analyses related to their specific position. Also will cover response to environmental or safety incidents and emergency shutdown procedures.

Supervisor Training	
Scope	All employees who supervise an employee required to have Reclaimed Catalyst training
Duration	2 hours
Description	Training will include information on supervising employees handling Reclaimed Catalyst. Will also include an overview of the process training of those supervised.

Refresher Training	
Scope	Applicable employees
Duration	varies
Description	<p>Annual refresher training will be completed per schedule maintained by the Safety Department. Topics may include but may not be limited to:</p> <ul style="list-style-type: none"> • Access to Medical and Exposure Records • Emergency Action Plan • Fire Extinguishers • Hazard Communications • HAZWOPER • Noise Exposure (Hearing Protection) • Respiratory Protection • Confined Space • Cranes • Electrical Safety • Fall Protection • Lockout / Tagout • Stairways and Ladders (Slips, Trips and Falls)

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¹ If equivalent training is provided at the Cambridge Facility, it will satisfy the training requirement of the Zanesville Facility.

Appendix B

Training Matrix

Training Requirementsⁱ

Title	Contingency Plan Level 1	Contingency Plan Level 2	Reclaimed Catalyst	Process	Supervisor
Secondary Arc Furnace Operator	X			X	
Primary Arc Furnace Operator	X			X	
Accounting Manager	X				
Arc Furnace Utility	X			X	
Auto Repair Standard	X			X	
Buyer	X				
Crusher Operator	X			X	
EHS Clerk	X				
Environmental Specialist		X	X		
Furnace Room Floorman	X			X	
Janitor	X			X	
Lab Supervisor		X	X		X
Lab Technician		X	X		
Laborer		X	X	X	
Lift Truck Operator/Shipping	X			X	
Maintenance "A" Machinist		X	X	X	
Maintenance Clerk	X				
Maintenance General Foreman		X	X	X	
Maintenance Scheduler/Planner	X				
Maintenance Standard		X	X	X	
Maintenance/Roaster Supervisor		X	X	X	X
Melt Shop Process Engineer		X	X	X	
Melt Shop Supervisor		X	X	X	X
Mobile Equipment Operator		X	X	X	
Overhead Crane Operator	X			X	
Packer	X			X	
Plant Manager		X	X	X	X
Production Clerk	X				
Project Engineer	X				
Quality Manager		X	X		X
Rail Unloading/Mobile Equipment Operator		X	X	X	
Receptionist	X				
Relief Foreman		X	X	X	X
Roaster Clerk	X				
Roaster Foreman		X	X	X	X
Roaster Operator	X			X	
Roaster Operator/Helper		X	X	X	
Roaster Process Engineer		X	X	X	
Roaster Utility		X	X	X	
Safety Manager		X	X		
Safety Specialist		X	X		
Sampler		X	X	X	
Shipping Supervisor	X		X	X	X
Silo/Loader Operator		X	X	X	

Title	Contingency Plan Level 1	Contingency Plan Level 2	Reclaimed Catalyst	Process	Supervisor
Storeroom Supervisor		X	X	X	
Storeroom/Maintenance C		X	X	X	
Welder A		X	X	X	
Yard Supervisor		X	X	X	X

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¹ If equivalent training is provided at the Cambridge Facility, it will satisfy the training requirement of the Zanesville Facility.

Appendix C

Job Descriptions

Job Descriptions

Title	Job Description
Secondary Arc Furnace Operator	Operate the secondary electric arc furnace for the purpose of making Ferrovan® and Revan™
Primary Arc Furnace Operator	Operate the primary electric arc furnace for the purpose of making slag and FeNiMoly®
Accounting Manager	Manages accounting functions and employees, including inventory audits
Arc Furnace Utility	Assists furnace operator in the operation and service of arc furnace. Secures and prepares furnace room samples.
Auto Repair Standard	Repairs mobile equipment
Buyer	Manages procurement transactions
Crusher Operator	Crushes Ferrovan® and recycled materials
EHS Clerk	Performs clerical functions
Environmental Specialist	Environmental auditing and reporting
Furnace Room Floorman	Makes blends using the silo mixing system, hooks up cranes, prepares molds and pours furnaces.
Janitor	Maintains plant cleanliness to keep areas free of contamination
Lab Supervisor	Performs analytical services and supervises Lab Technicians
Lab Technician	Performs analytical services
Laborer	Completes tasks necessary for the mixing/blending/storing and cleanup of the yard and services area
Lift Truck Operator/Shipping	Moves alloys into shipping area and moves packaged alloy onto trailers for shipment
Maintenance "A" Machinist	Knowledgeable in machinery and lathe skills to manufacture parts and other items
Maintenance Clerk	Administrative support of maintenance department
Maintenance General Foreman	Oversees all maintenance department operations
Maintenance Scheduler/Planner	Plans and schedules maintenance work
Maintenance Standard	Multi-craft maintenance support to plant equipment
Maintenance/Roaster Supervisor	Shift supervision of roaster and maintenance employees
Melt Shop Process Engineer	Provide technical expertise on metallurgical processes
Melt Shop Supervisor	Shift supervision of melt shop operations and employees
Mobile Equipment Operator	Uses front loader, forklifts and other devices to transport and mix raw materials prior to the production process
Overhead Crane Operator	Operates overhead crane, transports full and empty ladles over head of the furnace work area

Title	Job Description
Packer	Packs alloy into shipping containers and readies containers for shipping
Plant Manager	Manages overall production operations of the facility
Production Clerk	Administrative support of Plant Manager and production department
Project Engineer	Manages plant engineering functions and capital budget
Quality Manager	Oversees furnace blend for production and product quality evaluation
Rail Unloading/ Mobile Equipment Operator	Operates any mobile equipment for purpose of unloading, loading, transporting, or other manipulation of raw materials, slags, scrap products, equipment
Receptionist	Performs clerical functions
Relief Foreman	Provide supervisory coverage, as needed, in all production departments
Roaster Clerk	Performs clerical functions
Roaster Foreman	Supervision of all Roaster activities and employees
Roaster Operator	Operates and monitors roaster operations from the control room
Roaster Operator/Helper	Completes hearth checks, checks settings, removes filled super sacks from loading area
Roaster Process Engineer	Provide technical expertise on chemical processes
Roaster Utility	Charge and operate the Roaster feed system and auxiliary equipment
Safety Manager	Oversight of all safety tasks and reports
Safety Specialist	Assists Safety Manager and performs safety audits
Sampler	Prepares samples of raw materials and finished goods for laboratory analysis
Shipping Supervisor	Supervision of all shipping activities and employees
Silo/Loader Operator	Loads silo, moves and loads slag, unloads silo materials into silo feeder
Storeroom Supervisor	Inventory control and management of parts for production operations
Storeroom/Maintenance C	Verifies received goods, issues parts, controls inventory and performs minor repairs. Fabricates minor parts as assigned
Welder A	Plant welder
Yard Supervisor	Supervision of all yard activities and employees

Attachment 7

Waste Analysis Plan

Attachment 7
WAP

Attachment 7
Waste Analysis Plan
Revision 0

November 1, 2019

Submitted to:

AMG Vanadium LLC
3400 East Pointe Drive
Zanesville, Ohio 43701
EPA ID No. OHR000212902

Submitted by:

Cox-Colvin & Associates, Inc.
7750 Corporate Blvd.
Plain City, Ohio 43064
(614) 526-2040



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7-1 Underlying Hazardous Constituents for K171/K172 Waste

7-2 Underlying Hazardous Constituents for Metallic D Wastes

Appendices

- A [Intentially Left Blank]
- B Example Waste Acceptance Form
- C Quality Assurance Project Plan

I.0 General Facility Description

The address of the Facility is:

AMG Vanadium LLC
3400 East Pointe Drive
Zanesville, Ohio 43701

A Facility location map is included as Figure 8-1 of the Contingency Plan in this Application. The Facility property encompasses approximately 163 acres and contains numerous buildings and paved access areas. Approximately 27 acres of the property is used for industrial operations. The Facility layout map (Figure 8-2 of the Contingency Plan) shows the main Facility operational areas and the associated structures.

The Zanesville Facility has standard industrial classification (SIC) codes of 3313 (electrometallurgical products) and 3341 (secondary smelting and refining) and North American Industrial Classification System (NAICS) codes of 331110 (iron and steel mills and ferroalloy manufacturing) and 331492 (secondary smelting, refining, and alloying of nonferrous metal). The Facility produces ferrous and non-ferrous metal Products. The primary Product is ferrovanadium alloy (FeroVan®). Other Products include iron-nickel-molybdenum alloy (FeNiMoly®), calcium aluminate Slag conditioner (Revan™), and Roasted Catalyst. The co-products calcium sulfite/sulfate (LimeAdd™), Baghouse Dust, Cyclone Dust, Free Liquid, Slag, and oil and water that have come in contact with Reclaimed Catalyst, Roasted Catalyst, or other Process Residuals are considered Process Residuals. Raw materials used at the Facility include Reclaimed Catalyst obtained from hydrotreating, hydrorefining and hydrocracking refining processes.

Reclaimed Catalyst unloaded from bulk railcars are discharged into RMSB #4 by enclosed conveyors or loaded into a truck for transport to the Cambridge Facility. The Reclaimed Catalyst may also be delivered to RMSB #4 by truck through the equipment entrance door and unloaded. This Reclaimed Catalyst from rail or truck is then, as demand requires, transported to the storage bins in RMSB #4 by heavy equipment. Alternatively, the Reclaimed Catalyst may be transported directly to the Roaster Feed Hoppers, located in RMSB #4. Reclaimed Catalyst is loaded into the Roaster Feed Hoppers via heavy equipment. The Reclaimed Catalyst is delivered to the Roaster from the Roaster Feed Hoppers via enclosed conveyor.

2.0 Parameters and Rationale

The U.S. EPA has listed two of the raw materials used in the Company's manufacturing process, spent hydrotreating and hydrorefining catalysts from refining operations (i.e., Reclaimed Catalyst), as listed hazardous wastes (K171 and K172, respectively). The

specific properties of these materials that have led to their listing are their potential benzene and arsenic contents and their potential pyrophoric and self-heating properties. The underlying hazardous constituents for K171 and K172 hazardous wastes and their associated treatment standards are presented in Table 7-1. Reclaimed Catalyst and other materials processed by the Company are not considered wastes based on the Variance; however, the Company must give consideration to the possibility that generated wastes may be characteristically hazardous. The underlying hazardous constituents for metal containing D-code wastes, and their associated treatment standards, are presented in Table 7-2.

This Waste Analysis Plan meets the requirements of OAC 3745-54-13. The Company will be required to follow this Waste Analysis Plan whenever Reclaimed Catalyst is Accepted at the Facility or when a Process Residual or hazardous waste is offered for sale or disposal.

The Company is committed to utilizing Best Management Practices (BMPs) in the handling of Reclaimed Catalyst and wastes to avoid spills or other uncontrolled releases to the environment and has procedures in place to achieve this and to effectively address uncontrolled releases should they occur.

The types of sampling that will be completed, and the rationale for their selection, are described in the following sections describing Reclaimed Catalyst, Products and Process Residuals. The decision tree (Figure 7-1) should be utilized in determining what type of analytical characterization needs to be performed prior to sale or disposal of any materials offsite. If the material is believed to have constituents of either K- or D- code wastes, it will be determined if they have constituents above regulatory limits and require disposal at regulated hazardous waste landfills.

FIGURE 7-1 – DECISION TREES FOR MATERIAL DISPOSITION

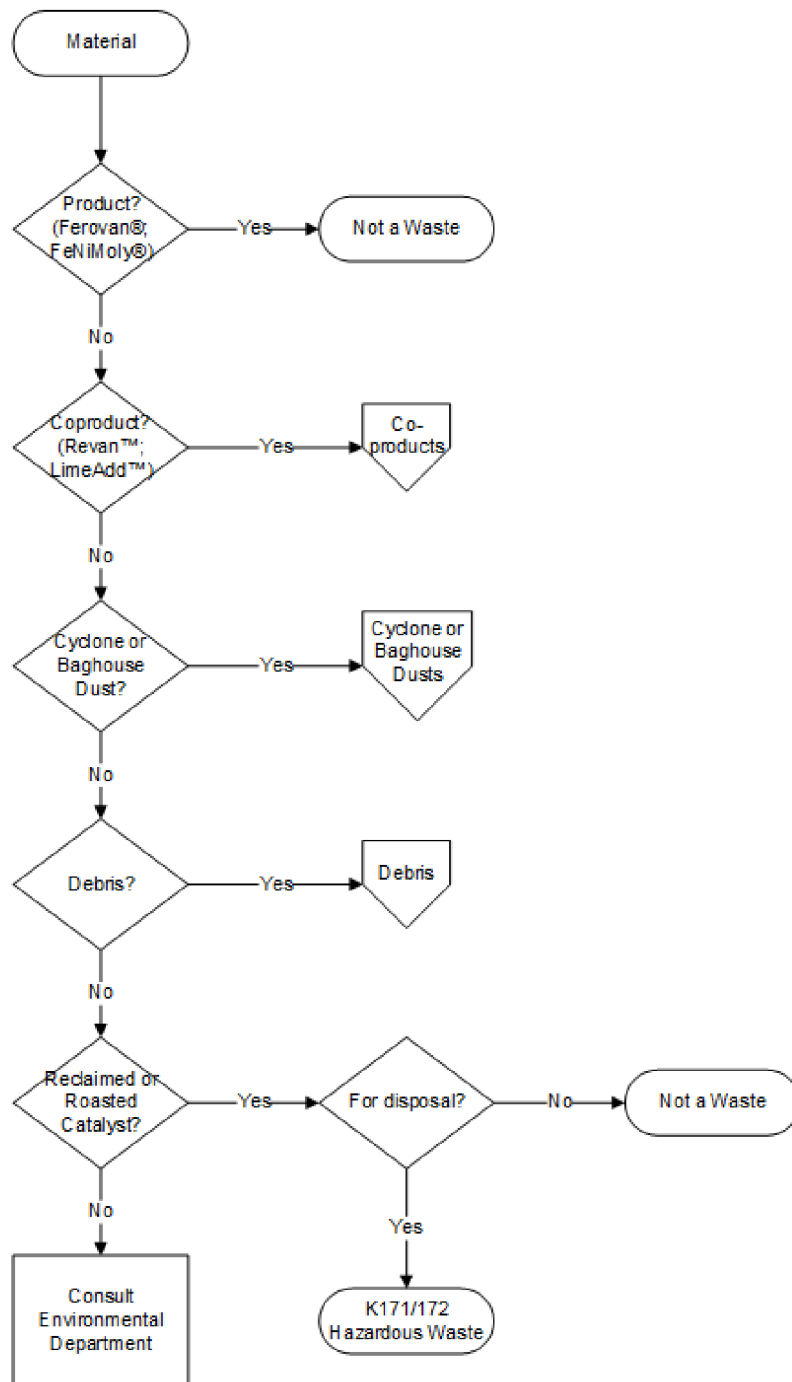


FIGURE 7-1 CONT. – DECISION TREES FOR MATERIAL DISPOSITION

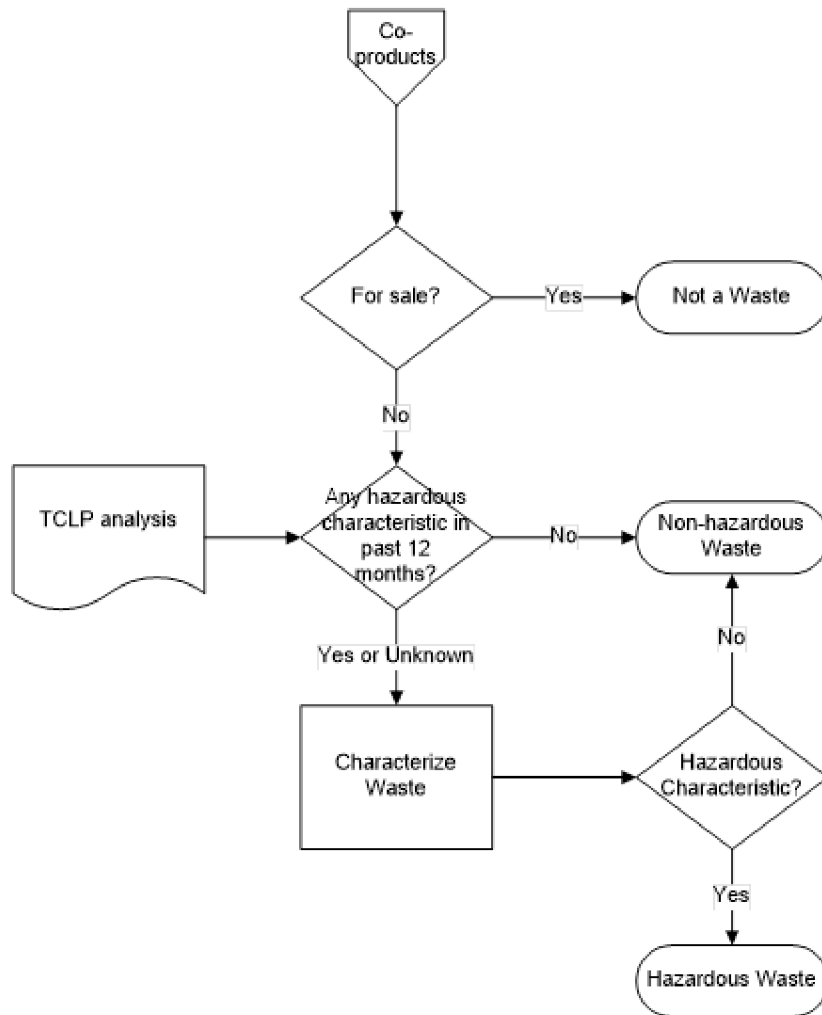


FIGURE 7-1 CONT. – DECISION TREES FOR MATERIAL DISPOSITION

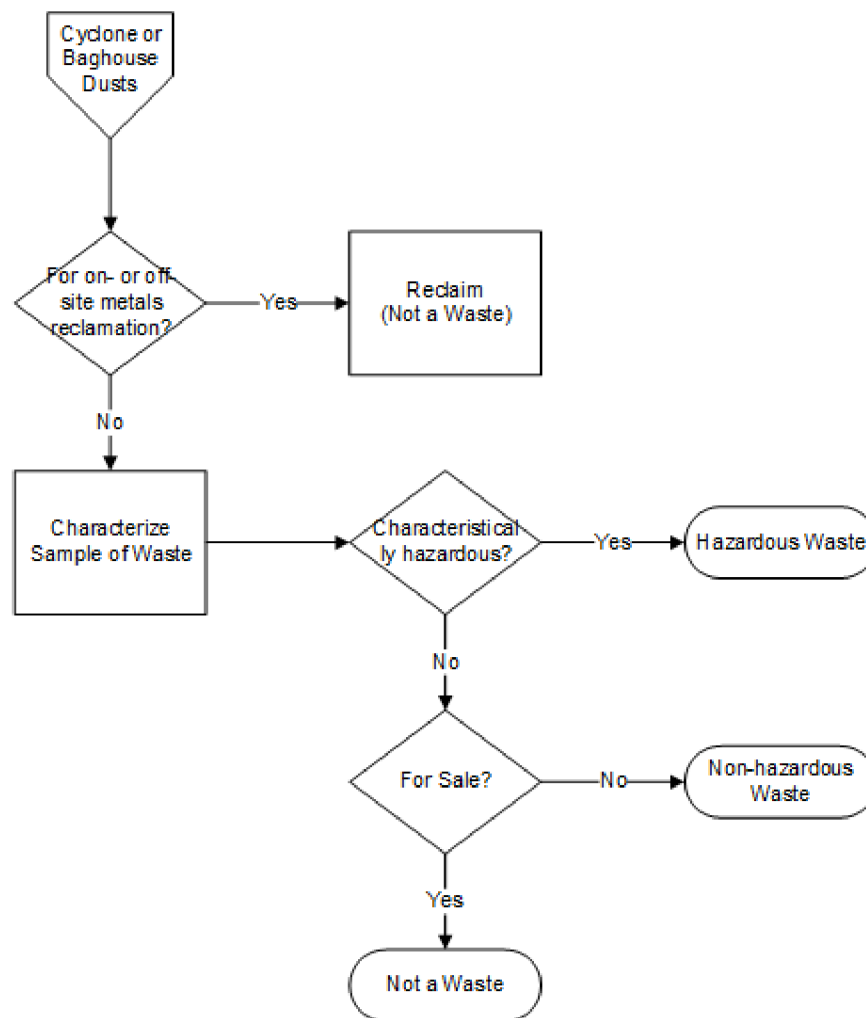
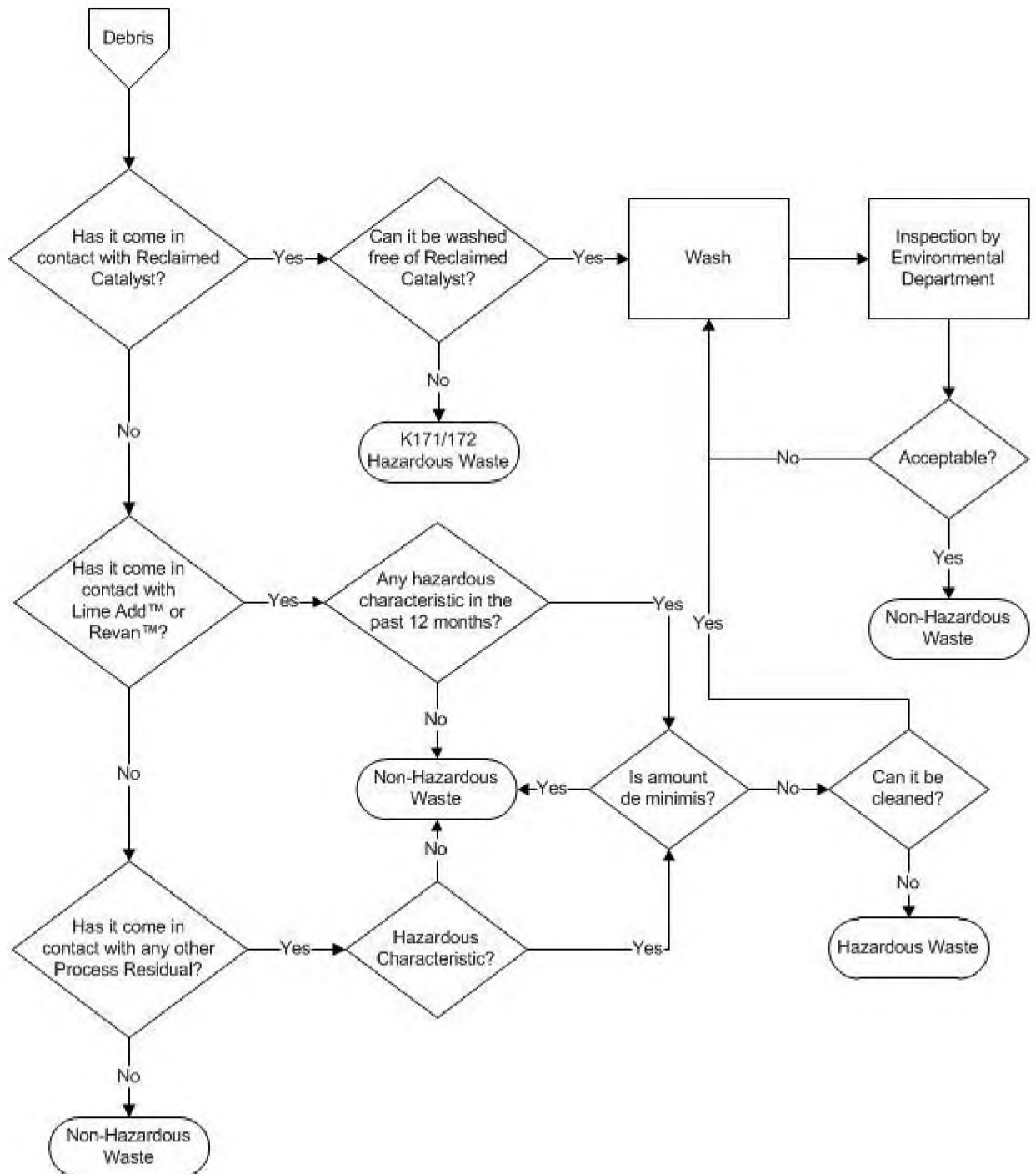


FIGURE 7-1 CONT. – DECISION TREES FOR MATERIAL DISPOSITION



**TABLE 7-1. UNDERLYING HAZARDOUS CONSTITUENTS FOR K171/K172
WASTE AND ASSOCIATED TREATMENT STANDARDS**

Constituent, CAS No.	K171 Wastewater	K171 non-wastewater	K172 wastewater	K172 non-wastewater
benz(a)anthracene, 56-55-3	0.059 mg/l	3.4 mg/kg	---	---
benzene, 71-43-2	0.14 mg/l	10 mg/kg	0.14 mg/l	10 mg/kg
chrysene, 218-01-9	0.059 mg/l	3.4 mg/kg	---	---
ethyl benzene, 100-41-4	0.057 mg/l	10 mg/kg	0.057 mg/l	10 mg/kg
naphthalene, 91-20-3	0.059 mg/l	5.6 mg/kg	---	---
phenanthrene, 81-05-8	0.059 mg/l	5.6 mg/kg	---	---
pyrene, 129-00-0	0.067 mg/l	8.2 mg/kg	---	---
toluene, 108-88-3	0.080 mg/l	10 mg/kg	0.080 mg/l	10 mg/kg
total xylene(s), 1330-20-7	0.320 mg/l	30 mg/kg	0.320 mg/l	30 mg/kg
antimony, 7740-36-0	---	---	1.90 mg/l	1.15 mg/l TCLP
arsenic, 7740-38-2	1.40 mg/l	5 mg/l TCLP	1.40 mg/l	5 mg/l TCLP
nickel, 7440-02-0	3.98 mg/l	11.0 mg/l TCLP	3.98 mg/l	11.0 mg/l TCLP
vanadium, 7440-62-2	4.30 mg/l	1.6 mg/l TCLP	4.30 mg/l	1.6 mg/l TCLP
reactive sulfides, NA	Deactivation	Deactivation	Deactivation	Deactivation

**TABLE 7-2. UNDERLYING HAZARDOUS CONSTITUENTS FOR METAL
BASED D WASTES AND ASSOCIATED TREATMENT STANDARDS**

Constituent, CAS No.	Wastewater	Non-wastewater	Waste code
		TCLP	
arsenic, 7440-38-2	1.4 mg/l	5.0 mg/l	D004
barium, 7440-39-3	1.2 mg/l	21 mg/l	D005
cadmium, 7440-43-9	0.69 mg/l	0.11 mg/l	D006
chromium (total), 7440-47-3	2.77 mg/l	0.60 mg/l	D007
lead, 7439-92-1	0.69 mg/l	0.75 mg/l	D008
mercury, 7782-49-2	0.15 mg/l	0.025 mg/l	D009
selenium, 7782-49-2	0.82 mg/l	5.7 mg/l	D010
silver, 7440-22-4	0.43 mg/l	0.14 mg/l	D011

2.1 Raw Materials

2.1.1 Reclaimed Catalyst

Reclaimed Catalyst obtained by the Company is substantially partially reclaimed outside of the refining process prior to being shipped to Applicant's Facility for further reclamation. This meets the requirements of the standards and criteria set forth in OAC rule 3745-50-24(C) for issuing a Variance in that the material has undergone processing and will undergo further processing to obtain a saleable Product. As such a Variance is anticipated to be issued to the Company that includes Reclaimed Catalyst pursuant to the authority vested in the Director of the Ohio EPA under ORC 3734.02, 3734.14, 3745.01 and OAC 3745-50-23.

Reclaimed Catalyst is therefore not a hazardous waste when intended for use as a raw material in the manufacture of ferroalloys at the Company's Zanesville and Cambridge Facilities or Roasted and sold for metals reclamation. Under the terms of the Variance, Reclaimed Catalyst will be handled using best management practices to eliminate uncontrolled release or spill of this material. Wastes generated on site during processing of Reclaimed Catalyst will not be considered derived from hazardous wastes, but will instead be evaluated on their own characteristic properties.

Since Reclaimed Catalyst is a raw material used in the manufacturing process, it is not envisioned that it will be disposed of offsite.

2.2 Products and Coproducts

2.2.1 Ferovan[®]

Ferovan[®] is the Company's primary and most valuable Product. This material is handled to eliminate spillage. Any un-saleable material is returned to the furnaces for rework. There is no waste generated for this Product. Apart from analysis completed for specification purpose for our customers, no analysis will be performed on this Product.

2.2.2 FeNiMoly[®]

FeNiMoly[®] is a Product that has very significant financial value. This material is handled to eliminate spillage. Any un-saleable material is returned to the furnaces for rework. There is no waste generated for this Product. Apart from analysis completed for specification purpose for our customers, no analysis will be performed on this Product.

2.2.3 Revan[™]

Revan[™] is the trademarked name for an engineered calcium aluminate Product that has significant financial value to the Company.

Clarification from Ohio EPA was obtained regarding the regulatory status of Revan[™] in March 2006. Ohio EPA determined that saleable Products such as Revan[™] are not derived from listed hazardous wastes. The regulatory status of residuals of Products or of un-saleable (e.g. out of specification) Products destined for waste will be determined using a combination of generator knowledge and sampling and analysis.

Utilizing generator knowledge, organic volatile and semi-volatile species are discounted as potential constituents of concern since in the production of Revan[™] utilizes three thermal processes, heating the material sequentially to approximately 1500 °F, 3000 °F and 3500 °F. Similarly, these thermal processes will deactivate any reactive sulfides, eliminate any heating value, and there will no longer be any ignitability or pyrophoric properties. Therefore no sampling or analysis will be required for any of these parameters.

Metals are likely to be present in Revan[™] Product. However, these metals are expected to be intimately dispersed in the calcium aluminate lattice of the Revan[™] and hence have no or limited leachability. Additionally the physical form of the Revan[™] (large, low surface area pieces) further reduces the likelihood of leachability of any metals. Thus, generator knowledge suggests waste Revan[™] is not characteristically hazardous.

2.2.4 Roasted Catalyst

Roasted Catalyst is a Product that has significant financial value. This material has been processed through a Roaster and is handled to eliminate spillage. Roasted Catalyst is further processed as a raw material to reclaim its metal values. There is no waste generated for this Product. Apart from analysis completed for specification purpose for our customers, no analysis will be performed on this Product.

Utilizing generator knowledge, organic volatile and semi-volatile species are discounted as potential constituents of concern since in the production of Roasted Catalyst utilizes a thermal process, heating the material to approximately 1500 °F. This thermal process will deactivate any reactive sulfides, eliminate any heating value, and the material will no longer be ignitable or pyrophoric. Therefore, no sampling or analysis will be required for any of these parameters.

2.3 Process Residuals

2.3.1 LimeAdd™

LimeAdd™ is the Co-Product formed from the desulfurization process that occurs in the Circulating Dry Scrubber. This process removes sulfur dioxide (SO₂) from the air-stream exiting the Roaster and Primary Electric Arc Furnace (EAF). LimeAdd™ is a very dry material consisting mainly of calcium sulfite, calcium sulfate, un-reacted lime and a minor amount of dust from the Primary EAF. LimeAdd™ is stored in the LimeAdd™ Silo. LimeAdd™ is sold as a Product that has significant financial value to the Company.

LimeAdd™ is a Process Residual, not a “derived from” listed hazardous waste. The regulatory status of residuals of Products or of un-saleable (e.g. out of specification) products destined for waste will be determined using a combination of generator knowledge and sampling and analysis.

Utilizing generator knowledge, organic volatile and semi-volatile species are discounted as potential constituents of concern since the processing of Reclaimed Catalyst which generates LimeAdd™ utilizes a high temperature thermal processes, heating the Reclaimed Catalyst to approximately 1500 °F and burning off any volatile and semi-volatile organic species; analytical data supports this. EAF dusts have further been processed at 3000 °F. Reactive sulfides, heating value, and ignitability or pyrophoric properties are not a concern with LimeAdd™. Therefore no sampling or analysis will be required for any of these parameters.

Metals have the potential to be present in LimeAdd™. However, these metals are expected to be present at extremely low levels and have limited leachability. Thus, generator knowledge suggests waste LimeAdd™ is not characteristically hazardous.

2.3.2 Secondary Electric Arc Furnace Baghouse Dusts

Secondary electric arc furnace (EAF) Baghouse Dust is generated in the ferrovanadium alloy manufacturing process and collected in roll-off boxes in the Secondary Baghouse. This dust is sold as a product.

Secondary EAF Baghouse Dust is a Process Residual, not a “derived from” listed hazardous waste. Secondary EAF Baghouse Dust must be characterized and its regulatory status determined using a combination of generator knowledge and sampling and analysis.

Utilizing generator knowledge, organic volatile and semi-volatile species are discounted as potential constituents of concern since the generation of Secondary EAF Baghouse Dust utilizes three thermal processes, heating the material sequentially to approximately 1500 °F, 3000 °F and 3500 °F. Similarly, these thermal processes will deactivate any reactive sulfides, eliminate any heating value, and there will no longer be any ignitability or pyrophoric properties. Therefore no sampling or analysis will be required for any of these parameters.

Each roll off container of Secondary EAF Baghouse Dust will be sampled and analyzed for hazardous metallic constituents by TCLP. If TCLP analysis determines that no hazardous constituents are present above the regulatory limits, the Secondary EAF Baghouse Dust will be made available for sale or disposed of to a solid waste landfill. Otherwise, the Secondary EAF Baghouse Dust will be disposed at a regulated hazardous waste landfill under the relevant D waste codes.

2.3.3 Primary Electric Arc Furnace Cyclone Dusts

Primary EAF Cyclone Dust is generated in the ferrovanadium alloy manufacturing process and collected in roll-off boxes. They are sought after, saleable materials. Cyclone Dust also has commercial value since it contains levels of metals, which makes it economically possible to recycle. Cyclone Dusts that contain high levels of vanadium are typically recycled by combining them with other raw materials and melting it in secondary EAF. Other metals (e.g. zinc) may accumulate to a level where they are valuable to outside recyclers.

Cyclone Dust is a Process Residual, not a “derived from” listed hazardous waste. Cyclone Dust that is sold or disposed must be characterized and its regulatory status determined using a combination of generator knowledge and sampling and analysis.

Utilizing generator knowledge, organic volatile and semi-volatile species are discounted as potential constituents of concern since the generation of Cyclone Dust utilizes two thermal processes, heating the material sequentially to approximately 1500 °F and 3000 °F. Similarly, these thermal processes will deactivate any reactive sulfides, eliminate any

heating value, and there will no longer be any ignitability or pyrophoric properties. Therefore no sampling or analysis will be required for any of these parameters.

Therefore, each roll off container of Cyclone Dust destined for sale or disposal will be sampled and analyzed for hazardous metallic constituents by TCLP prior to disposition. If TCLP analysis determines the presence of these constituents above the regulatory limits the Cyclone Dust will be disposed of to a registered hazardous waste landfill under the relevant D waste codes or recycled on site.

If TCLP analysis determines that no hazardous constituents are present above the regulatory limits the Cyclone Dust will be sold or disposed at a solid waste landfill.

2.3.4 Debris

The Facility generates debris from the management of Reclaimed Catalyst. This debris may be liners from roll-off boxes, spent PPE including disposable coveralls, cleanup materials from spills and other materials generated during maintenance activities that have come in contact with Reclaimed Catalyst. Most often, generator knowledge will be used to decide the disposal route for debris.

If the debris contains Reclaimed Catalyst that cannot be effectively removed, it will be treated as a hazardous waste and disposed of at a registered hazardous waste disposal site.

If debris has been mixed with characteristic hazardous waste, or organic volatile and semi-volatile compounds, its regulatory status will be determined using a combination of generator knowledge and sampling and analysis. If TCLP analysis determines the presence of these constituents above the regulatory limits the debris will be disposed at a registered hazardous waste landfill under the relevant D waste codes.

3.0 Test Methods

3.1 Visual Inspection

Reclaimed Catalyst is delivered to the Facility primarily in bulk railcars or trucks. The railcar or truck is sampled upon arrival according to this Waste Analysis Plan. Reclaimed catalyst may also be delivered to the site containerized, typically, but not limited to, 55-gallon steel drums, steel flow bins, or roll-off containers.

Prior to shipment to the Facility, the Reclaimed Catalyst has already been qualified for acceptance based on the pre-shipment waste acceptance form (example in Appendix B) and annual testing results. Therefore, upon arrival, the Company will need only to verify that the material shipped matches the material described on the manifest. The manifest

for the arriving shipment will be examined to confirm the generator, hazard class, and the waste codes. The number and weight of containers will be checked against the manifest. If there is a discrepancy with the container count or catalyst description, the discrepancy will be resolved.

Before processing a shipment of Reclaimed Catalyst in drums, flow bins or super sacks, at least one in four containers from each truckload will be selected and opened for visual inspection. Each roll-off container will be opened for inspection. The visual inspection will be used to determine that the material matches the identification on the manifest and pre-shipment characterization. Safety Data Sheets shipped with the material or on file may be used as the source of physical descriptions.

3.2 Free Liquid Analyses

A RMSB is compatible with the storage of Reclaimed Catalyst that contains Free Liquid. Therefore, Free Liquid testing is not required.

3.3 TCLP Analyses

TCLP analysis will always include all eight metals found in the universal treatment standards (Arsenic, Barium, Cadmium, Chromium, Lead, Mercury, Selenium and Silver). The analytical data will be examined by an authorized and qualified person within the Company.

4.0 Sampling Methods

4.1 Reclaimed Catalyst Sampling

AMG executes a contract with each generator of Reclaimed Catalyst prior to shipment of the Reclaimed Catalyst to the Company's Facility. Each contract is specifically tailored to the contracting parties and identifies changes in circumstances, with respect to the Reclaimed Catalyst, that would require the generator to notify the Company.

4.1.1 Annual Sampling

If necessary, AMG will request the generator of Reclaimed Catalyst provide specified analytical results on an annual basis. AMG reserves the right to conduct the annual sampling itself.

4.1.2 Sampling upon Receipt

At the Facility, samples of Reclaimed Catalyst will be collected for the purposes of completing discretionary confirmation analyses.

4.1.2.1 Sampling Railcars

Representative samples may be taken from Railcars in one of two ways:

4.1.2.1.1 Railcar Top Sampling

For Reclaimed Catalyst delivered in railcars it is necessary to take a representative sample of the railcar. The sampler should be inserted as far as possible into the material to avoid taking a surface sample and instead to obtain material from deep within the bulk of the material. A composite sample of ½ to 1 gallon of Reclaimed Catalyst should contain material from each compartment of the railcar, approximately proportional to the material in the compartments. The sampling equipment should be decontaminated so that it is free of Reclaimed Catalyst after use.

4.1.2.1.2 Railcar Auger Sampling

An alternative method of obtaining a representative sample is to take it during discharge of the railcar. The sample should be taken via the outlet located on the elevator auger. A composite sample of ½ to 1 gallon of Reclaimed Catalyst should contain material from each compartment of the railcar, approximately proportional to the material in the compartments.

4.1.2.2 Sampling Dump Trucks & Roll off Boxes

Dump Trucks and Roll Off Boxes containing Reclaimed Catalyst are sampled by collecting a minimum of 12 grab samples from disparate locations to generate a composite of ½ to 1 gallon.

4.1.2.3 Sampling Bags, Boxes, & Drums

Representative samples of Reclaimed Catalyst contained in Bags, Boxes or Drums (or other similar packaging) are collected by taking a grab sample from a minimum of 25% of the containers in the shipment. A composite of the samples from each shipment should be ½ to 1 gallon.

4.2 REVAN™ Sampling

A small sample of Revan™ is collected from each lot generated during the manufacturing process, while the material is still molten. A composite of these samples is created quarterly and tested for leachable concentrations of metals using the TCLP analysis method.

If slag resulting from the processing of Reclaimed Catalyst is bound for disposal, the composite results will be reviewed. Should any characteristic hazards be identified in the composites from the prior 12 months, a sample of the Revan™ to be shipped shall be sampled and tested, per the procedure below.

In order to ensure that a representative sample is collected, the slag that is being sampled is divided into four (4) equal quadrants. Two (2) samples are collected by hand from each quadrant. The slag samples are crushed, composited, and then analyzed.

4.3 Electric Arc Furnace Baghouse and Cyclone Dust Sampling

Baghouse Dust and Cyclone Dust resulting from the processing of Reclaimed Catalyst that is to be sold or disposed is tested in the laboratory for leachable concentrations of metals using the TCLP analysis method.

Representative samples from the roll-off box containing Baghouse Dust or Cyclone Dust will be collected by taking one sample from a minimum of 3 disparate locations of the roll-off box and compositing into one sample of ½ to 1 gallon.

4.4 LimeAdd™ Sampling

LimeAdd™ resulting from the processing of Reclaimed Catalyst is tested in the laboratory for leachable concentrations of metals using the TCLP analysis method.

Grab samples (approximately 1 tablespoon) are collected each operating day. These samples are composited for testing quarterly.

Appendix A

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Appendix B

Example Waste Acceptance Form

PQR-6117 Spent Refinery Catalyst Waste Acceptance Form	
Reference Document: N/A	
Date: 19 April 2019	Page 1 of 3

AMG Vanadium LLC

The purpose of this form is to facilitate identification of spent refinery catalyst for possible use as a raw material by AMG Vanadium LLC (AMG V). This form must be completed and signed by the generator and returned to AMG V before any specific lot of spent refinery catalyst is accepted at AMG V's facility. AMG V may also require a sample to be submitted.

1. Generator's Name: _____
Address: _____

2. Generator's EPA ID No.: _____
3. Manifest Document No.: _____
4. Is Waste Analysis available for this lot? Yes____ No____. If yes, attach copy.
5. Process generating this spent catalyst:
 - a. Hydrotreating (K171) _____
 - b. Hydrorefining (K172) _____
 - c. Dual Purpose Reactor Hydrocracking (K171)¹ _____
 - d. Other (specify) _____
6. Certain Waste Properties:
 - a. Benzene concentration < 10 ppmw Yes____ No____
 - b. Total Arsenic (ppmw) _____
7. Does the waste contain benzene which is required to be managed and treated in accordance with the Benzene Waste Operations NESHAP?
Yes____ No____ N/A____
8. Partial Reclamation. Spent refinery catalyst must undergo partial reclamation (for example: a deoiling process) prior to being shipped to AMG V for further reclamation.

Will the catalyst undergo partial reclamation prior to being shipped to AMG V?² Yes____ No____

¹ Spent catalyst from dual purpose reactors that both hydrotreat and hydrocrack are regulated (K171 waste)

² Description of partial reclamation process will be required prior to first shipment

PQR-6117 Spent Refinery Catalyst Waste Acceptance Form	
Reference Document: N/A	
Date: 19 April 2019	Page 2 of 3

9. **Treatment Standards:** K171 and K172 wastes have been restricted from land disposal effective February 8, 1999. If your waste is classified as K171 or K172, please check the following applicable statement.

a. Restricted Waste Requiring Treatment Prior to Land Disposal

___ I certify that I personally examined and am familiar with the waste through analysis and testing or through knowledge of the waste to support this notification that the waste does not comply with the treatment standards specified in 40 CFR 268 Subpart D. Therefore, if land disposal was required the waste must be treated to the appropriate regulatory treatment standards as indicated on page 3 of this form.

b. Restricted Wastes from Generators that can be Land Disposed without Further Treatment

___ I certify that I personally have examined and am familiar with the waste through analysis and testing or through knowledge of the waste to support this certification that the waste complies with the land disposal treatment standards specified in 40 CFR 268 Subpart D. I believe the information I submitted is true, accurate, and complete. I am aware that there are significant penalties for submitting a false certification, including the possibility of a fine and imprisonment.

Signature: _____ Date: _____

Printed Name: _____ Title: _____

AMG V Only (to be completed by Environmental Department)	
1. Is the metals content (V+Ni+Mo) \geq 2% on a dry weight basis?	
Yes _____	No _____
Signature: _____ Date: _____	
Printed Name: _____ Title: _____	

PQR-6117 Spent Refinery Catalyst Waste Acceptance Form	
Reference Document: N/A	
Date: 19 April 2019	Page 3 of 3

**TREATMENT STANDARDS REFERENCE TABLE (FOR QUESTION 9)
FOR SPENT REFINERY CATALYST**

Constituent	CAS No.	K171		K172	
		Wastewater	Non-wastewater	Wastewater	Non-wastewater
		mg/l	mg/kg ¹	mg/l	mg/kg ¹
Benz(a)anthracene	56-55-3	0.059	3.4	-	-
Benzene	71-43-2	0.14	10	0.14	10
Chrysene	218-01-9	0.059	3.4	---	---
Ethyl benzene	100-41-4	0.057	10	0.057	10
Naphthalene	91-20-3	0.059	5.6	---	---
Phenanthrene	81-05-8	0.059	5.6	---	---
Pyrene	129-00-0	0.067	8.2	---	---
Toluene	108-88-3	0.080	10	0.080	10
Xylene(s) (total)	1330-20-7	0.32	30	0.32	30
Antimony	7740-36-0	---	---	1.9	1.15 mg/l TCLP
Arsenic	7740-38-2	1.4	5 mg/l TCLP	1.4	5 mg/l TCLP
Nickel	7440-02-0	3.98	11.0 mg/l TCLP	3.98	11.0mg/lTCLP
Vanadium	7440-62-2	4.3	1.6 mg/l TCLP	4.3	1.6 mg/l TCLP
Reactive sulfides	NA	deactivation	deactivation	deactivation	deactivation

¹Concentration standard for non-wastewater is in "mg/kg" unless noted as "mg/l TCLP."

Appendix C

Quality Assurance Project Plan

Attachment 7 - Appendix C
Quality Assurance Project Plan
Revision 0

November 1, 2019

Submitted to:

AMG Vanadium LLC
3400 East Pointe Drive
Zanesville, Ohio 43701
EPA ID No. OHR000212902

Submitted by:

Cox-Colvin & Associates, Inc.
7750 Corporate Blvd.
Plain City, Ohio 43064
(614) 526-2040



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- C-1 Waste Analysis Plan Analytical Summary
- C-2 Accuracy and Precision QC Limits

Attachments

- A Quality Assurance Manual

Acronyms and Abbreviations

DQO	Data Quality Objective
US EPA	U.S. Environmental Protection Agency
LCS	laboratory control sample
MS/MSD	Matrix Spike/Matrix Spike Duplicate
Ohio EPA	Ohio Environmental Protection Agency
QA/QC	Quality Assurance/Quality Control
QAPP	Quality Assurance Project Plan
RCRA	Resource Conservation Recovery Act
%R	Percent Recovery
RPD	Relative Percent Difference
SOP	Standard Operating Procedure
SOW	Statement of Work
TCLP	Toxicity Characteristic Leaching Procedure
WAP	Waste Analysis Plan

I.0 Introduction

I.1 Program Description

This quality assurance project plan (QAPP) describes the Quality Assurance/Quality Control (QA/QC) procedures used to support the technical data generated in association with the Waste Analysis Plan (WAP) for the AMG Vanadium LLC (the Company) Facility in Zanesville, Ohio. These QA/QC procedures ensure that data generated from waste sampling are representative of actual conditions and meet the data quality objectives (DQOs) for precision, accuracy and completeness. This QAPP contains the elements outlined in Ohio Environmental Protection Agency's Guidelines and Specifications for Preparing Quality Assurance Project Plans (Ohio EPA, 1998), and is also in general conformance with federal guidance for preparing QAPPs.

I.2 Sampling Location and Schedule

The sampling locations and schedule are described in the WAP.

I.3 Project Organization and Responsibilities

The responsibilities of key Ohio EPA, the Company, and the laboratory are outlined below. Note that the individuals identified are subject to change; however, the responsibilities described are not expected to change.

Ohio EPA Project Manager

Scott Bergreen or Designee
Ohio EPA SEDO – Division of Environmental Response and Revitalization
2195 Front Street
Logan, Ohio 43138

The WAP and QAPP is performed under the authority of Ohio EPA.

Company Project Manager

Mary McCoy
Environmental Manager
AMG Vanadium LLC
60790 Southgate Road
Cambridge, Ohio 43725
mmccoy@amg-v.com

The Environmental Manager serves as the Company Project Manager and will manage and coordinate activities to be conducted as part of WAP and QAPP. The Environmental Manager has the authority to commit the necessary Company resources to complete the work. The Environmental Manager will be the primary contact for communications between the Company and Ohio EPA.

Laboratory

Eurofins TestAmerica
4101 Shuffel Street NW
North Canton, OH 44720
(330) 497-9396

External chemical analyses of samples collected as part of the WAP will be performed by Eurofins TestAmerica located in North Canton, Ohio or a laboratory with comparable qualifications. TestAmerica's Quality Assurance Manual is provided in Section 7.0.

I.4 Data Quality Objectives

The overall data quality objective (DQO) is to obtain analytical data that are of known and acceptable quality and are representative of the material being sampled. QA objectives for analytical data are usually expressed in terms of accuracy, precision, and completeness. These characteristics are defined as follows:

- Accuracy—The degree of conformity of a measurement with an accepted reference value.
- Precision—A measure of agreement among individual measurements of the same property, usually under prescribed similar conditions. For two measurements, precision is expressed in terms of relative percent difference (RPD).
- Completeness—A measure of the amount of valid data obtained from a measurement system compared with the amount that was expected to be obtained under normal conditions, expressed as a percentage.

QC acceptance criteria will be those QC criteria established within the method or as established by the laboratory using its historical data. These limits may vary depending on the specific analyte of interest and the method used.

Attainment of these quantitative DQOs will ensure that the data collected are of appropriate quality for their intended use(s). Data that do not meet target DQOs will be qualified during laboratory data validation.

2.0 Sampling

The overall quality of the data collected depends largely on the quality of the sampling activities. To ensure that samples are representative of the waste collected, sample collection procedures as outlined in the WAP will be followed.

2.1 Sampling

Sample containers will be provided by the laboratory and will be kept closed until used. Disposable gloves will be worn by the sampling personnel during sample collection. Dedicated or disposable equipment will be used to collect the samples to eliminate the possibility of cross contamination of samples. Thus, collection of equipment rinsate blanks will not be necessary.

Whenever feasible, samples will be of sufficient size to attain appropriate quantitation limits and allow for analysis of laboratory QC samples. Much of the sampling described in the WAP consists of collection of aliquots collected at periodic intervals over a specified timeframe (from daily up to quarterly). Individual aliquots collected will be placed in a container of appropriate size and material and held under conditions to avoid sample contamination or analyte loss. Chain-of-custody will be maintained over the sampling timeframe. At the end of the specified sampling timeframe, the aliquots collected will be homogenized (manually mixed). A composite sample to be submitted to the laboratory will then be taken from the homogenized aliquots. Given the solid matrix and the composite nature of the sampling, field duplicate samples will not be collected.

2.2 Sample Labeling and Documentation

To maintain sample integrity and establish legal defensibility, the possession and proper handling of samples must be documented and traceable from the time the aliquots are collected until the analytical data have been accepted, or reanalysis has occurred if required.

An important aspect of maintaining sample integrity is thorough recordkeeping. The container holding the aliquots will be clearly labeled with the sampling location and date that sampling began.

For the sample to be submitted to the laboratory, a sample label will be affixed to each sample container, and, at a minimum, will include the sample identification number and date of sample collection.

Any modifications to the sampling procedures in the QAPP or WAP will be documented and identified as a change from the intended method. Major modifications to the sampling

strategy or collection procedures must be approved in advance by the Company Project Manager, in consultation with Ohio EPA. Prior to sample storage or shipping, chain-of-custody forms will be completed by a designated sample custodian.

2.3 Sample Handling, Custody, and Shipping

As they are collected, samples for analysis will be labeled, recorded on a spreadsheet, and placed in shipping containers as soon as possible. Samples will be handled as little as possible after collection. Field personnel will use care to preserve the integrity of the samples.

Sample custody procedures will be rigidly followed to preserve sample integrity and to ensure the validity of the data. Prior to transferring custody of the samples, a chain-of-custody form will be completed. Any necessary changes to the chain-of-custody forms or sample container labels will be made by striking out the error with one line and re-entering the correct information. The new entries will be initialed and dated.

All sample containers to be shipped for chemical analysis will be placed in plastic bags and packed inside shipping containers. The original chain-of-custody form will be signed, dated, and the time the shipping container is sealed or relinquished to the laboratory will be noted. The original chain-of-custody form will be placed in the shipping container, with the Company retaining a copy. All containers to be shipped via common carrier will be sealed with packing tape and signed custody seals. Packaging will conform to U.S. Department of Transportation (DOT) regulations.

The designated sample custodian will be responsible for sample custody and appropriate sample storage prior to shipment, as well as for shipping samples in a timely manner to meet holding time requirements. The sample custodian will also contact the laboratory to notify them of the sample shipment.

2.4 Laboratory Operations

The laboratory QA Officer will verify receipt for each sample shipment and will contact the Company to verify that all samples were received and to note any concerns or observations regarding sample integrity. The laboratory QA Officer also will be responsible for ensuring that laboratory chain-of-custody forms and other tracking records are filled out upon receipt of the samples, and are maintained through all stages of laboratory sample processing and analysis. The sample tracking records must show the date of sample extraction or preparation and the date of instrument analysis. These records will be used to determine compliance with holding time requirements.

3.0 Analytical Procedures and Reporting

3.1 Analytical Methods

Chemical analyses to be completed are referenced in the WAP, and will be performed by a laboratory that has established protocols and QA procedures that meet or exceed any applicable EPA guidelines. Sample concentrations for target analytes will be determined using standard analytical techniques in accordance with the US EPA's SW-846: *Test Methods for Evaluating Solid Waste, Physical/Chemical Methods*.

Samples will be analyzed using EPA SW-846 methods and will include all associated QA procedures recommended by each method. Alternate methods or significant variations on existing methods may only be used if these have been approved for use by Ohio EPA as acceptable alternate methods.

Parameters of interest include TCLP analysis for regulated metals. Table C-1 lists the analytes, methods, container, preservative and holding time requirements.

3.2 Laboratory Calibration

Initial and continuing calibration procedures for laboratory instruments will be performed in accordance with the cited analytical method for each analysis. The method SOWs and SOPs specify the required acceptance criteria for initial and continuing calibration, and state the conditions where recalibration is necessary.

3.3 Laboratory Preventive Maintenance

Preventive maintenance of laboratory instruments is essential. Preventive maintenance will take two forms: 1) a schedule of preventive maintenance activities to minimize downtime and ensure the accuracy of measurement systems, and 2) availability of critical spare parts and backup systems and equipment. The performance of these maintenance procedures will be documented by the laboratory.

The laboratory QA officer will be responsible for ensuring that routine preventive maintenance is performed and documented for each analytical instrument used, and that spare parts or additional instruments are available in case of instrument breakdown or failure.

3.4 Laboratory Quality Control

Laboratory QC checks will be employed to verify the validity of the data generated. These

QC checks reveal information about the sample collection technique, analytical methodology, instrument capability, possible sources of contamination, precision and accuracy of the reported results, and possible interferences due to the sample matrix.

The specific QC measures to be performed are included in the EPA SW-846 methods, and may include samples such as method blanks, laboratory control samples (LCS), matrix spike (MS) and matrix spike duplicate (MSD) samples, and laboratory duplicate samples.

- **Method Blanks**—Method blanks are used to assess possible laboratory contamination associated with all stages of sample preparation and analysis. Blank corrections will not be applied by the laboratory to the original data.
- **Laboratory Control Samples**—LCS (blank check samples) are prepared by the laboratory and consist of a clean matrix spiked with representative analytes. LCS results will be reported as concentrations and as percent recovery values. One LCS typically will be analyzed for every digestion batch or for every 20 samples.
- **Matrix Spikes**—Matrix spike samples will be used to evaluate the effects of the sample matrices on the quantification of analyte concentrations, and therefore assess the bias of the analytical results reported. A matrix spike is a sample, prepared in duplicate, to which a known concentration of pure analyte is added prior to digestion or extraction and analysis. Matrix spike samples generally will be analyzed at a frequency of 1 for every 20 samples.
- **Laboratory Duplicates/Matrix Spike Duplicates**—Laboratory duplicates (or matrix spike duplicates for some analyses) will be used to determine the precision of the analytical methods. Duplicate results are calculated and reported as RPD values using the equation listed in Section 3.7 of this QAPP. Duplicates generally will be analyzed at a frequency of 1 for every 20 samples.

3.5 Data Reduction

The laboratory will perform data reduction as specified in the referenced analytical methods and will maintain appropriate documentation for all chemical analyses, including basic QC information for method blanks, LCS samples, and MS/MSDs, as applicable. The laboratory QA officer is responsible for checking data reduction prior to submittal of the analytical report. Any transcription and computation errors identified during this review will be corrected by the laboratory.

General equations used to determine precision and accuracy are included in Section 3.7 of this QAPP. The methods used to identify and treat laboratory QC outliers are specified in the method SOWs and SOPs, and in the data validation guidelines.

3.6 Data Validation

The data validation procedures summarized below should be performed by the laboratory for all analyses:

- Review chain-of-custody documentation to verify completeness of the sample set for each data package submitted;
- Verify that holding time requirements were met;
- Review results for laboratory QC samples including laboratory blanks, laboratory duplicate samples, matrix spike samples, LCS samples, and other QC measures. Ensure QC results are within target required control limits and DQOs for the project.
- Assess the impact of QC results and assign any necessary data qualifiers.

3.7 Data Assessment

This section details the specific equations and procedures used to assess accuracy and precision of laboratory data. It should be noted that accuracy and precision control limits are continually updated by the laboratory. Accuracy and precision QC limits for the analytes of concern for the WAP are presented in Table C-2.

3.7.1 Accuracy Assessment

Accuracy (the degree of agreement of a measured value with a true or expected value) objectives are expressed in terms of % recovery (%R) from analysis of samples of known analyte concentrations (LCS, MS/MSD).

The following equation will be used to calculate %R:

$$\%R = (A-B)/C \times 100$$

where:

A = result of spiked sample

B = result of unspiked sample

C = amount of spike added

3.7.2 Precision Assessment

Precision (the reproducibility or repeatability of a measurement) will be evaluated by calculating the relative percent difference (RPD) for each pair of duplicate analyses (i.e., laboratory duplicates or MS/MSDs):

$$RPD = \frac{\text{abs}(D_1 - D_2)}{(D_1 + D_2)/2} \times 100$$

where:

RPD = relative percent difference

D₁ = sample value

D₂ = duplicate sample value

3.7.3 Completeness Assessment

Completeness will be measured for each data set by dividing the number of valid measurements actually obtained by the number of valid measurements that were planned:

$$\text{Completeness} = \frac{\text{valid data points obtained}}{\text{total data points planned}} \times 100$$

3.8 Analytical Data Reporting

For every sample set provided, the laboratory will submit a data package to the Company containing, at a minimum, the following information:

- Sample numbers and corresponding laboratory numbers (if applicable) for all samples included in the data package;
- Copy of the chain-of-custody forms for all samples included in the data package;
- The analytical procedures used;
- Date(s) of sample collection and analysis;
- Analyte concentrations and units;
- Practical quantitation limits for each analyte;
- Problem(s) encountered during sample analysis (if any);
- Appropriate laboratory data qualification codes and their definitions; and
- Signature of a laboratory representative.

The laboratory will perform internal QA checks on the data prior to submitting data packages to the Company for review. Close contact between the laboratory and the Company will be maintained so that any QC issues can be resolved in a timely manner. The laboratory will maintain, and will provide if requested by the Company, additional information related to the analyses, such as:

- Sample login information;
- Laboratory QC samples results, recovery, and/or RPDs when required for laboratory method blanks, LCS samples, laboratory duplicates, and MS/MSD samples;
- Information regarding method blank/sample association;
- Instrument calibration information; and
- Raw data generated during analyses.

4.0 Performance and System Audits

Performance and system audits of both field and laboratory activities may be conducted to verify that sampling and analysis are performed in accordance with procedures established in the QAPP. Audits of field and laboratory activities may include internal and external audits.

4.1 Field Performance and System Audits

Field performance and system audits may be conducted to ensure that field sampling is carried out in a way to maximize the precision, accuracy, and completeness of samples. All personnel engaged in sampling and analysis tasks will have appropriate training. The Company Project Manager may make scheduled or non-scheduled visits to the site to evaluate the performance of field personnel during a targeted activity, such as sampling.

4.2 Laboratory Performance and System Audits

The Company relies on the QA/QC procedures of the laboratories that are providing analytical services. Laboratory performance and system audits may be conducted to ensure that laboratory analytical techniques are carried out in a way to maximize the precision, accuracy and completeness of analytical data.

5.0 Corrective Action

Corrective action is the process of identifying, recommending, approving, and implementing measures to counter unacceptable procedures or out-of-quality-control performance which can affect data quality. Corrective action may be required during field activities, laboratory analyses, laboratory data validation, and data assessment. This type of corrective action should not be confused with RCRA Corrective Action. Specific procedures for field and laboratory corrective action, respectively, are described below.

5.1 Field Corrective Action

Corrective action in the field may be necessary when the sample network is modified (e.g., more or fewer samples) or sampling procedures require modification due to unexpected conditions.

Any member of the field team or the Company Project Manager may identify the need for corrective action. The Company Project Manager will approve the appropriate corrective measure which will be implemented by the field team, and will ensure the corrective action has been implemented. If corrective actions result in fewer samples or other significant changes, which may cause project objectives not to be achieved, it will be necessary for the Company Project Manager and Ohio EPA Project Manager to concur with the proposed corrective action. All corrective actions will be documented and maintained by Company.

5.2 Laboratory Corrective Action

Corrective action in the laboratory may occur prior to, during, and after initial analyses. Several conditions such as broken sample containers or potentially high-concentration samples may be identified during log-in or just prior to analysis. Following consultation with lab analysts and laboratory supervisors, it may be necessary for the laboratory to implement corrective action. These conditions may include dilution of samples, additional sample extract cleanup, automatic re-injection/re-analysis when certain QC criteria are not met, etc. All corrective actions will be documented and made known to the Company Project Manager.

Corrective action procedures may be handled at the bench level by the analyst. If the problem persists or cannot be identified, the matter is referred to the laboratory supervisor or manager for further investigation. The laboratory manager, in consultation with the laboratory supervisor, will approve the required corrective action to be implemented by the laboratory staff. The laboratory will document the corrective action. If the nonconformance causes project objectives not to be achieved, it will be necessary to inform all levels of project management including the Ohio EPA Project Manager and obtain concurrence with the corrective action. Once resolved, full documentation of the

corrective action procedure will be presented in the case narrative of the final laboratory report.

6.0 References

- Ohio EPA. 1998. Guidelines and Specifications for Preparing Quality Assurance Project Plans. Ohio Environmental Protection Agency, Division of Emergency and Remedial Response, Columbus, OH.
- U.S. EPA. 1987. Data quality objectives for remedial response activities. Vol 1 — development process. QPA 540/G-87/003A, March 1987. U.S. Environmental Protection Agency, Office of Emergency and Remedial Response and Office of Waste Programs Enforcement, Washington, DC.
- U.S. EPA. 1986., SW 846 Test methods for evaluating solid waste — physical/chemical methods. Third edition, November 1986 and its updates. U.S. Environmental Protection Agency, Washington, DC.

7.0 Quality Assurance Manual

The Quality Assurance Manual is provided as Attachment A.

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Tables

Table C-1. Waste Analysis Plan Analytical Summary, AMG Vanadium LLC, Zanesville, Ohio.

Revision 0

Analyte	Method	Units	Eurofins TestAmerica PQL	Holding Time	Preservative	Container
TCLP METALS						
Silver	1311/6010D	MG/L	0.050	180 Days; 180 Days	None	8-oz glass or plastic jar
Arsenic	1311/6010D	MG/L	0.05	180 Days; 180 Days	None	8-oz glass or plastic jar
Barium	1311/6010D	MG/L	0.50	180 Days; 180 Days	None	8-oz glass or plastic jar
Cadmium	1311/6010D	MG/L	0.05	180 Days; 180 Days	None	8-oz glass or plastic jar
Chromium	1311/6010D	MG/L	0.05	180 Days; 180 Days	None	8-oz glass or plastic jar
Lead	1311/6010D	MG/L	0.05	180 Days; 180 Days	None	8-oz glass or plastic jar
Selenium	1311/6010D	MG/L	0.05	180 Days; 180 Days	None	8-oz glass or plastic jar
Mercury	1311/7470A	MG/L	0.002	28 Days; 28 Days*	None	8-oz glass or plastic jar

K:\CCA\PROJECTS\AMG Zanesville\Variance Application 2019\Att 7 WAP\Appx C QAPP\Table C-1 Analytical Summary.xlsx]C-1

PQL Practical Quantitation Limit

Holding times refer to time between sampling and extraction; extraction and analysis.

Methods:

SW846 Method 1311: Toxicity Characteristic Leaching Procedure, Revision 0, July 1992.

SW846 Method 6010D: Inductively Coupled Plasma-Optical Emission Spectrometry, Revision 5, July 2018.

SW846 Method 7470A: Mercury in Liquid Waste (Manual Cold-Vapor Technique), September 1986.

PQLs were provided by Eurofins TestAmerica in 2019, and are revised periodically.

*For composite sampling requiring one month or greater to complete, it will not be possible to meeting the holding time.

Table C-2. Accuracy and Precision QC Limits, AMG Vanadium LLC, Zanesville, Ohio.

Revision 0

Compound	Eurofins TestAmerica		
	Laboratory Control Sample Percent Recovery (%R)	MS and MSD Percent Recovery (%R)	MS/MSD Relative Percent Difference (RPD)
TCLP Metals			
Silver	50 - 150	75 - 125	20
Arsenic	50 - 150	75 - 125	20
Barium	50 - 150	75 - 125	20
Cadmium	50 - 150	75 - 125	20
Chromium	50 - 150	75 - 125	20
Lead	50 - 150	75 - 125	20
Selenium	50 - 150	75 - 125	20
Mercury	80 - 120	80 - 120	20

MS/MSD - Matrix Spike/Matrix Spike Duplicate

Control limits were provided by Eurofins TestAmerica in 2019, and are revised periodically.

K:\CCA\PROJECTS\AMG Zanesville\Variance Application 2019\Att 7 WAP\Appx C QAPP\[Table C-2 Accuracy Precision.xlsx]C-2

Attachment A

Quality Assurance Manual

Quality Assurance Manual Cover Page

TestAmerica Canton
4101 Shuffel Street NW
North Canton, OH 44720
Phone: 330-497-9396
Fax: 330-497-0772

www.testamericainc.com

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Quality Assurance Manual Approval Signatures


Laboratory Director – Carolynne Roach

03/29/19
Date


Quality Assurance Manager – Mark Loeb

04/02/19
Date


Operations Manager – Aaron Martin

04/01/19
Date


Technical Director – Raymond Riden

03/29/19
Date

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REFERENCED CORPORATE SOPs AND POLICIES

SOP / Policy Reference	Title
CA-C-S-001	Work Sharing Process
CA-I-P-002	Electronic Reporting and Signature Policy
CA-L-P-002	Contract Compliance Policy
CA-Q-M-002	Corporate Quality Management Plan
CA-Q-QM-001	Policy on Tentatively Identified Compounds (TICs) – GC/MS Analysis
CA-Q-S-001	Acid and Solvent Lot Testing and Approval Program
CA-Q-S-002	Manual Integrations
CA-Q-S-006	Detection and Quantitation Limits
CA-Q-S-009	Root Cause Analysis
CA-T-P-001	Qualified Products List
CW-E-M-001	Corporate Environmental Health & Safety Manual
CW-F-P-002	Company-Wide Authorization Matrix
CW-F-P-004	Procurement and Contracts Policy
CW-F-S-007	Fixed Asset Acquisition, Retention and Safeguarding
CW-I-M-001	IT Change Control Procedure Manual
CW-L-P-001	Records Retention Policy
CW-L-P-004	Ethics Policy
CW-L-S-002	Internal Investigation
CW-L-S-004	Subcontracting
CW-Q-S-001	Corporate Document Control and Archiving
CW-Q-S-002	Writing a Standard Operating Procedure (SOPs)
CW-Q-S-003	Internal Auditing
CW-Q-S-004	Management Systems Review
CW-Q-S-005	Data Recall Process
CW-Q-S-001	Corporate Document Control and Archiving

REFERENCED LABORATORY SOPs

SOP Reference	Title
NC-QA-015	Balance and Thermometer Calibration, Container Verification
NC-QA-018	Statistical Evaluation of Data and Development of Control Charts
NC-QA-019	Records Information Management
NC-QA-027	Preparation and Management of SOPs
NC-QA-028	Employee Orientation and Training
NC-QA-029	Nonconformance and Corrective Action System
NC-QA-030	Document Control
NC-SC-005	Sample Receiving and Sample Control
NC-SC-006	Sample Procurement Protocol
CA-Q-T-005	Laboratory Documentation
NC-QA-031	Internal Audits

SECTION 3. INTRODUCTION, SCOPE AND APPLICABILITY

3.1 Introduction and Compliance References

TestAmerica Canton'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 The NELAC Institute (TNI) Standard, dated 2009, Volume 1 Modules 2 and 4, and ISO/IEC Guide 17025:2017. In addition, the policies and procedures outlined in this manual are compliant with TestAmerica's Corporate Quality 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 Requirements for Quality Management Programs" (QA/R-2) (EPA/240/B-01/002, May 31, 2006).
- 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.
- APHA, *Standard Methods for the Examination of Water and Wastewater*, 18th Edition, 19th, 20th, 21st, and on-line Editions.
- *Test Methods for Evaluating Solid Waste Physical/Chemical Methods (SW846)*, Third Edition, September 1986, Final Update I, July 1992, Final Update IIA, August 1993, Final Update II, September 1994; Final Update IIB, January 1995; Final Update III, December 1996; Final Update IV, January 2008; Final Update V, August 2015.
- Federal Register, 40 CFR Parts 136, 141, 172, 173, 178, 179 and 261.
- 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. Sample matrices vary among 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 Appendix 2. 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 and/or the Quality Assurance (QA) Manager. In some cases, QAPPs and DQOs may specify less stringent requirements. The Laboratory Director and the QA Manager must determine if it is in the lab's best interest to follow the less stringent requirements.

Ohio VAP requirements are listed throughout the document.

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. This 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 (NC-QA-030) and Updating Procedures (NC-QA-027).

SECTION 4. MANAGEMENT REQUIREMENTS

4.1 Overview

TestAmerica Canton is a local operating unit of TestAmerica Laboratories, Inc. and includes various Service Centers. Service Centers under the direct authority of TestAmerica Canton include (but are not limited to) the Cambridge, Cincinnati, Columbus, and Dayton facilities in Ohio and the Grand Rapids and Brighton facilities in Michigan. The Brighton Michigan Service Center also houses a small laboratory that performs short hold analysis as needed. 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., President and Chief Executive Officer (CEO), Chief Operating Officer (COO), Executive Vice President (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 Canton is presented in Figure 4-1. Employee names are provided to demonstrate range and size of departments however the actual staff members may vary over time. The most current Organization Chart may be obtained from Quality Assurance Manager or Laboratory Director.

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 impartially and 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 Canton laboratory.

Canton Laboratory Key Personnel

Name	Position
Rusty Vicinie	VP of Operations, Central
Carolynne M. Roach	Laboratory Director
Raymond Riden	Technical Director
Aaron M. Martin	Operations Manager
Mark J. Loeb	Quality Assurance Manager
Tom Stiller	GC/MS Volatiles Group Leader
Steve Jackson	Regional Safety Director, Waste Management Supervisor
Brittany Blythe	Extractions Group Leader
Will Cordell	Field Analytical Group Leader
Olguita Colon	GC Volatile/Semivolatiles Group Leader
Tom Hula	GC/MS Semivolatiles Group Leader
Joseph Weisend	General Chemistry Group Leader
Darren Miller	Maintenance
Karen Counts	Metals Group Leader
Patrick O'Meara	Project Management Group Leader

Name	Position
Nick Sutek	Sample Control Group Leader
Lance Hershman	Canton Shipping Hub Manager
Bonnie Bridwell	Cambridge Service Center Contact
Matt Barbieri	Cincinnati Service Center Contact
Gina Rivera	Columbus Service Center Contact
Theresa Daniels	Dayton Service Center Contact
Terri Harlin	Brighton Michigan Service Center / Laboratory Contact
Gary Wood	Grand Rapids Michigan Service Center Contact

4.2.2 President and Chief Executive Officer (CEO)

The President and CEO is a member of the Board of Directors and is ultimately responsible for the quality and performance of all TestAmerica facilities. The President and CEO establishes the overall quality standard and data integrity program for the Analytical Business, providing the necessary leadership and resources to assure that the quality standard and integrity program are met.

4.2.3 Chief Operation Officer (COO)

The COO reports directly to the President and CEO of TestAmerica. The COO is responsible for the operations of TestAmerica's subsidiary companies and the company's strategic growth.

4.2.4 Senior Vice President of Operations and Client Service

The SVP of Operations and Client Service leads the Client Service Organization (CSO); and oversees the operations of all TestAmerica laboratories, the Corporate Technical Services group and the Sales Opportunity Optimization efforts. The SVP provides direction to the VPs of Operations, Client Service Directors, Manager of Project Managers, Director of Technical Services and a Director of Sales. The SVP of Operations and Client Service reports directly to the President and CEO of TestAmerica.

4.2.5 Vice President of Operations (VPO)

Each VP of Operations (VPO) reports directly to the SVP of Operations and Clients Services. Each VPO is responsible for the overall administrative and operational management of their respective laboratories. The VPO's responsibilities include allocation of personnel and resources, long-term planning, goal setting, and achieving the financial, business, and quality objectives of TestAmerica. The VPO's ensure timely compliance with Corporate Management directives, policies, and management systems reviews. The VPO's are also responsible for restricting any laboratory from performing analyses that cannot be consistently and successfully performed to meet the standards set forth in this manual.

4.2.6 Vice President of Quality and Environmental Health and Safety (VP-QA/EHS)

The Vice President (VP) of QA/EHS reports directly to the President and CEO. With the aid of the Executive Committee, Laboratory Directors, Quality Directors, Safety Managers, EH&S Coordinators and QA Managers, the VP-QA/EHS has the responsibility for the establishment, general overview and Corporate maintenance of the Quality Assurance and EH&S Programs within TestAmerica. Additional responsibilities include:

- Review of QA/QC and EHS aspects of Corporate SOPs & Policies, national projects and expansions or changes in services.
- Work with various organizations outside of TestAmerica to further the development of quality standards and represent TestAmerica at various trade meetings.
- Prepare monthly reports for quality and EH&S metrics across the analytical laboratories and a summary of any quality and EH&S related initiatives and issues.
- With the assistance of the Corporate Senior Management Teams and the EHS Managers development and implementation of the TestAmerica Environmental, Health and Safety Program.

4.2.7 Quality Assessment Director

The Quality Assessment Director reports to the VP-QA/EHS. The Quality Assessment Director has QA oversight of laboratories; is responsible for the internal audit system, schedule and procedure; monitors laboratory internal audit findings; identifies common laboratory weaknesses; and monitors corrective action closures. Together with the Quality Compliance Director, the Quality Systems Director, and the VP-QA/EHS, the Quality Assessment Director has the responsibility for the establishment, general overview and maintenance of the Analytical Quality Assurance Program within TestAmerica.

4.2.8 Quality Compliance Director

The Quality Compliance Director reports to the VP-QA/EHS. The Quality Compliance Director has QA oversight of laboratories; monitors and communicates DoD / DoE requirements; develops corporate tools for ensuring and improving compliance; develops corporate assessment tools; identifies common laboratory weaknesses; and monitors corrective action closures. Together with the Quality Assessment Director, Quality Systems Director and the VP-QA/EHS, the Quality Compliance Director has the responsibility for the establishment, general overview and maintenance of the Analytical Quality Assurance Program within TestAmerica.

4.2.9 Quality Systems Director

The Quality Systems Director reports to the VP-QA/EHS. The Quality Systems Director has QA oversight of laboratories; develops quality policies, procedures and management tools; monitors and communicates regulatory and certification requirements; identifies common laboratory weaknesses; and monitors corrective action closures. Together with the Quality Assessment Director, Quality Compliance Director and the VP-QA/EHS, the Quality Systems Director has the responsibility for the establishment, general overview and maintenance of the Analytical Quality Assurance Program within TestAmerica.

4.2.10 Quality Information Manager

The Quality Information Manager is responsible for managing all company official documents

(e.g., Policies, Procedures, Work Instructions), the company's accreditation database, intranet websites, external laboratory subcontracting, regulatory limits for clients on the company's TotalAccess website; internal and external client support for various company groups (e.g., Client Services, EH&S, Legal, IT, Sales) for both quality and operational functions. The Quality Information Manager reports to the VP-QA/EHS; and works alongside the Quality Assessment, Quality Compliance and Quality System Directors and EHS Managers to support both the Analytical Quality Assurance and EHS Programs within TestAmerica.

4.2.11 Technical Services Director

The Technical Services Director is responsible for establishing, implementing and communicating TestAmerica's Analytical Business' Technical Policies, SOPs, and Manuals. Other responsibilities include conducting technical assessments as required, acting as a technical resource in national contracts review, coordinating new technologies, establishing best practices, advising staff on technology advances, innovations, and applications.

4.2.12 Ethics and Compliance Officers (ECOs)

TestAmerica has designated two senior members of the Corporate staff to fulfill the role of Ethics and Compliance Officer (ECO) – i.e., the Corporate Counsel & VP of Human Resources and the VP-QA/EHS. Each ECO acts as a back-up to the other ECO and both are involved when data investigations occur. Each ECO has a direct line of communication to the entire senior Corporate and lab management staff.

The ECOs ensure that the organization distributes the data integrity and ethical practices policies to all employees and ensures annual trainings and orientation of new hires to the ethics program and its policies. The ECO is responsible for establishing a mechanism to foster employee reporting of incidents of illegal, unethical, or improper practices in a safe and confidential environment.

The ECOs monitor and audit procedures to determine compliance with policies and to make recommendations for policy enhancements to the President and CEO, VPOs, Laboratory Director or other appropriate individuals within the laboratory. The ECO will assist the laboratory QA Manager in the coordination of internal auditing of ethical policy related activities and processes within the laboratory, in conjunction with the laboratory's regular internal auditing function.

The ECOs will also participate in investigations of alleged violations of policies and work with the appropriate internal departments to investigate misconduct, remedy the situation, and prevent recurrence of any such activity.

4.2.13 Chief Information Officer (CIO)

The CIO is responsible for establishing, implementing and communicating TestAmerica's Information Technology (IT) Policies, SOPs and Manuals. Other responsibilities include coordinating new technologies, development of electronic communication tools such as TestAmerica's intranet and internet sites, ensuring data security and documentation of software, ensuring compliance with the NELAC standard, and assistance in establishing, updating, and maintaining Laboratory Information Management Systems (LIMS) at the various TestAmerica facilities.

4.2.14 Environmental Health and Safety Managers (Corporate)

The EHS Managers report directly to the VP-QA/EHS. The EHS Managers are responsible for the development and implementation of the TestAmerica Environmental, Health and Safety program. Responsibilities include:

- Consolidation and tracking all safety and health-related information and reports for the company, and managing compliance activities for TestAmerica locations.
- Coordination/preparation of the corporate Environmental, Health and Safety Manual Template that is used by each laboratory to prepare its own laboratory-specific Safety Manual/ CHP.
- Preparation of information and training materials for laboratory EHS Coordinators.
- Assistance in the coordination of employee exposure and medical monitoring programs to insure compliance with applicable safety and health regulations.
- Serving as Department of Transportation (D.O.T.) focal point and providing technical assistance to location management.
- Serving as Hazardous Waste Management main contact and providing technical assistance to location management.

4.2.15 Laboratory Director

TestAmerica Canton'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 VPO. The Laboratory Director is also responsible for any service centers connected with their laboratory that perform analytical tests, such as short holding time analyses for pH. The Laboratory Director provides the resources necessary to implement and maintain an effective and comprehensive Quality Assurance and Data Integrity Program.

Specific responsibilities include, but are not limited to:

- Provides one or more technical directorss for the appropriate fields of testing. If the Technical Director 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 Technical Director to temporarily perform this function. If the absence exceeds 35 consecutive calendar days, the primary 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 SOPs as directed by the Quality Assurance department 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.
- Captains the management team, consisting of the QA Manager, the Technical Director, and the Operations Manager as direct reports.

4.2.16 Quality Assurance (QA) Manager or Designee

The QA Manager has responsibility and authority to ensure the continuous implementation of the quality system at the laboratory where they work. The QA Manager is also responsible for any service centers connected with their laboratory that perform analytical tests, such as short holding time analyses for pH.

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 (e.g., 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 officers to accomplish specific responsibilities, which include, but are not limited to:

- Serves as the focal point for QA/QC in the laboratory.
- Have functions independent from laboratory operations for which he/she has quality assurance oversight.
- Have documented training and/or experience in QA/QC procedures and the laboratory's Quality System.
- Have a general knowledge of the analytical test methods for which data audit/review is performed (and/or having the means of getting this information when needed).
- Arrange for or conducting internal audits on quality systems and the technical operation
- 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.
- 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.
- The laboratory QA Manager or designee will maintain records of all ethics-related training, including the type and proof of attendance.
- Maintain, improve, and evaluate the corrective action database and the corrective and preventive action systems.
- Objectively monitor standards of performance in quality control and quality assurance without outside (e.g., managerial) influence.
- Coordinating of document control of SOPs, MDLs, control limits, and miscellaneous forms and information.
- Review a percentage of all final data reports for internal consistency. Review of Chain of Custody (COC), correspondence with the analytical request, batch QC status, completeness of any corrective action statements, evaluate manual calculations, format, holding time, sensibility and completeness of the project file contents.
- 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.
- Captains 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.
- Evaluation of the thoroughness and effectiveness of training.
- Compliance with ISO 17025.

4.2.17 Technical Director or Designee

The Technical Director reports directly to the Laboratory Director. He/she is accountable for all analyses and analysts under their experienced supervision and for compliance with the ISO 17025:2017 Standard. 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.
- Compliance with ISO 17025.

4.2.18 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 Director 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 Director and QA Manager and in compliance with regulatory requirements.
- Works with the Departmental Group Leaders to ensure that scheduled instrument maintenance is completed.

- 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.
- 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/her substitute in the interim.

4.2.19 Environmental Health and Safety 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.
- 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 Material Safety Data Sheet (MSDS) 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.

4.2.20 Department Group Leaders

Department Group Leaders report to the Operations Manager. 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 (as documented in Section 17.3), 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 Personnel 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 Director, 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 Director, 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.

4.2.21 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 Director, 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 Director, 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.

4.2.22 Project Manager (PM)

The PM reports to the Manager of Project Management (MPM) and serves as the interface between the laboratory's technical departments and the laboratory's clients. There is an entire staff of Project Managers that makes up the Project Management team. With the overall goal of total client satisfaction, the functions of this position are outlined below:

- Technical training and growth of the Project Management team.
- Technical liaison for the Project Management team.
- Human resource management of the Project Management team.
- Responsible to ensure that clients receive the proper sampling supplies.
- Accountable for response to client inquiries concerning sample status.
- Responsible for assistance to clients regarding the resolution of problems concerning COC.
- Ensuring that client specifications, when known, are met by communicating project and quality assurance requirements to the laboratory.
- Notifying the supervisors of incoming projects and sample delivery schedules.
- Accountable to clients for communicating sample progress in daily status meeting with agreed-upon due dates.
- Responsible for discussing with client any project-related problems, resolving service issues, and coordinating technical details with the laboratory staff.
- Responsible for staff familiarization with specific quotes, sample log-in review, and final report completeness.
- Monitor the status of all data package projects in-house to ensure timely and accurate delivery of reports.
- Inform clients of data package-related problems and resolve service issues.
- Coordinate requests for sample containers and other services (data packages).

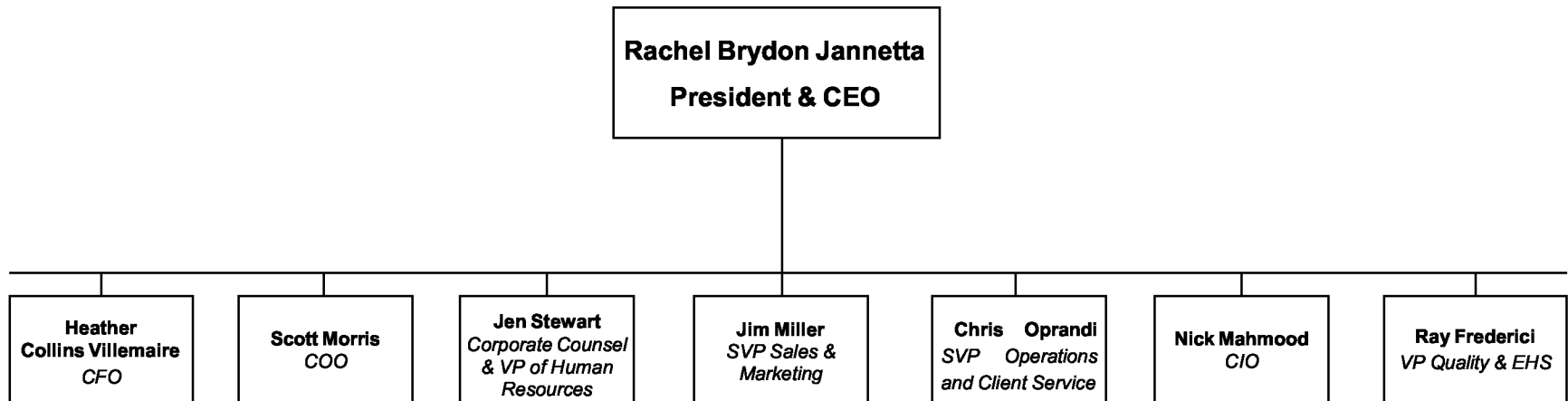
4.3 Deputies

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

Key Personnel	Deputy
Laboratory Director	Technical Director QA Manager
Operations Manager	Technical Director Laboratory Director
Quality Assurance Manager	Quality Assurance Coordinator Laboratory Director
Technical Director	Operations Manager Laboratory Group Leaders
EHS Coordinator	EHS Manager Facilities Manager

Figure 4-1. Corporate and Laboratory Organization Charts

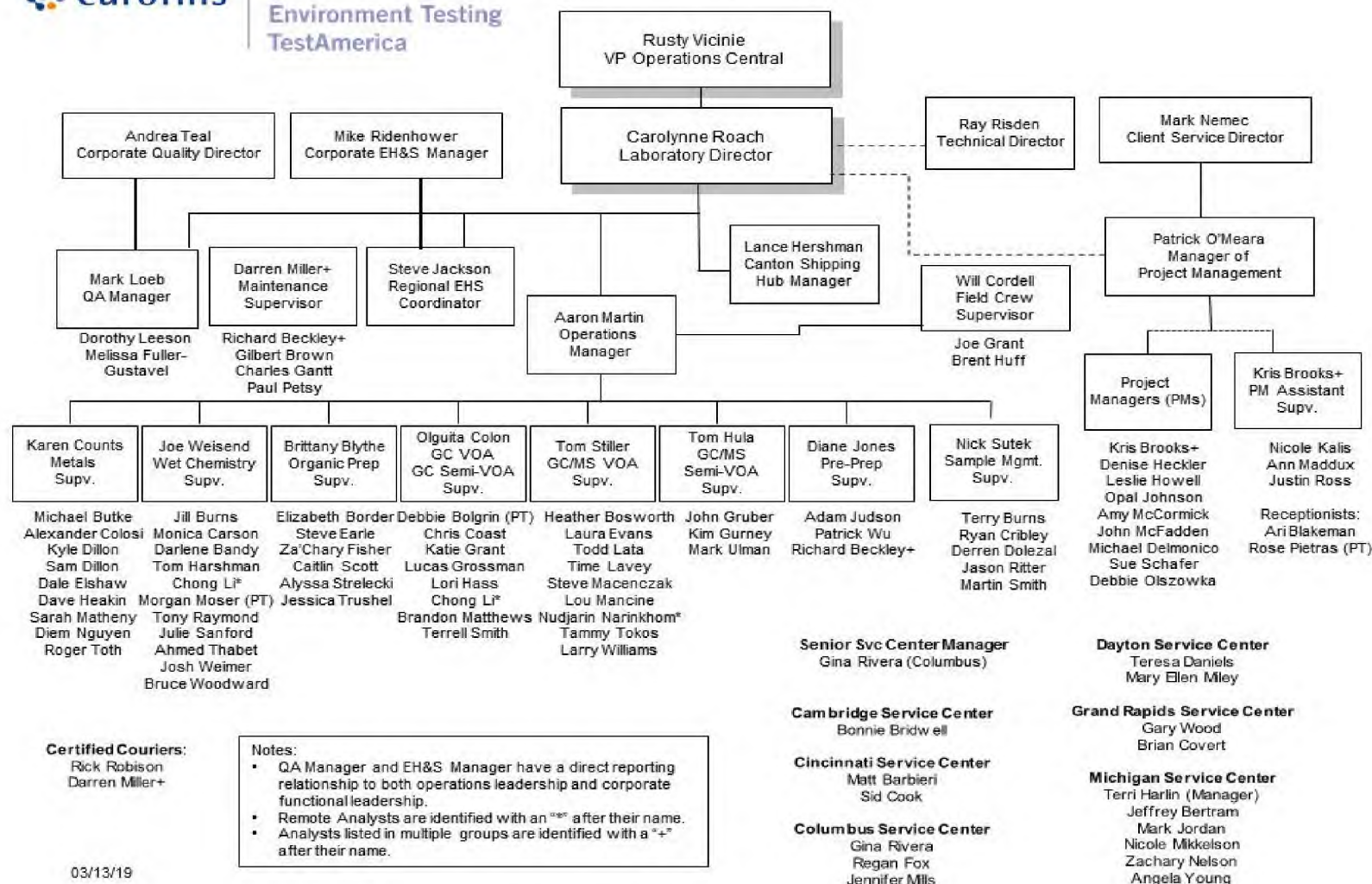
Note: Organization Charts are subject to change without notice.





Environment Testing
TestAmerica

Canton Laboratory Organization



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 ISO/IEC 17025:2017 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 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 CW-Q-S-005).
- 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.
- Provide procedures and guidance to ensure the impartiality and confidentiality of all data and customer information.
- Operate our facilities in a manner that protects the environment and the health and safety of employees and the public.
- Obey all pertinent federal, state and local laws and regulations and encourage other members of our industry to do the same.
- Educate clients as to the extent and kinds of services available.
- Assert competency only for work for which adequate personnel and equipment are available and for which adequate preparation has been made.
- Promote the status of environmental laboratories, their employees, and the value of services rendered by them.

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 laboratory's 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. In order to ensure the ability of the laboratory to meet the Data Quality Objectives (DQOs) specified in the QAPP, clients are advised to allow time for the laboratory to review the QAPP before being finalized. The client is responsible for developing the QAPP; however, the laboratory will provide support to the client for developing the sections of the QAPP that concern laboratory activities.

Historically, laboratories have described their QC objectives in terms of precision, accuracy, representativeness, comparability, completeness, selectivity and sensitivity (PARCCSS).

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), and specific electrodes (separation and identification).

5.4.7 Sensitivity

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

5.5 Criteria for Quality Indicators

The laboratory maintains tables, housed in TALS that summarize the precision and accuracy acceptability limits for performed analyses. This summary includes an effective date, is updated each time new limits are generated, and are managed by the laboratory's QA department. Unless otherwise noted, limits within these tables are laboratory generated. Some acceptability limits are derived from US EPA methods when they are required. Where US EPA method limits are not required, the laboratory has developed limits from evaluation of data from similar matrices. Criteria for development of control limits are contained in NC-QA-018 Statistical Evaluation of Data and Development of Control Charts and 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 analysts use the current limits entered into TALS. The Quality Assurance department maintains an archive of all limits used within the laboratory. 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 TALS following the guidelines described in Section 24. All calculations and limits are documented and dated when approved and effective. On occasion, a client requests contract-specified limits for a specific project.

Current QC limits are entered and maintained in the TALS analyte database. As sample results and the related QC are entered into TALS, the sample QC values are compared with the limits in TALS 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 laboratory's procedures for the creation of control charts are described in laboratory SOP No. NC-QA-018, "Statistical Evaluation of Data and Development of Control Charts." Control charts are created from data stored in the LIMS. The charts are evaluated by QA and/or technical staff to determine if limits need to be updated or to assess the need for corrective actions to improve method performance.

Control charts are used to develop control limits, trouble-shoot analytical problems, and, in conjunction with the non-conformance system, to monitor for trends. Program-specific data analysis requirements for control charts are followed as required for data generated under those programs. These additional requirements shall be documented in a QAPP.

5.6.2 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

The Corporate QA Department 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 NC-QA-030 Document Control and in SOP NC-QA-027 Preparation and Management of SOPs.

The laboratory QA Department also maintains access to various references and document sources integral to the operation of the laboratory. This includes reference methods and regulations. Instrument manuals (hard or electronic copies) are also maintained by the laboratory.

The laboratory maintains control of records for raw analytical data and supporting records such as audit reports and responses, logbooks, standard logs, training files, MDL studies, Proficiency Testing (PT) studies, certifications and related correspondence, and corrective action reports (*however named*). Raw analytical data consists of bound logbooks, instrument printouts, any other notes, magnetic media, electronic data, and final reports.

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 QA personnel are responsible for the maintenance of this system.

Controlled documents are authorized by the QA Department. In order to develop a new document, a responsible 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 retains 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 annually and revised as appropriate. Changes to documents occur when a procedural change warrants.

6.3 Procedures for Document Control Policy

For changes to the QA Manual, refer to SOPs NC-QA-027 and CW-Q-S-001. Uncontrolled copies must not be used within the laboratory. Previous revisions and back-up data are stored by the QA department. Electronic copies are stored on the Public server in the SOP folder for the applicable revision.

For changes to SOPs, refer to SOP No. CW-Q-S-002, Writing a Standard Operating Procedure SOP and SOP NC-QA-027 Preparation and Management of Standard Operating Procedures.. The SOPs identified above also define the process of changes to SOPs.

Forms, worksheets, work instructions and information are organized by the QA department in accordance with the procedures specified in laboratory SOP NC-QA-030.

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 NC-QA-030.

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 Relationship 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)

- Contract Administrator
- VP of Operations
- Laboratory Project Manager
- Laboratory Directors and/or Corporate Technical Managers
- Laboratory Directors and/or Corporate Information Technology Managers
- Account Executives
- 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.

7.3 Documentation

The Contracts Department maintains copies of all signed contracts. TestAmerica Canton Project Manager Assistants and/or PMs maintain electronic copies of signed contracts as needed.

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. Records are maintained electronically.

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. It is the PM's responsibility to ensure that project-specific technical and QC requirements are effectively evaluated and communicated to the laboratory personnel before and during the project. QA department involvement may be needed to assist in the evaluation of custom QC requirements.

PM's are the primary client contact and they ensure resources are available to meet project requirements. Although PM's do not have direct reports or staff in production, they coordinate opportunities and work with laboratory management and supervisory staff to ensure available resources are sufficient to perform work for the client's project. 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 supervisory 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 operations meetings, via emails, or directly. Such changes are updated to the project notes and are introduced to the managers at these meetings. The laboratory staff is then introduced to the modified requirements via the PM or the individual laboratory Technical Director. After the modification is implemented into the laboratory process, documentation of the modification is made in the case narrative of the data report(s).

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.
- Assisting client-specified third party data validators as specified in the client's contract.
- Supplemental information pertaining to the analysis of their samples. Note: An additional charge may apply for additional data/information that was not requested prior to the time of sample analysis or previously agreed upon.

When the client requests a statement of conformity to a specification or standard based on the analysis performed by the laboratory (e.g., pass/fail, in-tolerance/out-of-tolerance), the decision rule shall be clearly defined. Unless inherent in the requested specification or standard, the decision rule selected shall be communicated to the client. Associated reporting requirements are addressed in Section 25.2.18.

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.

The Technical Director is 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 develop 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 (CW-L-S-004) and the Work Sharing Process (CA-C-S-001).

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) or other responsible CSO members, for the Export Lab (i.e., the 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 arrangement in writing and when possible approval from the client shall be obtained and 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 (e.g., USDA) or contracts require notification prior to placing such work.

8.2 Qualifying and Monitoring Subcontractors

Whenever a PM becomes aware of a client requirement or laboratory need where samples must be outsourced to another laboratory, the other laboratory(s) shall be selected based on the

following:

- Subcontractors specified by the client - In these circumstances, the client assumes responsibility for the quality of the data generated from the use of a subcontractor.
- Subcontractors reviewed by TestAmerica – Firms which have been reviewed by the company and are known to meet standards for accreditations (e.g., State, TNI and DoD/DOE); technical specifications; legal and financial information.

A listing of vendors is available on the TestAmerica intranet site.

All TestAmerica laboratories are pre-qualified for work sharing provided they hold the appropriate accreditations and can adhere to the project/program requirements. Client approval is not necessary unless specifically required by the contract. In these cases, the client must provide acknowledgement that the samples can be sent to that facility (an e-mail is sufficient documentation or if acknowledgement is verbal, the date, time, and name of person providing acknowledgement must be documented). The originating laboratory is responsible for communicating all technical, quality, and deliverable requirements as well as other contract needs. (Corporate SOP No. CA-C-S-001, Work Sharing Process).

8.2.1 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 Client Relations Manager (CRM) or Laboratory Director. The CRM or Laboratory Director requests that the QA Manager or PM begin the process of approving the subcontract laboratory as outlined in Corporate SOP No. CW-L-S-004, Subcontracting Procedures.

Once the appropriate accreditation and legal information is received by the laboratory, it is evaluated for acceptability and forwarded to the Corporate Quality Information Manager (QIM) for review. After the Corporate QIM reviews the documents for completeness, the information is forwarded to the Finance Department for formal signature and contracting with the laboratory. The approved vendor will be added to the approved subcontractor list on the intranet site, and the finance group is concurrently notified.

The client will assume responsibility for the quality of the data generated from the use of a subcontractor they have requested the lab to use. The qualified subcontractors on the intranet site are known to meet minimal standards. TestAmerica does not certify laboratories. The subcontractors on our approved list can only be recommended to the extent that we would use them.

8.3 Oversight and Reporting

8.3.1 The status and performance of qualified subcontractors will be monitored by the Corporate Quality department, and includes an annual review process (see Subcontracting SOP CW-L-S-004). Any problems identified will be brought to the attention of TestAmerica's Corporate Finance, Legal and 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.
- 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. CSO personnel will notify all TestAmerica laboratories, 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 CSO Personnel, Laboratory Directors, QA Managers, and Sales Personnel.

Prior to initially sending samples to the subcontracted laboratory, the PM confirms their certification status to determine if it's current and scope-inclusive. The information is documented within the project records.

8.3.2 For continued use of a subcontractor, verification of certification is placed upon the subcontractor for the defined project. Samples are subcontracted under Chain of Custody with the program defined as 'Accreditation Required' and the following statement for verification upon sample receipt:

Note: Since laboratory accreditations are subject to change, TestAmerica Laboratories, Inc. places the ownership of method, analyte & accreditation compliance upon our subcontract laboratories. This sample shipment is forwarded under Chain of Custody. If the laboratory does not currently maintain accreditation in the State of Origin listed above for analytes/tests/matrix being analyzed, the samples must be shipped back to the TestAmerica laboratory or other instructions will be provided. Any changes to accreditation status should be brought to TestAmerica Laboratories, Inc. attention immediately. If all requested accreditations are current to date, return the signed Chain of Custody attesting to said compliance to TestAmerica Laboratories, Inc.

For TestAmerica laboratories, certifications can be viewed on the company's TotalAccess Database.

8.3.3 All subcontracted samples must be accompanied by a TestAmerica Chain of Custody (COC). A copy of the original COC sent by the client must be available in TALS for 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, facilitates successful execution of the work, and ensures the timeliness and completeness of the analytical report.

Non-TNI accredited work must be identified in the subcontractor's report as appropriate. If TNI accreditation is not required, the report does not need to include this information.

Reports submitted from subcontractor laboratories are not altered and are included in their original form in the final project report. This clearly identifies the data as being produced by a subcontractor facility. If subcontract laboratory data is incorporated into the laboratory's EDD (i.e., imported), the report must explicitly indicate which lab produced the data for which methods and samples.

Note: The results submitted by a 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 full qualification of a subcontractor may be waived to meet emergency needs. This decision and justification must be documented in the project files, and the 'Purchase Order Terms And Conditions For Subcontracted Laboratory Services' must be sent with the samples and COC.

In the event this provision is utilized, the laboratory (e.g., PM) will be required to verify and document the applicable accreditations of the subcontractor. All other quality and accreditation requirements will still be applicable, but the subcontractor need not have signed a subcontract agreement with TestAmerica at this time.

The use of any emergency subcontractor will require the PM to complete a New Vendor Add Form in order to process payment to the vendor and add them to TALS. This form requires the user to define the subcontractor's category/s of testing and the reason for testing.

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 Fixed Asset Acquisition, Retention and Safeguarding 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, consumables, 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. Approval information for the solvents and acids tested under SOP CA-Q-S-001 is stored on the TestAmerica SharePoint, under Solvent Approvals. A master list of all tested materials, as well as the certificates of analysis for the materials, is stored in the same location.

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. The analyst may check the item out of the on-site consignment system that contains items approved for laboratory use. If the item is not in consignment, the analyst must provide the master item number, item description, package size, catalogue page number, and the quantity needed. If an item being ordered is not the exact item requested, approval must be obtained from the Operations Manager or Group Leader prior to placing the order. The Canton purchasing manager places the order.

9.3.2 Receiving

It is the responsibility of the warehouse manager to receive the shipment. It is the responsibility of the analyst who ordered the materials to document the date materials were received. Once the ordered reagents or materials are received, the analyst compares the information on the label or packaging to the original order to ensure that the purchase meets the quality level specified. This is documented through the addition of the received date and initials to the information present on the daily order log.

The purchasing manager verifies the lot numbers of received solvents and acids against the pre-approval lists. If a received material is listed as unapproved, or is not listed, it is sequestered and returned to the vendor. Alternatively, the laboratory may test the material for the intended use, and if it is acceptable, document the approval on the approval list. Records of any testing performed locally are maintained on the shared "public" folder on the computer network.

Materials may not be released for use in the laboratory until they have been inspected, verified as suitable for use, and the inspection/verification has been documented.

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 as outlined below

- An expiration date **cannot** be extended if the dry chemical/solvent is discolored or appears otherwise physically degraded. In this case, 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/solvent meets CCV limits. The comparison studies are maintained on-file and available for review in the reagent module of the LIMS.

Note: Some programs (such as OVAP) do not allow the use of verified standards and/or reagents.

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 samples, standards or reagents must have a specific conductivity of less than 1- $\mu\text{mho/cm}$ (or specific resistivity of greater than 1.0 megohm-cm) at 25°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 Technical Director 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 bottlenecks used for sampling must be certified clean and the certificates must be maintained. If uncertified sampling bottlenecks are 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 electronically in the LIMS or in 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 Director 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 Director 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, are followed. A decision is made as to which piece of equipment can best satisfy the requirements. The appropriate written requests are completed and purchasing places the order.

Upon receipt of a new or used piece of equipment, a unique identification name is assigned and added to the equipment list in the LIMS. 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). This can be tracked by use of the New Equipment Tracking Form (WI-NC-091). 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, Group Leaders, and/or the Technical Director. The service providers that perform the services are approved by the Group Leaders or Operations Manager.

Analytical balances are serviced and calibrated annually in accordance with SOP NC-QA-015. The calibration and maintenance services are performed on-site, and the balances are returned to use immediately following successful calibration. When the calibration certificates are received (usually within two weeks of the service), they are reviewed and documentation of the review is filed with the certificates. If the calibration was unsuccessful, the balance is immediately removed from service and segregated pending either further maintenance or disposal.

Calibration services for support equipment such as thermometers, weight sets, autopipettors, etc., are obtained from vendors with current and valid ISO 17025 accreditation for calibration of the specific piece of equipment. Prior to utilizing the vendor's services, the vendor's accreditation status is verified. Once the equipment has been calibrated, the calibration certificates are reviewed by the QA department, and documentation of the review is filed with the calibration certificates. The equipment is then returned to service within the laboratory

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 Procurement & 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 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.

Suppliers are subject to re-evaluation, as deemed appropriate, through the use of Vendor Performance Reports used to summarize and review to determine corrective action necessary, or service improvements required by vendors

The laboratory has access to a listing of all approved suppliers of critical consumables, supplies and services. This information is provided through the purchasing system.

9.6.1 New Vendor Procedure

TestAmerica employees who wish to request the addition of a new vendor must complete a Vendor Add Request Form.

New vendors are evaluated based upon criteria appropriate to the products or services provided as well as their ability to provide those products and services at a competitive cost. Vendors are also evaluated to determine if there are ethical reasons or potential conflicts of interest with 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 Services Director 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 both external and internal complaints with the goal of providing satisfactory resolution to complaints in a timely and professional manner.

The nature of the complaint is identified, documented and investigated, and an appropriate action is determined and taken. In cases where a client complaint indicates that an established policy or procedure was not followed, the QA Department must evaluate whether a special audit must be conducted to assist in resolving the issue. A written confirmation or letter to the client, outlining the issue and response taken is recommended as part of the overall action taken.

The process of complaint resolution and documentation utilizes the procedures outlined in Section 12 (Corrective Actions) and is documented following SOP NC-QA-029 Nonconformance and Corrective Action System. A copy of this procedure will be made available to any interested party on request.

10.2 External Complaints

An employee that receives a complaint initiates the complaint resolution process by first documenting the complaint according to SOP NC-QA-029.

Complaints fall into two categories: correctable and non-correctable. An example of a correctable complaint would be one where a report re-issue would resolve the complaint. An example of a non-correctable complaint would be one where a client complains that their data was repeatedly late. Non-correctable complaints should be reviewed for preventive action measures to reduce the likelihood of future occurrence and mitigation of client impact.

The general steps in the complaint handling process are:

- Receiving and documenting complaints
- Acknowledging receipt of complaint, whenever possible
- Complaint investigation and service recovery
- Process improvement

The laboratory shall inform the initiator of the complaint of the results of the investigation and the corrective action taken, if any.

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 12. In addition, Corporate Management, Sales and Marketing and 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 Director and Quality Director in the QA Monthly report. Monitoring and addressing the overall level and nature of client complaints and the effectiveness of the solutions is part of the Annual Management Systems Review (Section 16).

SECTION 11. CONTROL OF NON-CONFORMING WORK

11.1 Overview

When data discrepancies are discovered or deviations and departures from laboratory SOPs, policies and/or client requests have occurred, corrective action is taken immediately. First, the laboratory evaluates the significance of the nonconforming work. Then, a corrective action plan is initiated based on the outcome of the evaluation. If it is determined that the nonconforming work is an isolated incident, the plan could be as simple as adding a qualifier 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 supervisor for resolution. The supervisor may elect to discuss it with the Technical Director 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 laboratories 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 Operations Manager and 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 TNI (or the analytical method) requirements and the reason. Data being reported to a non-TNI state would need to note the change made to how the method is normally run.

11.2 Responsibilities and Authorities

Under certain circumstances, the Laboratory Director, a Technical Director, or a member of the QA team may authorize departures from documented procedures or policies. The departures may be a result of procedural changes due to the nature of the sample; a one-time procedure for a client; QC failures with insufficient sample to reanalyze, etc. In most cases, the client will be informed of the departure prior to the reporting of the data. Any departures must be well documented using the laboratory's corrective action procedures. This information may also be documented in logbooks and/or data review checklists as appropriate. Any impacted data must be referenced in a case narrative and/or flagged with an appropriate data qualifier.

Any misrepresentation or possible misrepresentation of analytical data discovered by any laboratory staff member must be reported to facility Senior Management within 24-hours. The Senior Management staff is comprised of the Laboratory Director, the QA Manager, and the Technical Director. The reporting of issues involving alleged violations of the company's Data Integrity or Manual Integration procedures must be conveyed to an ECO (e.g., the VP-QA/EHS) and the laboratory's Quality 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, 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.

Corporate SOP entitled Data Recalls (CW-Q-S-005) is the procedure to be followed when it is discovered that erroneous or biased data may have been reported to clients or regulatory agencies.

Corporate SOP entitled Internal Investigations (CW-L-S-002) is the procedure to be followed for investigation and correction of situations involved alleged incidents of misconduct or violation of the company's ethics policy.

Laboratory level decisions are documented and approved using the laboratory's standard nonconformance/corrective action reporting in lieu of the data recall determination form contained in TestAmerica's Corporate SOP No. CW-Q-S-005.

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 analyte which constitutes significant risk and/or liability to the laboratory. Suspension/restriction procedures can be initiated by any of the persons noted in Section 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 e-mailed by the laboratory to the appropriate VP of Operations and member of Corporate QA. This e-mail acts as notification of the incident.

After suspension/restriction, the lab will hold all reports to clients pending review. No faxing, mailing or distributing through electronic means may occur. The report must not be posted for viewing on the internet. It is the responsibility of the Laboratory Director to hold all reporting and to notify all relevant laboratory personnel regarding the suspension/restriction (e.g., Project Management, Log-in, etc.). Clients will NOT generally be notified at this time. Analysis may proceed in some instances depending on the non-conformance issue.

Within 72 hours, the QA Manager will determine if compliance is now met and reports can be released, OR determine the plan of action to bring work into compliance, and release work. A team, with all principals involved (e.g., Laboratory Director, Technical Director, QA Department, Group Leader) 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.

SECTION 12. CORRECTIVE ACTION

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
- Isolated reporting / calculation errors
- Client complaints
- Discrepancies in materials / goods received vs. manufacturer packing slips (Forms of documentation other than NCMs in TALS are also acceptable)

12.2.2 Corrective Actions Documented In the ICAT Database - Internal and external audit findings

- Failed or unacceptable PT results
- Identified poor process or method performance trends
- Systematic reporting / calculation errors
- Data recall investigations
- Questionable trends that are found in the review of NCMs.
- Client complaints
- Excessive revised reports

The ICAT database is used to document background information, track the results of corrective action investigations and root cause analysis, and to provide reports of corrective action plans.

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. An entry into the ICAT system must be initiated, someone is assigned to investigate the issue and the event is investigated for cause. Table 12-1 provides some general guidelines on determining responsibility for assessment.
- The cause analysis step is the key to the process as a long term corrective action cannot be determined until the cause is determined.
- If the cause is not readily obvious, the Technical Director, Laboratory Director, 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 ICAT record 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. Corporate SOP Root Cause Analysis (No. CA-Q-S-009) describes the procedure.

Systematically analyze and document the root causes of the more significant problems that are reported. Identify, track, and implement the corrective actions required to reduce the likelihood of recurrence of significant incidents. Trend the root cause data from these incidents to identify root causes that, when corrected, can lead to dramatic improvements in performance by eliminating entire classes of problems.

Identify the one event associated with problem and ask why this event occurred. Brainstorm the root causes of failures; for example, by asking why events occurred or conditions existed; and then why the cause occurred consecutive times until you get to the root cause. For each of these sub events or causes, ask why it occurred. Repeat the process for the other events associated with the incident.

Root cause analysis does not mean the investigation is over. Look at technique or other systems outside the normal indicators. Often creative thinking will find root causes that ordinarily would be missed and continue to plague the laboratory or operation.

12.3.4 Monitoring of the Corrective Actions

- The Group Leader, 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. Group Leaders and the Operations Manager are accountable to the Laboratory Director to ensure final acceptable resolution is achieved and documented appropriately.
- The QA Manager or designee reviews monthly NCM and ICAT records 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 or designee 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 an NCM or record in the ICAT system.

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.

Note: For the Ohio EPA Voluntary Action Program (VAP), please refer to the associated analytical SOPs for the acceptable criteria, corrective actions, and exceptions.

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.

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 < RL. - See details in Method SOP	- Prepare another blank. - If same response, determine cause of contamination: reagents, environment, instrument equipment failure, etc..
Initial Calibration Standards (Analyst, Group Leaders)	- 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, Group Leaders)	- % 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 Reviewers)	- % 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

QC Activity (Individual Responsible for Initiation/Assessment)	Acceptance Criteria	Recommended Corrective Action
		the data set. - For matrix spike or duplicate results outside criteria the data for that sample shall be reported with qualifiers.
Laboratory Control Sample (LCS) (Analyst, Data Reviewers)	- % Recovery within limits specified in LIMS.	- Check calculations and instrument performance - Re-analyze the LCS and if still outside of control limits, re-prepare and re-analyze all samples in the batch. It is acceptable to report data 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. Note: If there is insufficient sample or the holding time cannot be met, contact the project manager for client instruction.
Surrogates (Analyst, Data Reviewers)	- % Recovery within limits specified in LIMS.	- Reprep and analyze the QC batch for MB surrogates below control limits - Report data with narrative if the surrogate is biased high and associated samples are < RL
Method Blank (MB) (Analyst, Data Reviewers)	< Reporting Limit with the exception of Common Laboratory Contaminants listed in QA-003 QC Policy.	- 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. - Results are acceptable if the same contaminants were not found in the associated samples.
Proficiency Testing (PT) Samples (QA Department,, Analysts, Group Leaders)	- Criteria supplied by PT Supplier.	- Any failures must be investigated for cause. Failures may result in the need to repeat a PT sample to show the problem is corrected.
Internal / External Audits (QA Department, Operations)	- Defined in Quality System documentation such as SOPs, QAM, etc..	- Non-conformances must be investigated system and necessary corrections must be made.

QC Activity (Individual Responsible for Initiation/Assessment)	Acceptance Criteria	Recommended Corrective Action
Manager, , Group Leaders, Laboratory Director)		
Reporting / Calculation Errors (Depends on issue – possible individuals include: Analysts, Data Reviewers, Project Managers, Group Leaders, QA Manager, Corporate QA,)	SOP CW-Q-S-005, Data Recall	- Corrective action is determined by type of error. Follow the procedures in SOP CW-L-S-002 or your lab's CA SOP.
Client Complaints (Project Managers, Lab Director, QA Department, Sales and Marketing)	-	- Corrective action is determined by the type of complaint.
QA Monthly Report (Refer to Section 16 for an example) (QA Manager, Lab Director, Group Leaders)		- Corrective action is determined by the type of issue.
Health and Safety Violation (EH&S Coordinator, Lab Director, Operations Manager, Group Leaders)	- Environmental Health and Safety (EHS) Manual.	- Non-conformance is investigated.

Note:

1. Except as noted below for certain compounds, the method blank should be below the detection limit. Concentrations up to five times the reporting limit will be allowed for the ubiquitous laboratory and reagent contaminants. This allowance presumes that the detection limit is significantly below any regulatory limit to which the data are to be compared and that blank subtraction will not occur. For Ohio VAP, the method blank must be below the detection limit for all compounds of interest.

SECTION 13. 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 through any of the following:

- review of the monthly QA Metrics Report,
- trending NCMs,
- review of control charts and QC results,
- trending proficiency testing (PT) results,
- performance of management system reviews,
- trending client complaints,
- review of processing operations, or
- staff observations.

The monthly Management Systems Metrics Report shows performance indicators in all areas of the laboratory and quality system. These areas include revised reports, corrective actions, audit findings, internal auditing and data authenticity audits, client complaints, PT samples, holding time violations, SOPs, ethics training, etc. The metrics report is reviewed monthly by the laboratory management, 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, Lessons 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/process improvement system:

- Identification of an opportunity for preventive action or process improvement
- Process for the preventive action or improvement
- Define the measurements of the effectiveness of the process once undertaken
- Execution of the preventive action or improvement
- Evaluation of the plan using the defined measurements
- Verification of the effectiveness of the preventive action or improvement

- Close-Out by documenting any permanent changes to the Quality System as a result of the Preventive Action or Process Improvement. Documentation of Preventive Action/process Improvement is incorporated into the monthly QA reports, corrective action process and management review.

13.1.2 Any preventive actions/process improvement undertaken or attempted shall be taken into account during the annual Management Systems Review (Section 16). A highly detailed report is not required; however, a summary of successes and failures within the preventive action program is sufficient to provide management with a measurement for evaluation.

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. The laboratory has a graded approach for managing change based on the Management Systems Review.

SECTION 14. CONTROL OF RECORDS

The laboratory maintains a records management system appropriate to its needs and that complies with applicable standards or regulations as required. The system produces unequivocal, accurate records that document all laboratory activities. The laboratory retains all original observations, calculations and derived data, calibration records and a copy of the analytical report for a minimum of five years after it has been issued. Exceptions for programs with longer retention requirements are discussed in Section 14.1.2.

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. More detailed information on retention of specific records is provided in CW-L-P-001, Records Retention Policy and CW-L-WI-001, TestAmerica Records Retention/Storage Schedule. Quality records are maintained by the QA department electronically. Electronic files are backed up as part of the regular laboratory backup. Records are of two types; either electronic or hard copy paper formats depending on whether the record is computer or hand generated (some records may be in both formats). Technical records are maintained by the individual analysts under the direct supervision of their group leader.

Table 14-1. Record Index¹

<u>Record Types ¹:</u>	<u>Retention Time:</u>
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	Record Types ¹:	Retention Time:
Technical Records	<ul style="list-style-type: none"> - Raw Data - Logbooks² - Standards - Certificates - Analytical Records - MDLs/IDLs/DOCs - Lab Reports 	5 Years from analytical report issue*
Official Documents	<ul style="list-style-type: none"> - Quality Assurance Manual (QAM) - Work Instructions - Policies - SOPs - Policy Memorandums - Manuals - Published Methods 	Indefinitely
QA Records	<ul style="list-style-type: none"> - Certifications - Method and Software Validation / Verification Data 	Indefinitely
QA Records	<ul style="list-style-type: none"> - Internal & External Audits/Responses - Corrective/Preventive Actions - Management Reviews - Data Investigation 	5 Years from archival* Data Investigation: 5 years or the life of the affected raw data storage whichever is greater (beyond 5 years if ongoing project or pending investigation)
Project Records	<ul style="list-style-type: none"> - Sample Receipt & COC Documents - Contracts and Amendments - Correspondence - QAPP - SAP - Telephone Logbooks - Lab Reports 	5 Years from analytical report issue*
Administrative Records	Financial and Business Operations	Refer to CW-L-WI-001
	EH&S Manual, Permits	Indefinitely
	Disposal Records	Indefinitely
	Employee Handbook	Indefinitely
	Personnel files, Employee Signature & Initials, Administrative Training Records (e.g., Ethics)	Refer to HR Manual
	Administrative Policies	Indefinitely
	Technical Training Records	7 years
	Legal Records	Indefinitely
	HR Records	Refer to CW-L-WI-001
	IT Records	Refer to CW-L-WI-001
	Corporate Governance Records	Refer to CW-L-WI-001
	Sales & Marketing	5 years
	Real Estate	Indefinitely

¹ Record Types encompass hardcopy and electronic records.

² Examples of Logbook types: Maintenance, Instrument Run, Preparation (standard and samples), Standard and Reagent Receipt, Archiving, Balance Calibration, Temperature (hardcopy or electronic records).

* Exceptions listed in Table 14-2.

14.1.1 All records are stored and retained in such a way that they are secure and readily retrievable at the laboratory facility or an offsite location that provides a suitable environment to prevent damage or deterioration and to prevent loss. All records shall be protected against fire, theft, loss, environmental deterioration, and vermin. In the case of electronic records, electronic or magnetic sources, storage media are protected from deterioration caused by magnetic fields and/or electronic deterioration.

Access to the data is limited to laboratory and company employees and shall be documented with an access log. Records archived off-site are stored in a secure location where a record is maintained of any entry into the storage facility. Whether on-site or off-site storage is used, logs are maintained in each storage box to note removal and return of records. Retention of records are maintained on-site at the laboratory for approximately one month after their generation and moved offsite for the remainder of the required storage time. Records are maintained for a minimum of five years unless otherwise specified by a client or regulatory requirement.

For raw data and project records, record retention shall be calculated from the date the project report is issued. For other records, such as 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.

Table 14-2. Example: Special Record Retention Requirements

Program	¹Retention Requirement
Michigan Department of Environmental Quality – all environmental data	10 years 12 years for Lead and Copper results
Ohio VAP	10 years and State contacted prior to disposal
OSHA	30 years

¹Note: Extended retention requirements must be noted with the archive documents or addressed in facility-specific records retention procedures.

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. For analytical reports that are maintained as copies in PDF format, refer to Section 19.15.1 for more information.

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 (Records

stored off site should be accessible within 2 days of a request for such records). The history of the sample from when the laboratory took possession of the samples must be readily understood through the documentation. This shall include inter-laboratory transfers of samples 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 COC is stored with the invoice and the work order sheet generated by TALS. The TestAmerica 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. SOP NC-QA-019, Records Information Management outlines this procedure. Instrument data is stored sequentially by instrument. A given day's analyses are maintained in the order of the analysis. Run logs are maintained for each instrument or method; a copy of each day's run log or instrument sequence is stored with the data to aid in re-constructing an analytical sequence. Where an analysis is performed without an instrument, electronic spreadsheets are used to record and file data, or the data is manually entered into TALS at the time of analysis. Standard and reagent information is recorded in logbooks or entered into TALS for each method as required.
- Changes to hardcopy records shall follow the procedures outlined in Section 12 and 19. Changes to electronic records in TALS 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 or entered directly into LIMS at the time the data is generated.
- Hard copy data may be scanned into PDF format for record storage as long as the scanning process can be verified in order to ensure that no data is lost and the data files and storage media must be tested to verify the laboratory's ability to retrieve the information prior to the destruction of the hard copy that was scanned.
- Also refer to Section 19.15.1 '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 results.

14.2.2 Observations, data and calculations are recorded real-time and are identifiable to the specific task.

14.2.3 Changes to hardcopy records shall follow the procedures outlined in Section 12 and 19. Changes to electronic records in TALS or instrument data are recorded in audit trails.

The essential information to be associated with analysis, such as strip charts, tabular printouts, computer data files, analytical notebooks, and run logs, include:

- laboratory sample ID code;
- Date of analysis; time of analysis is also required if the holding time is seventy-two (72) hours or less, or when time critical steps are included in the analysis (e.g., drying times, incubations, etc.); instrumental analyses have the date and time of analysis recorded as part of their general operations. Where a time critical step exists in an analysis, location for such a time is included as part of the documentation in a specific logbook or on a benchsheet.
- Instrumentation identification and instrument operating conditions/parameters. Operating conditions/parameters are typically recorded in instrument maintenance logs where available.
- analysis type;
- all manual calculations and manual integrations;
- analyst's or operator's initials/signature;
- sample preparation including cleanup, separation protocols, incubation periods or subculture, ID codes, volumes, weights, instrument printouts, meter readings, calculations, reagents;
- test results;
- standard and reagent origin, receipt, preparation, and use;
- calibration criteria, frequency and acceptance criteria;
- data and statistical calculations, review, confirmation, interpretation, assessment and reporting conventions;
- quality control protocols and assessment;
- electronic data security, software documentation and verification, software and hardware audits, backups, and records of any changes to automated data entries
- Method performance criteria including expected quality control requirements. These are indicated both in TALS and on specific analytical report formats.

14.2.4 All logbooks used during receipt, preparation, storage, analysis, and reporting of samples or monitoring of support equipment shall undergo a periodic, documented supervisory or peer review.

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
- 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

All records (including those pertaining to test equipment), certificates and reports are safely stored, held secure and in confidence to the client. Certification related records are available upon request.

All information necessary for the historical reconstruction of data is maintained by the laboratory. Records that are stored only on electronic media must be supported by the hardware and software necessary for their retrieval.

Records that are stored or generated by computers or personal computers have hard copy,

write-protected backup copies, or an electronic audit trail controlling access.

The laboratory has a record management system (a.k.a., document control) for control of laboratory notebooks, instrument logbooks, standards logbooks, and records for data reduction, validation, storage and reporting. All data are recorded sequentially within a series of sequential notebooks. Bench sheets, if used, are filed sequentially. Standards are maintained in TALS – no logbooks are required to be used to record that data. Records are considered archived when noted as such in the records management system (a.k.a., document control.)

14.5.1 Transfer of Ownership

In the event that the laboratory transfers ownership or goes out of business, the laboratory shall ensure that the records are maintained or transferred according to client's instructions. Upon ownership transfer, record retention requirements shall be addressed in the ownership transfer agreement and the responsibility for maintaining archives is clearly established. In addition, in cases of bankruptcy, appropriate regulatory and state legal requirements concerning laboratory records must be followed. In the event of the closure of the laboratory, all records will revert to the control of the 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.

14.5.2 Records Disposal

Records are removed from the archive and destroyed after 5 years unless otherwise specified by a client or regulatory requirement. On a project specific or program basis, clients may need to be notified prior to record destruction. Records are destroyed in a manner that ensures their confidentiality such as shredding, mutilation or incineration. (Refer to Tables 14-1 and 14-2).

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. CW-Q-S-003. The types and frequency of routine

internal audits are described in Table 15-1. Special or ad hoc assessments may be conducted as needed under the direction of the QA staff.

Table 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 QA Technical Audits	Joint responsibility: a) QA Manager or designee b) Technical Director or Designee (Refer to CW-Q-S-003)	QA Technical Audits Frequency: 50% of methods annually
SOP Method Compliance	Joint responsibility: a) QA Manager or designee b) Technical Director or Designee (Refer to CW-Q-S-003)	SOP Compliance Review Frequency: Every 2 years
Special	QA Department or Designee	Surveillance or spot checks performed as needed, e.g., to confirm corrective actions from other audits.
Performance Testing	Analysts with QA oversight	Two successful per year for each TNI-field of testing or as dictated by regulatory requirements

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 assess data authenticity and analyst integrity. These audits are based on client projects, associated sample delivery groups, and the methods performed. Reported results are compared to raw data to verify the authenticity of results. The validity of calibrations and QC results are compared to data qualifiers, footnotes, and case narratives. Documentation is assessed by examining run logs and records of manual integrations. Manual calculations are checked. Where possible, electronic audit miner programs (e.g., Chrom AuditMiner) are used to

identify unusual manipulations of the data deserving closer scrutiny. QA technical audits will include all methods within a two-year period. All analysts should be reviewed over the course of a two year period through at least one QA Technical Audit.

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 Director or qualified designee at least every two years. It is also recommended that the work of each newly hired analyst is 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: non-potable water and soil

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 investigations for unacceptable PT results are required. In some cases it may be necessary for blind QC samples to be submitted to the laboratory to show a return to control.

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. 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 lab's 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 (see Section 12). The laboratory’s corrective action responses may include action plans that could not be completed within a predefined timeframe. In these instances, a completion date must be set and agreed to by operations management and the QA Manager.

Developing and implementing corrective actions to findings is the responsibility of the Group Leader of the department 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 Director, 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, VP of Operations 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 Directors prepare 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 Director, QA Manager / Department, and Operations Manager) conducts a review annually of its quality systems and TALS 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 TALS review consists of examining any audits, complaints or concerns that have been raised through the year that are related to TALS. The laboratory will summarize any critical findings that cannot be solved by the lab and report them to Corporate IT.

This management systems review (Corporate SOP No. CW-Q-S-004 and Work Instruction No. CW-Q-WI-003) uses information generated during the preceding year to assess the “big picture” by ensuring that routine actions taken and reviewed on a monthly basis are not components of larger systematic concerns. The monthly review should keep the quality systems current and effective, therefore, the annual review is a formal senior management process to review specific existing documentation. Significant issues from the following documentation are compiled or summarized by the QA Manager prior to the review meeting:

- Matters arising from the previous annual review
- Prior Monthly QA Reports issues
- Laboratory QA Metrics
- Review of report reissue requests
- Review of client feedback and complaints
- Issues arising from any prior management or staff meetings
- Minutes from prior senior lab management meetings - Issues that may be raised from these meetings include:
 - Adequacy of staff, equipment and facility resources
 - Adequacy of policies and procedures
 - Future plans for resources and testing capability and capacity
- The annual internal double blind PT program sample performance (if performed),
- Compliance to the Ethics Policy and Data Integrity Plan - Including any evidence/incidents of inappropriate actions or vulnerabilities related to data Integrity
- For labs analyzing radioactive samples, also include the following:
 - Radiation health and safety
 - Radioactive hazardous waste management
 - Radioactive materials management

- Evaluation of overall risk, including risks to impartiality, confidentiality, reporting statements of conformity, and nonconforming work

A report is generated by the QA Manager and management. The report is distributed to the appropriate VP of Operation 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 (Action Table)]

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

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. TestAmerica's Corporate Internal Investigations 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 President and CEO, Executive VP of Operations, VP of Client & Technical Services, VPs of Operations and Quality Directors receive a monthly report from the VP-QA/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 staffs that possess 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 on 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, or 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)
GFAA, CVAA, FLAA, 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

Specialty	Education	Experience
Group Leaders – <u>General</u>	Bachelor's 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
Group Leaders - <u>Microbiology</u>	Bachelor's degree in applied science with at least 16 semester hours in general microbiology and biology An advanced (MS, PhD.) degree may substitute for one year of experience	And 2 years of relevant experience

When an analyst does not meet these requirements, they can perform a task under the direct supervision of a qualified analyst, peer reviewer or Group Leader, 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 – Comprehensive Refresher	Annually	All
Initial Demonstration of Capability (DOC)	Prior to unsupervised method performance	Technical

The laboratory maintains records of relevant authorization/competence, education, professional qualifications, training, skills and experience of technical personnel (including contracted

personnel) as well as the date that approval/authorization was given. These records are kept on file at the laboratory. Also refer to "Demonstration of Capability" in Section 19.

The training of technical staff is kept up to date by:

- Each employee must have documentation in their training file that they have read, understood and agreed to follow the most recent version of the laboratory QA Manual and SOPs in their area of responsibility. This documentation is updated as SOPs are updated.
- Documentation from any training courses or workshops on specific equipment, analytical techniques or other relevant topics
- Documentation of proficiency (refer to Section 19).
- An Ethics Agreement signed by each staff member (renewed each year) and evidence of annual ethics training.
- A Confidentiality Agreement signed by each staff member signed at the time of employment.
- Human Resources maintains documentation and attestation forms on employment status and records; benefit programs; timekeeping/payroll; and employee conduct (e.g., ethics violations). This information is maintained in the employee's secured personnel file.

Evidence of successful training could include such items as:

- Adequate documentation of training within operational areas, including one-on-one technical training for individual technologies, and particularly for people cross-trained.
- Analysts knowledge to refer to QA Manual for quality issues.
- Analysts following SOPs, i.e., practice matches SOPs.
- Analysts regularly communicate to supervisors and QA if SOPs need revision, rather than waiting for auditors to find problems.

Further details of the laboratory's training program are described in the Laboratory Training SOP NC-QA-028 Employee Orientation and 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 (Policy No. CW-L-P-004) and an Ethics Statement. All initial and annual training is documented by signature on the signed Ethics Statement 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

The laboratory is a 54,440 ft² 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 sample receiving, sample preparation, volatile organic sample analysis, non-volatile organic sample analysis, inorganic sample analysis, microbiological sample analysis, and administrative functions.

18.2 Environment

Laboratory accommodation, test areas, energy sources, and 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. A 225KVA UPS is installed in the main electrical bus to provide at least 15 minutes of backup power in the event of a power failure. This unit also provides voltage and frequency control of lab and office power. A spike/surge arrestor is installed to protect against power surge/sag and lightning strikes. A 30 KW natural gas-fueled backup generator is installed to provide power to the I.T. area in the event of a power failure. Additionally, this generator provides power to two walk-in sample storage coolers and several other smaller sample storage coolers. Smaller portable generators are available to provide "spot power" where needed in the event of a power failure.

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 TALS are regulated to protect against raw data loss.

Specific requirements for facility and environmental conditions, as well as periodic monitoring of conditions, are given in the Environmental Health & Safety Manual plus each laboratory's Facility Addendum.

When the laboratory performs laboratory activities at sites or facilities outside its permanent control, it shall ensure that the requirements related to facilities and environmental conditions of this document are met.

18.3 Work Areas

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

- Microbiological culture handling and sample incubation areas

- 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
- Standard Methods, current Ed., 9020B, Sec. 2
- TNI V1M5, 1.7.3.7.a

18.4 Floor Plan

A floor plan can be found in Appendix 1.

18.5 Building Security

Building key badges are distributed to employees as necessary.

Visitors to the laboratory sign in and out in a visitor's logbook. A visitor is defined as any person who visits the laboratory who is not an employee of the laboratory. In addition to signing into the laboratory, the Environmental Health and Safety 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. 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 entitled 'Writing a Standard Operating Procedure', No. CW-Q-S-002 or the laboratory's SOP NC-QA-027 Preparation and Management of Standard Operating Procedures.
- SOPs are reviewed at a minimum of every 2 years (annually for the state of Kentucky), and where necessary, revised to ensure continuing suitability and compliance with applicable requirements.

19.3 Laboratory Methods Manual

For each test method, the laboratory shall have available the published referenced method as well as the laboratory developed SOP.

Note: If more stringent standards or requirements are included in a mandated test method or regulation than those specified in this manual, the laboratory shall demonstrate that such requirements are met. If it is not clear which requirements are more stringent, the standard from the method or regulation is to be followed. Any exceptions or deviations from the referenced methods or regulations are noted in the specific analytical SOP.

The laboratory maintains an SOP Index for both technical and non-technical SOPs. Technical SOPs are maintained to describe a specific test method. Non-technical SOPs are maintained to describe functions and processes not related to a specific test method.

19.4 Selection of Methods

Since numerous methods and analytical techniques are available, continued communication between the client and laboratory is imperative to assure the correct methods are utilized. Once client methodology requirements are established, this and other pertinent information is summarized by the Project Manager. These mechanisms ensure that the proper analytical methods are applied when the samples arrive for log-in. For non-routine analytical services (e.g., special matrices, non-routine compound lists), the method of choice is selected based on client needs and available technology. The methods selected should be capable of measuring the specific parameter of interest, in the concentration range of interest, and with the required precision and accuracy.

19.4.1 Sources of Methods

Routine analytical services are performed using 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.

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:

- Methods for Chemical Analysis of Water and Wastes, EPA 600 (4-79-020), 1983.
- 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.
- Standard Methods for the Examination of Water and Wastewater, 18th/19th /20th/ 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; Final Update V, August 2015.
- Annual Book of ASTM Standards, American Society for Testing & Materials (ASTM), Philadelphia, PA.
- Code of Federal Regulations (CFR) 40, Parts 136, 141, 172, 173, 178, 179 and 261
- 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
- Method 1630, Methyl Mercury in Water by Distillation, Aqueous Ethylation, Purge and Trap and CVAFS, August, 1998.
- Method 1631, Revision E: Mercury in Water by Oxidation, Purge and Trap, and Cold Vapor Atomic Fluorescence Spectrometry, EPA-821-R-02-19, August 2002.
- Modified DRO, Method for Determining Diesel Range Organics, Wisconsin DNR, PUBL-SW-141, September 1995.
- Modified GRO, Method for Determining Gasoline Range Organics, Wisconsin DNR, PUBL-SW-140, September 1995.

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.

A demonstration of capability (DOC, Lab SOP NC-QA-028, Employee Orientation and Training) is performed whenever there is a change in instrument type (e.g., new instrumentation), matrix, method or personnel (e.g., analyst has not performed the test within the last 12 months).

Note: The laboratory shall have a DOC for all analytes included in the methods that the laboratory performs, and proficiency DOCs for each analyst shall include all analytes that the laboratory routinely performs. Addition of non-routine analytes does not require new DOCs for all analysts if those analysts are already qualified for routine analytes tested using identical chemistry and instrument conditions.

The initial demonstration of capability must be thoroughly documented and approved by the Group Leader and QA Manager prior to independently analyzing client samples. All associated documentation must be retained in accordance with the laboratory's archiving procedures.

The laboratory must have an approved SOP, demonstrate satisfactory performance, and conduct an MDL study (when applicable). There may be other requirements as stated within the published method or regulations (e.g., retention time window study).

Note: In some instances, a situation may arise where a client requests that an unusual analyte be reported using a method where this analyte is not normally reported. If the analyte is being reported for regulatory purposes, the method must meet all procedures outlined within this QA Manual (SOP, MDL, and Demonstration of Capability). If the client states that the information is not for regulatory purposes, the result may be reported as long as the following criteria are met:

- The 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

At least four aliquots must be prepared (including any applicable clean-up procedures) in the same fashion, and following all of the same procedures, as client samples, and analyzed according to the test method (either concurrently or over a period of days).

Using all of the results, calculate the mean recovery in the appropriate reporting units and the standard deviations for each parameter of interest. Refer to SOP NC-QA-028, Employee Orientation and Training, for details on this procedure.

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

A certification statement (see Figure 19-1 as an example) must be used to document the completion of each IDOC. 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.

When changes are made to any validated methods, the influence of such changes shall be documented and, if appropriate, a new validation shall be performed.

19.6.1.1 Determination of Method Selectivity – Method selectivity is the demonstrated ability to discriminate the analyte(s) of interest from other compounds in the specific matrix or

matrices from other analytes or interference. In some cases to achieve the required selectivity for an analyte, a confirmation analysis is required as part of the method.

19.6.1.2 Determination of Method Sensitivity – Sensitivity can be both estimated and demonstrated. Whether a study is required to estimate sensitivity depends on the level of method development required when applying a particular measurement system to a specific set of samples. Detection limit studies are conducted as described in Section 19.7 below. Where other protocols for estimations and/or demonstrations of sensitivity are required by regulation or client agreement, these shall be followed.

19.6.1.3 Relationship of Limit of Detection (LOD) to the Limit of Quantitation (LOQ) – An important characteristic of expression of sensitivity is the distinction between the LOD and the LOQ. The LOD is the minimum level at which the presence of an analyte can be reliably concluded. The LOQ is the minimum concentration of analyte that can be quantitatively determined with acceptable precision and bias, equivalent to the laboratory's routine reporting limit (RL). For most instrumental measurement systems, there is a region where semi-quantitative data is generated around the LOD (both above and below the estimated MDL or LOD) and below the LOQ. In this region, detection of an analyte may be confirmed but quantification of the analyte is unreliable within the accuracy and precision guidelines of the measurement system. When an analyte is detected below the LOQ, and the presence of the analyte is confirmed by meeting the qualitative identification criteria for the analyte, the analyte can be reliably reported, but the amount of the analyte can only be estimated. If data is to be reported in this region, it must be done so with a qualification that denotes the semi-quantitative nature of the result.

19.6.1.4 Determination of Interferences – A determination that the method is free from interferences in a blank matrix is performed.

19.6.1.5 Determination of Range – Where appropriate to the method, the quantitation range is determined by comparison of the response of an analyte in a curve to established or targeted criteria. Generally the upper quantitation limit is defined by highest acceptable calibration concentration. The lower quantitation limit or QL cannot be lower than the lowest non-zero calibration level, and can be constrained by required levels of bias and precision.

19.6.1.6 Determination of Accuracy and Precision – Accuracy and precision studies are generally performed using replicate analyses, with a resulting percent recovery and measure of reproducibility (standard deviation, relative standard deviation) calculated and measured against a set of target criteria.

19.6.1.7 Documentation of Method – The method is formally documented in an SOP. If the method is a minor modification of a standard laboratory method that is already documented in an SOP, an SOP Attachment describing the specific differences in the new method is acceptable in place of a separate SOP.

19.6.1.8 Continued Demonstration of Method Performance – Continued demonstration of method performance is addressed in the SOP. Continued demonstration of method performance is generally accomplished by batch specific QC samples such as LCS, method blanks or PT samples.

19.7 Method Detection Limits (MDL) / Limits of Detection (LOD)

The MDL is the minimum measured quantity of a substance that can be reported with 99% confidence that the concentration is distinguishable from method blank results, consistent with 40CFR Part 136 Appendix B, August, 2017. The MDL is equivalent to the TNI LOD, and is also equivalent to the DoD/DOE Quality Systems Manual (QSM) DL. The working or final MDL is the higher of the MDL value determined from spikes (MDLs) and the MDL value determined from blanks (MDLb). An initial MDL study shall be performed during the method validation process and when the method is altered in a way that can reasonably be expected to change its sensitivity. On-going data are collected during each quarter in which samples are being analyzed. At least once every 13 months the MDLs and MDLb are re-calculated and re-evaluated using data collected during the preceding period. Details of TestAmerica's procedure for conducting MDL studies are given in SOP # CA-Q-S-006).

19.8 Verification of Detection Limits

If it is found during the re-evaluation of detection limit results that more than 5% of the spiked samples do not return positive numeric results that meet all method qualitative identification criteria, then the spiking level shall be increased and the initial MDL study pre-performed at the new spiking concentration.

19.9 Instrument Detection Limits (IDL)

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

IDLs are calculated to determine an instrument's sensitivity independent of any preparation method. IDLs are calculated either using 7 replicate spike analyses, like MDL but without sample preparation, or by the analysis of 10 instrument blanks and calculating 3 x the absolute value of the standard deviation.

19.10 Limit of Quantitation

The LOQ shall be at a concentration equivalent to the lowest calibration standard concentration, with the exception of methods using a single-point calibration, and shall be greater than the MDL. The LOQ is verified by preparing and analyzing spikes at concentrations two times or less than the selected LOQ, employing the complete analytical process.

When the laboratory establishes a quantitation limit, it must be initially verified by the analysis of a low level standard or QC sample at 1-2 times the reporting limit and annually thereafter. The annual requirement is waived for methods that have an annually verified MDL. The laboratory will comply with any regulatory requirements.

19.11 Retention Time Windows

Most organic analyses and some inorganic analyses use chromatography techniques for qualitative and quantitative determinations. For every chromatography analysis or as specified in the reference method, 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 on-file and available for review. Complete details are available in the laboratory SOPs.

19.12 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, spectrochemical, atomic absorption or fluorescence profiles, and specific electrode response factors.

19.13 Estimation of Uncertainty of Measurement

19.13.1 Uncertainty is “a parameter associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand” (as defined by the International Vocabulary of Basic and General Terms in Metrology, ISO Geneva, 1993, ISBN 92-67-10175-1). Knowledge of the uncertainty of a measurement provides additional confidence in a result’s validity. Its value accounts for all the factors which could possibly affect the result, such as adequacy of analyte definition, sampling, matrix effects and interferences, climatic conditions, variances in weights, volumes, and standards, analytical procedure, and random variation. Some national accreditation organizations require the use of an “expanded uncertainty” defined as the range within which the value of the measurand is believed to lie within at least a 95% confidence level with the coverage factor $k=2$.

19.13.2 Uncertainty is not error. Error is a single value (i.e., the difference between the true result and the measured result). On environmental samples, the true result is never known. The measurement is the sum of the unknown true value and the unknown error. Unknown error is a combination of systematic error, or bias, and random error. Bias varies predictably, constantly, and independently from the number of measurements. Random error is unpredictable, assumed to be Gaussian in distribution, and reducible by increasing the number of measurements.

19.13.3 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.

19.13.4 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.

19.13.5 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.

19.14 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 ± 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 Area Supervisor or Laboratory Director if unsure.

19.15 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.

19.15.1 Computer and Electronic Data Related Requirements

The three basic objectives of our computer security procedures and policies are shown below. The laboratory is currently using the TestAmerica TALS LIMS system, which has been highly customized to meet the needs of the laboratory. It is referred to as TALS for the remainder of this section. More detailed descriptions of computer systems and associated controls given in the "IT Change Control Procedure Manual" (CW-I-M-001) policies and procedures posted on TestAmerica's intranet site, Oasis.

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

- LIMS Database Integrity is achieved through data input validation, internal user controls, documentation of system failures and corrective actions taken, and data change requirements.
- Spreadsheets and other software developed in-house must be verified with documentation through hand calculations prior to use. Cells containing calculations must be lock-protected and controlled.

- Instrument hardware and software adjustments are safeguarded through maintenance logs, audit trails and controlled access.

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

19.15.1.3 Maintain Confidentiality – Ensure data confidentiality through physical access controls such as password protection or website access approval when electronically transmitting data.

19.15.2 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 Group Leader or alternate analyst once the data is uploaded or entered into TALS. The spreadsheets, or any other type of applicable documents, are initialed 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 No. 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.

19.15.2.1 All raw data must be retained in the worklist folder, computer file (if appropriate), and/or runlog. 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.

19.15.2.2 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.

19.15.2.3 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 TALS, the results should be entered in TALS with at least three significant figures. In general, results are reported to 2 significant figures on the final report.

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

19.15.2.5 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 TALS, the raw results and dilution factors are transferred into TALS electronically after reviewing the quantitation report, and removing unrequested or poor spectrally-matched compounds. The analyst prints a copy of what has been entered to check for errors. This printout and the instrument's printout of calibrations, concentrations, retention times, chromatograms, and mass spectra, if applicable, are retained with the data file. The data file is stored in a monthly folder on the instrument computer; periodically, this file is transferred to the server and, eventually, to a tape file.

19.15.3 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"ed out, signed and dated.
- Worksheets are created with the approval of the QA Manager or designee at the facility. The QA Manager or designee controls all worksheets following the procedures in Section 6.

19.15.4 Review / Verification Procedures

Review procedures are outlined in several SOPs 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. The general review concepts are discussed below, more specific information can be found in the SOPs.

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

19.15.4.2 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 TALS, data qualifiers are added as needed. All first level reviews are documented.

19.15.4.3 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, verification of units vs matrix, 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

19.15.4.4 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 Director, or Supervisor for further investigation. Corrective action is initiated whenever necessary.

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

19.15.4.6 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 the COC is followed, cover letters / narratives are present, flags are appropriate, reported units are appropriate for the sample matrix, and project specific requirements are met. The Project Manager may also evaluate the validity of results for different test methods given expected chemical relationships.

19.15.4.7 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 electronically signs the final report which is sent out to the client.

19.15.4.8 A visual summary of the flow of samples and information through the laboratory, as well as data review and validation, is presented in Figure 19-2.

19.15.5 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 TestAmerica's Corporate SOP (CA-Q-S-002).

19.15.5.1 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 to determine when manual integrating is required. Analysts are encouraged to ask for assistance from a senior analyst or manager when in doubt.

19.15.5.2 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.

19.15.5.3 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.

19.15.5.4 All manual integrations receive a second level review. Manual integrations must be indicated on expanded scale "before" and "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

GC Analyst Demonstration of Capability

TestAmerica Canton

Analyst:

DOC Run Date:

Preparation Method(s):

8151 Herbicide SOP: NC-GC-038	WI DRO SOP: NC-GC-013	8315 Formaldehyde SOP: NC-GC-035	WI GRO Prep/Analysis SOP: NC-GC-031	8082/608 PCBs SOP: NC-GC-007/NC-GC-038
8081/608 Pesticides SOP: NC-GC-038	8015 DRO SOP NC-GC-043	8015 GRO Prep/Analysis SOP: NC-GC-025	Aromatic Acids Analysis (solid and water), solid prep SOP: NC-GC-036	RSK-175 SOP: NC-GC-032
1630 MeHg	8011			

Prep/Analysis SOP: NC-GC-039	Prep/Analysis SOP: NC-GC-040			
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Matrix: ☐Water ☐Solid

We, the undersigned, CERTIFY that:

1. The analyst identified above, using the cited test method with the specifications in the cited SOP, which is in use at the facility for the analysis of samples under the laboratory's Quality Assurance Plan, has completed the Demonstration of Capability (DOC).
2. The test method(s) was performed by the analyst identified on this certificate.
3. The data associated with the demonstration of capability are true, accurate, complete, and self-explanatory.
4. All raw data to reconstruct and validate these analyses have been retained at the facility.
5. The associated information is organized and available for review.

Department Supervisor

Signature

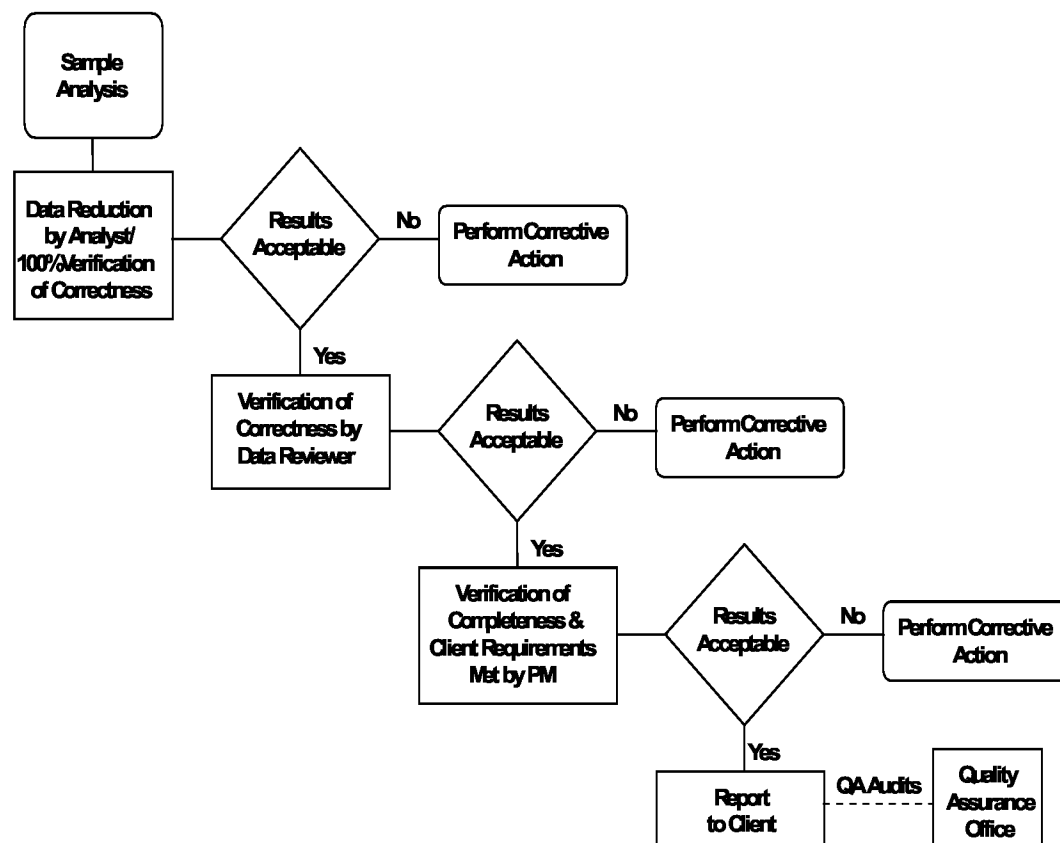
Date

Quality Assurance Officer

Signature

Date

Figure 19-2. Example: Work Flow



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 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

The laboratory follows a well-defined maintenance program to ensure proper equipment operation and to prevent the failure of laboratory equipment or instrumentation during use. This program of preventive maintenance helps to avoid delays due to instrument failure.

Routine preventive maintenance procedures and frequency, such as cleaning and replacements, should be performed according to the procedures outlined in the manufacturer's manual. Qualified personnel must also perform maintenance when there is evidence of degradation of peak resolution, a shift in the calibration curve, loss of sensitivity, or failure to continually meet one of the quality control criteria.

Table 20-2 lists examples of scheduled routine maintenance. It is the responsibility of each Group Leader to ensure that instrument maintenance logs are kept for all equipment in his/her department. Preventative maintenance procedures are also outlined in analytical SOPs and/or instrument manuals. (**Note:** for some equipment, the log used to monitor performance is also the maintenance log. Multiple pieces of equipment may share the same log as long as it is clear as to which instrument is associated with an entry.)

Instrument maintenance logs are controlled and are used to document instrument problems, instrument repair and maintenance activities. Maintenance logs shall be kept for all major pieces of equipment. Instrument maintenance logs may also be used to specify instrument parameters.

- Documentation must include all major maintenance activities such as contracted preventive maintenance and service and in-house activities such as the replacement of electrical components, lamps, tubing, valves, columns, detectors, cleaning and adjustments.
- Each entry in the instrument log includes the analyst's initials, the date, a detailed description of the problem (or maintenance needed/scheduled), a detailed explanation of the solution or maintenance performed, and a verification that the equipment is functioning properly (state what was used to determine a return to control. e.g. CCV run on 'date' was acceptable, or

instrument recalibrated on 'date' with acceptable verification, etc.) must also be documented in the instrument records.

- When maintenance or repair is performed by an outside agency, service receipts detailing the service performed 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.

If an instrument requires repair (subjected to overloading or mishandling), gives suspect results, or otherwise has shown to be defective or outside of specified limits it shall be taken out of operation and tagged as out-of-service or otherwise isolated until such a time as the repairs have been made and the instrument can be demonstrated as operational by calibration and/or verification or other test to demonstrate acceptable performance. The laboratory shall examine the effect of this defect on previous analyses.

In the event of equipment malfunction that cannot be resolved, service shall be obtained from the instrument vendor manufacturer, or qualified service technician, if such a service can be tendered. If on-site service is unavailable, arrangements shall be made to have the instrument shipped back to the manufacturer for repair. Back up instruments, which have been approved, for the analysis shall perform the analysis normally carried out by the malfunctioning instrument. If the back-up is not available and the analysis cannot be carried out within the needed timeframe, the samples shall be subcontracted.

At a minimum, if an instrument is sent out for service or transferred to another facility, it must be 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, thermal/pressure sample preparation 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.

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. Further details on balance calibrations and verifications can be found in SOP NC-QA-015 Balance and Thermometer Calibration, Container Verification.

20.3.2 pH, Conductivity, and Turbidity Meters

The pH meters used in the laboratory are accurate to ± 0.1 pH units, and have a scale readability of at least 0.05 pH units. The meters automatically compensate for the temperature, and are calibrated with at least two working range buffer solutions before each use.

Conductivity meters are also calibrated before each use with a known standard to demonstrate the meters do not exceed an error of 1% or one umhos/cm.

Turbidity meters are also calibrated before each use. All of this information is documented in logs.

Consult pH, Conductivity, and Turbidity SOPs for further information.

20.3.3 Thermometers

All liquid in glass thermometers are calibrated on an annual basis with a NIST-traceable thermometer.

- If the temperature measuring device is used over a range of 10°C or less, then a single point verification within the range of use is acceptable;
- If the temperature measuring device is used over a range of greater than 10°C, then the verification must bracket the range of use.

IR thermometers, digital probes and thermocouples are calibrated quarterly.

The digital NIST thermometer is recalibrated every year (unless thermometer has been exposed to temperature extremes) by an approved outside service and the provided certificate of traceability is kept on file. The NIST thermometer(s) have increments of 0.01 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 spreadsheets, logsheets, and/or electronically. Monitoring method-specific temperatures, including incubators, heating blocks, water baths, and ovens, is documented on unit specific logsheets or in TALS. More information on this subject can be found in NC-QA-015 Balance and Thermometer Calibration, Container Verification.

20.3.4 Refrigerators/Freezer Units, Water baths, Ovens and Incubators

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

Ovens, water baths and incubators are monitored on days of use.

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

Sample storage refrigerator temperatures are kept between $> 0^{\circ}\text{C}$ and $\leq 6^{\circ}\text{C}$.

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

All of this information is documented on Daily Temperature Logsheets and/or electronically via TALS or the Temperature Guard System.

20.3.5 Autopipettors, Dilutors, and Syringes

Mechanical volumetric dispensing devices including burettes (except Class A Glassware) and 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 shall be applied to the device stating that it is not calibrated. Any device not regularly verified cannot 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 and considers the statement valid for the first six months. After six months, syringes that dispense volumes greater than 20 μL must be verified or replaced.

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 semiannually or as needed 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 20%, the procedure is repeated and if the result is still greater than 20%, 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.

20.4 Instrument Calibrations

Calibration of analytical instrumentation is essential to the production of quality data. Strict calibration procedures are followed for each method. These procedures are designed to

determine and document the method detection limits, the working range of the analytical instrumentation and any fluctuations that may occur from day to day.

Sufficient raw data records are retained to allow an outside party to reconstruct all facets of the initial calibration. Records contain, but are not limited to, the following: calibration date, method, instrument, analyst(s) initials or signatures, analysis date, analytes, concentration, response, and type of calibration (Avg RF, curve, or other calculations that may be used to reduce instrument responses to concentration.)

Sample results must be quantitated from the initial calibration and may not be quantitated from any continuing instrument calibration verification unless otherwise required by regulation, method or program.

If the initial calibration results are outside of the acceptance criteria, corrective action is performed and any affected samples are reanalyzed if possible. If the reanalysis is not possible, any data associated with an unacceptable initial calibration will be reported with appropriate data qualifiers (refer to Section 12).

Note: Instruments are calibrated initially and as needed after that and at least annually.

20.4.1 Calibration Standards

Calibration standards are prepared using the procedures indicated in the Reagents and Standards section of the determinative method SOP. If a reference method does not specify the number of calibration standards, a minimum of 3 calibration points will be used.

Standards for instrument calibration are obtained from a variety of sources. All standards are traceable to national or international standards of measurement, or to national or international standard reference materials.

The lowest concentration calibration standard that is analyzed during an initial calibration must be at or below the stated reporting limit for the method based on the final volume of extract (or sample).

The other concentrations define the working range of the instrument/method or correspond to the expected range of concentrations found in actual samples that are also within the working range of the instrument/method. Results of samples not bracketed by initial instrument calibration standards (within calibration range to at least the same number of significant figures used to report the data) must be reported as having less certainty, e.g., defined qualifiers or flags (additional information may be included in the case narrative). The exceptions to these rules. ICP and ICPMS methods which define the working range with periodic linear dynamic range studies, rather than through the range of concentrations of daily calibration standards.

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, a standard made by a different analyst at a different time or a different preparation would be considered a second source. This verification occurs immediately after the calibration curve has been analyzed, and before the analysis of any samples.

20.4.1.1 Calibration Verification

The calibration relationship established during the initial calibration must be verified initially and at least daily as specified in the laboratory method SOPs in accordance with the referenced analytical methods and in the 2009 TNI Standard. The process of calibration verification applies to both external standard and internal standard calibration techniques, as well as to linear and non-linear calibration models. Initial calibration verification (ICV) is with a standard source secondary (second source standard) to the calibration standards, but continuing calibration verifications (CCV) may use the same source standards as the calibration curve.

Note: The process of calibration verification referred to here is fundamentally different from the approach called "calibration" in some methods. As described in those methods, the calibration factors or response factors calculated during calibration are used to update the calibration factors or response factors used for sample quantitation. This approach, while employed in other EPA programs, amounts to a daily single-point calibration.

All target analytes and surrogates, including those reported as non-detects, must be included in periodic calibration verifications for purposes of retention time confirmation and to demonstrate that calibration verification criteria are being met, i.e., RPD, per 2009 TNI Std. EL-V1M4 Sec. 1.7.2.

All samples must be bracketed by periodic analyses of standards that meet the QC acceptance criteria (e.g., calibration and retention time). The frequency is found in the determinative methods or SOPs.

Note: If an internal standard calibration is being used then bracketing calibration verification standards are not required, only daily verifications are needed. The results from these verification standards must meet the calibration verification criteria and the retention time criteria (if applicable).

Generally, the calibrations must be verified by an ICV analyzed immediately following initial calibration and before sample analysis. The ICV may be used as the first bracketing CCV, if criteria for both are met.

A continuing instrument calibration verification (CCV) is generally analyzed at the beginning of each 12-hour analytical shift during which samples are analyzed. The 12-hour analytical shift begins with the injection of the calibration verification standard (or the MS tuning standard in MS methods). The shift ends after the completion of the analysis of the last sample, QC, or standard that can be injected within 12-hours of the beginning of the shift. For methods that have quantitation by external calibration models, a CCV is analyzed at the end of each analytical sequence. Some methods have more frequent CCV requirements. See specific SOPs. Most inorganic methods require the CCV to be analyzed after every 10 samples or injections, including matrix or batch QC samples.

Note: If an internal standard calibration is being used (e.g., GCMS) then bracketing standards are not required, only daily verifications are needed, except as specified by program or method requirements.

If the results of a CCV are outside the established acceptance criteria and analysis of a second consecutive (and immediate) CCV fails to produce results within acceptance criteria, corrective action shall be performed. Once corrective actions have been completed and documented, the laboratory shall demonstrate acceptable instrument / method performance by analyzing two consecutive CCVs, or a new initial instrument calibration shall be performed.

Sample analyses and reporting of data may not occur or continue until the analytical system is calibrated or calibration verified. However, data associated with an unacceptable calibration verification may be fully useable **reported based upon discussion and approval of the client** under the following special conditions:

a).when the acceptance criteria for the CCV are exceeded high (i.e., high bias) and the associated samples within the batch are non-detects, then those non-detects may be reported with a case narrative comment explaining the high bias. Otherwise the samples affected by the unacceptable CCV shall be re-analyzed after a new calibration curve has been established, evaluated and accepted; or

b).when the acceptance criteria for the CCV are exceeded low (i.e., low bias), those sample results may be reported if they exceed a maximum regulatory limit/decision level. Otherwise the samples affected by the unacceptable CCV shall be re-analyzed after a new calibration curve has been established, evaluated and accepted.

Samples reported by the 2 conditions identified above will be appropriately flagged.

20.4.1.2 Verification of Linear and Non-Linear Calibrations

Calibration verification for calibrations involves the calculation of the percent drift or the percent difference of the instrument response between the initial calibration and each subsequent analysis of the verification standard. (These calculations are available in the laboratory method SOPs.) Verification standards are evaluated based on the % Difference from the average CF or RF of the initial calibration or based on % Drift or % Recovery if a linear or quadratic curve is used.

Regardless of whether a linear or non-linear calibration model is used, if initial verification criterion is not met, then no sample analyses may take place until the calibration has been verified or a new initial calibration is performed that meets the specifications listed in the method SOPs. If the calibration cannot be verified after the analysis of a single verification standard, then adjust the instrument operating conditions and/or perform instrument maintenance, and analyze another aliquot of the verification standard. If the calibration cannot be verified with the second standard, then a new initial calibration is performed.

- When the acceptance criteria for the calibration verification are exceeded high, i.e., high bias, and there are associated samples that are non-detects, then those non-detects may be reported. Otherwise, the samples affected by the unacceptable calibration verification shall be reanalyzed after a new calibration curve has been established, evaluated and accepted.
- When the acceptance criteria for the calibration verification are exceeded low, i.e., low bias, those sample results may be reported if they exceed a maximum regulatory limit/decision level. Otherwise, the samples affected by the unacceptable verification shall be reanalyzed

after a new calibration curve has been established, evaluated and accepted. Alternatively, a reporting limit standard may be analyzed to demonstrate that the laboratory can still support non-detects at their reporting limit. For Ohio VAP samples, results may not be reported when calibration verifications fail the lower limit criterion.

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. 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. Data system library search routines should not use normalization routines that would misrepresent the library or unknown spectra when compared to each other. Further details are given in policy memorandum CA-Q-QM-001, Policy on Tentatively Identified Compounds (TICs) – GC/MS Analysis.

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).

20.6 GC/MS Tuning

Prior to any GC/MS 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 spectrometer, the parameters may be adjusted within the specifications set by the manufacturer or the analytical method. These generally do not 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. Example: Instrumentation List

Equipment Instrument	Manufacturer	Model Number	Serial Number	Year in Service	Condition When Received
MSV UX2 MSD (screen)	Hewlett Packard	5972	US00029070	1992	NEW
MSV UX2 Concentrator	OI Analytical	4560	J615460591		
MSV UX2 Sampler	Varion	Archon	12175		
MSV HP6 MSD (screen)	Hewlett Packard	5973	US00005571	1998	NEW
MSV HP6 Concentrator	OI Analytical	4560	M943460127		
MSV HP6 Sampler	OI Analytical	4552	12258		

Equipment Instrument	Manufacturer	Model Number	Serial Number	Year in Service	Condition When Received
MSV UX7 MSD (screen)	Hewlett Packard	5973	US00010937	1998	NEW
MSV UX7 Concentrator	OI Analytical	4560	N251460461		
MSV UX7 Sampler	Dynatech Precision Sampling Corp.	Archon 5100A	12019		
MSV UX8 MSD	Hewlett Packard	6890	US00027773	1999	NEW
MSV UX8 Concentrator	OI Analytical	Eclipse 4660	B444466152P		
MSV UX8 Sampler	OI Analytical	4552	14092		
MSV UX9 MSD	Hewlett Packard	5973	US00028329	2000	NEW
MSV UX9 Concentrator	OI Analytical	4560	M946460832		
MSV UX9 Sampler	Environmental Sample Technology, Inc.	Archon	13667		
MSV UX10 MSD	Hewlett Packard	5973	US00032072	2000	NEW
MSV UX10 Concentrator	OI Analytical	Eclipse 4660	BETA 6		
MSV UX10 Sampler	OI Analytical	4552	012058		
MSV UX11 MSD	Agilent	5973 Network	US00038093	2000	NEW
MSV UX11 Concentrator	OI Analytical	4560	K811460270		
MSV UX11 Sampler	OI Analytical	4552	13408		
MSV UX12 MSD	Agilent	5973 Network	US10202133	2002	NEW
MSV UX12 Concentrator	OI Analytical	4560	M041460393		
MSV UX12 Sampler	Varion	Archon	12151		
MSV UX14 MSD	Agilent	5973 Inert	CN10340027	2003	NEW
MSV UX14 Concentrator	OI Analytical	4660	D829466914P		
MSV UX14 Sampler	OI Analytical	4552	14092		
MSV UX15 MSD	Agilent	5973 Inert	CN10515062	2005	NEW
MSV UX15 Concentrator	OI Analytical	Eclipse 4660	C511466149F		
MSV UX15 Sampler	OI Analytical	4552	14368		
MSV UX16 MSD	Agilent	5973 Inert	CN10539865	2005	NEW
MSV UX16 Concentrator	OI Analytical	Eclipse 4660	D539466261P		
MSV UX16 Sampler	OI Analytical	4552	14519		
MSV UX17 MSD	Agilent	5975 Inert	US10831043	2012	NEW
MSV UX17 Concentrator	OI Analytical	Eclipse 4660	H224455292P		
MSV UX17 Sampler	OI Analytical	4552	US12160002		

Equipment Instrument	Manufacturer	Model Number	Serial Number	Year in Service	Condition When Received
MSV UX18 MSD	Hewlett Packard	5973	US00020913	2013	NEW
MSV UX18 Concentrator	OI Analytical	4560	N213460621		
MSV UX18 Sampler	Varion	Archon	12174		
MSV UX19 MS	Agilent	5977B	US1813M021	2018	NEW
MSV UX19 GC	Agilent	7890B	CN1750321		
MSV UX19 Concentrator	OI Analytical	4760	A818447017		
MSV UX19 Sampler	OI Analytical	4100	D818410016		
MSS HP7 MSD	Hewlett-Packard	5973-6890	US71190756	1998	NEW
MSS HP7 Sampler	Hewlett-Packard	6890 Series	US64900400		
MSS HP7 Tower	Hewlett-Packard	6890 Series	US64900400		
MSS HP7 GC	Hewlett-Packard	G1530A	US00009247		
MSS HP9 MSD	Hewlett-Packard	5973-6890	US91422379	2000	NEW
MSS HP9 Sampler	Hewlett-Packard	7683	US94606476		
MSS HP9 Tower	Hewlett-Packard	7683	US93408794		
MSS HP9 GC	ALS	Ready	US00027943		
MSS HP10 MSD	Agilent	5973	US33220074	2003	NEW
MSS HP10 Sampler	Agilent	7683 Series	US83501650		
MSS HP10 Tower	Agilent	7683 Series	CN33832656		
MSS HP10 GC	Agilent	6890N	CN10340002		
MSS AG2 MSD	Agilent	5975C Inert XL	US71235692	2007	NEW
MSS AG2 Sampler	Agilent	7683B Series	US91204712		
MSS AG2 Tower	Agilent	7683B Series	CN53827833		
MSS AG2 GC	Agilent	7890A	CN10721110		
MSS AG3 MSD	Agilent	5977A	US12203016	2014 in use:2017	NEW
MSS AG3 Sampler	Agilent	7693	CN11120088		
MSS AG3 Tower	Agilent	7693	CN11120088		
MSS AG3 GC	Agilent	7890A	CN10501006		
GC A	Agilent	6890 FID	US10402056	2004	NEW
GC O	Hewlett Packard	6890 FID	US00007206	1997	NEW
GC Y	Hewlett Packard	6890 FID	US10337062	2003	NEW
GC Z	Agilent	6890 EPC & PDD/FID	10205072	2000	NEW
GC P1	Hewlett Packard	6890 EPC & Dual ECD Y-Splitter	US00023208	1998	NEW
GC P1	Hewlett Packard	Sampler	US83401589	1998	NEW
GC P1	Hewlett Packard	Tower	CN14422923	1998	NEW
GC P2 (Screening only)	Hewlett Packard	6890 EPC & Dual ECD Y-Splitter	US83802337	1998	NEW

Equipment Instrument	Manufacturer	Model Number	Serial Number	Year in Service	Condition When Received
GC P2	Hewlett Packard	Sampler	US93806108	1998	NEW
GC P2	Hewlett Packard	Tower	US83602262	1998	NEW
GC P3	Hewlett Packard	6890 EPC & Dual ECD Y-Splitter	US00023674	1998	NEW
GC P3	Hewlett Packard	Sampler	US92205419	1998	NEW
GC P3	Hewlett Packard	Tower	CN42637504	1998	NEW
GC P4	Hewlett Packard	6890 EPC & Dual ECD Y-Splitter	US00029531	1999	NEW
GC P4	Hewlett Packard	Sampler	CN51232596	1999	NEW
GC P4	Hewlett Packard	Tower	US82401457	1999	NEW
GC P5	Hewlett Packard	6890 EPC & Dual ECD Y-Splitter	US00029508	2010	NEW
GC P5	Hewlett Packard	Sampler	CN33826455	2010	NEW
GC P5	Hewlett Packard	Tower	US92407745 US00311160	2010	NEW
GC P6	Hewlett Packard	6890 EPC & Dual ECD Y-Splitter	US00032848	2000	NEW
GC P6	Hewlett Packard	Sampler	CN43130187	2000	NEW
GC P6	Hewlett Packard	Tower	CN14422929 US82401457	2000	NEW
GC P9 (screening only)	Agilent	6890 EPC & Dual ECD Y-Splitter	US10205045	2005	NEW
GC P9	Agilent	Sampler	US01708111	2005	NEW
GC P9	Agilent	Tower	CN14523156	2005	NEW
GC P10	Agilent	6890 EPC & Dual ECD Y-Splitter	US91907177	1999	NEW
GC P10	Agilent	Sampler	CN14920067	1999	NEW
GC P10	Agilent	Tower	US83802337	1999	NEW
GC P11	Agilent	6890N EPC & Dual ECD Y-Splitter	CN10517088	2004	NEW
GC P11	Agilent	Sampler	US12411936	2004	NEW
GC P11	Agilent	Tower	CN43220375	2004	NEW
GC P12	Agilent	6890N EPC & Dual ECD Y-Splitter	CN10512025	2005	NEW
GC P12	Agilent	Sampler	US92205419	2005	NEW
GC P12	Agilent	Tower	CN51124095	2005	NEW
GC P13	Agilent	6890N EPC & Dual ECD Y-Splitter	CN10435032	2004	NEW
GC P13	Agilent	Sampler	CN42429315	2004	NEW
GC P13	Agilent	Tower	CN51825000	2004	NEW
GC P14	Agilent	7890 EPC & Dual ECD Y-Splitter	CN10281044	2012	NEW

Equipment Instrument	Manufacturer	Model Number	Serial Number	Year in Service	Condition When Received
GC P14	Agilent	Sampler	CN10220022	2012	NEW
GC P14	Agilent	Tower - front	CN10290167	2012	NEW
GC P14	Agilent	Tower - rear	CN10290169	2012	NEW
GC P15	Agilent	6890N EPC & Dual ECD Y-Splitter	CN10427010	2012	NEW
GC P15	Agilent	Sampler	US11911568	2012	NEW
GC P15	Agilent	Tower	CN43220375	2012	NEW
GC P16	Agilent	6890 EPC & Dual ECD Y-Splitter	US00025858	2014	Borrowed
GC P16	Agilent	Sampler	US83001373	2014	Borrowed
GC P16	Agilent	Tower	CN14422847	2014	Borrowed
GC P18	Agilent	6890 EPC & Dual ECD Y-Splitter	US00006438	2015	NEW
GC P18	Agilent	Sampler	US93806073	2015	NEW
GC P18	Agilent	Tower	CN53827833	2015	NEW
GC HPLC L2	Agilent	HPLC 1100	US82404153	1998	NEW
GC M	Tekran	Tekran 2700	25	2012	NEW
GC N	Agilent	7890 Atomic Fluorescence	CN10820009	2008	NEW
Metals I-12	Thermo	Trace Analyzer 6500 Duo Ash	ICP-20101711	2013	NEW
I-12 Sampler	Elemental Scientific	SC-0500-04	FST04-TSP-090815		
I-12 Pump	Elemental Scientific	FVA	FVA-100203		
Metals I-9	Thermo	Trace Analyzer 6500 Duo Ash	ICP 20102403	2010	NEW
I-9 Sampler	Elemental Scientific	SC-4DX	X4DX-HS-TSP-16-100210		
I-9 Pump	Elemental Scientific	FVA	FVA-090915		
Metals I-14	Agilent	7800	JP18131103	2018	NEW
I-14 Sampler	Agilent	SPS4	AU17494204		
Metals I-10	Agilent	7700 ICPMS Series	JP124521145	2013	NEW
I-10 Sampler	Agilent	ASX-500	US121435A520		
Metals H2	Leeman	Hydra II AA	5VV5ZQ1	2015	NEW
H2 Sampler	Teldyne Leeman	Hydra II	4090		
Metals H3	Leeman	Hydra II AA	17010003	2015	NEW
H3 Sampler	Teldyne Leeman	Hydra II	4055		
Metals H6	Leeman	Hydra AF Gold+	1012	2011	NEW
H6 Sampler	Leeman	Hydra II	0014		
H6 Pump	Leeman	Hydra II	0011		

Equipment Instrument	Manufacturer	Model Number	Serial Number	Year in Service	Condition When Received
H6 Pump	Leeman	Hydra II	2013		
Metals H7	Leeman	Hydra AF Gold+	2011	2012	NEW
H7 Sampler	Leeman	Hydra II	2070		
H7 Pump	Leeman	Hydra II	3023		
H7 Pump	Leeman	Hydra II	2009		
WC Autotitrator (Severus)	Mantech	PC-1000-102/E	MT-1G8-798	2018	NEW
WC Severus Pump	Mantech	PC-1300-475	MT-117-1019		
WC Severus Burette	Mantech	PC-1000-1040	MT-1G8-219		
WC Severus Sampler	Mantech	Automatic 73	191C8020		
WC BOD (Bugsy) Sampler	Mantech	AutoMax 122	261H3N236	2013	NEW
WC Bugsy Pump	Mantech	PC-1000-443	MT-1J3-182		
WC Bugsy Pump	Mantech	PC-1000-408	MT-1K3-508		
WC Bugsy Pump	Mantech	PC-1000-475	MT-1J3-280		
WC Bugsy Interface	Mantech	PB-10030	MT-1A4-169		
WC Spec (Oscar)	Genesys	Spectronic 20	3SGK137005	2016	NEW
WC Spec (Ernie)	Genesys	Spectronic 20	3SGL226006	2008	NEW
WC IC (Veronica)	Dionex	ICS 2100	12031443	2012	NEW
WC Veronica Sampler	Thermo Sci / Dionex	AS-AP	12050895		
WC IC (Thor)	Dionex	Dionex Integrion	16081629	2016	NEW
WC Thor Sampler	Thermo Sci / Dionex	AS-AP	16110203		
WC Discrete Analyzer (Maggie)	Systea	Easy Chem Plus	07004	2013	USED
WC TOC (Clark)	OI Analytical	1030W	P428730168/ PARA	2014	NEW
WC Clark Sampler	OI Analytical	1088 AS	E427788106		
WC Block Digester (Larry)	Andrews	110-40-PA	None on unit	1999	NEW
WC Block Digester (Moe)	Andrews	110-40-PA	None on unit	1999	NEW
WC Block Digester (Curly)	Andrews	110-40-PA	None on unit	1999	NEW
WC Block Digester (Carol)	Lachat	BD46 TKN	00000993	1992	NEW
WC Spec (Snuffleupagus)	Genesys	Spectronic 20	3SGU022007	2016	NEW
WC DO Meter	Mantech	YSI 1500	13D 100737	2013	NEW
WC Conductivity (Xavier)	Orion	Star A112	J14311	2017	NEW
WC Cyanide Analyzer (CNthia)	Astoria Pacific	rAPID-T	4600-1035	2017	NEW

Equipment Instrument	Manufacturer	Model Number	Serial Number	Year in Service	Condition When Received
WC Cyanide Hotblock (Phil)	Simple Dist Micro	C8000	2017MDISW137	2017	NEW
WC Cyanide Hotblock (Lil)	Simple Dist Micro	C8000	2017MDISW136	2017	NEW
WC Flashpoint (Whitey)	Herzog	HFP 339	073390084	2007	NEW
WC pH Meter (Randolph)	Orion	320	020032	2007	NEW
WC Turbidimeter (Gyarados)	Hach	2100Q Turbidimeter	16040C049659	2016	NEW
WC Sulfide Distillation	Westco	Easy Dist 483-B000-01	1193	2008	NEW
WC Solid Phase Extraction Unit (Earl)	Horizon	SPE-DEX 3000XL	14-1971	2014	NEW
WC Conductivity Screening Meter (Myron II)	Myron L Company	TechPro II	T3201412	2018	NEW
COD Block (W1)	Hach	16500-10	870512456	1998	USED
COD Block (W3)	Hach	45600	900201914	1998	USED
COD Block (W4)	Hach	16500-10	890512473	1998	USED
COD Block (W5)	Biosciences	100 003	COD-B0075	2000	NEW
COD Block (W6)	Hach	16500-10	880911479	2018	USED
MBAS Shaker	Eberbach	6010	049817	2015	USED

Note: Laboratory instrumentation, model numbers, and serial numbers are subject to change without notice.

Table 20-2. Example: Schedule of Routine Maintenance

(Refer to manufacturer's instructions for each instrument to identify and perform maintenance operations. Maintenance procedures below are examples only and are subject to frequent change)

ION CHROMATOGRAPH

As Needed	Daily	Weekly	Monthly
Check fuses when power problems occur.	Check plumbing/leaks	Check pump heads for leaks. Check Filter inlet	

As Needed	Daily	Weekly	Monthly
Reactivate or change column when peak shape and resolution deteriorate or when retention time shortening indicates that exchange sites have become deactivated.	Check pump pressure		
De-gas pump head when flow is erratic.	Check conductivity meter		

HIGH PRESSURE LIQUID CHROMATOGRAPH

Daily	As Needed
Check level of solution in reservoirs. If adding, verify that solvent is from the same source. If changing, rinse delivery lines to prevent contamination of the new solvent.	Replace columns when peak shape and resolution indicate that chromatographic performance of column is below method requirements.
Flush with an appropriate solvent to remove all bubbles.	Rinse flow cell with 1N nitric acid if sensitivity low.
Pre-filter all samples.	Change pump seals when flow becomes inconsistent.
	Repack front end of column Back-flush column.

ICP AND ICP/MS

Daily	Monthly or As Needed	Semi-Annually	Annually
Check vacuum pump gage. (<10 millitorr)	Clean plasma torch assembly to remove accumulated deposits	Change vacuum pump oil	Notify manufacturer service engineer for scheduled preventive maintenance service
Check cooling water supply system is full and drain bottle is not full. Also drain tubing is clear, tight fitting, and has few bends.	Clean nebulizer and drain chamber; keep free flowing to maintain optimum performance	Replace coolant water filter (may require more or less frequently depending on quality of water)	
Check nebulizer is not clogged	Clean filters on back of power unit to remove dust		

Daily	Monthly or As Needed	Semi-Annually	Annually
Check capillary tubing is clean and in good condition	Replace when needed: <ul style="list-style-type: none">- peristaltic pump tubing- sample capillary tubing- autosampler sipper probe		
Check peristaltic pump windings are secure	<ul style="list-style-type: none">- Check yttrium position- Check O-rings- Clean/lubricate pump rollers		
Check high voltage switch is on			
Check torch, glassware, aerosol injector tube, and bonnet are clean			

CVAS AND CVAFS

Daily	As Needed	Annually
Change drying tube	Change pump tubing	Change Hg lamp
Check pump tubing/drain tubing	Check/change Hg lamp	
Check gas pressure	Clean optical cell	
Check aperture reading	Lubricate pump	
Check tubing		

GAS CHROMATOGRAPH

Daily *	As Needed
Check for sufficient supply of carrier and detector gases. Check for correct column flow and/or inlet pressures.	Clip off front portion of capillary columns. Replace column if this fails to restore column performance, or when column performance (e.g., peak tailing, poor resolution, high backgrounds, etc.) indicates it is required. Quarterly FID: clean detector, only as needed—not quarterly/or semi-annually.
Check temperatures of injectors and detectors. Verify temperature programs by RT shift.	Replace injection port liner when front portion of capillary column is clipped.
Clean injector port weekly for TPH for 8015B, when breakdown fails; otherwise, when RT shift or bad samples run.	Annually FID: replace flame tip, only as needed. Only as needed: ECD--detector cleaning and re-foiling, whenever loss of sensitivity, erratic response, or failing resolution is observed

Daily *	As Needed
Check baseline level during analysis of run—not maintenance.	Perform gas purity check (if high baseline indicates that impure carrier gas may be in use).
Inspect chromatogram to verify symmetrical peak shape and adequate resolution between closely eluting peaks, when analyzing pesticides; part of analysis—not maintenance. Clip column leader when chromatography looks bad—not daily.	Replace or repair flow controller if constant gas flow cannot be maintained. Detectors: clean when baseline indicates contamination or when response is low. FID: clean/replace jet, replace ignitor. ECD: follow manufacturer's suggested maintenance schedule. HP 7673 Autosampler: replace syringe, fill wash bottle, dispose of waste bottle contents.

**No daily maintenance done on any instrument/method. Weekly change IPL on TPH instrument. Everything else is on an "as needed" basis.*

MASS SPECTROMETER

Daily	Weekly	As Needed	Quarterly	Annually
Check for sufficient gas supply. Check for correct column flow and/or inlet pressure.	Check mass calibration	Check level of oil in mechanical pumps and diffusion pump if vacuum is insufficient. Add oil if needed between maintenance.	Check ion source and analyzer (clean, replace parts as needed)	Replace the exhaust filters on the mechanical rough pump every 1-2 years.
Check temperatures of injector, detector. Verify temperature programs.		Replace electron multiplier when the tuning voltage approaches the maximum and/or when sensitivity falls below required levels.	Check vacuum, relays, gas pressures and flows	
Check inlets, septa		Clean Source, including all ceramics and lenses - the source cleaning is indicated by a variety of symptoms including inability of the analyst to tune the instrument to specifications, poor response, and high background contamination.	Change oil in the mechanical rough pump.	
Check baseline level		Repair/replace jet separator.		

Check values of lens voltages, electron multiplier, and relative abundance and mass assignments of the calibration compounds.		Replace filaments when both filaments burn out or performance indicates need for replacement.		
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ANALYTICAL/TOP LOADING BALANCES

Daily	Annually
Check using Class 1-verified weights once daily or before use Clean pan and weighing compartment	Manufacturer cleaning and calibration

REFRIGERATORS/WALK-IN COOLERS

Daily	As Needed
Temperatures checked and logged	Refrigerant system and electronics serviced

OVENS

Daily	As Needed
Temperatures checked and logged	Electronics serviced

SPECIFIC DIGITAL ION ANALYZER

Daily	As Needed
Daily when used: Calibrate with check standards Inspect electrode daily, clean as needed Inspect electrode proper levels of filling solutions daily; fill as needed Clean probe after each use	Electronics serviced

TURBIDIMETER

Daily	Monthly	As Needed
Daily when used: Adjust linearity on varying levels of NTU standards. Standardize with NTU standards Inspect cells	Clean instrument housing	Electronics serviced

DISSOLVED OXYGEN METER

Daily	As Needed
Daily when used: Calibrate with saturated air Check probe membrane for deterioration Clean and replace membrane with HCl solution	Electronics serviced Clean and replace membrane with HCl solution

CONDUCTANCE METER

Daily	As Needed
Daily when used: Check probe and cables Inspect conductivity cell	Electronics serviced

CHEMICAL OXYGEN DEMAND (COD) REACTOR 1

Daily	As Needed
Daily when used: Calibrate with check standards	Electronics serviced

SPECTROPHOTOMETER

As Needed	Daily	Monthly	Annually
Dust the lamp and front of the front lens	Check the zero % adjustment	Clean windows	Check instrument manual
	Clean sample compartment		Perform wavelength calibration
	Clean cuvettes		Replace lamp annually or when erratic response is observed
			Clean and align optics

pH METER

As Needed	Daily
Clean electrode	Inspect electrode. Verify electrodes are properly connected and filled
Refill reference electrode	Inspect electrode proper levels of filling solutions. Make sure electrode is stored in buffer

TOTAL ORGANIC CARBON ANALYZER

Daily	As Needed	Weekly	Monthly
Check: Oxygen supply Persulfate supply Acid supply Carrier gas flow rate (~ 150 cc/min) IR millivolts for stability (after 30 min. warm-up) Reagent reservoirs	Check injection port septum Indicating drying tube NDIR zero, after change in color indicator Permeation tube, every 6 months of use	Check liquid-flow- rate-pump-tubing conditions on autosampler Check injection port septum	Clean digestion vessel Clean condenser column Do the leak test

DIGESTION BLOCK

Annually
Check temperature with NIST thermometer

Flash Point Tester

Daily
Check tubing Clean sample cup each use
Clean flash assembly
Check stirrer

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, quarterly accuracy checks are performed for all mechanical volumetric devices. Micro syringes used to dispense volumes greater than 20 uL are verified at least 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 should be routinely inspected for chips,

acid etching or deformity (e.g., bent needle). If the Class A glassware 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 calibration certificate and scope of accreditation is kept on file at the laboratory.

21.3 Reference Standards / Materials

Reference standards/materials, where commercially available, are traceable to certified reference materials. Commercially prepared reference standards, to the extent available, are purchased from vendors that are accredited to ISO Guide 34 and ISO/IEC Guide 17025. 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 number and expiration date. All documentation received with the reference standard is retained as a QC record and references the standard 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, 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. 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 TestAmerica's Corporate SOP (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 in TALS or in binders in the laboratory departments. Records must be kept of the date of receipt and date of expiration of standards, reagents and reference materials. In addition, records of preparation of laboratory standards, reagents, and reference materials must be retained, stored appropriately, and be readily available for use and inspection. For detailed information on documentation and labeling, please refer to SOP NC-QA-017 Standards and Reagents.

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's LIM TALS system, and are assigned a unique identification number. The following information is typically recorded in the electronic database within the TALS.

- 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 box (text field)

Records are maintained electronically 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 (include prep date for reagents)
- Standard ID from TALS

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 analytical SOPs.

21.4.3 In addition, the following information may be helpful:

- Date opened (for multi-use containers, if applicable)
- Description of standard (if different from manufacturer's label or if standard was prepared in the laboratory)
- Recommended Storage Conditions
- Concentration (if applicable)
- Initials of analyst preparing standard or opening container

All containers of prepared reagents must include an expiration date and an ID number to trace back to preparation.

Procedures for preparation of reagents can be found in the Method SOPs.

Standard ID numbers must be traceable through associated logbooks, worksheets and preparation/analytical batch records.

All reagents and standards must be stored in accordance to the following priority: 1) with the manufacturer's recommendations; 2) with requirements in the specific analytical methods as specified in the laboratory SOP.

SECTION 22. SAMPLING

22.1 Overview

The laboratory provides sampling services. Sampling procedures are described in SOP NC-SC-006, Sample Procurement Protocol.

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 on-line.

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 COC form establishes the day and time zero. As a general rule, when the maximum allowable holding time is expressed in days (e.g., 14 days, 28 days), the holding time is based on calendar day measured. Holding times expressed in hours (e.g., 6 hours, 24 hours, etc.) are measured from date and time zero. Holding times for analysis include any necessary reanalysis. However, there are some programs that determine holding time compliance based on the date and specific time of analysis compared to the time of sampling regardless of how long the holding time is.

22.4 Sampling Containers, Preservation Requirements, Holding Times

The preservation and holding time criteria specified in the laboratory SOPs are derived from the source documents for the methods. If method required holding times or preservation requirements are not met, the reports will be qualified using a 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.

Guidelines on taking sample aliquots and subsampling are located in each analytical SOP and in Subsampling SOP NC-OP-046.

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 personnel. The sample collector must assure that each container is in his/her physical possession or in his/her view at all times, or stored in such a place and manner to preclude tampering. The field technician relinquishes the samples in writing on the COC form to the sample control personnel at the laboratory or to a 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 the laboratory when personnel at the fixed laboratory facility have physical contact with the samples.

Note: Independent couriers are not required to sign the COC form. The COC is usually kept in the sealed sample cooler. The COC is stored with project information and the report.

23.1.2 Legal / Evidentiary Chain-of-Custody

If samples are identified for legal/evidentiary purposes on the COC, login will complete the custody seal retain the shipping record with the COC, and initiate an internal COC for laboratory use by analysts and a sample disposal record.

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. SOP NC-SC-005, Sample Receiving, describes the laboratory's sample receipt procedure.

23.2.1 Laboratory Receipt

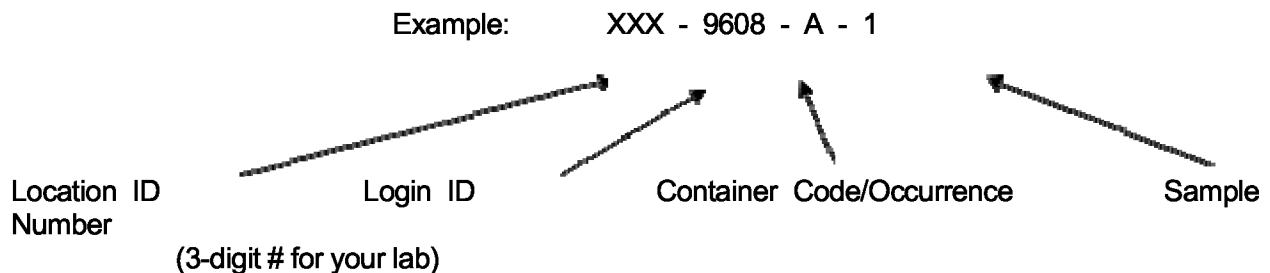
When samples arrive at the laboratory, sample receiving personnel inspect the coolers and samples. The integrity of each sample must be determined by comparing sample labels or tags with the COC and by visual checks of the container for possible damage. Any non-conformance, irregularity, or compromised sample receipt must be documented on a Cooler Receipt Form (CRF) 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

Note: Example sample IDs from TALS.

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 the TestAmerica Laboratory Location ID (Location XXX), the Login ID (9608) which is unique to a particular client/job occurrence, the container code (A) indicating the first container and Sample Number (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 outlined in SOP NC-SC-005 Sample Receiving 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);
- All samples submitted for water/solid Volatile Organic analyses must have a Trip Blank submitted at the same time
- 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 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 TALS according SOP NC-SC-005.

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. Metals samples may be unrefrigerated. 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 every two weeks.

Analysts and technicians retrieve the sample container allocated to their analysis from the designated refrigerator and place them on carts, analyze the sample, and return the remaining sample or empty container to the refrigerator from which it originally came. All unused portions of samples, including empty sample containers, are returned to the secure sample control area. All samples are kept in cold storage for 30 days after report generation, which meets or exceeds most sample holding times. After this time period, the samples are removed from the refrigerator

shelves and prepared for disposal. Special arrangements may be made to store samples for longer periods of time.

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, hazardous and foreign soil samples are stored in an isolated area designated for hazardous waste only. For any sample that is known to be hazardous at the time of receipt or, if after completion of analysis the result exceeds the acceptable regulatory levels, a Hazardous Sample Notice must be completed by the analyst. This form may be completed by Sample Control, Project Managers, or analysts and must be attached to the report. The sample itself is clearly marked with a red stamp, stamped on the sample label reading "HAZARDOUS" or "FOREIGN SOIL" and placed in a colored and/or marked bag to easily identify the sample. The date, log number, lab sample number, and the result or brief description of the hazard are all written on the Hazardous & Foreign Soil Sample Notice. A copy of the form must be included with the original COC and Work Order and the original must be given to the Sample Control Custodian. Analysts will notify Sample Control of any sample determined to be hazardous after completion of analysis by completing a Hazardous Sample Notice. All hazardous samples are either returned to the client or disposed of appropriately through a hazardous waste disposal firm that lab-packs all hazardous samples and removes them from the laboratory. Foreign soil samples are sent out for incineration by a USDA-approved waste disposal facility.

See SOP NC-SC-019 Procedure of Acceptance and Handling of USDA Regulated Domestic and Foreign Soil for further information.

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). A trip blank is enclosed for those samples requiring water/solid volatile organic analyses (see Note). 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 not analyze the trip blanks that were supplied. However, in the interest of good client service, the laboratory will advise the client at the time of sample receipt that it was noted that they did not request analysis of the trip blank; and that the laboratory is providing the notification to verify that they are not inadvertently omitting a key part of regulatory compliance testing.

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 NC-SC-005, Sample Receiving). All procedures in the laboratory Environmental Health and Safety Manual are followed during disposal. Samples are normally maintained in the laboratory no longer than two months 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 must 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, nature of disposal (such as sample depletion, hazardous waste facility disposal, return to client), names of individuals who conducted the arrangements and physically completed the task. The laboratory will remove or deface sample labels prior to disposal unless this is accomplished through the disposal method (e.g., samples are incinerated). A Waste Disposal Record should be completed.

[illegible]

Figure 23-2. Example: Cooler Receipt Form (CRF)

TestAmerica Canton Sample Receipt Form/Narrative Canton Facility				Login # : _____	
Client _____ Site Name _____			Cooler unpacked by: _____		
Cooler Received on _____ Opened on _____					
FedEx: 1 st Grd Exp UPS FAS Clipper Client Drop Off TestAmerica Courier Other _____					
Receipt After-hours: Drop-off Date/Time _____			Storage Location _____		
TestAmerica Cooler # _____ Foam Box _____ Client Cooler _____ Box _____ Other _____					
Packing material used: Bubble Wrap _____ Foam _____ Plastic Bag _____ None _____ Other _____					
COOLANT: Wet Ice _____ Blue Ice _____ Dry Ice _____ Water _____ None _____					
1. Cooler temperature upon receipt <input type="checkbox"/> See Multiple Cooler Form					
IR GUN# IR-8 (CF +0 °C) Observed Cooler Temp. _____ °C Corrected Cooler Temp. _____ °C					
IR GUN #36 (CF -0.3°C) Observed Cooler Temp. _____ °C Corrected Cooler Temp. _____ °C					
IR GUN # 627 (CF -1.3°C) Observed Cooler Temp. _____ °C Corrected Cooler Temp. _____ °C					
2. Were tamper/custody seals on the outside of the cooler(s)? If Yes Quantity _____			Yes No		
-Were the seals on the outside of the cooler(s) signed & dated?			Yes No NA		
-Were tamper/custody seals on the bottle(s) or bottle kits (LLHg/MeHg)?			Yes No		
-Were tamper/custody seals intact and uncompromised?			Yes No NA		
3. Shippers' packing slip attached to the cooler(s)?			Yes No		
4. Did custody papers accompany the sample(s)?			Yes No		
5. Were the custody papers relinquished & signed in the appropriate place?			Yes No		
6. Was/were the person(s) who collected the samples clearly identified on the COC?			Yes No		
7. Did all bottles arrive in good condition (Unbroken)?			Yes No		
8. Could all bottle labels be reconciled with the COC?			Yes No		
9. Were correct bottle(s) used for the test(s) indicated?			Yes No		
10. Sufficient quantity received to perform indicated analyses?			Yes No		
11. Are these work share samples?			Yes No		
If yes, Questions 12-16 have been checked at the originating laboratory.					
12. Were all preserved sample(s) at the correct pH upon receipt?			Yes No NA pH Strip Lot# HC740840		
13. Were VOAs on the COC?			Yes No		
14. Were air bubbles >6 mm in any VOA vials? Larger than this.			Yes No NA		
15. Was a VOA trip blank present in the cooler(s)? Trip Blank Lot # _____			Yes No		
16. Was a LL Hg or Me Hg trip blank present? _____			Yes No		
Contacted PM _____ Date _____ by _____ via Verbal Voice Mail Other _____					
Concerning _____					
17. CHAIN OF CUSTODY & SAMPLE DISCREPANCIES					Samples processed by: _____
18. SAMPLE CONDITION					
Sample(s) _____ were received after the recommended holding time had expired.					

Sample(s) _____ were received in a broken container.
Sample(s) _____ were received with bubble >6 mm in diameter. (Notify PM)

19. SAMPLE PRESERVATION

Sample(s) _____ were further preserved in the laboratory.
Time preserved: _____ Preservative(s) added/Lot number(s): _____.

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.

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).

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) 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
- 3) Proper sample containers with adequate volume for the analysis and necessary QC are required for each analysis requested. See Lab Sampling Guide.
- 4) Samples must be preserved according to the requirements of the requested analytical method (See Sampling Guide).
- 5) Most analytical methods require chilling samples to 4° C (other than water samples for metals analysis). For these methods, the criteria are met if the samples are chilled to below 6° C and above freezing (0°C). For methods with other temperature criteria (e.g. some bacteriological methods require $\leq 10^{\circ}\text{C}$), the samples must arrive within $\pm 2^{\circ}\text{C}$ of the required temperature or within the method specified range.
 - Samples that are delivered to the laboratory on the same day they are collected may not meet the requirements of Section 5. In these cases, the samples shall be considered acceptable if the samples were received on ice.
 - If sample analysis is begun within fifteen (15) minutes of collection, thermal preservation is not required.
 - Thermal preservation is not required in the field if the laboratory receives and refrigerates the sample within fifteen (15) minutes of collection.
 - 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.

SECTION 24. 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. Note: Requirements for OVAP can be found in the OVAP specific SOPs.

24.3 Negative Controls**Table 24-1. Example – Negative Controls**

Control Type	Details
Method Blank (MB)	<p>Used to assess preparation and analysis for possible contamination during the preparation and processing steps.</p> <p>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.</p> <p>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.</p> <p>The method blank goes through all of the steps of the process (including as necessary: filtration, clean-ups, etc.).</p> <p>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.</p>
Calibration Blanks	Prepared and analyzed along with calibration standards where applicable. They are prepared using the same reagents that are used to prepare the standards. In some analyses the calibration blank may be included in the calibration curve.
Instrument Blanks	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	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	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	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. (TNI)
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) 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)

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.

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 is 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.

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.).

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.

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). 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.

- For methods that have 1-10 target analytes, spike all components.
- For methods that include 11-20 target analytes, spike at least 10 or 80%, whichever is greater
- For methods with more than 20 target analytes, spike at least 16 components.
- Exception: Due to analyte incompatibility in pesticides, Toxaphene and Chlordane are only spiked at client request based on specific project needs.
- 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 24-3. 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.

Table 24-3. Sample Matrix Control

Control Type	Details	
	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)

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.

Note: For Ohio VAP the laboratory must implement Corrective Action procedures to resolve the deviation and limit qualification of the final results. The laboratory is not permitted to deviate from its VAP approved SOP if it intends to attest under affidavit that the "results" are VAP certified. When all corrective actions listed in the SOP have been exhausted, it may be necessary to use technical judgment in which case the decision process and rationale will be presented in the final report and/or affidavit and the data will be noted as 'not VAP certified' on the affidavit.

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.

Laboratory generated % Recovery acceptance (control) limits are generally established by taking ± 3 Standard Deviations (99% confidence level) from the average recovery of a minimum of 20-30 data points (more points are preferred).

- Regardless of the calculated limit, the limit should be no tighter than the Calibration Verification (ICV/CCV) (unless the analytical method specifies a tighter limit).
- In-house limits cannot be any wider than those mandated in a regulated analytical method. Client or contract required control limits are evaluated against the laboratory's statistically derived control limits to determine if the data quality objectives (DQOs) can be achieved. If laboratory control limits are not consistent with DQOs, then alternatives must be considered, such as method improvements or use of an alternate analytical method.

- The lowest acceptable recovery limit will be 10% (the analyte must be detectable and identifiable). Exception: The lowest acceptable recovery limit for Benzidine will be 5% and the analyte must be detectable and identifiable.
- The maximum acceptable recovery limit will be 200%.
- The maximum acceptable RPD limit will be 35% for waters and 40% for soils. The minimum RPD limit is 10%.
- If either the high or low end of the control limit changes by $\leq 5\%$ from previous, the control chart is visually inspected and, using professional judgment, they may be left unchanged if there is no affect on laboratory ability to meet the existing limits.

24.6.1 The lab must be able to generate a current listing of their control limits and track when the updates are performed. In addition, the laboratory must be able to recreate historical control limits. Refer to NC-QA-018, Statistical Evaluation of data and Development of Control Charts for details.

24.6.2 A LCS that is within the acceptance criteria establishes that the analytical system is in control and is used to validate the process. Samples that are analyzed with an LCS with recoveries outside of the acceptance limits may be determined as out of control and should be reanalyzed if possible. If reanalysis is not possible, then the results for all affected analytes for samples within the same batch must be qualified when reported. The internal corrective action process (see Section 12) is also initiated if an LCS exceeds the acceptance limits. Sample results may be qualified and reported without reanalysis if:

- The analyte results are below the reporting limit and the LCS is above the upper control limit.
- If the analytical results are above the relevant regulatory limit and the LCS is below the lower control limit.

Or, for TNI work, there are an allowable number of Marginal Exceedances (ME):

<11 analytes	0 marginal exceedances are allowed.
11 – 30 Analytes	1 marginal exceedance is allowed
31-50 Analytes	2 marginal exceedances are allowed
51-70 Analytes	3 marginal exceedances are allowed
71-90 Analytes	4 marginal exceedances are allowed
> 90 Analytes	5 marginal exceedances are allowed

- Marginal exceedances are recovery exceedances between 3 SD and 4 SD from the mean recovery limit (TNI).
- Marginal exceedances must be random. If the same analyte exceeds the LCS control limit repeatedly, it is an indication of a systematic problem. The source of the error must be located and corrective action taken. The laboratory has a system to monitor marginal exceedances to ensure that they are random.

Note: Ohio VAP does not allow the use of marginal exceedance. For Ohio VAP the laboratory must implement Corrective Action procedures to resolve the deviation and limit qualification of the final results. The laboratory is not permitted to deviate from its VAP approved SOP if it intends to attest under affidavit that the "results" are VAP certified. When all corrective actions listed in the SOP have been exhausted, it may be necessary to use technical judgment in which case the decision process and rationale will be presented in the final report and/or affidavit and the data will be noted as 'not VAP certified' on the affidavit.

Though marginal exceedances may be allowed by other programs, the data must still be qualified to indicate it is outside of the normal limits.

24.6.3 If the MS/MSDs do not meet acceptance limits, the MS/MSD and the associated spiked sample is reported with a qualifier for those analytes that do not meet limits. If obvious preparation errors are suspected, or if requested by the client, unacceptable MS/MSDs are reprocessed and reanalyzed to prove matrix interference. A more detailed discussion of acceptance criteria and corrective action can be found in the lab's method SOPs and in Section 12.

24.6.4 If a surrogate standard falls outside the acceptance limits, and 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

The laboratory has written and approved method SOPs to assure the accuracy of the test method including calibration (see Section 20), use of certified reference materials (see Section 21) and use of PT samples (see Section 15).

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

- Use of formulae to reduce data is discussed in the method SOPs and in Section 20.
- Selection of appropriate reagents and standards is included in Section 9 and 21.
- A discussion on selectivity of the test is included in Section 5.
- Constant and consistent test conditions are discussed in Section 18.
- The laboratories sample acceptance policy is included in Section 23.

SECTION 25. REPORTING RESULTS

25.1 Overview

The results of each test are reported accurately, clearly, unambiguously, and objectively in accordance with State and Federal regulations as well as client requirements. Analytical results are issued in a format that is intended to satisfy customer and laboratory accreditation requirements as well as provide the end user with the information needed to properly evaluate the results. Where there is conflict between client requests and laboratory ethics or regulatory requirements, the laboratory's ethical and legal requirements are paramount, and the laboratory will work with the client during project set up to develop an acceptable solution. Refer to Section 7.

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

In cases where a client asks for simplified reports, there must be a written request from the client. There still must be enough information that would show any analyses that were out of conformance (QC out of limits) and there should be a reference to a full report that is made available to the client. Review of reported data is included in Section 19.

25.2 Test Reports

Analytical results are reported in a format that is satisfactory to the client and meets all requirements of applicable accrediting authorities and agencies. A variety of report formats are available to meet specific needs. 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)

25.2.2 The cover page shall include the laboratory name, address and telephone number.

25.2.3 A unique identification of the report (e.g., TestAmerica Job ID #) and on each page an identification in order to ensure the page is recognized as part of the report and a clear identification of the end.

Note: Page numbers of report are represented as page # of ##. Where the first number is the page number and the second is the total number of pages.

25.2.4 A copy of the chain of custody (COC)

- Any COCs involved with Subcontracting are included.

25.2.5 The name and address of client and a project name/number, if applicable.

25.2.6 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 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
- 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).
- 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, except when information is provided by the client. When data is provided by the client there shall be a clear identification of it, and a disclaimer shall be put in the report when the client supplied data can affect the validity of the test.
- 25.2.19** 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. Authorized signatories are qualified Project Managers appointed by the Manager of Project Managers.
- 25.2.21** When TNI accreditation is required, the lab shall certify that the test results meet all requirements of TNI or provide reasons and/or justification if they do not.
- 25.2.22** 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.
- 25.2.23** When soil samples are analyzed, a specific identification as to whether soils are reported on a “wet weight” or “dry weight” basis.
- 25.2.24** Appropriate laboratory certification number for the state of origin of the sample, if applicable.
- 25.2.25** 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, or how your lab identifies it). A complete report must be sent once all of the work has been completed.

25.2.26 Any non-TestAmerica subcontracted analysis results are provided as a separate 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.

25.2.27 A 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.

Note: Refer to the Corporate SOP on Electronic Reporting and Signature Policy (No. CA-I-P-002) for details on internally applying electronic signatures of approval.

25.2.28 Reports for Ohio VAP work require a VAP affidavit be completed and included with the report.

25.2.29 Where the laboratory is responsible for the sampling stage, in addition to the requirements listed above, reports containing the results of sampling shall include the following, where necessary for the interpretation of test results:

- the date of sampling;
- unambiguous identification of the material sampled;
- the location of sampling plan and procedures, and deviations, addition to or exclusions from the sample procedures;
- a reference to the sampling plan and procedure, and deviations, additions to or exclusions from the sample procedures;
- details of any environmental conditions during sampling that affect the interpretation of test results;
- information required to evaluate measurement uncertainty for subsequent testing

25.3 Reporting Level or Report Type

The laboratory 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 1 is a report with all of the elements outlined in Section 25.2 above, excluding 25.2.15 (QC data).
- Level II is a Level I report plus summary information, including results for the method blank reported to the laboratory MDL, 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 the 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. Procedures used to ensure client confidentiality are outlined in Section 25.6.

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 Canton offers a variety of EDD formats including Environmental Restoration Information Management System (ERPIMS), Staged Electronic Data Deliverable (SEDD) Environmental Quality Information System (EQIS), Electronic Deliverable Format (EDF), Excel and custom files.

EDD specifications are submitted to the IT department by the PM for review and undergo the contract review process. Once the facility has committed to providing data in a specific electronic format, the coding of the format may need to be performed. This coding is documented and validated. The validation of the code is retained by the IT staff coding the EDD.

EDDs shall be subject to a review to ensure their accuracy and completeness. If EDD generation is automated, review may be reduced to periodic screening if the laboratory can demonstrate that it can routinely generate that EDD without errors. Any revisions to the EDD format must be reviewed until it is demonstrated that it can routinely be generated without errors. If the EDD can be reproduced accurately and if all subsequent EDDs can be produced error-free, each EDD does not necessarily require a review.

25.4 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.

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

Where quality system requirements are not met, a statement of compliance/non-compliance with requirements and/or specifications is required, including identification of test results derived from any sample that did not meet TNI sample acceptance requirements such as improper container, holding time, or temperature.

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

When, as requested by the client and agreed to by TestAmerica, the report includes a statement of conformity to specification or standard (see Special Services, Section 7.4), the report shall clearly identify:

- to which results the statement applies,
- which specifications, standard or parts thereof are met or not, and
- the decision rule that was applied (unless the decision rule is inherent in the requested specification or standard, taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule.

Opinions and Interpretations - The test report contains objective information, and generally does not contain subjective information such as opinions and interpretations. If such information is required by the client, the Laboratory Director will determine if a response can be prepared. If so, the Laboratory Director will designate the appropriate member of the management team to prepare a response. The response will be fully documented, and reviewed by the Laboratory Director, before release to the client. There may be additional fees charged to the client at this time, as this is a non-routine function of the laboratory.

Note: Review of data deliverable packages for submittal to regulatory authorities requires responses to non-conforming data concerning potential impact on data quality. This necessitates a limited scope of interpretation, and this work is performed by the QA Department. This is the only form of "interpretation" of data that is routinely performed by the laboratory.

When opinions or interpretations are included in the report, the laboratory provides an explanation as to the basis upon which the opinions and interpretations have been made. Opinions and interpretations are clearly noted as such and where applicable, a comment should be added suggesting that the client verify the opinion or interpretation with their regulator.

25.5 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 the Corporate SOP on Subcontracting SOP No. CW-L-S-004.

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

TestAmerica is responsible for maintaining in confidence all client information obtained or created. In situations involving the transmission of environmental test results by telephone, facsimile or other electronic means, client confidentiality must be maintained.

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.

Information about the client obtained from sources other than the client (e.g., complainant, regulators) shall be confidential between client and the laboratory. The source of this information shall be confidential to the laboratory and shall not be shared with the client, unless agreed by the source.

Note: This shall not apply to the extent that the information is required to be disclosed by 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 to meet all requirements of this document, including cover letter.

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" or "amended" next to the date rather than the word "reported".

When the report is re-issued, a notation of "report re-issue" is placed on the cover/signature page of the report *or at the top of the narrative page* with a brief explanation of reason for the re-issue and a reference back to the last final report generated.

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

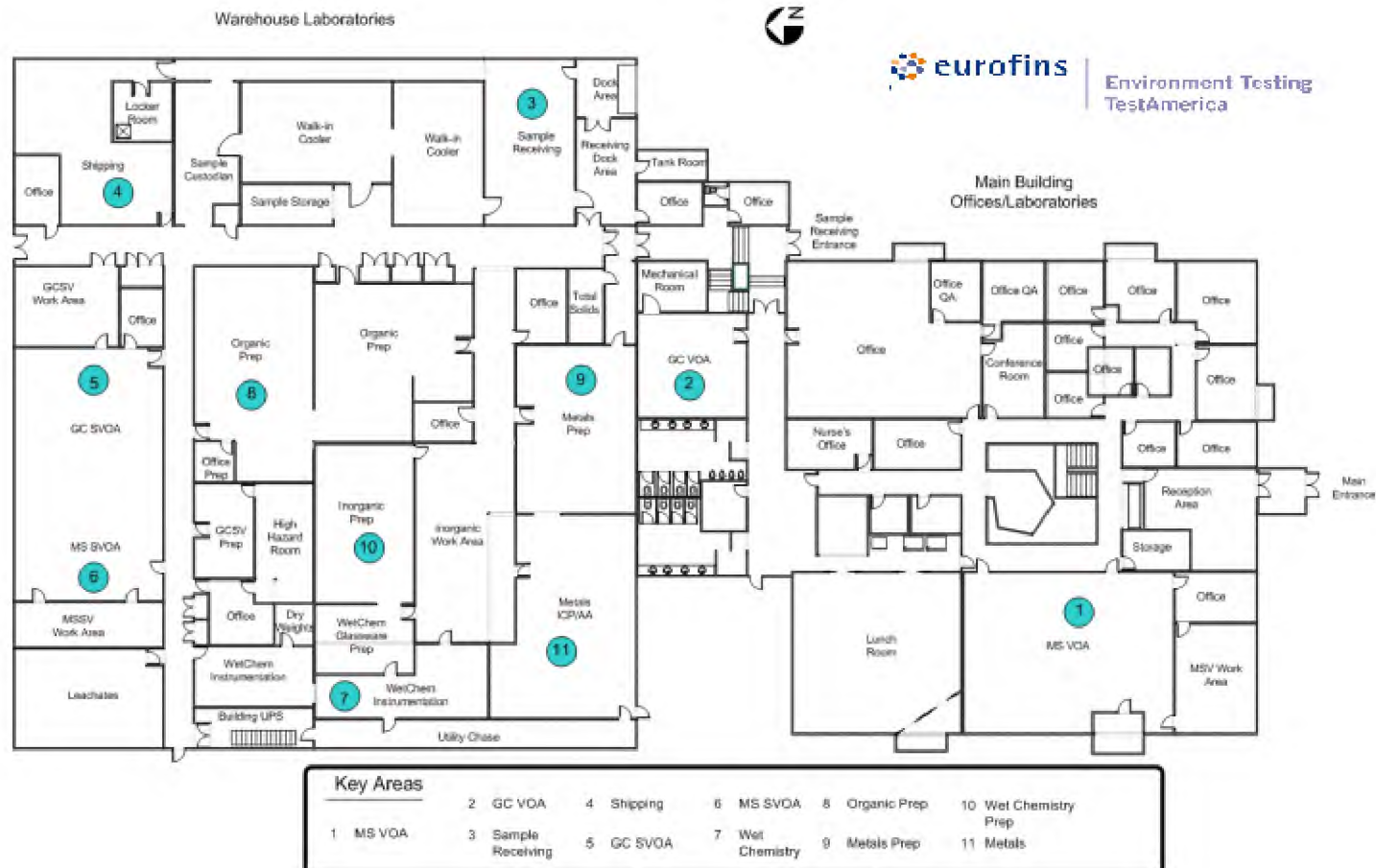
TestAmerica does not issue multiple reports for the same work order where there is different information on each report (this does not refer to copies of the same report) unless required to meet regulatory needs and approved by QA.

Appendix 1. Laboratory Floor Plan**Eurofins TestAmerica Canton**

4101 Shuffel Dr NW
North Canton, OH 44720



Environment Testing
TestAmerica



Appendix 2. Glossary/Acronyms (EL-V1M2 Sec. 3.1)

Acceptance Criteria: Specified limits placed on characteristics of an item, process, or service defined in requirement documents. (ASQC)

Accreditation: The process by which an agency or organization evaluates and recognizes a laboratory as meeting certain predetermined qualifications or standards, thereby accrediting the laboratory.

Accuracy: The degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components which are due to sampling and analytical operations; a data quality indicator. (QAMS)

Analyst: The designated individual who performs the “hands-on” analytical methods and associated techniques and who is the one responsible for applying required laboratory practices and other pertinent quality controls to meet the required level of quality.

Analytical Uncertainty: A subset of Measurement Uncertainty that includes all laboratory activities performed as part of the analysis. (TNI)

Anomaly: A condition or event, other than a 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 that are prepared and/or analyzed together with the same process and personnel, using the same lot(s) of reagents. A **preparation batch** is composed of one (1) to twenty (20) environmental samples of the same quality systems matrix, meeting the above mentioned criteria and with a maximum time between the start of processing of the first and last sample in the batch to be twenty-four (24) hours. An **analytical batch** is composed of prepared environmental samples (extracts, digestates or concentrates) which are analyzed together as a group. An analytical batch can include prepared samples originating from various quality system matrices and can exceed twenty (20) samples. (TNI)

Bias: The systematic or persistent distortion of a measurement process, which causes errors in one direction (i.e., the expected sample measurement is different from the sample’s true value). (TNI)

Blank: A sample that has not been exposed to the analyzed sample stream in order to monitor contamination during sampling, transport, storage or analysis. The blank is subjected to the usual analytical and measurement process to establish a zero baseline or background value and is sometimes used to adjust or correct routine analytical results. (ASQC)

Calibration: A set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards. (TNI)

1) In calibration of support equipment the values realized by standards are established through the use of reference standards that are traceable to the International System of Units (SI).

2) In calibration according to methods, the values realized by standards are typically established through the use of Reference Materials that are either purchased by the laboratory with a certificate of analysis or purity, or prepared by the laboratory using support equipment that has been calibrated or verified to meet specifications.

Calibration Curve: The mathematical relationship between the known values, such as concentrations, of a series of calibration standards and their instrument response. (TNI)

Calibration Standard: A substance or reference material used to calibrate an instrument (QAMS)

Certified Reference Material (CRM): A reference material accompanied by a certificate, having a value, measurement uncertainty, and stated metrological traceability chain to a national metrology institute. (TNI)

Chain of Custody (COC) Form: Record that documents the possession of the samples from the time of collection to receipt in the laboratory. This record generally includes: the number and types of containers; the mode of collection; the collector; time of collection; preservation; and requested analyses. (TNI)

Compromised Samples: Those samples which are improperly sampled, insufficiently documented (chain of custody and other sample records and/or labels), improperly preserved, collected in improper containers, or exceeding holding times when delivered to a laboratory. Under normal conditions, compromised samples are not analyzed. If emergency situation require analysis, the results must be appropriately qualified.

Confidential Business Information (CBI): Information that an organization designates as having the potential of providing a competitor with inappropriate insight into its management, operation or products. TNI and its representatives agree to safeguard identified CBI and to maintain all information identified as such in full confidentiality.

Confirmation: Verification of the identity of a component through the use of an approach with a different scientific principle from the original method. These may include, but are not limited to Second Column Confirmation; Alternate wavelength; Derivatization; Mass spectral interpretation; Alternative detectors or Additional Cleanup procedures. (TNI)

Conformance: An affirmative indication or judgment that a product or service has met the requirements of the relevant specifications, contract, or regulation; also the state of meeting the requirements. (ANSI/ASQC E4-1994)

Correction: Actions necessary to correct or repair analysis specific non-conformances. The acceptance criteria for method specific QC and protocols as well as the associated corrective actions. The analyst will most frequently be the one to identify the need for this action as a result of calibration checks and QC sample analysis. No significant action is taken to change behavior, process or procedure.

Corrective Action: The action taken to eliminate the causes of an existing nonconformity, defect or other undesirable situation in order to prevent recurrence. (ISO 8402)

Data Audit: A qualitative and quantitative evaluation of the documentation and procedures associated with environmental measurements to verify that the resulting data are of acceptable quality (i.e., that they meet specified acceptance criteria).

Data Reduction: The process of transforming the number of data items by arithmetic or statistical calculations, standard curves, and concentration factors, and collation into a more useable form. (TNI)

Deficiency: 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 is performed. (ASQC)

Duplicate Analyses: The analyses or measurements of the variable of interest performed identically on two subsamples of the same sample. The results from duplicate analyses are used to evaluate analytical or measurement precision but not the precision of sampling, preservation or storage internal to the laboratory. (EPA-QAD)

Equipment Blank: Sample of analyte-free media which has been used to rinse common sampling equipment to check effectiveness of decontamination procedures.

External Standard Calibration: Calibrations for methods that do not utilize internal standards to compensate for changes in instrument conditions.

Field Blank: Blank prepared in the field by filling 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 $\pm 100\%$. The IDL represents a range where qualitative detection occurs on a specific instrument. Quantitative results are not produced in this range.

Laboratory Control Sample (however named, such as laboratory fortified blank, spiked blank, or QC check sample): A sample matrix, free from the analytes of interest, spiked with verified known amounts of analytes or a material containing known and verified amounts of analytes, taken through all preparation and analysis steps of the procedure unless otherwise noted in a reference method. It is generally used to establish intra-laboratory or analyst specific precision and bias or to assess the performance of all or a portion of the measurement system.

An LCS shall be prepared at a minimum of 1 per batch of 20 or less samples per matrix type per sample extraction or preparation method except for analytes for which spiking solutions are not available such as total suspended solids, total dissolved solids, total volatile solids, total solids, pH, color, odor, temperature, dissolved oxygen or turbidity. The results of these samples shall be used to determine batch acceptance.

Least Squares Regression (1st Order Curve): The least squares regression is a mathematical calculation of a straight line over two axes. The y axis represents the instrument response (or Response ratio) of a standard or sample and the x axis represents the concentration. The regression calculation will generate a correlation coefficient (r) that is a measure of the "goodness of fit" of the regression line to the data. A value of 1.00 indicates a perfect fit. In order to be used for quantitative purposes, r must be greater than or equal to 0.99 for organics and 0.995 for inorganics.

Limit(s) of Detection (LOD) [a.k.a., Method Detection Limit (MDL)]: The MDL is the minimum measured quantity of a substance that can be reported with 99% confidence that the concentration is distinguishable from method blank results, consistent with 40CFR Part 136 Appendix B, August, 2017.

Limit(s) of Quantitation (LOQ) [a.k.a., Reporting Limit]: The minimum levels, concentrations, or quantities of a target variable (e.g., target analyte) that can be reported with a specified degree of confidence.

(QS) Matrix: The component or substrate that contains the analyte of interest. For purposes of batch and QC requirement determinations, the following matrix distinctions shall be used:

Aqueous: Any aqueous sample excluded from the definition of Drinking Water or Saline/Estuarine. Includes surface water, groundwater effluents, and TCLP or other extracts.

Drinking Water: Any aqueous sample that has been designated as a potable or potential potable water source.

Saline/Estuarine: Any aqueous sample from an ocean or estuary, or other salt water source such as the Great Salt Lake.

Non-Aqueous Liquid: Any organic liquid with <15% settleable solids.

Biological Tissue: Any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origin.

Solids: Includes soils, sediments, sludges, and other matrices with >15% settleable solids.

Chemical Waste: A product or by-product of an industrial process that results in a matrix not previously defined.

Air & Emissions: Whole gas or vapor samples including those contained in flexible or rigid wall containers and the extracted concentrated analytes of interest from a gas or vapor that are collected with a sorbant tube, impinger solution, filter, or other device. (TNI)

Matrix Spike (spiked sample or fortified sample): A sample prepared, taken through all sample preparation and analytical steps of the procedure unless otherwise noted in a referenced method, by adding a known amount of target analyte to a specified amount of sample for which an independent test result of target analyte concentration is available. Matrix spikes are used, for example, to determine the effect of the matrix on a method's recovery efficiency.

Matrix Spike Duplicate (spiked sample or fortified sample duplicate): A replicate matrix spike prepared and analyzed to obtain a measure of the precision of the recovery for each analyte.

Method Blank: A sample of a matrix similar to the batch of associated samples (when available) that is free from the analytes of interest and is processed simultaneously with and under the same conditions as samples through all steps of the analytical procedures, and in which no target analytes or interferences are present at concentrations that impact the analytical results for sample analyses.

Method Detection Limit: See Limit of Detection (LOD)

Negative Control: Measures taken to ensure that a test, its components, or the environment do not cause undesired effects, or produce incorrect test results.

Non-conformance: An indication, judgment, or state of not having met the requirements of the relevant specifications, contract, or regulation.

Observation: A record of phenomena that (1) may assist in evaluation of the sample data; (2) may be of importance to the project manager and/or the client, and yet not at the time of the observation have any known effect on quality.

Performance Audit: The routine comparison of independently obtained qualitative and quantitative measurement system data with routinely obtained data in order to evaluate the proficiency of an analyst or laboratory.

Positive Control: Measures taken to ensure that a test and/or its components are working properly and producing correct or expected results from positive test subjects.

Precision: The degree to which a set of observations or measurements of the same property, obtained under similar conditions, conform to themselves; a data quality indicator. Precision is usually expressed as standard deviation, variance or range, in either absolute or relative terms. (TNI)

Preservation: Any conditions under which a sample must be kept in order to maintain chemical and/or biological integrity prior to analysis. (TNI)

Proficiency Testing: A means of evaluating a laboratory's performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by an external source. (TNI)

Proficiency Testing Program: The aggregate of providing rigorously controlled and standardized environmental samples to a laboratory for analysis, reporting of results, statistical evaluation of the results and the collective demographics and results summary of all participating laboratories. (TNI)

Proficiency Test Sample (PT): A sample, the composition of which is unknown to the laboratory and is provided to test whether the laboratory can produce analytical results within specified acceptance criteria. (TNI)

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

Quality Assurance [Project] Plan (QAPP): A formal document describing the detailed quality control procedures by which the quality requirements defined for the data and decisions pertaining to a specific project are to be achieved. (EAP-QAD)

Quality Control: The overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer; operational techniques and activities that are used to fulfill requirements for quality; also the system of activities and checks used to ensure that measurement systems are maintained within prescribed limits, providing protection against “out of control” conditions and ensuring that the results are of acceptable quality. (TNI)

Quality Control Sample: A sample used to assess the performance of all or a portion of the measurement system. One of any number of samples, such as Certified Reference Materials, a quality system matrix fortified by spiking, or actual samples fortified by spiking, intended to demonstrate that a measurement system or activity is in control. (TNI)

Quality Manual: A document stating the management policies, objectives, principles, organizational structure and authority, responsibilities, accountability, and implementation of an agency, organization, or laboratory, to ensure the quality of its product and the utility of its product to its users. (TNI)

Quality System: A structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required QA and QC activities. (TNI)

Raw Data: The documentation generated during sampling and analysis. This documentation includes, but is not limited to, field notes, electronic data, magnetic tapes, untabulated sample results, QC sample results, print outs of chromatograms, instrument outputs, and handwritten records. (TNI)

Record Retention: The systematic collection, indexing and storing of documented information under secure conditions.

Reference Material: Material or substance one or more properties of which are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials. (TNI)

Reference Standard: Standard used for the calibration of working measurement standards in a given organization or a given location. (TNI)

Sampling: Activity related to obtaining a representative sample of the object of conformity assessment, according to a procedure.

Second Order Polynomial Curve (Quadratic): The 2nd order curves are a mathematical calculation of a slightly curved line over two axis. The y axis represents the instrument response (or Response ratio) of a standard or sample and the x axis represents the concentration. The 2nd order regression will generate a coefficient of determination (COD or r^2) that is a measure of the "goodness of fit" of the quadratic curvature the data. A value of 1.00 indicates a perfect fit. In order to be used for quantitative purposes, r^2 must be greater than or equal to 0.99.

Selectivity: The ability to analyze, distinguish, and determine a specific analyte or parameter from another component that may be a potential interferent or that may behave similarly to the target analyte or parameter within the measurement system. (TNI)

Sensitivity: The capability of a method or instrument to discriminate between measurement responses representing different levels (e.g., concentrations) of a variable of interest. (TNI)

Spike: A known mass of target analyte added to a blank, sample or sub-sample; used to determine recovery efficiency or for other quality control purposes.

Standard: The document describing the elements of laboratory accreditation that has been developed and established within the consensus principles of standard setting and meets the approval requirements of standard adoption organizations procedures and policies. (TNI)

Standard Operating Procedures (SOPs): A written document which details the method for an operation, analysis, or action, with thoroughly prescribed techniques and steps. SOPs are officially approved as the methods for performing certain routine or repetitive tasks. (TNI)

Storage Blank: A blank matrix stored with field samples of a similar matrix (volatiles only) that measures storage contribution to any source of contamination.

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 Director: A member of the staff of an environmental laboratory who exercises actual day-to-day supervision of laboratory operations for the appropriate fields of accreditation and reporting of results

Technology: A specific arrangement of analytical instruments, detection systems, and/or preparation techniques.

Traceability: The ability to trace the history, application, or location of an entity by means of recorded identifications. In a calibration sense, traceability relates measuring equipment to national or international standards, primary standards, basic physical constants or properties, or reference materials. In a data collection sense, it relates calculations and data generated throughout the project back to the requirements for the quality of the project. (TNI)

Trip Blank: A blank matrix placed in a sealed container at the laboratory that is shipped, held unopened in the field, and returned to the laboratory in the shipping container with the field samples.

Uncertainty: A parameter associated with the result of a measurement that characterizes the dispersion of the value that could reasonably be attributed to the measured value.

Acronyms:

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
SDS - Safety Data Sheet
NELAP - National Environmental Laboratory Accreditation Program
PT – Performance Testing
TNI – 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
SOP – Standard Operating Procedure
TAT – Turn-Around-Time
VOA – Volatiles
VOC – Volatile Organic Compound

Appendix 3. Laboratory Certifications, Accreditations, Validations

TestAmerica Canton maintains accreditations, certifications, and approvals with numerous state and national entities. Programs vary but may include on-site audits, reciprocal agreements with another entity, performance testing evaluations, review of the QA Manual, Standard Operating Procedures, Method Detection Limits, training records, etc. At the time of this QA Manual revision, the laboratory has accreditation/certification/licensing with the following organizations:

Organization	Certificate Number	Organization	Certificate Number
California	2927	Nevada	OH-00048208A
Connecticut	PH-0590	New Jersey	OH001
Florida	E87225	New York	10975
Georgia	---	OVAP	CL0024
Illinois	004188	Pennsylvania	017
Kansas	E-10336	USDA (Dept. of Agriculture)	P330-08-00123
Kentucky Underground Storage Tank Program	112225	Washington	C971
Minnesota	039-999-348	West Virginia	210
Texas	T104704517-13-2 Changes based on the year and month of date of issue	Virginia	9448
Oregon	4062	Kentucky Wastewater	KY98016
Minnesota Petrofund	3506		

The certificates and accredited parameter lists are available for each State/Program at www.testamericainc.com under Analytical Services Search – Certifications.

Attachment 8

Contingency Plan

Attachment 8
Contingency Plan

Attachment 8 Contingency Plan Revision 0

November 1, 2019

Submitted to:

AMG Vanadium LLC
3400 East Pointe Drive
Zanesville, Ohio 43701
EPA ID No. OHR000212902

Submitted by:

Cox-Colvin & Associates, Inc.
7750 Corporate Blvd.
Plain City, Ohio 43064
(614) 526-2040



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In the event of a fire, explosion, severe weather, power outages or unplanned sudden or non-sudden release (Emergency Spill) of regulated hazardous waste or other hazardous waste constituents to air, soil, or surface water immediately utilize:

APPENDIX A, B, and D

I.0 Purpose and Implementation of this Contingency Plan (OAC 3745-54-52)

This Contingency Plan has been designed to minimize hazards to human health and the environment from emergencies which include fires, explosions, severe weather, power outages or Emergency Spill of:

- Reclaimed Catalyst (the Catalyst as-received at the Facility);
- Roasted Catalyst (the Catalyst after it has been roasted);
- Process Residuals (those secondary materials generated from the processing and management of Reclaimed Catalyst and Roasted Catalyst including but is not limited to LimeAdd™, EAF Cyclone Dust, EAF Baghouse Dust, Free Liquid, Slag, water that has come in contact with Reclaimed Catalyst or other Process Residuals, and vehicle wash water)
- Free Liquid (liquids which readily separate from the solid portion of a material under ambient temperature and pressure, includes the Free Oil that runs off the Reclaimed Catalyst)
- Hazardous waste; or
- Other hazardous waste constituents to air, soil, or surface water.

Industrial Materials are referenced collectively in this document and refer to the above materials.

An Emergency Spill is defined as any on-site release of Industrial Materials that could result in or pose an imminent danger which requires prompt action to mitigate or minimize the impact of the incident on human health or the environment; or any release that Applicant is required to report to Ohio EPA's Spill Hotline or the National Response Center.

An Incidental Spill is a release of Industrial Materials that may occur within the Facility boundaries and which does not pose an imminent danger to human health and the environment.

The purpose of this plan is to protect the safety and welfare of the Company employees, the community, and the local environment in the event of an emergency at the Facility and to describe the actions Facility personnel will take in response to emergency situations.

The provisions of the Contingency Plan shall be implemented immediately whenever there is a fire, explosion, or release of Industrial Materials which could threaten human health or the environment.

- Any fire involving Industrial Materials; or
- Any explosion involving Industrial Materials; or
- Any uncontrolled Industrial Materials reaction that produces or has the potential to produce hazardous conditions, including noxious, poisonous, flammable and/or explosive gases, fumes, or vapors; harmful dust; or explosive conditions; or
- Any Industrial Materials release, outside of a secondary containment system, that causes or has the potential to cause off-site soil and/or surface water contamination; or
- Any Industrial Materials release that produces or has the potential to produce hazardous conditions, including noxious, poisonous, flammable and/or explosive gases, fumes, or vapors; harmful dust; or explosive conditions.

This plan is also intended as a reference source to familiarize local service providers with Industrial Materials operations at the Facility. Copies of this plan are maintained at the Facility. This plan is maintained by the Environmental Department and can be found in the Company's document control system, where any changes must go through an approval and notification process.

The Facility operates/maintains equipment and follows procedures to minimize threats to human health and the environment. In general, serious threats are not likely to happen and typically are easy to minimize, given the types of waste management activities at the Facility. Emergency Spills that would impact the environment, or affect off-site surface waters, soils or groundwater are unlikely because of the nature of the Reclaimed Catalyst, which is not liquid (although it may be coated in a Free Liquid). Reclaimed Catalyst handling, receiving, and storage activities are conducted within the confines of the Facility and the materials are protected from the elements and contained at all times. Since most of the hazardous materials associated with Reclaimed Catalysts are adsorbed onto the Reclaimed Catalyst, spills will be easily contained and removed. In addition, the primary storage area for the Reclaimed Catalyst is inside a RMSB, which has a high strength concrete floor with a dual containment system.

Most incidents involving a fire or spill at the Facility are expected to be minor and not considered emergencies: they can be handled on-site expeditiously, and without threatening human health or the environment. However, all incidents involving a spill shall be handled according to the Stormwater Pollution Prevention Plan and Spill Prevention Control and Countermeasure Plan.

A RMSB (constructed of non-combustible materials) poses the greatest major fire threat due to the Free Oil coating on the Reclaimed Catalyst.

If the Emergency Coordinator (EC) is not on site, he or she may identify, in writing, a "Designee" to assume EC responsibilities. Otherwise, the responsibilities shall fall to the

Alternate ECs (AEC) as provided for in this document (See Appendix C). The EC or Environmental Manager can elect a “Designee” as necessary.

I.I Purpose and Implementation of Contingency Plan for Reclaimed Catalyst or RCRA-related Incidents (OAC 3745-54-56)

- A. Whenever there is an imminent or actual emergency situation involving Industrial Materials that results in a release to the environment, fire or explosion, the EC must immediately:
 - 1. Activate the internal Facility alarms or communication systems, where applicable, to notify all Facility personnel; and
 - 2. Contact the Environmental Manager. If the Environmental Manager is unavailable, the EC will contact the Senior Vice President.
- B. Whenever there is a release, fire or explosion involving Industrial Materials, the Environmental Manager, in consultation with the EC, shall identify to the best of his or her ability, the character, exact source, amount, and extent of any released materials.
- C. The Environmental Manager, in consultation with the EC, shall also assess possible hazards to human health or the environment that may result from the release, fire, or explosion. This assessment shall consider both direct and indirect effects of the release, fire or explosion (e.g., the effects of any toxic, irritating, or asphyxiating gases that are generated, or the effects of any hazardous surface water run-off from water or chemical agents used to control fire and heat-induced explosions).
- D. If the Environmental Manager, after consulting with the EC, determines that the Facility has had a release, fire, or explosion which could threaten human health or the environment outside the Facility, he or she must report the findings as follows:
 - 1. If the assessment indicates evacuation of local areas may be advisable, the EC, shall immediately notify appropriate local authorities and assist officials in deciding whether local areas should be evacuated; and
 - 2. The EC shall immediately notify the Ohio EPA Emergency Response Unit using their 24-hour toll free number 800-282-9378. The report must include:
 - a. Name and telephone number of the EC, who is making the notification;

- b. Name and address of Facility;
 - c. Time and type of incident (e.g., release, fire, etc.);
 - d. Name and quantity of material(s) involved, to the extent known;
 - e. The extent of injuries, if any; and
 - f. The possible hazards to human health, or the environment, outside the Facility.
- E. During the emergency, the EC shall take all reasonable measures necessary to ensure that fires, explosions, and releases do not occur, recur, or spread to other Industrial Materials at the Facility. These measures shall include, where applicable, stopping processes and operations, collecting and containing released Industrial Materials, and removing or isolating containers.
- F. If the Facility stops operations in response to a fire, explosion, or release, the EC shall monitor for leaks, pressure buildup, gas generation, or ruptures in valves, pipes, or other equipment wherever appropriate.
- G. Immediately after an emergency, the EC, in consultation with the Environmental Manager, shall provide for treating, storing, or disposing of recovered Industrial Materials, contaminated soil or surface water, or any other material that results from a release, fire, or explosion at the Facility.
- H. The EC, shall ensure that in the affected area of the Facility:
 - 1. No Industrial Materials that may be incompatible with the released material is treated, stored or disposed of until cleanup procedures are complete; and
 - 2. All emergency equipment listed in the Contingency Plan is cleaned and fit for its intended use immediately after the emergency and prior to resuming operations, if operations were stopped.
- I. The Company shall note in the operating log the time, date, and details of any incident that requires implementing the Contingency Plan. Within fifteen (15) days after the incident, the Environmental Manager, on behalf of the EC shall submit a written report on the incident to the Director of the Ohio EPA. The report shall include:
 - 1. Name, address, and telephone number of the owner or operator;
 - 2. Name, address and telephone number of the Facility;
 - 3. Date, time and type of incident (e.g., fire, explosion);

4. Name and quantity of materials involved;
 5. The extent of injuries, if any;
 6. An assessment of actual or potential hazards to human health or the environment, where this is applicable; and
 7. Estimated quantity and disposition of recovered material that resulted from the incident.
- J. A verification signed by a qualified professional engineer will be submitted to the Director of Ohio EPA when appropriately required by OAC 3745-205-101.

2.0 General Facility Information

AMG Vanadium LLC is located on East Pointe Drive in Zanesville, Muskingum County, Ohio. The mailing address and general telephone number of the Facility is:

AMG Vanadium LLC
3400 East Pointe Drive
Zanesville, Ohio 43701

The location of the Facility is illustrated on the site location map (Figure 8-1). The Company property encompasses approximately 163 acres of which approximately 27 acres are used for industrial activities and contain numerous buildings and paved access areas.

The Facility has standard industrial classification (SIC) codes of 3313 (electrometallurgical products) and 3341 (secondary smelting and refining) and North American Industrial Classification System (NAICS) codes of 331110 (iron and steel mills and ferroalloy manufacturing) and 331492 (secondary smelting, refining, and alloying of nonferrous metal). The Facility produces ferrous and non-ferrous metal Products. The primary Product is ferrovanadium alloy (FeroVan®). Other Products include iron-nickel-molybdenum alloy (FeNiMoly®), calcium aluminate Slag conditioner (Revan™), and Roasted Catalyst. The co-product calcium sulfite/sulfate (LimeAdd™), Baghouse Dust, Cyclone Dust, Free Liquid, Slag, and oil and water that have come in contact with Reclaimed Catalyst, Roasted Catalyst, or other Process Residuals are considered Process Residuals. Raw materials used at the Facility are Reclaimed Catalyst obtained from hydrotreating, hydrorefining and hydrocracking refining processes. The Facility receives Reclaimed Catalyst, which is subject to a Variance from Classification as a Waste (Variance), primarily in bulk shipments *via* rail or truck. The Reclaimed Catalyst is stored in a RMSB. The Facility layout is shown on Figure 8-2.

The Company utilizes a contract security service on site twenty-four (24) hours per day, seven (7) days per week. Security service personnel are provided training to be able to identify emergency situations. This training includes, but is not limited to, the following:

- Location of Industrial Materials and hazardous waste storage areas;
- Physical and chemical hazards of the Industrial Materials and hazardous waste managed at the Facility;
- Means and methods to protect one's self from these hazards; and
- The contents of this Contingency Plan.

3.0 Hazardous Waste Information

On occasion the Facility generates hazardous waste as the result of production activities. The Company is responsible for proper handling of Industrial Materials and ultimate disposition/disposal of hazardous waste. Hazardous waste managed or generated at the Facility may include:

- Baghouse Dust and Cyclone Dust from air pollution control devices;
- Occasionally there are times when the Facility will generate other hazardous waste such as lead paint, asbestos, and various chemicals from lab packs;
- PPE contaminated with Reclaimed Catalyst or hazardous waste.

Hazardous waste can be stored in a RMSB, covered roll-off boxes, drop boxes, drums, or other appropriate container.

Universal Wastes are stored in maintenance/storeroom and also collected at various satellite locations.

Waste solvents are stored in satellite accumulation containers in the maintenance building. It may also be collected in other various satellite stations.

4.0 Arrangements with Local Emergency Services

Arrangements have been made to familiarize the local hospital with the hazardous properties of the Industrial Materials handled at the Facility in addition to the types of injuries or illnesses that could result from fires, explosions, or a release. Copies and modifications to the Contingency Plan are forwarded to local emergency services and the Company requests a written agreement to provide assistance to the Facility in the event of an emergency. If agreements are secured from the local emergency services, they will be maintained by the Environmental Department. A refusal to provide services will also be maintained in the Environmental Department along with copies of any contracts with emergency response contractors and equipment suppliers.

Current emergency services include Muskingum County Emergency Management

Agency, Zanesville Fire Department, Muskingum County Sheriff's Department, Genesis Hospital, Zanesville Police Department and Ohio EPA Emergency Response Division. The Company has designated the Zanesville Fire Department and Zanesville Police Department as primary emergency authorities.

5.0 Emergency Coordinator and Alternate Emergency Coordinators

The EC and Alternate EC (AEC) or ("Designee") are the ECs for the Facility. Appendix C identifies the designated EC and AECs. There will be at least one employee either at the Facility or on call (i.e., available to respond to an emergency by reaching the Facility within a short period of time), with the responsibility for coordinating all emergency response activities. The EC will be thoroughly familiar with all aspects of the Facility's Contingency Plan, all operations and activities at the Facility, the location and characteristics of all Industrial Materials handled at the Facility, the location of Facility records, and the Facility layout. The designated EC and AEC have the authority to commit all available resources required to carry out the Contingency Plan. The designated personnel by manned shifts are identified below:

During Day Shift (6am – 6pm) Weekdays:

Primary EC	Facility Manager
Alternate #1 EC	Environmental Manager
Alternate #2 EC	Senior Vice President
Alternate #3 EC	[To be Hired]

During Night Shift (6pm – 6am) and Weekends and Holidays

EC Shift Supervisor [To be Hired]

Note: During the night shift or on weekends or holidays, the Shift Supervisor is the EC until verbally relieved of that responsibility by a day shift EC/AEC.

6.0 Emergency Coordinator Responsibilities and Considerations

6.1 Emergency Assistance

In the event of an emergency, the EC will immediately assess the situation and determine if outside emergency assistance is required. If outside emergency assistance is required, the EC will arrange to have emergency assistance contacted by dialing 9 for an outside line

and then 911 (9-911). The person dialing 9-911 will provide, at a minimum, the following information:

- AMG Vanadium LLC, Zanesville Facility is located at 3400 East Pointe Drive;
- Nature of the emergency (e.g., fire, explosion, release, etc.);
- Number of injured personnel (if applicable);
- Type or nature of injuries (if known); and,
- Volume and source of release (if known or applicable).

The person dialing 9-911 will remain on the line with the 911 Operator until directed to hang up the telephone.

The EC must work and coordinate with outside emergency agencies to disclose the nature and extent of the emergency situation at the Facility. At a minimum, the EC must provide detailed Facility information to emergency responders concerning the type and nature of the threat to the adjacent community. The Initial Emergency Information Form found in Appendix A should be used to document specifics of the emergency for briefing purposes. The EC will advise the outside emergency agencies of the need for evacuation of community members down-wind of the site during an emergency event. Information can be collected from publications such as safety data sheets, regulatory guidance, the United States Department of Transportation (DOT) Emergency Response Guidebook, and the National Institutes of Occupational Safety and Health (NIOSH) Pocket Guide to Chemical Hazards.

The EC will evaluate the Facility's emergency response equipment to determine if Company personnel can safely handle the emergency. Emergency response personnel will only respond to chemical incidents where proper chemical identification and concentrations can be determined.

6.2 Evacuation

The EC must determine if the emergency prompts the evacuation of affected site areas or the entire manufacturing Facility and implement an evacuation as necessary.

All buildings have multiple egress points. In the event of an emergency, an employee must determine if the nearest egress point is involved in the emergency. If so, an alternate egress must be used to evacuate to the roadway and out to the parking lot leading to the Emergency Evacuation Rally Point. Figure 8-3 shows the evacuation routes from the manufacturing areas, as well as the location of the designated Emergency Evacuation Rally Point. Refer to Appendix D for Emergency Evacuation procedures.

Note: Due to the unknown nature of emergencies, the EC may have employees redirected to an alternative rally point in the event the rally point is involved in the emergency.

6.3 Assign Duties

The EC, when appropriate, will assign individual(s) to direct emergency authorities (e.g., ambulance, fire trucks, etc.) to the location of the emergency. Supervisors will ensure evacuation of the building(s), as appropriate. If outside of normal working hours, Supervisors may designate a responsible person to secure an accurate headcount.

The EC may assign, as appropriate, trained individuals to perform additional duties (e.g., rescue activities, collect environmental samples, operate fire pumps, provide additional information, etc.) as required. Only appropriately trained personnel will be assigned to perform additional duties.

6.4 Emergency Actions and Considerations for Fires, Explosions, and Releases

As with any emergency situation, the EC must consider a wide variety of variables and actions. These considerations would include:

- If an area or site evacuation is required.
- If injured persons have been properly attended to.
- The effect of any toxic, irritating or asphyxiating gases to Facility personnel or the general public that may be generated as a result of the release or the potential of any released material reacting with other materials in the vicinity of the release. This assessment can be completed utilizing process knowledge, operating record, safety data sheets, regulatory guidance, and additional emergency release information sources such as the United States Department of Transportation (DOT) Emergency Response Guidebook, and the National Institutes of Occupational Safety and Health (NIOSH) Pocket Guide to Chemical Hazards;
- Reclaimed Catalyst may contain reactive sulfides and petroleum distillates. If ignition occurs, carbon monoxide and sulfur dioxide may be released.
 - Carbon monoxide is a potentially lethal poison
 - Sulfur dioxide is a respiratory irritant in low concentrations and is also a potentially lethal poison
 - Portable monitoring equipment such as a Ventis MX4 or equivalent would be used to determine when an area is exceeding the threshold limit value (TLV) for carbon monoxide (25 ppm) or sulfur dioxide (2 ppm)
- Potential effects from run-off water or chemical agents used to control fire and explosions: Reclaimed Catalyst, Roasted Catalyst, and Process Residuals potentially contain reactive sulfides, petroleum distillates and heavy metals, which must be kept from entering storm sewers or otherwise running off the Facility and

entering the environment. Dikes or berms would be placed around the release to prevent run-off from entering adjacent storm sewers. Drain covers located in the store room will be placed over the storm water sewers to provide additional protection against a release entering the storm water sewer.

- Determining if any hazards exist that would have potential to impact beyond the Facility's boundaries. If it is determined it may occur, authorities will be notified.
- Implementing reasonable measures to ensure fires, explosions, and discharges relating to Industrial Materials do not occur, recur, spread to other areas of the Facility, or spread off of the Facility property.
- Stopping Facility processes and operations as necessary, if doing so will not endanger the health of any individuals.
- Monitoring for leaks, pressure buildup, ruptures in valves and pipes in the event that Facility operations are stopped due to fire, explosion, or release.
- Requesting additional Facility employees or outside agencies/contractors for assistance (See Appendix B for telephone numbers).
- Consulting applicable Safety Data Sheets to determine the appropriate emergency response, safety equipment, and personal protective gear.
- Obtaining safety equipment and personal protective equipment necessary to complete the appropriate emergency response.
- Containing and collecting released material.
 - Removing and/or isolating containers
 - Ensuring any release to a containment area is removed within 24 hours
- Separating material that may be incompatible with the released material. Although most metal sulfides are insoluble in water, they dissolve in acids with the evolution of H₂S gas. Therefore, liquid acidic materials are incompatible with reactive wastes and are not kept in the storage areas where reactive wastes are stored. Because of the homogeneous nature of the wastes stored at this Facility, there is no need to segregate the Reclaimed Catalysts.
- If an injury has occurred, immediately arranging for the compilation of all information pertinent to the accident. It is essential that all facts associated with the accident be recorded including, but not limited to, conditions prior to and at the time of the accident, contributing factors, persons directly and indirectly involved, witnesses and their statement, and what actually occurred at the moment of the accident. No detail is to be considered insignificant. All appropriate accident forms, with attached supporting information, will be completed.

7.0 Emergency Procedures When Company Employees Are not On-site

Facility employees are normally on site twenty-four (24) hours per day, seven (7) days per week. However; there may be an occasion when production is not occurring and this may result in regular Company employees being absent from the site. In those instances, the contract security service monitors for fires, explosions, releases, or other critical events. The procedures listed below will be followed by the security service if an emergency or critical event occurs while they are on duty.

- In the event of an emergency situation or critical event, Security will immediately call for emergency assistance by dialing 9-911 and then contact Facility personnel using the EC list in Appendix C until verbal contact is made.

The first EC, AEC, or member of the Company Management team to arrive on site will assume the responsibility of primary EC until notified otherwise.

8.0 Employee Responsibilities

Any employee discovering an emergency situation or critical event such a fire, explosion, spill (release of greater than an Incidental Spill quantity of Industrial Materials to air, soil or surface water), shall contact their Department Supervisor and/or the EC immediately. Contact shall be made either by telephone, Facility phone paging system, Facility radio, or verbally. The caller must have voice contact, a voice mail message is not sufficient. The employee will state the nature of the emergency (e.g., release, injury, fire, explosion, etc.) and will not hang up the telephone or put down the radio until instructed to do so.

If an immediately life-threatening situation occurs, all employees are empowered to announce the nature of the emergency via the Facility paging/phone system and to make contact with emergency responders via 9-911 to summon immediate help as they judge appropriate.

When there is a notification to evacuate, all employees will evacuate to the Emergency Evacuation Rally Point. The rally point is shown on Figure 8-3. All employees will remain at the rally point and wait for further instruction.

Note: Due to the unknown nature of emergencies, the EC may have employees redirected to an alternative rally point in the event the rally point is involved in the emergency.

If instructed, perform emergency shutdown procedures if doing so will not create a risk of being injured.

9.0 Internal Reporting Requirements for Industrial Materials Release

Any release of Industrial Materials to the environment, including an Incidental Spill is to be immediately reported to the Environmental Manager (See the Stormwater Pollution Prevention Plan and Spill Prevention Control and Countermeasure Plan).

10.0 Potential Waste/Chemical/Material Releases

Waste/Chemical/Material	Form	Location
Reclaimed Catalyst	solid	RMSB #4, Railcar area, Roaster
Roasted Catalyst	solid	Roaster, Melt Shop
Baghouse Dust and Cyclone Dust	solid	RMSB #4, Baghouses, Cyclone, Roll-offs
LimeAdd™	solid	LimeAdd™ Silo, CDS, RMSB #4, Roll-offs
Other Vanadium-bearing Raw Materials	solid	Melt Shop
Hydrated Lime	solid	Hydrated Lime Silo
Gasoline, Diesel, Kerosene, Oil	liquid	Tanks, Vehicles, Equipment, Transformers
Antifreeze	liquid	Vehicles On-site
Firefighting water runoff	liquid	Facility-Wide
Propane	gas	Propane Storage Area, Fork trucks
Sulfuric acid	*liquid	Roaster, CDS, Intake Water Treatment
Vanadium Pentoxide	*solid	Melt Shop
Material in totes and secondary containment	liquid	Facility-wide

* = Extremely hazardous substance

11.0 External Reporting Requirements for Industrial Materials Release

See Section 1.1 (Purpose and Implementation for RCRA-related Incidents).

12.0 Industrial Materials Releases

For releases greater than an Incidental Spill occurring on site, the EC, in consultation with the Environmental Manager will immediately evaluate:

- The character, source, and extent of any released materials;
- Person(s) injured and seriousness of injury; and
- Location of the release.

This information must be obtained without entering the contaminated area.

If it is determined Facility personnel cannot safely and effectively perform corrective action, the EC, in consultation with the Environmental Department, will:

- Arrange for outside response contractors/agencies to perform the mitigation and remedial actions.
- Have all Facility response personnel stand down and assist as required.
- Directly relate all pertinent information to outside emergency personnel.

The EC, in consultation with the Environmental Manager, will evaluate the Facility's emergency response equipment to determine if Facility personnel can safely handle the emergency. Emergency response personnel will only respond to incidents where proper chemical identification and concentrations can be determined.

If Facility personnel can safely respond to the release and effectively implement corrective action and cleanup, the following steps will be taken:

- Don appropriate personal protective equipment and utilize the proper safety equipment;
- Immediately set up a barrier to alert unauthorized personnel to keep out of the impacted area;
- If the release involves fire, use nearby firefighting equipment to provide early containment of the fire to significantly reduce the release or total damage.

NOTE: No firefighting activities will be performed if there is a risk of injury to any response personnel.

- Attempt to eliminate all possible sources of ignition;
- Immediately begin containment by placing absorbent material or containment barriers in and on the release area;
- Establish a decontamination zone to ensure proper decontamination procedures;
- Label appropriately all containers filled with regulated waste;
- Continue cleanup until all contamination hazards are eliminated;

- Transfer contents of any leaking containers into another container or in the case of a leaking drum, over packed into a salvage drum or other suitable container;
- A leaking drum will be picked up with a forklift and tilted to one side to cease any discharge. The drum will be placed into either an over pack drum or into a roll-off box to isolate and contain the release. If the container is no longer leaking, the forklift may transport the drum to a RMSB;
- Spills involving Reclaimed Catalyst, residue, LimeAdd™, Baghouse Dust, Cyclone Dust or other similar material may require the use of a front-end loader or backhoe to recover materials and place in a roll-off box or transferred to the dump truck for transportation to a RMSB;
- Secure storm drains or other conveyance systems capable of allowing migration of the material;
- Utilize silt fencing and or plastic to prevent migration of material by rain or wind;
- Contaminated areas will be assessed and remediated, as applicable. This may include such activities as soil/debris removal and/or concrete decontamination. All material destined for disposal will be characterized and disposed of properly;
- Operating equipment is shut down, as necessary and practical.

After cleanup has occurred, the EC will ensure:

- All emergency equipment is clean and fit for its intended use immediately after the emergency and prior to resuming operations, if operations were stopped;
- All equipment used during the incident is recorded/replaced in its appropriate area.

For an Incidental Spill occurring on site, a Department Supervisor, in consultation with the Environmental Manager will take necessary actions to clean up the spill within 24 hours of discovery. If clean up cannot be completed within 24 hours of discovery, the Company will notify Ohio EPA and provide an anticipated schedule.

13.0 Power Outage

In case of power outage, the telephones will not work. Cell phones are the preferred means of communication. Critical Facility employees are issued cell phones and their phone numbers can be found in the Emergency Contact List found in Appendix B.

The EC will ensure Department Supervisors follow safe shutdown procedures for their respective operational areas.

The Laboratory will stop all chemical reactions and work in the laboratory hoods until power is restored. If the power outage shuts down gas flow, valve the gas to the off position and restart using the manufacturer's recommended procedure when power returns.

If a power outage or emergency interrupts material flow, or causes a fire, explosion, or smoke within the Roaster building, carbon monoxide gas ("CO") and sulfur dioxide ("SO₂") may be present or generated. CO is an odorless, colorless, flammable gas that can cause severe headaches, unconsciousness, and death. Both CO and SO₂ are potentially lethal poisons.

14.0 Severe Weather

In the event of severe weather such as extreme winds or tornado, employees are required to proceed to the tornado shelter located in the office.

If a shelter is not readily accessible, go to the nearest concrete structure or a hallway away from glass and windows. Get beneath a heavy piece of equipment or machinery. The prime focus is to protect the head, neck and back as these areas are most vulnerable to severe injury.

15.0 Emergency Equipment

There are various types of equipment at the Facility that will be used in the event of an emergency situation. These include equipment designed for personnel safety and equipment that is used to complete the cleanup of any spills or releases. A descriptive narrative of this equipment follows:

- Spill Response Trailer – The trailer can be moved with the storeroom or Guard's trucks. Typical equipment maintained in the trailer includes: booms, silt fence, plastic for storm water drains, absorbent material, shovels, brooms, safety vests, leak plugging material, and PPE. Additional spill kits are located throughout the Facility. The spill response trailer is provided to enable employees to keep material from getting to the environment or minimizing the impact by controlling the magnitude of the spill;
- Internal and External Alarms – An alarm can be activated throughout the active Facility in the event of an evacuation or other emergency. Plant radios are also used to communicate an emergency;
- Communication Equipment – cell phones and radios;
- PPE such as Tyvek coveralls, boots, gloves, etc. is located in the storeroom;

- Respirators and cartridges - disposable half mask respirators and full-face respirators and cartridges are stored in the storeroom. Capabilities are listed on the individual respirator cartridges (i.e., Organic Compounds, Volatile Organic Compounds, Particulate Matter, etc.);
- Self-Contained Breathing Apparatus (SCBA) – SCBA's are equipped with 30-minute air bottles. SCBA's are located on the Confined Space Equipment Cart. Extra air bottles are stored in a rack in the garage adjacent to the guardhouse. Capabilities are limited to 30 minute supply of air;
- Emergency power - In case of a power failure, a diesel-fueled electrical generator will supply electrical power to the cooling pumps for the electric arc furnaces. In addition, a gasoline powered portable power generator is available. It can be used for electrical power anywhere inside or outside the building. Capabilities are limited to the amount of power that can be supplied and has the potential for running out of fuel;
- Emergency lighting - consists of fixed battery-operated emergency exit signs and lights located at each exit man door. Capabilities are to help personnel identify key safety exits. Portable light stanchions are available;
- Absorbents - Bags of clay absorbent are stored on pallets at each dock area and is also an inventory item in the Spill Response Trailer. Capable of absorbing liquids such as oils, fuel, acids or bases;
- Fire suppression system – Sprinklers are present within select buildings. A fire water loop with connections is present around the main area of plant operations. A fire hydrant is located near the Railcar Unloading Area;
- Fire extinguishers – The Facility utilizes multiple types of fire extinguishers, such as ABC dry chemical type, D for metals fires, and carbon dioxide. They are located throughout the Facility. To be used in the event of a small fire as most are limited to approximately 15 seconds of usage;
- Shovels - Standard shovels are available throughout the Facility. Brooms are also located at each of these areas; and
- Heavy equipment (e.g. front-end loaders) used in the Facility operation are available for emergency response as needed. This equipment is normally in use, but may be stored in a RMSB. Capable of moving larger amounts of material from location to location. Limited to the size of the individual buckets.

If deemed necessary, modifications to the equipment list will be performed.

NOTE: The above equipment is inspected per the frequency in the Inspection Program (Attachment 5).

16.0 Post-Emergency Procedures and Notifications

This Contingency Plan will be implemented in the event of a spill of Industrial Materials or other environmental release that threatens the environment or human health, fire, explosion, or any combination of these (see OAC 3745-54-56). Additionally, the Contingency Plan will be implemented if the EC determines that a threat to human health or the environment exists. Implementation of this Contingency Plan is intended to mitigate or protect the Facility and neighboring community from injury; contamination of storm sewers with hazardous materials; damage to equipment; damage to the environment; or a combination of these.

After an emergency, the EC, with input from the Environmental Manager, will arrange for the treatment, storage, and disposal of all recovered Industrial Materials, contaminated soil or water, and disposable personal protective equipment. All Industrial Materials will be managed according to applicable local, state, and federal regulations.

After the initial response and cleanup, the Environmental Manager will complete the follow-up investigation and cleanup verification procedures. The purposes of these follow-up procedures are to:

- Document the cause of the emergency situation;
- Assess the actions taken during the emergency to ensure all required procedures were followed;
- Assess the procedures followed to ensure they are adequate and to make any necessary changes;
- Determine if soil, water, or equipment sampling will be necessary to ensure remediation actions were adequate;
- Arrange for additional remediation, if necessary;
- Determine if Contingency Plan was implemented.

The Environmental Manager will note in the Facility's operating record the time, date, and details of any incident that requires implementing the Contingency Plan.

The Environmental Manager will determine if a written report to the Director of the Ohio EPA is required. Such a report must be submitted within 15 days of the incident. This report should include the following information:

- The name, address, and telephone number of the Facility owner;
- The name, address and telephone number of the Facility;
- The date, time, and type of incident (e.g., fire, explosion, or release);

- The name and quantity of material(s) involved in the incident;
- The extent of injuries (if any);
- An assessment of the actual or potential hazards to human health or the environment, if any;
- The estimated quantity and the ultimate disposition of any recovered material that resulted from the incident;
- Any other information as the Director may require.

The report will be sent to the following parties:

1. Director
U.S. EPA, Region V
77 W. Jackson Blvd.
Chicago, IL 60604
2. Chief
Environmental Emergency Branch
U.S. EPA, Region V
77 W. Jackson Blvd.
Chicago, IL 60604
3. Director, Ohio EPA
Lazarus Government Building
P.O. Box 1049
Columbus, OH 43216-1049
4. Hazardous Waste Supervisor
Ohio EPA
Division of Materials and Waste Management
Southeast District Office
2195 Front Street
Logan, OH 43138-8637

16.I Post-Emergency Equipment Maintenance

All emergency equipment will be clean and fit for its intended use at all times. Therefore, immediately after an emergency event requiring the activation of the Contingency Plan, all emergency equipment used will be inspected for proper function, completeness and condition. The equipment used for spill cleanup will be documented on the Emergency report form. The equipment will be evaluated for hazardous characteristics, decontaminated, or properly disposed of in containers. Decontamination procedures include a pressurized water rinse, scrubbing equipment with brushes and water-compatible

cleaning solutions, or steam cleaning. If the equipment remains contaminated, additional decontamination efforts will be completed.

Contamination will be determined through visual observation and, if necessary, sampling. Residue from equipment decontamination will be collected in containers. Any residue destined for disposal will be assessed for characteristic hazards utilizing process knowledge and/or chemical analysis and disposed of appropriately.

The Facility will notify the Director of the Ohio EPA, and other appropriate state and local authorities, that the Facility is in compliance with the emergency equipment requirements described above before operations resume in the affected area of the Facility.

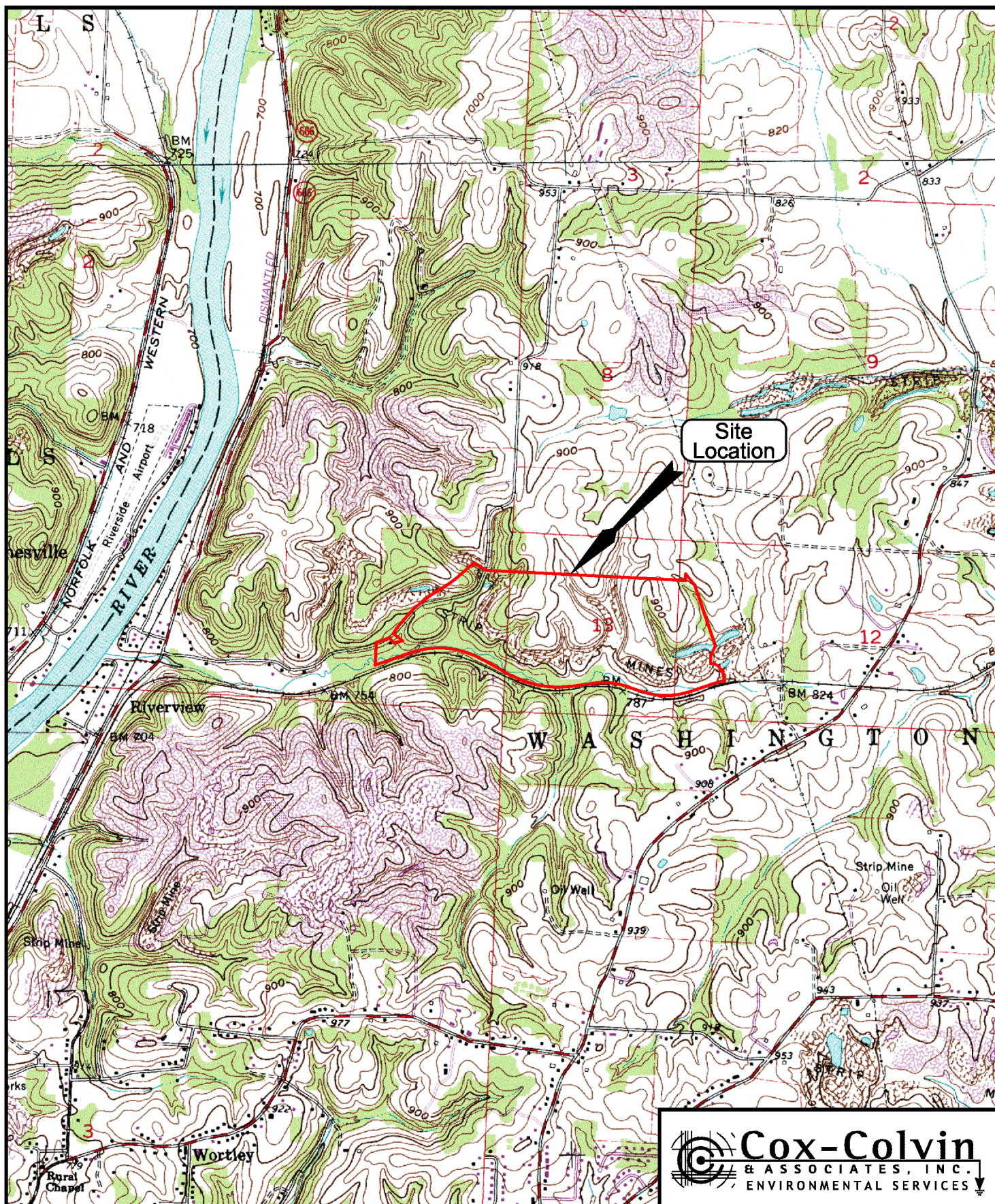
17.0 Amendment of the Contingency Plan

The Contingency Plan will be reviewed and amended whenever:

- The Facility Variance is revised;
- The plan fails in an emergency;
- The Facility implements changes in its design, construction, operation, maintenance, or other circumstances, in a way that materially increases the potential for fire, explosions, releases of hazard waste, hazardous waste constituents, or changes the response necessary in an emergency;
- The list of EC's change;
- The list of emergency equipment changes; or
- Required by the Ohio EPA Director.

If an amendment to the Contingency Plan requires Ohio EPA approval, the Company is not required to submit the amended Contingency Plan to outside emergency response parties until after approval is received from Ohio EPA.

Figures



Cox-Colvin
 & ASSOCIATES, INC.
 ENVIRONMENTAL SERVICES

Scale 1:24,000
 0' 1000' 2000' 3000' 4000' 5000'

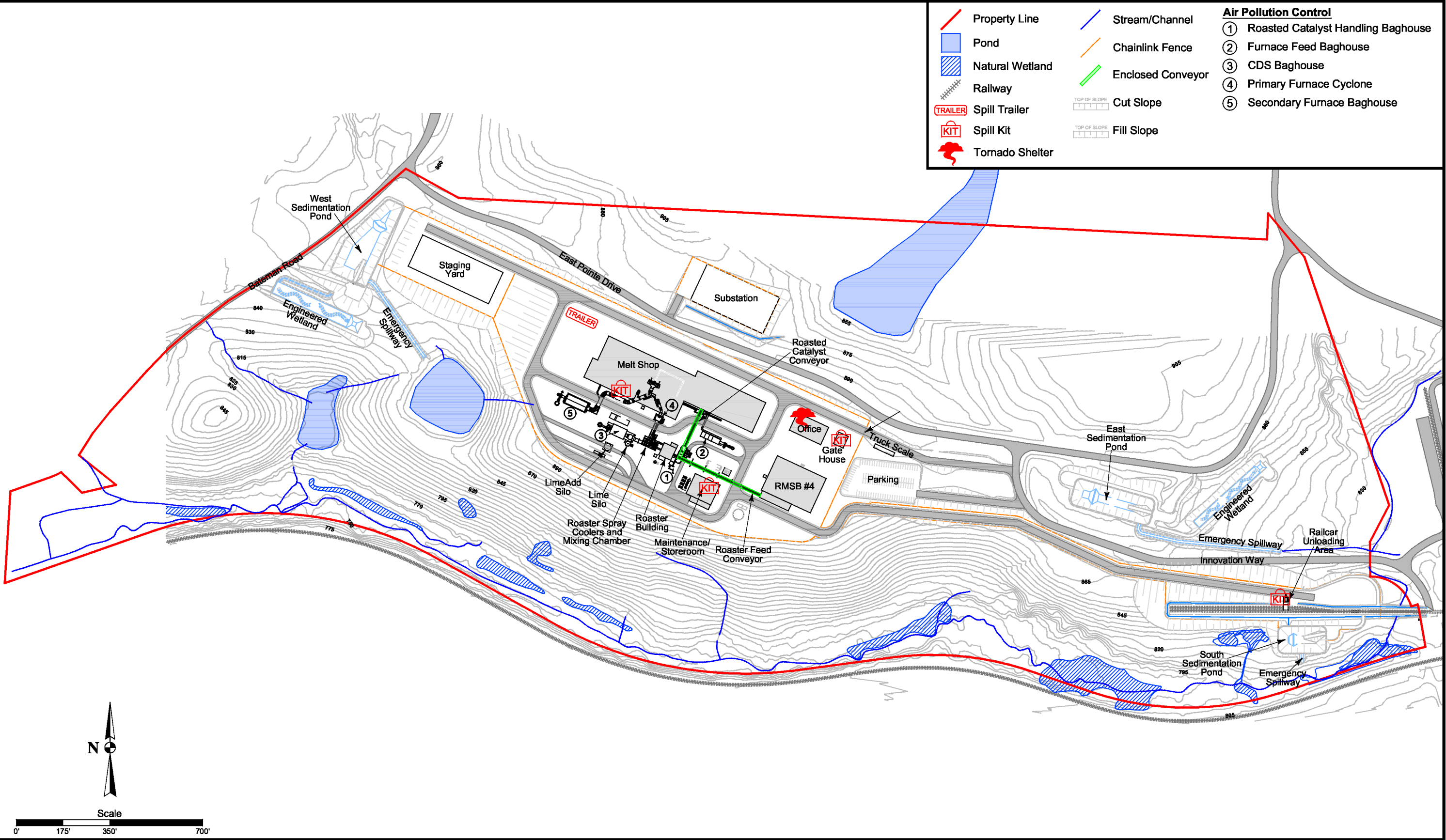


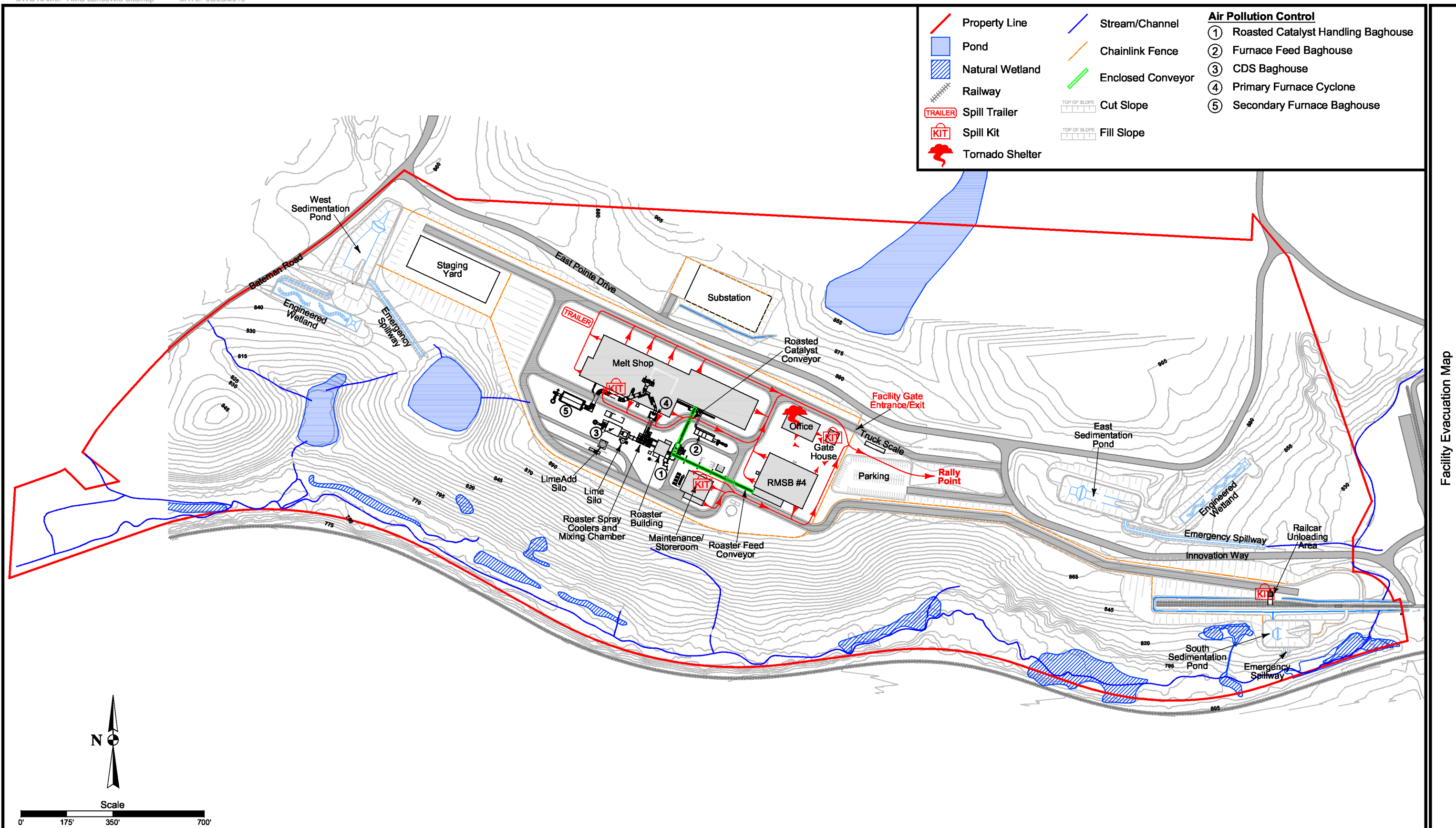
Figure 8-1

Site Location Map,
 AMG Vanadium LLC,
 Zanesville, Ohio

Revision 0

Source: 7.5 Minute Series Quadrangle
 Adamsville, Ohio (1962, Photorevised 1987)
 Zanesville East, Ohio (1961, Photorevised 1987)





Facility Evacuation Map

Appendix A

Initial Emergency Information Form

**Contingency Plan
Appendix A
Initial Emergency Information Form**

1. ___ Release ___ Fire ___ Explosion ___ Other (explain).

2. This event occurred at (time) _____ on (date) _____
3. The material involved is _____. The material (is)___ (is not)___ an Extremely Hazardous Substance. (Note: The only Extremely Hazardous Substances at Cambridge are sulfuric acid and Vanadium Pentoxide).
4. The material is a _____ gas _____ liquid _____ solid
5. The amount involved is (units)_____
6. The incident (is ongoing) _____ (terminated as of) _____
7. The incident (is) ___ (is not) ___ affecting a waterway (name if applicable)

8. There (are) ___ (are not) ___ injuries. Number of injuries (if applicable) _____
9. The potential health and environmental effects from exposure to the material are:

10. Recommend action(s) (not required): _____
11. _____
12. Further information can be obtained by calling _____ at

Appendix B

Emergency Contact List



Please Note: Pages of this application which contain facility staff personal/home phone numbers have been removed from this web-available version of the document

To review redacted copies of these removed pages, please contact DERR's record management staff at (614) 644-2924.

Thank you.

**Contingency Plan
Appendix B
Emergency Contact List**

External	
Ohio EPA Emergency Response Team	800-282-9378
Fire Department (Zanesville)	911
Emergency Squad (Zanesville)	911
Police Department (Zanesville)	911
Muskingum County Sheriff	740-452-3637
National Response Center	800-424-8802
Muskingum County Emergency Management Agency	740-453-1655
City of Zanesville Pretreatment	740-455-0641
Ohio Emergency Management Agency	614-644-2260
Nuclear Regulatory Commission (Region III – Chicago)	630-829-9500
Nuclear Regulatory Commission (Operations Center)	301-816-5100
Chemtrec	800-424-9300
Utilities and Contractors	
American Electric Power	800-672-2231
Columbia Gas	800-344-4077
Genesis Health Care	740-454-4000
Poison Control Center	800-222-1222
Ohio EPA Central Office	614-644-3020
Ohio EPA Southeast District Office	740-385-8501
Ohio Department of Health	614-466-1390
Muskingum County Health Department	740-454-9741
Zemba Bros.	740-452-1880
PSI Industrial Solutions	740-622-9795

Appendix C

List of Emergency Coordinators and Alternates




Please Note: Pages of this application which contain facility staff personal/home phone numbers have been removed from this web-available version of the document

To review redacted copies of these removed pages, please contact DERR's record management staff at (614) 644-2924.

Thank you.

Appendix D

Emergency Evacuation Procedure

AMG V Zanesville Plant Emergency Evacuation Procedure	
Reference Document: Contingency Plan, VSR-7593 Emergency Drill Reporting Form	
Revision Date: October 29, 2019	

If an immediately life threatening situation occurs, all employees are empowered to sound the electronic emergency evacuation alarm and to make contact with emergency responders via 9-911 to summon immediate help as they judge appropriate.

In case an immediate evacuation is required, the ENTIRE plant shall be evacuated to the Rally Point. Once all employees, contractors, and visitors are accounted for the Emergency Coordinator (EC) will determine if employee(s) can return to their jobs.

1. Purpose

- 1.1. Establish a uniform procedure for the orderly evacuation of the AMG Vanadium LLC, Zanesville, Ohio, facility in the event of an emergency.
- 1.2. This procedure addresses the required actions to ensure an orderly and complete evacuation of the facility in the event of an emergency. Once the evacuation is completed and all employees are safe from the hazard, refer to the "Contingency Plan" to resolve the emergency.

2. Scope

- 2.1. AMG Vanadium employees, contractors and visitors

3. Reference


- 3.1. The Electronic Evacuation Alarm activation will be located at the Gate House.

4. Definitions

- 4.1. **Alternative Emergency Coordinator** – A person designated by the Emergency Coordinator in charge in interactions with both internal company and external personnel.
- 4.2. **Contingency Plan** - A plan designed to take a possible future event or circumstance into account.
- 4.3. **Designee** - A person selected or designated to carry out a duty or role.
- 4.4. **Emergency Coordinator** – A person in charge in interacting with both internal company and external contract personnel

5. Resources

- 5.1. Electronic Evacuation Alarm
- 5.2. Two-Way Radios
- 5.3. Phone System (Intercom system)
- 5.4. Cell Phones
- 5.5. One Call Now (phone app)

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6. Emergency Coordinator (EC)

6.1. Designation of EC

6.1.1. The Plant Manager is the Emergency Coordinator (EC).

6.1.2. The EC shall ensure that his designee and direct reports are notified prior to leaving the facility (out of area), indicating who will be the EC in his/her absence.

6.2. Once the EC is made aware of any given emergency (i.e. fire, explosion, etc.), the EC is in charge of the event.

6.3. Duties of the EC

6.3.1. Responsible for the effective handling of all emergency/evacuation situations.

6.3.1.1. Determine if the effect of the emergency is an imminent threat to human health or the environment and take effective action(s) commensurate to the scope of the threat.

6.3.1.2. Clearly identify themselves as the person in charge in interactions with both internal company and external personnel.

6.3.2. Determine if the emergency prompts an evacuation and implement an evacuation as necessary.

6.3.2.1. Direct activation of the Electronic Evacuation Alarm when necessary.

6.3.2.2. Direct the Receptionist to issue Plant Wide telephone page announcing an evacuation when necessary.

6.3.2.3. Ensure all supervisors have been notified of the emergency and direct shut down and evacuation when necessary.

6.3.2.4. Issue a "One Call" notification of the issue and/or evacuation.

6.3.2.5. The EC shall inform the President, by phone, a Plant Evacuation is required or had taken place as soon as it is safe to do so.


6.3.3. Evaluate the facility's emergency response equipment to determine if AMG V personnel can safely handle the emergency.

6.3.4. Immediately assess the situation and determine if outside emergency assistance is required. If outside emergency assistance is required, the EC will:

6.3.4.1. Arrange to have emergency assistance contacted by dialing 9-911.

6.3.4.2. Assign individual(s) to direct emergency authorities (i.e. ambulance, fire trucks, etc.)

6.3.4.3. Work and coordinate with outside emergency agencies to disclose the nature and extent of the emergency situation at the AMG V facility.

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6.3.4.4. Advise the outside emergency agencies of the need for evacuation of community members downwind of the site emergency event.

6.3.5. Reference the "Contingency Plan" and address the emergency as required and determine when it is safe for personnel to return to work.

7. Alternative Emergency Coordinator (AEC)

7.1. In the event of the EC's absence from the facility, the appointed designee will become the Alternative Emergency Coordinator (AEC)

7.2. The AEC assumes all duties assigned to the EC stated in section 6.3.

8. Receptionist

8.1. If the Receptionist cannot be reached, the Staff Accountant or the Safety Clerk will perform the duties of the Receptionist.

8.2. Maintain a list of all visitors, vendors, delivery drivers, and non- AMG Vanadium employees entering through the Office.

8.3. Use the intercom system when contacted by the EC or the AEC to issue a Plant Wide telephone page announcing the emergency and directing all personnel to evacuate to the Rally Point. The page shall be repeated 3 times over the telephone page.

8.4. Obtain any relevant documentation of staff employees present in the Administration Building and the Visitors Sign in Book.

8.5. Proceed to the Rally Point, using available documentation; perform a head count to verify complete evacuation of the Administration Building.

9. Headcount: Office Manager and Director of Human Resources

9.1. The Officer Manager will notify the Director of Human Resources that an evacuation and head count are taking place in the Plant.


9.1.1. If the Office Manager is not present, the Environmental Specialist will be the backup.

9.2. The Director of Human Resources will provide a head count of the Plant's employees at the 209 Office Building if any are present.

9.2.1. If the Director of Human Resources is not present, the Senior Customer Service Representative will be the backup.

9.3. Receive head count verification from production supervisors, Human Resources, and security guards and report information to the EC or AEC.

9.4. The Office Manager or their designee will monitor all radio channels in case of emergency to ensure all individuals are accounted for.

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10. Employees


- 10.1. If instructed, perform emergency shutdown procedures if doing so will not create a risk of being injured.
- 10.2. Any employee discovering an emergency situation or critical event such as a fire, explosion, or spill, flooding, shall contact their Department Supervisor, the Environmental Manager, and/or the EC immediately.
- 10.3. The employee will state the nature of the emergency (e.g., release, injury, fire, explosion, etc.) and, if safe to do so, will not hang up the telephone or put down the radio until instructed to do so.
- 10.4. When the alarm whistle sounds or there is a notification to evacuate, all employees will evacuate to the Emergency Evacuation Rally Point (east of the main parking lot and southeast of the Office and Gate House).
- 10.5. All employees will remain at the Rally Point and wait for further instruction.
- 10.6. Assist in accounting for personnel in the respective areas.

11. Supervisors

- 11.1. If instructions are made, ensure emergency shutdown procedures are completed if doing so will not create a risk of being injured.
- 11.2. Using the two-way radios, announce the emergency on all channels and direct all employees to evacuate to the Rally Point. Repeat announcement 3 times on each channel.
- 11.3. Maintain a current copy of the work schedule.
- 11.4. Perform a sweep of their department to ensure all employees are aware of the emergency.
- 11.5. Proceed to the Rally Point, conduct a head count of employees and report to the Receptionist that all employees are accounted for.

12. Security Guards

- 12.1. Maintain a list of all on-site contractors, visitors, vendors, delivery drivers, shipment pick up drivers, and non-AMG Vanadium employees entering through the Gate House.
- 12.2. Direct employees to exit through the pedestrian gate while exiting to the Rally Point.
- 12.3. Take the Visitor Hold Harmless Sign in Log Book; perform a sweep of the employee locker rooms (men's and women's) to ensure all occupants have evacuated.
- 12.4. Proceed to the Rally Point. The Receptionist shall be informed that all on-site contractors, visitors, vendors, delivery drivers, shipment pick up drivers, and non-

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AMG Vanadium employees are accounted for.

- 12.5. Monitor the gate and Gate House entrance to prevent anyone, except emergency responders, from entering the premises during an evacuation.
- 12.6. After reporting head count information, return to Gate House to allow entrance of emergency personnel and vehicles.

13. Emergency requiring evacuation on night shift, weekend, and holidays

13.1. Melt Shop Supervisor


- 13.1.1. The Melt Shop Supervisor is the Emergency Coordinator (EC) in the absence of the Plant Manager or his appointed designee.
- 13.1.2. The Melt Shop Supervisor is responsible for all EC duties listed in section 6.3. and all Supervisor duties listed in section 11.
- 13.1.3. The Melt Shop Supervisor will attempt to contact management in the following order until personal contact is made:
 - 13.1.3.1. Plant Manager
 - 13.1.3.2. President
 - 13.1.3.3. Senior Vice President
 - 13.1.3.4. Environmental Manager
 - 13.1.3.5. Director of Technical Services
 - 13.1.3.6. Management Systems Auditor
- 13.1.4. The Melt Shop Supervisor will remain the EC until relieved by the EC or his designee.

13.2. Security Guard

- 13.2.1. The Security Guard will be responsible for all duties listed in section 12
- 13.2.2. During a night shift, weekend, or holiday when the Receptionist is not on-site, the Security Guard will report head count information directly to the EC.

14. Emergency Procedures When AMG V Employees Are Not On-Site (Security Guard)

- 14.1. Facility employees are normally on site twenty-four (24) hours per day, seven (7) days per week. However; there may be an occasion when production is not occurring and this may result in regular AMG V employees being absent from the site. In those instances, the contract security service monitors for fires, explosions, releases, or other critical events.
- 14.2. In the event of an emergency situation or critical event, Security will immediately call for emergency assistance by dialing 911 and then will attempt to contact management in the following order until personal contact is made:
 - 14.2.1. Plant Manager

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- 14.2.2. President
- 14.2.3. Senior Vice President
- 14.2.4. Environmental Manager
- 14.2.5. Director of Technical Services
- 14.2.6. Management Systems Auditor
- 14.3. The first EC, AEC, or member of the AMG V Management team to arrive on-site will assume the responsibility of primary EC until notified otherwise.

15. AMG Vanadium

- 15.1. Periodically, AMG V shall test its procedures to respond to emergency situations by conducting a plant evacuation.
- 15.2. Effectiveness of evacuation is evaluated by the EC/AEC and the Safety Department on VSR-7593 Emergency Drill Reporting Form.

*****NOTE***** The EC or AEC shall notify the President or his designee as defined in the “Contingency Plan” as soon as it is safe to do so. The EC or AEC will ensure that the President or his designee have been informed of the evacuation as soon as possible, by phone and email.