APPENDIX G

First Quarter 2018 Analytical Laboratory Methods, Method Detection Limits, Reporting Limits, QA/QC Procedures, and ELAP Certifications

ANNUAL LIST OF ANALYTICAL METHODS BY ANALYTE WITH CORRESPONDING LABORATORY REPORTING LIMITS AND METHOD DETECTION LIMITS

							Permit Limits (PL)					
				TestAmerica	SWRCB	Laboratory	Monthly Average Limits	Daily Maximum Limits	Daily Maximum Limits	Daily Maximum Limits	Receiving Water Limits	Receiving Water Sediment Limits
Method	Analyte Units	Laboratory 2018 MDL	Laboratory 2018 RL	ML	vs ML ⁽¹⁾	019, 020	001, 002 011, 018	003-007, 009, 010	008	Arroyo Simi	Arroyo Sim	
EPA 624 - Low-level	1,1,1-Trichloroethane	μg/L	0.250	0.500	2	^(b)						
	1,1,2,2-Tetrachloroethane	μg/L	0.250	0.500	1	^(b)						
	1,1,2-Trichloroethane	μg/L	0.250	0.500	2	^(b)						
	1,1-Dichloroethane	μg/L	0.250	0.500	1	^(b)						
	1,1-Dichloroethene	μg/L	0.250	0.500	2	^(a)	3.2	6.0				
	1,2-Dichlorobenzene	μg/L	0.200	0.500	2	^(b)	-					
	1,2-Dichloroethane	μg/L	0.250	0.500	2	^(a)		0.5				
	1,2-Dichloropropane	μg/L	0.250	0.500	1	^(b)						
	1,3-Dichlorobenzene	μg/L	0.250	0.500	2	^(b)						
	1,3-Dichloropropene (reported as cis & trans)	µg/L	0.250	0.500	2	^(b)						
	1,4-Dichlorobenzene	µg/L	0.250	0.500	2	^(b)						
	Benzene	µg/L	0.250	0.500	2	^(b)						
	Bromoform	μg/L	0.400	1.00	2	^(b)						
	Bromomethane	μg/L	0.250	0.500	2	^(b)						
	Carbon tetrachloride	μg/L	0.250	0.500	2	^(b)						
	Chlorobenzene	μg/L	0.250	0.500	2	^(b)						
	Chlorodibromomethane	µg/L	0.250	0.500	2	^(b)						
	Chloroethane	μg/L	0.400	1.00	2	^(b)						
	Chloroform (Trichloromethane)	μg/L	0.250	0.500	2	^(b)						
	Chloromethane (Methyl Chloride)	µg/L	0.250	0.500	2	^(b)						
	Dibromochloromethane	μg/L	0.250	0.500	2	^(b)						
	Ethylbenzene	µg/L	0.250	0.500	2	^(b)						
	Methylene chloride	µg/L	0.880	2.00	2	^(b)						
	Tetrachloroethene	μg/L	0.250	0.500	2	^(b)						
	Toluene	μg/L	0.250	0.500	2	^(b)						
	trans-1,2-Dichloroethene	μg/L	0.250	0.500	1	^(b)						
	Trichloroethene	μg/L	0.250	0.500	2	^(a)		5.0				
	Vinyl chloride	μg/L	0.250	0.500	2	^(b)						
	m,p-Xylenes	μg/L	0.500	1.00	n/a	^(d)						
	Naphthalene	μg/L	0.400	1.00	n/a	^(d)						
	o-Xylene	μg/L	0.250	0.500	n/a	(d)						
	Trichlorofluoromethane	µg/L	0.250	0.500	n/a	^(d)						
VOC - Add-ons (EPA 624)	1,1,2-Trichloro-1,2,2-trifluoroethane	µg/L	0.500	2.00	n/a	^(d)						
	1,2-Dichloro-1,1,2-trifluoroethane	µg/L	1.00	2.00	n/a	^(d)						
	Cyclohexane	µg/L	1.00	2.00	n/a	(d)						

ANNUAL LIST OF ANALYTICAL METHODS BY ANALYTE WITH CORRESPONDING LABORATORY REPORTING LIMITS AND METHOD DETECTION LIMITS

							Permit Limits (PL)					
			TestAmerica	TestAmerica	SWRCB	Laboratory	Monthly Average Limits	Daily Maximum Limits	Daily Maximum Limits	Daily Maximum Limits	Receiving Water Limits	Receiving Water Sediment Limits
Method	Analyte		Laboratory 2018 MDL	Laboratory 2018 RL	ML	vs ML ⁽¹⁾	019, 020	001, 002 011, 018	003-007, 009, 010	008	Arroyo Simi	Arroyo Simi
EPA 624/8260B A-A+2CVE LOW	Acrolein	μg/L	2.50	5.00	5	^(b)						
	Acrylonitrile	μg/L	1.00	2.00	2	^(b)						
	2-Chloroethyl vinyl ether	µg/L	1.00	2.00	1	^(C)						
				1				1				
EPA 625+NDMA+Hydrazine -Low-level	1,2,4-Trichlorobenzene	µg/L	0.500	1.00	1	^(b)						
	1,2-Dichlorobenzene	µg/L	0.200	0.500	2	^(b)						
	1,2-Diphenylhydrazine/Azobenzene	µg/L	0.500	1.00	1	^(b)						
	1,3-Dichlorobenzene	µg/L	0.200	0.500	1	^(b)						
	1,4-Dichlorobenzene	µg/L	0.200	0.500	1	^(b)						
	2,4,6-Trichlorophenol	µg/L	0.500	1.00	10	^(a)	6.5	13				
	2,4-Dichlorophenol	µg/L	1.00	2.00	5	^(b)						
	2,4-Dimethylphenol	µg/L	1.00	2.00	2	^(b)						
	2,4-Dinitrophenol	µg/L	2.00	5.00	5	^(b)						
	2,4-Dinitrotoluene	μg/L	2.00	5.00	5	^(a)	9.1	18				
	2,6-Dinitrotoluene	µg/L	2.00	5.00	5	^(b)						
	2-Chloronaphthalene	µg/L	0.200	0.500	10	^(b)						
	2-Chlorophenol	μg/L	0.500	1.00	5	^(b)						
	2-Methyl-4,6-Dinitrophenol	µg/L	2.00	5.00	5	^(b)						
	2-Nitrophenol	μg/L	1.00	2.00	10	^(b)						
	3,3'-Dichlorobenzidine	µg/L	2.00	5.00	5	^(b)						
	4-Bromophenyl phenyl ether	µg/L	0.500	1.00	5	^(b)						
	4-Chloro-3-methylphenol	µg/L	0.200	2.00	1	^(D)						
	4-Chlorophenyl phenyl ether	µg/L	0.200	0.500	5	^(b)						
	4-Nitrophenol	µg/L	2.00	5.00	10	^(b)						
	Acenaphthene	µg/L	0.200	0.500	1	^(b)						
	Acenaphthylene	µg/L	0.200	0.500	10	^(b)						
	Anthracene	µg/L	0.200	0.500	10	(b)						
	Benzidine	μg/L	5.00	10.0	5	^(C)						L
	Benzo(a)anthracene	µg/L	2.00	5.00	5	^(b)						L
	Benzo(a)pyrene	µg/L	0.500	2.00	10	^(b)						
	Benzo(b)fluoranthene	μg/L	1.00	2.00	10	^(b)						
	Benzo(g,h,i)perylene	μg/L	2.00	5.00	5	^(b)						
	Benzo(k)fluoranthene	μg/L	0.250	0.500	10	^(b)						
	Bis (2-chloroethoxy) methane	μg/L	0.200	0.500	5	^(b)						
	Bis (2-chloroethyl) ether	μg/L	0.200	0.500	1	^(b)						
	Bis (2-chloroisopropyl) ether	µg/L	0.200	0.500	2	(b)						┢─────
	Bis (2-ethylhexyl) phthalate	µg/L	2.00	5.00	5	^(a)		4.0				
	Butyl benzylphthalate	µg/L	2.00	5.00	10	^(b)						
	Chrysene	µg/L	0.200	0.500	10	^(b)						<u> </u>

ANNUAL LIST OF ANALYTICAL METHODS BY ANALYTE WITH CORRESPONDING LABORATORY REPORTING LIMITS AND METHOD DETECTION LIMITS

							Permit Limits (PL)					
				TestAmerica	SWRCB	Laboratory	Monthly Average Limits	Daily Maximum Limits	Daily Maximum Limits	Daily Maximum Limits	Receiving Water Limits	Receiving Water Sediment Limits
Method	Analyte	Units	Laboratory 2018 MDL	Laboratory 2018 RL	ML	vs ML ⁽¹⁾	019, 020	001, 002 011, 018	003-007, 009, 010	008	Arroyo Simi	Arroyo Simi
EPA 625+NDMA+Hydrazine -Low-level	Dibenz(a,h)anthracene	µg/L	0.250	0.500	10	^(b)						
	Diethyl phthalate	μg/L	0.500	1.00	2	^(b)						
	Dimethyl phthalate	μg/L	0.250	0.500	2	^(b)						
	Di-n-butyl phthalate	μ <u>μ</u> g/L	1.00	2.00	10	^(b)						
	Di-n-octyl phthalate	μ <u>μ</u> g/L	2.00	5.00	10	^(b)						
	Fluoranthene	μg/L	0.200	0.500	1	^(b)						
	Fluorene	μg/L	0.200	0.500	10	^(b)						
	Hexachlorobenzene	μg/L	0.500	1.00	1	^(b)						
	Hexachlorobutadiene	μ <u>μ</u> μμμμμμμμμμμμμμμμμμμμμμμμμμμμμμμμμμ	0.500	2.00	1	^(D)						
	Hexachlorocyclopentadiene	µg/L	2.00	5.00	5	^(b)						
	Hexachloroethane	µg/L	0.500	3.00	1	^(D)						
	Indeno(1,2,3-cd)pyrene	µg/L	1.00	2.00	10	^(b)						
	Isophorone	µg/L	0.500	1.00	1	^(b)						
	Naphthalene	µg/L	0.500	1.00	1	^(b)						
	Nitrobenzene	µg/L	0.500	1.00	1	^(b)						
	n-Nitrosodimethylamine	µg/L	1.00	2.00	5	^(a)	8.1	16				
	n-Nitroso-di-n-propylamine	µg/L	1.00	2.00	5	^(b)						
	n-Nitrosodiphenylamine	µg/L	0.500	1.00	1	^(D)						
	Pentachlorophenol	µg/L	1.00	2.00	5	^(a)	8.2	16.5				
	Phenanthrene	µg/L	0.200	0.500	5	^(b)						
	Phenol	μg/L	0.500	1.00	1	^(b)						
	Pyrene	µg/L	0.200	0.500	10	^(b)						
PCB, Low Level (EPA 608)	Aroclor 1016	µg/L	0.250	0.500	0.5	^(g)					0.0003	
	Aroclor 1221	µg/L	0.250	0.500	0.5	^(g)					0.0003	
	Aroclor 1232	µg/L	0.250	0.500	0.5	(g)					0.0003	
	Aroclor 1242	µg/L	0.250	0.500	0.5	(g)					0.0003	
	Aroclor 1248	µg/L	0.250	0.500	0.5	(g)					0.0003	
	Aroclor 1254 Aroclor 1260	μg/L μg/L	0.250	0.500 0.500	0.5 0.5	(g)					0.0003	
	Aroclor 1260 Aroclor 1016		0.250	0.049	0.5 n/a	(c)		+			0.0003	0.12
	Aroclor 1016 Aroclor 1221	µg/g	0.017	0.049	n/a n/a	(c)						0.12
	Aroclor 1221 Aroclor 1232	µg/g	0.017	0.049	n/a n/a	(c)		+				0.12
	Aroclor 1232 Aroclor 1242	µg/g	0.017	0.049		(c)		-				0.12
		µg/g			n/a	(c)						
	Aroclor 1248	µg/g	0.017	0.049	n/a	(c)						0.12
	Aroclor 1254	µg/g	0.017 0.017	0.049 0.049	n/a	^(c)						0.12
	Aroclor 1260	µg/g	0.017	0.049	n/a	``'	1	1	1	1	1	0.12

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							Permit Limits (PL)					
				TestAmerica	SWRCB	Laboratory	Monthly Average Limits	Daily Maximum Limits	Daily Maximum Limits	Daily Maximum Limits	Receiving Water Limits	Receiving Water Sediment Limits
Method	Analyte Units	Laboratory 2018 MDL	Laboratory 2018 RL	ML	vs ML ⁽¹⁾	019, 020	001, 002 011, 018	003-007, 009, 010	008	Arroyo Simi	Arroyo Simi	
Pesticides, Low Level (EPA 608)	Aldrin	μg/L	0.0015	0.0050	0.005	^(b)						
	alpha-BHC	μ <u>g</u> /L	0.0025	0.0050	0.01	^(a)	0.01	0.03				
	alpha-Endosulfan	μ <u>g</u> /L	0.00300	0.00500	0.01	^(b)	0.01	0.00				
	beta-BHC	μg/L	0.0040	0.0100	0.005	^(D)						
	beta-Endosulfan	μ <u>g/L</u> μg/L	0.00200	0.00500	0.000	^(b)						
	delta-BHC	μg/L	0.00200	0.0050	0.005	(b)						
			0.0030	0.0050	0.005	(b)		-				
	gamma-BHC (Lindane)	μg/L				(g)					0.001	
	Chlordane	μg/L	0.0800	0.100	0.1	(g)					0.001	
	4,4'-DDD	μg/L	0.00400	0.00500	0.05	(g)					0.0014	
	4,4'-DDE	μg/L	0.00300	0.00500	0.05	(g)					0.001	
	4,4'-DDT	μg/L	0.00400	0.0100	0.01	(g)					0.001	
	Dieldrin	μg/L	0.00200	0.00500	0.01	(b)					0.0002	
	Endosulfan sulfate	µg/L	0.00300	0.0100	0.05							
	Endrin	µg/L	0.00200	0.00500	0.01	^(b)						
	Endrin aldehyde	µg/L	0.00200	0.0100	0.01	^(b)						
	Heptachlor	μg/L	0.00300	0.0100	0.01	^(b)						
	Heptachlor epoxide	μg/L	0.00250	0.00500	0.01	^(b)						
	Toxaphene	µg/L	0.250	0.500	0.5	^(g)					0.0003	
	Chlordane	µg/g	0.0100	0.0500	n/a	^(f)						0.0033
	4,4'-DDD	μg/g	0.00150	0.00500	n/a	(c)						0.002
	4,4'-DDE	μg/g	0.00150	0.00500	n/a	^(f)						0.0014
	4,4'-DDT	μg/g	0.00150	0.00500	n/a	(f)						0.0003
	Dieldrin	μ <u>g</u> /g	0.00150	0.00500	n/a	(f)						0.0002
			0.0500	0.200	n/a	(f)						0.0002
	Toxaphene	µg/g	0.0500	0.200	11/a	**		-				0.0000
EPA 525.2	Chlorpyrifos	μg/L	0.500	1.00	n/a	(T)	}	+			0.02	
	Diazinon	μg/L	0.120	0.250	n/a	 (C)	1				0.02	
		<u>рдуг</u>	0.120	0.200	11/ C						0.10	
SW8141	Chlorpyrifos	µg/L	0.500	1.00	n/a	(T)	1				0.02	
000171	Diazinon	μg/L	0.120	0.250	n/a	(C)	1				0.16	
		µg/L	0.120	0.230	11/a		1				0.10	
ICP/MS 200.8	Antimony	μg/L	0.500	2.00	0.5	^(a)	1	6.0	6.0	6.0		
	Cadmium	μg/L	0.250	1.00	0.25	^(a)	2.0	4.0/3.1	4.0	4.0/3.1		
	Copper	μ <u>μ</u> μμ	0.500	2.00	0.5	^(a)	5.8	14	13	14		
	Lead	μg/L	0.500	1.00	0.5	^(a)	2.6	5.2	5.2	5.2		
	Selenium	μg/L	0.500	2.00	2	(a)	4.1	8.2/5	0.2	5		
	Silver	μg/L	0.500	1.00	0.25	(a)	2.0	4.1		5		
	Thallium		0.500	1.00	0.25	(a)	2.0	2.0	2.0	2.0		
	TTAIIUTT	μg/L	0.500	1.00		``		∠.0	∠.0	2.0		

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					_		Permit Limits (PL)					
			TestAmerica	TestAmerica	SWRCB	Laboratory	Monthly Average Limits	Daily Maximum Limits	Daily Maximum Limits	Daily Maximum Limits	Receiving Water Limits	Receiving Water Sediment Limits
Method	Analyte	Units	Laboratory 2018 MDL	Laboratory 2018 RL	ML	vs ML ⁽¹⁾	019, 020	001, 002 011, 018	003-007, 009, 010	008	Arroyo Simi	Arroyo Simi
ICP 200.7	Aluminum	µg/L	50.0	100	n/a	^(d)						<u> </u>
	Arsenic	μg/L	8.90	10.0	10	^(a)		10.0				
	Barium	μg/L	5.00	10.0	n/a	^(C)		1000				
	Beryllium	μg/L	1.00	2.00	2	^(a)		4.0				
	Boron	mg/L	0.0250	0.0500	n/a	^(C)			1.0	1.0		
	Chromium	µg/L	2.50	5.00	10	^(a)	see Cr VI	see Cr VI				
	Cobalt	μg/L	5.00	10.0	n/a	^(d)						
	Hardness (as CaCO3)	mg/L	0.170	0.330	n/a	^(d)						
	Iron	mg/L	0.0500	0.100	n/a	^(c)		0.3				
	Manganese	μg/L	10.0	20.0	n/a	(c)		50				
	Nickel	µg/L	5.00	10.0	20	(a)	35	94	86	86		
	Vanadium	µg/L	5.00	10.0	n/a	^(d)						
	Zinc	µg/L	12.0	20.0	20	(a)	43	119	120	120		
Mercury (EPA 245.1)	Mercury	μg/L	0.100	0.200	0.2	^(†)	0.05	0.10	0.13	0.13		
Chromium VI (EPA 218.6)	Chromium VI (Hexavalent)	μg/L	0.250	1.00	n/a	(c)	8.0	16				
Cyanide by EPA (SM4500)	Cyanide	μg/L	2.50	5.00	5	^(a)	4.3	8.5	9.5	9.5		
Asbestos by EPA 600	Asbestos	MFL	n/a ⁽²⁾	n/a ⁽²⁾	n/a	(d)						
EPA 8260B-Mod	1,4-Dioxane	μg/L	0.500	2.00	n/a	^(d)						
EPA 8015-Mod	Diesel Range Organics (DRO C13-C28)	mg/L	0.100	0.500	n/a	(d)						
	Gasoline Range Organics (GRO C4-C12)	mg/L	0.0250	0.0500	n/a	(d)						
EPA 314.0	Perchlorate	μg/L	0.950	4.00	n/a	(c)		6.0	6.0	6.0		
EPA 1613	TCDD TEQ	μg/L	n/a	n/a	n/a	(e)	1.4E-08	2.8E-08	2.8E-08	2.8E-08		
		μg/∟	11/4		Π/α		1.42 00		2.02.00	2.02 00		
General Chemistry, (Field Test)	Chlorine, Total Residual ⁽³⁾	mg/L	n/a	0.1	n/a	^(C)		0.1				
	Dissolved Oxygen ⁽³⁾	mg/L	n/a	1	n/a	^(d)						<u> </u>
General Chemistry, EPA 120.1	Conductivity	µmhos/cm	n/a	1.00	n/a	^(d)						
General Chemistry, EPA 1664	Oil & Grease	mg/L	1.40	5.00	n/a	^(c)	10	15	15	15		<u> </u>
General Chemistry, EPA 180.1	Turbidity	NTU	0.0400	0.100	n/a	(d)						

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				TestAmerica	SWRCB	Laboratory	Monthly Average Limits	Daily Maximum Limits	Daily Maximum Limits	Daily Maximum Limits	Receiving Water Limits	Receiving Water Sediment Limits
Method	Analyte	Units	Laboratory 2018 MDL	Laboratory 2018 RL	ML	vs ML ⁽¹⁾	019, 020	001, 002 011, 018	003-007, 009, 010	008	Arroyo Simi	Arroyo Sim
General Chemistry, EPA 300	Chloride	mg/L	0.250	0.500	n/a	(c)		150	150	150		
<i>,</i> ,	Nitrate + Nitrite as Nitrogen (N)	mg/L	0.070	0.15	n/a	^(c)		8	10	8		
	Nitrate - N	mg/L	0.0550	0.110	n/a	^(c)		8		8		
	Nitrite - N	mg/L	0.0700	0.150	n/a	^(C)		1		1		
	Sulfate	mg/L	0.250	0.500	n/a	^(c)		300	250	300		
General Chemistry, SM2540C	Total Dissolved Solids	mg/L	5.00	10.0	n/a	(c)		950	850	950		
General Chemistry, SM2540D	Total Suspended Solids	mg/L	0.500	1.00	n/a	(c)	15	45				
General Chemistry, SM2540F	Settleable Solids	ml/L	n/a	0.100	n/a	^(c)	0.1	0.3				
General Chemistry, SM4500F-C	Fluoride	mg/L	0.250	0.500	n/a	^(c)		1.6	1.6	1.6		
General Chemistry, SM4500-NH3	Ammonia – N	mg/L	0.100	0.200	n/a	^(c)	1.96	10.1		10.1		
General Chemistry, SM5210B	Biochemical Oxygen Demand (BOD)(5-Day @ 20 deg. C)	mg/L	0.500	2.00	n/a	^(c)	20	30				
General Chemistry, SM5310B	Total Organic Carbon	mg/L	0.650	1.00	n/a	^(d)						
General Chemistry, SM5540	Detergents (as MBAS)	mg/L	0.0500	0.100	n/a	^(c)		0.5				
Radiochemistry	Uranium	pCi/L	n/a	1.00 ⁽⁴⁾	n/a	^(c)		20	20	20		
Radiochemistry, EPA 900	Gross Alpha	pCi/L	n/a	3.00 (4)	n/a	^(c)		15	15	15		
**	Gross Beta	pCi/L	n/a	4.00 (4)	n/a	^(c)		50	50	50		
Radiochemistry, EPA 901.1	Cesium-137	pCi/L	n/a	20.0 ⁽⁴⁾	n/a	(c)		200	200	200		
	Potassium-40	pCi/L	n/a	200 (4)	n/a	^(d)						
Radiochemistry, EPA 903/904	Combined Radium-226 & Radium-228	pCi/L	n/a	n/a	n/a	(e)		5.0	5.0	5.0		
Radiochemistry, EPA 905.0	Strontium-90	pCi/L	n/a	3.00 (4)	n/a	^(c)		8.0	8.0	8.0		
Radiochemistry, EPA 906.0	Tritium	pCi/L	n/a	500 ⁽⁴⁾	n/a	^(c)		20000	20000	20000		

TABLE G ANNUAL LIST OF ANALYTICAL METHODS BY ANALYTE WITH CORRESPONDING LABORATORY REPORTING LIMITS AND METHOD DETECTION LIMITS

FIRST QUARTER 2018 NPDES PERMIT CA0001309 THE BOEING COMPANY **VENTURA COUNTY, CALIFORNIA**

									Permit	Limits (PL)		
Method			TestAmerica Tes Units Laboratory La		SWRCB	Laboratory	Monthly Average Limits	Daily Maximum Limits	Daily Maximum Limits	Daily Maximum Limits	Receiving Water Limits	Receiving Water Sediment Limits
	Analyte	Units	Laboratory 2018 MDL	2018 RL	ML	vs ML ⁽¹⁾	019, 020	001, 002 011, 018	003-007, 009, 010	008	Arroyo Simi	Arroyo Simi
8315M (Truesdail Lab)	Monomethyl hydrazine	µg/L	0.245	10.0	n/a	^(d)						
Toxicity (Aquatic Lab), EPA 1002	Chronic Toxicity	Pass or Fail, % Effect	n/a	n/a	n/a	(e)	Pass or Fail	Pass or % Effect <50	Pass or % Effect <50	Pass or % Effect <50		
Biological, SM9221F	E. Coli	MPN/100ml	n/a	1.80	n/a	(c)					235	

Notes:

Benchmark limitations: Outfalls 001, 002 Compliance limitations: Outfalls 003-011, 018-020

Columns are used to compare laboratory's reporting limits (RLs) and method detection limits (MDLs) to the SWRCB Minimum Levels (MLs) and the permit limits (PLs).

(1) This column indicates the status of analytical capabilities if the ML is less than the laboratory RL and/or MDL. See explanation for "--" below.

The following designations summarize the comparison of RLs, MDLs, MLs, and permit limits:

-- = Laboratory reporting limit meets ML if applicable and permit limit requirements

- --^(a) Laboratory reporting limit or method detection limit meets ML and permit limit requirements
- --^(b) Laboratory reporting limit or method detection limit meets ML. This analyte has no permit limit requirements.
- --^(c) Laboratory reporting limit or method detection limit meets permit limit. This analyte has no ML.
- --^(d) This analyte has no ML or permit limit.
- --^(e) This analyte is a calculation or chronic toxicity and does not have a reporting limit. This calculation or chronic toxicity has no ML.
- --^(f) This analyte has no ML. Laboratory reporting limit or method detection limit does not meet permit limit.
- --⁽⁹⁾ Laboratory reporting limit or method detection limit meets ML, but does not meet permit limit requirements

The receiving water sediment limits do not have a ML and are included for reference only.

(2) The RL and MDL for asbestos varies based upon the sample.

(3) Total residual chlorine (TRC) and dissolved oxygen (DO) are measured in the field. The RL is the lowest limit of the instrument. The MDL is not relevant for field parameters.

(4) This value is the minimum detectable activity (MDA) which applies only to radiological constituents.

Acronyms:

MFL = million fibers per liter mg/L = milligrams per liter MPN = most probable number per 100 milliliters pCi/L = picoCuries per liter SWRCB = State Water Resources Control Board

TIC = tentatively identified compound

 $\mu g/L = micrograms per liter$

- µg/g = micrograms per gram
- n/a = not applicable



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Quality Assurance Manual Cover Page

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Title Page:

Quality Assurance Manual Approval Signatures

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Date

03/14/17

Date

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REFERENCED CORPORATE SOPS AND POLICIES

SOP / Policy Reference	Title
CA-I-P-002	Electronic Reporting and Signature Policy
CA-L-P-002	Contract Compliance Policy
CA-L-S-002	Subcontracting Procedures
CA-Q-M-002	Corporate Quality Management Plan
CA-Q-S-001	Solvent and Acid Lot Testing and Approval
CA-Q-S-002	Acceptable Manual Integration Practices
CA-Q-S-006	Detection Limits
CA-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	Capital Expenditure, Controlled Purchase Requests and Fixed Asset Capitalization
CW-L-P-004	Ethics Policy
CW-L-S-002	Internal Investigation
CW-Q-S-001	Corporate Document Control and Archiving

SOP / Policy Reference	Title	
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	
CA-C-S-001	Work Sharing Process	

REFERENCED LABORATORY SOPs

SOP Reference	Title
IR-QA-DOC	Document Control and Review
IR-QA-CNTRLLIM	Control Charts and Statistical Process Control
IR-QA-ARCH	Record Archiving
IR-IT-COMPUSEC	Computer Security and Software Maintenance
IR-QA-BAL	Balance Calibration, Verification and Documentation
IR-QA-THERMA	Thermometer Calibration, Temperature Monitoring, and Documentation
IR-QA-PIPET	Pipette, Syringe, and Dispenser Calibration
IR-MICRO-AUTOCLAVE	Microbiological Sterilization Equipment – Autoclave
IR-QA-TRAIN	Training and Documentation
IR-QA-MDL	Determination of Method Detection Limits
IR-QA-LOTTEST	Container and Reagent Verification by Lot Testing
IR-QA-STDCNTRL	Reagent and Standard Preparation, Control and Documentation
IR-SC-FIELD	Field Sampling and Testing
IR-QA-SUBSAMP	Subsampling, Compositing and Homogenization
IR-SC-LOGIN	Sample Login
IR-EHS-WASTE	Hazardous Waste Disposal

SECTION 3. INTRODUCTION, SCOPE AND APPLICABILITY

3.1 Introduction and Compliance References

TestAmerica Irvine'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 17025:2005(E). 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:

- ANSI/ASQC, E4-1994, "Specifications and Guidelines for Quality Management Systems for Environmental Data Collection and Environmental Technology Programs" (American National Standard, January 5, 1995, or most recent version).
- "EPA Requirements for Quality Management Programs" (QA/R-2) (EPA/240/B-01/002, May 31, 2006).
- EPA 600/4-88/039, 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.
- <u>Test Methods for Evaluating Solid Waste Physical/Chemical Methods (SW846)</u>, Third Edition, September 1986, Final Update I, July 1992, Final Update IIA, August 1993, Final Update II, September 1994; Final Update IIB, January 1995; Final Update III, December 1996; Final Update IV, January 2008; Final Update V, August 2015.
- Federal Register, 40 CFR Parts 136, 141, 172, 173, 178, 179 and 261.
- Manual for the Certification of Laboratories Analyzing Drinking Water (EPA 815-R-05-004, January 2005).
- <u>Statement of Work for Inorganics & Organics Analysis</u>, SOM and ISM, current versions, USEPA Contract Laboratory Program Multi-media, Multi-concentration.
- APHA, Standard Methods for the Examination of Water and Wastewater, 18th Edition, 19th, 20th, 21st, and on-line Editions.
- Toxic Substances Control Act (TSCA).

3.2 <u>Terms and Definitions</u>

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 <u>Scope / Fields of Testing</u>

The laboratory analyzes a broad range of environmental and industrial samples every month. Sample matrices vary among air, drinking water, effluent water, groundwater, hazardous waste, sludge and soils. The Quality Assurance Program contains specific procedures and methods to test samples of differing matrices for chemical, physical and biological parameters. The Program also contains guidelines on maintaining documentation of analytical processes, reviewing results, servicing clients and tracking samples through the laboratory. The technical and service requirements of all analytical requests are thoroughly evaluated before commitments are made to accept the work. Measurements are made using published reference methods or methods developed and validated by the laboratory.

The methods covered by this manual include the most frequently requested methodologies needed to provide analytical services in the United States and its territories. The specific list of test methods used by the laboratory can be found the laboratory's network shared folder Irvine-QA. 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 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.

3.4 Management of the Manual

3.4.1 <u>Review Process</u>

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 annually 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 and Review procedures (refer to SOP No. IR-QA-DOC).

SECTION 4. MANAGEMENT REQUIREMENTS

4.1 <u>Overview</u>

TestAmerica Irvine is a local operating unit of TestAmerica Laboratories, Inc. The organizational structure, responsibilities and authorities of the corporate staff of TestAmerica Laboratories, Inc. are presented in the CQMP. The laboratory has day-to-day independent operational authority overseen by corporate officers (e.g., 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 Irvine is presented in Figure 4-1.

4.2 Roles and Responsibilities

In order for the Quality Assurance Program to function properly, all members of the staff must clearly understand and meet their individual responsibilities as they relate to the quality program. The following descriptions briefly define each role in its relationship to the Quality Assurance Program.

4.2.1 Additional Requirements for Laboratories

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

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 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 oversees the operations of all TestAmerica laboratories and the EMLab P&K business unit. The VP's of Operations report directly to COO.

4.2.4 <u>Vice President of Operations</u>

Each VP of Operations reports directly to the Executive VP of Operations and is a part of the Executive Committee. Each VP of Operations is responsible for the overall administrative and operational management of their respective laboratories. The VP's responsibilities include allocation of personnel and resources, long-term planning, goal setting, and achieving the financial, business, and quality objectives of TestAmerica. The VP's ensure timely compliance

with Corporate Management directives, policies, and management systems reviews. The VP'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.

4.2.5 <u>Vice President of Quality and Environmental Health and Safety (VP-QA/EHS)</u>

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 Manager, 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.
- Preparation of a monthly report that includes quality metrics across the analytical laboratories and a summary of any quality related initiatives and issues.
- Preparation of a monthly report that includes EH&S metrics across the analytical laboratories and a summary of any EH&S related initiatives and issues.
- Work with various organizations outside of TestAmerica to further the development of quality standards and represent TestAmerica at various trade meetings.
- With the assistance of the Corporate Senior Management Teams and the EHS Director, development and implementation of the TestAmerica Environmental, Health and Safety Program.

4.2.6 Vice President of Client Service

The VP of Client Services leads the Client Service Organization (CSO) and is responsible for client satisfaction, driving operational excellence and improving client responsiveness. The VP provides direction to the Client Service Directors, Programs Managers and Project Managers.

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; 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;

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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 <u>Quality Systems Director</u>

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 <u>Technical Services Director</u>

The Technical Services Director is responsible for establishing, implementing and communicating TestAmerica's Analytical Business's 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) – 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 laboratories 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 internal and external 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 <u>Laboratory Director</u>

TestAmerica Irvine'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 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:

- Provide one or more technical managers for the appropriate fields of testing. If the Technical Manager is absent for a period of time exceeding 15 consecutive calendar days, the Laboratory Director must designate another full time staff member meeting the qualifications of the Technical Manager to temporarily perform this function. If the absence exceeds 65 consecutive calendar days, the primary accrediting authority must be notified in writing.
- Ensure that all analysts and supervisors have the appropriate education and training to properly carry out the duties assigned to them and ensure that this training has been documented.
- Ensure that personnel are free from any commercial, financial and other undue pressures which might adversely affect the quality of their work.
- Ensure TestAmerica's human resource policies are adhered to and maintained.
- Ensure that sufficient numbers of qualified personnel are employed to supervise and perform the work of the laboratory.
- Ensure 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.
- Review and approve all SOPs prior to their implementation and ensures all approved SOPs are implemented and adhered to.
- Pursue and maintain appropriate laboratory certification and contract approvals. Support ISO 17025 requirements.
- Ensure client specific reporting and quality control requirements are met.
- Captain the management team, consisting of the QA Manager and the Technical Manager(s) as direct reports.
- Evaluate the level of internal/external non-conformances for all departments.
- Continuously evaluate production capacity and improve capacity utilization.
- Continuously evaluate turnaround time and address any problems that may hinder meeting the required and committed turnaround time from the various departments.
- Develop and improve the training of all analysts in cooperation with the Technical Manager and QA Manager and in compliance with regulatory requirements.
- Ensure that scheduled instrument maintenance is completed.
- Manage efficient utilization of supplies.
- Constantly monitor and modify the processing of samples through the departments.

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. 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 also directs the activities of the QA officers.

Specific responsibilities include, but are not limited to:

- Serve as the focal point for QA/QC in the laboratory.
- Have functions independent from laboratory operations for which he/she has quality assurance oversight.
- Maintain and update this Quality Assurance Manual (QAM).
- Monitor and evaluate laboratory certifications; scheduling proficiency testing samples.
- Monitor and communicate regulatory changes that may affect the laboratory to the management.
- Train and advise the laboratory staff on quality assurance/quality control procedures that are pertinent to their daily activities.
- Have documented training and/or experience in QA/QC procedures and the laboratory's Quality System.
- Have a general knowledge of the analytical test methods for which data audit/review is performed (and/or have the means of getting this information when needed).
- Arrange for or conduct internal audits on quality systems and the technical operation.
- 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.
- Notify the laboratory management of deficiencies in the quality system and ensure corrective action is taken. Procedures that do not meet the standards set forth in the QAM or laboratory SOPs shall be investigated following procedures outlined in Section 12 and if deemed necessary may be temporarily suspended during the investigation.
- Objectively monitor standards of performance in quality control and quality assurance without outside (e.g., managerial) influence.
- Coordinate document control of SOPs, MDLs, control limits, and miscellaneous forms and information.
- Review a percentage of all final data reports for internal consistency. Review Chain of Custody (COC) records, correspondence with the analytical request, batch QC status, and completeness of any corrective action statements. Evaluate manual calculations, format, holding time, sensibility and completeness of the project file contents.
- Review external audit reports and data validation requests.
- Follow-up with audits to ensure regulatory and/or client QAPP requirements are met.
- Establish reporting schedule and prepare various quality reports for the Laboratory Director, clients and/or Corporate QA.

- Develop suggestions and recommendations to improve quality systems.
- Research current state and federal requirements and guidelines.
- Captain the QA team to enable communication and to distribute duties and responsibilities.
- Communicate and monitor standards of performance to ensure that systems are in place to produce the level of quality as defined in this document.
- Notify the laboratory management of deficiencies in the quality system and ensure corrective action is taken. Procedures that do not meet the standards set forth in the QAM or laboratory SOPs are temporarily suspended following the procedures outlined in Section 12.
- Evaluate the thoroughness and effectiveness of training.
- Ensure compliance with ISO 17025 (where applicable).

4.2.17 <u>Technical Manager or Designee</u>

The Technical Manager(s) report(s) directly to the Laboratory Director. The Technical Manager is accountable for all analyses and analysts under their experienced supervision and for compliance with the ISO 17025 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:

- Exercise day-to-day supervision of laboratory operations for the appropriate field of accreditation and reporting of results. Coordinate, write, and review the preparation of all test method 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. Ensures that the SOPs are properly managed and adhered to at the bench. Develop standard costing of SOPs to include supplies, labor, overhead, and capacity (design vs. demonstrated versus first-run yield) utilization.
- Review and approve, 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, and 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.
- Monitor the validity of the analyses performed and data generated in the laboratory. This
 activity begins with reviewing and supporting all new business contracts, ensuring 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.

- Provide training and development programs to applicable laboratory staff as new hires and, subsequently, on a scheduled basis. Training includes instruction on calculations, instrumentation management, troubleshooting and preventive maintenance.
- Enhance efficiency and improve quality through technical advances and improved LIMS utilization. Perform capital forecasting and instrument life cycle planning for second generation methods and instruments as well as asset inventory management.
- Coordinate sample management from "cradle to grave," and ensure no time is lost in locating samples.
- Schedule all QA/QC related requirements for compliance, e.g., MDLs, etc.
- Captain department personnel to communicate quality, technical, personnel, and instrumental issues for a consistent team approach.
- Coordinate audit responses with the QA Manager.
- Ensure compliance with ISO 17025 (where applicable).

4.2.18 <u>Hazardous Waste Coordinator</u>

The Hazardous Waste Coordinator reports directly to the Laboratory Director.

Specific responsibilities include, but are not limited to:

- Stay current with the hazardous waste regulations.
- Continue training on hazardous waste issues.
- Review and update annually the Hazardous Waste Contingency Plan in the Environmental Health & Safety Manual.
- Audit the staff with regard to compliance with the Hazardous Waste Contingency Plan.
- Contact the hazardous waste subcontractors for review of procedures and opportunities for minimization of waste.

4.2.19 <u>Supervisors</u>

Supervisors report to the Technical Managers.

Specific responsibilities include, but are not limited 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.
- Participate in the selection, training (as documented in Section 8.1), development of performance objectives and standards of performance, appraisal (measurement of objectives), scheduling, counseling, discipline, and motivation of analysts, and document these activities in accordance with systems developed by the QA and Personnel

Departments. Evaluate staffing sufficiency and overtime needs. Conduct trainings consisting 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 preparation/analysis in conjunction with the Technical Manager, Operations Manager, and/or QA Manager. Each is responsible for 100% of the data review and documentation, non-conformance and CPAR issues, the timely and accurate completion of performance evaluation samples and MDLs, for his/her department.
- Ensure all logbooks are maintained, current, and properly labeled or archived.
- Report all non-conformance conditions to the QA Manager, Technical Manager, Operations Manager, and/or Laboratory Director.
- Ensure that preventive maintenance is performed on instrumentation as detailed in the QA Manual or SOPs. Develop and implement 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.

4.2.20 Laboratory Analysts

Laboratory analysts are responsible for conducting analysis and performing all tasks assigned to them by the group leader or supervisor. Specific responsibilities include, but are not limited to:

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

- Perform 100% review of the data generated prior to entering and submitting for secondary level review.
- Suggest method improvements to their supervisor, the Technical Manager, and the QA Manager. These improvements, if approved, will be incorporated. Ideas for the optimum performance of their assigned area, for example, through the proper cleaning and maintenance of the assigned instruments and equipment, are encouraged.
- Work cohesively as a team in their department to achieve the goals of accurate results, optimum turnaround time, cost effectiveness, cleanliness, complete documentation, and personal knowledge of environmental analysis.
- Work Cell: A "work cell" is considered to be all those individuals who see a sample through the complete process of preparation, extraction, and analysis. To ensure that the entire preparation, extraction, and analysis process is completed by a group of capable individuals, the laboratory shall ensure that each member of the work cell (including a new member entering an already existing work cell) demonstrates capability in his/her area of responsibility in the sequence. Even though the work cell operates as a "team," the demonstration of capability at each individual step in the sequence, as performed by each individual analyst/team member, remains of utmost importance. A work cell may NOT be defined as a group of analysts who perform the same step in the same process (for example, extractions for Method 8270), represented by one analyst who has demonstrated capability for that step.

4.2.21 Safety Officer or EHS Coordinator

The Safety Officer reports to the Laboratory Director and ensures that systems are maintained for the safe operation of the laboratory.

Specific responsibilities include, but are not limited to:

- Conduct ongoing, necessary safety training and conduct new employee safety orientation.
- Assist in developing and maintaining the Chemical Hygiene/Safety Manual.
- Administer dispersal of all Safety Data Sheet (SDS) information.
- Perform regular chemical hygiene and housekeeping instruction.
- Give instruction on proper labeling and practice.
- Serve as chairman of the laboratory safety committee.
- Provide and train personnel on protective equipment.
- Oversee the inspection and maintenance of general safety equipment fire extinguishers, safety showers, eyewash fountains, etc. and ensure prompt repairs as needed.
- Supervise and schedule fire drills and emergency evacuation drills.
- Determine what initial and subsequent exposure monitoring, if necessary to determine potential employee exposure to chemicals used in the laboratory.
- When determined necessary, conduct exposure monitoring assessments.

- Determine when a complaint of possible over-exposure is "reasonable" and should be referred for medical consultation.
- Assist in the internal and external coordination of the medical consultation/monitoring program conducted by TestAmerica's medical consultants.

4.2.22 <u>Sample Control Manager</u>

The Sample Control Manager reports to the Laboratory Director and is responsible for the daily activities within the Sample Control department.

Specific responsibilities include, but are not limited to:

- Supervise the courier scheduling, initiation of container lot testing, sample container order preparation, sample receiving and tracking, shipping, login, and other sample management activities.
- Ensure timely and correct shipment of sample containers, including proper preservatives and instructions, to clients. Maintain accurate records of sample container shipments.
- Ensure that all tasks performed by the department are conducted according to the requirements of the QAM, laboratory SOPs, policies, and QAPPs (if applicable).
- Perform frequent SOP reviews to ensure that current practices are consistent with the published SOP. Changes in procedures or deviations from the SOP must be immediately reported to the Operations Manager and the QA Manager for approval and update to the applicable SOP.
- Assist PMs and analysts in resolving inconsistencies and problems with samples received.
- Assist in routing workshare and subcontract analyses.
- Report nonconforming situations to the Operations Manager and the QA Manager.
- Provide written responses to external and internal audit issues.
- Identify, initiate, and implement corrective actions through root-cause analysis and investigations.

4.2.23 Manager of Project Management (MPM)

The Manager of Project Management reports directly to the Client Service Director (Western Region) and indirectly to the Laboratory Director. The Manager of Project Management serves as the interface between the laboratory's Project Management team, technical departments, and clients.

Specific responsibilities include, but are not limited to:

- Oversee training and growth of the Project Management team.
- Act as technical liaison for the Project Management team.
- Provide human resource management support to the Project Management team.
- Assist PMs with responses to client inquiries or with resolutions to problems or complaints.

• Prepare price quotes or project bids.

4.2.24 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 clients. There is an entire staff of Project Managers that makes up the Project Management team with the overall goal of total client satisfaction.

Specific responsibilities include, but are not limited to:

- Ensure that clients receive the proper sampling supplies.
- Is accountable for response to client inquiries concerning sample status.
- Assist clients regarding the resolution of problems concerning COC.
- Ensure that client specifications, when known, are met by communicating project and quality assurance requirements to the laboratory.
- Notify the supervisors of incoming projects and sample delivery schedules.
- Is accountable to clients for communicating sample progress in daily status meeting with agreed-upon due dates.
- Discuss with client any project-related problems, resolve service issues, and coordinate technical details with the laboratory staff.
- Is responsible for staff familiarization with specific quotes, sample log-in review, and final report completeness.
- Monitor the status of all data packages 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).

4.2.25 <u>Sample Archiving/Disposal Technician</u>

The Sample Archiving/Disposal Technician reports to the Laboratory Director.

Specific responsibilities include, but are not limited to:

- Manage facility maintenance.
- Supervise the organized storage and appropriate climate control of samples.
- Supervise the disposal of samples in accordance with the Waste Disposal SOP, the Hazardous Waste Contingency Plan in the Chemical Hygiene/Safety Manual, and the U. S. Department of Agriculture requirements.

4.3 <u>Deputies</u>

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

Key Personnel	Deputy
Linda Scharpenberg	Fred Haley
Laboratory Director	VP Operations, West Region
Kathryn Chang	David Dawes
Quality Assurance Manager	Quality Assurance Specialist
Robert Culver	Compton Persaud
Volatiles Department Manager	Volatiles Department Supervisor
Robert Culver	Robert Culver
Semi-Volatile Department Manager	Volatiles Department Manager
Adriana Schow	Ethan Nguyen
Metals Department Manager	Metals Department Supervisor
Adriana Schow	Sarah Tan
Microbiology Department Manager	Microbiology Department Supervisor
Tung Nguyen	Nicole Nickloff
Wet Chemistry Department Manager	Wet Chemistry Department Supervisor
Roger Hoover	Linda Scharpenberg
Environmental Health and Safety Manager	Laboratory Director
Urvashi Patel	Camille Murray
Manager of Project Management	Manager of Project Management Assistants

4

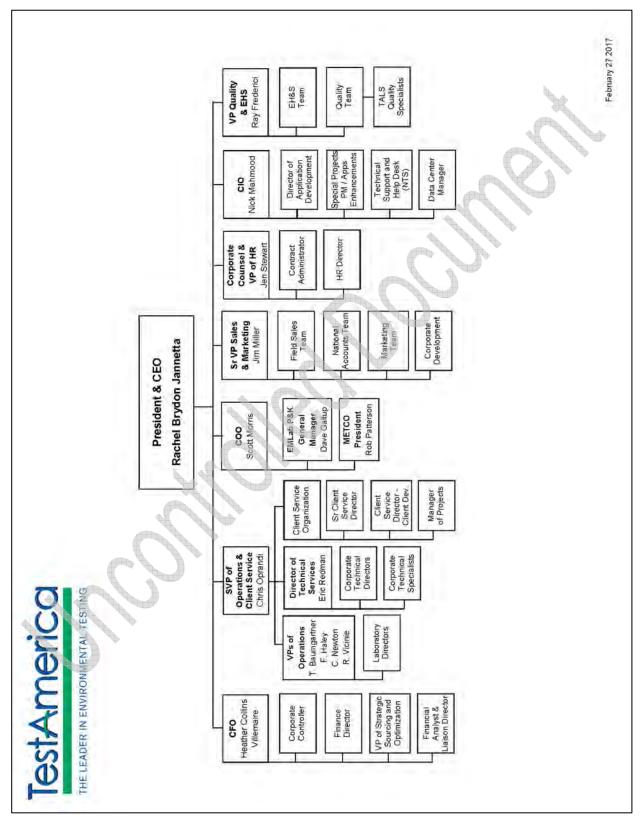


Figure 4-1. Corporate and Laboratory Organization Charts

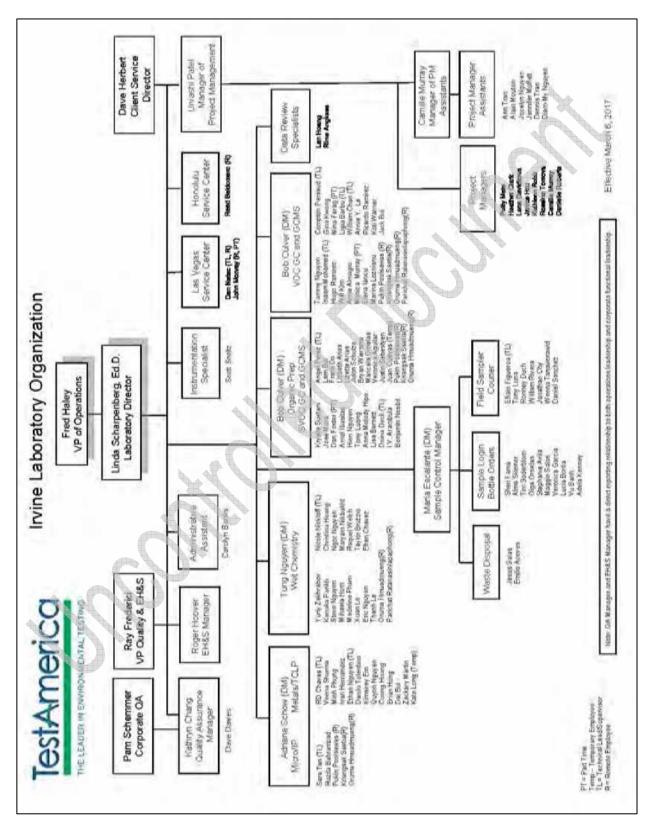


Figure 4-1. Corporate and Laboratory Organization Charts (Cont.)

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 17025:2005(E) International Standard, the 2009 TNI Standard and to continually improve the effectiveness of the management system.

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

5.2 <u>Ethics and Data Integrity</u>

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 No. CA-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 predefined Data Quality Objectives (DQOs).
- Present services in a confidential, honest and forthright manner.

- Provide employees with guidelines and an understanding of the Ethical and Quality Standards of our Industry.
- Operate our facilities in a manner that protects the environment and the health and safety of employees and the public.
- Obey all pertinent federal, state and local laws and regulations and encourage other members of our industry to do the same.
- Educate clients as to the extent and kinds of services available.
- Assert competency only for work for which adequate personnel and equipment are available and for which adequate preparation has been made.
- Promote the status of environmental laboratories, their employees, and the value of services rendered by them.

5.3 Quality System Documentation

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

- <u>Quality Assurance Manual</u> Each laboratory has a lab-specific quality assurance manual.
- <u>Corporate SOPs and Policies</u> 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.
- <u>Work Instructions</u> A subset of procedural steps, tasks or forms associated with an operation of a management system (e.g., checklists, preformatted bench sheets, forms).
- Laboratory SOPs General and Technical.
- Laboratory QA/QC Policy Memorandums.

5.3.1 Order of Precedence

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

- Corporate Quality Management Plan (CQMP)
- Corporate SOPs and Policies
- Laboratory QA/QC Policy Memorandum
- Laboratory Quality Assurance Manual (QAM)
- Laboratory SOPs and Policies
- Other (Work Instructions (WI), memos, flow charts, etc.)

Note: The laboratory has the responsibility and authority to operate in compliance with regulatory requirements of the jurisdiction in which the work is performed. Where the CQMP conflicts with those regulatory requirements, the regulatory requirements of the jurisdiction shall hold primacy. The laboratory's QAM shall take precedence over the CQMP in those cases.

5.4 QA/QC Objectives for the Measurement of Data

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

Quality Control is generally understood to be limited to the analyses of samples and to be synonymous with the term *"analytical quality control"*. QC refers to the routine application of statistically based procedures to evaluate and control the accuracy of results from analytical measurements. The QC program includes procedures for estimating and controlling precision and bias and for determining reporting limits.

Request for Proposals (RFPs) and Quality Assurance Project Plans (QAPP) provide a mechanism for the client and the laboratory to discuss the data quality objectives in order to ensure that analytical services closely correspond to client needs. The client is responsible for developing the QAPP. In order to ensure the ability of the laboratory to meet the Data Quality Objectives (DQOs) specified in the QAPP, clients are advised to allow time for the laboratory to review the QAPP before being finalized. Additionally, the laboratory will provide support to the client for developing the sections of the QAPP that concern laboratory activities.

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

5.4.1 <u>Precision</u>

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 <u>Accuracy</u>

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 <u>Representativeness</u>

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 <u>Comparability</u>

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 <u>Completeness</u>

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 <u>Selectivity</u>

Selectivity is defined as: The capability of a test method or instrument to respond to a target substance or constituent in the presence of non-target substances. Target analytes are separated from non-target constituents and subsequently identified/detected through one or more of the following, depending on the analytical method: extractions (separation), digestions (separation), interelement corrections (separation), use of matrix modifiers (separation), specific retention times (separation and identification), confirmations with different columns or detectors (separation and identification), specific wavelengths (identification), specific mass spectra (identification), specific electrodes (separation and identification), etc.

5.4.7 Sensitivity

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

5.5 <u>Criteria for Quality Indicators</u>

The laboratory maintains a Quality Control Limit Summary that contains tables (or however named) 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 is contained in the laboratory SOP No. IR-QA-CNTRLLIM.

5.6 <u>Statistical Quality Control</u>

Statistically-derived precision and accuracy limits are required by selected methods (such as SW-846) and programs. The laboratory routinely utilizes statistically-derived limits to evaluate method performance and determine when corrective action is appropriate. The analysts are instructed to use the current limits in the laboratory (dated and approved by the Technical Manager and QA Manager) and entered into the Laboratory Information Management System (LIMS). The Quality Assurance department maintains an archive of all limits used within the laboratory *via the LIMS historical limit group database*. If a method defines the QC limits, the method limits are used.

If a method requires the generation of historical limits, the lab develops such limits from recent data in the QC database of the LIMS following the guidelines described in Section 24. All calculations and limits are documented and dated when approved and effective. On occasion, a client requests contract-specified limits for a specific project.

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

5.6.1 <u>QC Charts</u>

When QC limits are calculated, QC charts are generated showing warning and control limits for the purpose of evaluating trends. The QA Manager evaluates these to determine if adjustments need to be made or for corrective actions to methods. All findings are documented and kept on file. Refer to laboratory SOP No. IR-QA-CNTRLLIM for more details regarding generation of control limits and development of control charts.

5.7 Quality System Metrics

In addition to the QC parameters discussed above, the entire Quality System is evaluated on a monthly basis through the use of specific metrics (refer to Section 16). These metrics are used to drive continuous improvement in the laboratory's Quality System.

SECTION 6. DOCUMENT CONTROL

6.1 <u>Overview</u>

The QA Department is responsible for the control of documents used in the laboratory to ensure that approved, up-to-date documents are in circulation and out-of-date (obsolete) documents are archived or destroyed. The following documents, at a minimum, must be controlled:

- Laboratory Quality Assurance Manual
- Laboratory Standard Operating Procedures (SOP)
- Laboratory Policies
- Work Instructions and Forms
- Corporate Policies and Procedures distributed outside the intranet

Corporate Quality posts Corporate Manuals, SOPs, Policies, Work Instructions, White Papers and Training Materials on the company intranet site. These Corporate documents are only considered controlled when they are read on the intranet site. Printed copies are considered uncontrolled unless the laboratory physically distributes them as controlled documents. A detailed description of the procedure for issuing, authorizing, controlling, distributing, and archiving Corporate documents is found in Corporate SOP No. CW-Q-S-001, Corporate Document Control and Archiving. The laboratory's internal document control procedure is defined in the laboratory SOP No. IR-QA-DOC.

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. 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, the Department Manager or Supervisor 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 (may include electronic access). Controlled documents are identified as such and records of their distribution are kept by the QA Department. Document control may be achieved by either electronic or hardcopy distribution.

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

Quality System Policies and Procedures will be reviewed at a minimum of every two years and revised as appropriate. Quality System Policies and Procedures that affect Drinking Water projects will be reviewed annually and revised as appropriate. Changes to documents occur when a procedural change warrants.

6.3 <u>Procedures for Document Control Policy</u>

For changes to the QA Manual, refer to the procedure outlined in Section 3.4 of this manual. 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 QA folder (or define location) for the applicable revision.

For changes to SOPs, refer to Corporate SOP No. CW-Q-S-002, Writing a Standard Operating Procedure SOP and the laboratory SOP No. IR-QA-DOC. The SOPs identified above also defines the process of changes to SOPs.

Forms, worksheets, work instructions and information are organized in the file cabinet of the QA department. Electronic versions are kept in the network shared folder Irvine-QA. The procedure for the care of these documents is in the laboratory SOP No. IR-QA-DOC.

6.4 <u>Obsolete Documents</u>

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 the laboratory SOP No. IR-QA-ARCH.

SECTION 7. SERVICE TO THE CLIENT

7.1 <u>Overview</u>

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 <u>Review Sequence and Key Personnel</u>

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 laboratory 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 laboratory 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 Manager of Project Management
- Laboratory Project Manager
- Laboratory and/or Corporate Technical Managers
- Laboratory 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.

The Contracts Department maintains copies of all signed contracts. A copy is also maintained by the assigned Laboratory Project Manager.

7.3 Documentation

Appropriate records are maintained for every contract or work request. All stages of the contract review process are documented and include records of any significant changes. These records are kept on file with the assigned laboratory Project Manager.

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 Project Manager 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 Project Manager keeps a phone log or e-mail documentation of conversations with the client. These documentations are kept on file and become part of the project records.

7.3.1 <u>Project-Specific Quality Planning</u>

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 production meetings. Such changes are updated to the project notes or work instructions and are introduced to the managers at these meetings. The laboratory staff is then introduced to the modified requirements via the PM or the individual laboratory Technical Manager. After the modification is implemented into the laboratory process, documentation of the modification is made in the case narrative of the data report(s).

The laboratory strongly encourages client visits to the laboratory and for formal/informal information sharing session with employees in order to effectively communicate ongoing client needs as well as project specific details for customized testing programs.

7.4 Special Services

The laboratory cooperates with clients and their representatives to monitor the laboratory's performance in relation to work performed for the client. It is the laboratory's goal to meet all client requirements in addition to statutory and regulatory requirements. The laboratory has procedures to ensure confidentiality to clients (Section 15 and 25).

The laboratory's standard procedures for reporting data are described in Section 25. Special services are also available and provided upon request. These services include:

- Reasonable access for our clients or their representatives to the relevant areas of the laboratory for the witnessing of tests performed for the client.
- Assist client-specified third party data validators as specified in the client's contract.
- Supplemental information pertaining to the analysis of their samples.

Note: An additional charge may apply for additional data/information that was not requested prior to the time of sample analysis or previously agreed upon.

7.5 <u>Client Communication</u>

Project Managers are the primary communication link to the clients. They shall inform their clients of any delays in project completion as well as any non-conformances in either sample receipt or sample analysis. Project Management will maintain ongoing client communication throughout the entire client project.

Technical Managers, QA Manager, and Laboratory Director are available to discuss any technical questions or concerns that the client may have.

7.6 <u>Reporting</u>

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

7.7 <u>Client Surveys</u>

The laboratory assesses both positive and negative client feedback. The results are used to improve overall laboratory quality and client service. TestAmerica's Sales and Marketing teams periodically develops laboratory and client specific surveys to assess client satisfaction.

SECTION 8. SUBCONTRACTING OF TESTS

8.1 <u>Overview</u>

For the purpose of this quality manual, the phrase subcontract laboratory refers to a laboratory external to the TestAmerica laboratories. The phrase "work sharing" refers to internal transfers of samples between the TestAmerica laboratories. The term outsourcing refers to the act of subcontracting tests.

When contracting with our clients, the laboratory makes commitments regarding the services to be performed and the data quality for the results to be generated. When the need arises to outsource testing for our clients because project scope, changes in laboratory capabilities, capacity or unforeseen circumstances, we must be assured that the subcontractors or work sharing laboratories understand the requirements and will meet the same commitments we have made to the client. Refer to TestAmerica's Corporate SOP's on Subcontracting Procedures (CA-L-S-002) 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), Client Relationship Managers or Account Executives (AE) (or others as defined by the laboratory) for the Export Lab (TestAmerica laboratory that transfers samples to another laboratory) are responsible for obtaining client approval prior to subcontracting any samples. The laboratory will advise the client of a subcontract arrangement in writing and when possible approval from the client shall be retained in the project folder. Standard TestAmerica Terms & Conditions include the flexibility to subcontract samples within the TestAmerica laboratories. Therefore, additional advance notification to clients for intra-laboratory subcontracting is not necessary unless specifically required by a client contract.

Note: In addition to the client, some regulating agencies (e.g., USDA) or contracts require notification prior to placing such work.

8.2 Qualifying and Monitoring Subcontractors

Whenever a PM [or Account Executive (AE) or Client Relationship Manager, etc.] becomes aware of a client requirement or laboratory need where samples must be outsourced to another laboratory, the other laboratory(s) shall be selected based on the following:

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

All TestAmerica laboratories are pre-qualified for work sharing provided they hold the appropriate accreditations, can adhere to the project/program requirements, and the client approved sending samples to that laboratory. The client must provide acknowledgement that the samples can be sent to that facility (an e-mail is sufficient documentation or if acknowledgement is verbal, the date, time, and name of person providing acknowledgement must be documented). The originating laboratory is responsible for communicating all technical,

quality, and deliverable requirements as well as other contract needs. (Corporate SOP No. CA-C-S-001, Work Sharing Process).

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

- **8.2.1** Once the appropriate accreditation and legal information is received by the laboratory, it is evaluated for acceptability (where applicable) and forwarded to the Corporate Quality Information Manager (QIM) for review. Once all documents are reviewed for completeness, the Corporate QIM will forward the documents to the Purchasing Manager for formal signature and contracting with the laboratory. The approved vendor will be added to the approved subcontractor list on the intranet site and the finance group is concurrently notified for JD Edwards.
- 8.2.2 The client will assume responsibility for the quality of the data generated from the use of a subcontractor they have requested the laboratory to use. The qualified subcontractors on the intranet site are known to meet minimal standards. TestAmerica does not certify laboratories. The subcontractor is on our approved list and can only be recommended to the extent that we would use them.
- 8.1.1
- **8.2.3** The status and performance of qualified subcontractors will be monitored periodically by the Corporate Contracts and/or Corporate Quality Departments. Any problems identified will be brought to the attention of TestAmerica's Corporate Finance or Corporate Quality personnel.
 - Complaints shall be investigated. Documentation of the complaint, investigation and corrective action will be maintained in the subcontractor's file on the intranet site. Complaints are posted using the Vendor Performance Report.
 - 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.

8.3 Oversight and Reporting

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

consent to the subcontract as appropriate, and provide the scope of work to ensure that the proper requirements are made a part of the subcontract and are made known to the subcontractor.

Prior to sending samples to the subcontracted laboratory, the PM confirms their certification status to determine if it's current and scope-inclusive. The information is documented within the project records. For TestAmerica laboratories, certifications can be viewed on the company's TotalAccess Database.

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

All subcontracted samples must be accompanied by a TestAmerica Chain of Custody (COC). A copy of the original COC sent by the client must be available in TestAmerica LIMS (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 laboratories EDD (i.e., imported), the report must explicitly indicate which laboratory produced the data for which methods and samples. A copy of the subcontracting laboratory's report must be included in the originating laboratory's final report, regardless of whether the subcontract laboratory's results are inserted into the originating laboratory's report.

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 laboratory 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 <u>Contingency Planning</u>

The Laboratory Director may waive the full qualification of a subcontractor process temporarily to meet emergency needs; however, this decision & justification must be documented in the project files, and the 'Purchase Order Terms And Conditions For Subcontracted Laboratory Services' must be sent with the samples and Chain-of-Custody. In the event this provision is utilized, the laboratory (e.g., PM) will be required to verify and document the applicable accreditations of the subcontractor. All other quality and accreditation requirements will still be applicable, but the subcontractor need not have signed a subcontract with TestAmerica at this

time. The comprehensive approval process must then be initiated within 30 calendar days of subcontracting.

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 guality critical consumables and equipment conform to specified requirements, which may affect quality, all purchases from specific vendors are approved by a member of the supervisory or management staff. Capital expenditures are made in accordance with TestAmerica's Capital Expenditure, Controlled Purchase Requests and Fixed Asset Capitalization, SOP No. CW-F-S-007.

Contracts will be signed in accordance with TestAmerica's Company-Wide Authorization Matrix Policy, Policy No. CW-F-P-002. Request for Proposals (RFP's) will be issued where more information is required from the potential vendors than just price. Process details are available in TestAmerica's Corporate Procurement and Contracts Policy (Policy No. CW-F-P-004). RFP's allow TestAmerica to determine if a vendor is capable of meeting requirements such as supplying all of the TestAmerica facilities, meeting required quality standards and adhering to necessary ethical and environmental standards. The RFP process also allows potential vendors to outline any additional capabilities they may offer.

9.2 Glassware

Glassware used for volumetric measurements must be Class A or verified for accuracy according to laboratory procedure. Pyrex (or equivalent) glass should be used where possible. For safety purposes, thick-wall glassware should be used where available.

9.3 **Reagents, Standards & Supplies**

Purchasing guidelines for equipment, 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. Procedures for laboratory tested materials are outlined in the laboratory SOP No. IR-QA-LOTTEST.

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 completes the Material Request Sheet when requesting reagents, standards, or supplies. The analyst may check the item out of the on-site consignment system that contains items approved for laboratory use.

The analyst must provide the master item number (from the master item list that has been approved by the Technical Manager), 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 Technical Manager prior to placing the order. The Technical Manager or Laboratory Director places the order.

9.3.2 <u>Receiving</u>

It is the responsibility of the Sample Control Department 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 supervisor or analyst 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 in 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 SOPs expiration date unless 'verified' (refer to item 3 listed below).

- An expiration date **cannot** be extended if the dry chemical/solvent is discolored or appears otherwise physically degraded, the dry chemical/solvent must be discarded.
- Expiration dates can be extended if the dry chemical/solvent is found to be satisfactory based on acceptable performance of quality control samples (Continuing Calibration Verification (CCV), Blanks, Laboratory Control Sample (LCS), etc.).
- If the dry chemical/solvent is used for the preparation of standards, the expiration dates can be extended 6 months if the dry chemical/solvent is compared to an unexpired independent source in performing the method and the performance of the dry chemical/solvent is found to be satisfactory. The comparison must show that the dry chemical/solvent meets CCV limits. The comparison studies are maintained in the shared "public" folder on the computer network.

Wherever possible, standards must be traceable to national or international standards of measurement or to national or international reference materials. Records to that effect are available to the user.

Compressed gases in use are checked for pressure and secure positioning daily. To prevent a tank from going to dryness, or introducing potential impurities, the pressure should be closely watched as it decreases to approximately 15% of the original reading, at which point it should be replaced. For example, a standard sized laboratory gas cylinder containing 3,000 psig of gas should be replaced when it drops to approximately 500 psig. The quality of the gases must meet method or manufacturer specification or be of a grade that does not cause any analytical interference.

Water used in the preparation of standards or reagents must have a specific conductivity of less than 1- μ 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 appropriate Technical Managers must be notified immediately in order to notify all departments, decide on cessation (based on intended use) of activities, and make arrangements for correction.

The laboratory may purchase reagent grade (or other similar quality) water for use in the laboratory. This water must be certified "clean" by the supplier for all target analytes or otherwise verified by the laboratory prior to use. This verification is documented.

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

Purchased bottleware used for sampling must be certified clean and the certificates must be maintained. If uncertified sampling bottleware is purchased, all lots must be verified clean prior to use. This verification must be maintained.

Records of manufacturer's certification and traceability statements are maintained in files or binders in each laboratory section or uploaded to TestAmerica LIMS (TALS) Reagent program. These records include date of receipt, lot number (when applicable), and expiration

date (when applicable). Incorporation of the item into the record indicates that the analyst has compared the new certificate with the previous one for the same purpose and that no difference is noted, unless approved and so documented by the Technical Manager or QA Manager.

9.3.4 <u>Storage</u>

Reagent and chemical storage is important from the aspects of both integrity and safety. Lightsensitive 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 <u>Purchase of Equipment / Instruments / Software</u>

When a new piece of equipment is needed, either for additional capacity or for replacing inoperable equipment, the analyst or supervisor makes a supply request to the Technical Manager and/or the Laboratory Director. If they agree with the request, the procedures outlined in TestAmerica's Corporate Policy No. CA-T-P-001, Qualified Products List, are followed. A decision is made as to which piece of equipment can best satisfy the requirements. The appropriate written requests are completed and purchasing places the order.

Upon receipt of a new or used piece of equipment, an identification name is assigned and added to the equipment list. IT must also be notified so that they can synchronize the instrument for back-ups. Its capability is assessed to determine if it is adequate or not for the specific application. For instruments, a calibration curve is generated, followed by MDLs, Demonstration of Capabilities (DOCs), and other relevant criteria (refer to Section 19). For software, its operation must be deemed reliable and evidence of instrument verification must be retained by the IT Department or QA Department. Software certificates supplied by the vendors are filed with the IT Department. The manufacturer's operation manual is retained at the bench.

9.5 <u>Services</u>

Service to analytical instruments (except analytical balances) is performed on an as needed basis. Routine preventative maintenance is discussed in Section 20. The need for service is determined by analysts and/or Technical Managers. The service providers that perform the services are approved by the Technical Manager and the Laboratory Director.

Analytical balances are serviced and calibrated annually in accordance with SOP IR-QA-BAL. 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 <u>Suppliers</u>

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 JD Edwards purchasing system includes all suppliers/vendors that have been approved for use.

Evaluation of suppliers is accomplished by ensuring the supplier ships the product or material ordered and that the material is of the appropriate quality. This is documented by signing off on packing slips or other supply receipt documents. The purchasing documents contain the data that adequately describe the services and supplies ordered.

Any issues of vendor performance are to be reported immediately by the laboratory staff to the Corporate Purchasing Group by completing a Vendor Performance Report.

The Corporate Purchasing Group will work through the appropriate channels to gather the information required to clearly identify the problem and will contact the vendor to report the problem and to make any necessary arrangements for exchange, return authorization, credit, etc.

As deemed appropriate, the Vendor Performance Reports will be summarized and reviewed to determine corrective action necessary, or service improvements required by vendors.

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

9.6.1 <u>New Vendor Procedure</u>

TestAmerica employees who wish to request the addition of a new vendor must complete a J.D. Edwards 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 <u>Overview</u>

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). The laboratory utilizes the TestAmerica LIMS (TALS) Non-Conformance Memo (NCM) program or the Incident/Corrective Action Tracker (iCAT) database, as appropriate, to document complaints and the corrective action performed.

10.2 External Complaints

An employee that receives a complaint initiates the complaint resolution process by first documenting the complaint in the TALS NCM program or the iCAT database as appropriate.

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 shall 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
- 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 <u>Management Review</u>

The number and nature of client complaints is reported by the QA Manager to the laboratory and Quality Director in the QA Monthly report. Monitoring and addressing the overall level and nature of client complaints and the effectiveness of the solutions is part of the Annual Management Review (Section 16).

SECTION 11. CONTROL OF NON-CONFORMING WORK

11.1 <u>Overview</u>

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 or Department Manager for resolution. The Supervisor or Department Manager may elect to discuss it with the QA Manager and the Technical Manager. Depending on the nature of the departure, the Laboratory Director or the PM may 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 laboratory practice. Based on a technical evaluation, the laboratory 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 laboratory does not normally report. The laboratory 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 Technical 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 <u>Responsibilities and Authorities</u>

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

Any misrepresentation or possible misrepresentation of analytical data discovered by any laboratory staff member must be reported to facility Senior Management within 24-hours. The Senior Management staff is comprised_of the Laboratory Director, the QA Manager, and the Technical Managers. The reporting of issues involving alleged violations of the company's Data Integrity or Manual Integration procedures <u>must</u> 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 <u>Prevention of Nonconforming Work</u>

If it is determined that the nonconforming work could recur, further corrective actions must be made following the laboratory's corrective action system. On a monthly basis, 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 <u>Method Suspension / Restriction (Stop Work Procedures)</u>

In some cases, it may be necessary to suspend/restrict the use of a method or target compound which constitutes significant risk and/or liability to the laboratory. Suspension/restriction procedures can be initiated by any of the persons noted in Section 11.2, Paragraph 5.

Prior to suspension/restriction, confidentiality will be respected, and the problem with the required corrective and preventive action will be stated in writing and presented to the Laboratory Director.

The Laboratory Director shall arrange for the appropriate personnel to meet with the QA Manager as needed. This meeting shall be held to confirm that there is a problem, that suspension/restriction of the method is required and will be concluded with a discussion of the steps necessary to bring the method/target or test fully back on line. In some cases, that may not be necessary if all appropriate personnel have already agreed there is a problem and there is agreement on the steps needed to bring the method, target or test fully back on line. The QA Manager will also initiate a corrective action report as described in Section 12 if one has not already been started. A copy of any meeting notes and agreed upon steps should be faxed or e-mailed by the laboratory to the appropriate VP of Operations and member of Corporate QA. This fax/e-mail acts as notification of the incident.

After suspension/restriction, the lab will hold all reports to clients pending review. No faxing, mailing or distributing through electronic means may occur. The report must not be posted for viewing on the internet. It is the responsibility of the Laboratory Director to hold all reporting and to notify all relevant laboratory personnel regarding the suspension/restriction (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 (Laboratory Director, Technical Manager, QA Manager) can devise a start-up plan to cover all steps from client notification through compliance and release of reports. Project Management and the Directors of Client Services and Sales and Marketing must be notified if clients must be notified or if the suspension/restriction affects the laboratory's ability to accept work. The QA Manager must approve start-up or elimination of any restrictions after all corrective action is complete. This approval is given by final signature on the completed corrective action report.

SECTION 12. CORRECTIVE ACTION

12.1 <u>Overview</u>

A major component of TestAmerica's Quality Assurance (QA) Program is the problem investigation and feedback mechanism designed to keep the laboratory staff informed on quality

related issues and to provide insight to problem resolution. When nonconforming work or departures from policies and procedures in the quality system or technical operations are identified, the corrective action procedure provides a systematic approach to assess the issues, restore the laboratory's system integrity, and prevent reoccurrence. Corrective actions are documented using TALS NCM program and iCAT database (refer to Figure 12-1 and 12-2, respectively).

12.2 <u>General</u>

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(s) 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) Program

The TALS NCM program is used to document the following types of corrective actions:

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

12.2.2 Incident/Corrective Action Tracker (iCAT) Database

The iCAT database is used to document the following types of corrective actions:

- Questionable trends that are found in the review of NCMs.
- Issues found while reviewing NCMs that warrant further investigation.
- Internal and external audit findings.
- Failed or unacceptable PT results.
- Corrective actions that cross multiple departments in the laboratory.
- Systematic reporting / calculation errors.
- Client complaints.

- Data recall investigations.
- Identified poor process or method performance trends.
- Excessive revised reports.
- Health and safety violations.

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

12.3 <u>Closed Loop Corrective Action Process</u>

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 <u>Cause Analysis</u>

Upon discovery of a non-conformance event, the event must be defined and documented. An NCM or iCAT must be initiated, someone is assigned to investigate the issue and the event is investigated for cause. Table 12-1 provides some general guidelines on determining responsibility for assessment.

The cause analysis step is the key to the process as a long term corrective action cannot be determined until the cause is determined.

If the cause is not readily obvious, the Technical Manager, Laboratory Director, or QA Manager (or QA designee) is consulted.

12.3.2 <u>Selection and Implementation of Corrective Actions</u>

Where corrective action is needed, the laboratory shall identify potential corrective actions. The action(s) most likely to eliminate the problem and prevent recurrence are selected and implemented. Responsibility for implementation is assigned.

Corrective actions shall be to a degree appropriate to the magnitude of the problem identified through the cause analysis.

Whatever corrective action is determined to be appropriate, the laboratory shall document and implement the changes. The NCM or iCAT 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 5 consecutive times until you get to the root cause. For each of these sub events or causes, ask why it occurred. Repeat the process for the other events associated with the incident.

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

12.3.4 Monitoring of the Corrective Actions

The Technical Manager and QA Manager are responsible to ensure that the corrective action taken was effective.

Ineffective actions are documented and re-evaluated until acceptable resolution is achieved. Technical Managers are accountable to the Laboratory Director to ensure final acceptable resolution is achieved and documented appropriately.

Each NCM and iCAT is entered into a database for tracking purposes and a monthly summary of all corrective actions is reviewed to aid in ensuring that the corrective actions have taken effect.

TestAmerica laboratories began using the Incident/Corrective Action Tracker (iCAT) database developed by the company in 2015. An incident is an event triggering the need for one or more corrective actions as distinct from a corrective action, a potential deficiency stemming from an incident that requires investigation and possibly fixing. The database is independent of TALS, available to all local and corporate managers, and capable of notifying and tracking multiple corrective actions per event, dates, and personnel. iCAT allows associated document upload, categorization (such as, external/internal audit, client service concerns, data quality issues, proficiency testing, etc.), and trend analysis. Refer to Figure 12-2.

The QA Manager reviews monthly NCMs and iCAT issues for trends. Highlights are included in the QA monthly report (refer to Section 16). If a significant trend develops that adversely affects quality, an audit of the area is performed and corrective action implemented.

Any out-of-control situations that are not addressed acceptably at the laboratory level may be reported to the Corporate Quality Director by the QA Manager, indicating the nature of the out-of-control situation and problems encountered in solving the situation.

12.3.5 Follow-up Audits

Follow-up audits may be initiated by the QA Manager and shall be performed as soon as possible when the identification of a nonconformance casts doubt on the laboratory's compliance with its own policies and procedures, or on its compliance with state or federal requirements.

These audits often follow the implementation of the corrective actions to verify effectiveness. An additional audit would only be necessary when a critical issue or risk to business is discovered.

(Also refer to Section 15.1.4, Special Audits.)

12.4 <u>Technical Corrective Actions</u>

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 iCAT database.

Table 12-1 includes examples of general technical corrective actions. For specific criteria and corrective actions, refer to the analytical methods or specific method SOPs. The laboratory may also maintain Work Instructions on these items that are available upon request.

Table 12-1 provides some general guidelines for identifying the individual(s) responsible for assessing each QC type and initiating corrective action. The table also provides general guidance on how a data set should be treated if associated QC measurements are unacceptable. Specific procedures are included in Method SOPs, Work Instructions, QAM Sections 19 and 20. All corrective actions are reviewed monthly, at a minimum, by the QA Manager and highlights are included in the QA monthly report.

To the extent possible, samples shall be reported only if all quality control measures are acceptable. If the deficiency does not impair the usability of the results, data will be reported with an appropriate data qualifier and/or the deficiency will be noted in the case narrative. Where sample results may be impaired, the Project Manager is notified by an NCM and appropriate corrective action (e.g., reanalysis) is taken and documented.

12.5 Basic Corrections

When mistakes occur in records, each mistake shall be crossed-out, [not obliterated (e.g. no white-out)], and the correct value entered alongside. All such corrections shall be initialed (or signed) and dated by the person making the correction. In the case of records stored electronically, the original "uncorrected" file must be maintained intact and a second "corrected" file is created.

This same process applies to adding additional information to a record. All additions made later than the initial must also be initialed (or signed) and dated.

When corrections are due to reasons other than obvious transcription errors, the reason for the corrections (or additions) shall also be documented.

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Figure 12-1. Example – TALS NCM Program

Figure 12-2. Example – iCAT Database

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QC Activity (Individual Responsible for Initiation/Assessment)	Acceptance Criteria	Recommended Corrective Action		
Initial Instrument Blank <i>(Analyst)</i>	 Instrument response < MDL. 	 Prepare another blank. If same response, determine cause of contamination: reagents, environment, instrument equipment failure, etc. 		
Initial Calibration Standards (Analyst, Technical Manager(s))	 Correlation coefficient > 0.99 or standard concentration value. % Recovery within acceptance range. See details in Method SOP. 	 Reanalyze standards. If still unacceptable, remake standards and recalibrate instrument. 		
Independent Calibration Verification (Second Source) (Analyst, Technical Manager(s))	- % Recovery within control limits.	 Remake and reanalyze standard. If still unacceptable, then remake calibration standards or use new primary standards and recalibrate instrument. 		
Continuing Calibration Standards (Analyst, Data Reviewer)	- % Recovery within control limits.	 Reanalyze standard. If still unacceptable, then recalibrate and rerun affected samples. 		
Matrix Spike / Matrix Spike Duplicate (MS/MSD) (Analyst, Data Reviewer)	- % Recovery within limits documented in TALS Method Limit Groups.	 If the acceptance criteria for duplicates or matrix spikes are not met because of matrix interferences, the acceptance of the analytical batch is determined by the validity of the LCS. If the LCS is within acceptable limits the batch is acceptable. The results of the duplicates, matrix spikes and the LCS are reported with the data set. For matrix spike or duplicate results outside criteria the data for that sample shall be reported with qualifiers. 		

Table 12-1. Example – General Corrective Action Procedures

QC Activity (Individual Responsible for Initiation/Assessment)	Acceptance Criteria	Recommended Corrective Action
Laboratory Control Sample (LCS) (Analyst, Data Reviewer)	- % Recovery within limits specified in TALS Method Limit Groups.	 Batch must be re-prepared and re- analyzed. This includes any allowable marginal exceedance. When not using marginal exceedances, the following exceptions apply: 1) when the acceptance criteria for the positive control are exceeded high (i.e., high bias) and there are associated samples that are non- detects, then those non-detects may be reported with data qualifying codes; 2) when the acceptance criteria for the positive control are exceeded low (i.e., low bias), those sample results may be reported if they exceed a maximum regulatory limit/decision level with data qualifying codes.
		Note: If there is insufficient sample or the holding time cannot be met, contact client and report with flags.
Surrogates (Analyst, Data Reviewer)	 % Recovery within limits of method or within three standard deviations of the historical mean. 	 Individual sample must be repeated. Place comment in TALS. Surrogate results outside criteria shall be reported with qualifiers.
Method Blank (MB) (Analyst, Data Reviewer)	< Reporting Limit ^{1,2}	 Reanalyze blank. If still positive, determine source of contamination. If necessary, reprocess (i.e. digest or extract) entire sample batch. Report blank results. Qualify the result(s) if the concentration of a targeted analyte in the MB is at or above the reporting limit AND is > 1/10 of the amount measured in the sample.
Proficiency Testing (PT) Samples (QA Manager, Technical Manager(s))	 Criteria supplied by PT Supplier. 	 Any failures or warnings must be investigated for cause. Failures may result in the need to repeat a PT sample to show the problem is corrected.

QC Activity (Individual Responsible for Initiation/Assessment)	Acceptance Criteria	Recommended Corrective Action
Internal / External Audits (QA Manager, Technical Manager(s), Laboratory Director)	 Defined in Quality System documentation such as SOPs, QAM, etc. 	 Non-conformances must be investigated through iCAT database and necessary corrections must be made.
Reporting / Calculation Errors (Depends on issue – possible individuals include: Analysts, Data Reviewers, Project Managers, Technical Managers, QA Manager, Corporate QA, Corporate Management)	- SOP CW-Q-S-005, Data Recall.	- Corrective action is determined by type of error. Follow the procedures in SOP CW-L-S-002.
Client Complaints (Project Managers, Lab Director/Manager, Sales and Marketing)	- QAM.	- Corrective action is determined by the type of complaint. For example, a complaint regarding an incorrect address on a report will result in the report being corrected and then follow-up must be performed on the reasons the address was incorrect (e.g., database needs to be updated).
QA Monthly Report (Refer to Section 16 for an example) (QA Manager, Lab Director/Manager, <i>Technical</i> <i>Manager(s)</i>)	- QAM, SOPS.	 Corrective action is determined by the type of issue. For example, CARs for the month are reviewed and possible trends are investigated.
Health and Safety Violation (Safety Officer, Lab Director/Manager, <i>Technical</i> <i>Manager(s)</i>)	Environmental Health and Safety (EHS) Manual.	 Non-conformance is investigated and corrected through iCAT database.

Note:

¹ Program or project specific requirements may dictate that method blank must not contain target analytes greater than ¹/₂ the reporting limit (RL).

² 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: methylene chloride, toluene, acetone, 2-butanone and phthalates **provided** they appear in similar levels in the reagent blank and samples. 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 benzene and ethylene dibromide (EDB) and other analytes for which regulatory limits are extremely close to the detection limit, the method blank must be below the method detection limit (MDL).

SECTION 13. PREVENTIVE ACTION / IMPROVEMENT

13.1 <u>Overview</u>

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 be the laboratory management, Corporate QA and TestAmerica's Executive Committee. These metrics are used to in evaluating the management and quality system performance on an ongoing basis and provide a tool for identifying areas for improvement.

Items identified as continuous improvement opportunities to the management system may be issued as goals from the annual management systems review, recommendations from internal audits, white papers, Lesson Learned, Technical Services audit report, Technical Best Practices, or as Corporate or management initiatives.

The laboratory's corrective action process is integral to implementation of preventive actions. A critical piece of the corrective action process is the implementation of actions to prevent further occurrence of a non-compliance event. Historical review of corrective action and non-conformances provides a valuable mechanism for identifying preventive action opportunities.

- **13.1.1** The following elements are part of a preventive action/process improvement system:
- <u>Identification</u> of an opportunity for preventive action or process improvement.
- <u>Process</u> for the preventive action or improvement.
- Define the measurements of the effectiveness of the process once undertaken.
- <u>Execution</u> of the preventive action or improvement.
- Evaluation of the plan using the defined measurements.
- Verification of the effectiveness of the preventive action or improvement.
- <u>Close-Out</u> 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 <u>Management of Change</u>

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.

TestAmerica Irvine has not implemented the Management of Change process at the time of the effective date of this QAM.

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 <u>Overview</u>

The laboratory has established procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records. A record index is listed in Table 14-1. Quality records are maintained by the QA department in a local or network server,

which is backed up as part of the regular laboratory backup. Records are of two types; either electronic or hard copy paper formats depending on whether the record is computer or hand generated (some records may be in both formats). Technical records are maintained by the laboratory department responsible for generating the specific technical record. When archived, they are maintained by the individual Department Managers.

	Record Types ¹ :	Retention Time:
Technical Records	 Raw Data Logbooks² Standards Certificates Analytical Records MDLs/IDLs/DOCs Lab Reports 	5 Years from analytical report issue*
Official Documents	 Quality Assurance Manual (QAM) Work Instructions Policies SOPs Policy Memorandums Manuals 	5 Years from document retirement date*
QA Records	 Internal & External Audits/Responses Certifications Corrective/Preventive Actions Management Reviews Method & Software Validation / Verification Data Data Investigation 	5 Years from archival* <u>Data Investigation:</u> 5 years or the life of the affected raw data storage whichever is greater (beyond 5 years if ongoing project or pending investigation)
Project Records	 Sample Receipt & COC Documents Contracts and Amendments Correspondence QAPP SAP Telephone Logbooks Lab Reports 	5 Years from analytical report issue*
Administrative	Finance and Accounting	10 years
Records	EH&S Manual, Permits	7 years
	Disposal Records	Indefinitely
	Employee Handbook	Indefinitely
	Personnel files, Employee Signature & Initials, Administrative Training Records (e.g., Ethics)	Refer to HR Manual
	Administrative Policies Technical Training Records	7 years

Table 14-1. Record Index ¹

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. The procedures for record archiving and retrieval are outlined in the laboratory SOP No. IR-QA-ARCH.

Access to the data is limited to laboratory and company employees and shall be documented with an access log. Records archived off-site are stored in a secure location where a record is maintained of any entry into the storage facility. Whether on-site or off-site storage is used, logs are maintained in each storage box to note removal and return of records. Retention of records are maintained on-site at the laboratory for at least 1 year 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.

Program	Retention Requirement ¹
Drinking Water – All States	5 years (project records) 10 years - Radiochemistry (project records)
Drinking Water Lead and Copper Rule	12 years (project records)
Commonwealth of MA – All environmental data 310 CMR 42.14	10 years
FIFRA – 40 CFR Part 160	Retain for life of research or marketing permit for pesticides regulated by EPA
Housing and Urban Development (HUD) Environmental Lead Testing	10 years
Alaska	10 years
Louisiana – All	10 years

Table 14-2.	Example - Special Record	Retention Requirements
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Program	Retention Requirement ¹	
Michigan Department of Environmental Quality – all environmental data	10 years	
Navy Facilities Engineering Service Center (NFESC)	10 years	
NY Potable Water NYCRR Part 55-2	10 years	
Ohio VAP	10 years and State contacted prior to disposal	
TSCA - 40 CFR Part 792	10 years after publication of final test rule or negotiated test agreement	

Note:

¹ 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 19.14.1 and the laboratory's SOP No. IR-IT-COMPUSEC 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 scanned and stored with the invoice and the work order sheet generated by TALS in the designated project folder. If a correction was made to a COC at any time before the final report is issued, the corrected COC is scanned and stored with the first scanned copy in the same folder. The chain of custody would indicate the name of the sampler. If any sampling notes are provided with a work order, they are kept with this package.
- All information relating to the laboratory facilities equipment, analytical test methods, and related laboratory activities, such as sample receipt, sample preparation, or data verification are documented.
- The record keeping system facilitates the retrieval of all working files and archived records for inspection and verification purposes (e.g., set format for naming electronic files, set format for what is included with a given analytical data set, etc.). Instrument data is stored sequentially by instrument. A given day's analyses are maintained in the order of the analysis. Run logs are maintained for each instrument or method; a copy of each day's run log or instrument sequence is stored with the data to aid in re-constructing an analytical sequence. Where an analysis is performed without an instrument, bound logbooks or bench

sheets are used to record and file data. Standard and reagent information is recorded in logbooks or entered into the TALS Reagent program for each method as required.

- Changes to hardcopy records shall follow the procedures outlined in Section 12 and 19. Changes to electronic records in LIMS or instrument data are recorded in audit trails.
- The reason for a signature or initials on a document is clearly indicated in the records such as "sampled by," "prepared by," "reviewed by", or "analyzed by".
- All generated data except those that are generated by automated data collection systems, are recorded directly, promptly and legibly in permanent dark ink.
- Hard copy data may be scanned into PDF format for record storage as long as the scanning
 process can be verified in order to ensure that no data is lost and the data files and storage
 media must be tested to verify the laboratory's ability to retrieve the information prior to the
 destruction of the hard copy that was scanned.
- Also refer to Section 19.14.1 'Computer and Electronic Data Related Requirements'.

14.2 <u>Technical and Analytical Records</u>

- **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 LIMS or instrument data are recorded in audit trails.

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

- Laboratory sample ID code;
- Date of analysis; Time of Analysis is also required if the holding time is seventy-two (72) hours or less, or when time critical steps are included in the analysis (e.g., drying times, incubations, etc.); instrumental analyses have the date and time of analysis recorded as part of their general operations. Where a time critical step exists in an analysis, location for such a time is included as part of the documentation in a specific logbook or on a 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, but are not limited to, 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; and
- Method performance criteria including expected quality control requirements. These are indicated both in the LIMS 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 documented supervisory or peer review on a monthly basis.

14.3 Laboratory Support Activities

In addition to documenting all the above-mentioned activities, the following are retained QA records and project records (previous discussions in this section relate where and how these data are stored):

- All original raw data, whether hard copy or electronic, for calibrations, samples and quality control measures, including analysts' work sheets and data output records (chromatograms, strip charts, and other instrument response readout records);
- A written description or reference to the specific test method used which includes a description of the specific computational steps used to translate parametric observations into a reportable analytical value;
- Copies of final reports;
- Archived SOPs;
- Correspondence relating to laboratory activities for a specific project;
- All corrective action reports, audits and audit responses;
- Proficiency test results and raw data; and
- Results of data review, verification, and crosschecking procedures.

14.3.1 Sample Handling Records

Records of all procedures to which a sample is subjected while in the possession of the laboratory are maintained. These include but are not limited to records pertaining to:

- Sample preservation including appropriateness of sample container and compliance with holding time requirement;
- Sample identification, receipt, acceptance or rejection and login;
- Sample storage and tracking including shipping receipts, sample transmittal / COC forms; and
- Procedures for the receipt and retention of samples, including all provisions necessary to protect the integrity of samples.

14.4 <u>Administrative Records</u>

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

14.5 <u>Records Management, Storage and Disposal</u>

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. Laboratory notebooks or logbooks are issued on a per analysis basis, and are numbered sequentially. All data are recorded sequentially within a series of sequential notebooks. Bench sheets are filed sequentially. Standards are maintained in the TALS Reagent program – no logbooks are 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 <u>Records Disposal</u>

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.

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 Manager 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 Manager or designee (Refer to CW-Q-S-003)	SOP Compliance Review Frequency: Every 2 years, except for all SOPs affecting Drinking Water analyses (including QA and administrative SOPs)

Table 15-1.	Types of Internal Audits and Frequency
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Description	Performed by	Frequency
Special Audits	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 Manager or qualified designee at least every two years, or annually for methods, QA, and administrative SOPs related to the Drinking Water program. 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 <u>Performance Testing</u>

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

It is TestAmerica's policy that PT samples be treated as typical samples in the production process. Furthermore, where PT samples present special or unique problems, in the regular production process they may need to be treated differently, as would any special or unique request submitted by any client. The QA Manager must be consulted and in agreement with any decisions made to treat a PT sample differently due to some special circumstance.

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

15.2 <u>External Audits</u>

External audits are performed when certifying agencies or clients conduct on-site inspections or submit performance testing samples for analysis. It is TestAmerica's policy to cooperate fully with regulatory authorities and clients. The laboratory makes every effort to provide the auditors with access to personnel, documentation, and assistance. Laboratory supervisors are responsible for providing corrective actions to the QA Manager who coordinates the response for any deficiencies discovered during an external audit. Audit responses are due in the time allotted by the client or agency performing the audit. When requested, a copy of the audit report and the labs corrective action plan will be forwarded to Corporate Quality.

The laboratory cooperates with clients and their representatives to monitor the laboratory's performance in relation to work performed for the client. The client may only view data and systems related directly to the client's work. All efforts are made to keep other client information confidential.

15.2.1 <u>Confidential Business Information (CBI) Considerations</u>

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 <u>Audit Findings</u>

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

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

If any audit finding casts doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test results, the laboratory shall take timely corrective action, and shall notify clients in writing if the investigations show that the laboratory results have been affected. Once corrective action is implemented, a follow-up audit is scheduled to ensure that the problem has been corrected.

Clients must be notified promptly in writing, of any event such as the identification of defective measuring or test equipment that casts doubt on the validity of results given in any test report or amendment to a test report. The investigation must begin within 24-hours of discovery of the problem and all efforts are made to notify the client within two weeks after the completion of the investigation.

SECTION 16. MANAGEMENT REVIEWS

16.1 <u>Quality Assurance Report</u>

A comprehensive QA Report shall be prepared each month by the laboratory's QA Department and forwarded to the Laboratory Director, Technical Managers, their Quality Director as well as the VP of Operations. All aspects of the QA system are reviewed to evaluate the suitability of policies and procedures. During the course of the year, the Laboratory Director, 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 Managers, QA Manager, and the Manager of Project Management) conducts a review annually of its quality systems and LIMS to ensure its continuing suitability and effectiveness in meeting client and regulatory requirements and to introduce any necessary changes or improvements. It will also provide a platform for defining goals, objectives and action items that feed into the laboratory planning system. Corporate Operations and Corporate QA personnel is be included in this meeting at the discretion of the Laboratory Director. The LIMS review consists of examining any audits,

complaints or concerns that have been raised through the year that are related to the LIMS. The laboratory will summarize any critical findings that 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.
 - o Adequacy of policies and procedures.
 - Future plans for resources and testing capability and capacity.
- The annual internal double blind PT program sample performance (if performed).
- Compliance to the Ethics Policy and Data Integrity Plan. Including any evidence/incidents of inappropriate actions or vulnerabilities related to data Integrity.

A report is generated by the QA Manager and management. The report is distributed to the appropriate VP of 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 <u>Overview</u>

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, colony counting, aseptic or quantitation techniques, etc., are also considered).

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, etc.), HPLC, GCMS	A college degree in an applied science or 2 years of college chemistry	or 5 years of prior analytical experience
Spectra Interpretation	A college degree in an applied science or 2 years of college chemistry	And 2 years relevant experience Or 5 years of prior analytical experience
Technical Managers – <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
Technical Managers – <u>Wet Chemistry</u> only (no advanced instrumentation)	Associates degree in an applied science or engineering or 2 years of college with 16 semester hours in chemistry	And 2 years relevant experience

As a general rule for analytical staff:

Specialty	Education	Experience
Technical Managers – <u>Microbiology</u>	Bachelor's degree in applied science with at least 16 semester hours in general microbiology and biology	And 2 years of relevant experience
	An advanced (MS, PhD.) degree may substitute for one year of 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 Technical Manager, and are considered an analyst in training. The person supervising an analyst in training is accountable for the quality of the analytical data and must review and approve data and associated corrective actions.

17.3 <u>Training</u>

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 are maintained in their training file.
- 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 & 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 No. IR-QA-TRAIN.

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 <u>Overview</u>

The laboratory is a 45,000 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 <u>Environment</u>

Laboratory accommodation, test areas, energy sources, lighting are adequate to facilitate proper performance of tests. The facility is equipped with heating, ventilation, and air conditioning (HVAC) systems appropriate to the needs of environmental testing performed at this laboratory.

The environment in which these activities are undertaken does not invalidate the results or adversely affect the required accuracy of any measurements.

The laboratory provides for the effective monitoring, control and recording of environmental conditions that may affect the results of environmental tests as required by the relevant specifications, methods, and procedures. Such environmental conditions include humidity, voltage, temperature, and vibration levels in the laboratory.

When any of the method or regulatory required environmental conditions change to a point where they may adversely affect test results, analytical testing will be discontinued until the environmental conditions are returned to the required levels.

Environmental conditions of the facility housing the computer network and LIMS are regulated to protect against raw data loss.

18.3 <u>Work Areas</u>

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.

Refer to the following documents and procedures for specific requirements for microbiological laboratory facility requirements:

- Standard Methods, 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 <u>Building Security</u>

Building keys and alarm codes 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. Signs are posted in the laboratory designating employee only areas - "Authorized employees beyond this point".

SECTION 19. TEST METHODS AND METHOD VALIDATION

19.1 <u>Overview</u>

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 <u>Standard Operating Procedures (SOPs)</u>

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.
- SOPs are reviewed at a minimum of every 2 years (annually for Drinking Water SOPs), and where necessary, revised to ensure continuing suitability and compliance with applicable requirements.

19.3 <u>Laboratory Methods Manual</u>

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 <u>Selection of Methods</u>

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 <u>Sources of Methods</u>

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:

- <u>Guidelines Establishing Test Procedures for the Analysis of Pollutants Under the Clean Water Act;</u> <u>Analysis and Sampling Procedures</u>; 40CFR Part 136 as amended by Method Update Rule; May 18, 2012.
- Methods for Chemical Analysis of Water and Wastes, EPA 600 (4-79-020), 1983.
- <u>Methods for the Determination of Inorganic Substances in Environmental Samples</u>, EPA-600/R-93/100, August 1993.
- <u>Methods for the Determination of Metals in Environmental Samples</u>, EPA/600/4-91/010, June 1991. Supplement I: EPA-600/R-94/111, May 1994.
- <u>Methods for the Determination of Organic Compounds in Drinking Water</u>, EPA-600/4-88-039, December 1988, Revised, July 1991, Supplement I, EPA-600-4-90-020, July 1990, Supplement II, EPA-600/R-92-129, August 1992. <u>Supplement III EPA/600/R-95/131 - August 1995 (EPA 500 Series)</u> (EPA 500 Series methods)
- Technical Notes on Drinking Water Methods, EPA-600/R94-173, October 1994
- <u>Statement of Work for Inorganics & Organics Analysis</u>, SOM and ISM, current versions, USEPA Contract Laboratory Program Multi-media, Multi-concentration.
- <u>Standard Methods for the Examination of Water and Wastewater</u>, 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.
- <u>Test Methods for Evaluating Solid Waste Physical/Chemical Methods (SW846)</u>, 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.
- <u>Annual Book of ASTM Standards</u>, American Society for Testing & Materials (ASTM), Philadelphia, PA.
- <u>Manual for the Certification of Laboratories Analyzing Drinking Water (EPA 815-R-05-004, January 2005)</u>
- <u>Code of Federal Regulations (CFR) 40, Parts 136, 141, 172, 173, 178, 179 and 261</u>

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 <u>Demonstration of Capability</u>

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) is performed whenever there is a change in instrument type (e.g., new instrumentation), matrix, method or personnel (e.g., analyst hasn't performed the test within the last 12 months). Additional information on training and documentation can be found in the Laboratory SOP No. IR-QA-TRAIN.

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 Technical Manager and QA Manager prior to independently analyzing client samples. All associated documentation must be retained in accordance with the laboratories 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 (i.e., retention time window study).

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

- The instrument is calibrated for the analyte to be reported using the criteria for the method and ICV/CCV criteria are met (unless an ICV/CCV is not required by the method or criteria are per project DQOs).
- The laboratory's nominal or default reporting limit (RL) is equal to the quantitation limit (QL), must be at or above the lowest non-zero standard in the calibration curve and must be reliably determined. Project RLs are client specified reporting levels which may be higher than the QL. Results reported below the QL must be qualified as estimated values. Also see Section 19.6.1.3, Relationship of Limit of Detection (LOD) to Quantitation Limit (QL).

• The client request is documented and the lab informs the client of its procedure for working with unusual compounds. The final report must be footnoted: *Reporting Limit based on the low standard of the calibration curve.*

19.4.3 Initial Demonstration of Capability (IDOC) Procedures

- **19.4.3.1** The spiking standard used must be prepared independently from those used in instrument calibration.
- **19.4.3.2** The analyte(s) shall be diluted in a volume of clean matrix sufficient to prepare four aliquots at the concentration specified by a method or the laboratory SOP.
- **19.4.3.3** At least four aliquots shall be prepared (including any applicable clean-up procedures) and analyzed according to the test method (either concurrently or over a period of days).
- **19.4.3.4** Using all of the results, calculate the mean recovery in the appropriate reporting units and the standard deviations for each parameter of interest.
- **19.4.3.5** When it is not possible to determine the mean and standard deviations, such as for presence, absence and logarithmic values, the laboratory will assess performance against criteria described in the Method SOP.
- **19.4.3.6** Compare the information obtained above to the corresponding acceptance criteria for precision and accuracy in the test method (if applicable) or in laboratory generated acceptance criteria (LCS or interim criteria) if there is no mandatory criteria established. If any one of the parameters do not meet the acceptance criteria, the performance is unacceptable for that parameter.
- **19.4.3.7** When one or more of the tested parameters fail at least one of the acceptance criteria, the analyst must proceed according to either option listed below:
- Locate and correct the source of the problem and repeat the test for all parameters of interest beginning with 19.4.3.3 above.
- Beginning with 19.4.3.3 above, repeat the test for all parameters that failed to meet criteria. Repeated failure, however, will confirm a general problem with the measurement system. If this occurs, locate and correct the source of the problem and repeat the test for all compounds of interest beginning with 19.4.3.1 above.

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

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

Methods on line prior to the effective date of this Section shall be updated to the procedures outlined above as new analysts perform their demonstration of capability. A copy of the new record will replace that which was used for documentation in the past. At a minimum, the

precision and accuracy of four mid-level laboratory control samples must have been compared to the laboratory's quality control acceptance limits.

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 <u>Validation of Methods</u>

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 <u>Method Validation and Verification Activities for All New Methods</u>

While method validation can take various courses, the following activities can be required as part of method validation. Method validation records are designated QC records and are archived accordingly.

- **19.6.1.1** Determination of Method Selectivity Method selectivity is the demonstrated ability to discriminate the analyte(s) of interest from other compounds in the specific matrix or matrices from other analytes or interference. In some cases to achieve the required selectivity for an analyte, a confirmation analysis is required as part of the method.
- **19.6.1.2** Determination of Method Sensitivity Sensitivity can be both estimated and demonstrated. Whether a study is required to estimate sensitivity depends on the level of method development required when applying a particular measurement system to a specific set of samples. Where estimations and/or demonstrations of sensitivity are required by regulation or client agreement, such as the procedure in 40 CFR Part 136 Appendix B, under the Clean Water Act, these shall be followed.
- **19.6.1.3** Relationship of Limit of Detection (LOD) to the Quantitation Limit (QL) An important characteristic of expression of sensitivity is the difference in the LOD and the QL. The LOD is the minimum level at which the presence of an analyte can be reliably concluded. The QL is the minimum concentration of analyte that can be quantitatively determined with acceptable precision and bias. For most instrumental measurement systems, there is a region where semi-quantitative data is generated around the LOD (both above and below the estimated MDL or LOD) and below the QL. In this region, detection of an analyte may be confirmed but quantification of the

analyte is unreliable within the accuracy and precision guidelines of the measurement system. When an analyte is detected below the QL, and the presence of the analyte is confirmed by meeting the qualitative identification criteria for the analyte, the analyte can be reliably reported, but the amount of the analyte can only be estimated. If data is to be reported in this region, it must be done so with a gualification that denotes the semi-guantitative nature of the result.

- **19.6.1.4** <u>Determination of Interferences</u> 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** <u>Determination of Accuracy and Precision</u> 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** <u>Continued Demonstration of Method Performance</u> 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 <u>Method Detection Limits (MDL) / Limits of Detection (LOD)</u>

Method detection limits (MDL) are initially determined in accordance with <u>40 CFR Part 136</u>, <u>Appendix B</u> or alternatively by other technically acceptable practices that have been accepted by regulators. MDL is also sometimes referred to as Limit of Detection (LOD). The MDL theoretically represents the concentration level for each analyte within a method at which the analyst is 99% confident that the true value can be differentiated from blanks. The MDL is determined for each analyte initially during the method validation process and updated as required in the analytical methods, whenever there is a significant change in the procedure or equipment, or based on project specific requirements. Generally, the analyst prepares at least seven replicates of solution spiked at one to five times the estimated method detection limit (most often at the lowest standard in the calibration curve) into the applicable matrix with all the analytes of interest. Each of these aliquots is extracted (including any applicable clean-up procedures) and analyzed over 2-4 days to provide a more realistic MDL. To allow for some flexibility, this low level standard may be analyzed every batch or every week or some other frequency rather than

doing the study all at once. In addition, a larger number of data points may be used if the appropriate t-value multiplier is used.

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

19.8 Instrument Detection Limits (IDL)

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

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.

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

19.9 Verification of Detection and Reporting Limits

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

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.

19.10 <u>Retention Time Windows</u>

Most organic analyses and some inorganic analyses use chromatography techniques for qualitative and quantitative determinations. For every chromatography analysis or as specific 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 with the files associated with an instrument for later quantitation of the analytes. Complete details are available in the laboratory SOPs.

19.11 <u>Evaluation of Selectivity</u>

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, co-precipitation evaluations and specific electrode response factors.

19.12 <u>Estimation of Uncertainty of Measurement</u>

- **19.12.1** Uncertainty is "a parameter associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand" (as defined by the International Vocabulary of Basic and General Terms in Metrology, ISO Geneva, 1993, ISBN 92-67-10175-1). Knowledge of the uncertainty of a measurement provides additional confidence in a result's validity. Its value accounts for all the factors which could possibly affect the result, such as adequacy of analyte definition, sampling, matrix effects and interferences, climatic conditions, variances in weights, volumes, and standards, analytical procedure, and random variation. Some national accreditation organizations require the use of an "expanded uncertainty": the range within which the value of the measurand is believed to lie within at least a 95% confidence level with the coverage factor k=2.
- **19.12.2** Uncertainty is not error. Error is a single value, the difference between the true result and the measured result. On environmental samples, the true result is never known. The measurement is the sum of the unknown true value and the unknown error. Unknown error is a combination of systematic error, or bias, and random error. Bias varies predictably, constantly, and independently from the number of measurements. Random error is unpredictable, assumed to be Gaussian in distribution, and reducible by increasing the number of measurements.
- **19.12.3** The minimum uncertainty associated with results generated by the laboratory can be determined by using the Laboratory Control Sample (LCS) accuracy range for a given analyte. The LCS limits are used to assess the performance of the measurement system since they take into consideration all of the laboratory variables associated with a given test over time (except for variability associated with the sampling and the variability due to matrix effects). The percent recovery of the LCS is compared either to the method-required LCS accuracy limits or to the statistical, historical, in-house LCS accuracy limits.
- **19.12.4** To calculate the uncertainty for the specific result reported, multiply the result by the decimal of the lower end of the LCS range percent value for the lower end of the uncertainty range, and multiply the result by the decimal of the upper end of the LCS range percent value for the upper end of the uncertainty range. These calculated values represent uncertainties at approximately the 99% confidence level with a coverage factor of k = 3. As an example, for a reported result of 1.0 mg/L with an LCS recovery range of 50 to 150%, the estimated uncertainty in the result would be 1.0 + 0.5 mg/L.
- **19.12.5** In the case where a well-recognized test method specifies limits to the values of major sources of uncertainty of measurement (e.g., 524.2, 525, etc.) and specifies

the form of presentation of calculated results, no further discussion of uncertainty is required.

19.13 Sample Reanalysis Guidelines

Because there is a certain level of uncertainty with any analytical measurement, a sample repreparation (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 ≤ 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 laboratory was in error.
- Due to the potential for increased variability, reanalysis may not be applicable to Nonhomogenous, Encore, and Sodium Bisulfate preserved samples. See the Department Manager or Laboratory Director if unsure.

19.14 Control of Data

The laboratory has policies and procedures in place to ensure the authenticity, integrity, and accuracy of the analytical data generated by the laboratory.

19.14.1 Computer and Electronic Data Related Requirements

The three basic objectives of our computer security procedures and policies are shown below. More detail is outlined in the laboratory SOP No. IR-IT-COMPSEC. The laboratory is currently running the TALS which is a proprietary in-house developed LIMS system that has been highly customized to meet the needs of the laboratory. It is referred to as LIMS for the remainder of this section. The LIMS utilizes Microsoft SQL Server which is an industry standard relational database platform. It is referred to as Database for the remainder of this section.

- **19.14.1.1** <u>Maintain the Database Integrity</u> 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, and data change requirements.

- Spreadsheets and other software developed in-house must be verified with documentation through hand calculations prior to use. Cells containing calculations must be lock-protected and controlled.
- Instrument hardware and software adjustments are safeguarded through maintenance logs, audit trails and controlled access.
- **19.14.1.2** <u>Ensure Information Availability</u> 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.
- **19.14.1.3** <u>Maintain Confidentiality</u> Ensure data confidentiality through physical access controls such as password protection or website access approval when electronically transmitting data.

19.14.2 Data Reduction

The complexity of the data reduction depends on the analytical method and the number of discrete operations involved (e.g., extractions, dilutions, instrument readings and concentrations). The analyst calculates the final results from the raw data or uses appropriate computer programs to assist in the calculation of final reportable values.

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

Manual integration of peaks will be documented and reviewed and the raw data will be flagged in accordance with the TestAmerica Corporate SOP 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.

- **19.14.2.1** 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/<u>year</u>). It must be easily identifiable who performed which tasks if multiple people were involved.
- **19.14.2.2** In general, concentration results are reported in milligrams per liter (mg/L) or micrograms per liter (μ g/L) for liquids and milligrams per kilogram (mg/kg) or micrograms per kilogram (μ g/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 laboratory SOP.

- **19.14.2.3** In reporting, the analyst or the instrument output records the raw data result using values of known certainty plus one uncertain digit. If final calculations are performed external to LIMS, the results should be entered in LIMS with at least three significant figures. In general, results are reported to 2 significant figures on the final report.
- **19.14.2.4** For those methods that do not have an instrument printout or an instrumental output compatible with the LIMS System, the raw results and dilution factors are entered directly into LIMS by the analyst, and the software calculates the final result for the analytical report. LIMS has a defined significant figure criterion for each analyte.
- **19.14.2.5** The laboratory strives to import data directly from instruments or calculation spreadsheets to ensure that the reported data are free from transcription and calculation errors. For those analyses with an instrumental output compatible with the LIMS, the raw results and dilution factors are transferred into LIMS electronically after reviewing the quantitation report, and removing unrequested or poor spectrally-matched compounds. The analyst may print 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.

19.14.3 Logbook / Worksheet Use Guidelines

Logbooks and worksheets are filled out 'real time' and have enough information on them to trace the events of the applicable analysis/task. (e.g., calibrations, standards, analyst, sample ID, date, time on short holding time tests, temperatures when applicable, calculations are traceable, etc.).

- Corrections are made following the procedures outlined in Section 12.
- Logbooks are controlled by the QA department. A record is maintained of all logbooks in the lab.
- Unused portions of pages must be "Z"'d out, signed and dated.
- Worksheets are created with the approval of the Technical Manager/QA Manager at the facility. The QA Department controls all worksheets following the procedures in Section 6.

19.14.4 Review / Verification Procedures

Review procedures are outlined in several laboratory 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 applies the corporate SOP No. CA-Q-S-002 on Manual Integrations to ensure the authenticity of the data. The general review concepts are discussed below, more specific information can be found in the laboratory SOPs.

19.14.4.1 <u>Log-In Review</u> – The data review process starts at the sample receipt stage. Sample control personnel review chain-of-custody forms and project instructions from the project management group. This is the basis of the sample information and analytical instructions entered into the LIMS. The log-in instructions are reviewed by

the personnel entering the information, and a second level review is conducted by the project management staff.

- **19.14.4.2** <u>First Level Data Review</u> The next level of data review occurs with the analysts. As data are generated, analysts review their work to ensure that the results meet project and SOP requirements. First level reviews include inspection of all raw data (e.g., instrument output for continuous analyzers, chromatograms, spectra, and manual integrations), evaluation of calibration/calibration verification data in the day's analytical run, evaluation of QC data, and reliability of sample results. The analyst transfers data into LIMS, data qualifiers are added as needed. All first level reviews are documented.
- **19.14.4.3** <u>Second Level Data Review</u> All analytical data are subject to review by a second qualified analyst or supervisor. Second level reviews include inspection of all raw data (e.g., instrument output, chromatograms, and spectra) including 100% of data associated with any changes made by the primary analyst, such as manual integrations or reassignment of peaks to different analytes, or elimination of false negative analytes. The second review also includes evaluation of initial calibration/calibration verification data in the day's analytical run, evaluation of QC data, reliability of sample results, qualifiers and NCM narratives. Manual calculations are checked in second level review. All second level reviews are documented.

Issues that deem further review include the following:

- QC data are outside the specified control limits for accuracy and precision
- Reviewed sample data does not match with reported results
- Unusual detection limit changes are observed
- Samples having unusually high results
- Samples exceeding a known regulatory limit
- Raw data indicating some type of contamination or poor technique
- Inconsistent peak integration
- Transcription errors
- Results outside of calibration range
- **19.14.4.4** Unacceptable analytical results may require reanalysis of the samples. Any problems are brought to the attention of the Laboratory Director, Project Manager, Quality Director/Manager, Technical Manager, or Supervisor for further investigation. Corrective action is initiated whenever necessary.
- **19.14.4.5** The results are then entered or directly transferred into the computer database and a hard copy (or .pdf) is printed for the client.
- **19.14.4.6** As a final review prior to the release of the report, the Project Manager reviews the results for appropriateness and completeness. This review and approval ensures that client requirements have been met and that the final report has been properly

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completed. The process includes, but is not limited to, verifying that the COC is followed, cover letters / narratives are present, flags are appropriate, and project specific requirements are met. The Project Manager may also evaluate the validity of results for different test methods given expected chemical relationships.

- **19.14.4.7** Any project that requires a data package is subject to a tertiary data review for transcription errors and acceptable quality control requirements. The Project Manager then signs the final report. The accounting personnel also check the report for any clerical or invoicing errors. When complete, the report is sent out to the client.
- **19.14.4.8** 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.

19.14.5 <u>Manual Integrations</u>

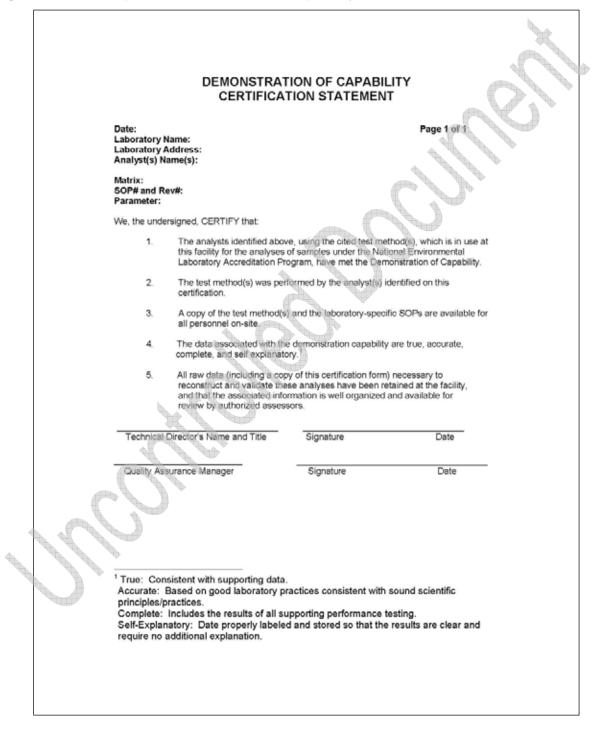
Computerized data systems provide the analyst with the ability to re-integrate raw instrument data in order to optimize the interpretation of the data. Though manual integration of data is an invaluable tool for resolving variations in instrument performance and some sample matrix problems, when used 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) as the guideline.

- **19.14.6** The analyst must adjust baseline or the area of a peak in some situations, for example when two compounds are not adequately resolved or when a peak shoulder needs to be separated from the peak of interest. The analyst must use professional judgment and common sense to determine when manual integrating is required. Analysts are encouraged to ask for assistance from a senior analyst or manager when in doubt.
- **19.14.7** Analysts shall not increase or decrease peak areas for the sole purpose of achieving acceptable QC recoveries that would have otherwise been unacceptable. The intentional recording or reporting of incorrect information (or the intentional omission of correct information) is against company principles and policy and is grounds for immediate termination.
- **19.14.8** Client samples, performance evaluation samples, and quality control samples are all treated equally when determining whether or not a peak area or baseline should be manually adjusted.
- **19.14.9** All manual integrations receive a second level review. Manual integrations must be indicated on an expanded scale "after" chromatograms such that the integration performed can be easily evaluated during data review. Expanded scale "before" chromatograms are also required for all manual integrations on QC parameters (calibrations, calibration verifications, laboratory control samples, internal standards,

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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.





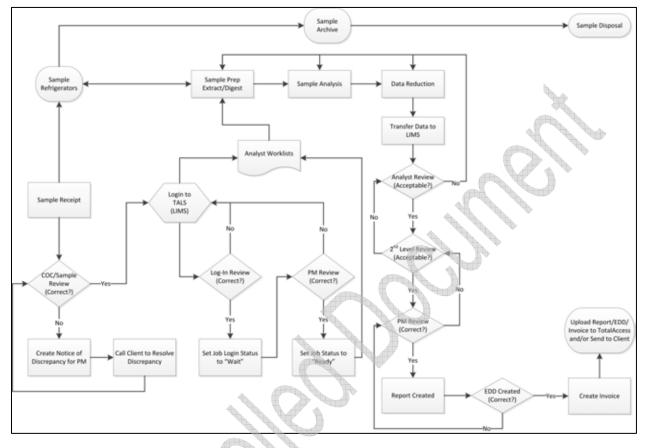


Figure 19-2. Example – Work Flow

SECTION 20. EQUIPMENT AND CALIBRATIONS

20.1 <u>Overview</u>

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 the 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 <u>Preventive Maintenance</u>

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 Technical Manager to ensure that instrument maintenance logs are kept for all equipment in his/her department. Preventative maintenance procedures may be / are also outlined in analytical SOPs or instrument manuals. (Note: For some equipment, the log used to monitor performance is also the maintenance log. Multiple pieces of equipment may share the same log as long as it is clear as to which instrument is associated with an entry.)

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

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

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 <u>Weights and Balances</u>

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. Refer to the laboratory SOP No. IR-QA-BAL for procedures.

20.3.2 pH, Conductivity, and Turbidity Meters

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

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

Turbidity meters are also calibrated before each use.

All of this information is documented in logs. Consult pH and Conductivity, and Turbidity SOPs for further information.

20.3.3 <u>Thermometers</u>

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

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

IR thermometers, digital probes and thermocouples are calibrated quarterly. IR Thermometers should be calibrated over the full range of use, including ambient, iced (4°C) and frozen (0°C to -5°C), per the Drinking Water Manual.

The mercury NIST thermometer is recalibrated every three years (unless thermometer has been exposed to temperature extremes or apparent separation of internal liquid) by an approved outside service and the provided certificate of traceability is kept on file. The NIST thermometer(s) have increments of 1 degree (0.5 degree or less increments are required for drinking water microbiological laboratories), and have ranges applicable to method and certification requirements. The NIST traceable thermometer is used for no other purpose than to calibrate other thermometers.

All of this information is documented in logbooks. Monitoring method-specific temperatures, including incubators, heating blocks, water baths, and ovens, is documented in method-specific logbooks. More information on this subject can be found in the laboratory SOP No. IR-QA-THERMA.

20.3.4 <u>Refrigerators/Freezer Units, Waterbaths, Ovens and Incubators</u>

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

Ovens, waterbaths and incubators are monitored on days of use (twice for microbiology).

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

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

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

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

20.3.5 <u>Autopipettors, Dilutors, and Syringes</u>

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

For those dispensers that are not used for analytical measurements, a label is applied to the device stating that it is not calibrated. Any device not regularly verified cannot be used for any quantitative measurements. More information on this subject can be found in the laboratory SOP No. IR-QA-PIPET.

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.

Glass micro-syringes with volumes of > 20 μ L are checked for accuracy every six months. Glass micro-syringes with volumes < 20 μ L are certified by the manufacturer (e.g., Hamilton Company). Certificate of accuracy and precision must be obtained and kept on file in the laboratory.

20.3.6 <u>Autoclaves</u>

Refer to the laboratory SOP No. IR-MICRO-AUTOCLAVE and 2009 TNI Standard V1M5 Section 1.7.3.7.b.ii. for performance evaluation and maintenance.

20.3.7 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.

Refer to the laboratory SOP No. IR-SC-FIELD for calibration and maintenance.

20.4 Instrument Calibrations

Calibration of analytical instrumentation is essential to the production of quality data. Strict calibration procedures are followed for each method. These procedures are designed to determine and document the method detection limits, the working range of the analytical instrumentation and any fluctuations that may occur from day to day.

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

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

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

Note: Instruments are calibrated initially and as needed after that and at least annually (the annual requirement does not apply to Isotope dilution). Project-specific requirements may dictate more frequent calibrations (e.g., quarterly), as agreed upon with the client.

20.4.1 <u>Calibration Standards</u>

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 are 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, such as air analysis where no other source or lot is available, a standard made by a different analyst at a different time or a different preparation would be considered a second source. This verification occurs immediately after the calibration curve has been analyzed, and before the analysis of any samples.

20.4.1.1 <u>Calibration Verification</u>

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 is with a standard source secondary (second source standard) to the calibration standards, but continuing calibration verifications may use the same source standards as the calibration curve.

Note: The process of calibration verification referred to 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 Standard EL-V1M4 Section 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 initial calibrations must be verified at the beginning of each 12-hour analytical shift during which samples are analyzed. (Some methods may specify more or less frequent verifications). The 12-hour analytical shift begins with the injection of the calibration verification standard (or the MS tuning standard in MS methods). The shift ends after the completion of the analysis of the last sample, QC, or standard that can be injected within 12-hours of the beginning of the shift.

A continuing instrument calibration verification (CCV) must be repeated at the beginning and, for methods that have quantitation by external calibration models, at the end of each analytical batch. Some methods have more frequent CCV requirements see specific SOPs. Most Inorganic methods require the CCV to be analyzed after every 10 samples or injections, including matrix or batch QC samples.

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

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

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

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 <u>Verification of Linear and Non-Linear Calibrations</u>

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

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

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

20.5 Tentatively Identified Compounds (TICs) – GC/MS Analysis

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

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

For example, the RCRA permit or waste delisting requirements may require the reporting of non-target analytes. Only after visual comparison of sample spectra with the nearest library searches may the analyst assign a tentative identification.

20.6 GC/MS Tuning

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

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

Table 20-1. Exam	nple – Instrum	entation List ¹			
Equipment/ Instrument	Manufacturer	Model Number	Serial Number	Placed in Service (Year)	Methods Performed
Gas Chromatograph (FID/PID)	Hewlett Packard	5890A	S/N2750A15898	1997-01-01	EPA 8015B Gas
Gas Chromatograph (FID/PID)	Hewlett Packard	5890 Series II	S/N3033A33301	1998-01-01	EPA 8015B Gas
Gas Chromatograph (FID/PID)	Hewlett Packard	5890 Series II	S/N3223A2733	1993-01-01	EPA 8015B Gas
Gas Chromatograph (FID/PID)	Hewlett Packard	5890 Series II	S/N3336A60064	1993-01-01	EPA 8015B Gas
Gas Chromatograph (FID/TCD)	Varian	CP-3800	11827	2013-05-20	EPA 25C
Gas Chromatograph (FID/TCD)	Varian	CP-3800	5262	2013-05-20	RSK-175
NanoPure Diamond (UV/UF)	Barnstead	D11931	1193040693134		
Flashpoint Tester	Koehler	K-162	10A/Y-2	1992-01-01	EPA 1010
Flashpoint Tester	Erdco	RT-0001-600	151436	2015-03-30	EPA 1020A
Microwave	CEM	MARS5	MD3165	2010-01-01	EPA 3546
Microwave	CEM	MARS XPRESS	MD8441	2010-01-01	EPA 3546
Gas Chromatograph/ Mass Spectrometer	Hewlett Packard	5890Ser.II/5971	3140A39653	1993-01-01	Screening
Gas Chromatograph/ Mass Spectrometer	Hewlett Packard	5890Ser.II/5971	3033A30488/ 3133A37717	1993-01-01	1,4-Dioxane

Table 20-1.	Example – Instrumentation List ¹
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Equipment/ Instrument	Manufacturer	Model Number	Serial Number	Placed in Service (Year)	Methods Performed
Gas Chromatograph/ Mass Spectrometer	Agilent	6890N/5973 Inert	CN10349032/ US33220240	2008-01-30	EPA 625, EPA 8270C
Gas Chromatograph/ Mass Spectrometer	Agilent	6890/5973	US10226108/ US21843299	2010-01-01	EPA 625, EPA 8270C
Gas Chromatograph/ Mass Spectrometer	Agilent	7890/5975	CN10752039/ US80148288	2010-01-01	EPA 625 LL, EPA 8270C LL
Gas Chromatograph/ Mass Spectrometer	Agilent	7890/5975	CN10824037/ US83140433	2010-01-01	EPA 1625(M)
Gas Chromatograph/ Mass Spectrometer	Hewlett Packard	5890/5970	3336A60053/ 3307A00396	2011-01-01	EPA 8270C Screening
Gas Chromatograph/ Mass Spectrometer	Agilent	6890N/5973N	US10232062/ US21863660	2009-01-01	EPA 525.2
Gas Chromatograph/ Mass Spectrometer	Agilent	6890/G1530N	US10243060	2010-01-01	EPA 548.1
Gas Chromatograph/ Mass Spectrometer	Agilent	6890N / 5973	CN10521030/ US40620627	2009-01-01	EPA 524.2 SIM
Gas Chromatograph/ Mass Spectrometer	Agilent	6890N / 5973	CN10503040/ US10461983	2009-01-01	EPA 524.2, EPA 8260B
Gas Chromatograph/ Mass Spectrometer	Agilent	6890N / 5973	US00002015/ US10440578	2009-01-01	EPA 524.2
Moisture Analysis Balance	Ohaus	MB90	B605073296	2016-08-12	Moisture
NanoPure Diamond (UV/UF)	Barnstead	D11931	119020964094		
Gas Chromatograph/ Mass Spectrometer	Hewlett Packard	6890/5973A	US00020097/ US72810389	1999-01-01	EPA 8260B
Gas Chromatograph/ Mass Spectrometer	Hewlett Packard	6890/5973A	US00007750/ US70810354	2000-01-01	EPA 8260B
Gas Chromatograph/ Mass Spectrometer	Hewlett Packard	6890/5973A	US00022931/ US82311546	2000-01-01	EPA 8260B
Gas Chromatograph/ Mass Spectrometer	Agilent	6850/5973N	US00001207/ US01140222	2001-01-01	EPA 8260B
Gas Chromatograph/ Mass Spectrometer	Agilent	6850/5973	US00001206/ US01140215	2001-01-01	EPA 8260B
Gas Chromatograph/ Mass Spectrometer	Agilent	6850/5973N	US0001947/ US10340261	2002-01-01	EPA 8260B SIM
Gas Chromatograph/ Mass Spectrometer	Agilent	6850/5973N	US00002140/ US10440793	2002-01-01	EPA 8260B

Equipment/ Instrument	Manufacturer	Model Number	Serial Number	Placed in Service (Year)	Methods Performed
Gas Chromatograph/ Mass Spectrometer	Agilent	6850/5973N	US00002860/ US21843317	2003-01-01	EPA 8260B
Gas Chromatograph/ Mass Spectrometer	Agilent	6890/5973	US00034262/ US01112246	2004-01-01	EPA 8260B
Gas Chromatograph/ Mass Spectrometer	Agilent	6890N/5973	CN10318006/ US30945515	2004-01-01	EPA 8260B Screening
Gas Chromatograph/ Mass Spectrometer	Agilent	6890N/5973	CN10318007/ US30945517	2004-01-01	EPA 8260B SIM
Gas Chromatograph/ Mass Spectrometer	Agilent	6890N/5973	CN01521014/ US44647184	2005-01-01	EPA 8260B
Gas Chromatograph/ Mass Spectrometer	Agilent	6890N/5973	US00001682/ US92522712	2001-01-01	EPA 8260B
Gas Chromatograph/ Mass Spectrometer	Agilent	6890N/5973N	US10222064/ US10462085	2006-01-01	EPA 8260B
Gas Chromatograph/ Mass Spectrometer	Agilent	6890N/5973 Inert	CN10339005/ US35120285	2007-01-01	EPA 524.2, EPA 524.2 LL
Gas Chromatograph/ Mass Spectrometer	Agilent	6890N/5973 Inert	CN10345035/ US33220184	2009-01-01	EPA 8260B SIM
Gas Chromatograph/ Mass Spectrometer	Hewlett Packard	6890/5973	US00029799	2011-01-01	EPA 8260B
Gas Chromatograph (Dual ECD)	Agilent	6890N	US10215019	2002-01-01	EPA 608, EPA 8082
Gas Chromatograph (Dual ECD)	Agilent	6890N/G1530N	US10250081	2005-01-01	EPA 608, EPA 8081
Gas Chromatograph (Dual ECD)	Agilent	6890N/G1540N	US10423015	2008-01-01	EPA 608, EPA 8081
Gas Chromatograph (Dual ECD)	Agilent	6890N/G1540N	US10423014	2008-01-01	EPA 608, EPA 8082
Gas Chromatograph (Dual ECD)	Agilent	6890N/1530N	CN10551059	2007-01-01	EPA 608 LL, EPA 8081 LL
Gas Chromatograph (Dual ECD)	Agilent	6890N/G1530N	US10322076	2007-01-01	EPA 608, EPA 8082
Gas Chromatograph (Dual ECD)	Agilent	7890A/G3440A	CN10741034	2007-01-01	EPA 608, EPA 8082, EPA 8082 LL
Gas Chromatograph (Dual FID)	Agilent	6890N/G1540N	US10546009	2007-01-01	EPA 8015B Diesel
Gas Chromatograph (Dual FID)	Agilent	6890N/G1540N	US10546010	2007-01-01	EPA 8015B Diesel

Equipment/ Instrument	Manufacturer	Model Number	Serial Number	Placed in Service (Year)	Methods Performed
Gas Chromatograph (FID/PID)	Agilent	5890 Series II	S/N3133A37568	2008-01-01	EPA 8015(M) Methanol/Ethanol
Gas Chromatograph (FID)	Agilent	6890N	CN10505005	2013-01-18	EPA 8015B Diesel
Gas Chromatograph (Dual ECD)	Agilent	6890N	US10212094	2009-01-01	EPA 505
Gas Chromatograph (Dual ECD)	Agilent	6890N	US10244152	2009-01-01	EPA 552.2
Gas Chromatograph (Dual ECD)	Agilent	6890N	US10402034	2009-01-01	EPA 552.2, EPA 504.1
Gas Chromatograph (Dual ECD)	Agilent	6890N	US10244151	2010-01-01	EPA 515.4
HPLC (FLD)	Agilent	1100	DE14903835	2009-01-01	EPA 547
HPLC (DAD)	Agilent	1100	DE14914766	2009-01-01	EPA 549.2
HPLC (FLD)	Agilent	1100	DE14903629	2009-01-01	EPA 531.1
HPLC (DAD)	Hewlett Packard	G1316A	US54000547	2009-01-01	EPA 8315A
pH Meter	Mettler Toledo	SevenEasy	1227116127	2006-01-01	Redox
pH Meter	Thermo	OrionStarA111	J00943	2006-01-01	pH for TCLP
pH meter	Hach	HQ40d	150800013699	2017-02-07	EPA 150.1, SM 4500- H+ B
pH meter	Thermo Scientific	STARA1110	J15139	2017-02-09	EPA 150.1, SM 4500- H+ B
Turbidity Meter	Orbeco-Hellige	965-10A	5187	2009-01-01	EPA 180.1, SM 2130 B
pH meter	Thermo Scientific	Orion 3 Star pH Portable	A12744	2017-01-01	EPA 150.1, SM 4500- H+ B
Flow Injection Mercury Analyzer	Perkin Elmer	FIMS 400	4167	1995-01-01	EPA 245.1, EPA 7470, EPA 7471
Flow Injection Mercury Analyzer	Perkin Elmer	FIMS 400	401510021001	2010-01-01	EPA 245.1, EPA 7470, EPA 7471
Inductively Coupled Plasma Optical Emission Spectrometer	Perkin Elmer	Optima 5300DV	077N5112802	2006-01-01	EPA 200.7, EPA 6010B
Inductively Coupled Plasma Optical Emission Spectrometer	Perkin Elmer	Optima 8300	078N1051001	2011-01-01	EPA 200.7, EPA 6010B

Equipment/ Instrument	Manufacturer	Model Number	Serial Number	Placed in Service (Year)	Methods Performed
Inductively Coupled Plasma Mass Spectrometer	Agilent	7700 series G3281A	JP09480189	2010-01-01	EPA 200.8 DW
Inductively Coupled Plasma Mass Spectrometer	Agilent	7700 series G3281A	JP12091608	2012-01-01	EPA 200.8, EPA 6020, EPA 6020 LL
Inductively Coupled Plasma Mass Spectrometer	Agilent	7900	JP16211410	2016-06-27	EPA 200.8, EPA 6020, EPA 6020 LL
Turbidity Meter	Orbeco-Hellige	965-10A	4389	2007-01-01	EPA 180.1, SM 2130 B
Stereo Microscope with Fluorescence Source	VWR	HF-745	V167693	2009-01-01	
Compound Microscope (10x100)	VWR	BB-P/TB-P	V167531	2009-01-01	
UV Lamp (small)	UVP	CC-10	95007201	2009-01-01	
UV Lamp (big)	UVP	C-65	95025701	2009-01-01	
UV Viewing Cabinet (big)	UVP	UVLMS	95025201	2009-01-01	
Autoclave	Tuttnaur/ Brinkman	3870E	2903420	2009-01-01	
Autoclave	Market Forge	STM-E Type C	3Y0521	2009-01-01	
Incubator for Micro (35C)	VWR	1915	800902	2009-01-01	MTF and QC
Incubator for Micro (35C)	VWR	1915	1102003	2009-01-01	P/A, HOC-SIM, HPC- PP, Q-Tray
Incubator for Micro	Fisher Scientific	Fisher-Isotemp	501N0018	2009-01-01	
Incubator for Micro (55C)	Fisher Scientific	516D	502N0034	2009-01-01	
pH Meter	Fisher Scientific	Accumet AB15 Plus	AB92334024	2010-01-01	Microbiology pH
pH Meter	Thermo Scientific	Orion Star AIII	J0791	2014-04-07	Microbiology pH
Quanti Tray Sealer	ldexx	89-10894-04	6345	2009-01-01	
UV Lamp with Black Box	UVLMS	38EL-Series UV	030510-001	2009-01-01	

Equipment/ Instrument	Manufacturer	Model Number	Serial Number	Placed in Service (Year)	Methods Performed
Colorimeter for Chlorine	Hach	Pocket ColrimeterII	13050E222500		SM 4500-CI G
Colorimeter for Chlorine	Hach	Pocket ColrimeterII	08120E115054		SM 4500-CI G
pH Meter	Oaktron	EcoTestr pH2	2491005	2016-06-08	Field pH
pH Meter	Oaktron	EcoTestr pH2	2490996	2016-06-08	Field pH
pH Meter	Oaktron	EcoTestr pH2	2491010	2016-06-08	Field pH
pH Meter	Oaktron	EcoTestr pH2	554915		Field pH
ISCO GLP Sampler	Teledyne ISCO	60-2954-00	210F01206	2006-01-01	Field Sampling
ISCO GLP Sampler	Teledyne ISCO	60-2954-00	202F00477	2006-01-01	Field Sampling
ISCO GLP Sampler	Teledyne ISCO	60-2954-00	210F01211	2006-01-01	Field Sampling
ISCO GLP Sampler	Teledyne ISCO	60-2954-00	210C01100	2006-01-01	Field Sampling
ISCO 3710 Sampler	Teledyne ISCO	603714001	198H00868	2006-01-01	Field Sampling
Colorimeter for Chlorine	Hach	Pocket ColrimeterII	09110E138552		SM 4500-CI G
Colorimeter for Chlorine	Hach	Pocket ColrimeterII	08030E089795		SM 4500-CI G
pH Meter	Thermo Scientific	Orion 3Star 1219000	A11235	2010-07-01	Field Sampling
pH Meter	Hach	Sens10N™+pH1	321113	2013-07-15	Field Sampling
Fluoride Probe	Orion	96-09	9609BN	2006-01-01	SM 4500-F C, EPA 9214
BOD probe	Jenco			2006-01-01	BOD
Colorimeter for Chlorine	Hach	Pocket ColrimeterII	06060D51326	2006-01-01	SM 4500-CI G
Conductivity Meter	VWR	21800-012	Q022545	2009-01-01	SM 2510 B
Conductivity/TDS Probe	Acument	AP75	943318	2013-01-01	SM 2510 B
NanoPure Diamond (UV/UF)	Barnstead	D4641	582910257268		
Furnace, Thermolyne 48000	Thermolyne	F48015	1205001206827	2015-01-01	TVS

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Equipment/ Instrument	Manufacturer	Model Number	Serial Number	Placed in Service (Year)	Methods Performed
UV/VS Spectrometer	Thermo Spectronic	Genesys20	3SGQ068003	2012-01-01	SM 3500-Cr D, EPA 365.3, SM 5220 D, EPA 410.4, EPA 7196A, EPA 9014, SM 4500-CN E/I, SM 4500-S2- D, SM 5540 C, SM 4500-KMnO4, LACSD 253B/258
UV/VS Spectrometer	Thermo Spectronic	Genesys20	3SGS260009	2014-10-06	SM 3500-Cr D, EPA 365.3, SM 5220 D, EPA 410.4, EPA 7196A, EPA 9014, SM 4500-CN E/I, SM 4500-S2- D, SM 5540 C, SM 4500-KMnO4, LACSD 253B/258
Ion Chromatograph	Dionex	LC25	2050420	2005-01-01	EPA 300.1
Ion Chromatograph	Dionex	ICS-1000	3110585	2002-01-01	EPA 300.0, EPA 9056, EPA 300.1
Ion Chromatograph	Dionex	LC 30	97040546	2002-01-01	EPA 300.0, EPA 9056
Ion Chromatograph	Dionex	LC20	94010215	2006-09-01	EPA 300.0, EPA 9056, EPA 300.1
Ion Chromatograph	Metrohm	861/838	1861004003159/ 1838001009124	2010-03-29	EPA 300.0, EPA 9056
Ion Chromatograph (with UV/VIS Detector)	Metrohm	881	1881000007119	2010-03-29	EPA 218.6, EPA 7199
Ion Chromatograph (with UV/VIS Detector)	Metrohm	881/887	15105/03140	2011-05-02	EPA 218.7
Ion Chromatograph	Metrohm	881	1881000123101	2012-11-05	EPA 218.6, EPA 7199
Ion Chromatograph	Metrohm	861	1861002008105	2013-10-03	EPA 300.0, EPA 9056
Ion Chromatograph (with UV/VIS Detector)	Dionex	ICS-2000-TC	8010736	2013-10-03	EPA 218.6, EPA 7199
Ion Chromatograph	Dionex	ICS-2000	4100753	2013-10-28	EPA 314.0
Ion Chromatograph	Dionex	ICS-2100	11021089	2014-01-24	EPA 314.0
Ion Chromatograph	Dionex	ICS-2100	13071408	2015-01-01	EPA 314.0
Ion Chromatograph	Dionex	ICS-1600	14028658	2016-04-06	EPA 300.0, EPA 9056
Ion Chromatograph	Dionex	ICS-1600	11071115	2016-04-06	EPA 300.0, EPA 9056
Ion Chromatograph/ Mass Spectrometer	Metrohm (IC)/ Agilent (MS)	Metrohm 820 IC/ Agilent LC/MSD SL	1820023004102/ US34800214	2005-01-01	EPA 332.0, EPA 6860

Equipment/ Instrument	Manufacturer	Model Number	Serial Number	Placed in Service (Year)	Methods Performed
Ammonia Probe	Orion	96-12		2005-01-01	SM 4500-NH3 D
Lachat Flow Injection Analyzer	Lachat	QuickChem 8500 Series 2	140100001626	2014-01-28	EPA 350.1
Auto-titrator	ManTech	PC-Titrate PC1000-102	MS-9K8-210	2009-01-01	SM2320B, 150.1, SM4500H-B, SM 4500-NH3 D
mV Meter	Denver Instrument	Basic	13036	2006-01-01	pH for BOD
pH Meter	Denver Instrument	UB-10	UB10107126	2008-01-02	pH for alkalinity
mV Meter	Accumet	Model 25	C0021582	2006-01-01	BOD
pH Meter	Accumet	AB15	AB92338994	2006-01-01	Fluoride
pH Meter	Sartorius	Basic Meter PB-	31350114	2014-10-14	рН
TOC Analyzer	Tekmar- Dohrmann	Phoenix 8000	US02106006	2002-01-01	SM 5310 C
TOC Analyzer	Shimadzu	TOV-V CSH	HS1104535257CS	2011-01-01	SM 5310 B, EPA 9060
TOC Analyzer	Tekmar- Dohrmann	Phoenix 8000	99099014	2016-01-31	EPA 9060 (Soil Only)
Kone Aquakem 250	Thermo Scientific	Aquakem 250	E2319629		EPA 351.2
Note:	N				

~ ¹ The Instrumentation List is subject to change. Refer to the Equipment database for the updated list.

Table 20-2.	Example – Schedule of Routine Maintenance
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Instrument	Procedure	Frequency
Graphite Furnace (GFAA)	Inspect graphite tube Inspect contact rings Clean windows Align lamp	Daily Daily Daily Daily
Mercury Analyzer	Check tubing for wear Fill rinse tank with 10% HCI Fill reductant bottle with 10% Stannous Chloride	Daily Daily Daily
ICP	Check/replace pump tubing Check liquid argon supply Check fluid level in waste container Check/clean/replace filters Check torch Clean torch and nebulizer	Daily/as needed Daily Daily Daily/as needed Daily As needed

Instrument	Procedure	Frequency
ICP/ MS	Check/replace pump tubing Inspect torch and injector cones Clean/replace ion lens Replace torch o-rings Check/replace gas filters Change rough pump oil Check chiller water level	Daily/as needed Daily As needed As needed As needed As needed Weekly
UV-Vis Spectrophotometer	Clean sample holder Precision check/alignment of flow cell Wavelength verification check	As required As required Semi-annually
Gas Chromatograph/Mass Spectrometer (GCMS)	Bake trap (VOC only) Clean source Check/change vacuum pump oil Clean injectors; replace liners (SVOC only) Replace column Clean cooling fan grills	Daily As needed Annually, as needed Daily As needed Semiannually
Gas Chromatograph (GC)	Change septum Check gases Replace or clip column Clean injectors; replace liners Clean cooling fan grills	As needed Daily As needed As needed Semiannually
Electron Capture Detector (ECD)	Detector wipe test (Ni-63) Detector cleaning	Semi-annually Sent out, as needed
Flame Ionization Detector (FID)	Detector cleaning	As required
Flame Photoionization Detector (FPD)	Clean and/or Replace Lamp	As required
Photoionization Detector (PID)	Change O-rings Clean lamp window	As required As required
Ion Chromatograph (IC)	Replace column disks Change guard columns Check pump seals Replace tubing Replace suppressor Check fluid level in waste container Clean cooling fan grills	As required As required As required As required As required Daily Semiannually
Balances	Class "S" traceable weight check Clean pan and check if level Outside calibration service	Daily, when used Daily At least Annually
Conductivity Meter	0.01 M KCl calibration Conductivity cell cleaning	Daily As required
Turbidimeter	Check light bulb Clean sample holder	Daily, when used Daily, when used
Deionized/Distilled Water	Daily conductivity check Check deionizer light Monitor for VOA's System cleaning Replace cartridge & large mixed bed resins	Daily Daily As required As required As required
Drying Ovens	Temperature monitoring Temperature adjustments	When used As required

Instrument	Procedure	Frequency
Refrigerators/ Freezers	Temperature monitoring Temperature adjustment Defrosting/cleaning	Daily As required As required
pH/Specific Ion Meter	Calibration/check slope Clean electrode	Daily As required
BOD Incubator	Temperature monitoring Incubator cleaning	Daily As required
Centrifuge	Check brushes and bearings	As needed
Water baths	Temperature monitoring Water replaced	Daily Monthly or as needed
Automated Solvent Extraction units (ASE)	Check solvent reservoirs Check tubing	Daily Daily
TurboVaps	Check gas lines Check water level Calibrate temperature	Daily Daily Annually
Total Organic Carbon Analyzer	Check gas flow Check reagent reservoir levels Replace o-rings Check autosampler needle Replace scrubbers Replace catalyst	Daily Daily As needed Daily Annually As needed
Automated Analyzer	Clean sampler Check all tubing Clean detector Clean optics and cells	Daily Daily Daily Daily
Infrared Spectrophotometer (IR)	Clean lens/optimize	As needed
Flashpoint Apparatus	Check gas line for leaks Check stirrer speed	Daily Annually
Rotators	Verify rotation speed	Annually

SECTION 21. MEASUREMENT TRACEABILITY

21.1 <u>Overview</u>

Traceability of measurements shall be assured using a system of documentation, calibration, and analysis of reference standards. Laboratory equipment that are peripheral to analysis and whose calibration is not necessarily documented in a test method analysis or by analysis of a reference standard shall be subject to ongoing certifications of accuracy. At a minimum, these must include procedures for checking specifications of ancillary equipment: balances, thermometers, temperature, Deionized (DI) and Reverse Osmosis (RO) water systems, automatic pipettes and other volumetric measuring devices. (Refer to Section 20.3). With the exception of Class A Glassware and Glass microliter syringes, quarterly (or monthly) accuracy checks are performed for all mechanical volumetric devices. Microsyringes 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 and Glass microliter syringes should be routinely

inspected for chips, acid etching or deformity (e.g., bent needle). If the Class A glassware or syringe is suspect, the accuracy of the glassware will be assessed prior to use.

21.2 <u>NIST-Traceable Weights and Thermometers</u>

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 <u>Reference Standards / Materials</u>

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 Identification Number and expiration date. All documentation received with the reference standard is retained as a QC record and references the Standard Identification Number.

All reference, primary and working standards/materials, whether commercially purchased or laboratory prepared, must be checked regularly to ensure that the variability of the standard or material from the 'true' value does not exceed method requirements. The accuracy of calibration standards is checked by comparison with a standard from a second source. In cases where a second standard manufacturer is not available, a vendor certified different lot is acceptable for use as a second source. For unique situations, such as air analysis where no other source or lot is available, a standard made by a different analyst would be considered a second source. The appropriate Quality Control (QC) criteria for specific standards are defined in laboratory SOPs. In most cases, the analysis of an Initial Calibration Verification (ICV) or

LCS (where there is no sample preparation) is used as the second source confirmation. These checks are generally performed as an integral part of the analysis method (e.g. calibration checks, laboratory control samples).

All standards and materials must be stored and handled according to method or manufacturer's requirements in order to prevent contamination or deterioration. Refer to the Corporate Environmental Health & Safety Manual or laboratory SOPs. 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 the TALS Reagent program or in binders or other organized files stored within each department. 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 method specific SOPs and the laboratory SOP No. IR-QA-STDCNTRL.

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 TALS Reagent program, and are assigned a unique identification number. The following information is typically recorded in the electronic database within TALS.
- Standard ID
- Description of Standard
- Department
- Preparer's name

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- 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 (Specify from TALS or logbook)
- Special Health/Safety warnings if applicable

Records must also be maintained of the date of receipt for commercially purchased items or date of preparation for laboratory prepared items. Special Health/Safety warnings must also be available to the analyst. This information is maintained in the TALS Reagent program.

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 <u>Overview</u>

The laboratory provides sampling services. Sampling procedures are described in the laboratory SOP No. IR-SC-FIELD.

22.2 <u>Sampling Containers</u>

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 <u>Preservatives</u>

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 <u>Sampling Containers, Preservation Requirements, Holding Times</u>

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 <u>Sample Aliquots / Subsampling</u>

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 & subsampling are located in the laboratory SOP No. IR-QA-SUBSAMP.

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 collector's 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 lab when personnel at the fixed laboratory facility have physical contact with the samples.

Note: Independent couriers are not required to sign the COC form. The COC is usually kept in the sealed sample cooler. The receipt from the courier is stored in log-in by date; it lists all receipts each date.

23.1.2 Legal / Evidentiary Chain-of-Custody

If samples are identified for legal/evidentiary purposes on the COC, sample receiving personnel 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 during login.

23.2 <u>Sample Receipt</u>

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 and are discussed in detail in laboratory SOP No. IR-SC-LOGIN.

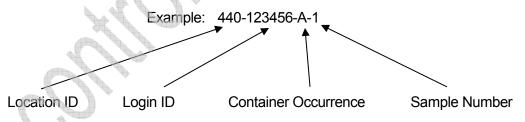
23.2.1 <u>Laboratory Receipt</u>

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 in the TALS NCM program and brought to the immediate attention of the client. The COC, shipping documents, documentation of any non-conformance, irregularity, or compromised sample receipt, record of client contact, and resulting instructions become part of the project record.

23.2.1.1 Unique Sample Identification

All samples that are processed through the laboratory receive a unique sample identification to ensure that there can be no confusion regarding the identity of such samples at any time. 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):



Note: Sample ID is generated by TALS.

The above example states that TestAmerica Irvine Laboratory (Location 440). Login ID is 123456 (unique to a particular client/job occurrence). The container code indicates it is the first container ("A") of Sample #1.

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

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Example: 440-123456-A-1-A

Secondary Container Occurrence

Example: 440-123456-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 <u>Sample Acceptance Policy</u>

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

- A COC filled out completely;
- Samples must be properly labeled;
- Proper sample containers with adequate volume for the analysis (Sampling Guide) and necessary QC;
- Samples must be preserved according to the requirements of the requested analytical method (Sampling Guide);
- sample holding times must be adhered to (Sampling Guide);

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 LIMS according to the laboratory SOP No. IR-SC-LOGIN.

23.4 <u>Sample Storage</u>

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 (for analyses requiring thermal preservation) or in protected locations like secured shelvings for acid-preserved water containers requiring only metals analysis. 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 the refrigerators for two to four weeks after analysis, which meets or exceeds most sample holding times. After two to four weeks the samples are moved to dry room temperature, sample archive area where they are stored for an additional four weeks before they are disposed of. This eight week holding period allows samples to be checked if a discrepancy or question arises. Special arrangements may be made to store samples for longer periods of time. This extended holding period allows additional metal analyses to be performed on the archived sample and assists clients in dealing with legal matters or regulatory issues.

Access to the laboratory is controlled such that sample storage need not be locked at all times unless a project specifically demands it. Samples are accessible to laboratory personnel only. Visitors to the laboratory are prohibited from entering the refrigerator and laboratory areas unless accompanied by an employee of TestAmerica.

23.5 Hazardous Samples and Foreign Soils

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

23.6 <u>Sample Shipping</u>

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 <u>Sample Disposal</u>

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 No. IR-EHS-WASTE). 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, etc.), 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.

Effective Date: 03/14/2017 Sumple Specific Notes: Month are retained longer than 1 month) SDG No. ate Time bate/T/im lob No.)ale/Tin 200 Ameduno Amedino Vine duno Date: Carrier: eccived by: ecenved by: eceived by: Site Contact: un Contac sigmes barantia E of Date/Time: Date Time Date/Time Matrix Analysis Turnaround Tim Calendar (C) or Work Days (W) Sample Unknown TAT If Billered from Belon 2 weeks I week: 2 days 1 day Sample Toject Manager Poison B 0000 Sample Date reservation Used: 1=Ics. 2=HCl; 3=H2SO4; 4=HNO3; 5=NaOH; 6= Other company: OCUPANV: ompano: XRJ/P.) Skin Irritan Sample Identification Phone FAX asible Hazard (dentification Client Cont.

Figure 23-1. Example – Chain of Custody (COC)

TestAmerica

Chain of Custody Record

phone 949.261.1022 fax 949.260.3299

17461 Derian Ave Suite 100 Irvine, CA 92614

Irvine

our Company Name here

XXXX-XXX (XXX XXXX-XXX (XXX

roject Name

#0

Site

City/State/Zip

Address

TestAmerica Laboratories, Inc.

OC Requi

ectal Instructions

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	to 4°C (other than water samples for metals analysis and samples for air 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 $\leq 10^{\circ}$ C), the samples must arrive within $\pm 2^{\circ}$ C of the required temperature or within the method specified range. Note: Samples that are hand-delivered to the laboratory immediately after collection may not have had time to cool sufficiently. In this case the samples will be considered acceptable as long as there is evidence that the chilling process has begun (arrival on ice).
	Chemical preservation (pH) will be verified at the time of analysis and the project manager will be notified immediately if there is a discrepancy. If analyses will still be reported, all affected results will be flagged to indicate improper preservation
5)	 Sample Holding Times TestAmerica will make every effort to analyze samples within the regulatory holding time. Samples must be received in the laboratory with enough time to perform the sample analysis. Except for short holding time samples (< 72hr HT) sample must be received with at least 48 hrs (working days) remaining on the holding time for us to ensure analysis.
	Analyses that are designated as "field" analyses (pH, Dissolved Oxygen, Residual Chlorine, and Redox Potential) should be analyzed within 15 minutes. Dissolved Metals samples should be filtered in the field within 15 minutes. Dissolved Sulfide samples should be flocculated in the field within 15 minutes. The actual times of all "field" sample analyses are noted on the "Short Hold Time Detail Report" in the final report. If the analysis is performed at the laboratory, the data will be flagged on the final report with an "HF' to indicate holding time is 15 minutes.
6)	All samples submitted for Volatile Organic analyses should have a Trip Blank submitted at the same time. TestAmerica will supply a blank with the bottle order.
7)	The project manager will be notified if any sample is received in damaged condition TestAmerica will request that a sample be resubmitted for analysis.
8)	Recommendations for packing samples for shipment.
	> Pack samples in "wet" Ice rather than "Blue" ice packs.
	Soil samples should be placed in plastic zip-lock bags. The containers often have dirt around the top and do not seal very well and are prone to intrusion from the water from melted ice.
6	Water samples would be best if wrapped with bubble-wrap or paper (newspaper, or paper lowels work) and then placed in plastic zip-lock bags.
	Fill extra cooler space with bubble wrap
\bigcirc	G:\FORMS\SampleControl\Sample Acceptance Policy 6-20-2014.doc
	Updated June 20, 2014

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Figure 23-3.	Example – Hazardous & Quarantine/Foreign Soil - Drum for Incineration S	Sample
Notice		

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UUIL	SAMPLE			
	67 (III) = E	Date:		
CLIENT		LOG N		
PROJECT ID NO		MATRI	A A A A	
	ntially Hazardous		LAC.	
Sample Haza				
	n Foreign Soil (Mexico, Ca	anada, Hawaii, etc.)		
SAMPLE ID	CONTAINER T		D (Compound &	È.
1		Result)		
				t
-				
1				
-				
A				
				1
DATE ARCHIVED:		Initia	c	1
(Sample placed on hazardous	shelves)		\$	
DATE DISPOSED:		Initia bosal, please date & return this		

SECTION 24. ASSURING THE QUALITY OF TEST RESULTS

24.1 <u>Overview</u>

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 <u>Controls</u>

Sample preparation or pre-treatment is commonly required before analysis. Typical preparation steps include homogenization, grinding, solvent extraction, sonication, acid digestion, distillation, reflux, evaporation, drying and ashing. During these pre-treatment steps, samples are arranged into discreet manageable groups referred to as preparation (prep) batches. Prep batches provide a means to control variability in sample treatment. Control samples are added to each prep batch to monitor method performance and are processed through the entire analytical procedure with investigative/field samples.

24.3 <u>Negative Controls</u>

Control Type	Details
Method Blank (MB)	Are used to assess preparation and analysis for possible contamination during the preparation and processing steps.
	The specific frequency of use for method blanks during the analytical sequence is defined in the specific standard operating procedure for each analysis. Generally, it is 1 for each batch of samples; not to exceed 20 environmental samples.
	The method blank is prepared from a clean matrix similar to that of the associated samples that is free from target analytes (e.g., Reagent water, Ottawa sand, glass beads, etc.) and is processed along with and under the same conditions as the associated samples.
	The method blank goes through all of the steps of the process (including as necessary: filtration, clean-ups, etc.).
	Reanalyze or qualify associated sample results when the concentration of a targeted analyte in the blank is at or above the reporting limit (or at or above $\frac{1}{2}$ the reporting limit) as established by the method or by regulation, AND is greater than 1/10 of the amount measured in the sample.
Calibration Blanks	Are prepared and analyzed along with calibration standards where applicable. They are prepared using the same reagents that are used to prepare the standards. In some analyses, the calibration blank may be included in the calibration curve.
Instrument Blanks	Are blank reagents or reagent water that may be processed during an analytical sequence in order to assess contamination in the analytical system. In general, instrument blanks are used to differentiate between contamination caused by the analytical system and that caused by the sample handling or sample prep process. Instrument blanks may also be inserted throughout the analytical sequence to minimize the effect of carryover from samples with high analyte content.

Table 24-1. Negative Controls

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

24.3.1 Negative Controls for Microbiological Methods

Microbiological Methods utilize a variety of negative controls throughout the process to ensure that false positive results are not obtained. These controls are critical to the validity of the microbiological analyses. Some of these negative controls are:

 Table 24-2.
 Negative Controls for Microbiology

Control Type	Details	
Sterility Checks (Media)	Are analyzed for each lot of pre-prepared media, ready-to-use media and for each batch of medium prepared by the laboratory.	
Filtration Blanks	Are run at the beginning and end for each sterilized filtration unit used in a filtration series. For pre- sterilized single use funnels, a sterility check is performed on at least one funnel per lot.	
Sterility checks (Sample Containers)	Are performed on at least one container per lot of purchased, pre-sterilized containers. If containers are prepared and sterilized by the laboratory, one container per sterilization batch is checked. Container sterility checks are performed using non-selective growth media.	
Sterility Checks (Dilution Water)	Are performed on each batch of dilution water prepared by the laboratory and on each batch of pre- prepared dilution water. All checks are performed using non-selective growth media.	
Sterility Checks (Filters)	Are also performed on at least one filter from each new lot of membrane filters using non-selective growth media.	

Negative culture controls demonstrate that a media does not support the growth of non-target organisms and ensures that there is not an atypical positive reaction from the target organisms. Prior to the first use of the media, each lot of pre-prepared selective media or batch of laboratory

prepared selective media is analyzed with at least one known negative culture control as appropriate to the method.

24.4 **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 <u>Method Performance Control - Laboratory Control Sample (LCS)</u>

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 µg/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.

24.4.2 <u>Positive Controls for Microbiological Methods</u>

Each lot of pre-prepared media (including chromofluorogenic reagent) and each batch of laboratory prepared media is tested with a pure culture of known positive reaction.

In addition, every analytical batch also contains a pure culture of known positive reaction.

A pure culture of known negative reaction is also tested with each analytical batch to ensure specificity of the procedure.

24.5 <u>Sample Matrix Controls</u>

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.
5	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.

Control Type	Details		
Surrogate	Description	Are similar to matrix spikes except the analytes are compounds with properties that mimic the analyte of interest and are unlikely to be found in environment samples.	
Duplicates ²	Use	For a measure of analytical precision, with each matrix-specific batch of samples processed, a matrix duplicate (MD or DUP) sample, matrix spike duplicate (MSD), or LCS duplicate (LCSD) is carried through the complete analytical procedure.	
	Typical Frequency ¹	Duplicate samples are usually analyzed with methods that do not require matrix spike analysis.	
	Description	Performed by analyzing two aliquots of the same field sample independently or an additional LCS.	
Internal Standards	Use	Are spiked into all environmental and quality control samples (including the initial calibration standards) to monitor the qualitative aspect of organic and some inorganic analytical measurements.	
	Typical Frequency ¹	All organic and ICP methods as required by the analytical method.	
	Description	Used to correct for matrix effects and to help troubleshoot variability in analytical response and are assessed after data acquisition. Possible sources of poor internal standard response are sample matrix, poor analytical technique or instrument performance.	

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

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

24.6 Acceptance Criteria (Control Limits)

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.

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 150%.
- 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 ≤ 5% from previous, the control chart is visually inspected and, using professional judgment, they may be left unchanged if there is no effect 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 laboratory SOP No. IR-QA-CNTRLLIM.

One example: The QA department generates a Quality Control Limit Summary that contains tables that summarize the precision and accuracy acceptability limits for analyses performed at TestAmerica Irvine. This summary includes an effective date, is updated each time new limits are generated and is located in the TestAmerica LIMS (TALS). An archive of all limits used within the laboratory is also maintained in TALS.

- **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.

For TNI work, there is 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.

Though marginal exceedences may be allowed, 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, 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 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 <u>Overview</u>

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 <u>Test Reports</u>

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 For Samples) with a "sample results" column header.
- **25.2.2** Each report cover page printed on company letterhead, which includes the laboratory name, address and telephone number.
- **25.2.3** A unique identification of the report (e.g., work order number) and on each page an identification in order to ensure the page is recognized as part of the report and a clear identification of the end.

Note: Page numbers of report are represented as 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.
- **25.2.19** A statement that the report shall not be reproduced except in full, without prior express written approval by the laboratory.
- **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** The laboratory includes a cover letter.
- **25.2.23** Where applicable, a narrative to the report that explains the issue(s) and corrective action(s) taken in the event that a specific accreditation or certification requirement was not met.

- **25.2.24** When soil samples are analyzed, a specific identification as to whether soils are reported on a "wet weight" or "dry weight" basis.
- **25.2.25** Appropriate laboratory certification number for the state of origin of the sample, if applicable.
- **25.2.26** If only part of the report is provided to the client (client requests some results before all of it is complete), it must be clearly indicated on the report (e.g., partial report). A complete report must be sent once all of the work has been completed.
- **25.2.27** Any non-TestAmerica subcontracted analysis results are provided as 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.
- **25.2.28** 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.

25.3 <u>Reporting Level or Report Type</u>

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 CD deliverable form. Initial reports may be provided to clients by facsimile or e-mail, or uploaded to TestAmerica's Total Access database. Procedures used to ensure client confidentiality are outlined in Section 25.6.

25.3.1 <u>Electronic Data Deliverables (EDDs)</u>

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 Irvine offers a variety of EDD formats

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including, but is not limited to, NAS, ADR, COELT EDF, EQuIS, GISKEY, Microsoft Excel, Locus EIM, Standard TestAmerica Format, FoxPro, and Terrabase.

EDD specifications are submitted to the IT department by the PM for review and undergo the contract review process. Once the laboratory 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 <u>Supplemental Information for Test</u>

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.

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 <u>Environmental Testing Obtained From Subcontractors</u>

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. CA-L-S-002).

Data reported from analyses performed by a subcontract 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 <u>Client Confidentiality</u>

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 <u>known</u> to be potentially endangering to national security or an entity's proprietary rights will not be released.

Note: This shall not apply to the extent that the information is required to be disclosed by TestAmerica under the compulsion of legal process. TestAmerica will, to the extent feasible, provide reasonable notice to the client before disclosing the information.

Note: Authorized representatives of an accrediting authority are permitted to make copies of any analyses or records relevant to the accreditation process, and copies may be removed from the laboratory for purposes of assessment.

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

This material is intended only for the use of the individual(s) or entity to which it is addressed, and may contain information that is privileged and confidential. If you are not the intended recipient, or the employee or agent responsible for delivering this material to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please notify us immediately by telephone at the 1-800-765-0980 (or for e-mails: please notify us immediately by e-mail or by phone (1-800-765-0980) and delete this material from any computer).

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 <u>Amendments to Test Reports</u>

Corrections, additions, or deletions to reports are only made when justification arises through supplemental documentation. Justification is documented using the laboratory's corrective action system (refer to Section 12).

The revised report is retained in the TestAmerica LIMS (TALS), as is the original report. The revised report is stored in TALS under the job number along with a sequential revision number.

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. For example: This final report, identified as Revision 1, was revised on 11/3/2014 to include toluene in sample NQA1504 per client's request. This final report replaces the final report identified as Revision 0.

25.9 Policies on Client Requests for Amendments

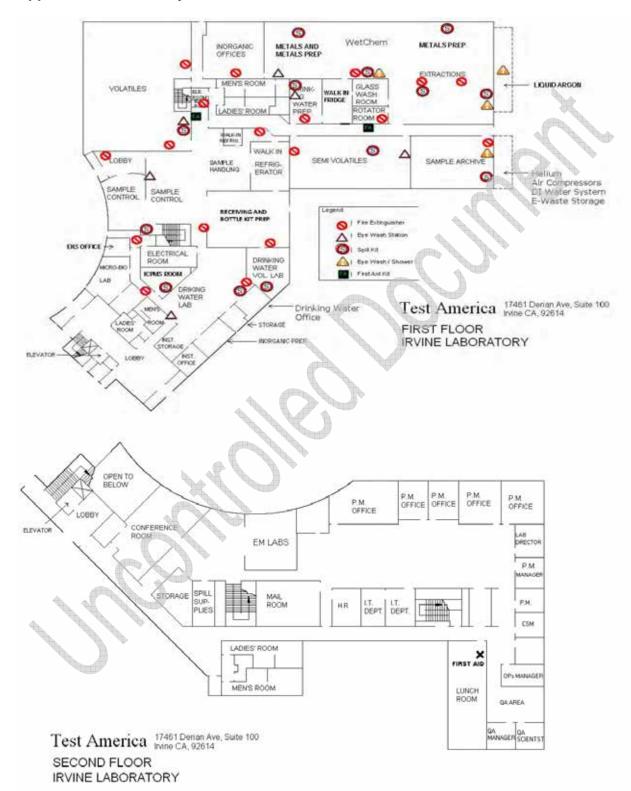
25.9.1 Policy on Data Omissions or Reporting Limit Increases

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 <u>no possible</u> impact on the interpretation of the analytical results and there is <u>no possibility</u> of the change being interpreted as misrepresentation by anyone inside or outside of our company.

25.9.2 <u>Multiple Reports</u>

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

Appendix 2. Glossary/Acronyms (EL-V1M2 Sec. 3.1)

Glossary:

Acceptance Criteria: Specified limits placed on characteristics of an item, process, or service defined in requirement documents. (ASQC)

Accreditation: The process by which an agency or organization evaluates and recognizes a laboratory as meeting certain predetermined qualifications or standards, thereby accrediting the laboratory.

Accuracy: The degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components which are due to sampling and analytical operations; a data quality indicator. (QAMS)

Analyst: The designated individual who performs the "hands-on" analytical methods and associated techniques and who is the one responsible for applying required laboratory practices and other pertinent quality controls to meet the required level of quality.

Analytical Uncertainty: A subset of Measurement Uncertainty that includes all laboratory activities performed as part of the analysis. (TNI)

Anomaly: A condition or event, other than a 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 re of acceptable quality (i.e., that they meet specified acceptance criteria).

Data Reduction: The process of transforming the number of data items by arithmetic or statistical calculations, standard curves, and concentration factors, and collation into a more useable form. (TNI)

Deficiency: An unauthorized deviation from acceptable procedures or practices, or a defect in an item (ASQC), whether in the laboratory's control or not.

Demonstration of Capability: A procedure to establish the ability of the analyst to generate analytical results of acceptable accuracy and precision. (TNI)

Document Control: The act of ensuring that documents (and revisions thereto) are proposed, reviewed for accuracy, approved for release by authorized personnel, distributed properly, and controlled to ensure use of the correct version at the location where the prescribed activity if performed. (ASQC)

Duplicate Analyses: The analyses or measurements of the variable of interest performed identically on two subsamples of the same sample. The results from duplicate analyses are used to evaluate analytical or measurement precision but not the precision of sampling, preservation or storage internal to the laboratory. (EPA-QAD)

Equipment Blank: Sample of analyte-free media which has been used to rinse common sampling equipment to check effectiveness of decontamination procedures.

External Standard Calibration: Calibrations for methods that do not utilize internal standards to compensate for changes in instrument conditions.

Field Blank: Blank prepared in the field by filing a clean container with pure de-ionized water and appropriate preservative, if any, for the specific sampling activity being undertaken. (EPA OSWER)

Field of Accreditation: Those matrix, technology/method, and analyte combinations for which the accreditation body offers accreditation.

Holding Times: The maximum time that samples may be held prior to analyses and still be considered valid or not compromised. (40 CFR Part 136)

Internal Standard: A known amount of standard added to a test portion of a sample as a reference for evaluating and controlling the precision and bias of the applied analytical test method. (TNI)

Internal Standard Calibration: Calibrations for methods that utilize internal standards to compensate for changes in instrument conditions.

Instrument Blank: A clean sample (e.g., distilled water) processed through the instrumental steps of the measurement process; used to determine instrument contamination. (EPA-QAD)

Instrument Detection Limit (IDL): The minimum amount of a substance that can be measured with a specified degree of confidence that the amount is greater than zero using a specific instrument. The IDL is associated with the instrumental portion of a specific method only, and sample preparation steps are not considered in its derivation. The IDL is a statistical estimation at a specified confidence interval of the concentration at which the relative uncertainty is ± 100%. The IDL represents a <u>range</u> where <u>qualitative</u> detection occurs on a specific instrument. Quantitative results are not produced in this range.

Laboratory Control Sample (however named, such as laboratory fortified blank, spiked blank, or QC check sample): A sample matrix, free from the analytes of interest, spiked with verified known amounts of analytes or a material containing known and verified amounts of analytes, taken through all preparation and analysis steps of the procedure unless otherwise noted in a reference method. It is

generally used to establish intra-laboratory or analyst specific precision and bias or to assess the performance of all or a portion of the measurement system.

An LCS shall be prepared at a minimum of 1 per batch of 20 or less samples per matrix type per sample extraction or preparation method except for analytes for which spiking solutions are not available such as total suspended solids, total dissolved solids, total volatile solids, total solids, pH, color, odor, temperature, dissolved oxygen or turbidity. The results of these samples shall be used to determine batch acceptance.

Least Squares Regression (1st Order Curve): The least squares regression is a mathematical calculation of a straight line over two axes. The y axis represents the instrument response (or Response ratio) of a standard or sample and the x axis represents the concentration. The regression calculation will generate a correlation coefficient (r) that is a measure of the "goodness of fit" of the regression line to the data. A value of 1.00 indicates a perfect fit. In order to be used for quantitative purposes, r must be greater than or equal to 0.99 for organics and 0.995 for inorganics.

Limit(s) of Detection (LOD) [a.k.a., Method Detection Limit (MDL)]: A laboratory's estimate of the minimum amount of an analyte in a given matrix that an analytical process can reliably detect in their facility. (TNI)

LOD Verification [a.k.a., MDL Verification]: A processed QC sample in the matrix of interest, spiked with the analyte at no more than 3X the LOD for single analyte tests and 4X the LOD for multiple analyte tests and processed through the entire analytical procedure.

Limit(s) of Quantitation (LOQ) [a.k.a., Reporting Limit]: The minimum levels, concentrations, or quantities of a target variable (e.g., target analyte) that can be reported with a specified degree of confidence. (TNI)

(QS) Matrix: The component or substrate that contains the analyte of interest. For purposes of batch and QC requirement determinations, the following matrix distinctions shall be used:

Aqueous: Any aqueous sample excluded from the definition of Drinking Water 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 sorbent 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: The minimum concentration of a substance (an analyte) that can be measured and reported with 99% confidence that the analyte concentration is greater than zero and is determined from analysis of a sample in a given matrix containing the analyte. (40 CFR Part 136, Appendix B)

Negative Control: Measures taken to ensure that a test, its components, or the environment do not cause undesired effects, or produce incorrect test results.

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 2^{nd} 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 2^{nd} 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 Manager: A member of the staff of an environmental laboratory who exercises actual day-today 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

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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 Irvine 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:

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tifications	Expiration Date 07/108/2018 06/30/2018 07/129/2017 * 06/30/2017 * 06/30/2017 * 01/29/2017 * 01/29/2017 * 01/29/2017 * 01/29/2017 * 01/29/2017 *	www.testamericatinc.com
FestAmerica Certifications	Identification P330-15-00184 10256 4028 4028 4028 CA01531 A20671 CA ELP4 2706 CA01531 CA ELP4 2706 CA ELP	with the Program Authority ou, please visit our website at
TestA	Authonity USDA California Cregon Kansas Alaska Arizona Guam Hawai Nerada Net Mexico Northern Mariana Islands Washington	* Certification Valid - Laboratory is Pending Renewal with the Program Authority ontact a local TestAmericarepresentative nearest you, please wisit our websi
	Program Federal LA Ch Sanitation Districts NELAP Secondary AB State Program State Program State Program State Program State Program State Program State Program	 Certification Valid - Laboratory is Pending Renewal with the Program Authority For more information, or to contact a local TestAmerica representative nearest you, please visit our website at www.lestamericainc.com
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The certificates and accredited parameter lists are available for each State/Program at <u>www.testamericainc.com</u> under Analytical Services Search – Certifications.

Company Confidential & Proprietary



Quality Assurance Summary (QAS)

Client / Project:	Boeing
QAPP or SOW:	Waste Discharge Requirements for the Boeing Company, Santa Susana Field Laboratory, Order R4-2015-0033, NPDES CA0001309, Los Angeles Regional Water Quality Control Board, April 1, 2015

Project Organization

Project Organization						
Project Managers	Urvashi Patel					
Special Notification	Management Changes					
Requirements	TestAmerica must notify all parties (Consultant, Mec ^x) within 30 days of any changes in senior management (Lab Director, QA Manager, Operations Manager, Manager of Project Management) or Project Manager at the laboratory.					
	Certification Changes					
	In addition to providing an annual update on current laboratory methods, certifications, reporting limits and MDLs, any changes in the laboratory's ability to perform requested analyses must be communicated to all parties immediately. Changes will generally be provided no later than October, prior to the start of the rainy season.					
Sampling Event Information	This discharge permit encom monthly, quarterly, and annua	or discharge under NPDES permit CA0001309. passes 16 outfalls that are monitored on routine, al frequencies as specified in the permit. neir monitoring parameter lists:				
	Monitoring List*	Outfall ID				
	E-2a	001, 002, 011, 018				
	E-2b	003, 004, 005, 006, 007, 008, 009, 010				
	E-2c	019,020				
	*From Permit table					



Sampling Event Information, continued	Monitoring Frequency			
	Tables E-2a, b, and c in the Permit specify the analytical parameters, units, sample type (grab or composite) and sampling frequency. Sampling frequencies may change based on detects, non-detects, and recommendations by the consultants and/or the SSFL expert panel.			
Special Bottle Order/Bottle Preps (containers, preservation, etc.)	 Bottle orders are coordinated between the TestAmerica project manager and the consultant. The laboratory will be instructed as to what Outfall and events are planned to be sampled so correct bottle sets can be sent. ISRA, BMP and GETs bottle orders are sent in bulk shipments when requested by Consultant Preserved bottles must be individually bagged and an absorbent pad must also be placed each cooler in case of a spill. Laboratory pre-printed labels on NPDES outfall bottle orders when requested by consultant. Laboratory-supplied water for trip blanks must be lot-traceable. When requested by consultant, low level 1631 mercury kits will be utilized for sample collection for method 245.1. Consultant will inform the lab as to whether these unpreserved VOA vials should have nitric acid added to them prior to or after sample collection. Interim Source Removal Action (ISRA) Performance Monitoring Samples are collected in accordance with the Los Angeles Regional Water Quality Control Board (LARWQB). Consultant indicates on the COC which samples are to be run through the Dekaport Cone Splitter. These split samples are analyzed by both TestAmerica Irvine and American Scientific Laboratories (ASL). 			
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Sample Pickup		
	1)	All couriers must be on pre-approved courier list to be granted access to SSFL. If an outside courier service is used, the courier must have been audited by TestAmerica.
	2)	TestAmerica will submit a list of couriers to Consultant with the appropriate documentation so that the courier will be granted access to the site.
	3)	If a new courier is hired and it is anticipated that he/she will be servicing SSFL, then TestAmerica will pro-actively submit the documentation to Consultant for SSFL approval.
	4)	At a minimum, appropriate courier documentation consists of the full name of the courier.
	5)	Custody seals must be placed on the cooler whenever samples are not counted in the field.
	6)	Check for short-hold analyses on COCs and notify the TestAmerica project manager.
		a) Bioassay-36 hour holding time may need to be delivered immediately to Aquatic Bioassay Laboratories.
		 b) Hydrazine has a 72 hour holding time so may need to be sent via Fed-ex direct from site to the appropriate subcontract lab: TestAmerica Denver for SSFL NPDES work.
		c) Notify the TestAmerica project manager of all other analyses with short holding times (48 hours or less) such as Micro, bioassays, Chromium VI, nitrate, pH, and turbidity.
		d) 525.2 Diazinon and Chloropyrifos has a 24-hour extraction holding time.



Subsampling or Compositing?	Cone Splitting Procedure (see IR-WI-CONE_SPLIT, current revision)
	 The Cone Splitter must be correctly assembled, cleaned, leveled and pre- rinsed prior to use. A Performance Check must be run prior to the first sampling event of the season.
	 There are two levels of cleaning for the cone splitter. Each has a checklist:
	a) Level 1 is performed each time before use for samples collected from different sites on the same day.
	 b) Level 2 cleaning is performed if the splitter has dried before cleaning or was used for splitting sample with known or suspected high level target analytes.
	 Only laboratory staff with documented training on the Cone Splitter Work Instruction (can be involved in the cone splitting procedure.
	Clarification on Cone Splitter Protocol
	 Performance tests are performed at the request of the Consultant, typically on an annual basis.
	2) Sample Volumes: the client submits approximately 4 liters of sample. The final volumes after splitting are approximately 800mL in each 1 Liter container and approximately 400mL in each 500mL container. For dioxin analysis, the dioxin testing laboratory is provided with instructions on the COC to use the contents of both a 1 liter amber and a 500mL amber for testing and to perform a solvent rinse on both containers. For equipment blanks, volume from all 3-500mL ambers are used and solvent rinsed.
	3) Holding time: Lab performs cone splitting within 24 hours of receipt. SOP has a recommended holding time of 5 hours if splitting is performed in field or "best professional judgment." Analyses being performed have holding times of 7 days or greater.



[
Subcontract Labs	Radiological Sample Preparation			
	 Radiological samples subcontracted to an outside laboratory require documentation of sample preparation procedure performed at TestAmerica Irvine. 			
	 a) Either the Sample Control department manager or the Metals dept manager oversees the processing of these samples. 			
	 b) Every batch of samples (each 2.5 gallon container) requires a trip blank with the exception of samples for tritium analyses. 			
	c) Prepare the trip blank by filling a 2.5 gallon container with Laboratory Reagent-Grade Water (RGW).			
	d) Add 25mL of nitric acid to each sample and trip blank.			
	 e) Check pH with pH paper by taking an aliquot of sample using a disposable transfer pipette and squeezing a few drops on the pH strip. (Do not dip pH strip directly into sample container). 			
	f) If pH<2, record on log sheet.			
	g) If pH>2, add another 5mL and recheck pH.			
	 h) Record sample ID, acid vendor, lot#, date and time on log sheet-see Attachment 2. Note any comments if needed. 			
	i) Notify Sample Control that samples have been prepared/are ready to be shipped.			
	j) Sample Control logs in the trip blank (use prep date/time as sample date) on the same work order and logs in the applicable test methods, prints subcontract COC and sends to a pre-approved radiological testing laboratory with original pH adjustment log. Sample Control attaches a copy of pH adjustment log to work order.			
	k) Samples must not be filtered.			
	 A site specific sample duplicate must be run with each batch of samples. 			
	Dioxin Analysis			
	1) Report in µg/L.			
	2) Report down to the EDL for non-detects and below the EDL for isomers			
	meeting required signal-to-noise ratios.			
	3) Narrate any detection below EDL.			
	4) Confirm all 2,3,7,8-TCDF J-flag hits and report both results.			
	5) EMPCs are reported as positive results with the appropriate qualifiers.			
	6) Flag total results as the summation of all flags within the homolog group.			

Sample Receiving/Login Instructions

Special forms?	1) Receipt Acknowledgements should be sent within 24 hours of receipt. The format and the delivery instructions are specified in LIMS under the
	Deliverables section for the project.



Other Comments	1)	Log in the sample with dioxin, TSS, metals analysis as indicated on COC and add the following containers with TestAmerica labels for the analyst: 2-1 gal ambers (as received from client) 1-500mL poly for TSS 1-500mL poly w/Nitric acid 1-1000mL amber 1-500mL amber
	2)	Log in an equipment blank per sample and an equipment blank after the last sample that will be placed on hold. Equipment Blank and Analyses to be provided by the Client to the TestAmerica project manager. Provide empty containers with TestAmerica labels with each equipment blank in sequential order (equipment blank #1, #2, etc.) for: 1-1000mL poly for TSS 1-1000mL poly w/Nitric acid
		3-500mL ambers
	3)	After the cone splitting is completed, the TestAmerica project manager will update the equipment blank sample descriptions and add any analyses requested per the Equipment Blank COC provided.
	4)	Note any comments on the COC in LIMS (for example "high concentrations").
	5)	Field blanks do not go through cone splitter and will be logged in for analyses or placed on a "hold" status as indicated on COC.
	6)	The split samples: For each sample, the following containers will have labels with client descriptions and will be sent directly to ASL labs (info below). These will NOT be logged into TestAmerica's LIMS. Consultant will provide the COC that will accompany the samples to ASL.
		1-500mL poly for TSS 1-500mL poly w/Nitric acid 1-1000mL amber
	(1-500mL amber
		Once split samples are ready, a courier will send splits and the COC to ASL labs at the address listed below. A copy of COC will also be emailed to Consultant.
		Molky Brar
		American Scientific Laboratories, LLC
		2520 North San Fernando Road
		Los Angeles, CA 90065 Phone: 323 223 9700
		Fax: 323 223 9500
	1	



Deliverable Requirements

Report on Dry-Weight Basis?	N/A				
Special Flagging/Reporting	Level 2				
	 Analyses performed at TestAmerica Irvine and dioxin work are due in 10 business days unless otherwise noted on the COC. GETS program is typically requested on a 48 hour rush as indicated on the chain of custody. 				
	 Complete level 2 report (with all subcontract data), equis EDD, and Access 7 EDD is due 28 calendar days from sample receipt. 				
	 Upon receipt of the dioxin and radiological data they will each be merged into the report and EDD. 				
	 Bioassay and particle size data is merged into the PDF report but not included in the EDD. 				
	 No partial EDDs are needed unless specifically requested by Consultant or MEC^x. 				
	6) J-flag all results to MDL (to the EDL for dioxins).7) Report must be in NPDES format.				
	8) Geotracker EDF needed when requested on COC.				
	 Grab and composite samples from the same sampling event must be merged into a single report and SDG. 				
	10) NPDES SSFL-significant figures and units must match permit.				
	11) Deliverable instructions are specified in TALS.				
	Level 4				
	 Data package due 28 days after sample collection date unless otherwise noted on the COC. 				
	2) Post to Total Access and mail CD and hard copy to Kim Schultz at MEC ^x for NPDES reports or when specifically requested by the Consultant project manager for other programs.				
	3) Data packages from sublabs are saved into the subcontract folder in the level IV deliverable so that one complete data package is completed.				
	 Unless otherwise requested by Consultant, Level 4 data packages are not generated for ISRA, BMP, and GETs sampling events. 				
Special Narrative	NPDES format (includes perjury statement)				
EDD	StdAccess 7 (UDS) and Equ_HaleyAldrich_HdrY (UDS)				
Special Invoice	None				
Other	None				

Technical Requirements for All Lab Areas

	Yes	No	Notes
Full Analyte Spike List?		х	
Reporting Multiple Dilutions?		х	



	Yes	No	Notes
Special reanalysis requirements?	x		See Technical Requirements for Specific Areas
Project-specified action limits?	x		 An Action Limit Group is set up in LIMS for each outfall group.
			 The appropriate action limit is applied to analysis during the login process.
			 Automated exceedence notifications are emailed to the TestAmerica project manager for review and distribution to Consultant and MEC^x.
			 Action limits do not apply to ISRA, BMP, and GETs sampling events.
Project-specified QC limits?		Х	
Project-specified RLs?	x		For select parameters from each outfall, daily maximum and monthly average discharge levels are specified in the permit.
Special MDL Requirements?		x	
Special QC Samples or Frequency?	x		See Technical Requirements for Specific Areas
Special Blank Control Requirements		X	
Reagents and Standards		X	

Technical Requirements for Specific Areas

Method	Special Requirements
	 Report down to the EDL for ND and below the EDL for isomers meeting required signal-to-noise ratios.
	2) Narrate any detection below EDL.
1613-Dioxin	 Confirm all 2,3,7,8-TCDF J-flag hits and report both results.
	 EMPCs are reported as positive results with the appropriate qualifiers.
	5) Flag total results as the summation of all flags within the homolog group.
	 A low level MS is required on any samples with elevated baseline (baseline above the height of the 4ppb standard)
Perchlorate 314.0	 All samples with detected (>MDL) results for perchlorate must be post-spiked with perchlorate at a concentration 2-5x the native sample concentration to verify that the peak identified in the samples is perchlorate.



Method	Special Requirements
DI Leach	On an as-needed basis, the laboratory will be requested to perform a 1:10 DI leaching procedure for solid materials that are being used at the site in order to determine if they could introduce target analytes into the monitored outfalls. For specifics of the leaching process, see, IR-WI-BOEING_LEACH
Microbiology (SM9221B & Enterolert)	Samples must be prepared at 1X, 10X and 100X dilutions. The dilutions are indicated on the COC. Laboratory must report the geometric mean of these results.
Mercury 245.1	1631 low level mercury kits will be utilized upon client request. Consultant will inform the lab if nitric acid should be added to the unpreserved vials prior to or after sample collection. Vials will remain bagged through log in and sample storage. The vials will only be opened by metals staff trained in special sample handling: hands and forearms must be washed prior to preparation, wear clean gloves when handling these samples, analyst will not wear a watch or use cell phone or IR temperature probe.
Volatile Organics	Method Blanks must be < 1/2 RL or 1/10 associated sample concentrations

Sample Archive/Disposal Instructions

Long-term sample storage required?	After analysis is complete, samples from this site are to be refrigerated for 30 days and maintained at room temperature storage at the laboratory for six months.
Disposal requirements:	Approval for disposal is communicated to Sample Control staff by the laboratory project manager for all Boeing work.

Attachments

1) pH adjustment Log for Radiological Samples

Revision History

This section has been added beginning with Revision 0. Only details of the last two revisions are incorporated into this SOP. Prior revisions are documented in the QA files.

Revision 2, dated 03/13/2015

- This revision supersedes IR-QAS-BOEING_NPDES, revision 1, 11/21/2014
- o Addition of microbiology requirements for multiple dilutions and geometric mean.

QAS ID: IR-QAS-BOEING_NPDES, Rev. 3 Effective Date: 03/18/2016 Page 10 of 11

THE LEADER IN ENVIRONMENTAL TESTING

TestAmerico

Revision 3, dated 03/18/2016

- o This revision supersedes IR-QAS-BOEING_NPDES, revision 2, 03/13/2015
- Added special mercury sample bottle and handling
- Updated references to new permit (dates, revision, tables, action limits)
- o Updated Project Manager and subcontract lab for hydrazine and bioassays
- o Removed Outfall Discharge Limit tables
- o Removed attachments for work instructions IR-WI-CONE_SPLIT and IR-WI-BOEING_LEACH

Laboratory Review/Approval

Title	Name	Signature	Date
Project Manager	Urvashi Patel		
Manager of Project Management	Urvashi Patel		
Interim Quality Assurance Manager	Dave Dawes	0100	03/17/16
Operations Manager	Debby Wilson	Debly blackson	03/17/16
Laboratory Director	Linda Scharpenberg	All Elerentera	5/17/16



THE LEADER IN ENVIRONMENTAL TESTING

Revision 3, dated 03/18/2016

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Laboratory Review/Approval

Title	Name	Signature	Date
Project Manager	Urvashi Patel	Islei Paul	3/17/16
Manager of Project Management	Urvashi Patel	Jali Patt	3/17/16
Interim Quality Assurance Manager	Dave Dawes		
Operations Manager	Debby Wilson	- N	
Laboratory Director	Linda Scharpenberg	$\langle \rangle$	



		F	H Adustment Lo	g		Ę,
	Laboratory:	TestAmerica Irvine	Method:			
	Analyst:		Nitric Acid Lot #:		201	•
	DATE:		TIME:	. 4	AN	
	Lab Sample Number	Sample Volume (gal)	Nitric Acid Volume added (ml)	Check pH < 2	Comments	
			~			
(
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1 A 1						

Attachment 1 pH adjustment Log for Radiological Samples





CALIFORNIA STATE

ENVIRONMENTAL LABORATORY ACCREDITATION PROGRAM

CERTIFICATE OF ENVIRONMENTAL ACCREDITATION

Is hereby granted to

TestAmerica Irvine

Irvine

17461 Derian Avenue, Suite 100

Irvine, CA 92614-5817

Scope of the certificate is limited to the "Fields of Testing" which accompany this Certificate.

Continued accredited status depends on successful completion of on-site inspection, proficiency testing studies, and payment of applicable fees.

This Certificate is granted in accordance with provisions of Section 100825, et seq. of the Health and Safety Code.

Certificate No.: 2706

Expiration Date: 6/30/2018

Effective Date: 7/1/2016

anistenite

Christine Sotelo, Chief Environmental Laboratory Accreditation Program

Sacramento, California subject to forfeiture or revocation



CALIFORNIA STATE ENVIRONMENTAL LABORATORY ACCREDITATION PROGRAM Accredited Fields of Testing



TestAmerica Irvine Irvine 17461 Derian Avenue Irvine, CA 92614-5817 Phone: (949) 261-1022

Certificate No. 2706 Expiration Date 6/30/2018

-		: 101 - Microbiology of Drinking Water	
101.010		Heterotrophic Bacteria	SM9215B
101.010	002	Heterotrophic Bacteria	SimPlate
101.020	001	Total Coliform P/A	SM9221B
101.020	002	Fecal Coliform P/A	SM 9221 B,E
101.020	003	E. coli P/A	SM 9221 B,F
101.050	005	Total Coliform P/A	SM9223B (Colilert 18)
101.050	006	E. coli P/A	SM9223B (Colilert 18)
101.050	007	Total Coliform (Enumeration)	SM9223B (Colilert 18 Quantity Tray)
101.050	800	E. coli (Enumeration)	SM9223B (Colilert 18 Quantity Tray)
101.050	009	Total Coliform P/A	SM9223B (Colisure)
101.050	010	E. coli P/A	SM9223B (Colisure)
101.050	011	Total Coliform (Enumeration)	SM9223B (Colisure)
101.050	012	E. coli (Enumeration)	SM9223B (Colisure)
Field of	Testing	: 102 - Inorganic Chemistry of Drinking Water	
102.015	001	Hydrogen Ion (pH)	EPA 150.1
102.020	001	Turbidity	EPA 180.1
102.026	001	Calcium	EPA 200.7
102.026	002	Magnesium	EPA 200.7
102.026	003	Potassium	EPA 200.7
102.026	004	Silica	EPA 200.7
102.026	005	Sodium	EPA 200.7
102.026	006	Hardness (calculation)	EPA 200.7
102.030	003	Chloride	EPA 300.0
102.030	005	Fluoride	EPA 300.0
102.030	006	Nitrate (as N)	EPA 300.0
102.030	007	Nitrite (as N)	EPA 300.0
102.030	800	Phosphate, Ortho (as P)	EPA 300.0
102.030	009	Sulfate	EPA 300.0
102.040	001	Bromide	EPA 300.1
102.040	002	Chlorite	EPA 300.1
102.040	003	Chlorate	EPA 300.1
102.040	004	Bromate	EPA 300.1
102.045	001	Perchlorate	EPA 314.0
102.048	001	Perchlorate	EPA 332.0
102.095	001	Turbidity	SM2130B-2001
102.100	001	Alkalinity	SM2320B-1997
102.120	001	Hardness (calculation)	SM2340B-1997
102.121	001	Hardness	SM2340C-1997

102.130	001	Conductivity	SM2510B-1997
102.140	001	Residue, Filterable TDS	SM2540C-1997
102.175	001	Chlorine, Free	SM4500-CI G-2000
102.175	002	Chlorine, Total Residual	SM4500-CI G-2000
102.190	001	Cyanide, Total	SM4500-CN E
102.200	001	Fluoride	SM4500-F C
102.203	001	Hydrogen Ion (pH)	SM4500-H+ B-2000
102.262	001	Total Organic Carbon TOC	SM5310C
102.263	001	Dissolved Organic Carbon (DOC)	SM5310C
102.270	001	Surfactants	SM5540C
102.564	001	Cyanide	Kelada-01
Field of	Testing	: 103 - Toxic Chemical Elements of Drinking Wa	ater
103.130	001	Aluminum	EPA 200.7
103.130	003	Barium	EPA 200.7
103.130	004	Beryllium	EPA 200.7
103.130	005	Cadmium	EPA 200.7
103.130	007	Chromium	EPA 200.7
103.130	008	Copper	EPA 200.7
103.130	009	Iron	EPA 200.7
103.130	011	Manganese	EPA 200.7
103.130	012	Nickel	EPA 200.7
103.130	015	Silver	EPA 200.7
103.130	017	Zinc	EPA 200.7
103.130	018	Boron	EPA 200.7
103.140	001	Aluminum	EPA 200.8
103.140	002	Antimony	EPA 200.8
103.140	003	Arsenic	EPA 200.8
103.140	004	Barium	EPA 200.8
103.140	005	Beryllium	EPA 200.8
103.140	006	Cadmium	EPA 200.8
103.140	007	Chromium	EPA 200.8
103.140	800	Copper	EPA 200.8
103.140	009	Lead	EPA 200.8
103.140	010	Manganese	EPA 200.8
103.140	012	Nickel	EPA 200.8
103.140	013	Selenium	EPA 200.8
103.140	014	Silver	EPA 200.8
103.140	015	Thallium	EPA 200.8
103.140	016	Zinc	EPA 200.8
103.140	018	Vanadium	EPA 200.8
103.160	001	Mercury	EPA 245.1
103.310	001	Chromium (VI)	EPA 218.6
103.311	001	Chromium (VI)	EPA 218.7
Field of	Testing	: 104 - Volatile Organic Chemistry of Drinking W	/ater
104.030	001	1,2-Dibromoethane	EPA 504.1
104.030	002	1,2-Dibromo-3-chloropropane	EPA 504.1

104.035	001	1,2,3-Trichloropropane	SRL 524M-TCP
104.040	000	Volatile Organic Compounds	EPA 524.2
104.040	001	Benzene	EPA 524.2
104.040	007	n-Butylbenzene	EPA 524.2
104.040	800	sec-Butylbenzene	EPA 524.2
104.040	009	tert-Butylbenzene	EPA 524.2
104.040	010	Carbon Tetrachloride	EPA 524.2
104.040	011	Chlorobenzene	EPA 524.2
104.040	015	2-Chlorotoluene	EPA 524.2
104.040	016	4-Chlorotoluene	EPA 524.2
104.040	019	1,3-Dichlorobenzene	EPA 524.2
104.040	020	1,2-Dichlorobenzene	EPA 524.2
104.040	021	1,4-Dichlorobenzene	EPA 524.2
104.040	022	Dichlorodifluoromethane	EPA 524.2
104.040	023	1,1-Dichloroethane	EPA 524.2
104.040	024	1,2-Dichloroethane	EPA 524.2
104.040	025	1,1-Dichloroethene	EPA 524.2
104.040	026	cis-1,2-Dichloroethene	EPA 524.2
104.040	027	trans-1,2-Dichloroethene	EPA 524.2
104.040	028	Dichloromethane	EPA 524.2
104.040	029	1,2-Dichloropropane	EPA 524.2
104.040	033	cis-1,3-Dichloropropene	EPA 524.2
104.040	034	trans-1,3-Dichloropropene	EPA 524.2
104.040	035	Ethylbenzene	EPA 524.2
104.040	037	Isopropylbenzene	EPA 524.2
104.040	039	Naphthalene	EPA 524.2
104.040	041	N-propylbenzene	EPA 524.2
104.040	042	Styrene	EPA 524.2
104.040	043	1,1,1,2-Tetrachloroethane	EPA 524.2
104.040	044	1,1,2,2-Tetrachloroethane	EPA 524.2
104.040	045	Tetrachloroethene	EPA 524.2
104.040	046	Toluene	EPA 524.2
104.040	047	1,2,3-Trichlorobenzene	EPA 524.2
104.040	048	1,2,4-Trichlorobenzene	EPA 524.2
104.040	049	1,1,1-Trichloroethane	EPA 524.2
104.040	050	1,1,2-Trichloroethane	EPA 524.2
104.040	051	Trichloroethene	EPA 524.2
104.040	052	Trichlorofluoromethane	EPA 524.2
104.040	054	1,2,4-Trimethylbenzene	EPA 524.2
104.040	055	1,3,5-Trimethylbenzene	EPA 524.2
104.040	056	Vinyl Chloride	EPA 524.2
104.040	057	Xylenes, Total	EPA 524.2
104.040	061	Carbon Disulfide	EPA 524.2
104.040	062	Methyl Isobutyl Ketone	EPA 524.2
104.045	000	Trihalomethanes, Total	EPA 524.2
104.045	001	Bromodichloromethane	EPA 524.2
104.045	002	Bromoform	EPA 524.2

104.045	003	Chloroform	EPA 524.2
104.045	004	Dibromochloromethane	EPA 524.2
104.050	000	Gasoline Additives	EPA 524.2
104.050	002	Methyl tert-butyl Ether (MTBE)	EPA 524.2
104.050	003	tert-Amyl Methyl Ether (TAME)	EPA 524.2
104.050	004	Ethyl tert-butyl Ether (ETBE)	EPA 524.2
104.050	005	Trichlorotrifluoroethane	EPA 524.2
104.050	006	tert-Butyl Alcohol (TBA)	EPA 524.2
Field of	Testing	: 105 - Semi-volatile Organic Chemistry of Drin	king Water
105.010	002	Alachlor	EPA 505
105.010	004	Chlordane	EPA 505
105.010	006	Endrin	EPA 505
105.010	007	Heptachlor	EPA 505
105.010	008	Heptachlor Epoxide	EPA 505
105.010	009	Hexachlorobenzene	EPA 505
105.010	010	Hexachlorocyclopentadiene	EPA 505
105.010	011	Lindane	EPA 505
105.010	012	Methoxychlor	EPA 505
105.010	014	Toxaphene	EPA 505
105.010	015	PCBs as Aroclors (screen)	EPA 505
105.083	000	Chlorinated Acids	EPA 515.4
105.083	001	2,4-D	EPA 515.4
105.083	002	Dinoseb	EPA 515.4
105.083	003	Pentachlorophenol	EPA 515.4
105.083	004	Picloram	EPA 515.4
105.083	005	2,4,5-TP	EPA 515.4
105.083	006	Dalapon	EPA 515.4
105.083	007	Bentazon	EPA 515.4
105.083	800	Dicamba	EPA 515.4
105.090	000	Semi-volatile Organic Compounds	EPA 525.2
105.090	001	Alachlor	EPA 525.2
105.090	002	Aldrin	EPA 525.2
105.090	003	Atrazine	EPA 525.2
105.090	004	Benzo(a)pyrene	EPA 525.2
105.090	005	Butachlor	EPA 525.2
105.090	007	Dieldrin	EPA 525.2
105.090	800	Adipates	EPA 525.2
105.090	009	Phthalates	EPA 525.2
105.090	016	Hexachlorobenzene	EPA 525.2
105.090	017	Hexachlorocyclopentadiene	EPA 525.2
105.090	018	Lindane	EPA 525.2
105.090	019	Methoxychlor	EPA 525.2
105.090	022	Molinate	EPA 525.2
105.090	025	Simazine	EPA 525.2
105.100	000	Carbamates	EPA 531.1
105.100	001	Aldicarb	EPA 531.1
105.100	002	Aldicarb Sulfone	EPA 531.1

105.100	003	Aldicarb Sulfoxide	EPA 531.1
105.100	004	Carbaryl	EPA 531.1
105.100	005	Carbofuran	EPA 531.1
105.100	006	3-Hydroxycarbofuran	EPA 531.1
105.100	007	Methomyl	EPA 531.1
105.100	008	Oxamyl	EPA 531.1
105.120	001	Glyphosate	EPA 547
105.140	001	Endothall	EPA 548.1
105.150	001	Diquat	EPA 549.2
105.200	001	Bromoacetic Acid	EPA 552.2
105.200	003	Chloroacetic Acid	EPA 552.2
105.200	005	Dibromoacetic Acid	EPA 552.2
105.200	006	Dichloroacetic Acid	EPA 552.2
105.200	007	Trichloroacetic Acid	EPA 552.2
105.200	008	Haloacetic Acids (HAA5)	EPA 552.2
Field of	Testing	: 106 - Radiochemistry of Drinking Water	
106.092	001	Uranium	EPA 200.8
		: 107 - Microbiology of Wastewater	
107.010			SM9215B
107.010	001	Heterotrophic Bacteria Total Coliform (Enumeration)	SM9213B SM9221B,E-2006
107.020	002	Total Coliform with Chlorine Present	SM9221B,C-2006
107.030	002	Fecal Coliform (Enumeration)	SM9221C,E-2006
107.040	002	Fecal Coliform with Chlorine Present	SM9221C,E-2006
107.242	002	Enterococci	Enterolert
107.242	001		
107.245		E. coli (Enumeration) E. coli (Enumeration)	SM9223B (Colilert) SM9223B (Colisure)
107.245		E. coli (Enumeration)	SM9221B,F-2006
			3///72210,1-2000
-		: 108 - Inorganic Chemistry of Wastewater	
108.020	001	Conductivity	EPA 120.1
108.090	001	Residue, Volatile	EPA 160.4
108.110		Turbidity	EPA 180.1
108.112		Boron	EPA 200.7
108.112		Calcium	EPA 200.7
108.112		Hardness (calculation)	EPA 200.7
108.112		Magnesium	EPA 200.7
108.112		Potassium	EPA 200.7
108.112	006	Silica, Dissolved	EPA 200.7
108.112		Sodium	EPA 200.7
108.112		Phosphorus, Total	EPA 200.7
108.120		Bromide	EPA 300.0
108.120	002	Chloride	EPA 300.0
108.120	003	Fluoride	EPA 300.0
108.120	800	Sulfate	EPA 300.0
108.120		Nitrate (as N)	EPA 300.0
108.120	013	Nitrate-Nitrite (as N)	EPA 300.0
108.120	014	Nitrite (as N)	EPA 300.0

108.120	015	Phosphate, Ortho (as P)	EPA 300.0
108.209	001	Ammonia (as N)	EPA 350.1
108.211	002	Kjeldahl Nitrogen, Total (as N)	EPA 351.2
108.264	001	Phosphate, Ortho	EPA 365.3
108.265	001	Phosphorus, Total	EPA 365.3
108.323	001	Chemical Oxygen Demand	EPA 410.4
108.381	001	Oil and Grease	EPA 1664A
108.385	001	Color	SM2120B-2001
108.390	001	Turbidity	SM2130B-2001
108.400	001	Acidity	SM2310B-1997
108.410	001	Alkalinity	SM2320B-1997
108.420	001	Hardness (calculation)	SM2340B-1997
108.421	001	Hardness	SM2340C-1997
108.430	001	Conductivity	SM2510B-1997
108.439	001	Residue, Volatile	SM2540E-1997
108.440	001	Residue, Total	SM2540B-1997
108.441	001	Residue, Filterable TDS	SM2540C-1997
108.442	001	Residue, Non-filterable TSS	SM2540D-1997
108.443	001	Residue, Settleable	SM2540F-1997
108.465	001	Chlorine, Total Residual	SM4500-CI G-2000
108.465	002	Chlorine, Free	SM4500-CI G-2000
108.470	001	Cyanide, Total	SM4500-CN B or C-1999
108.472	001	Cyanide, Total	SM4500-CN E-1999
108.490	001	Hydrogen Ion (pH)	SM4500-H+ B-2000
108.502	002	Ammonia (as N)	SM4500-NH3 B,D-1997
108.506	002	Ammonia (as N)	SM4500-NH3 G-1997
108.536	001	Oxygen, dissolved	SM4500-0 G-2001
108.584	001	Sulfide (as S)	SM4500-S= D-2000
108.592	001	Biochemical Oxygen Demand	SM5210B-2001
108.592	002	Carbonaceous BOD	SM5210B-2001
108.595	001	Chemical Oxygen Demand	SM5220D-1997
108.596	001	Organic Carbon-Total (TOC)	SM5310B-2000
108.605	001	Surfactants	SM5540C-2000
Field of	Testina	: 109 - Toxic Chemical Elements of Wastewater	
109.010		Aluminum	EPA 200.7
109.010		Antimony	EPA 200.7
109.010	002	,	EPA 200.7
109.010		Arsenic Barium	EPA 200.7
109.010	004		EPA 200.7
109.010	005	Beryllium	
		Boron	EPA 200.7
109.010	007	Cadmium	EPA 200.7
109.010		Chromium	EPA 200.7
109.010	010	Cobalt	EPA 200.7
109.010		Copper	EPA 200.7
109.010		Iron	EPA 200.7
109.010		Lead	EPA 200.7
109.010	015	Manganese	EPA 200.7

109.010	016	Molybdenum	EPA 200.7	
109.010	017	Nickel	EPA 200.7	
109.010	019	Selenium	EPA 200.7	
109.010		Silver	EPA 200.7	
109.010		Thallium	EPA 200.7	
109.010		Tin	EPA 200.7	
109.010		Titanium	EPA 200.7	
109.010		Vanadium	EPA 200.7	
109.010		Zinc	EPA 200.7	
109.020		Aluminum	EPA 200.8	
109.020		Antimony	EPA 200.8	
109.020		Arsenic	EPA 200.8	
109.020		Barium	EPA 200.8	
109.020	005	Beryllium	EPA 200.8	
109.020		Cadmium	EPA 200.8	
109.020	007	Chromium	EPA 200.8	
109.020		Cobalt	EPA 200.8	
109.020	009	Copper	EPA 200.8	
109.020		Lead	EPA 200.8	
109.020 109.020		Manganese Maket de surre	EPA 200.8	
		Molybdenum	EPA 200.8	
109.020	013	Nickel	EPA 200.8	
109.020	014 015	Selenium Silver	EPA 200.8	
109.020		Thallium	EPA 200.8 EPA 200.8	
109.020	010	Vanadium	EPA 200.8	
109.020		Zinc	EPA 200.8	
109.020		Iron	EPA 200.8	
109.020		Tin	EPA 200.8	
109.104	001	Chromium (VI)	EPA 218.6	
109.190	001	Mercury	EPA 245.1	
109.445		Chromium	SM3500-Cr B-2009	
109.449		Iron	SM3500-Fe B-1997	
Field of	Testina	: 110 - Volatile Organic Chemistry of Wastewate	er	
110.040		Purgeable Organic Compounds	EPA 624	
Field of	Testina	: 111 - Semi-volatile Organic Chemistry of Wast		
111.100	_	Base/Neutral & Acid Organics	EPA 625	
111.100		Nitrosamines	EPA 625	
111.120		Semi-volatile Organic Compounds	EPA 1625B	Interim
111.120		Organochlorine Pesticides and PCBs	EPA 608	Interim
		-		
		: 114 - Inorganic Chemistry of Hazardous Waste		
114.010		Antimony	EPA 6010B	
114.010		Arsenic	EPA 6010B	
114.010		Barium	EPA 6010B	
114.010	004	Beryllium	EPA 6010B	
114.010	005	Cadmium	EPA 6010B	

114.010	006	Chromium	EPA 6010B
114.010	007	Cobalt	EPA 6010B
114.010	008	Copper	EPA 6010B
114.010	009	Lead	EPA 6010B
114.010	010	Molybdenum	EPA 6010B
114.010	011	Nickel	EPA 6010B
114.010	012	Selenium	EPA 6010B
114.010	013	Silver	EPA 6010B
114.010	014	Thallium	EPA 6010B
114.010	015	Vanadium	EPA 6010B
114.010	016	Zinc	EPA 6010B
114.020	001	Antimony	EPA 6020
114.020	002	Arsenic	EPA 6020
114.020	003	Barium	EPA 6020
114.020	004	Beryllium	EPA 6020
114.020	005	Cadmium	EPA 6020
114.020	006	Chromium	EPA 6020
114.020	007	Cobalt	EPA 6020
114.020	800	Copper	EPA 6020
114.020	009	Lead	EPA 6020
114.020	010	Molybdenum	EPA 6020
114.020	011	Nickel	EPA 6020
114.020		Selenium	EPA 6020
114.020	013	Silver	EPA 6020
114.020		Thallium	EPA 6020
114.020	015	Vanadium	EPA 6020
114.020	016	Zinc	EPA 6020
114.103	001	Chromium (VI)	ЕРА 7196А
114.106	001	Chromium (VI)	EPA 7199
114.140	001	Mercury	EPA 7470A
114.141	001	Mercury	EPA 7471A
114.222	001	Cyanide	EPA 9014
114.230		Sulfides, Total	EPA 9034
114.240		Corrosivity - pH Determination	EPA 9040B
114.241	001	Corrosivity - pH Determination	EPA 9045C
114.250 114.270	001	Fluoride Fluoride	EPA 9056 EPA 9214
			EFA 9214
	-	: 115 - Extraction Test of Hazardous Waste	
115.020		Toxicity Characteristic Leaching Procedure (TCLP)	EPA 1311
115.021	001	TCLP Inorganics	EPA 1311
115.022	001	TCLP Extractables	EPA 1311
115.023	001	TCLP Volatiles	EPA 1311
115.030	001	Waste Extraction Test (WET)	CCR Chapter11, Article 5, Appendix II
1 <u>15.040</u>		Synthetic Precipitation Leaching Procedure (SPLP)	EPA 1312
	-	: 116 - Volatile Organic Chemistry of Hazardous	
116.020	031	Ethanol and Methanol	EPA 8015B

116.030	001	Gasoline-range Organics	EPA 8015B
116.080	000	Volatile Organic Compounds	EPA 8260B
116.080	120	Oxygenates	EPA 8260B
116.100	001	Total Petroleum Hydrocarbons - Gasoline	LUFT GC/MS
116.110	001	Total Petroleum Hydrocarbons - Gasoline	LUFT
Field of	Testing	: 117 - Semi-volatile Organic Chemistry of Haza	ardous Waste
117.010	001	Diesel-range Total Petroleum Hydrocarbons	EPA 8015B
117.016	001	Diesel-range Total Petroleum Hydrocarbons	LUFT
117.110	000	Extractable Organics	EPA 8270C
117.150	000	Carbonyl Compounds	EPA 8315A
117.210	000	Organochlorine Pesticides	EPA 8081A
117.220	000	PCBs	EPA 8082
111.220	000	1 085	
		: 120 - Physical Properties of Hazardous Waste	
Field of	Testing	: 120 - Physical Properties of Hazardous Waste	
Field of 120.010	Testing 001	: 120 - Physical Properties of Hazardous Waste Ignitability	EPA 1010
Field of 120.010 120.020	Testing 001 001 001	: 120 - Physical Properties of Hazardous Waste Ignitability Ignitability	EPA 1010 EPA 1020A
Field of 120.010 120.020 120.070 120.080	Testing 001 001 001 001 001	: 120 - Physical Properties of Hazardous Waste Ignitability Ignitability Corrosivity - pH Determination	EPA 1010 EPA 1020A EPA 9040B
Field of 120.010 120.020 120.070 120.080	Testing 001 001 001 001 001 Testing	: 120 - Physical Properties of Hazardous Waste Ignitability Ignitability Corrosivity - pH Determination Corrosivity - pH Determination	EPA 1010 EPA 1020A EPA 9040B
Field of ⁷ 120.010 120.020 120.070 120.080 Field of ⁷	Testing 001 001 001 001 001 Testing	 120 - Physical Properties of Hazardous Waste Ignitability Ignitability Corrosivity - pH Determination Corrosivity - pH Determination 126 - Microbiology of Recreational Water 	EPA 1010 EPA 1020A EPA 9040B EPA 9045C
Field of 120.010 120.020 120.070 120.080 Field of 126.010	Testing 001 001 001 001 001 001 001 001 001	 120 - Physical Properties of Hazardous Waste Ignitability Ignitability Corrosivity - pH Determination Corrosivity - pH Determination : 126 - Microbiology of Recreational Water Total Coliform (Enumeration) 	EPA 1010 EPA 1020A EPA 9040B EPA 9045C SM9221B,C-2006
Field of 120.010 120.020 120.070 120.080 Field of 126.010 126.030	Testing 001 001 001 001 001 001 001 001 001 001 001 001 001 001	 120 - Physical Properties of Hazardous Waster Ignitability Ignitability Corrosivity - pH Determination Corrosivity - pH Determination 126 - Microbiology of Recreational Water Total Coliform (Enumeration) Fecal Coliform (Enumeration) 	EPA 1010 EPA 1020A EPA 9040B EPA 9045C SM9221B,C-2006 SM9221B,E-2006
Field of 120.010 120.020 120.070 120.080 Field of 126.010 126.030 126.050	Testing 001 001 001 001 001 001 001 001 001 001 001 001 001 001 001 001 001	 120 - Physical Properties of Hazardous Waster Ignitability Ignitability Corrosivity - pH Determination Corrosivity - pH Determination 126 - Microbiology of Recreational Water Total Coliform (Enumeration) Fecal Coliform (Enumeration) Total Coliform (Enumeration) 	EPA 1010 EPA 1020A EPA 9040B EPA 9045C SM9221B,C-2006 SM9221B,E-2006 SM9223B (Colilert/Quanti-Tray)





CALIFORNIA STATE

ENVIRONMENTAL LABORATORY ACCREDITATION PROGRAM

CERTIFICATE OF ENVIRONMENTAL ACCREDITATION

Is hereby granted to

TestAmerica Denver

4955 Yarrow Street

Arvada, CO 80002

Scope of the certificate is limited to the "Fields of Testing" which accompany this Certificate.

Continued accredited status depends on successful completion of on-site inspection, proficiency testing studies, and payment of applicable fees.

> This Certificate is granted in accordance with provisions of Section 100825, et seq. of the Health and Safety Code.

Certificate No.: 2513 Expiration Date: 1/8/2018 Effective Date: 9/1/2016

Writing Set

Christine Sotelo, Chief Environmental Laboratory Accreditation Program

Sacramento, California subject to forfeiture or revocation



CALIFORNIA STATE ENVIRONMENTAL LABORATORY ACCREDITATION PROGRAM Accredited Fields of Testing



TestAmerica Denver

4955 Yarrow Street Arvada, CO 80002 Phone: (303) 736-0100 Certificate No. 2513 Expiration Date 1/8/2018

08.090		Residue, Volatile	EPA 160.4
08.110	001	Turbidity	EPA 180.1
08.112	001	Boron	EPA 200.7
08.112	002	Calcium	EPA 200.7
08.112	003	Hardness (calculation)	EPA 200.7
08.112	004	Magnesium	EPA 200.7
08.112	005	Potassium	EPA 200.7
08.112	006	Silica	EPA 200.7
08.112	007	Sodium	EPA 200.7
08.120	001	Bromide	EPA 300.0
08.120	002	Chloride	EPA 300.0
08.120	003	Fluoride	EPA 300.0
08.120	004	Nitrate	EPA 300.0
108.120	005	Nitrite	EPA 300.0
08.120	006	Nitrate-nitrite	EPA 300.0
108.120	007	Phosphate, Ortho	EPA 300.0
108.120	008	Sulfate	EPA 300.0
108.183	001	Cyanide, Total	EPA 335.4
108.200	001	Ammonia	EPA 350.1
108.211	001	Kjeldahl Nitrogen	EPA 351.2
108.232	001	Nitrate-nitrite	EPA 353.2
108.232	002	Nitrite	EPA 353.2
108.260	001	Phosphate, Ortho	EPA 365.1
108.261	001	Phosphorus, Total	EPA 365.1
108.360	001	Phenois, Total	EPA 420.1
108.362	001	Phenols, Total	EPA 420.4
108.381	001	Oil and Grease	EPA 1664A
108.400	001	Acidity	SM2310B
108.410	001	Alkalinity	SM2320B
108.420	001	Hardness (calculation)	SM2340B
108.430	001	Conductivity	SM2510B
108.440	001	Residue, Total	SM2540B
108,441	001	Residue, Filterable TDS	SM2540C
108.442	001	Residue, Non-filterable TSS	SM2540D
108.443	001	Residue, Settleable	SM2540F
108.470		Cyanide, Manual Distillation	SM4500-CN C
108.472		Cyanide, Total	SM4500-CN E
108.473	1002	Cyanide, amenable	SM4500-CN G

As of 3/15/2017 , this list supersedes all previous lists for this certificate number. Customers: Please verify the current accreditation standing with the State.

108.490	001	Hydrogen Ion (pH)	SM4500-H+ B	
108.510	001	Nitrite	SM4500-NO2 B	
108.560	001	Sulfite	SM4500-SO3 B	
108.580	001	Sullide	SM4500-S= D	
108.582	001	Sulfide	SM4500-S= F (19th/20th)	
108.590	001	Biochemical Oxygen Demand	SM5210B	
108.591	001	Carbonaceous BOD	SM5210B	
108.610	001	Total Organic Carbon TOC	SM5310B	
Field of	Testin	g: 109 - Toxic Chemical Elements of	Wastewater	
109.010	001	Aluminum	EPA 200.7	
109.010	002	Antimony	EPA 200.7	
109.010	003	Arsenic	EPA 200.7	
109.010	004	Barium	EPA 200.7	
109.010	005	Beryllium	EPA 200.7	
109.010	007	Cedmium	EPA 200.7	
109.010	009	Chromium	EPA 200.7	
109.010	010	Cobalt	EPA 200.7	
109.010	011	Copper	EPA 200.7	
109.010	012	Iron	EPA 200.7	
109.010	013	Lead	EPA 200.7	_
109.010	015	Manganese	EPA 200.7	
109.010	016	Mölybdenum	EPA 200.7	
109.010	017	Nickel	EPA 200.7	
109.010	019	Selenium	EPA 200.7	
109.010	021	Silver	EPA 200.7	
109.010	023	Thallium	EPA 200.7	
109.010	024	Tin	EPA 200.7	
109.010	026	Vanadium	EPA 200.7	
109.010	027	Zinc	EPA 200.7	
109.020	002	Antimony	EPA 200.8	
109.020	003	Arsenic	_ EPA 200.8	
109.020	004	Barium	EPA 200.8	
109.020	005	Beryllium	EPA 200.8	
109.020	006	Cadmlum	EPA 200.8	
109.020	007	Chromium	EPA 200.8	
109.020	800	Cobalt	EPA 200.8	
109.020	009	Copper	EPA 200.8	
109.020	010	Lead	EPA 200.8	
109.020	011	Manganese	EPA 200.8	
109.020	012	Molybdenum	EPA 200.8	
109.020	013	Nickel	EPA 200.8	
109.020	014	Selenium	EPA 200.8	
109.020	015	Silver	EPA 200.8	
109.020	016	Thallium	EPA 200.8	
109.020	017	Vanadium	EPA 200.8	
109.020	018	Zinc	EPA 200.8	
109.190	001	Mercury	EPA 245.1	

As of 3/15/2017 , this list supersedes all previous lists for this certificate number. Customers: Please verify the current accreditation standing with the State.

	Secon	g: 110 - Volatile Organic Chemistry of W	
10.020	000	Aromatic Volatiles	EPA 802
10.040	040	Halogenated Hydrocarbons	EPA 624
10.040	041	Aromatic Compounds	EPA 624
10.040	042	Oxygenates	EPA 624
10.040	043	Other Volatile Organics	EPA 624
leid of	Testing	g: 111 - Semi-volatile Organic Chemistry	of Wastewater
11.060	000	Polynuclear Aromatics	EPA 610
11.101	032	Polynuclear Aromatic Hydrocarbons	EPA 625
11.101	033	Adipates	EPA 625
11.101	034	Phthalates	EPA 625
11.101	036	Other Extractables	EPA 625
11.103	001	N-nitrosodimethylamine	EPA 625
11.120	000	Semi-volatile Organic Compounds	EPA 16258
11.120	999	N-nitrosodimethylamine	EPA 1625
111.170	030	Organochlorine Pesticides	EPA 608
111.170	030	Pesticides & PCBs	EPA 608
11.170	031	PCBs	EPA 608
ield of	Testin	g: 114 - Inorganic Chemistry of Hazardo	us Waste
114.010	001	Antimony	EPA 6010B
114.010	002	Arsenic	EPA 6010B
114.010	003	Barium	EPA 6010B
114.010	004	Beryllium	EPA 6010B
114.010	005	Cadmium	EPA 6010B
114.010	006	Chromium	EPA 6010B
114.010	007	Cobalt	EPA 6010B
114.010	008	Copper	EPA 6010B
114.010	009	Lead	EPA 6010B
114.010		Molybdenum	EPA 6010B
114.010	011	Nickel	EPA 6010B
114.010	11.01.000	Selenium	EPA 6010B
114.010		Silver	EPA 6010B
114.010		Thallium	EPA 6010B
114.010		Vanadium	EPA 6010B
114.010		Zinc	EPA 6010B
114.020		Antimony	EPA 6020
114.020		Arsenic	EPA 6020
114.020	alanda origina	Barium	EPA 6020
114.020		Beryllium	EPA 6020
114.020		Cadmium	EPA 6020
114.020		Chromium	EPA 6020
114.020		Cobalt	EPA 6020
114.020		Copper	EPA 6020
114.020		Lead	EPA 6020
114.020		Molybdenum	EPA 6020
114.020	010	Nickel	EPA 6020

As of 3/15/2017 , this list supersedes all previous lists for this certificate number. Customers: Please verify the current accreditation standing with the State.

Certificate No 2513 Expiration Date 1/8/2018

14.020	012	V20,5	
	VIG	Selenium	EPA 6020
14.020	013	Silver	EPA 6020
14.020	014	Thallium	EPA 6020
14.020	015	Vanadium	EPA 6020
14.020	016	Zinc	EPA 6020
14.103	001	Chromium (VI)	EPA 7196A
14.140	001	Mercury	EPA 7470A
14.141	001	Mercury	EPA 7471A
14.221	001	Cyanide, Total	EPA 9012B
14.222	001	Cyanide	EPA 9014
14.230	001	Sulfides, Total	EPA 9034
14.240	001	Corrosivity - pH Determination	EPA 9040B
14.241	001	Corrosivity - pH Determination	EPA 9045C
14.250	001	Fluoride	EPA 9056
14.280	001	Organic Lead	HML 939-M
ield of	Testing	g: 115 - Extraction Test of Hazardous Waste	
15.020	001	Toxicity Characteristic Leaching Procedure (TCLP)	EPA 1311
15.021	001	TCLP Inorganics	EPA 1311
15.022	001	TCLP Extractables	EPA 1311
15.023		TCLP Volatiles	EPA 1311
15.030	10.0	Waste Extraction Test (WET)	CCR Chapter11, Article 5, Appendix II
		Synthetic Precipitation Leaching Procedure (SPLP)	EPA 1312
15.040	001	Olympic to complete the comming recording for critic	
		de la contra de la c	
ield of	Testin	g: 116 - Volatile Organic Chemistry of Hazardo	ous Waste
ield of 16.010	Testin 000	g: 116 - Volatile Organic Chemistry of Hazardo EDB and DBCP	EPA 8011
Teld of 16.010 16.020	Testin 000 030	g: 116 - Volatile Organic Chemistry of Hazardo EDB and DBCP Nonhalogenated Volatiles	EPA 8011 EPA 8015B
Teld of 16.010 16.020 16.020	Testin 000 030 031	g: 116 - Volatile Organic Chemistry of Hazardo EDB and DBCP Nonhalogenated Volatiles Ethanol and Methanol	EPA 8011 EPA 8015B EPA 8015B
Teld of 16.010 16.020 16.020 16.030	Testin 000 030 031 001	g: 116 - Volatile Organic Chemistry of Hazardo EDB and DBCP Nonhalogenated Volatiles Ethanol and Methanol Gasoline-range Organics	EPA 8011 EPA 8015B EPA 8015B EPA 8015B EPA 8015B
Teld of 16.010 16.020 16.020 16.030 16.030	Testin 000 030 031 001 001	g: 116 - Volatile Organic Chemistry of Hazardo EDB and DBCP Nonhalogenated Volatiles Ethanol and Methanol Gasoline-range Organics Gasoline-range Organics	EPA 8011 EPA 8015B EPA 8015B EPA 8015B EPA 8015B EPA 8015B
Teld of 16.010 16.020 16.020 16.030 16.030 16.040	Testin 000 030 031 001 001 041	g: 116 - Volatile Organic Chemistry of Hazardo EDB and DBCP Nonhalogenated Volatiles Ethanol and Methanol Gasoline-range Organics Gasoline-range Organics Methyl tert-butyl Ether (MTBE)	EPA 8011 EPA 8015B EPA 8015B EPA 8015B EPA 8015B EPA 8015B EPA 8021B
ield of 16.010 16.020 16.020 16.030 16.030 16.040 16.040	Testin 000 030 031 001 001 041 061	g: 116 - Volatile Organic Chemistry of Hazardo EDB and DBCP Nonhalogenated Volatiles Ethanol and Methanol Gasoline-range Organics Gasoline-range Organics Methyl tert-butyl Ether (MTBE) Aromatic Volatiles	EPA 8011 EPA 8015B EPA 8015B EPA 8015B EPA 8015B EPA 8015B EPA 8021B EPA 8021B
Teld of 16.010 16.020 16.020 16.030 16.030 16.040 16.040	Testin 000 030 031 001 001 041 061 062	g: 116 - Volatile Organic Chemistry of Hazardo EDB and DBCP Nonhalogenated Volatiles Ethanol and Methanol Gasoline-range Organics Gasoline-range Organics Methyl tert-butyl Ether (MTBE) Aromatic Volatiles BTEX	EPA 8011 EPA 8015B EPA 8015B EPA 8015B EPA 8015B EPA 8015B EPA 8021B EPA 8021B EPA 8021B
Teld of 16.010 16.020 16.030 16.030 16.040 16.040 16.040 16.040	Testin 000 030 031 001 001 041 061 062 000	g: 116 - Volatile Organic Chemistry of Hazardo EDB and DBCP Nonhalogenated Volatiles Ethanol and Methanol Gasoline-range Organics Gasoline-range Organics Methyl tert-butyl Ether (MTBE) Aromatic Volatiles BTEX Volatile Organic Compounds	EPA 8011 EPA 8015B EPA 8015B EPA 8015B EPA 8015B EPA 8015B EPA 8021B EPA 8021B EPA 8021B EPA 8021B
Teld of 16.010 16.020 16.030 16.030 16.040 16.040 16.040 16.080	Testin 000 030 031 001 041 061 062 000 120	g: 116 - Volatile Organic Chemistry of Hazardo EDB and DBCP Nonhalogenated Volatiles Ethanol and Methanol Gasoline-range Organics Gasoline-range Organics Methyl tert-butyl Ether (MTBE) Aromatic Volatiles BTEX Volatile Organic Compounds Oxygenates	EPA 8011 EPA 8015B EPA 8021B
Teld of 16.010 16.020 16.030 16.030 16.040 16.040 16.040 16.040 16.080	Testin 000 030 031 001 041 061 062 000 120 Testin	g: 116 - Volatile Organic Chemistry of Hazardo EDB and DBCP Nonhalogenated Volatiles Ethanol and Methanol Gasoline-range Organics Gasoline-range Organics Methyl tert-butyl Ether (MTBE) Aromatic Volatiles BTEX Volatile Organic Compounds Oxygenates g: 117 - Semi-volatile Organic Chemistry of Ha	Eva sol1 EPA 8015B EPA 8021B
Teld of 16.010 16.020 16.020 16.030 16.030 16.040 16.040 16.080 16.080 Teld of 17.010	Testin 000 030 031 001 041 061 062 000 120 Testin 001	g: 116 - Volatile Organic Chemistry of Hazardo EDB and DBCP Nonhalogenated Volatiles Ethanol and Methanol Gasoline-range Organics Gasoline-range Organics Methyl tert-butyl Ether (MTBE) Aromatic Volatiles BTEX Volatile Organic Compounds Oxygenates g: 117 - Semi-volatile Organic Chemistry of Ha Diesel-range Total Petroleum Hydrocarbons	EPA 8011 EPA 8015B EPA 8015B EPA 8015B EPA 8015B EPA 8015B EPA 8021B EPA 8260B EPA 8260B EPA 8015B
Teld of 16.010 16.020 16.030 16.030 16.040 16.040 16.040 16.080 16.080 16.080 16.080 16.080 16.080	Testin 000 030 031 001 041 061 062 000 120 Testin 001 000	g: 116 - Volatile Organic Chemistry of Hazardo EDB and DBCP Nonhalogenated Volatiles Ethanol and Methanol Gasoline-range Organics Gasoline-range Organics Methyl tert-butyl Ether (MTBE) Aromatic Volatiles BTEX Volatile Organic Compounds Oxygenates g: 117 - Semi-volatile Organic Chemistry of Ha Diesel-range Total Petroleum Hydrocarbons Extractable Organics	EPA 8011 EPA 8015B EPA 8015B EPA 8015B EPA 8015B EPA 8015B EPA 8021B EPA 8021B
Teld of 16.010 16.020 16.030 16.030 16.040 16.040 16.040 16.040 16.080 16.080 16.080 117.010 117.110	Testin 000 030 031 001 041 061 062 000 120 Testin 001 000 000	g: 116 - Volatile Organic Chemistry of Hazardo EDB and DBCP Nonhalogenated Volatiles Ethanol and Methanol Gasoline-range Organics Gasoline-range Organics Methyl tert-butyl Ether (MTBE) Aromatic Volatiles BTEX Volatile Organic Compounds Oxygenates g: 117 - Semi-volatile Organic Chemistry of Ha Diesel-range Total Petroleum Hydrocarbons Extractable Organics Polynuclear Aromatic Hydrocarbons	EPA 8011 EPA 8015B EPA 8021B EPA 8260B EPA 8260B EPA 8310
Teld of 16.010 16.020 16.020 16.030 16.030 16.040 16.040 16.080 16.080 16.080 16.080 17.010 17.110 17.140 17.170	Testin 000 030 031 001 041 061 062 000 120 Testin 001 000 000 000	g: 116 - Volatile Organic Chemistry of Hazardo EDB and DBCP Nonhalogenated Volatiles Ethanol and Methanol Gasoline-range Organics Gasoline-range Organics Methyl tert-butyl Ether (MTBE) Aromatic Volatiles BTEX Volatile Organic Compounds Oxygenates g: 117 - Semi-volatile Organic Chemistry of Ha Diesel-range Total Petroleum Hydrocarbons Extractable Organics Polynuclear Aromatic Hydrocarbons Nitroaromatics and Nitramines	EPA 8011 EPA 8015B EPA 8021B EPA 8270C EPA 8310 EPA 8330
ield of 16.010 16.020 16.030 16.030 16.040 16.040 16.040 16.080 16.080 16.080 17.010 17.110 17.110 17.170 17.210	Testin 000 030 031 001 041 061 062 000 120 Testin 001 000 000 000 000	g: 116 - Volatile Organic Chemistry of Hazardo EDB and DBCP Nonhalogenated Volatiles Ethanol and Methanol Gasoline-range Organics Gasoline-range Organics Methyl tert-butyl Ether (MTBE) Aromatic Volatiles BTEX Volatile Organic Compounds Oxygenates g: 117 - Semi-volatile Organic Chemistry of Ha Diesel-range Total Petroleum Hydrocarbons Extractable Organics Polynuclear Aromatic Hydrocarbons Nitroaromatics and Nitramines Organochlorine Pesticides	EPA 8011 EPA 8015B EPA 8021B EPA 8260B EPA 8260B EPA 8260B EPA 8260B EPA 8310 EPA 8330 EPA 8081A
ield of 16.010 16.020 16.030 16.030 16.040 16.040 16.040 16.040 16.080 16.080 17.010 17.110 17.110 17.110 17.120	Testin 000 030 031 001 041 061 062 000 120 Testin 001 000 000 000 000 000	g: 116 - Volatile Organic Chemistry of Hazardo EDB and DBCP Nonhalogenated Volatiles Ethanol and Methanol Gasoline-range Organics Gasoline-range Organics Methyl tert-butyl Ether (MTBE) Aromatic Volatiles BTEX Volatile Organic Compounds Oxygenates g: 117 - Semi-volatile Organic Chemistry of He Diesel-range Total Petroleum Hydrocarbons Extractable Organics Polynuclear Aromatic Hydrocarbons Nitroaromatics and Nitramines Organochlorine Pesticides Pesticides & PCBs	Image: State Stat
Teld of 16.020 16.020 16.030 16.030 16.040 16.040 16.040 16.040 16.080 16.080 16.080 17.110 17.110 17.140 17.140 17.210 17.210	Testin 000 030 031 001 041 061 062 000 120 Testin 001 000 000 000 000 000 000	g: 116 - Volatile Organic Chemistry of Hazardo EDB and DBCP Nonhalogenated Volatiles Ethanol and Methanol Gasoline-range Organics Gasoline-range Organics Methyl tert-butyl Ether (MTBE) Aromatic Volatiles BTEX Volatile Organic Compounds Oxygenates g: 117 - Semi-volatile Organic Chemistry of Ha Diesel-range Total Petroleum Hydrocarbons Extractable Organics Polynuclear Aromatic Hydrocarbons Nitroaromatics and Nitramines Organochlorine Pesticides Pesticides & PCBs PCBs	EPA 8011 EPA 8015B EPA 8021B EPA 8260B EPA 8260B EPA 8310 EPA 8330 EPA 8081A EPA 8081A EPA 8081A EPA 8081A
Teld of 16.010 16.020 16.030 16.030 16.040 16.040 16.040 16.080 16.080 16.080 16.080 17.010 17.110 17.110 17.170 17.210 17.220 17.220	Testin 000 030 031 001 041 061 062 000 120 Testin 001 000 000 000 000 000 000 000	g: 116 - Volatile Organic Chemistry of Hazardo EDB and DBCP Nonhalogenated Volatiles Ethanol and Methanol Gasoline-range Organics Gasoline-range Organics Methyl tert-butyl Ether (MTBE) Aromatic Volatiles BTEX Volatile Organic Compounds Oxygenates g: 117 - Semi-volatile Organic Chemistry of Ha Diesel-range Total Petroleum Hydrocarbons Extractable Organics Polynuclear Aromatic Hydrocarbons Nitroaromatics and Nitramines Organochlorine Pesticides Pesticides & PCBs PCBs Organophosphorus Pesticides	EPA 8011 EPA 8015B EPA 8021B EPA 8260B EPA 8260B EPA 8260B EPA 8260B EPA 8260B EPA 8270C EPA 8310 EPA 8330 EPA 8081A EPA 8081A EPA 8081A EPA 8081A EPA 8082 EPA 8141A
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As of 3/15/2017 , this list supersedes all previous lists for this certificate number. Customers: Please verify the current accreditation standing with the State.

Certificate No 2513 Expiration Date 1/8/2018

120.070 001	Corrosivity - pH Determination	EPA 9040B	
120.080 001	Corrosivity - pH Determination	EPA 9045C	

As of 3/15/2017 , this list supersedes all previous lists for this certificate number. Customers: Please verify the current accreditation standing with the State.

×.





CALIFORNIA STATE

ENVIRONMENTAL LABORATORY ACCREDITATION PROGRAM

CERTIFICATE OF ENVIRONMENTAL ACCREDITATION

Is hereby granted to

TestAmerica Denver

4955 Yarrow Street

Arvada, CO 80002

Scope of the certificate is limited to the "Fields of Testing" which accompany this Certificate.

Continued accredited status depends on successful completion of on-site inspection, proficiency testing studies, and payment of applicable fees.

> This Certificate is granted in accordance with provisions of Section 100825, et seq. of the Health and Safety Code.

Certificate No.: 2513

Expiration Date: 1/8/2018

Effective Date: 9/1/2016

Sacramento, California subject to forfeiture or revocation Christine Sotelo, Chief Environmental Laboratory Accreditation Program



EDMUNIO G. BROWN JR. BOWERNON MATTHEW RODRIGUEZ BOWERNAME FOR ENVIRONMENTAL PROTECTOR

State Water Resources Control Board

March 15, 2017

William S. Cicero TestAmerica Denver 4955 Yarrow Street Arvada, CO 80002

Dear William S. Cicero:

Certificate No. 2513

This notice advises that the laboratory named above has been certified as an environmental testing laboratory pursuant to the provisions of the Health and Safety Code (HSC), Division 101, Part 1, Chapter 4, Section 100825, *et seq.*

The Fields of Testing for which this laboratory has been certified are indicated on the enclosed "Fields of Testing" list. The certificate shall remain in effect until **January 08, 2018** unless it is revoked. This certificate is subject to an annual fee as determined by HSC 100860.1(a).

The application for renewal of this certificate must be received 90 days prior to the expiration date to remain in force according to HSC 100845(a). You must submit annual Proficiency Testing results before the due date of your annual fee to remain in compliance.

Any change in laboratory location or alteration to laboratory structure that could adversely affect quality of analysis in certified methods require notification prior to the change. Notification is also required for a transfer in ownership or appointment of new laboratory director within 30 days of the change (HSC, Section 100845(b) and (d)).

Your continued cooperation with the above requirements is essential for maintaining the high quality of the data produced by environmental laboratories certified by the State of California.

Please contact our office at (916) 323-3431 or elapca@waterboards.ca.gov with questions.

Sincerely

Christine Sotelo, Chief Environmental Laboratory Accreditation Program

Enclosure



OREGON

Environmental Laboratory Accreditation Program



NELAP Recognized

TestAmerica Irvine

4028

17461 Derian Ave, Suite 100

Irvine, CA 92614

IS GRANTED APPROVAL BY ORELAP UNDER THE 2009 TNI STANDARDS, TO PERFORM ANALYSES ON ENVIRONMENTAL SAMPLES IN MATRICES AS LISTED BELOW :

Air	Drinking Water	Non P <mark>ot</mark> able Water	Solids and Chem. Waste	Tissue
	Chemistry	Chemistry	Chemistry	100

AND AS RECORDED IN THE LIST OF APPROVED ANALYTES, METHODS, ANALYTICAL TECHNIQUES, AND FIELDS OF TESTING ISSUED CONCURRENTLY WITH THIS CERTIFICATE AND REVISED AS NECESSARY.

ACCREDITED STATUS DEPENDS ON SUCCESSFUL ONGOING PARTICIPATION IN THE PROGRAM AND CONTINUED COMPLIANCE WITH THE STANDARDS.

CUSTOMERS ARE URGED TO VERIFY THE LABORATORY'S CURRENT ACCREDITATION STATUS IN OREGON.

Scott Hoatson Oregon State Public Health Laboratory Interm ORELAP Program Manager 3150 NW. 229th Ave, Suite 100 Hillsboro, OR 97124

EFFECTIVE DATE: 01/30/2017 EXPIRATION DATE: 01/29/2018 Certificate No: 4028 - 004





OREGON

Environmental Laboratory Accreditation Program

ORELAP Fields of Accreditation

ORELAP ID: 4028



TestAmerica Irvine

17461 Derian Ave, Suite 100

EPA CODE: CA01531

Certificate: 4028 - 004

Irvine, CA 92614

Issue Date: 1/30/2017 Expiration Date: 1/29/2018

As of 1/30/2017 this list supersedes all previous lists for this certificate number.

MATRIX	Reference	Code	Analyte	Code	Description
Drinking		~			
Water	EPA 120.1	1	DEC	10006209	Conductance - Specific @ 25 C
		1610	Conductivity	00	
	EPA 150.1			10008205	pH - Electrometric Measurement
		1900	pH	-10	
	EPA 160.1	1900		10009004	Total Dissolved Solids, dried @ 180 C.
				10000004	
		1705	Total dissolved solids		
	EPA 160.4			10010409	Total Volatile Solids, ignition @ 550 C.
		1970	Res <mark>idue</mark> -volatile		
	EPA 180.1			10011402	Turbidity - Nephelometric
		2055	Turbidity		
	EPA 200.7 4.4			10013806	ICP - metals
		1000	Aluminum		
		1015	Barium		
		1020	Beryllium		
		1025	Boron		
		1030	Cadmium		
		1035	Calcium		
		1040	Chromium		
		1055	Copper		
		1760	Hardness (calc.)		
		1070	Iron		
		1085	Magnesium		
		1090	Manganese		
		1105	Nickel		
		1125	Potassium		
		1990	Silica as SiO2		
		1150	Silver		
		1155	Sodium		
		1185	Vanadium		
	EPA 200.8 5.4	1190	Zinc	10014605	Metals by ICP-MS
		1000	Aluminum		
		1000	Antimony		
		1005	Antimony		
		1015	Barium		
		1020	Beryllium		
		1020	Cadmium		

Environmental Laboratory Accreditation Program ORELAP Fields of Accreditation ORELAP ID Water Environmental Laboratory Accreditation Program Accreditation Control Program Accreditation Control Program Control Program <	ORELAS			OR	OREGON		
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Inorganic Substances in Environmental Samples Inorganic Samples Inorganic			1095	Mercury			
1730 Fluoride 1810 Nitrate as N 1820 Nitrate-nitrite 1840 Nitrite as N 1870 Orthophosphate as P 2000 Sulfate EPA 300.0 10053006 Ion chromatography - anions. 1835 Nitrite EPA 300.1 10053608 Ion chromatography - anions. 1535 Bromate 1540 Bromide 1570 Chlorate		EPA 300.0 2.1				10053200	Inorganic Substances in Environmental
1810 Nitrate as N 1820 Nitrate-nitrite 1840 Nitrite as N 1870 Orthophosphate as P 2000 Sulfate EPA 300.0 Ion chromatography - anions. 1835 Nitrite EPA 300.1 10053608 1535 Bromate 1536 Bromide 1570 Chlorate			1575	Chloride			
1820 Nitrate-nitrite 1840 Nitrite as N 1870 Orthophosphate as P 2000 Sulfate EPA 300.0 10053006 1835 Nitrite EPA 300.1 10053608 IS35 Bromate 1535 Bromate 1540 Bromide 1570 Chlorate			1730	Fluoride			
1840 Nitrite as N 1870 Orthophosphate as P 2000 Sulfate EPA 300.0 10053006 Ion chromatography - anions. 1835 Nitrite EPA 300.1 10053608 Ion chromatography - anions. 1535 Bromate 1540 Bromide 1570 Chlorate			1810	Nitrate as N			
1870 Orthophosphate as P 2000 Sulfate EPA 300.0 10053006 Ion chromatography - anions. 1835 Nitrite EPA 300.1 10053608 Ion chromatography - anions. 1535 Bromate 1540 Bromide 1570 Chlorate			1820	Nitrate-nitrite			
2000SulfateEPA 300.010053006Ion chromatography - anions.1835Nitrite10053608Ion chromatography - anions.EPA 300.110053608Ion chromatography - anions.1535Bromate1540Bromide1540Bromide1570Chlorate			1840	Nitrite as N			
EPA 300.010053006Ion chromatography - anions.1835NitriteEPA 300.110053608Ion chromatography - anions.1535Bromate1540Bromide1570Chlorate			1870	Orthophosphate as	P		
1835 Nitrite EPA 300.1 10053608 Ion chromatography - anions. 1535 Bromate 1540 1540 Bromide 1570 Chlorate 1570			2000	Sulfate			
EPA 300.110053608Ion chromatography - anions.1535Bromate1540Bromide1570Chlorate		EPA 300.0				10053006	Ion chromatography - anions.
1535Bromate1540Bromide1570Chlorate			1835	Nitrite			
1540Bromide1570Chlorate		EPA 300.1			· · · · ·	10053608	Ion chromatography - anions.
1540Bromide1570Chlorate			1535	Bromate			
1595 Chlorite			1570	Chlorate			
			1595	Chlorite			

ORELA	ORE ORE		OREGON		UNS RECOGNES
	Environmental Laborato ORELAP Fields of Accreditation		-	-	TNL
1150	Acci	reditat	ion	ORELAP ID:	4028 Cheorranon 80
<u>TestAme</u>	<u>rica Irvine</u>			EPA CODE:	CA01531
17461 Der	an Ave, Suite 100	C		Certificate:	4028 - 004
Irvine, CA	Irvine, CA 92614		Issue Date: 1/30/2017		
		norood	es all previous lists for this c		
Drinking	EPA 314.0	perseu		10277006	Perchlorate in Drinking Water by Ion
Water					Chromatography
Water		1895	Perchlorate	-	
	EPA 332.0 1.0		DEC	10059742	Determination of Perchlorate in Drinking Water by Ion Chromatography and
			OKEL		Electrospray Mass Spectrometery
		1895	Perchlorate	U (1) A	
	EPA 350.1 2			10063602	Ammonia Nitrogen - Colorimetric, Auto Phenate
		1515	Ammonia as N		Fliendle
	EPA 351.2 2	1010		10065404	Total Kjeldahl Nitrogen - Block Digest,
	EI // 001.2 2			10000404	Phenate
		1790	Kjeldahl nitrog <mark>en</mark>		
	EPA 504.1 1.1			10082801	EDB/DBCP/TCP micro-extraction, GC/ECD
		4570	1,2-Dibromo-3-chloropropane (DBC	P)	GC/ECD
		4585	1,2-Dibromoethane (EDB, Ethylene		
			dibromide)		
	EPA 505 2.1			10083406	Organohalide pesticides/PCBs (Drinking Water)
		7005	Alachlor		
		8880	Aroclor-1016 (PCB-1016)		
		8885	Aroclor-1221 (PCB-1221)		
		8890	Aroclor-1232 (PCB-1232)		
		8895	Aroclor-1242 (PCB-1242)		
		8900	Aroclor-1248 (PCB-1248)		
		8905	Aroclor-1254 (PCB-1254)		
		8910	Aroclor-1260 (PCB-1260)		
		7250	Chlordane (tech.)		
		7470	Dieldrin		
		7540	Endrin		
		7120	gamma-BHC (Lindane, gamma- HexachlorocyclohexanE)		
		7685	Heptachlor		
		7690	Heptachlor epoxide		
		6275	Hexachlorobenzene		
		6285	Hexachlorocyclopentadiene		
		7810	Methoxychlor		
		8870	PCBs		
		8250	Toxaphene (Chlorinated camphene)		
	EPA 515.4 1			10088503	Chlorinated acids Liquid/Solid and GC/ECD
		8655	2,4,5-T		
		8545	2,4-D		
		8560	2,4-DB		
		8600	3,5-Dichlorobenzoic acid		
		5000			

RELA	<u>Envi</u>	ironme	OREGC		IM HELOCOLE
		ELAP F reditat	ields of ion	ORELAP ID:	4028
TestAmer	rica Irvine			EPA CODE:	CA01531
17461 Deria	an Ave, Suite 100	2		Certificate:	4028 - 004
			Iccus Date: 1/20/	2017 Expiration Dat	
Irvine, CA 9				·	
		-	es all previous lists for th	is certificate numbe	er.
Drinking	EPA 515.4 1	8505	Acifluorfen		
Water		8530	Bentazon		
		8540	Chloramben		
		8550	Dacthal (DCPA)		
		8555	Dalapon		
		8595	Dicamba		
		8605	Dichloroprop (Dichlorprop)	phenol,	
		8620	Dinoseb (2-sec-butyl-4,6-dinitro DNBP)	ophenol,	
	1.91	6605	, Pentachlorophenol		
		8645	Picloram		
		8650	Silvex (2,4,5-TP)		
	EPA 524.2 4.1			10088809	Volatile Organic Compounds GC/MS Capillary Column
		5105	1,1,1,2-Tetrachloroethane		Capitally Column
		5160	1,1,1-Trichloroethane		
		5110	1,1,2,2-Tetrachloroethane		
		5195	1,1,2-Trichloro-1,2,2-trifluoroett (Freon 113)	nane	
		5165	1,1,2-Trichloroethane		
		7450	1,1-Dichloro-2-propanone		
		4630	1,1-Dichloroethane		
		4640	1,1-Dichloroethylene		
		4670	1,1-Dichloropropene		
		5150	1,2,3-Trichlorobenzene		
		5180	1,2,3-Trichloropropane		
		5155	1,2,4-Trichlorobenzene		
		5210	1,2,4-Trimethylbenzene		
		4570	1,2-Dibromo-3-chloropropane (DBCP)	
		4585	1,2-Dibromoethane (EDB, Ethy dibromide)	lene	
		4610	1,2-Dichlorobenzene		
		4635	1,2-Dichloroethane (Ethylene c	lichloride)	
		4655	1,2-Dichloropropane		
		5215	1,3,5-Trimethylbenzene		
		4615	1,3-Dichlorobenzene		
		4660	1,3-Dichloropropane		
		4620	1,4-Dichlorobenzene		
		4480	1-Chlorobutane		
		4665	2,2-Dichloropropane		
		4410	2-Butanone (Methyl ethyl ketor	ne, MEK)	
		4500	2-Chloroethyl vinyl ether		
		4535	2-Chlorotoluene		
		4860	2-Hexanone (MBK)		
		4540	4-Chlorotoluene		

ORELAS	Environme	OREGON ental Laboratory Accredi	itation Progra	am	HULP RECOGRE
ALL P	ORELAP F Accreditat	Fields of	ORELAP ID:		FOR THIN BOD
TestAmerica	Irvine		EPA CODE:	CA01531	
17461 Derian A			Certificate:		
		Issue Date: 1/30/2017			
Irvine, CA 926			·		
	7 this list supersed PA 524.2 4.1 4910 4315 4340 4355 4375 4385 4390 4395 4390 4395 4395 4300 4395 4385 4390 4395 4395 4400 4450 4450 4455 4475 4575 4485 4605 4625 4725 9375 4810 4765 4770 4835 4840 4870 4900 5240 4925 4900 5240 4925 4945 4950 4900 5200 5005 4435 5015 5090 5250	es all previous lists for this co 4-lsopropyltoluene (p-Cymene) 4-Methyl-2-pentanone (MIBK) Acetone Acrylonitrile Allyl chloride (3-Chloropropene) Benzene Bromobenzene Bromochloromethane Bromodichloromethane Bromodichloromethane Bromoform Carbon disulfide Carbon tetrachloride Chlorobenzene Chlorodibromomethane Chlorodibromomethane Chlorothane (Ethyl chloride) Chloroform cis-1,2-Dichloropropene Dibromomethane (Methylene bromid Dichlorodifluoromethane (Freon-12) Diethyl ether Di-isopropylether (DIPE) Ethyl methacrylate Ethyl-t-butylether (ETBE) (2-Ethoxy-: methylpropane) Hexachlorobutadiene Hexachlorobutad	2-		
	5250 4440	o-Xylene sec-Butylbenzene			

	<u>Env</u>	ironme	OREGON ental Laboratory Accreditation Program
		ELAP F reditat	Tields of ORELAP ID: 4028
TestAme	rica Irvine		EPA CODE: CA01531
17461 Deri	an Ave, Suite 10	0	Certificate: 4028 - 004
Irvine, CA 9	2614		Issue Date: 1/30/2017 Expiration Date: 1/29/2018
			es all previous lists for this certificate number.
Drinking Water	EPA 524.2 4.1	5100 4370 4420	Styrene T-amylmethylether (TAME) tert-Butyl alcohol
		4445 5115 5120	tert-Butylbenzene Tetrachloroethylene (Perchloroethylene) Tetrahydrofuran (THF)
		5140 5205 4700	Toluene Total trihalomethanes trans-1,2-Dichloroethylene
	1	4685 4605 5170	trans-1,3-Dichloropropylene trans-1,4-Dichloro-2-butene Trichloroethene (Trichloroethylene)
		5175 5235	Trichlorofluoromethane (Fluorotrichloromethane, Freon 11) Vinyl chloride
		5260	Xylene (total)
	EPA 525.2 2		10090003 Semi-Volatile by SPE extraction and
		9106	GC/MS 2,2',3,3',4,4',6-Heptachlorobiphenyl (BZ-171)
		9112	2,2',3,3',4,5',6,6'-Octachlorobiphenyl (BZ-201)
		9159	2,2',3,4',6'-Pentachlorobiphenyl (BZ- 98)
		9174	2,2',4,4',5,6'-Hexachlorobiphenyl (BZ- 154)
		8920	2,3-Dichlorobiphenyl (BZ-5)
		6185	2,4-Dinitrotoluene (2,4-DNT)
		6190	2,6-Dinitrotoluene (2,6-DNT)
		8915	2-Chlorobiphenyl (BZ-1)
		7355	4,4'-DDD
		7360	4,4'-DDE
		7365	4,4'-DDT Acenaphthylene
		5505 7005	Alachlor
		7025	Aldrin
		7110	alpha-BHC (alpha- Hexachlorocyclohexane)
		7035	Ametryn
		5555	Anthracene
		7060	Atraton
		7065	Atrazine
		5575	Benzo(a)anthracene
		5580	Benzo(a)pyrene
		5590	Benzo(g,h,i)perylene
		5600	Benzo(k)fluoranthene

OREGON Environmental Laboratory Accreditation Program							
ALEY.	ORELAP F Accreditat						
TestAmerica Irvine	<u>}</u>	EPA CODE: CA01531					
17461 Derian Ave, Su	ite 100	Certificate: 4028 - 004					
Irvine, CA 92614		Issue Date: 1/30/2017 Expiration Date: 1/29/2018					
	liet suppread	es all previous lists for this certificate number.					
Drinking EPA 525.2		Benzo[b]fluoranthene					
Water	7115	beta-BHC (beta-					
Water		Hexachlorocyclohexane)					
	6062	bis(2-Ethylhexyl)adipate					
	7130	Bromacil					
	7160	Butachlor Butyl benzyl phthalate Butylate Chlorobenzilate					
	5670	Butyl benzyl phthalate					
	7175	Butylate					
	7260	Chlorobenzilate					
	7265	Chloroneb					
1 - 1 -	7275	Chloropropham					
	7300	Chlorpyrifos					
	5855	Chrysene					
	4550	Cycloate					
	7105	delta-BHC					
	6065	Di(2-ethylhexyl) phthalate (bis(2- Ethylhexyl)phthalate, DEHP)					
	7410	Diazinon					
	5895	Dibenz(a,h) anthracene					
	8610	Dichlorovos (DDVP, Dichlorvos)					
	7470	Dieldrin					
	6070	Diethyl phthalate					
	6135	Dimethyl phthalate					
	5925	Di-n-butyl phthalate					
	7500	Diphenamid					
	7570	Ethoprop					
	7590	Fenarimol					
	6265	Fluoranthene					
	6270	Fluorene					
	7120	gamma-BHC (Lindane, gamma- HexachlorocyclohexanE)					
	6275	Hexachlorobenzene					
	6285	Hexachlorocyclopentadiene					
	6315	Indeno(1,2,3-cd) pyrene					
	6320	Isophorone					
	7810	Methoxychlor					
	7835	Metolachlor					
	7845	Metribuzin					
	7850	Mevinphos					
	7875	Molinate					
	6440	Napropamide					
	9537	Pebulate					
	7975	Permethrin (total)					
	6615	Phenanthrene					

RELA	<u>Env</u>	OREGON Environmental Laboratory Accreditation Program				
ORELAP Fie Accreditatio				ORELAP ID:	4028	
TestAme	rica Irvine			EPA CODE:	CA01531	
17461 Deri	an Ave, Suite 10	00		Certificate:	4028 - 004	
Irvine, CA 9			Iccup Date: 1/20	2017 Expiration Dat		
Drinking Water	EPA 525.2 2	8040 6650 8045 8060 6665 8125	es all previous lists for t Prometryn Pronamide (Kerb) Propachlor (Ramrod) Propazine Pyrene Simazine	COGI		
	N.N.	8130 8180 8195 8220 8255 8295 8320	Simetryn Terbacil Terbutryn (Igran) Thiobencarb Triademefon Trifluralin (Treflan) Vernolate			
	EPA 531.1 3.1	6320		10091006	Carbamates HPLC with post column	
	EPA 547 EPA 548.1 1 EPA 549.2 1	7710 7010 7015 7020 7195 7205 7800 7805 7940 8080 9411 7525	3-Hydroxycarbofuran Aldicarb (Temik) Aldicarb sulfone Aldicarb sulfoxide Carbaryl (Sevin) Carbofuran (Furaden) Methiocarb (Mesurol) Methomyl (Lannate) Oxamyl Propoxur (Baygon) Glyphosate Endothall	10092009 10092805 10093400	Glyphosate by Direct Aqueous Injection by Post-column Derivitization and HPLC/Fluorescence Endothall by Ion Exchange, Methylation and GC/MS Diquat/Paraquat by Liquid/Liquid Extraction and HPLC/UV-VIS	
	EPA 552.2 1	9528 9312 9315 9336 9357 9360 9414 9642	Paraquat Bromoacetic acid Bromochloroacetic acid Chloroacetic acid Dibromoacetic acid Dichloroacetic acid Total haloacetic acids Trichloroacetic acid	10095804	Haloacetic Acid/Dalapon, Liquid/Liquid Extraction, Derivitization and GC/ECD	

ORELA	8						
	<u>Envi</u>	ronme	ental Laboratory Acc	im Autorite			
ORELAP Fields of Accreditation				ORELAP ID:	4028		
<u>TestAmerica Irvine</u> 17461 Derian Ave, Suite 100				EPA CODE:	CA01531		
				Certificate:	4028 - 004		
Irvine, CA	92614		Issue Date: 1/30	/2017 Expiration Dat	e: 1/29/2018		
As of 1/30	/2017 this list su	persed	es all previous lists for t	his certificate numbe	er.		
Drinking Water	Kelada-01 1.2	1645	Total cyanide	60005303	Kelada Automated Test Methods for Total Cyanide, Acid Dissociable Cyanide, and Thiocyanate		
	SM 2120 B 20th ED	102 1605	Apparent Color Color	CO 20224004	Color by Visual Comparison		
	SM 2130 B 20th ED	101	True Color	20042404	Turbidity by Nephelometric Determination		
	SM 2150 B 20th ED	2055 1855	Turbidity Odor	20043407	Odor by Threshold Odor Test		
	SM 2310 B 20th ED	1500	Acidity, as CaCO3	20044206	Acidity by Titration		
	SM 2320 B 20th ED	1505	Alkalinity as CaCO3	20045209	Alkalinity by Titration		
	SM 2330 B 20th Ed	1615	Corrosivity	20003309	Calcium Carbonate Indices		
	SM 2340 B 20th ED	1550 1750 1755	Calcium hardness as CaCO3 Hardness Total hardness as CaCO3	20046202	Hardness by calculation		
	SM 2340 C 20th ED	1750	Hardness	20047205	Hardness by EDTA Titration		
	SM 2510 B 20th ED	1610	Conductivity	20048208	Conductivity by Probe		
	SM 2540 B 20th ED	1950	Residue-total	20049007	Total Solids		
	SM 2540 C 20th ED	1955	Residue-filterable (TDS)	20050004	Total Dissolved Solids		
	SM 3500-Cr B 20th ED	1045	Chromium VI	20065809	Chromium by Colorimetric Method		
	SM 3500-Fe B 20th ED	1070	Iron	20068604	Iron by Colorimetric Method		
	SM 4500-CI G 20th ED	1580	Chlorine	20081203	Residual Chlorine by DPD Colorimetric Determination		
		1945	Residual free chlorine				
		1940	Total residual chlorine				

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