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Q-5

MS-16

August 05, 2010

Ms. Betsy Ulrich
Senior Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety
Nuclear Regulatory Commission, Region 1
475 Allendale Road
King of Prussia, PA 19406-1415

2010 AUG - 6 AM 10:41

RECEIVED

Re: NRC License No. 06-00221-08, Docket Number: 030-03759

Subject: Decommissioning of Bethany, Connecticut Site Only

Dear Ms. Ulrich:

Pursuant to your request for additional information regarding our request to amend Nuclear Regulatory Commission License No. 06-00221-08 we are making the following changes in the "Proposed Sampling Plan for Final Radiological Status" dated June 11, 2010. The numbered responses below coincide with those in your letter dated July 15, 2010.

1, 2. Based on a conversation on 29 July 2010 between you and Jay R. Dockendorff of Radiation Safety Associates, Inc. we are making the assumption that background contribution from Carbon 14 will be zero.

As a result, we are abandoning the use of the Wilcoxon Rank Sum statistical test and will instead be using the Sign Test. We will assume that any Carbon 14 found in the samples is due to licensed activity. Additionally, we will remediate the individual survey unit areas if any single test result exceeds the site specific and State of Connecticut mandated DCGL of 9.12 pCi/g. Following any additional remediation a new random start point will be selected and a new triangular grid sampling pattern will be established. We do not plan to do double-sampling or two-stage sampling.

The number of samples required under the Sign test was recalculated with a resultant sample count of 18 samples per survey unit. A new triangular grid has been established for each survey unit based on the increased number of sampling points required. For the "corral", "grape" and "apple" survey units the same random start point was utilized to calculate the new sampling grid. For the "peach" survey unit a new random starting point was generated to establish the sampling grid. The up-dated sampling maps are attached.

3. For this final status survey, we are using the following classifications:



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Peach Tree: Class 2 (remediation already accomplished)
Corral: Class 2 (remediation already accomplished)
Grape: Class 1
Apple: Class 1

4. Due to the low concentrations of Carbon 14 found in the affected areas on initial sampling, and the inherently low efficiency of instruments for detecting Carbon 14 on direct survey, no surveys using hand held instruments are planned for this site.

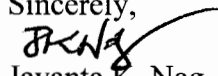
5. The soil samples will be analyzed at Eberline Services, 601 Scarboro Rd, Oak Ridge, TN 37830. The following documents are attached, which deal with sample analysis, QA, QC and sample chain-of-custody

1. Eberline Soil Analysis Method AP-026 along with an example of the previously reported analytical results summary for the soil samples.
2. Eberline Quality Systems Implementation Plan.
3. Eberline QA Program.
4. Sample Chain-of custody form.

6. Soil samples will be collected using a manual core sampler with a 7 inch long by 3-inch diameter core bit. Each collected sample (500g-1000g) will be placed in zip-lock type plastic bag labeled with the sample location and depth. The bagged sample will then be placed in a second zip lock bag and sealed with security tape. No sample prep, such as drying or preservation will be carried out. To avoid cross contamination, the sample core bit will be cleaned after each use with a two stage washing process as outlined in the FSSP. One sample from each depth in the survey area will be collected and sent as a duplicate.

As I indicated earlier, Chemtura hired Radiation Safety Associates (RSA), Inc. as a consultant for this project. If you have any further questions or issues concerning the additional information/responses, you may directly contact Mr. K. Paul Steinmeyer, RSA (Tel: 860-228-0487 and E-mail: kpstein@radpro.com). We would appreciate your prompt review and input to us on this decommissioning work so that we can finish it before cold weather sets in.

Sincerely,


Jayanta K. Nag
Radiation Safety Officer

RECEIVED
JAN 10 10:41

CORRAL

36N

32N

28N

24N

20N

16N

12N

8N

4N

0

0

4E

8E

12E

16E

6.5EW

5.5NS

RS

E

N

1

0' 10"

4' 4"

2

7' 4"

4' 4"

3

13' 10"

4' 4"

4

4' 1"

9' 10"

5

10' 7"

9' 10"

6

0' 10"

15' 4"

7

7' 4"

15' 4"

8

13' 10"

15' 4"

9

4' 1"

20' 10"

10

10' 7"

20' 10"

11

0' 10"

26' 4"

12

7' 4"

26' 4"

13

13' 10"

26' 4"

14

4' 1"

31' 10"

15

10' 7"

31' 10"

16

0' 10"

37' 4"

17

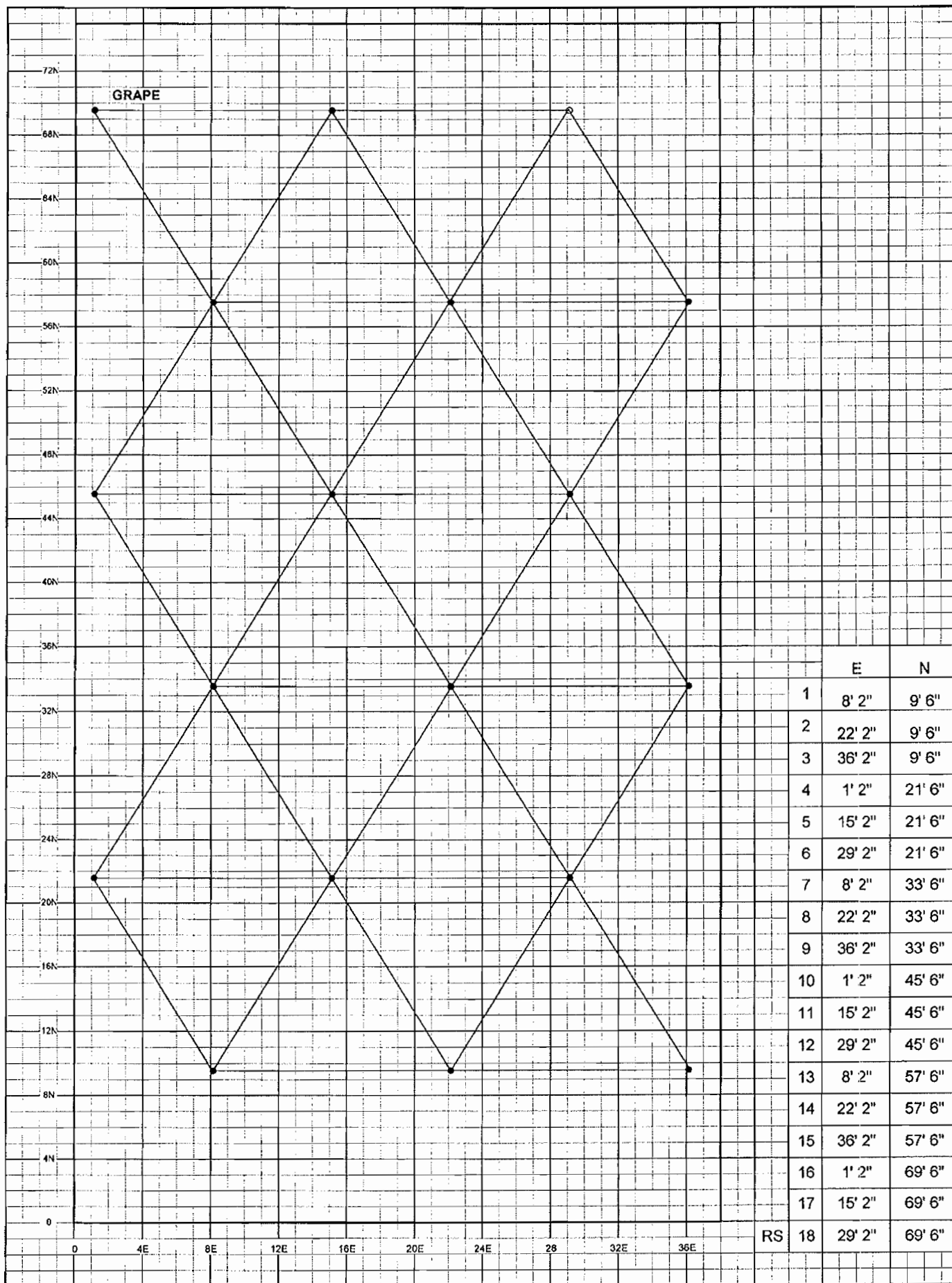
7' 4"

37' 4"

18

13' 10"

37' 4"



APPLE

40N

36N

32N

28N

24N

20N

16N

12N

8N

4N

0

0

4E

8E

12E

16E

20E

24E

	E	N
1	5' 4"	0' 6"
2	13' 4"	0' 6"
3	21' 4"	0' 6"
4	1' 4"	7' 6"
5	9' 4"	7' 6"
6	17' 4"	7' 6"
7	5' 4"	14' 6"
8	13' 4"	14' 6"
9	21' 4"	14' 6"
10	1' 4"	21' 6"
11	9' 4"	21' 6"
12	17' 4"	21' 6"
13	5' 4"	28' 6"
14	13' 4"	28' 6"
15	21' 4"	28' 6"
16	1' 4"	35' 6"
17	9' 4"	35' 6"
18	17' 4"	35' 6"

RS

PEACH TREE

Δ

24N

Δ

20N

Δ

Δ

Δ

16N

12N

Δ

Δ

Δ

8N

Δ

Δ

Δ

Δ

4N

0

0

4E

8E

12E

16E

E

N

1	2' 0"	0' 3"
2	7' 4"	0' 3"
3	12' 8"	0' 3"
4	4' 8"	4' 11"
5	10' 0"	4' 11"
6	15' 4"	4' 11"
7	2' 0"	9' 7"
8	7' 4"	9' 7"
9	12' 8"	9' 7"
10	4' 8"	14' 3"
RS 11	10' 0"	14' 3"
12	15' 4"	14' 3"
13	2' 0"	18' 11"
14	7' 4"	18' 11"
15	12' 8"	18' 11"
16	4' 8"	23' 7"
17	10' 0"	23' 7"
18	15' 4"	23' 7"

Chain of Custody Document

Shipped From: Jay Nag
Chemtura Corporation
199 Benson Rd
Middlebury, CT 06749
Phone 203-573-3698
Fax 203-573-3660
jay.nag@chemtura.com

To: Michael McDougall
Eberline Services
601 Scarboro Rd
Oak Ridge, TN 37830
Phone 865-481-0683

Shipping Conditions: ambient temperature

Shipping Carrier: FedEx

Shipper Signature: _____ Date: _____

Sample No.	Description	Sampling Date	Box No.	Shipped	Received

Acknowledgement of Receipt:


Received in _____ condition. If other than good condition, please explain.

Signature: _____ Date: _____

Printed Name: _____

Please send a signed copy of this document to the Shipper at the address above.

The samples above are submitted for the analysis of ^{14}C content with standard 7-day turn-around time and Level IV Analytical Data Package with Standard EDD at an MDA of < 5 pCi/g. The NRC specification for decommissioning is 12 pCi/g.

 EBERLINE SERVICES Oak Ridge Laboratory	<h1>Internal Chain of Custody</h1>	Work Order #	08-10099
		Lab Deadline	10/24/2008
		Analysis	C0014 - Level 4
		Sample Matrix	Soil/Solid

Comments	Sample Fraction	HP 210 / 270 Detector Activity	Storage Location
	04	43	A1.1
	05	51	A1.1
	06	59	A1.1
	07	51	A1.1
	08	42	A1.1
	09	60	A1.1
	10	46	A1.1
	11	42	A1.1
	12	50	A1.1
	13	53	A1.1
	14	44	A1.1
	15	60	A1.1
	16	63	A1.1
	17	52	A1.1
	18	51	A1.1
	19	54	A1.1
	20	55	A1.1

	Location (circle one)					Initials	Date
Received by	Sample Storage	Rough Prep	Prep	Separations	Count Room	J. P. Helle	10-21-08
Relinquished by	Sample Storage	Rough Prep	Prep	Separations	Count Room	J. P. Helle	10-23-08
Received by	Sample Storage	Rough Prep	Prep	Separations	Count Room	ICB	10/23/08 1201
Relinquished by	Sample Storage	Rough Prep	Prep	Separations	Count Room	ICB	10/24/08 1456
Received by	Sample Storage	Rough Prep	Prep	Separations	Count Room		
Relinquished by	Sample Storage	Rough Prep	Prep	Separations	Count Room		
Received by	Sample Storage	Rough Prep	Prep	Separations	Count Room		
Relinquished by	Sample Storage	Rough Prep	Prep	Separations	Count Room		
Received by	Sample Storage	Rough Prep	Prep	Separations	Count Room		
Relinquished by	Sample Storage	Rough Prep	Prep	Separations	Count Room		
Received by	Sample Storage	Rough Prep	Prep	Separations	Count Room		
Relinquished by	Sample Storage	Rough Prep	Prep	Separations	Count Room		



Eberline Services Oak Ridge Laboratory Analytical Procedure

AP-026

Analysis of Carbon-14 in Water & Soil By CO₂ Evolution

AUTHORIZATION AND APPROVAL STATEMENT

This Eberline Services - Oak Ridge Laboratory, Analytical Procedure,
"Analysis of Carbon-14 in Water & Soil By CO₂ Evolution"
is authorized and approved in its entirety by:

Cecilia H. Searcy MPH, NRRPT
Deputy Laboratory Manager

Date: July 23, 2010

Ahmed A. Halouma
Quality Assurance Manager

Date: July 23, 2010

Michael R. McDougall
Laboratory Manager

Date: July 23, 2010

**1.0 SCOPE, PURPOSE, AND APPLICABLE MATRICES**

This method provides a protocol for the determination of C-14 in aqueous or solid samples. The method covers oxidation of radiocarbon in the sample to carbon dioxide, collecting the carbon dioxide in a complexing agent and subsequent counting of the sample in a low background liquid scintillation counter.

2.0 DETECTION LIMITS FOR THE

2.1 Method detection limits are method specific and are not addressed in this procedure

3.0 SUMMARY OF TEST METHOD

3.1 A 500 ml aliquot of water is conditioned with sodium carbonate and oxidized using potassium permanganate. Sulfuric acid is used to evolve any radiocarbon in the sample as CO₂. The generated ¹⁴CO₂ is purified using an HCl trap, and the gas is absorbed by Harvey Carbon-14 Cocktail complexing agent. After the evolution process the cocktail is transferred into a LSC vial and the vial is counted for activity with a low background liquid scintillation counter.

4.0 DEFINITIONS

4.1 NIST – National Institute of Standards and Technology

4.2 EPA – Environmental Protection Agency

4.3 MSDS – Material Safety Data Sheet

5.0 INTERFERENCES

None

6.0 SAFETY

Laboratory chemical and general safety shall be conducted as required within "Eberline Services – Oak Ridge Laboratory, Site Specific Chemical Hygiene Plan", Latest Version

Laboratory radiation safety shall be conducted as required within "Eberline Services – Radiation Protection Plan and Attachments", Latest Version

Waste management and sample return shall be conducted as required within "Eberline Services – Waste Management Plan", Latest Version

6.1 Housekeeping

6.1.1 All work areas shall be kept as clean as possible at all times and the entire work area shall be cleaned at the conclusion of the last shift of the day.

6.1.2 Minimize unnecessary clutter.

6.1.3 Promptly clean any spills that occur using the guidance contained in the Emergency Action Plan, Spill Response Procedure and support of the Radiation Safety Officer and Health and Safety Officer if necessary.

6.2 Clearly, label all sample containers (beakers, bottles, c-tubes etc.) with the work order number, analysis fraction, and analyte identification information such as "Total Sr", "Iso-U", or some other recognizable wording.



- 6.3 Any labels that identify the hazards associated with a particular sample container at the time of receipt will remain affixed to that container AND to ALL subsequent sub sampling from, and disposal of, that container.
- 6.4 Dispose of all waste in the appropriate containers as directed by the Waste Management Plan.
- 6.5 Dispose non-rad waste in appropriate containers, DO NOT PUT NON-RAD WASTE INTO RAD WASTE CONTAINERS.
- 6.6 Personal protective equipment for this procedure shall consist of a lab coat or protective apron, safety glasses or goggles and chemical resistant laboratory gloves.

7.0 EQUIPMENT AND SUPPLIES

- 7.1 500-ml round bottom distillation flask
- 7.2 Nesbit absorption bottle, Kontes #657250-2525 or equivalent
- 7.3 Vacuum pump
- 7.4 Analytical balance
- 7.5 Eppendorf pipettor with disposable pipette tips or equivalent: 0.10, 0.25, 0.50, and 1.0-ml
- 7.6 Oxford pipettor with disposable pipette tips or equivalent: 0-5 and 5-10-ml
- 7.7 Scintillation vials with caps, with low Potassium content, glass or polyethylene, 20-ml capacity
- 7.8 Liquid scintillation counter
- 7.9 Filter apparatus: 300-ml capacity Millipore apparatus or equivalent with 1.0-liter filter flask and 0.45 μ m membrane filter (2" diameter)
- 7.10 Absorption bulb (Corning # 406990)
- 7.11 The laboratory may use pre-cleaned disposable plastic lab ware as appropriate and applicable to this or any other analytical procedure. Disposable plastic ware will be disposed of in the appropriate waste container after use.

8.0 REAGENTS AND STANDARDS

- 8.1 Hydrochloric acid, (HCl), concentrated, 37%, reagent grade
- 8.2 0.6M Hydrochloric acid: Measure 26 ml of concentrated HCl into a 500-ml volumetric flask containing 400 ml of DI water and mix solution. Add DI water to the 500 ml mark, stopper flask, and mix solution well.
- 8.3 Anhydrous Sodium carbonate, (Na₂CO₃), powder, reagent grade
- 8.4 0.5M KmnO₄ Solution (see LIMS for preparation instructions)
- 8.5 9M H₂SO₄ acid



- 8.6 0.25M Na₂CO₃: Weigh out 26.4 grams of Na₂CO₃ powder into a 1000-ml volumetric flask containing 850 ml of DI water and mix solution to dissolve the Na₂CO₃. Use some heat, if necessary - do not boil. Add DI water to the 1.0-liter mark, stopper flask, and mix solution well.

NOTE

Prepare solution fresh just prior to use.

- 8.7 Sulfuric Acid, (H₂SO₄), ACS reagent grade
- 8.8 Magnesium Perchlorate, anhydrous (drying agent)
- 8.9 Harvey Carbon-14 Scintillation Cocktail

9.0 SAMPLE COLLECTION, PRESERVATION, AND STORAGE

- 9.1 Sample collection and preservation is not the responsibility of the laboratory and is not applicable to this procedure. Samples for C-14 determination should not be acid preserved.
- 9.2 Unless otherwise directed by the client, after receipt, all soil, solid, water, and vegetation samples will be segregated according to preliminary activity scans and stored in a secure, climate controlled location. Tissue samples will be stored in a freezer prior to analysis.

10.0 QUALITY CONTROL

- 10.1 One "Laboratory Control Sample (LCS)" shall be analyzed with every 20 samples. The LCS will be prepared and analyzed the same way and along with the analysis batch for the same analytical parameter.
- 10.2 One analysis blank shall be run with every 20 samples. If there are less than 20 samples per analysis batch, then one blank per batch shall be analyzed.
- 10.3 A minimum of one or a designated number of client samples shall be replicated with every 20 samples. If there are less than 20 samples per analysis batch, then a minimum of one or a sufficient number of duplicates to meet client criteria shall be analyzed per analysis batch. Unless the matrix type, limited sample volume or other special considerations preclude this as a viable option.
- 10.4 If requested by a client, a matrix spike composed of a sample spiked with a standard containing at least one of the isotopes in question (NIST traceable or equivalent) shall be run with each batch.

11.0 CALIBRATION AND STANDARDIZATION

- 11.1 There are no standardized carriers used for this procedure.
- 11.2 The calibration of the Beta Liquid Scintillation detectors is covered in procedure AP-023.
- 11.3 The dilution of NIST traceable standard solutions is covered in procedure MP-009.
- 11.4 The calibration verification of the analytical balances is covered in procedure MP-010
- 11.5 The use, maintenance, and volume verification of the mechanical pipettes is covered in MP-025

**12.0 PROCEDURE**

- 12.1 Pour a 500ml aliquot of each water sample into a clean 500-ml round bottom flask labeled with the Laboratory sample number and "C-14 sample". Document aliquots using the LIMS, "Laboratory Technician Functions, Aliquot/Dilution Data".
- 12.2 For soils, add an appropriate mass to the 500 ml round bottom flask, add ~500ml of DI water
- 12.3 Pour a second 500 ml aliquot of one of the water samples, or second aliquot of soil (Sec. 12.2), into a clean 500-ml round bottom flask labeled with the Laboratory sample number and "C-14 Sample Duplicate"
- 12.4 Pour a 500 ml aliquot of DI water into a clean 500-ml round bottom flask labeled with the Laboratory sample number and "C-14 LCS". Add approximately 250 dpm C-14 Spike to the flask and mix solution.
- 12.5 Pour a 500 ml aliquot of DI water into a clean 500-ml round bottom flask labeled with the Laboratory sample number and "C-14 Blank".
- 12.6 To each flask add 2 ml Na₂CO₃ carrier and 1 ml 0.5M KMnO₄ solution.

NOTE

Activity in the quality control and client samples is equilibrated with Na₂CO₃ carrier and with the KMnO₄. Equilibration is performed by sealing the flasks with a stopper or parafilm after adding the solutions and letting them stand overnight before proceeding with the evolution procedure.

- 12.7 Fill the acid bubbler (the first impinger assembly) with 40 ml of 0.6N HCl.
- 12.8 Fill the C-14 trap (the second impinger assembly) with exactly 20 ml of Harvey Carbon-14 Cocktail complexing agent
- 12.9 Connect the acid bubbler to the condenser and the C-14 trap to the acid bubbler as shown in Figure 1.
- 12.10 Fill the acid dispenser with the stopcock closed with 5 ml of 9M H₂SO₄.
- 12.11 Start a slow bubbling of CO₂ free air at an appropriate flow by vacuum pumping the system.

NOTE

Slow bubbling will be visible in the trap. If bubbling does not appear, inspect the whole system for possible leakage.

- 12.12 Continue the evolution for 30 minutes.
- 12.13 After evolution, turn off the vacuum system.
- 12.14 Disconnect the C-14 trap from the bubbler and disassemble the apparatus.
- 12.15 Transfer the cocktail into a labeled LSC vial. Rinse the dispersion tube of the impinger.
- 12.16 Complete paperwork in the LIMS and include all the pertinent information. (Enter the amount of spike solution used in the LSC vials in place of tracer and spike information).



- 12.17 Deliver the samples and work sheet to the count room.
- 12.18 After the data has been reviewed and approved, return the vial to the lab and add 0.10 ml (1500 dpm) of C-14 spike (in Toluene). Mark the label to indicate that the spike has been added. Shake well and return the vial for spike counting.

13.0 WASTE MANAGEMENT AND POLLUTION PREVENTION

- 13.1 All excess sample materials, extracts, byproducts, and associated waste will be disposed of in the appropriate containers and segregated into the appropriate waste streams for final disposal according to the Waste Management Plan, WMP-01.
- 13.2 All laboratory activities associated with this procedure will be carried out in the fashion designed to generate the least amount of waste possible and still achieve the necessary quality of data.
- 13.3 Pre-cleaned disposable plastic lab ware will be placed in the appropriate waste container following its use in the laboratory.

14.0 CALCULATIONS

- 14.1 After counting the samples by Liquid Scintillation Counting, the counting uncertainty and minimum detectable activity (MDA) are calculated in accordance to the equations listed in laboratory procedures AP-023.

14.2 Chemical Recovery/Efficiency

14.2.1 Chemical recovery/efficiency is calculated as follows when using matrix spikes.

$$Cr/Eff = \frac{\text{Spiked Sample} - \text{Sample cpm}}{(\text{Std Vol}) * (\text{Std Conc})} * 100$$

Where:

CR/Eff	= Combined chemical recovery/detector efficiency
Spiked cpm	= The cpm result of the spiked sample
Sample cpm	= The cpm of the sample
Std vol	= The volume of the Technetium standard used (ml)
Std conc	= The concentration of the Technetium standard (dpm/ml)

- 14.3 Alternatively, the efficiency can be determined by a quench curve where the data will be empirically fit to a third-degree polynomial as detailed in AP-030, "Determination of Self Absorption and Quench Curves".

15.0 METHOD PERFORMANCE

- 15.1 The initial method performance shall be determined using the method detailed in procedure MP-028.
- 15.2 The continuing method performance is monitored through the use to the laboratory control standards, blanks and replicates.

16.0 DATA ASSESSMENT AND ACCEPTANCE CRITERIA FOR QUALITY CONTROL MEASUREMENTS

It is the laboratory policy to analyze a Laboratory Control Sample (LCS), a Laboratory Method Blank (MBL), and a Duplicate (DUP) with each work order. Soil samples will be reported on a dry weight basis unless otherwise requested by the client. Work orders are unique for each client, matrix, and isotope. Specific client requirements may supersede the following laboratory default criteria.



- 16.1 The default, laboratory limits for evaluating the performance of the Laboratory Control Standard is the 75% to 125% recovery range or a normalized difference of <3.0 for low activity standards (U-235). Generally, we have found that these limits are equal to or more restrictive than three standard deviations from the mean. Results within this range are acceptable; results that are outside this range either require reanalysis or explanation in the sample case narrative portion of the data report.
- 16.2 Counting uncertainties are estimated by the square root of counts except when there are zero (0) counts. In the case of zero (0) counts, the value under the radical is assumed to be one count.
- 16.3 The blank result should be less than or equal to 2 times the Combined Standard Uncertainty (CSU). If the blank result is greater than 2 times the CSU, the samples in the work order may require reanalysis or the situation should be explained in the case narrative section of the data report. If blanks containing Naturally Occurring Radioactive Material (NORM) are >2 times the CSU, they will be evaluated against typical background activity levels and noted as such in the case narrative.
- 16.4 The replicate analyses are compared using either the normalized difference comparison or relative percent difference. The normalized difference result should be less than or equal to a value of 3.0 and the relative percent difference result should be less than or equal to 25%. When either the relative percent difference or the normalized difference pass, then the duplicate is acceptable. If the replicate fails both tests, the samples in the work order may require reanalysis or the situation will be explained in the case narrative section of the data report. Relative percent difference and normalized difference for non-positive, background equivalent or noise equivalent results will be discussed in the case narrative, but not be grounds for re-analysis.
- 16.5 The default laboratory limits for acceptance or rejection of the Matrix Spike are 60% to 140%. Results within this range are acceptable, results that are outside this range are not acceptable and either requires reanalysis or explanation in the sample case narrative portion of the data report.
- 16.6 The limits for tracer recovery of any sample are 30% to 110%. The limits for carrier recovery are 40% to 110%. Analytical results within this range will be calculated using the determined chemical recovery. Samples with tracer or carrier recoveries outside this range will be reanalyzed or the situation will be thoroughly explained in the client case narrative. Chemical recoveries >110 are typically within reason and are simply statistical artifacts of counting. Elemental carriers that are present within the sample that cause high recoveries will be noted within the case narrative and corrected to 110%.
- 16.7 RCRA Methods 9310 (Gross Alpha/ Beta), 9315 (Alpha Emitting Radium Isotopes), and 9320 (Radium-228) require a sample duplicate be analyzed at a frequency of one in every ten samples.

17.0 CORRECTIVE ACTIONS FOR OUT-OF-CONTROL OR UNACCEPTABLE DATA

Sample data that is deemed to be unacceptable will be reanalyzed when it is not possible to relate the deficiency to a calculation or clerical error and there is sufficient sample available for reanalysis.

18.0 REFERENCES

- 18.1 DOE (U. S. Department of Energy), 1990. Environmental Measurements Laboratory Procedures Manual, HASL-300, Volume I, 27th Edition, New York, New York 10014-3621.
- 18.2 EPA (U. S. Environmental Protection Agency), 1984. Eastern Environmental Radiation Facility Radiochemistry Procedures Manual, EPA 520/5-84-006, Office of Radiation Programs, Montgomery, Alabama 36109.



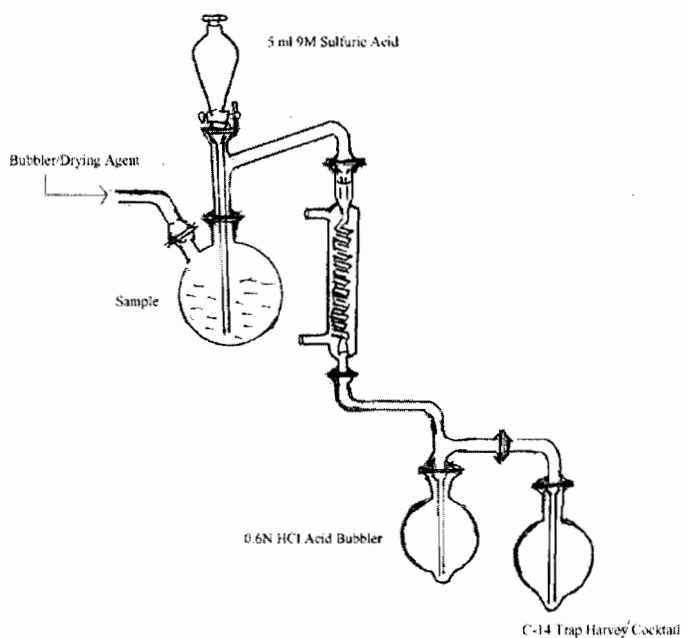
18.3 Knowles, G.K., "C-14 in Reactor Plant Water", Exxon Nuclear Idaho Co. (ENIC), Radio-element Analysis Progress and Problems, Ann Arbor Science, Ann Arbor MI, 1980.

18.4 EPA – 520/5-84-006, C-01

19.0 TABLES, DIAGRAMS, FLOWCHARTS, AND VALIDATION DATA

Validation data is available on file.

Figure 1.



An example of the previously reported analytical results summary for the soil samples.

Printed: 11/5/2008 9:35 AM

Page 1 of 1

Eberline Analytical Final Report of Analysis			Report To:					Work Order Details:					
			Jay Nag Chemtura Corporation 199 Benson Road Middlebury, CT 06749					SDG: 08-10100 Purchase Order: 4603003657 Analysis Category: ENVIRONMENTAL Sample Matrix: SO					
Lab ID	Sample Type	Client ID	Sample Date	Receipt Date	Analysis Date	Batch ID	Analyte	Method	Result	CU	CSU	MDA	Report Units
08-10100-01	LCS	KNOWN	10/21/08 00:00	10/21/2008	10/23/2008	08-10100	Carbon-14	EPA 520.0 Modified	3.81E+02	1.07E+01			pCi/g
08-10100-01	LCS	SPIKE	10/21/08 00:00	10/21/2008	10/23/2008	08-10100	Carbon-14	EPA 520.0 Modified	4.26E+02	4.61E+00	4.66E+00	1.95E+00	pCi/g
08-10100-02	MBL	BLANK	10/21/08 00:00	10/21/2008	10/23/2008	08-10100	Carbon-14	EPA 520.0 Modified	-7.24E-01	1.11E+00	1.11E+00	1.93E+00	pCi/g
08-10100-03	DUP	PES 16	10/17/08 00:00	10/21/2008	10/23/2008	08-10100	Carbon-14	EPA 520.0 Modified	2.74E+00	1.12E+00	1.12E+00	1.82E+00	pCi/g
08-10100-04	DO	PES 16	10/17/08 00:00	10/21/2008	10/23/2008	08-10100	Carbon-14	EPA 520.0 Modified	2.74E+00	1.12E+00	1.12E+00	1.83E+00	pCi/g
08-10100-05	TRG	PES 17	10/17/08 00:00	10/21/2008	10/24/2008	08-10100	Carbon-14	EPA 520.0 Modified	4.88E+00	1.18E+00	1.18E+00	1.86E+00	pCi/g
08-10100-06	TRG	PES 18	10/17/08 00:00	10/21/2008	10/24/2008	08-10100	Carbon-14	EPA 520.0 Modified	2.77E+00	1.14E+00	1.14E+00	1.85E+00	pCi/g
08-10100-07	TRG	PES 19	10/17/08 00:00	10/21/2008	10/24/2008	08-10100	Carbon-14	EPA 520.0 Modified	1.44E+00	1.15E+00	1.15E+00	1.92E+00	pCi/g
08-10100-08	TRG	PES 20	10/17/08 00:00	10/21/2008	10/24/2008	08-10100	Carbon-14	EPA 520.0 Modified	3.54E+00	1.18E+00	1.18E+00	1.89E+00	pCi/g
08-10100-09	TRG	PES 21	10/17/08 00:00	10/21/2008	10/24/2008	08-10100	Carbon-14	EPA 520.0 Modified	7.10E-01	1.12E+00	1.12E+00	1.89E+00	pCi/g
08-10100-10	TRG	PES 22	10/17/08 00:00	10/21/2008	10/24/2008	08-10100	Carbon-14	EPA 520.0 Modified	2.09E+00	1.13E+00	1.13E+00	1.86E+00	pCi/g
08-10100-11	TRG	PES 23	10/17/08 00:00	10/21/2008	10/24/2008	08-10100	Carbon-14	EPA 520.0 Modified	2.73E+00	1.12E+00	1.12E+00	1.82E+00	pCi/g
08-10100-12	TRG	PES 24	10/17/08 00:00	10/21/2008	10/24/2008	08-10100	Carbon-14	EPA 520.0 Modified	7.05E+00	1.24E+00	1.24E+00	1.88E+00	pCi/g
08-10100-13	TRG	PES 25	10/17/08 00:00	10/21/2008	10/24/2008	08-10100	Carbon-14	EPA 520.0 Modified	3.39E+00	1.13E+00	1.13E+00	1.81E+00	pCi/g
08-10100-14	TRG	PES 26	10/17/08 00:00	10/21/2008	10/24/2008	08-10100	Carbon-14	EPA 520.0 Modified	6.64E-01	1.05E+00	1.05E+00	1.77E+00	pCi/g
08-10100-15	TRG	PES 27	10/17/08 00:00	10/21/2008	10/24/2008	08-10100	Carbon-14	EPA 520.0 Modified	0.00E+00	1.09E+00	1.09E+00	1.87E+00	pCi/g
08-10100-16	TRG	PES 28	10/17/08 00:00	10/21/2008	10/24/2008	08-10100	Carbon-14	EPA 520.0 Modified	2.75E+00	1.13E+00	1.13E+00	1.83E+00	pCi/g

CU=Counting Uncertainty;CSU=Combined Standard Uncertainty (2-sigma);MDA=Minimal Detected Activity;LCS=Laboratory Control Sample; MBL=Blank; DUP=Duplicate; TRG=Normal Sample; DO=Duplicate Original



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Eberline Services Oak Ridge Laboratory Quality Assurance Program Manual

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MISSION STATEMENT

Our mission is to ensure that all of The Eberline Services, Oak Ridge Laboratory's systems, services, processes, and deliverables are of a quality that meets or exceeds client requirements; and to foster a Laboratory culture in which there is a commitment to a rising standard of quality. This culture demands that the quality of those systems, services, processes, and deliverables and the methods used to achieve that quality be continuously improved.

Quality Assurance is a spirit that pervades all aspects of an organization. It is the quality attitude developed by a quality culture in an organization. It is the spirit in which any organization, procedure or activity is documented, implemented and performed. This spirit produces empowerment and motivation in all employees to achieve the highest level of quality. The result of this attitude is **"Quality Assurance."**

The policy guidelines are presented in this Oak Ridge Laboratory Quality Assurance Program Manual, and are based on the philosophy and premises that:

- People are our greatest asset and are ultimately responsible for the quality of the items and services we provide. Therefore, each person is treated with the greatest possible respect and consideration.
- Employees are inherently proud and want to produce top quality and on time services and deliverables. In order to do this they must be made aware of the quality requirements that are expected, and they must be provided appropriate facilities, equipment, and proper training.
- A culture of quality embodied within the entire Oak Ridge Laboratory organization is the most effective way to provide support for the employee's commitment to quality.
- Management support is paramount, and organizational responsibilities must ensure integration of quality requirements in the day-to-day operations.
- All systems, services, processes, and deliverables can be planned, performed, assessed, and improved.
- Improvements allow operations to become more efficient and result in contractual requirements performed "on time" and done "right the first time."
- Quality improvements lead to reduced costs and allow the ultimate objective of providing the highest quality items and services to be a viable goal.

Quality is our client's perception of us. Our actions must assure our clients that the Oak Ridge Laboratory organization provides for quality systems, services, processes, and deliverables that will meet or exceed their requirements. To this end, each employee must understand and exercise the highest standards of ethics in the performance of their duties and ensure the integrity of the data they report.



STATEMENT OF COMPLIANCE AND MATRIX COMPARISON

This Quality Assurance Program Manual addresses the basic requirements of the following list, and requirements outlined in several regulatory manuals, standards, and regulations. Matrix comparison to some of these documents is included in the following pages. Additional regulatory requirements are listed in Section 1.0.

NQA-Quality Assurance Requirements for Nuclear Facility Application; 1997
USEPA-National Environmental Laboratory Accreditation Conference (NELAC), USEPA; 2003
USEPA Requirements for the Certification of Laboratories Analyzing Drinking Water; 2005
ISO/IEC 17025 for the General Requirements for the Competence of Calibration and Testing; 1999
DOE Quality Systems for Analytical Services (QSAS) Document; 2006

This manual is organized as follows:

Name, Title, Authorization and Approval
Table of Contents
Mission Statement
Statement of Compliance and Matrix Comparison
Introduction and Description
Organization and Responsibility
Quality Assurance Objectives
Personnel Qualification and Training
Instructions and Procedures
Procurement Document Control
Material Receipt and Control
Material Storage and Control
Control of Process
Preventative Maintenance
Control of Measurement and Test Equipment
Data Reduction, Verification, and Reporting
Document Control
Internal Quality Control
Audits
Quality Assurance and Inspection Records
Corrective Action
Quality Assurance Reports to Management


MATRIX COMPARISON

NQA-1, 1994 Cross Reference to - Oak Ridge Laboratory Q.A. Program Manual

NQA-1-1994 -Quality Assurance Requirements for Nuclear Facility Applications (<i>Basic Requirements</i>)		Oak Ridge, TN laboratory Quality Assurance Program Manual	
BASIC RQMT	TITLE	QAM SECT	TITLE
1.	Organization	2.0	Organization and Responsibility
2.	Quality Assurance Program	3.0 4.0	Quality Assurance Objectives Personnel Indoctrination and Training
3.	Design Control	N/A	Does not apply
4.	Procurement Document Control	6.0	Procurement Document Control
5.	Instructions, Procedures, and Drawings	5.0	Instructions and Procedures
6.	Document Control	13.0	Document Control
7.	Control of Purchased Items and Services	7.0	Material Receipt and Control
8.	Identification and Control of Items	8.0	Material Storage and Control
9.	Control of Process	9.0	Control of Process
10.	Inspection	14.0	Internal Quality Control
11.	Test Control	14.0	Internal Quality Control
12.	Control of Measurement and Test Equipment	11.0	Control of Measurement and Test Equipment
13.	Handling, Storage, and Shipping	8.0	Material Storage and Control
14.	Inspection, Test, and Operating Status	14.0	Internal Quality Control
15.	Control of Nonconforming Items	8.0	Material Storage and Control
16.	Corrective Actions	17.0	Corrective Actions
17.	Quality Assurance Records	16.0	Quality Assurance and Inspection Records
18.	Audits	15.0	Audits
	N/A	N/A	Title Page
	N/A	N/A	Authorization and Approval Statement
	N/A	1.0	Introduction and Description
	N/A	10.0	Preventive Maintenance
	N/A	12.0	Data Reduction, Verification, and Reporting
	N/A	18.0	Quality Assurance Reports to Management

**MATRIX COMPARISON**

10 CFR Part 50, Appendix B Cross Reference to Oak Ridge Laboratory Q.A. Program Manual

NRC 10 CFR Part 50 Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants."		Oak Ridge, TN Laboratory Quality Assurance Program Manual	
Criterion No.	TITLE	QAM SECT	TITLE
I	Organization	2.0	Organization and Responsibility
II	Quality Assurance Program	3.0	Quality Assurance Objectives
III	Design Control	N/A	Does not apply
IV	Procurement Document Control	6.0	Procurement Document Control
V	Instructions Procedures, and Drawings	5.0	Instructions and Procedures
VI	Document Control	13.0	Document Control
VII	Control of Purchased Material, Equipment, and Deliverables	7.0	Material Receipt and Control
VIII	Identification and Control of Materials, Parts, and Components	8.0	Material Storage and Control
IX	Control of Special Process	9.0	Control of Process
X	Inspections	14.0	Internal Quality Control
XI	Test Control	14.0	Internal Quality Control
XII	Control of Measuring and Test Equipment	11.0	Control of Measurement and Test Equipment
XIII	Handling, Storage, and Shipping	8.0	Material Storage and Control
XIV	Inspection, Tests, and Operating Status	14.0	Internal Quality Control
XV	Nonconforming Materials, Parts or Components	7.0	Material Receipt and Control
XVI	Corrective Actions	17.0	Corrective Actions
XVII	Quality Assurance Records	16.0	Quality Assurance Inspection Records
XVIII	Audits	15.0	Audits
		N/A	Title Page
		1.0	Introduction and Description
		10.0	Preventative Maintenance
		12.0	Data Reduction, Verification, and Reporting
		18.0	Quality Assurance Reports to Management

**MATRIX COMPARISON**

DOE Order 414.1 B Cross Reference to Oak Ridge Laboratory Q.A. Program Manual

DOE Order 414.1 B "Quality Assurance"			Oak Ridge, TN Laboratory Quality Assurance Program Manual
Criterion No.	TITLE	QAM SECT	TITLE
1.	Program	1.0 2.0 3.0 12.0 13.0	Introduction Organization and Responsibility Quality Assurance Objectives Data Reduction, Verification, and Reporting Document Control
2.	Personnel Training and Qualification	4.0	Personnel Indoctrination and Training
3.	Quality Improvement	17.0	Corrective Actions
4.	Documents and Records	16.0 18.0	Quality Assurance Records Quality Assurance Reports to Management
5.	Work Process	5.0 9.0 10.0 14.0	Instructions and Procedures Control of Process Preventive Maintenance Internal Quality Control
6.	Design	N/A	Does not apply
7.	Procurement	6.0 7.0 8.0	Procurement Document Control Material Receipt and Control Material Storage and Control
8.	Inspection and Acceptance Testing	11.0 14.0 15.0	Control of Measurement and Test Equipment Internal Quality Control Audits
9.	Management Assessment	2.0	Organization and Responsibility
10.	Independent Assessment	15.0	Audits
N/A		N/A	Title Page
N/A		N/A	Authorization and Approval Statement


MATRIX COMPARISON

NELAC Chapter 5 Cross Reference to - Oak Ridge Laboratory Q.A. Program Manual

This cross-reference applies to the DOE QSAS, Rev. 2.2, 2006.

NELAC Chapter 5 "Quality Systems"		Oak Ridge, TN Laboratory Quality Assurance Program Manual	
5.5.2 RQMT	TITLE	QAM SECT	TITLE
	Title Page		Title Page
(a)	Policy statement, objectives, commitment by top management	1.0 3.0	Introduction and Description Quality Assurance Objectives
(b)	Organization and Management structure, Org Charts	2.0	Organization and Responsibility
(c)	Relationship between management, technical operations, support services and the quality system	2.0	Organization and Responsibility
(d)	Document control and records retention	16.0	Quality Assurance & Inspection Records
(e)	Job Descriptions	4.0	Personnel Indoctrination and Training
(f)	Approval signatories, signed concurrences	A&A	Authorization and Approval Statement
(g)	Traceability of measurements	14.0	Internal Quality Control
(h)	List of test methods	9.0	Control of Process
(i)	Review for facility and resource availability	9.0	Control of Process
(j)	Calibration or verification test procedures	5.0	Instructions and Procedures
(k)	Procedures for handling submitted samples	9.0	Control of Process
(l)	Major equipment and measurement standards	9.0 11.0	Control of Process Control of Measurement & Test Equipment
(m)	Calibration, verification, & maintenance	11.0	Control of Measurement & Test Equipment
(n)	Interlaboratory comparison, proficiency testing, reference material, internal Q.C.	14.0	Internal Quality Control
(o)	Corrective actions	17.0	Corrective Actions
(p)	Departures from policy/procedures	5.0	Instructions and Procedures
(q)	Complaints	1.0	Introduction and Description
(r)	Confidentiality and Proprietary rights	1.0	Introduction and Description
(s)	Audits and Data reviews	12.0 15.0	Data Reduction, Verification, and Reporting Audits
(t)	Personnel experience and training	4.0	Personnel Indoctrination and Training
(u)	Ethical and legal responsibilities	1.0	Introduction and Description
(v)	Analytical results reporting	12.0	Data Reduction, Verification, and Reporting
(w)	Table of Contents	TOC	Table of Contents


MATRIX COMPARISON

10 CFR Part 830.122 Cross Reference to Oak Ridge Laboratory Q.A. Program Manual

10CFR 830.122 "Quality Assurance Criteria"			Oak Ridge, TN Laboratory Quality Assurance Program Manual
Criterion No.	TITLE	QAM SECT	TITLE
830.122 (a)	Management/Program	1.0	Introduction
		2.0	Organization and Responsibility
(b)	Management/Personnel Training and Qualification	4.0	Personnel Indoctrination and Training
(c)	Management/Quality Improvement	3.0	Quality Assurance Objectives
		14.0	Internal Quality Control
		17.0	Corrective Actions
(d)	Management/Documents and Records	5.0	Instructions and Procedures
		9.0	Control of Process
		12.0	Data Reduction, Verification, and Reporting
		13.0	Document Control
		16.0	Quality Assurance Records
		18.0	Quality Assurance Reports to Management
(e)	Performance/Work Process	7.0	Material Receipt and Control
		8.0	Material Storage and Control
		10.0	Preventive Maintenance
		14.0	Internal Quality Control
(f)	Performance/Design	N/A	Does not apply
(g)	Performance/Procurement	6.0	Procurement Document Control
(h)	Performance/Inspection and Acceptance Testing	11.0	Control of Measurement and Test Equipment
		14.0	Internal Quality Control
		15.0	Audits
(i)	Assessment/Management Assessment	2.0	Organization and Responsibility
(j)	Assessment/Independent Assessment	2.0	Organization and Responsibility
		15.0	Audits
N/A		N/A	Title Page
N/A		N/A	Authorization and Approval Statement


MATRIX COMPARISON

EPA SW-846 Cross Reference to - Oak Ridge Laboratory Q.A. Program Manual

EPA SW-846 (Essential Elements)		Oak Ridge, TN Laboratory Quality Assurance Program Manual	
BASIC RQMT	TITLE	QAM SECT	TITLE
1.	Title Page	N/A	Title Page
2.	Table of Contents	N/A	Table of Contents
3.	Project Description	1.0	Introduction and Description
4.	Project Organization and Responsibility	2.0	Organization and Responsibility
5.	Q.A. Objectives	3.0	Quality Assurance Objectives
6.	Sampling Procedures	N/A	Does not apply to laboratory
7.	Sample Custody	9.0	Control of Process
8.	Calibration Procedures and Frequency	11.0	Control of Measurement and Test Equipment
9.	Analytical Procedures	5.0 9.0	Instructions and Procedures Control of Process
10.	Data Reduction, Validation, and Reporting	12.0	Data Reduction, Verification, and Reporting
11.	Internal Quality Control Checks	14.0	Internal Quality Control
12.	Performance and System Audits	15.0	Audits
13.	Preventive Maintenance	10.0	Preventive Maintenance
14.	Specific Routine Procedures Used to Assess Data Precision, Accuracy, and Completion	14.0	Internal Quality Control
15.	Corrective Action	17.0	Corrective Actions
16.	Quality Assurance Reports to Management	18.0	Quality Assurance Reports to Management
N/A		N/A	Authorization and Approval Statement
N/A		4.0	Personnel Indoctrination and Training
N/A		6.0	Procurement Document Control
N/A		7.0	Material Receipt and Control
N/A		8.0	Material Storage and Control
N/A		13.0	Document Control
N/A		16.0	Quality Assurance and Inspection Records



MATRIX COMPARISON
 EPA QA/R-5 "EPA Requirements for Quality Assurance Project Plans"

EPA QA/R-5, "EPA Requirements for Quality Assurance Project Plans"		Oak Ridge, TN Laboratory Quality Assurance Program Manual	
RQMT	TITLE	SECT	TITLE
A	Project Management		
A1	Title and Approval Sheet		Title Page Authorization and Approval (A&A) Statement
A2	Table of Contents		Table of Contents Page Headers (document control)
A3	Distribution List		Title Page
A4	Project/Task Organization	1.4 2.1 2.2 2.5	Introduction Organizational Structure Responsibility Organization Charts
A5	Problem Definition/Background	3.0 9.0 14.0	Quality Assurance Objectives Control of Process Internal Quality Control
A6	Project/Task Description	9.0	Control of Process
A7	Quality Objectives and Criteria	3.0	Quality Assurance Objectives
A8	Special Training/Certification	4.0	Personnel Indoctrination and Training
A9	Documents and Records	5.0 9.2 13.0 16.0	Instructions and Procedures Documented Procedures Document Control Quality Assurance and Inspection Records
B	Data Generation and Acquisition		
B1	Sampling Process Design (Experimental Design)	N/A	
B2	Sampling Methods	N/A	
B3	Sample Handling and Custody	14.4	Sample Custody
B4	Analytical Methods	5.0 9.0	Instructions and Procedures Control of Process
B5	Quality Control	14.0	Internal Quality Control
B6	Instrument/Equipment Testing, Inspection, and Maintenance	10.0 11.0	Preventive Maintenance Control of Measurement and Test Equipment
B7	Instrument/Equipment Calibration and Frequency	11.0	Control of Measurement and Test Equipment
B8	Inspection/Acceptance of Supplies and Consumables	7.0 8.0	Material Receipt and Control Material Storage and Control
B9	Non-direct Measurements	10.0	Data Reduction, Verification, and Reporting
B10	Data Management	10.0	Data Reduction, Verification, and Reporting
C	Assessment and Oversight		
C1	Assessments and Response Actions	15.0 17.0	Audits Corrective Action
C2	Reports to Management	18.0	Quality Assurance Reports to Management
D	Data Validation and Usability		
D1	Data Review, Verification, and Validation	12.0 14.3	Data Reduction, Verification, and Reporting Data Verification
D2	Verification and Validation Methods	12.0	Data Reduction, Verification, and Reporting



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EPA QA/R-5, "EPA Requirements for Quality Assurance Project Plans"		Oak Ridge, TN Laboratory Quality Assurance Program Manual	
RQMT	TITLE	SECT	TITLE
D3	Reconciliation with User Requirements	12.0	Data Reduction, Verification, and Reporting

1.0 INTRODUCTION AND DESCRIPTION

1.1 PREFACE

Eberline Services –Oak Ridge Laboratory is a radiochemistry laboratory that specializes in providing services for radiological assays to the environmental industry. Radionuclides are quantified within materials such as surface water, ground water, drinking water, wastewater, soil, sediment, sludge, vegetation, and hazardous waste. The objective of the laboratory is to produce the highest quality data that are accurate, precise, legally defensible, and meet our clients data needs and requirements in a timely and cost effective manner.

The management of Eberline Services, Oak Ridge Laboratory is committed to a rigorous Quality Assurance (Q.A.) Program. While this commitment is necessary for the normal conduct of business, our basic policies dictate the highest standards of ethics and integrity in the conduct of our affairs. This philosophy and the specific procedures to attain policy objectives form the framework of our Q.A. Program. We will provide only those services that are within our qualifications and with confidence that our Q.A. Program and all related operating procedures dictate reliable performance of those services.

1.2 PURPOSE

This manual outlines management's Q.A. policy and establishes a requirement that procedures be promulgated and implemented to accomplish all of the quality assurance elements necessary to fulfill our responsibility to meet or exceed client or regulatory specifications. It also provides a means for creating mutual understanding regarding our Q.A. program and reliability techniques with our subcontractors, suppliers, and clients. This Eberline Services-Oak Ridge Laboratory Quality Assurance Program provides the structure, policies and responsibilities for the execution of quality control and quality assessment operations to assure that the laboratory meets defined standards of quality.

1.3 SCOPE

This Quality Assurance Program Manual provides guidance to meet operational Q.A. requirements.

In addition to the documents identified in the Cross Reference Section, this Manual complies with applicable requirements of the following regulations:

1.3.1 NRC 10 CFR Part 21, "Reporting of Defects and Non-compliance."

1.3.2 ANSI/ANS-10.3-1995, "Documentation of Computer Software."

1.3.3 NRC Regulatory Guide 4.15, Rev. 1, "Quality Assurance for Radiological Monitoring Programs - Effluent Streams and the Environment."

1.3.4 U.S. EPA QA/R-5, "EPA Requirements for Quality Assurance Program Plans."

1.3.5 DOE Order 414.1B "Quality Assurance."

1.3.6 ISO/IEC 17025, "General Requirements for the Competence of Calibration and Testing Laboratories."

1.3.7 USEPA Directive 2185, "Good Automated Laboratory Practices" (GALP).

1.3.8 DOE Quality Systems for Analytical Services Revision 2.4, 2008.

1.3.9 EPA National Environmental Laboratory Accreditation Conference (NELAC) Chapter 5

"Quality Systems", July 2003.

- 1.3.10 USEPA Manual for the Certification of Laboratories Analyzing Drinking Water, EPA 815-R-004, January 2005.

1.4 INTRODUCTION

Quality assurance, as outlined herein, is a tool that allows management to utilize the expertise and experience of all personnel on the job. It requires each worker to be aware of his/her work environment and to continually evaluate methods and processes to ensure that the best and correct operation is being performed. It requests each employee to identify and suggest any improvement to the processes while performing an operation. Improvements or changes shall be coordinated with management who will validate improvement and disseminate the information to all affected personnel. Management shall also, as needed, change procedures and provide additional training. This program also requires that all personnel be qualified, and trained on a continuing basis to maintain that qualification and be assimilated into the Oak Ridge Laboratory quality culture.

Management will provide resources, tools, equipment, scheduling, and training to ensure personnel can perform their duties effectively.

- 1.4.1 Management will also ensure that assessments internal are performed annually to evaluate management and processes with feed back for review with a goal of improving all areas of operations.
- 1.4.2 It is only by having a quality assurance culture, with all personnel involved, that a system, service, or product can be provided with full assurance that the best possible work, the best possible product, or the best possible service has been provided.
- 1.4.3 In order to ensure that this manual is an effective management tool, subjects that are not normally considered quality assurance, i.e. safety, security, etc., may be addressed.
- 1.4.4 The following titled designations of positions are used within the Oak Ridge, TN Laboratory:

Laboratory Manager: Refers to the General Manager of the Oak Ridge Laboratory.

Deputy Laboratory Manager: Refers to the Deputy General Manager of the Oak Ridge Laboratory.

Technical Director: Refers to the individual who provides technical direction or advice for laboratory operations and/or special programs, projects, or activities.

Project Manager: Refers to an individual who is responsible for client service activities and is the single point of contact with a client for the laboratory.

Supervisor: Refers to individuals within the laboratory who are responsible for the operational functions of a group of personnel.

Q.A. Manager: Refers to the individual who is responsible for the Laboratory's Q.A. Program.

1.5 DESCRIPTION

This document outlines the organization of the Q.A. functions within the laboratory. It depicts the lines of authority, and lists the duties and responsibilities within the organization. It provides direction for the preparation of Procedures Manuals, which provide the detailed methods of processes and analyses that accomplish the goal of quality data in terms of precision, accuracy and reproducibility.

**1.6 CONFIDENTIAL AND PROPRIETARY INFORMATION**

Oak Ridge Laboratory employees are exposed to confidential and/or proprietary information pertaining to the company and its clients. Information concerning the report of analysis, radiation dosimetry records, audit reports, calibration reports, and other documents relating to a project are considered confidential. This information is to be released only to the client or to the client's authorized representative. Each employee will sign an agreement with the Oak Ridge, TN Laboratory concerning the security of proprietary and confidential information. A copy of the agreement will be retained in the employee's personnel file (at the corporate office in Albuquerque NM).

1.7 TECHNICAL COMPLAINTS

Technical complaints will be addressed by the Laboratory Manager, Deputy Laboratory Manager, Technical Director, Project Manager, or staff member with expertise in the area of complaint. If the complaint is not valid, every attempt will be made to satisfy the client. If the complaint is determined to be valid, the cause of the complaint shall be identified and corrected as soon as feasible. Verification that the cause for a valid complaint has been corrected is the responsibility of the individual addressing the complaint. Details of all technical complaints shall be recorded and maintained in the customer's project file.

1.8 ETHICAL AND LEGAL RESPONSIBILITIES

Eberline Services-Oak Ridge Laboratory utilizes a clearly stated ethics policy that is discussed with all new employees during orientation. Each employee is required to understand the high standards of ethics and integrity required in order to perform their duties and to ensure the integrity of the data reported in connection with their employment at the Oak Ridge Laboratory. Each employee will understand that intentionally reporting data that are not the actual values obtained, intentionally reporting dates and/or times or data analyses that are not the actual dates and/or times of analyses, intentionally representing another individual's work as their own; or any other action that may affect the integrity of the data reported by the laboratory; will be the cause for dismissal.

1.9 ACCREDITATIONS

Through applications, pre-qualification, performance testing, and external auditing programs; the laboratory has been granted certification by different agencies, organizations, and states. The Laboratory maintains proficiency as required by the clients and regulatory certifying agency. The Quality Assurance Manager maintains credentials and lists of certifying agencies. The list of certifications maintained by the Oak Ridge Laboratory include:

State of Tennessee Dept of Health Lab Division 630 Hart Lane Nashville, TN 37247-0801	Renewed Annually - Audit every Three Years	
State of California		
State of South Carolina Dept of Health & Environmental Control Environmental Lab certification Program P. O. Box 72, 8500 Farrow Road, Bldg # 9 State Park, SC 29147	Renewed Annually	



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State of Utah Department of Health Bureau of Laboratory Improvement 46 North Medical Drive Salt Lake City, Utah 84113-1105 Phone: (801) 584-8261	Renewed Annually - Audit every 2 years	Primary NELAP Accrediting Authority
State of New Jersey Department of Environmental Protection Office of Quality Assurance P. O. Box 424, 9 Ewing Street Trenton, New Jersey 08625	Renewed Annually	Secondary NELAP Accrediting Authority
State of New York Department of Health Environmental Lab Approval Program Wadsworth Center P.O. Box 509, Albany, NY 12201-0509	Renewed Annually	Secondary NELAP Accrediting Authority
State of North Dakota Department of Health Environ. Lab. Certification Program Chemistry Division 2635 East Main Avenue P.O. Box 937 Bismarck, North Dakota 58502-0937	Renewed Annually	
State of Nevada Dept of Conservation Div. Environmental protection Bureau of water Quality Environmental lab Services 333 W. Nye Lane, Room 138 Carson City, Nevada 89706	Renewed Annually	
Department of Energy Consolidated Audit Program (DOECAP)	Renewed and Audited Annually	



2.0 ORGANIZATION AND RESPONSIBILITY

2.1 ORGANIZATIONAL STRUCTURE

The Laboratory Manager has overall responsibility for this Quality Assurance Program (hereafter referred to as the Program). In this capacity, he has delegated the responsibility for formulation, implementation, and execution of the Program to the Laboratory Q.A. Manager.

Current organizational charts, identifying key individuals and the structure of the laboratory, are included in the "Statement of Qualifications." Additional organizational structure, functional responsibilities, levels of authority, and lines of communication for management, direction, and execution of the Program are documented below.

2.2 RESPONSIBILITY

Laboratory Management will periodically assess the integrated quality assurance program, its performance, and its effectiveness. Problems that hinder the organization from achieving its objectives will be identified and corrected.

Professional qualifications and experience of all individuals and positions are maintained. Position descriptions and resumes are kept on file in the QA office. The specific duties of selected personnel are described below. Other job descriptions are located within an employee's training file in the QA office.

2.2.1 Laboratory Manager / Deputy Laboratory Manager

The Laboratory Manager / Deputy Laboratory Manager is responsible for the overall laboratory productivity and optimization of the efforts of the analytical staff and those who directly support the analytical effort. Staff interacts with the Lab Manager throughout the day. The Laboratory Manager is responsible for the all safety aspects of the laboratory operations.

The duties of the Laboratory Manager include the following.

- Overall direction and general administration.
- Daily operation of the laboratory.
- Review of analytical procedures and practices.
- Recruitment, hiring, assignment, evaluation and termination of personnel.
- Training and professional development of staff.
- Review of proposals, bids, pricing and quotations.
- Perform an annual assessment of the laboratory operation.

2.2.2 Quality Assurance Manager

The Quality Assurance Manager reports directly to the President of Eberline Services. The QA Manager has sufficient authority and organization freedom to identify quality problems, to initiate, recommend or provide solutions; to verify implementation of solutions, and if necessary, to stop work until the problem is resolved.

The duties and responsibilities of the QA Manager are as follows.

- Develop QA procedures, instructions and plans.

- Maintain surveillance over all applications of the QA Plan, make recommendations for resolution of problems, or further evaluation by management.
- Monitor external audits, write responses, and ensure corrective actions.
- Issue non-conformances and formal corrective action(s).
- Issue stop-work orders for work that is not in compliance with requirements.
- Direct, and maintain records of analytical performance evaluation programs to ensure full and prompt participation and evaluation of results and derivation of all benefits relating there from.
- Direct, and maintain records of laboratory certification programs.
- Authorized to sign and designate other personnel to sign client related Certificates of conformance and/or non-conformance.

2.2.3 Health and Safety Manager

The Health and Safety Manager reports directly to the Laboratory Manager and oversees the daily implementation of the laboratory's health and safety program. The program includes an integrated chemical hygiene plan, safety orientation and training, radiation safety plans and training, sample disposal and shipment, and safety checks and audits.

The duties and responsibilities of the Health and Safety Manager are as follows.

- Administer chemical hygiene, safety, fire extinguisher, etc. training.
- Management of sample disposal in conformance with the waste disposal policy.
- Packaging and shipment of samples, or designation thereof, following DOT regulations.
- Maintain Material Safety Data Sheet (MSDS) documentation.
- Direct spill response.
- Direct safety checks and audits.

2.2.4 Technical Manager

The Technical Manager reports directly to the Laboratory Manager and provides technical direction or advice for the laboratory operations and/or special programs, projects, or activities.

The duties and responsibilities of the Technical Manager are as follows.

- Perform technical analysis for specific projects.
- Make recommendations for research and development.
- Write technical manuals.
- Design systems, procedures, and documentation as necessary.
- Assist chemistry supervisors and technicians in technical interpretation of program requirements.
- Consult with clients, make recommendations regarding analytical schemes.



2.2.5 Data Review Department Staff

The Data Review Department has been formed to handle the specific project requirements of our clients. The Department is responsible for quality control (QC) reports for ensuring proper assembly of data packages and production of electronic data deliverables (EDDs) that meet the requests of the clients. Data Review personnel, in concert with the QA Manager, will assess the requirements of the various programs and client specific requirements, then interact with the appropriate laboratory personnel to ensure compliance with the client's statement of work. These efforts improve the accuracy and efficiency with which QC reports and data packages are prepared and forwarded to the client. Data deliverables are those items associated with the analyses of samples that are provided to the client.

Data Review staff responsibilities include the following.

- Assuring that analytical data have been correctly entered in the final report.
- Assuring that data are not released without reviews.
- Assuring that all data are released to the correct contact person.
- Producing QC reports.
- Assembling Data Packages.
- Ensuring that submitted EDD are complete, verified and in appropriate format.

2.3 ASSESSMENT

2.3.1 The Laboratory Manager will perform routine and continuous assessment of the management system to identify, correct, and prevent management problems that hinder achievement of the organization's objective. The assessment will focus on broad categories of management issues to determine the effectiveness of the integrated management system.

2.3.2 Laboratory Manager's assessments will not be conducted to verify conformance to regulations, product standards, or established procedures, but will evaluate customer and employee perceptions relative to the following key issues.

- Mission and strategic objectives of the organization.
- Employees role in the organization.
- Customers' expectations and degree to which expectations are being met.
- Opportunities for improving quality and cost effectiveness.
- Recognizing and enhancing human resource capabilities.

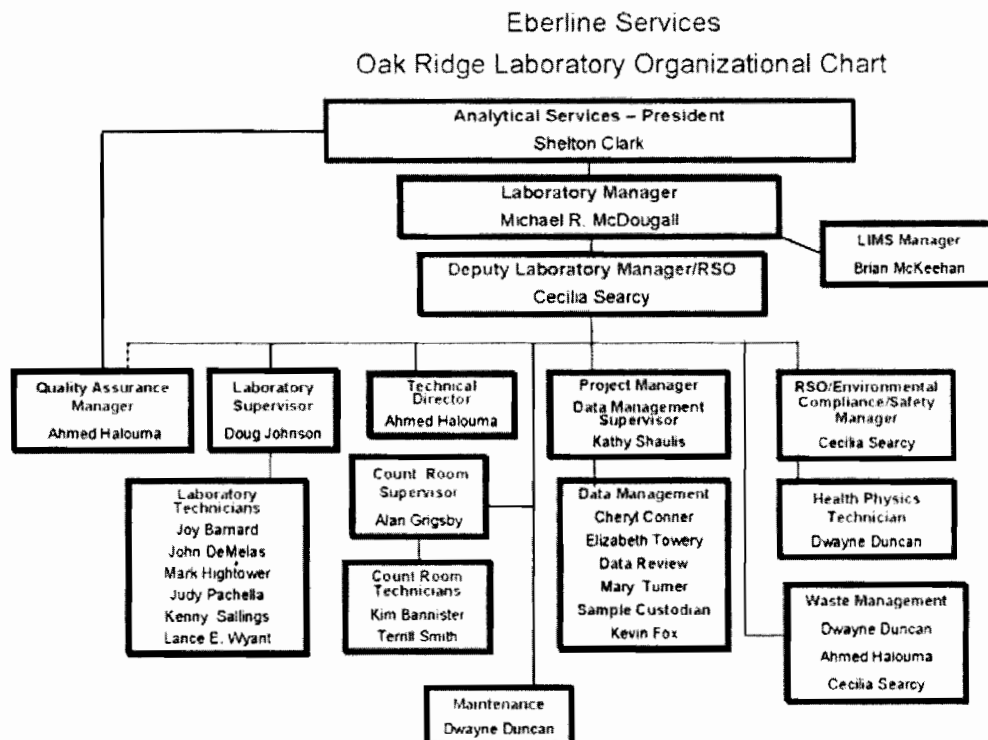
2.3.3 Results of the Laboratory Manager's management assessment and recommendations will be documented annually. Decisions and related actions resulting from the recommendations will be properly followed up and evaluated for their effectiveness.

2.4 ORGANIZATION CHARTS

2.4.1 The Oak Ridge Laboratory Organization is illustrated in Figure 2.1



Figure 2.1
Oak Ridge, TN Laboratory
ORGANIZATION





3.0 QUALITY ASSURANCE OBJECTIVES

3.1 OBJECTIVES

The Oak Ridge Laboratory Q.A. Program is organized to meet the following objectives.

- 3.1.1 To ensure performance of those actions that provide confidence that quality is achieved.
- 3.1.2 To provide an effective control for the verification of characteristics of all systems, services, and processes that produce data of the required quality.
- 3.1.3 To ensure that systems, services, processes, and deliverables meet the rigid quality and reliability standards of the Oak Ridge Laboratory. Also, to ensure that individual client criteria pursuant to these standards are met.
- 3.1.4 To provide a continuing monitoring service for review of operating procedures, and for overall effectiveness and evaluation of the Q.A. Program. Also, to provide observations and recommendations for improvement in all areas of laboratory operations where quality may be affected.
- 3.1.5 To ensure the program provides valid records of the control measures applied to all factors bearing on the result of investigations.
- 3.1.6 To ensure the assessment of results provides feedback to improve the process.
- 3.1.7 To foster a culture of commitment to achieve a rising standard of quality that demands that the methods utilized to achieve the quality systems, services, processes, and deliverables be continuously monitored and improved.

3.2 QUALITY IMPROVEMENT

Operational processes will be reviewed continually by management and employees to detect and prevent problems and to ensure quality improvement. Any item or process that does not meet established requirements will be identified, controlled, and corrected. The cause of problems will be identified with corrections made to prevent recurrence. Item reliability, process implementation, and quality-related information will be reviewed and the data analyzed to identify items and processes needing improvement.

3.3 RESPONSIBILITIES

Employees are an integral part of the organization and are responsible to be aware of their work environment, to review operational processes and materials utilized, to identify any problems, and to make suggestions and recommendations for improvement. Employees are empowered to make and/or recommend corrections to improve operations and to prevent recurrence of the problems. Employees are also empowered, through their supervisor, to stop work where detrimental ethical, contractual, quality, safety, or health conditions exist. Management will immediately be made aware of any situations requiring work stoppage.

All employees are responsible for supporting the Program in principle and in detail and shall retain responsibility for the quality of their work.

Management is responsible to be actively involved in the quality improvement process to ensure proper focus is maintained and for resolution of difficult issues. Management will maintain a "no fault" attitude to encourage employees to identify problems that compromise safety and reliability. Management will consider all recommendations for quality improvement and will recognize employee contributions.



3.4 CORRECTIONS

Items and processes that do not meet established requirements must be identified, documented, analyzed, and resolved. Corrective actions will be implemented and followed up to ensure effectiveness.

No laboratory analytical data will be revised or corrected after reporting to clients without full documentation of the process. The documentation must show: a) what necessitated the change; b) details of the change in terms of re-run records or recalculation; c) approval process for the change; d) formal client notification.

4.0 PERSONNEL QUALIFICATION AND TRAINING**4.1 QUALIFIED PERSONNEL**

- 4.1.1 The Oak Ridge Laboratory personnel who perform activities that affect quality will have education, experience and training to ensure that suitable proficiency is achieved and maintained. A job description, identifying position qualification and duty requirements, will be included in each individual's training records.
- 4.1.2 All personnel will have training outlining their ethical and legal responsibilities, including the potential punishment and penalties for improper, unethical, or illegal actions.
- 4.1.3 Personnel performing technical functions or processes will have known and documented related work experience and minimum qualifications of education.

4.2 RESPONSIBILITY

- 4.2.1 Supervisors are responsible for initial evaluation of capabilities and qualifications of assigned personnel and will assign those personnel to perform functions based on the individual's qualifications and abilities.
- 4.2.2 Supervisors and managers are responsible for the day-to-day monitoring of assigned personnel for evidence of unethical, improper, or illegal activities.
- 4.2.3 Appropriate training is the responsibility of the supervisors with support from management. Training will address specific needs and will vary according to each job's requirements and previous experience of the employee, and will ensure:
 - 4.2.3.1 Understanding of the fundamentals of the work and its context,
 - 4.2.3.2 Understanding of the processes and tools being used, the extent and sources of variability in those processes and tools, and the degree to which control over the variability is maintained,
 - 4.2.3.3 Emphasis on correct performance of the work, understanding why quality requirements exist, and potential consequences of improper work, and
 - 4.2.3.4 Emphasis on "doing it right the first time."
- 4.2.4 Management will provide ALL employees the resources, tools, equipment, scheduling, and structured training to ensure personnel can perform their duties effectively. New employees will receive detailed information concerning the general corporate policies and the specific laboratory safety practices, and security policies. Training shall be conducted on an individual basis to achieve and maintain suitable proficiencies. The training will include, but will not be limited to:
 - Ethical and Legal responsibilities (Annual Refresher)
 - Health and Safety (Annual Refresher)
 - Radiation Protection (Annual Refresher)
 - Waste Management (Annual Refresher)
 - Quality Assurance (Annual Refresher)
 - Laboratory Procedures (Annual Demonstration of Capabilities)

- LIMS Operation (OTJ Continuing Training)

- 4.2.5 Current copies of the laboratory documents and procedures such as: the Chemical Hygiene/Health and Safety Plan; Radiation Protection Plan; Waste Management Plan; Quality Assurance Plan; Laboratory Analytical Procedures will be available at all times to all employees who will be expected to familiarize themselves with these documents.
- 4.2.6 Milestone achievements or unique training will be noted by the supervisors via entry in the training records. Available certificates of training, education, or awards will also be maintained with the individual's training records.
- 4.2.7 Supervisors will monitor individual work habits to ensure proficiency is maintained, to note progressive improvement, and to identify any needed supportive training. Additional training requirements will be developed by the individual's supervisor.
- 4.2.8 As needed, employees will be informed of the requirements of special clients/programs necessary to achieve their duties and responsibilities. Familiarization will be made a matter of record.
- 4.2.9 All personnel training records will be maintained in the QA office. The details for maintenance of training requirements and records are outlined in the Oak Ridge Laboratory Management Procedure, MP-042 "Personnel Training."

5.0 INSTRUCTIONS AND PROCEDURES**5.1 POLICY**

The Oak Ridge Laboratory policy uses written and approved procedures for routine activities and for analytical and operational processes. Applicable Laboratory procedures are available to all personnel. The most current and accessible copy of the appropriate procedure will be maintained and documented on the laboratory computer server. Departures from routine procedures due to non-standard situations or specific requests from clients will be approved by management and fully documented.

5.2 ANALYTICAL PROCEDURES

Analytical procedures are descriptions of particular protocols for testing or operations. Analytical procedures will be developed based on published reference procedures for each test or process, and authorized for use by the Technical Director or QA Manager.

5.2.1 Qualification requirements for personnel performing operations and criteria used to determine the proficiency of the operator will be documented.

5.2.2 Each technical procedure will include a list of Personal Protective Equipment (PPE) required for the operation being performed. Training for the identification, operation, use, limitations, and disposal of the PPE will be conducted.

5.2.3 Each technical procedure will identify any chemicals/reagents required for completion of the operation. Material Safety Data Sheets (MSDSs) for those chemicals/reagents will be readily available, and training applicable to the MSDSs will be conducted.

5.2.4 Training will be conducted to the procedures used for processing wastes generated within the appropriate chemistry laboratory.

5.3 PROCEDURE MANUALS

Procedure manuals consist of the individual analytical procedures for a laboratory area or for an operation combined into one document. The procedures within the manual define all parameters of the operations being performed to include required accuracy and completeness of specific measurement parameters involved. Procedures will be incorporated into procedure manuals. Signature on the Authorization and Approval page applies to all procedures in the manual.

5.4 FORMAT AND DISTRIBUTION

5.4.1 Procedures will comply to the format prescribed in the laboratory document control procedure and will be approved by the responsible supervisor, the relevant manager or designated cognizant technical personnel and the Q.A. Manager.

5.4.2 Employee access to the most current revision of procedures and manuals will be through the Laboratory computer server. Any distribution of controlled copies of any Laboratory procedure will be in accordance with the laboratory's document control procedure, MP-023. The original copy of each department's procedure manual will be maintained by the Q.A. staff.

5.4.3 The Laboratory Deputy Manager is responsible for the maintenance and security of the original electronic version of all laboratory procedures and manuals and for ensuring that the most current revision of the procedures and manuals are promptly posted and accessible to all employees.

5.5 REVIEW

Technical procedures will be reviewed every three years and updated if required. Quality Assurance

procedures are reviewed annually.

5.6 REVISION

- 5.6.1 The appropriate supervisor, or designated representative, is responsible for revisions or changes to the applicable procedure manuals.
- 5.6.2 Revisions are reviewed and approved by the organization(s) and personnel responsible for the original document. When possible, revisions or changes will be accomplished on a page replacement basis.
- 5.6.3 The Q.A. Manager will be advised of any changes in procedures required to satisfy specifications of the client.
- 5.6.4 The final revision shall be reviewed, approved, and authorized by the laboratory manager and QA manager. The original signed hard copy will be maintained by the QA department and a protected electronic copy is placed on the laboratory LIMS for access.
- 5.6.5 The Q.A. Manager will be responsible for retention of the original copy of each superseded procedure, marked "Revised" or "Obsolete." The original copy of each superseded or obsolete technical procedure will be designated for retention.

6.0 PROCUREMENT DOCUMENT CONTROL**6.1 PURCHASING**

Procurement of material, components, supplies, reagents, equipment, and services necessary to carry on the business interests of the Oak Ridge Laboratory is initiated by purchase requisition and controlled by the use of an authorized purchase order number. To the extent necessary, purchase orders will require suppliers to have a Q.A. program consistent with the requirements of this document. Detailed information on procurement is outlined in the laboratory's Purchasing Policies and Procedures Manual.

6.2 PURCHASE REQUISITION REVIEW

Purchase requisitions or change orders are reviewed by purchasing department personnel to ensure conformance to the procurement requirements. As applicable, quality related requisitions are reviewed by Q.A. personnel prior to being processed. Change orders undergo the same review process.

6.3 CERTIFICATION/CERTIFICATE OF CONFORMANCE

All materials and processes requiring certification and certificates of conformance are identified on the face of the purchase requisition. Adequate information is provided to ensure supplier compliance to the required specifications. The Q.A. Manager is responsible for the retention, filing, and recall of material certification or certificates of conformance.

6.4 SUBCONTRACTS

When subcontracting analytical work, Oak Ridge Laboratory Management will ensure, to the extent necessary, that the subcontractor has a Q.A. program consistent with the requirements of this document. The Q.A. Manager is responsible for evaluation and acceptance of the subcontractor's Q.A. program.

6.5 VENDORS

6.5.1 For procurement of quality-related items or services, the Q.A. Manager is responsible for vendor evaluation and approval. Vendor evaluation and qualification will be through accreditation as a secondary standard calibration laboratory (NVLAP, NIST); an audit by Oak Ridge Laboratory personnel or an acceptable audit agency; or facility inspection, test reports, or receipt inspections, when the quality of the materials can be verified by these methods. Documentary evidence that products and services conform to procurement requirements will be provided and retained. A list of approved vendors will be maintained by the Procurement Office.

6.5.2 The effectiveness of the control of quality by contractors and subcontractors will be assessed at intervals consistent with the importance, complexity, and quantity of the product or services.

6.5.3 The purchasing department is responsible for maintaining a record of quality related materials received from vendors including any reports for non-conforming material.

6.6 QUALITY RELATED SERVICES

Q.A. personnel will review the purchase requisitions for quality related services. Those services that are determined to be quality related will include, as applicable, the following statement, or similar wording, in the body of the purchase order or by attachment: "The pieces of equipment and/or services to be furnished under this purchase order are subject to the applicable requirements of EPA National Environmental Laboratory Accreditation Conference (NELAC) Chapter 5 "Quality Systems".



7.0 MATERIAL RECEIPT AND CONTROL

7.1 POLICY

Only material with acceptable quality characteristics will be allowed into stock.

7.2 RESPONSIBILITY

Receipt and initial verification of all materials and equipment received by the Oak Ridge Laboratory, either purchased or contract (client) supplied, is the responsibility of the receiving or designated individual. Technical verification for materials and equipment will be performed by the requisitioner or Q.A. personnel, whichever is applicable. Quality related purchase order items will be receipt inspected by Q.A. personnel.

7.3 MATERIAL CONTROL

Purchased material is controlled by the Laboratory Supervisor or designated individual.

7.3.1 The receiving and stock control clerk, or designated individual, is responsible for the expedient and correct routing of all initially accepted received materials to stock, or to the requisitioner.

7.3.2 Purchasing department personnel are responsible for maintaining a record of materials received from vendors, including Rejected Material Report (RMR), or equivalent form, for any non-conforming material.

7.4 NON-CONFORMING MATERIAL

When received material, affecting quality, has been determined to be non-conforming, the requisitioner or the Q.A. Manager will be responsible for proper processing.



8.0 MATERIAL STORAGE AND CONTROL

8.1 POLICY

All materials and supplies in storage will have the necessary protection to preclude deterioration, corrosion, or damage during storage life and will carry identification sufficiently clear to ensure that only those materials specified by process instructions will be withdrawn from material storage and issued for processing.

Only analytical grade chemicals and reagents, bearing such grade identification will be utilized by the Laboratory. Each container will be assigned a unique identification number upon receipt. The date of receipt will be posted on each container. The use and the retention (shelf life) of such chemical will be monitored by the Laboratory Supervisor.

All standards used by the Laboratory must be NIST certified. Each standard must be accompanied with a certificate showing the name, composition, concentration, reference number and NIST Certification. The use and distribution of these standards will be monitored by the LIMS. The certificate and certification documents of standards will be controlled by the QA department.

8.2 RESPONSIBILITY

Only authorized personnel will have access to, and the responsibility for, control and issue of materials or supplies. Materials and supplies will be stored to allow for ready identification. Care will be taken to preclude mixing of rejected material and supplies with those that are qualified for issue.

**9.0 CONTROL OF PROCESS****9.1 STANDARD PRACTICES**

Standard practices applicable to services provided by the Oak Ridge Laboratory are contained in documented procedures and this Q.A. Program Manual. Every effort is made to fulfill the requirements of the following laws, rules, guidance(s), and directives as may be applicable to the operational practices within the Oak Ridge Laboratory.

- 9.1.1 Federal and State rules and regulations.
- 9.1.2 Consensus standards related to the services performed (e.g., American National Standards Institute).
- 9.1.3 Regulatory Guides published by the Nuclear Regulatory Commission, Department of Energy, or the Environmental Protection Agency.
- 9.1.4 Specific contractual agreements with clients.
- 9.1.5 Where conflict occurs among the above four items, or other appropriate authority, the client will be notified and requested to specify the policy to be followed.

9.2 DOCUMENTED PROCEDURES

Routine operating procedures are documented. Each procedure includes quality control criteria that are applicable to that process. The laboratory management will develop, promulgate, and implement procedures that document the operations performed in the laboratory. Additionally, the following general procedures or documents, as applicable, will be developed:

- 9.2.1 Quality Assurance Procedures
- 9.2.2 Radiation Safety Manual and Procedures
- 9.2.3 Sample Control Procedures
- 9.2.4 Purchasing Policies and Procedures
- 9.2.5 Data Review Procedures
- 9.2.6 Environmental Compliance Procedures
- 9.2.7 Safety Procedures
- 9.2.8 Chemical Hygiene Plan
- 9.2.9 Hazard Communications Program
- 9.2.10 LIMS Procedures

9.3 RESPONSIBILITY

The Laboratory Manager, or designated representative, determines which instructions or procedures require quantitative or qualitative acceptance criteria and specify the appropriate criteria on special contracts or projects.

9.4 WORK POLICY

All work to be performed by the Oak Ridge Laboratory on client samples is authorized by the client and controlled through a Laboratory Information Management System (LIMS) work order document which incorporates the client's requirements. Or by some other document deemed necessary by the Program Manager.

- 9.4.1 The work order specifies those analyses necessary to assure compliance with contractual obligations.
- 9.4.2 The Program Managers, or designated personnel, are responsible for notifying the Q.A. Manager and performing laboratory departments, through the appropriate supervisor, of all contract requirements including reporting format and quality control criteria. This may be done by reference to other documents (e.g., Purchase Order, statement of work, technical specifications, etc.) that delineates the contract requirements.
- 9.4.3 The Program Manager, Operations Manager, or designee, will ensure planning, scheduling, and resources are considered when contracting for or accepting work.
- 9.4.4 When subcontracting analytical services, the Program Manager, or designated individual, will assure that:
- The client is notified in writing of the intention to subcontract any portion of the testing to another party.
 - If the work is covered under NELAP, the work will be placed with a laboratory accredited under NELAP for the tests to be performed.
 - Records, demonstrating that the above requirements have been met, are retained in the project folder.

**10.0 PREVENTIVE MAINTENANCE****10.1 POLICY**

Preventive maintenance is performed as required on instrumentation and equipment to prevent down time and to ensure reliable performance. The laboratories maintain instrument redundancy that precludes the requirement for a repair and maintenance capability for instrumentation. Maintenance and/or repair of equipment are performed by the equipment manufacturer or authorized representative under contract or purchase order.

10.2 MAINTENANCE

Preventive maintenance procedures will be developed for use where instructions are not provided in the manufacturer supplied operator's manual. As applicable, each department will maintain a major equipment and measurement standards list. A record of instrument maintenance, calibration, and repair, if applicable, will also be maintained. The supervisors and operating personnel are responsible for complying with the department maintenance schedule.

10.3 SPARE PARTS

Supervisors will ensure that an adequate inventory of spare parts and consumables is requisitioned and maintained for instrumentation in their area in order to prevent down time or compromise operating conditions.

**11.0 CONTROL OF MEASUREMENT AND TEST EQUIPMENT****11.1 MEASUREMENT AND TEST EQUIPMENT CALIBRATION POLICY**

This section establishes the controls and calibration requirements for all analytical and nuclear measurement equipment. An equipment list will be maintained indicating calibration status.

- 11.1.1 All equipment, whose operation and function directly affect the quality of service, will be inspected/calibrated at established intervals. As applicable, equipment will be suitably identified to reflect calibration status. If an instrument is determined to be out-of-tolerance, it will be segregated, or otherwise clearly identified as inoperable. Records of each calibration will be kept in appropriate logbooks or files. Instruments whose calibrations are performed during method operations are calibrated and controlled in accordance with the method requirements. Run logs will be maintained for this category of instrumentation.
- 11.1.2 The equipment used to determine the quality characteristics and accuracy of instruments will be checked and verified either internally (dependent upon capability), or by qualified calibration services.
- 11.1.3 Frequency of inspection/calibration will be based on use of the equipment or instrument, environmental conditions in which it is used, its inherent stability, manufacturer's recommendation, and the wear or deterioration resulting from its use.
- 11.1.4 Certified standards are used for all primary calibrations. National Institute of Standards and Technology (NIST) or NIST traceable, Environmental Protection Agency (EPA), New Brunswick Laboratory (NBL), or Department of Energy (DOE) standards are used, when available, for the primary calibrations or verification of primary calibrations.
- 11.1.5 All preparations of standard solutions are recorded in a standards preparation logbook or file. Identities of standards are such that a secondary standard or dilution can be traced, through subsequent actions, back to the initial certification.
- 11.1.6 Quality control check standards are used to record instrument sensitivity and linearity and to verify proper response. Methods and calibration entries are dated, initialed, and documented by the analyst.
- 11.1.7 Measuring and test equipment are tagged as to calibration or operating status for periodic processes performed on a scheduled interval of greater than one month. For processes performed more frequently, separate documentation will be available for verification of operational status. Instruments that are too small to be tagged or are subject to a wide variety of calibrations shall have separate documentation of status available.

11.2 RESPONSIBILITY

Testing and/or calibration of equipment and instruments will be performed under the direction of the supervisor, the department manager, or the operations manager and performed under suitable environmental conditions.

11.3 PROCEDURES

All tests and calibrations will be performed in accordance with written procedures that contain provisions for ensuring that all prerequisites for the given test have been met, including appropriate equipment to be used.

11.4 CERTIFICATION AND CERTIFICATES OF CALIBRATION

- 11.4.1 To the extent possible, calibration will be traceable to NIST. Records of traceability will be



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maintained along with records of routine calibrations of each instrument or measurement system. Where no NIST traceability exists, the basis used for calibration will be documented.

11.4.2 Equipment records will be maintained to indicate past and current status, and to provide reproducibility and traceability of results.

11.5 RADIOACTIVE SOURCE CALIBRATION

Radioactive sources used as calibration standards will be periodically calibrated and controlled. Current calibration certificates will be kept on file.

11.6 CALIBRATION RECORDS

Supervisors will ensure that calibration data for instruments and radioactive sources is recorded in the instrument logbook, on data work sheets, on computer files and/or control charts. . When required, new calibration charts will be prepared when there is measurable change in calibration effect on instruments that have been calibrated. If an instrument is determined to be out of tolerance, it will be segregated or otherwise clearly tagged as inoperable and not used until repaired.

11.7 REPORTS GENERATED FROM USE OF A DEFICIENT INSTRUMENT

If a major deficiency in an instrument or device is detected during periodic calibration procedures, the technician will immediately notify the supervisor, the operations manager, and the Q.A. Manager. A conference will immediately be scheduled to investigate and decide what corrective action is to be taken on past data and reports resulting from the use of the deficient instrument or device. A record of corrective actions will be maintained.

11.8 PERFORMANCE CHECKS OF RADIATION SCREENING INSTRUMENTS

Performance checks will be made to ensure the continuing capability of radiation screening instruments. Procedures will include efficiency checks and background determinations. The procedure and frequency of each check is optimized for each detector system to provide assurance of the detector's performance. Documentation of the checks and the results are kept for all operations.



12.0 DATA REDUCTION, VERIFICATION, AND REPORTING

12.1 USE OF COMPUTER HARDWARE AND SOFTWARE

Computer programs used in the production or support of client data are either purchased, or developed using approved development methodology. Such programs are independently validated, verified, and documented. Changes are controlled to assess the potential impact of the change on the performance of the program.

12.2 DATA REDUCTION AND VERIFICATION

12.2.1 The successful completion of a count is monitored by the Counting Room staff. The Laboratory Manager, or designated individual, performs the final review and approves the data.

12.2.2 Calculation methods, transcriptions, and data flow, plus times and locations of the various tiers of review are detailed in the specific procedure.

12.3 REPORTING

The Program Manager or designated individual is responsible for providing the client with the required analytical results. Reports to clients will be reviewed for accuracy and completeness and, where required, analytical methods and minimum/method detection limits (MDL) will be reported. Laboratory reports of analyses will be signed by an authorized individual who, along with the person who signed the data sheets, can attest to the fact that the data was generated in accordance with established procedures.

**13.0 DOCUMENT CONTROL****13.1 POLICY**

The primary formal communication methods within the Oak Ridge Laboratory departments are documents that inform or direct activities affecting purchasing, sample analyses and reporting, instrument calibration and/or testing, proper handling of wastes, and Health and Safety. These documents are controlled by the Q.A. Program Manual, Operating Procedure Manuals, other documented procedures, or by interoffice memoranda. Drawings and specifications are not controlled as separate documents but are included in controlled procedures where applicable. The QA Office controls logbooks used to document the analysis of samples (see MP-023, Documentation of Analytical Laboratory Notebooks).

13.2 RESPONSIBILITY

13.2.1 The Q.A. Manager is primarily responsible for maintaining files of all controlled documents and will:

13.2.1.1 Annually review the Quality Assurance Program Manual and provide recommendations for updating.

13.2.1.2 Ensure that all holders of controlled documents receive updates to the documents.

13.2.1.3 Maintain files of controlled document distribution indicating document title, number, revision number, assigned date, and the name of the individual to whom the document is assigned.

13.2.1.4 Forward revisions of controlled documents to assigned individuals. An acknowledgment form will accompany each document revision for verification of receipt and to provide disposition instructions for the superseded pages.

13.2.2 Uncontrolled copies of controlled documents will be distributed only if marked "Uncontrolled."

13.2.3 Superseded and/or obsolete documents are isolated from use or destroyed.

13.2.4 Each employee is responsible for requesting revisions or changes to operating procedures for their area of responsibility.

13.2.5 The Q.A. Manager will be advised of any changes in procedures required to satisfy client requirements.

13.2.6 Client information and records such as contract requirements, project descriptions, analytical data and results submitted to the client; and all laboratory records associated with such submittal will be maintained by the laboratory for a minimum of 5 (Five) years. Clients will be contacted and queried for disposition instructions for their related documentation if or when a laboratory transfers ownership, is decommissioned, or goes out of business prior to the conclusion of the requirement to store client documentation.

14.0 INTERNAL QUALITY CONTROL**14.1 LABORATORY ANALYTICAL SERVICES**

Precautions are taken in the chemistry laboratories to avoid cross-contamination of samples and to ensure the reporting of accurate results. Quality control samples are analyzed along with routine samples to indicate when results may be in error due to improper operation or calibration of equipment, inadequate training of personnel, a deficiency in the procedure, or cross-contamination from other samples.

14.1.1 Laboratory Precision - Laboratory management personnel are responsible to ensure that analytical results are reproduced internally within acceptable limits.

14.1.2 Precision and Accuracy - Replicate standards and/or samples are used to estimate the precision of each analytical test procedure for a known matrix. Data control limits are established to satisfy the requirements of specific measurements based on prior knowledge of the measurement system and method validation studies. Certified standards and/or spiked samples are used to estimate chemical recovery and accuracy for these procedures for known matrices.

14.1.3 Calibration and Performance Checks of Nuclear Measurement Systems - Reference standards are used for calibrating nuclear measurement systems. In addition to calibration of all instrumentation, routine monitoring is performed to ensure the continuing integrity of the instrument performance. The monitoring parameters performed include efficiency checks, background determinations, and energy calibrations. The procedure and frequency of each check is optimized for each detector system to provide assurance of the detector's performance. Documentation of the checks and the results are kept for all systems. The supervisor is responsible for these calibration and performance checks.

14.1.4 Duplicate Analysis - Duplicate aliquots of randomly selected samples will be processed on a routine basis. The analyst will always process samples in accordance with approved operating procedures. The evaluation of the duplicate analysis will be based on examination of the difference between the duplicates. A statistical analysis of the data may be performed when a cursory evaluation indicates problems with the results. If the two results agree with the three standard deviation limits, a more detailed evaluation will generally not be necessary. Results of duplicate analyses will be included in the monthly Q.C./Q.A. report.

14.1.5 Detection and Elimination of Bias - Where possible, calibration will be with standards that are traceable to NIST. However, traceability to NIST is not always possible and reliance on other suppliers may be necessary (e.g., International Atomic Energy Agency, U.S. Department of Energy, U.S. Environmental Protection Agency, or commercial supplier such as Analytcs, Amersham Biosciences, AEA Technology, etc.). Standards in the appropriate geometry or form will be used to determine efficiency of instruments on a periodic basis. In the calibration process, the ideal standard will be a known quantity of the radionuclide to be measured, prepared in exactly the same geometry as the samples and counted under the same conditions. In this way, factors such as self-absorption, backscatter, sample geometry, and detector efficiency will be accounted for empirically.

14.1.5.1 Spiked Samples - A known quantity of calibrated radioactive standard solution will be added to an aliquot of the sample or to a "blank" sample for replicate analysis. When the entire analytical system is operating properly, the laboratory record will demonstrate the accuracy and precision of the data. Divergent data from the spiked sample will point out problem areas. If the data is consistently higher or lower than the known value, bias in the analytical procedure is indicated. This may require a

search for personnel errors, restandardization of carriers or tracers, and/or recalibration of counting equipment.

14.1.5.2 Background Determination - The type of equipment and environmental factors contribute to variation in the counting rate of instrument background. The background of each system instrument will be determined and recorded with sufficient frequency to provide a firm statistical basis for that measurement and to ensure response to potential instrument problems or other artifacts such as controlled contamination.

14.1.5.3 These background determinations will include use of the items that most closely duplicate the analytical configuration in type, geometry, and with any associated fixtures. In some cases, true blanks are not available, but the closest practicable analog is used.

14.1.5.4 Some systems are sufficiently stable to require no change in backgrounds used for data reduction (e.g., uranium daughter gamma-rays found in gamma spectra due to adjacent building materials and earth). In this case, backgrounds will be compared to historical data to insure sufficient stability. Other systems experience enough variability to require computed backgrounds based upon running averages.

14.1.5.5 Background data will be recorded in the logbook or computer file for that specific instrument along with calibration data and instrument maintenance records.

14.1.6 Blanks - Blank samples are routinely analyzed to verify control of contamination and process. Results of processed blanks will be included in the monthly Q.C./Q.A. report.

14.1.7 Collaborative Testing - The Oak Ridge Laboratory participates in collaborative testing or interlaboratory comparison programs. Natural or synthetic samples prepared to contain known concentrations of certain radionuclides are sent to participating laboratories by an independent referee group such as the DOE Radiological and Environmental Sciences Laboratory DOE, Idaho Falls, Idaho (MAPEP); by a NELAC approved provider such as the Environmental Resources Agency (ERA), Environmental Measurements Laboratory, or by client(s).

These programs enable Oak Ridge Laboratory personnel to document the precision and accuracy of radioactivity measurements, identify instrumental and procedural problems, and compare performance with other laboratories.

14.2 QUALITY CONTROL AND DATA REPORTS

14.2.1 Quality Control Reports

Quality control results will be summarized with distribution to management and others upon request.

14.2.2 Data Reports

Routine performance requires documentation of all pertinent information with the basic documents dated and initialed or signed. Required documentation will be the initial work order, Chain-of-Custody (CoC), or document, that records all pertinent information such as the identity of the sample and analyses to be performed. The data report will include technical analysis notes, logbooks, work sheets all raw data and other information used in performing the analysis. The report of analysis will be the final report of the data to the client and is issued in accordance with the laboratory's procedure for review and processing.



14.3 DATA VERIFICATION

Routine performance requires inclusion of all pertinent information with basic documents dated and initialed or signed. The work order has recorded such information as the identity of the samples and analyses to be performed. All raw data and other information used in performing the analyses are documented.

14.3.1 Electronic Deliverables Verification - Program managers, or designated individuals, are responsible for ensuring that electronic deliverables are complete and accurate.

14.4 SAMPLE CUSTODY

Samples are assigned a unique laboratory identification number, marked on a label that is applied directly to the container and which identifies the work order and laboratory fraction. Sample control personnel are designated sample custodians for strict (legally defensible) CoC samples. Locked buildings, refrigerators, freezers, and cabinets are available for CoC samples. Sample custody forms or technician analysis notes are used for tracking all samples through the analytical process. Details for radiological survey of samples, sample security, sample disposal, etc. are outlined in approved Sample Control Procedures. Sample chemistry and nuclear counting requirements are assigned by the laboratory manager, or designated individuals.

15.0 AUDITS**15.1 POLICY**

The Oak Ridge Laboratory has established a comprehensive system of planned and documented audits to verify compliance with all aspects of the Q.A. Program. An audit is defined as a documented activity performed in accordance with written procedures or checklists to verify, by examination and evaluation of objective evidence, that applicable elements of the Q.A. Program have been developed and effectively implemented in accordance with specific requirements. Audits will be performed by persons not having direct responsibility for those areas being audited.

- 15.1.1 Customer Access to the Oak Ridge Laboratory Facilities and Personnel - The client is frequently responsible for auditing the Oak Ridge Laboratory's performance relative to contractual requirements. The exact nature of this responsibility is relative to the nature of the regulatory or licensing requirements, the significance of the services, and the technical expertise available or inherent within the client's organization. The need for, and frequency of, client audits is dependent upon the above factors. A client may authorize an independent agency to perform an audit on its behalf. When possible, the facilities, equipment, and records (proprietary information excluded) of the Oak Ridge Laboratory will be made available for client inspection along with the necessary personnel to permit verification of quality characteristics.
- 15.1.2 The Q.A. Manager will coordinate and participate in audits conducted by the client or the client's representative.
- 15.1.3 Internal Audits - The Q.A. Manager will audit the laboratory operations to verify compliance with established procedures and requirements set forth in the Q.A. Program Manual. Use of a checklist will insure items in compliance are noted as well as any requirements for improvement.
- 15.1.4 External Audits - External audits of organizations providing services to the Analytical Services Group are scheduled at a frequency commensurate with the status and importance of the activity.

15.2 RESPONSIBILITY

Audits will be directed by the Q.A. Manager with assistance from designated personnel.

- 15.2.1 The Q.A. Manager will be responsible for an independent quality assurance audit of each department.
- 15.2.2 The Q.A. Manager will be responsible for assuring that audits are performed by knowledgeable professionals.
- 15.2.3 An independent qualified auditor will audit areas of responsibility assigned to the Q.A. Manager.

15.3 DOCUMENTATION

Audit results will be documented by the Q.A. Manager.

- 15.3.1 The Laboratory Manager will be provided a copy of the audit report.
- 15.3.2 The QA Manager will determine if there any corrective actions required and the individual responsible for implementing the corrective action



15.4 DEFICIENT AREAS

- 15.4.1 The responsible Manager will ensure correction of the identified deficiencies.
- 15.4.2 The Q.A. Manager will verify that action is taken to correct any deficiency and will take follow-up action to ensure that corrections have been completed.
- 15.4.3 The Q.A. Manager will ensure close out, with documentation, of the audit after corrective actions have been completed.
- 15.4.4 For uncorrected or unresolved deficiencies, after due diligence, the Q.A. Manager will petition the Laboratory Manager to bring to bear his authority for resolution of the deficiencies.

15.5 FREQUENCY OF AUDITS

The Q.A. Manager will ensure internal audits are conducted on an annual basis. Additional selective audits will be conducted when one or more of the following conditions exist:

- 15.5.1 When significant changes are made in functional areas of the Q.A. Program, including significant reorganization or procedure revisions.
- 15.5.2 When assessment of the Program's effectiveness is considered necessary.

**16.0 QUALITY ASSURANCE AND INSPECTION RECORDS****16.1 POLICY**

Records that provide objective evidence of the quality of work are generated and maintained. These records include controlled logbooks, customer instructions, sample analyses data sheets, and results of reviews, inspections, tests, audits, corrective actions, reports, and training records. Also included are related data such as personnel qualifications, procedures, and equipment records.

16.2 RESPONSIBILITY

The responsibility for initiation, completeness, and reliability of Q.A. records is vested in the appropriate supervisor, with periodic verification checks by the Q.A. Manager. All Oak Ridge Laboratory personnel performing processes or services associated with the work being performed will assist in the efforts.

16.3 RECORDS

16.3.1 Inspection and test records will, at a minimum, identify the inspector or data recorder, the type of observation, the results, the action taken in connection with any deficiencies noted, and the date of the inspection or test.

16.3.2 All required records will be legible and of a quality that can be copied. Records shall be completed using reproducible ink. Errors or incorrect entries will be lined through with a single line, dated, and initialed by the recorder.

16.3.3 Correspondence from clients may be made available for inspection at the discretion of client representatives and authorization from the originating organization.

16.3.4 Q.A. records will be identified and controlled by customer number and/or client identification as applicable.

16.4 STORAGE OF RECORDS

Quality assurance records will be firmly attached in binders, or placed in folders or envelopes, and, if applicable, cross referenced by client identification and stored in a secure area.

16.4.1 Q.A. records will be properly stored and made available to the client upon request.

16.4.2 Records will be maintained in a secured and protective storage area.

16.4.3 Records will be identified and be retrievable.

16.4.4 CoC records are included with the sample set records.

16.4.5 Longer retention or duplication of records is available at the specific direction from the client. .

16.4.6 Laboratory management will be responsible for governing access to, and controlling the records. .

16.4.7 Analytical reports and source calibration data will be retained for a minimum of five years after results are reported to the client.

16.4.8 Procurement records will be retained for a minimum of five years or as required by the contract. All records and analyses performed pertaining to (NELAC) accreditation will be kept for a minimum of 5 years and would be available for inspection by the accrediting authorities during this period even without prior notification to the laboratory.

**17.0 CORRECTIVE ACTION****17.1 POLICY**

The Oak Ridge Laboratory policy is to ensure continuous acceptable quality levels for services provided. Conditions adverse to quality will be identified and corrected as soon as practical.

17.2 CORRECTIONS**17.2.1 CORRECTIVE ACTION REQUEST (CAR)**

In the case of a significant condition adverse to quality, the cause of the condition shall be determined and corrective action taken to preclude recurrence. The identification, cause, and corrective action shall be documented and reported to appropriate levels of management. Follow-up action shall be taken to verify implementation of this corrective action. The Corrective Action Request (CAR) Form shall be used to document this condition. Typically, the Q.A. Manager will initiate investigation and corrective action by issuing a Corrective Action Request (CAR) in any of the following situations:

- When an audit reveals circumstances that will adversely affect quality (Audit Finding) as determined by the Q.A. Manager.
- When any results of an intercomparison study are out of control, or for non-participation.
- When procedural or technical problems arise and the Q.A. Manager determines that they will significantly affect quality.

17.3 NON-CONFORMANCE REPORT (NCR)

A non-conformance is a deficiency in a characteristic, procedure, or documentation that renders the quality of an item unacceptable, however, is not considered a significant condition that would require an investigation by use of a CAR. In the laboratory, non-conformances can include physical defects, incorrect or inadequate documentation, and deviations from an established protocol, plan, or documented technical requirement. This condition is documented using a Non-Conformance Report (NCR) Form.

17.4 RESPONSIBILITY

All laboratory personnel are responsible to communicate any evidence of unacceptable quality performance to their supervisor, the responsible manager, and/or the Q.A. Manager.

17.4.1 The responsible manager will ensure investigation of a condition adverse to quality, determine assignable cause, and provide recommendation(s) for corrective action.

17.4.2 The responsible manager will ensure action is initiated to correct the assignable cause of the adverse condition and to determine and initiate the specific corrective action(s) necessary to preclude recurrence.

17.4.3 The Q.A. Manager will review CARs, NCRs, and routine Q.C. reports for evidence of unacceptable quality.

17.4.4 Copies of the completed CARs and NCRs will be kept on file by the Q.A. Manager.

17.5 CLIENT NOTIFICATION

The client will be notified when any Corrective Action is initiated due to evidence of unacceptable quality that is related to their contract.



18.0 QUALITY ASSURANCE REPORTS TO MANAGEMENT

18.1 POLICY

The Oak Ridge Laboratory policy is to keep management apprised of all quality assurance problems, actions taken to correct them, and any actions taken to prevent recurrence.

18.2 QUALITY ASSURANCE REPORTS

18.2.1 Special reports to management are provided whenever results of intercomparison studies or tests are received and whenever CARs are initiated.

18.2.2 The Q.A. Manager will report all general or system audit results, problems, corrective actions, and replies.



Eberline Services Oak Ridge Laboratory Management Procedure

MP-030

Quality Systems Implementation Plan

The Oak Ridge Laboratory management staff, in compliance with the Eberline Services philosophy and policies, clearly expresses their commitment to provide the highest quality radiochemical services. The implementation protocols of the Eberline Services policies – as they relate to Federal, State, and National requirements- within the Oak Ridge Laboratory operation are delineated within this document. The release and use of this document has been authorized by:

Ahmed A. Halouma
Quality Assurance Manager

Cecilia H. Searcy MPH, NRRPT.
Deputy Laboratory Manager

Michael R. McDougall
Laboratory Manager

DATE: 10/31/09

Eberline Services
Oak Ridge Laboratory
601 Scarboro Road
Oak Ridge, TN 37830
865-481-0683

**1.0 PURPOSE AND SCOPE**

- 1.1 This plan defines the everyday practices and policies employed to ensure quality performance of the analytical radiological services provided by the Eberline Services – Oak Ridge Laboratory.
- 1.2 This plan defines the elements of the Oak Ridge Laboratory Quality System and operational practices to satisfy statutory, regulatory and national requirements.

2.0 REFERENCES

- 2.1 Eberline Services – Oak Ridge Laboratory; Quality Assurance Program Manual (latest version), Quality Assurance - Management Procedures Manual (latest version).
- 2.2 National Environmental Laboratory Accreditation Conference (NELAC), Quality Systems Document, Chapter 5, USEPA, 2003.
- 2.3 ASME NQA-1 "Quality Assurance Program Requirements for Nuclear Facilities" American Society of Mechanical Engineers, 345 East 47th Street, New York, New York 10017 (for the 18 criteria, but not necessarily all supplements and appendices).
- 2.4 EPA QAMS-005/80 "Interim Guidelines and Specifications for preparing Quality Assurance Project Plans".
- 2.5 DOE Order 414.1B, "Quality Assurance"
- 2.6 Title 10, Code of Federal Regulations, Part 50 (10CFR50), Appendix B.
- 2.7 DOE Quality Systems for Analytical Services, latest version

3.0 POLICY

- 3.1 It is the commitment of the Eberline Services - Oak Ridge Laboratory staff to provide analytical services and deliverables of a quality that meets or exceeds client or regulatory requirements and to foster a culture of commitment to quality.
- 3.2 It is the commitment of the Oak Ridge Laboratory Management to provide written and clear procedures; to motivate and empower all employees to achieve the highest level of quality and to provide comprehensive, technically sound, defensible analytical services to all clients; and to conduct business with the highest standards of ethics and integrity.
- 3.3 It is the policy of the Oak Ridge Laboratory that all client inquiries are handled as follows:
 - 3.3.1 The Laboratory Manager, Deputy Laboratory Manager, Quality Assurance Manager or the Project Manager, or an individual specifically designated by the manager, is authorized to communicate information about the laboratory operation to the client.
 - 3.3.2 All client inquiries or complaints received by an Oak Ridge employee other than a manager must be relayed to the Project Manager immediately in writing and captured in MP-032 Inquiry Trax.
 - 3.3.3 The Project Manager will investigate (may assign a designee to investigate or deal with) the problem.
 - 3.3.4 Results of investigations, recommended action, response, and corrective action must be documented.
 - 3.3.5 The Project Manager or designee will determine the final response to the client.
 - 3.3.6 Records of the initial inquiry/complaint, investigation results, communications with clients and final resolution will be maintained in MP-032, Inquiry Trax.

**4.0 Organization and Structure****4.1 Facilities**

- 4.1.1 Eberline Services – Analytical Corporation specialize in providing analytical services. The group comprises three laboratories located in Richmond, CA, Oak Ridge, TN, and Lionville, PA. The group is wholly owned by Glen Rose Partnership LLP, a holding company incorporated in Delaware.
- 4.1.2 The Oak Ridge Laboratory, located at 601 Scarboro Road, Oak Ridge, Tennessee 37830, (865) 481-0683, is licensed for operation in Anderson County of the State of Tennessee. The laboratory is staffed by 19 professionals and managed by Michael R. McDougall. All aspects of the laboratory operation are housed in 9,800 square feet of building space.
- 4.1.3 The Oak Ridge Laboratory has the instrumentation, personnel, and expertise to handle most radiochemical analytical requirements. The laboratory facilities are divided into separate work areas to facilitate sample throughput. These areas include:
- Sample receiving and storage
 - Rough preparation
 - Preparation Laboratory
 - Separation Laboratory
 - Counting Room
- 4.1.4 A floor plan is included as Attachment 1.

4.2 Organization

- 4.2.1 The specific duties, responsibilities, and qualifications of the Eberline Services – Oak Ridge Laboratory staff, namely the laboratory manager, deputy manager, technical director, project manager, quality assurance manager, radiation safety officer, laboratory supervisor, sample custodian and laboratory technician are included as Attachment 2.
- 4.2.2 In the absence of any one individual, the deputy or assistant within each group who has the required skills and/or training will perform the functions of that individual. This will ensure continuance of the day-to-day operation of the laboratory. The technical manager may provide backup during the absence of the laboratory manager. A copy of the Oak Ridge Laboratory organization chart is included as Attachment 3.

5.0 Management and the Quality System

- 5.1 Eberline Services – Oak Ridge Laboratory maintains a quality system to ensure that the analytical services provided conform to client(s) specified requirements. The Oak Ridge Laboratory quality system is documented within the Laboratory Quality Assurance Program Manual, the Oak Ridge Laboratory Quality Systems Implementation Plan, the associated Management Procedures, and the Oak Ridge Laboratory Standard Operating Procedures. Other Oak Ridge Laboratory program specific documents may augment the laboratory overall quality systems.
- 5.2 The Oak Ridge Laboratory Management will provide the resources, tools, equipment, scheduling and training to ensure that all laboratory staff and each phase of the laboratory operation conform to the requirements of the quality system.
- 5.3 The QA Manager is responsible for implementing and monitoring the laboratory Quality Assurance Program.
- 5.4 It is the policy at the Oak Ridge Laboratory that:
- 5.4.1 The QA personnel will have knowledge of the analytical test procedures for which data review is performed



- 5.4.2 The QA Manager will have documented training and/or experience in QA/QC procedures as well as knowledge of Quality Systems as defined under NELAC and ANSI standards
- 5.4.3 The QA Manager reports to the Laboratory Manager with a direct reporting line to the Corporate Analytical Laboratories President.
- 5.4.4 The QA Manager has sufficient authority, access to work area, and laboratory work force with sufficient independence from cost and schedule considerations.
- 5.4.5 The QA Manager – without any managerial influence – can identify and record any problems affecting the quality systems; issue nonconformance reports and/or corrective action reports; initiate actions to initiate, recommend, or provide solutions to problems; and verify implementation of solutions.
- 5.4.6 The QA Manager through designated channels has the authority to stop or control work until resolution of a nonconformance, deficiency, or unsatisfactory condition regarding quality has occurred and the deficiency or unsatisfactory condition has been corrected.

6.0 Document Control and Record Retention

- 6.1 It is the policy of the Eberline Services – Oak Ridge Laboratory to control, store and retrieve, and when permission is granted dispose of laboratory documents and the analytical data that is generated for clients. Management Procedure “MP_023 – Documentation of Analytical Laboratory Notebooks” is in place to control laboratory notebooks. Management Procedure “MP_046 – Storage and Retrieval of Laboratory Records” is in place to outline the process of storage and retrieval of laboratory records.
- 6.2 It is the Oak Ridge Laboratory policy to control laboratory documents.
 - 6.2.1 For internal use: Documents are placed on the laboratory server for quick access and reference in a format that prevents any unauthorized changes. The original hard copy will always have a multicolor logo, authorization statement and signature and is retained in the Quality Assurance office.
 - 6.2.2 Laboratory Management Procedure MP-021 – “Preparation and Modification of Technical and Project Quality Assurance Documents” describes the approach for requesting a document revision process. A document will periodically be submitted for review and revision. Once authorized for use, it is controlled.
 - 6.2.3 For external use: Upon request, laboratory documents will be distributed to clients, business partners, or representative of regulatory agencies. The distribution may be as a controlled or uncontrolled status. Controlled status assures the continuous distribution of the latest revision of a laboratory document. Uncontrolled status is the single submittal of the latest revision of the requested document. Controlled distribution is achieved through a Controlled Document Receipt form and tracked on a “Document Distribution Record” form managed by the Quality Assurance Office, Attachment 4.
- 6.3 It is the Oak Ridge Laboratory policy to control laboratory analytical data.
 - 6.3.1 All information associated with the generation of any analytical data shall be maintained for a minimum of 5 years.
 - 6.3.2 Records shall be protected against fire, theft, loss, environmental deterioration, vermin and, in the case of electronic records, electronic or magnetic sources.
 - 6.3.3 The information will include – but not be limited to – papers related to the receipt of the samples at the laboratory; log-in information; internal chain of custody; volumes, weight of samples aliquots; volume or weights of standards used; records of certification of standards used; instrument print outs, records of reviews and data handling; as well as the final report submitted to the client. Hard copy of such information is organized by work order number and is maintained in storage.



6.4 It is the policy of the Oak Ridge Laboratory that, the LIMS information is backed up on electronic media and stored in a controlled environment.

- The laboratory IS manager is responsible for accurate and timely LIMS backups. The backups are performed using Symantec Backup Exec 11d.
- Analytical data is backed up on a daily basis on disk.
- The disk backups that are made on Friday (weekly backups) are duplicated to tape. The first tape backup of each month is labeled with the date of the backup, and retained in a fireproof cabinet.
- A daily backup of the LIMS database is performed on the SQL Server. The backup that is performed each Friday is compressed and stored on an external drive.
- The tape backups of analytical data, and the backups that are stored on an external drive will be retained for a minimum of five years.

6.5 Document Review Retention Cycle

Document	Location	Review	Revision	Retention
Laboratory Quality Assurance Program Manual (latest version)	Original authorized hard copy in QA office	Annually	Every 3 yrs or as may be necessary	(1)
Laboratory QA Management Procedure Manual	Original authorized hard copy in QA office	Annually	Every 3 yrs or as may be necessary	(1)
Laboratory Analytical Procedures (AP)	Original authorized hard copy in QA office. Controlled access to pdf file on the laboratory server	Annually	Every 3 yrs or as may be necessary	(1)
Laboratory Management Procedures (MP)	Original authorized hard copy in QA office. Controlled access to pdf file on the laboratory server	Annually	Every 3 yrs or as may be necessary	(1)
Laboratory Chemical Hygiene/Health and Safety Plan (CH/HSP) and CHP procedures	Original authorized hard copy in QA office. Controlled access to pdf file on the laboratory server	Annually	Every 3 yrs or as may be necessary	(2)
Laboratory Emergency Action/Contingency Plan (EAP)	Original authorized hard copy in QA office. Controlled access to pdf file on the laboratory server	Annually	Every 3 yrs or as may be necessary	(2)
Radiation Protection Plan (RPP)	Original authorized hard copy in QA office. Controlled access to pdf file on the laboratory server	Annually	Every 3 yrs or as may be necessary	(2)
Waste Management Plan (WMP)	Original authorized hard copy in QA office. Controlled access to pdf file on the laboratory server	Annually	Every 3 yrs or as may be necessary	(2)

(1) When revised, and re-authorized for use, the previous authorized hard copy is stamped or marked as retired copy and retained on file for at least 5 years.



(2) When revised, a copy of the previous version may be maintained on file for reference purposes only.

7.0 Job Descriptions

- 7.1 The Oak Ridge Laboratory Organization Chart is included as Attachment 3. The minimum educational/experience requirement for each position within the laboratory operation and the corresponding duties or responsibility is discussed within the job description.
- 7.2 It is the Oak Ridge Laboratory policy that in the case of absence of an individual, the deputy or a staff member who has the required skill and experience is the designee.

8.0 Laboratory Approved Signatories

- 8.1 It is the Oak Ridge Laboratory policy that all laboratory documents be reviewed, authorized, and approved prior to use. The line of authority for the laboratory procedures includes the Deputy Laboratory Manager, the Quality Assurance Manager, and the Laboratory Manager. For other lab documents such as the Health and Safety, Radiation Protection, and Waste Management Plans the line of authority includes the H&S and Radiation Safety Officer, the Quality Assurance Manager, and the Laboratory Manager.
- 8.2 The final release of laboratory analytical data must include the technical review, the QA review and the final authorization to release the data by the Laboratory Manager.
- 8.3 It is the Oak Ridge Laboratory lab policy to maintain current records of all laboratory employee formal signatures and initials, see Attachment 5

9.0 Traceability of Measurements

- 9.1 It is the policy of the Oak Ridge Laboratory to trace, record and document the movement of every sample received at the laboratory through receiving, analysis, reporting, and disposal or return to the client. It is the laboratory policy to maintain current and technically sound procedures for each task in the laboratory.
- 9.2 It is the policy of the Oak Ridge Laboratory to use NIST traceable standards for instrument calibration/daily performance checks and for tracers and spikes. Records of certificates, dilutions, and verification are maintained on file. MP_009 Radioactive Reference Standards Solutions and Records is the procedure that defines the process of verifying standards and solutions.
- 9.3 It is the laboratory policy to calibrate balances annually by an independent qualified vendor, and to perform a daily check on all balances and Class A dispensing pipettes prior to their use.
- 9.4 The Oak Ridge Laboratory uses numerous types of counting equipment. It is the laboratory policy to monitor the performance of each counting unit daily prior to use. Laboratory analytical procedures define the parameters and the acceptable limits for each counting technique.

10.0 Test Methods

- 10.1 It is the Eberline Services Oak Ridge Laboratory policy to use the best available, state of the art, technically sound methods and equipment in performing all analyses. All analytical procedures used by the Oak Ridge laboratory are compliant with Federal and State rules and regulations, and Regulatory Guides. The Oak Ridge Laboratory procedures are based on the following references (as authorized by 40CFR Section 141.25).
 - 10.1.1 "Prescribed Procedures for Measurement of Radioactivity in Drinking Water," EPA 600/4-80-032, August 1980
 - 10.1.2 "Interim Radiochemical Methodology for Drinking Water," EPA 600/4-75-008 (revised) March 1976. PB253258
 - 10.1.3 "Radiochemistry Procedures Manual," EPA 520/5-84-006, December 1987



- 10.1.4 Radiochemical Analytical Procedures for Analysis of Environmental Samples," U.S. Department of Energy, March 1979. EMSL LV 053917
 - 10.1.5 Standard Methods for the Examination of Water and wastewater, 13th, 17th, 18th, 19th, 21st Editions, 1971, 1989, 1992, 1995, 2005 respectively.
 - 10.1.6 "Methods for Determination of Radioactive Substances in Water and Fluvial Sediments," Chapter A5 in Book 5 of Techniques of Water-Resources Investigations of the United States Geological Survey, 1977. U.S. Geological Survey, Denver, CO
 - 10.1.7 The U.S. Department of Energy (DOE) Environmental Measurements Laboratory, "EML Procedures Manual", HASL-300; June 2001
- 10.2 A complete listing of the laboratory analytical procedures is included as Attachment 6.

11.0 Laboratory Resources and Project Specific Requirements

- 11.1 The staff and management of the Oak Ridge Laboratory are committed to meet or exceed the requirements of each project/contract. It is the policy of the Oak Ridge Laboratory to review and evaluate each new request or contract for
 - 11.1.1 Laboratory capacity and schedule
 - 11.1.2 Requested analysis and proper methods and procedures
 - 11.1.3 Regulatory requirements
 - 11.1.4 Required detection and reporting limits
 - 11.1.5 Sample turn around time, type, size available, type of deliverable and electronic format, and any hazards or special requirements
- 11.2 The laboratory manager and the project manager review the new project requirements to ensure that the appropriate resources can be deployed. Project information is disseminated to the technical managers and QA manager to evaluate any unique aspects of the project.
- 11.3 Prior to the start of the project, the laboratory manager or project manager introduces the new project and requirements to the laboratory staff.
- 11.4 Any change to the scope of an active project is agreed upon between the client and the project manager. Such changes are documented, maintained in the project file, and relayed to the laboratory staff for implementation.

12.0 Calibration and Verification Test Procedures

- 12.1 It is the policy of the Eberline Services Oak Ridge Laboratory to use written and approved procedures for all routine operations through the laboratory.
- 12.2 Standards are purchased from commercial vendors. All standards must be traceable to the National Institute of Standards and Technology (NIST). Each standard must possess a unique ID, chemical name, manufacturer, lot number, and reference date documented in a certificate by the vendor. Standards used for counting equipment are of special form and geometry. Liquid standards that are used for spikes, tracers, and lab control standards are received in a concentrated form. These standards are diluted and verified prior to use (See MP_009, "Radioactive Reference Standard Solutions and Records" for records maintained and acceptance criteria).
- 12.3 Radiation measurement instruments are subject to calibration prior to initial use, when the instrument is placed back in service after malfunctioning and the instrument's response has changed as determined by a performance check or when the instrument's response exceeds predetermined acceptance criteria for the instrument QC. The calibration and continuing calibration process and measurement parameters are detailed in the counting instrument operating procedure.
 - Gamma Spectroscopy System: see AP_011, Gamma Spectroscopy Operation



- Alpha Spectroscopy System: ee AP 018, Alpha Spectroscopy System Operation
 - Gas Proportional Counters. ee AP-029, Gas Proportional Counting System.
 - Liquid Scintillation Counters: ee AP-23 , Operation of the Packard 3100 Alpha/Beta Liquid Scintillation Counting Systems
- 12.4 Detection limits are determined and reported for each isotope in each matrix (Refer to counting procedure for approach and calculation).
- 12.5 All laboratory balances are calibrated and serviced annually by a factory representative or an approved service representative. Certificates of calibration are retained in the QA office. Additionally, balances are checked daily with a minimum of two masses, both in the range of the analytical weights used for the analysis. Records of the daily checks are maintained on the LIMS (See MP-010, Balance Calibration Checks)
- 12.6 Class A pipettes are checked daily prior to use and records are maintained on the LIMS (See MP-025, Use and Maintenance of Mechanical Pipettor)
- 12.7 Any laboratory equipment or counting instrument that fails to meet its designated quality control limits or criteria will be removed immediately from service until repaired or replaced. The laboratory maintains a redundancy of equipment to ensure continuous and un-interrupted operation.

13.0 SAMPLE RECEIVING

- 13.1 The Oak Ridge Laboratory policy for sample receiving and tracking throughout the laboratory is described in "MP_001, Sample Receiving". The procedure describes the conditions under which samples will be accepted, or rejected or segregated, and the checks, documentation, and notification process. Upon acceptance and receipt, samples are assigned a unique laboratory sample identification in the following manner:

XX-YY-ZZZ-aa

Where XX is the last two digits of the calendar year

YY is the month (01,...,12)

ZZZ is the sequential ascending number indicating the number of groups of samples received at the laboratory within a given month.

aa is the sequential number assigned to each sample within a group of samples.

The "XX-YY-ZZZ" unique number, referred to as "Work Order" or Analytical Batch number is utilized throughout the lab to track the analysis and reporting of this group of samples.

- 13.2 Although most log-in information is maintained electronically on the LIMS, hardcopy of the client Chain of Custody, laboratory receiving check list, and any communication with the client regarding samples or any special instruction associated with a group of samples are maintained in the project file.

14.0 LABORATORY EQUIPMENT

- 14.1 The Oak Ridge Laboratory maintains a wide variety of counting and laboratory equipment. A listing of the laboratory equipment is shown as Attachment 7.

15.0 INTERNAL QUALITY CONTROL

- 15.1 It is the Oak Ridge Laboratory policy to:
- 15.1.1 Use NIST traceable standards
 - 15.1.2 Assign a unique work order number for each group of common matrix samples from a single client.



- 15.1.3 Utilize a tracer or carrier to determine the overall chemical yield for the analytical preparation steps whenever possible or practical. Tracers or carriers will be added to the sample aliquot after grinding but prior to muffling, and counted to achieve relative uncertainties of less than 10% at the 2-sigma level, and to accumulate at least 400 net counts.
- 15.1.4 Include with each work order a laboratory control standard (LCS), method blank (MB), a duplicate (DUP), and in some cases a matrix spike (MS), regardless of the number of samples in the work order.
- 15.1.4.1 QC samples are prepared according to the following criteria:
- Prepared concurrently and in the same manner as the samples
 - Counted with the client samples
 - A true duplicate analysis for Gamma Spectroscopy will be performed when the client's sample size and nature (composition, homogeneity, etc.) allows.
- 15.1.4.2 LCS
- LCS is the same element as the sample analyte, except for gamma spectroscopy LCS.
 - Activity level is at least five times, but not greater than twenty times the RDL. The counting error should not exceed 10% in the counting time required to attain the RDL.
 - For gross alpha/beta analysis, the analytes in the LCS is the same analyte used for the calibration curve.
 - The standard used to prepare the LCS or MS is from a source independent of the standards used for instrument calibration.
 - The LCS is prepared using an aliquot size similar to the sample aliquot.
- 15.1.4.3 MS
- samples are required for samples that do not utilize a tracer or carrier.
 - MS samples are not required for GAGB, gamma, or non-aqueous tritium analyses.
- 15.1.5 Limit the number of common matrix samples in a work order to 16 or 17.
- 15.1.6 List the default laboratory quality control sample acceptance criteria in every analytical procedure.
- 15.1.7 Participate in performance testing programs twice annually.
- DOE MAPEP
 - ERA

16.0 CORRECTIVE ACTION

- 16.1 It is the policy of the Oak Ridge Laboratory to continuously monitor all phases of the operation to ensure compliance with client's project requirements and internal quality control criteria. If a deviation from the established criteria is recognized, immediate action to correct the deficiency prior to data reporting is taken.
- 16.2 Corrective actions taken are documented to:
- 16.2.1 Identify the deviation from the requirement



- 16.2.2 Determine the appropriate corrective action
- 16.2.3 Notify all concerned parties
- 16.2.4 Implement the correction
- 16.3 The project manager is immediately notified if problems are discovered during sample receipt. The client is then notified of the issue. The incident, actions, and resolution are documented in the "Discrepant Sample Receipt Form MP-001-01 (See MP-01, Sample Receiving).
- 16.4 If QA parameters deviate from the client specified and/or internal quality control limits, a re-analysis request is initiated. If reanalysis or recount is not possible, the client is contacted for guidance. Responses to the re-analysis request can include:
 - Re-analyses or re-count of identified samples
 - Re-analysis or re-count of entire work order
 - Notation in Case Narrative of deviations and subsequent course of action.
- 16.4.1 QA parameter failure that may result in a re-analysis include, but are not limited to:
 - QC samples do not meet the RDL
 - LCS outside acceptance range
 - Blank result is greater than two times the combined standard uncertainty (CSU)
- 16.4.2 QA parameter failure that may result in a re-count include, but are not limited to:
 - RDL was not achieved due to inadequate count duration, low detector efficiencies, or high backgrounds.
- 16.4.3 Sample and Analyte-Specific Conditions: Any one of the following are additional conditions that require reanalysis for a particular sample and analyte.
 - If, for any reason, sample or batch QC integrity becomes suspect (e.g. spillage, mis-identification, cross-contamination), all potentially affected samples will be analyzed from a point before that at which the integrity of the came into question. If new batch QC must be prepared for reanalysis, samples for reanalysis shall be restarted at the normal point of initiation for the batch QC.
 - All samples fail the defined criteria for tracers or carriers in Section 16 of the analytical procedures.
 - Samples are analyzed with expired standards.
- 16.5 The reason for the failure and the corresponding action is recorded and maintained within the work order file and reported to the client as part of the final analysis report.
- 16.6 Any deviation beyond those described for immediate action will be addressed in a formal, detailed and investigated Corrective Action Report (MP-044). All Oak Ridge Laboratory staff is authorized to request the initiation of a CAR. Any requested CAR will be investigated and monitored by the QA manager. Such actions may include – but are not limited to procedure revision, training, and assignment of new systems as may be necessary.
- 16.7 If a CAR deals with any client samples, the client will be notified of the CAR, any action, and the final closure in writing as the process progresses.

**17.0 BUSINESS CONDUCT**

- 17.1 It is Eberline Services Company's policy to deliver quality products and services to all customers, Government or private, at fair and reasonable prices. The Company's fiduciary and ethical obligations to customers, employees and the public at large are paramount. The Company has a special obligation to ensure that contracts are administered, and products and services are delivered, in a manner that fully satisfies all legal requirements.
- 17.2 All employees are required to protect company technical data from disclosure to third parties during the course of their employment. "Technical Data" includes trade secrets, proprietary information, computer software, etc.
- 17.3 It is the Oak Ridge Laboratory policy to enforce the company's policy for business conduct and to offer the employees training and written directions regarding the conduct of operation and their ethical obligation during their employment with the company. The employee Code of Safe Conduct and Ethics Training forms are listed in Attachment 8.
- 17.4 Client specific requirements, including DQOs and tracer requirements, are captured during contract negotiations, recorded by the project manager in the project file, and conveyed to the appropriate personnel.

18.0 DATA REVIEW AND REPORTING

- 18.1 Analytical data within the Oak Ridge Laboratory is always referenced to a unique sample identification number. The unique number is assigned to the sample at the time of receiving and is used to track the progress of the sample through the laboratory until reporting of the data. System reviews and multiple tier checks are performed at all levels.
- 18.2 Information related to the sample log in is initiated by the sample custodian, reviewed by the data management group, and finally approved by the data management supervisor before samples are circulated in the laboratory.
- 18.3 At the bench level, analysts review the log in information and the internal Chain of Custody. The laboratory manager or technical director reviews the sample aliquots and assigns the spikes and tracer. In most cases, sample preparation proceeds in two stages, sample dissolution and chromatographic separation. Thus allowing for another tier of review during this process.
- 18.4 Following completion of the preparation, the samples are delivered to the counting room accompanied by the paper trail associated with it since receiving. At the count room, counting technicians perform and document the daily and routine checks of counting equipment prior to counting samples. The count room technician reviews the raw data print out from the instrument and notes any problems.
- 18.5 All raw data together with all analysis information for a specific parameter is reviewed and approved by the count room supervisor. The preliminary data report for these parameters and the data folder goes to the data management group. The hard copy data is reviewed to ensure that all records associated with the analysis of a given parameter are complete. The process is repeated for each parameter. When all parameters requested within a work order are complete, the data is submitted for a technical review.
- 18.6 The technical review process is detailed in MP-022 Analytical Data Review, The technical review will deal with all aspects and documentation of the analytical process. It will also deal with the relationship between the different parameters.
- 18.7 The process of generating a case narrative is detailed in MP-022 Analytical Data Review. The case narrative summarizes the results, any deviations in the analytical process, or any problems with the client samples such as elevated activity, matrix interferences, high suspended solids, multiphase liquids, etc.



- 18.8 A second tier of the technical review is performed, followed by a QA review for all data produced. At the same time, the data management group will review the electronic version of the data against project requirements and against the hard copy.
- 18.9 Form MP-001-4 defines the sequence of the data review process within the Oak Ridge Laboratory. MP-022 lists the criteria for each step of the data review process.
- 18.10 Following the data review process, the final report is printed and the data is authorized for release by the lab manager (or designee). Data is submitted to the client and the original data is maintained on record for a minimum of 5 years. The data retained on file will include all laboratory records regarding:
 - 18.10.1 Sample receipt and internal COC
 - 18.10.2 Records of sample preparation and separation (including weight or volume used for analysis, associated LCS and blanks, type of standard and concentration including certificates)
 - 18.10.3 Records and instrument print out from the counting room
 - 18.10.4 Results of laboratory control samples
 - 18.10.5 Records of review process
 - 18.10.6 Records of authorization to release results
 - 18.10.7 Copy of transmittal letter or case narrative
 - 18.10.8 Records of data transmission both in hard copy and electronically to the client.
- 18.11 If data submitted to the client is changed or modified for any reason, documentation will be included to the file copy to document the reason for the change, the change made and the final authorization and released data.

19.0 TRAINING

- 19.1 It is the Oak Ridge Laboratory policy to provide the time and resources to all employees to ensure that personnel who perform technical functions possess training that is commensurate with the scope and the nature of their activities. Upon hire, employees are offered the company's training in the following areas:
 - 19.1.1 Quality Assurance Program and Procedures
 - 19.1.2 Radiation Protection Plan
 - 19.1.3 Ethical and Legal Responsibilities
 - 19.1.4 Chemical Hygiene/Health and Safety Program
 - 19.1.5 Waste Management Plan
 - 19.1.6 Hazards Communication Program
 - 19.1.7 Personnel Protective Equipment
 - 19.1.8 Analytical process applicable to the assigned analytical procedure
 - 19.1.9 Laboratory Information Management System (LIMS)
- 19.2 Training records are maintained on file in the QA office.
- 19.3 Annual Analyst Demonstration of Capability – the proficiency of each analyst is routinely evaluated to demonstrate their capability of performing the test to which they are assigned. The demonstration is based on the results obtained for the laboratory control samples and performance testing samples analyzed by analysts. A certification statement is issued on each analyst's or work cell's behalf that describes the acceptance criteria. The certification is



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STANDARD OPERATING PROCEDURE

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maintained on file. The minimum acceptable score for general (H&S, Rad, etc.) initial and continuing proficiency testing is 80%. When a trainee does performance does not meet the acceptance criteria, the course of action is remedial training and subsequent retesting.

**20.0 LABORATORY CERTIFICATIONS**

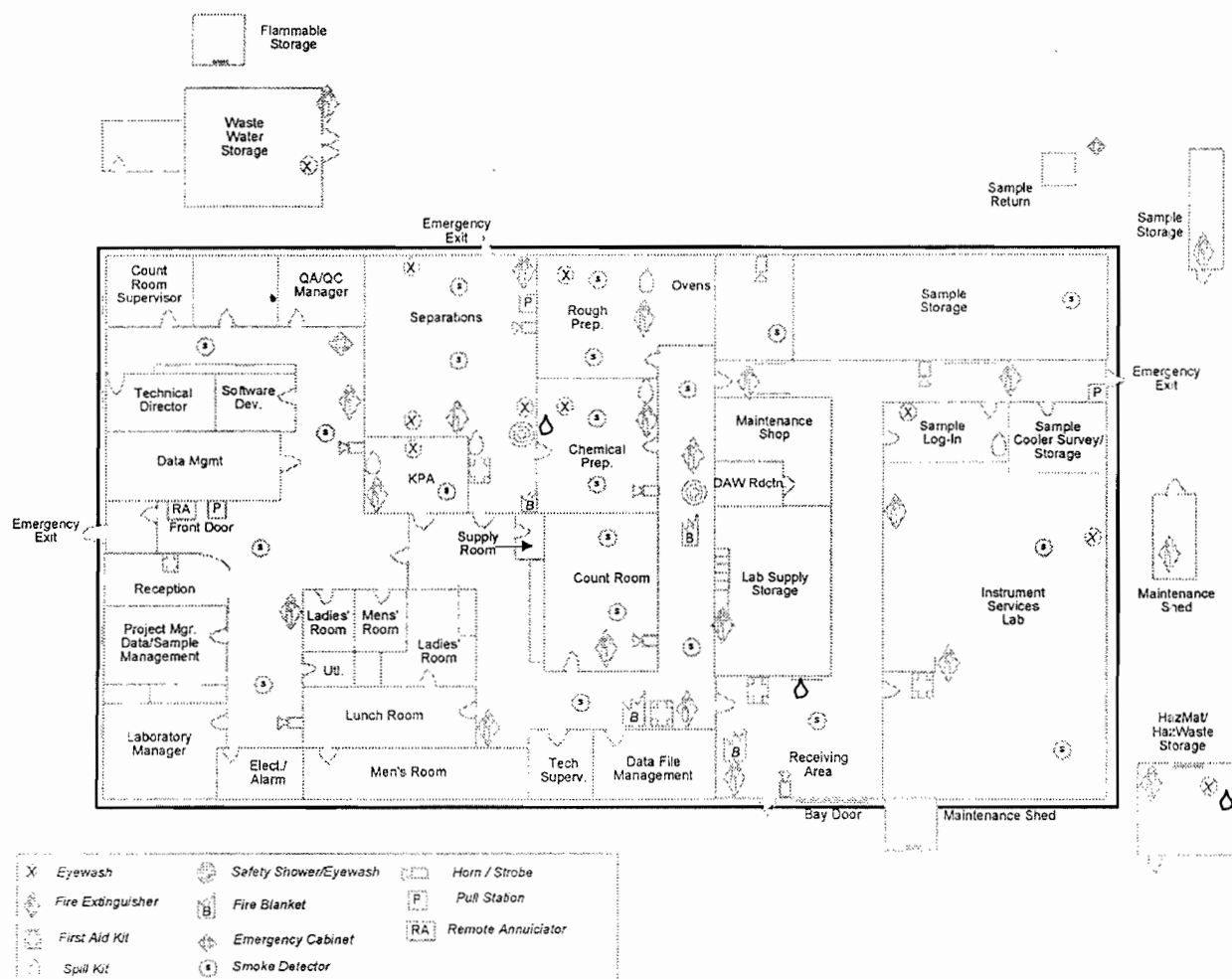
20.1 The following certifications are maintained by the Oak Ridge Laboratory.

1.0 AGENCY	2.0 REMARKS
State of Utah Department of Health Bureau of Laboratory Improvement	Primary NELAC Accrediting Authority
State of New York Department of Health Environmental Lab Approval Program	Secondary NELAC Accrediting Authority
State of California Department of Public Health Environmental Laboratory Accreditation Program Branch	Secondary NELAC Accrediting Authority
State of Texas Texas Commission on Environmental Quality	Secondary NELAC Accrediting Authority
State of New Jersey Department of Environmental Protection Office of Quality Assurance	Secondary NELAC Accrediting Authority
State of South Carolina Dept of Health & Environmental Control Environmental Lab certification Program	State Certification
State of Tennessee Dept of Environment & Conservation, Division of Water Supply	State Certification
State of Nevada Division of Environmental Protection	State Certification
State of North Dakota Department of Health	State Certification

20.2 The Oak Ridge Laboratory also maintains certifications with the US Department of Agriculture, the Department of Energy, and the US Army - Corps of Engineers USACE.



Attachment 1



**Attachment 2****EBERLINE**
SERVICES**Oak Ridge, TN Laboratory**
Employee Job/Task Description**Job Title:** LABORATORY MANAGER**Job Summary:**

A senior staff position reporting to the Vice President. Performs managerial functions related to the operation of the analytical chemistry departments of the laboratory. Routinely handles hazardous materials. Is accountable for safety.

Duties and Responsibilities:

Controls and directs the activities of personnel involved in the laboratory departments. Sets department goals, approves work plans, and develops new procedures to improve efficiency.

Insures adequate throughput to meet business sales and gross profit goals. Assists in the preparation of annual laboratory budget and makes recommendations for staff and capital equipment as well as facility planning. Conducts and supervises the personnel performance review process for the analytical laboratory departments. Develops systems for the improvement of productivity, record keeping, and cost control.

Has responsibility for the technical side of the business. Designs and implements new methods. Implements the Quality Assurance, Safety, and Hazardous Waste Programs and assures proper training and compliance with Standard Operating Procedures in all areas of the laboratory.

Has hiring and termination authority.

Assists the President in special management projects to improve the performance of the laboratory. May substitute for the Vice President in their absence.

Qualifications:

Bachelor's degree in chemistry or other scientific field and five years laboratory experience with at least two years in management. Related work experience may be substituted for formal degree. Requires experience in chemistry lab supervision, technical planning, and project management. Good organizational skills are essential. Understanding of financial, contract, and systems management desirable.

**Attachment 2 continued****EBERLINE**
SERVICES**Oak Ridge, TN Laboratory**

Employee Job/Task Description

Job Title: DEPUTY LABORATORY MANAGER**Job Summary:**

A staff position reporting to the Laboratory Manager. Performs managerial functions related to the operation of the analytical chemistry departments of the laboratory. Routinely handles hazardous materials. Is accountable for safety.

Duties and Responsibilities:

Controls and directs the activities of personnel involved in the laboratory departments. Sets department goals, approves work plans, and develops new procedures to improve efficiency.

Insures adequate throughput to meet business sales and gross profit goals. Assists in the preparation of annual laboratory budget and makes recommendations for staff and capital equipment as well as facility planning. Conducts and supervises the personnel performance review process for the analytical laboratory departments. Develops systems for the improvement of productivity, record keeping, and cost control.

Has responsibility for the technical side of the business. Designs and implements new methods. Implements the Quality Assurance, Safety, and Hazardous Waste Programs and assures proper training and compliance with Standard Operating Procedures in all areas of the laboratory.

Has hiring and termination authority.

Assists the Laboratory Manager in special management projects to improve the performance of the division. May substitute for the Vice President in their absence.

Qualifications:

Bachelor's degree in chemistry or other scientific field and five years laboratory experience with at least two years in management. Related work experience may be substituted for formal degree. Requires experience in chemistry lab supervision, technical planning, and project management. Good organizational skills are essential. Understanding of financial, contract, and systems management desirable.

**Attachment 2 continued****EBERLINE**
SERVICES**Oak Ridge, TN Laboratory**

Employee Job/Task Description

Job Title: TECHNICAL MANAGER**Job Summary:**

A senior staff position reporting directly to the laboratory manager. Performs technical functions and is responsible for technical aspects of the daily operation of the laboratory. Ensures that the highest standards are employed to produce and report quality data to clients.

Duties and Responsibilities:

Executes the duties and responsibilities designated by the laboratory manager. Develops new procedures to improve efficiency and productivity. Makes recommendation for staffing, capital equipment and facility planning. Evaluates technical requirements of business proposals and consults with clients. Makes recommendations regarding analytical schemes, regulations, safety, and quality assurance.

Assists the laboratory manager with the technical responsibilities for the laboratory operation. Leads investigations into technological expansions, modifications, and reorganizations. Performs technical analysis for specific projects when directed. Assists laboratory supervisors and technicians in technical interpretation of programs requirements. Makes recommendations for research and development. Writes technical manuals. Designs systems, procedures, and documentation as necessary. Implements new methods and procedures.

Evaluates the performance of laboratory personnel. Ensures the implementation of the laboratory Quality Assurance program, Health and Safety plan, and the Hazardous Waste Control Program. Ensures proper personnel training and compliance with laboratory Standard Operating Procedures and programs requirements. Ensures clients satisfaction and responds to client concerns and inquiries.

Attends conferences and meetings on behalf of the Company. Keeps abreast of new technology developments.

May substitute for the laboratory manager or another senior staff member in their absence. .

Qualifications:

Bachelor's degree in chemistry, Masters or PhD preferred. Minimum of ten years laboratory experience with at least five years in management. Related work experience may be substituted for formal degree. Requires experience in chemistry laboratory supervision, technical planning, and project management. Must possess knowledge of environmental laws and regulations. Must possess good organizational and communication skills.

**Attachment 2 continued****EBERLINE**
SERVICES**Oak Ridge, TN Laboratory**
Employee Job/Task Description**Job Title:** QUALITY ASSURANCE MANAGER**Job Summary:**

Under minimum supervision of the QA Director or Vice President, is responsible for implementing and maintaining a laboratory Quality Assurance Program. Is accountable for safety.

Duties and Responsibilities:

Maintains and updates quality assurance manuals to ensure they comply with all applicable regulatory requirements. Directs internal audits of the laboratory functions to verify Quality Assurance Manual compliance. Maintains appropriate documentation on required corrective actions and follow-up on compliance efforts. Primary contact for quality assurance audits of the laboratory by outside organizations. Duties also include scheduling and hosting of quality assurance audits.

Schedule, conduct, and follow-up on audits of outside organizations as required. Responsible for record keeping, standard/tracer preparation and documentation of quality control results as required by the quality assurance program.

Responsible for all quality assurance and quality control programs including establishing performance criteria and evaluations.

Qualifications:

Bachelor's degree in science field with three years of experience in an analytical laboratory. Additional experience may be substituted for formal education requirements.

**Attachment 2 continued****EBERLINE**
SERVICES**Oak Ridge, TN Laboratory****Employee Job/Task Description****Job Title:** LABORATORY PROJECT MANAGER**Job Summary:**

Primary contact for clients requesting information on our capabilities including pricing and status of work-in-house. Communicates client requirements to operations groups. Tracks progress of samples through the laboratory and prepared various reports and invoices as necessary. Communicates to sales and marketing departments on leads, successes and failures. Works under moderate supervision of the Laboratory Manager.

Duties and Responsibilities:

Responds to client inquiries with information about services provided in areas of current turnaround times, pricing, sampling information and related matters. Queries clients regarding additional business opportunities. Communicates to Log-In on information about samples submitted for analysis including analysis, methods, detection limits, turnaround times, disposal methods, and various related matters. Tracks progress of samples through the laboratories and communicates any delays or problems to appropriate personnel/clients. Attends status meetings to facilitate interaction with laboratory operations group and clients. Technically reviews orders and contracts for work received. Arranges for subcontract services for client needs that cannot be met by in-house capabilities.

Qualifications:

Bachelor's degree in physical science area or equivalent. Two years laboratory experience in the area of analysis relating to the program management. Experience and knowledge of full range of analytical services. General knowledge of current environmental regulations and the ability to communicate on a professional level with clients required.

**Attachment 2 continued****EBERLINE**
SERVICES**Oak Ridge, TN Laboratory**

Employee Job/Task Description

Job Title: LABORATORY RADIATION SAFETY OFFICER**Job Summary:**

Under minimum supervision of Laboratory Manager, is responsible for implementing and maintaining a Radiation Protection Program. Is accountable for safety.

Duties and Responsibilities:

Ensures that the Radiation Protection Program is promulgated and all personnel are in compliance. Ensures compliance with local, state, and federal regulations. Directs training of new and continuing employees and where applicable, indoctrination of visiting and contracting personnel. Ensures periodic environmental monitoring is performed, if required. Maintains and preserves records required by state and federal regulations. Will take emergency actions as required with notification of proper departments and agencies. Investigates accidents and incidents assuring that all required information is recorded. Assures that radioactive material is stored to maintain dosage ALARA. Maintains radioactive material inventories to verify license limitations are not exceeded. Ensures proper and timely disposal of wastes with records maintained. Maintains a dosimetry program for personnel working with radioactive material ensuring that no individual exceeds the allowable limits. Ensures Radioactive Material License is maintained current. Reviews Program on an annual basis with recommendations to the Laboratory Manager for any changes needed or desired.

Qualifications:

Bachelor's degree in related field or equivalent experience. Successfully complete a Radiation Safety Officer course. Strong written and verbal communication skills and computer literacy.

**Attachment 2 continued**

3.0

Oak Ridge, TN Laboratory

Employee Job/Task Description

Job Title: LABORATORY HEALTH & SAFETY MANAGER**Job Summary:**

A staff position reporting directly to the laboratory manager. Performs functions and duties related to the health and safety and chemical hygiene management aspect of the daily operation of the laboratory. Has responsibility for the laboratory Health and Safety program and staff training. Ensures compliance with OSHA health and safety regulations and requirements.

Duties and Responsibilities:

Executes the duties and responsibilities designated by the laboratory manager. Directs the laboratory Health and Safety program. Develops manuals, procedures, and instructions to ensure the implementation of an effective health and safety program throughout the laboratory.

Manages the Chemical Hygiene Program including receipt, classification, and storage of chemicals. Serves as the Emergency Coordinator. Directs any investigation or corrective recommendations for any accidents involving chemical, radiological, or physical hazards; and files reports with regulatory agencies. Manages the Laboratory Safety Inspection program, the airborne pollutants monitoring program, and the respiratory protection program. Hosts any external inspections, or safety audits.

Maintains knowledge of current Federal, state, and local regulations. Interprets standards, codes, and regulations. Assesses the effectiveness of the laboratory programs and procedures, and implements changes to programs/policies to maintain laboratory compliance. Serves as a resource for chemical, radiological, and general safety and health information to all laboratory employees.. Maintains records of all permits and reports related to the execution and implementation of the health & safety programs.

Develops safety and related regulatory compliance training for the laboratory staff. Enforces the use of personal protective equipment. Updates plans, policies, and other safety information pertaining to the chemical, radiological, and general safety. Performs safety inspections and surveillances. Ensures personnel training and compliance with laboratory safety program requirements

May substitute for the laboratory manager or another senior staff member in their absence. .

Qualifications:

Bachelor's degree in chemistry, industrial hygiene, environmental health and safety or other related science; a minimum of five years experience with laboratory safety programs. Related work experience may be substituted for formal degree. Requires experience with chemistry laboratory operation. Must have knowledge of OSHA, and environmental laws and regulations. Must possess good interpersonal relations, organizational and communication skills.

**Attachment 2 continued****EBERLINE**
SERVICES**Oak Ridge, TN Laboratory**

Employee Job/Task Description

Job Title: LABORATORY INFORMATION TECHNICAL SUPPORT**Job Summary:**

In collaboration with technical staff, and under the direction of the Laboratory Manager, performs systems, network, help desk, and database administration.

Duties and Responsibilities:

Installs new software releases, system upgrades, evaluates and installs patches and resolves software related problems. Administrator performs system backups and recovery and maintains data files and monitors system configuration to ensure data integrity.

Installs, configures and maintains organization's network. Administrator builds networks and maintains external and internal web presence, administers the networks and performs systems backups on its internal and external web network servers. Designs and supports server system(s) and supporting software.

Provides support to end users on a variety of issues. Administrator identifies, researches, and resolves technical problems and responds to telephone calls, e-mail and personnel requests for technical support. Documents, tracks, and monitors the problem to ensure a timely resolution.

Administers, maintains, develops and implements policies and procedures for ensuring the security and integrity of the company database. Administrator implements data models and database designs, data access and table maintenance codes; resolves database performance issues, database capacity issues, replication and other distributed data issues.

Qualifications:

Associate's degree in Information Technology or other IT/IS related field. Related training or work experience may be substituted for formal degree. Good organizational skills are essential.

**Attachment 2 continued**

4.0

Oak Ridge, TN Laboratory**Employee Job/Task Description****Job Title:** DATA REVIEW SPECIALIST**Job Summary:**

A staff position reporting directly to the laboratory manager. Performs technical functions and is responsible for final technical review, evaluation, and the final approval of the laboratory data. Ensures that the highest standards have been employed to produce and report data to clients.

Duties and Responsibilities:

Executes the duties and responsibilities designated by the laboratory manager. Ensures staff adherence to procedures and protocols necessary to improve productivity and quality. Evaluates technical requirements of clients' proposals and contracts. Makes recommendations regarding analytical schemes, regulations, and quality assurance.

Assists the laboratory manager with the technical responsibilities for the final approval of laboratory data prior to reporting to clients. Provides technical lead for specific projects or investigations when directed. Assists laboratory supervisors and technicians in technical interpretation of programs' requirements. Writes technical manuals, procedures, and documentation as necessary.

Reviews and ensures correctness and documentation of all phases and aspects of the analyses within a laboratory work order. Reviews technicians' notes and count room raw data. Evaluates the analysis report data for completeness and adherence to client requirements and laboratory quality control limits. Drafts case narrative reports and interacts with the data management staff for completion.

Keeps abreast of new technology developments.

May substitute for the project manager or another staff member in their absence. .

Qualifications:

Bachelor's degree in chemistry, Masters preferred. Minimum of ten years laboratory experience with at least five years in a radiochemistry laboratory. Related work experience may be substituted for formal degree. Requires experience in a chemistry, technical planning, project management and radiological counting techniques and instruments. Must possess knowledge of environmental laws and regulations. Must possess good organizational and communication skills.

**Attachment 2 continued****EBERLINE**
SERVICES**Oak Ridge, TN Laboratory****Employee Job/Task Description****Job Title:** LABORATORY SUPERVISOR**Job Summary:**

Directs the planning, coordination, and direction of the operations to meet holding times and provide data of appropriate quality. Works under minimum supervision and provides work direction and training to assigned personnel. Requires advanced knowledge and understanding of operational functions and management procedures, environmental regulations and laboratory procedures. Establishes schedules and supervises assigned personnel. Is accountable for safety and ensures assigned personnel are accountable for safety. Reports directly to Lab Manager, or other management as assigned. Handles hazardous materials.

Duties and Responsibilities:

Has an advanced understanding of department operational functions. Provides work direction and training to assigned personnel. Assists manager(s) in hiring of personnel, organization and coordination of assigned staff, daily and long-term operational planning, and purchasing of supplies. Independently plans and accomplishes complete projects of broad scope and complexity. Ensures compliance with all applicable safety requirements. Processes hazardous materials as required.

Coordinates and maintains communication among groups within the company. Exhibits technical guidance, leadership, and motivation. Implements standards of conduct and professionalism for assigned personnel. Routinely inform managers of status of workflow, personnel performance, and other matters as assigned. Reviews analytical work for integrity of data and compliance with quality standards.

Responsible for proper operation and maintenance of equipment, development and documentation of procedures, and compliance with environmental regulations and laboratory procedures. Communicates information on laboratory performance status results.

Qualifications:

Bachelor's degree in physical science area, chemistry, or related field. Work experience may be substituted for a college degree. Five years experience and extensive knowledge of the full range of analytical services. Strong knowledge of environmental regulations and the ability to communicate on a professional level. May require other technical training as assigned.

**Attachment 2 continued****EBERLINE**
SERVICES**Oak Ridge, TN Laboratory**

Employee Job/Task Description

Job Title: COUNTING ROOM SUPERVISOR**Job Summary:**

Directs the planning, coordination, and direction of the count room operations to provide data of appropriate quality. Works under minimum supervision and provides work direction and training to assigned personnel. Requires advanced knowledge and understanding of count room operations and management procedures. Establishes schedules and supervises assigned personnel. Is accountable for safety and ensures assigned personnel are accountable for safety. Reports directly to the Deputy Lab Manager, or other management as assigned.

Duties and Responsibilities:

Has an advanced understanding of department operational functions. Provides work direction and training to assigned personnel. Assists manager(s) in hiring of personnel, organization and coordination of assigned staff, daily and long-term operational planning, and purchasing of supplies. Independently plans and accomplishes complete projects of broad scope and complexity. Ensures compliance with all applicable safety requirements.

Exhibits technical guidance, leadership, and motivation. Implements standards of conduct and professionalism for assigned personnel. Routinely inform managers of workflow status, personnel performance, and other matters as assigned. Reviews analytical work for data integrity and compliance with quality standards.

Responsible for proper operation and maintenance of counting equipment, development and documentation of counting procedures, and compliance with environmental regulations.

Qualifications:

Bachelor's degree in physical science area, electronics, or related field. Work experience may be substituted for a college degree. Five years experience and extensive knowledge of the full range of count room operations. Strong computer skills and the ability to communicate on a professional level. May require other technical training as assigned.

**Attachment 2 continued****EBERLINE**
SERVICES**Oak Ridge, TN Laboratory**

Employee Job/Task Description

Job Title: COUNT ROOM TECHNICIAN**Job Summary:**

Position assignments reporting directly to the count room supervisor. Responsible for all aspects of count room operation, instrument maintenance, and handling of radioactive samples and standards. Performs routine computer data entry of sample analysis information with a high degree of accuracy. Able to interact with other technicians to meet client's schedule and laboratory turn around time. Maintains documentation for location of samples and laboratory data information.

Duties and Responsibilities:

Executes the duties and responsibilities designated by the count room supervisor. Interacts with laboratory personnel to prioritize count schedule. Informs management of any problems or issues associated with counting. Follows counting procedures. Complies with all applicable safety and QA requirements.

Receives and reviews laboratory analysis assignments / count room aliquot information. Receives samples from laboratory technicians and initiates internal chain of custody. After receipt, logs-in samples and sorts appropriately. Determines counting equipment and procedures for use in accordance with the counting procedures and/or specific instructions issued by the count room supervisor.

Prepares data for entry into computer and/or calculation. Operates and maintains appropriate computer equipment in order to process instrument quality control data following quality control tests and procedures.

Maintains related files and performs minor maintenance on detector equipment as requested. Maintains laboratory supplies necessary for the performance of the Counting room operation. Performs other related duties as assigned or directed. Works under moderate supervision following written procedures. Maintains internal chain of custody and ensures the return of samples to their appropriate location in the sample storage area.

Must adhere to all laboratory policies and procedures regarding safety, ethics, and QA requirements. Responsible for all facilities and equipment used within the laboratory

Qualifications:

Associate degree in chemistry or related science. Related work experience may be substituted for formal degree. Knowledge of basic computer operations required. Knowledge of radiation safety. Ability to work independently and follow written and verbal instructions with a high degree of accuracy

**Attachment 2 continued****EBERLINE**
SERVICES**Oak Ridge, TN Laboratory**

Employee Job/Task Description

Job Title: LABORATORY TECHNICIAN**Job Summary:**

Under moderate supervision of a Laboratory Supervisor, performs a variety of chemical laboratory tests and analyses applying standard formulas and routine procedures. Is accountable for safety. Routinely handles hazardous materials.

Duties and Responsibilities:

Using routine chemical procedures performs qualitative and quantitative radiochemical analysis of materials, operating a variety of laboratory equipment. Performs a wide variety of analytical procedures including sample preparation, dissolution, and purification such as distillations, extractions, and precipitations. Works under moderate supervision following written procedures. Complies with all applicable safety requirements. Processes hazardous materials as required.

Qualifications:

High school graduate with two years of college level chemistry or equivalent. Familiarity with wet chemistry techniques and apparatus required.

**Attachment 2 continued****EBERLINE**
SERVICES**Oak Ridge, TN Laboratory****Employee Job/Task Description****Job Title:** LABORATORY WASTE MANAGEMENT & TRANSPORTATION**Job Summary:**

A staff position reporting directly to the laboratory manager. Performs functions and duties related to the management of the laboratory waste on daily basis. Has responsibility for the definition, classification, segregation, and disposal of laboratory waste. Responsible for training employee on the safe handling of waste. Ensures compliance with EPA, DOT, and OSHA health and safety regulations and requirements.

Duties and Responsibilities:

Executes the duties and responsibilities designated by the laboratory manager. Directs the laboratory Waste Management program. Develops manuals, procedures, and instructions to ensure the implementation of an effective Waste Management program throughout the laboratory.

Manages the laboratory waste management program including the definition, classification, collection, segregation, storage, treatment, and disposal of all laboratory-generated waste. Serves as the Emergency Coordinator. Directs any investigation or corrective recommendations for any accidents involving chemical or radiological waste; and files reports with regulatory agencies as may be required. Manages the Laboratory waste storage inspections. Hosts any external inspections, or audits.

Maintains knowledge of current Federal, state, and local regulations. Interprets standards, codes, and regulations. Assesses the effectiveness of the laboratory programs and procedures, and implements changes to programs/policies to maintain laboratory compliance. Serves as a resource for laboratory employees.. Maintains records of all permits and reports related to the collection, treatment, shipping and disposal of laboratory waste

Develops regulatory compliance training for the laboratory staff. Assists the laboratory Health and Safety Manager in enforcing the Health and Safety practices, procedures, and programs.

Qualifications:

Bachelor's degree in chemistry, industrial hygiene, environmental health and safety or other related science; a minimum of five years experience with laboratory safety programs or waste management. Related work experience may be substituted for formal degree. Must have knowledge of OSHA, environmental laws and regulations, and DOT regulation. Must possess good interpersonal relations, organizational and communication skills.

**EBERLINE**
SERVICES

Oak Ridge, TN Laboratory

Employee Job/Task Description

Job Title: SAMPLE CONTROL TECHNICIAN

Job Summary:

Position reporting directly to the Senior Project manager. Responsible for all aspects of sample custody. Performs routine computer data entry of sample control information with a high degree of accuracy. Able to interact with technicians to maintain complete documentation for location of samples and laboratory data information. Works under minimum supervision and interacts with clients and the laboratory management to resolve problems with sample receiving. .

Duties and Responsibilities:

Executes the duties and responsibilities designated by the laboratory manager. Receives, inspects, and performs initial radiological screening on samples received for analysis. Acknowledges receipt of all samples on Chain-of-Custody documentation as required. Informs laboratory project manager of any discrepancies encountered with any received samples; Assists project manager in contacting clients; ensures resolution of problems; and maintains records of discrepancies and resolution.

Logs samples into Laboratory Information Management System (LIMS). Prepares and accurately applies labels for samples received to be analyzed. When necessary, inspects pH of samples and preserves samples as prescribed by the sample control procedures. Notifies management and appropriate lab personnel of samples received under a RUSH status. Stores samples in designated locations as necessary. Complies with all applicable safety requirements.

Initiates inventory of samples in-house to determine archival and disposal schedules. Packages samples for return to clients.

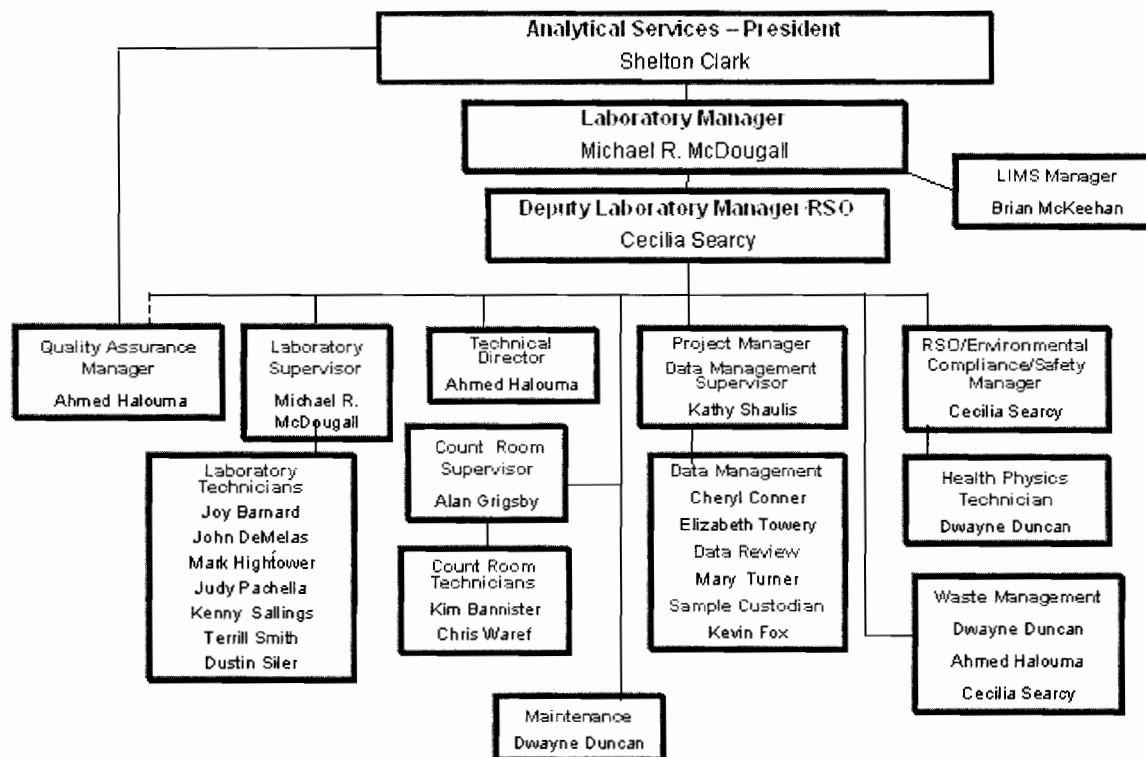
Qualifications:

Associate degree in chemistry or related science. Related work experience may be substituted for formal degree. Strong knowledge of basic sample handling techniques and procedures. Strong knowledge of basic computer operations required. Knowledge of radiation safety. Ability to work independently and follow written and verbal instructions with a high degree of accuracy.



Attachment 3

**Eberline Services
Oak Ridge Laboratory Organizational Chart**



October 9, 2008



Quality Systems Implementation Plan

Attachment 4

Title:

[illegible]

**Attachment 4 continued****Date:** _____**ACKNOWLEDGEMENT****CONTROLLED DOCUMENT RECEIPT****Quality Assurance Control Number** _____

Attached is your copy of the following document(s):

<u>Document Title</u>	<u>Rev No.</u>	<u>Rev Date</u>	<u>Copy No</u>
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Please make the necessary deletions and insertions. Do not return the superseded pages or document(s). Process them in accordance to your document control procedures

The documents assigned to you are the property of Eberline Services – Oak Ridge Laboratory and are furnished with the understanding that the information within will be held in confidence and will not be duplicated, used, or disclosed either in whole or in part without the written permission of Eberline Services - Oak Ridge Laboratory Manager.

To ensure receiving future revisions of this document, please sign this form and return it to the QA Department at Eberline Services – Oak Ridge Laboratory

ACKNOWLEDGEMENT

I have received the above listed document(s). All superseded record of this document(s) has been destroyed, removed from files, or marked OBSOLETE.

Acknowledged by:**Name:** _____**Title:** _____**Company Name:** _____**Address:** _____

_____**Signature:** _____**Date:** _____**Attachment 5**

Copy No. _____

Radiochemical Services

**Attachment 5****TABLE OF CONTENTS**

AP	Rev.	Title
001	13	SAMPLE PREPARATION (I): PRE-CHEMISTRY
002	14	SAMPLE PREPARATION (II):DIGESTION FOR CHEMICAL SEPARATIONS
003	4	RADIUM-226 IN WATER RADON EMANATION TECHNIQUE
004	12	DETERMINATION OF GROSS ALPHA AND/OR BETA ACTIVITY
005	13	ALPHA ISOTOPIC ANALYSES
006	10	RADIUM - 226 ANALYSIS
007	15	RADIUM - 228 ANALYSIS
008	13	TOTAL URANIUM ANALYSIS BY KINETIC PHOSPHORESCENCE ANALYZER
009	7	TOTAL ACTIVITY SCREENING
010	7	NEPTUNIUM-237 ANALYSIS BY EICHROM RESIN SEPARATION
011	12	OPERATION OF THE GAMMA SPECTROSCOPY SYSTEM
012	10	TRITIUM ANALYSIS OF SOIL SAMPLES
013	11	TRITIUM ANALYSIS OF AQUEOUS SAMPLES
014	5	AMERICIUM AND CURIUM ANALYSIS BY EICHROM RESIN SEPARATION
015	4	RADIUM-226/228 BY EICHROM CHEMICAL SEPARATION
016	4	ANALYSIS OF CHLORINE-36 IN WATER & SOIL SAMPLES BY SILVER CHLORIDE CO-PRECIPIATION AND GAS PROPORTIONAL COUNTING
017		NOT IN USE
018	12	OPERATION OF THE ALPHA SPECTROSCOPY SYSTEM
019		NOT IN USE
020	11	CHEMICAL PREPATAION FOR LEAD-210
021	10	LEAD-210 ANALYSIS
022		NOTE IN USE
023	9	OPERATION OF THE PACKARD 3100 BETA LIQUID SCINTILLATION COUNTING SYSTEM
024		NOT IN USE
025	10	ANALYSIS OF POLONIUM - 210
026	11	ANALYSIS OF CARBON - 14 IN WATER
027	6	CARBON-14 AND TRITIUM IN SOILS, SOLIDS, AND BIOLOGICAL SAMPLES: HARVEY OXIDIZER METHOD
028		NOT IN USE
029	12	OPERATION OF THE LB4100 ALPHA/BETA COUNTING SYSTEM
030	11	DETERMINATION OF SELF ABSORPTION FACTORS AND GENERATION OF QUENCH CURVES
031	9	ANALYSIS OF PROMETHIUM-147
032		NOT IN USE
033		NOT IN USE
034		NOT IN USE
035		NOT IN USE
036	11	STRONTIUM 89/90 AND TOTAL STRONTIUM
037	9	ANALYSIS OF TECHNETIUM - 99 BY EICHROM® RESIN SEPARATION
038	9	TOTAL RADIUM BY GROSS ALPHA COUNTINGF
039		NOT IN USE
040	9	NICKEL - 59 AND NICKEL - 63 DETERMINATION
041	10	ANALYSIS OF IODINE - 129 IN WATER SAMPLES
042	9	DETERMINATION OF IRON - 55

**Attachment 6****TABLE OF CONTENTS**

MP	REV.	TITLE
001	11	SAMPLE RECEIVING
002	3	SHIPPING PLAN
003	5	LABORATORY INFORMATION MANAGEMENT SYSTEM (LIMS)
004		NOT IN USE
005		NOT IN USE
006		NOT IN USE
007		NOT IN USE
008		NOT IN USE
009	12	RADIOACTIVE REFERENCE STANDARD SOLUTIONS AND RECORDS
010	6	BALANCE CALIBRATION CHECKS
011	8	CONTROL, RETENTION, AND DISPOSAL OF QUALITY ASSURANCE RECORDS
012	10	GLASSWARE WASHING AND STORAGE
013		NOT IN USE
014	7	BUILDING SECURITY
015	6	DATA PACKAGE ASSEMBLY AND GENERATION OF ELECTRONIC DELIVERABLE
016		NOT IN USE
017		NOT IN USE
018	7	SEGREGATION OF OUT-OF-TOLERANCE INSTRUMENTS
019	7	CALIBRATION AND OPERATION OF PH METER
020	7	OPERATION AND MAINTENANCE OF DEIONIZED AND NANOPURE WATER SYSTEMS
021	7	PREPARATION AND MODIFICATION OF TECHNICAL AND PROJECT QUALITY ASSURANCE DOCUMENTS
022	8	ANALYTICAL DATA REVIEW
023	8	DOCUMENTATION OF ANALYTICAL LABORATORY LOGBOOKS
024		NOT IN USE
025	6	USE AND MAINTENANCE OF MECHANICAL PIPETTOR
026	7	DEIONIZED WATER BACK-UP CHECK
027	8	SOFTWARE CONTROL AND SECURITY
028	10	ANALYTICAL METHOD VERIFICATION
029		NOT IN USE
030	7	QUALITY SYSTEMS IMPLEMENTATION PLAN
031	2	REAGENT TRACKING
032	2	INQUIRY TRACKING
033	2	PROUREMENT OF QUALITY RELATED ITEMS/SERVICES
034		RESERVED FOR QUALITY SYSTEMS
035		RESERVED FOR QUALITY SYSTEMS
036		RESERVED FOR QUALITY SYSTEMS
037		RESERVED FOR QUALITY SYSTEMS
038		RESERVED FOR QUALITY SYSTEMS
039		RESERVED FOR QUALITY SYSTEMS
040		NOT IN USE
041	3	QUALITY ASSURANCE AUDITS
042	3	PERSONNEL TRAINING
043	2	DATA INTEGRITY
044	2	CORRECTIVE ACTION
045	2	QUALIFICATION OF QUALITY ASSURANCE PROGRAM AUDIT PERSONNEL
046	3	STORAGE AND RETRIEVAL OF LABORATORY RECORDS

**Attachment 7**

Eberline Services – Oak Ridge Laboratory Instrumentation

No Each	INSTRUMENT	DATE INSTALLED
ALPHA SPECTROMETERS		
2	Canberra Alpha Spectroscopy System, VAX	6/99
16	Canberra (Model 7401) Alpha Spectroscopy Chambers	5/95
16	Tennelec (Model TC-256) Alpha Spectroscopy Chambers	1/92
16	Canberra (Model Alpha Analyst) Alpha Spectroscopy Chambers	7/02
GAMMA DETECTORS		
2	Canberra Gamma Spectroscopy System, VAX	6/99
1	Canberra HPGe Gamma Spec. Detector (GE-1, Model: GR 4020; Serial #: 8006161)	9/00
1	Canberra HPGe Gamma Spec. Detector, Type N (GE-2; Model: GR3521; Serial #: 3006147)	3/00
1	Oxford HPGe Gamma Spec. Detector, Type N (GE-3; Model: CNVDS30-40195; Serial # 2393)	2/92
1	Oxford HPGe Gamma Spec. Detector, Type P (GE-4; Model: CNVDS30-20190D; Serial #: 3001)	7/92
1	Canberra HPGe Gamma Spec. Detector, LEPS (GE-5; Model: GL2020R; Serial #: 12964309)	2/98
GAS PROPORTIONAL COUNTERS		
1	Tennelec LB-5100 Gas Proportional Counters (Model #: LB5100-W, Serial #: 22201)	1/92
1	Tennelec LB-5100 Gas Proportional Counters (Model #: LB5130A, Serial #: 646 Rev. 4)	5/96
2	Tennelec LB-4110-W 16 Place GPC with 2 controllers (Serial #: 42414; Controller #1 SN: 141; Controller 2 SN: 138)	8/99
LIQUID SCINTILLATION COUNTERS		
2	Canberra 3100 Beta LSC Packard 3100 Tri Crab, Model CP-10/115, Serial#: 426825 and 427086)	6/01 and 6/06
HARVEY OXIDIZER		
1	R. J. Harvey Instrument Corporation OX-700, SN 04028A	10/2004
KINETIC PHOSPHORESCENCE ANALYZER		
1	ChemChek KPA – 11	8/91
1	Upgraded Laser, Electronic, and Operating System	5/00
1	Mettler Analytical Balance AB204-S	8/02
1	Mettler Analytical Balance	8/98
1	Denver Analytical Balance	6/98
1	Denver Analytical Balance	9/94
1	Sartorius Analytical Balance	2/92
2	Bico Pulverizers	2/92 & 8/96
1	Bico Jaw Crusher	2/92
1	Whiley Laboratory Mill No.4	2/92

Various other laboratory equipment as required such as fume hoods, apparatus and associated material.

**Attachment 8**

Oak Ridge Laboratory

CODE OF SAFE PRACTICES

The policy at the Oak Ridge Laboratory is to do everything possible to protect employees, clients, visitors, and sub-contractors from accidents and injuries. Safety is a cooperative undertaking, requiring participation by every employee. Failure by any employee to comply with the safety rules will be grounds for corrective discipline. Supervisors shall insist that employees observe all applicable Company, State, and Federal safety rules and practices and take any action that is necessary to ensure compliance.

To carry out this policy, each employee shall:

1. Report all unsafe conditions to your supervisor or to the Health & Safety Director.
2. Report all accidents, near accidents, injuries, and illnesses to your supervisor and to the Health & Safety Director immediately.
3. Wear eye protection at all times while in the chemistry laboratory or where chemicals are stored and handled.
4. Not wear contact lenses in the laboratory.
5. Wear protective gloves when working in the chemistry laboratory.
6. Wear buttoned-up lab coats when working in the chemistry laboratory.
7. Confine long hair and loose clothing when in the chemistry laboratory.
8. Avoid startling or distracting another worker. Practical jokes or horseplay will not be tolerated at any time. *Horseplay in the chemistry laboratory is grounds for immediate dismissal.*
9. Not use mouth suction to pipette chemicals or to start a siphon; a pipette bulb or an aspirator should be used to provide the vacuum.
10. Not store, prepare, or consume food or beverages in the chemistry laboratory areas.
11. Not use laboratory glassware for food or beverage containers.
12. Not smoke in any area of the laboratory.
13. Turn off all services, such as water, electricity, compressed gas, and vacuum, when not in use.
14. Not wear any foot coverings with exposed toes when working with or handling chemicals.
15. Be familiar with the location and operation of all safety equipment.
16. Be familiar with the Emergency Action/Evacuation Procedure.
17. Maintain good housekeeping in the laboratory areas including clear 24" walkways. Maintain emergency shower, eyewash fountain, electrical panel, and fire extinguisher locations clear of obstructions.
18. Maintain work area clean and orderly. Trash and refuse are to be thrown into the proper containers.
19. Clean up all spills immediately.
20. Always use the proper lifting technique. Never attempt to lift or push an object that is too heavy. Contact your supervisor when help is needed to move a heavy object.
21. When use of a fume hood is required, it shall be used in the high speed operating position to meet state required airflow.
22. If assigned a TLD, wear it while in the laboratory; leave it in its proper location when leaving the laboratory.
23. Arrange for periodic crosschecks with another individual when working alone in the chemistry laboratory.
24. Limit stocks of chemicals in the chemistry laboratory to those needed for the operations being performed; avoid surplus.
25. Dispose of waste chemicals properly, do not let them accumulate. Rinse and mark empty containers and dispose of them in a timely manner.
26. Be familiar with the Health and Safety Manual for Laboratories, the Corporate Safety Procedures Manual, the Laboratory Safety Procedures Manual, and the Laboratory Chemical Hygiene Plan.
27. Think, act, and encourage safety until it becomes a habit.

**Attachment 8 continued****ETHICAL AND LEGAL RESPONSIBILITIES, Directive**

The dictionary defines ethics as "the principles of right conduct" and/or "the study of standards of conduct and moral judgment." It defines legal as "permitted by or in conformity with the law."

Permanent and temporary personnel in the Eberline Services Analytical Services Group organization (hereafter called the Company) are charged with ethical and legal responsibilities. These responsibilities are outlined in the Company's Policies and Procedures Manual that all personnel receive and agree to comply with when becoming an employee of the Company. The policy is emphasized in the Quality Assurance Program Manual with the statement "our basic policies dictate the highest standards of ethics and integrity in the conduct of our affairs." Additionally, the manual states that management "will vigorously enforce this policy and will take prompt and appropriate action, including termination, against any officer or employee found to be in violation."

All personnel in the Company must be dedicated to the highest standard of ethical and legal behavior. The employee's ethical and legal behavior, including a dedication to integrity and honesty, are critically important to the Company and behavior outside of the highest possible standards of conduct is unacceptable.

The Company depends on the honesty and integrity of each and every employee within the organization. No acceptable reason exists for any unethical or illegal practice within any part of the organization. Clients for whom the Company performs services can hold not only the organization, but also the particular individual, legally liable for unethical or illegal behavior. Numerous examples now exist within the environmental testing market place where individuals have been fined thousands of dollars and sentenced to extended prison terms for unethical or illegal behavior. This type of behavior has also caused companies to be fined, subjected to contract suspensions, and bidding restrictions.

Department, by the Company's employees, demonstrating the highest level of personal ethics, along with quality assurance, personal safety, customer service, and attainment of production objectives will assure our capability to deliver the highest quality analytical services in a timely manner and allow the Company to achieve business excellence.

To this end, each employee must understand the high standards of ethics and integrity required in the performance of his/her duties and in the data they report in connection with employment. No employee shall intentionally report data that are not the actual values obtained, report the dates and/or times of data analyses that are not the actual dates and/or times of data analyses, nor represent another individual's work as their own. Each employee shall and must inform the Q.A. Manager and the Laboratory Manager of any operational events inconsistent with policy or procedure, or accidental reporting of authentic data by themselves in a timely manner. Furthermore, each employee shall and must inform the Q.A. Manager and the Laboratory Manager of any accidental or intentional reporting of non-authentic data or any operational events inconsistent with policy or procedure by other employee(s).

To protect the rights of all employees and to enhance the successful operation of the Company, certain rules and regulations applicable to all personnel are listed on the next page. These are examples of common offenses that may result in disciplinary action up to and including discharge, depending on the circumstances. Since it is impractical to predict all possible types of improper conduct or various combinations of rule infractions, the Company reserves the right to treat any offense according to the individual circumstances and specify the appropriate disciplinary action.

**Attachment 8 continued****EXAMPLES OF COMMON OFFENCES**

- | | |
|--|---|
| <ol style="list-style-type: none">1. Intentional falsification of procedural operation, procedure data, or analytical reports2. Divulging confidential or proprietary information to unauthorized individuals.3. Intentional representation of an others work as ones own.4. Excessive absenteeism.5. Frequent tardiness or abuse of break time (three or more times within thirty days).6. Leaving the plant or assigned job during working hours without supervisor's approval.7. Being absent from work without authorization8. Selling tickets, soliciting contributions, distributing or posting handbills, notices, or other written matter on company property without prior approval of the company.9. Failure to report breakage of tools; careless workmanship, negligence resulting in excessive scrap or tool breakage, or abuse or waste of materials.10. Failure to observe instructions, written or oral.11. Unauthorized operating of machines, tools, or equipment, or tampering with same, or performing personal work on Company time.12. Creating or contributing to unsanitary conditions.13. Threatening, intimidating, coercing (including by abusive language) or interfering with other employees, visitors, or supervisors.14. Making false or malicious statements concerning any employee, the company, or its products.15. Incompetent or below standard performance. | <ol style="list-style-type: none">16. Failure to report work-incurred injuries promptly to supervisor or other Company official in supervisor's absence.17. Violating and/or disregarding safety rules and common safety practices or contributing to unsafe conditions.18. Fighting on Company property.19. Reporting to work under the influence of narcotics, marijuana, or alcohol.20. Consuming or possessing, on Company property, alcoholic beverages, narcotics, or other items that could impair an employee's work performance.21. Willful damage or destruction of Company property or the property of others.22. Gross insubordination, deliberate disregard of instructions, or refusal to carry out orders or to do job assignments given by an employee's supervisor.23. Possession or bringing firearms, explosives, or weapons of any kind on Company property.24. Intentional falsification of personal records, time cards, or other company records, or withholding of material facts from application or otherwise in securing employment.25. Divulging information from personnel, payroll, or other official records of the company without Company authorization.26. Willfully hindering or limiting production or participating in any production slowdown, stoppage, or strike in violation of any labor agreement.27. Theft or attempted theft of Company property. |
|--|---|

I have read, understand, and agree to comply with the Eberline Services, Analytical Services Group's Ethical and Legal Responsibilities directive. I also understand that the potential punishment and penalties for improper, unethical, or



EBERLINE
SERVICES

STANDARD OPERATING PROCEDURE

Quality Systems Implementation Plan

MP-030, Rev. 7

Effective: 10/31/09

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illegal actions could include job termination and legal action.

Printed Name _____

Signature _____

Date

Copy No. _____

Radiochemical Services