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DATACHEM LABORATORIES
ENVIRONMENTAL CHEMISTRY
QUALITY ASSURANCE
PROGRAM PLAN

QA-2/83

Revised 8/91

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LEADING ANALYTICAL CHEMISTRY INTO THE 21ST CENTURY™

DATACHEM LABORATORIES
ENVIRONMENTAL CHEMISTRY
QUALITY ASSURANCE
PROGRAM PLAN

QA-2/83

Revised 8/91

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ENVIRONMENTAL CHEMISTRY
QUALITY ASSURANCE PROGRAM PLAN
REVISION CONTROL LOG

Revision No.	Revision Date	Affected Pages	Document Control No.	Description of Change
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1.0 QUALITY ASSURANCE PROGRAM PLAN IDENTIFICATION FORM AND POLICY

Document Title:	DataChem Laboratories Environmental Chemistry Quality Assurance Program Plan
Document Control Number:	QA-2/83
Organization Title:	DataChem Laboratories
Address:	DataChem Laboratories 960 West LeVoy Drive Salt Lake City, Utah 84123
Director:	James H. Nelson, Ph.D. Phone Number: 801-266-7700
Quality Assurance Manager:	Ronald H. Marsden, B.S. Phone Number 801-266-7700

Plan Coverage: This document describes DataChem Laboratories' (DCL) Quality Assurance Program Plan. The Plan addresses environmental data generated and processed by DCL from the analysis of environmental samples. The Plan applies to data derived from the analysis of air, drinking water, groundwater, surface water, wastewater, soil, sludge, sediment, solid and hazardous wastes, toxic substances, and other matrices.

QUALITY ASSURANCE POLICY

It is the policy of DCL that the analytical aspects of all environmental data generated and processed in the laboratory, subject to EPA, DOE or other project specific requirements, be of known and acceptable quality. It is the intention of this Program to establish and assure that an effective quality controlled management system is maintained in order to meet the quality requirements of the intended use(s) of data.

This Program Plan is designed, at a minimum to satisfy the applicable requirements of the ANSI/ASME NQA-1 Standard.

This quality assurance policy and the Program described herein, has the commitment and support of DataChem Laboratories corporation and management.

CONCURRENCES:

By: Ronald H. Marsden Date: 8/30/91
Ronald H. Marsden, B.S.
Quality Assurance Manager

Approval for Implementation:

By: James H. Nelson Date: 9-9-91
James H. Nelson, Ph.D.
President and Laboratory Director
DataChem Laboratories

2.0 INTRODUCTION

2.1 Purpose

The Environmental analyses component of DCL provides services to clients that are unique to the laboratory. It is the purpose of this program to describe the specific aspects of quality assurance as it pertains to environmental analyses. In addition, this program has been written to meet the general requirements of the United States Department of Energy and the United States Environmental Protection Agency.

2.2 Applicability and Scope

The quality assurance program plan presented in this document is applicable to environmental data generated and processed at DCL and serves to assure that such data meets users' requirements in terms of accuracy, precision, completeness, and comparability.

This program is designed to meet analytical and documentation requirements, including litigation requirements, chain-of-custody procedures, QA of computer related activities, document control procedures and noncompliance activities. The program outlines the purpose, organization, objectives, and operations established to support environmental analyses conducted at DataChem Laboratories. Since DCL is primarily responsible for only the analysis of environmental samples and not the sample collection, this quality assurance program plan does not address sample representativeness. When applicable, sample representativeness will be addressed in individual QA project plans. Project plans will also be written to meet the contractual and regulatory demands of specific projects.

This program is intended to provide general direction for the environmental analyses and is not intended to provide in-depth technical discussions. Standard Operating Procedures (SOPs) are designed to provide in-depth technical discussions in support of analytical activities necessary to provide consistent quality data.

2.3 Revision, Distribution and Control

All quality assurance program documents are controlled for the purpose of traceability, distribution, and revision. All controlled documents must have distribution approval by designated personnel. The approvals required for issuing and revising the controlled documents are:

DCL Quality Assurance Program Plan

- DCL President and Laboratory Director
- DCL Quality Assurance Manager

DCL Standard Operating Procedures

- DCL President and Laboratory Director
- DCL Quality Assurance Manager

Approval of program manuals and SOPs will be indicated by concurrences signature and date. Responsibility for control, distribution and revision of quality related manuals resides with the Quality Assurance Unit as addressed in the DCL Quality Assurance Program Plan, Section 4.5.

3.0 QUALITY ASSURANCE MANAGEMENT

3.1 Introduction

Ultimate responsibility for the conduct of all projects, and approval for the implementation of all programs at DCL, resides with the Laboratory Director. Functional responsibility for the analytical work is delegated to various Project Managers and Technical Operations Department Management, Section Managers and to the Quality Assurance Manager (QAM). The QAM reports directly to the Laboratory Director.

Figure 3.1 is a DCL organization chart; this chart illustrates the relationship of the QA section to other components of the laboratory. The QAM is organizationally independent of all programs involved in the data generation process.

3.2 Assignment of Responsibilities

3.2.1 Laboratory Director

The Laboratory Director is responsible to assure that DCL resources are adequately allocated to specific projects and that sufficient staffing and equipment are provided. He oversees and supports the Quality Assurance Manager.

3.2.2 Project Manager

The Project Manager has the responsibility of communication with Client Contract Officers and Managers and oversees and supports the Technical Operations Department Managers and Section Managers in the development, implementation, and operation of pertinent analytical programs. The DCL Project Manager is also responsible to assure that QA/QC recommendations and corrective actions are implemented.

3.2.3 Technical Operations Department Manager

The Technical Operations Department Manager has the responsibility of implementing the QA Plan and for coordinating the sample analysis flow in the laboratory.

3.2.4 Quality Assurance Manager

The Quality Assurance Manager (QAM) has the responsibility of establishing, overseeing, and auditing specific procedures for documenting, controlling, and validating analytical data quality. This is accomplished, in part, through the following:

1. Monitoring the QA and QC activities of the laboratory to ensure conformance with authorized policies, procedures, and good laboratory practices, and recommending improvements as appropriate;

2. Informing specific Project Managers and/or Technical Operations Section Managers of noncompliance with the approved QA Program;

3. Ensuring that all records, logs, standard operating procedures, project plans, and analytical results are maintained in a retrievable fashion;

4. Ensuring that standard operating procedures and project QA/QC plans are distributed to all appropriate laboratory personnel;

5. Establishing the correct procedures and criteria for evaluating whether analytical performance is acceptable and in-control;

6. Reviewing laboratory data before those data are released, verifying that data were collected properly under an in-control analytical system;

7. Maintaining documentation of corrective actions, and ensuring that analysts implement and document corrective actions as they become necessary;

8. Ensuring that sample logs, instrumentation logs, and all QC documents are properly maintained;

3.3 Communication

Effective communication is necessary for a responsive, efficient QA program. DCL employs a system of routine communications to ensure the efficacy of the QA program. This system includes daily, weekly, and monthly communications as described in the following.

3.3.1 Daily

Environmental samples received at DCL are evaluated on a daily basis to assess QA requirements. Both management and analytical personnel are consulted by the QAM to ascertain QA program status and current needs or problems.

Environmental samples and the associated analytical work requests are reviewed by the QAM before analytical procedures are initiated. This ensures adherence to the requirements of applicable QA project plans during analysis.

The QAM evaluates analytical data reports for precision, accuracy, completeness, and adherence to project plan QA requirements.

3.3.2 Weekly

The QAM meets weekly with the laboratory management personnel. Specific QA project information is exchanged and QA needs evaluated. Specific items of activity are identified and implemented.

3.3.3 Monthly

The QAM submits a monthly summary report of QA activity to the Laboratory Director. The report includes:

1. Data relevant to specific QA activities in the laboratory.
2. A summary of significant problems and the corrective actions implemented.
3. A summary of special achievements.
4. A short-range projection of activities or anticipated projects.

3.3.4 Annually

The QAM submits an annual QA summary report to the Laboratory Director. The report includes:

1. The status of, or changes to, existing QA Program Plans.
2. The status of QA Project Plans.
3. A Data Quality Assessment, to include:
   - accuracy
   - precision

- completeness
- comparability

4. A summary of significant QA problems, corrective actions, accomplishments, and recommendations.

5. The results of performance audits.

6. The results of system audits.

7. A summary of QA training.

8. Other information specifically requested by the Laboratory Director.

3.4 Sample Custody

Methods and procedures to be used for sample custody and processing are described here.

3.4.1 Sample Receiving and Logging

DCL utilizes well established and controlled procedures for sample handling including receiving, logging and tracking. Samples are examined upon receipt by the authorized DCL Sample Receipt Officer (SRO) to assure that all required conditions are met. Any problems are resolved by consultation with appropriate personnel and the samples are cleared for logging. Samples are logged in a special computerized logbook (established for individual projects). The SRO assigns each individual sample a specific laboratory number for logging and accounting purposes. The following information is entered into the log for each set of samples: A DCL reference number; DCL laboratory numbers; number of samples; analyses requested; sample type; date of receipt; date of analytical report; date of assignment of samples to the analyst; name of analyst; and source of samples. An example of a page from a typical DCL logbook is presented in Exhibit 3.1.

3.4.2 Sample Security, Storage, and Disposal

The laboratory is locked except during the regular business day between the hours of 7:30 a.m. and 5:30 p.m. Admittance to the building during non-business hours is available through coded personnel identification cards or through the security agent on duty. Non-employees are required to sign the

visitor register upon admittance and are escorted at all times. Non-employees are not permitted in the laboratory during non-business hours.

To facilitate the proper storage of samples after receipt and prior to the initiation of analysis, DCL maintains secured walk-in refrigerators as well as freezers and other secured sample storage areas. All samples requiring special storage conditions (e.g., cold, frozen) are stored in accordance with specifications.

Samples are properly disposed of after appropriate designated holding periods.

3.4.3 Sample Tracking

Samples are received at the laboratory by the designated Sample Receipt Officer or (designee). At the time of sample receipt at the laboratory, the individual accepting the samples signs the field Chain-of-Custody Record. Ideally, the Chain-of-Custody Record is initiated by appropriate field sample collection personnel. The laboratory provides blank Chain-of-Custody Records if another Chain-of-Custody Record is not specified for use.

After sample receipt and the accompanying required documentation of the Chain-of-Custody Record is completed, DCL reference numbers are assigned and a DCL Work Order is generated. Samples are then split as required. The splits are recorded on the Chain-of-Custody and appropriate copies of all paperwork are generated. Sample information is then entered into the computer based logbook, then verified by a second entry. Samples are assigned by the Technical Operations Section Managers to appropriate analytical or extraction personnel. Samples, splits and extracts are maintained under Chain-of-Custody at all stages of analysis through final sample storage following analysis.

A copy of a current laboratory Chain-of-Custody Record is provided as Exhibit 3.2.

3.5 Document Control

QA procedure documents, program plans, and project plans are maintained under document control procedures described in Section 1.4.1 of

the *Quality Assurance Handbook for Air Pollution Measurement Systems*, Volume 1 (EPA-600/9-76-005).

The standard laboratory operating procedures address the organization, assembly, dissemination, and filing of all documents pertinent to the analysis of each set of samples. The goal of the Document Control Program is to assure that all required documents for a specific sample set are appropriately completed, distributed, and filed. Document control addresses, but is not limited to: sample tags, Chain-of-Custody records, sample tracking records, information recorded in analysts' notebooks and in instrumentation logbooks, hardcopy output from instrumentation (e.g., chromatograms, tapes of absorbance values, recorder output), computer printouts, raw data summaries, analytical request documentation and accompanying correspondence, analytical reports, methodology reports, and quality assurance reports.

The Project Manager prepares a complete list (inventory) of all required documentation and designates the specific individual responsible for the collection and completion of each type of documentation after the samples of a set are received, logged, and a Work Order is completed. At this point, the analytical work is well defined and the documentation required has been identified. The Document Control Officer reviews the development of documentation as the project proceeds, and collects and organizes all essential documents at the conclusion of the work. It is the current policy of the laboratory to file all documentation packages indefinitely unless directed otherwise by contract. A copy of the laboratory Document Control form is provided as Exhibit 3.3.

3.6 Calibration Procedures, References and Frequency

It is standard operating procedure at DCL to analyze appropriate standards with each set of samples. EPA Standard Reference Materials (SRM) are used as standards for all parameters for which these are available. For those parameters for which an EPA SRM is not available, a commercially available product of the highest available purity is used. The purity of commercial products is verified by analysis before acceptance by the laboratory. High purity inorganic SRMs and selected organic-mixture SRMs

available from the National Institute of Standards and Technology (NIST) are also used. When appropriate, commercial products are analyzed for purity against EPA or NIST reference materials.

The calibration procedures followed for selected instrumental methods of analysis are presented in Table 3.1.

3.7 Program Assessment

The QC Program is monitored continually for quality through utilization of computerized data collection, reduction, storage, and retrieval. Assessment of data precision is available on a continuing basis to the analysts through automated data precessing procedures. Computerized evaluation of quality assurance sample data provides to the analyst, management personnel, and the QAM, a timely appraisal of both accuracy and precision.

Utilizing sample data stored in computer files, acceptance/rejection criteria are periodically updated as the volume of data allows.

Internal quality control samples are analyzed on a routine basis for environmental samples not addressed by specific Project Plans. Otherwise, the analysis of quality control samples is in accordance with the QA requirements of applicable Project Plans.

3.8 Performance Audits, System Audits, and Frequency

3.8.1 Performance Audits

The DCL Quality Assurance Manager (QAM) is not directly involved in measurement or production processes. The QAM administers a continuous internal performance audit in the laboratory. Under direction of the QAM, quality control (QC) samples are prepared from either standard reference materials (EPA or NIST) or from QC samples provided for this purpose. These audit samples are analyzed routinely within the laboratory as part of the internal quality control program. The data are evaluated by the QAM. Any required corrective measures are initiated by the QAM.

Extramural performance audit programs include those administered by the State of Utah Department of Health (annually) and the by EPA (two programs, each biannually). These programs include EPA's Water Supply

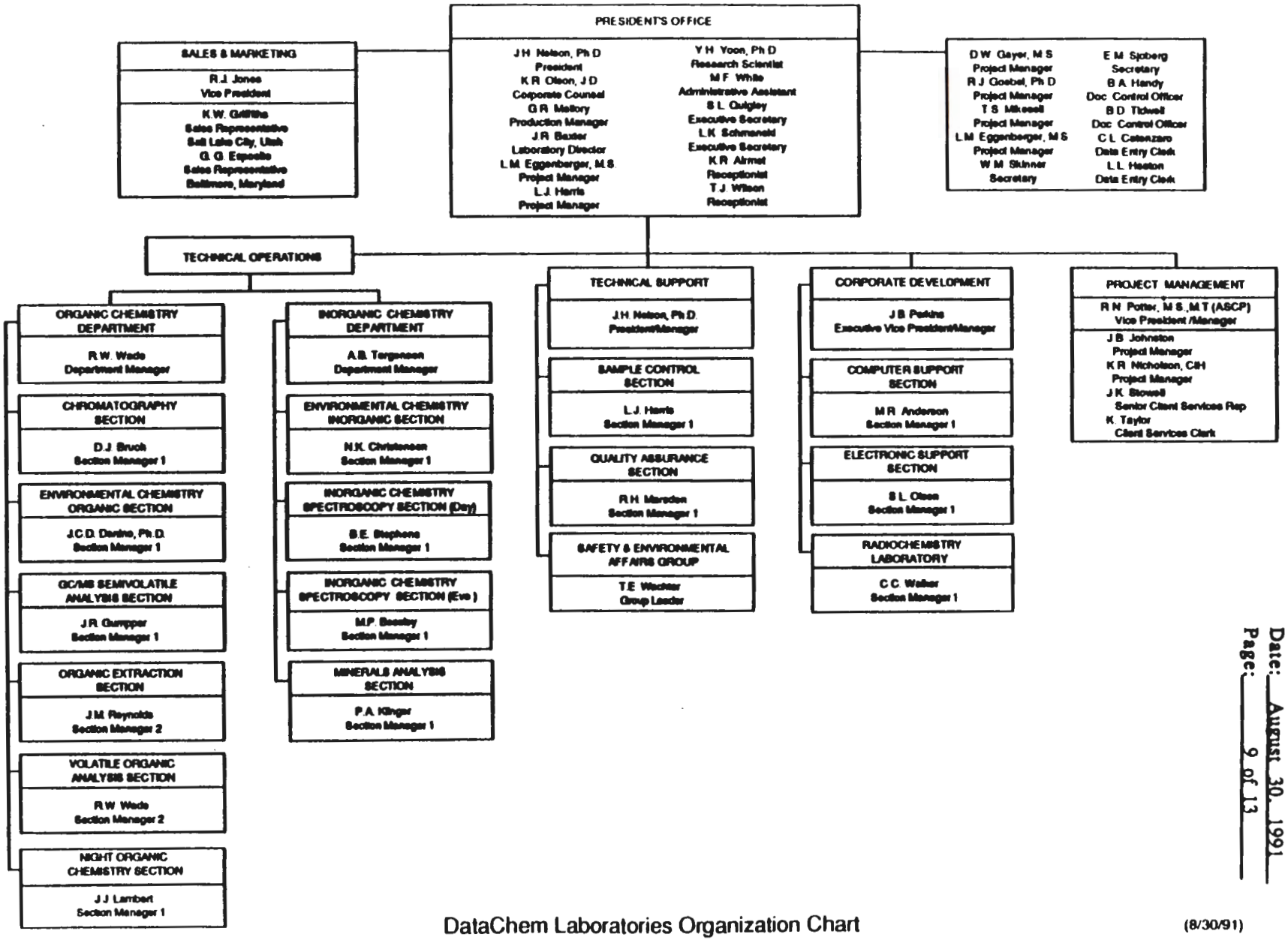
Laboratory Performance Evaluation Study and the Water Pollution Performance Evaluation Study. DCL participates in several additional extramural performance audit programs, including individual state environmental certification audit programs. Additional audit programs address blood lead determinations, two programs involve the analysis of bulk asbestos samples, and another administered quarterly by the American Industrial Hygiene Association; the latter is a Proficiency Analytical Testing (PAT) round robin which addresses organic solvents, asbestos, free silica, and metals.

3.8.2 System Audits

System audits are conducted regularly by the DCL QA Section. There may be either announced or unannounced. In addition, system audits are performed for environmental measurement related systems at DCL by the State of Utah, Department of Health, on a biannual schedule. In alternate years, only a performance audit is conducted.

Tri-annually, DCL participates in a system audit for accreditation by the American Industrial Hygiene Association.

Individual contractors also perform routine system audits.



DataChem Laboratories Organization Chart (8/30/91)

Figure 3.1

Reference Number	Lab Number	Sample Type	Num Sam	Num Anl	Inst	G	Sc	Cl	Date Received	Hold Status	Ana Sta	TAT	RES	Hold Date	Releas Date	Assign Date	Chm	Customer Name / Analyte(s)
S90-0781	EJ 4608	SOIL	1	5	GC	O	GV	R	10-SEP-90		U	9	9					Certified Environmental Consul Benzene, Ethyl Benzene, Toluene, Xylene, Total Petroleum Hydrocarbons
S90-0784-AI	EJ 4634	SOIL	6	8	ICP	I	ID	R	10-SEP-90			9	9			12-SEP	MPB	Dames & Moore Arsenic, Barium, Cadmium, Chromium, Lead, Selenium, Silver, Mercury
S90-0784-BI	EJ 4634	SOIL	6	13	ICP	I	ID	R	10-SEP-90		A	9	9			12-SEP	MPB	Dames & Moore Antimony, Nickel, Silver, Zinc, Beryllium, Cadmium, Chromium, Copper, Lead, Selenium, Thallium, Arsenic, Mercury
S90-0784-CI	EJ 4638	WATER	2	13	ICP	I	ID	R	10-SEP-90		A	9	9			12-SEP	MPB	Dames & Moore Antimony, Copper, Nickel, Zinc, Silver, Beryllium, Cadmium, Chromium, Lead, Selenium, Thallium, Arsenic, Mercury
S90-0784-DI	EJ 4634	SOIL	6	1	IR	I	IE	R	10-SEP-90		X	9	9			18-SEP	RMM	Dames & Moore Total Petroleum Hydrocarbons
S90-0784-EI	EJ 4638	WATER	1	1	IR	I	IE	R	10-SEP-90		X	9	9					Dames & Moore Total Petroleum Hydrocarbons
S90-0784-FI	EJ 4636	SOIL	3	7	GC	O	OE	R	10-SEP-90		U	9	9					Dames & Moore Aroclor 1016, Aroclor 1221, Aroclor 1232, Aroclor 1242, Aroclor 1248, Aroclor 1254, Aroclor 1260
S90-0784-GI	EJ 4638	WATER	1	7	GC	O	OE	R	10-SEP-90		U	9	9					Dames & Moore Aroclor 1016, Aroclor 1221, Aroclor 1232, Aroclor 1242, Aroclor 1248, Aroclor 1254, Aroclor 1260
S90-0784-HI	EJ 4636	SOIL	3	1	GC/M	O	SV	R	10-SEP-90		U	9	9					Dames & Moore EPA 8270
S90-0784-II	EJ 4638	WATER	2	1	GC/M	O	SV	R	10-SEP-90		U	9	9					Dames & Moore EPA 625
S90-0785	EJ 4631	WATER	3	7	GC	O	OE	R	11-SEP-90		U	8	8					EnviroMD Aroclor 1016, Aroclor 1221, Aroclor 1232, Aroclor 1242, Aroclor 1248, Aroclor 1254, Aroclor 1260
S90-0786-AC	EJ 4642	WATER	1	1		I	EX	R	11-SEP-90		U	8	8					Western Zirconium

HITLIST OF UNREPORTED SETS IN-HOUSE BETWEEN 5 AND 10 DAYS CUSTOMER GROUP ********** ACCOUNT 03018 19-SEP-1990 15.20 PAGE 1

Exhibit 3.1 Example of Sample Logbook

Exhibit 3.2 DCL Chain-of-Custody

THIS LOT DIES
Extraction: _____
Analysis: _____

DATA CHEM

CHAIN OF CUSTODY RECORD

RESULTS DUE TO CUSTOMER: _____

SAMPLE EXTRACTION DATE: _____

SAMPLE ANALYSIS DATE: _____

PROJECT/JOB/TASK/CLIENT	LOT/SET-ID	ANALYSIS METHOD

Date Sampled	Site ID	DCL Sample Number(s)	Sample Matrix	Depth (ft)	Field Sample Number	Moisture Lot	Preserv.	Remarks

Original Field Samples

Relinquished by: (Signature)	Date/Time	Received by: (Signature)	Relinquished by: (Signature)	Date/Time	Received by: (Signature)
Relinquished by: (Signature)	Date/Time	Received by: (Signature)	Relinquished by: (Signature)	Date/Time	Received by: (Signature)

Sample Preparation

Relinquished by: (Signature)	Date/Time	Received by: (Signature)	Relinquished by: (Signature)	Date/Time	Received by: (Signature)
Relinquished by: (Signature)	Date/Time	Received by: (Signature)	Relinquished by: (Signature)	Date/Time	Received by: (Signature)
Relinquished by: (Signature)	Date/Time	Received by: (Signature)	Relinquished by: (Signature)	Date/Time	Received by: (Signature)

Final Disposition: _____ Signature: _____

DataChem Laboratories/ 960 West LeVoy Drive / Salt Lake City, Utah 84123

EXHIBIT 3.3

Document #_____

Case #_____

DOCUMENT INVENTORY

Document Control #	Document Title
Case-Re-0001	Document Inventory Sheet
Case-Re-0002	Sample Log-In Sheet
Case-Re-0003	Chain-of-Custody Records
Case Re-0004	Shipping Manifests
Case Re-0005	Sample Tags
Case Re-0006	SMO Organics Traffic Reports
Case Re-0007	GC Screening Chromatograms
Case Re-0008	Deliverables Index
Case Re-0009	Case Narrative
Case-Re-0010	QC Data Summary Forms
Case-Re-0011	Report Pages - Sample XX###
Case-Re-####	Current Lab Instrument Detection Limits
Case-Re-####	Initial Calibration Forms
Case-Re-####	Continuing Calibration Forms
Case-Re-####	Pesticide Forms
Case-Re-####	VOA Standards Data Pages
Case-Re-####	BNA Standards Data Pages
Case-Re-####	Pesticide Evaluation Standards Data Pages
Case-Re-####	Pesticide Individual Standard Mix Data Pages
Case-Re-####	Pesticide Quantitation Standards Data Pages
Case-Re-####	DFTPP Raw Data Pages
Case-Re-####	BFB Raw Data Pages
Case-Re-####	Blank Raw Data Pages
Case-Re-####	Matrix Spike Raw Data Pages
Case-Re-####	Matrix Spike Duplicate Raw Data Pages
Case-Re-####	Analysts' Notebook Pages
Case-Re-####	Instrument Injection Logbook Pages
Case-Re-####	Standards Logbook Pages
Case-Re-####	Internal Quality Control Data
Case-Re-####	Pesticide Original Chromatograms
Case-Re-####	GC/EC Raw Data Sheets
Case-Re-####	Pesticide Computer Generated Worksheets
Case-Re-####	Pesticide Benchsheets
Case-Re-####	Contract Compliance Screening Records

Document Control Officer _____

TABLE 3.1
Calibration Procedures

INSTRUMENT	STANDARDS	FREQUENCY
G C	Three Analytical Standards to verify linearity plus one mid-range check sample.	Inject all standards at beginning of run. Inject check standard or evaluation standard every five analyses.
GC/MS	Mass calibration with PFTBA (tuning) and meet DFTPP criteria or BFB.	Every 12 hours
	Performance check SPCC and CCC compound criteria for standard must be met.	Before analysis of samples or blanks.
	Five Analytical Standards and continuing standard must pass CCC and SPCC criteria.	Before analysis of samples and blanks.
ICP	One analytical standard per analyte. One blank	Analysis of an ICV and an ICB at beginning of analytical run and a CCV and a CCB every 10 samples.

4.0 STANDARD OPERATING PROCEDURES (SOPs)

4.1 Introduction

All environmental analytical work will be performed in accordance with tested, written and approved procedures (SOPs). This section contains an outline of the functions and activities that relate to the quality requirements associated with the procedures employed at DCL.

A brief description and delineation of some of the key laboratory operational functions are listed in Table 4.1.

4.2 Standard Operating Procedure Format

The QAM shall have the primary responsibility for approving, issuing, revising and controlling the SOPs. These SOPs will include analytical methods and any ancillary activities required for the completion and reporting of analytical data.

All Standard Operating Procedures shall have a unique format with all necessary approval signatures, revision control identification, date and title description (Exhibit 4.1).

DCL SOPs are written to conform with the following format:

1.0 Purpose of the Document

2.0 Scope and Area of Application

3.0 Responsibilities of Specified Personnel

4.0 Referenced Documents; e.g., Analytical Methods, Instrument Operational Instruction Manual

5.0 Procedural Requirements; e.g. equipment, reagents, materials

6.0 Procedural Details

7.0 Precision and Accuracy Statements

8.0 QA/QC Requirements

9.0 Definitions or Calculations Applicable to SOP

10.0 Appendices

4.3 Responsibility and Approval

All new or revised SOPs must be approved in writing by authorized personnel in accordance with the following:

DCL Director - Ultimate responsibility for approving all general and Quality Assurance Unit (QAU) SOPs relating to the operation performed in DCL.

Quality Assurance Unit - This unit, under direction of the QAM, is responsible for approval and designation of all SOPs.

4.4 Distribution and Control

All documents associated with the quality assurance program are regulated with regard to their traceability, distribution, and revision. Document control extends to all DCL Standard Operating Procedures and analytical methods written by DCL. Document control does not extend to analytical methods or procedures produced or published outside of DCL. The standard indexing format which is included at the top right-hand corner of each page of the document will include the following information:

- Document Identification
- Section
- Revision Number
- Date
- Page

The QAU maintains a master file of all SOPs, analytical methods, revisions, and history of distribution. Authorized copies of SOPs, revisions and analytical methods are exclusively made through the QAU.

The QAU is responsible for distribution and control of all DCL authorized SOPs, revisions and analytical methods. Technical Operations Managers will maintain a controlled SOP file in each laboratory for which the manager is

responsible. As new documents are approved, authorized copies are distributed by the QAU to the applicable controlled SOP file. A record of the distribution of controlled SOP files, including revisions, is maintained by the QAU. Exhibits 4.2 and 4.3 are examples of the Revision Control Log and Assignment Page used to document the distribution and control of DCL Program Plans, manuals or SOPs. Exhibit 4.4 is an example of a controlled SOP Distribution Record used for internal tracking of documents.

TABLE 4.1
OPERATIONAL FUNCTIONS

FUNCTION	DESCRIPTION	DOCUMENTS USED	PERFORMED BY
Sample Receiving	Containers are unpacked, inspected and secured. Transfer and chain-of-custody documents are reviewed and signed. Project and Technical Operations Managers are notified. Sample information is entered into the LIMS. Sample numbering and labeling is performed. Samples are stored in a designated storage area.	Chain-of-Custody Standard Operating Procedures Analytical Request Form Sample Labels	Sample Receipt Officer
Initiation of Analysis	Completed work order initiated for analytical request.	Analytical Request Form Sample Work Order	Sample Receipt Officer
Analysis	Samples acquired from storage and procedural preparation is performed.	Lab Notebooks/Worksheets SOPs	Analyst
	Analytical test performed on prepared sample.	SOPs	Analyst
	Samples are analyzed on appropriate instrument(s).	Lab Notebooks/Worksheets Instrument Calibration Logs Instrument printouts SOPs	Analyst
Data Processing and Validation	Analytical data and print-outs reviewed, calibrations verified.	Lab Notebooks/Worksheets Instrument Calibration Logs QC Data	Peer Analyst/ Group Leader
	Data reviewed for completeness and DQO verification; approval or rejection of results.	Lab Notebooks/Worksheets QC Data Client/Project Requirements	Technical Operations Manager
Reporting	Data entered into computer network is generated and verified.	Lab Worksheets Client Data Report	Analyst/Data Entry Technicians
	Client report is verified, approved and signed.	Client Data Report	Technical Operations Manager
File Records	Client/project files are updated	Client forms; notebooks copies; worksheets; instrument print-outs; data reports; QC data	Record Custodian

EXHIBIT 4.1
STANDARD OPERATING PROCEDURE APPROVAL SHEET

SOP TITLE:

DOCUMENT CONTROL NUMBER:

EFFECTIVE DATE:

APPROVALS:

PRESIDENT/DIRECTOR _____ Date _____

QUALITY ASSURANCE UNIT _____ Date _____

RECORD OF MINOR REVISIONS:

DATE	LOCATION OF REVISION	QAU APPROVAL

RECORD OF MAJOR REVISIONS:

NEW	1	2	3	4	5	6

EXHIBIT 4.2

REVISION CONTROL LOG				
Revision No.	Revision Date	Affected Pages	Document Control No.	Description of Change

EXHIBIT 4.3
ASSIGNMENT PAGE

Document Control No.:_____

Assigned To:_____

NOTICE TO RECIPIENT

This Document is maintained under document control. The document control number for this copy of the Document is indicated above. Controlled copies of revisions and changes will be issued from time to time. You are charged with the responsibility for:

1) Insertion of new revisions, and
2) Dispensation of outdated or; superseded page.

The revision control page indicates the most current revisions of the plan. If you find that your controlled copy is not current, contact the Quality Assurance Manager for updates.

EXHIBIT 4.4
DataChem Laboratories
SOP DISTRIBUTION RECORD

SOP- - :			REVISION #		REVISION #		REVISION #	
BOOK #	SIGNED TO	LOCATION	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS

5.0 PERSONNEL QUALIFICATIONS AND TRAINING

5.1 Introduction

All DCL personnel assigned to perform tasks related to environmental sample data quality shall have education, training, and experience commensurate with responsibilities and duties.

The QAM assists the Laboratory Management in the assessment of personnel training needs and in the accomplishment of such training to assure compliance with contractual requirement, and state and federal regulations.

The specific training of each individual employed at DCL will be documented in a file established for the individual training and the maintenance of files documenting training shall be conducted in accordance with DCL Document Number SOP-GLP-007.

Technical Operations Section Managers shall review and update pertinent analyst training files at least monthly.

5.2 Quality Assurance Training

The QAM is responsible for conducting the orientation of personnel to the DCL Quality Assurance Program Plan. All QA personnel training will be documented on the QA training form (Exhibit 5.1) and will be retained in the analysts QA training file. In addition, a record of the SOPs for which the analyst has received indoctrination will be maintained by the QAM in the analysts QA training file (Exhibit 5.2).

The QAM in conjunction with the pertinent Technical Operations Managers will assess the personnel training needs as developments occur, and will conduct such training to assure compliance with contractual requirements, and state and federal regulations.

5.3 Analytical Training and Proficiency

All DCL personnel shall receive the necessary technical training to assure that procedures are followed and data of known and expected quality is obtained. The pertinent DCL Manager will initiate training records for all new

and current DCL employees. This record will contain details of the analysts training and experience in record keeping procedures, sample preparation, analytical procedures, and on analytical instrumentation and will be maintained by the QAM in the analysts training file (Exhibit 5.3). DCL Technical Operations Managers will also retain copies in the training files.

Experience gained prior to the analysts employment at DCL will be verified through performance evaluated by the Supervisor. All pertinent training and experience obtained while employed at DCL shall be documented and included in the training file.

Each analyst is responsible for maintaining current training records. As training is accomplished, the analyst shall notify the appropriate supervisor. The supervisor shall then verify and document the current status of training on the analysts original training record and submit this updated file record to the Technical Operations Manager. The Manager shall retain a copy and distribute the original to the QAM.

Analysts without prior training or experience in the use of a specific analytical procedure are required to demonstrate satisfactory performance by analyzing a blind performance audit sample within acceptance limits. Upon demonstration of satisfactory performance for a procedure or analytical method, the personnel training record will be updated. A copy of the results of the performance will accompany the updated training record to be included in the file.

The QAM, or designee, will conduct training record verification audits routinely.

5.4 Safety Training

The Safety Section is responsible for conducting safety training for all new employees and will provide additional training as required or deemed appropriate.

Exhibit 5.1

DATACHEM LABORATORIES
QUALITY ASSURANCE PROGRAM PLAN TRAINING

ANALYST: _____

SECTION: _____

*SYSTEM	DESCRIPTION/COMMENTS	QA APPROVAL	DATE

* Indicates section and/or procedure covered

Exhibit 5.2

ANALYST SOP READING RECORD

ANALYST: _____

SECTION: _____

I have read and understand the following SOPs:

SOP No.	DESCRIPTION	DATE READ	VERIFICATION (Supervisor's Initials)

Exhibit 5.3

ANALYST RECORD OF TRAINING AND PROFICIENCY

ANALYST: _____

SECTION: _____

*SYSTEM	DESCRIPTION/ SUPERVISOR COMMENTS	SUPERVISOR APPROVAL	DATE APPROVED

* Indicate the system by an analytical procedure, instrumentation or preparation.

6.0 FACILITIES, EQUIPMENT AND SERVICES

DCL ensures that the following are maintained in the laboratory:

- Adequate and acceptable facilities (e.g., lighting, ventilation, temperature, humidity, etc.).
- Adequate and acceptable utility services (e.g., voltage control, air, water, vacuum, gas, etc.).
- Adequate and acceptable general laboratory facilities and equipment (e.g., refrigerators, laboratory fume hoods, sinks, bench area, etc.).

Each item of major analytical equipment is maintained under a program of regularly scheduled preventative maintenance, performed by a trained engineer. Equipment performance checks are performed by each analyst prior to the analysis of each batch of environmental samples through the use of standard and control samples.

Records of equipment maintenance and standards checks are maintained.

7.0 DATA GENERATION

QA Project Plans are developed and implemented for environmentally related measurement activities addressed by DCL so that all data generated and processed by DCL are scientifically valid, defensible, of known accuracy and precision, and of acceptable completeness, representativeness, and comparability.

7.1 Quality Assurance Project Plans

DCL does not routinely participate in field sample collection procedures; these are primarily extramural activities. In fulfillment of some specific Project Plan requirements, however, DCL provides acceptable field sample containers and preservatives prepared in accordance with applicable project guidelines.

As required, QA Project Plans are prepared for specific projects or continuing operations to ensure that data generated and processed are of known quality and integrity. QA Project Plans contain the following, as applicable:

1. Title Page, with provision for approval signatures;
2. Table of Contents;
3. Project Description, including objectives, goals, data usage, etc.;
4. Project Organization and Responsibilities;
5. QA Objectives for Measurement Data, in terms of precision, accuracy, completeness, comparability, and representativeness;
6. Sampling Procedures;
7. Calibration Procedures and References;
8. Analytical Procedures;
9. Data Reduction, Validation, and Reporting;
10. Internal Quality Control Checks;

11. Performance and Systems Audits;

12. Preventive Maintenance Procedures and Schedules;

13. Specific procedures to be used routinely to assess data precision, accuracy, and completeness of the specific measurement parameters involved;

14. Corrective Action;

15. Quality Assurance Reports to Management.

QA Project Plans also address the following activities, as applicable:

1. General network design, objectives, limitation, etc.;

2. Specific sampling site selection criteria;

3. Sampling and analytical methodology;

4. Probes, collection devices, storage containers, sample additives and preservatives, temperature, pH, etc.;

5. Federal reference, equivalent, and alternate test procedures;

6. Instrumentation selection and use;

7. Calibration and standardization;

8. Preventive and remedial maintenance and service contracts;

9. Replicate sampling and analysis;

10. Blind and spiked samples;

11. Quality control procedures such as inter- and intra-field and laboratory activities;

12. Sample custody and handling procedures, including special precautions such as holding times, protection from heat and light, reactivity, combustibility, packaging, etc.;

13. Sample labeling, package marking and placarding in accordance with Department of Transportation Regulations prior to shipment or transportation;

14. Safety;

15. Data handling evaluation procedures;

16. Precision, accuracy, completeness, representativeness and comparability;

17. Document control.

7.1.1 Standard Operating Procedures

Unique Standard Operating Procedures (SOPs) may be developed for specific projects. Standard Operating Procedures, detailed documents describing who does what, when, where, how, and why in a stepwise manner, are prepared for routine tasks. They are sufficiently complete and detailed to ensure:

1. Data of known quality and integrity are collected to meet the project objectives;

2. A minimum loss of data due to out-of-control conditions.

7.1.2 Analytical Procedures

Generally, analytical procedures are selected from a multitude of published sources including the EPA, U.S. Army Toxic and Hazardous Materials Agency (USATHAMA) and other federal and state agencies. Procedures often vary according to the character of the individual environmental sample being analyzed. Representative references have been compiled in Appendix A. The compilation is neither all inclusive nor exclusive and is subject to revision.

8.0 DATA PROCESSING

Data processing includes the collection, validation, storage, transfer, and reduction of analytical data. DCL employs extensive automated data processing procedures, including:

- The generation of standard calibration curves
- Mathematical modeling of standard curves
- Statistical analysis
- Calculations
- Data storage and retrieval
- The generation of hard copy output

DCL uses a computer-based data processing system for all pertinent areas of data processing.

8.1 Collection

DCL utilizes a sophisticated data collection and reduction system consisting of the following automated data handling systems:

A. Mainframe Data Collection Systems

1. Digital Equipment Corporation VAX-SERVER 3602 super minicomputer, 1989, equipped with 32 Mb memory, 1.25 Gb disk storage, and 300 Mb Cartridge tape drive.

2. Digital Equipment Corporation MicroVax II microcomputer, 1986, equipped with 16 Mb memory, 1.3 GB Mb disk storage, and 9-track 1600 to 6250 BPI tape drive.

3. Digital Equipment Corporation MicroVax II microcomputer, 1987, equipped with 16 Mb memory, 900 Mb disk storage, 96 Mb Cartridge tape drive, and Fortran and C languages.

4. Hewlett-Packard HP-1000 computer, 1982, equipped with 1.2 Mb memory, 100 Mb disk storage, and 9-track 800 BPI tape drive.

5. Hewlett-Packard HP-1000 computer, 1982, equipped with 1 Mb memory, 196 Mb disk storage, 9-track 1600 BPI tape drive, cartridge tape drive, and RTE-6 operating system.

B. Networks

1. Networking Systems

Digital:
- Delni network controller (3)
- Decserver 100 network server (2)
- Decserver 200 network server (10)
- Decserver 300 network server (2)
- Dempr thin-wire ethernet controller (2)
- Depca thin-wire ethernet adapter for PC systems (15)
- PCSA VAX to DOS Software

Hewlett-Packard:
- DS-1000 networking software and hardware
- 3357 gas chromatography data system
- Three instrument loops

Apple:
- Appletalk network using phonenet hardware.

2. Peripherals on the networking system.

Digital:
a) Hardware
- Video terminals (40)
- High speed laser graphics printers 4-(LNO3)
- Dialup capability @ 1200 or 2400 baud (3)
- Hewlett-Packard 8 pen plotter (7550A)

b) Software
- Relational database management system (RDB)
- TEX typesetting software
- Forms management software
- Transaction processing software
- Code Management system
- Language sensitive editor
- Various programming tools (pca, dtm, spm)

Hewlett-Packard:
- Hewlett-Packard 4-color plotter
- Terminals (8)
- Fortran-77 and Fortran IV languages
- Graphics software
- Printer (3)
- Terminals (6)

Apple:
- Macintosh SE (4)
- Macintosh IICX (3)
- Macintosh IICI (1)
- Laser Writer II (3)

C. Personal Data Collection Systems

1. Digital Equipment Corporation VAXmate personal computer system, 1987, (3 systems) each equipped with IBM PC-AT compatible, Memory, 1 Mb, Monochrome monitor, Disk Drive 1.2 Mb floppy drive; variable size hard disk drive located on a MicroVAX II computer, Serial ports (2), VT200 series terminal emulation, and Support software.

2. Digital Equipment Corporation DecMate work processing system, 1984, 1985, and 1986 (4 systems), each equipped with Disk drives 256 Kb floppy drive (2), WPS word processing, Monochrome monitor, and VT100 series terminal emulation.

3. Digital Equipment Corporation DecMate word processing system, 1986, equipped with Disk drives 256 Kb floppy drive (1), hard drive 20 Mb, WPS word processing, Monochrome monitor, and VT100 series terminal emulation

4. Burgoyne XTC 8088 personal computer system, 1986 (12 systems). Networked.

5. IBM PC personal computer system, 1982. Networked.

6. Hewlett-Packard HP-9000 300 computer, 1986, equipped with 1 Mb memory, Color display, Think-jet printer, Basic language, 20 Mb disk storage, and Microfloppy diskette drive.

7. Hewlett-Packard HP-9000 300 computer, 1987, equipped with 1 Mb memory, Color display, 55 Mb disk storage, with 2934 Graphics Printer, Basic language, Nelson Analytical Chromatography Software and Cartridge tape drive.

8. Hewlett-Packard HP-9000 300 computer, 1988, equipped with 1 Mb memory, Color display, with 2934 Graphics Printer, Basic language, Nelson Analytical Chromatography Software, 81 Mb disk storage, and Cartridge tape drive (2 systems).

9. IBM PS/2 30 8086 Based computer system, 1987, with 5-1/4 external floppy, 30 megabyte hard disk, Color monitor, 640 K RAM (2 systems).

10. IBM PS/2 30 8086 Based computer system, 1987, with 5-1/4 external floppy, 30 Megabyte hard disk, Monochrome monitor, and 640 K RAM (2 systems).

11. IBM PS2/50Z 80286 Computer, 1989, with 1 megabute RAM, 60 Megabyte hard disk, 5'1/4 external floppy drive, and Color monitor.

12. Wyse 80286 Computer, 1988, with Color monitor, 640 K RAM, 1 meg expanded memory, 20 megabyte hard disk (2 systems). Networked.

13. Nec Powermate II 80286 Computer, 1988/1989, with 20 Megabyte disk, Monochrome monitor, 640 K RAM + 1 meg expanded memory (2 systems). Networked.

14. NEC 386SX Computer, 1989, with 40 Megabyte disk, 1 Meg RAM, 3 Meg expanded memory, and Color Monitor. Networked.

15. IBM AT 80286 Computer with 20 Meg hard drive, Monochrome monitor, and 640 K + 1 meg expanded memory. Networked.

D. Data Collection System in Conjunction with Specific Instrumentation.

1. Hewlett-Packard Model 5880/5970 Quadruple Gas Chromatograph/ Mass Spectrometer System with:

   - IBM XT with Teknivent software and hardware interface data system;
   - 38,000-Compound NIH/EPA library; and
   - Quantitation software.

2. DuPont Model DP-102 Magnetic Sector GC/MS/DS System with:

- Hewlett-Packard 21 MX-E (2113) data system;
- 7906 20 Megabyte disk drive;
- 7970B Magnetic tape drive system;
- 36,000 Compound NIH/EPA library on system disk; and
- Multiple scanning modes software.

3. Three Finnigan MAT Model 5100B quadruple GC/MS/DS gas chromatography/mass spectrometers, with the Finnigan Super Incos Data System which includes:

   - Memory mapping software;
   - Printer spooling;
   - Second terminal operation (4X computer required);
   - Priority interrupt foreground/background operation;
   - Auto Quan software for automatic quantitation;
   - Multiple data file processing;
   - Library search and display programs including the NBS-EPA spectral library; and
   - Complete data processing programs.

4. Three Finnigan MAT Model 5100EF quadruple GC/MS/DS gas chromatography/mass spectrometers, each with the Finnigan Super Incos Data System.

5. Hewlett-Packard 5992B gas chromatograph/mass spectrometer with the HP 9825A data system.

6. A PDP 11/05 computer with DECwriter console which is used to collect and process data derived from the analysis of selected elements by inductively coupled argon plasma emission spectrophotometry.

7. Perkin-Elmer Nelson Systems Access*Chrom Chromatography Data System running on a Vaxserver 3602 System which serves 50 instruments, each instrument having a 941 A/D buffered interface.

8.2 Validation

Analytical data generated at DCL are validated using several procedures, the most universally applicable of which involves the established quality assurance system.

At the completion of the analysis of a sample set, each chemist calculates the results and reports such on the Sample Data and Laboratory Report sheet. Results for internal QC samples are calculated immediately after analysis. The results are checked either by computer or by the QAM. Thus, the chemist may determine immediately if the QC samples and the overall analysis are in control. A peer scientist, other than the analyst, is assigned to check the results for possible errors in calculations or data processing. The checker must approve the results reported for both the quality control samples and the field samples. Should the QC data be out of control (Section 9.0), the chemist and his supervisor are required to assess possible problems. They must notify the QAM of the problem and its proposed solution. The Technical Operations Section Manager, after his evaluation of the data, gives the report to the QAM for evaluation and implementation of any required corrective action. Upon approval by the QAM, the completed report is routed through to the Project Manager for final review and reporting.

8.3 Data Storage

The paperwork containing the raw data for a sample set (i.e., chart paper, computer readouts, paper tapes, calibration curves, tables of data, etc.) is collected and placed in an 8 1/2" by 11" envelope which has been labeled with sample numbers, analyst, date, and other pertinent information. Appropriate and complete data, along with a description of the samples and analytical method, are also entered in the chemist's notebook. The data envelopes are filed by laboratory number for future reference and data retrieval.

Each chemist at DCL maintains a bound laboratory notebook in which are detailed events related to sample analyses. Completed notebooks are filed by each chemist. At termination of employment, all laboratory notebooks are placed in archives.

8.4 Transfer

QA Project Plans describe procedures to be used to ensure that data transfer to the data user is error free and that no information is lost in the transfer. Because of the extensive use of a computerized data processing system, data transfer steps are minimized.

8.5 Reduction

To accomplish data reduction, mathematical models based on the analysis of standard solutions or standard samples are generated in order to determine the quantity of analyte present in field samples. Data processing by the computer includes calculations, generation of standard calibration curves, mathematical modeling of standard curves, statistical analyses, and the generation of hard copy output. Four different computerized mathematical models are available at DCL to fit data derived from the analysis of standards and to generate calibration curves. The analyst has the option of selecting the model which best fits standard data and the analytical system. DCL's computer program provides an equation for the calibration curve and the value of the corresponding correlation coefficient. The optional mathematical models are:

Linear	$y = ax + b$
Quadratic	$y = ax^2 + bx + c$
Exponential	$y = a + b(1 - e^{cx})$
Nernst	$y = a + b(\log(c + x))$

where y is the experimental observation and x is the concentration or amount of the analyte of interest.

Data from the analysis of standards are used to determine the coefficients a, b and c, as appropriate. These values define the equation of the standard curve which is used to determine x from the value of y, which is determined experimentally for each analyte of each field sample.

The data reduction program allows the analyst to generate a printed plot of the standard curve as an aid in selecting the curve of best fit. Although a

correlation coefficient is provided, it is not always the best indication of a reasonable data fit.

8.6 Reporting

Analytical reports are submitted immediately following the completion of the analyses and the associated calculations for each work effort. A typical analytical report may be comprised of the analytical results and limits of detection (Exhibit 8.1).

A copy of all reports is placed in a master file for storage and retrieval of information as required. This file is organized and maintained according to DCL sample number and general sample type. Material filed for each sample set includes reports of (1) analytical results; (2) methodology; and (3) QC results.

Exhibit 8.1

ANALYTICAL REPORT

DATA CHEM LABORATORIES

Form ARF-AL
Page 1 of 1
Part 1 of 1

Date August 30, 1991
Agency Identification Number S91-0608
Account No. 03018

FAX (
Telephone (

Sampling Collection and Shipment

Sampling Site _____ Date of Collection August 19, 1991

Date Samples Received at DataChem August 21, 1991

Analysis

Method of Analysis 8015MOD

Date(s) of Analysis August 22, 1991

Analytical Results

[redacted]			TPH-Gasoline µg/g	Benzene µg/g	Ethyl Benzene µg/g	Toluene µg/g	Xylene µg/g			
DE-9	EX 3390	SOIL	160	ND*	ND*	.007	.04			
DE-10	EX 3391	SOIL	140	ND*	.30	.32	.35			
DE-11 (8)	EX 3392	SOIL	23.	.011	.21	.037	.08			
DE-11 (9)	EX 3393	SOIL	230	.15	2.2	.12	.38			
DE-17	EX 3394	SOIL	120	ND*	.20	.12	.25			
[redacted]										

* See comment on last page.
ND Parameter not detected.
NR Parameter not requested.

** See comment on last page.
( ) Parameter between LOD and LOQ.

Analyst: Thomas N. Bosch

Reviewer:

Laboratory Supervisor: Terry P. Vayo

960 West LeVoy Drive / Salt Lake City, Utah 84123-2547 / (801) 266-7700
A Sorenson Company

9.0 RECORDS MANAGEMENT

9.1 Introduction

This section describes the classification and records management operations at DCL. All logbooks and associated records must be legible and contain identification of the item(s) involved. The Document Control Officer (DCO) shall be responsible for verifying that records are initialed, approved, and validated by appropriate personnel.

Records will be archived and maintained in a facility that will provide organized retention and timely retrieval, restricted access, and will minimize deterioration or damage to prevent loss of information.

All records shall be maintained under document control. Archive records control shall have an index format that will include:

- DCL Reference Numbers
- DCL Sample/Report Numbers
- Client/Project Name
- Record Retention Period
- Record Location

An archive log-out record will be maintained for all records that are temporarily removed from archives (Exhibit 9.1). An archive inventory record (Exhibit 9.2) shall be maintained by the DCO in order to document records traceability and facilitate timely retrieval.

9.2 Classification

All records that are either archived or retained at DCL, shall be classified as permanent (lifetime) or nonpermanent. The two general categories for DCL Records are:

- *Project Records* - data sets and documents that are specific to a client or project.

- *Operational Records* - documents related to the operations and performance of the DCL.

These records are maintained and controlled in accordance with the management operations outlined below.

9.3 Project Records

All records related to work performed under specific project contract requirements shall be maintained. Specific project records will be maintained by the DCO in a secure designated cabinet. The DCO will maintain a log identifying the project number. Project records will contain copies of sample data packages, reports, signed and dated transmittal letters. Project Records will contain all necessary information and documentation to verify complete compliance with project requirements.

9.4 Operational Records

Operational records are those that pertain to the routine functions and operations of DCL. A controlled file of operational records shall be maintained at DCL.

The general operational records file shall contain, but is not limited to:

9.4.1 Audit Reports

Separate files will be maintained for all external/internal performance and systems audits conducted by DCL personnel or any client or outside agency. These files shall include all correspondence, evaluations, audit reports, noncompliance and corrective action associated with a specific audit.

9.4.2 Equipment Inventory

A current list of all DCL equipment shall be compiled in this file. This list shall include copies of equipment requisitions, approvals, vendor identification, and intended use of equipment.

9.4.3 Controlled Documents

A copy of all DCL controlled documents and revisions thereof, shall be maintained in this file. A system of revision control is established such that each person issued a unique controlled copy will be identified by name, organization and current mailing address so that revision updates can be

issued to the appropriate individual. A signed notice of receipt record with the controlled document identification number will be maintained for each copy issued.

9.4.4 Qualifications and Training Records

This file contains a job description for each position in the DCL, current employee curriculum vitaes and resumes, position qualification statements, training and SOP indoctrination records for each employee.

Other records directly related to quality assurance and safety will be controlled and maintained in the respective section.

9.5 Records Retention

All records contained at DCL, or archived at a later date, shall be classified as permanent (lifetime) or non-permanent. Permanent (lifetime) records shall be those that are maintained for the lifetime of the project or as required by contract. At the end of the contract, these records shall be forwarded to the client to be maintained in their records management system.

Non-permanent records shall be those that contain documented evidence that project required activities were performed in accordance with contractual agreement, but do not need to be retained for the life of the project. DCL shall maintain these records for five years, or until the client's requirements are met. EPA and/or DOE records may require retention for ten years or longer.

The following is a list of the permanent quality assurance related records that should be maintained for the life of a project:

- DCL SOPs and revisions
- DCL analyst notebooks
- EPA intercomparison audit/evaluation data
- Computer software documentation
- Instrument calibration/maintenance logbooks
- Quality control charts and QC samples analyses
- Sample receipt/screening logbooks

The following is a list of the non-permanent quality assurance related records that will be maintained for five years, or for the duration of contractual agreement, whichever is longer:

- Noncompliance and corrective action reports
- Personnel qualification and training records
- Performance and systems audit reports and resources
- Operational surveys and reports

The QAM shall be responsible for reviewing all records prior to destruction to verify that retention times have been achieved.

9.6 Reference Documents

DCL shall maintain a current compilation of reference documents (journals, procedure manuals, instrument instruction manuals) available to the employees. These documents will be reviewed, updated and revised routinely to maintain as current information as is possible.

Exhibit 9.1

LOG-OUT RECORD

OUT TO	FILE # OR NAME OUT	DATE	OUT TO	FILE # OR NAME OUT	DATE

Exhibit 9.2

ARCHIVE INVENTORY RECORD
(BY BOX)

CONTRACT	DCL SAMPLE NUMBERS FROM	TO	INSTALLATION (IF APPLICABLE)	DATE OF ANALYSIS	DATE TO SHIP/ DESTROY

10.0 INTERNAL QUALITY CONTROL CHECKS AND FREQUENCY

DCL performs three general types of quality control determinations. The first type involves the duplicate analysis of selected field samples submitted to the laboratory. The second type is comprised of the analysis of quality control samples which have either been generated at DCL or obtained from other sources (e.g., EPA or NIST). The QC samples prepared at DCL are either produced in such a way as to reproduce (insofar as is possible) the specific matrix and properties of the samples under consideration or are method blanks. The third type involves the addition of a known amount of a compound (spike) to a duplicate (split) of a specific sample.

Unless superseded by the requirements of a specific QA Project Plan, the policy of DCL is to complete a minimum of one replicate determination (for field samples) for each analyte in each sample set. Furthermore, policy requires that the minimum number of replicate determinations to be completed for each analyte equal or exceed 5% of the total numbers of samples analyzed for that analyte at a given time.

GC/MS procedures include the analysis of internal standards and surrogates with each sample. These compounds function as quality control analytes.

The frequency of sample splits, spiking field samples, and duplicate samples is delineated in individual project plans.

11.0 DATA QUALITY ASSESSMENT

The quality of all data generated and processed by DCL is assessed before it is reported to ensure that it satisfies the needs of the user and fulfills QA Project Plan requirements. The data are assessed for accuracy, precision, completeness, representativeness, and comparability.

11.1 Data Sources

There are two primary data parameters which are adaptable to control limit calculations. These parameters are accuracy and precision. Accuracy data are obtained from either separately prepared integral QC samples or from analyte enriched (spiked) field samples. The data are utilized in the format of percent recovery. Precision data are obtained from either quality control sample analyses or from the replicate analysis of field samples. There are two types of precision data obtainable. Two essentially identical samples processed through the entire analytical method from sample preparation through analysis will produce analytical method precision data. One sample analyzed twice on the same instrument will produce instrumental precision data. The two types of precision data are handled separately. In like manner, accuracy data from separately prepared quality control samples are handled separately from accuracy data obtained from spiked field samples.

11.2 Calculation of Quality Control Limits

Quality control limits and accompanying charts are generated from the statistical analysis of QC sample results. To address the entire range of analyte levels expected for field samples, quality control samples are prepared in the laboratory at multiple concentrations or levels. These levels are not necessarily duplicated exactly from sample set to sample set. To optimize comparative use of the quality control data, the results are normalized by dividing each analytical result by the corresponding theoretical (target) value so that these normalized results are distributed around 1.00 or 100% recovery. In one procedure used at DCL, statistical quality control methods [1,2,3] have been modified and applied to the normalized results to produce accuracy and precision control charts.

For the ith sample result of n_i replicate determinations obtained in the laboratory for a specific quality control sample, two statistics are calculated:

$$x_i = \frac{\textit{Calculated Mean}}{\textit{Theoretical Value}} \tag{11.1}$$

$$R_i = \frac{\textit{Range of Values}}{\textit{Theoretical Value}} \tag{11.2}$$

When a control data set on N sample results has been accumulated for the determination of a specified analyte in a given sample matrix using a specified method, the following summary statistics are computed:

Mean Percent Recovery:

$$\overline{X} = \frac{\sum_{i=1}^{N}(n_i X_i)}{\sum_{i=1}^{N}(n_i)} \tag{11.3}$$

Average Standard Deviation Among Replicates:

$$\sigma' = \frac{\sum_{i=1}^{N}\frac{(n_i - 1)R_i}{d_{2i}}}{\sum_{i=1}^{N}(n_i - 1)} \tag{11.4}$$

where d_{2i} is the factor to convert a range to a standard deviation for sample size n_i (Table 2).

The precision component of the quality control program is based on the range of results rather than on the standard deviation because the range is conceptually easier for the chemist to relate to analytical results. The actual standard deviation could be applied with equal facility. Most of the quality

control results compiled in the laboratory are comprised of sets of two determinations derived from the duplicate analysis of the same sample. For this situation, the range divided by the constant d_2 is equal to the calculated standard deviation.

Accuracy and precision performance criteria of many quality control programs are based only on the repeated analysis of the same sample. Such programs utilize only one standard deviation, that attributable to repeated measurements. This standard deviation corresponds to the standard deviation among replicates σ' applied in the DCL program and defined by Equation (10.4). Since the program involves the analysis of different quality control samples (with the same or different analyte levels) for the purpose of establishing performance criteria, sample-to-sample variation must also be considered. Accordingly, quality control criteria for assessing accuracy are based on a consideration of both the replicate standard deviation σ' and the standard deviation amount samples σ_s [3].

Using analysis of variance procedures [4], the standard deviation among samples can be estimated as follows:

$$\sigma_S = \left[\frac{\left(MS_S - \sigma'^2\right)(N - 1)}{\sum_{i=1}^{N} n_i - \frac{\left(\sum_{i=1}^{N} n_i\right)^2}{\sum_{i=1}^{N} n_i}} \right]^{\frac{1}{2}} \qquad (11.5)$$

MS_s is the mean square among samples from the analysis of variance and is calculated as follows:

$$MS_S = \frac{\sum_{i=1}^{N} \frac{(n_i X_i)^2}{n_i} - \left(\overline{X}^2 \sum_{i=1}^{N} n_i\right)}{N - 1} \qquad (11.6)$$

The standard error S_x of our result x_i is them [3]:

$$S_x = \sqrt{\frac{\sigma'^2}{n_i} + \sigma_s^2} \qquad (11.7)$$

Accuracy limits for quality control charts are calculated, establishing control limits and warning limits at three standard errors and two standard errors, respectively, from the mean. It is important to note that the accuracy control limits applied to the analytical results for a given quality control sample are dependent not only on the previously established values of σ' and σ_s, but also on the number of replicate analytical results. For example, for a new quality control sample of n_j replicates with results x_j and R_j, the accuracy limits are:

Accuracy Control Limits for x_j:

$$\overline{X} \pm 3\sqrt{\frac{\sigma'^2}{n_j} + \sigma_s^2} \qquad (11.8)$$

Accuracy Warning Limits for x_j:

$$\overline{X} \pm 2\sqrt{\frac{\sigma'^2}{n_j} + \sigma_s^2} \qquad (11.9)$$

To calculate quality control limits for precision charts, only the replicate standard deviation σ' is needed. Precision control limits [1,2] (three standard deviations) for a range are:

Lower Limit = $D_1\sigma'$ Upper Limit = $D_2\sigma'$

Values of D_1 and D_2 are a function of the number of replicates and are given in References [1] and [2]. Selected values are also provided in Table 11.1. Constants similar to D_1 and D_2 are required to calculate warning limits (two

standard deviations). These are not commonly tabled, however, they can be derived from a table of the studentized range [5]. These warning limit constants, denoted as D_1' and D_2' are tabulated along with D_1 and D_2 in Table 11.2.

Warning limits are:

Lower Limit = $D_1's'$ Upper Limit = $D_2's'$

TABLE 11.2

Constants for the Computation of Quality Control Charts

n	d_2	D_1	D_2	D_1'	D_2'
2	1.128	0	3.69	0	2.83
3	1.693	0	4.36	0	3.47
4	2.059	0	4.70	0.30	3.82
5	2.326	0	4.92	0.60	4.05
6	2.534	0	5.08	0.84	4.23
7	2.704	0.20	5.20	1.04	4.37
8	2.847	0.39	5.31	1.21	4.49
9	2.970	0.55	5.39	1.35	4.59
10	3.078	0.69	5.47	1.48	4.67

$d2$, D_1 and D_2 were taken directly from standard tables [1,2].

$D'1$ and $D'2$ correspond to two standard deviation limits from ranges and were calculated from a table of the studentized range [5].

Although results are normalized (divided by the theoretical value) for purposes of comparability, the normalized replicate standard deviation still tends to decrease slightly with increasing concentration or analyte level [6]. The influence of analyte level is reduced by grouping the data into several concentration (level) ranges and calculating limits separately for each range. Data are plotted on a single chart, with the limits changing appropriately for

each data point. The number of concentration ranges selected is determined from the nature and characteristics of the data. Data obtained at relatively low analyte levels near the limit of detection, when separated from high concentration level data, often generates expanded control limits.

The control data set is updated after evaluation of 20 successive quality control samples and includes data on the 50 most recent results. Any value xi or Ri which is out of control is not used in the subsequent determination of new limits. Figures 11.1 and 11.2 show sample plots of the accuracy and precision control charts.

11.3 Accuracy

Individual QA Project Plans describe the specific, detailed mechanisms required for that project to demonstrate that reported data are favorably comparable to true values. These mechanisms usually include the analysis of references or spiked samples, and participation in performance audit programs.

Since the "true" analyte values for field samples are not known, no accuracy measurement can be made using field sample analyses (excepting spikes). Although actual acceptable precision measurements are indicative of an analytical system that is in control, the accuracy of the data generated for field samples is assessed through the analysis of QC samples processed with the field samples. Unacceptable results for accuracy in the analysis of internal quality control samples analyzed with a field sample set overrides any acceptability based upon field sample precision measurements.

11.4 Precision

Individual QA Project Plans describe the specific, detailed mechanisms required for that project to demonstrate the reproducibility of the measurements performed by DCL. These mechanisms generally require that the results of replicate analyses of an environmental sample or reference sample be within predetermined acceptance limits.

For any single field sample, the range of the replicate analytical values is divided by the average of the values, resulting in a measure of the precision of the analysis. This precision value is usually evaluated using precision

control limits established previously from the analysis of quality control samples of the same analyte analyzed by the same method. If quality control limits are not available for a particular analyte an evaluation is made employing control limits established for a similar compound, analyzed by the same method.

11.5 Completeness

The application of QA Project Plans prepared by DCL is normally limited to the laboratory analysis of environmentally related samples. The Plans normally do not address parameters of field samples. QA Project Plans address the completeness of sample analysis and data reporting. All samples received by DCL are accounted for under normal laboratory procedures.

11.6 Representativeness

Representativeness is the degree to which a sample accurately and precisely represents the actual environmental conditions at the sampling location. Field sampling is an extramural activity and normally is not under the auspices of DCL. To the extent to which DCL is responsible for field sampling procedures for any specific Project, the QA Project Plan addresses representativeness.

11.7 Comparability

QA Project Plans contain a description of any special procedures required to ensure data comparability. EPA approved methods of analysis and guidelines for data reporting and quality assurance are the primary basis for insuring comparability of measurement data.

Plot generated
4 APR., 1990

DATACHEM LABORATORIES
ACCURACY QUALITY CONTROL CHART
LEAD IN WATER OR SOIL BY ICP

Range 1 updated
27 MAR., 1990

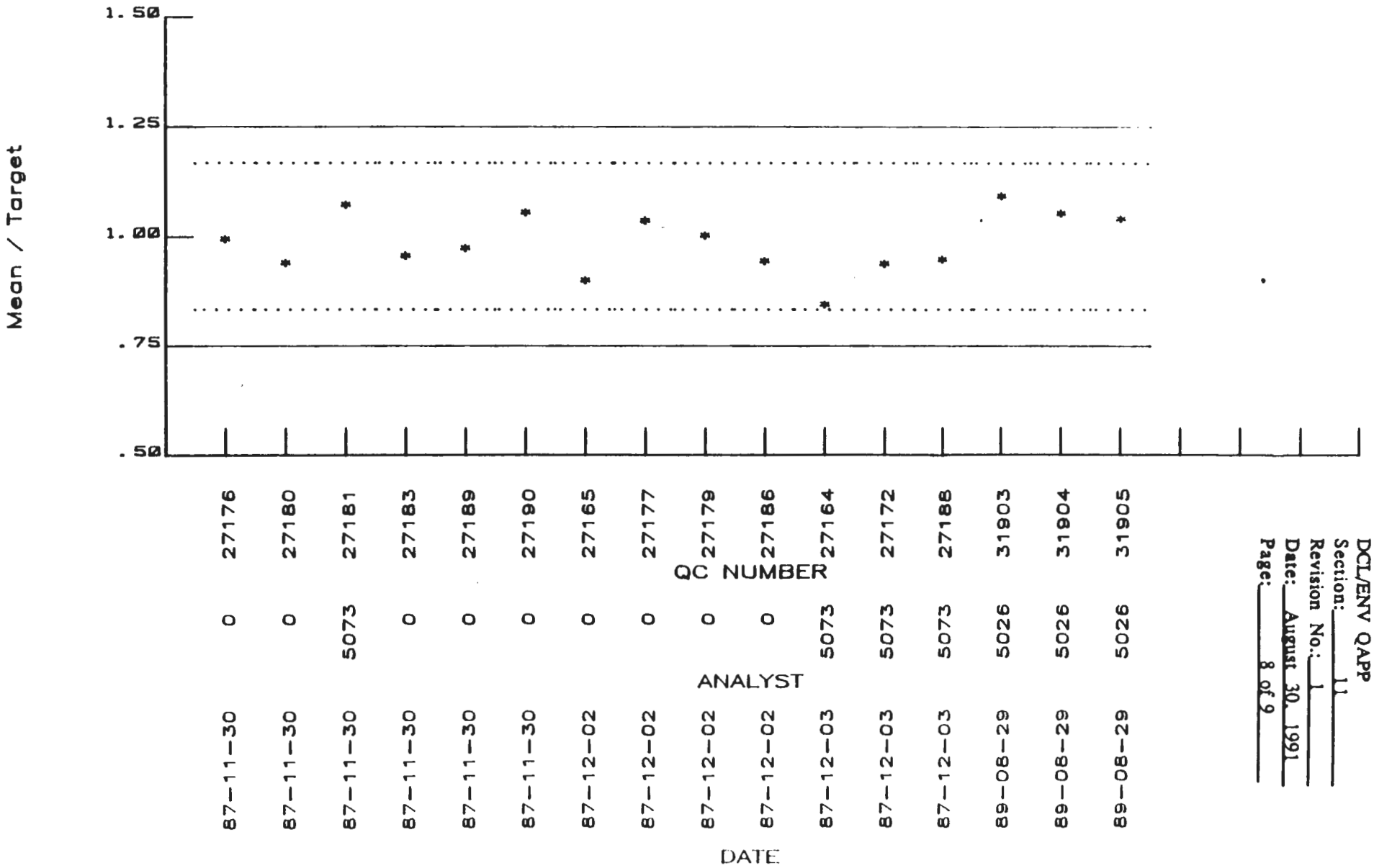


Figure 11.1 Accuracy Control Chart

Plot generated
4 APR., 1990

DATACHEM LABORATORIES
PRECISION QUALITY CONTROL CHART
LEAD IN WATER OR SOIL BY ICP

Range 1 updated
27 MAR., 1990

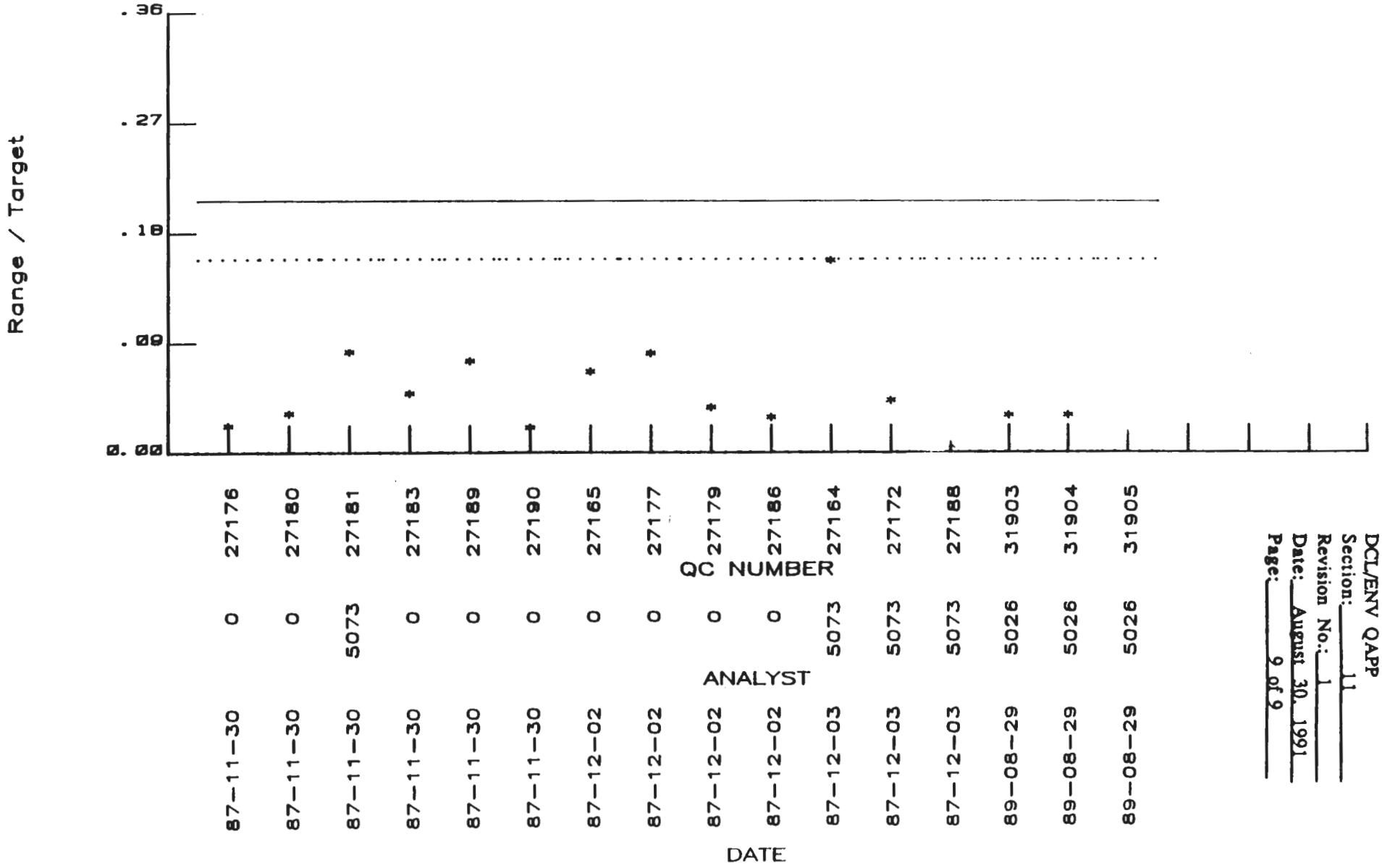


Figure 11.2 Precision Control Chart

12.0 CORRECTIVE ACTION AND NONCOMPLIANCE REPORTS

12.1 Introduction

This section details the requirements and procedures for controlling and correcting deficient and/or noncompliant items, objects or procedures determined to be adverse to DCL data quality.

12.2 Responsibility

Analysts have the responsibility for reporting observed or suspected deficiencies or noncompliance items to their immediate supervisor. A noncompliance form (Exhibit 12.1) will be initiated by the analyst and given to the QAM with a copy distributed to the appropriate supervisor(s). The responsible Section Manager shall identify the noncompliance source and implement corrective action procedures. The QAM is responsible for determining if the deficiency is non-compliant and the proposed corrective action is adequate.

12.3 Noncompliance

Any item that by deficiency in characteristic, systems, documentation, or procedure results in unacceptable or variable quality shall be identified as a noncompliance item. Noncompliance can be due to, but is not limited to, excessive data outliers for precision and accuracy, improper instrument calibration and maintenance, or improper data reduction and verification. Any activity which adversely affects the data quality objectives at DCL can constitute a noncompliance.

Noncompliance encompasses all activities at DCL from sample receiving, preparation and analysis, equipment verification and calibration, quality records, and any other activity addressed in the quality assurance plan or by contractual agreement.

The QAM is responsible for maintaining a noncompliance file. This file contains a list of all noncompliance items with their associated proposed and approved corrective action measures.

Noncompliant items will be controlled and identified by marking, tagging and segregating, when necessary. If physical segregation is impractical due to such conditions as size, weight or limited access, the noncompliant item will be identified by other physical means.

12.4 Corrective Action

Any quality review that detects or determines data and/or documentation or instruction which does not comply with required specifications shall initiate subsequent investigation and initiation of corrective action. The QAM is responsible for implementing and approving all corrective actions affecting data quality. A Corrective Action Record (Exhibit 12.2) shall be prepared by the QAM and shall contain details for the action deemed necessary to correct the deficiency or noncompliance. The DCL Section Manager, Group Leader, and analysts are responsible for implementing the approved corrective action measures. The QAM will monitor the effectiveness of the corrective action and recommend additional or alternative measures as deemed necessary. The QAM will maintain all corrective action records in the quality assurance units files.

12.5 QC Data Evaluations and Related Actions

QA Project Plans provide for establishing and maintaining QA reporting or feedback channels to the appropriate management authority (extramural and intramural) to ensure that early and effective corrective action can be implemented when required. Corrective action is required when the data for a specific sample set or a specific work effort are determined to be unacceptable.

An unacceptable situation is generally defined as an analytical value outside of the established control limits. When an unacceptable situation is detected, efforts are directed toward the determination of the cause of the problem(s) and corrective actions are implemented to reinstate a reliable analytical system. Once problems are identified and corrected, data considered to be invalid are re-evaluated. If identified errors can be corrected without the reanalysis of the field samples (as for example, in the case of calculation

errors or improper processing reliable raw analytical data), corrections are effected without additional analytical work. All samples for which reanalysis is the only reasonable corrective measure are reanalyzed, if sufficient sample is available and if the integrity of the remaining portion of the sample is intact. Resampling and reanalysis may be required to correct unacceptable results if the conditions noted in the preceding cannot be satisfied.

The QAM carefully monitors the results of the control samples analyzed and, in the event that a QC result is unacceptable, implements specific steps to identify and correct the deficiency. Generally, a Corrective Action Record (Exhibit 12.2) is prepared by the QAM and forwarded to the appropriate Technical Operations Section Manager. Action for correcting the problem, pursued jointly by the analyst, the appropriate Group Leader, the appropriate Section Manager, and the Project Manager, is recorded on the Corrective Action Record. The steps to be followed include:

1. Check all data processing procedures and calculations.

2. Check blank samples for identification of possible interferences or other problems.

3. Check instrumentation performance (if applicable) by observing the response of the instrument while processing a sample material for which the expected response is known. Operating conditions must be similar to those used for analysis of the samples under consideration.

4. Check the original standard preparation procedures by preparing new standards, obtaining a new standard calibration curve from the new data, and comparing the new standard curve with the original standard calibration curve.

5. Check the integrity of the original QC samples by preparing new QC samples following the same procedures and analyzing the new QC samples.

6. Carefully review raw data (e.g., recorder output, chromatograms, computer output) in an effort to identify interferences, unusual signals (unusual peak shapes, etc), or other factors which could produce inaccuracies.

7. Reanalyze the samples with new standards and new QC samples if sufficient field sample material is available. The entire analytical

process including, for example, extractions, digestions, etc. should be repeated if possible.

8. If QC results are still unacceptable and no reason has been identified after completing Step 7, discuss the problem in detail with personnel from the sponsor and determine how results should be reported.

12.6 Corrective Action/Noncompliance Resolution

Corrective action is a system designed to discover and eliminate noncompliance as it relates to the various aspects of data quality at DCL. The QAM, in conjunction with Technical Operations Managers and Project Managers, is responsible for approving and coordinating corrective action measures. Differences arising from proposed noncompliance corrective action measures that can not be resolved between the QAM, Technical Operations Managers and/or Project Managers will be evaluated and resolved by the DCL Director.

Exhibit 12.1

NONCOMPLIANCE FORM

NONCOMPLIANCE ITEM: _____

REASON FOR NONCOMPLIANCE: _____

_____

_____

IS ITEM TAGGED AS NONCOMPLIANT: _____ YES; _____ NO.

COMMENTS: _____

_____

_____	_____
ANALYST	DATE

_____	_____
SUPERVISOR	DATE

EXHIBIT 12.2

Problem Analyte(s) _____ DCL or Agency ID No. _____

QUALITY ASSURANCE/QUALITY CONTROL CORRECTIVE ACTION RECORD

Quality Assurance Comments:

QAM: Date:

Management Action:

Signature: Date:

Analyst Response (see back of form):

Analyst: Date:

Quality Assurance Approval:

QAM: Date:

13.0 PROCUREMENT AND PROCESS CONTROL

13.1 Introduction

All materials purchased by the DCL for process work will be of commercial grade, or better, and meet the requirements for which they are intended.

13.2 Procurement and Quality Monitoring of Material

All Purchase Order requisitions are approved by Department Managers, Section Managers or the Laboratory Director. Shipping and receiving personnel will perform an inspection of items that have been requisitioned and received to determine that:

- Damage was not incurred in shipping;
- Order is complete;
- Transfer documentation is complete and accurate;

The items received shall be rejected and returned to the supplier if any of the criteria stated above are not met.

The pertinent Section Manager is responsible for determining that the lot quality of reagent or bulk chemicals received are acceptable. This will be achieved by performing reagent blank analysis on a representative aliquot of each new lot.

If the analytical method or SOP does not specify the purity of materials, ACS reagent grade will be used.

Deionized/Demineralized water is used for dilutions and preparations of standardized solutions and reagents solutions. The specific conductance of the supply water will be determined on a daily or as use basis and will be recorded in a database file or bound logbook. A specific conductance reading of 2.0 µmhos/cm at 25°C is considered acceptable.

13.3 Control Requirements for Containers

Specifications for containers used for a specific analysis shall be identified in the SOP or analytical method.

The glassware in general use is Borosilicate unless mandated otherwise. The use of plastic containers and apparatus made of Teflon® or polypropylene is generally recommended. Polyethylene, and polystyrene is suitable for particular operations.

The guidelines listed below shall be followed when selecting the composition of a laboratory containment vessel:

- Borosilicate or Polypropylene containers used for storage of reagent and standardized solutions.
- Polyethylene or Teflon® containers used for shipping aqueous samples.

13.4 Reagent and Solution Labeling

All reagents and solutions at DCL are labeled to ensure proper storage and prevent the use of deteriorated or outdated solutions and solutions of unknown origin. Containers must have a typed or handwritten self-adhesive or pressure sensitive label or indelible marking. The label or marking contains the following:

- Identification of contents
- Identification of responsible person
- Concentration, or percent purity
- Storage requirements
- Preparation date, date of receipt or date of dilution from concentrate
- Expiration date, if applicable

If it is impracticable to record the information listed above on the label, the information shall be recorded in a bound notebook and the container shall have the necessary information to direct anyone to the book and page in which the necessary information can be located.

13.5 Computer Program Verification

Computer software used to perform environmental data collection, processing or reporting shall be validated, verified, and documented as appropriate according to the intended use of the software. The software must demonstrate that it correctly performs to stated or required capabilities and that statistical models embodied in the software are valid and produce an acceptable representation of the process or system for which it is intended. The computer support section will have the responsibility for conducting and documenting all software verification.

13.6 Glassware Cleaning

The purpose of cleaning glassware used at DCL is to ensure that all contaminants at trace level concentrations have been removed and do not contribute to error propagation. All containers are rinsed with tap water as soon after use as is possible. The glassware is then be scrubbed with a brush in hot tap water with laboratory-grade nonphosphate detergent. It is then be rinsed three times with tap water. If residues persist, repeated scrub and rinse cycles and/or sonication with detergent is employed. If residue still persist, containers/glassware is cleaned with hot nitric acid. Once clean, glassware receives a final rinse with deionized water. Glassware exposed to abnormal levels of contamination is labeled and segregated from the routine labware.

All glassware is safety inspected for cleanliness, cracks, and etching before being placed in storage for continued use.

13.7 Procurement of Analytical Services

Contracted laboratories which perform analytical services for DCL are required to maintain quality programs consistent with the quality requirements of DCL. In those instances for which DCL has specific QA/QC requirements as a result of a contract agreement or a project plan, these requirements will also apply to any pertinent work subcontracted by DCL. Implementation of subcontractors Quality Assurance Programs shall be verified by on-site audit by DCL Quality Assurance. Before any subcontracted

analytical services are performed for DCL, DCL QA shall conduct a source audit to assess laboratory capabilities, personnel, and implementation of the Quality Assurance Program. During this audit, an assessment of the operation shall be made by reviewing documents to support implementation of a quality program. A report of the results of the audit will be prepared by the audit team. Required corrective action will be listed in the report. Verification of implementation of required corrective action will be documented in a report approved by the QAM. Verification must occur before subcontract work is initiated. Follow-up audits focusing on maintenance of the quality program, and raw data generated for analytical reports will be performed as deemed necessary by DCL QA. Before subcontracted analytical data are sent from DCL to the client, DCL QA shall review final reports to assure compliance. After review, the report may then be sent to appropriate personnel.

Analytical services which fail to meet the contracted quality requirements will result in non-acceptance by DCL QA of the data provided by subcontractor. Such data will not be provided to the client. Payment in such instances will be governed according to contractual agreements.

14.0 QUALITY ASSURANCE AUDITS AND REPORTS TO MANAGEMENT

14.1 Introduction

The QAM is required to submit reports to management regarding the evaluation and verification of the implementation and effectiveness of the Quality Assurance Program.

14.2 Performance Audit Reports

DCL participates in various environmental chemistry performance audits. The QAM is responsible for coordinating and reporting the performance audit results to the regulatory agency in a timely manner. A performance audit file will be maintained by the QAM for all performance audits in which DCL is involved.

The QAM will submit a report to the DCL Director, Technical Operations Managers and other involved management personnel on the performance evaluation results obtained from each Intercomparison Study. Indicated deficiencies, biases and unacceptable performance results will initiate a corrective action investigation and compliance report by the QAM.

The performance audit file will contain the initial report, raw data, performance, QAM performance audit report and associated corrective action and compliance reports.

14.3 Procedure/System Audit Reports

Internal audits and inspections are conducted by the DCL Quality Assurance Unit (QAU), under the direction of the QAM, to review systems and verify that DCL procedures and practices are in compliance with written and approved policy.

Routine procedure and systems audits will be conducted at least quarterly by the QAU. An audit of a specific procedure or system may be requested by an Analyst, Group Leader or DCL Manager at any time. Audits shall be coordinated and scheduled through the QAM.

Systems and procedures subject to QAU audit include, but are not limited to:

- Analytical standards and source material procurement, preparation, use, storage and disposal;
- Analytical procedures and methods, including sample screening and preparation, instrumental calibration, analysis, data collection, sample storage and inventory control;
- Analytical data reduction, validation, and reporting procedures;
- Complete analytical data sets, analyst's notebooks, maintenance and instrument logs, and other laboratory record books;
- Quality control sample preparation and documentation;

An internal audit checklist will be completed and a copy will be attached to the evaluation report. This evaluation report will be completed by the QAM and submitted to the DCL Director, DCL Managers and other involved management personnel.

Any deficiencies or noncompliance that are revealed by the audit will constitute the initiation of corrective action measures by the QAU. A Corrective Action Report (CAR) will be completed by the QAM following the initiation of corrective action measures. This CAR will document the effectiveness of the action taken and a copy will be included with the audit report in the procedure/system audit file.

14.4 Operational Audit Reports

The operations of the DCL shall be audited by the QAU at least quarterly for compliance with SOPs, analytical methods, contractual project and program requirements. The audit shall consist of observations by the QAU auditor of routine operational procedures at DCL for comparison against, and compliance with, established program and project criteria and requirements.

Operational aspects selected for routine audit by the QAU shall be independent of the DCL management.

All compliance and noncompliance with established program and project criteria shall be documented during the audit. The QAU personnel shall submit their findings to the QAM. The QAM shall prepare and submit an operational audit report to the DCL Director, DCL Managers and other involved management personnel. All noncompliance shall constitute corrective action measures. Documentation and verification of these measures will be maintained with the audit report in the operational audit file.

15.0 IMPLEMENTATION REQUIREMENTS AND SCHEDULE

Several milestones and action items are identified and scheduled to implement the DCL environmental QA program in an efficient, satisfactory manner. These include:

	ITEM	STATUS
1.	Preparation of QA Program Plan	Completed
2.	Designation of QA Officers	Completed
3.	Preparation of QA Project Plans	Ongoing
4.	Participation in Annual Performance or System Audits	Ongoing

APPENDIX A
Analytical Procedures

Three major references from which inorganic environmental analytical methods are derived are:

1. USEPA, Methods for Chemical Analysis of Water and Wastes, EPA-600/4/79- 020, Revised March 1983 (MCAWW).

2. American Public Health Association (APHA), Standard Methods for Examination of Water and Wastewater, 17th Edition, 1989.

3. USEPA, Test Methods for Evaluating Solid Waste, Volume One, Sections A and C, USEPA publication SW-846, Third Edition, November 1986, Revision 1, December 1987.

4. USEPA-CLP, Statement of Work for Inorganics Analysis, Multi-Media, Multiconcentration, 3/90.

Two major references from which organic environmental analytical methods are derived are:

1. USEPA Methods for Organic Chemical Analysis of Municipal and Industrial Wastewater, FR. Vol. 49, No. 209, October 26, 1984 (EPAMOCA).

2. USEPA, Test Methods for Evaluating Solid Waste, Vol. One, Section B USEPA Publication SW-846, Third Edition, November 1986, Revision 1, December 1987.

3. USEPA-CLP, Statement of Work for Organics Analysis, Multi-Media, Multiconcentration, 3/90.

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[4] Johnson, N.L. and F.C. Leone: *Statistics and Experimental Design* Vol. II., pp. 1-103. John Wiley and Sons, New York (1984).

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[6] *Handbook for Analytical Quality Control in Water and Wastewater Laboratories*, pp. 6/1-6/13. EPA 600/4/79/019, Cincinnati (1979).