



November 18, 1999

Tammy Chang  
Parsons Engineering Science  
8000 Centre Park Drive #200  
Austin, TX 78754

Re: Response to Adequacy Evaluation of the Corrective Action

Dear: Tammy Chang,

Below are itemized responses to the "Adequacy Evaluation of the Corrective Actions". The responses are listed in the exact order as received in your Adequacy report faxed on November 4, 1999.

#### **Chromatography (HPLC) Action Items**

1. DataChem will present a SOP for manual integrations by December 10<sup>th</sup>, 1999.
2. DataChem will purchase min/max thermometers for the sample receiving refrigerator and record the temperature extremes detected over the weekend or holidays for this project.  
  
The procedure for sample handling in refrigeration units not functioning properly is outlined in Section 4 of SOP QC-DC-002 "Refrigeration Units". This SOP is attached.
3. None
4. In the future, DCL will write down the lot number of sodium chloride in the extraction notebook in order to insure traceability for all compounds added to explosive samples from your project. A sample starting with QC is the DCL lab control sample. A sample starting with QD is a lab control sample duplicate.
5. Soil samples are dried in an operating fume hood at ambient conditions until in the samples are, in the judgement of the analyst, dry. This usually takes several hours to overnight, but occasionally takes longer. DataChem has also contacted the EPA's MICE line and believes this is a reasonable approach to constant weight at  $\pm 0.1g$  of sample. Waiting a period of time and reweigh of samples does not add any value to this analysis.
6. None.
7. None.

8. DataChem will perform a 72-hour retention time window study and provide data to Parsons by December 10<sup>th</sup>, 1999.
9. None.
10. None.
11. All CCVs in a run come from the same CCV solution already identified in the analyst's notebook.
12. None.
13. A revised SOP will be provided by December 10<sup>th</sup>, 1999.
14. None.
15. See 1 above.
16. None.
17. The concentration of the lowest standard for 2-Nitrotoluene is 0.08ug/ml, which equates to 0.40 ug/g reporting limit for soil analysis.
18. There is no mention in the AFCEE 3.0 QAPP or in the method of a verification standard. Since no validation criteria exists for this verification standard it adds nothing to the data set.
19. No response can be given to this statement.

#### **Sample Receipt, Storage, Preservation, Custody & Disposal Action Items**

1. Acceptance criteria are present in the front of each balance record book.
2. None.

#### **LIMS Action Items**

None.

#### **Facility Security Action Items**

None.

#### **Instrument Maintenance and Equipment Monitoring/Calibration Action Items**

1. DataChem has never been asked to certify microsyringes. There is no procedure for verifying microsyringes. A six-place microbalance would be needed to accurately calibrate a 10 ul syringe, which normally delivers 1 to 3 ul for spiking. DataChem will not change its position on this action item.
2. Passing calibration curve criteria is more than enough documentation that a system is brought back into control. No record is needed in the maintenance logbook.

**QA/QC Functions Action Items**

1. An internal audit of laboratory operations will be provided by January 25<sup>th</sup>, 2000.
2. None.
3. None.

**Safety Program Action Items**

1. None.
2. None.

**END of Responses**

Please feel free to call me anytime regarding these responses at (801) 266-7700. Thank you for your time and the efforts you have taken to approve DataChem for this important project.

Sincerely,



Robert P. Di Rienzo  
Vice President  
Quality Assurance / Information Technology  
DataChem Laboratories, Inc.

Enclosures: SOP # QC-DC-002

CC: James H. Nelson, DCL Laboratory Director  
Kevin Griffiths, DCL Project Manager  
Richard Wade, DCL Organics Manager

**DATA CHEM LABORATORIES, INC.**

**STANDARD OPERATING PROCEDURE APPROVAL SHEET**

SOP TITLE: Refrigeration Units

DOCUMENT CONTROL NUMBER: QC-DC-002 Revision 7

EFFECTIVE DATE: July 30, 1998

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APPROVALS:

MANAGER

\_\_\_\_\_

Date

\_\_\_\_\_

Q A MANAGER

\_\_\_\_\_

Date

\_\_\_\_\_

LAB DIRECTOR

\_\_\_\_\_

Date

\_\_\_\_\_

## **STANDARD OPERATING PROCEDURE**

### **REFRIGERATION UNITS**

#### **1.0 INTRODUCTION**

- 1.1 The purpose of this Standard Operating Procedure is to describe the procedures for documenting the verification of refrigeration unit performance. This is to ensure that refrigeration units always provide the highest quality performance.
- 1.2 The objective of checking refrigeration unit temperatures is to monitor and ensure the steady-state temperature of the units, not to detect temperature spikes due to opening of the doors during regular daily use.

#### **2.0 RESPONSIBILITY**

- 2.1 Technical Operations is responsible for the verification and documentation of all refrigeration unit steady-state temperatures at DataChem Laboratories (DCL).
- 2.2 Technical Operations personnel are responsible for notification of appropriate Technical Operations Section Managers of any nonconformant situations.
- 2.3 Technical Operations personnel are responsible for initiating corrective action to return nonconformant refrigerators to an acceptable state of operation. This may require the assistance of DCL Engineering Support or outside vendors.
- 2.4 Each analyst is responsible for notifying the appropriate Section Manager or the Quality Control Section of any nonconformant equipment.
- 2.5 Quality Control personnel are responsible to audit this system a minimum of annually to determine compliance.

#### **3.0 DOCUMENTATION OF REFRIGERATOR TEMPERATURE**

- 3.1 Validation of refrigeration unit temperatures is documented a minimum of once each day, with an optimum of two times each working day Monday - Friday, by assigned laboratory personnel.
- 3.2 The two steady-state temperature verifications are spaced at least four hours apart.
- 3.3 Refrigeration units are assigned a unique unit number by the QC Section (see Table 1).
- 3.4 Each uniquely numbered refrigeration unit contains a correspondingly numbered thermometer immersed in glycerin. The thermometer is read at eye level by assigned personnel.
- 3.5 Refrigerator thermometers are validated annually against a National Institute of Standards and Technology (NIST) traceable thermometer.

**3.6** Documentation of each refrigeration unit temperature is recorded in degrees Celsius on a "DCL Record of Temperature" form (see Exhibit I). The form is attached to each refrigeration unit and contains the following information:

- 3.6.1** Unit number
- 3.6.2** Acceptable temperature range
- 3.6.3** Month for which temperatures were recorded
- 3.6.4** Thermometer correction factor
- 3.6.5** Date of thermometer calibration
- 3.6.6** Day the temperature was taken
- 3.6.7** Temperature (in C°)
- 3.6.8** Time of verification
- 3.6.9** Initials of QC personnel verifying temperatures
- 3.6.10** NCR issued (if applicable)
- 3.6.11** Maintenance schedule

**3.7** The responsible individual must verify the temperature reading, record the time and temperature, and initial the appropriate space according to the day of the reading. If any temperature readings are nonconformant and an NCR was issued, a check mark is made next to the date the NCR was issued.

**3.8** After refrigeration unit temperatures for each calendar month have been recorded, all pertinent forms are collected and bound.

#### **4.0 CRITERIA AND NONCONFORMANT SITUATIONS**

**4.1** The criterion for refrigerators and walk-in coolers used for sample storage is that temperatures must be in the range of 2 - 6°C (36 - 43°F). Freezers are required to be at -5°C (23°F) or below. Variances of these criteria will be posted on the applicable refrigeration unit and kept on file by the Quality Control Section Manager.

**4.2** If, at the time of temperature reading, the temperature of a refrigeration unit is above or below the criterion range, the unit should be closed and rechecked in approximately one hour. However, the temperature shall be recorded and a comment noted that a re-check will be made.

**4.3** If the temperature of a rechecked unit is still above the temperature-range criterion after approximately one hour, a notice should be placed on the door of the unit requesting that the unit not be opened until the notice is removed. This is to ensure a steady-state condition without the effect of door openings.

- 4.4 If, after following 4.3 above, the temperature of a closed and rechecked unit is still above or below the criterion range, personnel in the laboratory area who may have been using the unit should be consulted to determine if current use may have caused the temperature variance; this could include the introduction of a significant quantity of room-temperature materials or individuals ignoring the request to leave the door closed. If no obvious cause can be determined immediately, the temperature should be recorded on the DCL Record of Temperature, and a DCL Nonconformance/ Corrective Action Report (NC/CAR) should be issued. If an acceptable probable cause is determined, the cooperation of laboratory personnel should be enlisted to allow the unit to attain a steady-state temperature. After an appropriate time period, the temperature should be read again and recorded with appropriate comment documented to explain the occurrence.
- 4.5 If a refrigeration unit found to be outside its temperature criterion range has not returned to the criterion range on its own or by adjustment by the day following the issuance of an NC/CAR, the materials stored in the unit must be removed and placed in a compliant unit. The unit must be tagged as non-conformant and taken out of service.
- 4.6 Refrigeration units which temperatures have returned within range on re-checks shall have the second temperature reading also recorded and noted as "2nd Temperature Check" in the comment section on the DCL "Record of Temperature" form.
- 4.7 Nonconformant refrigeration units which are removed from service should be tagged with a tag similar to Exhibit II. The tag may be removed only by the Quality Control Section.
- 4.8 A nonconformant unit may be returned to service when it has returned to the acceptable criterion and the temperature has been documented.
- 4.9 Units requiring adjustment or maintenance service must have such recorded in the Maintenance Schedule section of the DCL Record of Temperature form.

EXHIBIT I

**DCL RECORD OF TEMPERATURE**

Unit Number :

Correction Factor :

Acceptable Temperature Range:

Date of Thermometer:

Record for Month of:

Calibration:

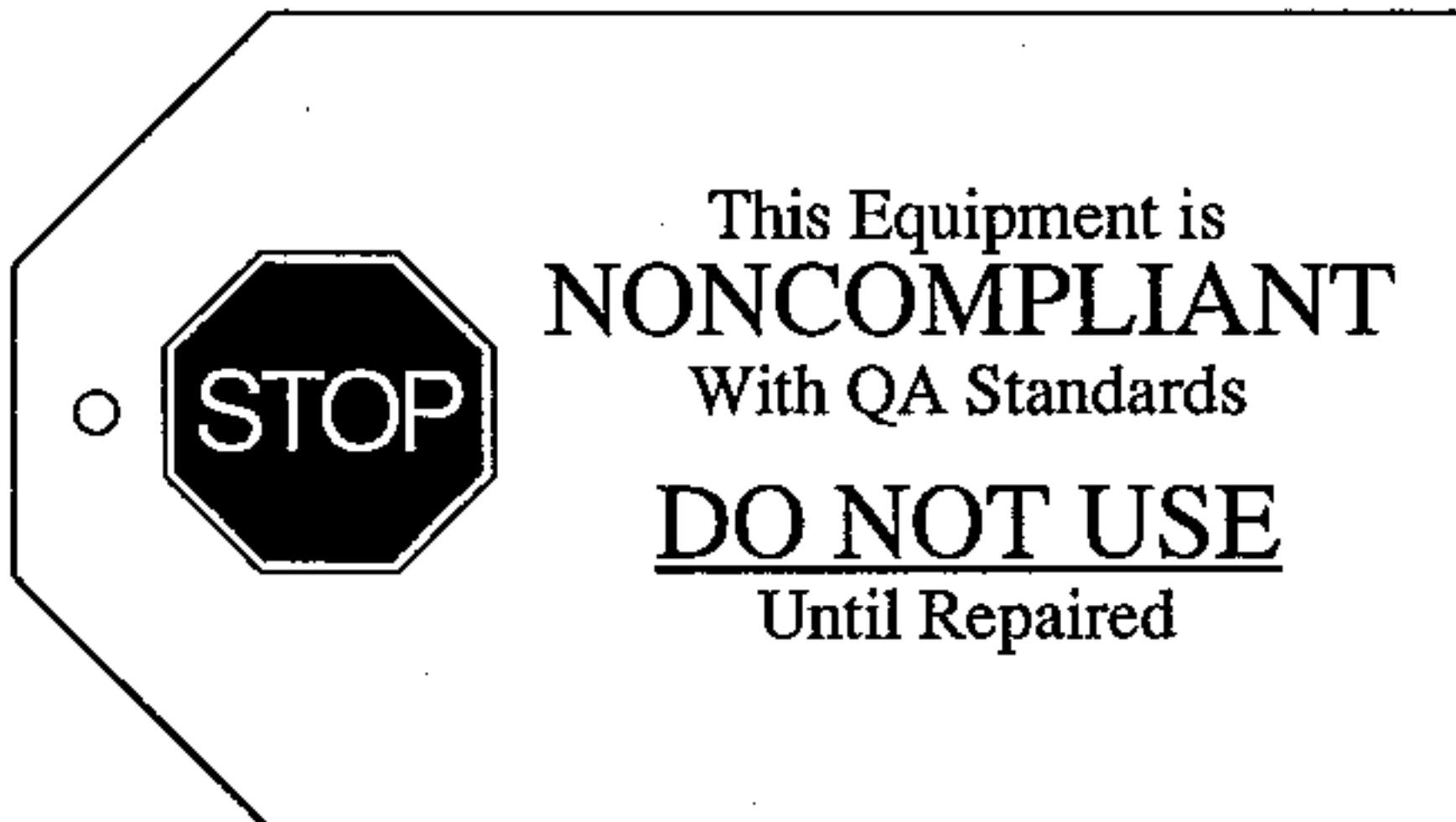
Day	T(°C)	Initials /Time	T(°C)	Initials /Time	NCR	Day	T(°C)	Initials /Time	T(°C)	Initials /Time	NCR
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1						17					
2						18					
3						19					
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13						29					
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16											

**MAINTENANCE SCHEDULE**

DAY	COMMENTS/ACTION

EXHIBIT II



**TABLE 1**  
**DATA CHEM LABORATORIES**  
**DESIGNATED STORAGE AREAS AND REFRIGERATORS**

Operations	Room No.	Refrigerator No.	Freezer No.	Designated Storage	Key List
Organic Extraction	16	NA	F-16-1	SAMPLES ONLY	not locked
	16	R-16-1C	NA	SAMPLE EXTRACTS ONLY	0386
	16	R-16-3	NA	SAMPLE EXTRACTS ONLY	KL802
	16	R-16-5	NA	SAMPLES ONLY	1454
	16	R-16-6	NA	STANDARDS AND SPIKING SOLUTIONS	not locked
	16	R-63-4	NA	STANDARDS AND SPIKING SOLUTIONS	not locked
	50	R-16-4	NA	STANDARDS ONLY	not locked
Inorganic	19	R-20-1	NA	NOT IN USE	not locked
	21	R-21-1	NA	SAMPLES ONLY	GMKAD,AD8
	82	NA	NA	FURNACE DIGESTS - POST ANALYSIS	GMKAD,AD4
	83	NA	NA	ICP & FURNACE DIGESTS, MERCURY SAMPLES	GMKAD,AD4
	84	R-84-1	NA	SAMPLES ONLY	0386
	84	R-84-2	NA	STANDARDS ONLY	not locked
Sample Receiving	23	R-23-1	NA	SAMPLES ONLY	cipher lock
	24	NA	F-24-1	IH SAMPLES ONLY	0386
	24	R-24-2	NA	VOA SAMPLES ONLY	0386
	24	R-24-3	NA	IH SAMPLES ONLY	0386
	24	R-24-4	NA	VOA SAMPLES ONLY	0386
	13	NA	F-15-1	ICE ONLY	not locked
Organic Preparation	32	R-32-1C	NA	PESTICIDE EXTRACTS ONLY	P609
	32	NA	F-32-2	STANDARDS ONLY	not locked
	32	R-63-3	NA	STANDARDS ONLY	combination lock
Sample Archives	33	R-33-1	NA	SAMPLES	AAB1
	34	R-34-1C	F-34-1C	ORGANIC SAMPLES	cipher lock
	34	R-34-2C	F-34-2C	ORGANIC SAMPLES	cipher lock
	34	R-34-3C	F-34-3C	INDUSTRIAL HYGIENE SAMPLES	cipher lock
	34	NA	NA	INORGANIC SAMPLES	GGMKAAB1,AAB2
	88	NA	NA	INORGANICS, ASBESTOS SAMPLES	AAB1
	--	R-34-5	NA	POST ANALYSIS SAMPLES	3354
	--	R-MW-1	NA	MIXED-WASTE POST ANALYSIS SAMPLES	0330
GC/MS SV Analysis	60	R-60-1C	NA	SV SAMPLE EXTRACTS ONLY	0386
	60	R-60-2C	NA	SV STANDARDS ONLY	not locked
	60	R-60-3	NA	SV SAMPLE EXTRACTS ONLY	0386
	60	NA	F-60-3	STANDARDS ONLY	not locked
	85	R-60-5	NA	SV STANDARDS ONLY	not locked
	60	R-60-6	NA	SV STANDARDS ONLY	0386
	65	R-65-1C	F-65-1C	STANDARDS ONLY	not locked
	65	R-65-2	NA	SAMPLES ONLY	0386

TABLE 1 (Continued)

Operations	Room No.	Refrigerator No.	Freezer No.	Designated Storage	Key List
GC/MS VOA Analysis	61	R-61-5	NA	STANDARDS ONLY	not locked
	61	R-61-2C	NA	VOA SAMPLES ONLY	0386
	61	NA	F-61-2C	VOA IH SAMPLES ONLY	0386
	61	R-61-4C	NA	VOA SAMPLES ONLY	0386
	61	NA	F-61-4C	VOA IH SAMPLES ONLY	0386
	61	NA	F-61-5	VOA STANDARDS ONLY	not locked
Gas Chromatography VOA Analysis	63	R-63-1	NA	VOA SAMPLES ONLY	0386
	63	R-63-2	NA	VOA SAMPLES ONLY	0386
	63	NA	F-63-5	VOA STANDARDS ONLY	not locked
Gas Chromatography	71	R-71-1C	F-71-1C	STANDARDS ONLY	not locked
	75	R-75-2C	F-75-2C	ENVIRONMENTAL STANDARDS ONLY	not locked
	75	R-75-3	NA	SAMPLES ONLY	2396
	75	R-75-4	NA	IH STANDARDS ONLY	not locked
Pesticide Analysis	72	R-72-1	NA	SAMPLE EXTRACTS ONLY	P609
	72	R-72-2	NA	EPA-CLP SAMPLE EXTRACTS ONLY	P609
	72	R-72-3	NA	STANDARDS ONLY	not locked
	72	R-72-4	NA	STANDARDS ONLY	not locked
	72	R-72-5	NA	STANDARDS ONLY	not locked
	72	R-72-6	NA	STANDARDS ONLY	P609
	72	R-72-7	NA	OP SAMPLE EXTRACTS ONLY	P609
	72	R-72-8	NA	EPA-CLP STANDARDS ONLY	not locked
	72	R-72-9	NA	STANDARDS ONLY	not locked
	77	R-77-1	NA	SAMPLE EXTRACTS ONLY	0386
	77	R-77-2	F-77-2	STANDARDS ONLY	not locked
HPLC	85	NA	F-85-1	STANDARDS ONLY	not locked
	89	NA	F-89-1	IH SAMPLES ONLY	2396
	89	R-89-2	NA	STANDARDS ONLY	not locked
	89	R-89-3	NA	SAMPLES ONLY	2396
	89	R-50-2	NA	STANDARDS ONLY	0386
	50	R-50-3	NA	SAMPLE EXTRACTS ONLY	0386
Quality Control	102	R-102-1C	P-102-1C	STANDARDS AND SPIKE SOLUTIONS	not locked
	102	R-102-2C	F-102-2C	SARMS ONLY	2416
	102	R-102-3	F-102-3	IH STANDARDS AND SPIKE SOLUTIONS	not locked
Radiochemistry	303	NA	F-303-1	SAMPLES ONLY	cipher lock
	303	R-303-1	NA	REAGENTS ONLY	cipher lock
Mixed Waste - Organic	306	R-306-1	NA	SAMPLE EXTRACTS ONLY	0386
	306	R-306-2	NA	SURROGATES AND STANDARDS ONLY	not locked
	319	R-319-1	NA	TCLP EXTRACTS AND SAMPLES ONLY	0319
	407	R-407-1	NA	VOA SAMPLES ONLY	0386
	410	R-410-1	NA	SAMPLE EXTRACTS ONLY	0386
	410	R-410-2	NA	STANDARDS ONLY	not locked
	407	NA	F-407-2	STANDARDS ONLY	not locked
Mixed Waste - Inorganic	403	R-403-1	NA	SAMPLES ONLY	BH0151
XRD/Media	96	R-96-1	NA	MEDIA SUPPLIES	not locked