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Superfund

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User's Guide to the Contract Laboratory Program

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User's Guide to the Contract Laboratory Program

Office of Emergency and Remedial Response
U.S. Environmental Protection Agency
Washington, DC 20460

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FOREWORD

This document has been prepared by the Contract Laboratory Program (CLP) Sample Management Office (SMO) specifically for the guidance and direction of program clients. The CLP User's Guide is designed to clarify procedures for CLP analysis. The CLP User's Guide acts as a reference for the Regions and laboratory contractors to promote consistency in procedures throughout the Regions and ensure the proper adherence to CLP requirements. This document along with the CLP Sampler's Guide provides a thorough overview of the CLP.

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CHAPTER I

BACKGROUND AND INTRODUCTION

In this chapter...

CLP Objective and Orientation
CLP Structure
  Clients/Users
  Regional Program Support
  Analytical and Support Services Contractors

A. CLP Objective and Orientation

The Contract Laboratory Program (CLP) is made up of contractor laboratories and supports the Environmental Protection Agency's (EPA) Superfund effort. It was begun under the 1980 Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and continues under the 1986 Superfund Amendments and Reauthorization Act (SARA). The CLP provides a range of state-of-the-art chemical analytical services of known quality on a high volume, cost effective basis. The CLP is structured to provide legally defensible analytical results for use in supporting Agency enforcement actions. The CLP can also meet other requirements of the user community. Quality assurance procedures and documentation designed for the intended purposes of the data are part of all program activities.

Client orientation is a key factor in the design and application of all CLP services and responses. The CLP supplies analytical services in direct response to requests from the EPA Regions, the primary users of the program. States and other Agency programs are also part of the CLP user community.

The CLP objective is to develop, manage and improve its analytical programs in support of all Superfund requirements. This is accomplished by increasing analytical capacity and improving analytical program requirements and related support services.

B. CLP Structure

CLP services involve numerous Agency programs, contractors and other groups throughout the country. These organizations are identified and their role in the program described in the following sections. Figures 1 and 2, "Relationship of CLP Principals," and "Relationship of Other CLP Offices," illustrate the interaction of these groups in CLP operation. In addition, a directory listing addresses and telephone numbers of key program personnel is located in Appendix B.

1. Clients/Users

a. EPA Regions

The ten EPA Regions are the primary clients of the CLP. Each Region has established a Regional Sample Control Center (RSCC) that schedules all Regional CLP analysis requests. The RSCC balances Regional sampling with allocated numbers of CLP sample analyses available each month and prioritizes the Region's analytical workload when conflicts occur. RSCC personnel coordinate closely with the Sample Management Office (SMO) throughout Regional sampling events, assisting in tracking sample shipments to the laboratory and resolving any problems that arise. The RSCC also processes analytical requests from state or other program users that are located in the Region's geographical area.

b. States

Any state undertaking initial site investigations and entering into cooperative agreements [under the Resource Conservation and Recovery Act (RCRA)- CERCLA Cooperative Agreements] with the Government for clean up of local waste sites can use CLP services. States must access CLP analytical services through the RSCC. Data packages are also distributed to states through the RSCC.

c. Non-Superfund Clients

Program services are available to support Non-Superfund clients. Non-Superfund analyses and other support are provided by the CLP through transfer of funds from the Non-Superfund program. Non-Superfund clients currently include other government agencies and EPA programs, such as the Office of Acid Deposition, the Office of Solid Waste, the Office of Water, and RCRA.

FIGURE 1. RELATIONSHIP OF CLP PRINCIPALS

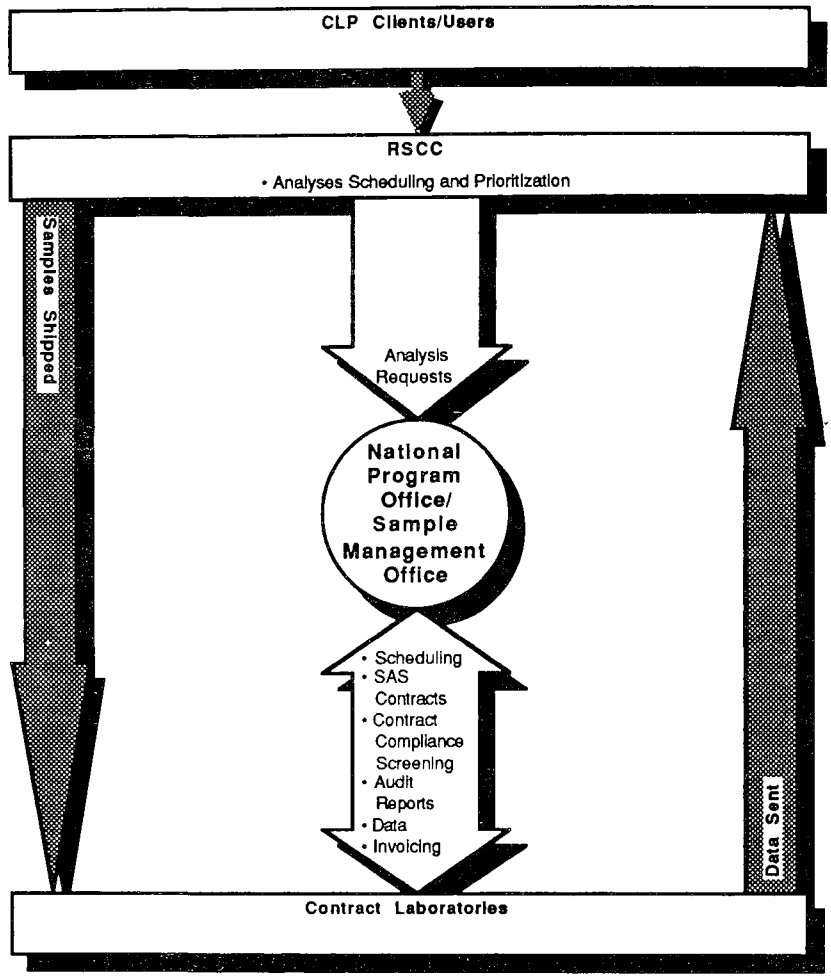


FIGURE 2. RELATIONSHIP OF OTHER CLP OFFICES

2. Program Management

a. National Program Office

The CLP is directed by the National Program Office (NPO), in EPA Headquarters Analytical Operations Branch (AOB), Hazardous Site Evaluation Division (HSED), Office of Solid Waste and Emergency Response (OSWER), located in Washington, DC. The NPO is comprised of the AOB Branch Chief and Deputy Branch Chief, the Analytical Methods Implementation Section (AMIS) Chief who also serves as the National Program Manager, the National Organics Program Manager and National Inorganics Program Manager, the Regional Operations Section Chief, the Quality Assurance Coordinator, the Data Integrity Specialist, the SMO Project Officer, and the ADP Officer.

NPO responsibilities include:

- overall management of the CLP in terms of program objectives;
- expansion and interface with clients and other groups;
- policy and budget formation and implementation;
- development and administration of CLP analytical and support services contracts;
- development and technical review of analytical protocols;
- review of Special Analytical Services subcontracts;
- review of CLP–generated laboratory data;
- monitoring and formal evaluation of analytical and support contractors; and
- direction of CLP quality assurance in coordination with overall OSWER quality assurance activities.

The National Program Manager (NPM) assisted by the National Organics and Inorganics Program Managers, in addition to directing the AMIS section staff, is responsible for the formulation of CLP policies and direction. By communicating with Regional and Agency communities on a continuing basis, the NPM keeps all parties apprised of program activities and receives input on program effectiveness. The NPM and Organics and Inorganics Project Managers also directs annual technical caucuses for the purpose of reporting initiatives and progress of the past year. AMIS is also responsible for development of sample bottle specifications and data review guidelines for all analytical services.

The Regional Operations Chief directs a staff responsible for the Sample Management Office contract, the Environmental Services Assistance Teams contracts, and the Shipment Management contract. In addition, the Regional Operations Section tracks the supply and demand between CLP capacity and client needs, and provides budget support and administration. (Note: AMIS manages this using information from ROS.)

The Quality Assurance Coordinator manages all aspects of program quality assurance needed to provide information to the Branch Chief and Section Chiefs to determine if management's QA expectations/needs are being met. The QA Coordinator works closely with the Office of Research and Development's Environmental Monitoring Systems Laboratory in Las Vegas (ORD EMSL/LV) in administering and improving the QA program. The QA Coordinator interacts with the APOs in refining and updating analytical method QA. The QA Coordinator also communicates with the Regions and other program users to resolve QA issues related to analytical data. For purposes of QA procedures review and guidance development, the QA coordinator conducts volunteer workgroups throughout the year.

The APOs are responsible for administrative and technical program decisions, contract monitoring and contractor performance evaluation. On a daily basis, the APOs work closely with the Regional Technical Project Officers and contract laboratories to resolve technical issues. The APOs also direct the continuing effort to improve contract language and to develop analytical methodologies. For the purposes of CLP protocol review, method development, and QC criteria development, the APOs conduct volunteer workgroups throughout the year.

The Data Integrity Specialist is responsible for implementing Good Automated Laboratory Practices into analytical services, developing policy to protect the Government from alleged fraud in the laboratory community, and heading projects/workgroups focussing on the integrity of Superfund analytical data.

b. Sample Management Office

The contractor-operated SMO provides management, operations and administrative support to the CLP. The primary objective of SMO is to maintain optimal use of program analytical resources. SMO activities fall into the following areas:

- sample scheduling and tracking;
- Contract Compliance Screening;
- Special Analytical Services subcontracting;
- laboratory invoice processing;
- maintenance of CLP records and management reporting;
- procurement/IFB support and statement of work production;
- coordinating CLP meetings and conferences; and
- NPO management, technical, and administrative support.

SMO routinely receives Regional analytical requests, coordinates and schedules sample analyses, tracks sample shipment and analyses, receives and checks data for completeness and compliance, processes laboratory invoices, and maintains a repository of sampling records and program data. In response to client requests for specialized analyses, SMO subcontracts for Special Analytical Services (SAS), scheduling and tracking for SAS efforts as outlined above. SMO maintains a comprehensive database of CLP services, performance and utilization in order to generate a variety of management and user reports.

c. Office of Research and Development, Environmental Monitoring Systems Laboratory/Las Vegas (EMSL/LV)

ORD provides program QA support through EMSL/LV. EMSL/LV assists in the following functions:

- performing preaward and postaward on-site laboratory evaluations;
- preparing performance evaluation (PE) samples for preaward and postaward laboratory performance evaluations;
- evaluating preaward and postaward PE sample data;
- performing QA audits on CLP-generated data including mass spectrometer data tapes; and
- assisting in the evaluation and development of CLP analytical methods and protocols.

EMSL/LV also operates the program's QA database to conduct program and laboratory trend analyses used in developing and updating contract quality control criteria.

d. National Enforcement Investigations Center

The National Enforcement Investigations Center (NEIC) advises the NPO in defining and applying program enforcement requirements. NEIC-developed sample custody procedures, chain-of-custody records, sample tags, and custody seals are used to maintain the integrity of sample analyses for supporting Agency enforcement actions. NEIC routinely performs evidence audits of contract laboratories and generates sample profiles used in Agency enforcement litigation. A description of the enforcement support provided by NEIC appears in Chapter IV, Section D.

3. Regional Program Support

The Regions play an integral role in program activities, both as the primary CLP user and as a key part of analytical program management. The decentralization of program responsibilities to the Regions is an effective means of directing program operations nationwide. Extended Regional participation in the program has and will continue to increase the program's responsiveness to Superfund requirements.

a. Regional Technical Project Officers

In 1984, Regional Administrators appointed a CLP Technical Project Officer (TPO) for each Regional office. Under the guidance of the NPO, the Regional TPO monitors the contract laboratories located in the Region. The TPO works closely with the APO in responding to identified problems in laboratory operations and participating in on-site evaluations. The TPO is the first line of contact for the laboratory for all technical problem resolution and only reverts technical problems to the NPO that appear to have program implications.

b. Regional Sample Control Centers (RSCC)

In 1984, each Region established an RSCC to centralize scheduling of CLP sample analyses within the Region. The RSCC is comprised of one or more individuals. One individual is named as the primary RSCC. The RSCC is responsible for coordinating the level of Regional sampling activities to correspond with the monthly projected demand for analytical services. When conflicts occur, the primary RSCC makes the final determination of Regional analysis priorities. The RSCC routinely places all Regional requests for CLP analyses, coordinates with SMO during sampling and sample shipment, and resolves any problems concerning the samples. The RSCC also serves as the central point of contact for questions concerning Regional sampling efforts.

c. Regional/Laboratory Communication System

In 1983, the NPO established a system by which the Regions and contract laboratories can communicate in the most timely and direct manner possible. Regional communication contacts routinely call laboratory communication contacts to resolve technical questions concerning program data. This communication link also benefits the laboratory by providing direct feedback on its data product.

4. Analytical and Support Services Contractors

a. Analytical Contract Laboratories

The CLP's analysis contractors come from the nationwide community of chemical analytical laboratory facilities. To become part of the CLP, laboratories must meet stringent requirements and standards for equipment, personnel, laboratory practices, and analytical and quality control operations. Firm, fixed–price contracts are awarded to the lowest responsive, responsible bidders through the Government's Invitation for Bid (IFB) process. Before a contract is awarded, low priced bidders must successfully analyze performance evaluation samples and pass a preaward laboratory audit. After contract award, laboratories are closely monitored to ensure compliance with the terms and conditions of the contract. Details of preaward and postaward evaluations are addressed in Chapter V.

b. Shipment Management Program

The Shipment Management program was created by the NPO in 1988 to provide a consistent means of tracking the various shipping accounts established for CLP use. The Shipment Management contractor establishes, maintains and monitors the shipping accounts for the transportation of sample containers, sample coolers, contract compliance screening results and other items requested by the NPO. Further information on the Shipment Management program is provided in Chapter IV, Section B.

CHAPTER II

DESCRIPTION OF ANALYTICAL SERVICES

In this chapter ...

Organic Routine Analytical Services
Inorganic Routine Analytical Services
Dioxin/Furan Routine Analytical Services
Special Analytical Services
  RAS Plus SAS
  All SAS
  Contract Delivery and Quality Control Requirements
Analytical Methodology Improvement/ Development
  Protocol Standardization and Improvement
  Method Development

The CLP provides routine and specialized analytical services to support a variety of Superfund sampling activities. These activities range from those associated with the smallest preliminary site investigation to those of large scale, complex remedial, monitoring and enforcement actions. In response to the increasing analytical demands of Regional clients, the CLP has continually expanded its capacity for standardized analyses through frequent contract solicitations. On the average, the CLP provides over 6,000 sample analyses per month through its routine and specialized analytical services programs. The CLP will continue to adjust analytical capabilities and capacity in response to client needs.

The CLP operates the following analytical programs:

- Organic Routine Analytical Services (RAS),
- Inorganic RAS,
- High Concentration Organics
- High Concentration Inorganics
- Organics Low Concentration (Drinking Water)
- Inorganics Low Concentration (Drinking Water)
- Volatile Organics Low Concentration (Drinking Water)
- Dioxins/Furans
- Special Analytical Services (SAS).

In the future, many other analytical programs will be included under RAS:

- Fast Turnaround GC Screen Organics
- Air Toxics
- Geotechnical
- Water and Soil Characterization
- Mixed Waste

Laboratories operating under firm, fixed-price contracts with the EPA provide Routine Analytical Services to Superfund clients. Non-Superfund clients can also access RAS programs once special funding arrangements have been made.

Figure 3 summarizes RAS services. For detailed analytical information, users are instructed to consult the Region's Master Copy

FIGURE 3. ROUTINE ANALYTICAL SERVICES

	Organic Routine Analytical Services				Inorganic Routine Analytical Services			Dioxin/ Furan RAS
	Multi-Media, Multi-Concentration	Low Concentration Water	Low Concentration Water, VOA Only	High Concentration	Multi-Media, Multi-Concentration	Low Concentration Water	High Concentration	
Concentration	Low, Medium	Low	Low	High	Low, Medium	Low	High	Low, Medium
Matrices	Water, Soil/Sediment	Water	Water	Water, Soil/Sediment	Water, Soil/Sediment	Water	Water, Soil/Sediment	
Fractions	• Volatiles (VOAs) • Semi-volatiles (SVs) • Pesticide/ Aroclors	• VOAs • SVs • Pesticide/ Aroclors	• VOAs	• VOAs • Extractables • Aroclors/ Toxaphenes	• Total Metals • Dissolved Metals • Cyanide	• Total Metals • Cyanide • Total Nitrogen • Fluoride	• Metals • Cyanide • pH • Conduc-tivity	

Statements of Work under which CLP RAS laboratory contractors operate.

Routine Analytical Services apply to the analysis of water and soil/sediment samples. Samples for analysis should be single–phase and homogeneous with the exception of high concentration analysis which may be multi–phase. Sample matrices other than water or soil/sediment are processed through the SAS program.

Organic and inorganic low and medium concentration RAS contract methods are used to analyze low to medium sample concentrations for organic target compounds and inorganic target analytes, respectively. The sampler identifies low and medium levels of concentration in the field to determine sample collection volume and packaging and shipment procedures. Low level samples are considered to be those collected off–site in areas where hazards are thought to be significantly reduced by normal environmental processes. Medium level samples, where a compound or element may comprise as much as fifteen percent of the total sample, are most often those collected on–site in areas of moderate dilution by normal environmental processes. The contract laboratory performs preliminary characterizations to determine the appropriate analytical protocol (low or medium) to be used.

Organic high concentration RAS contract methods are used to analyze high concentration samples for organic target compounds. High concentration samples are considered to be those collected directly from drums, pits, ponds, lagoons or areas where no dilution of waste is evident.

Required sample volume and container types used for sample collection for RAS analyses are detailed in the CLP Sampler's Guide. Contractors should acquire sample bottles which meet EPA quality assurance standards. These containers may also be utilized in SAS projects as appropriate.

Contract delivery requirements for each RAS program are specified in the following sections. The contract laboratory is required to deliver all analytical results and quality control (QC) data for each Sample Delivery Group (SDG) in one data package. An SDG is defined by one of the following, whichever occurs first:

- each case of field samples; or
- each twenty field samples within a case; or
- each fourteen calendar day (seven days for low concentration inorganic) period during which field samples in a Case are received, beginning with the receipt of the first sample in the SDG.

Laboratories are subject to liquidated damages for late delivery and incentives for early delivery of the data package.

The SAS program provides specialized analytical services to Superfund and Non–Superfund clients for organics, inorganics, dioxin and other compounds in a variety of matrices. SAS services are offered to meet specific analytical requirements which do not fall under RAS programs and are solicited through individual fixed–price subcontracts awarded to qualified laboratories.

Figure 4 outlines the services available under the CLP's SAS programs. The client should carefully consider the provisions of each CLP analytical program during the planning stages of a sampling event to determine the applicability of the analysis to user needs.

FIGURE 4. SPECIAL ANALYTICAL SERVICES

RAS Plus SAS Examples

- Fast Turnaround Analysis by RAS Organic or Inorganic IFB Protocol
- RAS Organic Analysis with Additions/Adjustments to IFB Protocol
- RAS Inorganic Analysis with Additions/Adjustments to IFB Protocol
- RAS High Concentration Analysis with Additiona/Adjustments to IFB Protocol

All SAS Examples

- Organic Analysis Per Non-RAS Protocols, Matrices, Compounds
- Inorganic Analysis Per Non-RAS Protocols, Matrices, Compounds
- Dioxin Analysis
- Special Topics Analysis (As Requested)

NOTE: The client is responsible for designating IFB method adjustments for "RAS Plus SAS" requests and for supplying suitable analytical protocols for "All SAS" requests. Additionally, the client must provide quality assurance/quality control procedures and criteria, and must specify data delivery schedules. All information must accompany the client's request for SAS services.

The CLP QC program for RAS laboratory analysis is structured to provide consistent results of known and documented quality. Sample data packages contain QC documentation that allow an experienced chemist to determine the quality of

the data and its applicability to each sampling activity. In addition, laboratory contracts contain provisions for sample reanalysis if specified QC criteria are not met by the contract laboratory. Each CLP laboratory is also encouraged to develop additional internal QA/QC procedures.

The minimum QC requirements of the RAS programs consist of both an initial and ongoing demonstration of laboratory capability to generate acceptable performance with the contract methods. The contract laboratory must demonstrate that instrument calibration criteria have been met, that interferences from the analytical system are under control, and that spike and duplicate recoveries falling outside contract acceptance windows are attributable to sample matrix interferences and not to laboratory analytical errors. The QC requirements for each RAS program are provided in the following sections.

A. Organic Routine Analytical Services

Organic Routine Analytical Services are comprised of four analytical contracts which allow the analysis of different media and concentrations. Figures 5-8 detail each of these four analytical contracts.

B. Inorganic Routine Analytical Services

Inorganic Routine Analytical Services are comprised of three analytical contracts which allow the analysis of different media and concentrations. Figures 9-11 detail each of these three analytical contacts.

C. Dioxin/Furan Routine Analytical Services

Dioxin/Furan Routine Analytical Services are detailed in Figure 12.

D. Special Analytical Services

In addition to the standardized analyses available under the RAS program, SMO provides Regional clients with specialized analyses under the SAS program. While these analytical services are beyond the scope of RAS contract protocols, they are consistent with CLP objectives. Services provided through the SAS program include fast turnaround analyses, verification analyses, analyses requiring lower detection limits than RAS methods provide, identification and quantification of non-TCL constituents, general waste characterizations, analysis of nonstandard matrices and other specific analyses.

As part of the SMO contract with EPA, Viar and Company solicits, awards and administers SAS subcontracts. By utilizing subcontracts, SMO can procure specialized services in a timely manner on an as-needed basis. Due to the often unusual nature of SAS requests, users must plan their projects in advance to allow SMO sufficient time to procure these services.

For each SAS request, the client provides SMO with the necessary analytical methods, QA/QC requirements and acceptance criteria in writing. SMO procures SAS by subcontracting with laboratories with RAS contracts in the appropriate analytical program. When RAS laboratories cannot meet the analytical requirement of the SAS, requests are solicited to other laboratories which have indicated the ability to meet program performance requirements. RAS contract laboratories are evaluated for current RAS performance before they are considered for SAS solicitations, and are not solicited for SAS work if deficient in this area. Other laboratories qualify to perform certain types of SAS work by successfully completing performance evaluation sample analyses or by justification of unique analytical capability.

Once the laboratory community is determined, SMO provides the community with the particular requirements of the SAS. Laboratories are asked to bid firm, fixed-price(s) for the performance of specific types of analyses on a defined number of samples.

A laboratory's ability to bid for SAS work and the prices being bid may vary depending on the size or scope of the analytical request, data turnaround requirements and analytical parameters of a particular task, weekly RAS sample loading, and laboratory operating conditions at the time of solicitation. SMO evaluates laboratory bids in terms of bid price and responsiveness to the specified task. The SAS is awarded to the lowest bidding laboratory which responds to the client's analytical requirement. A written, individual SAS subcontract agreement is then made between the laboratory and Viar.

FIGURE 5. ORGANIC ROUTINE ANALYTICAL SERVICES, MULTI-MEDIA, MULTI-CONCENTRATION

SOW Reference	Statement of Work for Organics Analysis Multi-Media, Multi-Concentration Document Number OLM01.0		
Concentration	Low or Medium		
Matrices	Water Soil/Sediment		
Fractions	• Volatiles (VOAs) • Semivolatiles (SVs) • Pesticide/Aroclors		
Compounds Identified & Quantified	• Target Compounds • Library Matches of 10 volatile components • Library Matches of 20 semivolatile components		
Volumes Required and Required and Preservation Techniques	Consult Sampler's Guide or Regional instructions		
Contract Delivery Requirements	**Deliverable**	**Delivery Schedule**	**Description**
	• Updated SOPs	45 days after contract receipt	Updated copies of all required SOPs submitted with prebid PE sample results. SOPs must address any and all issues of laboratory performance and operation identified through the review of PE sample data and evaluation of Bidder-Supplied Documentation.
	• Sample Traffic Reports	3 days after receipt of last sample in SDG	
	• Sample Data Summary Package	35 or 14 (see contract) days after receipt of last sample in SDG	
	• Sample Data Package	35 or 14 (see contract) days after receipt of last sample in SDG	See "Data Package Contents."
	• Complete SDG File	35 or 14 (see contract) days after receipt of last sample in SDG	See Exhibit B, Sections III and IV of SOW.
	• Quality Assurance Plan	Submit copy within 7 days of written request by APO	The QAP must present, in specific terms, the policies, organization, objectives, functional guidelines, and specific QA and QC activities designed to achieve the data quality requirements in the contract.
	• Data in Computer Readable Form	35 or 14 (see contract) days after receipt of last sample in SDG	See Exhibit H of SOW.
	• GC/MS Tapes	Retain for 365 days after data submission, or submit within 7 days after receipt of written request by APO and/or EMSL/LV	
	• Extracts	Retain for 365 days after data submission, or submit within 7 days after receipt of written request by APO or SMO.	
Data Package Contents	1. SDG Narrative 2. Traffic Reports 3. Volatiles Data 4. Semivolatiles Data 5. Pesticide/Aroclor Data		
Analytical Procedures	• Sample Preparation and Storage • GC/MS Analysis ◦ GC/EC Analysis		
QA/QC Summary	• Matrix Spike • Matrix Spike Duplicate Per Sample Delivery Group For Each Matrix and Concentration On Per-Fraction Basis • Various Instrument QA/QC (see SOW)		

FIGURE 6. ORGANIC ROUTINE ANALYTICAL SERVICES, LOW CONCENTRATION WATER

SOW Reference	Statement of Work for Low Concentration Water for Organics Analysis Document Number OLC01.0		
Concentration	Low		
Matrices	Water		
Fractions	• Volatiles • Semivolatiles • Pesticides/Aroclors		
Compounds Identified & Quantified	• Target Compound List • 10 non-surrogate organic compounds for volatile • 20 non-surrogate organic compounds for semivolatile		
Volumes Required and Preservation Techniques	Consult Sampler's Guide or Regional instructions		
Contract Delivery Requirements	**Deliverable**	**Delivery Schedule**	**Description**
	• Updated SOPs	45 days after contract receipt	Updated copies of all required SOPs submitted with prebid PE sample results. SOPs must address any and all issues of laboratory performance and operation identified through the review of PE sample data and evaluation of Bidder-Supplied Documentation.
	• Sample Traffic Reports	3 days after receipt of last sample in SDG	
	• Sample Data Summary Package	21 days after receipt of last sample in SDG	
	• Sample Data Package	21 days after receipt of last sample in SDG	See "Data Package Contents."
	• Complete SDG File	21 days after receipt of last sample in SDG	See Exhibit B, Sections III and IV of SOW.
	• Data in Computer Readable Form	21 days after receipt of last sample in SDG	See Exhibit H of SOW.
	• GC/MS Tapes	Retain for 365 days after data submission, or submit within 7 days after receipt of written request by APO and/or EMSL/LV	
	• Extracts	Retain for 365 days after data submission, or submit within 7 days after receipt of written request by APO or SMO	
	• QA Plan	Submit witin 7 days after receipt of written request by APO	The QAP must present, in specific terms, the policies, organization, objectives, functional guidelines, and specific QA and QC activities designed to achieve the data quality requirements in the contract.
Data Package Contents	1. SDG Narrative 2. Sample Traffic Reports 3. Volatiles Data 4. Semivolatiles Data 5. Pesticides/Aroclors Data		
Analytical Procedures	• GC Analysis • GC/MS Analysis • GC/EC Analysis for pesticides/Aroclor		
QA/QC Summary	• Surrogate Spike Recovery • Laboratory Evaluation Sample • Blanks • GC/MS Instrument Performance Checks (BFB and DFTPP) • Initial and Continuing Calibration Data		

FIGURE 7. ORGANIC ROUTINE ANALYTICAL SERVICES, LOW CONCENTRATION WATER – VOLATILES ONLY

SOW Reference	Statement of Work for Low Concentration Water for Volatile Organics Analysis Document Number OLV01.0		
Concentration	Low		
Matrices	Water		
Fractions	• Volatiles		
Compounds Identified & Quantified	• Target Compounds • 10 non-surrogate organic compounds		
Volumes Required and Preservation Techniques	Consult Sampler's Guide or Regional instructions		
Contract Delivery Requirements	**Deliverable**	**Delivery Schedule**	**Description**
	• Update SOPs	45 days after contract receipt or within 14 days of request by APO/TPO	Updated copies of all required SOPs submitted with prebid PE sample results. SOPs must address any and all issues of laboratory performance and operation identified through the review of PE sample data and evaluation of Bidder-Supplied Documentation.
	• Sample Traffic Reports	3 days after receipts of last sample in SDG	
	• Sample Data Summary Package	7 days after receipt of last sample in SDG	
	• Sample Data Package	7 days after receipt of last sample in SDG	See "Data Package Contents."
	• Complete SDG File	7 days after receipt of last sample in SDG	See Exhibit B, Section III of SOW
	• Data in Computer Readable Form	7 days after receipt of last sample in SDG	See Exhibit H of SOW
	• GC/MS Tapes	Retain for 365 days after data submission, or submit within 7 days after receipt of written request by APO and/or EMSL/LV	
	• QA Plan	Submit within 7 days after receipt of written request by APO	
Data Package Contents	1. SDG Narrative 2. Sample Traffic Reports 3. Volatiles Data		
Analytical Procedures	• Sample Preparation and Storage • GC/MS Analysis		
QA/QC Summary	• Blank Analysis • Laboratory Control Samples • Performance Evaluation Samples • Various Instrument QA/QC (see SOW)		

FIGURE 8. ORGANIC ROUTINE ANALYTICAL SERVICES, MULTI-MEDIA, HIGH CONCENTRATION

SOW Reference	Statement of Work for Organics Analysis Multi-Media, High Concentration SOW No. Rev. 9/88 including Rev 4/89		
Concentration	High		
Matrices	Water Soil/Sediment		
Fractions	• Volatiles • Extractables • Aroclors/Toxaphenes		
Compounds Identified & Quantified	• Target Compounds • 10 volatile components • 20 extractable components		
Volumes Required and Preservation Techniques	Consult Sampler's Guide or Regional instructions		
Contract Delivery Requirements	**Deliverable**	**Delivery Schedule**	**Description**
	• Contract Start-Up Plan	7 days after contract award	Proposed schedule for receiving samples starting with the 30th calendar day after award and ending with the date the contractor is capable of receiving the full monthly sample allotment stipulated in the Contract.
	• Updated SOPs	120 days after contract award	Updated copies of all required SOPs submitted with prebid PE sample results. SOPs must address any and all issues of laboratory performance and operation identified through the review of PE sample data and evaluation of Bidder-Supplied Documentation.
	• Sample Traffic Reports • Sample Data Summary Package	35 days after receipt of last sample in SDG	
	• Sample Data Package	35 days after receipt of last sample in SDG	See "Data Package Contents."
	• GC/MS Tapes	Retain for 365 days after data submission, or submit within 7 days after receipt of written request by APO and/or EMSL/LV	
	• Extracts	Retain for 365 days after data submission, or submit within 7 days after receipt of written request by APO or SMO	
	• Complete Case File Purge	Submit 180 days after data submission or 7 days after receipt of written request by APO or SMO	Includes all laboratory records received or generated for a specific Case that have not been previously submitted to EPA as a deliverable. These items include but are not limited to: sample tags, custody records, sample tracking records, analysts logbook pages, bench sheets, chromatographic charts, computer printouts, raw data summaries, instrument logbook pages, correspondence, and the document inventory.
Data Package Contents	1. Case Narrative 2. Traffic Reports 3. High Concentration Volatiles Data 4. Extractables Data 5. Aroclor/Toxaphene Data		
Analytical Procedures	• GC/MS Analysis • GC/EC Analysis • Following Sample Preparation/ Extraction		
QA/QC Summary	• Matrix Spike Sample Analysis (per 20 single phase units/14 calendar days, whichever most frequent) • Method blank (per Case/20 units/14 calendar days/extraction, whichever most frequent)		

FIGURE 9. INORGANIC ROUTINE ANALYTICAL SERVICES, MULTI-MEDIA, MULTI-CONCENTRATION

SOW Reference	Statement of Work for Inorganics Analysis Multi-Media, Multi-Concentration Document Number ILM01.0		
Concentration	Low or Medium		
Matrices	Water Soil/Sediment		
Fractions	• Total Metals or Dissolved Metals • Cyanide		
Compounds Identified & Quantified	• Metals • Cyanide		
Volumes Required and Preservation Techniques	Consult Sampler's Guide or Regional instructions		
Contract Delivery Requirements	**Deliverable**	**Delivery Schedule**	**Description**
	• Updated SOPs	45 days after contract receipt	Updated copies of all required SOPs submitted with prebid PE sample results. SOPs must address any and all issues of laboratory performance and operation identified through the review of PE sample data and evaluation of Bidder-Supplied Documentation.
	• Sample Traffic Reports	3 days after receipt of last sample in SDG	
	• Sample Data Package	35 days after receipt of last sample in SDG	See "Data Package Contents."
	• Data in Computer Readable Form	35 days after receipt of last sample in SDG	See Exhibit H of SOW.
	• Complete SDG File	35 days after receipt of last sample in SDG	See Exhibit B, Sections III and IV of SOW.
	• Quarterly/Annual Verification of Instrument Parameters	Quarterly: 15th day of January, April, July, October	The Contractor shall perform and report quarterly verification of instrument detection limits and linear range methods specified in Exhibit E for each instrument used under this contract. For the ICP instrumentation, the Contractor shall also perform and report annual interelement correction factors (including method of determination), wavelengths used and integration times.
	• Quality Assurance Plan	Submit copy within 7 days of written request by APO	The QAP must present, in specific terms, the policies, organization, objectives, functional guidelines, and specific QA and QC activities designed to achieve the data quality requirements in the contract.
Data Package Contents	1. Cover Page 2. Sample Data 3. Sample Traffic Reports		
Analytical Procedures	• Following Sample Preparation/Distillation • ICP Analysis • Flame, Graphite Furnace and Cold Vapor AA Analysis • Cyanide Analysis		
QA/QC Summary	• ICP-ICS Analysis (at beginning and end of analysis run or minimum of twice per 8 hr shift, whichever is more frequent • Spiked Sample Analysis (per matrix/concentration) • Duplicate Sample Analysis (per matrix/concentration) • LCS Analysis (per group/batch) • ICP Serial Dilution (per group/batch) • Other QA/QC (see SOW)		

FIGURE 10. INORGANIC ROUTINE ANALYTICAL SERVICES, LOW CONCENTRATION WATER

SOW Reference	Statement of Work Low Concentration Water for Inorganic Analytes Document Number ILC01.0		
Concentration	Low		
Matrices	Water		
Fractions	• Total Metals • Cyanide • Total Nitrogen • Fluoride		
Compounds Identified & Quantified	• 23 indicated elements • Cyanide • Total Nitrogen • Fluoride		
Volumes Required and Preservation Techniques	Consult Sampler's Guide or Regional instructions		
Contract Delivery Requirements	**Deliverable**	**Delivery Schedule**	**Description**
	• Updated SOPs	45 days after contract receipt	Updated copies of all requires SOPs submitted with prebid PE sample results. SOPs must address any and all issues of laboratory performance and operation identified through the review of PEsample data and evaluation of Bidder-Supplied Documentation.
	• Sample Traffic Reports	3 days after receipt of last sample in SDG	
	• Sample Data Package	14 days after receipt of last sample in SDG	See "Data Package Contents."
	• Data in Computer Readable Format	14 days after receipt of last sample in SDG	See Exhibit H of SOW.
	• Complete SDG File	14 days after receipt of last sample in SDG	See Exhibit B, Sections III and IV of SOW.
	• Quarterly/Annual Verification of Instrument Parameters	Quarterly: 15th day of January, April, July, October	The Contractor shall perform and report quarterly verification of instrument detection limits and linear range methods specified in Exhibit E for each instrument used under this contract. For the ICP instrumentation, the Contractor shall also perform and report annual interelement correction factors (including method of determination), wavelengths used and integration times.
	• ICP/MS Diskettes/Tapes	Retain for 365 days after submission; or submit them within 7 days of written request by APO or EMSL	
	• Quality Assurance Plan	Submit within 7 days of written request by APO	The QAP must present, in specific terms, the policies, organization, objectives, functional guidelines, and specific QA and QC activities designed to achieve the data quality requirements in the contract.
Data Package Contents	1. Cover Page for the LC-Inorganic Analyses Data Package 2. Sample Data 3. Sample Traffic Reports and Cover Sheet for each sample		
Analytical Procedures	• ICP Analysis • ICP/MS Analysis • Graphite Furnace, Flame, and Cold Vapor AA Analysis • Cyanide, Total Nitrogen, and Fluoride Analysis		
QA/QC Summary	• ICP and ICP/MS Interference Check Sample (ICS) Analyses • Matrix Spike Sample Analysis (S) • Duplicate Sample Analysis (D) • Laboratory Control Sample (LCS) Analysis • Performance Evaluation Sample (PES) • Serial Dilution Analysis (L) • Internal Standards for ICP/MS • Instrument Detection Limit (IDL) Determination • Interelement Corrections for ICP and ICP/MS • Hydride ICP (HYICP) and Furnace AA QC Analysis • Other QA/QC (see SOW)		

FIGURE 11. INORGANIC ROUTINE ANALYTICAL SERVICES, MULTI-MEDIA, HIGH CONCENTRATION

SOW Reference	Statement of Work for Inorganic Analysis Multi-Media, High Concentration Document Number IHC01.0		
Concentration	High		
Matrices	Water Soil/Sediment		
Fractions	• Metals • Cyanide • pH • Conductivity		
Compounds Identified & Quantified	• Target Analyte List		
Volumes Required and Preservation Techniques	Consult Sampler's Guide or Regional instructions		
	Deliverable	**Delivery Schedule**	**Description**
Contract Delivery Requirements	• Updated SOPs	45 days after contract receipt	Updated copies of all requires SOPs submitted with prebid PE sample results. SOPs must address any and all issues of laboratory performance and operation identified through the review of PE sample data and evaluation of Bidder-Supplied Documentation.
	• Sample Traffic Reports	3 days after receipt of last sample in SDG	
	• Sample Data Package	35 days after receipt of last sample in SDG	See "Data Package Contents."
	• Data in Computer Readable Format	35 days after receipt of last sample in SDG	See Exhibit H of SOW.
	• Complete SDG File	35 days after receipt of last sample in SDG	See Exhibit B, Sections III and IV of SOW.
	• Quarterly/Annual Verification of Instrument Parameters	Quarterly: 15th day of January, April, July, October	The Contractor shall perform and report quarterly verification of instrument detection limits and linear range methods specified in Exhibit E for each instrument used under this contract. For the ICP instrumentation, the Contractor shall also perform and report annual interelement correction factors (including method of determination), wavelengths used and integration times.
	• Quality Assurance Plan	Submit within 7 days of written request by APO	The QAP must present, in specific terms, the policies, organization, objectives, functional guidelines, and specific QA and QC activities designed to achieve the data quality requirements in the contract.
Data Package Contents	1. Cover Page 2. Sample Data 3. Sample Traffic Reports		
Analytical Procedures	• ICP Analysis • HYICP Analysis • CVAA Analysis • Cyanide Analysis • pH Analysis • Following Sample Preparation/Extraction		
QA/QC Summary	• ICP Interference Check Sample (ICS) Analyses. • Matrix Spike Sample Analysis (S). • Analytical Spike Sample Analysis (A). • Duplicate Sample Analysis (D). • Laboratory Control Sample (LCS) Analysis. • Method Detection Limit (MDL) Determination. • Interelement Corrections for ICP (ICP). • Hydride ICP (HYICP) QC Analysis.		

FIGURE 12. DIOXIN/FURAN ROUTINE ANALYTICAL SERVICES

SOW Reference	Statement of Work for Analysis of Polychlorinated Dibenzo- *p*-Dioxins (PCDD) and Polychlorinated Dibenzofurans (PCDF), Multi-Media, Multi-Concentration Document Number DFLM01.0		
Concentration	At least 10 parts per trillion for water samples or 10 parts per billion for soil, fly ash and chemical waste samples.		
Matrices	Water Soil Fly Ash Chemical Waste		
Compounds Identified & Quantified	• Total tetrachlorinated Dibenzo- *p*-dioxins • Total pentachlorinated Dibenzo- *p*-dioxins • Total hexachlorinated Dibenzo- *p*-dioxins • Total heptachlorinated Dibenzo- *p*-dioxins • Total octachlorinated Dibenzo- *p*-dioxins • Total tetrachlorinated Dibenzofurans • Total pentachlorinated Dibenzofurans • Total hexachlorinated Dibenzofurans • Total heptachlorinated Dibenzofurans • Total octachlorinated Dibenzofurans • 17 specific "2,3,7,8-substituted PCDDs/PCDFs"		
Volumes Required	• 2 L for Water samples • 3 oz. for Soil, Fly Ash and Chemical Waste samples		
Contract Delivery Requirements	**Deliverable**	**Delivery Schedule**	**Description**
	• Updated SOPs	45 days after contract receipt	Updated copies of all required SOPs submitted with prebid PE sample results. SOPs must address any and all issues of laboratory performance and operation identified through the review of PE sample data and evaluation of Bidder-Supplied Documentation.
	• Sample Traffic Reports	3 days after receipt of last sample in SDG	
	• Sample Data Summary Package	45 days after receipt of last sample in SDG	
	• Sample Data Package	45 days after receipt of last sample in SDG	See "Data Package Contents."
	• Complete SDG File	45 days after receipt of last sample in SDG	See Exhibit B, Section II of SOW.
	• Quality Assurance Plan	Submit within 7 days of written request by APO	The QAP must present, in specific terms, the policies, organization, objectives, functional guidelines, and specific QA and QC activities designed to achieve the data quality requirements in the contract.
	• GC/MS Tapes	Retain for 365 days after data submission, or submit within 7 days after written request by APO or EMSL-LV.	
	• Extracts	Retain for 365 days after data submission, or submit within 7 days after written request by APO or SMO.	
Data Package Contents	1. SDG Narrative 2. Traffic Reports 3. PCDD/PCDF Data		
Analytical Procedures	High Resolution GC/Low Resolution MS		
QA/QC Summary	• Matrix Spike Sample Analysis (S) • Duplicate Sample Analysis (D) • Other QA/QC (see SOW)		

SAS requests are separated into two basic categories, "RAS Plus SAS" and "All SAS". These categories are utilized in defining client requests and pursuant SAS solicitation and contract award. Analytical services available through the SAS program are described below.

1. RAS Plus SAS

a. Fast Turnaround

Fast turnaround requests require the application of existing RAS analytical parameters, methodologies and detection limits with a shorter timeframe for performance of analysis and/or delivery of data. Procurement for fast turnaround SAS is dependent upon program sample load, laboratory capacities and laboratory operating conditions at the time of the request. Because of constant fluctuations of these factors, it may not be possible to obtain fast turnaround service on an unlimited basis. Fast turnaround contracts are solicited only in situations of demonstrated need and are used primarily to support EPA emergency actions and to meet impending litigation deadlines.

The following illustrates common "RAS Plus SAS" fast turnaround requests. The SAS portion is underlined:

- RAS organic target compound analysis with data delivery in seven days.
- RAS inorganic target compound analysis with data delivery in fourteen days.

b. Special Requirements in Addition to RAS

A client may need to access the standardized RAS programs and add to the contract requirements. The following examples illustrate common "RAS Plus SAS" requests. The SAS portion is underlined:

(1) Organic

- Organics RAS TCL analysis with additional non–target compounds.
- Pesticide target compound analysis with minor alterations or additional procedures applied.

(2) Inorganic

- Metals and cyanide analyses with special rigorous sample homogenization requirements.
- Metals analysis at lower detection limits than required by the RAS requirements.
- RAS metals and cyanide analysis with minor alterations or additional analytical procedures applied.

(3) High Concentration Organic

- RAS High Concentration Analyses
- RAS analysis at lower detection limits than required by the High Concentration protocol.

2. All SAS

CLP clients frequently request types of analyses that are not directly applicable to the RAS program. These requests occur most often with samples of difficult or unusual matrices and measurements of analytical parameters not provided through the RAS program. The SAS program accommodates unusual analytical requests on an "All SAS" basis. Complete methodology and QA/QC specifications must accompany the request. These types of analyses include, but are not limited to, the following:

- Volatile target compound analysis at lower detection limits than required by the IFB.
- Seven TCL Aroclors analysis only (i.e., not the entire IFB pesticide fraction).
- Non–target compound analyses.
- RAS compound/analyte analysis by non–RAS methods.
- Specified RAS elemental analysis only (e,g., cadmium, mercury and selenium).
- Metals analysis by non–RAS methods.
- Air samples (e.g., tenax, charcoal and florisil tubes) for specific organic analyses.
- Methods comparison/evaluation studies.
- Asbestos analysis.
- Acid deposition parameters.
- Non–Superfund analytical services of any type.
- Geotechnical/Geophysical tests on soil samples.
- Radioactivity analyses.
- Leaching procedures (TCLP, EPTOX).
- Wet chemistry procedures.
- Physical tests.

- Bioassays.
- RCRA parameters.
- "Explosives" Analyses.
- Others as defined by client.

3. Contract Delivery and Quality Control Requirements

SAS contracts require delivery schedules for sample extraction, analysis and data reporting, and require laboratory QC procedures and reporting of QC parameters as defined by the client requestor. Delivery and QC requirements as detailed in RAS program contracts may be used as a guide but must be specified by the client at the time of request. The requestor must specify all deliverables required to ensure that the appropriate data packages are received. Clients are encouraged to maintain a high level of QC in all analysis requests, unless there is substantial reason for deleting certain QC requirements.

E. Analytical Methodology Improvement/Development

1. Protocol Standardization and Improvement

In order to maintain state-of-the-art protocols and accommodate newly defined or changed requirements of the Superfund effort, CLP participants are constantly refining and improving analytical protocols. To accomplish this, program participants submit comments and suggestions to the NPO. The NPO reviews all submitted information and considers recommendations for program modification on a periodic basis.

Since 1982, the NPO has planned technical meetings to utilize all available resources in updating analytical program methodologies and data reporting requirements. Technical meetings – such as workgroups, and caucuses – are initiated by the NPO on a periodic basis. Participants include the Regions, NPO, EMSL/LV, EMSL/Cincinnati, NEIC, SMO, contract laboratories, program support contractors, other EPA programs, and other government agencies, as appropriate. These meetings are instrumental in improving CLP protocols and ensuring that deliverables meet user needs.

EPA personnel review the discussions of the technical meetings and compile recommendations for protocol changes. Following NPO approval of recommended changes, existing laboratory contracts are modified by the Contracting Officer to include the recommended revisions. Whenever possible, all laboratory contracts within an analytical program are changed simultaneously to maintain consistency within the program. NPO-approved protocol revisions are included in any new IFB solicitations.

2. Method Development

Development of new analytical methods may be initiated by a newly identified or redefined Agency analysis requirement. Analytical methods utilized in the CLP are based on methodologies developed and approved by EPA. The NPO, EMSL/LV, the Regions, and the contractor community have historically contributed to the development of new program analytical methodologies. Methods are reviewed by several sources and are tested prior to implementation to the extent possible to meet program requirements.

CHAPTER III

UTILIZATION OF ANALYTICAL SERVICES

In this chapter ...

Analysis Request Procedures
- RAS Initiation Process
- SAS Initiation Process
- Procedures for Making Changes to Analytical Requests

Regional Organic/Inorganic Allocation System
Sample Documentation
- Sample Traffic Report
- SAS Packing List
- Sample Number
- Sample Tag
- Chain–of–Custody Record

Sample Packaging and Shipment
- Packaging Requirements
- Shipping Instructions
- Shipment Coordination

Procedures for Problem Resolution
- Resolving Problems Concerning Sample Shipment and Analysis
- Resolving Problems Concerning Analytical Data

The CLP provides clients with prompt access to laboratory services through a documented system of sample scheduling and tracking. Individuals interested in obtaining CLP analytical support must contact their Regional EPA office's RSCC. SMO coordinates the scheduling of sample analyses through the CLP and tracks the progress of samples from collection through final data production.

The RSCC is established by the EPA Regional Administrator and is centered in each Region's Environmental Services Division or Waste Management Division (see Appendix B). The RSCC, consisting of one or more individuals, places analytical requests. SMO is authorized to accept analytical requests only through the RSCC. In addition, the RSCC is responsible for ensuring Regional compliance with the CLP's projection/allocation system. The primary RSCC determines analytical priorities for the Region when conflicts occur.

SMO seeks to effectively match the analytical needs of program clients with the capabilities of contract laboratories. To this end, SMO tracks current utilization, availability of resources and laboratory performance limitations for each program.

The success of the CLP scheduling process depends on two factors:

- ongoing communication among the RSCC, field sampler, SMO and laboratory personnel, and
- correct use of sample scheduling and tracking documents by the RSCC, field sampler and laboratory personnel.

A. Analysis Request Procedures

1. RAS Initiation Process

a. User Information Required

To initiate a RAS request, the RSCC or Regional designee contacts the appropriate SMO Coordinator by telephone or fax and provides a complete description of the analytical requirement. (SMO personnel are identified in Appendix B.) The information SMO requires to initiate a RAS request is listed in Figure 13.

The RSCC or designee is responsible for estimating the number and types of samples and the sample shipment dates for the analytical request. Overestimation of the number of samples to be collected or miscalculation of shipment dates unnecessarily ties up available laboratory capacity and lessens program responsiveness. Underestimation of the number and types of samples to be collected may result in unavailable services for any additional analyses needed.

b. Lead–time Required

By noon EST on the Wednesday of the week prior to the scheduled start of a planned sampling activity, the RSCC or designee contacts SMO to place a request for RAS services and to provide scheduling information to SMO. Allowing this lead–time makes laboratory scheduling and resolution of sampling questions easier. It also

allows the sampler time to prepare the required sample documentation prior to field activity, if appropriate. Advance scheduling is available and should be utilized whenever necessary. Late scheduling requests (i.e., requests received between Wednesday noon and Friday) are accommodated with laboratory capacity availability. To avoid possible shortfalls, Regions are strongly encouraged to submit all RAS scheduling requests by Wednesday noon, where possible.

FIGURE 13. RAS ANALYSIS REQUEST PROCEDURES – USER INFORMATION REQUIRED

Name of the individual RSCC, or designated requestor.
Name(s), association and telephone number(s) of sampling personnel.
Name, city and state of the site to be sampled.
Superfund site/spill ID (2 digit alpha–numeric code).
Number and matrix of samples to be collected.
Type of analyses required.

- Organic: Volatiles (VOAs), Semivolatiles (SVs), Pesticides/Aroclors.
- Inorganic: Total Metals, Dissolved Metals, Cyanide.
- High Concentration Organic: VOAs, Extractables, Aroclors/Toxaphenes.
- High Concentration Inorganic: Metals, Cyanide, pH, Conductivity.
- Low Concentration Water for Organic Compounds: VOAs, SVs, Pesticides/Aroclors.
- Low Concentration Water for Inorganic Analytes: Total Metals, Cyanide, Total Nitrogen, Fluoride.
- Low Concentration Water for VOAsOnly: VOAs.
- Dioxins/Furans.

Scheduled sample collection and shipment dates.
Nature of sampling event.

- Preliminary Assessment
- Site Investigation
- Expended Site Investigation
- Remedial Investigation/Feasibility Study
- Remedial Design
- Remedial Action
- Enforcement Lead
- Emergency Response (Removal)
- National Priorities List Delete
- Operation and Maintenance
- State Lead Preliminary Assessment
- State Lead Site Investigation
- State
- National Dioxin Study
- Facility Assessment
- Compliance Monitoring Effort
- Enforcement
- Ground Water Monitoring Task Force
- Resource Conservation and Recovery Act
- Office of Water
- Clean Air

Suspected contaminants associated with the sample and/or site.
Other information which may affect sample scheduling or shipment (i.e., anticipated delays due to site access, weather conditions, sampling equipment).
Name(s) of Regional or contractor contacts for immediate problem resolution.
Other – describe

c. *Case Number Assignment and Laboratory Scheduling*

At the time of request, SMO assigns a sequential Case number to each RAS sampling activity for identification throughout sample tracking and data production. A Case number designates a group of samples collected at one site or geographical location during a predetermined and finite time period. The RSCC records the Case number and uses it in referencing that request throughout sampling and analysis.

SMO then schedules the requested analyses through an appropriate RAS laboratory. Laboratory selection is determined by

- the types of analyses,
- number of samples,
- contract capacity,
- sample balance among the various laboratories, and
- laboratory loading and instrument conditions.

Laboratory selection is also based on the Regional Distribution of Laboratories System developed by the NPO and designed to minimize the number of laboratories producing data for any one Region. When possible, the nearest available laboratory is assigned in order to minimize sample shipping costs.

Once RAS laboratory assignments are made, SMO contacts the RSCC or designee to confirm the field investigation plans, identify the laboratories to be used for the Case, and answer any further questions regarding program procedures or documentation. At that point, the RSCC or designee must indicate all known or anticipated sample scheduling changes. Any further changes should be communicated to SMO immediately upon identification to ensure the timely resolution of conflicts and the optimal allocation of program resources. After the initial placement of the RAS request, the RSCC or designee may assign a logistical contact, such as the team leader in the sampling effort, to coordinate with SMO in finalizing sampling requirements, and initiating and arranging sample shipment.

d. *User Knowledge of Analytical Protocol*

Each RSCC is responsible for gaining and maintaining a working knowledge of current RAS protocols and analytical services. SMO provides each Regional TPO (listed in Appendix B) with Master Copy notebooks of each RAS program IFB Statement of Work (SOW). The Master Copy notebooks are periodically updated to reflect program protocol changes.

The SOW represents the standardized requirements that each individual RAS laboratory is contractually bound to follow. The analytical SOWs contain specific information on

- sample types suited to RAS analysis,
- compounds identified and quantified,
- analytical methods, protocols, detection limits,
- deliverable requirements, and
- quality control requirements.

Program users should consult the appropriate SOW to confirm that the RAS program is suited to an analytical request.

2. SAS Initiation Process

a. User Information Required

Analytical requirements differing from RAS parameters are processed through the SAS program as described in Chapter II, Section D. Initiating a SAS request is a two–part process.

- The RSCC or designee sends a copy of the SAS client request, appropriate attachments (if needed) and a copy requested analytical method to SMO.
- The RSCC or designee contacts the appropriate SMO Regional Coordinator by telephone and provides a complete description of the analytical requirement.

The information SMO requires to initiate a SAS request is listed in Figure 14.

FIGURE 14. SAS ANALYSIS REQUEST PROCEDURES – USER INFORMATION REQUIRED

Name of RSCC or client requestor.
Name(s), association and telephone number(s) of sampling personnel.
Name, city and state of the site to be sampled.
Superfund site/spill ID (2 digit alpha–numeric code).
Number and matrix of samples to be collected.
Specific analyses required, appropriate protocols and QA/QC limits.
Required detection limits.
Matrix spike, matrix spike duplicate, duplicate or LCS frequency, if applicable.
Data turnaround and data format.
Justification for fast turnaround request, if appropriate.
Scheduled sample collection and shipment dates.
Nature of sampling event.

- Preliminary Assessment
- Site Investigation
- Expended Site Investigation
- Remedial Investigation/Feasibility Study
- Remedial Design
- Remedial Action
- Enforcement Lead
- Emergency Response (Removal)
- National Priorities List Delete
- Operation and Maintenance
- State Lead Preliminary Assessment
- State Lead Site Investigation
- State
- National Dioxin Study
- Facility Assessment
- Compliance Monitoring Effort
- Enforcement
- Ground Water Monitoring Task Force
- Resource Conservation and Recovery Act
- Office of Water
- Clean Air

Suspected contaminants associated with the samples and/or site.
Other information which may affect sample scheduling or shipment (i.e., anticipated delays due to site access, weather condition, sampling equipment).
Name(s) of Regional or contractor contacts for immediate problem resolution.

Most SAS requests are made in writing using the SAS client request form. In emergency situations, the verbal request may be made prior to a written request. Following the verbal request, the RSCC must submit a completed SAS Client Request form to SMO. This form serves as the written record to clarify and confirm the client's requirement for specialized analytical work.

The RSCC is responsible for estimating the number and types of samples and the sample shipment dates for the SAS request. Overestimation of the number of samples to be collected or miscalculation of shipment dates unnecessarily ties up available laboratory capacity lessening program responsiveness. Underestimation of the number and types of samples to be collected may result in unavailable services for any additional analyses needed. Depending on the size and extent of the miscalculation, the entire request may have to be resolicited and sampling plans postponed accordingly. SAS solicitations result in binding contracts. If the contract has been awarded, it may not be possible to make changes.

b. Lead–time Required

When a sampling activity has been planned, the RSCC contacts SMO and places the specific written request for SAS services. Because SAS services are individually procured on a competitive basis, a minimum lead–time of two weeks, from receipt of the request, is required to process a properly completed SAS request. Three to four weeks lead–time is strongly recommended whenever possible. SAS solicitation will not be started until the SAS requirements have been completely defined by the RSCC. Modifications to any SAS request will cause the entire process to begin again. Fully defined requests initiated with less than two weeks lead–time may not be solicited and awarded in time to meet the original shipment date.

Certain types of SAS requests require a longer lead–time. A minimum lead–time of two to three weeks is required for SAS requests which involve distribution of protocols (see item d, below). A minimum lead–time of four or more weeks is recommended for large scale, analytically complex or Non–Superfund SAS requests. Award of Non–Superfund SAS subcontracts may only be made after the appropriate funding process is complete. The RSCC should contact SMO several

weeks in advance if there is a question regarding the lead-time needed to schedule a particular SAS request.

c. SAS Number Assignment and Laboratory Scheduling

At the time of request, SMO assigns a sequential SAS number to each SAS sampling activity for identification throughout sample tracking and data production. If SAS services are being provided in association with RAS services, SMO also assigns a Case number. Like the Case identification, the SAS number designates a group of samples collected at one site or geographical location during a predetermined and finite time period. The RSCC or designee records the SAS number and Case number (if applicable) and uses both numbers in referencing the request throughout sampling and analysis.

SAS laboratory selection is based on a verbal and written solicitation process for each individual request. This solicitation results in a written SAS award to the lowest qualified bidder. Once SAS laboratory assignments are made, SMO notifies the RSCC of the laboratories that will be performing the analyses.

The nature of the SAS laboratory solicitation process requires the RSCC to be as exact as possible with all elements of a request at the time of request. SMO understands that actual site conditions can vary considerably from expected conditions and necessitate changes in the sampling plan. However, the requestor is responsible for notifying SMO immediately of any changes to allow sufficient time to amend the SAS contract(s) to meet the changed needs. If an original request is changed significantly, the original SAS contract will be voided, and the entire analysis effort will be resolicited. SAS resolicitation requires additional time before sample shipment can take place.

d. User Provided Analytical Protocol

At the time of request, the RSCC must provide the analytical methodology and quality control requirements to be utilized for the SAS request before SMO can initiate a solicitation. For SAS requests that are based on the use of amended RAS protocols, the RSCC must specify modifications or additions to these protocols. If such changes are extensive, the client request preparer must submit changes under the SAS to SMO in written form two to three weeks in advance of scheduled sample shipment. For SAS requests which require use of a method that is not commonly available, the RSCC must submit the method two to three weeks in advance of sample shipment. Additional lead-time is required for protocol distribution and review by solicited laboratories.

SAS requests which cite well known analytical publications do not require additional lead-time for distribution since laboratories have immediate access to this information. Examples of frequently utilized method manuals are as follows:

- Methods for Chemical Analysis of Water and Waste, USEPA, Current Edition, or as specified.
- Test Methods for Evaluating Solid Waste, Physical/Chemical Methods, SW-846, USEPA Office of Water and Waste Management, Current Edition, or as specified.
- Standard Methods for the Examination of Water and Waste Water, APHA, AWWA, WPCF, Current Edition, or as specified.

Further analytical references are supplied in Appendix C. The RSCC should contact SMO several weeks in advance if there is a question as to whether a particular method will require additional lead-time for distribution.

3. Procedures for Making Changes to Analytical Requests

The RSCC or designated logistical contact must immediately notify the appropriate SMO Coordinator of all changes in sampling plans before and during the sampling event and after shipment of samples to the laboratory. Changes in plans include changes in sample matrices, numbers of samples, analyses requested, detection limits, shipping dates, postponements or cancellations. Failure to notify SMO of such changes can result in delay in sampling to accommodate scheduling changes, delay in start of analysis due to conflicts, unsuitability of a particular sample to an analytical program, or analysis data inappropriate for client purposes.

B. Regional Organic/Inorganic Allocation System

The NPO has established an allocation system to equitably apportion available laboratory capacity to the Regions during periods of heavy sampling activity and limited laboratory capacity. Currently, capacity is available for the projected sample demand; however, when the allocation system is in effect, all organic and inorganic RAS and "RAS Plus SAS" Cases will be scheduled accordingly.

During the last month of each fiscal year quarter, the NPO provides the RSCC with the Region's monthly allocation of organic and inorganic sample analyses for the following quarter. The RSCC is responsible for planning monthly sampling activities in accordance with the NPO allocation.

Under the scheduling/allocation system, the RSCC requests sample analyses for all planned Regional sampling activities for a week on the Wednesday of the prior week and assigns a priority, if requested by SMO, to each request. Upon receiving the Region's analytical requests, SMO makes laboratory assignments for the week and schedules received requests up to each Region's allocation limit. Requests in excess of the monthly allocations will not be processed by SMO until all Regional requests which fall within allocations have been placed at a laboratory. At this time, any excess laboratory capacity for the week is determined, and the NPO prioritizes Regional sampling requests that exceed allocations. SMO assigns available laboratory capacity for sampling activities as prioritized by the NPO. For additional information concerning the allocation system, users should contact the SMO Regional Coordinator or Analyst for their Region (see Appendix B).

C. Sample Documentation

Each sample processed by the CLP must be properly documented to ensure timely, correct and complete analysis for all parameters requested, and most importantly, to support the use of sample data in potential enforcement actions. The CLP documentation system provides the means to individually identify, track and monitor each sample from the point of collection through final data reporting. As used herein, a sample is defined as a representative specimen collected at a specific location of a waste site at a particular time for a specific analysis. The term sample may refer to field samples, duplicates, replicates, splits, spikes or blanks that are shipped from the field to a laboratory. Whenever questions arise, samplers should contact SMO or the RSCC for direction and clarification concerning the proper completion and distribution of CLP paperwork.

1. Sample Traffic Report

RAS organic and inorganic samples are documented with corresponding CLP sample Traffic Reports (TRs), a four part carbonless form. Each TR may document up to twenty samples shipped to one CLP laboratory under one Case Number and one RAS analytical program. Samplers must complete the appropriate TRs for every shipment of RAS samples to a CLP laboratory. Copies of properly completed TR forms are included in the CLP Sampler's Guide.

TR forms must also be used when an individual sample is to be analyzed for both RAS and SAS parameters. A SAS Packing List must *not* be used for RAS + SAS Cases. Both the Case number and the SAS number must be entered at the top right of the form in order to clearly identify and track the sampling event. Samplers must take caution not to include the Case number on "All SAS" samples taken at the same site. Additionally, the sampler must briefly describe the SAS requirement on each TR (e.g., "VOA – 1 ppb detection limit").

Each TR form includes a Chain–of–Custody Record. Information about the Chain–of–Custody Record follows.

SMO provides TR forms to each Region through the RSCC. The RSCC should contact SMO two or more weeks in advance to order additional TR forms.

2. SAS Packing List

For "All SAS" samples, samplers should use the SAS Packing List (PL), a four part carbonless form. The PL provides space to list up to twenty samples on one form. SAS samples are numbered using the SAS number followed by a two digit number beginning with "01" (e.g., 4100-E-01, 4100-E-02, etc.). If the sampling activity extends over several days and more than one PL is used, care must be taken not to repeat sample numbers.

Regions should consult SMO to verify that the PL is appropriate to use in their situation.

Alternatively, the samplers may also use TRs for all SAS requests but must be careful to ensure that RAS Case numbers do not appear on those forms.

Each SAS PL includes a Chain-of-Custody Record. Information regarding the Chain-of-Custody Record follows.

SMO provides SAS PL forms to each Region through the RSCC. The RSCC should contact SMO two or more weeks in advance to order additional SAS PL forms.

3. Sample Number

A unique sample number, recorded on the TR and SAS PL, identifies each sample. Inorganic and organic/VOA sample numbers have different formats and are not interchangeable. Strips of adhesive labels preprinted with individual sample numbers are provided by SMO with TR forms. Samplers must provide sample labels, marked in indelible ink with the appropriate SAS sample numbers, for use with "All SAS" samples.

The sampler affixes the sample label to the corresponding containers that make up the sample and, if appropriate, to the outside of the metal can in which the sample is packed (see Section D for packaging requirements). The top edge of the label should be placed at the level of initial sample volume so that any loss of volume can be easily detected. In order to protect the labels from the effects of water and solvent, labels are covered with clear, waterproof tape.

4. Sample Tag

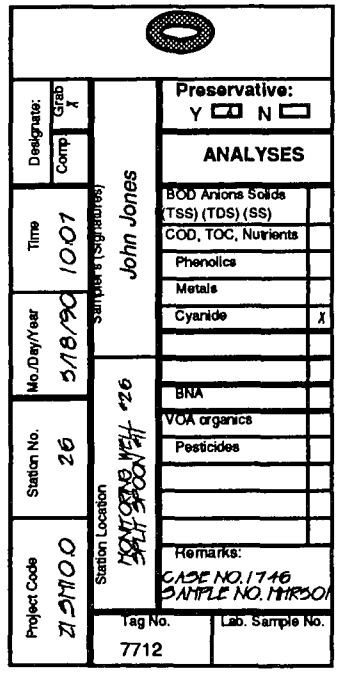
Each sample removed from a waste site and transferred to a laboratory for analysis must be identified by a sample tag which contains specific sample information as defined by NEIC. Sample tags are retained by the laboratory as physical evidence of sample receipt and analysis. Sample tags may be obtained through the Regional office; in some instances, sampling contractors may be required to provide their own sample tags. An example sample tag is shown in Figure 15.

Additionally, the sample tag contains appropriate spaces for noting that the sample has been preserved and indicating the analytical parameter(s) for which the sample will be analyzed. After the sample tag is completed, each tag is securely attached to the sample container. Samples are then shipped under chain-of-custody procedures as described in the following section.

5. Chain-of-Custody Record

In accordance with Agency enforcement requirements, official custody of samples must be documented from the time of collection until the time of introduction as evidence during litigation. The Chain-of-Custody Record is not a separate document and is included as part of the Sample Traffic Reports and SAS Packing Lists.

FIGURE 15. SAMPLE TAG



A sample is considered to be in an individual's custody if any of the following criteria are met: 1) the sample is in your possession or it is in your view after being in your possession; 2) it was in your possession and then locked up or sealed to prevent tampering; or 3) it is in a secured area. The team member performing the sampling is responsible for the care and custody of the collected samples until they are dispatched properly. In follow up, the sampling team leader reviews all field activities to confirm that proper custody procedures were followed during the field work.

The Chain-of-Custody Record is employed as physical evidence of sample custody. The sampler completes a Chain-of-Custody Record to

accompany each cooler shipped from the field to the laboratory. Chain–of–Custody Record forms can be obtained through the Regional office.

The sampler records the project number, samplers' signatures and the Case and/or SAS number as header information on the Chain–of–Custody Record. The commonly known name of the site should not be included since CLP laboratories may perform work for the responsible party of that site. For each station number, the sampler indicates date, time, whether the sample is a composite or grab, station location, number of containers, analytical parameters, CLP sample number(s) and sample tag number(s). When shipping the samples, the sampler signs the bottom of the form and enters the date and time the samples are relinquished. The sampler enters shipper name and airbill number under the "Remarks" section on the bottom right of the form.

The custody record is completed using waterproof ink. Any corrections are made by drawing a single, ball–point pen line through, initialing and dating the error, then entering the correct information. Erasures or use of fluid correction procedures are not permissible.

The original signature copy of the Chain–of–Custody Record is enclosed in plastic (with CLP sample documentation) and secured to the inside of the cooler lid. A copy of the custody record is retained for the sampler's files. Whenever samples are split with a source or government agency, a separate Chain–of–Custody Record should be prepared for those samples to indicate with whom the samples are being split and sample tag serial numbers from splits.

Shipping coolers are secured and custody seals are placed across cooler openings. As long as custody forms are sealed inside the sample cooler and custody seals remain intact, commercial carriers are not required to sign off on the custody form.

The laboratory representative who accepts the incoming sample shipment signs and dates the Chain–of–Custody Record to acknowledge receipt of the samples. Once the sample transfer process is complete, the laboratory is responsible for maintaining internal logbooks and records that provide a custody record throughout sample preparation and analysis.

D. Sample Packaging and Shipment

1. Packaging Requirements

Samples processed through the CLP must be packaged for shipment in compliance with the most current U.S. Department of Transportation, state, local, and commercial carrier regulations. All required government and commercial carrier shipping papers must be filled out and shipment classifications made according to these regulations. (Consult Appendix C for shipping references.)

Waterproof, metal or hard plastic ice chests or coolers are the only acceptable type of sample shipping container. Inside the cooler, sample containers must be enclosed in clear plastic bags so that sample tags and labels are visible. Water and soil samples suspected to be of medium/high concentration or soil samples suspected to contain dioxin must be enclosed in a metal can with a clipped or sealable lid (e.g., paint cans). The outer metal can must be labeled with the number of the sample contained inside. Containers which do not fit into paint cans should be double bagged.

Shipping containers should be packed with noncombustible, absorbent packing material (e.g., vermiculite) surrounding the sample bottles or metal cans containing samples to avoid breakage during transport. Earth or loose ice should never be used to pack samples; earth is a contaminant, and ice melts resulting in container breakage.

Water samples for low level organic analysis and low/medium level cyanide analysis must be cooled to 4° C with ice when shipped. Shipping with ice is optional for soil samples for low/medium level organic analysis or low/medium level cyanide analysis. Ice is not required in shipping high concentration water or soil samples for organic analysis or for any matrix/concentration samples for metals or dioxin analysis. *Ice should be in sealed plastic bags* to prevent melting ice from soaking packing material which, when soaked, makes handling of samples difficult in the laboratory.

Low level inorganic and VOA water samples require chemical preservation. Users should consult Chapter II as well as the analytical method and Regional requirements for preservation techniques.

TRs, SAS PLs, Chain–of–Custody Records, and any other sample documentation accompanying

the shipment must be enclosed in a waterproof plastic bag and taped to the underside of the cooler lid. Coolers must be sealed with custody seals in such a manner that the custody seal would be broken if the cooler were opened.

Shipping coolers must have clearly visible return address labels on the outside. Shipping coolers that are labeled in this manner will be returned to the sampler by the laboratory within fourteen days following laboratory sample receipt.

2. Shipping Instructions

All samples should be shipped through a reliable commercial carrier, such as Federal Express, Emery, Purolator or equivalent. Sampling offices are responsible for sample shipping charges.

Samples for organic analysis must be shipped for overnight delivery. If shipment requires more than a 24–hour period, 40 CFR sample holding times might be exceeded, thus compromising the integrity of the sample analysis. Samples for inorganic RAS analysis should be held until sampling for the Case is complete and then shipped for two–day delivery. In the inorganic RAS program, three days is the recommended period for collection of a Case of samples.

The NEIC/Denver and the ERT/Cincinnati hazardous waste site manuals provide extensive information on EPA–approved sample packaging and shipment techniques. References for these materials are provided in Appendix C. In addition, general questions concerning sample packaging and shipment may be directed to SMO.

To facilitate return of the coolers, shippers should clearly mark the name and address of return destination on the coolers. Use of stencils and paint is highly recommended for permanent identification.

3. Shipment Coordination

To enable SMO to track the shipment of samples from the field to the laboratory and ensure timely laboratory receipt of samples, the sampler must notify SMO of all sample shipments on the day of shipment. At that time, the sampler should provide the following information:

- Sampler name and phone number.
- Case number and/or SAS number of the project.
- Exact number(s), matrix(ces) and concentration(s) of samples shipped.
- Laboratory(ies) to which samples were shipped.
- Carrier name and airbill number(s) for the shipment.
- Method of shipment (e.g., overnight, two–day).
- Date of shipment.
- Suspected contaminants associated with the samples or site.
- Any irregularities or anticipated problems with the samples, including special handling instructions, or deviations from established sampling procedures.
- Status of the sampling project (e.g., final shipment, update of future shipping schedule).

Sample shipments made after 5:00 p.m. EST should be called in to SMO at the start of business the next day (8:00 a.m. EST). SMO must be notified by 3:00 p.m. EST Friday of sample shipments intended for Saturday delivery. CLP laboratories remain open to receive Saturday shipments only upon advance notification by SMO and only when shipment information has been provided to SMO by the sampler.

The success of sample shipment coordination depends on the proper use and handling of the sample tracking forms and timely, complete communication among the RSCC, samplers, SMO and laboratories. Any postponements, cancellations, changes in the number or type of samples to be collected or changes in shipping dates must be communicated to SMO immediately.

E. Procedures for Problem Resolution

1. Resolving Problems Concerning Sample Shipment and Analysis

Program laboratories notify SMO of problems with sample receipt or during sample analysis. SMO immediately contacts the RSCC to relay the problem and to assist in formulating a solution. SMO then contacts the laboratory involved to communicate the recommended action and to authorize processing of the sample(s) in question. Timeliness is the key to problem resolution since

delays could affect contractual time requirements for sample extraction and analysis and, if extreme, could invalidate the analysis.

Users should refer general questions regarding sample shipment, required sample analysis, laboratory contracts or the status of data deliverables on a particular Case or SAS to the appropriate SMO personnel through the RSCC. Technical questions regarding contract analytical procedures should be referred to the TPO of the laboratory or the APO if the TPO is unavailable.

2. Resolving Problems Concerning Analytical Data

In the CLP's Regional/Laboratory Communication System, authorized Regional personnel can contact specified laboratory personnel to resolve questions regarding the final data package. This system may only be used after laboratory data submission and may never be used to initiate additional analytical work to resolve data questions. All communications between laboratories and Regional contacts are recorded by each party on a Telephone Record Log. Documented information includes Case and/or SAS number, individuals making contact, subject of the discussion and its resolution. As a follow up, the Region and laboratory send copies of completed telephone logs to SMO, where the logs become a permanent part of the Case/SAS file. Telephone Record Logs are available from SMO.

Prior to the laboratory's submission of the final data package, client queries regarding those analyses or data are handled by SMO through the RSCC. Depending on the nature of the question, SMO will respond or will direct the client to the appropriate NPO official for resolution. Comments regarding laboratory performance, whether positive or negative, should be directed in writing to the TPO of the laboratory with a copy provided to the APO.

CHAPTER IV

AUXILIARY SUPPORT SERVICES

In this chapter ...

Shipment Management Program
- Sample Coolers
- Contract Compliance Screening Results

Information Services
- Backlog Status Reports
- Sample Status Information
- General Program Information

Enforcement Support
- Generation of Known Quality Data Suitable for Use in Enforcement/Litigation
- Additional CLP Enforcement Support

Cost Recovery Substantiation
Contract Compliance Screening
Data Review Services

The CLP provides several supplementary services that have developed as a natural extension of the program's analytical services. A description of each auxiliary service and the procedures for accessing the service are provided in the following sections.

A. Shipment Management Program

The Shipment Management Contractor establishes, maintains and monitors all shipping accounts for the transportation of CLP materials. Currently, the Contractor coordinates accounts for the shipment of sample containers, sample coolers and contract compliance screening results. Other items that are routed for CLP use may also be addressed by this program at the request of the NPO.

1. Sample Coolers

Field samplers package samples into coolers for transportation to contract laboratories per the procedures specified in Chapter III, Section D. Sampling contractors are responsible for clearly marking a return address on the outside of each cooler. Contract laboratories are required to return each cooler to the indicated sampling office within fourteen days of sample receipt. The Shipment Management Contractor is responsible for tracking and paying for cooler shipments from the laboratories to the sampling offices.

2. Contract Compliance Screening Results

After reviewing each data package via the Contract Compliance Screening (CCS) process (see Section F), SMO distributes the results to EMSL/LV, the appropriate Region and the appropriate laboratory. SMO also sends a copy of the air carrier manifest to the Shipment Management Contractor who uses the manifest to verify and pay shipping invoices. If any problems arise regarding the shipment of CCS results, both SMO and the Shipment Management Contractor should be notified immediately.

B. Information Services

1. Backlog Status Reports

SMO distributes the Laboratory Sample Backlog Status Report and Regional Sample Backlog Status Report. These reports show the status of each sample until it is complete or continues to be incomplete for a maximum of 180 days. These reports are distributed twice monthly to all TPOs, RSCCs and Contract Laboratories.

a. Laboratory Sample Backlog Status Report

The Laboratory Sample Backlog Status Report is available by laboratory contract. Information is presented by laboratory contract number and Case number. Contract type and Regional Lab location are indicated for each contract. SDG number; sample number; sample suffix; data due date (DDD); data receipt date (DRD), if applicable; number of days late, if applicable; data complete date (DCD) and a status message are also indicated.

The sample suffix column is used to distinguish additional analyses performed on an original sample. These codes include:

B	=	Blanks
M	=	Matrix
D	=	Duplicate
Q	=	Requested Rerun
R	=	Replicate

X	=	Automatic Rerun
L	=	Laboratory Control Sample

There are six sample status messages. Samples only appear under one status message. The status messages are as follows:

(1) Data Not Due – This message indicates that samples have been received by the laboratory, but the data have not been received and are not yet due.

(2) Data Late – This message indicates that the due date has past and data have not yet been delivered by the laboratory. If this message appears in the status column for a sample, the number of days late will appear in the days late column.

(3) In CCS Review – This message indicates that data for a sample have been received and the results of the Contract Compliance Screen have not been sent to the laboratory.

(4) In 10 Day Resolution Period – This message will appear in the Status column for any sample data which have been received, screened and screening results sent to the laboratory, but the 10 day resolution period has not yet passed. The resolution period is 10 days from the date the laboratory receives the screening results. The laboratory has 10 days to resolve any noncompliance issues, including technical noncompliance and incompleteness.

(5) Incomplete After XX Days – This message will appear when data have been received, screened and the 10 day resolution period has passed, and the sample data remain incomplete. The number of days since the lab received the initial screening results is printed in the status column. This sample will continue to appear on the backlog list until it remains incomplete for 180 days.

(6) Complete – This message will appear in the Status column for any sample made complete since the last Backlog Status Report was generated.

b. Regional Backlog Status Report

The Regional Sample Backlog Status Report is very similar to the Laboratory Report. The status information is presented by Client, rather than by laboratory. The laboratory code name and contract type are listed for each sample next to the sample suffix column.

Both the Laboratory and Regional Sample Backlog Status Reports include three totals at the end of each report. The "total number of outstanding samples" includes samples for which data are not due, late, in 10 Day Resolution period or are incomplete. The "total number of samples late" includes only those samples which do not have an initial data receipt date. If data were received, but were incomplete, it would not count in this category. "Total Number of Samples Incomplete" refers to samples that either are in the 10 Day Resolution Period or remain incomplete after the 10 day resolution period has passed.

2. Sample Status Information

After scheduling analysis, SMO tracks samples from shipment through data reporting via manual and computerized tracking systems. SMO maintains ongoing communication with the TPOs, RSCCs and laboratories regarding sample status and responds to inquires from concerned parties, as appropriate.

3. General Program Information

Under the direction of CLP management, SMO serves as the program's information center for incoming calls and correspondence. Program participants and other interested parties may request from SMO information and materials on program services and procedures. SMO provides this information when possible and refers callers to the proper sources for additional information.

C. Enforcement Support

1. Generation of Known Quality Data Suitable for Use in Enforcement/Litigation

One major objective of Superfund is to recover costs incurred in the investigation and clean up of hazardous waste sites from responsible parties. The process by which these parties are identified and determined to be responsible often involves litigation. Frequently, procedures necessitate the use of CLP data generated from the analysis of samples collected at a given site. The CLP supports these and other enforcement requirements of Superfund by ensuring that CLP analytical data are documented and available for litigation. Through NEIC, the CLP has established detailed

procedures and documentation to ensure that sample data meet Agency enforcement standards.

Each CLP analytical contract requires the laboratory contractor to implement a comprehensive document control system and to employ strict chain–of–custody documentation procedures in the receipt and handling of samples throughout the analytical and data reporting process. The laboratory must have the following:

- written standard operating procedures for receipt and log–in of samples,
- maintenance of sample security after log–in,
- tracking of samples through all steps of preparation and analysis, and
- organization and assembly of all sample–related documentation on a Case–specific basis.

At a minimum, required document control and chain–of–custody records include

- custody records,
- sample tracking records,
- analyst logbook pages,
- bench sheets,
- chromatographic charts,
- computer printouts,
- raw data summaries,
- instrument logbook pages,
- correspondence and document inventory.

Before a laboratory is awarded a CLP contract and continuing periodically throughout the life of the contract, NEIC audits each laboratory facility to ensure compliance with chain–of–custody and document control requirements. In addition to facility audits, NEIC reviews laboratory data and evidence documentation on a regular basis.

2. Additional CLP Enforcement Support

Court appearances and other mandated deadlines often do not allow sufficient time for completion of the normal complete SDG File, data package, and traditional file purge package submission, review and audit process. In this event, enforcement activities require direct CLP support. Data package evaluation and/or testimony from laboratory or CLP personnel may also be needed. Through SMO, the CLP has established procedures to coordinate and respond to short term (no more than 180 days) enforcement–related requirements. These procedures are detailed in Figure 16.

OWPE provides this CLP information along with documentation gathered from other sources to the Regional case development team in the full cost recovery package.

FIGURE 16. ADDITIONAL CLP ENFORCEMENT SUPPORT

Request through	Lead Time	Request Procedures	Requestor Information Required	Documentation Provided By CLP
NPO	2 weeks	• Submit the enforcement-related request in a memorandum to the NPO. • NPO reviews the memorandum, determines the CLP response, and forwards the request and directions to SMO. • *If a request requires immediate response, the requestor should contact SMO directly by telephone and follow up with a written request memorandum to the NPO.*	• Name and telephone number of Regional contact coordinating the enforcement activity • Case/SAS number(s) of specific site sampling(s) • Sample number(s) • Date(s) of sample collection • Laboratory(ies) that performed the analysis • Type of support needed	• Arranges for the timely delivery of all laboratory and evidence documentation relating to specific sample analyses (within a minimum of seven days of request, if designated). • Obtains information relating to sample analysis or handling not specifically required under laboratory contracts. • Assists in arranging for expert testimony by laboratory or CLP personnel. • Augments Regional resources for analytical data review.

FIGURE 17. COST RECOVERY SUBSTANTIATION

Request through	Lead Time	Request Procedures	Requestor Information Required	Documentation Provided By CLP
OWPE	4-6 weeks	• Complete a Cost Recovery (CR) checklist • Mail completed CR checklist to OWPE • OWPE collects and organizes cost-related documentation	• Name and state of site • Site/Spill ID • Date the cost report is needed	• Financial Summary for Cost Analysis • Summary of Invoices, Vouchers and Canceled Checks • Routine Analytical Services Cost Report • Routine Analytical Services Case Sample List • Special Analytical Services (SAS) Cost Report • Copies of all SAS-Related Canceled Checks and Laboratory Invoices

D. Cost Recovery Substantiation

The CLP provides documentation for program analytical costs to the EPA's Office of Waste Programs Enforcement (OWPE) in support of Superfund cost recovery efforts. These procedures are detailed in Figure 17.

E. Contract Compliance Screening (CCS)

SMO performs CCS on all RAS data produced by the CLP. Modified CCS can also be performed on a case–by–case basis on "RAS Plus SAS" or "All SAS" data.

CCS is a structured review which determines completeness of data deliverables and compliance of QA/QC parameters with contract specifications. The primary objectives of CCS are to resolve identified discrepancies in a timely manner and to identify the liquidated damages category for data not in compliance. Data which meet all CCS criteria at initial receipt are recommended for 100% payment of the amount due. Data with CCS defects are recommended to have some payment withheld, either temporarily or permanently, depending on the nature and extent of the defect identified.

CCS procedures are applied to organic, inorganic and dioxin data. CCS results are produced on a fast–turnaround basis (fifteen days) and identify compliance discrepancies by code, criterion, fraction and sample. Results are distributed to the relevant laboratory, Region and EMSL/LV.

Results are accumulated in the CCS Database in order to produce routine and requested summaries of laboratory performance and compliance trends.

F. Data Review Services

A full range of review services are used to assess CLP data. Objectives of the review services are:

- To determine the useability and limitations of data given particular field or policy assessment criteria.
- To maximize the amount of useable data by identifying critical properties of data and by resolving or proposing solutions to analytical or quality control problems.
- To provide systematic and standardized data quality assessment and status summary to determine method, laboratory and program performance.

These review services are performed by a number of operations:

- Review for data useability is performed by Regional personnel and contractors. Recommended review procedures have been standardized and organized into functional guidelines for evaluating CLP data. EPA Data Validation Workgroups have produced specific documents for review of organic, inorganic and dioxin analyses.

FIGURE 18. DATA REVIEW SERVICES

Request through	Lead Time	Request Procedures	Requestor Information Required	Documentation Provided By CLP
SMO, APO, RSCC	2 weeks	• Complete SMO Data Review Request memorandum • Submit copies of the memorandum to SMO (Attn: Data Review Team), the SMO APO and the RSCC. • Upon APO approval, SMO schedules the review and notifies the requestor of the date of scheduled completion. *Data review cannot be initiated until all deliverables for the subject Case(s) have been received from the laboratory.*	• SMO Case number • Site name • Analytical laboratory name(s) • Number of samples • Sample list • Type(s) of review requested • Requested date for review completion • User name and contact • Intended use of data	• An evaluation report that includes a sample/result matrix and supporting statistics and documentation is produced for each type of review. For each sample fraction, the report indicates whether the data are considered acceptable, acceptable given qualifications noted or unacceptable. Reasons for the designation are discussed and complete data review forms for each of the areas of performance are included in the report to the client.

- Comprehensive QA review is performed by EMSL/LV on specific data packages. Review and assessment of some program-wide QA results are also performed by EMSL/LV to evaluate method and laboratory performance and the quality of analytical data.
- Under direction of the CLP management, EMSL/LV and/or SMO may perform additional data review to assess a problem Case or provide a second opinion on data useability.
- Under direction of the CLP management, SMO third party data reviews may be used to resolve disputes, especially for SAS cases.

All requests for SMO data review services should be placed using the SMO Data Review Request memorandum available from SMO. Request procedures are detailed in Figure 18. Copies of the request should be submitted to SMO (Attention: Data Review Team), the SMO PO and the RSCC. Upon authorization by the APO, SMO schedules the review and notifies the requestor of the date of scheduled completion. (Data review cannot be initiated until all deliverables for the subject Case(s) have been received from the laboratory.)

CHAPTER V

LABORATORY SELECTION AND STARTUP

In this chapter ...

Laboratory Selection Process
- Qualification Requirements
- Bidder Responsibility

Laboratory Startup Process
- APO
- APO/TPO/SMO/Laboratory Communication

Laboratory Performance Evaluation
- Performance Evaluation Sample Analysis
- On–site Laboratory Evaluation
- Corrective Action

A. Laboratory Selection Process

From time to time, when EPA needs to replace existing IFB contract resources where contracts are due to expire, to increase capacity over what is currently provided under existing contracts, or to initiate a procurement for a new type of analysis, EPA solicits laboratories for the CLP. This process is summarized in Figure 19. EPA solicits bids from interested laboratories, evaluates each laboratory on the basis of the criteria listed below, and awards contracts to qualified, low-bidding laboratories.

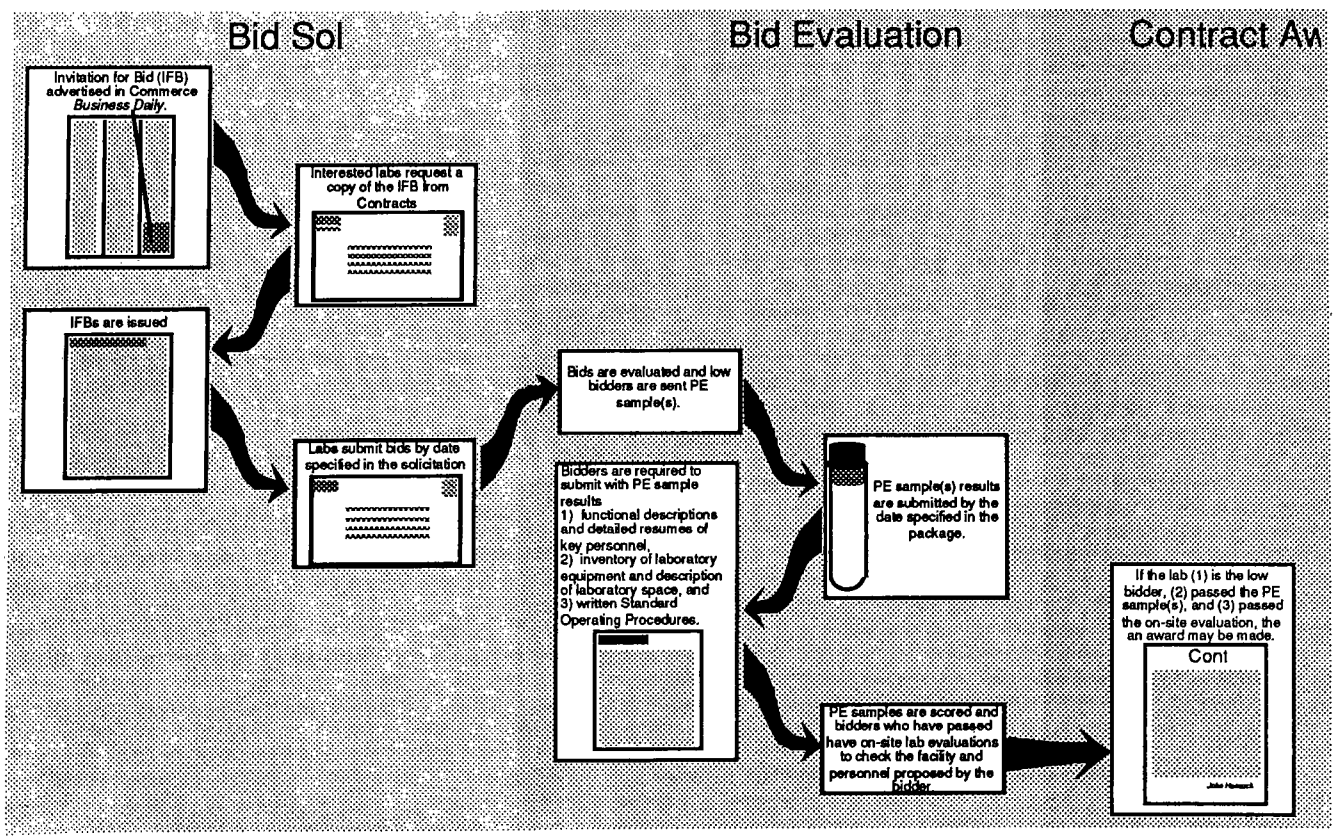
1. Qualification Requirements

a. Bid Price

The first criterion for laboratory selection is bid price. Following bid opening, the bid prices are reviewed and evaluated by NPO and Contracts Management Division (CMD) officials. The lowest competitive bidders will be sent performance evaluation (PE) samples at the direction of the Contracting Officer (CO).

b. Preaward Performance Evaluation Sample

FIGURE 19. THE CLP LABORATORY SELECTION PROCESS



Analysis

The second criterion for laboratory selection is acceptable preaward PE sample analysis. PE samples are sent to laboratories at the direction of the CO.

PE samples, distributed by EPA, are representative of the types of field samples that the laboratory would be routinely analyzing under the subject procurement. The laboratory is required to analyze PE samples according to contract procedures set forth in the IFB and to report PE sample data according to IFB requirements. The turnaround time for PE sample data submission is indicated in each IFB. Bidders' PE sample data are evaluated by NPO and EMSL/LV personnel for compliance with contract requirements and accuracy of determination of compounds at the levels known to be in the PE samples. Analysis results are rated by a scoresheet developed by the EPA; currently, the acceptable performance score is seventy-five percent.

2. Bidder Responsibility

a. Bidder-Supplied Documentation

At the time of submission of PE sample data, bidders are required to submit documented evidence that they have the internal procedures, equipment and personnel in place for successful performance of contract requirements. Required documentation includes:

- functional descriptions and detailed resumes of key personnel;
- inventory of laboratory equipment;
- description of laboratory space; and
- written Standard Operating Procedures (SOPs).

Submitted documentation is reviewed by NPO and EMSL/LV personnel and is utilized by the EPA in performance of the site evaluation. After contract award, bidders are required to submit revised SOPs to the APO.

b. Laboratory Site Evaluation

NPO, TPO, CMD, EMSL/LV and NEIC personnel participate in on-site evaluations of laboratory facilities of bidders which scored acceptably on the PE sample analyses and are within the EPA-determined competitive range. The results of the on-site evaluation are considered in the final determination of bidder responsibility for contract award.

B. Laboratory Startup Process

Laboratories are expected to be capable of receiving full contract sample requirements upon award. At award, laboratories must provide standards in compliance with the performance specifications supplied in the contract.

1. APO Review of First Data Packages

Initial data packages are targeted for immediate review and evaluation by the APO, EMSL/LV and the Region. This intensive review focuses on any problems the laboratory may have in applying methodologies or in reporting data. The APO and TPO supply feedback to the laboratory concerning the status of the data and work with the laboratory in identifying and remedying problems. Depending on the extent of the problems found during the review of an initial data package, the APO or TPO may visit the laboratory facility and work on-site with laboratory personnel to rectify problems.

2. APO/TPO/SMO/Laboratory Communication

Telephone communication is the most widely applied method for problem-solving and maintaining efficient laboratory operations during both the laboratory startup phase and throughout the performance of the contract. In general, the laboratory notifies SMO immediately upon identification of any problem regarding the samples. Any questions regarding difficulties encountered in analysis should be addressed to the TPO of the Region of sample origin with SMO serving as a go-between to record resolution of the issue. SMO routinely resolves sample-related problems in coordination with the Regional client and refers technical problems to the APO or TPO, who then contacts the laboratory to resolve the problem. The resolution and any specific actions taken are reported to the appropriate SMO personnel who records this information as part of the permanent Case record. The laboratory also records the problem and resolution in the narrative portion of the sample data report so that the Region will consider this information when evaluating and using the data.

C. Laboratory Performance Evaluation

1. Performance Evaluation Sample Analysis

EPA may distribute PE samples to contract laboratories for analysis. EMSL/LV evaluates the laboratories' PE sample data, and the NPO uses this evaluation in formally assessing laboratory contract performance. Additionally, EMSL/LV enters PE sample data into the program's QA and Results Database. These data are utilized, along with other laboratory data, in trend analyses and evaluation of contract QC criteria. Refer to Chapter VI, Section C for a more detailed description of PE samples.

2. On–site Laboratory Evaluation

Regional, NEIC and EMSL/LV personnel visit each contract laboratory facility in order to evaluate laboratory procedures or to identify laboratory problems for correction. The frequency of on–site evaluation depends, in part, upon laboratory performance. The APO and TPO utilize the evaluation reports which result from these on–site visits in identifying and remedying laboratory performance problems. Chapter VI, Section E details the on–site laboratory evaluation process.

3. Corrective Action

The APO and TPO, work closely with each laboratory to correct identified laboratory performance problems. Depending on the scope of the problems, the laboratory may be placed on temporary hold and will not receive additional samples for analysis until the problem has been corrected.

If the laboratory's noncompliance to contract performance or delivery requirements continues, the NPO may request the CO to initiate a contract action such as a Show Cause Notice or a Cure Notice.

A Show Cause Notice requires the Contractor, within a ten–day period, to present any facts the government can use to determine if the Contractor's failure to perform arose without any fault or negligence on the part of the Contractor. The Contractor must submit substantial evidence to demonstrate that the contract should not be terminated for default. A recovery plan is generally included as part of the Contractor's response to the Show Cause Notice. NPO and CMD officials review the Contractor's response and proposed recovery plan to determine whether the Contractor has presented sufficient evidence to demonstrate timely remedy of the noncompliance. Following this review, if the Contractor has presented acceptable evidence toward recovery, the government issues a Cure Notice to the Contractor.

A Cure Notice specifies the Government–accepted recovery plan that the Contractor must follow to avoid contract termination. The recovery plan includes actions and time schedules for completion of each step of the recovery process, and specifies an overall time period acceptable for completion of recovery.

Should the Contractor not comply with the recovery schedule, the Government's next and final step may be contract termination for default. In addition to terminating the laboratory's contract, this action affects the evaluation of the laboratory's responsibility for award under future CLP solicitations.

CHAPTER VI

PROGRAM QUALITY ASSURANCE

In this chapter ...

Laboratory Quality Control Criteria
- Standard Operating Procedures
- Quality Assurance Plan
- Analytical Standards Traceability Requirements

Analytical Data Review
- Contract Compliance Screening
- Regional Data Review

Laboratory Evaluation Samples
GC/MS Tape Audits
On–Site Laboratory Evaluations
- Quality Assurance On-Site Evaluation
- Evidentiary Audit
- Discussion of the On-Site Team's Findings

Corrective Action Reports For Follow-Through to Quality Assurance and Evidentiary Audit Reports
Quality Assurance and Data Trend Analysis
Data Management

Quality assurance (QA) and quality control (QC) are integral parts of the CLP. The quality assurance process consists of management review and oversight at the planning, implementation, and completion stages of the environmental data collection activity. The QA process ensures that data provided are of the quality required. The quality control process includes those activities required during data collection to produce the data quality desired and to document the quality of the collected data.

During the planning of an environmental data collection program, QA activities focus on defining data quality criteria and designing a QC system to measure the quality of data being generated. During the implementation of the data collection effort, QA activities ensure that the QC system is functioning effectively, and that the deficiencies uncovered by the QC system are corrected. After environmental data are collected, QA activities focus on assessing the quality of data obtained to determine its suitability to support enforcement or remedial decisions.

A complete QA/QC program includes internal laboratory QC criteria that must be met to ensure acceptable levels of performance. These performance levels are determined by QA review. External review of data and procedures is accomplished by the monitoring activities of the NPO, the Regions, SMO, NEIC and EMSL/LV. Laboratory evaluation samples, magnetic tape audits and laboratory on–site evaluations provide an external QA reference for CLP. A feedback loop supplies the results of the various review functions to the contract laboratories through direct communication with the APOs and TPOs. The following sections describe overall QA/QC operations and how the CLP meets the QA/QC objective.

A. Laboratory Quality Control Criteria

1. Standard Operating Procedures

In order to obtain reliable results, adherence to prescribed analytical methodology is imperative. In any operation that is performed on a repetitive basis, reproducibility is best accomplished through the use of Standard Operating Procedures (SOPs). As defined by the EPA, an SOP is a written document which provides directions for the step-by-step execution of an operation, analysis, or action which is commonly accepted as the method for performing certain routine or repetitive tasks.

SOPs prepared by the Contractor must be functional: i.e., clear, comprehensive, up-to-date, and sufficiently detailed to permit duplication of results by qualified analysts. All SOPs, as presented to the Agency, must reflect activities as they are currently performed in the laboratory. In addition, all SOPs must:

- Be consistent with current EPA regulations, guidelines, and the CLP contract's requirements.
- Be consistent with instrument manufacturers' specific instruction manuals.

- Be available to the EPA during an On-Site Laboratory Evaluation. A complete set of SOPs shall be bound together and available for inspection at such evaluations. During on-site evaluations, laboratory personnel may be asked to demonstrate the application of the SOPs.
- Provide for the development of documentation that is sufficiently complete to record the performance of all tasks required by the protocol.
- Demonstrate the validity of data reported by the Contractor and explain the cause of missing or inconsistent results.
- Describe the corrective measures and feedback mechanisms utilized when analytical results do not meet protocol requirements.
- Be reviewed regularly and updated as necessary when contract, facility, or Contractor procedural modifications are made.
- Be archived for future reference in useability or evidentiary situations.
- Be available at specific work stations as appropriate.
- Be subject to a document control procedure which precludes the use of outdated or inappropriate SOPs.

a. SOP FORMAT:

The format for SOPs may vary depending upon the kind of activity for which they are prepared, however, at a minimum, the following sections must be included:

- Title Page
- Scope and Application
- Definitions
- Procedures
- QC Limits
- Corrective Action Procedures, Including Procedures for Secondary Review of Information Being Generated
- Documentation Description and Example Forms
- Miscellaneous Notes and Precautions
- References

b. SOPs Delivery Requirements

Within forty-five (45) days of contract receipt, a complete set of SOPs, relevant to the contract shall be sent to the Technical Project Officer, SMO and EMSL/LV. Also, during the term of performance of the contract, copies of SOPs which have been amended or new SOPs which have been written shall be sent to the Technical Project Officer, EMSL/LV (quality assurance SOPs) and NEIC (evidentiary SOPs).

2. Quality Assurance Plan

The Contractor shall establish a quality assurance program with the objective of providing sound analytical chemical measurements. This program shall incorporate the quality control procedures, any necessary corrective action, and all documentation required during data collection as well as the quality assessment measures performed by management to ensure production of acceptable data.

As evidence of such a program, the Contractor shall prepare a written Quality Assurance Plan (QAP) which describes the procedures that are implemented to achieve the following:

- Maintaining data integrity, validity, and useability.
- Ensuring that analytical measurement systems are maintained in an acceptable state of stability and reproducibility.
- Detecting problems through data assessment and establishing corrective action procedures which keep the analytical process reliable.
- Documenting all aspects of the measurement process in order to provide data which are technically sound and legally defensible.

The QAP must present, in specific terms, the policies, organization, objectives, functional guidelines, and specific QA and QC activities designed to achieve the data quality requirements in each contract. Where applicable, SOPs pertaining to each element shall be included or referenced as part of the QAP. The QAP must be available during on-site laboratory evaluation and upon written request by the Administrative Project Officer.

The following elements should be contained in the Quality Assurance Plan.

A. Organization and Personnel
   1. QA Policy and Objectives
   2. QA Management
      a. Organization
      b. Assignment of QC and QA Responsibilities
      c. Reporting Relationships
      d. QA Document Control Procedures
      e. QA Program Assessment Procedures
   3. Personnel
      a. Resumes
      b. Education and Experience Pertinent to this Contract
      c. Training Progress

B. Facilities and Equipment
   1. Instrumentation and Backup Alternatives
   2. Maintenance Activities and Schedules

C. Document Control
   1. Laboratory Notebook Policy
   2. Samples Tracking/Custody Procedures
   3. Logbook Maintenance and Archiving Procedures
   4. Case File Organization, Preparation and Review Procedures
   5. Procedures for Preparation, Approval, Review, Revision, and Distribution of SOPs
   6. Process for Revision of Technical or Documentation Procedures

D. Analytical Methodology
   1. Calibration Procedures and Frequency
   2. Sample Preparation/Extraction Procedures
   3. Sample Analysis Procedures
   4. Standards Preparation Procedures
   5. Decision Processes, Procedures, and Responsibility for Initiation of Corrective Action

E. Data Generation
   1. Data Collection Procedures
   2. Data Reduction Procedures
   3. Data Validation Procedures
   4. Data Reporting and Authorization Procedures

F. Quality Control
   1. Solvent, Reagent and Adsorbent Check Analysis
   2. Reference Material Analysis
   3. Internal Quality Control Checks
   4. Corrective Action and Determination of QC Limit Procedures
   5. Responsibility Designation

G. Quality Assurance
   1. Data Quality Assurance
   2. Systems/Internal Audits
   3. Performance/External Audits
   4. Corrective Action Procedures
   5. Quality Assurance Reporting Procedures
   6. Responsibility Designation

3. Analytical Standards Traceability Requirements

The U.S. Environmental Protection Agency may not supply analytical reference standards either for direct analytical measurements or for the purpose of traceability. All contract laboratories may be required to prepare from neat materials or purchase from private chemical supply houses those standards necessary to successfully and accurately perform the analyses required in this protocol.

a. Preparation of Chemical Standards from the Neat High Purity Bulk Material

A laboratory may prepare their chemical standards from neat materials unless their contract specifies otherwise. Commercial sources for neat chemical standards pertaining to compounds listed on the Target Compound List are given in the Appendix C of the "Quality Assurance Materials Bank: Analytical Reference Standards" Seventh Edition, January 1988. Laboratories should obtain the highest required purity when purchasing neat chemical standards; standards purchased at less than 97% purity must be documented as to why a higher purity could not be obtained.

b. Purchase of Chemical Standards Already in Solution

Solutions of analytical reference standards can be purchased by Contractors provided they meet the following criteria:

1. Laboratories must maintain the following documentation to verify the integrity of the standard solutions they purchase:
   a. mass spectral identification confirmation of the neat material
   b. purity confirmation of the neat material
   c. chromatographic and quantitative documentation that the solution

standard was QC checked according to the following section

2. The Contractor must purchase standards for which the quality is demonstrated statistically and analytically by a method of the supplier's choice.

The laboratory is responsible for the quality of the standards employed for analyses under this contract.

c. Requesting Standards From the EPA Standards Repository

Under special or emergency circumstances only, solutions of analytical reference materials can be ordered from the U.S. EPA Chemical Standards Repository, depending on availability. The Contractor can place an order for standards only after demonstrating that these standards are not available from commercial vendors either in solution or as a neat material.

d. Documentation of the Verification and Preparation of Chemical Standards

It is the responsibility of each laboratory to maintain the necessary documentation to show that the chemical standards they have used in the performance of CLP analysis conform to the requirements previously listed. Weighing logbooks, calculations, chromatograms, mass spectra, etc., whether produced by the laboratory or purchased from chemical supply houses, must be maintained by the laboratory and may be subject to review during on-site inspection visits. Documentation of standards preparation may be required to be sent to EPA for verification of contract compliance. In those cases where the documentation is supportive of the analytical results of data packages sent to EPA, such documentation is to be kept on file by the laboratories for a period of one year.

B. Analytical Data Review

Upon completion of analysis and data reporting, the contract laboratory simultaneously sends a copy of the complete data package to SMO, EMSL/LV and the Regional client. Each of these groups performs complementary aspects of data review. SMO CCS review identifies contractual discrepancies; EMSL/LV review determines technical quality and consistency; and Regional data review relates useability of the data to a specific site.

1. Contract Compliance Screening

CCS is one aspect of the Government's contractual right of inspection of analytical data. CCS examines the Contractor's adherence to the contract requirements based on the sample data package delivered to the Agency.

CCS is performed by the Sample Management Office (SMO) under the direction of the EPA. To assure a uniform review, a set of standardized procedures have been developed to evaluate the sample data package submitted by a Contractor against the technical and completeness requirements of the contract.

CCS results are mailed to the Contractor and all other data recipients. The Contractor has a period of time to correct deficiencies. The Contractor must send all corrections to the Regional Client, and SMO.

CCS results are used in conjunction with other information to measure overall Contractor performance and to take appropriate actions to correct deficiencies in performance.

2. Regional Data Review

Contract laboratory data are generated to meet the specific needs of the Regions. In order to verify the useability of data for the intended purpose, each Region reviews data from the perspective of end-user, based upon functional aspects of data quality. General guidelines for data review have been developed jointly by the Regions and the National Program Office. Each Region uses these guidelines as the basis for data evaluation. Individual Regions may augment the basic guideline review process with additional review based on Region-specific or site-specific concerns. Regional reviews, like the sites under investigation, vary based on the nature of the problems under investigation and the Regional response appropriate to the specific circumstances.

Regional data reviews, relating useability of the data to a specific site are part of the collective assessment process. They complement the review done at the Sample Management Office, which is designed to identify contractual discrepancies and the review done at EMSL/LV which is designed to evaluate Contractor and method performance. These individual evaluations are integrated into a collective review that is necessary for program and laboratory administration and management and

may be used to take appropriate action to correct deficiencies in the Contractor's performance.

C. Laboratory Evaluation Samples

Although intralaboratory QC may demonstrate Contractor and method performance that can be tracked over time, an external performance evaluation program is an essential feature of a QA program. As a means of measuring Contractor and method performance, Contractors participate in interlaboratory comparison studies conducted by the EPA. Results from the analysis of these laboratory evaluation samples will be used by the EPA to verify the Contractor's continuing ability to produce acceptable analytical data. The results are also used to assess the precision and accuracy of the analytical methods for specific analytes.

Sample sets may be provided to participating Contractors as frequently as on an SDG-by-SDG basis as a recognizable QC sample of known composition; as a recognizable QC sample of unknown composition; or not recognizable as a QC material. The laboratory evaluation samples may be sent either by the Regional client or the National Program Office, and may be used for contract action.

Contractors are required to analyze the samples and return the data package and all raw data within the contract required turnaround time.

At a minimum, the results are evaluated for compound identification, quantification, and sample contamination. Confidence intervals for the quantification of target compounds are based on reported values using population statistics. EPA may adjust the scores on any given laboratory evaluation sample to compensate for unanticipated difficulties with a particular sample. Contractors are required to use the NIST/EPA/MSDC mass spectral library to tentatively identify a maximum number of non-target compounds in each fraction that are present above a minimal response. Tentative identification of these compounds, based on contractually described spectral interpretation procedures, is evaluated and integrated into the evaluation process.

A Contractor's results on the laboratory evaluation samples will determine the Contractor's performance as follows:

1. *Acceptable, No Response Required* (Score greater than or equal to 90 percent):

   Data meet most or all of the scoring criteria. No response is required.

2. *Acceptable, Response Explaining Deficiency(ies) Required* (Score greater than or equal to 75 percent but less than 90 percent):

   Deficiencies exist in the Contractor's performance.

   Within 14 days of receipt of notification from EPA, the Contractor shall describe the deficiency(ies) and the action(s) taken to correct the deficiency(ies) in a letter to the Administrative Project Officer, the Technical Project Officer and EMSL/LV.

3. *Unacceptable Performance, Response Explaining Deficiency(ies) Required* (Score less than 75 percent):

   Deficiencies exist in the Contractor's performance to the extent that the National Program Office has determined that the Contractor has not demonstrated the capability to meet the contract requirements.

   Within 14 days of receipt of notification from EPA, the Contractor shall describe the deficiency(ies) and the action(s) taken to correct the deficiency(ies) in a letter to the Administrative Project Officer, the Technical Project Officer and EMSL/LV.

   The Contractor shall be notified by the Administrative Project Officer or Technical Project Officer concerning the remedy for their unacceptable performance. A Contractor may expect, but EPA is not limited to, the following actions: Reduction of the number of samples sent under the contract, suspension of sample shipment to the Contractor, a site visit, a full data audit, analysis of remedial PE samples, and/or a contract sanction, such as a Cure Notice.

   Note: A Contractor's prompt response demonstrating that corrective actions have been taken to ensure the Contractor's capability to meet contract requirements will facilitate continuation of full sample delivery.

D. GC/MS Tape Audits (Organics Only)

Periodically, EPA requests from Contractors the GC/MS magnetic tapes corresponding to a specific case in order to accomplish tape audits. Generally, tape submissions and audits are requested for the following reasons:

- Program overview
- Indication of data quality problems from EMSL/LV, SMO, or Regional data reviews
- Support for on-site audits
- Specific Regional requests

Depending upon the reason for an audit, the tapes from a recent case, a specific case, or a laboratory evaluation sample may be requested. Tape audits provide a mechanism to assess adherence to contractual requirements and to ensure the consistency of data reported on the hardcopy/floppy diskettes with that generated on the GC/MS tapes. This function provides external monitoring of Program QC requirements and checks adherence of the Contractor to internal QA procedures. In addition, tape audits enable EPA to evaluate the utility, precision, and accuracy of the analytical methods.

The GC/MS tape shall include raw data and quantitation reports for samples, blanks, laboratory evaluation samples, initial calibrations, continuing calibration, BFB and DFTPP associated with the case requested.

Upon request of the Administrative Project Officer or EMSL/LV, the required tapes and all necessary documentation shall be submitted to EPA within seven days of notification.

E. On–Site Laboratory Evaluations

At a frequency dictated by a contract laboratory's performance, the Administrative Project Officer, Technical Project Officer or their authorized representative will conduct an on-site laboratory evaluation. On-site laboratory evaluations are carried out to monitor the Contractor's ability to meet selected terms and conditions specified in the contract. The evaluation process incorporates two separate categories: Quality Assurance Evaluation, and an Evidentiary Audit.

1. Quality Assurance On-Site Evaluation

Quality assurance evaluators inspect the Contractor's facilities to verify the adequacy and maintenance of instrumentation, the continuity of personnel meeting experience or education requirements, and the acceptable performance of analytical and QC procedures. The Contractor should expect that items to be monitored will include, but not be limited to the following items.

- Size and appearance of the facility
- Quantity, age, availability, scheduled maintenance and performance of instrumentation
- Availability, appropriateness, and utilization of SOPs
- Staff qualifications, experience, and personnel training programs
- Reagents, standards, and sample storage facilities
- Standard preparation logbooks and raw data
- Bench sheets and analytical logbook maintenance and review
- Review of the Contractor's sample analysis/data package inspection procedures

Prior to an on-site evaluation, various documentation pertaining to performance of the specific Contractor is integrated in a profile package for discussion during the evaluation. Items that may be included are previous on-site reports, laboratory evaluation sample scores, Regional review of data, Regional QA materials, GC/MS tape audit reports, results of CCS, and data trend reports.

2. Evidentiary Audit

Evidence auditors conduct an on-site laboratory evaluation to determine if laboratory policies and procedures are in place to satisfy evidence handling requirements as stated in Exhibit F. The evidence audit is comprised of the following three activities

a. Procedural Audit

The procedural audit consists of review and examination of actual standard operating procedures and accompanying documentation for the following laboratory operations:

- sample receiving,
- sample storage, sample identification,
- sample security, sample tracking (from receipt to completion of analysis) and
- analytical project file organization and assembly.

b. Written SOPs Audit

The written SOPs audit consists of review and examination of the written SOPs to determine if they are accurate and complete for the following laboratory operations:

- sample receiving,
- sample storage,
- sample identification,
- sample security,
- sample tracking (from receipt to completion of analysis) and
- analytical project file organization and assembly.

c. Analytical Project File Evidence Audit

The analytical project file evidence audit consists of review and examination of the analytical project file documentation. The auditors review the files to determine:

- The accuracy of the document inventory
- The completeness of the file
- The adequacy and accuracy of the document numbering system
- Traceability of sample activity
- Identification of activity recorded on the documents
- Error correction methods

3. Discussion of the On-Site Team's Findings

The quality assurance and evidentiary auditors discuss their findings with the Administrative Project Officer/Technical Project Officer prior to debriefing the Contractor. During the debriefing, the auditors present their findings and recommendations for corrective actions necessary to the Contractor personnel.

4. Corrective Action Reports For Follow-Through to Quality Assurance and Evidentiary Audit Reports

Following an on-site evaluation, quality assurance and evidentiary audit reports which discuss deficiencies found during the on-site will be forwarded to the Contractor. The Contractor must discuss the corrective actions taken to resolve the deficiencies discussed during the on-site visit and discussed in the on-site reports in a letter to the Administrative Project Officer, Technical Project Officer, EMSL/LV (response to the quality assurance report) and NEIC (response to the evidentiary report) within 14 days of receipt of the finding or within the time agreed upon between the Administrative Project Officer/Technical Project Officer and the Contractor. If SOPs are required to be written or SOPs are required to be amended, the Contractor must provide the SOPs to the Technical Project Officer, EMSL/LV (quality assurance/technical SOPs) and NEIC (evidentiary SOPs) within 30 days of receipt of the finding or within the time agreed upon between the Administrative Project Officer/Technical Project Officer and the Contractor.

If the Contractor fails to take appropriate corrective action to resolve the deficiencies discussed in the on-site reports, a Contractor may expect, but the Agency is not limited to, the following actions: reduction of the number of samples sent under the contract, suspension of sample shipment to the Contractor, a follow-up site visit, a full data audit, analysis of remedial PE samples and/or contract sanction, such as a Cure Notice.

F. Quality Assurance and Data Trend Analysis

Data submitted by laboratories are subject to review from several aspects: compliance with contract-required QC, useability, and full data package evaluation. Problems resulting from any of these reviews may determine the need for a GC/MS tape audit, an on-site laboratory evaluation and/or a remedial laboratory evaluation sample. In addition, QC prescribed in the methods provides information that is continually used by the Agency to assess sample data quality, Contractor data quality and Program data quality via data trend analysis. Trend analysis is accomplished by entering data into a computerized data base. Statistical reports that evaluate specific anomalies or disclose trends in many areas are generated from this database.

Program-wide statistical results are used to rank laboratories in order to observe the relative

performance of each Contractor using a given protocol against its peers. The reports are also used to identify trends within laboratories. The results of many of these trends analyses are included in overall evaluation of a Contractor's performance, and are reviewed to determine if corrective action or an on-site laboratory evaluation is indicated in order to meet the QA/QC requirements of the contract.

Contractor performance over time is monitored using these trend analysis techniques to detect departures of Contractor output from required or desired levels of quality control, and to provide an early warning of Contractor QA/QC problems which may not be apparent from the results of an individual case.

As a further benefit to the Program, the data base provides the information needed to establish performance-based criteria in updated analytical protocols, where advisory criteria has been previously used. The vast empirical data set produced by contract laboratories is carefully analyzed, with the results augmenting theoretical and research-based performance criteria. The result is a continuously monitored set of quality control and performance criteria specifications of what is routinely achievable and expected of environmental chemistry laboratories in mass production analysis of environmental samples. This, in turn, assists the Agency in meeting its objectives of obtaining data of known and documented quality.

G. Data Management

Data management procedures are defined as procedures specifying the acquisition or entry, update, correction, deletion, storage and security of computer readable data and files. These procedures must be in written form and contain a clear definition for all databases and files used to generate or resubmit deliverables. Key areas of concern include: system organization (including personnel and security), documentation operations, traceability and quality control.

Data manually entered from hard-copy must be reevaluated through quality control measures and the error rates estimated. Systems should prevent entry of incorrect or out-of-range data and alert data entry personnel of errors. In addition, data entry error rates must be estimated and recorded on a monthly basis by reentering a statistical sample of the data entered and calculating discrepancy rates by data element.

The record of changes in the form of corrections and updates to data originally generated, submitted, and/or resubmitted must be documented to allow traceablilty of updates. Documentation must include the following for each change:

- Justification or rationale for the change.
- Initials of the person making the change or changes. Data changes must be implemented and reviewed by a person or group independent of the source generating the deliverable.
- Change documentation must be retained according to the schedule of the original deliverable.
- Resubmitted diskettes or other deliverables must be reinspected as a part of the laboratories' internal inspection process prior to resubmission. The entire deliverable, not just the changes, must be inspected.
- The Laboratory Manager must approve changes to originally submitted deliverables.
- Documentation of data changes may be requested by laboratory auditors.

Lifecycle management procedures must be applied to computer software systems developed by the laboratory to be used to generate and edit contract deliverables. Such systems must be thoroughly tested and documented prior to utilization.

- A software test and acceptance plan including test requirements, test results and acceptance criteria must be developed, followed, and available in written form.
- System changes must not be made directly to production systems generating deliverables. Changes must be made first to a development system and tested prior to implementation.
- Each version of the production system will be given an identification number, date of installation, date of last operation and archived.
- System and operations documentation must be developed and maintained for

each system. Documentation must include a users manual and an operations and maintenance manual.

Individual(s) responsible for the following functions must be identified:

- System operation and maintenance including documentation and training.
- Database integrity, including data entry, data updating and quality control.
- Data and system security, backup and archiving.

APPENDIX A

LIST OF ACRONYMS

AA	Atomic Absorption
AMIS	Analytical Methods Implementation Sections
AOB	Analytical Operations Branch
APO	Administrative Project Officer
AR	Authorized Requestor
B/N/A	Base, Neutral, Acid Extractable Compounds
CCS	Contract Compliance Screening
CEAT	Contractor Evidence Audit Team
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
CLP	Contract Laboratory Program
CMD	Contracts Management Division
CO	Contracting Officer
CR	Cost Recovery
CRQL	Contract Required Quantitation Limit
DCD	Data Complete Date
DDD	Data Due Date
DR	Delivery Request
DRD	Data Receipt Date
EMSL	Environmental Monitoring Systems Laboratory
EPA	Environmental Protection Agency
ERT	Environmental Response Team
ESAT	Environmental Services Assistance Teams
FIT	Field Investigation Team
FR	Federal Register
FSCC	Fused Silica Capillary Column
GC/EC	Gas Chromatography/Electron Capture
GC/MS	Gas Chromatography/Mass Spectrometry
HRGC	High Resolution Gas Chromatography
HRMS	High Resolution Mass Spectrometry
HSED	Hazardous Site Evaluation Division
ICP/MS	Inductively Coupled Plasma/Mass Spectrometry

IDL	Instrument Detection Limit
IFB	Invitation for Bid
LCS	Laboratory Control Sample
NEIC	National Enforcement Investigations Center
NIST	National Institute for Standards and Technology
NPM	National Program Manager
NPO	National Program Office
ORD	Office of Research and Development
OSWER	Office of Solid Waste and Emergency Response
OWPE	Office of Waste Programs Enforcement
PE	Performance Evaluation
PEST	Pesticides
PL	Packing List
QA	Quality Assurance
QAP	Quality Assurance Plan
QC	Quality Control
QTM	Quick Turnaround Method
RAS	Routine Analytical Services
REM	Remedial Action Team
ROS	Regional Operations Section
RSCC	Regional Sample Control Center
SARA	Superfund Amendments and Reauthorization Act
SAS	Special Analytical Services
SDG	Sample Delivery Group
SICP	Selected Ion Current Profile
SIM	Selected Ion Monitoring
SMO	Sample Management Office
SOP	Standard Operating Procedure
SOW	Statement of Work
SV	Semivolatile
TAT	Technical Assistance Team
TCL	Target Compound List
TIC	Tentatively Identified Compound
TPO	Technical Project Officer
TR	Traffic Report
VOA	Volatile Organics Analysis

APPENDIX B

CLP DIRECTORY

National Program Office

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APPENDIX C

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NOTE: The references in this appendix are supplied for general information purposes and do not necessarily represent methods or procedures utilized in the CLP.

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