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QUALITY ASSURANCE PROGRAM

and

QUALITY CONTROL PROCEDURES

REVISION 7.0

Effective Date: June 13, 2008

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Approved By:

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Section 2.0 Table of Contents

- 1. Title and Extramural Signatures**
- 2. Table of Contents & List of Tables and Figures**
- 3. Statement of Policy**
 - 3.1. Purpose of This Manual
 - 3.2. Scope of GD Air Testing, Inc. Laboratory
 - 3.3. Objectives
 - 3.4. Quality Assurance Defined
 - 3.5. Quality Assurance Philosophy
 - 3.6. Objectives of the Quality Assurance Program
 - 3.7. Quality Assurance Manual Review
 - 3.8. Employee Responsibility
- 4. Organization and Responsibility**
 - 4.1. Organization Chart
 - 4.2. Technical Qualifications
 - 4.3. Job Descriptions and Responsibilities
 - 4.4. Laboratory Space and Design
 - 4.5. Client Contact Issues
 - 4.6. Laboratory Security
 - 4.7. Communication Within the Laboratory
 - 4.8. Project Management
 - 4.9. Turnaround Time
 - 4.10 Information Management
 - 4.11 Procurement and Subcontracting
- 5. Training**
 - 5.1 Introduction
 - 5.2 Formal Training Requirements
 - 5.3 In-House Training Requirements
 - 5.4 Manual Calculations and Manual Integrations
 - 5.5 Trained and Experienced New Hires
 - 5.6 Maintenance of Technical Competence
 - 5.7 Literature Awareness
- 6. Equipment Calibration and Maintenance**
 - 6.1 Equipment Maintenance
 - 6.2 List of Equipment

7. Test Methods and Procedures

- 7.1 Analytical Methods Discussion
- 7.2 Table of Methods Performed by GDAT

8. Routine Quality Assurance Objectives

- 8.1 Precision
- 8.2 Accuracy
- 8.3 Completeness
- 8.4 Control Charts
- 8.5 Instrument and Equipment Calibration
- 8.6 Reagents and Calibration Standards
- 8.7 Method Detection Limits
- 8.8 Interferences and Monitoring
- 8.9 Background Signal
- 8.10 Preventive Maintenance
- 8.11 Electronic Data Processing & Computer Access

9. Document Control

- 9.1 Introduction
- 9.2 Sample Receipt/Chain of Custody
- 9.3 Documentation Required
- 9.4 Instrument and Calibration Log Book Requirements
- 9.5 Laboratory Analytical Records
- 9.6 Quality Control Data Sheets/Log Books
- 9.7 Maintenance of Laboratory Notes

10. Data Review and Reporting

- 10.1 Data Reduction
- 10.2 Data Validation
- 10.3 Data Reporting
- 10.4 Report Content
- 10.5 Amendments
- 10.6 Electronic Reporting & Customer Confidentiality

11. Corrective Actions, Complaint Resolution, Preventive Actions

12. System and Performance Audits

13. Code of Ethics

Section 3.0 Statement Of Policy

3.1 The Purpose of This Manual - The purpose of this manual is to provide a written directive which is intended to 1) promote effective operations within this laboratory; 2) assist members of the laboratory in performing their duties; and 3) ensure that information generated by the laboratory is reliable and correct.

3.2 Scope of GD Air Testing, Inc. Laboratory - GD Air Testing, Inc. offers analytical capabilities for a broad range of Air Toxics and Air Quality applications in support of industry, engineering, and government projects. In-house analyses are centered around established EPA methodologies including the TO compendium procedures. Custom analytical sequences which vary from established procedures referenced herein will require a project specific quality plan to define data quality objectives.

3.3 GD Air Testing, Inc. Objectives - The following objectives are considered to be relevant to our client base and are understood and supported by the GD Air Testing, Inc. staff:

3.3.1 Our staff intends to provide excellent service in responding to the needs of the client by adhering to standards associated with good laboratory practices, Customer quality assurance project plans, and NELAC criteria.

3.3.2 Our staff will maintain a quality control program that ensures the accuracy and reliability of analytical services that also detects and corrects factors which may adversely affect data quality.

3.3.3 Our staff will utilize methods and procedures considered to be state-of-the-art in the analytical community.

3.3.4 Our staff will maintain a high level of professional integrity by following the ethical standards required in this manual.

3.3.5 GD Air Testing, Inc. will maintain a technical staff that is well-trained and competent.

3.3.6 Our staff will maintain a properly functioning facility in which to perform analyses.

3.4 Quality Assurance Defined - Quality assurance is defined as the sum of all activities in which a laboratory is engaged. In essence, it is the “master plan” that details procedures and objectives applicable to all analytical work undertaken in the laboratory. A quality assurance program is an essential part of a sound analytical protocol used by the laboratory to detect and correct problems in analytical and interpretational processes. Quality assurance activities include preventative activities, assessment activities, and corrective activities.

3.4.1 Preventative activities include tasks undertaken prior to the examination of samples that are intended to establish systems conducive to accuracy in analytical testing. These include the development and consistent use of standard operating procedures, instrument preventative maintenance, calibration of instruments, testing of materials, training of personnel, and strict adherence to the principles of good laboratory practice.

3.4.2 Assessment activities are those functions undertaken during testing to determine if the control systems are performing correctly. Assessment activities include the use of standards, controls, blanks, maintenance of control charts and proficiency testing.

3.4.3 Corrective activities are performed when loss of control (error) or possible error is detected somewhere in the analytical system. Examples include instrument troubleshooting, instrument re-calibration, personnel re-training, and reanalysis of unused sampling materials.

3.5 Quality Assurance Philosophy - It is imperative that all work conducted by GD Air Testing, Inc. is technically correct. This applies not only to actual laboratory work, but also to written reports, verbal reports and court testimony.

Technical competency may be achieved only by the amalgamation and synthesis of a number of factors, including initial training, experience, supervision of casework, continuing education, proficiency testing, and an appreciation of the scientific method, all of which must be projected against a background of proper professional ethics.

This landscape is vast, but each component is important and is inextricably tied to the others. No component can be ignored, and no component may be properly considered in isolation. Quality assurance does not, and cannot rest on a single component. One cannot embrace one component of quality assurance and disregard the others. The successful completion of proficiency testing samples, for example, is not a guarantee of technical competency, nor is an unacceptable result on a proficiency sample a brand of technical incapability. Quality assurance is, and must be, a dynamic endeavor; it is both all-encompassing and never-ending.

Quality assurance, as countenanced by GD Air Testing Inc., will address the major areas enunciated in this document. The initial step in the implementation of quality assurance procedures will be the compilation of quality assurance procedures in the form of a quality assurance plan, of which this is a part.

This quality assurance plan is, for all intent and purpose, a public document. It is open to inspection by any interested party, just as the basis for any opinion must be open to inspection. The quality assurance document will be reviewed as often as is appropriate – but no less than annually. Previous versions of documents will be retired, but not destroyed. Any analyst may propose amendments of the quality assurance document at any time, and in fact - a duty to do so is incumbent upon them when there is a perceived

need. Upon receipt of a proposed amendment to the quality assurance document, an attempt will be made by management to develop a consensus among all staff. If a consensus cannot be reached, the Laboratory Director will resolve the issue, with all analysts being notified as to the decision.

It is expected that this document will, with periodic amendments, serve as a durable quality assurance document for GD Air Testing, Inc. Amended versions will exist years in the future, at a time when the laboratory staff will be greatly expanded. For the benefit of trainees and relatively inexperienced analysts, this document will of necessity be complex and detailed in order to communicate not only the essence of certain issues, but also the logical and historical underpinnings of these issues.

3.6 Objectives of the Quality Assurance Program - It should be recognized that absolute infallibility in analytical chemistry is not humanly possible; an effective quality assurance program can, however, provide a mechanism whereby technical correctness may be achieved and maintained. The objective of the quality assurance program is to reduce measurement errors in analytical determinations to a level below established limits. It is the goal of this program to preserve the integrity of samples, to ensure the precision and accuracy of results obtained in the examination of samples, and to provide clear documentation of results, supporting data and conclusions related to those samples.

The quality assurance program encompasses all facets of the analytical process from “chain of custody” to final analytical report review and court testimony. The program also includes issues such as the clarity of client reports, the handling and issuance of final results and reporting guidelines. The quality assurance procedures for chain of custody issues and the security of evidence storage are documented herein.

Three main goals of quality assurance activities are to:

- Reinforce effective policies and procedures
- Monitor the development of staff and technical procedures
- Identify and correct problems or deficiencies in the work product

The approaches employed to ensure and maintain a quality product are as follows:

- Hire qualified staff (minimum of a 4-year, science degree)
- Promote qualified staff
- Dismiss unacceptable staff
- Implement, in a timely fashion, actions to correct any deficiencies that may arise
- Develop employees through personnel evaluations
- Formulate policies and procedures
- Use training protocols

- Emphasize the necessity of staying informed thorough literature, meetings, seminars and continuing education
- Maintain secure facilities
- Maintain proper sample, document, and evidence handling procedures
- Sufficiently document all project and case related activities
- Use reliable technical procedures
- Use properly maintained and calibrated equipment
- Adhere to a professional code of ethics

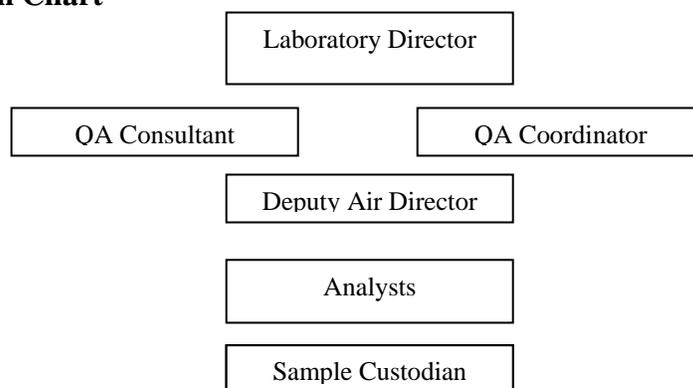
3.7 Quality Assurance Manual Review - The review and amendment of this manual is the responsibility of the laboratory Director and must be accomplished, minimally, on an annual basis. It is also the Director's responsibility to ensure that each current and new employee reads and understands the requirements set forth in this document. Further, the Director, along with the Quality Assurance Coordinator will periodically review this manual for accuracy, completeness, and applicability. This review will be completed, at a minimum, of once per year.

3.8 Employee Responsibility - It is the intent of this laboratory to provide only the highest quality and most reputable analytical results. Therefore, the plans, requirements and instructions set forth in this document require mandatory and strict adherence by all employees. This manual must be read and followed by each employee. Employee participation in this program is encouraged through review of deficiencies and impracticalities. Suggestions for improvements should be made to the Management team. Proposed deviations from this manual must be justified and brought to the attention of the Director and/or relevant supervisors. Deviations may at times be required, and in fact may be in accordance with good professional practice. Expediency, in the absence of compelling professional reasons, will not represent sufficient justification.

Section 4.0 Organization and Responsibility

GD Air Testing, Inc. (GDAT) is an independent environmental laboratory specializing in the field of air toxic and gas composition analyses. Incorporated in April of 1998, GDAT currently operates from a state of the art facility located in the prestigious "Technology Corridor" of North Dallas. The company is dedicated to providing its customers, including industry, consulting engineers, and government, with high quality analytical data and superior customer service.

4.1 Organization Chart



A list of all approved signatories for GDAT can be found in the personnel file.

4.2 Technical Qualifications

Though relatively recent in its beginnings, GDAT has only experienced and qualified chemists in all technical and analytical roles. Each staff member possesses a Bachelor's of Science degree, or higher, and no less than five years experience in an analytical laboratory. The company's founder, Dr. George Dai, Ph.D., has more than 20 years experience as an air testing chemist. His expertise is unsurpassed in the industry and he is recognized world wide as a leader in the field of air quality analysis.

GDAT is an operation capable of handling a variety of air and gas samples using EPA, ASTM, NIOSH, and other methodologies. The full EPA TO compendium series such as TO-1, TO-2, TO-14, TO-15, the IP/IA series, and ASTM methodologies such as ASTM 1945, 1946, BTU method, etc., are mainstays of GDAT product line.

4.3 Job Descriptions and Responsibilities

4.3.1 Laboratory Director

The responsibility for the quality of laboratory services resides with the Laboratory Director. The Director is the final authority as to the acceptance of analytical data and approval of analytical results. The Laboratory Director Coordinates and supervises all technical activities of the laboratory and is responsible for the development and implementation of the Quality Assurance Plan for the laboratory. Further, the Director schedules work flow through the laboratory based on factors such as turn-around-time required and difficulty of work. The Director is responsible for working with clients' requests and overseeing the laboratory's daily operations.

4.3.2 Deputy Air Director

The Deputy Air Director coordinates and supervises the technical activities of the department, and is the primary reviewer of analytical results. Approval at this stage indicates that all requirements of the clients' Quality Assurance Project Plan and the GDAT Quality Assurance Program are fulfilled using methodology and quality control that complies with federal, state, and/or local regulations for certified laboratory analyses. In addition to technical responsibilities, the Deputy Air Director schedules work flow through the department based on factors such as turn-around time required and difficulty of work. The Deputy Air Director also is responsible for working with clients' work request and overseeing the labs operations whenever the laboratory director is not available.

4.3.3 Quality Assurance Consultant

The Quality Assurance (QA) Consultant is an outside agent that assists the Laboratory Director, as needed, by providing expertise in the development of quality control procedures and coordinating the revision of various quality program components. The QA Consultant provides advice and direction in initiating and monitoring quality control procedures and revising both the program and procedures when necessary to meet and exceed the industry standard of quality assurance. The QA Consultant also provides assistance in conducting data and system audits on an annual basis, reporting findings to the Laboratory Director.

4.3.4 Quality Assurance Coordinators

The Quality Assurance Coordinators assist the Laboratory Director in the implementation of the overall QA program by ensuring that the QAP is in place and being observed on a day-to-day basis. The QA Coordinators serve as the focal point for QA/QC and are responsible for the oversight and/or review of QC data. The QA Coordinators shall be independent from the laboratory operations over which they are responsible. All data evaluation performed by the QA Coordinators shall be performed objectively and may not be unduly influenced by management. The QA Coordinators shall have relevant experience in QA/QC procedures and shall be knowledgeable in quality systems as defined under NELAC. The QA Coordinators serve as the repository for the SOPs and other laboratory documentation including the QAP and controls the distribution of these documents. The QA Coordinators also conduct internal audits, facilitates analysis and

reporting of Performance Evaluation Samples, Determines that analysts are properly trained, makes recommendations for improvement where necessary, and assist in tracking and defining appropriate corrective actions. The QA Coordinators shall also ensure that the QAP is compliant with NELAC Standards.

4.3.4 Analysts

Analysts are responsible for performing analyses using current Standard Operating Procedures (SOP) and generating results that are technically sound and legally defensible. In addition to the required analysis of quality control samples, one of the most important aspects of data defensibility is maintaining records of every sample analyzed that entail enough information that another competent chemist can independently generate the same results from the raw data at any given time in the future.

4.3.5 Sample Custodian

Upon sample receipt, sample control personnel verify the integrity of the samples, the proper chain-of-custody (COC), and that correct containers and preservatives are used. Sample control personnel continuously monitor the temperature of all storage refrigerators and freezers and track the location of samples at all times.

4.4 Laboratory Space and Design

The GD Air Testing, Inc. facility currently consists of one principal analytical laboratory section dedicated to a variety of air toxics analyses. The facility also has administrative and storage space. The laboratory space in each section is sufficient for the proper analysis of samples. The storage space consists of two dedicated areas in which chemical storage cabinets and storage areas for laboratory documentation and administrative supplies are kept.

Each laboratory room is equipped with adequate space to perform assigned tasks. Each laboratory room includes cabinetry for the storage of supplies, instrumentation accessories, equipment and tools. Each laboratory has sufficient counter space for the operation of instrumentation and the documentation of findings. In addition, each analyst has a separate desk space for performing administrative duties. File cabinets and bookshelves are provided to store records, reference texts and other documents.

The physical design of the laboratory provides for the efficient flow of samples and data from the time of its acceptance until its return to the client. The facility is equipped with adequate lighting for personnel to carry out assigned tasks. The laboratory is equipped with the adequate plumbing and wiring needed to carry out assigned tasks. The laboratory is also equipped with proper ventilation for the handling and examination of volatile organics in air samples. The laboratory is equipped with proper heating, cooling and humidity controls to provide the conditions necessary for laboratory analyses.

Prior to accepting new work types and projects of a significant nature that would pose potential strains, the Laboratory Director will make a determination as to the appropriateness of the facilities and capabilities of the lab. Work types that are inconsistent with capability will be turned down. Where method development or additional resources are necessary, the customer will be informed and agreements reached prior to initiation of the project.

4.5 Client Contact Issues

A client, or customer, is defined in this document as any individual or company that is authorized to submit samples for analysis. GDAT recognizes that customers have the right to choose their service providers and to specify the conditions and quality assurance objectives by which their samples will be analyzed and assessed.

4.6 Laboratory Security

Strict policies for security have been implemented and will be maintained. The fundamental doctrine is that no individual will be permitted into the laboratory area where samples are being examined unless a member of the GDAT staff is present and is in a position to ensure that samples and/or data will not be lost, altered, or corrupted.

4.7 Communication within the Laboratory

Channels of communication within the laboratory should exist for coordination of project related work, and to ensure dissemination of technical information. All communications, both internal and external, should be clear, concise and simply stated. Tact and diplomacy are a must in GDAT communications. The Director should ensure that communications exists between all levels (vertical, horizontal and diagonal) of the laboratory. This will be partly accomplished through regular staff meetings, and dissemination of information via e-mail and Lab bulletin boards.

4.8 Project Management

Sample submissions may require analysis by more than one discipline. In these cases the responsibilities of the designated project manager to 1) distribute samples to other sections of the Lab, 2) collate all reports after analysis, and 3) function as the main contact with the client.

4.9 Turn-around-Time

Turnaround time begins when samples are received in the Lab and logged into the laboratory computer data base. The GDAT staff are obligated to meet the needs of the client by meeting, insofar as possible, requested turnaround times. In no instance, however, will the quality of the work performed be compromised to meet a specified turnaround time.

Preliminary reports and “verbal” communications are permitted with appropriate “qualifiers” on data. It must be understood by analysts and customers that data of this type is considered “indicative” and inherently “screening” in nature.

4.10 Information Management

The Laboratory Director will utilize statistical reports to provide a sound basis for accurately making decisions about laboratory workload, lab productivity, management and planning.

4.11 Procurement and Subcontracting

The laboratory shall ensure that purchased products and services conform to specifications. Subcontractors and service providers must be pre-approved, with designated “back up” suppliers. Evaluations are to be provided to management and subcontractors regarding performance, along with recommendation for further utilization. Mechanisms for real-time assessment of product and services are detailed below:

4.11.1 Assessment of Subcontractors

- A. Laboratories: Approved vendors are listed in a designated notebook in the sample receiving area. Subcontract laboratories referenced must have an approved Quality Assurance Plan on file. All newly identified subcontractors must be audited in support of the procurement plan and must meet the customer specified certification requirements, must maintain appropriate sample integrity and chain-of-custody, and must achieve all data quality objectives. Clients will be informed of subcontract lab use if a subcontract lab is required. If available, all subcontract work will be NELAC accredited.

Subcontractor Audit will include , at a minimum: good lab practices, data, and systems audit for subcontracted analytes of concern. Existing laboratories, with established and demonstrated capabilities may have the audit requirement waived during the implementation phase of this plan.

Ongoing assessment of supplied data packages apply at all times.

GDAT will provide notification to customers and seek their input prior to subcontracting any samples.

- B. Laboratory Supplies:

Approved vendor lists are maintained within the purchasing department. All purchases are to be made from suppliers on this list. Newly identified subcontractors must be approved by the Laboratory Director prior to purchases.

4.11.2 Purchase Orders

Generally, purchases can be made without the use of "Purchase Order Forms." When necessary, based on vendor requirements or complex purchases which need significant detail, a GDAT PO Form will be completed in accordance with supplier requirements. At a minimum, all purchases will reference the following specifications to ensure that appropriate items are purchased:

- A. Positive identification of the item, i.e. Test Name with target analyte lists, part numbers, etc.
- B. Catalog Number with page references where applicable
- C. Description
- D. Quantity
- E. Price
- F. Other specifics as applicable (i.e. type, style, grade, etc.)

4.11.3 Receipt of Materials

Upon receipt of materials, verification is conducted whereby packing lists, shipped contents, and purchase orders are compared. Incomplete, substandard, or damaged items are rejected, and the vendor is to replace with a viable/specified item. Costs for replacement of non-conforming items remains with the vendor

4.11.4 Delivery

Deliveries are to designated areas only. Deliveries for goods are to be made at the front desk during normal business hours unless other arrangements are made.

4.11.5 Storage

On-site storage of goods and materials is to be in designated areas, under appropriate environmental and security levels.

4.11.6 Corrective Actions

Causes for nonconforming products and services must be identified and corrective action implemented to prevent recurrence in accordance with Section 11 of the manual.

Section 5.0 Analyst Training

5.1 Introduction - It is the intent of the GD Air Testing, Inc., to ensure that all analysts are properly trained, acquire an adequate amount of experience prior to performing project related analyses and maintain technical competence. These factors are essential parts of the laboratory's quality assurance program

At GDAT, each analyst is required to demonstrate competency for all the procedures for which he/she is assigned responsibility. Accordingly, each analyst must first demonstrate proficiency with quality assurance both in general and how it relates to the specific method.

5.2 Formal training can be provided through public or private educational institutions, public or private-sector training groups and professional organizations. At GDAT, analysts are expected to possess a degree in chemistry, biology, environmental science or a related field. Employees will provide copies of degrees/certifications, resumes, and references. All of which will be verified by the Director or his designee prior to beginning in-house training and certification.

5.3 In-House Training Requirements - In-house training is provided by the GDAT Director or other assigned, experienced Analysts. Each analyst is required to demonstrate a thorough understanding of their assigned areas of responsibility, and these requirements must be satisfied for each method to be performed. Each analyst must demonstrate data integrity as well as proficiency with quality assurance both in general and how it relates to specific methods.

Prior to performing independent analyses, each analyst will undergo training that ensures familiarity with applicable Standard Operating Procedures, Data Acquisition software, Equipment Operation, Calculations, Data Reduction Procedures, Data Integrity, and Quality Assurance/Quality Control. Each Step of the process for each method the analyst performs will be documented in an "Employee Training Sheet." Additionally the employee must participated in a testing period which includes completion of Method Detection Limit Studies, Method Validation Samples, Proficiency Evaluation Samples, and Quality Control Indicators. Finally, an audit and SOP exam of the employee's techniques and understanding of assigned responsibility will be conducted. Upon successful completion of each of these components, the supervising employee (where applicable) and the Director will certify the competency of the analyst.

The Director or his designee shall perform periodic, in-depth monitoring of various issues such as data integrity, manual calculations, and overall systems competency to determine if additional training and testing is necessary. The evaluation and determination of the length of additional testing must be accomplished on an ongoing basis.

5.4 Manual Calculations and Manual Integrations - GDAT employs several types of software programs that have various levels of capabilities in the areas of data calculation and peak integration. For this reason, GDAT analysts need to be familiar not only with the methods for each analysis, but also the software associated with each instrument acquiring the relevant data. As mentioned in Section 5.3, each analyst will be trained in data acquisition software as well as calculations.

5.4.1 Manual Calculations - Some of the largest deficiencies that can occur with manual calculations are transcription errors. For this reason, analysts will be required to show all raw numbers and final results used for manual calculations on the relevant data sheets and chromatograms. The analyst will also initial and date each of these data sheets and chromatograms. Finally, the manual calculations will be reviewed by the QA Coordinator and checked for completeness and accuracy. The QA Coordinator will also initial and date the data sheets/chromatograms to confirm the review has been completed.

5.4.2 Manual Integrations - In most cases, automatic software integration of chromatographic peaks is fast, consistent, and accurate. However, it is the responsibility of the analyst to ensure that all peaks are integrated properly. In those cases where the software fails to perform adequate peak integration, the analyst is required to step in and perform a manual integration. Appropriate manual integration is integration that can be technically justified. Integration below the baseline is never appropriate. Inappropriate and inconsistent peak integration to meet quality requirements is never allowed, nor is to be used as a substitute for corrective action on any aspect of the chromatographic system. Inappropriate peak integration used to meet quality control criteria is possible grounds for dismissal.

The most important aspect to manual integration is determining where the baseline stops and where the peak begins. Software problems that occur with peak integration can be most often seen during MDL studies. As part of the initial training program mentioned in Section 5.3, each analyst will undergo training that ensures familiarity with the processes of the chromatographic systems. Relevant to manual integrations, the analyst will be required to perform an MDL study. This MDL study will be checked by GDAT management for manual integration issues. Approval of this portion of the Employee Training Sheet will include a check of manual integration skills. Once employee training is complete, the QA Coordinator will occasionally spot check the analyst's work for proper manual integrations.

5.5 Trained and Experienced New Hires - New employees who have been hired with prior experience must undergo a period of evaluation before being incorporated into the routine analysis of samples. This evaluation process includes sample handling procedures, and the analysis of proficiency samples under the supervision of the director or his designee. The same process referenced in section 5.3, above, including the "Employee Training Sheet" will be required documentation for all employees.

5.6 Maintenance of Technical Competence - Employees are encouraged to maintain their technical competency by attending training courses and conferences and participating in professional organizations. The expected frequency of attendance at professional meetings will not be dictated by GDAT, but consistent abstinence from meetings of professional organizations is antipathetic to good professional practice. Presentation of research findings at meetings or professional organizations is encouraged, as is committee work and serving as an officer for scientific, environmental, and analytical oriented organizations.

5.7 Literature Awareness - Every GDAT analyst, whether working in a specialty area or not, will be expected to review applicable technical journals as supplied by GDAT. Further, each analyst will be expected to exert an effort to keep reasonably abreast of current developments within his/ her area of responsibility. This requirement may be satisfied in part by being familiar with the environmental science literature, and with the literature of other disciplines as appropriate.

GD AIR TESTING EMPLOYEE TRAINING SHEET

This document certifies that the employee named below is capable of performing the following tasks with little or no supervision.

EMPLOYEE NAME: _____

QAP Read and Understood: _____
 Employee Signature

Instructions for the use of this form: This form should be completed each time the analyst performs a new procedure. The date and/or reference for each item should be entered as appropriate indicating that the requirement has been successfully met.

Analytical Test	Date Initiated	Read SOP	MDL (1)	MVS (2)	PE (3)	QCIs (4)	Audit (5)	Instr. Oper.	SOP Exam	Date Comp	Init QAC	Init Supv	Cert by

Key

- (1) MDL = Method Detection Limit Study performed according to QAP and Detection Limit SOP
- (2) MVS = Method Validation Study performed. Refer to method specific SOP For Details
- (3) PE = Proficiency Evaluation samples administered according to method specific SOP. Must Pass acceptance criteria.
- (4) QCI = Quality Control Indicators. Verify that the analyst understands definition, purpose, and control limits for the procedure.
- (5) Audit = Verify that the analyst is following appropriate SOP and Good Laboratory Practices

6.0 Analytical Equipment and Maintenance

GDAT uses state-of-art instrumentation in order to provide analytical data of the highest quality. AN equipment list is included on the following pages. Preventative maintenance programs and/or service contracts are in place for all major equipment. Personnel are trained to perform many routine and non-routine maintenance procedures and of which is documented in maintenance logbooks.

Table 6-1: Equipment Inventory at GDAT

<u>Instrument</u>	Quantity	Model	Manufacturer
GC/MS	1	6890/5973	Hewlett-Packard
GC/MS	1	3900/2100T	Varian
GC/FID/TCD	1	5890 Series II	Hewlett-Packard
GC/TCD	1	5890 Series II	Hewlett-Packard
GC/FID	1	3400	Varian
Drying Oven	1	Isotemp 500	Fisher Scientific
Sample Concentrator	2	8900DS	NuTech
Analytical Balance	1	300 XE	Denver Instrument Co.
Mold Pump	1	1531-107B-G-557	Gast Co.
Air Pump	1	224-PCXR-3	SKC
Air Pump	1	222-3	SKC
Refrigerator	1	TDX11	GE
Dessicator	1		Dry Keeper
Weights	1 Set	15887	Troemner
Water Bath	1	280	Precision

Section 7.0 TEST METHODS AND PROCEDURES

7.1 Procedures Discussion: The following test methods and procedures are employed by GD Air Testing, Inc. Standard Operating Procedures of the referenced Version Number and Promulgation Date are available to each analyst within the laboratory. The referenced procedures have been used in developing protocol for analytical sequences. However, modifications may have been implemented in accordance with forethought and sound professional judgment of staff. Analyses are to be conducted in strict accordance with the most current version of methods, as listed below:

7.2 Table of Procedures

Procedure	Reference Method	Promulgation Date	Version Number
Fixed Gases, Methane, and Light Hydrocarbons in Ambient Air or Other Gas Phase	ASTM 1945/1946	4/1/2002	GD-ASTM1945-1946-2
Dissolved Gases in Water and Ground Water by Headspace	RSK-175/EPA3810	4/1/2002	GD-EPA3810-2
Volatile Organic Compounds in Air and Gas Phase	EPA TO-14/EPA TO-15	1/23/2003	GD-TO15-3
Sampling for Hydrogen Sulfide in Air (Source not under Pressure)		5/9/2000	GD-H2S-1
Emission Potential of Individual Volatile Organic Compounds in Waste	EPA 25D/305	1/23/2003	GD-305-2
Integrated Sampling with Canisters	Summa	1/23/2003	GD-CAN-2
Method 25D	EPA 25D	1/23/2003	GD-25D-2
Air Pump Instructions	Pump Model 224-30		
Volatile Organic Compounds in Air and Gas Phase by EPA TO-14	EPA TO-14	4/1/2002	GD-TO-14-4
Grab Sampling with Canisters	Summa	1/23/2003	GD-CAN-2
Grab Sampling with Bags		1/23/2003	GD-CAN-2
Volatile Organic Compounds (VOCs) from Incinerator exhaust by EPA 5040	EPA 5040	1/23/2003	GD-5040-2
Determination of Dissolved Gases in Water and Ground Water by Headspace RSK-175/EPA 3810/25E	RSK 175 EPA 3810 EPA 25E	1/23/2003	GD-EPA25E-2
Determination of Volatile Organic Compounds (VOCs) in Ambient Air by EPA TO1&2	EPA TO-1 EPA TO-2	1/23/2003	GD-TO1&2-2

Section 8.0 - ROUTINE QUALITY ASSURANCE OBJECTIVES

8.1 Precision

Precision is the measure of dispersion among results obtained for a given parameter. In contrast to bias, which indicates systematic deviation (error), precision indicates random variation inherent in the analytical process. When three or more values are measured, precision is calculated as Percent Relative Standard Deviation (%RSD).

$$\%RSD = \frac{S \times 100}{\bar{X}}$$

Where S is the standard deviation:

$$S = \sqrt{\frac{\sum (X - \bar{X})^2}{n-1}}$$

When only two values are measured, precision is calculated as Relative Percent Difference (RPD).

$$RPD = \frac{(X1 - X2)}{(X1 + X2)/2} \times 100$$

8.2 Accuracy

Accuracy is the measure of agreement between the experimental (reported) value and the true value. The following practices are used to assess accuracy in the laboratory.

- a. Blank Spike and Blank Spike Duplicate (BS/BSD): GDAT reports the BS/BSD as a component of the routine QA/QC summary package. These laboratory control samples include partial or full component mixtures of target compounds spiked into "blank" matched matrices that will undergo the same preparatory and analysis procedures as the "unknown" samples. Control limit and acceptance criteria for performance are based on applicable methodology requirements. The BS/BSD standard is generally from a secondary from a second source. In cases where a secondary source is not readily available, a separately prepared solution of the daily standard will be utilized to demonstrate precision and accuracy.
- b. Surrogate Spike: For all the internal standard calculation methods, GDAT will spike with appropriate surrogate standards as an analysis efficiency check. Surrogate recovery results are reported for each sample and QC sample in all data packages.

8.3 Completeness

Completeness is the amount of valid data obtained from analytical measurement. The QA objective for this study is to obtain acceptable data for at least 90 percent of the samples received. Completeness also implies the ability of the final report to answer the customer's questions. GDAT scientists are available to interpret analytical reports and to consult with the customer to recommend future course of action. Completeness is defined as:

$$C = 100 * (V/T)$$

Where C = Percent Completeness

V = Number of measurements judged valid

T = Total number of measurements

8.4 Control Charts

Control charts are used to assess QC efforts over a period of time. The laboratory will run four sets of control charts (one for precision, one for accuracy, one for external or internal standard recoveries, and one for blanks) for each method performed in the laboratory. Separate charts shall be maintained for each matrix.

Each control chart shall consist of a center line, two warning limits and two control limits. The control chart parameters should be calculated according to the formulae provided below.

A minimum of 20 points per chart shall be obtained prior to the initial attempt to establish the control chart parameters. Until 20 points are attained and limits calculated, the recommended recoveries for the specified method will be used.

Control Chart Formulae and Definitions:

Definitions:

Precision Audits, X = RPD for each individual compound

Accuracy Audits, X = % Recovery for each individual compound

External Standard Audit, X = % Recovery for each individual compound

Blank Audit, X = the blank result

Formulae:

$X_1, X_2, X_3, X_4 \dots X_n$ ($n \geq 20$) represents the first n time ordered determinations

$$\bar{X} = \text{Average} = \frac{X_1 + X_2 + X_3 + X_4 + \dots + X_n}{n}$$

$$\text{Standard Deviation (SD) of } \bar{X} = \frac{X_1^2 + X_2^2 + X_3^2 + X_4^2 + \dots + X_n^2}{n-1}$$

Control Chart Parameter Estimation

<u>Parameter</u>	<u>Symbol</u>	<u>Formula</u>
Center line	CL	X
Upper Control Limit	UCL	X + 3SD
Lower Control Limit	LCL	X - 3SD
Upper Warning Limit	UWL	X + 2SD
Lower Warning Limit	LWL	X - 2SD

8.5 Instrument and Equipment Calibration

All Instrumentation and equipment have specific performance and calibration criteria that must be met with each batch of sample analyzed, at least on a daily basis. Primary calibration materials include Certified weights, certified thermometers, and certified analytical standards. This section describes standard calibration procedures, sources, and traceability of standards used. Frequency of calibration is prescribed in the reference methods listed in Table 8.5.

Calibration standards are supplied by Scott Specialty Gases, Restek, and Supelco, Inc. (which operates as NIST traceability program for these standards)

All calibrations are verified by running a laboratory control sample to verify the efficacy of the calibration standards used.

Table 8.5

Analysis Type	Calibration Procedure
Volatiles by GCMS	Five point calibration curve on file. CCC: % RSD <30 % for 80% of target compounds. SPCC: mean RF > 0.05
Volatiles by GC	Five point calibration curve on file for continuing calibration check compounds (CCC), the Percent Relative Standard Deviation, (%RSD) must be <30% for 90% of target compounds. One point daily calibration: For CCC, the Percent Difference (%Diff) between the daily response factor (RF) and the mean RF must be < 30% for 90% of target compounds

8.6 Reagents & Calibration Standards

In addition to the certified primary standards or titrants, a second standard from another source is analyzed in order to confirm the primary source. Tolerances are normally specified by the method, but more stringent criteria may be applied at the discretion of the analyst depending on the application. Every standard is labeled with pertinent information that includes manufacturer/vendor, date of receipt, preparation date, initials of the person that prepared the standard (where applicable), and an expiration date - beyond which the standard must be discarded regardless of whether it passes criteria. Manufacturer's certificate of analysis will be maintained on file, and the standard will be stored under all recommended conditions.

8.7 Method Detection Limits

Method Detection Limits (MDL) studies are conducted for all methods performed in the laboratory. The MDL is performed using the standard replicate study at five to 10 times the signal detection limit. The MDL study is performed annually for each analyst/instrument/matrix configuration.

8.8 Interferences and Monitoring

Because even a minor stray signal can be extrapolated into a significant concentration by the laboratory, which can then be extrapolated into a large population by the end user, extensive precautions are taken to minimize sources of interferences in the laboratory. Specifically, samples may be retested to confirm the original values. Also, replicate tests may be performed on other instruments and detectors as applicable. For example, methane may be found on an FID as well as a TCD. In these cases, the sample may be run on both instruments to confirm concentration. Correlation of results for different characteristics of a sample may also be used. An example of this is Total Petroleum Hydrocarbons. The total value for TPH must be greater than the sum of all individually reported results.

8.9 Background Signal

When detection limits are reported that are close to background levels, the risk of false positives increases. GDAT had established Practical Quantitation Limits (PQLs) for all analytes and includes them on analytical reports. PQLs are determined in order to assure that false positives are not reported.

8.10 Preventive Maintenance

Preventive Maintenance procedures such as lubrication, source cleaning, detector cleaning, and the frequency of such maintenance are performed according to the procedures delineated in the manufacturer's instrument. Chromatographic carrier gas purification traps, injector liners, and injector septa are cleaned or replaced on a regular basis. Precision and accuracy data are examined for trends and excursions beyond control limits to determine evidence of instrument malfunction. Maintenance must be

performed when the instrument begins to degrade as evidenced by the degradation of peak resolution, shift in calibration curves, decreased sensitivity, or failure to meet one or another of the quality control criteria. For a schedule of common preventive maintenance tasks, see table 8.10, below. The frequency of preventive maintenance is also outlined in the instrument maintenance manuals.

Instrument logbooks containing usage, calibration, maintenance, and repair records are kept in the laboratories at all times. The laboratories also maintain adequate supplies of spare parts such as GC columns, syringes, septa, injection port liners, and electronic parts so that they are available when needed.

In the event of equipment malfunction that cannot be resolved within two working days, service shall be obtained for the instrument vendor or manufacturer, if such a service agreement exists or can be tendered. If on-site service in the laboratory is unavailable, arrangements shall be expedited to have the instrument shipped to the manufacturer for repair.

Backlogs of samples queued for analysis are reviewed on a daily basis, and in the event that instrument “down-time” appears to negatively impact turn-around-time obligations or other data quality objectives such as “holding times,” the customer will be contacted and arrangements made to sub-contracted in accordance with the customer’s wishes.

Table 8.10 A. Maintenance Procedures and Schedule for Major Instrumentation

Instrument	Maintenance Procedure	Spare Parts
Gas Chromatograph/ Mass Spectrometer (GC/MS)	1. Replace pump oils as needed, or every six months 2. Change septa as needed 3. Change gas line dryers as needed 4. Clean source as needed 5. Replace electron multiplier as needed	1. Syringes 2. Septa 3. Various electronic components 4. Plumbing supplies, tubing, fittings, etc.
Gas Chromatograph	1. Change septa as needed 2. Change gas line dryers as needed. 3. Leak check when installing new analytical columns 4. Check inlet system for residue buildup, periodically	1. Syringes 2. Septa 3. Various electronic components 4. Plumbing supplies, tubing, fittings, etc.
Sample Concentrator	1. Replace trap as needed 2. Decontaminate system as required 3. Leak check system 4. Transfer lines – replace as needed	1. Spare traps 2. Various electronic components 3. Plumbing supplies, tubing, fittings, etc.

8.11 Electronic data Processing and Computer Access

Computers used in the acquisition and processing of data are to be maintained within the laboratory setting in a manner that insures the integrity and security of data. Within GDAT, the network upon which data is stored is secure – with no external access to records. All system “users” are assigned unique access codes that are password protected. In the event of employee termination, assigned access codes will be immediately deleted.

Data acquisition software employed by GDAT has been validated through Method Detection Limit (MDL) studies and Initial Demonstration of Capability (IDC) processes, wherein proper identification and integration of target analytes are verified. In the event of the purchase of new software packages, validation will be in accordance with manufacturer’s recommendations.

All data are “backed up” onto a second hard disk on a monthly basis.

Section 9.0 Documentation Control

9.1 Introduction - This section serves to outline procedures to be followed to maintain control over the flow of documents containing chains of custody and analytical data. This section details proper record keeping guidelines, document review guidelines and document storage guidelines. The goal of the laboratory document control program is to ensure that all documents for a specified group of delivered samples will be accounted for when the project is complete. This includes, but is not limited to logbooks, chain of custody records, sample work sheets, bench sheets, and other documents relating to the evidence. The following document control procedures have been established to assure that all laboratory records are created and maintained for proper accountability.

All documentation in logbooks and other documents shall be in ink. If an error is made in a logbook assigned to one individual, that person should cross a single line through the error and enter the correct information. Subsequent changes are dated and initialed. Corrections to other data records or logbooks are made by crossing a single line through the error, entering the correct information, and initialing and dating the correction. (No obliterations of records, and no “white out” is permitted.)

Before releasing analytical results, the laboratory assembles and cross checks the information on custody records, lab bench sheets, analyst and instrument logs, as well as other relevant data to ensure that the information pertaining to each particular sample is consistent throughout the record.

9.2 Sample Receipt and Chain-of-Custody. All samples submitted to the GDAT laboratory are required to include a formal chain-of-custody form. Requests for “legal chain-of-custody” will be evaluated on a case-by-case basis and can be accommodated under certain contractual conditions.

9.2.1 Clients responsibility: It is the responsibility of each client to provide and maintain proper chain of custody records for their samples prior to submission and to convey their requirements to the laboratory.

9.2.2 Laboratory responsibility: Once samples arrive at the laboratory, it is the responsibility of GDAT to ensure that proper chain of custody procedures are continued during each step of analysis and through disposal. The GDAT sample custodian, or designee, documents the condition of locked or sealed shipping boxes on the custody form. Sample label information is compared to custody forms and project plans, then logged in to the GD Air Testing, Inc., Sample Log Book and assigned a unique laboratory ID number that follows the sample through the entire analytical and reporting process including all raw data references. Typical log information includes the receipt date, by whom it was received, the customer name, sample type, and total sample volume. Additionally, any discrepancies associated with sample condition, labeling, or other information will be noted. (i.e. damaged containers, limited sample volume, missing samples, etc.) After the Sample Log Book has been used, client and sample information are also entered into a LIMS system.

9.2.3 Sample Storage: Samples will be stored in the designated locations, separate from standards, food, and other sources of contamination. Storage of samples will be consistent with all method prescribed requirements. Analysts will maintain samples in their possession or in view at all times when the samples are outside of the designated storage area. Any unique storage requirements requested by the Customer will be evaluated on a case-by-case basis. It is anticipated that most situations could be accommodated and such requirements will be documented in project specific Quality Assurance Project Plans (QAPPs).

When custody is transferred to an outside party, both the issuing and receiving parties will verify that the information in the sample label and custody forms is recorded properly and that chain-of-custody documentation is maintained.

9.2.4 Non-conforming samples. If discrepancies occur with samples, sample labels, shipping forms, or chain-of-custody forms, the samples and forms

will be segregated from normal sample processing, and the designated client contact will be notified immediately. Notes regarding the non-conformances, customer contact, and agreed upon resolution will be recorded on the chain-of-custody form. Once agreement is reached with

customer regarding the disposition of samples and analysis, samples will be returned to the normal storage and analysis sequences.

If no chain-of-custody form is received, one will be initiated by the sample receiving personnel. Samples will be flagged as “non-conforming” and segregated pending reconciliation with customer requests and specifications.

All issues involving non-conformances for samples and chain-of-custody will be documented and incorporated into the analytical report as a component of the case narrative.

Change requests must be made in writing.

9.2.5 Maintenance of Record - The original clients chain of custody form must be maintained in the original case file, and will be completed and returned to the customer as a part of the final analytical report. Copies of the chain of custody as well as the original shipping documentation, when appropriate, will be maintained with the GDAT file copy of the analytical report.

9.2.6 Required Documentation for the chain of custody form should indicate the following:

- Clients Company / Agency name
- Client Phone / Fax Information
- Project Name/Number
- Reporting/Billing Information
- Purchase Order Numbers
- Sampler's Name
- Sample ID (Item numbers/description)
- Relinquished date and time
- Person relinquishing the samples
- Received date and time
- Person receiving the samples
- Remarks

9.2.7 Sample Disposal - After samples have been tested, they are placed in a designated sample storage area. At an appropriate time, the samples are disposed of. The following chart gives a summary for each sample type:

TYPE	LOCATION	MINIMUM HOLD TIME	DISPOSAL METHOD
Canister	Can Cleaning Area	No Minimum	Can Clean System
Tedlar Bag	Bin	1 Month	Popped Outside
Water	Refrigerator	1 Month	Water in Sink, Glass in Trash
Other	Varies	No Minimum	Varies

9.3 Documentation Required

9.3.1 Documentation Requirements - All analytical data sheets must include the Project number, a title which identifies the analysis, evidence identification information, a space for the analysts initials, a space to document the date of the analysis, a detailed format for documenting analytical results and all pages must be numbered. When analytical results are being recorded in a separate Lab notebook, the case notes should refer to the other source of data.

9.3.2 Document Review Requirements - Analysts are responsible for the primary review of data generated through their analyses. Accordingly, reviews of processes that occur prior to actual analyses should be verified, such that all known non-conforming issues are addressed prior to actual analysis. Analysts are responsible for reviewing analytical paperwork to confirm that all documentation requirements are being met.

9.3.3 Maintenance and Storage Requirements -Analytical data sheets (raw data), analytical reports, laboratory notebooks, maintenance logs, all current and retired SOPs, the current and retired QAPs, and other documentation must be maintained for a standard period of ten (10) years. In some cases, customer specific Quality Assurance Project Plans and certain states or regulatory programs may require record retention beyond this policy. Accordingly, the project manager will “flag” these case files with a destruct date appropriate to the specific project.

In order to remove a document from storage, an access log is required. The log will contain the date, the initials of the person removing the document, the document in question, and the date of the document replacement.

In the event that a change of ownership occurs or GD Air Testing, Inc. goes out of business, the data records will be maintained or transferred according to each client's wishes, and all state/federal requirements will be adhered to.

9.4 Instrumentation and Calibration Log Books - Instruments used during analysis of customer samples must have a maintenance log book. These records will document usage, calibration, maintenance, and repair records. These records are to be kept in the laboratory, near the instrument, and available to analysts at all times. Records retention are these log books are subject to the same requirements referenced in 9.3.3, above.

The log book must indicate the instrument name, manufacture, model number, and GDAT identification number. The log book must also include calibration and maintenance schedules, calibration and maintenance instructions, and service contract information where applicable.

9.5 Laboratory Analytical Records

9.5.1 Each record keeping page must be pre-printed, numbered and include a title which identifies the activity recorded. Records of calibration and maintenance activities must include the initials of the individual performing the activity, the date of the activity, a description of the activity and/or a detailed format for documenting calibration data. All entries must be in chronological order.

9.5.2 Sample Reference Requirements - Some calibration activities may need to be traceable to specific sample sets. Log pages must include a space to record information which references the sample set.

9.5.3 Document Review Requirements - It is the responsibility of the Analyst and the Quality Assurance Coordinator to periodically review all log books to ensure that proper documentation procedures are being maintained.

9.5.4 Log Book Maintenance and Storage - Active instrument and calibration log books must be maintained with the instrument at all times. Retired log books must be maintained in the designated records retention area.

9.6 Quality Control Data Sheets/Log Books - All quality control activities are documented on QC data sheets.

9.6.1 Documentation Requirements - QC data sheets must include a title which identifies the QC activity, sequential page numbering, a space for the initials of the individual performing the activity, a space for the date on which the activity is performed, spaces to record sample identification information and a detailed format for documenting QC data. All entries must be in chronological order.

9.6.2 Document Review Requirements - QC data which fall outside its acceptable range must be corrected immediately. It is the responsibility of the analyst to recognize when corrective action is necessary and the responsibility of the Director and the Quality Assurance Coordinator to periodically review QC documents to ensure that the quality of all analyses is acceptable.

9.6.3 Maintenance and Storage - QC data sheets/records in use must be maintained at the appropriate work area. Retired QC data sheets/records must be maintained in the designated and secured records retention area. No unauthorized access to the storage area is permitted.

9.7 Maintenance of Laboratory Notes - Laboratory notes may be generated by staff members during analytical procedures. Upon analytical completion, all laboratory notes must be filed in the corresponding project files. These notes will be created in the event that a deviation from protocols, an inconsistency in analysis, or an unusual occurrence is noticed during analysis. Laboratory notes will be sufficiently detailed so the reviewer will know the basis for any conclusions, the methods employed, and any test results. Other documents produced during the processing of customer samples, including memos, fax, e-mail transmissions and miscellaneous client information, which relate to project specific detail, will be filed with the associated project file.

Section 10.0 - DATA REDUCTION, VALIDATION, AND REPORTING

10.1 Data Reduction

Analytical Results will be reduced to appropriate concentration units using appropriate methods given in the analytical procedure and standard operating procedures. All calculations will be checked independently by peer or senior laboratory staff.

10.2 Data Validation

Data Validation is the process of examining data and accepting or rejecting it based on pre-defined criteria. GDAT management and supervisory personnel use the following criteria to validate laboratory data:

- Analytical sequence is consistent with customer request (correct target analyte lists)
- Use of approved analytical procedure
- Use of appropriate standards
- Use of properly operating and calibrated instruments, and
- Precision and accuracy comparable to that achieved in similar analytical programs

Records of all data will be maintained. Persons validating the data will have sufficient knowledge of the technical work to identify questionable values.

10.3 Data Reporting

Analytical results will be reported on formats acceptable to the customer. These reports will be assembled by the project manager and delivered to the customer within the timeframe specified by the customer and agreed to by the laboratory.

Additional data required by the customer, such as operating conditions, raw QA/QC data, method blanks, method detection limit studies, recommendations or problems, will be reported by the project manager.

10.3.1 Data Review: The following details the data review and reporting procedures for all methods analyzed in the laboratory:

- a) Upon sample receipt and after custody transfer has been documented and a laboratory I.D. has been assigned, the analyst or member of the management staff enters the project information into a data transfer system (NEXU). The NEXU is only programmed for data transfer from the HP GC/MS. Data from the SRI 8610 and Varian GC 3400 is manually calculated and entered using Excel program.
- b) The analyst or management reviews the COC for special instructions and contacts the client if clarification is needed.
- c) The analysts verifies that all of the proper QA/QC requirements have been fulfilled and that QC data is within acceptance limits, or otherwise takes the necessary corrective action.

10.3.2 Analyst Review and Group Leader Approval

The analyst is responsible for verifying the following:

- a) Raw data is present and makes sense.
- b) Data represents the requirements as stated on the COC.
- c) All proper QA/QC has been included and is within acceptance limits.
 - 1) Holding times has been met.
 - 2) Proper custody requirements have been met.
 - 3) Instrument calibrated and tuned as required.
 - 4) Analytical standards of independent sources have been analyzed and confirm each other's concentration.
 - 5) Spike and duplicates indicate the analyses are within laboratory established and method required accuracy and precision limits.
 - 6) PQLs are reported as requested and are appropriate for analytical method and sample matrix.
 - 7) Documentation is such that data is legally defensible.
- d) Overall validity of the analytical results.
- e) Project requirements have been met.
- f) If there is a problem with the data, corrective action is initiated. If the data is approved, the group leader and the analyst sign the preliminary reports. Each analytical report and corresponding QA/QC reports are initialed and dated by first the analyst and then by group leader or management. The data can then be transferred to final report using NEXU or Excel programs.

10.3.3 Final Review and Certification

The approved folder from the analyst and group leader is routed to the lab director for final review and signature before being mailed to the client. This final signature represents and certifies to the customer that all requirements have been met in accordance with applicable methods, except as otherwise noted.

The final package that is received by the client includes the invoice, the original COC, original analytical results and QC reports. Copies of the above originals are included in the day's folder with the raw data.

On occasion, there may be unforeseen circumstances that will cause the laboratory to depart from documented policies and procedures and from standard specifications. In these cases, the laboratory management will require the use of a corrective action form (see Section 11) to document the departure and will require approval from management to allow the departure to be carried out. When relevant, the client will be informed of any such issues that require a departure from these policies and/or procedures.

10.4 Report Content. Each report will contain at minimum, the following information:

1. Name and address of testing laboratory;
2. Title of report, unique identification of report (such as log number), identification of each page of the report by number, and total number of pages in the report;
3. Description and identification of the sample(s);
4. Date of receipt of sample(s) and date(s) of performance of test, as appropriate;
5. Identification of the test method;
6. Any deviations, additions to, or exclusions from the test method and any other information relevant to a specific test;
7. Disclosure of any nonstandard test method utilized;
8. Measurements, examinations, and results, accompanied by appropriate quality assurance (QA) documents;
9. A statement on measurement uncertainty (where relevant); and
10. A signature and title of person(s) accepting technical responsibility for the test report and date of issue.

10.5 Amendments.

Amendments and supplements will be completed in a manner that ensures traceability of causal event, will be clearly identified as "Amended" or "Supplemental" to the original report, and will carry the date and other distinguishing information associated with the amendment.

10.6 Electronic Reporting and Customer Confidentiality

In instances where customer request transmission of results through electronic media, data will only be conveyed to client confirmed fax numbers and e-mail addresses. Further, the following statement shall be attached to cover fax cover sheets and in the body of e-mail messages:

“This message, including attached files, is confidential and intended for the addressee only. Any unauthorized use, dissemination of the information, or copying of this message is prohibited. If you receive a message not being the addressee, please notify the sender by returning the e-mail immediately and delete the message.”

It should also be noted that each customer's data is proprietary to that particular client and GDAT exclusively. All data will be held in confidence, unless the client offers written permission to release the data to a third party.

Section 11 - Corrective Actions

An important part of any quality assurance program is a well-defined, effective policy for correcting quality issues. GDAT maintains a closed-loop corrective action system that operates under the direction of the Laboratory Director. While the entire quality assurance program is designed to avoid problems, it also serves to identify and correct those that are discovered. Usually, quality problems are categorized into long-term and immediate concerns.

Specific quality control procedures are designed to help analysts detect the need for corrective action. Often, an analyst's experience will be most valuable in identifying suspicious data or malfunctioning equipment; immediate corrective action then may be taken. Such actions are to be noted in laboratory notebooks, but often, no other formal documentation is required.

The need for long-term action may be identified by standard QC procedures, control charts, performance or system audits. Any quality problem that cannot be solved by immediate corrective action falls into this “long-term” category. GDAT uses a system to ensure that the condition is reported to a person who is part of the closed-loop action and follow-up plan. A corrective action report form is shown in table 11.1.

Essential steps in the closed loop corrective action system are:

1. Identify the problem
2. Assign responsibility for investigating
3. Investigate and determine cause
4. Determine a corrective action to eliminate the problem
5. Assign responsibility for implementing the corrective action
6. Establish the effectiveness of the corrective action: Implement the plan
7. Verify that the corrective action eliminated the problem
8. Document the complete process of establishing and implementing the corrective action

A formal system of reporting and recording corrective actions has been established for the resolution of major problems.

A Corrective Action Report is issued when an out-of-control situation exists or a condition that will trigger an out-of-control situation is discovered. Anyone who discovers the situation, or is notified of a deficiency by a client, is authorized and required to initiate the corrective action report (CAR). Although multiple CAR may be used in support of disciplinary action, the purpose of the CAR is to uncover the source of the problem and to develop a specific, effective corrective action plan to prevent recurrence of the situation. CAR must be verified and signed by analysts, supervisors and the lab director. CAR are available to the entire laboratory and any clients whose results have been affected by the situation. The client is notified via case narrative if their data has been altered in any way.

TABLE 11.1 SAMPLE CORRECTIVE ACTION REPORT

Number	Date
Source	Area of Standard
Audit Title	Procedure
Department	Fault Category
Raised by	Priority
Non-conformance Details:	
Product/Service	File name

Corrective Action Details

Target CA Date	Actual CA Date	Cost	Responsible for CA
Corrective Action			

Follow-up / Verification

User Defined Field	Responsible for Follow-up Action
Follow-up / Verification	

Status	Actual Close Date	Approved by
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Section 12 - Assessment and Response

This section covers the process by which management determines the assessment activities for a project. It covers the how and by whom assessment of programs are planned, conducted, and evaluated. Assessment tools include:

- Management Systems Reviews
- Surveillance
- Audits
- Performance Evaluations
- Audits of Data Quality

12.1 System Audits

The system audit is a systematic check of a qualitative nature, consisting of an on-site review of a laboratory's quality assurance systems, and environmental testing activities. System audits are performed on a regular basis by various state and federal agencies and by GDAT (executive management) on at least an annual basis. The QA Coordinators shall plan and organize audits as required by the schedule and requested by management. GDAT will submit to external on-site audits at the request of any client and at their convenience. The findings of any audit as well as the actions that arise from them will be kept on file. Management shall insure that those actions are carried out within an appropriate and agreed timescale. System audits may include several components listed below:

- Personnel, facilities, and equipment
- Chain-of-custody procedures
- Instrument calibration and maintenance
- Standards preparation and verification
- Analytical procedures (environmental testing activities)
- Quality control procedures
- Data handling procedures
- Documentation control procedures
- Compliance with NELAC standards

When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of test results, the laboratory shall take timely corrective action, and shall notify clients in writing if investigations show the laboratory results may have been affected. Such writing shall occur within two business weeks. The area of activity, the audit findings, and corrective actions that arise from them shall be recorded. The laboratory management shall ensure that these actions are implemented within two business weeks, barring uncontrollable circumstances. Follow up audit activities shall verify and record the implementation and effectiveness of the corrective action taken.

12.2 Performance Audits

Performance Audits provide a systematic check of laboratory operations and measurement systems. The laboratory director or his designee routinely submits "double blind" samples through the laboratory to gauge the laboratories performance. Splits of

these samples are submitted to participating affiliate laboratories for inter-laboratory comparison. GDAT has identified a “third party” service provider to assist in this endeavor, and annual samples will be processed to assess the laboratory’s performance.

12.3 Quality Assurance Reports

The laboratory’s Quality Assurance Coordinator reports to the Laboratory Director through scheduled meetings to discuss short term and long term goals. Written reports are also submitted to detail events affecting data quality, results on performance or system audits, and other issues affecting the laboratory’s overall operation (i.e. training or equipment needs, upcoming rule changes, etc.)

12.4 Deficiencies

It is the intention of GDAT to respond to and correct all deficiencies discovered as the result of audits and performance evaluation studies. Deficiencies will be evaluated and corrected in accordance with the procedures outlined in section 11 of this manual dealing with corrective actions.

Section 13 - CODE OF ETHICS

It is neither unethical nor misconduct to make mistakes or to inadvertently misinterpret data. However, it is unethical, and therefore unacceptable, for GD Air Testing employees to alter or falsify data in any way to support a particular interpretation. While it is careless to make mistakes in calculations and manipulations that could lead to incorrect results being collected and reported, it is unethical, and therefore unacceptable for any GD Air Testing employees to use and report analysis of data that are inappropriate or that attempt to distort interpretation.

All members of the GDAT are committed to establishing and maintaining high standards of ethics and quality in our industry. Accordingly, employees must demonstrate their continuing commitment to ethics and quality by agreeing to:

- Build on existing relationships with state and local agencies. Promote open and timely communication between government regulators and the regulated community.
- Increase client knowledge. Educate clients regarding technical issues as well as their legal and ethical rights and responsibilities.
- Train employees sufficiently. Ensure minimum competency before allowing employees to perform sample preparation, chemical analysis or data generation.
- Encourage all employees and members of our industry to obey all pertinent federal, state and local laws and regulations. Lead by example.
- Maintain laboratory facilities, equipment and instrumentation adequately to ensure the accuracy and precision of measurements.

- Elevate the status of all commercial environmental laboratories, their employees and the value of the services they perform.
- Willingly submit to critical review through EPA and third party Performance Evaluation programs, agency audits and client challenges of data.
- Accept work only when there exists a reasonable expectation that the client will gain something of value. Satisfy all commitments to quality, timeliness and other project objectives. Provide services in a confidential, honest and forthright manner and charge reasonable fees.
- Legally and ethically manage laboratory waste. Make responsible decisions regarding disposal, recycling, reuse and minimization.
- Treat clients, employees and the environment with respect. Operate facilities in a manner that protects the environment and the health and safety of employees and the public.
- Appropriately “qualify” all data with comments regarding its reproducibility and statistical accuracy so that others can draw their own conclusions.

In addition, all members of GDAT will read and sign the Data Integrity and Ethical Conduct Agreement (shown on the following pages). This agreement shall be renewed and resigned by all members of GDAT on an annual basis. This agreement shall be kept on file for audit purposes, and shall be reviewed and updated on an annual basis.

GD AIR TESTING, INC.

Data Integrity and Ethical Conduct Agreement

Introduction

GD Air Testing (GDAT) is committed and dedicated to providing only the highest quality analytical data possible to its clients. This means that data produced, managed, and reported by GDAT must meet the requirements of its clients and comply with both the letter and spirit of the various municipal, state, and federal regulations and guidelines. Protocols and procedures utilized by GDAT are based primarily on EPA guidelines for the analysis of organic contaminants. GDAT's QA/QC program encompasses the requirements for producing and reporting traceable, defensible data to its clients. It is understood that GDAT analytical data is used by clients to make rational, confident, cost effective decisions regarding assessment and resolution of their environmental compliance requirements.

Policy

It is the policy of GDAT to incorporate the highest standard of quality into all analytical programs by adhering to the following practices:

- A. GDAT will only offer environmental analyses for which it can consistently demonstrate compliance with high quality, traceable and legally defensible performance standards;
- B. All GDAT staff are committed to the practice of complete honesty in the production and reporting of data;
- C. Staff who are aware of misrepresentation of facts or data manipulation to bypass established QA/QC requirements, are required to immediately inform the QA Coordinator or another appropriate member of the corporate leadership team.
- D. GDAT is operated under an Open Door Policy that enables every staff member to have free access to the senior leadership team and corporate officers. This Open Door Policy is intended to foster two-way communication and encourage each staff member to carefully consider their duty and responsibility to report inappropriate data production and reporting practices to the executive management. It is clearly understood that such information brought forth shall be treated confidentially, if so requested by the reporting staff member.

Ethical Conduct and Data Integrity Agreement

Personal Pledge: I understand that I am charged with meeting the highest degree of ethical standards, as defined in this agreement, in performing all of my duties and responsibilities. Further, I understand that as a part of my duties at GDAT, I have an obligation to produce timely and accurate analytical data. This requires that I maintain high standards of integrity so as to never compromise the quality of our work.

Accordingly, I understand that GDAT will strictly enforce a policy that prohibits, under any circumstances, the willful misrepresentation of data. Willful misrepresentation means purposefully falsifying data or reporting false data. Examples of misrepresentation include, but are not limited to:

- Reporting false data of preparation or analysis to meet holding time.
- Time traveling or resetting the computer acquisition clock (time or date) to meet holding time.
- Changes in peak integration to meet QC control limits, including peak shaving or area adding.
- Changing instrument quantitation in the reporting software such as manual input of incorrect peak counts.
- Falsifying instruments logbooks or run logs.

Training Acknowledgment: I have been formally instructed to consider quality as the most important aspect of all my job requirements. I have reviewed and understand QAP. Through these activities, I acknowledge that I have been formally instructed to be honest in the production and reporting of data and to insist on excellence in QC.

Pledges: I agree to adhere to the following protocols and principals of ethical conduct in fulfilling my work assignments at GDAT:

1. All work assigned to me will be performed using Analytical Methods and SOPs that are based on EPA approved methods or GDAT methods.
2. I will only report results or data that matches the actual results observed or measured.
3. I will not intentionally nor improperly manipulate or falsify data in any manner, including both sample and QC data. Furthermore, I will not modify data values unless the modification can be technically justified through a measurable analytical process or method acceptable to GDAT. All such modifications will be clearly and thoroughly documented in the appropriate laboratory notebooks and raw data and include my initials or signature and date.
4. I will not intentionally report dates and times of analyses that are not the actual dates and times the analyses were conducted.
5. I will not intentionally represent another individual's work as my own or represent my work as someone else's.
6. I will not make false statements to, or seek to the otherwise deceive, GDAT staff, management or clients. I will not, through acts of commission, omission, erasure or destruction, improperly report measurements, standard result, data, test results or conclusions.
7. I will not condone any accidental or intentional reporting of inauthentic data by other GDAT staff and will immediately report such occurrences to my supervisor. I understand that failure to report such occurrences may subject me to immediate discipline, including termination.
8. If a supervisor or other member of the GDAT leadership group requests me to engage in or perform an activity that I felt is compromising data validity or quality, I have the right to not comply with the request and appeal this action through the lab director.
9. I understand that, if my job includes supervisory responsibilities, then I will not instruct, request or direct any subordinate to perform any laboratory practice that is unethical or improper. Also, I will not discourage, intimidate or inhibit a staff member who may choose to appropriately appeal my supervisory instruction,

request or directive that may be perceived to be improper, nor retaliate in anyway to those who do so.

10. I understand that if for any reason I feel pressured to manipulate or falsify data, I am to immediately contact the QA Coordinator or executive management.

Agreement Signature: I have read and fully understand all provisions of the Ethical Conduct and Data Integrity Agreement. I further realize, acknowledge and pledge my responsibility as a GDAT staff member to follow these standards. I clearly understand that adherence to these standard is a requirement of continued employment at GDAT.

Employee signature

Corporate Signature

Printed Name

Printed Name

Date

Date

Review Requirements

The Data Integrity and Ethical Conduct Agreement must be signed at the time of hire (or within 2 weeks of a staff member receipt of this policy, if later). Furthermore, each staff member will be required to review and sign this agreement between January 1 and January 31 of every year. Such signature is a condition of continued employment at GDAT. Failure to comply with these requirements will result in immediate discharge from GDAT employment. This agreement is not an employment contract and does not modify in any manner the company's Employment-at-Will Agreement.