ANALYTICAL LABORATORY QA/QC MANUAL

(suitable for Aerospace application)

(Mo/Yr)

Revisions		Rev:	
Letter	E.O. Number - Description		Date

Used On	Contract#:		**Your Company Name**				
Prepared By:							
Your Dept:							
Your Dept:			**POLICIES AND PROCEDURES**				
Your Dept:			Your #				
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Your Logo

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1.0 INTRODUCTION

This manual describes the quality assurance system employed in the Analytical Chemistry Laboratory at (Your Co). Any quality assurance items that are specifically applicable to environmental will be noted. This document is intended for use by employees and Customers of (Your Co) to provide a working knowledge of Policies and Standard Operating Procedures (SOP's) used to control the quality of work performed in the laboratory. These procedures have been developed as a result of (Your Co) continuing commitment to quality. Government Agencies and Customer requirements have provided guiding influences on this development.

Responsibility for quality compliance begins with each analyst and ultimately resides with management. No quality system can succeed without constant adherence in daily practice. This will only be accomplished when the system is given proper attention by the company's leaders. The signatures on the cover page of this manual signify full authorization and approval by the Management and Chemistry Laboratory Technicians of (Your Co). The provisions of this manual are binding on those individuals given the responsibilities outlined herein.

2.0 QUALITY GOALS AND OBJECTIVES

The primary goal of the laboratory quality assurance system is accuracy, consistency, and defensibility of results. This goal is accomplished through sample analysis from the lab's primary customers: Environmental and Manufacturing. The sample analysis results must be consistently accurate and precise. The lab focuses on factors contributing to reliability, accuracy, precision, comparability, sensitivity, and defensibility of procedures and data produced. The following objectives are designed to improve laboratory performance in these areas:

1. [redacted]
2. [redacted]
3. [redacted]
4. [redacted]
5. [redacted]

6. [redacted]

7. [redacted]

3.0 QUALITY POLICIES

The following policies are set forth in order to achieve the objectives listed in Chapter 2 and to provide the structure of the overall laboratory quality assurance system. Detailed procedures for carrying out these policies appear in later chapters of this manual.

1. [redacted]

2. [redacted]

3. [redacted]

4. [redacted]

5. [redacted]

6. [redacted]

7. [redacted]

8. [redacted]

9. [redacted]

10. [redacted]

11. [redacted]

12. [redacted]

13. [redacted]

14. [redacted]

15. [redacted]

4.0 QUALITY ORGANIZATION

The (Your Co) analytical laboratory quality organization has two main components. Laboratory management and staff are directly responsible for laboratory quality assurance (QA). However, the Quality Assurance Manager [redacted]

4.1 Laboratory Supervisor

The Laboratory Supervisor maintains oversight of the laboratory QA program. This position reports directly to the company (Your Mgr), who is the senior manager at the facility. QA responsibilities of the Laboratory Supervisor include the following:

1. [redacted]
2. [redacted]
3. [redacted]
4. [redacted]
5. [redacted]
6. [redacted]

4.2 Quality Assurance Manager

The Quality Assurance Manager works in association with the Laboratory Supervisor in the development of quality assurance systems. Responsibilities with respect to laboratory quality assurance include the following:

1. [redacted]
2. [redacted]
3. [redacted]

Figure 1-1 Personnel Organizational Chart

(Your Org Chart)

5.0 QUALITY PLANNING

5.1 Quality Management

The Quality Group is responsible for [redacted]

5.2 Engineering Management

The Engineering Group is responsible for [redacted]

5.3 Evaluation Record

As a result of the evaluation, a Requirements Analysis Form, (Your #), shall be prepared to serve as an overview of the contract. Specific elements of the quality effort shall be detailed in a Compliance Matrix, (Your #), to the extent determined by the Quality Group. A careful review of all documents and reference documents provided by the contract shall be performed. The Compliance Matrix serves as a Work breakdown Structure for the Quality Group, and is required to list the following:

1. [redacted]
2. [redacted]

Appropriate planning records shall be produced to monitor compliance to the tasks, assignments, and completion dates produced by the Work Breakdown Structure. Planning for indoctrination and training of personnel performing work that affects quality shall [redacted]

6.0 QUALITY IN PROCUREMENT

A close control of all purchased supplies and contracted services is essential to assuring the quality of the end product. The supplier should [redacted]

6.1 Materials Procurement

Chemical reagents must be of sufficient purity for the intended use. Normally, [redacted]

Chemical standards are purchased either as neat materials or prepared solutions. The purity of neat materials and the concentration of solutions must be certified by the manufacturer.

Calibration standards are either traceable to National Institute of Standards and Technology (NIST) [redacted]

Sample containers must [redacted]

Replacement parts for instruments and equipment must [redacted]

Purchase requisitions are completed by laboratory personnel and submitted to (Your Mgr) for approval. Purchase orders are prepared by the purchasing department using information from the purchase requisition in accordance with (Your Co) purchasing procedure (Your #).
The receiving department [redacted]

Materials that are subject to degradation such as standard solutions and some chemical reagents are clearly marked with an expiration date. This date may [redacted]

6.2 Contracted Services

In cases where the (Your Co) laboratory does not have the capability or the capacity to perform requested analyses, samples are [redacted]

[redacted]

Purchase orders are prepared in accordance with (Your Co) purchasing procedure (Your #) to identify the scope of services to be provided. The purchase order [redacted]

7.0 SAMPLE HANDLING

Sample handling procedures are in place to preserve the integrity of the sample. A number of factors must be considered which may compromise [redacted]

7.1 Containers, Preservatives, and Holding Times

The first step in preserving sample integrity is selection of the proper container. Container types [redacted]

Environmental samples are subject to degradation by biological or chemical means. Preservation requirements are [redacted]

Holding times define the maximum time allowed between sample collection and analysis. Samples submitted to the (Your Co) laboratory are [redacted]

Environmental regulations specify sample container materials, preservatives, and holding times. Table 1-1 summarizes these requirements for wastewater's (Reference 1 and 2) and groundwater's (Reference 3). Minimum volumes required for each analysis are [redacted]

Table 1-1
Sample Containers, Preservation, and Holding Times for Wastewater's and Groundwater's

Analysis	Material	Volume*	Preservative	Holding Time
[redacted]				

*Minimum volume required for analysis

7.2 *Sample Identification*

7.2.1 Identification for Environmental Samples

Each sample is given a unique identifier (ID) at the time of collection. The sample ID must be unique and must [redacted]

Sampling personnel write the sample ID on the label that [redacted]

7.2.2 Identification for Production Samples

Each sample is given a unique identifier (ID) at the time of collection. The sample ID must [redacted]

Sampling personnel write the sample ID on the container prior to submittal to the laboratory. Laboratory personnel check [redacted]

7.3 Storage

It is the laboratory's responsibility to maintain sample integrity during sample storage before and after analysis. Refrigerated storage is [redacted]

The temperature is checked and [redacted]

All environmental discharge samples will be held in Custody and stored for [redacted]

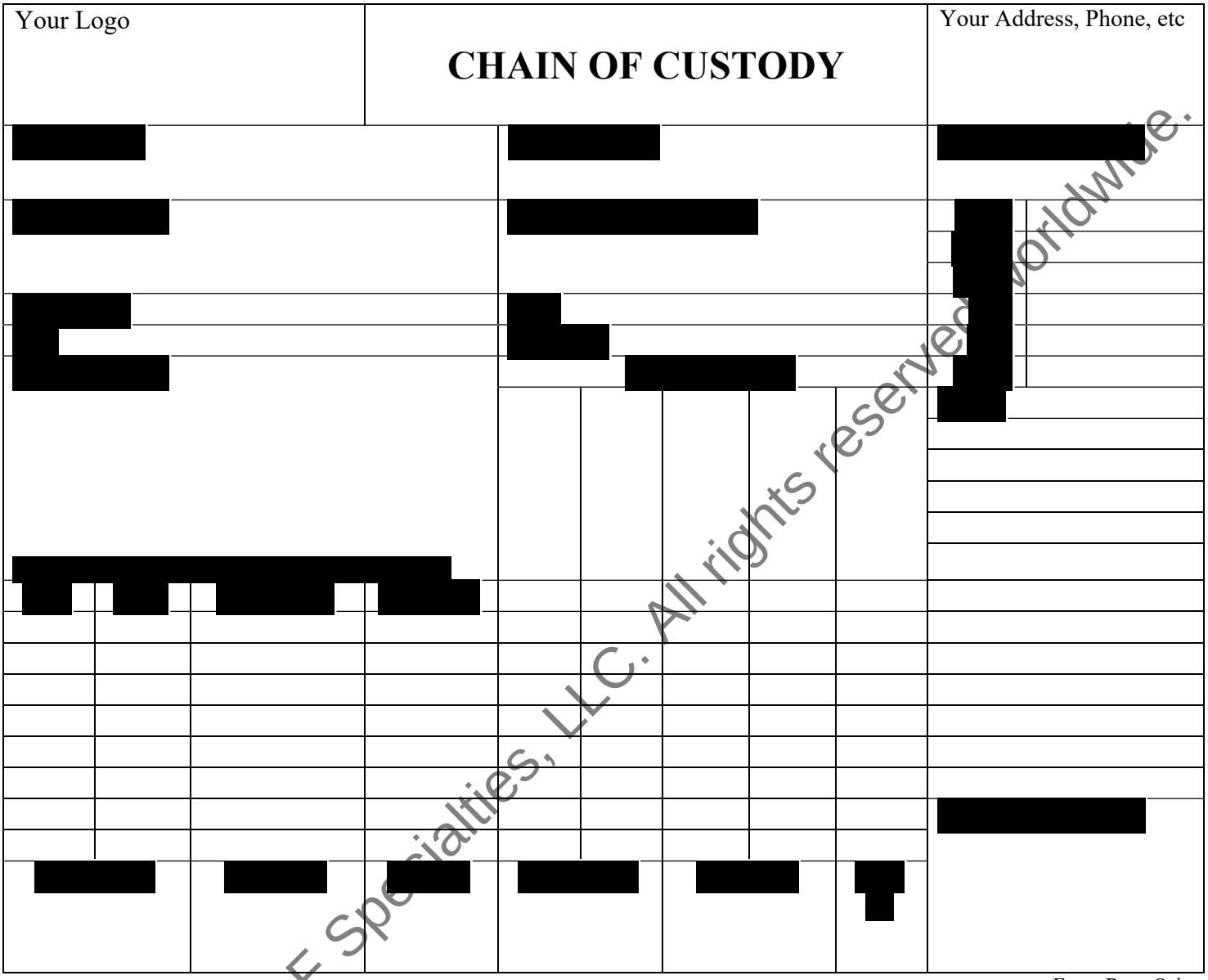
All production samples are held for a minimum of 24 hours upon completion of analysis before being disposed unless [redacted]

8.0 CHAIN-OF-CUSTODY PROCEDURES

The (Your Co) Analytical Chemistry Laboratory does not adhere to strict chain-of-custody procedures in handling routine samples submitted for analysis. All custody transfers are [redacted]

A completed chain-of-custody form accompanies samples sent to an outside laboratory for analysis. Blank chain-of-custody forms are [redacted]

Figure 1-2: Chain of Custody Record



Form Rev: Orig

CHEMISTRY LABORATORY

Chemistry Laboratory policies,

*

*

To help assure that accurate data is generated in the Chemistry Laboratory. The following information is required by the Chemistry Laboratory personnel and will enable them to expedite sample analysis requests. These forms are available [redacted]

1. [redacted]%
2. [redacted]
3. [redacted]

Information required for each sample bottle shall [redacted]

9.0 ANALYTICAL QUALITY CONTROL

Quality control samples, such as blanks, control standards, duplicates/replicates, matrix spikes, and performance evaluation samples, are [redacted]

9.1 Internal Quality Control.

Internal quality control samples are analyzed on a batch basis. A single sample or group of samples (up to 10) is prepared and analyzed using the same reagents under the same conditions. A blank, a control standard, and a duplicate/replicate are [redacted]

9.1.1 Blanks.

Blanks are prepared from analyte-free water or solvent and are taken through the entire process like a sample. The blank measures [redacted]

9.1.2 Control Standards.

A control standard is a blank with a known amount of analyte added. It is used to [redacted]

[redacted] The control standard recovery is calculated as follows:

$$P = (R/T) \times 100$$

where: [redacted]

9.1.3 Duplicates/Replicates

A duplicate/replicate is an additional aliquot of sample that is prepared and analyzed in the same manner as the original sample. It is used to [redacted]
The relative percent difference (RPD) between the duplicate results is calculated as follows:

$$RPD = \left(\frac{R_1 - R_2}{R_{avg}} \right) * 100$$

where: [redacted]

The RPD shall be within established control limits for the data to be deemed valid. Relative precision is [redacted]

9.1.4 Matrix Spikes.

Matrix spikes are prepared by adding a known amount of analyte to an additional aliquot of sample. The same sample that is analyzed in duplicate is also used for the matrix spike.
The spike recovery measures [redacted]

The amount of analyte added should approximately double the analyte concentration in the sample, or more if the sample concentration is low. However, [redacted] The spike recovery is calculated as follows:

$$P = 100 \times (S - R_{avg})/T$$

where: [redacted]

The spike recovery is compared to control standard recovery limits. If it is out of range, and the control standard is within limits, [redacted]

9.2 Inter-laboratory Performance Evaluations.

Inter-laboratory performance evaluation samples are prepared by an external organization and distributed to participating laboratories. The external organization determines [redacted]

Performance evaluation samples are issued to analysts by the (Your Co) Laboratory Supervisor on a quarterly basis. The results are compared to [redacted] Any time a result falls outside limits, the supervisor issues a follow-up sample. If the second analysis is outside limits, [redacted]

Acceptable limits for results from procedures used for testing production samples will [redacted]

10.0 QUALITY DOCUMENTATION AND RECORDS

The laboratory quality assurance system provides for controlling documents and maintaining records that pertain to laboratory analyses.

10.1 Document Control

While this manual is the primary document describing procedures for assuring laboratory quality, SOPs provide [redacted]

Both the QA manual and the SOPs are subject to [redacted]

[redacted]

Controlled copies are serially numbered and a distribution list is [redacted]

The QA Manual and SOPs are reviewed periodically to determine the necessity for revision. Approved changes are [redacted]

10.2 Records Maintenance

Laboratory records include the following:

1. [redacted]
2. [redacted]
3. [redacted]
4. [redacted]
5. [redacted]
6. [redacted]
7. [redacted]
8. [redacted]

The Laboratory Supervisor is responsible for [redacted]

Corrections are made using [redacted]

Environmental records are retained on file for a period of five years after generation. Process records are retained for 20 years. All records are stored by DCC so they can be [redacted]

11.0 CALIBRATION

Analytical instrument calibration involves comparing measured values to standards of known accuracy. All instruments used to generate data are [redacted]

Calibration records are maintained for each calibration event. The minimum information to be documented includes:

1. [redacted]
2. [redacted]
3. [redacted]
4. [redacted]
5. [redacted]

Calibration procedures differ by analytical method. The Standard Operating Procedures "SOP's" otherwise referred to as the Laboratory Procedure XXXX "(Your #) XXXX" contain [redacted]

12.0 PREVENTIVE MAINTENANCE

Preventive maintenance is applied to equipment to help ensure continuous operation and optimum performance at all times. This activity results in [redacted]

Maintenance records are kept for major pieces of equipment in the laboratory. Preventive maintenance schedules include [redacted]

[redacted]

In the case of non-routine maintenance, troubleshooting, and repairs, minimum documentation includes [redacted]

13.0 REFERENCE STANDARDS

Documentation is kept on all standards used for calibration and quality control to provide traceability. Starting materials are [redacted]

The following information is recorded on receipt of standard materials in the laboratory:

1. [redacted]
2. [redacted]
3. [redacted]
4. [redacted]
5. [redacted]
6. [redacted]
7. [redacted]
8. [redacted]

Certificates of analysis and/or traceability supplied with the standard material are kept on file for future reference.

The following information is recorded on preparation of standards:

1. [redacted]
2. [redacted]

3. [redacted]

4. [redacted]

5. [redacted]

6. [redacted]

7. [redacted]

8. [redacted]

A reference to the documented information is written on the label of each standard container to allow [redacted]

Manufacturer's expiration dates are used when provided. Otherwise, [redacted]

14.0 DATA VALIDATION

Data validation is the process by which analytical results are accepted, rejected, or qualified based on an established set of criteria. The criteria used are [redacted] Although criteria vary between different analyses, the guidelines of ASTM E 29 and the following shall be employed:

The analyst who generates the data performs the first level of assessment for validity.
The following criteria shall be met for the data to be accepted with no further action.

1. [redacted]

2. [redacted]

When failure to meet these criteria is observed, the analyst [redacted]

Records of rejected data are kept along with usable data and include documentation of why [redacted]

All environmental data records undergo second party review prior to release. The Laboratory Supervisor or a trained analyst who did not generate the data conducts this review. It includes the following checks, plus details required by the requester, but are not limited to:

1. [redacted]
2. [redacted]
3. [redacted]

If any deficiencies are found in the data records, they are [redacted]

15.0 ENVIRONMENTAL CONTROLS

The laboratory environment is controlled ([redacted]) to prevent exposure to extreme conditions. Air conditioning provides [redacted]

Access to the laboratory is restricted to [redacted]

16.0 PERSONNEL

The quality of work produced by the laboratory is largely dependent on the expertise of its staff. Acquisition of qualified personnel and thorough training in laboratory methods provides [redacted]

New employees are screened to ensure that minimum qualifications are met. Personnel assigned to perform laboratory analyses must [redacted] New hires undergo orientation that includes the following:

1. [redacted]

2. [redacted]

3. [redacted]

4. [redacted]

5. [redacted]

Analytical training is structured to ensure that the analyst receives [redacted]

A training checklist that documents completion of formal training and qualification is prepared and kept on file. The checklist is shown in Figure 1-3. The signature and initials on the checklist can be used to trace identity by signature or initials on future documents.

Figure 1-3 Analyst Training Checklist

This form is intended for use in documenting completion of each analytical training assignment. The Laboratory Supervisor makes assignments and [redacted]

Analysis:_____

Trainee (print name):_____

Initials		
Trainer	Trainee	
		[redacted]

Trainee's signature:_____ Date:_____

Supervisor's signature:_____ Date:_____

17.0 STATISTICAL METHODS

Statistical methods have wide applicability to laboratory data. Among the most significant of these applications is calculating control limits, determining detection limits, plotting calibration curves, and rejecting statistical outliers. Inferential statistics also play a role in providing confidence in lab control.

17.1 Control Limits

Quality control measurements as described in Chapter 9 provide a means for evaluating [redacted]

Laboratory, control limits are calculated for accuracy in terms of control standard percent recovery (%R) as follows.

1. [redacted]

[redacted]

2. Calculate the mean % and the standard deviation using the following equations:

$$\%\overline{R} = \frac{\sum \%R_i}{n} \qquad s = \left[\frac{\sum \%R_i - \%\overline{R}}{n-1}\right]$$

wh [redacted]

3. Set the upper and lower control limits at [redacted]

Control limits for precision are calculated by [redacted]

Control charts provide a graphical representation of QC measurements and are valuable in detecting trends towards an out-of-control situation. Control charts are generated for some analyses as described in Reference 4.

17.2 Detection Limits

Method detection limits (MDL) are determined using [redacted]

17.3 Linear Regression

Least squares linear regression analysis is often applied to calibration data to define the calibration curve. The calculations involved in defining the linear regression curve are [redacted] The resulting slope (m) and y-axis intercept (b) are [redacted]
This equation is used to calculate concentration for samples and QC measurements. Linear regression also yields [redacted]

17.4 Rejection of Data

When performing statistical analyses of data as described above, a representative set of data points is desired and statistical outliers should [redacted]

17.5 Measurement Uncertainty

Deriving a measurement equation and sensitivity coefficients by the use of partial differentiation can be accomplished by [redacted]

Another method is to use a published specification limit or tolerance, e.g., many analytical standards and measurement devices have a temperature coefficient:

±X deviation/degree Celsius

If the temperature is controlled to within ±2°C the change in the value of the standard or measurement device due to temperature fluctuations will be given by:

X deviation x 2°C

Most contributions to an uncertainty budget can be assessed using either method. The differentiation method will [redacted]

It is often not economical to perform several sets of measurements solely to produce a value for the random (Type-A) uncertainty contribution. When multiple measurements are performed it is [redacted] The estimated standard deviation of the uncorrected mean of the measurand is then calculated using:

$$E_{sd} = P_{sd} / \sqrt{N}$$

Where:

[redacted]

When the quantity of measurements to be performed is limited to one set of measurements then N in the equation above will [redacted]

In practice the Type-A contribution to the uncertainty budget can [redacted]

In a perfect world it would be simple to measure many times and obtain a good reliable estimate for the standard deviation. In reality, [redacted]

Generally, it is only necessary to provide a calibration that demonstrates a measurement device is operating within its specification limits. In this case it is not necessary to [redacted]

Aim for an accuracy ratio between uncertainty and the measurement device of greater than [redacted] If the instrument specification has the same coverage factor as the uncertainty, the following expression [redacted]

$$Es = \sqrt{S^2 + U^2}$$

Where:

[redacted]

In the case [redacted]

Es = √[redacted]

With an accuracy ratio of [redacted] the effective specification expands by [redacted] Repeating the same with an accuracy ratio of [redacted] produces an increase of only [redacted]

Using the model above the Type-A uncertainties are insignificant when they are less than [redacted]

Total Uncertainty = [redacted]

From the above the Type-A uncertainties can be regarded as insignificant when they are less than [redacted]

Verifying that an uncertainty contribution is less than a given value is much easier than assessing its precise magnitude. One method requires [redacted]

Total Uncertainty Budget

All of the uncertainty contributions should be listed in a table along with their probability distribution. In most cases it is simpler and more correct to [redacted]

Symbol	Source of Uncertainty	Value ± %	Probability Distribution	Divisor	C*i*	U*i* ± %

Mismatch loss uncertainties:

Where:

[redacted]

[redacted]

The standard uncertainties are combined using the usual $\sqrt{\sum^2}$ method and then multiplied by the appropriate coverage factor (e.g., k=2). In some cases [redacted]

Degrees of freedom:
This term is used to indicate [redacted] For the majority of calibrations performed under controlled conditions [redacted]
In cases where the Type-A uncertainty has been assessed using very few measurements a different coverage factor using the degrees of freedom should [redacted]

18.0 CUSTOMER COMPLAINTS

The Laboratory Supervisor is responsible for responding to all complaints received from customers (Reference Your #). Since most of the laboratory's customers are internal, these responses are normally handled internally. The Supervisor [redacted]

The supervisor may seek technical assistance from outside the laboratory if needed. If the complaint originates externally, [redacted]

19.0 NONCONFORMITY

Nonconformity is a departure from prescribed protocols that may lead to data being rendered unusable or suspect. It may be detected by a customer, by a regulatory agency, by the QA

Manager or within the laboratory. It may involve deviations from [redacted]

Whenever evidence of nonconformity is discovered, [redacted] Any customers affected by the nonconformity are [redacted]

20.0 CORRECTIVE ACTION

(Your Co) recognizes that problems occur in the normal course of work. Corrective action procedures are [redacted]

Minor corrective actions are often taken in response to QC failures. These may include [redacted] The entry includes the following:

1. [redacted]
2. [redacted]
3. [redacted]
4. D[redacted]

The Laboratory supervisor will decide if and when major corrective action is applied when a problem cannot be resolved immediately. The first step involves [redacted]

Figure 1-4 Corrective Action Report

[redacted]

21.0 QUALITY AUDITS

The QA Manager performs audits of laboratory practices on a timely basis to determine [redacted]

A checklist is completed and feedback is given, in writing, to [redacted]

22.0 REFERENCES

1. [redacted]
2. [redacted]
3. [redacted]
4. [redacted]
5. [redacted]
6. [redacted]
7 [redacted]
8. [redacted]D
9. [redacted]

ABBREVIATIONS

ACS	American Chemical Society
LP	Laboratory Procedure
PP	Procurement Procedure
QC	Quality Control
IAW	In Accordance With
GR&R	Gage Reproducibility and Repeatability
ID	Identifier
MDL	Method Detection Limit
NIST	National Institute of Standards and Technology
QA	Quality Assurance
QC	Quality Control
RPD	Relative Percent Difference
SOP	Standard Operating Procedure
SRM	Standard Reference Material