3.3 QUALITY PLANNING

Special Operational Procedures

Customer contracts or purchase orders, drawings and specifications are reviewed to identify and make timely provisions for special or unusual requirements.
3.4 Precision and Accuracy Procedures

This section describes procedures used to assess precision, accuracy, and completeness of the measurement systems both by the means required by EPA Methods, and by the statistical methods used by Truesdail Laboratories as part of internal quality control procedures.

3.4.1 Precision

Precision will be determined using data from the analysis of spiked laboratory duplicates of media materials. EPA Methods base precision control limits on the standard deviation of spike recovery data, as described in Section 3.2.7. The limits for precision are taken from the relevant EPA method. Results which fall outside these limits are considered out of control and require appropriate action to be taken as described in Section 7. In addition, Truesdail Laboratories uses the results of duplicate analyses to monitor precision.

The Relative Percent Difference (RPD) between the analyses of the duplicate samples is calculated as follows:

\[
\text{RPD} = \frac{(s-d)}{(s+d)/2} \times 100
\]

where \( s \) = the first sample value
and \( d \) = the duplicate value

Duplicate analyses which return values above five times the method detection limit and an RPD greater than 20% are considered to be insufficiently precise and out of control procedures are initiated as described in Section 7. RPD values are plotted as RPD versus sample number.
3.4.2 Accuracy

For EPA Organic Methods, spike recovery data are used to determine the accuracy of the measurement system. After data for five spiked environmental samples are collected, average percent recovery, P, is calculated, along with the standard deviation, SD. P is compared with the established limits for accuracy, and SD is compared with the limits for precision. In addition, a control chart is maintained for spike recovery results. Limits are set for a range from $P + 3SD$ to $P - 3SD$. Results which are outside these limits are out of control. See Section 7 for the appropriate action to be taken. For EPA Metals methods accuracy will be monitored using data from analysis of instrument check standards and a standard control chart as described in Section 3.2.11. A minimum of 20 determinations are needed for construction of the control chart. The mean is calculated and plotted on the graph. Standard deviation is calculated as follows:

$$SD = \sqrt{\frac{n\sum x^2 - (\sum x)^2}{n(n-1)}}$$

Warning limits are set at $X + 2SD$ and $X - 2SD$. Control limits are set at $X + 3SD$ and $X - 3SD$, and all four limits are plotted on the chart. Results of analysis of instrument check standards are plotted in sequence along the horizontal axis.

Failure of the results of analysis of the instrument check standards to be within $+25\%$ of true value or within established control limits, indicates that referral should be made to the out of control actions listed in Section 7.

For calibration blank data a similar chart is constructed with the exception that control limits are placed at $X + 2SD$. If the result of analysis of the calibration blank falls outside the control limits, the analysis is repeated twice and the average of all three determinations is plotted. If this result is still outside the control limits, the analysis is out of control; see Section 7 for out of control procedures.
3.5 Quality Assurance Reports to Management

The quality assurance manager reports to upper management which include assessments of data accuracy, precision, and completeness derived from summaries of standard control charts. Corrective actions and maintenance reports are also to be reported. These reports help management focus attention on areas which are not performing up to expectations. Results of external quality control checks and internal audits will be included as they become available.
SECTION 4 – OPERATIONAL PROCEDURES

4.1 INITIAL JOB ORDER PROCEDURE

Job orders are initiated on the basis of:

Written requests received with samples (typically on a chain of custody form) by mail, e-mail, facsimile, or purchase order.

Purchase orders (P.O.) are preferable when accepting a job. The P.O.s, or a release to a blanket P.O., shall be kept with the Laboratory Record as outlined below. When an order is received without a P.O. number on it, the words "Verbal" are recorded in the slot for a P.O. number. Occasionally a client’s P.O. is received after the samples arrive and the report and invoice are prepared. Late P.O.s are to be filed with the respective invoice and report paperwork.

Oral requests received either by telephone or personal contact.

Signed contracts with a schedule of tests to be performed.

Once a contract is signed, the original is kept in the "contracts" drawers in the accounting office and copies are distributed to the responsible departments.

Upon receipt at Truesdall of a sample, the job order is assigned a sequential number, labeled, and entered into Truesdall’s computer system. (The sequential numbers are audited weekly to ensure all jobs are processed.) Sample testing associated with contracts can also be tracked by contract identification – the client’s or Truesdall’s – in the computer system under the "job" segment of Truesdall’s accounting system.

From the data entered into the computer system, a green Laboratory Record is generated and any necessary yellow copies for intracompany testing. This Laboratory Record, with the respective paperwork including any P.O., and the sample are turned over to the project manager assigned to the job. The analysis of the sample is then scheduled on a "do" list.
4.2 Sampling Procedures

Obtaining representative samples and maintaining their integrity are critical parts of any testing program. Analytical methods have been standardized, but the results of analysis are only as good as the sampling methods.

If requested by the client, Truesdail can provide trained staff to collect samples or the client can be advised of the best way to collect, contain and deliver the samples. When samples are collected on-site by our staff, the method used will be in accordance with the pertinent regulations or standards and will be so described in the workbook and report. This specifically includes (but is not limited to) the collection of water and sewage, stack emissions, ambient air, and working atmosphere (industrial hygiene) samples.

When a client chooses to collect their own samples, our staff can brief clients and provide written directions on proper methods of sample selection or collection. The majority of the samples analyzed are submitted by the client. We have no control over their quality and no knowledge of whether they are truly representative of the material in question.

Truesdail Laboratories can also provide clients with the appropriate sample containers. A Sampling Guide Form lists the container types, sizes, preservatives, container closures and maximum holding times for analytical parameters. The form is made available to clients to assist with their sampling programs. A copy of the Sampling Guide form is included in Appendix B.
4.2.1 Sample Custody

Truesdail Laboratories recommends that all environmental samples submitted for analysis be accompanied by a chain-of-custody form. The chain-of-custody form is used to document the name of the person collecting the samples, the date and time of collection for each sample, and a description of each sample and the analyses it requires. We will use chain-of-custody forms provided by our clients, or we can provide our own form. When samples are delivered to Truesdail Laboratories, the log-in clerk signs the chain-of-custody form, including the date and time, establishing the change in custody of the samples. A copy of Truesdail's chain-of-custody form is given in Appendix B.

Upon arrival at Truesdail Laboratories, the condition of the samples is noted, and they are logged into a standard log book. The client is immediately notified if any problems are found with the samples at log-in. A laboratory identification number is assigned, sample information is entered into our log-in database system, and aliquots of the sample are dispersed for analysis. Samples sent from one laboratory to another within Truesdail Laboratories are accompanied by a two part intra-company analytical request form, which functions as an intra-company chain-of-custody form. One copy is retained by the originating lab, one travels with the sample or aliquot, and becomes part of the file used to compile the report when analyses are completed. The Laboratory Supervisor assigns the job to a qualified technical staff member who will be responsible for performing the work through his/her own individual efforts and with the assistance of other staff members when necessary. The assigned technical staff member will collect and assemble all laboratory work sheets with data and calculations.

4.2.2 Sample Storage

Environmental sample storage is available at room temperature, at refrigerator temperature (4°C), and frozen (-20°C). Samples are assigned to an appropriate storage area, depending on the nature of the analysis required. Each storage location has a unique identifying number, which is recorded on the Laboratory Record for that sample when the sample is stored. Refrigerators and freezers used for sample storage are used exclusively for sample storage. Standards are stored in separate refrigerators and freezers to avoid potential contamination of samples.

4.2.3 Sample Disposal

Samples and extracts are retained for three months after analysis and then disposed of appropriately. The results of analysis are used as a guide to determine whether the sample should be considered normal or hazardous waste. Longer periods of sample and extract storage can be arranged and, if requested, the client can be notified prior to disposal.
4.3 PROCEDURES, STANDARDS AND REGULATIONS PROCUREMENT

It is the responsibility of the Laboratory Managers/Supervisors to obtain and maintain the current edition of all official regulations, standard procedures and other documents and publications pertinent to their departments. This is accomplished by referring to the current index of a standard such as ASTM, or by placing a call to a document house, agency or the client to determine the latest revision date. The documents will be kept in the location designated by the department heads. Standards used in laboratory and field testing include:

- American Chemical Society (ACS)
- American Public Health Association (APHA)
- American Society for Testing and Materials (ASTM)
- Association of Official Analytical Chemists (AOAC)
- Bay Area Pollution Control District (BAPCD)
- California Department of Health Services (DOHS)
- Department of Defense (DOD)
- Environmental Protection Agency (EPA)
- Los Angeles County Sanitation District (LACSD)
- National Institute of Occupational Safety and Health (NIOSH)
- National Institute of Standards and Technology (NIST)
- Occupational Safety and Health Agency (OSHA)
- South Coast Air Quality Management District (SCAQMD)
- Truesdail Laboratories Inc. Standard Operating Procedure – Manual for Environmental Analysis
- United States Pharmacopoeia (USP)
4.4 Calibration Procedures and Frequency

When possible, all calibration standards are purchased from reliable vendors who can demonstrate traceability to NIST or EPA Standards. In cases where commercial standards of this quality are not available, we make our own standards using the highest grade reagents. Our analytical balances are calibrated against NIST traceable standards annually by an outside firm. We also have available NIST Class S weights for internal audits of the balances and for analyst use if a problem is encountered.

4.4.1 Environmental Analytical Instruments

Instruments are calibrated according to our Standard Operating Procedure (SOP) for the relevant method. Our SOPs for environmental methods are based on, and compliant with, EPA methods. Typically, after the instrument is demonstrated to be within specifications, a multi-point calibration curve is made and verified. Daily check standards, run prior to any sample analysis each day, are used to ensure the current calibration curve is still valid. When the results for the daily check standard show that the calibration curve is no longer valid, the corrective actions described in Section 7 will be applied. Some methods (especially those used in the EPA's Contract Laboratory Program) require a new calibration curve on a regular schedule, regardless of whether or not the existing curve is still valid.

4.4.2 Calibration of Supporting Equipment

4.4.2.1 Calibration

Measuring and test equipment which requires periodic calibration shall be described in accordance with ANSI/NCSL Z540-1, and ISO 10012-1. Measurement standards shall be maintained under the control of each department supervisor.

- All equipment which is calibrated is given a unique number and location.
- All equipment which is calibrated has an interval date and source of calibration on its calibration record.
- Each type of equipment (thermometer, micrometer, balance or gauge) is calibrated according to its own specification. These specifications state the required environmental test conditions for calibration, use and storage.
- Where required for coordination with use, the calibrated equipment (thermometer, gauge, or balance) shall be tagged giving the date calibrated and date due.

The Quality Assurance Director has ultimate responsibility for all phases of the quality assurance program, equipment calibration and documentation.

The Department Supervisors are responsible for assuring that the calibrations are performed properly and on time. All documentation, procedures, calibration data records and reference standards are kept by the Department Head.

The Quality Assurance Manager shall have access to these records and shall make them available to Client and Government representatives.
4.4.2.2 Adequacy of Standards

Inspection gauges and test equipment used in testing and analysis shall have the capabilities for accuracy, stability, range, and resolution required for the intended use. Calibration shall be performed by comparison with higher level accuracy standards.

4.4.2.3 Environmental Control

Measuring and test equipment shall be calibrated and utilized in an environment controlled to the extent necessary to assure continued measurement of required accuracy to maintain precision measurement under standard conditions. Environmental factors which may affect accuracy of measuring and test equipment include temperature, humidity, vibration, storage and cleanliness. Housekeeping and cleanliness are part of "Good Laboratory Practices" and shall be adhered to.

Thermometers

Thermometers shall be calibrated either by single point calibration at the temperature for which they monitor in service or multipoint calibration through their range or the range of intended use. Bulb thermometers shall be used and stored in a vertical position whenever possible to prevent liquid separation.

Micrometers

Micrometers shall be calibrated at the ambient air conditioned environment of the laboratory and used in the same manner. They shall be kept clean.

Balances

Balances shall be calibrated at the ambient air conditioned environment of the laboratory and used in the same manner. They shall be kept clean. Second floor analytical balances experience effects of vibration and floor movement. They shall be operated with this in mind and checked for proper zeroing with each use.

Gauges

Gauges shall be calibrated either by single point calibration at the humidity, pressure or flow which they monitor in service or multipoint calibration through their range or the range of intended use. They shall be calibrated at ambient temperature of the laboratory and used at these conditions unless otherwise required. in which case, they shall be calibrated at the temperature(s) of the intended use and so noted on the calibration records. In the event of use of environmental condition compensation corrections, the correction factors shall be developed over the range of use and kept with the record. All gauges shall be kept clean to the extent possible with their use.
4.4.2.4 Calibration Intervals

Measuring equipment and standards will be calibrated at periodic intervals established on the basis of stability, purpose, and degree of usage. Intervals shall be shortened as required to assure continued accuracy as determined by results of the previous calibrations, and a mandatory recall system shall be maintained to insure continued accuracy. The Microbiology Laboratory thermometers shall be calibrated at no less than once every six months. Maximum recommended intervals are as follows:

Laboratory Thermometers .................................................. 1 year
Secondary Standard Thermometers ................................. 1 year
Microbiology Thermometers ........................................... 6 months
Micrometers ..................................................................... 1 year
Gage Blocks ...................................................................... 2 years
Balances ............................................................................. 1 year
Weight Sets ........................................................................ 2 years
Pressure Gauges ................................................................. 1 year
Pressure Gauge Calibrators .............................................. 2 years
Humidity Gauges ................................................................. 1 year
Flow Gauges ....................................................................... 1 year
Volume Gauges ................................................................. 1 year
Water Meters ..................................................................... 1 year

The quality assurance manager may extend a calibration interval of an out of calibration instrument to allow for use until a calibration may be performed.

Recall System

A recall system shall be in effect for all measuring and test equipment (thermometers, micrometers, balances and gauges) to assure timely calibrations, thereby precluding use of an instrument beyond its calibration due date. The recall system may include provisions for the temporary extension of the calibration due date for limited periods of time under certain specific conditions such as the completion of a test in progress. The system shall be monitored by the quality department who informs the affected departments of the equipment coming due. It is recommended that these notices be distributed one month, one week and one day prior to the date due as needed. Inspections shall be performed by the quality department to insure compliance. Any equipment found past due will be impounded or appropriately tagged. Substitute equipment should be available where needed. Equipment which is currently performing a test shall not be impounded without replacement. Either or both of the following systems are acceptable:

- 4 X 6 Card File Recall System – Cards are maintained in chronological order by due date. Each card is headed by the item description and serial number. It then lists the location, date calibrated and date due.
• Computer Recall System – A system which performs as above.
• Any system approved by the Quality Assurance Manager.

4.4.2.5 Calibration Procedures

Calibration procedures of inspection gages and instruments by company personnel will be accomplished per MIL-STD-120 (or GGG-C-105B). Calibration of thermometers will be accomplished per ASTM E 77. Other calibrations will be performed in accordance with S.O.P.'s for each instrument.

Each class of calibrated equipment shall have a copy of the calibration method in the vicinity of the calibration records and available for utilization.

Calibration procedures shall specify the accuracy of the instruments being calibrated and the measurement standard to be used or the required accuracy of the standard. The procedure shall require that calibration be performed by comparison with higher accuracy level standards.

These procedures shall identify and prevent the use of any unsatisfactory equipment.
4.4.2.6 Out of Tolerance Evaluators

Data
Out of tolerance data shall be used to determine adjustments to calibration intervals, to determine the adequacy of measuring and test equipment, and to determine the adequacy of calibration and measuring and test procedures. Measuring and test equipment which does not perform satisfactorily shall be identified and its use prevented.

Significance
Equipment shall be considered significantly out of tolerance when it does not perform to the level it is calibrated and not necessarily to the level to which it was originally manufactured. For example, a de-rated set of Class S weights may be used as a set of Class P weights. Equipment so used shall be clearly identified to any changes in the original precision. Equipment determined to be inaccurate and not suitable for a downgrade in precision may not be reclassified and its use shall be prevented.

Reporting Channels
Reporting channels for out of tolerance data vary significantly due to the diversity of possible out of tolerance data. However, the department supervisor shall be notified. The supervisor then directs the action which often involves the department or group manager, the quality department and the maintenance/facilities department.

Notice of Out of Calibration Conditions
In the event that an inspection gage or instrument is found to be out of calibration when recalibrated, the department supervisor shall be notified and a record of the condition shall be made in the calibration file for the device. The supervisor then directs the action which often involves the department or group manager, the quality department and the maintenance/facilities department. The impact of accuracy of results on products tested or examined by equipment found to be out of tolerance during calibration will be determined. Appropriate corrective action will be taken to correct possible reporting errors. The calibration interval of the measuring or test equipment shall be adjusted to prevent recurrence.
4.4.2.7 Calibration Status

Calibration status of measuring equipment and standards will be indicated by labels to assure adherence to calibration schedules. The label will indicate date of last calibration, date when next calibration is due, and by whom calibrated. Any measuring or test equipment which does not perform satisfactorily shall be identified as such and preferably removed to prevent its use. Items not calibrated to their full capacity or which require functional check only shall be labeled to indicate condition. Although usually removed to prevent use, measuring and test equipment available for use which is not calibrated shall be tagged "NOT CALIBRATED, FOR REFERENCE USE ONLY". Red stickers are available from the Quality Assurance Manager for this purpose.

4.4.2.8 Storage and Handling

All inspection gages and test equipment shall be handled, stored and transported in a manner which shall not adversely affect the calibration or condition of the equipment. Items shall be packaged properly when required, and shall be stored under adequate storage conditions. Improper storage, handling or transportation of measuring and test equipment shall be reported to the department manager and as appropriate, to the quality department. Some storage recommendations are as follows:

<table>
<thead>
<tr>
<th>Item</th>
<th>Storage Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thermometers, bulb</td>
<td>Vertically, protected from shock</td>
</tr>
<tr>
<td>Micrometers/Calipers</td>
<td>In original cases away from corrosives, oiled lightly as appropriate, protected from vibration and shock</td>
</tr>
<tr>
<td>Balances</td>
<td>Cleaned of any daily spillage, left in &quot;rest&quot; or off position, analytical – protected from vibration</td>
</tr>
<tr>
<td>Gauges</td>
<td>Individually on appropriate shelves or boxes, kept clean of excessive dust</td>
</tr>
</tbody>
</table>
4.5 **ANALYTICAL AND TEST PROCEDURES**

All analyses, tests, and measurements preferably are to be in accordance with a standard method from Truesdail's Standard Operating Procedures Manuals or some standard publication and shall be so stated on the Laboratory Record. Detailed analytical procedures are found in Truesdail's Standard Operating Procedure Manual. This document is available in the Laboratory as a separate document. The methods described follow EPA standard procedures or other appropriate methods ("Standard Methods", or ASTM).

Frequently the client will specify a particular procedure to be used. The client's instructions will be authorized by the supervisor only. Many assignments or samples are received for which there is no standard method for analysis or testing. In such cases, procedures will be devised based on technical experience and judgment and approved by the supervisor. The procedure used must be described in the laboratory workbook or report in sufficient detail to enable repetition of the work by someone else at a later date. All in-house procedures shall indicate the revision number, date and preparer.

Any changes in procedures specified by a client shall be authorized by the client and preferably this notification will be in writing by the customer.
4.6 DATA ACQUISITION AND RECORDING

Two part laboratory workbooks are assigned to individuals and/or work stations. They are the preferred recording medium for all handwritten original (primary) data. Laboratory work sheets shall be signed, dated, and indicate the method used in analysis. To the extent practical, data shall be collected and processed utilizing automated and computer assisted systems. Hard copy of printed data and/or electronic media such as floppy discs or tapes shall be likewise labeled with the name of the analyst, date, methods of analysis, etc.

Any changes made to original data shall be single line crossed out and initialed by the person making the change. If the date of change is other than that indicated on the laboratory work sheet, then the initialed change shall also be dated. Original data shall be written in non-erasable ink. "White Out" shall never be used over original data. Where applicable, test data shall be rounded off per ASTM recommended Practice E29. Results of tests shall not include significant figures in excess of those substantiated by the precision of the instruments and methods used. For most analysis, no more than three significant figures are reported.

4.6.1 Certification of Reports

Purchase orders which stipulate that a Certificate of Conformance (C of C) is required with shipment of items on the purchase order is a request to certify the work was done as requested and not necessarily a statement of whether or not the items passed or failed a requested procedure. It is recommended that the QA Department review all reports requiring a C of C. This requirement is met by adding the following statement, or suitable facsimile, below the conclusion and above the signature:

Certification: The above testing was performed in accordance with the above purchase order, the above referenced methods and the Quality Assurance Manual, rev. 0, 3/31/03.

Caution must be used to be certain that the client has approved the version of the QA manual that the report is being certified to. If they have issued their purchase order on an old revision, then the C of C is written to that revision.
4.7 DATA REDUCTION AND VALIDATION

4.7.1 Data reduction for EPA gas chromatograph methods

Data collection and reduction is automated using Maxima software from Dynamic Solutions. Standard output from the Maxima software is passed to a custom spreadsheet application where QC data are checked, and final reports are generated. If QC data show an out of control situation, appropriate corrective action is taken as indicated in Section 7. When the QC data show that the system is in control, but above the warning limits, results are flagged for special review.

4.7.2 Data reduction for metals

For each ICP, data are collected and reduced using software provided by the manufacturer. These software packages report analytical results to the analyst in concentration units. QC results are reported like field sample results, and must be compared to the control charts by the analyst.

For AA data, a custom spreadsheet application is used to reduce data output from the instrument.

4.7.3 Data reduction for EPA GC/MS methods

GC/MS data collection and reduction is fully automated for all methods using Hewlett-Packard's Aquarius software system running on HP 1000 mini-computers. Final reports to the analysts are in EPA report format.

4.7.4 Data reduction for wet chemistry methods

Wet chemistry methods are not typically performed using computer-aided instruments. Analysts record raw data in lab notebooks, then enter these raw numbers into custom spreadsheet applications for final data reduction. QC data are handled in the same way as field samples. Reports in standard format are used for final report preparation.

4.7.5 Data Validation

Data validation begins with review of QC sample results by the analyst. For manually operated instruments QC sample results can be checked against control charts, to avoid collecting invalid data. Most environmental methods are automated, so validation does not begin until after field samples have been analyzed. Data collected while a system was in control but out of warning limits are marked for special attention during higher level reviews. Samples analyzed while the system was out of control follow the corrective actions in Section 7.
4.7.6 Outliers

QC charts are regularly updated to reflect results of QC sample analyses. However, points which are determined to be "outliers" will not be included in the population used to update control and warning limits. This is the first stage at which points will be screened for suitability. These results will still be taken as indications that a warning or control limit has been exceeded.

4.8 REPORTING PROCEDURE

Final reports are prepared using report forms generated by the computer-aided instruments, or the custom spreadsheet used to reduce raw data. During report preparation, QC sample results are again reviewed to verify that the system was in control when field samples were analyzed. Final reports are reviewed by a manager, and QC results are included in this process as well. At any stage, if a question arises about the validity of sample data, corrective action is taken.

The assigned technical staff member will prepare and submit a report along with all test data to the laboratory supervisor. The report should describe the scope of the problem, proper method numbers, other designation or procedures, summarize the results and present a conclusion or recommendation if required.

All test reports shall refer to the unique Laboratory Number assigned to the sample. In the event that a report is revised in any way and the client has received a report by any means, the preferred distinction is with revision letters, i.e. A, B, C, etc. The typed report is proofread by the supervisor. The handwritten or draft copy of the report should be discarded after proofreading to minimize file congestion.

The supervisor will evaluate the report, check data, and approve the accounting and invoice data.

The Laboratory Record and report are sent to billing for invoicing, packaging, and mailing.
4.8.1 Billing and Mailing of Invoice and Report

The papers are divided into two packets

1. The first packet is clipped together and forwarded to billing.
   - Green laboratory record
   - All original pages of the report
   - Duplicate pages of the report if client requested
   - All client paperwork that is to be returned, such as P.O. acknowledgments or client copies
2. The second packet is stapled together and retained in the department
   - A copy of the laboratory record
   - All client’s paperwork
   - All Truesdail paperwork including copies of the final report
   - All original data

The invoice is processed in billing and a package prepared for mailing to the client which includes an original with copies, plus packet No. 1.

Billing retains and files a copy of the invoice with the Laboratory Record and sends a copy of the invoice to the department.

The department attaches their copy of the invoice to packet No. 2 and files by client.
4.8.2 Record Retention

Laboratory worksheets with calculations and data, file copies and other records generated for a job assignment will be maintained in a secure location for ten years. This material is the property of the Laboratory and its clients and must be maintained intact for future reference. All such documentation shall be available for customer review upon request. After the ten-year retention period, the material will be discarded. Should a special request be made for extended retention, these records shall be kept in a separate file noting a discard date.

4.8.3 Confidentiality

Material generated as a result of work performed in the Laboratories and the fact a particular analysis has been performed for a client are confidential information between the client and the Laboratory. There will be no release of information to any individual other than the client without the client’s permission. The only exception to this is in response to subpoena, in which case the client will be notified of such.

4.9 Outside Review

Truesdail Laboratories will allow clients and/or their representatives reasonable access to relevant areas of the laboratory for the witnessing of tests and/or calibrations performed for the client.
SECTION 5 – INTERNAL QUALITY ASSURANCE AUDITS

5.1 GENERAL AUDITS

The Quality Department will audit the Laboratories annually.

The findings of each audit will be forwarded to the responsible department manager indicating corrective actions to be taken and a follow-up date. These findings shall be in the form of an internal memo. The Quality Assurance Manager will submit a signed and dated report to the upper management of the company. Any deficiencies noted will be resolved in a timely manner.

The audit will be performed to the check list of Appendix B so as to assure the following:

- Service performed was strictly in conformance with the details of a purchase order or that any deviation was covered by a change to the purchase order.

- All changes or corrections on the laboratory data sheets are initialed and dated by the person making the corrections.

- Controlled in-house methods and procedures have a signature and a date as to when issued to assure the latest revision is being used.

A copy of the results of each audit go to the department supervisor. A complete set is submitted to the Technical Director.

The Quality Department will audit the Purchasing Department annually to assure that technical and quality requirements are included in the purchase of services or products which are required to meet client specifications.
5.2 Systems and Performance Audits

5.2.1 Systems Audit

The measurement system for analysis of each parameter consists of four basic components: personnel, reagents and instrumentation, methods of analysis, and the quality assurance program. Standards for evaluation of each of these components are described or referenced below.

Requirements for personnel training and experience are contained in Section 2.

All reagents used are of the highest quality and meet or exceed the requirements listed in the EPA standard procedures used.

The instruments used are substantially in compliance with requirements of EPA standard methods. In all cases where instrument specifications deviate from requirements, the modification was made to improve performance. Documentation which demonstrates that these modified instruments do perform as well as or better than required by EPA standard methods has been demonstrated.

This quality assurance program has been prepared following “Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans” publication number QAMS-005/80 of the Office of Monitoring Systems and Quality Assurance, Office of Research and Development, U.S. Environmental Protection Agency, and U.S. Army Corps of Engineers regulation ER 1110-1-263.

5.2.2 Performance Audits

Summaries are made from quality control data for each parameter measured, and reviewed to determine that accuracy and precision remain within the allowed limits. If drift in the mean or excessive scattering of quality control analysis values outside warning limits is detected, action will be taken to bring the measurement system into better control. The quality control standards used in this process originate from the Environmental Monitoring and Support Laboratory of the U.S. Environmental Protection Agency in Cincinnati, Ohio, if available. This constitutes an external check on Truesdail Laboratories’ performance. In addition, external samples are analyzed on a semi-annual or annual basis as part of overall Laboratory auditing procedures. Examples of the EPA Cincinnati reports, as well as other outside audit reports, are given in Appendix E.
SECTION 6 – FACILITIES AND EQUIPMENT

6.1 FACILITIES

Truesdail Laboratories offers both engineering and chemical analytical services. The main facility in Tustin, California contains 40,000 square feet. This includes the Racing Chemistry Laboratories, Mechanical Testing on the first floor, and Air Analysis, Water and Waste, Instrumental Methods, Microbiology, and General Chemistry, on the second floor. Floor plans of the Laboratory and a list of the major pieces of equipment in laboratories which have most of their work in the environmental area are given in Appendix C.

The space available at Truesdail Laboratories is composed of operational areas, office services, sample preparation, wet chemistry rooms, and instrumentation facilities. All rooms which encompass the Chemistry Laboratories are equipped with adequate lighting, counter space, exits, and any other structural requirements as outlined by state and local building regulations. Each laboratory is equipped with a water sprinkler system, portable fire extinguishers, emergency eyewash and emergency shower systems.

6.2 PREVENTATIVE MAINTENANCE

Preventative maintenance is intended to keep an instrument operating within specifications. In some cases there are components which are expected to become dirty with use, such as the source in a GC/MS, which is therefore scheduled for cleaning at regular intervals. In other cases, there are components which are gradually destroyed or consumed during use, such as the septum on a gas chromatograph. These components are scheduled for regular replacement, and spare parts are always kept on hand. Specific preventative maintenance is part of the Standard Operating Procedure for each method.

Each instrument has a maintenance logbook which is used for documenting all maintenance of that instrument.
6.3 Volumetric Glassware, Analytical Balances and Thermometers

6.3.1 Volumetric Glassware

In order to maintain reliable results, standard solutions are prepared in class “A” volumetric flasks. Class “A” volumetric pipets are also used for sample and standard aliquots where applicable (see chart below). Serological pipets are employed for the dispensing of reagents where extreme accuracy is not required. For all titrimetric procedures class “A” microburets are used. All syringes are calibrated and certified by the distributor (Hamilton, Supelco), and inspected prior to each use by the analyst.

Tolerances for volumetric glassware:

<table>
<thead>
<tr>
<th>Type</th>
<th>Capacity, ml</th>
<th>Limit of Error, ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volumetric flasks</td>
<td>25</td>
<td>0.03</td>
</tr>
<tr>
<td></td>
<td>50</td>
<td>0.05</td>
</tr>
<tr>
<td></td>
<td>100</td>
<td>0.08</td>
</tr>
<tr>
<td></td>
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<tr>
<td></td>
<td>500</td>
<td>0.15</td>
</tr>
<tr>
<td></td>
<td>1000</td>
<td>0.30</td>
</tr>
<tr>
<td></td>
<td>2000</td>
<td>0.50</td>
</tr>
<tr>
<td>Volumetric pipets</td>
<td>1</td>
<td>0.003</td>
</tr>
<tr>
<td></td>
<td>2</td>
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</tr>
<tr>
<td></td>
<td>5</td>
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<td></td>
<td>10</td>
<td>0.02</td>
</tr>
<tr>
<td></td>
<td>25</td>
<td>0.025</td>
</tr>
<tr>
<td></td>
<td>50</td>
<td>0.05</td>
</tr>
<tr>
<td>Buret</td>
<td>5</td>
<td>0.01</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>0.02</td>
</tr>
<tr>
<td></td>
<td>25</td>
<td>0.025</td>
</tr>
</tbody>
</table>
6.3.2 Analytical Balances

The analytical balances are some of the most important equipment items in an analytical laboratory, because the accuracy of all weight-prepared standards will be affected by the accuracy of the balance. Balances are fragile instruments, subject to shock, vibration, temperature and humidity changes, mishandling, corrosion, and spilled material. A balance must be well protected and cared for if the laboratory is to produce reliable data.

Analytical balances are mounted on shock isolated tables away from traffic, temperature and humidity changes, vibration, shock, drafts, and air contaminants.

Analytical balances receive maintenance and are calibrated annually by an outside calibration service, using N.I.S.T. traceable weights. Calibration includes cleaning and inspection of the balance’s internal mechanism.

Calibration, in addition to the annually scheduled calibrations, will be performed at the discretion of the laboratory staff if daily operating checks are not satisfactory or if damage is suspected.

6.3.3 Thermometers

Thermometers are used throughout the lab to monitor ovens, water baths, refrigerators, and to provide standard conditions for analyses. Truesdail Laboratories maintains a number of N.I.S.T. traceable thermometers covering a variety of temperature ranges. The “primary” references are maintained in a secured area and are not available for routine use. All thermometers employed routinely are cross-checked against those reference thermometers on an annual basis. Microbiology Laboratory thermometers (±0.2°C), however, are cross-checked against reference thermometers every six months. Correction factors are noted and each thermometer is tagged noting the next due date for calibration. A copy of our standard form for checking thermometers is found in Appendix B, page B7.
6.4 REAGENTS, SOLVENTS AND GASES

The proper selection, preparation, and storage of chemical compounds is essential to the production of reliable analytical data. The composition of these compounds is a focal point of continuous scrutiny by the analyst. For this purpose, a "method blank" (a blank sample composed of those compounds incorporated into the analysis) is run concurrently with each analysis performed. Errors associated with the use of reagents, solvents and/or gases are minimized by the use of "method blanks", monitored inventory control, and use of proper techniques in the handling and storage of materials.

At any point that a "method blank" fails to perform according to the parameters of the method, an inquiry as to the source of the interference is conducted. Outlined below are the three areas of prominent concern.

6.4.1 Reagents

The purity of the reagents employed in any analysis has a direct effect on the accuracy of the results obtained. Therefore, the registered purity as published by the producer is noted along with other pertinent information (such as lot no., date received, quantity, etc.) to ensure the materials meet the requirements of the purchase orders. The analyst will use reagents of sufficient purity as recommended by the method and/or SOP employed in the analysis.

The labeling of all reagents employed includes compound or mixture name, lot no., date made, or date received, and quantity. Most suppliers also print a list of impurities and all chemicals are now accompanied with hazard information. The hazard information (material safety data sheets) is essential in the safe handling of reagents and is contained in the safety information file. The file is placed in a common area to allow all personnel access to the safety information of the chemicals used in the laboratory.

The preparation of standards and solutions is conducted in accordance with the method employed and all procedures and practices such as standardization, weight tolerances, or physical conditions are followed.

Commercially prepared calibration and stock standards are purchased for all analyses requiring such. Organic standards are purchased from commercial suppliers such as Ultra Scientific, Supelco and Chem Service. Fisher Scientific, Baker, MCB, etc., are the suppliers for inorganic and some metals standards (ACS grade). Calibration standards for metals are purchased from Banco, Fisher and other supply houses. Pesticide grade organic solvents are purchased from Burdick and Jackson and J.J. Baker. All other reagents are supplied as ACS grade by Fisher, Baker, MCB, Mallenkrödt, etc.

All reagents are stored in proper containers recommended by the procedure. Generally, dry chemical reagents are stored in a separate storage area at the rear of the building, in alphabetical order, for easy access. For those reagents with special handling or storage requirements, specific information is outlined in the manual under laboratory safety.
6.4.2 Solvents

The solvents employed at Truesdail Laboratories are certified by the producer as to the grade of solvent, (such as technical, pesticide spectral, etc.). The physical nature of solvents warrant special care in the handling and mixing of solutions. These guidelines are outlined in greater detail in the Laboratory Safety Manual.

Solvents are stored in a special vented, fire-resistant storage room. Small quantities employed in daily use are stored in special storage cabinets under the fume hoods. At no time will a solvent be subjected to an environment not conducive to safety or control.

6.4.3 Gases

A complete list of delivery invoices and contracts with the distributor are logged in the gas logbook. The handling of gas containers, installation of gas lines, or the day to day use in analyses is always conducted under the immediate control of the analyst. All gas lines are regulated with proper equipment and techniques in gas detection. Further information on these techniques are outlined in the Laboratory Safety Manual. All gases are stored in tanks certified by the producer as conforming to state and/or federal regulations. These tanks are stored in the loading dock area of the building for safe and easy access. Any tank brought into the laboratory for routine use is safely secured; i.e., chained or strapped down.
6.5 WATER, AIR, VACUUM, ELECTRICAL SERVICE & VENTILATION

6.5.1 Water

Each room is supplied with one or more sinks with hot and cold running water and deionized water as needed. Spaced periodically throughout the facility are floor drains to accommodate any water overflow. The following types of water are currently in use at Truestail Labs:

- **Deionized Water**
  
The deionized water is supplied by a service exchange deionization system composed of two packed bed ion exchange resin tanks and an activated carbon tank, followed by a particulate filter. This system was installed and is serviced by Pacific Industrial Water. The quality of the water produced by the system meets the specifications listed below. Resistivity is continuously monitored and a light changes color if resistivity is out of specification.

  - Particulates \(<0.1\) mg/l
  - Electrical resistivity \(>10^6\) ohms/cm \(25^\circ C\)

  The resin tanks are changed if the indicator lights show a problem.

- **Sterile Water**
  
Sterile water is produced by autoclaving deionized water at 121°C at 15 psi for 15 minutes. Once a month, Truestail performs a total plate count on the water employed for bacterial analyses. If it is found to be contaminated by any colony forming units, samples are retested after sterility has been reestablished.

- **Reagent Water and Hydrocarbon Free Water (ASTM - DH93, Type 1)**
  
Ultra-high purity water is produced in the laboratory from our standard D.I. water by passing it through a Barnstead "Nanopure" water purification system. The system employs ion exchange resin beds and an activated carbon bed to purify the water. After the resin and charcoal beds, a 0.2 filter removes particulates.

  - Particulate \(<0.2\)
  - Electrical resistivity \(>16\times10^6\) ohms/cm \(25^\circ C\)

  The reagent water is further purified for analyses of volatile (purgeable) organics by sparging with ultra-high purity nitrogen or helium. Bottles of water used for preparation of blanks, calibration solutions, and travel blanks are set up next to the analyses with a continuous purge.
6.5.2 Air

Compressed air available to the laboratory is supplied by an industrial compressor distributed by Ingersol-Rand, Rotary Screw Operations, Davidson, North Carolina. This compressor has a capacity of 125 CFM and a rated operating pressure of 150 PSIG. The compressor contains an oil and water trap, and is supplied with a blow down valve located outside of the laboratory building. This system is serviced by the facilities department as required.

6.5.3 Vacuum

Vacuum is provided by an A-B Industries air cooled, oil sealed, rotary vane pump directly coupled to operate by motor speed. The pumps are serviced and maintained by the facilities department at Truesdail Labs.

6.5.4 Electrical Service

Independent circuits for 110 volt lines are conveniently located throughout the laboratory to provide a safely grounded supply of power. Most hot plates, autoclaves and ovens are supplied with 220 volt lines with independent breakers. Power to sensitive instrumentation with microprocessors, computer systems, etc., are equipped with voltage surge protection and/or regulation as required to insure maximum up-time.

6.5.5 Ventilation

Fume hoods are provided in those rooms where extractions, digestions and distillations are conducted. These hoods have a volume of approximately 16 cubic feet to 30 cubic feet and are supplied with a cupsink, water and gas lines (some with D.I. water). Hood face velocities are checked with calibrated flow meters and with smoke tests to insure proper flows.

6.6 LABORATORY CONTAINERS

In all cases, polyethylene or borosilicate (Pyrex, Kimax) containers are used for storage of standards and reagents, including tinted glass for photosensitive reagents. Most metal stock solutions are stored in polyethylene bottles located in the spectroscopy laboratory, except for those elemental solutions known to react with polyethylene (such as antimony). Disposable glassware is used for instruments that employ autosamplers. Disposable glassware is rinsed prior to use with 10 percent nitric acid for metals analysis, or with reagent water for ion chromatography. Standard solutions of alkalies (silica, boron, and the alkali metals) are stored in polyethylene bottles.
6.7 **Cleaning**

All general glassware is cleaned by washing in detergents (Alconox, Liquinox, and Alcojet) followed by rinsing with tap water and then again with deionized water. After rinsing, the clean glassware is inverted on an open air drying rack. This method supplies clean glassware for most procedures employed; however, further steps are taken for specific analyses. These steps are outlined below according to procedure.

- Glassware used in trace metal analysis is washed with non-ionic detergent, rinsed three times with 10% nitric acid, rinsed three times with deionized water and air dried.
- Glassware used in anion analysis of ammonia, phosphate, nitrate and fluoride are cleaned by continuous rinsing with deionized water for a period of approximately one minute.
- Glassware for use in organic sampling and analyses is rinsed with reagent organic free water prior to being employed. Glassware used in sampling extractions, for standards and in analyses is fired in a ceramics kiln to oxidize any residual organics. After firing, it is stored wrapped in aluminum foil.
- Cells are cleaned with periodic soaking in non-ionic detergent followed by rinsing with deionized water and allowed to air dry. Glassware for critical low level determinations can also be rinsed with reagent/hydrocarbon free water.
- Glass bottles used for sample collection are cleaned with non-ionic detergent, tap water, and deionized water. Glassware used for sampling low level volatile organics determinations (such as drinking water) is treated as an expendable. Precleaned glassware that has been Q.C. inspected is purchased from major vendors (I-Chem, Eagle-Picher), used once and discarded.
SECTION 7 – CORRECTIVE ACTION

7.1 Nonconforming Incoming Chemicals and Supplies

In the event items are received defective, not as ordered or otherwise unacceptable, the responsible party shall notify the purchasing department as needed and the vendor to arrange for return. Such items shall be segregated from acceptable chemicals and supplies either by tag or physical placement to preclude their use.

7.2 Out of Control Procedures

Methods for establishing and updating limits for data acceptability are described in Appendix E. Standard control charts for each method contain the information necessary for determining when a process is out of control.

When a result for a quality control sample indicates that a measurement system is out of control, the series of actions described in Table 1 will be initiated. The tests are performed in order, until the cause of the out-of-control situation is found, then the remedial action listed for that cause will be taken. A corrective action form is filled out describing the initial indication of the out-of-control situation, the cause that was discovered, and the actions taken to return to control.

All corrective action forms must be filled out and signed by the analyst who took the corrective action. They must be reviewed and initialed by the applicable department manager. All procedures can be reviewed and initialed by the Technical Director. An example of a corrective action form is given in Appendix B.
Table 1: Out of Control Procedures

<table>
<thead>
<tr>
<th>Suspected Cause</th>
<th>Test</th>
<th>Remedial Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mathematical Error (Bookkeeping – right values for parameters)</td>
<td>Check Calculations</td>
<td>Correct error and continue analysis</td>
</tr>
<tr>
<td>Quality Control Check (or instrument check) Sample deviates from expected concentration</td>
<td>Prepare fresh Quality Control check sample and analyze</td>
<td>Proceed with analysis</td>
</tr>
<tr>
<td>Instrument Calibration</td>
<td>Make new calibration standards, recalibrate reanalyze quality control check sample</td>
<td>Reevaluate all environmental samples just preceding bad Q.C. result. If new result deviated by more than 25% and client specifications require tight precision, then reanalyze all samples since last valid Q.C. result.</td>
</tr>
<tr>
<td>Instrument Maintenance Required</td>
<td>Perform instrument maintenance as required in SOP manual. Perform sensitivity checks and recalibrate</td>
<td>Reanalyze all samples since last valid Q.C. result</td>
</tr>
</tbody>
</table>
7.3 **Correcting Test Reports**

If a customer should request a corrected test report, this request shall be evaluated at Truesdail by the person who signed and submitted the test report to the customer. If corrective action is deemed necessary by Truesdail Laboratories, a "CORRECTED REPORT" will be issued. A "CORRECTED REPORT" should be clearly labeled in order to distinguish it from the original report. A "CORRECTED REPORT" shall have the same laboratory number previously stated in "Reporting Procedure".

7.4 **Notice of Out of Calibration Conditions**

In the event that an inspection gage or instrument is found to be out of calibration when recalibrated, the department supervisor shall be notified and a record of the condition shall be made in the calibration file for the device. The supervisor then directs the action which often involves the department or group manager, the quality department and the maintenance/facilities department. The impact of accuracy of results on products tested or examined by equipment found to be out of tolerance during calibration will be determined. Appropriate corrective action will be taken to correct possible reporting errors. The calibration interval of the measuring or test equipment shall be adjusted to prevent recurrence.

7.5 **Notification to Clients**

Clients shall be notified of any out of calibration conditions, which affect results submitted to them. Clients will also be notified of any deviation from requirements listed in purchase orders or contracts.
SECTION 8 – EXTERNAL QUALITY ASSURANCE ACTIVITIES FOR ENVIRONMENTAL SAMPLES

Truesdail Laboratories participates in a number of external programs which provide our independent assessment of the laboratories capabilities. Appendix E gives some examples of reports which we routinely receive from the various auditing programs.

Water and Waste Analysis: We participated in the WS and WP audit programs from EPA Cincinnati. We also participated in the radiation audit program from EPA Las Vegas. For bulk asbestos determinations, we participated in the AIHA PAT program.

Industrial Hygiene: Truesdail Laboratories participates in the Proficiency Analytical Testing Program (PAT) sponsored by the National Institute for Occupational Safety and Health (NIOSH).

Air Analysis: The Environmental Protection Agency sponsors an Air Pollution audit program through its facility in Research Triangle Park, N.C. Also related to air pollution audits are results for fuel analyses.

Since 2000, we have participated in commercial P.E. programs for drinking water, waste water, solid waste. Microbiological P.E. have been from commercial sources starting in 2000. Examples of our results follow in Appendix E.
### QUALITY ASSURANCE/PERFORMANCE EVALUATION RESULTS

Listed below is a summary of our EPA Performance Evaluation results through 1998.

#### EPA WS - Drinking Water Proficiency Testing

<table>
<thead>
<tr>
<th>Date</th>
<th>Round</th>
<th># of Parameters Reported</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>9/98</td>
<td>041</td>
<td>100</td>
<td>90%</td>
</tr>
<tr>
<td>3/98</td>
<td>040</td>
<td>100</td>
<td>98%</td>
</tr>
<tr>
<td>10/97</td>
<td>039</td>
<td>89</td>
<td>99%</td>
</tr>
<tr>
<td>4/97</td>
<td>038</td>
<td>89</td>
<td>97%</td>
</tr>
<tr>
<td>10/96</td>
<td>037</td>
<td>67</td>
<td>97%</td>
</tr>
<tr>
<td>11/95</td>
<td>036</td>
<td>99</td>
<td>88%</td>
</tr>
<tr>
<td>4/95</td>
<td>035</td>
<td>101</td>
<td>84%</td>
</tr>
<tr>
<td>10/94</td>
<td>034</td>
<td>92</td>
<td>95%</td>
</tr>
<tr>
<td>2/94</td>
<td>033</td>
<td>82</td>
<td>92%</td>
</tr>
<tr>
<td>8/93</td>
<td>032</td>
<td>77</td>
<td>87%</td>
</tr>
<tr>
<td>2/93</td>
<td>031</td>
<td>66</td>
<td>100%</td>
</tr>
<tr>
<td>8/92</td>
<td>030</td>
<td>70</td>
<td>83%</td>
</tr>
</tbody>
</table>

#### EPA WP - Wastewater Proficiency Testing

<table>
<thead>
<tr>
<th>Date</th>
<th>Round</th>
<th># of Parameters Reported</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>03/00</td>
<td>040</td>
<td>75</td>
<td>96%</td>
</tr>
<tr>
<td>6/98</td>
<td>039</td>
<td>75</td>
<td>96%</td>
</tr>
<tr>
<td>12/97</td>
<td>038</td>
<td>75</td>
<td>99%</td>
</tr>
<tr>
<td>5/97</td>
<td>037</td>
<td>75</td>
<td>97%</td>
</tr>
<tr>
<td>12/96</td>
<td>036</td>
<td>75</td>
<td>99%</td>
</tr>
<tr>
<td>5/96</td>
<td>035</td>
<td>62</td>
<td>100%</td>
</tr>
<tr>
<td>10/95</td>
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<td>98%</td>
</tr>
<tr>
<td>3/95</td>
<td>033</td>
<td>146</td>
<td>95%</td>
</tr>
<tr>
<td>8/94</td>
<td>032</td>
<td>150</td>
<td>97%</td>
</tr>
<tr>
<td>12/93</td>
<td>031</td>
<td>143</td>
<td>96%</td>
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<td>6/93</td>
<td>030</td>
<td>138</td>
<td>90%</td>
</tr>
<tr>
<td>12/92</td>
<td>029</td>
<td>138</td>
<td>99%</td>
</tr>
<tr>
<td>6/92</td>
<td>028</td>
<td>141</td>
<td>94%</td>
</tr>
</tbody>
</table>
SECTION 9 – PURCHASING AND RECEIVING

9.1 MATERIAL AND EQUIPMENT PROCUREMENT

9.1.1 Purchase Requests

Routine replacement of chemicals, glassware, small hardware, etc. are initiated by any staff member by notifying the purchasing agent. Requests for new equipment or apparatus procurement involving $250 or less, capital expenditure will be made to a supervisor or department head for approval. Major (over $500) new equipment requests will be made in writing on the capital expenditure requisition form by department heads and submitted to the President for approval.

9.1.2 Purchase Orders

Purchases of chemicals and supplies shall be made by purchase order. The majority of purchase orders are made verbally but assigned a sequential number. A record of the order is maintained by the purchasing department. The record contains the purchase order number, date of order, supplier and items covered. The purchase order shall indicate the responsible recipient of the order. All chemicals or substances requiring certification will be procured per the specification required for the material and the purchase order will reflect these requirements. This is usually the catalog number of the chemical procured for which quality requirements are then traceable through the chemical catalog. Chemicals will be procured with reference to their standards. Purchase of outside services shall be made by written purchase order. Technical and quality requirements shall be stated as required. In no event shall nuclear safety related work be subcontracted without authorization of the Quality Assurance Manager. Any shipping of test samples shall be done in a manner that prevents contamination, damage, or loss and minimizes deterioration.

9.1.3 Repair and Replacement of Apparatus

The need of repair or adjustment of an apparatus will be reported at once to a supervisor or department head who will decide (after consultation with others) whether the equipment can be repaired either in-house or outside the facility, or should be replaced.

9.1.4 Quality Assurance Personnel

QA personnel are not involved in the procurement of ordinary laboratory chemicals, supplies, or apparatus.
9.2  APPROVED VENDORS

9.2.1 Selection of suppliers

Supplier selection will be based on historical performance and/or on-site surveys. Subcontractor approval for safety related testing services is covered in our Standard Operating Procedures Manual.

For subcontracted testing, Truesdail will review our clients requirements from either a purchase order or contract to make sure that the requirements are passed down to subcontractors and that the subcontractors have the capabilities to perform the work. Truesdail will be responsible for subcontracted work and the results from subcontractors will be reviewed to ensure adherence. Approval of laboratories by DOHS ELAP or NELAC programs may be substituted for on-site audits of subcontractors. Clients will be made aware of subcontracted work and their approval will be obtained as required.

9.2.2 Calibration Services

Quality Assurance personnel shall verify by survey the certification systems of outside calibration services that are used. This includes manufacturers who calibrate their own manufactured equipment. The outside calibration vendors shall be audited every two years. These audits may be extended by the quality assurance manager to permit convenient scheduling. Exceptions to this requirement are recognized government agencies serving as a branch of the National Institute of Standards and Technology (NIST).

9.2.3 Quality Assurance Personnel

QA personnel shall maintain a list and/or file of qualified vendors.

9.3  RECEIVING INSPECTION

Receiving of Chemicals and Supplies

Incoming items are logged in the receiving record for purposes of record of receipt and destination only. Receiving assures that material received corresponds with that ordered and that necessary labelling or certifications are included on all shipments. They are routed to the appropriate department or laboratory where they are inspected for content and condition. Shippers of items received in damaged condition shall be notified by telephone followed by a written confirmation. General use chemicals are inspected and preferably, dated prior to stocking (see Section 11 on Age Control). Packing slips are forwarded to Accounts Payable. Invoices correlated with the packing slips are approved by the person who requested the supply and then forwarded to Accounts Payable. The record of these inspections is manifested by the approval of invoices and is maintained in the “Accounts Payable” files.
SECTION 10 – DOCUMENT CONTROL

10.1 IN-HOUSE CONTROLLED DOCUMENTS

All controlled in-house procedures shall be dated and signed and reflect latest revision.

A list of all in-house controlled documents shall be maintained by the Quality Assurance Manager and/or the Technical Director.

Uncontrolled in-house procedures shall be noted as such.

It shall be the responsibility of each department manager to prepare, review, approve and issue documents and changes thereto relative to their department.

10.2 QUALITY RELATED DOCUMENTS

All quality related documents shall be reviewed for adequacy, approved for release by authorized personnel and properly distributed. Changes to documents shall receive the same degree of review and approval as original documents.

10.2.1 Quality Assurance Manuals

- Maintenance and distribution of the Quality Assurance Manual shall be the responsibility of the Quality Assurance Manager.

- Maintenance and distribution of the Environmental Quality Assurance Manual shall be the responsibility of the Technical Director.

- The distributions shall be controlled by distribution logs which include manual number, company name, address, date sent, date acknowledgment received and revision sent.

- When the quality assurance manual is revised, it shall be reviewed by the Technical Director and Quality Assurance Manager. It shall be approved by the Quality Assurance / Quality Control Manager, Technical Director and the President.

- Once the manual is approved, it shall be released and sent to controlled copy holders within 30 days.

- A letter of acknowledgment shall include instructions to dispose of superseded, obsolete or voided sections of the Quality Assurance Manual.

10.3 JOB RELATED DOCUMENT CONTROL

This subject is covered in Section 2.9.2.
SECTION 11 – AGE CONTROL

11.1 INCOMING CHEMICALS AND SUPPLIES

Procured items subject to age deterioration shall be dated upon receipt and the expiration date shall be indicated. It is preferred that all chemicals not rapidly consumed in the course of testing be dated upon stocking and dated when opened.

11.2 MEASUREMENT STANDARDS

Standard materials subject to age deterioration or otherwise dated as expired, shall not be used as primary standards after their expiration date. Such materials may be used as check standards providing that additional primary standards are used as appropriate.

11.3 TEST SAMPLES

Test samples shall be kept for three months and then disposed either by returning to the client or in accordance with state and local requirements.

Samples of a useful nature may be used as appropriate in the laboratory. Samples such as consumer items may be removed from company premises by employees with written permission from the department supervisor.
SECTION 12 – HOUSEKEEPING, SAFETY AND
ENVIRONMENTAL CONTROL

12.1 Truesdail Laboratories shall maintain all work areas relating to the function of any testing
area, handling area, or other related areas in a clean and orderly fashion so as not to
impair the process of obtaining reliable data or to interfere with the control and
identification of materials being processed.

All areas of operation shall be kept safe for workers.

Many chemicals in the laboratory are inherently unsafe. They cannot be made safe. Use
and handling shall be performed in accordance with Truesdail Laboratories Safety
Manual Rev. 2 or current.

The laboratory is temperature controlled within a normal range of 70-74°F during normal
working hours. Timer switches are located adjacent to thermostats for operation at night
or on weekends. Twenty-four hour environmental control is available as needed for
special sample and/or apparatus conditioning.

12.2 The Laboratory Managers are responsible for the overall cleanliness of the facility. They
are also responsible for the monitoring and control of environmental conditions relative
to test requirements.

12.3 The chemists and technicians operating in each area are responsible for maintaining
clean and safe work conditions in their work area.

12.4 The Technical Director shall make periodic inspections and direct the staff as needed.
No record of these inspections is required.
SECTION 13 – LABORATORY CERTIFICATIONS FOR ENVIRONMENTAL TESTING

Sample Certificates and letters from various certifying organizations are given in Appendix F.

We are currently certified or accredited by the following organizations:

- California Department of Health Services for analyses of Drinking Water, Wastewater, and Hazardous Waste.
- American Industrial Hygiene Association for industrial hygiene testing.
- California Air Resources Board for air pollution source testing.
- South Coast Air Quality Management District for air pollution source testing.
- U.S. Navy NEESA program.
- L.A. County Sanitation District.
- International Association of Plumbing and Mechanical Officials (IAPMO) for faucet testing.
- AHERA Inspector certification.
APPENDIX A – LIST OF PERSONNEL

A.1 PRINCIPAL OFFICERS

President and Member of the Board
Chairman of the Board
Secretary and Treasurer
Member of the Board

John C. Hill, Ph.D.
James A. Charley, Ph.D.
Linda C. Hill
William J. Charley

A.2 PRINCIPAL MANAGERS

President
Technical Director
Controller
Manager of Analytical Services

John C. Hill, Ph.D.
Norman E. Hester, Ph.D.
Mareda Murray
Mona Nassimi

A.3 ANALYTICAL SERVICES GROUP

Manager

Mona Nassimi, M.S.

A.3.1 Group Managers

Instrumental Methods
General Chemistry
Microbiology
Air Analysis
Field Services
Radiochemistry
Metals
Wet Chemistry

Harvey Abernatha
Ali Kharrazi, M.S.
Julie Tessener
Mark Kotani
Felipe Reyes
Rossina Tomova, M.S.
Riddhi Patel
Hope Trinidad
A.4  **RACING CHEMISTRY**
Manager
Chris Nattrass, B.S.
Chief Pharmaceutical Chemist
Robert E. Vessiny, B.S.
Assistant Manager
Julie Hagihara, B.A.

A.5  **MECHANICAL TESTING**
Manager
Pat Iyer, Ph.D., P.E.

A.6  **FORENSICS DEPARTMENT**
Engineer
Gordon Banerian, Ph.D., P.E.

A.7  **QUALITY DEPARTMENT**
Quality Assurance and Control
Pat Iyer, Ph.D., P.E.

A.8  **SAFETY DEPARTMENT**
Safety Officer
Mareda Murray, B.A.

A.9  **FACILITIES DEPARTMENT**
Manager
Harvey Abernatha, B.A.
APPENDIX B – SAMPLE FORMS

B.2-4 Quality Assurance Audit
B.5 Q.A. Corrective Action Request
B.6 Controlled Stamp Record
B.7 Calibration History Record
B.8 Laboratory Record “Green Sheet”
B.9 Laboratory Workbook Record
B.10 Survey Checklist – Calibration Services
B.11 Chain of Custody Form
B.12 Sampling Guide
CONTROLLED STAMP RECORD
CALIBRATION HISTORY RECORD