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Technology Development Laboratory Operations

QUALITY ASSURANCE MANUAL

Laboratory - Specific Attachment

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TDL 1.0 INTRODUCTION

The Technology Development Laboratory (TDL) differs greatly from other IT Analytical Services (ITAS) Laboratories due to the wide variety of speciality services provided by the group. In addition to providing unique analytical services, (such as analysis of chlorinated dibenzo-p-dioxins and dibenzofurans) TDL performs treatability testing from bench scale testing up to full-size testing demonstrations. When needed, methodologies can be developed and tested for unique situations and matrices.

Due to the variety of TDL procedures, some routine ITAS Quality Assurance (QA) practices may not be readily applicable. On the other hand, many QA practices which are not implemented in a standard analytical laboratory will be necessary for QA in TDL. Many of these additional QA procedures are of a "project planning" nature and will follow a format similar to the IT Environmental Projects Group Engineering Operations QA Manual (QAM). These considerations make this Laboratory-Specific Attachment to the ITAS QAM both vital in its contribution to the QA program for TDL and unique in relation to other laboratory-specific attachments.

ITAS has developed a QA Program applicable to all analytical laboratories within IT Corporation (IT). The Program, as documented in the ITAS QAM, describes the activities to be undertaken by a laboratory so that data of acceptable quality are produced.

The ITAS Program recognizes that some QA activities must be detailed and adopted on a laboratory-specific basis. Also, certain practices described in the ITAS Program may require adoption by a laboratory for implementation because of necessary individual operations. To document individual laboratory QA practices, the ITAS Program requires the preparation of a laboratory-specific attachment to the ITAS QAM.

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The TDL is part of ITAS and is located at 304 Directors Drive, Knoxville, Tennessee. The organization of TDL with respect to the rest of ITAS is shown in Figure 1.1.

The manual contained herein is the laboratory-specific attachment for the ITAS TDL operations. As required by the ITAS QA Program, this attachment is a supplement to, and is incorporated with, the ITAS QAM to provide the QA Program for the TDL operations.

TDL 1.1 Format of the Attachment

The laboratory-specific attachment is formatted in the same manner as the ITAS QAM so that personnel in TDL operations can readily merge the requirements of the ITAS QAM and this document. Section headings for both documents are the same with the exception that this attachment uses the section prefix TDL so that attachment sections are clearly delineated. Section 17, Project Planning, has been added to this laboratory-specific attachment and has no counterpart in the ITAS QAM.

Since the attachment is not meant to be a self-standing document, the ITAS QAM must be included with the attachment to fully describe the laboratory-specific QA Program. In the event that the attachment describes an alternative means for implementation when compared with the manner prescribed in the ITAS QAM, the implementation described in this attachment shall prevail for TDL. Review and approval of the attachment, as prescribed by the ITAS QAM, demonstrates that the practices described in this manual are in accordance with the requirements of the ITAS QA Program.

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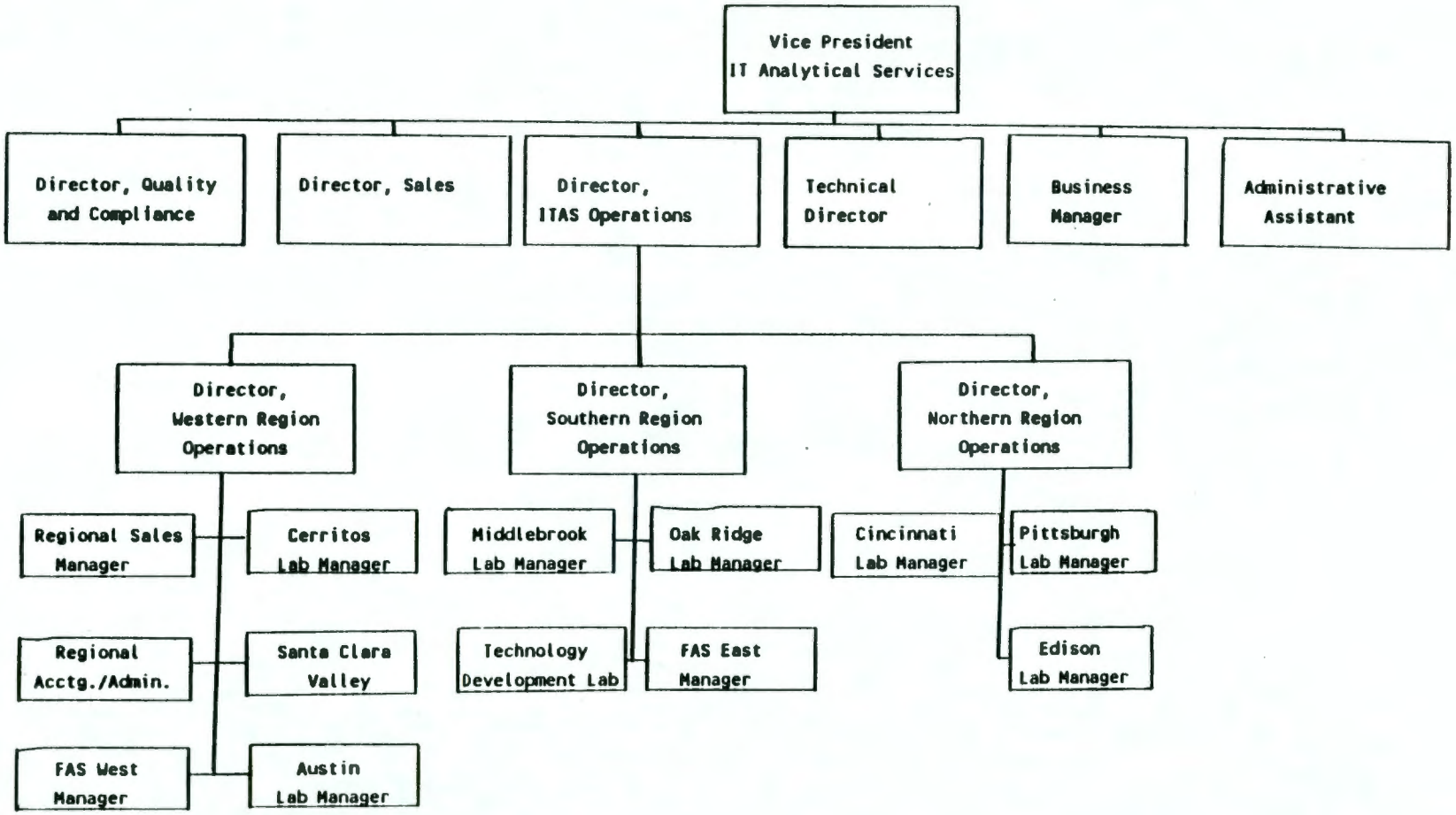
Figure 1.1
ITAS Organizational Chart



TDL 2.0 ORGANIZATION

Organization responsibilities in TDL are unlike that of most ITAS labs. Many persons within TDL are responsible for duties which normally fall to several different people in larger analytical labs. Relationships of responsibilities for TDL are shown in Figure TDL 2-1.

The quality-related responsibilities assigned to the laboratory manager and the operations manager, in the ITAS QA Manual, will be the responsibility of the Director of Technology Development Laboratory. TDL group leaders will take on responsibilities normally assigned to technical directors as well as those of group leaders. A listing of quality-related responsibilities follows:

- Director
  - Reports directly to Vice President, IT Analytical Services, or Regional Director Analytical Operations
  - Implements the Quality Assurance Program within the laboratory
  - Periodically determines the effectiveness of the Quality Assurance Program in the laboratory
  - Approves Laboratory-Specific Attachments to the Quality Assurance Manual and Project-Specific Manuals (QAPPs), SOPs, and revisions
  - Recommends to the Quality Assurance/Control Director, ITAS, changes in the Quality Assurance Program
  - Maintains current laboratory organization chart
  - Supervises laboratory participation in inter-laboratory accreditation and proficiency programs.
  - Prepares/Reviews Quality Assurance Project Plans*
- Operations Manager
  - Approves final issuance of laboratory reports*
  - Manages laboratory daily analytical and treatability testing operations
  - Supervises Quality Control activities performed as part of routine operations
  - Consults on development of experimental plans*

*Can be performed by Distinguished Technical Associate or Senior Process Consultant if designated by Director.

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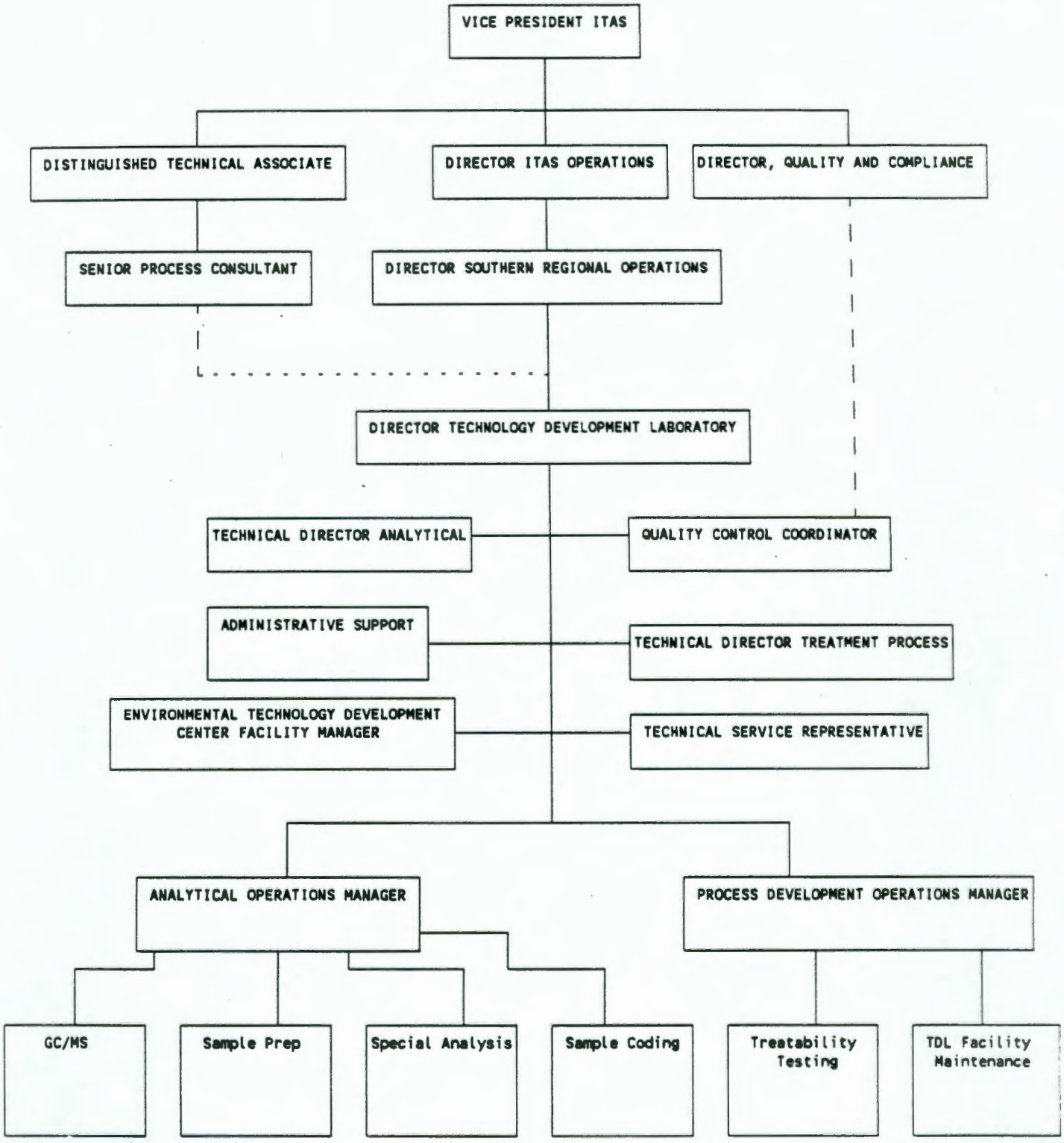
FIGURE 2.1

TECHNOLOGY DEVELOPMENT LABORATORY ORGANIZATIONAL CHART



- Reviews experimental plans for technical correctness and safety*
- Supervises the preparation and maintenance of laboratory records
- Oversees preventive maintenance program.
- Organizes and schedules the analytical testing program with consideration for sample-holding times
- Implements data verification procedures
- Assigns analysts for data processing and validation activities
- Reviews and approves all analytical data and submits to Director for issue
- Evaluates instrument performance and supervises instrument calibration and preventive maintenance programs
- Reports out-of-control or nonconforming situations to Director and Quality Control Coordinator as appropriate.

• <u>Technical Director</u>

- Provides technical overview of laboratory activities
- Serves as an "in-house" consultant for the applicability of general Quality Control practices to specific needs
- Leads the training of analysts, engineers and technicians in laboratory operations and analytical procedures
- Evaluates analytical techniques, procedures, instrumentation and Quality Control procedures, and provide recommendations to the Laboratory Director
- Supervises the verification of software for data processing
- Recommends standards for purchasing instrumentation, equipment, reagents, gases, and chemicals
- Defines the instrument preventive maintenance schedule
- Defines the calibration program within the laboratory

- Quality Control Coordinator:

  - Prepares Quality Control standards, arranges insertion of Quality Control samples into the laboratory sample stream, and reviews the results

  - Performs statistical analyses utilizing results of QC samples analyses

  - Informs the Director and Group Leaders of data which lies outside of acceptable limits

  - Serves as the "focal point" for reporting and disposition of nonconformances; verifies corrective action

  - Resolves ongoing and recurring nonconformances within the Laboratory

  - Recommends corrective actions for resolution of nonconformances; verifies corrective action

  - Reviews statistical data to verify the laboratory is meeting stated Quality Control goals

  - Maintains current distribution lists for Laboratory-Specific Attachments and Project-Specific Manuals and Standard Operating Procedures

  - Closes findings and recommendations of Quality Assurance Audits

  - Notifies the Director of out-of-control situations

  - Stops production of data in a laboratory area where the review of quality control data or procedures shows significant problems

  - Reports nonconformances to the ITAS Director of Quality and Compliance or the Director, Quality Assurance, Environmental Project Group if the situation is not corrected within the Laboratory

  - Assists in the performance of Quality Assurance audits and performs Quality Control audits.

  - Establishes and supervises the laboratory Quality Assurance training program.

- Analysts/Engineers/Technicians

  - Performs procedures and data recording in accordance with accepted methods

  - Performs and documents calibration and preventive maintenance of instrumentation, as appropriate

  - Performs data processing and validation

  - Immediately reports out-of-control situations, instrument malfunction, calibration failure, or other nonconformances to the Group Leader and Quality Control Coordinator, as appropriate.

- Sample Coordinator

  - Oversees the log-in of all samples received, completion of chain-of-custody records, and maintenance of sample logs.

  - Supervises sample storage

TDL 3.0 STANDARD LABORATORY PRACTICE

Standard procedures as well as new or experimental procedures will conform to standard laboratory practice as much as possible in TDL. Exceptions will be noted on an individual basis in the project plan.

The basic steps of standard laboratory practice modified for TDL organization are outlined in Table TDL 3-1.

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TABLE TDL 3-1

EXPERIMENTAL FLOW CHART

STEP NO.	DESCRIPTION	PERFORMED BY	DOCUMENTS USED OR PRODUCED
1	SAMPLE ARRIVES AT LABORATORY	Sample Coordinator	Chain-of-Custody Request for Analysis
2	SAMPLE(S) ARE UNPACKED AND INSPECTED AND PAPERWORK VERIFIED FOR COMPLETENESS. SAMPLES ARE NUMBERED AND PLACED IN STORAGE.	Sample Coordinator	Chain-of-Custody Request for Analysis Field Records
3	INTERNAL PAPERWORK INITIATED	Sample Coordinator	
4	SAMPLE(S) ARE SCHEDULED FOR EXPERIMENTATION	Operations Manager or Designated Project Manager	Sample Tracking Book, Analysis Schedule Form, Sample Tracking Sheets
5	SAMPLE(S) PROJECT FILE PREPARED	Administrative Support	Chain-of-Custody Request for Analysis Special Instructions from Client Price Quotes
6	SAMPLE(S) INFORMATION ENTERED INTO COMPUTER SYSTEM	Sample Coordinator	Computer Printout
7	EXPERIMENT PERFORMED	Chemists/Engineers	Sample Tracking Sheets, Logbook, Data Sheets, Maintenance Log.
8	RESULTS ANALYZED	Chemists/Engineers Chemists	Sample Tracking Sheets, Data Sheets

TABLE TDL 3-1 (continued)

EXPERIMENTAL FLOW CHART

STEP NO.	DESCRIPTION	PERFORMED BY	DOCUMENTS USED OR PRODUCED
9	DATA REVIEW/QC REVIEW	Chemists/Engineers Group Leader QA/QC Coordinator	QC Review Check-list
10	REPORT TO CLIENT	Lab Director Operations Manager	Final Report
11	RECORD MANAGEMENT	Administrative Support	All previously mentioned documents

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TDL 4.0 MATERIAL PROCUREMENT AND CONTROL

The quality of reagents, solvents, gases, water and laboratory vessels will be closely monitored due to the potential impact on experimental test results.

TDL 4.1 Air - Precautions are taken at the compressor to protect the quality of compressed air produced in-house. At the point of use, compressed air is passed through filters as needed depending upon the needs of the analyst or instrumentation.

TDL 4.2 Water - Deionized water is monitored to meet ASTM Type II water quality standards. A daily log book is kept to document requirements have been met.

TDL 4.3 Purchased Items (General) - Project Managers and Group Leaders are responsible for controlling and confirming quality in purchase orders at TDL. Individual project managers and group leaders are responsible for specifying the quality grade requirements for individual items with consent of the Quality Control Coordinator when necessary. The project manager will make the decision based on method requirements, project requirements and experience. The project manager is also responsible for verifying materials received meet requirements specified and overseeing proper storage after receipt.

Group leaders are responsible for overseeing purchase orders to verify suitable grades of materials are being ordered, received, labeled and stored. The group leader should see that certificates which come with certified materials are filed in the Quality Operations files. Materials should be removed when shelf life has expired.

TDL 4.4 Purchased Items and Services (Projects) - The control of purchased items and services shall, as appropriate to the specific project and each individual procurement, include:

- Prequalifications of subcontractor
- Bid evaluation
- Procurement source evaluation and selection
- Subcontractor performance verfication.

Control is provided by Purchasing, Project and Quality Assurance personnel. It shall be applied as necessary to verfity that an item or service conforms with the procurement documents. Items which do not meet Quality Assurance requirements shall not be accepted.

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TDL 5.0 SAMPLE HANDLING

Laboratory treatment tests and sample analyses are performed to produce data representative of conditions which existed at the time of sample collection or experimental testing. To provide representative samples for analysis, both field and laboratory procedures must be satisfactorily followed.

TDL 5.1 Field Collection and Shipment

To provide representative samples for testing or analysis, standard operating plans and project plans must be designed with that purpose in mind. The procedures must then be followed carefully to provide for sample integrity.

Prior to collecting samples, consideration must be given to the testing to be performed and the "hazard level" of the media being sampled so that proper sample containers and shipping containers can be assembled and the proper preservatives added to samples. In addition, field logs and record sheets, Chain of Custody forms, and Request for Analysis records must be assembled. All records required for documentation of field collection must be completed by the field team.

Field collection also includes uniquely identifying and labeling samples and packaging to preclude breakage during shipment. The interval between acquiring the sample and testing (holding time) should be monitored to assure representation of the sample.

High hazard (medium/high concentration) samples must be packaged according to DOT regulations. The ITAS Manual of Practice: "Sample Packaging and Shipment" should be used, in conjunction with 49 CFR, parts 100-177, when packaging hazardous samples. The manual also presents detailed instructions on packaging non-hazardous or environmental samples.

TDL 5.2 Chain of Custody/Request for Analysis

All samples shipped by TDL personnel or received at TDL should be accompanied by a Chain-of-Custody (example given in figure TDL 5-1) and a Request for Analysis (example given in figure TDL 5-2). Upon receipt, the sample coordinator will:

- Compare samples received against those listed on the Chain-of-Custody,
- Verify that sample holding times have not been exceeded,
- Note condition of samples upon receipt,
- Sign and date the Chain-of-Custody form and file with waybill, and,
- Initiate corrective measures for samples received without proper paperwork.

TDL 5.3 Receipt

After checking the samples and noting condition on the Chain-of-Custody, the Sample Coordinator enters all appropriate sample and project information in the sample tracking log book (example form given in figure TDL 5-3). The project manager is then informed of their location. As needed, laboratory blanks, duplicates and other QC samples are added to the project by the Sample Coordinator in accordance with the project manager's instructions.

TDL 5.4 Storage

Samples will be stored in laboratory refrigerators, freezers or properly ventilated areas for a period not to exceed six months after receipt, unless the client has made special arrangements for samples to be kept longer. Fate of samples should be agreed upon by the client at the onset of a project.

INTERNATIONAL TECHNOLOGY CORPORATION

Figure TDL 5-1

CHAIN-OF-CUSTODY RECORD

R/A Control No. _____

C/C Control No. A 93064

PROJECT NAME/NUMBER _____ LAB DESTINATION _____

SAMPLE TEAM MEMBERS _____ CARRIER/WAYBILL NO. _____

Sample Number	Sample Location and Description	Date and Time Collected	Sample Type	Container Type	Condition on Receipt (Name and Date)	Disposal Record No.

Special Instructions: _____

Possible Sample Hazards: _____

SIGNATURES: (Name, Company, Date and Time)

1. Relinquished By: _____

   Received By: _____

2. Relinquished By: _____

   Received By: _____

3. Relinquished By: _____

   Received by: _____

4. Relinquished By: _____

   Received By: _____

WHITE - To accompany samples
YELLOW - Field copy

Figure TDL 5-2

INTERNATIONAL TECHNOLOGY CORPORATION

REQUEST FOR ANALYSIS

R/A Control No. B 96874
C/C Control No. _____

PROJECT NAME _____
PROJECT NUMBER _____
PROJECT MANAGER _____
BILL TO _____

PURCHASE ORDER NO. _____

DATE SAMPLES SHIPPED _____
LAB DESTINATION _____
LABORATORY CONTACT _____
SEND LAB REPORT TO _____

DATE REPORT REQUIRED _____
PROJECT CONTACT _____
PROJECT CONTACT PHONE NO. _____

Sample No.	Sample Type	Sample Volume	Preservative	Requested Testing Program	Special Instructions

TURNAROUND TIME REQUIRED: (Rush must be approved by the Project Manager)

Normal _____ Rush _____ (Subject to rush surcharge)

POSSIBLE HAZARD IDENTIFICATION: (Please indicate if sample(s) are hazardous materials and/or suspected to contain high levels of hazardous substances)

Nonhazard _____ Flammable _____ Skin Irritant _____ Highly Toxic _____ Other _____ (Please Specify)

SAMPLE DISPOSAL (Please indicate disposition of sample following analysis. Lab will charge for packing, shipping, and disposal)

Return to Client _____ Disposal by Lab _____

FOR LAB USE ONLY

Received By _____ Date/Time _____

WHITE - Original, to accompany samples
YELLOW - Field copy

TDL 5.5 Sample Tracking

Samples should be tracked from field personnel to the laboratory by means of a Chain-of-Custody record. If samples are sent from the TD laboratory to any other site, a Chain-of-Custody record will accompany the samples. The sample tracking log book (example shown in figure TDL 5-3) will show storage location of the sample as well as the project manager responsible for the sample while it is in the TDL. The samples fate will also be recorded in this tracking log book.

Documentation of Chain-of-Custody and Disposal (if any) will be kept in the project file for that sample.

TDL 5.6 Treatability Study Accountability

A daily account must be kept on the Treatability Study Monthly Accountability Form (an example of this form is in figure TDL 5-4) during Treatability Studies in order to maintain compliance with state and Federal guidelines. The project manager is responsible for keeping the form up to date and the TDL director or his designee conducts inspections to be sure compliance is maintained.

TDL 5.7 Initiation of Testing

Initiation of testing is the responsibility of the project manager. The project manager is informed by the sample coordinator when samples are received. The project manager initiates testing keeping in mind any holding times which need to be met.

TDL 5.8 Disposal

The types of waste handled and generated by TDL vary greatly and unlike most laboratories TDI handles large quantities at times for treatability studies. For these reasons, it is necessary for

Figure TDL 5-3

TECHNOLOGY DEVELOPMENT LABORATORY
SAMPLE TRACKING

Project Name						
Project Number						
TDL Sample #						
Client Sample #						
Sample Quantity						
Sample Matrix						
Date Received						
Date Due						
Storage Location						
Project Manager						
EPA ID #						
Sample Fate						
Report Date						
Date Billed						

Sample Fate Codes:
DD - drummed and disposed of
SC - sent back to client
CE - completely used up or destroyed in extractions
TR - treated and rendered non-hazardous

Figure TDL 5-4

TREATABILITY STUDY MONTHLY ACCOUNTABILITY FORM

CLIENT_____ PROJECT NO._____

EPA ID#_____ PROJECT NAME_____

PROJ. MGR._____ MONTH_____ 19_____

The following information must be continually updated and the original copy kept in the MASTER TREATABILITY FILE. This information must be kept for three (3) years after the study has been completed.

DAY OF MO.	AMOUNT OF AS RECEIVED WASTE ON SITE	AMOUNT OF WASTE TREATED TODAY	PROCESS TREATMENT RATE	AMOUNT OF RESIDUE ON SITE	AMOUNT OF RESIDUE RETURNED TO GENERATOR	AMT OF RESIDUE SHIPPED OUT FOR DISPOSAL	DATA ENTERED BY
01							
02							
03							
04							
05							
06							
07							
08							
09							
10							
11							
12							
13							
14							
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TDL 5.8 Disposal (continued)

TDL's Waste Disposal Coordinator to maintain a waste packaging area (pre-drumming) to handle sorting and packaging of waste to be sent off site. The Waste Disposal Coordinator completes a "Drum Information Sheet" (example of sheet is in figure TDL 5-5) which is filed in the TDL Quality/Operations files Disposal and date is also noted in the sample tracking log book under "sample fate".

Shipments are made at least once every three months. A copy of the certification of incineration (or other disposal technique) is kept in the Quality/Operations file and in the project file if necessary. When certification of incineration of a sample is required by the client, the Waste Disposal Coordinator sends a copy of the certification to the client.

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Figure TDL 5-5

DRUM INFORMATION SHEET

Drum No._____ Arrival Date_____ (N/A)_____

Drum Type_____ Gross Wt._____

Project Name_____

Project No._____

Recieved From_____

Shippers ID# _____

Chemical/Hazardous Material Name_____

Lab Pack ( )Y/N

Description:

Note: "Lab debris and consumables" refers to lab coats, gloves, rinsed glassware, sample jars with residues; disposable plastic sample cups, glass pipets and towels; rubber tubing, metal cans or other waste-contaminated articles; small volume (100g) stabilized waste samples combined with fly ash, cement or kiln dust.

DOT proper shipping name_____

_____

UN/NA NO._____ Hazard Class_____

EPA Waste Code No._____

Chemist/Drum Packer_____

Shipping
Destination_____

_____EPA ID #_____

Shipping Date_____

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TDL 6.0 CALIBRATION PRACTICES

TDL 6.1 Calibration System

Each piece of equipment to be calibrated is assigned a unique identification number. Standard operating procedures are followed for each instrument used by the lab. Reference standards are used or calibration by an outside firm is documented. At a minimum, standards are checked against a standard that has been prepared independently or against a standard from an independent supplier. The frequency and acceptable performance tolerances follow those prescribed by the ITAS QAM, SOP, method or project plan being used, whichever is appropriate to the project.

Records are kept for periodic as well as operational calibrations. Calibrations which fall outside of acceptable limits result in corrective action.

TDL 6.2 Operational Calibration

Operational calibration is generally be performed as part of an analytical procedure or test method. Tables 6.1 and 6.2 give summaries from the ITAS QAM for instruments used by TDL.

TDL 6.3 Periodic Calibration

Periodic calibration is be performed for equipment such as balances, thermometers and ovens.

- Balances are calibrated to NBS traceable, class S weights once every three months. The acceptance criteria for an operational calibration to 0.01 gram shall be ±0.01g for 0 to 100g and ±0.1 percent of the applied weight over 100g.

- Reference thermometers are calibrated to an NBS traceable thermometer once every three years. Working thermometers are calibrated to a reference thermometer once every 12 months.

- Micropipettors are calibrated on a quarterly basis according to manufacturers' specifications using the calibration tool provided by the manufacturer.

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Table 6.1. Summary of Operational Calibration Requirements

Instrument	Calibration Standards Used, Initial & Daily Minimum	Acceptance Limits	Corrective Actions	Reference
Atomic Absorption Spectrophotometer	Initial: 3 levels + blank Daily: 1 check standard (midrange) per 10 samples;	Linear regression correlation coefficient >0.995; ±5% of true value	Make new standards or establish new calibration curve	1,2
Gas Chromatograph	Initial: 3 levels + blank	Linear regression correlated coefficient >0.995; or 5 levels using point to point calibration with quadratic corr. coeff. >0.997	Make new standards, or	1
	Daily: 1 level of check standards	±20% of original curve	new calibration curve	
Ion Chromatograph	Initial: 3 levels ± blank Daily: 1 level of check standards every 20 samples (midrange)	±10% of original curve	Make new standards recalibrate	3

Table 6.1. Summary of Operational Calibration Requirements (cont'd)

Instrument	Calibration Standards Used, Initial & Daily Minimum	Acceptance Limits	Corrective Actions	Reference
pH Meter	Daily: 3 levels	±0.05 pH unit	Clean or replace electrode; recalibrate	1

References:
1) EPA SWL 846, "Test Methods for Evaluating Solid Waste"
2) USEPA Methods for Chemical Analysis of Water and Wastes, 1979
3) USEPA 300.0, 1984

Table 6.2. Summary of Periodic Calibration Requirements

Instrument	Calibration Standards Used, Initial & Daily Minimum	Acceptance Limits	Corrective Actions
Analytical Balance	Daily: Sensitivity	0.001 gm	Adjust, sensitivity
	Monthly: Reproducibility	Mean, Std. Dev. less than 0.1 mg	Service balance
	Monthly: Consistency	Difference less than 0.1 mg	Replace weights
	Quarterly: Class "S" weights Check	Difference less than 0.1 mg	Service balance
Thermometers	Calibrate in constant temperature baths at two temperatures against precision thermometers certified by NBS annually	±0.5°C	Tag and remove from service, replace
Pipettors	Gravimetric check quarterly	High volume (>100uL): ≤ 1.0% relative error and RSD Low volume (<100 uL): ≤ 2.0% relative error and RSD	Service or replacement

TDL 8.0 ANALYSIS OF QUALITY CONTROL SAMPLES

TDL 8.1 Frequency of QC Samples

The minimum frequency for analysis of QC samples in TDL is 15%, that is; a blank, a spike and a duplicate or spike duplicate out of every 20 samples.

TDL 8.2 Verification Samples

Verification samples are used when available and appropriate to assure levels of concentration or qualitative accuracy. These verification standards (ex. NBS or EPA standards) may not be appropriate for experimental procedures, but are used wherever needed for calibration prior to analytical procedures or certain types of experimental procedures.

TDL 8.3 QC Levels

Level I -- ITAS standard practice. Use available analytical procedures. Fifteen percent QC samples (blank/spike and duplicate for every 20 samples). QC samples may not be performed for a specific project, but as part of compiled sets of samples. QC data are not reported as part of analytical results.

Level II - Use available analytical (reference) methods. Fifteen percent QC samples minimum (blank/spike/duplicate) per 20 samples. QC samples are project or client-specific. QC summary report is included as part of the analytical results reported. No raw data are included.

Level III - The highest level requires use of referenced regulatory procedures, and/or established/verified procedures using confirmatory type techniques (i.e., GC/MS dual column GC). Method blank plus two other QC samples (duplicate, spike or matrix spike duplicate pairs) minimum per 20 samples of each matrix. A QC summary report is supplied with supporting data. Where applicable, this level is the USEPA Contract Laboratory Program (CLP) package.

Project-specific requirements must be defined in a QA Project Plan or Work Plan. Project specific documentation should be submitted to the laboratory before beginning work. Project requirements for QC samples cannot be less than Level I.

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TDL 9.0 ANALYTICAL PROCEDURES

Analytical procedures in TDL will generally fall into four categories: Standard and non-standard analytical procedures, and standard and non-standard experimental procedures. The standard methods follow an accepted method documented in TDL standard operating procedures (SOPs). The non-standard methods go through a predetermined process of decision making, however, the actual procedure is decided upon on a project specific basis.

TDL 9.1 Standard Analytical Procedures

Standard analytical procedures performed by TDL follow TDL SOPs. The SOPs are based on prior experience with approved methods or modifications thereof (such as EPA methods 608 and 8080 for PCB's in water and soil).

TDL 9.2 Non-Standard Analytical Procedures

Analyses which have no previously implemented method prescribed to them fall under the non-standard category. Methods and procedures are compiled from previous knowledge or experience on a project specific basis. Standard Operating Procedures are developed during these analysis for future use.

TDL 9.3 Standard Experimental Procedures

Experimental procedures which can follow a SOP are considered standard. A SOP is followed for each different type of experimental procedure.

TDL 9.4 Non-Standard Experimental Procedures

The procedure for each non-standard experimental procedure is determined and defined for each project by the project manager. Newly developed procedures are documented as SOPs.

TDL 10.0 DATA VERIFICATION

TDL 10.1 QC Data

Quality control samples are inserted into the sample stream at a rate of not less than one spike, one duplicate and one blank for every twenty samples in a given matrix (referred to as a batch). Accuracy and precision calculated from these QC samples must meet the requirements prescribed by the method, SOP or Project Plan. If QC samples do not meet the QC goals, they will be redone or a nonconformance will be filed with the QC Coordinator. This means of evaluating QC data assures verification of procedures.

TDL 10.2 Data Validation

Validation of data takes place on two levels. The first level of validation is to unveil problems as soon as possible during an ongoing project. The second level is to keep unvalidated results from being reported to the clients.

The first level consists of either review by a project manager or peer. This review is covers the following three items:

1. Are QC results are acceptable?
2. Check for outliers
3. Re-compute calculations at a rate of at least 20%

The second level is the independent review which must be done before the final report goes out. All results prior to the independent review are considered "draft" or "preliminary".

Data validation on both levels is documented by signing and dating the draft or hard copy of the data and indicating "project manager review" or "independent final review." For longer, more formal projects, a Review Documentation form (figure 10-1 is an example of one) should be completed and filed in the appropriate project file.

9 1 1 2 3 5 4 0 4 6 3

FIGURE 10-1

To_____ Date_____

From_____

Please review the document described below for the items indicated. This document is (a) attached, (b) already in your possession. Following your review, place your signature and the date in the spaces provided, provide your review comments or conclusions, send the original of the form to Central Files, and provide me with a copy of the form with the document reviewed (a) attached, or (b) retained by you unless marked with comments, by _____ _____. date (and time, if applicable)

Charge No. for review time _____

_____

REVIEW DOCUMENTATION

Project No. _____ Project Name _____

Document title and, if applicable, subject, revision no., draft no., or other description necessary for specific identification _____

_____

_____

Date document was prepared_____
Document preparer or originator_____

_____

Please review this document for _____

_____

_____

_____

_____

_____

Reviewer_____

Date Reviewed _____

Review Comments or Conclusions

_____

_____

_____

_____

_____

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TDL 10.3 Verification of Software

If computer software is used to acquire, process, or report data, it is necessary to demonstrate that the software correctly performs its intended function.

Software verification can be documented by comparing its performance against known results and filing both results in the Quality/Operations files. The standard operating procedure for software verification can be found in the ITAS omnibus SOP manual.

ds/CP17

TDL 11.0 REPORT PREPARATION

TDL 11.1 Types of Report

1. Letter Report or Letter of Analysis

   - Usually written for a project that lasts less than two weeks in the lab.
   - Simply describes the experiment and gives the results.

2. Project Report

   - More formal report, for projects lasting more than two weeks.
   - Contains a table of contents.
   - Results are given in tabular form.
   - QA procedures and results are given, if applicable.

3. Full Research Report

   - Written for a large project which follows a quality assurance project plan or work plan.
   - Document stands alone, all raw data are included.
   - The format follows the outline in Figure 11-1 which shows the sections in order, with suggested topics which would fall under each section. (Suggestions are also made under the "comments" column as to the length of each section.)

FIGURE 11-1

Final Report Outline	Comments
1. Executive Summary	1 page
Statement of Scope and Purpose	
	• Identify waste source • Technologies evaluated (why? regulatory driven?) • Goals for project (cleanest? cheapest? cleanup criteria?) • Test results (Key data) • Conclusion • Recommendation
2. Introduction	3-4 pages
Statement of Scope and Purpose	Concise Statement of Scope and purpose
Background Ex. Literature Search Results	Rationale for the project Very brief in introduction.
Approach	Brief and concise, generalized description of activities to provide enough background for reader to relate to and comprehend results in later section.
Environmental Compliance	Compliance requirements for project such as special permits or treatability study exemption.
3. Experimental Methods	4+ pages test, tables and figures Include sample prep, preservation and analysis method (method no. if possible) and QA/QC results (unless they are significant enough to be a section of their own - See 5)

- Approach - justification if needed information to be gained
- Setup - physical description of experiment including sizes, types and vendor names and a photo or figure of setup
- Feed Preparation (where applicable) - was it filtered, decanted or composited?

4. Test Results

7-10 pages text, tables and figures

- Initial analysis
- Results for each technology tested

5. QA/QC Results (if part of QAPP)

1-3 pages

Tables showing results and statistical analysis performed

6. Process Design (if needed)

- Design Basis including experimental results
- Process Design including figures, flow diagrams and physical description of the process
- Economics

7. Summary and Conclusions

2+ pages

Summary of Results

Provides more details than in Section 1.

Conclusions

Shows relevant scientific thoughts to tie-in the above sections, and the study.

9 1 1 2 7 1 0 1 6 8

8. Recommendations	1+ pages Provides a detailed discussion of further research areas based on information gaps identified in this study, and considerations for future research.
Appendices	May include permits, copies of actual analytical methods, certificates of analysis, preliminary data, etc.

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TDL 11.2 Method of Preparation

For each report the project manager, or designated representative, shall:

- Determine the content of the report based on the scope of the project, client requirements and any regulatory requirements that might exist.
- Determine the report format and type (from the list in TDL 11.1).
- Assign personnel to prepare the items required for the report.
- Assign personnel as needed to review the work prepared for the report.

TDL 11.3 Review

The project manager is responsible for initiation of the report. The report can be written by other technical personnel on the project and reviewed by the project manager, or can be written by the project manager and must be reviewed by peers.

The independent review by either the TD Lab Director or the Senior Process Consultant must then take place before the final report can be released.

TDL 12.0 RECORDS MANAGEMENT

Records are maintained that include documents which demonstrate the testing performance of the laboratory.

Laboratory records are maintained in two broad categories:

Project Files

- Documents which are specific to a project or a group of samples within an ongoing project, such as chain-of-custody and raw analytical data.

Quality/Operation Files

- Documents which demonstrate overall laboratory operation, such as instrument log books and control charts. These records will directly affect the data for a specific project, but in general their applicability is not limited to one project.

All laboratory records from time of sample receipt through reporting and disposal must be available and stored in a manner that safeguards their integrity from tampering or physical damage and loss. Any documentation that bears on the reported results must be available if requested by the client or other entitled individual. This includes operational and project-specific data. Data may be stored in "real-time" as it is produced, or filed in a manner to

allow prompt retrieval and assembly into a complete project file as described in the following section.

TDL 12.1 Project Records

Separate record packages are maintained for each project. Filing of records for a specific project shall be by the unique project identification number assigned by the laboratory for that project. Within a project file, categories of information are filed separately.

Figure 12-1 presents the categories used within a TDL project file. It is not expected that all categories will be applicable for every project. However, in all project files, specific information will be filed in accordance with the category designation provided. Each project file shall have an index that lists each record unit within the project file. A copy of this index page with the sections which apply to the specific project circled is located at the beginning of each project file.

9 1 1 2 1 5 1 0 1 7 2

TDL Project Index

TDL Project Mgr._____ Proj. Mgr._____

Project Name _____ Project Number_____

Date Began _____

A Project Index

B Correspondence (including contracts, proposals and permits)

C Project Plans (QAPPs, work plans, operating plans, Health & Safety Plans)

D Chain-of-Custody

E Field Records

F Request-for-Analysis

G Calibration Records

H Analytical Data (copies of log book pages,log book pages, chromatograms)

I Experimental Data (operating log sheets)

J QC Samples

K Data Reports

L Project Specific Requirements

M Nonconformances

N QA Plans

O Miscellaneous

P Method Description

Q Work Order Records

R Subcontractor Records

S Engineering Calculations or Process Designs

T Compliance Records (treatability study, inspection logs)

U Vendor Files

Comments _____

_____

_____

_____

TDL 12.2 Quality/Operations Records

Other records, which do not necessarily pertain to a particular project, are filed as the quality/operations records. An example of the list of records kept by TDL is given in Figure 12-2.

Many of the laboratory operations records are in daily use and are not filed in a central location until they are completed. Other files are kept in a central location for easy access to all personnel.

TDL 12.3 Record Control

The TDL secretary is responsible for the records management system. This person shall:

- Initiate new project files including the project index.
- Add new records to existing files, initiate new files within a category, and update the index.
- Assist laboratory personnel in withdrawing and returning records.

9 1 1 2 7 1 0 4 7 4

FIGURE 12-2

TDL Quality and Operations Files

Stock Solution Data Sheets (by date received)
Periodic Calibrations (pipetters, balances and thermometers)
Material Safety Data Sheets
Extraction Notebooks
Preventive Maintenance Schedules
Maintenance Logs
Run Logs for items on the Nelson System
Training Records, Resumes, & Certificates
TDL Job Descriptions
Organizational Charts
Signature Initial Record
Nonconformance Memos (monthly file)
Monthly QC reports
Monthly Surveillance Reports
Audit Reports
Performance Evaluations
Control Charts
Master Copy and Extra Copies of TDL SOP's & QA Manual
Distribution Lists for TDL SOP's & Lab Specific QA
Contents of Drums/Disposal logs
Radiological Material License File for EC Detectors
Treatability Study Files
Tailgate Safety Meeting Records
Monthly Safety Inspection Records
Computer Software Verifications
Certifications
Material Procurement & Control
Temperature Logs
Water Quality Logs
Master Sample Log

TDL 13.0 NONCONFORMANCES AND CORRECTIVE ACTION

A nonconformance is a deficiency in procedure sufficient to render the quality of an item unacceptable or indeterminate or any event which is beyond the limits documented and established for laboratory operation. Non-conformances may be caused by non-Laboratory operations (e.g., field collection paperwork not complete) and be identified at the laboratory.

Nonconformances may include (but are not limited to) the following:

- Sample receiving documentation not correct
- Sample condition on receipt not acceptable
- Sample holding time exceeded
- Sample storage conditions outside criteria
- Incorrect sample preparation/analysis procedures used
- QC sample data (blank, spike, duplicate, surrogates, etc.) outside limits
- Calibration requirements not met
- Data recording errors, transcription errors, or failure to document
- Data validation errors
- A recovery or relative percent difference result that is out of control (e.g., more than three standard deviations from the weighted mean (for that month)
- Relative standard deviation for response factors greater than accepted limits
- Positive blanks
- Any situation or result which might affect the quality of data

A corrective action is an appropriate measure applied to correct a deficiency and minimize the possibility of recurrence.

Corrective action will include, but not necessarily be limited to:

- Recalibration of instruments, using freshly prepared calibration standards
- Reanalysis of samples
- Replacement of lots of solvent or other reagents that give unacceptable blank values.
- Additional training of laboratory personnel in correct implementation of sample preparation and analytical methods
- Reassignment of personnel, if necessary, to improve the overlap between operator skills and method requirements
- Communication with the clients to determine the appropriate action (e.g., insufficient sample remaining for reanalysis).

TDL 13.1 Procedure for Documenting Nonconformance and Corrective Action

Any laboratory employee noticing a deficiency suspected of being a nonconformance shall report the deficiency to the responsible supervisor and to the QCC on a nonconformance memo form.

The Quality Control Coordinator shall maintain a log of nonconformances that includes a description of the problem and corrective action, and lists the responsible manager, the affected projects and sample numbers, and initial and closeout dates.

Once the corrective action has been taken, the QCC shall verify, through a special surveillance or audit, that the problem has been corrected. The QCC shall document that the corrective action has been completed satisfactorily (closed out) by signing the nonconformance memo.

The QCC shall file a copy of all records pertaining to the nonconformance with the nonconforming item records (i.e., specific project files or procurement files). The nonconformance log maintained by the QCC shall contain a reference to the file location.

TDL 13.2 Variances

Variances from standard approved operational procedures and plans shall be documented in a Variance form. It is recognized that procedures such as work plans cannot be prepared which properly foresee all conditions encountered during a field program. The project manager shall initiate and maintain the variances for each project. All items recorded on the Variance form require the approval of the Project Manager's supervisor and the Quality Control Coordinator. The Variance form shall contain: date and nature of the variance, applicable document, and IT personnel initiating the variance. In no case shall a subcontractor initiate a variance. If a variance is proposed by the client, it shall be so recorded.

The Project Manager shall keep a copy of all variances with the project file. The Project Manager's supervisor shall review copies of the forms and, when in agreement, indicate approval by signing and dating each variance. The copy shall be forwarded to the Quality Control Coordinator for review, signing, and dating and then returned to the Project Manager for inclusion in the project files. Originals of the Variance form shall be kept on site (when appropriate) until the field work is complete.

Variances to approved procedures and plans will be approved prior to implementing the deviating action.

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TDL 14.0 QA/QC AUDITS

In-house audits (often called surveillances) are performed on a monthly basis by the Quality Control Coordinator. They are conducted on behalf of the laboratory management to verify that the Quality Assurance Program is implemented and functioning on a daily basis.

The QCC schedules the audit and sends a memo to the TDL staff announcing the date and scope of the audit. This is done at least one week prior to the audit. The laboratory manager discusses the scope of the audit and has a post audit review with the QCC.

Results of the in-house audits are reported to the Laboratory Manager and the ITAS Director of QA & Compliance. Appropriate personnel are informed of actions needing to be performed as a result of in-house audit findings. Audits are filed in the laboratory Quality/Operations files.

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TDL 15.0 QUALITY REPORTS TO MANAGEMENT

The Quality Control Coordinator is responsible for providing monthly reports to the management indicating the effectiveness of the Quality Assurance Program. These reports are written to the ITAS Director of Quality Assurance with copies sent to the Operations Managers and Laboratory Director. The report contains those sections from the following list which are appropriate to that month's activities:

- Internal audits, performance evaluations, audit information in general.
- Certification information.
- Nonconformance/corrective action summary.
- Summary of monthly QC data.
- New or revised laboratory SOPs.
- Personnel changes or training.
- Instrumentation changes, additions, deletions.
- New test methods.
- Training courses attended by lab staff.
- Miscellaneous information.
- QAPPs received or written.

The QCC Monthly Report Format is attached. All sections are included each month with appropriate information or comments such as "no external audits this month".

QCC MONTHLY REPORT FORMAT

1. **AUDITS**

   - INTERNAL AUDIT/SURVEILLANCE(S)
   - EXTERNAL AUDITS(S)
   - SUBCONTRACTOR AUDIT(S)

2. **PERFORMANCE EVALUATION SAMPLES**

   - PE SAMPLES IN-HOUSE
   - PE RESULTS SUBMITTED/PENDING
   - PE RESULTS RECEIVED

3. **CERTIFICATIONS**

   - RECEIVED
   - INITIATED

4. **NONCONFORMANCE SUMMARY**

   - INCLUDE A COPY OF YOUR NONCONFORMANCE LOG OR TABULATE BY AREA (PREFERRED)

5. **HOLDING TIME VIOLATION SUMMARY**

   - SEPARATE FROM ITEM 4.0
   - TABULATE AS FOLLOWS:

DEPARTMENT	PARAMETER	# OF SAMPLES	EXPLANATION/ CORRECTIVE ACTION	% OF TOTAL SAMPLES ANALYZED

   - INDICATE LABORATORY-CONTROLLABLE VS. OUTSIDE OF LAB CONTROL

6. **QC DATA/CONTROL CHART SUMMARY**

   - DESCRIBE OUT-OF-CONTROL DATA POINTS, TRENDS OBSERVED, CORRECTIVE ACTIONS

7. **SOPs ISSUED/REVISED**

8. **TRAINING RECEIVED/CONDUCTED**

9. **OAPPs RECEIVED/REVIEWED**

10. **MISCELLANEOUS**

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TDL 16.0 TRAINING

Training and qualifications of all personnel is documented with resumes which include academic credentials, employment history, experience and professional registrations. An Individual Training record, example given in figure 16-1, is kept for each employee showing on-the- job training and courses taken as well. Each employee has a Personnel Qualification Record, similar to the one shown in figure 16-2, signed by his or her supervisor indicating the procedures which he/she is qualified to perform. Specific training procedures and deocumentation are covered in laboratory SOPs.

TDL 16.1 Personnel Training and Qualification

All quality related activities performed by IT shall be accomplished by personnel qualified on the basis of education, experience, and training.

TDL 16.1.1 Project Staff Training

General training in the reauirements of the Quality Assurance Program is required of all personnel. Formal training sessions are conducted and documented by the Quality Control Coordinator. The training program shall address: regulatory requirements (as appropriate); basic Quality control practices, including checks and balances inherent in the system; responsibilities of the Project Staff; responsibilities of Quality Assurance personnel; and the performance of audits.

New technical employees are given training in Quality Assurance practices and policies. The training must take place soon after the new employee begins work at IT, preferably the first week of employment. It is the joint responsibility of the Laboratory Director and the Quality Control Coordinator to implement this training. New employee training is documented by the Quality Control Coordinator.

Quality Assurance training documentation includes the name(s) of those trained, date(s) of training, and topics covered in training. The documentation is maintained in the Quality/Operations files.

For projects requiring a departure from standard Quality Level I practices, the Project Manager is responsible for reviewing the revised practices with members of the Project Staff. At the request of the Project Manager, this will be done by the Quality Control Coordinator or senior members of the Project Staff. Project-specific reviews shall include contractual and regulatory reuqirements, amendments of standard practice adopted for the project, project-specific procedures, and project-specific Quality Assurance documents. As necessary, Quality Assurance documents or summaries will be issued to the Project Staff. The review is documented by a memorandum to the project file. The documentation includes the date of the review, the topics discussed, and the names of the participating Project Staff.

TDL 16.1.2 <u>Project Staff Qualifications</u>

Project Staffs are primarily composed of professional personnel who are engineers or scientists. Such personnel shall be assigned duties within the capabilities of their education and experience by the Laboratory Director or Project Manager. The Project Manager shall be appointed by the Laboratory Director. Qualifications of all professional personnel shall be documented by resumes which include academic credentials, employment hisotry, experience, and professional registrations. Resumes are maintained in the Quality/Operations files.

Technicians and support personnel performing a technical function for a project are qualified through experience which is indicated in their resumes. These personnel shall also be assigned by the

Laboratory Director or Project Manager based on their capabilities. Technicians and support personnel shall be supervised in their activities by experienced personnel until the Project Manager approves independent performance of their duties.

If subcontractors are used by IT on a project, the Project Manager is responsible for establishing necessary qualification of subcontractor personnel and verifying their capability. Qualifications shall be established in the procurement documents.

If a project requires personnel with specific certifications (such as engineering registration in a given state or technical certification by a state or national organization), personnel meeting the necessary qualifications will be provided by IT.

TDL 16.1.3 <u>Quality Assurance Personnel, Training and Qualifications</u>

Quality Assurance personnel qualifications shall be documented in resumes as for professional personnel.

If audits are required for projects governed by USNRC Quality Assurance requirements (10 CFR 50, Appendix B), lead auditors shall be quialified in accordance with ANSI NQA-1, Supplement 2S-3. Qualifications shall be performed by the Director of ITAS Quality Assurance.

The auditor responsible for conducting a Quality Assurance audit is designated the Lead Auditor. Lead Auditors shall have the expertise necessary to direct all phases of the audit.

Lead Auditors for nuclear-related projects (10 CFR 50, Appendix B requirements applied) shall meet several training and experience requirements for certification, as outlined below. First, they shall obtain a minimum of ten credits using the certification system presented in ASI NQA-1, Appendix 2A-3.

Lead Auditors shall be capable of communicating effectively, in writing and orally. In addition, Lead Auditors shall have participated in a minimum of five Quality Assurance audits within the three-year period immediately prior to initial certification. One of these audits shall have been for a nuclear-related project and must have taken place within the 12-month period prior to initial certification.

Finally, Lead Auditors must undertake and pass a formal examination. This examination may be either written or oral, and should cover applicable aspects of the IT Quality Assurance Program, regulatory requirements, aned Quality Assurance auditing. The Director of ITAS Quality Assurance is responsible for preparing and administering the examination and evaluating examination results. Evidence of the examination shall be documented in the training files.

Continued proficiency of Lead Auditors shall be maintained through active participation in Quality Assurance audits and the preparation and review of Quality Assurance documents.

If a previously certified Lead Auditor fails to maintain proficiency for two consecutive years, formal requalification, by the Director of ITAS QA shall be required. The requalification will consist of:

- Reexamination
- Satisfactory participation in at least one Quality Assurance audit of a nuclear-related project,
- Additional training and/or experience as deemed necessary by the Director, Quality Assurance and Discipline Management.

Formal certification and the annual evaluation of nuclear Lead Auditors shall be documented and maintained by the Director, ITAS Quality Assurance.

TDL 16.1.4 Subcontractor Personnel, Training and Qualifications

If specific qualifications are required of subcontractor personnel, it is the responsibility of the Project Manager to impose such qualification requirements upon the subcontractor through procurement documents, specifications, and other means, and to verify fulfillment. Necessary qualifications may be due to accepted standard of practice, regulation (such as engineering registration), technician registration and/or certification, or craft requirements (such as welder certification).

As appropriate for a specific project, the project manager is responsible for the training of subcontractor personnel with regard to IT quality-related requirements and documenting this training.

Figure 16 - 2

PERSONNEL QUALIFICATION RECORD

NAME: _____ HIRE DATE: _____

TITLE: _____ SUPERVISOR: _____

PROCEDURE NAME, NUMBER	QUALIFY DATE	RENEW BY	APPROVAL

TRAINING SESSION	DATE	APPROVAL

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TDL 17.0 PROJECT PLANNING

This section presents quality-related activities that are appropriate during the project planning stage. This section also includes a discussion of proposal preparation as part of project planning. The selection of activities for implementation, and needed degree of implementation, is dependent upon the needs of the specific project. The means for implementing several topics are included.

Project planning will fall into two types:

1) Large (Research) Projects requiring a full Quality Assurance Project Plan or at least a QAPP form (example of form in Figure TDL 17-1).

2) Short Projects typically requiring less than 200 hours total effort and usually lasting less than two weeks in the lab. The short project requires no QAPP, however, the short project form (like the one shown in Figure 17-2) must be completed.

Figure TDL 17-1
TDL QAPP FORM

Project Name _____

Project Number _____

Client Contact _____

Phone _____

Address _____

Send report to same as above/other _____

Due Date _____

TDL Project Manager (filling out this form) _____

Reviewed By _____

QC Approval _____

List of Subcontractors _____

1) Project Description (include anticipated start and completion dates, brief description of work plan and intended use of acquired data)

_____

_____

_____

_____

_____

_____

2) Project Organization/Responsibilty (list of persons involved, their title and responsibility for this project-may attach org. chart)

_____

_____

_____

_____

3) QA Objectives (include minimum no. of blks, dups, spikes and precision, accuracy and completeness specifications)

_____

_____

_____

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Figure TDL 17-1 (Cotinued)

4) Sampling Plan (when and how taken, container requirements storage and preservative and purpose formal or screening)

5) Sample Custody (what forms needed C of C, R for A etc.)

6) Calibrations (requirements and frequency)

7) Analytical Procedures (list method nos. when possible)

8) Data Reduction (List calculations to be performed using A,B,C and X,Y,Z)

9) Surveillance or Audit (by whom prior to start, during or after completion)

10) Preventive Maintenance (list instruments and frequency)

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Figure TDL 17-2
TDL Short Project Form

Project Name _____

Project Number _____

Client Contact _____

Phone _____

Address _____

Send Report to same as above/other _____

Due Date _____

TDL Project Manager (filling out this form) _____

Other TDL Personnel Involved _____

TDL Sample Numbers _____

Lab Notebook Reference Pages (book:pages) _____

Computer Data File Reference analyses: _____ report: _____

List of Subcontractors _____

Brief Description of Work Plan _____

_____

_____

_____

_____

_____

_____

_____

_____

_____

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TDL 17.1 Project Preparation

The Quality Assurance activities required during a project must be determined and implemented during the planning stage of a project. Quality must be "built-in" from the beginning. Several key decisions must be made during planning, the first being the selection of quality level as discussed in Section TDL 17.2.

However, defining the quality level does not provide all of the detail needed to plan the project. Questions of specific actions to be taken during the project must be addressed. Following are typical questions that should be asked during planning. The list is representative, not inclusive:

- What is the problem? Why is IT involved?
- What do we need to know about the site, or problem?
  - Contaminants present
  - Identification and extent of contaminants
  - Ground water regime
  - Sources of the contanimants and likelihood of unknown contaminants
  - Means for in situ or on-site treatment
  - General chemistry of the waste stream or contaminated soil and water
  - Potential for concentrating contaminants for off-site disposal or treatment
- What is the end product of our work?
  - Preparation of a regulatory submittal
  - Report to client characterizing the site and/or containing recommendations for remediation
  - Report presenting designs or results of technology development
  - Specifications/drawings for direct implementation of remediation
- How can we determine the data we need to know?
  - Collection and analysis of samples

- Bench scale prototype testing
- Geophysical surveys
- Theoretical modeling

- If data is needed, what kind of samples do we need; how are the samples obtained; how will samples be analyzed?
- Do we have the equipment and materials required?
- Do we have needed data sheets; should they be changed or new ones prepared?
- What will the data be used for?
  - Baseline site characterization
  - Ongoing monitoring to verify regulatory compliance
  - Comparison of alternative treatment technologies
  - Remedial design and construction
  - Litigation
- How "good" must the data be?
  - Are there regulatory criteria?
  - What accuracy and precision are required?
  - Are the results to be used for comparative or absolute calculations
  - What are the capabilities of existing analytical procedures?
- What is IT's exposure?
  - Are we developing criteria or implementing criteria development by others (including regulation)?
  - Are we originating design/remediation?
  - Is it expected that we will be required to demonstrate our performance through documentation to the client?
- Who will do the work; are qualified people in IT; are they available?
- What controls are needed for subcontractor services?
- Do we have needed computer software; has it been documented and verified?
- Is peer review planned; who will do it; are they available?
- Finally, has planning addressed the proposal prepared by IT, and included contractual/regulatory demands? Does planning provide the means for satisfying our contract?

9 1 1 2 7 0 1 0 4 9 3

TDL 17.2 Selection of Quality Level

Three levels of application of the Quality Assurance Program are defined for use in treatability and engineering projects. See Section 8.3 of this QAM for Analytical QC levels. The three quality levels are:

- Level I - The "standard" IT quality requirements are applied. There is minimal involvement of Quality Assurance personnel during the course of work, generally auditing is not performed.
- Level II - Specifically detailed QC procedures are implemented and the results of QC activities reported.
- Level III - The maximum application of Quality Assurance practices and substantial participation of Quality Control personnel.

If the Project Manager does not select a different level, Level I shall be applied. If Level II or III is selected, a specific implementing Quality Assurance Project Plan is prepared.

The level selected defines the intensity of application of Quality Assurance functions. The major difference between Levels I and II is the required formal audits.

The level selection process must occur during the project proposal preparation stage so that the cost of implementation and schedule considerations can be included. At the latest, the selection shall be made during the planning stage of a project. The level selection is documented by a TDL short or QAPP form stating the project quality level selected.

To select a project quality level, the following points shall be evaluated:

- Institutional needs that control the end use of project information and results (i.e., what must the project satisfy?)

- Criteria which govern the performance of the project (such as regulations, contract requirements, and IT policies)
- State of knowledge necessary to satisfactorily complete the project (i.e., what is the degree of technology required?)
- Project complexity.

Start by defining a general review of project objectives. Consider if the performance of project activities and end use of data and results are controlled by government regulations or expected legal action. Regulations promulgated by th USNRC mandate the adoption of Level II with a full Quality Assurance Program for projects regulated by USNRC. In a similar fashion, federal (e.g., U.S. EPA) and state environmental agencies often mandate through their regulations the use of a formal Quality Assurance Program for a project, so that Level II implementation is appropriate. Projects controlled by consent decrees or impending legal proceedings should be considered for Level III implementation because of the expected need to demonstrate performance.

The project control needed is a function of the expected magnitude of IT liability, industry, or public exposure; the future technical use of data generated; and the objectives of a research and development effort. In addition, the Project Manager or other IT management may require Level II commitment (e.g., formal audits) in any project to serve as a management review tool.

Once the appropriate control category has been determined, the degree of technology required to satisfactorily complete a project shall be defined.

The final determination which must be made prior to selection of the project quality level is the degree of project complexity.

If the project is amended from Level I practice, the following courses of action shall be taken:

- If the project is to be conducted at Quality Level II, the appropriate Quality Assurance Officer shall prepare a Quality Assurance Outline or Quality Assurance Project Plan for the project listing all Quality Assurance activities which exceed Level I and the means for implementation. This could include preparation of work plans, project-specific Quality Assurance Plans, audits to be performed, and formal subcontracting practices. The outline on a Quality Assurance Project Plan shall be reviewed and approved by the Director, Quality Assurance and Discipline Management.

- If Level I practices must be increased, the appropriate Quality Control Coordinator shall prepare, in concert with the Project Manager, a Project Quality Control document for distribution to the affected Project Staff stating the changes.

- Work plans, sampling protocols, and Quality Assurance plans, developed for a specific project, shall be approved.

- Regulatory and client requirements which affect established Quality Assurance practices shall be discussed by the Project Committee and addressed in the form of the documents discussed above.

- If a nonconformance is not resolved to the satisfaction of the appropriate Quality Assurance Officer, the reporting and resolution mechanism shall be instituted.

- If a request for corrective action resulting from an audit is not adequately resolved, a reporting and a resolution mechanism shall be instituted.

TDL 17.3 <u>Subcontractor Procurement</u>

Outside testing services will not be used to bypass quality assurance requirements. The control of procurement documents and resulting subcontractor furnished quality-related items and/or services shall be based on the effect an item or service will have on project requirements and needed results. Subcontractors may be required by IT for: the purpose of providing a service under direct IT supervision (such as drilling); or performing activities independent of IT (such as for specialty testing, supplying equipment, or detail design engineering). The degree of independence of the subcontractor's service must be considered in determining the procurement controls needed. As a general comment, the more independent a subcontractor is of IT supervision, the more

stringent should be the Quality Assurance requirements placed upon them.

The procurement process shall be adequately documented. The documentation shall include, as appropriate:

- Requests for proposal
- Specifications and scopes of work
- Quotes (proposals) submitted by subcontractors
- Telephone conversation documentation
- Meeting notes
- Purchase order requisition
- Purchase orders
- Prequalification forms
- Bid reviews
- Bid comparisons
- Change order documentation

TDL 17.3.1 Procurement Document Control

Procurement documents issued by IT; including bid requests, purchase orders, and contracts; shall be prepared, reviewed, and approved as a joint effort of Purchasing, Project, and Quality Assurance personnel. The extent of each group's involvement is a function of the particular project and the item or service procured. Determination of necessary involvement shall be made by the Project Manager. Project procurement documents require review and approval by the Quality Control Coordinator.

Changes in a procurement document shall be subject to the same degree of control as was utilized in the preparation of the original document.

TDL 17.3.1.1 Procurement Document Content

Procurement documents shall state applicable requirements for personnel qualification, technical performance, quality, acceptability, and documentation.

The documents shall, as appropriate, specify the following technical requirements:

- General requirements (scope of work)
- Pertinent codes and standards
- Material composition and/or physical and chemical requirements
- Quantity and scheduling requirements
- Work procedures
- Testing and calibration requirements
- Performance and/or accept/reject criteria
- Reporting requirements.

Procurement documents specify the scope of work in sufficient detail so that it is reasonable to expect that confusion and misunderstandings are eliminated.

Technical requirements shall be included in the procurement documents or referenced to specific drawings, specifications, procedures, regulations, or codes (along with specific revision numbers and issue dates) that describe the items or services to be furnished.

Purchased items and services shall be controlled by invoking appropriate quality-related requirements and elements of the appropriate IT Quality Assurance Program in the procurement documents. The requirements which a subcontractor must satisfy will vary depending on the purpose of the procurement and the degree of subcontractor independence. IT's right to stop work for quality problems should be clearly stated.

The responsibility for compliance with applicable quality requirements and elements of the appropriate IT Quality Assurance Program can be delegated to the subcontractor in the procurement documents, or can be retained by IT. If the responsibility is

delegated, the subcontractor must have a documented Quality Assurance Program suitable for the needs of the project. If responsibility for compliance is retained, IT shall use the procurement documents to "pass down" the performance of specific quality requirements to the subcontractor. The "pass down" provides appropriate requirements which can be met without requiring the subcontractor to have their own Quality Assurance Program.

To verify acceptability, the procurement documents shall provide for IT access to subcontractors' facilities, work areas, and records for auditing and inspection. This may include prequalification (example in figure TDL 17-3) or audits by Quality Assurance personnel, a quality check by Project personnel prior to beginning work or inspections and tests by Project personnel during the performance of work.

Documentation required by IT to provide evidence that materials, equipment, and services are of specified quality shall be identified by the procurement documents. The right of IT to review and approve this documentation prior to acceptance of an item or service should be stated. Instructions for the preparation, control, retention, and disposition of documentation must also be included or referenced.

Required documentation can include:

- Quality Assurance Project Plan
- Procedures and drawings
- Equipment operating manuals
- Test and work plans and logs
- Test and analysis data, results, and verifications
- Calibration records
- Personnel qualifications
- Material certificates of conformance
- Nonconformance records
- Drawing and calculation checkprints
- Computer program verification records

In addition to the above; subcontractor submittals or nonconformance, work progress, results, and other deliverables shall be specified in the procurement documents, as appropriate.

INTERNATIONAL TECHNOLOGY CORPORATION

Figure TDL 17-3

Contractor Prequalification Form

BACKGROUND

1. Your company name and division or operation group. _____

2. Your company address. _____

3. Name(s) of persons to contact for additional information, including addresses and phone numbers.

Name	Address	Phone Number

4. Describe your type of work.

5. Describe assignment for this project. _____

6. List key personnel planned for this project. Please list names, expected positions, and safety performance on last three projects worked on.

Name	Position	Safety Performance

HEALTH AND SAFETY PRACTICES

1. Do you have a written safety program? Yes _____ No _____
2. Do you have an orientation program for new hires? Yes _____ No _____
   If yes, does it include instruction on the following?

	Yes	No		Yes	No
a. Head protection			i. Fire protection		
b. Eye protection			j. First aid facilities		
c. Hearing protection			k. Emergency procedures		
d. Respiratory protection			l. Toxic substances		
e. Safety belts and lifeline			m. Trenching and excavation		
f. Scaffolding			n. Signs, barricades, flagging		
g. Perimeter guarding			o. Electrical safety		
h. Housekeeping			p. Rigging and crane safety		

3. Do you have a development program for all newly hired or promoted supervisors? Yes _____ No _____
   If yes, does it include instruction on the following?

	Yes	No		Yes	No
a. Safe work practices			e. First aid procedures		
b. Safety supervision			f. Accident investigation		
c. "Tailgate" meetings			g. Fire protection and prevention		
d. Emergency procedures			h. New worker orientation		

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Figure TDL 17-3
(Continued)

HEALTH AND SAFETY PRACTICES (continued)

4. Do you hold "tailgate" safety meetings? Yes _____ No _____

   How often? _____

5. Do you hold site safety meetings for field supervisors? Yes _____ No _____

   How often? _____

6. Do you conduct project safety inspections? Yes _____ No _____

   If yes, who conducts this inspection (title)? _____

   And how often? _____

MEDICAL PRACTICES

1. Do you provide preemployment medical exams? Yes _____ No _____

   Describe content and pass/fail criteria. _____

2. Do you conduct periodic/update medical exams? Yes _____ No _____

   How often? _____

   Describe content and pass/fail criteria. _____

3. Do you conduct postemployment/termination medical exams? Yes _____ No _____

   Describe content. _____

ACCIDENT REPORT RESULTS

1. Please use your last year's OSHA No. 200 Log to fill in:

   a. Number of injuries and illnesses _____
   b. Number of lost workday cases _____
   c. Number of restricted workday cases _____
   d. Number of cases with medical attention only _____
   e. Number of fatalities _____

2. Employee hours worked last year (do not include any nonwork time, even though paid) _____ hours

ACCIDENT REPORTING MECHANISMS

1. Are accident reports (OSHA 200) and report summaries sent to the following? How often?

	No	Yes	Monthly	Quarterly	Annually		No	Yes	Monthly	Quarterly	Annually
Field Superintendent	___	___	_____	_____	_____	President of Firm	___	___	_____	_____	_____
Vice President of Operations	___	___	_____	_____	_____						

2. How are accident records and accident summaries kept? How often are they reported?

	No	Yes	Monthly	Annually		No	Yes	Monthly	Annually
Accidents totaled for the entire company	___	___	_____	_____	Subtotaled by manager	___	___	_____	_____
Accidents totaled by project	___	___	_____	_____	Subtotaled by foreman	___	___	_____	_____

3. How are the costs of individual accidents kept? How often are they reported?

	No	Yes	Monthly	Annually		No	Yes	Monthly	Annually
Costs totaled for entire company	___	___	_____	_____	Subtotaled by manager	___	___	_____	_____
Costs totaled by project	___	___	_____	_____	Subtotaled by foreman	___	___	_____	_____

Figure TDL 17-3
(Continued)

INSURANCE INFORMATION

1 List your firm's Interstate Experience Modification Rate for the three most recent years.

19____ _____ 19____ _____ 19____ _____

2. Describe the limits of your worker's compensation insurance coverage.

_____
_____
_____

3 Describe the limits of your comprehensive general liability insurance.

_____
_____
_____

4 Can you arrange for International Technology Corporation to be a named insured on your comprehensive general liability insurance for this project?

Yes _____ No _____

QUALITY ASSURANCE

1 Do you have an internal Quality Assurance Program applicable to your work activities?

Yes _____ No _____

2. Is the program documented in a QA manual and/or written procedures?

Yes _____ No _____

3. Provide a brief description of the QA Program and applicable regulations (such as NRC, EPA) which it meets.

_____
_____
_____
_____
_____

4 List governing standards (such as ANSI, ASTM, EPA) which have been adopted for testing, analysis, and work performance.

_____
_____
_____
_____

5. Have you previously been required to contract to have and implement a QA Program?

Yes _____ No _____

If yes, cite examples. _____
_____
_____
_____

6. Have you previously been included under a client's QA Program?

Yes _____ No _____

If yes, did you directly implement part of their QA Program?

Yes _____ No _____

Describe participation. _____
_____
_____
_____
_____

9 1 1 2 7 6 4 0 5 0 2

Figure TDL 17-3
(Continued)

QUALITY ASSURANCE (continued)

7 Will you provide IT personnel with access to your facilities/operations for the purpose of prequalification and in-process audits?

Yes _____ No_____

If no explain _____

8 Which of the following QA practices do you normally perform:

	Yes	No
a. Design Reviews (such as checking, data review, peer review)	_____	_____
b Calibration	_____	_____
c Preventive Maintenance	_____	_____
d In-process Inspection	_____	_____
e In-process Testing	_____	_____
f Formal Training	_____	_____
g. Personnel Certification	_____	_____
h Corrective Action (identification, reporting, resolution)	_____	_____
i Record Maintenance	_____	_____
j Audits	_____	_____

9 If the service to be provided to International Technology Corporation involves laboratory analyses, list the proficiency and certification programs in which you participate and provide the results of the most recent sample round.

_____

10 If you are supplying materials or equipment, are you prepared to provide certifications and/or test results?

Yes _____ No _____

Describe the industry standards which generally apply.

_____

11 List applicable certifications of key personnel (or include in attached resumes).

_____

12 Will you provide applicable quality-related records if requested by International Technology Corporation such as fabrication drawings, as-built drawings, calibration records operation logs, QA sample results?

Yes _____ No _____

Finally, procurement documents shall require subcontractors to incorporate applicable requirements in subtier procurements.

TDL 17.4.1.2 Procurement Document Review and Approval

Procurement documents shall be reviewed to verify that applicable IT, regulatory, and client requirements (performance, quality, acceptability, and documentation) have been incorporated. The reviews shall also verify that changes in the documents, as a result of bid evaluations or precontract negotiations, have been made. Reviews of bid requests and purchase orders shall be performed prior to their release. Reviews of contracts shall be performed prior to contract award. Purchasing, Project, and Quality Assurance personnel shall participate, as necessary. The Quality Control Coordinator will review all technical purchase order requisitions. Documentation of the review shall be by signing the document draft, or by signing a routing stamp on the document.

Contract and subcontractor service purchase order approval shall be indicated as required by IT purchasing policies. Bid requests shall be approved by the Project Manager and/or responsible Laboratory Director or designated Project Director for a specific project. Copies of all contracts, bid requests, and purchase orders for project services and review copies shall be maintained as records for the project.

TDL 17.5 Peer Review

This Quality Assurance Program provides controls for the formal verification (checking) of documents such as calculations and the presentation of information in the form of drawings, logs, and tables. Review and necessary approvals are also cited for quality related documents. However, quite often during the course of a project or proposal, verification of technical decisions and concepts such as interpretation of data and the evaluation of results is required so that the project or proposal can proceed on a

sound conceptual basis. The review of concept, or approach, may be needed for the following:

- During the planning stage have appropriate steps been taken to meet the goals of the project? This could include:
  - Does the sampling plan provide for the number, type, volume, etc. of samples anticipated to provide needed data?
  - Are analytical procedures adequate to provide data of sufficient detection, accuracy, precision, completeness for the project needs?
  - Are appropriate computation methods to be used during design?
- Are data of sufficient quality and properly interpreted so that conclusions can be justified and demonstrated?
- If design parameters are assumed, are they reasonable for the computations performed? What is the effect of variation of the assumptions upon results?
- Do the results presented by IT in the format of a report, or other document (Section 9.3), adequately present the work performed and the conclusions reached? Do the results fulfill the objectives of the project?

The mechanism to be used in the Technology Development Laboratory for such verification is peer review.

The need for peer review is dependent upon the scope of the individual project. The Laboratory Director and Project Manager shall determine during the planning stage of a project if peer review will be implemented, the points in the project when the review will be performed, and the individual(s) who will perform the review. The extent and importance of peer review for a specific project should be based on:

- Technical complexity of the work
- Experience of project personnel (peer review should also be a learning/teaching mechanism)
- Difficulty of implementing and fulfilling the methods/procedures to be used in the project

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- Complexity of the logistics required to manage the project
- Effect upon project schedule and succeeding project stages if part of the work does not meet project goals so that either project goals/objectives must be revised or the work repeated
- Potential for liability.

For peer review to be effective, the schedule for the reviews must be estimated and included as part of the project schedule, and time must be allowed for the reviews. The selected peer reviewers should be notified of their expected participation as soon as possible.

A peer reviewer should be selected based on the following:

- The reviewer must be independent of the project. The reviewer must be sufficiently informed concerning the project, but should not be making the decisions which determine the course of the project. It is intended that peer review be an "outside" overview of the project.
- The reviewer must be a person knowledgeable in the area of work, preferably a senior technical person. Peer reviewers can be part of the IT organization, or outside consultants or may sign off on project documents.

At the conclusion of a peer review, the reviewer(s) shall prepare a report to the Laboratory Director, Project Manager, and Quality Control Coordinator or may sign off on project documents.

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