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INTERNATIONAL TECHNOLOGY CORPORATION

POLLUTION CONTROL ENGINEERING

PROCESS DEVELOPMENT GROUP

GEOTECHNICAL LABORATORY

QUALITY ASSURANCE MANUAL

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LIST OF ACRONYMS

AASHTO - American Association of State Highway Transportation Officials

CoC - Chain of Custody

DCO - Document Control Office

DQAO - Division Quality Assurance Officer

ETDC - Environmental Technology Development Center

GL - Geotechnical Laboratory

HEPA - High Efficiency Particulate Air (filter)

NCR - Nonconformance Report

NIST - National Institute of Standards and Technology

PCE - Pollution Control Engineering

PD - Process Development

PDG - Process Development Group

QAM - Quality Assurance Manual

QAO - Quality Assurance Officer

QA/QC - Quality Assurance/Quality Control

RfA - Request for Analysis

RSO - Radiation Safety Officer

SOG - Standard Operating Guideline

SOP - Standard Operating Procedure

SRM - Standard Reference Material

1.0 INTRODUCTION

The Process Development Group (PDG) Geotechnical Laboratory (GL) performs geotechnical analyses to support the PDG Treatability Laboratory, other IT Corporation offices, and outside clients throughout the United States. The main scope of GL activities is in the analysis of hazardous and/or radioactive contaminated materials, although uncontaminated materials are also tested. The laboratory does not routinely perform field type work.

The number one priority at GL is laboratory safety. All personnel have not only the authority, but the responsibility, to stop work if anyone feels that safety is being compromised.

Quality is the number two priority at the GL. IT defines quality as "meeting the client's and IT's requirements and expectations". This is our goal. In order to meet this goal, the GL has been very aggressive in making operations as efficient as possible, stressing effective communications, and employing proven problem-solving techniques to rectify deficiencies. The Quality Assurance Officer (QAO) periodically performs internal audits, surveillances, and random client satisfaction surveys to determine how well the GL is meeting its goal.

This Quality Assurance Manual (QAM) describes the Quality Assurance program for the GL. It is used in conjunction with standard operating procedures (SOPs) and standard operating guidelines (SOGs) to define a method of operation whereby quality is built into the product. All GL associates are responsible for carrying out the requirements set forth in this QAM.

1.1 LABORATORY HISTORY

The PDG has performed limited geotechnical analyses for many years to support hazardous waste treatment development. The demand for a geotechnical analytical capability within IT had grown to the point where it was determined that a full-time geotechnical laboratory was economically feasible, and the GL was officially created in June, 1990.

At the time, IT was involved in a Remedial Investigation/Feasibility Study at a major Department of Energy nuclear site, which required geotechnical analyses. It was decided that the geotechnical laboratory would obtain a radioactive materials handling license, and target the hazardous/radioactive waste market. This market is quite different than the construction market, and poses some unique problems with sample analyses. In some cases, sample contaminates or final use of data require that standard methods be modified, or new methods and equipment be developed.

In the three years since it's creation, the GL has grown tremendously. It was obvious from the start that the only way the GL could effectively manage the growth was to become very efficient at handling data and preparing reports. A tremendous initial effort was expended in preparing computer programs to perform data reduction and reporting.

Today, almost all data calculations are performed by computer. Once data are entered into the computer and verified, preparing a report is a simple and quick process. Recognizing the opportunity for mistakes, a policy of checking all (100%) of data transcriptions, computer data entries, and manual calculations was instituted. The results are worthwhile, report mistakes are nearly nonexistent.

The original scope of laboratory operations did not include field work. However, in cases where samples could not be shipped to the GL, a field laboratories were setup, and technicians dispatched to perform the required work.

2.0 ORGANIZATION

The GL is operated by the PDG, of the Pollution Control Engineering (PCE) Division of IT Corporation. An organizational chart is shown in Figure 2-1. Following is a description of positions within the GL.

2.1 MANAGER, PROCESS DEVELOPMENT

The Manager, Process Development (PD) has overall authority for the GL, but is not involved in daily operations of the GL. The Manager, Process Development, reports to the Director, PCE, and is responsible for:

- Ensuring the GL has implemented effective Quality Assurance and health and safety programs.
- Providing senior management support in the areas of marketing and finances.
- Providing the GL with resources required to perform its work.

2.2 MANAGER, ENVIRONMENTAL TECHNOLOGY DEVELOPMENT CENTER

The Manager, Environmental Technology Development Center (ETDC), is the senior manager responsible for daily GL operations, and reports to the Manager, Process Development. His responsibilities include:

- Ensuring requirements of the QAM and health and safety program are being carried out.
- Communicating capital equipment and personnel needs to the Manager, Process Development.
- Ensuring the GL has proper resources to perform its work.
- Managing the overall GL operations.

Qualifications for this position include:

- Bachelors degree in engineering or other science oriented education and experience.
- Five years laboratory experience, of which at least two are in geotechnical testing.
- Two years laboratory supervisory experience, of which at least one is in geotechnical testing.
- Very good written and oral communication skills.

2.3 PROCESS DEVELOPMENT GROUP QUALITY ASSURANCE OFFICER

The PDG Quality Assurance Officer (QAO) is the individual responsible for implementing and monitoring the QA program as described in this QAM. The QAO reports to the Manager, PD. Other responsibilities include:

- Preparing and maintaining this QAM.
- Perform periodic audits and surveillances to ensure that the proper procedures and quality practices are being used.

The QAO has the authority to stop work when applicable QA/QC requirements are not being met, or when work is being performed in a manner which compromises quality.

Qualifications for this position include:

- Five years laboratory experience, two of which must have been involving geotechnical testing, and one year must have been in hazardous waste and radioactive materials testing. A bachelors degree in quality assurance, geology, or civil engineering may be substituted for two years general laboratory experience.
- Completion of IT Corporation Quality Assurance Officer Training course.
- Very good written and oral communication skills.

2.4 ETDC RADIATION SAFETY OFFICER

The ETDC Radiation Safety Officer (RSO) implements the facility health and safety and radiological safety programs, and reports to the Manager, Environmental Health and Safety. Duties include:

- Approving and coordinating shipments of radioactive samples.
- Establishing policy and procedures for radioactive sample handling and laboratory safety.
- Ensuring that the provisions of the facility radioactive materials license are met.

Qualifications for this position include:

- An associates degree in health physics or equivalent work experience.
- Completion of IT Corporation laboratory safety training.
- Good written and oral communication skills.

2.5 ENVIRONMENTAL COMPLIANCE COORDINATOR

The Environmental Compliance Coordinator (ECC) is responsible for ensuring that the facility remains in compliance with environmental regulations and facility licenses (except the radioactive materials license). The ECC exports to the Manager, Environmental Health and Safety. The ECC also coordinates the return and disposal of laboratory waste. Qualifications for this position include:

- A good working knowledge of applicable local, state, and federal regulations governing hazardous waste and radioactive materials.
- Good written and oral communication skills.
- Good organizational skills.

2.5 GL PROJECT MANAGER

The GL Project Manager is the clients point of contact. The GL Project Manager reports to the Manager, ETDC. This individual is responsible for:

- Preparing proposals and price quotes.
- Coordinating work load, project specific requirements, and scheduling with the laboratory supervisor.
- Maintaining the project files.
- Ensuring that laboratory data are generated according to the methods specified by the client.

- Reviewing laboratory data for accuracy and reasonableness.
- Informing the client whenever a problem occurs with a sample.
- Ensuring that project reports are completed and properly reviewed.
- Maintaining computer programs used to reduce data and produce reports.
- Writes standard operating procedures.

Qualifications for this position include:

- At least 4 years analytical laboratory experience, of which at least 1 year is in geotechnical testing, and 1 year is in hazardous/radioactive waste testing.
- A bachelors degree in geology or civil engineering, with courses in geotechnical testing, may be substituted for 2 years of experience.
- Very good written and oral communication skills.
- Certification in engineering technology by an independent agency (i.e. NICET) may be substituted for 2 years of experience.
- Good organizational skills.

2.6 GL SUPERVISOR

The GL Supervisor oversees all day-to-day laboratory operations and reports to the Manager, ETDC. This individual has ultimate responsibility for all data produced by the GL, and:

- Ensures that all laboratory technicians are properly trained in the procedures they perform.
- Informs management of resources required to perform work.
- Schedules work in the laboratory so that project schedules are met.
- Ensures that laboratory equipment is calibrated and properly maintained.
- Informs technicians of project specific requirements.
- Writes laboratory standard operating procedures.
- Reviews project reports and nonconformances.
- Determines if samples are appropriate for requested analyses.

Qualifications for this position include:

- Minimum of 5 years experience in geotechnical testing, one of which must be in a supervisory capacity.
- A bachelors degree in geology or civil engineering, with geotechnical testing courses, may be substituted for 2 years of experience.
- Certification in engineering technology by an independent agency (i.e. NICET) may be substituted for 2 years of experience.
- Good organizational skills.
- Good written and oral communication skills.

2.7 GL SENIOR TECHNICIANS AND TECHNICIANS

The GL technicians perform sample analyses, maintain laboratory equipment, notify management of problems or unusual occurrences, and perform other functions as required. Technicians report to the laboratory supervisor. Senior technicians have 3 or more years of experience in geotechnical testing, and may be certified in engineering technology by a independent agency. Junior technicians have little or no experience in geotechnical testing, and perform work under the supervision of a senior technician or the GL laboratory supervisor.

Qualifications for this position include:

- A willingness to learn test procedures.
- Works well with minimum supervision.
- Good written and oral communication skills.
- Good attention to details.

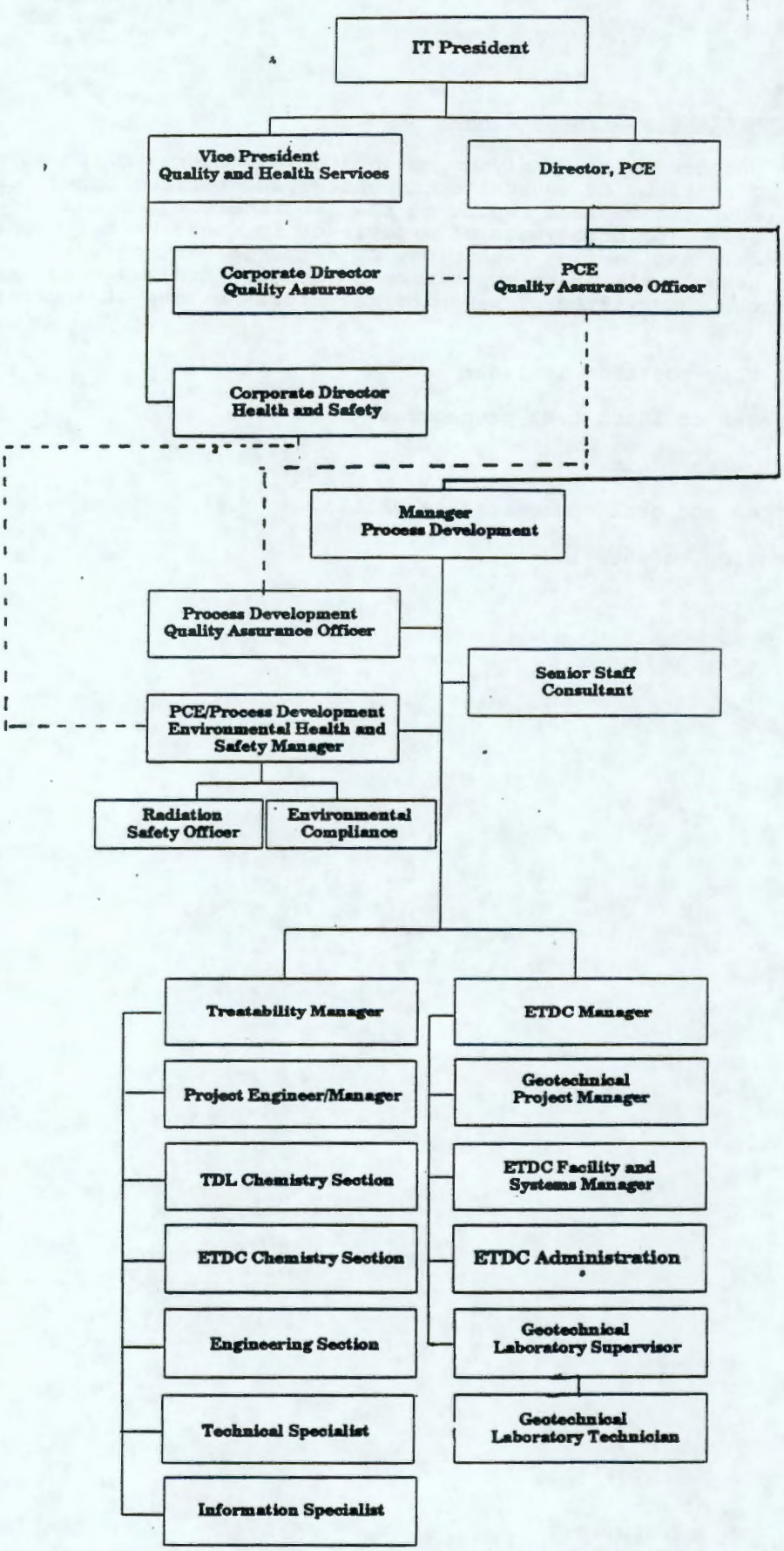


Figure 2-1. Organizational Chart

3.0 QUALITY ASSURANCE POLICY

IT Corporation and the GL have a strong commitment to quality. All levels within the GL are encouraged to use problem solving techniques to correct the root cause of a problem, and not place blame.

3.1 IT CORPORATION POLICY STATEMENT ON QUALITY AND SAFETY

It is It's policy to conduct its affairs with uncompromising integrity and honesty. Employees at all levels shall adhere to high standards of business ethics and comply with all local, state, and federal laws and regulations.

IT will develop and maintain a commitment and dedication to quality in everything we do. Achieving quality requires an on-going commitment by each Associate to improve performance every day.

IT shall strive to achieve peak performance by "doing it right the first time". The company is committed to training and monitoring the quality program, because quality is the foundation of our service.

IT is dedicated to safety. All Associates shall operate in a safe manner at all times. It is each Associates responsibility to stop work in the event of a known or potential compromise to the health and safety of any IT Associate, and to report the problem to a supervisor.

4.0 STANDARD OPERATING PROCEDURE PROGRAM

The GL SOP program is described in SOP PDGADM0001, Preparation, Review, and Use of Standard Operating Procedures and Standard Operating Guidelines. This procedure describes the standard format, review procedures, and control of SOPs/SOGs. A copy of this SOP is included as Appendix A.

5.0 QUALIFICATIONS AND TRAINING

The QAO maintains a training file for each individual. Training and qualifications of technical personnel are documented with resumes. Resumes include academic credentials, employment history, experience, and professional registrations and certifications. Individual training records are maintained for each technical employee, and document on-the-job training and technical courses. Training, Evaluation and Qualification Records (Figure 5-1) are completed by supervisors or other qualified individuals, indicating the procedures an individual has been qualified to perform.

5.1 QUALITY ASSURANCE/QUALITY CONTROL TRAINING

General training in the requirements of the QA/QC program is required of all personnel. Formal training sessions are conducted and documented by the QAO. Prior to working in the laboratory, each new employee shall receive an orientation on QA/QC , laboratory health and safety, and radioactive worker training. This training is documented on the Newcomers Orientation Checklist, maintained in the Quality and Operations files by the QAO. A Quality Orientation Session checklist was used to document the QA/QC orientation prior to April 1993. The QAO also presents training on selected QA/QC topics at regular intervals.

5.2 HEALTH AND SAFETY/HEALTH PHYSICS TRAINING

Prior to being allowed to work in the laboratory, all new employees must attend radioactive worker and laboratory health and safety training presented by the RSO.. This training is documented on the Newcomers Orientation Checklist. The laboratory has a chemical hygiene plan which is designed to make workers aware of the hazards involved in working with chemicals and hazardous materials, as well as administrative policies for performing work safely. Chemical hygiene plan training is conducted annually by the RSO.

5.3 PROCEDURAL TRAINING

All employees shall be qualified in the procedures they perform, prior to performing the procedure without supervision. Training on procedures shall generally follow these steps:

- Provide the trainee with a copy of the procedure.
- Review the procedure with the trainee.
- Perform the procedure while the trainee watches.
- Allow the trainee to perform the procedure under constant supervision until the trainer feels that the trainee is able to perform the procedure with minimal supervision. Document this training on a Training, Evaluation, and Qualification Record, available from the QAO.
- Allow the trainee to perform the procedure with minimal supervision until the laboratory supervisor feels that the trainee is qualified to perform the procedure without supervision.
- Perform qualification testing. If the trainee passes, document the qualification on a Training, Evaluation, and Qualification Record. A means of qualification testing is with the American Association of State Highway and Transportation Officials (AASHTO) Proficiency Sample program. The trainee shall demonstrate the test, and successful testing, results <2 standard deviations from the norm, will constitute qualification. Another means of qualification is to have a qualified technician and the trainee both perform the testing.

The laboratory supervisor shall review these results and judge whether the trainee is qualified. Unsatisfactory results indicate that further training is required.

5.4 REQUALIFICATION

The laboratory supervisor shall requalify all laboratory technicians annually for those procedures they have been qualified to perform. To requalify, the technician must demonstrate each procedure. If the demonstration is unsatisfactory, the laboratory supervisor shall review the procedure with the technician and have the technician demonstrate the procedure again until results are satisfactory. Results shall be recorded on the technicians Training, Evaluation, and Qualification Record, available from the QAO.

TRAINING, EVALUATION, AND QUALIFICATION RECORD

Technicians Name: **Page:**

TEST METHOD	DATE	EVALUATED BY	EVALUATION TYPE[1]	RESULTS/COMMENTS (Pass/Fail)

[1] Initial training, initial qualification, requalification, proficiency sample, blind check sample, other.

Figure 5-1. Training, Evaluation, and Qualification Record

6.0 FACILITIES, EQUIPMENT AND SERVICES

6.1 EQUIPMENT DESCRIPTION

The GL has much of the usual geotechnical testing equipment for performing soil characterization, including systems for determining hydraulic conductivity (permeability), soil moisture/density relationships, specific gravity, density, liquid and plastic limit of soils, particle-size distribution, triaxial shear, direct shear, one-dimensional consolidation, unconfined compressive strength, moisture content, and penetration resistance of soil. A listing of major laboratory equipment is presented in Table 6-1.

6.2 FACILITIES DESCRIPTION

The ETDC is located at 1570 Bear Creek Road, Oak Ridge, TN, 37830. For U.S. Mail, the city and zip code are changed to Kingston, TN, 37763. Shipments other than U.S. Mail use the Oak Ridge address. This facility has a Radioactive Materials License from the State of Tennessee for the receipt and handling of radioactive materials. A floor plan of this facility is shown in Figure 6-1.

The ETDC alarm system monitors access to the facility, as well as fire and emergency alarms. This alarm system is monitored 24 hours a day by a security company.

All fume hoods, except sample receiving, have carbon filters, most also have high efficiency particulate air (HEPA) filters. The exhaust on all hoods is monitored for radioactive emissions.

Three portable, self-contained environmental containment cubicles are available for working with radioactive and/or highly hazardous samples.

The geotechnical laboratory consists of two rooms and an upstairs storage area. The main laboratory has controls for maintaining both temperature and humidity. The upstairs area has a secured area for sample storage. Additional space for laboratory work is available if needed.

A large walk-in refrigerator for sample storage is located outside the building. This refrigerator is secured except when moving samples. A remote temperature monitoring system continuously monitors refrigerator temperature. The temperature display is conveniently located inside the building.

6.3 SERVICES PROVIDED

A listing of the services most requested is provided in Table 6-2. This listing is not complete, additional services are available on request.

EQUIPMENT	MODEL	MANUFACTURER/VENDOR	QTY
Permeability master panel	S-500	Brainard-Kilman	4
Permeability extension panel	S-502	Brainard-Kilman	12
Flexible wall permeameter	S-480	Brainard-Kilman	11
Triaxial permeameter	S-510	Brainard-Kilman	21
Bladder Accumulator	S-470	Brainard-Kilman	6
Digital readout	E-400	Brainard-Kilman	29
Pore-pressure transducer, 0-150 psig	E-124	Brainard-Kilman	11
General purpose transducer, 0-150 psig	E-114	Brainard-Kilman	15
4-way switching unit	E-180	Brainard-Kilman	9
Load cell, 500 lb	E-210	Brainard-Kilman	2
Load cell, 2000 lb	E-212	Brainard-Kilman	4
Flexible wall permeameter		Trautwein	4
Combination permeameter	K-605A	Soiltest	1
Compaction permeameter, 4"	K-610A	Soiltest	1
Water deaerator, 6l and 8l		Walter Nold	1 ea.
Triaxial permeameter, 2"	WF 10201	Wykeham-Farrance	6
Triaxial permeameter, 4"	WF 10751	Wykeham-Farrance	8
Triaxial permeameter, 6"	WF 11001	Wykeham-Farrance	3
Triaxial permeameter, 10"		Wykeham-Farrance	1
10kN Load frame	WF 10021	Wykeham-Farrance	1
5 ton Load frame	1005	Wykeham-Farrance	1
10 ton Load frame	10071	Wykeham-Farrance	2
Direct shear machine	25000	Wykeham-Farrance	1
Rear loading odeometer	24001	Wykeham-Farrance	2
Front loading odeometer	WF 24251	Wykeham-Farrance	3
Mechanical soil compactor	CN-4235A	Soiltest	1
Harvard miniature compaction apparatus	CN-435	Soiltest	1
Sample ejector	P-103	Soiltest	1
Large capacity soil splitter	CL-262	Soiltest	1
Sample splitter	CL-284	Soiltest	1

Table 6-1. Major Laboratory Equipment

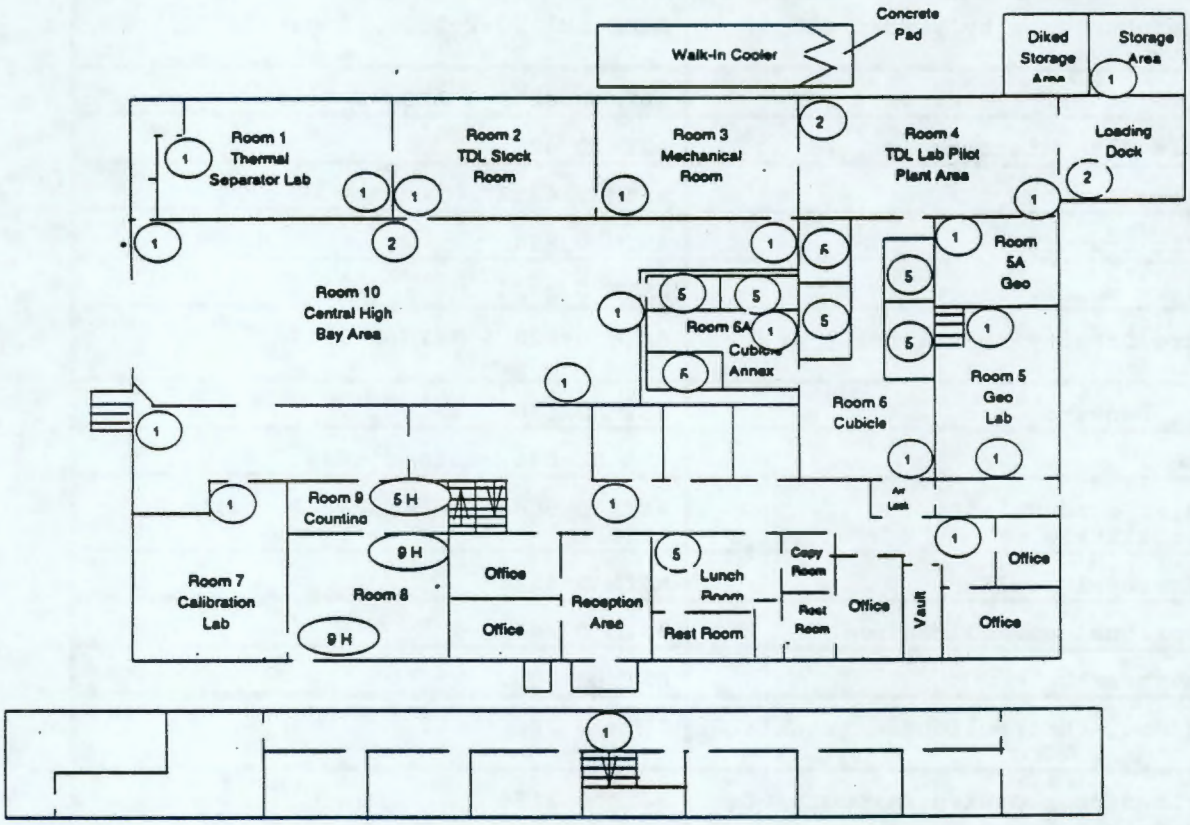
EQUIPMENT	MODEL	MANUFACTURER/VENDOR	QTY
Proving ring penetrometer	CN-970	Soiltest	1
Vicat apparatus	CT-1A	Soiltest	1
Blaine fineness apparatus	CT-415	Soiltest	1
Soil hydrometer	ASTM 152H	Soiltest	6
Liquid limit device	CL-204	Soiltest	2
Proctor penetrometer set	CN-433A	Soiltest	1
Proving rings, various capacities, 100 - 10,000 lb		Soiltest, Wykeham-Farrance, and others	
Electronic balances, 0.1 mg to 24 kg capacity		Mettler, Ainsworth, Sartorius	
Stereoscopic microscope	JD 1888	Bausch & Lomb	1
Microscope	33-45-58	Bausch & Lomb	1
Soil grinder	S9133	Hogentogler	1
Sieves, 3" to #400		Various manufacturers	
Gravity oven	OV-18A and OV-470A	Blue M	1 ea
Mechanical oven	STM-80 and DK-43	Baxter scientific	1 ea.
Muffle furnace	ISO 495	Fischer	1
Chest freezer	10	Kenmore	1
Motorized sample extruder	PMC-5456	Prince Hydraulics	1
Sieve shaker	SS-15	Gilson	1
Rotap sieve shaker	RX-29	W.S. Tyler	1
Orbital shaker	3590	Lab-Line	1
Microsplitter	SP-326	Hogentogler	1
Mechanical stirring apparatus	936-2	Hamilton-Beach	1
Dry test meter	175-S	Rockwell	4
Wet test meter	63125	Precision Scientific	3
Vacuum pump	1405	Sargent Welch	1
Vacuum pump	Hyvac 7	Cenco	1
Hot plate/stirrer		Peninsular Mfg.	3
Length change comparator	C1311	Hogentogler	1
Volume change meter	VC-25	SBEL	4
Hot plate	HPA2240M	Thermolyne	1

Table 6-1. Major Laboratory Equipment

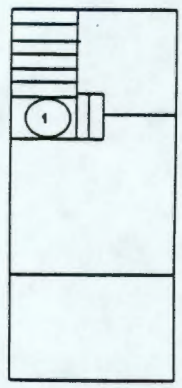
ANALYSIS	METHOD
Moisture content	ASTM D 2216
Unit weight (density), void ratio, porosity	ACOE EM1110-2-1906, Appendix II
Relative density (min/max)	ASTM D 4253 & ASTM D 4254
Particle-Size distribution	ASTM D 422
Atterberg limits	ASTM D 4318
Specific gravity	ASTM D 854
Capillary moisture	ASTM D 2324
Moisture/Density relationship of soils	ASTM D 698 & ASTM D 1557
Proctor penetrometer	ASTM D1558
Soil pH	EPA SW-846, method 9045
Hydraulic conductivity (permeability)	ASTM D 5084 & EPA SW-846, method 9100
1 Dimensional swell	ASTM D 4546
1 Dimensional consolidation	ASTM D 2435
Direct shear	ASTM D 3080
Unconfined, unconsolidated triaxial shear	ASTM D 2850
Unconfined compressive strength of soils	ASTM D 2166
Freeze/Thaw testing	ASTM D 4842
Wet/Dry testing	ASTM D 4843

Table 6-2. Services Offered

ENVIRONMENTAL TECHNOLOGY DEVELOPMENT CENTER
1570 BEAR CREEK ROAD
OAK RIDGE, TN 37830



MEZZANINE OFFICE LAYOUT



UPPER LEVEL STORAGE

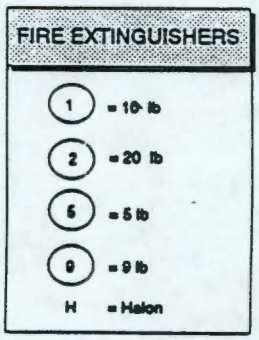


Figure 6-1. ETDC Floor Plan

7.0 EQUIPMENT CALIBRATION AND MAINTENANCE

Any piece of equipment that is used to make a measurement is subject to calibration requirements. Most equipment requires some routine preventive maintenance. There are two types of calibration requirements, periodic and operational. Calibration records are maintained in the Quality and Operations files by the QAO. It is each technicians responsibility to ensure that the equipment used is properly calibrated and in suitable condition for the work being performed.

7.1 PERIODIC CALIBRATION

Periodic calibration is performed on a scheduled basis, usually based on time interval. Equipment calibration tags shall be attached to equipment requiring periodic calibration to indicate its calibration status. It is the responsibility of each individual to check the calibration status of equipment prior to use.

Some equipment is shared between different laboratory functional groups, and acceptable calibration criteria may not always be the same. Method and/or project specific calibration acceptance criteria shall always supersede any other criteria.

A listing of periodic calibration requirements is presented in Table 7-1.

The QAO shall maintain a separate calibration record (Figure 7-1) for each piece of equipment requiring calibration.

7.2 OPERATIONAL CALIBRATION

Operational calibration is generally performed by the analyst as part of an analytical procedure or test method. Calibration tags are not used for operational calibrations.

Calibration acceptance criteria are specified in the analytical method or test.

Table 7-2 lists operational calibration requirements.

7.3 CALIBRATION STANDARDS

Calibration standards are chemical, physical, or radiological sources used to calibrate equipment. Normally these standards have calibration traceable to the National Institute of Standards and Technology (NIST), and calibration is certified for a specific period of time.

Chemical standards used for equipment calibration are procured from two different sources to provide a means of checking each other. Systems calibrated with chemical standards shall use one source for calibration, and another source for calibration verification. Chemical standards shall be certified as to concentration by the manufacturer and shall not be used past their expiration date.

A standard reference material (SRM) is a chemical or radiological standard that is certified for a concentration of an element(s), chemical or physical property, or radioactivity level. SRMs are used for calibration and calibration verification and may have limited life span .

Physical calibration standards include reference thermometers, gauge blocks, weights, etc. These standards are calibrated by an outside certified calibration agency, using NIST traceable standards. In turn they are used to calibrate many items used in the laboratory. Table 7-3 presents the calibration requirements for physical standards.

7.4 NEW EQUIPMENT

New equipment shall be calibrated prior to use. A certificate of calibration from the manufacturer may serve as the initial calibration.

7.5 EQUIPMENT REMOVED FROM SERVICE, DEFECTIVE, OR OUT OF CALIBRATION

If equipment is found to be defective, out of calibration, or otherwise unusable, it shall be immediately removed from service until repaired and/or calibrated. Equipment removed from service shall be clearly labeled as to its status, and the laboratory supervisor and QAO notified.

Equipment placed into storage shall be treated as equipment removed from service.

EQUIPMENT CALIBRATION RECORD

Equipment Name: _____

Manufacturer: _____

Serial/ID Number: _____

Inventory Number: _____

Calibration Procedure: _____

Calibration Interval: _____

Initial Calibration Date: _____

Date Placed In Service: _____

RECALIBRATION DATE					

Figure 7-1. Equipment Calibration Record

EQUIPMENT	CALIBRATION INTERVAL	CALIBRATION METHOD
Thermometer	Annual	SOP TDL102
Balance	Quarterly	SOP TDL103
Reusable molds	Annual	Check critical dimensions
Liquid limit device	Annual	ASTM D 4318
Grooving tool (Cassagrande)	Annual	ASTM D 4318
Grooving tool (plastic)	Quarterly	ASTM D 4318
Sieve shaker	Annual	SOP TDL2104
Sieve	6 months	SOP TDL1113
Hydrometer	24 months	SOP TDL2104
Straightedge	6 months	SOP TDL2165
Pycnometer	12 months	Check critical dimensions and condition
Vacuum system	Annual	Check vacuum, <100mm Hg
Manual compaction hammer	Annual	SOP TDL2164
Mechanical compaction hammer	Annual	ASTM D 2168-80
Proving ring	Annual	External calibration lab
Buret or volumetric flask	24 months	ASTM E 542-85
Pressure transducer and digital display	Annual	External calibration lab
Calipers	Annual	SOP PDGADM0006
Dial gage	Annual	SOP PDGADM0006
Weights	Annual	SOP PDGADM0006
Compression test machines	Annual	External calibration lab
Refrigerator	Daily	SOP TDL1716
Oven	Daily	SOP TDL1716

Table 7-1. Periodic Calibration Requirements

EQUIPMENT	CALIBRATION FREQUENCY	TOLERANCE
pH meter	Prior to use and every 2 hours thereafter	± 0.05 pH units
AA or ICP	Prior to use and every 8 hours thereafter	± 10%
Liquid limit device	Prior to use	Adjust cup drop height to 10 ± 0.2mm; check base, cup, cam, and hanger pin wear
Sieve	Prior to use	Check for integrity of mesh
Moist room or cure tank	Continuous while in use	Temperature 23 ±2°C; Humidity >95%

Table 7-2. Operational Calibration Requirements

STANDARD	CALIBRATION FREQUENCY
NIST reference thermometer	3 years
Gage blocks	3 years
Class S weights	~~3~~ 1 years
Pressure gauge	Annual
Brass weights	Annual

Table 7-3. Physical Measurement Standards Calibration

7.4 EQUIPMENT MAINTENANCE

Most mechanical systems have periodic maintenance requirements. Periodic maintenance is normally performed as specified by the equipment manufacturer. Specific requirements are listed in Table 7.4.

All equipment falls into one of two classes; operational and non-operational. Operational equipment is either in use, or being maintained for use when needed. Non-operational equipment is placed into storage, and is not maintained.

Non-operational equipment shall be thoroughly checked out and calibrated (if required) prior to use.

Batteries shall be removed from all equipment when not in use, or placed into storage.

EQUIPMENT	MAINTENANCE FREQUENCY	MAINTENANCE ACTION
Vacuum pump	Annual	Change oil
Mechanical compaction hammer	Annual	Lubricate, check operation and wear.
Hydraulic extruder	Annual	Check fluid level and hydraulic connections.
Load frames	Annual	Lubricate and check wear.
Permeability panels, permeameters, triaxial cells	Annual	Check fittings and lines for leaks, clean burets.
Sieve shaker	Annual	Lubricate
Fume hoods	Quarterly	Check air flow, filters, sash operation
Safety shower	Monthly	Check operation
Eye wash	Monthly	Check operation
Compressive strength tester	Annual	Lubricate, check wear
Bladder accumulator	Annual	Check bladder integrity, fittings and lines.
Microscope	Annual	Clean and lubricate

Table 7-4. Periodic Maintenance Requirements

8.0 LABORATORY NONCONFORMANCES AND CORRECTIVE ACTION

8.1 NONCONFORMANCES

A nonconformance is a deficiency in a 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. Nonconformances may be caused by non-laboratory operations (e.g., field paperwork incomplete, improper sample, etc.) and be identified at the laboratory. Any laboratory employee observing or identifying a nonconformance shall report the nonconformance to the responsible supervisor and the QAO by filling out a Nonconformance Report (NCR) as shown in Figure 8-1.

Nonconformances involving samples may require that the client be notified and asked to make a decision on an appropriate course of action.

8.2 NONCONFORMANCE REPORT

The person filing the nonconformance shall complete the following sections of the NCR: Project Name and Number, Date, Page, Nonconformance Description, Identified By, and Date. If more room is needed to describe the nonconformance, use the back side of the form. Additional sheets of paper may also be used. Nonconformance reports shall be forwarded to the laboratory supervisor.

The laboratory supervisor shall determine the cause of the nonconformance, determine what,if any, actions are required, and assign someone to perform the corrective action. The laboratory supervisor shall also determine if actions can be taken to preclude recurrence of the nonconformance. The laboratory supervisor shall complete the corresponding sections of the NCR and forward it to the project manager.

The project manager shall review the NCR, notify the client (if appropriate) of the problem, and inform the laboratory supervisor of the clients course of action. All of these action shall be documented on the NCR in the appropriate sections. The NCR shall then be sent to the QAO.

The QAO shall maintain a log of all NCRs, review all NCRs for completeness, verify that the appropriate actions have been completed, and assign a sequential NCR number. Once all sections of the NCR are completed, the NCR shall be placed in the project file. If more than one project is affected, each project file shall have a copy of the NCR. The QAO shall maintain a copy of all NCRs in the Quality and Operations files.

Either the laboratory supervisor or project manager shall approve all corrective actions.

NONCONFORMANCE REPORT

NCR Number:	Project Name/Number:	Date:	Page ___ of ___

Nonconformance Description (include specific requirement violated):

Identified by: Date:

Root cause of Nonconformance:

Corrective action (include expected completion date):

To be performed by: Anticipated Completion Date:

Action taken to preclude recurrence:

To be performed by: Anticipated Completion Date:

Client notified (include client name, how notified, and response):

Notified by: Date:

Corrective action completed by: Date:

Corrective action approved by:

Laboratory Supervisor: _____ Date: _____

Project Manager: Date:

QAO Approval: Date:

Figure 8-1. Nonconformance Report

9.0 PROJECT FILES

The project manager is responsible for maintaining project files. Information regarding a project in the proposal stage shall be maintained by the project manager. A project file is initiated when samples arrive at the laboratory and shall incorporate the proposal file. Inactive project files are stored in a records storage vault.

9.1 PROJECT FILE INITIATION

The project file is started when the project manager receives the sample Request for Analysis and Chain of Custody forms. A Project Index (Figure 9-1) is completed and provides a guide for organizing documents in the file. The Project Index is always located in section A.

A sample cross reference list is generated which provides a listing of client sample numbers and the corresponding assigned laboratory sample numbers.

For projects performed according to standard methods, a Short Project Form (Figure 9-2) is completed. This form gives information on the client, where to send reports, project due date, laboratory notebook references, computer data file names, and what analyses are requested.

If the project involves modified or new methodology, the project manager shall decide if the QAPjP Form (Figure 9-3) is required. The QAPjP Form replaces the Short Project Form, and provides for more specific information regarding methodology and quality control procedures.

9.2 IDENTIFICATION OF PROJECT DOCUMENTS

All project documents shall contain, at a minimum, the project name and number.

9.3 PROJECT FILE MAINTENANCE

The project manager shall maintain the project file while the project is active. A project becomes inactive when the final report is issued, and the project file is transferred to the records storage vault.

All project documents generated by laboratory personnel will be sent to the project manager for filing. Copies of applicable laboratory notebook pages shall be placed into the project file.

All project records shall be maintained for a minimum of seven years after the project is completed. Project records may be subject to regulatory requirements for length of retention. Requirements for records retention beyond the seven years shall be noted on the Short Project Form or the QAPjP Form, and on the outside of the project file.

In the event the records storage vault is filled, project records shall be sent to the Division Document Control Office (DCO) for storage. A record of all project files sent to the DCO shall be maintained by the project manager.

PROJECT INDEX

PROJECT MANAGER: _____ **PROJECT #:** _____

CLIENT CONTACT: _____ **CLIENT PROJECT #:** _____

PROJECT NAME: _____ **DATE BEGAN:** _____

PLEASE CIRCLE EACH CATEGORY THAT MAY APPLY

Completed (X or NA)		
_____	A	Project Index
_____	B	Correspondence (include contracts, proposals, and permits)
_____	C	Project Plans (QAPjPs, work plans, short project form, etc.)
_____	D	Chain-of-Custody (include shipping papers, combined CoC/RFA)
_____	E	Request for Analysis
_____	F	Field Records
_____	G	Calibration Records
_____	H	Computer Data Printouts
_____	I/J	Test Data/Rejected Data
_____	K	Reports
_____	L	Sample Cross Reference List
_____	M	Nonconformances
_____	N	Method Description (for modifications, or nonstandard methods)
_____	O	Project Set-up
_____	P/Q	Subcontractor Records/Engineering Calculations/Designs
_____	R	Compliance Records
_____	S	Vendor Files (copies of POs/P. Reqs. for supplies)
_____	T	Accounting Records (invoices, intercompany POs, etc.)
_____	U/V	Miscellaneous

PLEASE CIRCLE ALL CATEGORIES THAT MAY APPLY. IF A CATEGORY IS NOT USED IT WILL BE NOTED AS NA.

Figure 9-1. Project Index

SHORT PROJECT FORM

Project Name: _____

Project Number: _____

Client Contact: _____

Phone Number: _____

Company Name: _____

Company Address: _____

_____

Send Report to: _____

Due Date: _____

Project Manager: _____

Laboratory Sample Numbers: _____

Laboratory Notebook Reference (book#-page#): _____

Computer File Name(s): _____

List of Subcontractors: _____

_____

Brief Description of Work (include method reference):

_____

_____

_____

_____

_____

_____

_____

Project Specific Requirements:

_____

_____

_____

_____

_____

_____

Figure 9-2. Short Project Form

QAPjP FORM

Project Name: _____

Project Number: _____

Client Contact: _____

Phone Number: _____

Client Address: _____

Send Report to: _____

Due Date: _____

Project Manager: _____

QAPjP Reviewed By: _____

QAO 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/Responsibility (list of persons involved, their title and responsibility for the project-may attach organization chart)**

_____

_____

_____

_____

3) **QA Objectives (include minimum number and type of QC samples, specifications for precision, accuracy, and completeness)**

_____

_____

_____

_____

_____

Figure 9-3. QAPjP Form

4) Sampling Plan (when and how taken, container and sample size requirements, preservatives and storage, radiological screen needed)

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

6) Calibrations (requirements and frequency)

7) Analytical Procedures (list methods or provide procedure)

8) Data Reduction (list calculations to be performed)

9) Surveillance or Audit Requirements (by whom, when, area(s) covered)

10) Preventive Maintenance (list equipment and frequency)

Figure 9-3. QAPjP Form

10.0 DATA MANAGEMENT

Project records are to be recorded with blue or black ink only. A fine point, black ink pen is preferred. Red ink and yellow highlighters are used for quality control checks, but no other color ink, or pencil, is allowed in project records.

10.1 DATA COLLECTION

Data are to be recorded on standard data forms or in laboratory notebooks. Recording data on loose scraps of paper is to be avoided.

Standard data collection forms have been created for most analyses. Data may also be recorded in laboratory notebooks. Computer programs have been developed to perform data reduction and reporting. Once data have been entered into the computer, and the data entry verified, data manipulations are performed by the computer.

10.2 CORRECTIONS

All corrections to project records are to be accomplished by drawing a single line through the incorrect information, initialing and dating the strikeout, and then entering the correct information. If there is not enough room to enter the correct information, use an asterisk (*) or other such mark to reference to another section of the page and place the correct information there. The use of whiteout, correction tape, and write overs are strictly forbidden.

10.3 COMPUTER PROGRAM VERIFICATION

All computer programs used to reduce data shall be verified. To verify a program, a set of data is entered into the program and the output is compared to either hand calculated data, or data from a previously verified program. All options in the program shall be exercised. A printout of the computer program and program validation shall be maintained in the Quality and Operations files.

10.4 TRANSCRIPTION CHECKS

Transcribed data shall be checked 100% for accuracy by someone other than the transcriber. A yellow highlighter shall be used to mark the items checked. Incorrect transcriptions shall be lined out with red ink, and the correct information entered with red ink. The person performing the transcription check shall make the following entry on the form: "100% Transcription check completed by:" their initials and the date. Some data forms may have a signature block for transcription or computer entry checks that is used in place of the transcription check entry.

10.5 MANUALLY CALCULATED DATA

All (100%) of manually calculated data are to be checked by someone other than the person that performed the original calculation. Checked data shall be marked as described for transcription checks. A similar entry is made on the form to document the check, except that the word "Transcription" is changed to "Calculation". Some data forms may have a signature block for data calculation checks that is used in place of the calculation check entry.

10.6 RELEASE OF DATA

Only three individuals are authorized to release data; the project manager, laboratory supervisor, and ETDC facility manager. Either the project manager or the laboratory supervisor shall sign all data reports.

Data are controlled project records. Permission must be obtained from the clients point of contact prior to releasing data to someone other than the individual designated by the client to receive it.

Data which has not had the proper quality control checks and reviews is considered draft data. Care should be taken when releasing draft or preliminary data. The data the client first receives is often the data that is used, and corrected data in the final report may not be passed along to the end user of the data. Draft data that is released shall be on draft paper.

11.0 REPORTS

The GL project manager is responsible for issuing project reports. Project reports shall be on a Certificate of Analysis.

11.1 REPORT FORMAT

The format for a Certificate of Analysis is specified by IT Analytical Systems (ITAS). An example of this format is shown in Figure 11-1.

11.2 REPORT PREPARATION AND REVIEW

Reports are prepared by computer, with verified data files being electronically transferred into the report. Once a draft report is created, it receives a minimum of two reviews which are documented on a Report Checklist, Figure 11-2.

A technical review is performed by the laboratory supervisor, senior laboratory technician, or other qualified individual. This review is to ensure that reported data are correct, reasonable, and all data qualifications are correctly reported.

A QA/QC review is performed by either the project manager, QAO, or ETDC Manager. This review is for spelling, grammar, punctuation, and format, as well as for data correctness.

11.3 CORRECTING REPORTS

If a report requires correction, it shall be reissued in its entirety. It shall be reviewed in the same manner as the original report. To identify a corrected report, place the word "(Amended)" to the right of the project number on the front page. Describe the correction in Section I, Introduction/Case Narrative.

CERTIFICATE OF ANALYSIS

CLIENT
COMPANY
STREET ADDRESS
CITY, STATE, ZIP

Month day, year

Project Number: (Amended) ←for corrected/amended reports only

This is the Certificate of Analysis for the following samples:

Client Project ID:
Date Received by Lab:
Number of Samples:
Sample Type:

I. Introduction/Case Narrative

Describe the samples received and testing requested. Also describe client specific instructions, and list report appendices.

Sample testing results are included as an appendix.

Always include copies of the Request for Analysis and Chain of Custody forms as the appendix after the data.

Specially developed methodology may also be included as an appendix.

Reviewed and Approved:

_____

Geotechnical Laboratory Project Manager

Figure 11-1. Certificate of Analysis Format

Page of
Name: Client name
Client company
Date: Report date
Client Project ID: Client project name/number Project No.: GL project #

IT ANALYTICAL SERVICES
KINGSTON, TN
(615) 482-6497

II. Analytical Methodology

List method name and reference document.

III. Quality Control

Describe specific quality control procedures.

IV. Data Qualification

Describe any deviations from standard procedures and the effect such deviations may have on the data reported. Also describe problems that may have occurred and nonconformances.

Figure 11-1. Certificate of Analysis (continued)

Page of
Name: Client name
Client company
Date: Report date
Client Project ID: Client project name/number Project No.: GL project #

IT ANALYTICAL SERVICES
KINGSTON, TN
(615) 482-6497

Sample testing results.

Figure 11-1. Certificate of Analysis (continued)

REPORT CHECKLIST

Document File Name: _____ Due Date: _____

Start Date: _____ Report Date: _____

Project Name: _____

Project Number: _____

Project Manager: _____

REVIEW SIGNATURES

Prepared By: _____ Date: _____

Technical Review: _____ Date: _____

QA/QC Review: _____ Date: _____

Other Reviewers: _____ Date: _____

_____ Date: _____

_____ Date: _____

_____ Date: _____

_____ Date: _____

REPORT DISTRIBUTION

Copied By: _____ Date: _____

Distributed By: _____ Date: _____

Method: UPS FEDEX US MAIL INTERCOMPANY FAX OTHER: _____

Distribution List:	# Of Copies	
Client: _____	___	Complete Set
Central Files:	1	Complete Set
Project Manager: _____	1	Complete Set
Others: _____	___	Complete Set
_____	___	Complete Set
_____	___	Complete Set

Figure 11-2. Report Checklist

12.0 SAMPLE HANDLING AND STORAGE

Sample handling and storage can be critical to proper sample analysis. Undisturbed samples must be handled in a manner that minimizes disturbance.

Samples may be contaminated with highly hazardous and/or radioactive materials. Caution must be used when opening sample shipping containers and handling samples.

The facility Environmental Compliance Coordinator (ECC) must be informed of all sample receipts.

12.1 SAMPLE RECEIPT

Sample receipt, login, and paperwork processing is described in SOP PDGADM0005, Sample Receipt and Login. This SOP is included as Appendix B.

The following is a brief overview of sample receiving and processing. Samples are logged into the sample receiving notebook, checked for condition, assigned laboratory sample numbers, screened for radiological activity, placed into storage, and the laboratory supervisor and facility Environmental Compliance Coordinator are notified of sample arrival. Sample paperwork is passed to the facility administrative staff for processing. After processing, the sample paperwork is sent to the project manager. The project manager informs the laboratory supervisor of the requested testing, as well as any project specific requirements. The laboratory supervisor directs sample testing, and coordinates sample return (or disposal) with the Environmental Compliance Coordinator.

12.2 SAMPLE STORAGE

Improper sample storage can invalidate testing results. Samples with known or suspected chemical or biological activity may require refrigerated storage and/or immediate analysis. The sample storage refrigerator is maintained at 4°C ±2°C. A daily check is made of refrigerator temperature.

A special rack has been constructed for storage of shelby tube samples. This rack holds shelby tubes in an upright position, and minimizes jarring. Shelby tubes are placed into the rack with the top of the tube up.

Samples not requiring refrigerated storage may be taken directly to the laboratory.

12.3 SAMPLE ARCHIVAL, RETURN, AND DISPOSAL

The client may request that samples be archived. Archived samples shall be stored in a secured, nonrefrigerated area, unless refrigeration is specifically requested.

Samples are normally returned to the client within 180 days of project termination. Samples requiring disposal shall be batched and disposed of within 180 days of project termination. The decision regarding sample archival, return, or disposal, should be made before the samples arrive at the laboratory. The project manager is responsible for determining the clients wishes regarding method of sample disposal.

Samples may contain hazardous and/or radioactive materials, and specific regulatory requirements may apply for shipment. The ECC shall coordinate all sample return and disposal, and ensure that all applicable federal, state, and

local regulations are followed.

13.0 AASHTO PROFICIENCY SAMPLE AND ON-SITE INSPECTION PROGRAM

The GL participates in the American Association of State Highway Transportation Officials (AASHTO) soil and fine aggregate proficiency sample programs, and receives an on-site laboratory inspection every two years.

13.1 PROFICIENCY SAMPLE PROGRAM

Two sets of soil and two sets of fine aggregate proficiency samples are sent to participating laboratories by AASHTO each year. These samples are treated the same as any other laboratory sample. The laboratory supervisor shall determine which technician(s) performs sample testing, and which tests are to be performed. Every effort shall be taken to complete these samples by the deadline.

The project manager is responsible for ensuring that test results are reported by the deadline. Test results are reported on the form provided by AASHTO. Test results may be sent to AASHTO by fax.

AASHTO reviews and collates test results from all participating laboratories, performs statistical analyses, and publishes a report comparing results for the GL to results for the group of laboratories. The standard deviation of group test results is determined.

Any test results submitted by the GL that are greater than two standard deviations from the norm require an investigation to determine the cause. Corrective actions shall be taken as necessary. The GL shall send AASHTO a letter stating the results of the investigation and what corrective actions were taken.

13.2 ON-SITE INSPECTION

The GL shall have an on-site inspection by AASHTO once every two years. The GL shall perform selected test procedures to receive AASHTO certification in those procedures. All discrepancies noted by the AASHTO inspector shall be corrected, and a formal reply sent to AASHTO listing the corrective actions.

13.3 CORRECTIVE ACTIONS

An investigation shall be conducted by the laboratory supervisor to determine the cause of poor proficiency sample results. The investigation shall include the following, as appropriate:

- Were the correct results reported?
- Was the equipment used functioning properly and calibrated?
- Were the proper test procedures followed?
- Was the computer program used to calculate data functioning properly?
- Did AASHTO correctly enter the data?

When the cause of the poor results has been determined, the laboratory supervisor shall initiate corrective action. Corrective action may include replacing, repairing, or recalibrating equipment, or technician training.

Equipment deficiencies noted during an on-site inspection shall be corrected. The laboratory supervisor shall take the necessary actions to repair,

recalibrate, or replace defective equipment.

The laboratory supervisor shall discuss procedural deficiencies with the appropriate technicians, initiate changes to SOP where applicable, and observe technicians performing the test properly.

The QAO shall review all quality system deficiencies and take action as appropriate.

The results of all investigations and corrective actions shall be documented and maintained in the Quality and Operations files by the QAO.

14.0 INTERNAL QUALITY REVIEW SYSTEM

The QAO performs periodic surveillances and systems audits to ensure the provisions of this QAM and laboratory SOPs are being carried out. All records pertaining to quality system reviews are maintained in the Quality and Operations files by the QAO.

14.1 SURVEILLANCES

Surveillances are audits of a specific area, task or function. Examples include reviewing equipment calibration records, reviewing project files, observing sample testing, etc. Surveillance frequency and subjects are at the discretion of the QAO. A minimum of six surveillances of the PDG shall be conducted each calendar year. The ETDC Manager may request a specific surveillance be performed.

14.2 AUDITS

Audits are an indepth review of the activities of a functional group within the Process Development Group. Audits may be performed at the request of the Manager, Process Development or ETDC Manager. A minimum of one audit shall be performed each calendar year.

14.3 SURVEILLANCE AND AUDIT REPORTS

The QAO shall issue a surveillance or audit report within seven days of the audit/surveillance. Three types of remarks are used in surveillance and audit reports; findings, observations, and comments. Findings are items that are not in compliance with specific requirements, are required to be corrected, and require a written response. Observations are items that may need correction, but are not in violation of specific requirements. Comments are statements that may be descriptive in nature. Neither observations or comments require a formal response.

Replies to surveillance findings are due to the QAO thirty days after the date of the surveillance report. If a finding cannot be corrected in thirty days, a schedule for correction shall be provided. The QAO shall closely monitor such schedules, and the surveillance or audit shall remain open until all findings are corrected.

Audit and surveillance reports are sent to the ETDC Manager, with copies to the PD Manager, and Division QAO (DQAO).

14.4 CHECK SAMPLES

The QAO may submit blind check samples to the GL for testing. Check samples shall have known characteristics for the testing requested. Submission of check samples shall be coordinated with, or may be requested by, the ETDC Manager. Check samples may be used for qualifying a technician for a test procedure. Frequency of check samples is up to the discretion of the QAO.

The QAO shall develop criteria for judging the acceptability of check sample test results. Reanalysis shall be requested for check sample results outside the acceptable limits.

The QAO shall issue a written report of check sample test results to the ETDC Manager, with copies to the laboratory supervisor, Manager, PD, and DQAO. Check sample results shall become a part of the training records for the individual performing a specific test when used for test qualification.

14.5 RECORDS REVIEW

The QAO shall review annually, as a minimum, equipment calibration, inspection, and verification records, and Technician training and evaluation records. AASHTO proficiency sample reports, on-site inspection records, and external audit reports shall be reviewed when received.

After each review, the QAO shall discuss deficiencies with the appropriate staff, ensure corrective action is performed, and document the actions in a report to the ETDC Manager.

15.0 SUBCONTRACTING AND VENDOR QUALIFICATION

When using subcontractors, IT Corporation may assume liability for their work. It is imperative that subcontractors be approved prior to using their services.

15.1 SUBCONTRACTOR PREQUALIFICATION

The purchasing department performs subcontractor prequalification. It is the responsibility of the project manager to ensure that subcontractors are prequalified prior to using their services. If a subcontractor has not been prequalified, the project manager shall initiate prequalification by writing a memo to the purchasing department in Knoxville. A copy of the memo shall be sent to the QAO.

The purchasing departments prequalification may not be sufficient to determine the adequacy of a subcontractors quality assurance program. Where warranted, a copy of the subcontractors quality assurance manual shall be obtained and reviewed by the QAO. The QAO and ETDC Manager may decide that an on-site inspection of the subcontractors facilities are required.

15.2 VENDOR QUALIFICATION

If a vendor provides a service or equipment that impacts quality, the vendor must be prequalified in the same manner as a subcontractor. An example of such a vendor would be an equipment calibration service.

15.3 SUBCONTRACTOR/VENDOR PERFORMANCE VERIFICATION

The GL project manager shall periodically evaluate the performance of subcontractors. This evaluation shall be performed at least once a calendar year, and each time substandard performance is noticed. The Subcontractor/Supplier Performance Rating Form shown in Figure 15-1 shall be used for such evaluations.

Unacceptable performance by a vendor shall also be documented on the Subcontractor/Supplier Performance Rating Form. Vendors need not be evaluated annually.

SUBCONTRACTOR/VENDOR PERFORMANCE RATING

Project Name: _____ **Page** ___ **of** ___

Project Number: _____ **Date:** _____

Subcontractor/Vendor Name: _____

CATEGORY	RATING[2] (1-5)
Responsiveness	
Technical Performance	
Conformance to Quality Control Requirements	
Overall Performance Rating	

COMMENTS:

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Performance Rated By: _____

[2] 1 = Totally unsatisfactory, 3 = Acceptable, 5 = Outstanding

Figure 15-1. Subcontractor/Vendor Performance Rating Form

16.0 PURCHASING AND CONTROL OF EQUIPMENT AND SUPPLIES

The quality of supplies can have a large impact on testing results. It is important that the proper equipment and supplies are specified when purchased.

16.1 PURCHASING APPROVAL

All purchases of supplies and equipment shall be approved by the Manager, ETDC.

When purchasing chemicals new to the facility, both the ECC and Health & Safety Supervisor shall be notified prior to ordering. The ECC shall determine if the chemical presents a disposal problem, while the H&S supervisor determines what hazards the chemical presents and what measures are required to ensure employee safety. A Material Safety Data Sheet (MSDS) shall be requested when ordering new chemicals.

The QAO shall approve the first time purchase of reference materials and standards. The QAO shall maintain a listing of standards and reference materials approved for purchase. Certifications provided with reference materials or standards shall be maintained in the Quality and Operations files.

16.2 SPECIFICATIONS

Enough information shall be provided in the purchase order to ensure that what is ordered will meet the requirements for its intended use. When ordering stock items from a catalog, the catalog number is sufficient only if the catalog description is sufficient to determine the item meets requirements. If the description is insufficient, call the vendor and request additional information on the item.

When ordering fabricated parts or equipment, a drawing of sufficient detail to ensure the correct dimensions and tolerances shall be provided.

16.3 LABORATORY WATER SYSTEM

The GL maintains an ASTM Type I/II water system. This water is monitored with resistance meters to ensure it the requirements. A logbook is kept documenting water usage and resistance readings.

The laboratory water system consists of a carbon prefilter, two deionizer tanks, and a series of filter cartridges with a recirculating pump. The carbon prefilter, deionizer tanks, and filter cartridges are replaced annually at a minimum, or when resistance readings indicate a need for replacement. Filters and tanks shall be marked as to the date placed into service.

16.4 CONTROL OF EQUIPMENT

An inventory of all major laboratory equipment shall be maintained by the QAO. Where it is practical, laboratory equipment shall have a serialized PDG inventory tag attached to it.

The GL may have occasion to use government furnished and/or owned property. This property shall be handled in accordance with IT Corporation SOP PR015, Government Property Procedures, and SOP PDGADM0004, Government Property Ordering, Receiving, Tracking, and Use.

Equipment shall not be removed from this facility without the consent of the

laboratory supervisor, RSO, and ETDC manager. Government property must also have the consent of the government property custodian prior to removal. All items removed from the controlled area of ETDC must be surveyed by the health physics department prior to removal.

17.0 QUALITY REPORTS TO MANAGEMENT

The QAO is responsible for providing periodic reports to management indicating the effectiveness of the Quality Assurance program.

17.1 MONTHLY QUALITY REPORTS

A monthly report on quality issues affecting the laboratory shall be given to the Division QAO, with a copy to the Manager, Process Development. Topics to be addressed may include:

- Internal, external, and subcontractor audits
- Certifications pending and received
- Sample holding time violations
- QAPjPs received and reviewed
- Training sessions conducted and/or attended
- Summary of nonconformances
- Status of SOPs
- Any other miscellaneous information

Copies of all monthly quality reports shall be maintained in the Quality and Operations files.

APPENDIX A

INTERNATIONAL TECHNOLOGY CORPORATION

PROCESS DEVELOPMENT GROUP

Standard Operating Procedure

Title: PREPARATION AND CONTROL OF STANDARD OPERATING PROCEDURES AND STANDARD OPERATING GUIDELINES

Prepared by: Cay A. Kamen **Date:** 3/18/93

Reviewed by: [signature] **Date:** 3/18/93
Technical Specialist

Operations approval: Tom [signature] **Date:** 3/18/93
Group Leader/Manager

Interim approval: Cay A. Kamen **Date:** 3/18/93
Quality Assurance Officer

Management approval: [signature] **Date:** 3/18/93
Manager, Process Development Group

APPROVED FOR INTERIM USE

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PREPARATION AND CONTROL OF STANDARD OPERATING PROCEDURES AND GUIDELINES

1.0 Scope and Objectives

1.1 This procedure defines the standard operating procedure (SOP) and standard operating guideline (SOG) program. This program is administered by the Process Development Group (PDG) Quality Assurance Officer (QAO).

1.2 The procedures for SOP/SOG review, approval, control, and a standard format for interim SOPs, are defined in this document. Format for the final version of an SOP is described in IT Corporation Standard Quality Practice ITC0002. There is no standard format for an SOG.

1.3 SOPs are required for all work performed on a routine basis according to standard published methodology. SOPs are also used to describe administrative and environmental health and safety procedures.

1.4 SOGs may be used in place of SOPs for screening tests, modifications to published methods, project or task specific amendments to SOPs, creation of non-standard methodology, and seldom performed procedures. SOGs are a means of quickly documenting these procedures, with a streamlined approval process that maintains the validity of the procedure.

1.5 SOGs used to amend an SOP on a project or task specific basis supersede the SOP for the project or task for which it was intended.

1.6 The approval process for an SOG is not as rigorous as that for an SOP. For this reason SOPs may be substituted for SOGs, but SOGs may never be substituted when an SOP is required. The final determining factor for whether an SOG is appropriate rather than an SOP is the project requirements.

2.0 Definitions

2.1 Standard operating procedure (SOP) - A controlled document that describes how a task is to be performed, analogous to the Corporate Standard Quality Practice (SQP). An SOP is prepared in a standard format and undergoes a rigorous review process. Paragraph 1.3 describes when an SOP is required.

2.2 Standard operating guideline (SOG) - A controlled document that describes how a task is to be performed. An SOG has no specified format, but does require certain information to be presented. An SOG may be as simple as a memo, or as complex as a work plan. The review process is less rigorous than for an SOP. Paragraph 1.4 describes when an SOG may be used in place of an SOP. An SOG is a means for quickly documenting procedural variations, nonstandard procedures, and procedures with limited application or not used often enough to justify the cost of preparing an SOP.

2.3 Interim SOP/SOG - An SOP/SOG that has undergone a minimum level of review that allows confidence in the accuracy and completeness of the described procedure may be issued for interim use while further review and final approval is pending. To ease in distinguishing an interim SOP from a final version, the cover page of the interim SOP will be different from the final version. Appendix A is an example of an interim SOP.

2.4 Warning - A warning is a statement used to alert the reader of a potential hazard that may result in injury and/or equipment damage. Warning format is described in Attachment A.

2.5 Caution - A statement used to alert the reader of a potential for erroneous test results due to circumstances within control of the individual performing the task (i.e., time limitations, technique, etc.). Caution format is described in Attachment A.

2.6 Screening - A quantitative or qualitative analysis or test that provides information as to the presence and/or concentration of an element/compound, or provides information on a physical property(s) of a material. This information may be used to determine the feasibility or effectiveness of a process under development. Screenings provide limited information to project personnel or clients.

2.7 Quality Assurance Officer (QAO) - An individual(s) assigned by the Manager, Process Development Group, to administer the quality assurance program. The QAO works closely with the Pollution Control Engineering (PCE) Division QAO (DQAO).

2.8 Document Control Office (DCO) - The PCE Division office responsible for maintaining controlled documents.

2.9 Manager, Process Development Group - The individual appointed by the Director, PCE Division, to manage the Process Development Group (PDG).

2.10 Process Development Manager - The individual appointed by the Manager, PDG, to manage the treatability laboratory of the PDG.

2.11 Environmental Technology Development Center (ETDC) Manager - The individual appointed by the Manager, PDG, to manage the ETDC facility.

2.12 Environmental Health and Safety (EH&S) Manager - The individual appointed by the Manager, PDG, to administer the health and safety, radiological safety and compliance, and environmental compliance functions for the PDG.

2.13 Section Manager - An individual appointed to manage any of the sections of the PDG support functions, treatability, and geotechnical laboratories. For treatability these sections are (from 10/1/92 organization chart): project engineer/managers; TDL chemistry; ETDC chemistry; engineering; technical specialist; and information specialist. For the geotechnical laboratory the section manager is the geotechnical project manager. For environmental health and safety they are the ETDC safety/health physics, TDL safety/health physics, and ETDC/TDL environmental compliance managers. These sections are subject to change as the organization changes.

2.14 Operations Manager - Either a section manager or the next higher level of supervision.

3.0 Methodology

3.1 Document Control

3.1.1 The distribution of SOPs/SOGs is controlled by the QAO. All requests for copies of SOPs/SOGs shall be referred to the QAO.

3.1.2 The PCE Division Document Control Office (DCO) shall maintain a master copy of all SOPs/SOGs. They shall distribute these documents as requested by the QAO.

3.1.3 The DCO shall assign SOP/SOG numbers, assign serial numbers to individual controlled copies, and maintain a record, by name and organization, of all individuals with controlled copies of

SOPs/SOGs.

3.1.4 The DCO shall maintain a current index of all SOPs/SOGs approved for issuance. The index shall indicate which revision is current.

3.1.5 The QAO shall maintain a record of all SOPs/SOGs approved for interim use.

3.1.6 SOGs that amend an SOP shall become an attachment to the SOP.

3.1.7 Uncontrolled copies of SOPs/SOGs may be used in situations where the document may reasonably be expected to become contaminated or damaged. In such a situation every effort shall be made to ensure the document used is the latest revision.

3.1.8 Uncontrolled copies of SOPs/SOGs shall be marked "UNCONTROLLED COPY" on the first page, and the serial number shall be lined through.

3.1.9 Controlled copies of SOPs/SOGs shall be returned to the QAO when replaced by a new version, or when the individual assigned to the document leaves the PDG. Uncontrolled copies shall be destroyed when no longer needed.

3.2 Responsibilities for Preparation, Review, Approval, and Use

3.2.1 SOPs/SOGs shall be prepared by the most qualified individual available. This is usually an individual performing the procedure.

3.2.2 Each individual using an SOP/SOG shall ensure that the most current revision is used.

3.2.3 The individual making an uncontrolled copy of an SOP/SOG is responsible for marking it as described in paragraph 3.1.8.

3.2.3 SOPs shall be reviewed and approved in the following order:

3.2.3.1 A technical review shall be performed by the most qualified individual(s) available, other than the preparer. The operations manager for the group preparing the SOP shall appoint the individual(s) responsible for the technical review. If more than one

individual performs this review, only one individual will sign as reviewer.

3.2.3.2 An operations review shall be performed by an operations manager from the group performing the procedure.

3.2.3.3 The QAO shall review all SOPs and have authority to approve SOPs for interim use.

3.2.3.4 The QAO shall be responsible for ensuring that interim SOPs are approved by the Manager, PDG, put into the final format, then sent for final approval and issue as described in 3.2.3.6.

3.2.3.5 The Manager, PDG, shall review and approve all SOPs.

3.2.3.6 The PCE Division QAO (DQAO) shall have sole authority for final approval of all SOPs.

3.2.3.7 All reviews and approvals, except by the DQAO, shall be documented on the front page of interim SOPs. The DQAO shall approve and sign all final versions of SOPs.

3.2.4 SOG Review and Approval

3.2.4.1 SOGs shall be reviewed and approved in the same manner as an SOP except that the operations manager, as described in paragraph 3.2.3.2, may approve an SOG for interim use, and the review process stops with the QAO.

3.2.4.2 The QAO shall review and have final approval authority for SOGs.

3.2.4.3 All SOGs shall contain signature blocks for the preparer, technical review, operations review and QAO review.

3.2.4.4 SOGs are not meant to be permanent operating documents, and have a life span of 2 years. At the end of two years, an SOG shall be either converted into an SOP, or shall become inactive. Inactive SOGs must be reviewed prior to use.

3.2.5 Annual Review

3.2.5.1 An annual review shall be performed of all SOPs/SOGs. This review shall be accomplished by the most qualified individual available.

3.2.5.2 Any SOG that amends an SOP shall be included in the SOP annual review, and shall be considered for incorporation into the SOP.

3.2.5.3 The QAO shall provide an uncontrolled copy of the SOP/SOG to be reviewed to the operations manager with responsibility for the subject of the document, no less than 30 days prior to the review date. The manager is responsible for ensuring that the review is completed by the due date.

3.2.5.4 Changes to the document, other than editorial type (format, grammar, spelling, etc.) changes, shall go through the same review process as the original document.

3.3 The QAO shall provide the Process Development Group Manager with a monthly update of the status of documents being written or under review.

3.4 Document Change Procedures

3.4.1 SOPs may be amended through an SOG. If the SOP amendment is to be made permanent, this shall be stated in the SOG, and the SOG shall be incorporated into the SOP at the next review.

3.4.2 Changes to SOPs/SOGs, other than editorial (format, spelling, grammar, etc.), shall be reviewed and approved in the same manner as the original document. Change requests may be submitted to the QAO by memorandum or other written communication, but must include information on why the change is required and what project(s) will be impacted by the change. The QAO is responsible for initiating change requests in accordance with PCE procedures for changing controlled documents.

3.4.3 Data collection forms shall be treated separately from the SOP/SOG. Updated/changed data collection forms may be issued for inclusion with an SOP with approval of the operations manager and QAO.

3.4.4 Revised SOPs/SOGs shall be reissued in their entirety to each individual possessing a controlled copy of the document, and to others as deemed appropriate by the QAO. Previously issued controlled versions of the SOP/SOG shall be returned to the QAO. Previously issued uncontrolled versions of the SOP/SOG shall be destroyed.

4.0 Format/Forms

4.1 A computer file has been created with the SOP format and instructions for use. This format follows the guidelines in Corporate Standard Quality Practice ITC0002, with some additional requirements. A copy of this format is included as Appendix A. All SOPs shall follow the corporate format, which requires paragraphs 1 through 5. The additional information requested in subparagraphs are optional, but shall be included where applicable. Additional information may be supplied. A header shall be placed on all pages (including appendices) which contains the SOP number, revision number, document date, and page number.

4.2 After interim approval of an SOP, the QAO shall forward a copy of the document for word processing and final formatting according to Division guidelines. After final formatting, the QAO shall submit the SOP for final review and approval for use.

4.3 There is no set format for SOGs. They may be as simple as a memo, or as complex as necessary.

4.4 SOGs which amend, modify, or are derived from a published methodology or SOP must reference that document. A copy of the referenced document should be attached to the SOG, but is required only when the SOG amends an SOP.

4.5 The first few paragraphs of an SOG shall contain information on the purpose and specific use of the SOG. Examples include, but are not limited to, the task or project for which the SOG is to be used, any procedural limitations, how long the document is valid (up to 2 years, see para. 2.2), and methodology references.

4.6 SOP/SOGs shall contain the applicable cautions and health and safety warnings. Use the format described in Appendix A, paragraph 3.7.

4.7 List any specific QC and equipment calibration requirements in all SOP/SOGs.

4.8 SOP/SOGs shall contain any equations required to reduce data to a final product.

4.9 SOP/SOGs shall describe any documentation requirements, and include a copy of forms used with the procedure.

4.10 SOPs/SOGs that are more than twenty (20) pages long, excluding appendices, shall include a Table of Contents page immediately after the cover page.

5.0 References

5.1 IT Corp SQP ITC0002, Development, Approval, and Distribution of Standard Quality Practices.

Appendix A

PROCESS DEVELOPMENT GROUP

Standard Operating Procedure

Title:

Prepared by: _____ **Date:** _____

Reviewed by: _____ **Date:** _____

Technical Specialist

Operations approval: _____ **Date:** _____

Group Leader/Manager

Interim approval: _____ **Date:** _____

Quality Assurance Officer

Management Approval: _____ **Date:** _____

Manager, Process Development Group

SOP TITLE

1.0 Scope and Objectives

1.1 Describe what the procedure is for and what it applies to. Describe any limitations.

2.0 Definitions

2.1 Define technical terms or potentially confusing words.

3.0 Methodology

3.1 Summary - Give a brief summary of the procedure.

3.2 Interferences or potential problem areas - Describe any interferences or potential problem areas that are likely to be encountered while performing this procedure. Explain how to overcome these problems or interferences if possible.

3.3 Sample requirements, handling, preservation, and holding time - Describe any of these sample requirements which may apply.

3.4 Required equipment and reagents - List any specific equipment and reagent requirements. Describe reagent preparation, storage, and shelf life limitations.

3.5 Calibration requirements - List all applicable equipment calibration requirements and acceptance criteria. Include calibration procedure(s) if not described in another SOP.

3.6 Quality control requirements - List any specific quality control requirements.

3.7 Health and safety - List any health and safety concerns, emergency actions, or first aid. Safety warnings shall be repeated prior to the applicable step in the procedure. Use a text box, with the word **"WARNING!"** in bold capital letters. Adjust the width of the box to the maximum width acceptable; allow the computer to set the height.

3.8 Step-by-step procedure - Self explanatory.

3.9 Calculations - Provide all equations which are required to reduce data to a final product.

4.0 Format/Forms

4.1 Provide a copy of any data collection or other forms used with this procedure.

4.2 Describe any entries on the form(s) which are not self-explanatory.

5.0 References

5.1 List all references and/or SOPs which are applicable to this procedure.

APPENDIX B

INTERNATIONAL TECHNOLOGY CORPORATION

PROCESS DEVELOPMENT GROUP

Standard Operating Procedure

Title: Sample Receipt and Log in

Prepared by: _____ **Date:** _____

Reviewed by: _____ **Date:** _____

Technical Specialist

Operations approval: _____ **Date:** _____

Group Leader/Manager

Interim approval: _____ **Date:** _____

Quality Assurance Officer

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Sample Receiving and Log in

1.0 Scope and Objectives

1.1 This procedure describes the steps taken during the receipt and log in of a sample shipped to IT Process Development Group (PDG) laboratories.

1.2 This procedure contains guidance for surveying samples received from a client using portable radiation survey instruments.

1.3 This procedure applies to all samples received.

1.4 The Radiation Safety Officer (RSO) is responsible for training the sample receiving staff who may conduct a radiation survey, evaluate survey results, provide guidance and direct any remediation of receiving incidents involving radioactive materials.

1.5 The Supervisor of the Sample Receipt Group is responsible for verifying that a radiation survey has been completed on samples known or suspected to be radioactive before they are released for analysis to the laboratory.

2.0 Definitions

2.1 Counts Per Minute (cpm) - A relative unit used to measure the rate of radiation events detected by a sensitive radiation detector and survey rate meter, equivalent to a Ludlum Model 3.

2.2 Normal Background - The ambient radiation field to which we are exposed daily, originating from cosmic rays, naturally occurring radionuclides (^{40}K, etc.) and human endeavors (fallout, fuel cycle, etc.). This radiation field is variable, and causes a survey meter to respond in the absence of radioactive materials.

2.3 Radiation Survey Instrument - A hand held radiation survey instrument capable of detecting ionizing radiation.

2.4 DOT "Radioactive" - Radioactive Material as defined by the Department of Transportation (DOT) is any material which has a specific activity greater than 0.002 µCi/g.

3.0 Methodology

3.1 Summary

3.1.1 Samples shipped to the laboratory may be radioactive and as a result, shall be surveyed before they are handled by laboratory personnel.

3.1.2 Sample Receiving personnel shall be familiar with the paperwork accompanying samples known to be radioactive before handling the samples.

3.1.3 While it is anticipated that shipments received at the laboratory would be "nonradioactive" per DOT regulations, it is possible for samples containing DOT radioactive materials to arrive at the laboratory unmarked and unannounced.

3.1.3.1 This procedure provides the guidance required to evaluate all packages and identify samples that require a higher level of scrutiny.

3.1.3.2 If it is suspected that the shipment contains quantities of radioactive material requiring shipment as DOT "radioactive material", the RSO shall be notified.

3.1.4 Training in this procedure shall be conducted by the Radiation Safety Officer.

3.1.5 All training shall be documented and filed in the individual's training records.

NOTE: All radioactive sample shipments shall be pre-authorized by the site RSO. This pre-authorization is verified by an Authorization Number assigned by the RSO or his designee. Any radioactive sample shipments that arrive without this number may not be accepted into the facility.

3.2 Interferences or potential problem areas

3.2.1 This procedure is useful only for detecting

radiation that can penetrate the sample container (i.e. gamma radiation) or radioactive contamination (alpha, beta, gamma) on the outside of the sample container.

3.3 Sample requirements, handling, preservation, and holding time

3.3.1 Work shall be stopped in the event of a known or potential compromise to the health or safety of any IT Associate, and shall be reported immediately to a laboratory supervisor.

3.3.2 Vinyl, latex, or other approved glove shall be worn when handling samples.

3.4 Required equipment and reagents

3.4.1 Ludlum Model 1000 with alpha scintillation detector, or equivalent.

3.4.2 Ludlum Model 1000 with beta/gamma detector, or equivalent.

3.4.3 Tennelec LB5100 low background counter, or equivalent.

3.4.4 Ludlum Model 19 Micro-R meter for gamma exposure rate measurements, or equivalent.

3.4.5 Ludlum Model 3 with pancake GM detector.

3.4.5 Smears

3.4.6 Survey forms

3.4.7 Rubber/latex gloves

3.5 Calibration requirements

3.5.1 The Ludlum Model 1000s and Tennelec LB5100 shall have daily efficiency and background checks.

3.5.2 The exposure rate instrument is calibrated every six months.

3.6 Quality Control Requirements

3.6.1 The radiation survey instrument shall have been calibrated within the last six months.

3.6.2 All information recorded on any of the documents discussed in this procedure must be done so in a neat and legible manner.

3.6.3 Corrections to data entries must be done by drawing a single line through the incorrect entry and initialing and dating the correction.

3.6.4 Writeovers, erasures, blacking out, and use of correction fluid are unacceptable data recording practices.

3.7 Health and Safety

3.7.1 Initial Laboratory Receipt

3.8.1.1 All shipping containers arriving at the laboratory shall be inspected by sample receiving personnel.

3.8.1.2 All shipping containers shall be opened under a fume hood.

3.8.1.3 Chain of Custody Record forms are signed by the Sample Receiving personnel and condition of the sample(s) recorded. All sample paperwork shall be inspected for possible sample hazards.

3.8.1.4 Gloves are required at all times while handling samples.

3.8 Step-by-step Procedure

3.8.1 Radiological Contamination Surveys

3.8.1.1 Contamination survey - smear all samples and shipping containers, then count the smears on the Ludlum Model 1000s or Tennelec LB5100 for α/ß removable activity. Record results on the Sample Tracking Form.

3.8.1.2 If a sample or shipping container exceeds site contamination limits (20 dpm/100 cm^2 - α; 200 dpm/100cm^2 - ß),

wipe down and survey again. Ensure the area where the sample or container was placed is surveyed.

3.8.1.3 If a sample or container received is contaminated and cannot be decontaminated below site limits, post the item as "Contaminated" and contact the Radiation Safety Officer (RSO). A survey form shall be completed to document the location(s) and contamination level(s).

3.8.1.4 Surveys for Radioactive Materials Receipts and Shipments

3.8.1.4.1 Upon receiving a radioactive materials shipment other than exempt quantity shipment (i.e., LSA, White I, Yellow II, etc.) ensure that radiation and contamination surveys are performed and documented. Obtain a copy of the shipping papers to file with the survey information.

3.8.1.4.2 Radiation surveys shall include contact and 1 meter readings on the outside of the container as well as contact readings on each individual sample/item included in the shipment.

3.8.2 The Sample Receiving personnel check the samples for the following items:

3.8.2.1 The sample containers are checked for damage such as leaks, spills, broken glass, or unusual odor. Evidence of any damage is recorded on the Condition of Receipt / Variance Report (see 4.2).

3.8.2.2 Sample identification on the sample containers shall be compared to that on the Analysis Request and Chain of Custody Record form.

3.8.2.3 The custody seals and tapes on sample containers shall be checked to ensure that they are intact.