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TDI-Brooks International, Inc. B & B Laboratories

Quality Manual

*Scope: The Analysis of Geochemical, Geotechnical and
Environmental Samples*

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Revision History

QUALITY MANUAL SECTION	REVISION NUMBER	DATE	PURPOSE OF REVISION	APPROVED BY
ALL	0	02/25/2010	Baseline Issue	J. Brooks
Section 5.4.1	1	09/09/2010	Revised Quality Objectives and Policy	R. Putt
Org Chart	2	11/15/2010	Included note on chart to clarify project manager role.	K. Nease
Scope on front cover, Intro, p.2 and Core Process Chart, p.6 ,and Sections 4.2.2 and 7.3	2	11/15/2010	Changed Scope, Intro, Core Process Chart and Section 4.2.3 to delete Design Requirement, and removed Section 7.3, Design and Development as a requirement that must be addressed since no design occurs.	K. Nease
Section 4.1, last paragraph, Core Process Chart, p. 6, and Section 7.5.1.2	2	11/15/2010	Excluded machined parts and equipment manufacture from Outsourced Operations/Processes. Changed sub-heading in Section 7.5.1.2 to read, Outsourced Operations for Data Analysis.	K. Nease
Section 5.5.2, first sentence, cover page address; Section 6.3 last sentence	3	12/6/2010	Changed QA Manager to Management Representative, added second location address to cover page. Data backup procedure created to support this section	K. Nease
Section 4.2.4	4	1/1/2011	Referenced new Recordkeeping Procedure for Quote, Contract, QAPP and QMP.	K. Nease
Section 2	5	6/28/2012	Removed the ORV POWELL.	K. Nease
Section 4.2.4 and 7.2.2	6	9/25/2012	Removed QMP	K. Nease
Sections 3-Org Chart; 5.6.1 Mgmt Team Org Chart; and 7.1	7	11/27/2012	Revised org and mgmt team charts; defined QAPP in 7.1.	K. Nease
Section 2, Section 8.2.1	8	3/22/13	Changed number of employees; added Customer Audits	K. Nease
Section 7.2.2	9	5/10/13	Changed Client Information list to Job and Technical Report Index	K. Nease
Section 7.2.2, last paragraph	10	10/16/2013	Clarified invoicing process.	K. Nease

Annual Review History

Proof of Annual Review by Management Representative

(This review includes the quality manual and supporting procedures.)

DATE REVIEWED	REVIEWED BY
9/9/2010	R. Putt
9/15/2011	K. Nease
11/27/2012	K. Nease
10/16/2013	K. Nease

Quality Policy

TDI-Brooks International and B&B Laboratories strive to not only meet, but also exceed our customer's expectations with respect to data quality, documentation, and timeliness.

Our management complies with this quality policy by putting quality first in all of our operations. We focus on being one of the best trace organic laboratories in the nation through performance based, blind test exercises conducted by US federal agencies. Our surface geochemical exploration (SGE) and geotechnical laboratories service the international geochemical and geotechnical coring operations of our parent company, TDI-Brooks Int'l Inc. TDI-Brooks requires timely, accurate and consistent data from our geochemical and geotechnical laboratories.

Our team is our greatest asset. We encourage them to accept ownership and responsibility of their work as we promote employee advancement through training and education.

We are committed to continual improvement, and we will correct and prevent deficiencies related to data quality. We value working safely and in an environmentally responsible manner.

This policy provides a framework for establishing and reviewing the quality objectives. This policy, a controlled document, and all current quality objectives as well as overall QMS performance, are reviewed annually by the management review team for continuing suitability, further improvement, and to ensure that they are communicated and understood within the organization.

Dr. James Brooks
President/CEO

1 Introduction

This quality system manual describes the quality system and implementation of ISO 9001:2008 by TDI-Brooks International, including its affiliate, B&B Laboratories, Inc. (TDI-Brooks/B&B), College Station, Texas. This quality system is documented in accordance with the requirements of ISO 9001:2008.

This QMS (QMS) covers all activities of TDI-Brooks/B&B with respect to the following scope of operations:

The Analysis of Geochemical, Geotechnical and Environmental Samples.

The executive management of TDI-Brooks/B&B developed this system in order to:

- Insure that the deliverables provided by TDI-Brooks/B&B conform to all customer specified requirements and applicable legal requirements
- Promote the achievement of excellence and the continual improvement of organizational function
- Further the interest of all affected parties with respect to TDI-Brooks/B&B operations, including customers, end-users, shareholders and owners, employees, suppliers and other partners, and the community and society as a whole

This quality manual is designed to be a guide for TDI-Brooks/B&B personnel and our customers. Appropriate documented procedures exist within TDI-Brooks/B&B and are used to implement our QMS. Sections 7.3, Design and Development and 7.5.2, Validation of Processes for Production and Service Provision, do not apply to TDI-Brooks/B&B and are excluded from the QMS. No design of product/service is conducted so Section 7.3 is not required. All processes for production and service provision at TDI-Brooks/B&B can be verified by subsequent monitoring or measurement, which will reveal any deficiencies prior to delivery. These clauses will be addressed in the future if such requirements become relevant to the QMS.

This document applies to the described QMS, to all referenced lower tier documents, to all records documenting the performance of the QMS, and to all physical and informational systems referenced herein.

The terms “product” and “service” are interchangeable throughout this manual.

The following are referenced within the TDI-Brooks/B&B QMS:

- ANSI/ISO/ASQ Q9001-2008 – Quality Management System Requirements
- TDI-Brooks/B&B Procedures/SOP's

2 General

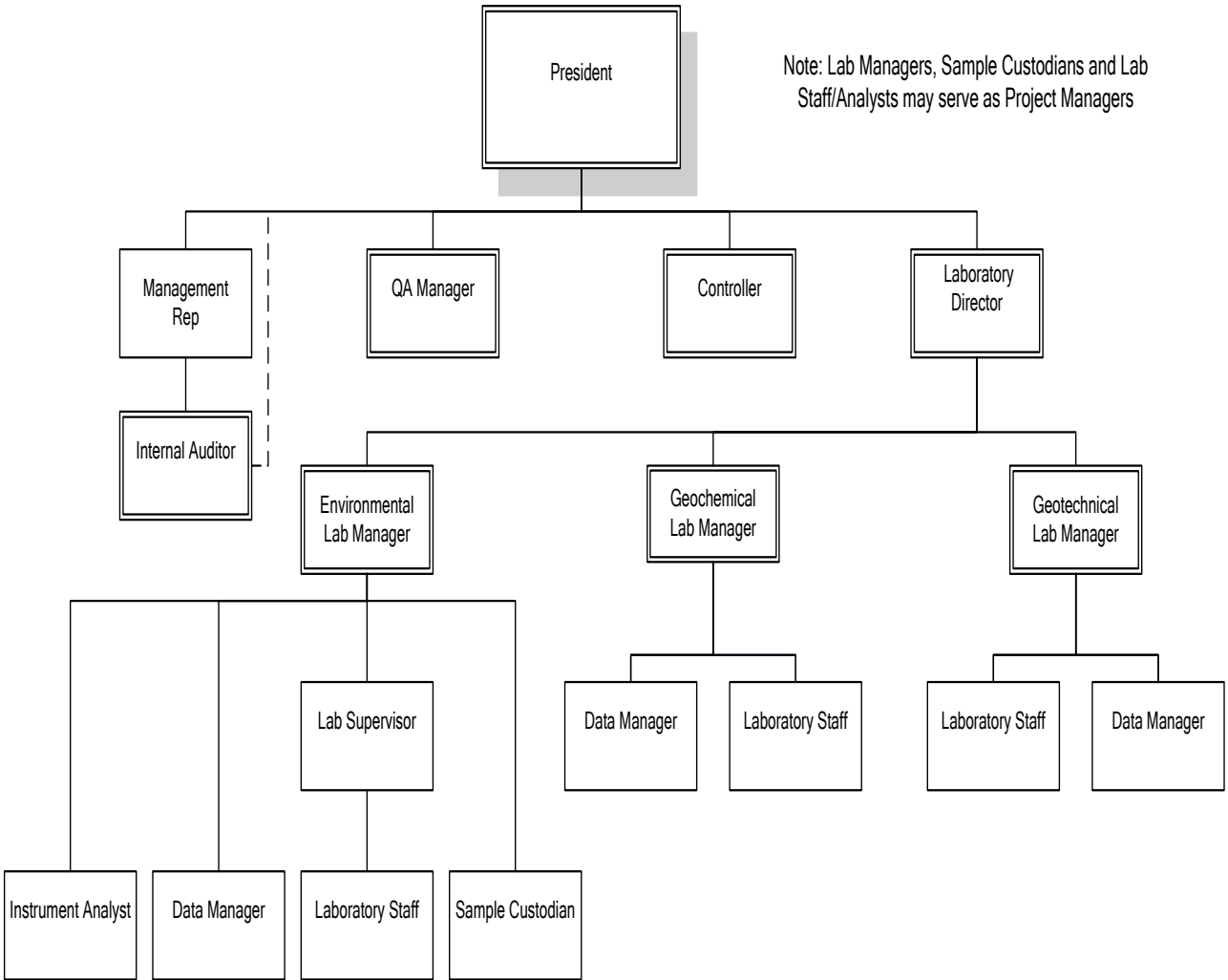
TDI-Brooks International, Inc., its affiliated laboratory (B&B Laboratories), is a research and service company specializing in high-end environmental chemistry; multi-disciplinary oceanographic and environmental projects; surface geochemical exploration; geotechnical and offshore survey projects for federal and state agencies as well as private industry. TDI-Brooks was formed in May of 1996 by a core group of staff with many years of experience. Our yearly revenue varies depending on the offshore survey market. Most of our private industry revenue comes from international projects in Africa, Latin American, Canada, SE Asia and the Mediterranean regions. TDI-Brooks has current federal projects from NOAA, USFWS, USEPA and MMS. One of our most prestigious federal projects has been the current five-year (2010-2015) NOAA National Status and Trends Mussel Watch Project. This is the premier coastal environmental monitoring program in the U.S.A. TDI-Brooks is also one of the U.S. Fish and Wildlife Service's three (3) contract laboratories for trace organic residue analyses primarily in tissue samples. These programs require meeting low level detection limits as well as stringent QA/QC requirements. Additionally, the laboratory has been involved in National Resource Damage Assessments resulting from oil spills. This type of work requires rapid data turn around times and analytical procedures and documentation necessary for litigation.

TDI-Brooks has a staff of nearly ninety (90) individuals, including fourteen (14) Ph.D. level oceanographers, geochemists, biologists and geologists. Some of our senior staff continue to have academic appointments and are considered experts in their fields. About a third of the staff is part of our affiliated laboratory, B&B Labs. The other staff is involved in our offshore research and survey operations. TDI-Brooks owns and operates two research vessels --- the R/V GEOEXPLORER and the R/V GYRE. We have a third (3rd), fourth (4th) and fifth (5th) vessel on long-term charter, the INEZ McCALL, the R/V BROOKS McCALL, and OSV RYLAN-T. Our vessels are primarily engaged in geotechnical, geochemical, environmental, geophysical, geothermal, metocean and hazard surveys for both private and federal clients. These are 120 to 180-ft vessels outfitted as multi-use oceanographic research vessels. All are specifically optimized for deepwater operations with high speed winches, A-Frames, multiple heavy coring rigs, sub bottom profilers and DGPS/USBL navigation systems. The GEOEXPLORER is outfitted additionally for analog and HR site surveys along with multibeam acquisition.

TDI-Brooks is a privately held Texas C Corporation wholly owned by Dr. James M. Brooks and Dr. Bernie B. Bernard. TDI-Brooks is our flagship company that interacts with clients. B&B Laboratories, Inc. operates as the support laboratory for TDI-Brooks with Drs. Brooks and Bernard being the majority shareholders. All B&B Laboratories revenue comes through TDI-Brooks projects. GEO3, Inc. operates as the facilities company for TDI-Brooks with Drs. Brooks and Bernard being the sole shareholders. TDI-Brooks has three current international affiliates: TDI-Brooks Nigeria Ltd. in Port Harcourt, Nigeria, GSI-Brooks Limited in Rio de Janeiro, Brazil and TDI-Sucursal in Bogotá, Colombia.

3 Organizational Structure

TDI-Brooks/B&B Organizational Chart



4 QMS

4.1 General Requirements

TDI-Brooks/B&B established and documented this QMS. The organization implements and maintains this QMS and continually improves its effectiveness in accordance with the requirements of ISO 9001:2008.

TDI-Brooks/B&B performs the following:

- a) Determines the processes needed for the continual improvement of the quality management system and their application throughout the company:

Core Processes

- *Business Development/Contract Review/Scope of Work/Project Planning*
- *Analytical Plan*
- *Purchasing*
- *Lab Processing, Sample Collection and Analysis*
- *Quality Control*
- *Data Submission*
- *Receiving*
- *Customer Service*

b) Determines the sequence and interaction of these processes as follows:

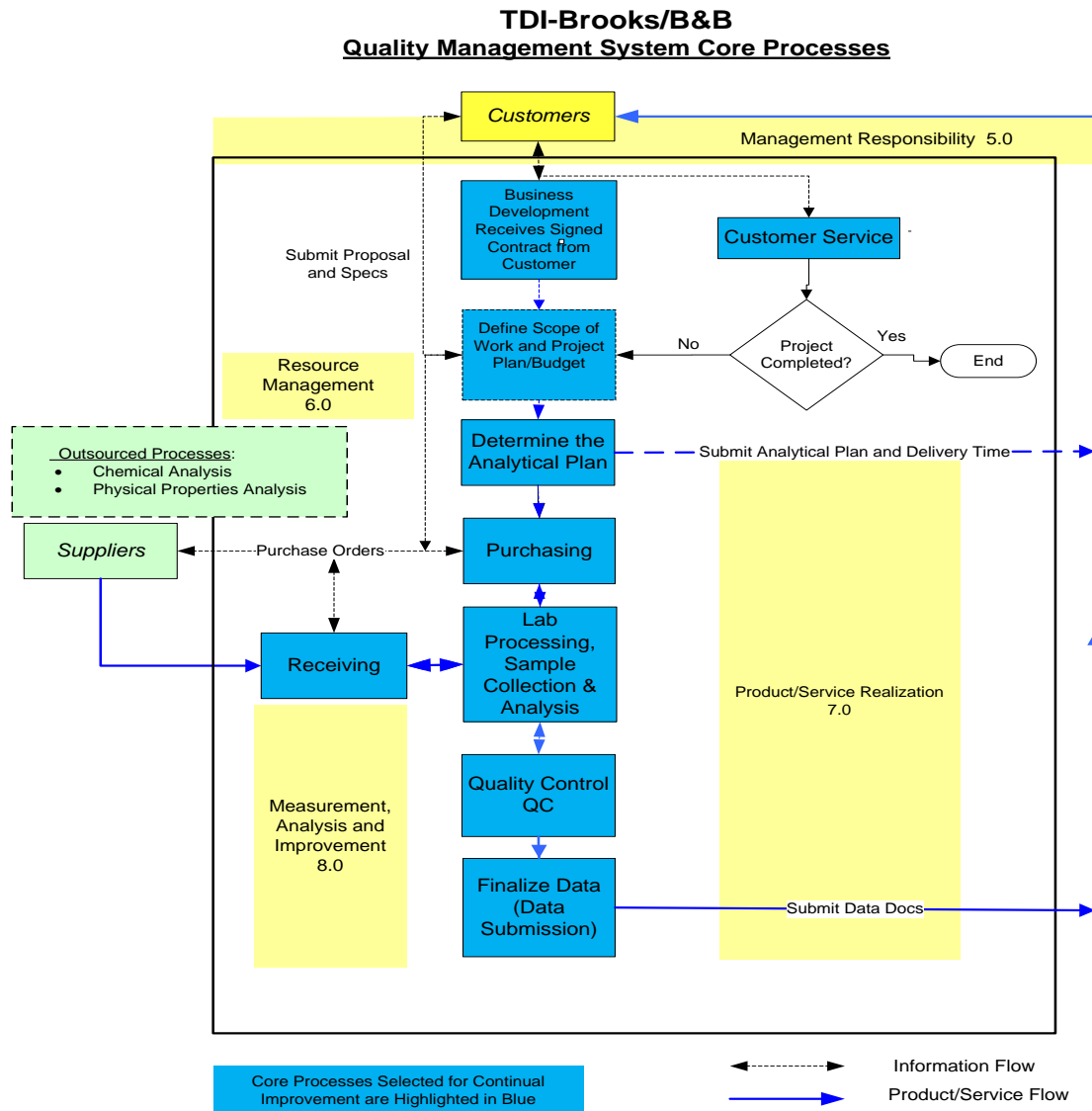


Figure 1

The above diagram is a graphical representation of the TDI-Brooks/B&B core processes (blue highlighted boxes are selected for continual improvement) showing basic relationships with customers and suppliers and basic material/product/service flows. Please note that the dotted lines represent information flow and do not necessarily represent specific, formal lines of communication. The dotted lines are intended to show that communication occurs between TDI-Brooks/B&B, its customers and suppliers, and between each of the various departments and processes within TDI-Brooks/B&B.

These processes include the management activities, provision of resources, product/service realization and measurement, analysis and improvement.

- c) Determines the criteria and methods needed to ensure that both the operation and control of these processes are effective;
- d) Ensures the availability of resources and information necessary to support the operation and monitoring of these processes;
- e) Monitors, measures (where applicable), and analyzes these processes; and
- f) Implements actions necessary to achieve planned results and continual improvement of these processes.

These processes are managed in accordance with the requirements of ISO 9001:2008. When TDI-Brooks/B&B chooses to outsource any process that affects product/service conformance to requirements and is needed by the QMS, the organization ensures control over such processes. The type and extent of control applied to the outsourced processes such as chemical or physical property analysis are defined in the QMS. Ensuring control over outsourced processes does not absolve TDI-Brooks/B&B of the responsibility of conformance to all customer and legal requirements.

4.2 Documentation Requirements

4.2.1 General

This QMS documentation includes:

- a) Quality Policy (page 1 of this manual) and Quality Objectives (see Section 5.4.1)
- b) Quality Manual
- c) Documented Procedures and records required by ISO 9001:2008
- d) Other documents, including records, determined by TDI-Brooks/B&B to be necessary to ensure the effective planning, operation and control of the processes

TDI-Brooks/B&B documentation may exist in any suitable format including electronic media and hard-copy. The extent of this documentation and any future creation of documentation by TDI-Brooks/B&B is based on the size of the organization, the type of activities performed, the complexity of the processes and their interactions, and the competence of the personnel.

4.2.2 Quality Manual

TDI-Brooks/B&B has established and maintains this quality manual which includes:

- a) The scope of the quality manual and justification for any exclusions:

SCOPE: **The Analysis of Geochemical, Geotechnical and Environmental Samples.**

EXCLUSIONS: *See Section 1, Introduction, for justification for exclusions.*

- b) A direct reference to the procedures required for the QMS
- c) A description of the interaction between all processes controlled by TDI-Brooks/B&B as demonstrated graphically in Section 4.1

Purchasing, Lab Processing, Sample Collection and Analysis, Quality Control, and Data Submission, Business Development/Contract Review/Scope of Work/Project Planning, Analytical Planning, Receiving and Customer Service are the core processes selected for improvement by TDI-Brooks/B&B, College Station, Texas.

4.2.3 Control of Documents

The documents required by the QMS are controlled (see Document Control Procedure and the Master List of Documents and Forms):

- a) To approve documents for adequacy prior to issue;
- b) To review and update as necessary and re-approve documents;
- c) To ensure that changes and the current revision status of documents are identified;
- d) To ensure that relevant revisions of applicable documents are available at points of use;
- e) To ensure that documents remain legible and readily identifiable;
- f) To ensure that documents of external origin determined by TDI-Brooks/B&B to be necessary for the planning and operation of the QMS are identified and their distribution controlled; and
- g) To prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

Documents may exist in any suitable format including electronic media and hard copy.

4.2.4 Control of Records

Records are established to provide evidence of conformance to requirements and to control the effective operation of the QMS. A Control of Records Procedure defines the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records. Records are legible, readily identifiable and retrievable. The Master List of Quality Records identifies the records controlled. Also reference Recordkeeping Procedure for Quote, Contract, and QAPP.

5 Management Responsibility

5.1 Management Commitment

Executive management of TDI-Brooks/B&B provides evidence of its commitment to the development and implementation of the QMS and continually improving its effectiveness by:

- a) Communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements using product and service specific training and posting of notices if necessary;
- b) Establishing the quality policy;
- c) Ensuring that the quality objectives are established;
- d) Conducting management reviews; and
- e) Ensuring the availability of resources.

5.2 Customer Focus

Executive management of TDI-Brooks/B&B ensures that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see Sections 7.2.1 and 8.2.1).

5.3 Quality Policy

Executive management of TDI-Brooks/B&B ensures that the Quality Policy (see page 1 of this manual):

- a) Is appropriate to the purpose of the organization;
- b) Includes a commitment to comply with requirements and continually improve the effectiveness of the QMS;
- c) Provides a framework for establishing and reviewing quality objectives;
- d) Is communicated and understood within the organization; and
- e) Is reviewed for continuing suitability, at least annually.

5.4 Planning

5.4.1 Quality Objectives

Executive management of TDI-Brooks/B&B ensures that the quality objectives, including those needed to meet requirements for service (see Section 7.1), are established at relevant functions and levels within the organization. These are measurable and consistent with the quality policy.

Quality Objectives for TDI-Brooks/B&B

- Be one of the best trace organic laboratories in the nation as demonstrated by blind, performance-based intercalibration exercises conducted by US federal agencies.
- Provide quality trace organic data that meets the quality assurance objectives of our federal agencies (US Fish and Wildlife Service, National Oceanic and Atmospheric Administration, Mineral Management Service, etc.) and private clients.
- Provide quality trace organic data that provide a low method detection limit (MDL) for the methods provided by our laboratory.
- In the Geotechnical Laboratory, meet the ASTM quality criteria of our major oil company clients.
- In the Geochemical Laboratory meet the quality requirements of the SGE SOP's.
- In the Geotechnical and Geochemical Laboratories, do what is necessary to meet the turn around requirements of our mostly oil company clients.

Once per year during a Management Review, or more frequently as required, the quality objectives are reviewed and updated in accordance with the TDI-Brooks/B&B policy of continual improvement (see 5.3c above).

5.4.2 QMS Planning

Executive management of TDI-Brooks/B&B ensures that:

- a) The planning of the QMS is carried out in order to meet the requirements given in Section 4.1, as well as the quality objectives; and
- b) The integrity of the QMS is maintained when changes to the QMS are planned and implemented.

5.5 Responsibility, Authority, and Communication

5.5.1 Responsibility and Authority

Executive management of TDI-Brooks/B&B ensures that the responsibilities and authorities for the implementation and maintenance of an effective QMS are defined and communicated within the organization using job descriptions. The reporting structure is outlined in Section 5.6.1 of this manual.

5.5.2 Management Representative

Executive management of TDI-Brooks/B&B has appointed a member of management as the Management Representative who performs the following:

- a) The Management Representative ensures that the processes needed for the QMS are established, implemented and maintained in accordance with ISO 9001:2008.
- b) The Management Representative reports on the performance of the quality system to upper management during the Management Review Meetings including any need for improvement.
- c) The Management Representative ensures the promotion of the awareness of customer requirements throughout the organization.
- d) The Management Representative oversees the internal quality audit process.

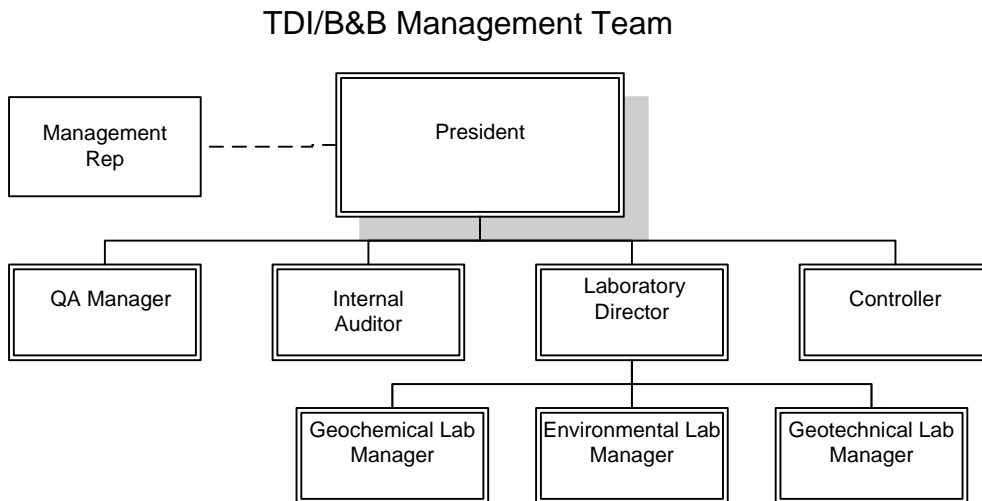
5.5.3 Internal Communication

Executive management of TDI-Brooks/B&B ensures that the appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the QMS. This may include employee meetings and published results, e-mail and written communications, and the daily word of mouth communications that supplement the required quality system documentation and the electronic methods.

5.6 Management Review

5.6.1 General

Executive management of TDI-Brooks/B&B reviews the organization’s QMS annually at a minimum, to ensure its continuing suitability, adequacy, and effectiveness. Management reviews are chaired by the Management Representative with the other Management Review Team members or designates present as required. Team membership is as follows:



The management reviews include assessing opportunities for improvement and the need for changes to the QMS, including the quality policy and quality objectives.

Records from management reviews are maintained (see Section 4.2.4).

5.6.2 Review Input

The input to management reviews includes:

- a) Results of audits (including internal, external, customer, or regulatory audits);
- b) Customer feedback (including complaints);
- c) Process performance and product/service conformance;
- d) Status of preventive and corrective actions;
- e) Follow-up actions from previous management reviews;
- f) Changes that could affect the QMS (need for change);
- g) Recommendations for improvement; and
- h) Review of the quality policy and current quality objectives and data, at least annually.

5.6.3 Review Output

The output from the management reviews includes any decisions and actions related to:

- a) Improvement of the effectiveness of the QMS and its processes;
- b) Improvement of product/service related to customer requirements; and
- c) Resource needs.

Meeting minutes are recorded and contain as a minimum:

- a) Record of attendees;
- b) Pertinent data reviewed for input (see 5.6.2 above);
- c) Action items determined and decisions made, if any;
- d) Person(s) responsible for follow-up of Action Items and due dates for completion;
- e) Assessment of the improvement of the effectiveness of the Quality System;
- f) Improvement of product/service related to customer requirements; and
- g) Resource needs

The action items will be tracked through to completion with the appropriate course of action taken for those items identified as requiring corrective and preventive action (see Sections 8.5.2 and 8.5.3).

6 Resource Management

6.1 Provision of Resources

TDI-Brooks/B&B determines and provides the resources needed:

- a) To implement and maintain the QMS and continually improve its effectiveness; and
- b) To enhance customer satisfaction by meeting customer requirements.

6.2 Human Resources

6.2.1 General

Personnel performing work affecting conformance to product requirements and quality are competent on the basis of appropriate education, training, skills, and experience. Each position has a job description identifying the qualifications required as relates to product/service quality and these are approved by the manager. Lab Management maintains records of employee qualifications and training in each employee's personnel folder.

6.2.2 Competence, Training and Awareness

TDI-Brooks/B&B performs the following:

- a) Determines the necessary competence for personnel performing work affecting conformance to product or service quality requirements.
- b) Provides training or takes other actions to achieve the necessary competence where applicable. Competency deficiencies discovered in any staffed position will be corrected by either re-staffing the position or providing the necessary training to satisfy the competency requirements of the position.
- c) Ensures that the necessary competence has been achieved (see Section 4.2.4), and evaluate effectiveness of actions taken such as testing, certifications, external training certificates, results of work, performance reviews, etc. Employees are initially evaluated after the first 90 days of their employment, and then annually after their anniversary date.
- d) Ensures that personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives during initial or remedial training and by means of periodic departmental meetings.
- e) Maintains the appropriate records of education, training, skills, and experience as detailed on the Master List of Quality Records (see Section 4.2.4).

If deficiencies in the qualification of an employee are determined by the appropriate manager, either due to new requirements, change in position, or need for refresher training, the manager shall schedule training for the individual. All training will have a measure of successful completion.

6.3 Infrastructure

TDI-Brooks/B&B determines, provides, and maintains the infrastructure needed to achieve conformance to service requirements. This infrastructure includes:

- a) Building, office and shop facility workspace, and associated utilities;

- b) Process and test equipment (both hardware and software); and
- c) Supporting services such as transport, communication or information systems.

TDI-Brooks/B&B data storage and backup protects all collected data and information (See Control of Data and Backup Procedure).

6.4 Work Environment

TDI-Brooks/B&B determines and manages the work environment (physical, environmental and other such as noise, temperature, humidity, etc.) needed to achieve conformance to product/service requirements.

7 Production/Service Realization

7.1 Planning of Product/Service Realization

TDI-Brooks/B&B has planned and developed processes needed for product/service realization. Planning of service realization is consistent with the requirements of the other processes of the QMS (see QMS Core Processes in Section 4.1.).

In planning service realization, TDI-Brooks/B&B determines the following, as appropriate:

- a) Quality objectives and requirements for the service;
- b) The need to establish processes and documents, and to provide resources specific to the service;
- c) Any required verification, validation, monitoring, measurement, inspection, and test activities specific to the service and the criteria for service acceptance; and
- d) Records needed to provide evidence that the realization processes and resulting service meet the requirements.

The output of this planning process is represented in the QMS Core Processes Flowchart in Section 4.1 of this Quality Manual and in the General or Client Specific Quality Assurance Project Plans (QAPP) for Environmental. The QAPP is a formal technical document containing or referencing the detailed quality assurance and control as well as technical procedures and specifications to assure the quality of data prepared for each data collection activity, project, contract or program.

7.2 Customer-Related Processes

7.2.1 Determination of Requirements Related to the Product/Service

TDI-Brooks/B&B determines:

- a) Requirements specified by the customer, including the requirements for delivery and post-delivery activities such as data deliverable requirements;
- b) Requirements not stated by the customer but necessary for specified or intended use when known;
- c) Any applicable statutory and regulatory requirements related to the product/service; and
- d) Any additional requirements considered necessary by TDI-Brooks/B&B.

The appropriate members of the administrative and management teams determine customer requirements via direct contact with the customer and document these requirements. Proposals and quotations are issued based on the requirements of the customer and the capabilities of TDI-Brooks/B&B.

7.2.2 Review of Requirements Related to Service

TDI-Brooks/B&B reviews the requirements related to the requested service. This review is conducted prior to the commitment to supply the service to the customer. The organization ensures:

- a) Service requirements are defined;
- b) Contract or order requirements differing from those previously expressed are resolved; and

- c) The organization has the ability to meet the defined requirements

Inquiries to TDI-Brooks/B&B may result in documented quotes. Purchase order, contract number or confirmation is received from the customer via facsimile, mail, e-mail, or telephone. Verbal Purchase Orders are documented by TDI-Brooks/B&B and confirmed with the client usually via email correspondence. Orders are received from the customer and confirmed based on requirements as defined by customer specifications supplied to TDI-Brooks/B&B. Order requirements are reviewed by the management team as applicable.

An entry in the Job and Technical Report Index is generated for new customers and maintained for existing customers to record project information. If a quote was supplied to the customer, the purchase order or permission to proceed is matched against the original quote and any differences are resolved before the quote becomes a project. The customer is made aware of the changed requirements by written confirmation using email or facsimile.

Records of the results of the order reviews and actions arising from the reviews are maintained for each customer in the Project Files (see Section 4.2.4).

TDI-Brooks/B&B and customer-generated changes are approved and recorded for each project in the Project Files. If the General Quality Assurance Project Plan Statement of Work (SOW) or other client designated plans have already been issued, each change order is personally communicated to the appropriate member of the management team involved in the change process. (Reference Recordkeeping Procedure for Quote, Contract and QAPP.)

The Project Files for each customer are electronically maintained and may consist of the following:

- SOW and any modifications;
- Quote;
- Client Purchase Order;
- Calibration Records; and
- Delivery or Reporting Requirements.

When the SOW is completed, the customer receives an invoice from the designated Accountant for each Lab. A copy of the invoice is placed in the accounts receivables file in Accounting. The SOW is placed in the Project file. (Reference the Recordkeeping Procedure for Quote, Contract and QAPP.)

7.2.3 Customer Communication

TDI-Brooks/B&B determines and implements effective arrangements for communicating with customers in relation to:

- a) Product information;
- b) Inquiries, contract, or order handling, including amendments; and
- c) Customer feedback, including customer complaints.

The TDI-Brooks/B&B website and contact with the laboratory managers are the primary sources for product information. Customer feedback, including complaints, is solicited using a survey or calling program (see Section 8.2.1, Customer Satisfaction).

7.3 Design and Development

7.3.1 Design and Development Planning

TDI-Brooks/B&B does not plan and control the design and development of new product/service so this entire section does not apply. If TDI-Brooks/B&B does pursue design of product/service in the future, this clause will be addressed as required.

7.4 Purchasing

7.4.1 Purchasing Process

TDI-Brooks/B&B ensures that purchased product conforms to specific purchase requirements. The type and extent of control applied to the suppliers and the purchased product is dependent on the impact of the purchased product/service on quality (Reference the Purchasing and Supplier Assessment Procedure). All purchases are contracted either with a Purchase Order or other document receipts approved by the appropriate supervisor.

The organization evaluates and selects suppliers based on their ability to supply product in accordance with the organization's requirements prioritized as follows:

- 1) Quality of Product and Service;
- 2) Pricing; and
- 3) Delivery.

Records of the results of selection and ongoing evaluations and any necessary actions arising from the evaluations are filed in the Purchasing Log Books (see Section 4.2.4).

7.4.2 Purchasing Information

Purchasing information is received using a purchase requisition clearly describing the product/service to be purchased. The Purchase Order is based upon the purchase requisition information provided by the project manager, and is reviewed for conformance with TDI-Brooks/B&B customer requirements as well as internal requirements, and may include:

- a) Requirements for approval of product, procedures, processes and equipment;
- b) Requirements for qualification of personnel; and
- c) QMS requirements.

After Purchasing reviews the requisition and current inventory levels, the purchase order is approved and sent to the appropriate supplier. TDI-Brooks/B&B ensures the adequacy of specified purchase requirements prior to their communication to the supplier.

Project managers also have the authority to make purchases directly with standard suppliers.

7.4.3 Verification of Purchased Product

TDI-Brooks/B&B establishes and implements the inspection and other activities necessary for ensuring that purchased product meets specified purchase requirements (Reference the Receiving and Inspection Procedure).

When purchased product does not meet specified purchase requirements, a nonconformance report is completed and the vendor is notified. The appropriate action is implemented including possible return of product to the vendor.

When TDI-Brooks/B&B or its customer intends to perform verification at the supplier's premises, the organization states the intended verification arrangements and method of product release in the purchasing information.

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

TDI-Brooks/B&B plans and carries out production and service provision under controlled conditions. Controlled conditions for equipment, processes, and production software include, as applicable:

- a) Availability of information that describes the characteristics of the product (such as specification, order requirements, or QAPP for environmental);
- b) Availability of standard operating procedures (Reference all SOP's), as necessary;
- c) Use of suitable equipment;
- d) Availability and use of monitoring and measuring equipment;
- e) Implementation of monitoring and measurement; and
- f) Implementation of product release, delivery and any post-delivery activities.

7.5.1.1 Production Planning, Supervision and Support Functions

TDI-Brooks/B&B controls their product provision processes by the application of appropriate production planning, supervision, and support processes. Production is driven by customer order.

7.5.1.2 Outsourced Operations for Data Analysis

Chemical, biological and physical properties analyses may be outsourced and these suppliers are selected and evaluated according to their ability to supply products and services in conformance to requirements. All data received from these suppliers are inspected to assure that TDI-Brooks/B&B requirements are met.

7.5.2 Validation of Processes for Production and Service Provision

All processes for production and service provision can be verified by subsequent monitoring or measurement, which will reveal any deficiencies prior to delivery; therefore, this section is currently not applicable. In the event that it becomes applicable, TDI-Brooks/B&B will validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement, and as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.

TDI-Brooks/B&B will establish arrangements for these processes including, as applicable:

- a) Defined criteria for review and approval of the processes;

- b) Approval of equipment and qualification of personnel;
- c) Use of specific methods and procedures;
- d) Requirements for records; and
- e) Revalidation

7.5.3 Identification and Traceability

TDI-Brooks/B&B identifies the product/service status with respect to monitoring and measurement requirements throughout product/service realization. TDI-Brooks/B&B controls and records unique identification of the product/service by using project and sample identification numbers and chain of custody procedures. Inventory is monitored periodically for all incoming and outgoing items. Traceability requirements are met using a series of logs. These records are maintained (see Section 4.2.4).

7.5.4 Customer Property

TDI-Brooks/B&B exercises care with customer property while it is under the organization's control or being used by the organization. The company identifies, verifies, protects and safeguards customer property such as samples and sampling equipment provided for use or incorporation into the product. A unique sample and project identifier are labeled on each sample and tracked within a log. If any customer property is lost, damaged or otherwise found to be unsuitable for use, TDI-Brooks/B&B reports this to the customer and maintains records (see Section 4.2.4). Samples are not disposed of unless such action is approved by the customer.

7.5.5 Preservation of Product

TDI-Brooks/B&B preserves the product and components necessary during internal processing and delivery to the intended destination in order to maintain conformance to the requirements. As applicable, preservation includes identification, handling, packaging, storage and protection for the product and constituent parts. Expiration dates are reviewed periodically and prior to use for those materials with shelf life restrictions that are used to generate the product. Shelf life restrictions and/or performance criteria may be measured to assess effectiveness. Shipments are packaged in a manner appropriate to preserve the integrity of the product and to meet customer requirements.

7.6 Control of Monitoring and Measuring Equipment

TDI-Brooks/B&B determines the monitoring and measurements to be undertaken (see Section 5.4) and the monitoring and measuring equipment needed to provide evidence of conformance of product to determined requirements.

TDI-Brooks/B&B establishes processes to ensure that the monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

When necessary to ensure valid results, measuring equipment is:

- a) Calibrated or verified , or both, at specified intervals, or prior to each use, against measurement standards traceable to an international or national measurement standard; where no such standards exist, the basis for calibration or verification is recorded;
- b) Adjusted or re-adjusted as necessary;
- c) Identified to determine its calibration status;
- d) Safeguarded from adjustments that would invalidate the measurement results; and

- e) Protected from damage and deterioration during handling, maintenance, and storage.

In addition, TDI-Brooks/B&B assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization takes appropriate action on the equipment and any product affected.

Records of the results of calibration and verification are maintained using a calibration log; project specific calibrations records are maintained in the Project File (see Section 4.2.4).

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy intended applications is confirmed. This is undertaken prior to initial use of the software and reconfirmed as necessary.

When calibration is outsourced to a calibration company, TDI-Brooks/B&B ensures control over this process by requiring calibration records and traceability to a national measurement standard.

8 Measurement, Analysis and Improvement

8.1 General

TDI-Brooks/B&B plans and implements the monitoring, measurement, analysis and improvement processes needed to:

- a) Demonstrate conformance to product requirements;
- b) Ensure conformance of the QMS; and
- c) Continually improve the effectiveness of the QMS.

This includes the determination of the applicable methods, including statistical techniques, and the extent of their use (see Sections 8.4 and 8.5.1).

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

TDI-Brooks/B&B monitors information relating to customer perception as to whether the organization has met customer requirements.

The methods for obtaining and using this information are:

- Customer Surveys and Calling Program;
- Feedback from the Field; and
- Customer Audits

The customer feedback is analyzed and opportunities for continual improvement are identified. Action plans for improvement are monitored by the management team.

8.2.2 Internal Audit

TDI-Brooks/B&B conducts internal audits at planned intervals, and at a minimum annually, to determine whether the QMS:

- a) Conforms to the planned arrangements (see Section 7.1), to the requirements of ISO 9001:2008 and the QMS requirements established by the organization; and
- b) Is effectively implemented and maintained.

The audit program is planned, taking into consideration the status and importance of the processes and areas to be audited, including the results of previous audits. The audit criteria, scope, frequency and methods are defined. The selection of auditors and conduct of audits is in a manner to ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

The responsibilities and requirements for planning and conducting audits, establishing records and reporting results are defined in the documented Internal Audit Procedure.

Records of the audit and their results are maintained (see Section 4.2.4).

The company may choose to outsource some or all of the internal auditing. The auditor(s) will possess the appropriate auditor qualifications.

The management responsible for the area being audited ensures that any necessary corrections and corrective actions are taken in a timely manner to eliminate detected nonconformances and their causes. Follow-up activities include the verification of the actions taken and the reporting of verification results.

8.2.3 *Monitoring and Measurement of Processes*

TDI-Brooks/B&B applies suitable methods for monitoring and, where applicable, measurement of the QMS processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action is taken, as appropriate, to ensure conformance of product or service.

8.2.4 *Monitoring and Measurement of Product or Service*

TDI-Brooks/B&B monitors and measures the characteristics of the product or service to verify that requirements have been met. This is carried out at the appropriate stages of the product or service realization process in accordance with the planned arrangements (see Section 7.1). Evidence of conformance with the acceptance criteria is maintained. The appropriate level of inspection takes place for each project received.

Records indicate the persons(s) authorizing the release of product or service for delivery to the customer (see Section 4.2.4).

Product release and service delivery to the customer do not proceed until the planned arrangements (see Section 7.1) have been satisfactorily completed, as indicated in the Final Data Report, unless otherwise approved by a relevant authority and, where applicable, by the customer.

8.3 Control of Nonconforming Product

TDI-Brooks/B&B ensures that product or service that does not conform to requirements is identified and controlled to prevent its unintended use or delivery. The documented Nonconforming Product Procedure defines the controls and related responsibilities and authorities for dealing with nonconforming product and services.

Where applicable, TDI-Brooks/B&B deals with nonconforming product/service by one or more of the following ways:

- a) Taking action to eliminate the detected nonconformance;
- b) Authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;
- c) Taking action to preclude its original intended use or application; and
- d) Taking action appropriate to the effects, or potential effects, of the nonconformance when nonconforming product is detected after delivery or use has started.

When nonconforming product/service is corrected, it is subject to re-verification to demonstrate conformance to the requirements.

Records of the nature of nonconformances and any subsequent action taken, including concessions obtained, are maintained (see Section 4.2.4).

8.4 Analysis of Data

TDI-Brooks/B&B determines, collects, and analyzes the appropriate data to demonstrate the suitability and effectiveness of the QMS and to evaluate where continual improvement of the effectiveness of the QMS can be made. This includes data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data provides information relating to:

- a) Customer satisfaction (see Section 8.2.1);
- b) Conformance to product or service requirements (see Section 8.2.4);
- c) Characteristics and trends of processes and products, including opportunities for preventive action (see Sections 8.2.3 and 8.2.4); and
- d) Suppliers (see Section 7.4).

8.5 Improvement

8.5.1 Continual Improvement

TDI-Brooks/B&B continually improves the effectiveness of the QMS through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive action and the management review.

8.5.2 Corrective Action

TDI-Brooks/B&B takes action to eliminate the causes of nonconformances in order to prevent recurrence. The corrective action is appropriate to the effects of the nonconformances encountered.

The Corrective Action Procedure defines the requirements for:

- a) Reviewing nonconformances (including customer complaints);
- b) Determining the causes of nonconformances;
- c) Evaluating the need for action to ensure that nonconformances do not recur;
- d) Determining and implementing the actions needed;
- e) Recording the results of the action taken (see Section 4.2.4); and
- f) Reviewing the effectiveness of the corrective action taken.

8.5.3 Preventive Action

TDI-Brooks/B&B determines the action to eliminate the causes of potential nonconformances in order to prevent their occurrence. The preventive action taken is appropriate to the effects of the potential problems.

The Preventive Action Procedure defines the requirements for:

- a) Determining the potential nonconformances and their causes;
- b) Evaluating the need for action to prevent occurrence of nonconformances;
- c) Determining and implementing the action needed;
- d) Recording results of the action taken (see Section 4.2.4); and
- e) Reviewing the effectiveness of the preventive action taken.