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**QUALITY MANAGEMENT PLAN
(QMP)**

**Revision No. 3
June 17, 2002**

**TDI-Brooks International
Quality Management Plan**

MANAGEMENT'S STATEMENT OF APPROVAL

This **Quality Management Plan** is management's statement of *the process* governing the QA/QC activities for B&B Laboratories, Inc. It describes how our company will conduct its business in terms of the standard elements of the **Quality System** we have implemented. These elements include our common values, our policies and their implementation, our organizational structure, the functional responsibilities of our management and staff, our lines of authority, and the required teaming for those who plan, implement, and assess our activities. Adherence to these standards ensures that the data are of the appropriate type and quality for their intended programmatic use. These standards also provide the framework and criteria used to create detailed, project-specific **Quality Assurance Project Plans** when needed for each new program, based on the fundamentals of assuring quality. Within these bounds, each such project-specific plan will be tailored to its particular need and maintained to respond effectively to diverse analytical programs.

By our signatures below, we hereby approve this Quality Management Plan:

James Brooks, *Project Director*

Date

Bernie B. Bernard, *Project Manager*

Date

Susanne J. McDonald, *Quality Assurance Manager*

Date

Quality Assurance Manager

Date

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1.0 MANAGEMENT AND ORGANIZATION

1.1 MISSION STATEMENT

Deliver high-quality analytical services and scientific interpretation to the environmental and geochemical marketplace.

1.2 STATEMENT OF COMMON VALUES

- We believe in technical and business integrity and quality.
- We believe in persevering until we deliver.
- We believe in delivering a higher level of value than the customer bargained for.
- We believe in being relentless in our drive to improve.
- We believe in giving first and receiving back later.
- We believe that our customers and suppliers are our friends.
- We believe that our employees are our family.
- We believe in honoring the deal we made.
- We believe in showing good faith.
- We believe in having fun.
- We believe that our reputations are more valuable than our income.

1.3 QUALITY SYSTEM AND OBJECTIVE

We place great value on achieving our mission, and, as a first principle, operating personally and professionally under the umbrella of basic values we have in common. We have developed a **Quality System** to help guide us.

Our Quality System is a structured and documented management system describing our values, objectives, policies, organizational authority, responsibilities, accountability, and implementation plan for ensuring high quality in our analytical services and scientific interpretations. The objective of our Quality System is to provide an effective process for management's review and oversight during planning, implementing, and assessment of our environmental and geochemical programs. This process is important for providing guidance to management toward mission-focus and for providing tools for quantifying the practice of our common values.

1.4 POLICY ON QUALITY

Recognizing the reasons for the high quality demands of environmental and geochemical data and interpretations, we have developed a **Quality Management Plan (QMP)** to ensure that appropriate quality standards are achieved and maintained in compliance with specific contract requirements. ***It is the policy of B&B Laboratories to conduct its operations in accordance with this formal, approved QMP.*** The management of B&B Laboratories is fully committed to ensure that, as a minimum, all specifications in the QMP are completely and vigorously followed in good faith. B&B Laboratories may subcontract certain functions to outside organizations, but will retain the responsibility for the assurance of quality in these functions.

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Our QMP is also designed to be consistent with the intent and detail of the following Quality guides for our industry:

- *EPA Requirements for Quality Management Plans*, EPA QA/R-2, October 1996;
- *Guidance for the Preparation of Standard Operating Procedures (SOPs) for Quality-Related Documents*, EPA QA/G-6, November 1995;
- *Guidance for the Data Quality Objectives Process*, EPA QA/G-4, September 1994;
- *EPA Requirements for Quality Assurance Project Plans*, EPA QA/R-5, October 1996;
- *Guidance for Data Quality Assessment*, EPA QA/G-9, QA96 Version, July 1996;
- *NOAA National Status and Trends Quality Assurance Guidelines*;
- *Good Laboratory Practice Standards*, 40 CFR Part 160 (FIFRA); and
- *Specification and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*, ANSI/ASQC E4-1994, January 1995.

Our effective management of quality involves providing and implementing programs for **Quality Assurance (QA)** and **Quality Control (QC)**. QA is an integrated system of management activities necessary to provide a stated level of confidence that our work conforms to the applicable project/contract specifications, regulatory requirements, and local, state, and federal codes. QA involves planning, quality control, quality assessment, reporting, and quality improvement. As such, QA encompasses QC, which measures the attributes of our data production and the performance of our processes against defined acceptance-standards associated with such activities, for the purpose of determining the extent of control of each analytical process. Our management uses results of such control measurements in planning, implementing, tracking, and taking corrective actions to assure quality in our operations and to improve our Quality System.

As resolved by the Board of Directors of B&B Laboratories, *management is charged with providing a professional environment that requires and encourages employees to strictly adhere to the QA and QC associated with their individual projects and to carryout their assigned tasks in a consistent and professional manner.* B&B Laboratories management is also charged with ensuring that there are adequate human and capital resources available for effecting our QA/QC. Our effective implementation of these Board directives ensures that we meet the requirements imposed by our customers and by regulatory agencies. We regard our corporate performance in this area as the measure of the level of our commitment to producing high-quality services, adding a high level of value at each level of operation, promoting excellence in the work place, and improving continually.

This QMP serves as guidance to produce project-specific **Quality Assurance Project Plans (QAPPs)**, implementation procedures, and a management philosophy that encourages, supports, and emphasizes the importance of QA in carrying out work activities.

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B&B Laboratories also provides its QMP as an integral part of any proposal that requires demonstration of an effective Quality System in place. This document adds another level of confidence that the activities we perform meet the established project requirements.

1.5 STATEMENT OF AUTHORITY FOR QUALITY ASSURANCE

Within the management structure of B&B Laboratories, the Quality Assurance Manager is the designated officer responsible for all Quality Assurance matters. The Quality Assurance Manager is hereby given authority and responsibility for preparation, revision and control of this QMP, including control of the necessary mandates, procedures, and instructions to ensure compliance. The Quality Assurance Manager will have the freedom to identify quality problems throughout our operations and to recommend, initiate, and provide solutions.

The Quality Assurance Manager will direct and monitor the quality effort *and will be independent of the process stream of the laboratory*. The General Manager (and Project Manager for this effort) will resolve any issues of conflict in full accordance with this QMP and any regulatory requirements.

Dr. Bernie B. Bernard
General Manager

Dr. Susanne J. McDonald
Quality Assurance Manager

1.6 ORGANIZATION FOR QUALITY ASSURANCE

We are organized to establish the necessary management controls and the QA functions to govern the quality activities of B&B Laboratories. Our organization-chart is detailed in Figure 1. This organizational framework provides the pool of qualified staff to be assigned to project-specific management teams. Project-specific management teams are assembled to meet individual project requirements and are detailed in each QAPP. B&B Laboratories personnel may fulfill different functions in different projects as needed.

The General Manager, Laboratory Manager, and Quality Assurance Manager constitute the senior management of B&B Laboratories. Specific responsibilities of each of these positions follow:

1.6.1 General Manager

The General Manager reports to the Board of Directors. He manages the business and administrative aspects of B&B Laboratories. He formulates, recommends, and implements programs, policies, and procedures designed to ensure maintenance of operational control, Quality Systems, fiscal soundness, expansion into appropriate markets, and growth. He supervises personnel responsible for human resource, financial, and general administration. Specific responsibilities include:

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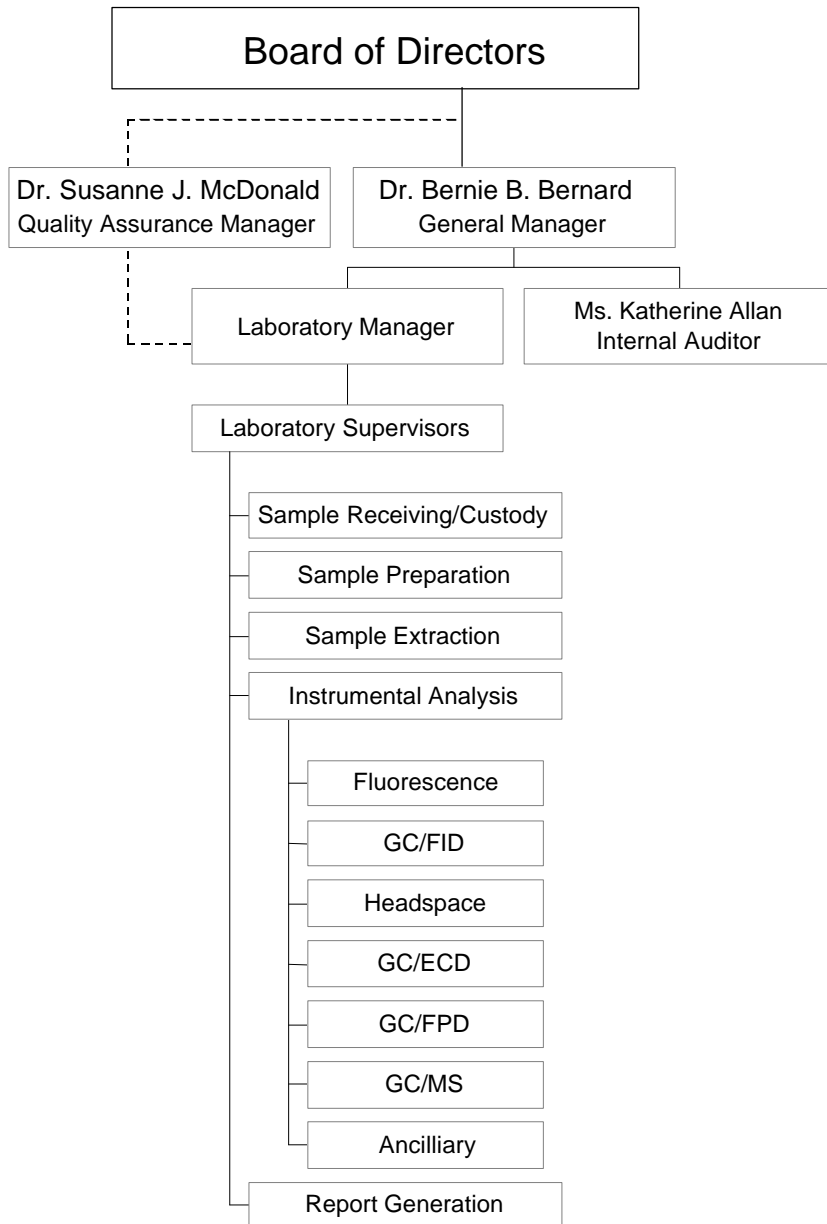


Figure 1. B&B Laboratories General Organization Chart.

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developing and communicating mission, vision, and values statements; developing a business plan for each fiscal year and 5-year strategic plan for growth; regularly reporting progress against the plan;

- developing and maintaining an assessment of market drivers, size, structure, competitive forces, and distribution channels for the environmental and geochemical analytical industries;
- developing and maintaining consensus on a business strategy for growth, market differentiation, and resource allocation; identifying and leveraging core competencies of the organization; developing and communicating objectives, monitoring progress against goals and schedules, and taking corrective actions as needed;
- developing and maintaining organizational structure and job descriptions; overseeing employee hiring, status changes, performance evaluations, and terminations according to policy, as needed;
- facilitating contacts with customers, suppliers, and regulatory agencies; reviewing and approving contracts, lease agreements, and capital purchase requisitions; approving pricing of services; approving the business/financial plan for each project;
- overseeing and facilitating the development, implementation, and continual improvement of the QMP; facilitating the auditing of the Quality System in place, through the Quality Assurance Manager;
- providing financial management by overseeing basic business and accounting parameters, ratios, and statements; setting normal bounds of financial indicators for maintaining control; and
- recommending and implementing administrative policies, including those concerning software, intellectual property, travel expenses, purchasing procedures, and vehicle use.

1.6.2 Laboratory Manager

The Laboratory Manager reports to the General Manager. This individual is responsible for the overall organization and management of the laboratory. This individual supervises personnel responsible for laboratory operations. Specific responsibilities include:

- organizing and directing the technical activities within the laboratory area; coordinating daily laboratory operations;

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- ensuring that these QMP requirements are reflected in all planning, investigative, analytical, and reporting activities;
- verifying that laboratory QC procedures are being followed as specified on a project by project basis;
- ensuring performance of laboratory procedures according to Standard Operating Procedures (SOPs);
- interfacing with Project or Program Managers on all aspects of a project, including progress, QA, problems, and recommended resolutions;
- scheduling, implementing, documenting, and ensuring proper training of laboratory operations staff; assigning qualified team members to projects;
- ensuring that applicable state and federal codes, standards, and regulations are appropriately specified and effectively implemented;
- submitting the appropriate plans, documents, data, control tools, and reports to the Quality Assurance Manager for review and approval;
- providing technical support in conducting sample collection, preservation, storage and preparation, laboratory analyses, and reviewing analytical data for quality, validity, completeness, and clarity; and
- recommending and implementing approved quality improvements.

1.6.3 Quality Assurance Manager

The Quality Assurance Manager reports to the General Manager. This individual is the designated officer responsible for all QA matters. This individual is given authority and responsibility for QA/QC protocol, including the authority to stop work due to quality problems and to control the necessary procedures and instructions to ensure compliance. This individual is independent of the project's management and the laboratory management. Specific responsibilities include:

- teaming in the development and continual improvement of the Quality System of B&B Laboratories;
- maintaining and recommending improvements for the QMP; providing approval and guidance for project-specific QAPPs;
- reviewing, evaluating, and approving data prepared by the laboratory prior to submission to the client;
- participating as a member of project teams;

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- evaluating the effectiveness of the QA program through audits, review of performance-evaluation results, and surveillance; making recommendations for corrective actions;
- in cases where unsatisfactory conditions are discovered, ensuring that further processing or delivery of the affected item is controlled until proper disposition can be made; stopping work when conditions adverse to quality are detected.
- Advising the other managers on QA matters; ensuring that the quality training and awareness program is established and implemented;
- assisting in the development of B&B Laboratories SOPs, instructions, training, and standards in support of programs and projects; approving all SOPs;
- ensuring that nonconformance and reportable occurrences are identified, tracked and resolved; assisting in the resolution of quality problems; and
- evaluating the Quality Systems of potential subcontractors for conformance to requirements; ensuring that QA/QC requirements are included in subcontracts; evaluating the effectiveness of subcontractor QA through data review, audits, and surveillance.

2.0 QUALITY SYSTEM AND DESCRIPTION

2.1 PURPOSE

This section specifies and discusses the principal components or “tools” comprising our Quality System and the process and procedures for their development and use. It presents basic policy on planning, objectives, methods, data quality, project plans, training, and qualifications of personnel. It also describes methods used for periodic assessment of the QA program.

2.2 GENERAL REQUIREMENTS

The necessary components of our Quality System are:

- a formal Quality Management Plan (QMP);
- a process for Data Quality Objectives (DQOs);
- a guide for Quality Assurance Project Plans (QAPPs) for specific projects;
- a set of Standard Operating Procedures (SOPs) describing our methods;
- Data Quality Assessments (DQAs);
- training programs with training documents and certifications; and
- a plan for assessments of our Quality System.

The basic requirements of our Quality System apply to all B&B Laboratories activities. Controls over activities that contribute to the achievement or verification of quality are to be described in written procedures for our operations. Personnel performing quality-

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assured activities must be properly and adequately trained and this training must be documented.

The QA program is to be reviewed regularly by senior management as the Quality Assurance Manager reports the results to the General Manager. The reports are used to revise the QMP when necessary.

2.3 RESPONSIBILITY

2.3.1 Each Manager

- Implementing and maintaining procedures that comply with applicable requirements of the QA program.
- Performing tasks, as applicable, in accordance with approved procedures consistent with the QA program.
- Assuring that personnel receive the necessary orientation and training to ensure compliance with existing, new or revised specifications and procedures.

2.3.2 Quality Assurance Manager

- Establishing and maintaining our QMP and providing approval and guidance for each QAPP.
- Specifying our Data Quality Objectives process and our Data Quality Assessment process.
- Reviewing and approving quality-related documents and procedures that are prepared and submitted by other managers and organizations, to ensure that specified quality requirements are incorporated. This includes final approval of all SOPs.

2.4 PROCEDURE

2.4.1 QMP

Our QMP is a blueprint to establish a QA program that provides for a planned and disciplined approach to achieving and assuring quality. The QMP is to be developed according to the following documents:

- *EPA Requirements for Quality Management Plans*, EPA QA/R-2, October 1996;
- *Good Laboratory Practice Standards*, 40 CFR Part 160 (FIFRA); and
- *Specification and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*, ANSI/ASQC E4-1994, January 1995.

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2.4.2 DQOs

Data Quality Objectives (DQOs) are qualitative and quantitative statements that clarify study objectives, define the appropriate type of data, and specify the tolerable levels of potential decision errors that will be used as the basis for establishing the quality and quantity of data needed to support decisions. The DQOs are to be developed according to the following documents:

- *Guidance for the Data Quality Objectives Process*, EPA QA/G-4, September 1994;
- *Guidance for Data Quality Assessment*, EPA QA/G-9, QA96 Version, July 1996; and
- *Good Laboratory Practice Standards*, 40 CFR Part 160 (FIFRA).

2.4.3 QAPPs

Our Quality Assurance Project Plans (QAPPs) are formal technical documents containing the detailed QA, QC and other technical procedures and specifications for assuring the quality of data prepared for each data collection activity, project, contract, or program. The QAPPs are to be developed according to the following documents:

- *EPA Requirements for Quality Assurance Project Plans*, EPA QA/R-5, October 1996;
- *Good Laboratory Practice Standards*, 40 CFR Part 160 (FIFRA); and
- The contract or individual project specifications.

2.4.4 SOPs

Activities are conducted in accordance with procedures that provide detailed information to personnel on the performance of their work. The bases of these procedures are control documents describing each activity. These documents are our Standard Operating Procedures (SOPs). The SOPs are to be developed according to the following documents:

- *Guidance for the Preparation of Standard Operating Procedures (SOPs) for Quality-Related Documents*, EPA QA/G-6, November 1995;
- *Good Laboratory Practice Standards*, 40 CFR Part 160 (FIFRA); and
- *Specification and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*, ANSI/ASQC E4-1994, January 1995.

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2.4.5 DQAs

Data Quality Assessments (DQAs) are statistical and scientific evaluations of data sets to assess the validity and performance of the data collection design and statistical test. These assessments establish whether a data set is adequate for its intended use. The DQAs are to be developed according to the following documents:

- *Guidance for the Data Quality Objectives Process*, EPA QA/G-4, September 1994;
- *Guidance for Data Quality Assessment*, EPA QA/G-9, QA96 Version, July 1996; and
- *Good Laboratory Practice Standards*, 40 CFR Part 160 (FIFRA).

2.4.6 Training Programs

Training programs include the following components of our Quality System:

- Corporate Goals and Expectations
- Quality Management Plan
- Data Quality Objectives
- Quality Assurance Project Plans
- Standard Operating Procedures
- Health and Safety Plan and Procedures
- Good Laboratory Practices

Our training program is discussed in detail in Section 3.0.

2.4.7 System Assessment

The Quality System of each section of the laboratory is reviewed at least once per year. The review is a management assessment of the effectiveness of the program and is accomplished by the following:

- A yearly assessment by the Quality Assurance Manager, the Laboratory Manager, and the General Manager, including a review of past quality problems and their underlying causes, an analysis of trends, and a review of other program assessment actions such as audits corrective-action status. The Quality Assurance Manager presents this assessment in a written report to the General Manager for review and appropriate action.
- Internal system audits or management assessments are directly scheduled by the General Manager to assess particular aspects of each laboratory section. Internal system audits are conducted in each section at least yearly in order to verify that laboratory personnel are following all QA/QC practices.

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- The QA Manager evaluates laboratory performance audits, consisting of the analysis of test samples, at least yearly. A written report documenting results, comparison to “true values”, an evaluation of accuracy and/or precision, and recommendations for improvement is presented to the General Manager for review and appropriate action. Standard intercalibration exercises may be used to assess laboratory performance, if conducted during the specified evaluation period.

- External experts may also be contracted to provide an assessment as necessary.

3.0 PERSONNEL QUALIFICATIONS AND TRAINING

3.1 PURPOSE

Training of personnel is performed to ensure that personnel are qualified to perform their assigned work at a high level of quality.

3.2 GENERAL REQUIREMENTS

All personnel are to be qualified and sufficiently proficient to perform the work required. Appropriate training will be performed and documented to ensure satisfactory job proficiency. When job requirements change the need for re-training is to be evaluated. All personnel will receive basic health and safety training (i.e., personal protective equipment, appropriate clothing and foot wear, eating, drinking and smoking policies, good laboratory practices, use of MSDS, chemical inventory, location of safety equipment, fire evacuation routes, use of fume hood, use of fire extinguishers). Basic safety training will be conducted by the Quality Manager. Personnel will also receive detail health and safety training specific to their job. Specific training will be conducted by the Supervisor and Quality Manager.

Personnel training will include:

- an initial orientation, including our mission, values, policies, facilities, and resources,
- a review of our markets and client expectations,
- a review of our policies and available documents and references,
- specific technical, laboratory, administrative, and computer skills,
- management and communication skills,
- fundamental principles of quality,
- Quality Management Plan
- Data Quality Objectives
- Quality Assurance Project Plans
- Standard Operating Procedures
- Health and Safety Plan and Procedures
- Good Laboratory Practices

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3.3 TRAINING RECORDS

Training records will be updated with the addition of new tasks/responsibilities or at least once a year. An example of a standard training document is appended at the end of this document.

3.4 RESPONSIBILITY

3.4.1 Management

- identifies certifications required to perform operations for the different programs for which we are responsible;
- establishes training requirements for personnel;
- identifies and satisfies technical and project management training needs, and identifies and designs training programs to meet these needs;
- provides initial and continuing training, and encourages professional development beyond initial qualifications;
- documents and maintains training records and certifications for personnel;
- identifies and approves qualified trainers;
- assesses the effectiveness of training and updates instructors on training techniques and technical changes; and
- reviews and continually updates training materials and content.
- provides annual refresher training for continuing personnel.

3.4.2 The Laboratory Manager

- undertakes the training of employees or assigns qualified personnel for such training;
- certifies an employee by signing a descriptive statement of employee skills (training record) that is attached to the employee's permanent record; and
- closely supervises and evaluates employee performance by review of QC results.

3.5 PROCEDURE

Personnel training and certification will be performed according to the B&B Laboratories procedures. When a new employee is hired, a training record must be initiated within ten (10) working days. The training record is updated as frequently as necessary to reflect new skills acquired by an employee. Training courses or certification courses completed by an employee are filled in the employee's permanent record. Qualifications in the form

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of a resume are kept on file for each employee and updated at least yearly. Each employee is provided refresher training at least yearly to ensure a high level of quality and safety are maintained.

4.0 PROCUREMENT OF ITEMS AND SERVICES

4.1 PURPOSE

The purpose of this section is to ensure procurement of items and services of adequate quality to implement the technical and quality objectives of each program.

4.2 GENERAL REQUIREMENTS

- Quality requirements are to be defined for all applicable procurements of products and services.
- Procurement documents are to require suppliers to demonstrate a QA program consistent with our standards.
- The procurement process is to be fully documented and controlled.
- Procured items and services must conform to all established specifications.
- Changes to procurement documents are to receive the same review approvals as the original documents.
- Purchased and subcontracted activities are to produce products and results of acceptable quality. Confirmation may include procurement source evaluation and selection, evaluation of supplied evidence of quality, source-site inspections, supplier audits, and examination and qualification of deliverables.

4.3 RESPONSIBILITY

Management is responsible for the quality of work performed or items and services provided by our subcontractors and suppliers. All quality issues concerning suppliers and subcontractors must be resolved through the approval of the Quality Assurance Manager.

4.4 PROCEDURES

- Our SOPs are to specify the necessary level of quality for materials required by each method.
- The managers are to evaluate objective evidence of quality provided by their immediate suppliers.
- Reports of compliance with B&B Laboratories QA standards must be demonstrated to the Quality Assurance Manager.

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- Deliverables are to be inspected and certified as acceptable.

5.0 QUALITY DOCUMENTS AND RECORDS

5.1 PURPOSE

Activities that affect quality are governed by controlled documents to ensure that the correct documents and revisions are used on all work. Control will be implemented over the issuing, receipt, and storage of such documents and will include instructions, procedures, and illustrations.

5.2 GENERAL REQUIREMENTS

Documents or changes to documents that specify quality requirements or prescribe activities affecting quality are reviewed for adequacy, approved for release by authorized personnel and controlled to ensure that the correct documents are being employed on each project.

5.3 RESPONSIBILITY

- Each Project Manager is responsible for preparing their procedures, obtaining the required reviews and approvals prior to issue, and issuing them as controlled procedures.
- The Project Manager is responsible for routing the document to other interfacing organizations for review and to ensure that the review and comment resolution process is completed.
- The Quality Assurance Manager is responsible for ensuring all documents are consistent with QA objectives and provides final institutional approval.
- Management personnel involved in document control are responsible for establishing and implementing procedures describing their control system.

5.4 PROCEDURE

- The SOPs are provided for control documents, describing the review, approval, distribution, and revision of procedures.
- Review and approval of control documents by the Quality Assurance Manager is mandatory. The review encompasses comparison to applicable contract and standard requirements and Quality Assurance guidelines.
- Document approvals are indicated and documented after review comments are resolved, in accordance with approved document control procedures. Document control procedures include a central document archive, a system of consecutive revision assignments, and authorized signatures.

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- Approved documents are issued to designated recipients in accordance with authorized distribution lists that are developed and maintained by the Project Manager.

6.0 USE OF COMPUTER SOFTWARE AND HARDWARE

6.1 PURPOSE

The purpose of this section is to ensure that the computer hardware and software utilized meet programmatic requirements. Changes in hardware must be evaluated to assess the impact on system performance.

6.2 REQUIREMENTS

- Analysts must only use software developed by approved methods.
- Programs are independently validated, verified and documented according to the intended use of the software.

6.3 RESPONSIBILITY

The Senior Data Manager is responsible for verification of computer hardware and software.

6.4 PROCEDURE

Software is developed using a plan that incorporates the guidelines of *IEEE Standard for Software Quality Assurance Plans*, ANSI/IEEE standard 730-1984, and *DEFT Software for the Data Quality Objectives Process*, EPA QA/G-4D.

7.0 QUALITY IMPLEMENTATION OF WORK PROCESSES

7.1 PURPOSE

The purpose of this section is to ensure that activities that affect quality will be accomplished in accordance with appropriate instructions, procedures and illustrations. These documents incorporate the criteria that are used to judge the acceptability of the activities and are termed Standard Operating Procedures.

7.2 GENERAL REQUIREMENTS

Written instructions, procedures, charts, and illustrations are developed and approved for the performance of activities that achieve or verify the quality of products or processes. These tools provide directions for activities to be performed under controlled conditions and in proper sequence. They also provide independent verification and for acceptability based on acceptance criteria that are incorporated into each Quality System document.

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7.3 RESPONSIBILITY

- Each Manager is responsible for assuring that activities affecting quality under his/her supervision are prescribed and controlled by instructions, procedures or illustrations.
- The Quality Assurance Manager will review and approve all documents used to ensure that requirements and procedures are adhered to during all phases of a prescribed activity or project.

7.4 PROCEDURE

- Procedures are developed and maintained to provide direction on the preparation of instructions, procedures, and illustrations used to control activities affecting quality.
- Management identifies routine operations that need SOPs; prepares SOPs; and approves SOPs.
- SOPs are reviewed, and verified by technically qualified personnel before use.
- Quality Assurance aspects are reviewed and approved by the Quality Assurance Manager.
- When appropriate external expert peer-review is implemented.

8.0 QUALITY IMPROVEMENT

8.1 PURPOSE

The purpose of this section is to establish a framework to prevent and/or detect problems that adversely affect quality during planning, implementation, and assessment of technical and management activities, and to foster a "problem-solving" attitude among personnel to encourage the identification of problems and recommendation of solutions.

8.2 GENERAL REQUIREMENTS

- Continual quality improvement in technical and management processes must be encouraged.
- Measures of performance success and standards of excellence must be established.

8.3 RESPONSIBILITY

All levels of management are responsible for improving quality in our operations.

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8.4 PROCEDURE

- Management ensures that the appropriate resources are allocated, that difficult issues are resolved, and that the client is fully informed of the resolution of any quality-related problems.
- Management encourages continual quality improvement.
- All personnel are encouraged to exceed client expectations whenever possible.
- Personnel are encouraged to actively participate in continual quality improvement by regular meetings (including weekly all staff as well as smaller group meetings as needed), discussion groups, and open lines of communication between management and other personnel.

9.0 PLANNING AND SCOPING

9.1 PURPOSE

The purpose of this section is to establish guidelines to plan, implement, and document each environmental project and to provide the type and quality of environmental data needed for the intended purpose. These guidelines provide a blueprint for the essential elements of a successful Quality Assurance Project Plan (QAPP).

9.2 GENERAL REQUIREMENTS

- Project goals, ultimate usage, implementation and scope must be clearly defined in a project description before initiation.
- Specific environmental data to be collected and analyzed must be specified including QA considerations.
- Identify applicable technical, regulatory, or program-specific quality standards, criteria, or objectives.
- Designate personnel, equipment, and other resources required for performing the program activities.
- Identify controlled conditions required for collection and analysis of environmental samples and data.
- Determine assessment tools needed for the QA program.
- Identify the SOPs for field and analytical activities including the mechanism for changing these plans.
- Define the records and reports that are required.

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9.3 RESPONSIBILITY

The Project Manager, in consultation with the Quality Assurance Manager, plans and scopes the program.

9.4 PROCEDURE

Identify the tools, documents and records required to write and initiate a project plan such as; SOPs, analyte lists, equipment lists, training records and resumes. Write the project description to include the goals, scope, and intended purpose of the project, and also include data to be collected, QA requirements, method requirements, and reporting requirements. This project description is the blueprint or template for the project specific QAPP.

10.0 DESIGN OF DATA COLLECTION OPERATIONS

10.1 PURPOSE

The purpose of this section is to establish written instructions for the handling, storage, shipping and preservation of materials and equipment that must meet Quality Assurance criteria so as to prevent damage, deterioration, contamination or loss. An additional purpose is to define analytical operations, data validation and verification methods, techniques for assessing limitations on data usage, and data reporting requirements. If a field activity is required by the client's program, additional elements must be specified in the QAPP.

10.2 GENERAL REQUIREMENTS

- Designate sample type, sampling locations, and with SOPs, sampling methods.
- Handling, storage, shipping, cleanliness, and preservation requirements must be defined in written SOPs.
- Inspection documents will specify appropriate inspection points to ensure that handling, storage, shipping, and preservation requirements are met.
- Define sampling and analysis personnel requirements and qualifications.
- Select the appropriate analytical methods with specified SOPs.
- Detail calibration and performance evaluation criteria for analytical methods.
- The design process must ensure that data is traceable to the sampling and analytical procedures, performance standards, analysts, and measuring and test equipment.
- Data transfer, reduction, validation and verification requirements must be detailed and specified in SOPs.

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- The required reports to management are detailed and specified including status reports, interim results, and project assessment summaries.

10.3 RESPONSIBILITIES

- Written instruction or procedures will be prepared by the Project Director and Manager, in consultation with the Quality Assurance Manager, that comply with all project requirements.
- Project Director, in consultation with the Quality Assurance Manager, is responsible for formulating the Quality Assurance Project Plan.
- The Quality Assurance Manager is responsible for ensuring that all Quality Assurance aspects of a project are performed and documented.

10.4 PROCEDURE

The design of the project will be documented in a Quality Assurance Project Plan (QAPP). The Quality Assurance Manager and other senior management review the QAPP to ensure accuracy and completeness. The QAPP includes sample and analysis plans, instruction guides, SOPs, and operating manuals when appropriate.

11.0 IMPLEMENTATION OF PLANNED OPERATIONS

11.1 PURPOSE

The purpose of this section is to ensure implementation of the approved QAPP and other planning documents. To ensure that the type and quality of environmental data required to meet program objectives are obtained.

11.2 GENERAL REQUIREMENTS

- Only qualified and accepted services or items are used as part of the project.
- All items must be traceable to original sources.
- Final acceptance of data is the responsibility of personnel independent from the specified project. When acceptance criteria are not met, deficiencies are resolved and the data is re-inspected as necessary.
- Instruments must be calibrated on a routine basis (as determined by manufacturer recommendations) and this calibration is fully documented and traceable to the instruments.
- Preventive and corrective maintenance is routinely performed and documented. A sufficient supply of replacement parts is maintained.

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- Sample custody is tracked and documented according to the QAPP. All procedures must conform to the approved QAPP to prevent loss, damage, deterioration, artifacts or interference.
- Data transmission, storage, validation, assessment, and processing are performed in accordance with the QAPP.

11.3 RESPONSIBILITY

The Project Director is the institutional officer responsible for implementing the program, however, all B&B Laboratories personnel assigned to the project should assist in assuring project goals are attained.

12.0 QUALITY ASSESSMENT AND RESPONSE

12.1 PURPOSE

To provide a regularly scheduled assessment and documentation of the adequacy of the framework and infrastructure of the program in order to identify conditions adverse to quality objectives and to institute corrective actions as soon as practical.

12.2 GENERAL REQUIREMENTS

- Management controls must be sufficient to ensure the achievement of programmatic quality objectives. Adequate resources and trained personnel must be provided to ensure quality in all activities.
- In the case of a significant condition adverse to quality, the cause of the condition will be determined and corrective action taken to preclude recurrence.
- The identification, cause, and corrective action for significant conditions adverse to quality will be documented with a Corrective Action Form and reported to appropriate levels of management.
- Follow-up action will be taken to verify implementation of corrective action.

12.3 RESPONSIBILITIES

- Management has overall responsibility to ensure an effective QA plan is established and implemented.
- When appropriate, external independent experts will be utilized for overall review or audit.
- The Quality Assurance Manager and Laboratory Manager are responsible for documenting significant conditions adverse to quality, reviewing the record of evaluation and specified corrective action, and performing verification of completion of corrective action.

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- The Laboratory Manager responsible for the activity in which the nonconforming condition occurred investigates the cause of the condition, determines corrective action, and documents cause and corrective action on a Corrective Action Form. The manager responsible for implementing corrective action obtains verification of work as acceptable from the Quality Assurance Manager, and completes the associated documentation required to close out the corrective action request.

12.4 PROCEDURE

- The Section Managers will maintain and update control charts to ensure that analyses are in control. The Quality Assurance Manager will review control charts to verify that analyses are in control.
- The General Manager, Quality Assurance Manager and the Laboratory Manager will conduct regularly scheduled management assessment of quality-related issues. These meetings will be on a monthly basis at a minimum.
- Quality assurance concerns can be reported to the Quality Assurance Manager or solicited by the Laboratory Manager.
- The responsible Laboratory Manager identifies the cause and the corrective action to preclude recurrence, completes a Corrective Action Form, and determines a schedule for implementation.
- The Laboratory QA Manager evaluates the corrective action specified.
- The responsible Laboratory Manager takes corrective action and ensures satisfactory completion.
- The QA Manager verifies completion of the corrective action and maintains files.

13.0 ASSESSMENT OF DATA USABILITY

13.1 PURPOSE

The purpose of this section is to establish a Quality Assurance Records System for controlling all records that represent objective evidence of quality.

13.2 GENERAL REQUIREMENTS

- Records that furnish documentary evidence of quality will be specified, prepared and maintained.
- Quality records will be legible, identifiable, and retrievable.
- Quality records will be protected against damage, deterioration, or loss.

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- Written instructions or procedures will specify quality records.

13.3 RESPONSIBILITIES

- Each Manager is responsible for developing and maintaining instructions or procedures for identifying and controlling records within their department.
- The Quality Assurance Manager is responsible for the review and approval of procedures dealing with Quality Assurance records control.

13.4 PROCEDURE

13.4.1 Specifications

Quality Assurance records will include, but not necessarily be limited to the following items as they specifically apply to a given project:

- *Design*: planning documents, calculations, applicable codes, drawings and audits.
- *Procurement*: planning documents, purchase documents, material certifications, inspections, and audits.
- *Inspection*: testing documents, calibration data, audits and results.
- *Training*: personnel training and certification records.

13.4.2 Archival

B&B Laboratories will maintain all Quality Assurance records for a minimum of six (6) years following completion of work unless otherwise specified by codes, standards or written authorization. Records will be transferred to the client at the end of the retention period if requested by the customer.

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