

**SoBran, Inc.**  
**Corporate Quality Management Plan**  
**for**  
**Projects and Activities**



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## **1.0 INTRODUCTION**

At SoBran, Inc., quality means doing the right job, in the best way, on time, the first time. The quality of work performed at SoBran, Inc. defines our future success. In our highly competitive business environment, sustained quality in conducting project activities—and a consistent approach to ensuring quality performance—are essential. This Quality Management Plan (QMP) brings to our proposed team this same spirit and commitment.

SoBran, Inc. provides services to meet customer expectations and requirements. Quality standards are specified by our customers and can be generated internally or externally of our organization. At SoBran, Inc., quality is a primary concern to us, and is equally as important as cost and schedule performance. Every employee applies the actions necessary to assure that we meet this commitment to our customer requirements.

This QMP addresses quality requirements from a program/project management perspective, providing managers with quality assurance/quality control (QA/QC) requirements and guidelines needed to plan, implement, and assess their programs. It forms a set of fundamental requirements commensurate with the scope, nature, and complexity of their projects and activities to ensure that all work performed under this program maintains the appropriate standards of quality. Specific task order quality requirements and details not covered by this QMP will be addressed in Quality Assurance Project Plans (QAPPs) or additional QIPs as required for each project. Procedures for preparing, reviewing, and approving QIPs are specified in QIP-3.2.

## **2.0 QUALITY MANAGEMENT AND ORGANIZATION**

The effective implementation of the QA/QC requirements of this QMP, coupled with project-specific QAPPs, ensures the quality of all SoBran, Inc. programs.

### **2.1 PROGRAM QUALITY POLICY**

It is SoBran's policy to establish, produce, and maintain services and products of the highest quality. SoBran, Inc. assures the quality of the products and services it provides to internal and external customers through the promulgation of its QMP. Individual projects are further managed through the preparation of QAPPs. The QMP and QAPPs, in combination with SoBran, Inc.'s Quality Assurance Organization, headed by the Corporate Director of Quality Assurance, form the basis for carrying out a thorough and cohesive Program Quality Policy that underlies our quality assurance organization.

### **2.2 PROGRAM ORGANIZATIONAL STRUCTURE**

Our QA organization is superimposed over the SoBran, Inc. management structure as well as over our project management structure. The Corporate Director of Quality Assurance is the functional head of the QA project directors. Staffing of SoBran, Inc.'s QA organization is dynamic and is determined by the management structure, which in turn will vary with changes in corporate size, geographic locations, and business units. The QA organization is a proactive management resource to help achieve SoBran, Inc. quality objectives and independent assessment of quality program effectiveness for feedback to line management. Figure 2.1 illustrates the division of quality assurance responsibilities among principal staff members of the

proposed project team as defined by this Quality Management Plan. The Corporate Director of Quality Assurance is independent from line management and project management. The project manager is the central point of contact for the project team and will be the primary point of contact for each project.

#### 2.2.1 CHIEF OPERATING OFFICER (COO)

The COO provides SoBran, Inc. direction, guidance and management support for the Corporate Quality Assurance Program. The COO has ultimate responsibility for the success of the QA Program. To achieve a successful QA Program, the COO:

- Provides appropriate resources to project managers and technical leaders to ensure quality in all activities;
- Provides policy objectives, direction, and guidance to the Corporate Director of Quality Assurance to maintain the highest levels of quality possible within the company;
- Delegates responsibility to project managers and technical leaders for project-specific quality achievement targets;
- Reviews evaluation and assessment reports in order to remain apprised of quality status; and
- Approves corporate management system documents.

#### 2.2.2 CORPORATE QUALITY ASSURANCE DIRECTOR (CQAD)

The Corporate QA Director oversees QA/QC in all program areas. The CQAD develops QA/QC policy and reports to the COO. The CQAD is independent of related technical activities and establishes QA/QC policy and guidance. The CQAD has the authority to approve QMPs, conduct QA management assessments, and implement corrective actions. If significant deficiencies are found, the CQAD can stop work on a project until corrective action is in place. This process ensures consistent quality management in all products and services. Specifically, the CQAD:

- Develops and disseminates QA/QC policy throughout all levels of staff and management;
- Maintains thorough knowledge of the principles of QA/QC and the QMP for each area;
- Develops guidance and training materials for staff QA education;
- Develops protocols for managing QA audits of each program area;
- Reviews and approves all QA/QC documentation (e.g., including the QMP and QAPPs);
- Meets with program and QA management staff to ensure QA/QC principles and requirements are current;
- Meets with PQAOs to ensure that QA objectives are achieved; and
- Works with COO to ensure that appropriate resources (staff and material) are available to meet quality goals.

#### 2.2.3 PROJECT MANAGERS

The Project Managers are responsible for directing and approving all technical work performed in a manner that meets the QMP and QAPP specifications. As shown in the organization chart (Figure 2.1) a Project Manager and QAO are identified for each organization. The Project Manager will:

- Review and approve the QMP to ensure that it adheres to Project requirements and QA policy;
- Determine the need for QAPPs for particular work assignments;
- Support implementation of corrective actions for any deficiencies in the project's QA program;
- Support the CQAD, as necessary, in conducting QA assessments;
- Assign resources to implement specific project QA requirements; and
- Approve project-specific QA requirements and implementing procedures necessary to achieve them.

The Project Manager ensures that corrective actions recommended by the CQAD or the PQAOs are carried out, and is accountable to the COO.

#### 2.2.4 PROJECT QA OFFICERS (PQAOS)

The PQAOs, with expertise in QA/QC as well as the technical objectives of the project, are responsible for developing the QMP and for maintaining, monitoring, auditing, and enforcing the QA program. The PQAOs are responsible for the quality of all work performed (e.g., data quality). The PQAOs are accountable to the CQAD to ensure that appropriate quality standards are maintained and conflict of interest is avoided. The PQAOs report to and derive the authority to enforce corrective actions from the CQAD. The PQAOs are responsible for ensuring the quality of work.

Additional specific responsibilities of the PQAOs include:

- Work with the CQAD, Project Managers to monitor QMP and QAPP implementation status and address quality issues;
- Review project plans to ensure that the appropriate level of QA/QC is included and that they adhere to the QMP and the QAPP;
- Assist the CQAD and the Project Managers with the revision of QMP, QAPPs and data quality objectives (DQOs);
- Identify to management situations that require corrective actions;
- Develop recommendations to the Project Managers for actions to correct work or data that do not conform to QMP or QAPP standards;
- Ensure and document compliance with recommendations regarding corrective action to address QA inadequacies;
- Review data quality and prepare reports for the Project Managers and CQAD concerning data quality and usability;
- Review QA nonconformance reports from audits, data quality and data usability statements, annual project review reports, DQOs, and corrective action reports; and
- Develop and/or maintain QA and data validation documentation.

#### 2.2.5 PROJECT STAFF

The project staff is responsible for performing all work in compliance with the QMP, work plan, QAPP, and project requirements. The project staff will:

- Develop project-specific documents;
- Implement project-specific quality requirements;
- Perform the project;
- Report results;
- Monitor work quality; and
- Identify, implement and document corrective actions.

Disputes regarding quality system requirements, QA/QC procedures, assessments, or corrective actions are resolved through discussions with the client and involved members of SoBran Inc.'s quality assurance organization. The SoBran, Inc.'s CQAD leads discussions and has ultimate authority for successful resolution of any disputes. Throughout the process, the COO, involved staff members, and the client are included and kept abreast of any and all decisions.

### 2.2.6 AUTHORITY TO STOP WORK FOR SAFETY AND QUALITY CONSIDERATIONS

Managers at all levels have the authority and responsibility to stop work under their direction when personnel safety is compromised or when continued work would produce unacceptable results. Members of the QA organization recommend formal stop work action when necessary to assure work activities meet quality and technical requirements. Stop work orders, if applicable, are approved and issued by the program director in accordance with an approved Quality Implementing Procedure (QIP-1.7).

## 2.3 QA ORGANIZATIONAL STRUCTURE

This section consists of two components, which incorporate elements of SoBran Inc.'s quality system and reviews and revisions of our Quality Management Plan.

### 2.3.1 QUALITY SYSTEM ELEMENTS

SoBran Inc.'s quality system elements include its COO corporate commitment; Corporate Director of Quality Assurance; Human Resources Department training; QA/QC, and various audit reports; this QMP; QAPPs for individual projects; SOPs where appropriate; management assessments; and corrective action plans.

### 2.3.2 QUALITY MANAGEMENT PLAN REVIEWS AND REVISIONS

Corporate Quality Management Plans, including this QMP, are reviewed annually by SoBran, Inc.'s Corporate Director of Quality Assurance for adherence to the latest QA requirements. Procedures for QAPP review are specified in Quality Implementing Procedure 3.1 (QIP-3.1).



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### **3.0 QUALITY SYSTEM AND DESCRIPTION**

The quality management system consists of management "tools" and processes that support the four major principles of the QMP: 1) planning, 2) implementation of quality work processes, 3) assessment of the quality system, and 4) improvement of the quality system. The tools, if required, that comprise the quality system as a whole are this QMP, QAPPs, an annual internal system review, the work assignment and work planning process, standard operating procedures (SOPs), and data quality assessments. The following sections describe the principles of the quality system, the major components, and includes how and when each component is applied and discusses the responsibilities of management and staff. As referenced, each component is discussed in detail later in the QMP.

#### **3.1 QUALITY PLANNING**

Quality planning includes the use of a systematic approach to planning projects and the documentation of this approach in a QMP, and QAPP as well as other scoping documents [e.g., Work Plans].

##### **3.1.1 SYSTEMATIC PLANNING**

The DQO process is the fundamental planning tool for all programs and consists of a series of planning steps that are designed to ensure that the type, quantity, and quality of data used in decision-making are appropriate for their intended application. The DQO process is used to plan all data collection efforts, including field and/or laboratory work, before the data are collected. Application of the DQO process will ensure that data requirements are defined and data of acceptable quality are collected. The DQO process will yield results of appropriate quality for defensible decision-making.

##### **3.1.2 SCOPING DOCUMENTS**

The project team documents the project requirements/DQOs into schedules, cost estimates, and scoping documents (e.g., QMP, QAPP, and Work Plans). The scoping documents describe the detailed QA/QC protocols that are required for the project specific activities. All aspects of sample handling, sample and field collection, analysis, QC procedures, data reporting, data validation, data management, and data archiving will be carried out as described in the project specific scoping documents.

#### **3.2 QUALITY IMPLEMENTATION OF WORK PROCESSES**

The Corporate QA Director has the primary responsibility of ensuring proper implementation of the quality system. This oversight is ongoing for the entire length of the contract. The Corporate QA Director ensures that project scoping documents and SOPs are followed, staff are adequately trained, and complete documentation is maintained. Implementation of the quality system is described in detail in Section 9.0.

The following tools and processes are used to ensure that the quality goals and objectives, described in the scoping documents, result in quality products:

- **Quality Management Plan** — This document describes SoBran’s quality system for planning, implementing, and assessing the effectiveness of activities supporting project operations.
- **Quality Project Plan** — The purpose of the QAPP is to specify the policies, organization, objectives, and the quality evaluation and quality control activities needed to achieve the DQOs. This document identifies the 16 elements that must be addressed in the QAPPs.
- **Standard Operating Procedures** — Work will be conducted in accordance with SOPs, where applicable. SOPs are available for a variety of activities including sampling and analysis.
- **Work Plans** — Work will be conducted in accordance with approved Work Plans, where applicable. Work Plans are available for a variety of activities including sampling and analysis.
- **Training** — The PQAOs ensures that personnel have the appropriate QA training. Periodic refresher courses are undertaken on an as-needed basis. Section 4.2 of this QMP addresses the approach to ensuring all personnel receive training, as needed.
- **Facilities and Services Maintenance** — All facilities (including equipment) and services supporting program activities will be properly maintained at a level that ensures achievement of overall program QA standards.
- **Data Processing Procedures Documentation** — All data processing procedures are documented and regularly reviewed. In addition, processed data are validated routinely according to criteria specified in the QAPPs and/or Work Plans. Section 7 provides further discussion of Data Quality Reviews.

### **3.3 QUALITY ASSESSMENT AND RESPONSE**

A variety of tools and processes will be applied to assess the effectiveness of the quality system and identify the need for corrective action. These tools consist of management, technical, and data quality assessments as summarized below and described in greater detail in Section 10.0:

- **Annual External System Review** — Each year the CQAD and the PQAOs team shall review the QA System and its adherence to the QMP.
- **Annual Internal System Review** — At least one time per year an internal system review shall be performed by the PQAOs with the assistance of the Project Manager. System evaluations are the review of the entire data production process and consist of on-site evaluation and a review of documentation.
- **Quality Documentation** — All results of management and technical assessments conducted in accordance with this QMP are documented and maintained on file. Data quality

documentation includes a statement of data usability to meet program/project objectives.

### **3.4 QUALITY IMPROVEMENT**

The quality system will ensure rapid correction of quality-related problems and is designed with the objective of continuous improvement. Section 11.0 describes quality improvement, which involves the following tools:

- Corrective Action Program for QA Problems — Establishing and implementing a corrective action program for identified QA problems is an integral part of the overall QA program. Identifying problems and expediting appropriate corrective actions is the responsibility of all staff members. Specific project requirements, acceptance criteria, and corrective actions as well as other policies or guidance will be specified in the project-specific documents such as the QAPPs, and Work Plans.

### **3.5 QA MANAGEMENT RESPONSIBILITIES**

In addition to relying on the tools and processes described above, SoBran ensures an effective quality system by designating top-level managers to key QA responsibilities and holding all staff involved in data collection and management efforts accountable for quality work. The following QA management framework demonstrates our commitment to QA:

- Designation of a Corporate Quality Assurance Director—The CQAD is ultimately responsible for the quality of all work performed. The CQAD is independent of the Project Manager and is accountable to the COO to ensure that appropriate quality standards are maintained. The CQAD reports to, and derives authority to enforce corrective actions from the COO. The CQAD blends QA skills with technical expertise to execute the QMP, QAPP, and QA policy.
- CQAD Coordination with the Project Manager — The CQAD works directly with the Project Manager to ensure that contract quality objectives are met and that the QAPP and QA policies are strictly adhered to.
- Technical Staff — The contract is staffed with personnel who are required and prepared to carry out QA policies and procedures.

### **3.6 TECHNICAL ACTIVITIES SUPPORTED BY THE QUALITY SYSTEM**

The quality system includes all activities relating to or affecting the collection, generation, documentation, evaluation, management, and analysis of project/program data or other defined requirements. These activities include, but are not limited to:

- Investigations and reviews;
- Analysis of systems;
- Modeling and risk assessments;
- Reduction, validation, and reporting of data;

- Preventative maintenance procedures and schedules for hardware and software; and
- Corrective actions.

By strictly adhering to the planning, implementation, and assessment requirements of the quality system described in this QMP, the CQAD will identify, execute, and document specific quality procedures that will meet the project quality expectations.

## **4.0 PERSONNEL QUALIFICATIONS AND TRAINING**

### **4.1 PERSONNEL QUALIFICATIONS**

This section describes procedures for personnel training, including formal qualifications and certifications, retraining, and evidence of job proficiency from SoBran, Inc. staff members.

#### **4.1.1 PERSONNEL TRAINING AND QUALIFICATION PROCEDURES**

All levels of SoBran, Inc. management are responsible to ensure SoBran, Inc. and any subcontractor personnel are trained and qualified to perform work within their specific discipline or scope of work. SoBran, Inc. and any subcontractor personnel performing work in accordance with this QMP are required to be qualified to perform their assigned work according to the requirements of this QMP and to specific task or work order requirements. This requirement applies specifically to all personnel performing or managing activities directly affecting quality. Procedures and training requirements are specified in Quality Implementing Procedure 2.1 (QIP-2.1).

SoBran, Inc. encourages all employees to seek additional training to expand their knowledge and technical skills. SoBran, Inc. contributes to its employees' training and additional education by subsidizing tuition and providing flexible hours as necessary during employee training. SoBran, Inc. emphasizes education and training of all employees to achieve and maintain proficiency and to create an environment of individual responsibility and accountability for quality.

Personnel selected to participate in quality assessment activities as assessors or other evaluators must have training and experience commensurate with the scope and complexity of the activities to be evaluated. Specific requirements and methods for training, qualifying, and certifying assessment personnel are included in Quality Implementing Procedure 1.3 (QIP- 1.3).

The Corporate QA Director ensures that personnel performing quality assessment activities are prepared for the activity, including training or retraining as necessary. Preparation activities include additional instruction for assessment personnel. The lead assessment team member assures that personnel participating in quality assessment activities are trained to be objective and understand the purpose of the planned activities.

#### **4.1.2 FORMAL QUALIFICATIONS AND CERTIFICATIONS FOR SPECIALIZED ACTIVITIES**

Formal qualification or certification is required for those professions that specify them, including engineers and industrial hygienists. Copies of certifications are obtained from these employees prior to their employment. Each corresponding qualification or certification document is verified by SoBran Inc.'s Human Resources Department prior to employing the individual. In

addition, periodic updates of training, through continuing education or other means, are maintained in Human Resources personnel files to ensure maintenance of the required qualification or certification. Project-specific qualifications and certifications are determined by the project manager in accordance with the contract Statement of Work (SOW).

## **4.2 TRAINING DOCUMENTATION**

SoBran, Inc.'s Human Resources Department maintains current files on all employees. Program specific training is documented in accordance with Quality Implementing Procedure 2.1 (QIP-2.1).

### **4.2.1 RETRAINING**

Retraining may be necessary when selected employees have job requirements that change. In these cases, retraining is coordinated by SoBran Inc.'s Human Resources Department and the Corporate Director of Quality Assurance. The need for retraining that involves quality assurance duties and expertise is evaluated by the QA Director based on an employee's experience and the description of the work to be performed. If retraining involves quality assurance activities, including auditing, then it is overseen jointly by the Corporate Quality Assurance Director and the Director of SoBran Inc.'s Human Resources Department. Together they plan and implement retraining for personnel that need additional training for QA-related jobs. The retraining may be obtained from internal resources or from outside training resources, including short courses, certified QA professionals, or courses taken at nearby colleges and universities.

### **4.2.2 EVIDENCE OF PERSONNEL JOB PROFICIENCY**

Each year job proficiency of all personnel is evaluated using a standard process and form. Supervisors perform the evaluation. If deficiencies are noted, the employee is counseled, corrective action is implemented, and the employee is monitored for improvement in the deficiency.

## **5.0 PROCUREMENT OF ITEMS AND SERVICES**

Procurement activities in this QMP include planning and control, technical quality requirements, documentation of vendors' and suppliers' conformance to quality, document review, and, of course, review and evaluation of services and items that have been procured.

### **5.1 PROCUREMENT PLANNING AND CONTROL**

Project managers and technical leaders, in addition to SoBran, Inc. contracts administrators, are responsible for ensuring that procurement documents contain all applicable technical and quality assurance (QA) requirements, including appropriate sections of the Federal Acquisition Regulations (FAR) that flow down from the prime contract.

SoBran, Inc.'s purchasing and subcontracting functions are integral activities to fulfilling its mission and attaining its objectives. Basic precepts of the procurement system include the following:

- All operations are conducted in compliance with federal regulations and cost principles;

- All actions are justified and awards documented in sufficient detail to establish a complete audit trail;
- Competition is employed to the maximum practicable extent;
- Best value selection decisions are made based on technical assessments, cost and price analyses, and other related factors;
- Audit requirements of the Defense Contract Audit Agency (DCAA) or other federal agencies are met.

## **5.2 PROCUREMENT TECHNICAL AND QUALITY REQUIREMENTS**

Reviews and approvals of all purchasing transactions are processed in accordance with SoBran Inc.'s purchasing procedures to ensure that the technical and quality requirements are sufficiently defined to enable supplies or services to be acquired that will meet the stated needs. When items are being purchased that must meet a specific level of performance based on use of performance specifications, offerors are required to submit documentation along with offers to enable a complete evaluation of the item/service being offered to ensure that it meets the specification requirements. The review and approval process for all SoBran Inc. purchases is built around the type of transaction and the dollar value of the action.

SoBran Inc.'s contract and purchasing personnel:

- Control procurement documents (e.g., purchase requisitions, purchase orders, basic ordering agreements, service contracts, etc.);
- Provide reports or other documentation related to quality on deficient items and services provided by suppliers to the QA staff; and
- Secure replacement or remedy from suppliers of deficient items and services.

Project managers and technical leaders:

- Provide SoBran Inc.'s contract and purchasing personnel with appropriate specifications, drawings, scope(s) of work, and other documentation necessary to obtain suitable and acceptable items and services;
- Identify quality-related items and services to contract and purchasing personnel;
- Monitor the quality of items and services provided by suppliers in support of work activities;
- Ensure all documents used for the procurement of quality-related items and services include appropriate quality requirements (e.g., applicable specifications, standards, regulations, drawings, and a scope of the work including quality requirements);
- Perform procurement source evaluations when requested by the project or program manager;
- Monitor supplier quality; and
- Provide methods for determining the level of supplier quality through inspections, tests, certifications, source inspection, and other valid methods of verifying compliance of items and services to procurement document requirements, upon management request.

## **5.3 PROCUREMENT DOCUMENT SPECIFICATION OF VERIFYING SUPPLIER'S CONFORMANCE**

Items and services are procured to meet SoBran, Inc. and customer requirements. Suppliers providing items and services according to the requirements of each contract must have a documented and implemented QA program capable of ensuring that items and services meet requirements of each and every procurement document. Suppliers must incorporate appropriate

quality requirements in their procurement documents. Therefore, appropriate methods, procedures, instructions, and inspections are instituted to ensure that requirements for items and services are clearly defined in procurement documents and that deliverables meet the applicable specifications. Suppliers are required to have a demonstrated capability to furnish items and services consistent with the required quality and technical specifications. Contractors/suppliers are subject to periodic evaluation to ensure that the specified quality is achieved and that quality procedures are followed.

#### **5.4 PROCUREMENT DOCUMENT REVIEW**

Project managers and technical leaders, in addition to SoBran, Inc. contracts administrators, are responsible for reviewing and ensuring that procurement documents contain all applicable technical and QA requirements, including appropriate sections of the Federal Acquisition Regulations (FAR), that flow down from the prime contract. This review process includes review by the appropriate project and corporate management, including the program manager, and Director of Contracts.

In the event subcontractors or consultants are required, procurement documents will specify technical and quality requirements relevant to the scope of work. To the extent necessary, procurement documents will require suppliers to have a quality assurance program consistent with applicable requirements of the SoBran, Inc. program. In the event subcontractors are required to perform technical work in accordance with their own QA program, SoBran, Inc. procurement documents will require right of access and necessary documentation to SoBran, Inc. for information, review, and approval.

In the event subcontractors are utilized in the performance of work, all applicable requirements, technical, regulatory, and quality, of the prime contract are flowed down to the subcontracts. All deliverables prepared by subcontracts must be submitted to SoBran, Inc. in accordance with the terms of the subcontract for submission to the client.

#### **5.5 REVIEW OF CHANGED PROCUREMENT DOCUMENTS**

The process followed for all changed procurement documents follow the same process that is followed for a new procurement transaction. The process requires submission of a Purchase Request identifying the contract or subcontract requiring a change, a complete description of the change, estimated cost of the action, background information leading to the required change, and if for new work, justification for not competing the action.

#### **5.6 REVIEW OF PROCURED ITEMS AND SERVICES**

The individual requesting the item/service receipts all deliverables resulting from SoBran, Inc. purchasing transactions. If the item/service is direct charged to a contract, the project manager also signs off that the items or service has been received and meets the contract requirement. This documentation is then forwarded to the contracts and accounting department for processing and payment.



## **6.0 QUALITY DOCUMENTATION AND RECORDS**

Scientific and engineering projects rely on accurate records of the procedures that were conducted. Documentation of records, data, and procedures is critical for relating the results of work performed and for assessing its adequacy for the intended use. Documents and records are the foundation upon which this QMP is based. The Quality Records Management System is specified in Quality Implementing Procedure 2.3 (QIP-2.3).

### **6.1 RECORDS MANAGEMENT PROCEDURES**

Project managers and technical leaders, in addition to SoBran, Inc. contracts administrators, are responsible for ensuring that contract documents contain all applicable technical and QA requirements, including appropriate sections of the FAR, that flow down from the prime contract. Documents for each contract are maintained by SoBran, Inc. at the office of the designated project officer for a period of five years or the amount of time specified by each contract. Records are stored in protected facilities to safeguard them from damage and deterioration. Records are stored in boxes that are labeled with the contract and program manager's contact information so that they can be easily accessed. Documents typically held in long-term storage include QAPPs, original data packages, field and laboratory records and notebooks, chain-of-custody forms, interim and final reports, and contract documents.

In the event subcontractors or consultants are required, procurement documents specify technical and quality requirements relevant to the scope of work that must be stored and accessible. To the extent necessary, procurement documents require suppliers to have a quality assurance storage program consistent with applicable requirements of the SoBran, Inc. program. In the event that subcontractors are required to perform technical work in accordance with their own QA program, SoBran, Inc. procurement documents require right of access and necessary documentation to SoBran, Inc. for information, review, and approval.

### **6.2 DOCUMENT CONTROL**

SoBran, Inc. has an established document control management system to exercise control over documents. It specifies quality requirements, provides evidence of quality achievement, and records QA implementation. Prior to release to authorized personnel, documents are reviewed for adequacy, completeness, and correctness. Procedures are specified in Quality Implementing Procedure 2.3 (QIP-2.3).

Project managers and technical leaders identify those documents that require controlled status. They also designate individuals in their respective offices, programs, and functional areas to receive and maintain QA records as prescribed by SoBran Inc.'s internal and external customers. QA coordinators under the direction of the Director of Quality Assurance provide leadership and direction for the document control management system, as well as a periodic self-assessment of its operation.

### **6.3 CONTROLLED DOCUMENT MANAGEMENT**

SoBran, Inc. has established protocols applicable to team members who generate, use, or manage controlled program documents in providing technical support to clients.

Controlled document management includes the following elements:

- Assignment of responsibility for preparing, reviewing, approving, and issuing documents (changes are approved by the same authority that performed the original review and approval);
- Controlled lists of documents to be maintained showing revision status;
- Specific distribution lists for controlled documents;
- Receipt acknowledgment transmittal system; and
- Periodic reviews to determine obsolete or superseded controlled documents.

## **7.0 USE OF COMPUTER HARDWARE AND SOFTWARE**

Most engineering and scientific projects conducted today rely on computer hardware and software. Use and maintenance of computer hardware and software is an essential component of this QMP.

### **7.1 CONFORMANCE TO USER AND EPA REQUIREMENTS**

Computer hardware and software configurations are developed to meet each user's requirements. Hardware includes disk drives, electrical components, monitors, and other such devices used to run computer programs. Computer programs are synonymous with software. Computer programs include, but are not limited to, requirements analysis, design, models, processes and conditions, operations or process control (including multiple concurrent users), and databases or document control registers (when used as the controlled source of quality information).

### **7.2 CONFIGURATION TESTING**

#### **7.2.1 INTERNAL SOBRAN, INC. INFRASTRUCTURE HARDWARE AND SOFTWARE**

Major changes to SoBran, Inc.'s infrastructure configuration are minimized. SoBran, Inc. makes use of widely implemented computer hardware and server software. Newly released versions are applied only in a test environment until SoBran, Inc. believes that current releases are stable and robust and potential risks are well known.

#### **7.2.2 DEVELOPMENT OF SOFTWARE FOR CLIENTS**

Computer program development and testing are accomplished using approved methodology. Applicable programs are validated, verified, and documented according to the intended use of the software. Test requirements for developed software include verification tests, in-use tests, testing procedures, documentation of results, and control and maintenance of all test records. Changes are controlled and assessed to determine the potential impact of the change on the performance of the software.

For larger systems, performance testing is conducted as required. This may involve testing with various sizes or data sets to simulate system growth as additional data is loaded.

Testing is conducted continuously throughout development, as software modules and sections are completed. Testing of systems is conducted in their final "live" environment as soon as technically feasible. Periodic testing in the final environment continues throughout the development period. This process avoids surprise problems that may occur due to differences in

configuration between the development and final computer network, hardware, and software environments.

### **7.3 CONFIGURATION CHANGE ASSESSMENT**

Major changes to SoBran, Inc.'s infrastructures are rare. Changes that are necessary are tested on a test network separate from SoBran, Inc.'s operational network. When changes are necessary to the lower layers of the network, like wiring and Internet connectivity, the new and replaced systems are run in parallel for a few days, whenever possible, to ensure that the replacement system is reliable. Major changes are implemented outside of business hours, usually on weekends, and only after notifying employees and affected clients.

## **8.0 QUALITY PLANNING**

Adequate planning prior to initiating work on any project is critical. Our Data Quality Objective Process stresses adequate initial planning to consider all the procedures and data that will be necessary in the context of time, budget, equipment, facilities, and other resources. Adequate planning is a major emphasis of this QMP.

### **8.1 SYSTEMATIC PLANNING**

Project managers and technical leaders are responsible for defining, planning, approving, and implementing specific requirements for planning and documenting the generation, acquisition and use of all data. The Corporate QA Director ensures those plans, procedures, and instructions that specify quality requirements are compatible with SoBran, Inc.'s quality assurance policies. These procedures are specified in Quality Implementing Procedures 3.1 and 3.2 (QIP-3.1 and QIP-3.2).

Project planning begins with the initial allocation of resources to a specific task and ends with the implementation of the task. The Project Manager assumes the primary responsibility for managing projects and assembling personnel for a project. The project team will develop DQOs, prepare project-specific plans, execute the project, and prepare technical reports describing the results, conclusions, and recommendations for the project. It is the responsibility of all members of the project team to make all necessary preparations and plans to ensure program and project quality objectives are met.

Phase I of the planning process involves the development of project-specific objectives. The Project Manager, project staff, QA staff, and clients will work jointly to determine the project DQOs. As described in Section 3.1, the DQO process is the fundamental planning tool for all programs that is designed to ensure that the type, quantity, and quality of data used in decision-making are appropriate for their intended application. The DQO process, consists of the following seven planning steps:

- 1) State the problem;
- 2) Identify the decision that will solve the problem;
- 3) Identify the information and the measurements needed to resolve the problem;
- 4) Identify the study boundaries;

- 5) Develop the decision rule;
- 6) Specify the acceptable error limits based on the consequences of making incorrect decisions; and finally
- 7) Optimize the design through an iterative process.

The DQO development process will provide a platform for the project team and client to come to a mutual understanding of the project's scope and objectives.

Additional Phase I planning activities that build on the DQO development process include:

- Defining the project goal, objectives, and questions and issues to be addressed;
- Identifying specific technical, regulatory, and contractual requirements;
- Determining the type, quantity, and quality of data required;
- Identifying how, when, and where the data will be acquired; and
- Identifying any cost and/or schedule constraints.

In Phase II of the planning process, the Project Manager directs the Project Team to translate the project requirements and DQOs into specific technical and QA requirements for the project. Specifically, the Project Manager and/or designated members of the Project Team will perform the following tasks:

- Develop project schedules, cost estimates, and resource requirements;
- Identify methods of data acquisition and SOPs to be followed;
- Define QA assessment tools, acceptance criteria, and corrective action requirements; and
- Document all of the above in the project work plan (WP) and other scoping documents.

Work on any task will not commence until the planning process has been completed and the results have been incorporated into the project scoping documents and approved through the QA system.

## **8.2 IDENTIFYING AND DOCUMENTING TYPE AND QUALITY OF DATA NEEDED**

All necessary references, procedures, instructions, and criteria for acceptance of data listed in Section 8.1 above provide documentation for the type and quality of data needed. SoBran, Inc. controls design, experiments, and other processes using procedures based on appropriate industry, national and international quality assurance standards. These requirements are applicable to SoBran, Inc. personnel who perform design reviews and who manage or perform activities involving experiments, scientific investigations, or engineering prototypes. Design activities may require design analyses, design verification, design change control, and configuration management. These activities are performed in accordance with applicable technology, specified by the customer or suggested by SoBran, Inc. technical staff, and conform to standards set by ASME, ANSI, and ISO.

## **8.3 PROJECT SCOPING DOCUMENTS**

Each of the specifications developed in the planning process outlined above will be documented in project scoping documents. This includes, but is not limited to the following document:

- Quality Assurance Project Plan (QAPP)—which establishes the framework for the project’s QA/QC program. The QAPP specifies acceptable methods of analysis for use by the laboratory. The QAPP also specifies the type, frequency, acceptance criteria, and corrective action requirements for QA activities, such as audits, performance evaluations, data review, data validation, and data verification; and QC activities, such as duplicate, blank, and spiked sample analyses.

A project-specific QAPP may be prepared for each project to ensure that QC objectives and criteria are commensurate with the objectives of individual projects. Once the DQOs are established for the project, and the type, quantity and quality of data are identified, the Project Manager, with assistance from the Corporate QA Director, will review the project-specific QAPP to identify any project-specific additions to or deviations from the procedures defined in the QAPP. These additions/deviations will be specified in the project-specific QAPP.

The Project Manager, the QA Team, and the project team will prepare work plans (WPs) and any necessary project-specific QAPPs. Such documents will be submitted within a time frame, which allows reviewing, revision, and document approval. No measurements will be made without a QAPP approved by the client, as appropriate.

The final, and perhaps most important, step in the planning process is ensuring that all project staff conduct a complete and thorough review of all scoping documents. Each member of the project team will read the scoping documents and keep them readily available for use. It is particularly important for the field team and/or laboratory personnel to have these documents readily available for reference as needed. Any deviation from the requirements set forth in the scoping documents must be approved by the Corporate QA Director or PQAOs, brought to the attention of the Project Manager, and documented in the project files.

#### **8.4 REVIEWING AND APPROVING PLANNING DOCUMENTS**

SoBran, Inc. project managers and technical leaders identify activities requiring design and experimental controls and implement applicable QAPPs. The Corporate QA Director verifies effective implementation of this policy. General procedures involve technical reviews; experiments, scientific investigations, and engineering studies, peer reviews, and data qualifications.

- **Technical Reviews**

These are critical reviews performed by technically qualified personnel to assure the technical adequacy of planning documents, procedures, and instructions prior to use. Technical reviews are also performed on SoBran, Inc., products to assure the quality of technical products provided to internal and external customers.

- **Experiments, Scientific Investigations, and Engineering Studies**

Prior to the start of these activities, a planning document (and appropriate QAPP) is prepared. Design adequacy is verified by persons other than those who accomplished the design. Design

changes are governed by control measures commensurate with those applied to the original design.

- **Peer Reviews**

These reviews are performed in accordance with an approved QAPP when the adequacy of information or the suitability of procedures and methods essential to demonstrating performance requirements cannot be established through calculations, testing, or reference to previously established standards and practices, or if activities are state-of-the-art or untried.

- **Data Qualification**

Data developed under an acceptable QA program is acceptable for use under the conditions for which it was designed and documented in Data Quality Objectives. Data for design input that was not collected or developed under a QA program that meets these quality assurance policies is qualified in accordance with approved QAPPs that document the decision process and factors used to qualify the data.

## **8.5 SECONDARY DATA**

SoBran may be required to evaluate and qualify data from sources outside the Program that did not use an approved QAPP for data collection. Analytical data are evaluated based on whether or not the data meets the DQOs of the program. If the DQOs have been developed and documented in an approved QAPP, the analytical data are evaluated and qualified for use based on compliance with those documents. However, additional steps are required when evaluating and qualifying data obtained from sources outside that do not use an approved QAPP for data collection.

Due to reporting variability, the level of data review must be determined on a case-by-case basis. The project DQOs must be specified or they must be developed before evaluating the data. A level of QC specified in the DQOs must be demonstrated. Four areas of concern must be addressed. These areas are sample preparation and analysis, QC measurements, adherence to QC requirements, and level of documentation. The data reviewer evaluates the data against the project DQOs using the data quality assessment (DQA) process and/or professional judgment. Section 10.1.2 describes the DQA, which can be applied to data with or without an approved QAPP.

Secondary data are qualified and clearly labeled when used for purposes other than that for which they were originally collected.

## **9.0 QUALITY IMPLEMENTATION OF WORK PROCESSES**

Work conducted by SoBran, Inc. will be planned, implemented, and assessed according to all applicable parts of this QMP. Task order specific requirements for work processes and operations are discussed in the individual task orders and QAPPs. Tasks are assigned and traced in accordance with Quality Implementing Procedures 2.2 (QIP-2.2).

## **9.1 IMPLEMENTATION OF WORK ACCORDING TO PLANNING DOCUMENTS**

Implementation of quality work will be performed only according to approved planning and technical documents. The DQO process and the nature, complexity, and scope of the work to be performed are key components in preparing approved documents. For characterization of environmental processes and conditions, planning includes a determination of the level, type, and quality of data required. For engineered systems, planning includes a determination of the appropriate design criteria and design bases. Planning also considers any special controlled conditions required ensuring that objectives are satisfactorily achieved.

Work will be performed according to approved work plans, drawings and specifications, sampling and analysis plans, appropriate QAPPs, SOPs, and other applicable procedures plus the requirements of this QMP.

## **9.2 STANDARD OPERATING PROCEDURES DOCUMENTATION**

Work will be implemented in a sequence consistent with the need for completion of prerequisite as well as final operations. SOPs will be developed and implemented for appropriate routine and standard work operations. Specialized and/or critical operations may use project-specific documents to perform work operations. SOPs will be written using a standard format. This ensures consistency of their content as well as helping to make sure that all applicable information is included in them.

SoBran, Inc. has a staff of dedicated technical writers and peer reviewers, who will develop SOPs that are easily understood by the user and contain sufficient detail and clarity so that they are easily followed. Using a standard SOP format, the project manager and the technical leaders develop an initial draft, which is typically written by technical staff most closely associated with a particular operation. Next, the appropriate technical leader will review the initial draft for detail and technical accuracy. The second draft will be submitted to the PQAO who will review the document for concurrence with project and corporate quality requirements. The third draft will be submitted to the project officer for comment and approval.

## **9.3 CHANGES TO PLANNING DOCUMENTS**

Changes to planning documents will be made according to a standard operating procedure that is agreed upon by the contract officer and SoBran, Inc.'s project manager. This SOP will be developed immediately after award of a contract so that consistency will be manifested throughout all task orders. Elements of the SOP will include verbal and written requests, documentation and approval processes, and communication of changes to all relevant personnel (i.e., the above managers plus on-site and off-site technical staff as applicable). Each planning document and operating guide will have a document control number (e.g., Document 34-A). Documents that have undergone approved changes will have their document control numbers modified to reflect a revision number (i.e., Document 34-A Rev. 1).

## **10.0 QUALITY ASSESSMENT AND RESPONSE**

SoBran, Inc. management will regularly assess the adequacy of the framework and infrastructure of the quality system and ensure its effective implementation. While specific quality assessment activities may be delegated to others, SoBran, Inc. management will not delegate overall

responsibility for assuring that an effective quality system has been established, implemented, and followed. All assessment activities will be performed in accordance with the requirements of this QMP. Additional project-specific requirements for assessments are discussed in the individual QAPPs. Program Assessments are specified in Quality Implementing Procedure 1.1 (QIP-1.1). Quality Surveillance and Trend Analysis requirements are specified in Quality Implementing Procedures 1.4 (QIP- 1.4) and 1.8 (QIP- 1.8), respectively.

## 10.1 PLANNING PROJECT ASSESSMENTS

SoBran, Inc.'s QA staff, under the Director of Quality Assurance, has prime responsibility to ensure independent assessment of implementation of corporate and project requirements. Management assessments require direct participation of all affected levels of management. Both organizational level and technical level managers will perform self-assessments of their respective organizations to determine the quality of products and technical work and the adequate implementation of corporate procedures. SoBran, Inc. management is responsible for implementing effective corrective action to remedy problems discovered by management assessments.

SoBran, Inc. management, including the Director of Quality Assurance, the project manager, and technical leaders, will determine the response actions necessary as a result of independent assessments and self-assessments and will implement appropriate corrective actions. Following completion of corrective action measures, SoBran, Inc. management will perform follow-up assessments to determine the effectiveness of implemented corrective measures and to confirm that corrective actions prevent a recurrence of the problem. QA personnel will provide reports to SoBran, Inc. management on the status of all corrective action(s) and follow-up results. Assessment tools consist of audits, management systems reviews, peer reviews, readiness reviews, and technical reviews. There are three major kinds of audits that may be used, depending on the nature of the problem:

### 10.1.1 MANAGEMENT SYSTEMS AUDITS

Senior managers (e.g., CQAD, Project Manager, and COO) annually assess the adequacy of a contract-wide quality assessment framework. These scheduled management assessments determine how well the integrated quality system is working, identify and correct management barriers to achieving QMP and QAPP objectives, address the effectiveness of management controls, consider accomplishments and significant QA problems, and identify opportunities for improvement.

Assessment performed according to written standard procedures are tailored to account for the specific project task being evaluated. The procedures specify required documentation; transmittal, review, and approval routing; technical requirements and procedural compliance issues; and administrative standards.

SoBran will use the following two types of Management Assessments for evaluating its QA activities.

- **QA Reviews**—the project-by-project review to identify and document compliance with the QMP. The PQAO conducts these audits on a semi-annual basis.



- **Management Assessment**—the qualitative assessment of a particular program operation and/or organization by those immediately responsible for overseeing and/or performing the work. The Project Manager conducts the management self-assessment annually with the assistance of the CQAD.

In addition to the two assessments described above, SoBran has an annual performance appraisal program for employees. This program consists of a supervisory appraisal, including compliance with corporate and contract QA responsibilities. Training requirements are identified as part of this process.

This management assessment framework allows SoBran to conduct in-depth performance examinations of existing quality management systems, proactively determine needs for correction to avoid out-of-control events, and identify opportunities to promote system effectiveness.

#### 10.1.2 TECHNICAL ASSESSMENTS

Technical assessments are conducted on a project level. After defining the status, risk, and complexity of the technical activities associated with the project task, the PQAQ, working with the Project Manager, schedules program/project assessments, selects personnel, and defines the assessment's scope and each responsible individual's authority. The type of assessment activity and tools for projects are determined during development of the project's work plan, using the evaluation process described previously in Section 10.1.

Furthermore, the PQAQ selects technically qualified, unbiased individuals and defines their responsibilities for independently reviewing project reports containing data and for reporting results. The individuals use standard assessment procedures to confirm that these data or results are presented correctly.

SoBran will use the following types of Technical Assessments, including technical systems audits, performance evaluation audits, and data quality assessments to evaluate its QC activities. The purpose, procedural details, and implementation frequency for each of these assessment methodologies are outlined below.

- **Technical Systems Audits:** The evaluation process for work performed will be done by qualified personnel knowledgeable with the technical aspect of the project and having experience in total quality management, quality protocols and processes. Audits are performed following a change in personnel, unacceptable or continued quality problems.
- **Data Quality Assessments**—The process for performing retrospective examinations of completed data. Data quality assessments are performed once data have been collected and validated in accordance with the QAPP and are used to determine whether the DQOs have been satisfied. DQA is built on the premise that data quality is meaningful only when it relates to the intended use of the data.

Upon completion and approval of each assessment, the PQAO will determine further action required and will initiate and track follow-up corrective or other actions, as required. Periodic reports of such actions will be provided to the Project Manager and to those individuals involved in the follow-up to ensure visibility and timeliness.

#### 10.1.3 REPORTS TO MANAGEMENT

All audits are performed under the direct supervision of the CQAD. All formal audit reports are developed, discussed with field and laboratory staff, and submitted to the Project Manager. All quality assessment activity reports will be forwarded to the COO, who will review them as necessary. Specific responsibilities for reporting and implementing corrective action are presented in Section 10.2, which follows.

These audits evaluate the quality management system. They provide evaluation and documentation of “top down” management guidance and demonstrate an emphasis on work being performed well the first time. A true quality system must be driven from top management. Management system audits document the thoroughness and commitment of management in supporting a quality system.

#### 10.1.4 ASSESSMENT DOCUMENTATION, REPORTING, AND REVIEW

Reports of all assessments will be required to be signed and approved by SoBran, Inc.’s Director of Quality Assurance. Prior to this step, the assessment results will be provided to the project manager and appropriate technical lead for review and comment. Their comments will be required to be in writing and will become a part of the official review document in a section of the assessment report delegated for these comments.

Deficiency reports and corrective action reports are specified in Quality Implementing Procedures 1.5 (QIP- 1.5) and 1.6 (QIP- 1.6).

All audits are performed under the direct supervision of the CQAD. All formal audit reports are developed, discussed with field and laboratory staff, and submitted to the Project Manager. All quality assessment activity reports will be forwarded to the COO, who will review them as necessary. Specific responsibilities for reporting and implementing corrective action are presented in Section 10.5, which follows.

These audits evaluate the quality management system. They provide evaluation and documentation of “top down” management guidance and demonstrate an emphasis on work being performed well the first time. A true quality system must be driven from top management. Management system audits document the thoroughness and commitment of management in supporting a quality system.

The summary section of each assessment report will contain a subsection labeled “Assessment Impact,” in which the assessor will describe potential impacts of a negative assessment result on planned operations. In addition to this discussion, the negative assessment must be classified into one of the three following categories:

- Minor Impact—Continue work with only minor corrections as listed;

- Major Impact—Continue work only after major corrections as listed are made;
- Severe Impact—Stop work and make major revisions to project plans and the QAPP.

## **10.2 RESPONSIBILITIES FOR QUALITY ASSESSMENT EXECUTION**

The general responsibilities and authorities for implementing the quality assessment process are outlined in Table 10.1.

**Table 10.1 Quality Assessment Responsibilities and Authorities Summary**

<b>Management/Staff Title</b>	<b>Responsibilities</b>	<b>Authorities</b>
Chief Operating Officer	<ul style="list-style-type: none"> <li>Ensures all products and services achieve the appropriate level of quality</li> <li>Accountable to the Contracting Officer</li> </ul>	<ul style="list-style-type: none"> <li>Commits resources to support the corporate quality system</li> </ul>
Project Manager	<ul style="list-style-type: none"> <li>Conducts QA management audits</li> <li>Develops protocols for managing QA audits</li> <li>Reviews and approves QA/QC documentation</li> </ul>	<ul style="list-style-type: none"> <li>Stop work authority in response to corrective action notification from CQAD or independent assessments</li> </ul>
CQAD	<ul style="list-style-type: none"> <li>Conducts QA management audits</li> <li>Develops protocols for managing QA audits</li> <li>Reviews and approves QA/QC documentation</li> </ul>	<ul style="list-style-type: none"> <li>Stop work authority in response to corrective action notification from PQA Manager or independent assessments</li> <li></li> </ul>
PQA	<ul style="list-style-type: none"> <li>Conducts QA audits</li> <li>Identifies situations that require corrective actions</li> <li>Develops recommendations and issue directives to the Project Managers for actions to correct work or data that do not conform to QAPP standards</li> <li>Reviews QA nonconformance reports of audits, data quality and data usability statements, DQOs, and corrective action reports</li> </ul>	<ul style="list-style-type: none"> <li>Stop work authority in response to corrective action notice from Project Manager,</li> <li>Stop work authority based on independent assessment</li> </ul>
Technical Staff	<ul style="list-style-type: none"> <li>Monitors work quality against project objectives</li> <li>Implements corrective actions</li> <li>Identifies and documents the need for corrective action</li> <li>Ensures QA practices are followed</li> </ul>	<ul style="list-style-type: none"> <li>Reports to the Project Manager the need for corrective actions</li> <li>Completes record of QA activities for auditing purposes</li> </ul>

### **10.3 ASSESSMENT PERSONNEL QUALIFICATIONS**

Assessors shall be qualified and capable of assessing technical requirements specified in planning documents. This requirement means that, in addition to being qualified to perform each type of assessment described above, assessors must also be sufficiently qualified in the technical area being assessed to understand the operations being performed, why they are being performed, and what QA/QC types of problems may be associated with the performance of these operations.

The Corporate QA Director has the responsibility for reviewing and approving the qualifications of each assessor for each assignment. If it is determined that an assessor is not completely qualified to perform a work assignment, then the director has the option of (1) assigning a different and more qualified person; (2) with the permission of the project officer, contract officer, and SoBran, Inc. project manager, hiring an outside professionally certified assessor; or (3) with the permission of the project officer and SoBran, Inc. project manager, delaying the assessment until the assessor takes additional training to become qualified to perform the assessment. Qualification of assessment personnel is specified in Quality Implementing Procedure 1.3 (QIP- 1.3).

### **10.4 ASSESSOR RESPONSIBILITY AND AUTHORITY TO STOP WORK**

The assessor has the responsibility and authority to issue a stop work order; however, before implementation of work stoppage, the stop work order must also be approved by the Corporate QA Director. The combined authority of the assessor and Corporate QA Director to issue a stop work order is absolute and independent of the COO of SoBran, Inc., the project officer, the SoBran, Inc. and project manager. Any disagreement between the assessor and the Corporate QA Director on a stop work order will be resolved by mediation involving the contract officer, the project officer, and the COO of SoBran, Inc. A majority vote would rule in the event that these three people could not come to a unanimous decision.

### **10.5 ASSESSMENT RESPONSES AND FOLLOW-UP ACTION**

As described in Sections 10.5 all assessments will document necessary changes in one of three impact categories. A corrective action form will be required as part of every negative assessment. The corrective action form will list each negative assessment result that must be corrected along with a recommended approach for implementing corrective actions. The technical leader will have 10 working days to respond to the recommended corrective actions and, as part of the response; a projected timetable must be included with the intended corrective actions. The project manager and SoBran, Inc.'s Corporate QA Director must approve the proposed procedures and timetable for accomplishing them. Copies of the approved corrective action report will be filed with the assessor, the CQAD, and the project officer. It is the technical leader's responsibility to ensure that the recommended corrective actions are carried out to the satisfaction of the project officer and the CQAD. Failure to do so will result in meetings to resolve technical, budget, or time issues that have impeded the corrective action, and modifications to the corrective action form will be required. This iteration will continue until all corrective actions have been concluded to the mutual satisfaction of the project officer and the CQAD.

For any project, a crucial requirement is the collection of sufficient data necessary to make defensible project-specific decisions and provide answers to investigation-related questions. At the conclusion of the data collection effort, the project team must be confident that the data are usable (i.e., adequate) for their intended purpose and capable of making decisions, which are dependent on the collected data as informational input. Stated differently, the data must be sufficient to drive project decisions with a level of confidence acceptable to those affected by the decisions being made (i.e., customers). This overall issue of adequate data, known as data usability, is directly related to the type, quantity, and quality of data collected.

There are three basic steps or components that make up the overall quality system that form the life cycle of project data. When any one of the three critical components of the life cycle of data is jeopardized, the quality system may break down resulting in project failure or at least data of uncertain and sometimes unacceptable quality. Quality system refers to the QA components responsible for producing data of known and acceptable quality.

Implementation of the up-front planning step (i.e., DQO Process) is of particular importance in the collection of usable data. This crucial step is necessary to relate the intended use of the data (usability) to the specific QA/QC requirements of the data collection process, thereby ensuring that data collection, analysis, and assessment are conducted appropriately. Without implementation of this planning phase component, which is integral in the production of usable data, a high risk of making a decision error (i.e., arriving at the wrong project conclusion) exists. SoBran, Inc. implements DQO Process as an integral part of all relevant projects that are designed to produce analytical data. By doing so, we can guarantee that data will be produced that will meet whatever confidence levels are specified by the customer. This up-front planning saves time and money by ensuring that the data produced will not only be acceptable, but also of adequate quality—not too much so that time and money are wasted, and not too little so that the usefulness of the data is jeopardized.

SoBran, Inc. has extensive experience in all areas related to the production of high-quality, legally defensible data. Specifically, SoBran, Inc. routinely prepares/reviews documents and performs/oversees work related to all three major areas that make up the life cycle of data: data planning, data collection, and data assessment. SoBran, Inc.'s technical experts have accomplished developed guidance—based on the DQO Process—for the collection of data for numerous projects. Provided third-party oversight to ensure that data collection is based on sound science with a clear understanding of project objectives.

## **11.0 QUALITY IMPROVEMENT**

The quality improvement process employed by SoBran, Inc. is an internal activity not applied to any specific project. The intent is to improve operations and work processes, thus providing better value to our work output. It is an on-going process that is embraced by every employee from the President and CEO down through the technical staff at every level of the company.

### **11.1 QUALITY IMPROVEMENT PROCESS**

SoBran Inc.'s management and staff conduct quality improvement activities to enhance work processes and detect and correct problems that adversely affect quality during planning, implementation, and assessment of technical and management activities. The improvement system used is based on this QMP and is aimed at improving all operations. The prime focus of our quality improvement system is to exceed internal and external client requirements and

expectations. SoBran, Inc. management and staff are all required to develop and implement solutions to correct quality-affecting problems, thus supporting and augmenting the overall improvement process. The CQAD is responsible for providing periodic quality assurance reports to management. They are distributed to the President and CEO, COO, and senior managers of the company. The senior managers, in turn, distribute them to the staff they manage so that they can be discussed and the recommendations can be understood in the context of which they were made and implemented by all employees. QA issues that involve specific customers or suppliers are also brought to their attention by the relevant SoBran, Inc. manager so that discussion, resolution, and continued improvement of a negative or inadequate product or service can be corrected.

### **11.2 PREVENTING, DETECTING, AND CORRECTING QUALITY SYSTEM PROBLEMS**

Follow-up actions based on corrective action forms from negative assessments (as described in Section 10 above) provide immediate procedures for preventing continued quality system problems. In addition, the emphasis on involving all of SoBran, Inc.'s employees to improve operations and work processes reinforces the importance and commitment of everyone to prevent quality system problems where possible, detect them as early as possible, and correct them when ever they are found.

### **11.3 RESPONSE ACTIONS**

Response actions for negative quality system problems have been documented in Section 10. Response actions for positive quality system results include incentive awards to employees, which are provided on a quarterly basis and published in our company newsletter. These response actions, in conjunction with the principals and operating procedures documented in this QMP, provide a sound basis for continuing to serve our other customers in a positive and productive manner. Our goal is always to get the job done right the first time, on time, and within budget. Thorough planning and experienced staffs that are committed to continuing quality improvement is the most effective way that we can guarantee we reach our goal.