QUALITY MANUAL

Santa Barbara Applied Research. Inc.
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Revision C	10 March 2009
Revision B	2 April 2007
Revision A	7 May 2005
Revision N/C	27 January 2004

QAP 2000

FOREWORD

This Quality Manual describes the quality system employed by Santa Barbara Applied Research (SBAR), Inc. Compliance with all procedures contained herein is mandatory, unless specifically exempted by the Quality Steering Committee and/or the President/CEO.

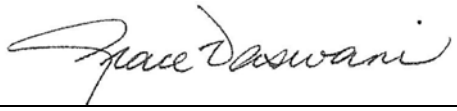
Prepared By:	Approved By:
	
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Table of Contents

LIST OF ILLUSTRATIONS

Figures **Page**

LIST OF TABLES

Table **Page**

1.0 Quality Policy Statement

"Santa Barbara Applied Research, Inc., is absolutely committed to the delivery of products and services that are consistent with the highest quality standards established by our customers, industry, statutory, and internal requirements. We will strive to exceed the highest expectations of our customers, and to continuously improve the quality of our products (including those purchased),based upon customer feedback and self-analysis of our processes and procedures."

SBAR and its team members/subcontractors continually strive for recognition as premier providers of products and services in the government services industries. To do this, we must continually satisfy our customers in the present and inspire confidence for the future. To further these ideals and to satisfy our customers, all company employees, as well as those of our team members/subcontractors, adhere to the spirit and the letter of our quality policy. Accordingly, all comply with the directives of this *Quality Manual* and its subordinate documents.

2.0 Revisions/Amendments to Quality Manual

The *Quality Manual* is intended to be a dynamic document to be revised/amended as required to reflect future changes in the business climate. Sources of Manual revisions include, but are not limited to: Quality Steering Committee (QSC) suggestions; audit results/findings; customer suggestions; changes to or new industry standards or requirements; employee suggestions.

The SBAR Quality Systems (QS) Manager revises the Manual as necessary and submits the revision to the President/CEO for approval. Revisions to the Manual are lettered sequentially. The QS Manager maintains the Manual and ensures that its distribution is controlled in accordance with the controlled circulation list. Further, the Quality Steering Committee (QSC) ensures compliance with Manual revisions.

3.0 Document Control Procedures

The *Quality Manual* contains SBAR proprietary material and its distribution is in strict accordance with the controlled distribution list. No extra copies are authorized without the prior approval of the Corporate Quality Systems Manager. If extra copies are authorized, a revision to the manual and a change to the controlled distribution list are required.

4.0 Scope/Overview/Objectives

The ISO 9000 Series standards provide a globally accepted model for companies to use when implementing a comprehensive quality system that meets or exceeds their customer needs and expectations. ISO standards are intended to be generic and define the required elements of an effective quality management system. Therefore, SBAR, Inc., has adopted ISO 9000 standards for its specific products and services. This manual describes SBAR's Quality Management System that fully implements the 2000 version of ISO 9001.

The SBAR O*rganization Manual* contains the organization charts for the various offices and functions within SBAR. Further, the *Manual* holds the organizational charters, i.e., "position descriptions," for the key managers and supervisors throughout the Corporation. Organizational charters, when applicable, list the duties and authority for implementing the quality program.

SBAR's quality objectives include:

- Using advanced analytical technologies to solve basic engineering problems.
- Providing quality management and an experienced workforce to all of our customers.
- Designing for simplicity, practicality, safety, and economy.
- Offering a favorable work environment where all of our employees are encouraged to expand their horizons and grow with the company.

5.0 References

International Organization for Standardization Documents:

- *ISO 9001: Quality Management Systems-Requirements,* (Fourth Edition 2008-11-15).
- *ISO 9000: Quality Management Systems-Fundamentals and Vocabulary, Second Edition.*
- *ISO 9004: Quality Management Systems-Guidelines for Performance Improvement, Second Edition.*
- Pande, Peter S. et al, (2000), *The Six Sigma Way,* McGraw-Hill.

US Navy Publications/Documentation

- NAVSEA 009-04, Quality System
- NAVSEA 9090-310D, NAVSEA Technical Specification: Ship Alteration
- San Diego Shipbuilding and Repair Community Single Quality Management System

6.0 Definitions

6.1 Terms Relating to Quality

Customer Satisfaction: Client's perception of the degree to which the client's requirements have been fulfilled.

Quality: Degree to which a set of inherent (i.e., permanent) characteristics fulfills requirements.

Requirement: Need or expectation that is stated, generally implied, or obligatory.

6.2 Terms Relating to Management

Continual Improvement: Recurring activity to increase the ability to fulfil requirements.

Contract Review: Systematic activities carried out by the supplier (i.e., SBAR) before signing the contract to ensure that customer needs are met and that quality requirements are adequately defined, free from ambiguity, documented, and realizable by the supplier (i.e., SBAR).

Quality Assurance: Planned and systematic activities implemented as part of quality management to provide confidence that quality requirements are fulfilled.

Quality Control: Operational techniques and activities (e.g., instrument calibration) that are used to ensure that the product or service will fulfill requirements.

Quality Improvement: Activities focused on increasing the ability to fulfill quality requirements.

Quality Management System (QMS): SBAR's coordinated activities to direct and control the SBAR quality program. Direction and control includes the establishment of the quality policy and quality objectives, quality planning, quality control, quality assurance, and quality improvement. Quality management is the responsibility of all levels of management in all functions within SBAR. Its implementation involves all SBAR employees.

Quality Objective: Something sought or aimed for and is generally based upon SBAR's Quality Policy Statement. Quality objectives are normally identified for specific functions/organizations within SBAR.

Quality Policy: SBAR's overall intentions and direction related to quality as formally expressed by Top Management. The Quality Policy Statement is in writing; it is signed by the President/CEO; and is distributed and enforced throughout SBAR.

Top Management: Persons or group of people who direct and control SBAR at the highest level, i.e., the President/CEO, Vice-Presidents, Program and Contract Managers.

"Voice of the Customer": A strategy and system developed by Pande, Nueman, and Cavanaugh (Pande, Peter S. et al, (2000), *The Six Sigma Way,* McGraw-Hill) that continually tracks and updates customer requirements, competitor activities, market changes, etc.

6.3 Terms Relating to Organization

Customer: Recipient of a product provided by the supplier. A customer may be a commercial firm, an individual, or a government agency. SBAR is the supplier.

Functional Area Manager (FAM): A supervisory individual who is responsible for the leadership, direction, and overall success of an area of the company, such as finance, human resources, contract administration, engineering, operations and maintenance, logistics, quality, specific projects/contracts, etc.

Quality Assurance Officer/Office (QAO): An individual or section assigned to manage the quality program for a specific SBAR contract, workplace, etc.

Supplier: The organization, i.e., SBAR that provides a product to the customer. In contractual terms, the supplier may be called the "contractor."

6.4 Terms Relating to Process and Product

Positive Recall Procedure: Methods to identify and return nonconforming products or services that were released to the field without the successful completion of the specified inspection and testing activity(s) taking place. Positive recall activities are documented, i.e., who, what, when, where, and why.

Procedure: Specified way to carry out an activity or a process. (NOTE: In this connotation, the term "procedure" is different from a "SBAR Procedure.")

Process: A set of interrelated or interacting activities that transform inputs into outputs.

Product: Result of activities or processes. A product may include services, software, hardware, processed materials, or a combination thereof. A product can be tangible (e.g., assemblies or processed materials) or intangible (e.g., knowledge or concepts), or a combination thereof.

Product Realization: The achievement of and delivery of products and services that meet or exceed regulatory and statutory requirements as well as customer expectations.

Service: Service is the result of at least one activity performed at the interface between SBAR and a customer. Service includes actions taken by SBAR after delivery of the product, in accordance with the contract statement of work (SOW).

6.5 Terms Relating to Characteristics

Characteristic: A distinguishing feature that can be inherent or assigned. Additionally, a characteristic can be qualitative or quantitative.

Traceability: The ability to determine the history, application, and/or location (past or present) of a product or service.

6.6 Terms Relating to Conformity

Concession: Permission to use or release a product that does not conform to specified requirements. The Customer normally grants concessions.

Conformity/Nonconformity: Conformity is the fulfillment of a requirement; nonconformity is the non-fulfillment of a requirement.

Corrective Action: Steps taken to eliminate the cause of a detected nonconformity or other undesirable situation.

Defect: Non-fulfillment of a requirement related to an intended or specified use.

Preventive Action: Steps taken to eliminate the cause of a potential nonconformity or other undesirable potential situation.

6.7 Terms Relating to Documentation

Checklist: A document controlled by a procedure, work instruction, or Master Documentation/Record List that contains the "who, what, when, where, and how" a specific process is accomplished. Checklists may either be generated by SBAR or an external source.

Documentation/Data: Any form of media (e.g., paper copy or electric media) that is historic in nature and used, in part, to verify specific aspects of the quality system. Documentation/data includes, but is not limited to, SBAR Procedures, WIs, audit/inspection reports, x-rays, Quality Steering Committee meeting minutes.

ISO Element: In ISO 9001: 2008, one of five defined individual standards that include:

- Quality Management System.
- Management Responsibilities.
- Resource Management.
- Product Realization.
- Measurement, Analysis, and Improvement

In the SBAR Quality Management System, these five elements, or clauses, are combined with the 20 elements defined in previous versions of ISO 9001 to form the basis of the SBAR *Quality Manual*.

Master Documentation/Record List (MDRL): A listing of all documentation, data, procedures, and records that affect quality.

SBAR Procedure: Corporate level, written direction that defines the specific strategy that SBAR employs in performing a task, e.g., quality, and human

resources, financial. Procedures give general guidance, and, where applicable, apply throughout all levels of the corporation.

Quality Manual: Document stating the quality policy and specifying the quality management system of an organization (i.e., SBAR).

Quality Plan: Document specifying which procedures and associated resources are to be applied by whom and when to a specific project, process, or contract. These are normally in the form of a procedure, work instruction, and/or checklist.

Record: Documentation stating results achieved or providing evidence of activities performed.

Work Instruction (WI): Written details that, when appropriate, state what shall be done and by whom; when, where and how it shall be done; what materials, equipment and documents shall be used; and how it shall be controlled and recorded. WIs will normally be used to implement corporate procedures and/or specific contractual requirements.

6.8 Terms Relating to Examination

Inspection: The evaluation by observation and judgement that conformity to specified requirements exists. Inspection is often accompanied, as appropriate, by measurement, testing, and/or gauging.

Objective Evidence: Data supporting the existence or reality of something.

Test: The determination of one or more characteristics according to a procedure.

Validation: Confirmation by examination and provision of objective evidence that the particular requirement for a specific intended use is fulfilled. In design and development, design validation occurs after the design has been verified and seeks to determine if the final product or service meets the Customers' needs and often involves some form of testing.

Verification: Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled. In design and development, verification occurs prior to design incorporation into the product or service being delivered to the Customer. It often involves independent calculations.

6.9 Terms Relating to Audit

Audit: Systematic, independent and documented process for obtaining "audit evidence" and evaluating it objectively to determine the extent to which "audit criteria" are fulfilled.

Audit Conclusion: Outcome of an audit after consideration of the audit objectives and all audit findings.

Audit Criteria: Set of policies, procedures, or requirements used as reference for an audit.

Audit Evidence: Records, statements of fact, and/or other information that is relevant to the audit criteria and verifiable.

Audit Findings: Results of the evaluation of the collected audit evidence against the audit criteria. Audit findings can indicate either conformity or nonconformity.

6.10 Terms Relating to Quality Assurance for Measurement Processes

Inspection, Measuring, and Test Equipment (IMTE): Instrumentation, software, auxiliary apparatus, etc. used to validate a specific quantity, normally within a specified range. IMTE can normally be calibrated or verified accurate.

7.0 Documentation and Records

7.1 Documentation

The approved procedures for accomplishing documentation control are contained in SBAR *Document and Data Control Procedure* (CP-00-9005) and apply to all quality-related documentation throughout SBAR. As illustrated in Figure 1, the documentation process begins with the SBAR Quality Policy Statement. The Policy Statement is defined in the SBAR *Quality Manual* and the ISO 9001: 2000 requirements (i.e., ISO Elements) are explained in corporate procedures. Using these basic documents, each program/contract team develops work instructions that define the activities and controls that are needed to meet the quality requirements for their area of responsibility. Work instructions (checklists) contain activities and controls that are unique (i.e., those activities that cannot or should not be included in a corporate procedure) to the area in which they apply. Quality records are maintained throughout SBAR to demonstrate operational conformance to the Quality Management System requirements in accordance with SBAR *Control of Quality Records Procedure*.

7.2 Records

Documentation is maintained in accordance with SBAR *Control of Quality Records Procedure (CP-00-9016)* and applies to all quality-related records throughout SBAR. See Figure1, Structure of Quality Management System Documentation.

Figure 1- Structure of Quality Management System Documentation

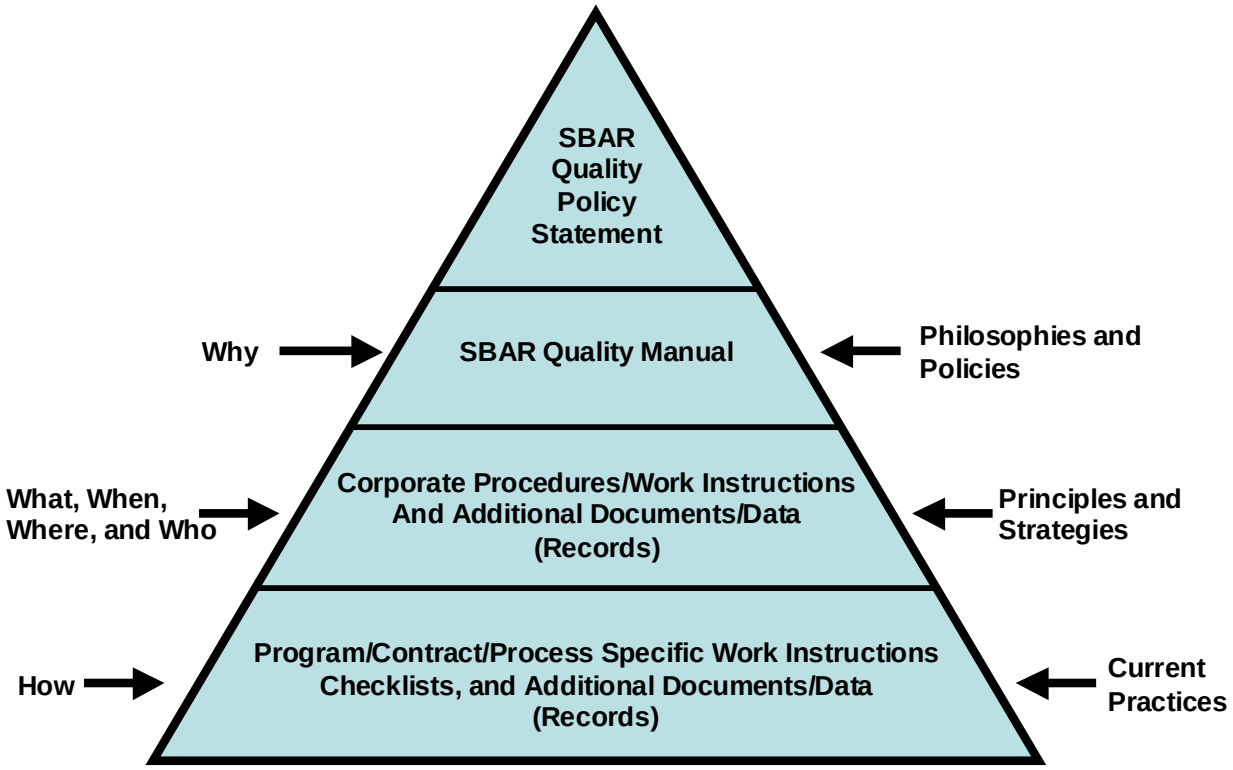

Table 1 - Correspondence between ISO 9001:2008 and SBAR Quality Management System

NOTE: The SBAR *Quality Manual* and SBAR Procedure column depicts where the ISO 9001: 2000 requirements are located.

ISO 9001:2008 (Para. Number)	SBAR *Quality Manual* (Para. number)	SBAR Procedure
1 Scope	N/A	N/A

ISO 9001:2008 (Para. Number)	SBAR *Quality Manual* (Para. number)	SBAR Procedure
1.1 General	4.0	
1.2 Application	N/A	
2 Normative Reference	5.0	
3 Terms and Definitions	6.0	All
4 Quality Management System (title only)	N/A	
4.1 General Requirements	8.1.4	
4.2 Documentation Requirements (title only)	N/A	N/A
4.2.1 General	8.1.4.1	
4.2.2 Quality Manual	All	
4.2.3 Control of Documents	8.1.4.2	*Document and Data Control*
4.2.4 Control of Records	8.1.4.3	*Control of Quality Records*
5 Management Responsibility (title only)	N/A	N/A
5.1 Management Commitment	8.1.3	
5.2 Customer Focus	8.2.4.1	Various
5.3 Quality Policy	1.0 & 8.2.4.1	N/A
5.4 Planning (title only)	N/A	
5.4.1 Quality Objectives	8.2.4.1	Various
5.4.2 Quality Management System Planning	8.2.4.1	
5.5 Responsibility, Authority, and Communication (title only)	N/A	N/A
5.5.1 Responsibility and Authority	Table B	All
5.5.2 Management Representative	8.2.3 & Table B	
5.5.3 Internal Communication	8.2.4.1/Table B	N/A
5.6 Management Review (title only)	N/A	
5.6.1 General	8.2.4.2 & 3	

ISO 9001:2008 (Para. Number)	SBAR *Quality Manual* (Para. number)	SBAR Procedure
5.6.2 Review Input	8.2.4.2	
5.6.3 Review Output	8.2.4.3	
6 Resource Management (title only)	N/A	
6.1 Provision of Resources	8.3.4.1	Various
6.2 Human Resources (title only)	N/A	N/A
6.2.1 General	8.3.4.2 & Table B	*Training*
6.2.2 Competence, Awareness, and Training	8.3.4.2	
6.3 Infrastructure	8.3.4.3	*Process Control*
6.4 Work Environment	8.3.4.4	
7 Product Realization (title only)	N/A	N/A
7.1 Planning of Product Realization	8.4.4.1	Various & *Inspection and Test Status*
7.2 Customer-Related Processes (title only)	N/A	N/A
7.2.1 Determination of Requirements Related to The Product	8.4.4.2	*Contract Review, Process Control*
7.2.2 Review of Requirements Related to The Product	8.4.4.2	*Contract Review*
7.2.3 Customer Communication	8.4.4.2	*Servicing*
7.3 Design and Development (title only)	N/A	N/A
7.3.1 Design and Development Planning	8.3.4.3	*Design Control & Process Control*
7.3.2 Design and Development Inputs	8.3.4.3	
7.3.3 Design and Development Outputs	8.3.4.3	
7.3.4 Design and Development Review	8.3.4.3	*Design Control & Process Control*
7.3.5 Design and Development Verification	8.3.4.3	
7.3.6 Design and Development Validation	8.3.4.3	
7.3.7 Control of Design and Development Changes	8.3.4.3	

ISO 9001:2008 (Para. Number)	SBAR *Quality Manual* (Para. number)	SBAR Procedure
7.4 Purchasing (title only)	N/A	N/A
7.4.1 Purchasing Process	8.3.4.4	*Purchasing*
7.4.2 Purchasing Information	8.3.4.4	
7.4.3 Verification of Purchased Product	8.3.4.4	*Purchasing & Inspection and Test Status*
7.5 Production and Service Provision (title only)	N/A	N/A
7.5.1 Control of Production and Service Provision	8.3.4.5	*Process Control*
7.5.2 Validation of Processes for Production and Service Provision	8.3.4.5	
7.5.3 Identification and Traceability	8.3.4.5	*Product ID and Traceability*
7.5.4 Customer Property	8.3.4.5	*Customer Property*
7.5.5 Preservation of Product	8.3.4.5	*HSPPD**
7.6 Control of Monitoring and Measuring Devices	8.3.4.6	*IMTE***
8 Measurement, Analysis, and Improvement (title only)	N/A	N/A
8.1 General	8.5.4	*Measurement and Analysis*
8.2 Monitoring and Measurement (title only)	N/A	N/A
8.2.1 Customer Satisfaction	8.4.4.1	*Servicing*
8.2.2 Internal Audit	8.4.4.1	*Internal Quality Audits*
8.2.3 Monitoring and Measurement of Processes	8.5.4.1	*Measurement and Analysis*
8.2.4 Monitoring and Measurement of Product	8.5.4.1	*Inspection and Testing*
8.3 Control of Nonconforming Product	8.5.4.2	*N/CAR*
8.4 Analysis of Data	8.5.4.3	*Measurement and Analysis*

ISO 9001:2008 (Para. Number)	SBAR *Quality Manual* (Para. number)	SBAR Procedure
8.5 Improvement (title only)	N/A	N/A
8.5.2 Corrective Action	8.5.4.4	*N/CAR*
8.5.3 Preventive Action	8.5.4.4	

**Handling, Storage, Packaging, Preservation, and Delivery Procedure*

***Control of Inspection, Measuring, and Test Equipment Procedure*

8.0 Quality System Requirements (ISO 9001: 2008)

Quality Management System (QMS): Includes general and documentation requirements to implement ISO 9001:2008. Documentation requirements include a quality manual, control of documents, and control of quality records.

Management Responsibility: Management responsibility includes:

- Top Management's commitment to quality.
- Customer focus.
- The establishment of a quality policy.
- Quality planning.
- Responsibility, authority, and communication requirements to support the QMS.
- Management review.

Resource Management: This element includes general direction on providing resources, specific directions on human resources, infrastructure, and the work environment.

Product Realization: Product Realization requires planning, emphasis on customer-related processes, design and development, purchasing, production and service provisions, and control of IMTE.

Measurement, Analysis, and Improvement: This element lists general provisions as well as specific requirements for monitoring and measurement, control of nonconforming product and services, data analysis, and improvement.

8.1 Quality Management System (ISO 9001, 4.0)

8.1.1 Policy

SBAR ensures that quality is built into the products and services provided by the company in accordance with ISO 9001, customer requirements, and regulatory/statutory provisions. Problem prevention is emphasized over problem correction. Activities are

documented and controlled throughout the life cycle of the specific product or service to be provided.

8.1.2 Purpose

This section describes responsibility, authority, and management of the Quality Management System (QMS).

8.1.3 Responsibility

The SBAR President/CEO, Vice President, General Managers and program/contract managers, i.e., Top Management, are responsible for and oversee the successful continuation of the company's QMS. To assist in this task, SBAR has a Quality Steering Committee (QSC) that meets annually and more often as necessary to assess the health of the QMS. Additionally, the Quality Systems Manager is responsible for the *Quality Manual* and the other SBAR procedures and statuary requirements associated with the QMS.

8.1.4 Requirements.

The major elements of the SBAR Quality Management System (QMS) are:

- Identify the processes needed for the QMS and their application throughout SBAR.
- The determination of the sequences and interaction of the critical processes required to implement the QMS.
- Establish criteria, methods and performance measurements to ensure that operation and control of critical processes are efficient and effective.
- Ensure the necessary resources including information are available to support the operation and monitoring of processes.
- Monitor, measure, and analyze processes.
- Take proactive action to achieve planned results and continual improvement of processes.
- When all or a part of a process that affects quality/conformity to product requirements is outsourced (i.e., subcontracted), SBAR documents and

institutes the proper controls through the subcontract to ensure that the requirements are met by the subcontractor.

8.1.4.1 Documentation Requirements

Documentation of the SBAR QMS includes:

- A quality policy statement and documented quality objectives.
- The SBAR *Quality Manual* that:
  - Includes the scope of the SBAR QMS as well as the details of and justification for any exclusion (e.g., ISO 9001 element, customer requirement, regulatory or statutory requirement).
  - Includes a description of the interaction between the various processes of the QMS.

Written procedures required by ISO 9001include:

- Procedures, work instructions, checklists, and external directives necessary to ensure the effective planning, operation, and control of SBAR processes. Note: A single procedures may address more than one ISO requirement.

8.1.4.2 Records documenting compliance with ISO 9001, customer requirements, and regulatory/statutory requirements. Document Control

SBAR *Document and Data Control Procedure (CP-00-9005)* establishes policies and procedures for the control of documents required by the QMS. The Procedure defines the controls needed:

- To approve documents for adequacy prior to issue.
- To review and update as necessary and revise documents.
- To ensure that the current revision status of documents are identified.
- To ensure that relevant versions of applicable documents are available when and where needed.

- To ensure that documents remain legible and readily identifiable.
- To ensure that documents of external origin are identified and their distribution controlled.
- To prevent the unintended use of obsolete documents and to apply suitable identification to them if they are retained for any purpose.

8.1.4.3 Control of Records

SBAR *Control of Quality Records Procedure (CP-00-9016)* establishes policies and procedures to ensure appropriate records are maintained to document the QMS. Records are/remain legible and are readily identifiable and retrievable. Additionally, they are stored and protected from deterioration. Further, the Procedure establishes requirements for retention times for records and, when appropriate, how records are disposed of when no longer needed.

8.1.5 SBAR Implementing Procedures

The following SBAR procedures implement the SBAR Quality Management System (ISO 9001, 4.0):

SBAR Quality Manual (0002).

SBAR *Documentation and Data Control Procedure (CP-00-9005).*

SBAR *Process Control Procedure (CP-00-9009).*

SBAR *Control of Quality Records (CP-00-9016).*

SBAR *Servicing Procedure (CP-00-9019).*

SBAR *Measurement and Analysis Procedure (CP-00-9020).*

8.1.6 Management Responsibility (ISO 9001, 5.0)

8.1.6.1 Commitment to the QMS

SBAR managers at all levels fully support SBAR's Quality Management System (QMS) to ensure customer, applicable regulatory and statutory requirements are achieved. The company's goal is to implement and maintain an effective system that that is responsive to the "Voice of the Customer" meets customer requirements, is

monitored, controlled and continuously improved to meet to evolving needs of the of the company The maintenance of an ISO 9001 QMS allows SBAR to continue to expand by successfully competing for national and international contracts.

8.1.7 Specific Responsibilities

This section defines the management responsibilities for SBAR's QMS.

8.1.7.1 President/CEO

The SBAR President/CEO appoints a corporate Quality Systems (QS) Manager who has the full management responsibility in accordance with ISO 9001, paragraph 5.5.2 to implement and manage SBAR's quality program. Additionally, the President/CEO establishes and chairs a Quality Steering Committee (QSC) comprised of the QS Manager, Vice President, the Human Resources Manager, the Contracts Manager, Program and Quality Assurance Officers for those offices being registered, and other invited individuals.

8.1.7.2 Top Management

The Quality Systems Manager is responsible for training personnel on the details of ISO 9001. Further, the responsibility, authority, and the interrelation of personnel who manage, perform, and verify work that affect quality is defined in each Functional Area's procedures/work instructions (See Table B, Summary of Quality Responsibilities).

Top Management responsibilities include:

- Communicating to SBAR personnel the importance of meeting customer as well as statuary and regulatory requirements.
- Establishing an appropriate quality policy (i.e., defining a quality policy, quality objectives including a framework to review/revise objectives, quality commitment, and continuous improvement). The quality policy must be periodically reviewed for continuing suitability, documented, and communicated to all employees and subcontractors who must understand, implement, and maintain the policy.
- Ensure customer requirements are identified and are achieved with the goal of enhancing customer satisfaction.

- Ensuring the availability of resources (e.g., personnel, equipment).
- Ensure that quality objectives, including those needed to meet requirements for specific products/services, are established at relevant functions and levels within SBAR. Further, quality objectives are measurable and consistent with the SBAR Quality Policy Statement.
- Require the planning of the QMS in accordance with ISO 9001, Element 4.1 and ensuring quality objectives are fulfilled.
- Taking steps to maintain the integrity of the QMS when changes to the System are planned and implemented.
- Define and communicate to all SBAR employees their responsibilities and authority. (**NOTE**: See SBAR *Organization Manual*.)
- Organizing personnel to enable advanced planning, a multidisciplinary approach to decision making, and the communication of information and data.
- Verifying the quality system via inspection, testing, monitoring, design review, and internal quality audits.
- Appointing a management representative (i.e., the Quality Systems Manager) who has authority to implement and maintain the quality system.
- Developing procedures/WIs as specifically required by this manual and/or to ensure that quality-related activities are properly controlled and documented.
- Effective, two-way communication with customers and employees.
- Further, regularly scheduled management reviews (i.e., QSC meetings) are conducted and address the following areas:
    - Audit results.
    - Customer feedback.
    - Process performance and product conformity.
    - Status of preventive and corrective actions.

- Follow-up actions from previous QSC meetings.
- Changes that could affect the QMS.
- Improvement recommendations.

- QSC meetings result in decisions and the assignment of Action Teams to:
  - Improve the effectiveness of the QMS and its processes.
  - Improve products/services relating to customer requirements.
  - Address resource needs.

8.1.7.3 SBAR Implementing Procedures:

The following SBAR procedures implement the Management Responsibility function (ISO 9001, 5.0):

SBAR Quality Manual (0002).

SBAR *Organization Manual.*

SBAR *Documentation and Data Control Procedure (CP-00-9005).*

SBAR *Process Control Procedure (CP-00-9009).*

SBAR Internal *Quality Audits (CP-00-9017).*

SBAR *Servicing Procedure (CP-00-9019).*

Table 2 - Summary of Quality Responsibilities

Who	Responsibility and Authority
President, Vice Presidents, and Corporate Managers	• Maintain the Quality Management System (QMS) • Develop and implement plans for improving the quality management system • Communicate and ensure the visibility and understanding of SBAR's quality policy throughout the company • Chair QSC meetings • Ensure customer requirements are identified and achieved to enhance customer satisfaction • Establish communication processes to ensure that there is feedback regarding the effectiveness of the QMS
Corporate Quality Systems (QS) Manager	• As a member of Corporate management, ensures that the QMS is established, implemented, and maintained in accordance with ISO standards throughout SBAR • Serve as Recorder for the QSC • Report QMS performance to Top Management/QSC and make recommendations for improvement • Ensure the promotion of customer requirements throughout SBAR
Functional Area Managers (division, branch, program/contract etc.) and supervisory personnel	• Obtain and communicate customer requirements to the appropriate management level • Ensure that qualified, skilled, and trained personnel, as well as other resources, are used to implement the QMS

Who	Responsibility and Authority
All Employees	• Ensure that products and services satisfy customer requirements, including quality, safety, cost, timeliness, performance, reliability, durability, accuracy, and maintainability • Comply with applicable standards, specifications, and documented procedures/work instructions • Demonstrate understanding of the quality process • Perform quality work • Comply with this manual • Stop work in-progress and notify the FAM when quality is in doubt or compromised

8.2 Resource Management (ISO 9001, 6.0)

8.2.1 Policy

In order to ensure the quality of our products and services, as well as the satisfaction of our customers, SBAR ensures the necessary resources (e.g., human, equipment, and materials) are available in a reasonable amount of time at an acceptable cost.

8.2.2 Purpose

This section defines the resource requirements for SBAR's Quality Management System.

8.2.3 Responsibility

All SBAR managers and supervisory personnel are expected to identify and, consistent within their level of authority, provide the necessary resources to ensure the quality of our products and services meet or exceed customer expectations. In cases involving the lack or perceived shortage of resources personnel report their concerns to the next level of management. If appropriate, a *Process Action Report (PAR)* is initiated.

8.2.4 Requirements.

The following resource requirements are detailed throughout this Manual and numerous SBAR Procedures and work instructions (WIs):

General resource provisions include:

- The implementation and maintenance of the SBAR QMS, as well as continuing to improve the effectiveness of the QMS.
- Enhancing customer satisfaction by meeting customer requirements.

Human resource requirements include:

- Personnel performing work affecting the quality of products and services have the appropriate education, training, skills, and experience.
- Provide necessary employee training.

- Ensure employees are aware of the relevance and importance of their activities and how they contribute to the achievement of quality objectives.

- SBAR evaluates the competency of its employees to fulfill the above requirements. (**NOTE**: Accomplished upon hiring and during annual performance appraisals.)

- Maintain appropriate records of education, training, skills, and experience. Infrastructure requirements include:

- Appropriate buildings, workspace, and associated utilities.

- Process equipment (hardware and software, as applicable).

- Supporting services (transportation, communication, safety, environmental, etc.)

Further, SBAR ensures the work environment (physical, social, psychological, ergonomics, atmospheric conditions, recognition schemes, etc.) is conducive to product/service quality.

8.2.5 SBAR Implementing Procedures

The following SBAR procedures implement the Resource Management function (ISO 9001, 6.0):

SBAR *Quality Manual (2000).*

SBAR *Employee Performance Appraisals and Training Assessments Procedure (CP-00-2000-002)*

SBAR *Process Control Procedure (CP-00-9009).*

Control of Nonconforming Product and Services/ Corrective and Preventive Action Procedure (CP-00-9013/14).

SBAR *Control of Quality Records Procedure (CP-00-9016).*

SBAR *Training Procedure (CP-00-9018).*

SBAR *Training Plan Preparation Procedure (CP-00-9018-01).*

8.3 Product Realization (ISO 9001, 7.0)

8.3.1 Policy

Effective, two-way communication with customers and employees is the key to product realization and is therefore stressed throughout SBAR. Product realization is closely associated with continual improvement.

8.3.2 Purpose

This section defines the key elements of SBAR's product realization program.

8.3.3 Responsibility

Managers and supervisory personnel at all levels within SBAR are charged with ensuring effective, two-way communication with both customers and employees to ensure the "Voice of the Customer" is heard and understood.

8.3.4 Requirements

Product realization includes planning requirements, customer emphasis, design and development, purchasing requirements, production and servicing provisions, and affecting conformity of product requirements and services.

8.3.4.1 Planning of Product Realization

Planning requirements for specific product/service realization include:

- The quality objectives and requirements.
- The need to develop and publish procedures and work instructions establishing processes and resources.
- Verification, validation, monitoring, inspection, and test activities.
- Product/service acceptance criteria.
- Quality records of the above activities.

8.3.4.2 Customer-related Processes

The determination of requirements related to products and services include:

- Customer requirements including delivery and post-delivery.
- Requirements not stated by the customer but necessary for the specified or intended use of the product or service.
- Statutory and regulatory requirements related to the product/service.
- All additional SBAR requirements, i.e., the Voice of the Customer.

Prior to SBAR committing to supplying a product or service (e.g., submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders), SBAR completes and records the following:

- Ensures scope of work requirements is clearly defined.
- Resolve any issues associated with conflicting prior contracts or order requirements.
- Ensures SBAR has the ability to meeting the customers' defined requirements.
- In cases were the customer provides no documented requirements statement, SBAR first confirms with the customer as to exactly what are the requirements.
- When product/service requirements are changed (e.g., contract modifications/amendments), SBAR ensures relevant documents are amended and that affected personnel are made aware of the new requirements.
- Customer communication, i.e., the Voice of the Customer, requirements include:
- Accurate knowledge of what products and services the customer needs and expects.
- Customer feedback, surveys, enquiries, complaints, etc.

8.3.4.3 Design and Development

SBAR's design and development planning includes:

- The determination of the design and development stages.

- Review, verification, and validation activities that are appropriate to each design and development stage. Note: These activities may be performed separately or in combination.

- Identification of responsibilities and authorities for design and development.

- Management of the various interfaces between different groups (customer and design group input requirements,.) involved in design and development, thereby ensuring effective, two-way communication and clear assignment of responsibility.

- Process to update planning output as the design and development progresses.

Records are maintained documenting design and development inputs. These inputs are reviewed for adequacy and completeness. Further, to the maximum extent possible, they are conflict free, unambiguous, and include:

- Functional and performance requirements.

- Applicable statutory and regulatory requirements.

- When applicable, information derived from previous similar designs.

- Other requirements essential for design and development.

(**NOTE:** Research and development (R&D) requirements, by there very nature, tend to ambiguous, especially in the early stages of R&D.

Records are maintained documenting design and development outputs. Requirements include:

- Outputs are approved prior to release.

- Verification that design and development inputs match the corresponding outputs.

- Provide appropriate information for purchasing, production, and servicing.

- Product acceptance criteria.

- Specific characteristics necessary for the safe and proper use of the product.

- Information Systems determined to be necessary of support the design and development processes and maintain the records

Systematic and planned, design and development reviews are conducted at suitable stages (e.g., customer directed, industry standard) of the design and development phase. Reviews are recorded and seek to:

- Evaluate the ability of the design and development results to meet requirements.

- Identify any problems and propose necessary actions.

Design and development verification activities are planned to ensure design and development outputs have met input requirements. Records are maintained on verification results, to include any necessary actions to correct identified deficiencies.

Design and development validation activities are planned to ensure the resulting products are capable of meeting the specified requirements for the intended application. Further, whenever practical, validation is completed prior to the delivery or implementation of the product. Additionally, validation records are maintained that include, when applicable, actions taken to address problems noted during the validation process.

8.3.4.4 Purchasing

The purchasing process includes:

- Assurance that purchased items conform to specified purchase requirements.

- The identification of the type and extent of control applied to personnel/companies supplying products and services to SBAR. (**NOTE:** This control is dependent upon the purchased products/services effect on the realization of the final SBAR product/service.)

SBAR maintains Approved Vendor Lists to ensure vendors can provide the necessary products and services according to specified requirements established by SBAR, customers, and/or regulatory agencies. Criteria for selection, evaluation, and re-

evaluation have been established. Further, there are records of evaluations that depict any necessary actions arising from an evaluation.

SBAR ensures specified purchase requirements are accurate prior to requesting bids or proposals from prospective vendors. Purchasing information describes the product or service to be purchased and, where appropriate, includes:

- Requirements for product approval, procedures, processes, and equipment.
- Personnel qualifications.
- Quality management system requirements.

SBAR has established and implemented an inspection program to ensure that purchased product meets specified requirements. In cases were inspection is not feasible, the product is released to the customer under Positive Recall Procedures.

When SBAR or its customers intend to perform verification at the premises of a SBAR vendor, the appropriate contractual vehicle (e.g., purchase order) records these provisions. Additionally, the purchase order or subcontract defines the method the product is released to SBAR and/or its customers.

8.3.4.5 Production and Service Provision

SBAR procedures, work instructions (WIs), and checklists define planned activities for the production of and service of SBAR products under controlled conditions. Controlled conditions include, as applicable:

- Availability of information that describes product characteristics.
- The proper equipment to be used.
- The availability and use of inspection, measuring, and test equipment (IMTE).
- Monitoring and measuring requirements to support product production.
- Release, delivery, and post-delivery (e.g., servicing) activities/requirements.

In cases where the product or service cannot be verified by subsequent monitoring or measurement, SBAR procedures and WIs require the affected processes to be validated prior to product or service release to the customer. This includes processes where nonconformances become apparent only after the product or service has been delivered. Therefore, validation activities are recorded and include:

- Defined criteria for review and approval of the process.
- Approval of equipment and the qualification of personnel (e.g., certified welder).
- Use of specified methods and procedures (e.g., Positive Recall).
- Revalidation.

SBAR's process for product identification and traceability includes product specific WIs that:

- When appropriate, identify the product by suitable means throughout product realization.
- Identify the product status as it relates to monitoring and measurement requirements.
- When applicable, the WI specifies methods to control and record the unique identification (traceability) of a product. (**NOTE**: Configuration Management is used to fulfill this requirement in certain sectors, i.e., software development.)

SBAR exercises due care when in possession of a customer's property and equipment. SBAR's procedure for controlling customer property includes:

- Processes to identify, verify, protect, and safeguard customer property.
- If customer property is lost, damaged, or otherwise found to be unsuitable, SBAR promptly investigates the circumstances and makes a report to the customer.
- Records are maintained on all actions associated with customer property.
- (**NOTE:** Customer property can include intellectual property.)

SBAR preserves the conformity of its products during internal processing and delivery to the intended destination. Procedures define identification, handling, packaging, storage, protection, and preservation, as applicable.

8.3.4.6 Control of Monitoring and Measuring Devices

When appropriate, SBAR procedures, WIs, checklists, etc. define monitoring and measurement activities (i.e., who, what, when, where) that are undertaken to ensure conformity. Further, when applicable, procedures, WIs, and checklists list the specific inspection, measuring, and test equipment (IMTE) required for specific processes.

- IMTE activities are recorded and requirements include:
- Calibration or verification at specific intervals, or prior to use.
- Measurement standards traceable to international/national standards.

If there is no recognized calibration/verification standard, SBAR defines the basis for calibration/verification.

- Adjustment or re-adjustment requirements for IMTE.
- Method to identify calibration status.
- Safeguards prohibiting adjustments that would invalidate a measurement result.
- The protection from damage and deterioration during handling, maintenance, and storage.
- A requirement to assess the validity of previous measurement results when the IMTE is nonconforming (i.e., “out of calibration”). Further, SBAR takes the appropriate action for the IMTE (e.g., recalibration) and/or product (e.g., Quality Hold until product is recalibrated). Records are maintained on these activities.

8.3.5 SBAR Implementing Procedures

The following SBAR procedures implement the Product Realization function (ISO 9001, 7.0):

SBAR *Quality Manual (2000).*

SBAR *Contract Review Procedure (CP-00-9003)*

SBAR *Design Control Procedure (CP-00-9004).*

SBAR *Purchasing Procedure (CP-00-4000).*

SBAR *Control of Customer Property Procedure (CP-00-9007).*

SBAR *Product Identification and Traceability Procedure (CP-00-9008).*

SBAR *Process Control Procedure (CP-00-9009).*

SBAR *Inspection and Testing Procedure (CP-00-9010).*

SBAR *Control of Inspection, Measuring, and Test Equipment Procedure (CP-00-9011).*

SBAR *Handling, Storage, Packaging, Preservation, and Delivery Procedure (CP-00-9015).*

SBAR *Control of Quality Records Procedure (CP-00-9016).*

SBAR *Servicing Procedure (CP-00-9019).*

8.4 Measurement, Analysis, and Improvement (ISO 9001, 8.0)

8.4.1 Policy

Managers at all levels monitor their processes to ensure products and services comply with customer expectations. Further, management measures customer satisfaction and seeks continual process improvement.

8.4.2 Purpose

This section defines the key elements of SBAR's measurement, analysis, and improvement program.

8.4.3 Responsibility

Managers and supervisory personnel at all levels within SBAR are charged with ensuring effective, two-way communication with both customers and employees to ensure the "Voice of the Customer" is heard and understood.

8.4.4 Requirements

SBAR plans and implements the monitoring, measurement, analyses, and improvement processes to:

- Demonstrate SBAR's products conform to their specified requirements.
- Ensure the conformity of the SBAR Quality Management System (QMS).
- Continually improve the effectiveness of the QMS.

8.4.4.1 Monitoring and Measurement

Customer satisfaction, to include customer perceptions, is recorded and measured through the following means:

- Customer Survey Forms.
- Meetings/conversations with customers.
- Periodic Performance Reviews with customers.
- Customer audits, inspections, etc. of SBAR operations.

- Periodic Customer Performance Appraisal Reporting System (CPARS)
- Customer draft statements of work (SOW) for follow-on contracts that SBAR currently possesses.

SBAR conducts internal quality audits to verify the QMS conforms to the requirements of ISO 9001 and is compliant with the specific requirements of the QMS. Further, internal audits verify that the QMS is effectively implemented and maintained. Additionally, SBAR *Internal Quality Audits Procedure (CP-00-9017)* contains the following information:

- Audits are planned with the more important audits, based upon status/importance or previous audit results, occurring earlier rather than later during the audit cycle.
- Define audit criteria, scope, frequency, and methods to conduct audits.
- Auditors are trained and selected based upon their objectivity and impartiality. Additionally, auditors do not audit their own work.
- The responsibilities and requirements for planning and conducting audits.
- Reporting audit results.
- Maintaining audit records.
- Management's responsibility to promptly eliminate each identified nonconformance and their causes.
- Audit team follow-up activities to verify previously enacted corrective and preventive actions are still effective. Further, these verification activities are reported.

SBAR monitoring requirements demonstrate that specified requirements are achieved, and, when applicable, the measurement of the SBAR QMS. Further, when planned results are not achieved, corrective and preventive actions are taken to ensure conformity. Additionally, the following requirements are also observed:

SBAR monitors and measures the characteristics of its products and services at the appropriate stages of the product realization process, in accordance with specified requirements.

Records are maintained that document conformance to the acceptance criteria and indicate the person authorizing release of the product to the customer.

Product release and service delivery proceed only after the planned arrangements have been satisfactorily completed, unless otherwise approved by a person authorized to make such a decision and, when applicable, the customer.

8.4.4.2 Control of Nonconforming Product

SBAR ensures its nonconforming products are identified and controlled to prevent their unintended use or delivery. Further, SBAR *Control of Nonconforming Product and Services/ Corrective and Preventive Action Procedure (CP-00-9013/14)*, contains the following additional requirements:

SBAR deals with nonconforming product by one of the following means:

- Taking action to eliminate the nonconformity.
- By authorizing its use, release or acceptance under concession by a person authorized to make the concession, and where applicable, the customer.
- And/or SBAR takes action to preclude its original intended use or application.
- Records of nonconformances are maintained to include any subsequent actions taken, including concessions.
- When nonconforming products are corrected, they are re-verified to ensure conformity.
- In cases when the nonconformity isn't discovered until after delivery or use has started, SBAR takes and records the appropriate action consistent with the effects or potential effects of the nonconformity.

8.4.4.3 Analysis of Data

SBAR collects and analyzes specific data to demonstrate the suitability, effectiveness, and when appropriate, the improvement of the effectiveness of the QMS. Data analysis provides information relating to:

- Customer satisfaction.

- Conformity to product requirements.
- Characteristics and process trends to include opportunities for preventive action.
- Suppliers, subcontractors, etc.

8.4.4.4 Improvement

SBAR continually seeks to improve the effectiveness and efficiency of its QMS to improve our products ans services through the use of the quality policy, quality objectives, audit results, analysis of data, corrective actions, preventive actions, and management review (e.g., regularly scheduled Quality Steering Committee Meetings). These activities are recorded. See Figure 2 for a graphic depiction of SBAR's quality improvement program. Additionally, SBAR *Servicing Procedure (CP-00-9019)* implements the continuous improvement program.

Control of Nonconforming Product and Services/ Corrective and Preventive Action Procedure (CP-00-9013/14) also addresses how the company eliminates the causes of nonconformances in order to prevent recurrences. Corrective actions are appropriate to the effect of the encountered nonconformances. Additionally, the Procedure defines requirements for:

- Reviewing nonconformance's, to include customer complaints.
- Determining the causes of nonconformance's.
- Evaluating the need for action to ensure that nonconformances do no recur.
- Determining and implementing necessary action.
- Review of the corrective action.
- Records of all of the above actions.

In addition to nonconformances and corrective actions, *Control of Nonconforming Product and Services/ Corrective and Preventive Action Procedure (CP-00-9013/14)* also addresses how the company eliminates the causes of potential nonconformances in order to prevent their occurrence. Preventive actions are implemented that are appropriate to the effects of the potential problems/nonconformances. Additionally, the Procedure defines requirements for:

- Determining potential nonconformances and their causes.
- Evaluating the need for action to prevent the occurrence of nonconformances.
- Determining and implementing necessary action to preclude problems/nonconformances.
- Reviewing preventive actions taken.
- Records of all of the above actions.

8.4.5 SBAR Implementing Procedures

The following SBAR procedures implement the Measurement, Analysis, and Improvement function (ISO 9001, 8.0):

SBAR *Quality Manual (2000)*.

SBAR *Control of Nonconforming Product and Services/ Corrective and Preventive Action Procedure (CP-00-9013/14).*

SBAR *Internal Quality Audits (CP-00-9017).*

SBAR *Servicing Procedure (CP-00-9019).*

SBAR *Measurement and Analysis Procedure (CP-00-9020).*

Pande, Peter S. et al, (2000), *The Six Sigma Way,* pp. 176-184,McGraw-Hill.

Figure 2 - Continuous Improvement