1.0 POLICY/PURPOSE

Santa Barbara Applied Research (SBAR), Inc. uses monitoring, measurement, analysis, and/or verification techniques to ensure the effectiveness of the Quality Management System (QMS). Additionally, where appropriate, process (i.e., product/service) work instructions define the specific monitoring, measurement, analysis, and/or verification techniques that are used to demonstrate process conformity. This procedure describes how the measurement and analysis program is implemented.

2.0 SCOPE

This procedure applies to all SBAR operations.

3.0 REFERENCES AND DEFINITIONS

3.1 References

ISO 9001: Quality Management Systems-Requirements, Third Edition (2000-12-15)

- ISO 9001 Elements 8.1 (Measurement, Analysis, and Improvement: General), 8.2.3 (Monitoring and Measuring of Processes), 8.2.4 (Monitoring and Measurement of Product), 8.4 (Analysis of Data)

SBAR Documents

- *Quality Manual (QAP 2000)*

3.2 Definitions

Characteristic: A distinguishing feature. Characteristics may be qualitative or quantitative.

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

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.

Defect: Non-fulfillment of a requirement related to an intended or specified use. (NOTE: The distinction between the concepts "defect' and "nonconformity" is important as it has

legal connotations, particularly those associated with product liability issues. Use extreme caution when using the term "defect.")

Functional Area Manager (FAM): A senior supervisory individual who is responsible for the leadership, direction, and overall success of an area of the company, such as procurement, specific contracts, logistics, quality, safety, engineering, or financial.

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. IMTE includes, but is not limited to, multimeters, confined space meters, torque wrenches, oscilloscopes, amprobes, Simpson meters, test software, etc.

Measurement and Analysis: A generic term that includes monitoring, measurement, analysis, verification, metrics, and/or statistics.

Metric: A measure of an action(s) to determine compliance with a specific requirement. To be meaningful, a metric contains specific measurable criteria. A metric may be qualitative, quantitative, objective, or subjective; however, "quantitative objective" metrics are preferred. For example, "The contractor must respond to emergency calls within one hour, 90 percent of the time." In this example, the metric is the response time and the criterion is 90 percent.

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.

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.

Requirement: A need or expectation that is stated, generally implied or obligatory. (**NOTE: "**Generally implied" means that it is custom or common practice.)

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).

Statistics: A branch of mathematics dealing with the collection, analysis, interpretation, and presentation of numerical data (a collection of quantitative data).

Verification: Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled. It often involves an independent review by someone not directly involved in producing the specific product or service that is being evaluated.

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.

4.0 RESPONSIBILITIES

4.1 The Quality Manager

The Quality Manager is responsible for developing and implementing this procedure.

4.2 Functional Area Managers (FAM)

FAMs responsible for processes/services are required to define those monitoring, measurement, analysis, and/or verification techniques necessary to demonstrate process conformity.

5.0 REQUIREMENTS/PROCEDURES:

5.1 General

Work instructions (WIs) are developed to provide direction and guidance for SBAR processes in order to demonstrate the conformity of SBAR products/services. Contained within these WIs are the appropriate measurement and analysis techniques necessary to ensure the quality of the specific product/service.

5.2 Measurement and Analysis Techniques

Where appropriate, the following measurement and analysis techniques are utilized:

- Specific monitoring techniques (e.g., senior technician will oversee junior technician, quality/safety/environmental inspector will be on-site).
- Specific contractual requirements (e.g., metrics).
- Specific statistical techniques (e.g., 100 % sampling, random sampling).
- Specific IMTE requirements (e.g., calibration software, torque wrench).
- Specific analytical requirements (e.g., certified laboratory analysis).
- Specific verification techniques (e.g., independent engineering calculations).

(**NOTE:** Inherent in the above is the ability to implement preventive and process improvement actions.)

5.3 Process Work Instructions

Work instructions define how, when, etc. the assembled data will be analyzed. The analysis of data provides information relating to:

- Customer satisfaction (see SBAR *Servicing Procedure, CP-00-9019*).
- Conformity to product/service requirements.

- Characteristics and trends of product/service processes, to include preventive actions (see SBAR *Control of Nonconforming Product and Services/ Corrective and Preventive Action Procedure (CP-00-9013/14).*

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

5.4 Positive Recall Procedures

If a product or service is authorized to be released to the customer prior to the fulfillment of all quality requirements, the controlling WI states the conditions that allow this premature release. These conditions include, but are not limited to:

- The FAM who is authorized to release the product/service.

- The specific conditions under which the product/service is released and how the product/serviced is to be recalled, if necessary.

- Any inspection criteria prior to release

- Whether or not customer prior approval is required. (**NOTE:** Whenever possible, obtain written/electronic confirmation from the customer.)

5.5 Records

Finally, WIs define the records to be maintained and where they will be maintained. Records include evidence (proof) of conformity with the acceptance criteria. Additionally, the records indicate the person(s) authorizing release of the product/service to the customer.

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