



Quality Assurance Procedure

CP-00-9016

Approved:

Date: 7 June 2005

Title: Control of Quality Records (ISO 9001, 4.2.4)

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1.0 POLICY/PURPOSE

Santa Barbara Applied Research (SBAR), Inc. maintains records to ensure effective operations and to demonstrate conformance to SBAR's Quality Management System and customer specifications. Quality records are appropriately identified, collected, indexed, filed, made readily accessible, stored, safeguarded, and disposed of properly. The purpose of this procedure is to define and establish the SBAR system for controlling quality-related records.

2.0 SCOPE

This procedure applies to all electronic and paper records associated with SBAR's quality program.

3.0 REFERENCES AND DEFINITIONS

3.1 References

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

- ISO 9001 Element 4.2.3 (Control of Documents)
- ISO 9001 Element 4.2.4 (Control of Records)

SBAR Documents

- SBAR *Quality Manual(QAP 2000)*
- SBAR *Document and Data Control Procedure (CP-00-9005)*

3.2 Definitions

Data Management Central Library (DMCL): The focal point for all SBAR quality records (e.g., documentation, data, and procedures). DMCLs are located at Corporate, Division, Branch, Contract, etc. level and are maintained and controlled by the applicable Quality Assurance Officer (QAO). As appropriate, records in electronic and paper form are stored in DMCLs. When appropriate, DMCLs have sub-libraries for records that are stored elsewhere.

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, work instructions (WIs), audit/inspection reports, x-rays, Quality Steering Committee meeting minutes.

File Plan (File Index): A record listing the documents that are stored in a specific file room, file drawer/cabinet, etc.

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.

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Master Documentation/Record List (MDRL): A listing of all documentation, data, procedures, and records that affect quality. MDRLs are in electronic format and, if needed, paper copies are authorized.

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 Record: Documentation stating results achieved or providing objective evidence (i.e., information that can be proved true, based on facts obtained through observation, measurement, test, or other means) of activities performed.

Record Custodian: Individual who assists a QAO in maintaining quality records.

4.0 RESPONSIBILITIES

4.1 Corporate Quality Manager

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

4.2 Functional Area Manager (FAM)

FAMs are required to inform the appropriate QAO of all quality records within their respective functional areas and identifying the retention period for each record. Further, FAMs ensure that quality records are stored in the appropriate DMCL or sub-library.

4.3 Quality Assurance Office/Officer



The QAO is responsible for the maintenance of the DMCL and MDRL for each area of responsibility (e.g., corporate level, division, branch, contract, etc.). The QAO is responsible for indexing, filing, storing, safeguarding, and retrieving all quality records as needed. The QAO is also responsible for removing records that are no longer required.

4.4 Record Custodian

Designated by the QAO, the record custodian maintains the DMCL and MDRL and indexes, files, stores, safeguards, and retrieves all quality records within each specific area of responsibility. Additionally, the record custodian periodically removes records after the retention period has expired and the record is no longer needed.

4.5 Employee Requesting Quality Records

Employees authorized temporary control of a quality record are required to protect the record in question.

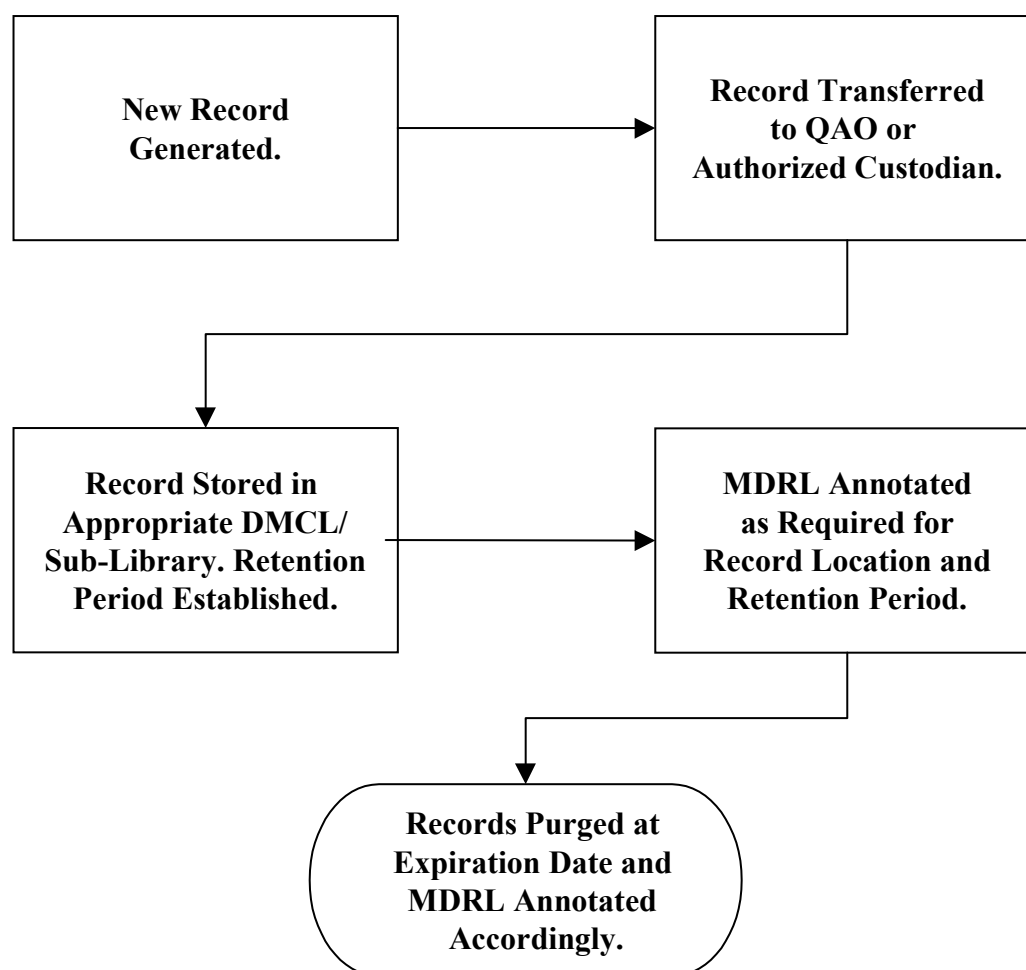
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4.6 SBAR Web Master

The SBAR Web Master is responsible for developing and maintaining the corporate MDRL (e.g., corporate procedures, work instructions, forms) at the corporate web site.

5.0 REQUIREMENTS/PROCEDURES

Figure 1 -- Process Flow for Storing and Logging Quality Records





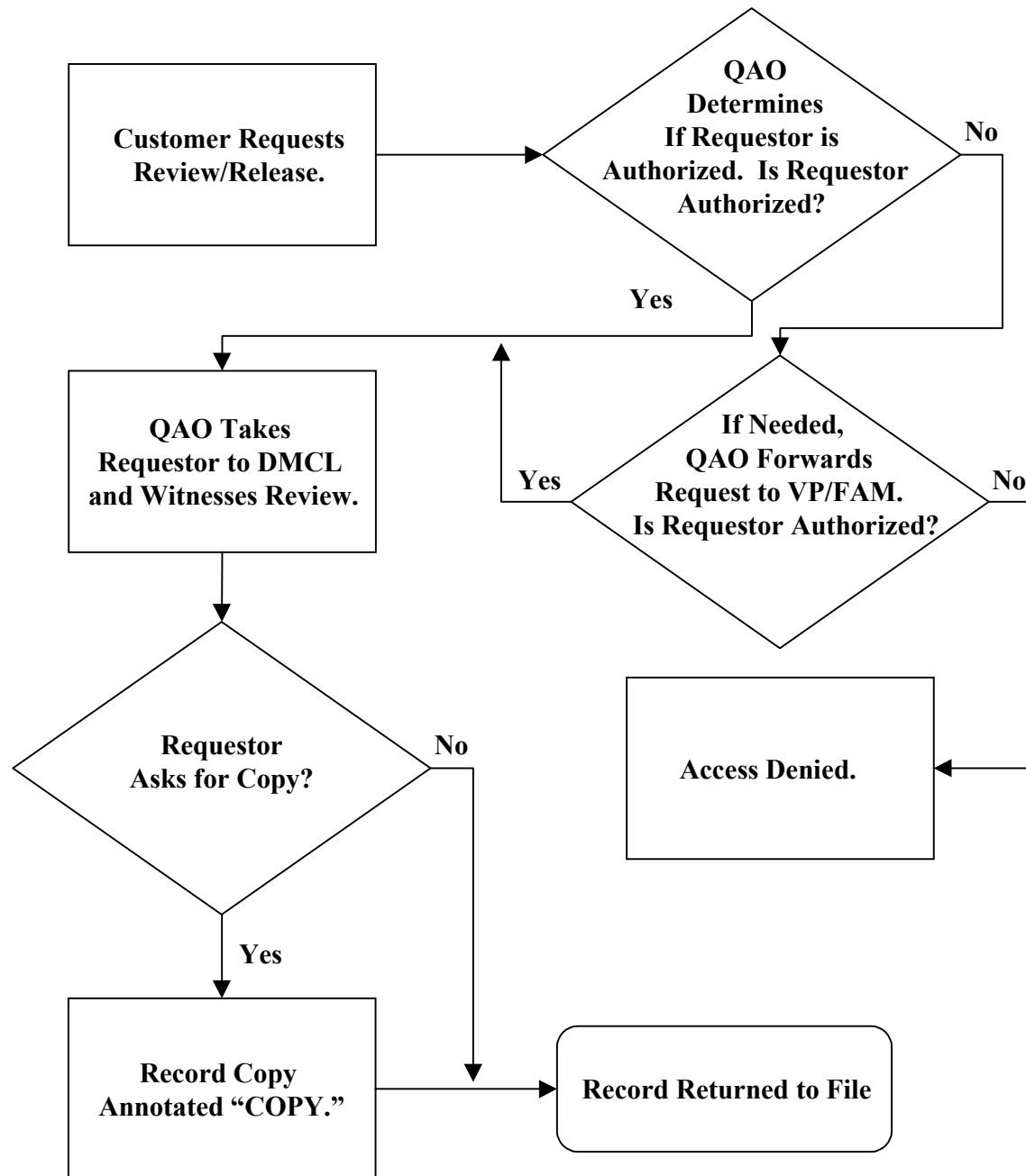
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Figure 2 -- Review/Release of Quality Records





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4.6 Record Generation/Collection

Sources for the generation and collection of quality records include:

- Specific ISO 9001 requirements (e.g., design and development reviews, purchasing, training records).
- SBAR procedures and work instructions (WIs).
- Specific contractual/customer requirements (i.e., contracts with customers and/or subcontractor contracts).
- Regulatory requirements (e.g., applicable Code of Federal Regulations).
- Any other source that requires objective evidence that a quality-related function is being performed in accordance with specified requirements.

When the generator of the quality record completes the record, the record is submitted to the applicable QAO or record custodian. The custodian updates the applicable MDRL and stores the record in the appropriate DMCL/sub-library.

4.7 Master Documentation/Record List (MDRL)

Under the direction of QAOs, record custodians maintain MDRLs at the various locations throughout the Company where quality records are generated, stored, maintained, and readily accessible. MDRLs identify all quality records that have been collected, indexed, accessed, filed, stored, and maintained. The MDRL includes the following information for each record, as appropriate:

- Document/data name
- SBAR agency responsible for the record
- Control number (if applicable)
- Revision/change letter (use NC for the initial publication of the procedure, form, etc.)
- Date of record, i.e. last revision date (if applicable)
- Record retention period
- Review date
- Record format (i.e., electronic, paper, X-ray, picture, etc.)
- DMCL/Sub-Library location
- Remarks

Examples of quality records that are maintained include:



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- SBAR procedures, WIs, forms, etc.
- Reports
- Warranties
- Certifications
- Externally generated manuals, directives, instructions, etc.
- Non-Destructive Examination (NDE) reports
- Service calls, task assignments, repair, work requests, etc.
- X-rays
- Preventive Maintenance reports
- Drawings
- Purchase orders
- Business Plans
- Foremen/lead technician logs
- Inspection and testing reports
- Personal air sampling results
- Meeting minutes (e.g., meeting with a customer)
- Work plans
- Letters/memoranda to and from a customer
- Forms (SBAR-generated or forms generated by external agencies)
- Pertinent records generated by SBAR subcontractors
- Other documentation/data necessary to document SBAR's QMS

5.1 Quality Record Retention Periods

After a quality record is generated, it is collected, indexed, filed, stored, and retained for a time period specified by the FAM. Quality record retention times, as applicable, are based upon one or more of the following considerations:

- A period of time required by law or regulation. This requirement establishes the minimum retention period over all other considerations.
- Specific contractual requirements or customer expectations. Similarly, this consideration establishes a minimum retention period.
- Warranty period plus 90 days
- Product shelf life

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- Life of a contract
- Life of a contract plus a specified time period, such as 90 days
- Three years after a product/service is provided
- Life of the media (for regeneration purposes)
- Life of the Corporation

4.8 Data Management Central Library

Under the direction of the QAO, the appropriate record custodian is responsible for the DMCL within a specific area of responsibility. Records in the DMCL are maintained in electronic (e.g. a database), paper (e.g. a purchase order), or other acceptable format (e.g. x-rays).

Quality records, both physical and electronic, are under the control of authorized personnel. Records are appropriately protected. The following requirements for the storage and control of quality records are observed at the DMCL and sub-libraries:

- All records (electronic, paper, etc.) are legible and readily retrievable.
- Records are stored in facilities that provide a suitable environment to prevent damage, deterioration, and/or loss.
- Electronic records are retained/"backed up" at another work station, server, etc.
- Records are retained for the retention period listed on the MDRL.
- Records are periodically reviewed to purge unneeded records, update the MDRL, and regain loaned records.
- Where agreed contractually, a customer or a customer's representative is authorized to review quality records.
- A MDRL is maintained for each DMCL, to include its sub-libraries (if applicable).
- Most records include a signature and date to verify the authenticity of the record. For records that cannot be signed (e.g., radiographs), associated documentation is maintained to attest to the record's origin.
- When warranted, a file plan is associated with each MDRL to further aid in the retrieval of records.

4.9 Review/Release of Records

Unless specifically approved by the appropriate QAO, only authorized customer officials (e.g., contract officer, contract technicians, and quality assurance evaluators), SBAR employees, and appropriate SBAR subcontractor personnel are authorized to review and/or receive copies of quality records. These personnel are only authorized to review and/or receive records within the scope of their official duties. For records containing proprietary information, the QAO first



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obtains permission from the appropriate corporate officer/manager, project/contract manager, etc.

When an authorized individual, other than a SBAR employee, requests to review a record, the record custodian escorts the official to the DMCL or the sub-library and witnesses the review. Original DMCL/sub-library records are **never** given to a non-SBAR employee.

If a copy of a record is authorized and requested, the record custodian makes the copy. For copies of electronic records, the copy is secured as an original, i.e. password protected, read only, encrypted, etc. Further, in cases where a copy of a record is required, the following or similar statement is prominently affixed to the electronic/paper copy:

“REFERENCE ONLY! DESTROY WHEN NO LONGER NEEDED.”

When an authorized SBAR employee requires a record maintained in the DMCL or sub-library, the record custodian makes a copy of the record, or portion thereof, and gives it to the requestor. The phrase (or similar) **“REFERENCE ONLY! DESTROY WHEN NO LONGER NEEDED”** is printed or stamped in bold print on the copy. When authorized by the QAO, an authorized employee may gain temporary custody of a record by signing for the record and providing an estimated return date. The individual signing for the record is responsible for returning the complete record to the DMCL/sub-library.

4.10 Password Protection

For electronic records, the following requirements apply:

- All computers storing quality records (e.g., a work center, DMCL) are password protected. (**NOTE:** Additionally, password protected screensavers (ten minutes or less) are highly recommended.)
- Folders and/or files containing quality records are also password protected, unless otherwise protected.

Passwords comply with the definition of a secure password at the time that the record is generated. Further, passwords comply with the customer's password security requirements and/or SBAR's company policy.


(**NOTE:** One system in use requires passwords to have a minimum of eight alpha-numeric characters with at least one special character (e.g., @, &) and one number. An example of a secure password using this system is “rx6m&agt.”)

Normally, files are “read only.” However, for financial data and other proprietary information, the FAM may require password protection to open the document. Finally, passwords are maintained inside a sealed envelope marked with the FAM's name and locked in a secure container (e.g., office safe) that limits access.



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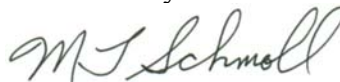
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