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### 0.1 Amendment Record

This quality manual (QM) contains only the pages issued by this facility. The Management Representative (MR) will process all authorized changes, inserting amendment pages into the official distribution copies. The MR will see that obsolete pages are withdrawn from use and disposed of to prevent unintentional usage. This QM is a controlled copy document. The MR maintains the master copy of this QM. This master copy is used as the final authority, regarding the latest revision level and amendment status for the USAMRAA QM.

Issue #	Section/s	Date	Page	Description of revisions	Approval
#1	1-20	02/10/00	All	Release Draft Quality Assurance Manual	
#2	1-20	03/14/00	All	Revision of Quality Assurance Manual	
#3	1-20	05/22/00	All	Revision of Quality Assurance Manual	
#4	1-20	06/06/00	All	Revision of Quality Assurance Manual	
#5	1-20	06/09/00	All	Revision of Quality Assurance Manual	
#6	1-20	12/04/00	All	Revision of Quality Assurance Manual	
#7	1-20	07/09/01	All	Revision of Quality Assurance Manual	
#8	1-20	08/03/01	All	Revision of Quality Assurance Manual	
#9	1-20	08/05/02	All	Revision of Quality Assurance Manual	
#10	All	11/04/02	All pages	Complete revision of Quality Manual for ISO 9001: 2000	

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0.2 Controlled Circulation List

<b>Number</b>	<b>Copy Custodian</b>	<b>Signature</b>
1	Management Representative	Craig D. Lebo
2	Director	Kenneth B. Connolly

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### 0.3 Glossary

- AFARS– Army Federal Acquisition Regulation Supplement
- AM– Account Manager
- CA– Corrective Action
- CIO– Chief Information Officer
- CSCC- Customer Service Center Chief
- DFARS– Defense Federal Acquisition Regulation Supplement
- DODGAR– Defense Grants and Assistance Regulation
- ERMS– Extramural Research Management System
- FAR– Federal Acquisition Regulations
- IQA– Internal Quality Audit
- MC– Master Copy
- MR– Management Representative
- PA– Preventive Action
- PD<sup>2</sup>– Procurement Desktop-Defense, also known as “Directives and Guidance for Use of SPS” or the “SPS Manual”
- PMR– Procurement Management Review
- PO– Purchase Order
- QAR– Quality Assurance Review
- QM– Quality Manual
- QPM– Quality Procedures Manual
- Records Holding– An Army activity responsible to holding and maintaining records
- SAAB– Solicitation Award Advisory Board
- SPS- AKA Procurement Desktop-Defense, also known as “Directives and Guidance for Use of SPS
- Standard(s)– industry, national and international quality standards and ISO 9001: 2000
- Top Management– The Director, the Deputy for Business Management/ MR, the Deputy for

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Business Operations, and the Deputy for Business Support

USAMRAA– United States Army Medical Research Acquisition Activity (the  
“organization”)

USAMRMC-AI– USAMRMC Acquisition Instruction

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## 0.4 Scope Statement

### Scope of Registration:

The scope of registration includes all activities affecting quality in the planning, execution, delivery and administration of acquisition and assistance solutions for research and development, services, construction and supplies for the U.S. Army and other customers.

The applicable SIC code is 9199 General Government, Not Elsewhere Classified.

### Permissible Exclusions:

USAMRAA is not a design-responsible organization, nor does it employ any special or qualified processes, therefore, the requirements of 7.3 and 7.5.2 do not apply and are excluded from the quality system. USAMRAA does not handle any customer-supplied product or property, nor does it use any verification devices requiring calibration; therefore, the requirements of 7.5.4 and 7.6 are also excluded from the scope of the quality system.

### Interaction of Processes:

The sequence and interaction of processes is described in detail in the U.S. Army Medical Research Acquisition Activity document “The Procurement Process: An Overview”. The document is available through USAMRAA’s web site:

<http://www.usamraa.army.mil/pages/index.cfm>.

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## Quality Management System

### 4.1 Scope and Purpose

The quality system described in this section of the QM conforms to the requirements of the standard: Section 4 - Element 4.0 Quality management system requirements. This policy defines the organization's commitment to quality.

### 4.2 Responsibility and Authority (R&A)

The R&A for overall administration of the quality management system activities are shared by top management, including the Management Representative. Employees have the responsibility to complete quality activities in support of the quality policy, quality system documentation and customer requirements. Employees have been granted authority in order to meet specified requirements.

### 4.3 Quality Management System Requirements

#### **General requirements:**

4.3.1 A quality management system has been established, documented, implemented, maintained and is continually improved in accordance with the requirements of ISO 9001:2000. To implement the system, the organization has:

- ◆ identified the processes needed for the quality management system and their application throughout the organization;
- ◆ determined the sequence and interaction of these processes;
- ◆ determined the criteria and methods needed to ensure that both the operation and control of these processes are effective;
- ◆ ensured the availability of resources and information necessary to support the operation and monitoring of these processes;
- ◆ monitored, measured, and analyzed these processes; and,
- ◆ implemented actions necessary to achieve planned results and continual improvement of these processes.

These processes are managed in accordance with ISO 9001:2000.

Control is ensured over any processes that may be outsourced, and control of such applicable processes is identified within the quality management system.

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**Documentation requirements:**

4.3.2 Quality management system documentation includes:

- ◆ documented statements of a quality policy and quality objectives;
- ◆ a Quality Manual;
- ◆ documented procedures required by ISO 9001:2000;
- ◆ documents needed by the organization to ensure the effective planning, operation and control of processes; and,
- ◆ quality records required by ISO 9001:2000.

4.3.3 A Quality Manual has been established and maintained that includes:

- ◆ the scope of the quality management system, including details of and justification for any permissible exclusions;
- ◆ the documented procedures established for the quality management system, or reference to them; and,
- ◆ a description of the interaction between the processes of the quality management system.

**Control of documents:**

4.3.4 Documents and quality records required by the quality management system are controlled.

A documented procedure has been established to define the controls needed to:

- ◆ approve documents for adequacy prior to issue;
- ◆ review and update as necessary and re-approve documents;
- ◆ ensure that changes and the current revision status of documents are identified;
- ◆ ensure that relevant versions of applicable documents are available at points of use;
- ◆ ensure that documents remain legible and readily identifiable;
- ◆ ensure that documents of external origin are identified and their distribution controlled; and,
- ◆ prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

**Control of quality records:**

4.3.5 Quality records are established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system.

Quality records are legible, readily identifiable and retrievable.

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A documented procedure has been established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of quality records.

#### 4.4 Related and Support Documentation

- QP4-1 Control of Documents Procedure
- QP4-2 Control of Records Procedure

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## Management Responsibility

### 5.1 Scope and Purpose

The quality system described in this section of the QM conforms to the requirements of the standard: Section 5 - Element 5.0 Management responsibility. This policy defines the organization's commitment to quality.

### 5.2 Responsibility and Authority (R&A)

The R&A for overall administration of the quality management system activities are shared by top management, including the Management Representative. Employees have the responsibility to complete quality activities in support of the quality policy, quality system documentation and customer requirements. Employees have been granted authority in order to meet specified requirements.

### 5.3 Management Commitment

#### **Management commitment:**

5.3.1 Top management has provided evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by:

- ◆ communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements;
- ◆ establishing the quality policy;
- ◆ ensuring that quality objectives are established;
- ◆ conducting management reviews; and,
- ◆ ensuring the availability of resources.

#### **Customer focus:**

5.3.2 Top management has ensured that customer requirements are determined and fulfilled with the aim of enhancing customer satisfaction.

#### **Quality policy:**

5.3.3 Top management has ensured that the quality policy is:

- ◆ appropriate to the purpose of the organization;

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- ◆ includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system;
- ◆ provides a framework for establishing and reviewing quality objectives;
- ◆ communicated and understood within the organization; and,
- ◆ reviewed for continuing suitability.

**Planning and quality objectives:**

5.3.4 Top management has ensured that quality objectives, including those needed to meet requirements for product, are established at relevant functions and levels within the organization. The quality objectives are measurable and consistent with the quality policy.

**Quality management system planning:**

5.3.5 Top management has ensured that:

- ◆ the planning of the quality management system is carried out in order to meet the requirements of the general requirements of this international standard (section 4.1); and,
- ◆ the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

**Responsibility and authority:**

5.3.6 Top management has ensured that the responsibilities, authorities and their interrelation are defined and communicated within the organization.

**Management representative:**

5.3.7 Top management has appointed a member of management who, irrespective of other responsibilities, has responsibility and authority that includes:

- ◆ ensuring that processes needed for the quality management system are established, implemented and maintained;
- ◆ reporting to top management on the performance of the quality management system, and any need for improvement; and,
- ◆ ensuring the promotion of awareness of customer requirements throughout the organization.

The Director has appointed the Deputy for Business Management as the Management Representative.

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**Internal communication:**

5.3.8 Top management has ensured that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

**Management review:**

5.3.9 Top management reviews the quality management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness. This review includes assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Records of management reviews are maintained.

**Management review input:**

5.3.10 Input to management review includes information on:

- ◆ results of audits;
- ◆ customer feedback;
- ◆ process performance and product conformity;
- ◆ status of preventive and corrective actions;
- ◆ follow-up actions from earlier management reviews;
- ◆ planned changes that could affect the quality management system; and,
- ◆ recommendations for improvement.

**Management review output:**

5.3.11 Output from management review includes any decisions and actions related to:

- ◆ improvement of the effectiveness of quality management system and its processes;
- ◆ improvement of product related to customer requirements; and,
- ◆ resource needs.

5.4 Related and Support Documentation

QP5-1 Management Responsibility Procedure

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## Resource Management

### 6.1 Scope and Purpose

The quality system described in this section of the QM conforms to the requirements of the standard: Section 6 - Element 6.0 Resource management. This policy defines the organization's commitment to quality.

### 6.2 Responsibility and Authority (R&A)

The R&A for overall administration of quality management system activities are shared by top management, including the Management Representative. Employees have the responsibility to complete quality activities in support of the quality policy, quality system documentation and customer requirements. Employees have been granted authority in order to meet specified requirements.

### 6.3 Resource Management

#### **Provision of resources:**

6.3.1 Resources have been determined and provided to:

- ◆ implement and maintain the quality management system and continually improve its effectiveness; and,
- ◆ enhance customer satisfaction by meeting customer requirements.

#### **Human resources:**

6.3.2 Personnel performing work affecting product quality are competent on the basis of appropriate education, training, skills and experience.

6.3.3 The organization has:

- ◆ determined the necessary competence for personnel performing work affecting product quality;
- ◆ provided training or taken other action to satisfy these needs;
- ◆ evaluated the effectiveness of the actions taken;
- ◆ ensured that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives; and,
- ◆ maintained appropriate records of education, training, skills and experience.

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**Infrastructure:**

6.3.4 The infrastructure needed to achieve conformity to product requirements has been determined, provided and maintained.

Infrastructure examples may include, but not be limited to:

- ◆ buildings, workspace and associated utilities;
- ◆ process equipment, both hardware and software; and,
- ◆ supporting services such as transport or communication.

**Work environment:**

6.3.5 The work environment needed to achieve conformity to product requirements has been determined and managed.

6.4 Related and Support Documentation

QP5-1 Management Responsibility Procedure

QP6-1 Competence, Awareness and Training Procedure

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## Product Realization

### 7.1 Scope and Purpose

The quality system described in this section of the QM conforms to the requirements of the standard: Section 7 - Element 7.0 Product realization. This policy defines the organization's commitment to quality.

### 7.2 Responsibility and Authority (R&A)

The R&A for overall administration of quality management system activities are shared by top management, including the Management Representative. Employees have the responsibility to complete quality activities in support of the quality policy, quality system documentation and customer requirements. Employees have been granted authority in order to meet specified requirements.

### 7.3 Product Realization

#### **Planning of product realization:**

7.3.1 The processes needed for product realization are planned and developed, and are consistent with the requirements of the other processes of the quality management system. In planning product realization, the following has been determined, as appropriate:

- ◆ quality objectives and requirements for the product;
- ◆ the need to establish processes, documents, and provide resources specific to the product;
- ◆ required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;
- ◆ records needed to provide evidence that the realization processes and resulting product fulfill requirements; and,
- ◆ planning output is in a suitable form for methods of operation.

#### **Determination of requirements related to the product:**

7.3.2 Requirements related to the product have been determined, including:

- ◆ requirements specified by the customer, including the requirements for delivery and post-delivery activity;
- ◆ requirements not stated by the customer but necessary for specified use or known and intended use;
- ◆ statutory and regulatory requirements related to the product; and,

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- ◆ determination of any additional requirements.

**Review of requirements related to the product:**

7.3.3 Requirements related to the product are reviewed. This review is conducted prior to committing to supply a product to customers, and ensures that:

- ◆ product requirements are defined;
- ◆ contract or order requirements differing from those previously expressed are resolved;
- ◆ the organization has the ability to meet the defined requirements; and,
- ◆ records of the results of review and actions arising from this review are maintained.

Where the customer provides no documented statement of requirements, customer requirements are confirmed before acceptance.

Where product requirements are changed, it is ensured that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

**Customer communication:**

7.3.4 Effective arrangements for communication with customers relating to the following are determined and implemented:

- ◆ product information;
- ◆ enquiries, contracts or order handling, including amendments; and,
- ◆ customer feedback, including customer complaints.

**Purchasing process:**

7.3.5 Purchasing processes are controlled to ensure purchased product conforms to specified purchase requirements. The type and extent of control is applied to suppliers and purchased product is dependent upon the effect of the purchased product on subsequent product realization or the final product.

Suppliers are evaluated and selected based on their ability to supply product in accordance with requirements. Criteria for selection, evaluation and re-evaluation and any necessary actions arising from the evaluation are maintained.

**Purchasing information:**

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7.3.6 Purchasing information describes the product to be purchased, including where appropriate:

- ◆ requirements for approval of product, procedures, processes, and equipment;
- ◆ requirements for qualification of personnel; and,
- ◆ quality management system requirements.

The adequacy of specified purchasing requirements prior to their communication to suppliers is ensured.

**Verification of purchased product:**

7.3.7 Inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements are established and implemented. Where verification of purchased product is intended at suppliers' premises, including customer verification of such product, the verification activity and the method of product release are stated in the purchasing information.

**Control of production and service provision:**

7.3.8 Production and service operations are planned and carried out under controlled conditions, including, as applicable:

- ◆ the availability of information that describes the characteristics of the product;
- ◆ the availability of work instructions;
- ◆ the use of suitable equipment;
- ◆ the availability and use of monitoring and measuring devices;
- ◆ the implementation of monitoring and measurement; and,
- ◆ the implementation of release, delivery and post-delivery activities.

**Identification and traceability:**

7.3.9 Product is identified, where appropriate, by suitable means throughout production realization. The status of the product is identified with respect to measurement and monitoring requirements. Where traceability is a requirement, the unique identification of product is controlled and recorded.

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**Preservation of product:**

7.3.10 Conformity of product during internal processing and delivery to the intended destination is preserved. This includes identification, handling, packaging, storage and protection. Preservation also applies to the constituent parts of a product.

7.4 Related and Support Documentation

- QP7-1 Planning Procedure
- QP7-2 Customer-Related Processes Procedure
- QP7-4 Purchasing Procedure
- QP7-5 Production and Service Provision Procedure

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## Measurement, Analysis and Improvement

### 8.1 Scope and Purpose

The quality system described in this section of the QM conforms to the requirements of the standard: Section 8 - Element 8.0 Measurement, analysis and improvement. This policy defines the organization's commitment to quality.

### 8.2 Responsibility and Authority (R&A)

The R&A for overall administration of quality management system activities are shared by top management, including the Management Representative. Employees have the responsibility to complete quality activities in support of the quality policy, quality system documentation and customer requirements. Employees have been granted authority in order to meet specified requirements.

### 8.3 Measurement, Analysis and Improvement

#### **General requirements:**

8.3.1 The organization has planned and implemented the monitoring, measurement, analysis and improvement processes needed to:

- ◆ demonstrate conformity of the product;
- ◆ ensure conformity of the quality management system; and,
- ◆ continually improve the effectiveness of the quality management system.

This includes determination of applicable methods, including statistical techniques, and the extent of their use.

#### **Customer satisfaction:**

8.3.2 As one of the measurements of the performance of the quality system, the organization monitors information relating to customer perception as to whether customer requirements have been fulfilled. The methods for obtaining and using this information are determined.

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**Internal audit:**

8.3.3 Periodic internal audits are conducted at planned intervals to determine whether the quality management system:

- ◆ conforms to the planned arrangements, to the requirements of this International Standard, and to the quality management system requirements established by the organization; and,
- ◆ is effectively implemented and maintained.

An audit program is in place that takes into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods are defined. Selection of auditors and conduct of audits ensures objectivity and impartiality of the audit process. Auditors do not audit their own work.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records, are defined in a documented procedure.

The management responsible for the audited area ensures that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities include the verification of the actions taken and the reporting of verification results.

**Monitoring and measurement of processes:**

8.3.4 Suitable methods are applied for monitoring and, where applicable, measurement of the quality management system processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action are taken, as appropriate, to ensure conformity of the product.

**Monitoring and measurement of product:**

8.3.5 The characteristics of the product are monitored and measured to verify that product requirements are fulfilled. This is completed at appropriate stages of the product realization process in accordance with planned arrangements.

Evidence of conformity with the acceptance criteria is maintained. Records indicate the person(s) authorizing the release of product.

Product release and service delivery do not proceed until all the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority, and where applicable by the customer.

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**Control of nonconforming product:**

8.3.6 Product that does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product are defined in a documented procedure.

Nonconforming product is dealt with by one or more of the following manners:

- ◆ by taking action to eliminate the detected nonconformity;
- ◆ by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer; and,
- ◆ by taking action to preclude its original intended use or application.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, are maintained.

When nonconforming product is corrected, it is subject to re-verification to demonstrate conformity to the requirements.

When nonconforming product is detected after delivery or use has started, actions are taken appropriate to the effects, or potential effects, of the nonconformity.

**Analysis of data:**

8.3.7 The determination of, collection, and analysis of appropriate data are completed to demonstrate the suitability and effectiveness of the quality management system, and to evaluate where continual improvement of the quality management system can be made. This includes data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data provides information relating to:

- ◆ customer satisfaction;
- ◆ conformance to product requirements;
- ◆ characteristics and trends of processes and products including opportunities for preventive action; and,
- ◆ suppliers.

**Continual improvement:**

8.3.8 The effectiveness of the quality management system is continually improved through the use of the following:

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- ◆ quality policy;
- ◆ quality objectives;
- ◆ audit results;
- ◆ analysis of data;
- ◆ corrective and preventive actions; and,
- ◆ management review.

**Corrective and preventive action:**

8.3.9 Corrective action is taken to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the impact of the problems encountered.

A documented procedure for corrective action is established defining requirements for:

- ◆ reviewing nonconformities (including customer complaints);
- ◆ determining the causes of nonconformities;
- ◆ evaluating the need for action to ensure that nonconformities do not recur;
- ◆ determining and implementing action needed;
- ◆ records of the results of actions taken; and,
- ◆ reviewing corrective action taken.

8.3.10 Preventive action is determined to eliminate the causes of potential nonconformities in order to prevent occurrence. Preventive actions are appropriate to the effects of the potential problems.

A documented procedure for preventive action is established defining requirements for:

- ◆ determining potential nonconformities and their causes;
- ◆ evaluating the need for action to prevent occurrence of nonconformities;
- ◆ determining and implementing action needed;
- ◆ records of results of action taken; and,
- ◆ reviewing preventive action taken.

8.4 Related and Support Documentation:

- QP8-1 Monitoring and Measurement Procedure
- QP8-2 Internal Audit Procedure
- QP8-3 Control of Nonconforming Product Procedure
- QP8-4 Analysis of Data Procedure
- QP8-5 Improvement Procedure

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