



P.O. Box 609036, San Diego, CA 92160

**QM-1**

**Rev. 3**

**QUALITY SYSTEMS MANAGEMENT MANUAL**

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P.O. Box 609036, San Diego, CA 92160

Procedure:	<b>QM-1</b>	Revision:	<b>3</b>
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Title:

**QUALITY MANAGEMENT SYSTEMS MANUAL**

**TABLE OF CONTENTS**

1. DOCUMENT REVISION HISTORY ..... 4

2. INTRODUCTION ..... 6

    2.1 Purpose..... 6

    2.2 Scope..... 6

    2.3 Quality Philosophy..... 7

3. APPROVALS ..... 8

4. QUALITY MANAGEMENT SYSTEM ..... 9

    4.1 General Requirements..... 9

    4.2 Veridiam Quality Requirements: ..... 9

    4.3 Documentation Requirements..... 10

    4.4 Quality Manual ..... 11

    4.5 Control of documents..... 11

    4.6 Control of records ..... 12

    4.7 Configuration Management ..... 13

5. MANAGEMENT RESPONSIBILITY ..... 13

    5.1 Management Commitment..... 13

    5.2 Customer Focus ..... 14

    5.3 Quality policy..... 14

    5.4 Planning ..... 14

    5.5 Responsibility, authority and communication ..... 15

    5.6 Management review ..... 16

6. Resource management ..... 17

    6.1 Provision of resources..... 17

    6.2 Human resources..... 18

    6.3 Infrastructure..... 18

    6.4 Work environment ..... 19

7. Product realization ..... 19

    7.1 Planning of product realization..... 19

    7.2 Customer-related processes ..... 20

    7.3 Customer communication ..... 21

    7.4 Design and development..... 21

    7.5 Purchasing..... 22

    7.6 Production..... 23

    7.7 Control of monitoring and measuring devices..... 28

8. MEASUREMENT, ANALYSIS AND IMPROVEMENT ..... 29

    8.1 General..... 29

Procedure:	<b>QM-1</b>	Revision:	<b>3</b>
Revised By:	<b>M.G. BLANKENSHIP</b>	Date:	<b>8/25/06</b>

Title:

**QUALITY MANAGEMENT SYSTEMS MANUAL**

8.2 Monitoring and Measurement.....	29
8.3 Control of Nonconforming Product .....	30
8.4 Analysis of Data.....	31
8.5 Improvement.....	32
APPENDIX A.....	34
- Structure of the Documentation Used in the Quality Management System - .....	34
APPENDIX B.....	36
Veridiam's Organization Chart.....	36
APPENDIX C.....	37
Manufacturing, Inspection, Testing, and Laboratory Processes at Veridiam .....	37



P.O. Box 609036, San Diego, CA 92160

Procedure:

**QM-1**

Revision:

**3**

Revised By:

**M.G. BLANKENSHIP**

Date:

**8/25/06**

Title:

**QUALITY MANAGEMENT SYSTEMS MANUAL**

**1. DOCUMENT REVISION HISTORY**

Paragraph:	Revisions:	Rev:	Date:
	Initial Issue	0	11/08/02
4.1	Added a note to clarify that paragraph 7.5.1.5 of AS9100 Rev. A is not applicable.	1	12/11/02
7.5.1.5	Added a paragraph to clarify that paragraph 7.5.1.5 of AS9100 Rev. A is not applicable.	1	12/11/02
All	Replaced "Carpenter Special Products Corporation" and "CSPC" with "Veridiam."	2	6/23/06
All	Removed section title pages.	2	6/23/06
All	Renumbered third and fourth sub-tiered paragraphs	2	6/23/06
3	Moved Table of Contents to be placed after Cover Page.	2	6/23/06
Revision Record	Moved Revision Record after Table of Contents, and before paragraph 1.0.	2	6/23/06
2.3	Expounded on definition of Big Q.	2	6/23/06
2	Removed "This "Quality Manual" for CSPC is approved." The approval sheet of para. 2 indicates this action. Also removed notation of designated "ISO Management Representative" on approval page.	2	6/23/06
3	The following text was deleted: "Initial Issue Date: November 8, 2002" and "This manual supersedes the Veridiam Quality Assurance Manuals designated "A", "AA" and "AAA", and their subsidiary documents." As it is redundant.	2	6/23/06
4.1.2c	Updated revision level of AS9100 to rev B.	2	6/23/06
4.1	In note under bullet "ASME NQA-1-2004," removed "Section" and replaced with "Requirement".	2	6/23/06
5.1.1	Added "(see Appendix B for a representative organization chart)"	2	6/23/06
5.5.2	Changed "The President shall assign...that includes:" to "The Director of Quality shall have the responsibility and authority that includes:"	2	6/23/06



P.O. Box 609036, San Diego, CA 92160

Procedure:

**QM-1**

Revision:

**3**

Revised By:

**M.G. BLANKENSHIP**


Date:

**8/25/06**

Title:

**QUALITY MANAGEMENT SYSTEMS MANUAL**

<b>Paragraph:</b>	<b>Revisions:</b>	<b>Rev:</b>	<b>Date:</b>
Appendix A	Updated titles of Managers to Directors	2	6/23/06
Appendix B	Added	2	6/23/06
Appendix C	Added	2	6/23/06
7.1.4	Added paragraph: "Risk Management: As Veridium does not perform any product design, risk management as defined in ISO 13485:2003E does not apply."	3	8/25/06
7.2.1	Replaced entire paragraph to align with ISO 13485.	3	8/25/06
7.6.3	Added entire paragraph: "Control of production — Specific requirements"	3	8/25/06
7.6.5	Added paragraph: "Particular requirements for sterile medical devices."	3	8/25/06
7.6.8	Added paragraph: "Particular requirements for active implantable medical devices and implantable medical devices."	3	8/25/06
Appendix B	Updated titles etc.	3	8/25/06

 P.O. Box 609036, San Diego, CA 92160	Procedure: <b>QM-1</b>	Revision: <b>3</b>
	Revised By: <b>M.G. BLANKENSHIP</b>	Date: <b>8/25/06</b>
Title:  <p style="text-align: center;"><b>QUALITY MANAGEMENT SYSTEMS MANUAL</b></p>		

## 2. INTRODUCTION

### 2.1 Purpose

- 2.1.1 This document has been prepared to describe the Quality Management System in place at Veridiam. It provides policy and programmatic guidelines for all processes related to hardware and s (referred to herein as “products”) provided by Veridiam to its customers.
- 2.1.2 This “Quality Management System Manual” is the top level of a multi-tiered structure, and is organized along the lines of ISO 9001:2000 and ISO 13485:2003. While this Quality Management Systems Manual is often referred to as the “Quality Manual”, the details for implementation of policies and guidelines are provided in second and their tier documents: Management System Procedures (MSP), Implementing Procedures (IP) and Amplifying Procedures (AP).
- 2.1.3 The program described herein confirms Veridiam’s commitment to Quality as reflected in our processes, products and customer-oriented staff.

### 2.2 Scope

The scope of the work performed at Veridiam is metal fabrication of specialty alloys, with emphasis on cold drawing, welding, cleaning and heat-treating of primarily tubular products of various shapes and sizes, used for nuclear, medical, aerospace, and automotive industries.

- 2.2.1 **Exclusions:** The Quality Management System shall not address the following, as they are not performed at Veridiam:
- a. Design requirements (reference ISO 9001 para 7.3.x, ISO 13485 para 7.3.x, 10CFR50 Appendix B, section 3).
  - b. Test Control (reference 10CFR50 Appendix B, section 9).
  - c. Installation and Servicing activities, ISO 13485, para 7.5.1.2.2/3.
  - d. Sterilization, ISO 13485, para 7.5.1.3, 7.5.2.2.
  - e. Agents, distributor and consignee requirements of ISO 13485 para 7.5.3.2.2.

For other areas not addressed in this QM, per the ISO requirements, a statement will be made in the corresponding paragraph location pertaining to the effect that the item is not applicable to the work performed at Veridiam.

Procedure:	<b>QM-1</b>	Revision:	<b>3</b>
Revised By:	<b>M.G. BLANKENSHIP</b>	Date:	<b>8/25/06</b>

Title:

**QUALITY MANAGEMENT SYSTEMS MANUAL**

**2.3 Quality Philosophy**

2.3.1 At Veridium we take a customer focused approach to our Business and thus to Quality. We define Quality as the extent to which we meet requirements and satisfy our customers. As part of Veridium’s competitive strategy, quality permeates all areas of the business and is not limited to manufacturing and product quality. Joseph Juran refers to this broadening of quality as Big Q.<sup>1</sup> Quality is, quite literally, the way we do business.

2.3.2 We at Veridium strive to maximize customer satisfaction, by meeting customer requirements, by responding quickly, by understanding and using existing corporate expertise and by building on our corporate expertise. At Veridium, every employee accepts responsibility for ensuring quality in every activity and interaction with both internal and external customers.

2.3.3 At Veridium, Quality is the way we do business!

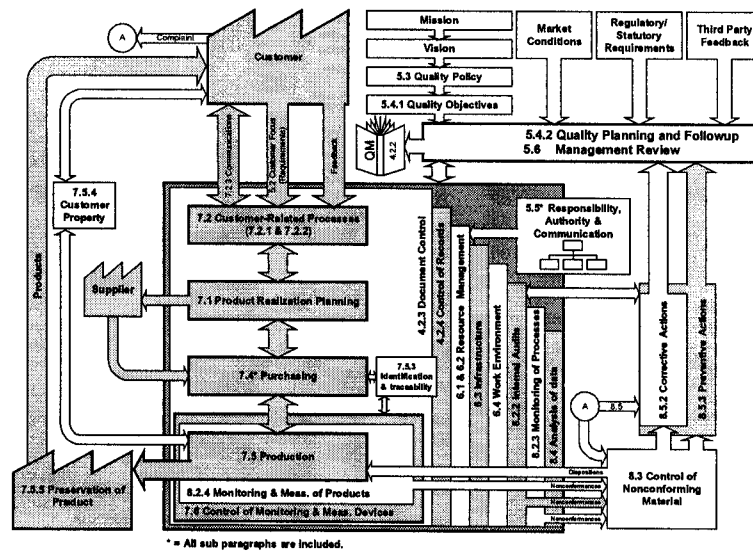


Figure 1: The Sequence and Interaction of The Quality Management System Processes

<sup>1</sup> Juran, Joseph M., Juran’s Quality Handbook, Fifth Edition, McGraw-Hill, 1999, p. 2.5



P.O. Box 609036, San Diego, CA 92160

Procedure:

**QM-1**

Revision:

**3**

Revised By:

**M.G. BLANKENSHIP**

Date:


**8/25/06**

Title:

**QUALITY MANAGEMENT SYSTEMS MANUAL**

**3. APPROVALS**

<b>APPROVED BY:</b>	<b>TITLE</b>	<b>DATE</b>
 N. C. Nordstrom	President	9/7/06
 P. A. Tremblay	Chief Financial Officer	9-5-06
 R. W. Hockman	Director, Sales and Marketing	9-5-06
 C. S. Frank	Director, Human Resources	9-5-06
 M. G. Blankenship	Director, Quality	9-3-06
 P. V. Lorenz	Director, Business Development	9/12/06
 J. W. Vance	Director, Product Development	9/7/06
 C. J. Hoehn	Director, Operations	9-8-06

 P.O. Box 609036, San Diego, CA 92160	Procedure: <b>QM-1</b>	Revision: <b>3</b>
	Revised By: <b>M.G. BLANKENSHIP</b>	Date: <b>8/25/06</b>
Title: <b>QUALITY MANAGEMENT SYSTEMS MANUAL</b>		

**DEFINITIONS:**

Top Management: Those individuals in the Veridiam organization serving in the office of President and Directors.

Process: A combination of activities that transforms inputs to outputs.

Quality Plan: Documents specifying the processes of the Quality Management System (including the product realization Processes) and the resources to be applied to a specific product, project or contract.

**4. QUALITY MANAGEMENT SYSTEM**

**4.1 General Requirements**

4.1.1 Veridiam has established, documented, implemented, and continues to maintain a Quality Management System (QMS). The effectiveness of the QMS is maintained in accordance with the following documents, hereafter are referred to as the “QMS Foundational Documents”.


4.1.2 Compliance of this Quality Systems Manual:

- a. ISO 9001-2000 “Quality Management System Requirements” (plain text)
- b. ISO 13485 rev 2003: “Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes”. (blue text)
- c. SAE AS 9100B: Quality Systems – Aerospace – Model for Quality Assurance in Design, Development, Production, Installation and Servicing.
- d. 10CFR 50: Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants.
- e. ASME NQA-1-2004: Quality Assurance Requirements for Nuclear Facility Applications.
- f. 10CFR21: Reporting of Defects and Noncompliance.

**4.2 Veridiam Quality Requirements:**

4.2.1 Identify the processes needed for the Quality Management System and their application throughout the organization;


4.2.2 Determine the sequence and interaction of these processes;

 P.O. Box 609036, San Diego, CA 92160	Procedure:	Revision:
	Revised By:	Date:
<b>QM-1</b>		<b>3</b>
<b>M.G. BLANKENSHIP</b>		<b>8/25/06</b>
Title:		
<b>QUALITY MANAGEMENT SYSTEMS MANUAL</b>		

- 4.2.3 Determine criteria and methods needed to ensure that both the operation and control of these processes are effective;
- 4.2.4 Ensure the availability of resources and information necessary to support the operation and monitoring of these processes;
- 4.2.5 Monitor, measure and analyzes these processes; and
- 4.2.6 Implement actions necessary to achieve planned results, continual improvement, and maintain the effectiveness of these processes.
- 4.2.7 Veridiam manages these processes in accordance with the requirements of the QMS Foundational Documents.
- 4.2.8 When Veridiam chooses to outsource any process that affects product conformity with requirements, Veridiam shall ensure control over such processes. Control of such outsource processes shall be identified within the Quality Management System.
- 4.2.9 NOTE: Processes needed for the Quality Management System referred to above include processes for management activities, provision of resources, product realization and measurement.

### **4.3 Documentation Requirements**

- 4.3.1 General: The Quality Management System documentation includes:
  - a. documented statements of a quality policy and quality objectives (ref. MSP 5.3);
  - b. this Quality Manual,
  - c. documented procedures required by the above referenced QMS Foundational Documents,
  - d. documents needed to ensure the effective planning, operation and control of processes,
  - e. records required by International Standard, and

 P.O. Box 609036, San Diego, CA 92160	Procedure:	Revision:
	Revised By:	Date:
<b>QM-1</b>		<b>3</b>
<b>M.G. BLANKENSHIP</b>		<b>8/25/06</b>
Title:		
<b>QUALITY MANAGEMENT SYSTEMS MANUAL</b>		


- f. any other documentation specified by national or regional regulations.
- g. Where any of the above referenced QMS Foundational Documents specifies that a requirement, procedure, activity or special arrangement be “documented”, it shall, in addition, be implemented and maintained.
- h. For each type or model of medical device, the organization shall establish and maintain a file either containing or identifying documents defining product specifications and Quality Management System requirements. These documents shall define the complete manufacturing process and, if applicable, installation and servicing.

#### **4.4 Quality Manual**

- 4.4.1 Veridiam has established and shall maintain a Quality Manual that includes:
  - a. the scope of the Quality Management System, including details of and justification for any exclusion and/or non-application;
  - b. the documented procedures established for the Quality Management System, or reference to them; and
  - c. a description of the interaction between the processes of the Quality Management System. This is accomplished within each section of this manual.
- 4.4.2 This Quality Manual outlines the structure of the documentation used in the Quality Management System in Appendix A.

#### **4.5 Control of documents**

- 4.5.1 Documents required by the Quality Management System shall be controlled in accordance with MSP 4.2. Records are a special type of document and shall be controlled according to the requirements given below.

 P.O. Box 609036, San Diego, CA 92160	Procedure:	Revision:
	Revised By:	Date:
Title:		
<b>QUALITY MANAGEMENT SYSTEMS MANUAL</b>		

4.5.2 MSP 4.2 defines the controls needed:

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


4.5.3 Veridiam shall ensure that changes to documents are reviewed and approved either by the original approving function or another designated function which has access to pertinent background information upon which to base its decisions.

4.5.4 Veridiam defines the period for which at least one copy of obsolete controlled documents shall be retained in IP 4.2.2. This period shall ensure that documents to which medical devices have been manufactured and tested are available for at least the lifetime of the medical device as defined by Veridiam, but not less than the retention period of any resulting record, or as specified by relevant regulatory requirements.

#### 4.6 Control of records

4.6.1 Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the Quality Management System.

4.6.2 Records shall remain legible, readily identifiable and retrievable. A documented procedure, AP 4.2.2A, is established to define the controls needed for the identification, storage, protection, retrieval, retention time,

 P.O. Box 609036, San Diego, CA 92160	Procedure:	Revision:
	Revised By:	Date:
<b>QM-1</b>		<b>3</b>
<b>M.G. BLANKENSHIP</b>		<b>8/25/06</b>
Title:  <p style="text-align: center;"><b>QUALITY MANAGEMENT SYSTEMS MANUAL</b></p>		

and disposition of records.

4.6.3 The organization shall retain the records for a period of time at least equivalent to the lifetime of the medical device as defined by the Veridiam, but not less than two years from the date of product release by Veridiam or as specified by relevant regulatory requirements.

4.6.4 Activities affecting Quality of products shall be prescribed by and performed in accordance with documented instructions (procedures, drawings, etc.), commensurate in detail with the complexity of the activity and the need to assure consistent and acceptable results. Management shall ensure that personnel have access to QMS documentation and are aware of relevant procedures. Customer and/or regulatory authority representatives shall have access to non-proprietary QMS documentation.

4.6.5 Records shall be available for review by customers and regulatory authorities in accordance with contract or regulatory requirements.

#### **4.7 Configuration Management (Ref. AS9100)**


4.7.1 Veridiam does not design products. Configuration management for processes and products is accomplished through the documentation control procedures referred to above; product realization procedures of Section 7; and monitoring and measurement processes of section 8.

### **5. MANAGEMENT RESPONSIBILITY**

#### **5.1 Management Commitment**

5.1.1 Top management shall provide evidence of its commitment to the development and implementation of the Quality Management System (see Appendix B for a representative organization chart) and maintain its effectiveness by:

- a. communicating to the Veridiam organization the importance of meeting customer as well as statutory and regulatory requirements,
- b. establishing the quality policy,
- c. ensuring that quality objectives are established,
- d. conducting management reviews,

 P.O. Box 609036, San Diego, CA 92160	Procedure:	Revision:
	Revised By:	Date:
<b>QM-1</b>		<b>3</b>
<b>M.G. BLANKENSHIP</b>		<b>8/25/06</b>
Title: <p style="text-align: center;"><b>QUALITY MANAGEMENT SYSTEMS MANUAL</b></p>		

- e. ensuring the availability of resources, and
- f. ensuring that those responsible for verifying Quality achievement have sufficient authority, direct access to management, organizational freedom, and access to work to perform their function.

## 5.2 Customer Focus


- 5.2.1 Top management shall ensure that customer requirements are determined and are met (see sections 7 and 8).

## 5.3 Quality policy

- 5.3.1 Top management shall ensure that the quality policy:
  - a. is appropriate to the purpose of Veridiam,
  - b. includes a commitment to comply with requirements, to continually improve, and to maintain the effectiveness of the Quality Management System,
  - c. provides a framework for establishing and reviewing quality objectives,
  - d. is communicated and understood within Veridiam, and
  - e. is reviewed for continuing suitability.
  - f. is based on customer focus,
  - g. is consistent with the Mission and Vision statements,

## 5.4 Planning

- 5.4.1 Quality objectives
  - a. Top management shall ensure that quality objectives, including those needed to meet requirements for product, are established at relevant functions and levels within Veridiam. The quality

 <b>Veridiam</b> P.O. Box 609036, San Diego, CA 92160	Procedure:	<b>QM-1</b>	Revision:	<b>3</b>
	Revised By:	<b>M.G. BLANKENSHIP</b>	Date:	<b>8/25/06</b>
Title: <b>QUALITY MANAGEMENT SYSTEMS MANUAL</b>				

objectives shall be measurable and consistent with the quality policy.

#### 5.4.2 Quality Management System planning

- a. Top management shall ensure that:
- b. the planning of the Quality Management System is carried out in order to meet the requirements given in section 4, as well as the quality objectives, and
- c. the integrity of the Quality Management System is maintained when changes to the Quality Management System are planned and implemented.

### 5.5 Responsibility, authority and communication

#### 5.5.1 Responsibility and authority

- a. Top management shall ensure that responsibilities and authorities are defined, documented and communicated within the organization. (Ref. MSP 5.1)
- b. Top management shall establish the interrelation of all personnel who manage, perform and verify work affecting quality, and shall ensure the independence and authority necessary to perform these tasks (Ref. Appendix B).

#### 5.5.2 Management representative: Top management appoints the Director of Quality, irrespective of other responsibilities, to have responsibility and authority that includes:

- a. ensuring that processes needed for the Quality Management System are established, implemented and maintained.
- b. reporting to top management on the performance of the Quality Management System and any need for improvement (see section 8), and



P.O. Box 609036, San Diego, CA 92160

Procedure:

**QM-1**

Revision:

**3**

Revised By:

**M.G. BLANKENSHIP**

Date:

**8/25/06**

Title:

**QUALITY MANAGEMENT SYSTEMS MANUAL**

- c. ensuring the promotion of awareness of regulatory and customer requirements throughout Veridiam.
- d. promoting awareness among Veridiam employees of the Quality Policy and the requirement for customer focus in all activities,
- e. organizational freedom to resolve matters pertaining to Quality, and
- f. serving as the Veridiam point of contact when liaison with external parties on matters relating to the QMS is required.

**5.5.3 Internal communication**

- a. Top management shall ensure that appropriate communication processes are established within Veridiam and that communication takes place regarding the effectiveness of the Quality Management System.


**5.6 Management review**

**5.6.1 General**

- a. Top management shall review the organization's Quality Management System, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the Quality Management System, including the quality policy and quality objectives.
- b. Records from management reviews shall be maintained (see section 4).

**5.6.2 Review input**

- a. The input to management review shall include information on:
- b. results of audits,
- c. customer feedback,

 P.O. Box 609036, San Diego, CA 92160	Procedure:	Revision:
	Revised By:	Date:
<b>QM-1</b>		<b>3</b>
M.G. BLANKENSHIP		8/25/06
Title:		
<b>QUALITY MANAGEMENT SYSTEMS MANUAL</b>		

- d. process performance and product conformity,
- e. status of preventive and corrective actions,
- f. follow-up actions from previous management reviews,
- g. changes that could affect the Quality Management System,
- h. recommendations for improvement, and
- i. new or revised regulatory requirements.

5.6.3 Review output

5.6.4 The output from the management review shall include any decisions and actions related to:


- a. improvements needed to maintain the effectiveness of the Quality Management System and its processes,
- b. improvement of product related to customer requirements, and
- c. resource needs.

**6. Resource management**

**6.1 Provision of resources**

6.1.1 Management shall determine and provide the resources needed:

- a. to implement the Quality Management System and to continually improve and maintain its effectiveness, and
- b. to meet regulatory and customer requirements.
- c. to achieve Veridiam business and quality objectives, and
- d. to enhance customer satisfaction, by meeting customer expectations.

 <b>Veridiam</b> P.O. Box 609036, San Diego, CA 92160	Procedure:	Revision:
	Revised By:	Date:
<b>QM-1</b>		<b>3</b>
<b>M.G. BLANKENSHIP</b>		<b>8/25/06</b>
Title:		
<b>QUALITY MANAGEMENT SYSTEMS MANUAL</b>		

## 6.2 Human resources

### 6.2.1 General

- a. Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.

### 6.2.2 Competence, awareness and training. Veridiam shall:

- a. determine the necessary competence for personnel performing work affecting product quality,
- b. provide training or take other actions to satisfy these needs,
- c. evaluate the effectiveness of the actions taken,
- d. ensure 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
- e. maintain appropriate records of education, training, skills and experience (see section 4).


## 6.3 Infrastructure

### 6.3.1 Veridiam shall determine the requirements for, provide, and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable:

- a. buildings, workspace and associated utilities,
- b. process equipment (both hardware and software), and
- c. supporting services (such as transport or communication)

### 6.3.2 Veridiam shall establish documented requirements for maintenance activities, including their frequency, when such activities or lack thereof can affect product quality.

### 6.3.3 Records of such maintenance shall be maintained (see section 4).

 P.O. Box 609036, San Diego, CA 92160	Procedure: <b>QM-1</b>	Revision: <b>3</b>
	Revised By: <b>M.G. BLANKENSHIP</b>	Date: <b>8/25/06</b>
Title: <b>QUALITY MANAGEMENT SYSTEMS MANUAL</b>		


## 6.4 Work environment

- 6.4.1 Veridiam shall determine the requirements for, and manage the work environment needed to achieve conformity to product requirements.
- 6.4.2 Furthermore, Veridiam shall maintain in a safe and efficient work environment for its employees in that the following requirements shall apply:
- a. Veridiam shall establish documented requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could adversely affect the quality of the product.
  - b. Where the work environment conditions can have an adverse effect on product quality, Veridiam shall establish documented requirements for the work environment conditions and documented procedures or work instructions to monitor and control these work environment conditions. Factors to be considered include temperature, humidity, lighting, cleanliness, protection from electrostatic discharge, etc.
  - c. Veridiam shall ensure that all personnel who are required to work temporarily under special environmental conditions within the work environment are appropriately trained or supervised by a trained person.
  - d. If appropriate, special arrangements shall be established and documented for the control of contaminated or potentially contaminated product in order to prevent contamination of other product, the work environment, or personnel.

## 7. Product realization

### 7.1 Planning of product realization

- 7.1.1 Veridiam shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the Quality Management System (see section 4).

 P.O. Box 609036, San Diego, CA 92160	Procedure: <b>QM-1</b>	Revision: <b>3</b>
	Revised By: <b>M.G. BLANKENSHIP</b>	Date: <b>8/25/06</b>
Title:  <p style="text-align: center;"><b>QUALITY MANAGEMENT SYSTEMS MANUAL</b></p>		

7.1.2 In planning product realization, Veridiam shall determine the following, as appropriate:

- a. quality objectives and requirements for the product;
- b. the need to establish processes, documents, and provide resources specific to the product;
- c. required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;
- d. records needed to provide evidence that the realization processes and resulting product meet requirements (see section 4).


7.1.3 The output of this planning shall be in a form suitable for Veridiam's method of operations.

7.1.4 Risk Management: As Veridiam does not perform any product design, risk management as defined in ISO 13485:2003E does not apply.

## 7.2 Customer-related processes

7.2.1 Veridiam shall review the requirements related to the product. This review shall be conducted prior to the Veridiam's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that the following are performed and documented:

- a. requirements specified by the customer, including product requirements, the requirements for delivery and post-delivery activities are defined,
- b. regulatory requirements are defined,
- c. requirements not stated by the customer but necessary for specified or intended use, where known,

 P.O. Box 609036, San Diego, CA 92160	Procedure: <b>QM-1</b>	Revision: <b>3</b>
	Revised By: <b>M.G. BLANKENSHIP</b>	Date: <b>8/25/06</b>
Title:  <p style="text-align: center;"><b>QUALITY MANAGEMENT SYSTEMS MANUAL</b></p>		

- d. contract or order requirements differing from those previously expressed are resolved, and
- e. Veridiam has the ability to meet the defined requirements.

7.2.2 Records of the results of the review and actions arising from the review shall be maintained (see section 4).

7.2.3 Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.

7.2.4 Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

7.2.5 NOTE: In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material etc as appropriate.


### 7.3 Customer communication

7.3.1 Veridiam shall determine and implement effective arrangements for communicating with customers in relation to:

- a. product information,
- b. inquiries, contracts or order handling, including amendments,
- c. customer feedback, including customer complaints (see section 8), and,
- d. advisory notices (see section 8).

### 7.4 Design and development

7.4.1 THIS SECTION IS NOT APPLICABLE. Veridiam neither designs nor develops products as defined in ISO 9001:2000 and ISO 13485:2003. All products manufactured by Veridiam are to customer designs and

 P.O. Box 609036, San Diego, CA 92160	Procedure: <b>QM-1</b>	Revision: <b>3</b>
	Revised By: <b>M.G. BLANKENSHIP</b>	Date: <b>8/25/06</b>
Title: <b>QUALITY MANAGEMENT SYSTEMS MANUAL</b>		

specifications.

## 7.5 Purchasing

### 7.5.1 Purchasing process


- a. The organization shall establish documented procedures to ensure that purchased product conforms to specified purchase requirements.
- b. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.
- c. The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained.

### 7.5.2 Purchasing information

7.5.3 Purchasing information shall describe the product to be purchased, including where appropriate:

- a. requirements for approval of product, procedures, processes and equipment,
- b. requirements for qualification of personnel, and
- c. Quality Management System requirements.
- d. The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.
- e. To the extent required for traceability, the organization shall maintain relevant purchasing information.

### 7.5.4 Verification of purchased product

 P.O. Box 609036, San Diego, CA 92160	Procedure: <b>QM-1</b>	Revision: <b>3</b>
	Revised By: <b>M.G. BLANKENSHIP</b>	Date: <b>8/25/06</b>
Title:  <p style="text-align: center;"><b>QUALITY MANAGEMENT SYSTEMS MANUAL</b></p>		


- a. The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.
- b. Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.
- c. Records of the verification shall be maintained.

## 7.6 Production

7.6.1 Note: As Veridiam does not perform product service, there are no requirements for "service provision".

7.6.2 Control of production. General requirements

- a. Veridiam shall plan and carry out production and service provision under controlled conditions.
- b. Controlled conditions shall include, as applicable:
- c. the availability of information that describes the characteristics of the product,
- d. the availability of documented procedures, documented requirements, work instructions, and reference materials and reference measurement procedures as necessary,
- e. the use of suitable equipment,
- f. the availability and use of monitoring and measuring devices,
- g. the implementation of monitoring and measurement,
- h. the implementation of release, delivery and post-delivery activities, and

 P.O. Box 609036, San Diego, CA 92160	Procedure: <b>QM-1</b>	Revision: <b>3</b>
	Revised By: <b>M.G. BLANKENSHIP</b>	Date: <b>8/25/06</b>
Title: <b>QUALITY MANAGEMENT SYSTEMS MANUAL</b>		

- i. the implementation of defined operations for labeling and packaging.
- j. Veridium shall establish and maintain a record for each batch of that provides traceability and identifies the amount manufactured and amount approved for distribution. The batch record shall be verified and approved.
- k. NOTE: A batch can be a single device or part.

7.6.3 Control of production — Specific requirements

- a. Cleanliness of Product and Contamination Control
  - i. The organization shall establish documented requirements for cleanliness to meet customer or regulatory requirements.
- b. Installation Activities
  - i. ISO 13485 para 7.5.1.2.2 does not apply as Veridium does not produce products requiring installation.
- c. Servicing Activities
  - i. ISO 13485 para 7.5.1.2.3 does not apply as Veridium does not perform servicing activities.
- d. Particular requirements for sterile medical devices
  - i. ISO 13485 para 7.5.1.3 does not apply as Veridium does not perform sterilization activities.

7.6.4 **Validation** of processes for production. General requirements:

- a. The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the



**Veridiam**

P.O. Box 609036, San Diego, CA 92160

Procedure:

**QM-1**

Revision:

**3**

Revised By:

**M.G. BLANKENSHIP**

Date:

**8/25/06**

Title:


**QUALITY MANAGEMENT SYSTEMS MANUAL**

product is in use or the service has been delivered.

- b. Validation shall demonstrate the ability of these processes to achieve planned results.
- c. The organization shall establish arrangements for these processes including, as applicable
  - i. defined criteria for review and approval of the processes,
  - ii. approval of equipment and qualification of personnel,
  - iii. use of specific methods and procedures,
  - iv. requirements for records (see section 4), and
  - v. revalidation.
- d. The organization shall establish documented procedures for the validation of the application of computer software (and changes to such software and/or its application) for production that affect the ability of the product to conform to specified requirements. Such software applications shall be validated prior to initial use.
- e. Records of validation shall be maintained (see section 4).

**7.6.5 Particular requirements for sterile medical devices**

- a. ISO 13485 para 7.5.2.2 does not apply as Veridiam does not perform sterilization activities.

 P.O. Box 609036, San Diego, CA 92160	Procedure:	Revision:
	Revised By:	Date:
<b>QM-1</b>		<b>3</b>
M.G. BLANKENSHIP		<b>8/25/06</b>
Title:		
<b>QUALITY MANAGEMENT SYSTEMS MANUAL</b>		

7.6.6 Identification and traceability


- a. Identification
- b. Veridiam shall identify the product by suitable means throughout product realization, and shall establish documented procedures for such product identification.
- c. Veridiam shall establish documented procedures to ensure that medical devices returned to the organization are identified and distinguished from conforming product.

7.6.7 Traceability

- a. General
- b. Veridiam shall establish documented procedures for traceability. Such procedures shall define the extent of product traceability and the records required.
- c. Where traceability is a requirement, Veridiam shall control and record the unique identification of the product.
- d. NOTE: Configuration management at Veridiam is a means by which identification and traceability can be maintained.

7.6.8 Particular requirements for active implantable medical devices and implantable medical devices.

- a. In defining the records required for traceability, Veridiam shall include records of all components, materials and work environment conditions, if these could cause the medical device not to satisfy its specified requirements.
- b. Requirements in ISO 13485 para 7.5.3.2.2 pertaining to agents and distributors and consignees do not apply as Veridiam does not have agents, distributors or consignees for implantable medical devices.

 P.O. Box 609036, San Diego, CA 92160	Procedure:	Revision:
	Revised By:	Date:
<b>QM-1</b>		<b>3</b>
<b>M.G. BLANKENSHIP</b>		<b>8/25/06</b>
Title:		
<b>QUALITY MANAGEMENT SYSTEMS MANUAL</b>		

7.6.9 Status identification.

- a. The organization shall identify the product status with respect to monitoring and measurement requirements.
- b. The identification of product status shall be maintained throughout production, storage, installation and servicing of the product to ensure that only product that has passed the required inspections and tests (or released under an authorized concession) is dispatched, used or installed.

7.6.10 Customer property


- a. The organization shall exercise care with customer property while it is under the organization's control or being used by the organization.

The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained.

- b. NOTE: Customer property can include intellectual property or confidential health information.


7.6.11 Preservation of product

- a. The organization shall establish documented procedures or documented work instructions for preserving the conformity of product during internal processing and delivery to the intended destination.
- b. This preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.
- c. The organization shall establish documented procedures or documented work instructions for the control of product with a limited shelf-life or requiring special storage conditions. Such special storage conditions shall be controlled and recorded.

 P.O. Box 609036, San Diego, CA 92160	Procedure: <b>QM-1</b>	Revision: <b>3</b>
	Revised By: <b>M.G. BLANKENSHIP</b>	Date: <b>8/25/06</b>
Title:  <p style="text-align: center;"><b>QUALITY MANAGEMENT SYSTEMS MANUAL</b></p>		

**7.7 Control of monitoring and measuring devices**

- 7.7.1 The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see section 7).
- 7.7.2 The organization shall establish documented procedures to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.
- 7.7.3 Where necessary to ensure valid results, measuring equipment shall
  - a. be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded;
  - b. be adjusted or re-adjusted as necessary;
  - c. be identified to enable the calibration status to be determined;
  - d. be safeguarded from adjustments that would invalidate the measurement result;
  - e. be protected from damage and deterioration during handling, maintenance and storage.
- 7.7.4 In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained.
- 7.7.5 When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

 <b>Veridiam</b> P.O. Box 609036, San Diego, CA 92160	Procedure: <b>QM-1</b>	Revision: <b>3</b>
	Revised By: <b>M.G. BLANKENSHIP</b>	Date: <b>8/25/06</b>
Title: <b>QUALITY MANAGEMENT SYSTEMS MANUAL</b>		

## **8. MEASUREMENT, ANALYSIS AND IMPROVEMENT**

### **8.1 General**

8.1.1 Monitoring, measurement, analysis and improvement processes shall be implemented to

- a. demonstrate conformity of products,
- b. ensure conformity of the Quality Management System (QMS), and
- c. continually improve the effectiveness of the QMS.

### **8.2 Monitoring and Measurement**

#### 8.2.1 Feedback


- a. Veridiam shall monitor information relating to whether it has met customer requirements. Veridiam shall establish a documented procedure for a feedback system to provide early warning of quality problems and for input into the corrective and preventive action processes.

#### 8.2.2 Customer satisfaction

- a. As one of the measurements of the performance of the QMS, Sales shall monitor information relating to customer perception as to whether Veridiam has met customer requirements, and take action as appropriate.

#### 8.2.3 Internal audits

- a. Veridiam shall conduct internal audits at planned intervals to determine whether the QMS is consistent with applicable external requirements, and whether it is being effectively implemented. Qualified auditors shall audit all elements of the QMS at a frequency commensurate with their influence on customer satisfaction. Discrepancies shall be identified for prompt

 P.O. Box 609036, San Diego, CA 92160	Procedure: <b>QM-1</b>	Revision: <b>3</b>
	Revised By: <b>M.G. BLANKENSHIP</b>	Date: <b>8/25/06</b>
Title:  <p style="text-align: center;"><b>QUALITY MANAGEMENT SYSTEMS MANUAL</b></p>		

correction, and for follow-up to ensure effectiveness of actions taken.

#### 8.2.4 Monitoring and measurement of processes


- a. Managers responsible for specific QMS processes shall apply suitable methods for monitoring and, where applicable, measurement of those processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, remedial and corrective action shall be taken, as appropriate, to ensure no adverse effects on the conformity of products.

#### 8.2.5 Monitoring and measurement of product

- a. Active measures shall be taken to monitor and measure the characteristics of the product to verify that product requirements have been met. Planning and work instructions shall ensure that this is carried out at appropriate stages of the product realization process and is completed before the product is released for shipment. Product shipped to customers must conform to the customer's requirements. Records of actions taken to confirm conformity with the acceptance criteria shall be maintained.

### 8.3 Control of Nonconforming Product

- 8.3.1 Veridiam will not knowingly ship nonconforming products to customers without their consent. Actions will be taken to ensure that product which 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, and also with nonconforming material received from vendors, are provided in MSP 8.3. (NOTE: The term "nonconforming product" includes nonconforming product returned from a customer).
- 8.3.2 Nonconforming material shall be separated from conforming material physically and/or by clear marking or labeling, to ensure that no confusion is possible regarding the status of the material.
- 8.3.3 Responsibility for review, authority for disposition of nonconforming product, and the process for approving personnel making these decisions

 P.O. Box 609036, San Diego, CA 92160	Procedure: <p style="text-align: center;"><b>QM-1</b></p>	Revision: <p style="text-align: center;"><b>3</b></p>
	Revised By: <p style="text-align: center;"><b>M.G. BLANKENSHIP</b></p>	Date: <p style="text-align: center;"><b>8/25/06</b></p>
Title: <p style="text-align: center;"><b>QUALITY MANAGEMENT SYSTEMS MANUAL</b></p>		

are addressed in MSP 8.3 and subordinate documents.

- 8.3.4 Veridium shall not ship nonconforming product that has been dispositioned as “use-as-is” or “repair”, unless specifically authorized by the customer.
- 8.3.5 When nonconforming product is detected after delivery or use has started, Veridium shall take action appropriate to the effects, or potential effects, of the nonconformity, (including possible issuance of an Advisory Notice for medical products).
- 8.3.6 In addition to any contract or regulatory authority reporting requirements, Veridium shall provide for timely reporting of delivered nonconforming product that may affect reliability or safety, and shall comply with the requirements of 10CFR21 for nuclear products and with FDA Advisory Notice requirements for medical products. Notification shall include a clear description of the nonconformity, which includes as necessary parts affected, customer and/or organization part numbers, quantity, and dates(s) delivered. Parties requiring notification of nonconforming product may include suppliers, internal organizations, customers, distributors, and regulatory authorities.

**8.4 Analysis of Data**

- 8.4.1 Management shall determine which data should be collected to demonstrate the suitability and effectiveness of the QMS, and to evaluate where continual improvement of its effectiveness can be made. This shall include data generated as a result of monitoring and measurement, and from other relevant sources. This data shall be made available for ongoing review and analysis, to provide information relating to
  - a. customer satisfaction,



**Veridiam**  
P.O. Box 609036, San Diego, CA 92160

Procedure:

**QM-1**

Revision:

**3**

Revised By:

**M.G. BLANKENSHIP**

Date:

**8/25/06**

Title:

**QUALITY MANAGEMENT SYSTEMS MANUAL**

- b. customer complaints,
- c. conformity to product requirements,
- d. characteristics and trends of processes and products including opportunities for preventive action, and
- e. performance and reliability of suppliers
- f. other feedback.

**8.5 Improvement**

8.5.1 Continual improvement

8.5.2 Veridiam shall continually improve the effectiveness of the QMS through the implementation of a Quality Policy and Quality Objectives; collection and analysis of performance data (internal and external); and actions resulting from management review of the data. Actions directed by management will be augmented and supported by an ongoing program of corrective and preventive actions, initiated and executed at all levels of the company.

8.5.3 Veridiam shall establish documented procedures for the issue and implementation of advisory notices. These procedures shall be capable of being implemented at any time (Ref AP 8.5.1b).

8.5.4 Corrective action

8.5.5 Systematic action shall be taken to eliminate the cause of deficiencies in implementation of the QMS, in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the deficiencies encountered. Procedures regarding corrective actions shall be documented.

8.5.6 Preventive action



**Veridiam**  
P.O. Box 609036, San Diego, CA 92160

Procedure:  
**QM-1**

Revision:  
**3**


Revised By:  
**M.G. BLANKENSHIP**

Date:  
**8/25/06**

Title:

**QUALITY MANAGEMENT SYSTEMS MANUAL**

- a. Managers and employees shall vigorously work to eliminate the potential sources of nonconformances or failure to effectively implement the QMS, including:
  - i. poor communication of requirements;
  - ii. inadequate or poorly executed processes; and
  - iii. inadequate or poorly maintained facilities.
- b. Programs that help to eliminate sources of problems include process qualifications, process control, configuration control, training and preventive maintenance.
- c. Preventive actions shall be appropriate to the effects of the potential problems. For preventive actions that cannot be taken immediately, a documented system for managing them will be implemented.

 <b>Veridiam</b> P.O. Box 609036, San Diego, CA 92160	Procedure: <b>QM-1</b>	Revision: <b>3</b>
	Revised By: <b>M.G. BLANKENSHIP</b>	Date: <b>8/25/06</b>
Title: <b>QUALITY MANAGEMENT SYSTEMS MANUAL</b>		

## APPENDIX A

### **- Structure of the Documentation Used in the Quality Management System -**

Documents which describe the Quality Management System, listed below in order of precedence:

#### **Quality Manual (QM)**

The Quality Manual (QM) is structured to include the requirements of the Foundational Documents (ref section 4) in the applicable section of the manual. The section and paragraph numbers are formatted to parallel ISO 13485 (which also parallels ISO 9001:2000). The QM describes the policy requirement that Veridiam, as an organization, is to meet.

#### **Management System Procedures (MSP)**

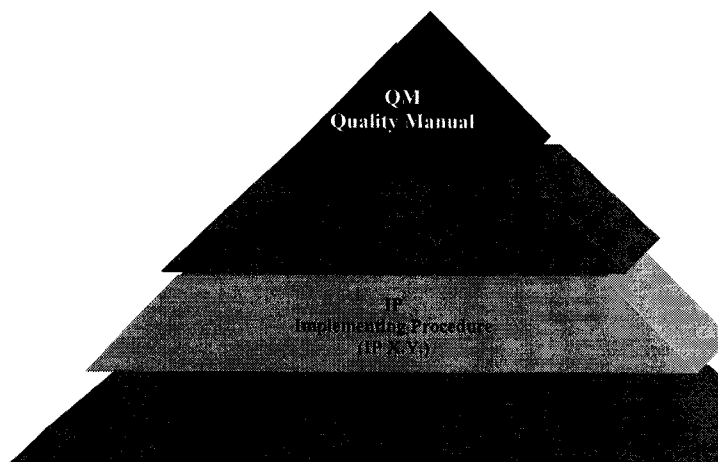
A second-tier of documentation, called Management System Procedures (MSP) elaborates on the policy addressed in the Quality Manual. MSP's discuss further details for meeting requirements and, for simple processes, how a requirement will be met. The MSP's carry the first two digits of the paragraph number from the Quality Manual. Successive MSP's are sequentially numbers.

#### **Implementing Procedures (IP)**

Implementing Procedures (IP) are the third-tier of documentation. These procedures address how a requirement will be met at Veridiam. The IP's carry the first two digits of the paragraph number from the QM. Successive IPs are sequentially numbers.

#### **Amplifying Procedures (AP)**

Amplifying Procedures (AP) are the fourth-tier of documentation. The AP addressed details of how Quality System requirements are met. The APs carries the three numbers from the IP it is detailing, and then sequentially letters each AP.



- Figure A1 -  
QMS Procedure Pyramid

#### **Process Document and Other Documents**

Process Document and other documents are exclusively numbered, and are controlled per the requirements of this manual. Such document include, but not limited to:

1. Document concerning procurement, identification, manufacturing, inspection, preservation, maintenance, personnel training, and personnel qualifications and certifications.



**Veridiam**  
P.O. Box 609036, San Diego, CA 92160

Procedure:  
**QM-1**

Revision:  
**3**

Revised By:  
**M.G. BLANKENSHIP**

Date:  
**8/25/06**

Title:

**QUALITY MANAGEMENT SYSTEMS MANUAL**

2. Documents provided by customers to provide requirements and guidance for supplier systems, processes, and products.
3. Regulatory and industry standards and specifications.

**SECOND-TIER DOCUMENTS REQUIRED TO IMPLEMENT THE QUALITY MANUAL**

<b>MSP NO.</b>	<b>TITLE</b>	<b>RESPONSIBLE MANAGER</b>
4.2	Documentation Requirements	Director - Quality
5.1	Veridiam Organization	President
5.3	Quality Policy	President
5.6	Quality Planning and Follow up	President
6.2	Human Resource Requirements	Director - Human Resources
6.3	Infrastructure	Director - Quality
7.1	Planning of Product Realization	Director - Product Development
7.2	Customer-related processes	Director - Sales and Marketing
7.4	Purchasing	Chief Financial Officer
7.5	Manufacturing	Director - Operations
7.6	Control of Monitoring and Measurement Devices	Director - Quality
8.2	Monitoring and Measurement	Director - Quality
8.3	Control of Nonconforming Product	Director - Operations
8.5	Improvement	Director - Quality



**Veridiam**  
P.O. Box 609036, San Diego, CA 92160

Procedure:

**QM-1**

Revision:

**3**

Revised By:

**M.G. BLANKENSHIP**

Date:

**8/25/06**

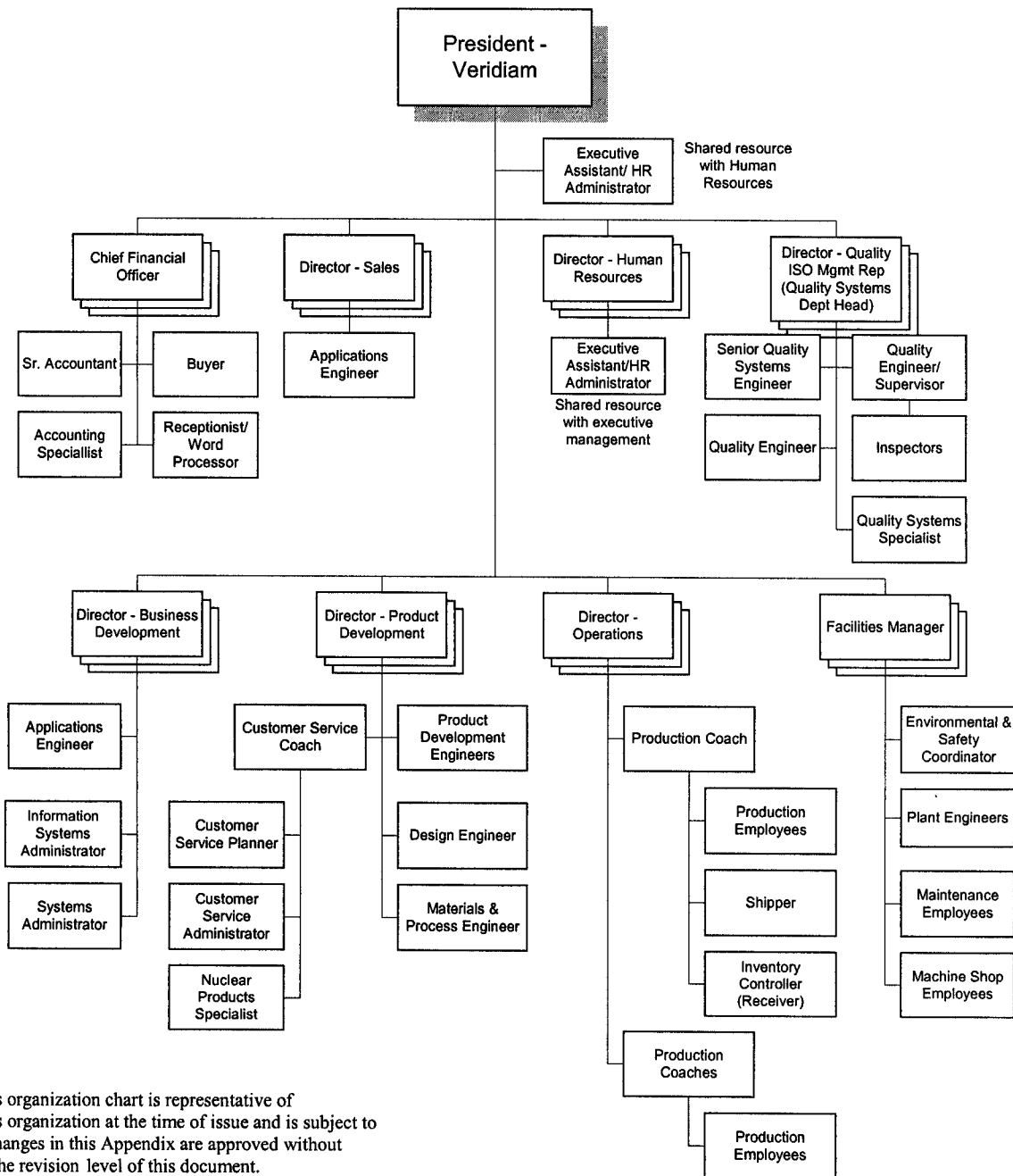
Title:


**QUALITY MANAGEMENT SYSTEMS MANUAL**

**APPENDIX B**

**Veridiam's Organization Chart**

For more information on the organizational layout, reference MSP 5.1.



 P.O. Box 609036, San Diego, CA 92160	Procedure: <b>QM-1</b>	Revision: <b>3</b>
	Revised By: <b>M.G. BLANKENSHIP</b>	Date: <b>8/25/06</b>
Title: <b>QUALITY MANAGEMENT SYSTEMS MANUAL</b>		

### APPENDIX C

#### **Manufacturing, Inspection, Testing, and Laboratory Processes at Veridium**

The following list includes processes performed at Veridium. This list is subject to change. Changes in this Appendix are approved without changing the revision level of this document.

#### **Manufacturing Process**

- 6 Roll Tube Straightener
- Abrasive Conditioning
- Abrasive Cutoff Saw
- Annealing
- Brake Press Forming
- Circumferential Welding
- Cleaning (Vertical and Horizontal Baths, Hand Cleaning including Acetone, DI water, Dry Wipe)
- Drawing Operation (Rod Draw, Plug Draw, Sinking)
- Electrically Heated Autoclave
- Electrolytic Saw
- Face Milling (Mega Mill)
- Hand and Automatic Surface Conditioning
- Hand Straightening
- Heat Treating (Hydrogen Bright Anneal Continuous Furnace, Vacuum H.T. in Retort, H.T. to increase magnetic permeability)
- Hone
- Laser (YAG) Welding
- Oxalate
- Packaging
- Part Marking and Identification (Ink Stamp, Ink Jet, Etch, and Engraving)
- Pointing for Drawing Preparation
- Precipitation Hardening
- Receiving
- Retort Furnace
- Screw Deformation
- Sheet Metal Bending/Forming
- Sheet Metal Shearing
- Silver Recovery (X-ray Film)
- Solid Bars Straightening
- Storage



**Veridium**  
P.O. Box 609036, San Diego, CA 92160

Procedure:

**QM-1**

Revision:

**3**

Revised By:

**M.G. BLANKENSHIP**

Date:

**8/25/06**

Title:

**QUALITY MANAGEMENT SYSTEMS MANUAL**

- Stretch Straightening Tubular Product
- Strip Stock Rolling
- Surface Conditioning (Wet Polishing)
- T.I.G. Semi-Automatic Machine Tube Welding
- Tube Trim
- Turbhead Forming
- Vacuum Furnace Operations
- Vapor Blast
- Welded Tube Manufacturing
- Whizzy Straightener for Small Diameter Tubes

**Inspection, Testing and Laboratory Process**

- A.C. Magnetic Testing
- Alloy Check Analysis by X-Ray Fluorescence (Portaspec)
- Calibration
- CMM (Zeiss and Mycrona)
- Corrosion Testing
- DC Testing of Soft Magnetic Materials
- Determining Residual Chloride and Fluoride
- Dimensional Air Gaging
- Dimensional Inspection
- Eddy Current Inspection
- Hardness Testing (Macro and Micro)
- Hydraulic Pressure Test Bench
- Hydrostatic Pressure Testing
- Intergranular Attack Test
- Laboratory Weld Test
- Liquid Penetrant Inspection
- Magnetic Particle Inspection
- Metallographic Preparation
- Radiographic Inspection (X-Ray)
- Stress Corrosion Cracking Resistance Test
- Stress Tang Preparation and Measurement
- Surface Roughness Inspection
- Titration
- Ultrasonic Contact Testing
- Ultrasonic Inspection (Round Tube Flaw, Weld Flaw, Material Thickness)
- Visual Inspection