Veridiam

QUALITY MANAGEMENT SYSTEMS MANUAL

QM-1

Revision 12

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QUALITY MANAGEMENT SYSTEMS MANUAL

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0.0 Revision History

Paragraph	Description of changes	Rev.	Date
	See historic files for revisions 1-7	8	12/7/2013
1.1.2	Removed reference to Oceanside and Supplement 2		
2.0	Updated job titles and responsibilities		
7.1.1	Added description of project management		
7.1.3	Added “Configuration Management” section		
7.1.4	Added description of work transfers		
7.4	Added section j regarding commercial grade dedication		
7.5.1.1	Added “Production Process Verification” section		
7.5.1.1 - 7.5.1.6	Renumbered section accordingly		
7.5.1.4	Added “Veridiam excludes section 7.5.1.4 Post-Delivery Support for AS9100C.”		
8.2.2	Added “… and consideration of customer contractual requirements.”		
Appendix B	Removed reference to CQP and QSP and Oceanside		
Appendix C	Updated Org Chart, added reference to HR0030		
Appendix D	Updated titles		
1.2.2e	Changed “NQA-1-2008” to “NQA-1a-2009”.	9	8/22/14
1.2.2f	Added section for “NQA-1-1994”.		
7.4.1j	Corrected typo to read “…current ASL listing as nuclear safety-related or an approved commercial grade dedication process…”		

Appendix C	Updated Veridiam Organizational chart		
Appendix D	Added Director of Engineering and Director of Quality positions		
2.2.2 e	Corrected format reference to NQA-1 2008:2009a	10	3/17/15
	Updated signature page with current names and titles Updated references to Operations to Manufacturing		
Appendix D 2.8	Updated Quality Director position description to include responsibility as Veridiam's Management Representative		
2.2.3 2.2.4 Figure 1 Appendix C Appendix D	Revised QMS Exclusion statement details Corrected type and formatting of process interactions Update Appendices to current organization structure Update Org responsibility descriptions to align with current organization structure	11	1/15/16
All	Complete rewrite of QMS to comply with latest revision of ISO9001:20015 and AS9100D. ISO13485:2016 requirements were also included. Cross reference of ISO13485 clauses vs ISO9001 & AS9100 are included in QM Supplement.	12	11/3/17

1.0 Purpose

1.1 This document has been prepared to describe the Quality Management System in place at Veridiam. It provides policy and guidelines for all processes related to product provided by Veridiam El Cajon to its customers.

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, AS9100 and ISO 13485. While this Quality Management Systems Manual is referred to as the "Quality Manual", the details for implementation of policies and guidelines are provided in lower tiered documents such as procedures and work instructions.

1.3 Separate document, QM-1 Supplement, lists lower tiered documents associated with the applicable sections of this Quality Manual and correlation between different international standards. The supplemental document may be revised independently of this Quality Manual.

2.0 Scope

2.1 This manual is prepared for the purpose of defining the company's interpretations of the AS9100 Rev. D, ISO9001:2015, ISO 13485:2016 international standards and others that may apply, as well as to demonstrate how the company complies with these standards.

3.0 Terms and Definitions

Veridiam adopts the following terms and definitions within its Quality Management System. Where no definition is provided, the company typically adopts the definitions provided in *ISO 9000: Quality Management – Fundamentals and Vocabulary* .In some cases, specific procedures or documentation may provide a different definition to be used in the context of that document; in such cases, the definition will supersede those provided for in this Quality Manual or the referenced definition sources.

General Terminology

Veridiam – Veridiam Inc.

Document – written information used to describe how an activity is done.

Record – captured evidence of an activity having been done.

Advisory Notice: A notice issued by the organization subsequent to the delivery of a medical device. An advisory notice provides information regarding the use or modification of the medical device, the return of the medical device to the organization, or the destruction of the medical device.

Critical items: Items that have a significant effect on the product realization and use of the product, including safety, performance, fit, function, producibility, and service life; all which may require specific actions to ensure they are adequately managed.

Key Characteristic: An attribute or feature whose variation has a significant impact on product fit, form, function, performance, service life, or producibility, and requires specific actions for the purpose of controlling variation.

Medical Device: Any instrument, apparatus, implement, machine, appliance, implant intended to be used alone or in combination, for human beings for one or more of the following purposes:

a. Diagnosis, prevention, monitoring, treatment or alleviation of disease

b. Diagnosis, monitoring, treatment, alleviation of or compensation of an injury

c. Investigation, replacement, modification, or support of the anatomy of a physiological process

d. Support or sustain life

e. Control of conception

f. Disinfection of medical devices

g. Provide information for medical purposes by means of in vitro examination of specimens derived from the human body.

Special Requirements: Those requirements identified by the customer or determined by the organization to have high risks to being achieved. Such requirements are typically subject to the risk management process.

Risk-Based Thinking Terminology

Risk – Negative effect of uncertainty

Opportunity – Positive effect of uncertainty

Uncertainty - A deficiency of information related to understanding or knowledge of an event, its consequence, or likelihood. (Not to be confused with measurement uncertainty.)

Nonconforming Product Terminology

Rework: Efforts to bring nonconforming product into conformance through additional operations that *do not* alter the original design of the product.

Repair: Efforts to bring nonconforming product into conformance through additional operations that alter the original design of the product; this may be through the addition of material not specified in the original design, or through altering pre-existing design features.

Scrap: The discard of nonconforming product in lieu of rework or repair.

4.0 Context of the Organization

4.1 Understanding the Organization and Its Context

Veridiam has reviewed and analyzed key aspects of itself and its stakeholders to determine the strategic direction of the company. This requires understanding internal and external issues that are of concern to Veridiam and its interested parties (per 4.2 below); the interested parties are identified and documented.

Such issues are monitored and updated as appropriate, and discussed as part of management reviews.

4.2 Understanding the Needs and Expectations of Interested Parties

The issues determined per 4.1 above are identified through an analysis of risks facing Veridiam and its interested parties. “Interested parties” are those stakeholders who receive our Products, or who may be impacted by them, or those parties who may otherwise have a significant interest in our company.

This information is then used by Top management to determine the company’s strategic direction. This is defined in records of management review, and periodically updated as conditions and situations change.

4.3 Determining the Scope of the Quality Management System

Based on an analysis of the above issues of concern, interests of stakeholders, and in consideration of its products and services, Veridiam has determined the scope of the management system as follows:

	Veridiam El Cajon
ISO9001/AS9100	Contract Manufacturing of Components and Assemblies of Specialty Metal Products.
ISO 13485	Contract Manufacturing of components, cannula, tubes and assemblies for use in medical and dental devices.

The Quality System applies to all processes, activities, and employees of the following locations within the company:

Veridiam El Cajon
1717 North Cuyamaca Street
El Cajon, CA 92020-1110
Tel: (619) 448-1000
Fax: (619) 562-5776
Email: sales@veridiam.com

The following clauses of the standards indicated below, were determined to be not applicable to Veridiam

Table 1 – List of Applicable Exclusions

Item #	Standard	Section	Rationale
1	ISO9001 AS9100D	8.3 Design and Development of Products and Services	Not a designing facility
2		8.5.5 Post Delivery Activities. f, g, h,i	Processes not performed at Veridiam
3	ISO 13485:2016	7.3 Design and Development	Not a designing facility
4		7.5.3 Installation activities	Processes not performed at Veridiam
5		Sterilization activities: 7.5.2 Cleanliness of Product a), 7.5.5 Particular requirements for sterile medical devices 7.5.7 Particular Requirements for validation of processes for sterilization and sterile barrier systems.	Processes not performed at Veridiam
6		7.5.3 Installation activities	Processes not performed at Veridiam
7		7.5.4 Servicing activities	Processes not performed at Veridiam

4.4 Quality Management System and Its Processes

4.4.1 Process Identification

Veridiam has adopted a process approach for its management system. By identifying the top-level processes within the company, and then managing each of these discretely, this reduces the potential for nonconforming products discovered during final processes or after delivery. Instead, nonconformities and risks are identified in real time, by actions taken within each of the top-level processes.

The following top-level processes have been identified for Veridiam:

- Customer Focus (5.1.2)
- Purchasing (8.4)
- Production (8.5)

Each process may be supported by other activities, such as tasks or sub-processes. Monitoring and control of top level processes ensures effective implementation and control of all subordinate tasks or sub-processes.

Each top-level process has a Process Effectiveness Assessment Report (PEAR) documented which defines:

- applicable inputs and outputs
- process owner(s)
- applicable responsibilities and authorities
- applicable risks and opportunities
- critical and supporting resources
- criteria and methods employed to ensure the effectiveness of the process
- quality objectives related to that process

The sequence of interaction of these processes is illustrated in Appendix A.

4.4.2 Process Controls & Objectives

Each process has at least one objective established for it; this is a statement of the intent of the process. Each objective is then supported by at least one "metric" or key performance indicator (KPI) which is then measured to determine the process' ability to meet the quality objective.

Throughout the year, metrics data is measured and gathered by process owners or other assigned managers, in order to present the data to Top Management. The data is then analyzed in order that Top Management may set goals and make adjustments for the purposes of long-term continual improvement.

The specific quality objectives for each process are defined in the applicable procedure.

Metrics, along with current standings and goals for each objective, are recorded in records of management review.

When a process does not meet a goal, or an unexpected problem is encountered with a process, the corrective and preventive action process is implemented to research and resolve the issue. In addition, opportunities for improvement are sought and implemented, for the identified processes.

4.4.3 Outsourced Processes

Any process performed by a third party is considered an "outsourced process" and must be controlled, as well. The company's outsourced processes, and the control methods implemented for each, are defined in Veridiam's internal procedures.

The type and extent of control to be applied to the outsourced process take into consideration:

a) the potential impact of the outsourced process on the company's capability to provide product that conforms to requirements,

b) the degree to which the control for the process is shared,

c) the capability of achieving the necessary control through the purchasing contract requirements.

5.0 Leadership

5.1 Leadership & Commitment

5.1.1 General

Veridiam's Top Management provides evidence of its leadership and commitment to the development and implementation of the management system and continually improving its effectiveness by:

a) taking accountability of the effectiveness of the management system;

b) ensuring that the *Quality Policy* and quality objectives are established for the management system and are compatible with the strategic direction and the context of the organization;

c) ensuring the integration of the management system requirements into the organization's other business processes, as deemed appropriate (see note);

d) promoting awareness of the process approach;

e) ensuring that the resources needed for the management system are available;

f) communicating the importance of effective quality management and of conforming to the management system requirements;

g) ensuring that the management system achieves its intended results;

h) engaging, directing and supporting persons to contribute to the effectiveness of the management system;

i) promoting continual improvement;

j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

Note: "business processes" such as accounting, employee benefits management and legal activities are out of scope of the QMS.

5.1.2 Customer focus

Veridiam's Top Management adopts a customer-first approach which ensures that customer needs and expectations are determined, converted into requirements and are met with the aim of enhancing customer satisfaction.

This is accomplished by assuring:

a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met;

b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;

c) the focus on enhancing customer satisfaction is maintained;

d) product and service conformity and on-time delivery performance are measured and appropriate action is taken if planned results are not, or will not be, achieved.

5.2 Policy

Veridiam's Top Management has developed the Quality Policy that governs day-to-day operations to ensure quality.

The Quality Policy is released as a standalone document as well, and is communicated and implemented throughout the organization.

The Quality Policy of Veridiam is as follows:

We are committed to total customer satisfaction through compliance to requirements, maintenance of the quality management system and continuous improvement of our processes, products and services.

5.3 Organizational Roles Responsibilities and Authorities

Veridiam's Top Management has assigned responsibilities and authorities for all relevant roles in the company. These are communicated with Veridiam's Organizational Chart.

The Quality Director has been assigned the role of Management Representative when having a single point of contact to represent the Veridiam quality system is useful or required by customer or regulations. The Management Representative shall also be responsible for:

a) ensuring that the quality management system conforms to the requirements of this International Standard;

b) ensuring that the processes are delivering their intended outputs;

c) reporting on the performance of the quality management system and on opportunities for improvement, in particular to top management;

d) ensuring the promotion of customer focus throughout the organization;

e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

6.0 Planning

6.1 Actions to Address Risks and Opportunities

Veridiam considers risks and opportunities when taking actions within the management system, as well as when implementing or improving the management system; likewise, these are considered relative to products and services. Risks and opportunities are identified as part of the "Context of the Organization", as well as throughout all other activities of the QMS.

Risks and opportunities are managed in accordance with Veridiam internal procedures. This procedure defines how risks are managed in order to minimize their likelihood and impact, and how opportunities are managed to improve their likelihood and benefit.

6.2 Quality Objectives and Planning to Achieve Them

As part of the adoption of the process approach, Veridiam utilizes its process objectives, as discussed in 4.4 above, as the main quality objectives for the QMS. These include overall product-related quality objectives; additional product-related quality objectives may be defined in work instructions or customer requirements.

The process objectives have been developed in consideration that they:

a) be consistent with the quality policy;

b) be measurable;

c) take into account applicable requirements;

d) be relevant to conformity of products and services and to enhancement of customer satisfaction;

e) be monitored;

f) be communicated;

g) be updated as appropriate.

Process quality objectives are defined in the minutes of management review per section 9.3 below.

The planning of process quality objectives is defined in section 4.4. above.

6.3 Planning of Changes

Changes to the quality management system and its processes are carried out in a planned manner per the internal procedures.

7.0 Support

7.1 Resources

7.1.1 General

Veridiam determines and provides the resources needed:

a) to implement and maintain the management system and continually improve its effectiveness

b) to enhance customer satisfaction by meeting customer requirements

Resource allocation is done with consideration of the capability and constraints on existing internal resources (People, Infrastructure, Work Environment, Organizational Knowledge, etc), as well as needs related to external provider's expectations.

Resources and resource allocation are assessed during management reviews, staff meetings or department reviews as needed.

Top management ensures that it provides sufficient staffing for the effective operation of the management system, as well its identified processes.

7.1.2 People

Personnel performing work affecting conformity to product requirements are competent on the basis of appropriate education, training, skills and experience.

7.1.3 Infrastructure

Veridiam determines, provides and maintains the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable:

a) buildings, workspace and associated facilities;

b) process equipment, hardware and software;

c) supporting services such as transport;

d) information and communication technology.

Equipment is validated and maintained per internal procedures.

7.1.4 Environment for the Operation of Processes

Veridiam determines, provides and maintains the environment necessary for the operation of its processes and to achieve conformity of products and services. Environment for the operation of processes can include:

- Physical, Social, Psychological and Environmental
- Temperature and Humidity – Maintained at comfortable working levels
- Lighting – As required for adequacy in the particular work area
- Human Factors of Work Area
- Safety Equipment and Training

7.1.5 Monitoring and Measuring Resources

Veridiam determines the monitoring and measurement to be undertaken and the monitoring and measuring devices required to provide evidence of conformity of product to determined requirements.

Veridiam maintains a register of these monitoring and measuring devices, and defines the process employed for their calibration including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria.

Processes are established to ensure that monitoring and measurement can be and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Veridiam ensures that environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out.

Where necessary to ensure valid results, measuring equipment is:

a) Calibrated and 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 is recorded

b) Adjusted or re-adjusted as necessary

c) Identified to enable the calibration status to be determined

d) Safeguarded from adjustments that would invalidate the calibration result

e) Protected from damage and deterioration during handling, maintenance and storage;

f) Be recalled to defined method when requiring calibration.

The validity of previous measuring results when the equipment is found not to conform to requirements is assessed and recorded. Appropriate action is taken on the equipment and any product affected

Records of the results of calibration and verification are maintained.

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application is confirmed. This confirmation is undertaken prior to initial use and is reconfirmed as necessary.

7.1.6 Organizational Knowledge

Veridiam also determines the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This may include knowledge and information obtained from:

a) internal sources, such as lessons learned, feedback from subject matter experts, and/or intellectual property;

b) external sources such as standards, academia, conferences, and/or information gathered from customers or suppliers.

This knowledge shall be maintained, and made available to the extent necessary.

When addressing changing needs and trends, Veridiam shall consider its current knowledge and determine how to acquire or access the necessary additional knowledge.

7.2 Competence

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

7.3 Awareness

Training and subsequent communication ensures that staff is aware of:

a) the quality policy;

b) relevant quality objectives;

c) their contribution to the effectiveness of the management system, including the benefits of improved performance;

d) the implications of not conforming with the management system requirements,

e) relevant quality management system documented information and changes thereto;

f) their contribution to product or service conformity;

g) their contribution to product safety;

h) the importance of ethical behavior.

7.4 Communication

Veridiam's Top Management ensures internal communication takes place regarding the effectiveness of the management system. Internal communication methods include:

a) use of corrective and preventive action processes to report nonconformities or suggestions for improvement

b) use of the results of analysis of data

c) meetings (periodic, scheduled and/or unscheduled) to discuss aspects of the QMS

d) use of the results of the internal audit process

e) regular company meetings with all employees

f) internal emails

g) memos to employees

7.5 Documented Information

The management system documentation includes both documents and records.

Note: the ISO 9001:2015 standard uses the term "documented information"; Veridiam does not use this term, but instead relies on the terms "document" and "record" to avoid confusion.

Documents required for the management system are controlled in accordance with internal procedures**.** The purpose of document control is to ensure that staff has access to the latest, approved information, and to restrict the use of obsolete information. All documented procedures are established, documented, implemented and maintained.

A documented procedure has been established to define the controls needed for the identification, storage, retrieval, protection, retention time, and disposition of quality records. This procedure also defines the methods for controlling records that are created by and/or retained by suppliers.

These controls are applicable to those records which provide evidence of conformance to requirements; this may be evidence of product requirements, contractual requirements, procedural requirements, or statutory/regulatory compliance. In addition, quality records include any records which provide evidence of the effective operation of the management system.

8.0 Operation

8.1 Operational Planning and Control

Veridiam plans and develops the processes needed for realization of its products. Product realization is consistent with the requirements of the other processes of the management system. Such planning considers the information related to the context of the organization (see section 4.1 above), current resources and capabilities, as well as product requirements.

Product realization is the sequence of processes and sub-processes required to manufacture product in accordance with planned arrangements.

Such planning is accomplished through:

a) Quality Objectives and requirements for the product/process;
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) The records needed to provide evidence that the realization processes and resulting product meet requirements;
e) Determining the products and services to be obtained from external providers;
f) Configuration management appropriate to the product, and
g) Establishing the controls needed to prevent the delivery of nonconforming products and services to the customer.
h) Resources to support the use and maintenance of the product and to meet on-time delivery

Planning of the product realization processes includes:

a) Planning of the Quality Objectives and requirements for the product is performed during the initial quotation and contract negotiation processes. This is based on the customer, statutory, regulatory, and other specified requirements; and on any other customer expectations that have been determined. The results of this planning are reflected in the Quotations and Customer Purchase Orders
b) Planning of the required processes and documentation, including resources and facilities specific to the product, is performed by Management based on the Quality Objectives, the product drawings, and consideration of the required facilities and work environment. The results of this planning are reflected in the Sales Orders and associated work package documents **.**
c) Verification, validation, monitoring, measurement, inspection and test activities specific to the product and criteria for product acceptance are planned by Product Planning based on the Quality Objectives, product drawings and specifications, and any other known product quality requirements**.**

The Records that are necessary to provide evidence that the realization processes and resulting product fulfillment requirements are planned and defined by the responsible Process Owners during development of the various Procedures and Instructions that make up the Quality Management System documentation.

Changes to operational processes are done in accordance with internal procedures.

Outsourced processes and the means by which Veridiam controls them are defined in the documented procedure.

Project management

As appropriate for the product, VERIDIAM plans and manages product realization in a structured and controlled manner to meet requirements at acceptable risk, within resource and schedule constraints.

A project is a unique process consisting of a set of coordinated and controlled actives undertaken to achieve specific requirements, including constraints of time, cost and resources.

VERIDIAM Top Management assigns technical and logistical responsibility for product realization project management, ensuring that product realization is planned and managed in a controlled manner, meeting requirements at an acceptable risk, within resource and schedule constraints. Each phase of product realization includes procedures with assigned responsibilities

When special projects with unique or high risk criteria require a heightened level of project management, Top Management assesses the risks. Top Management then assists with the quoting and planning of the special project, monitoring and controlling all phases of the project as it progresses through product realization. This Top Management oversight of special projects ensure control of time, costs, resources, and customer requirements. Although our standard production planning process covers risk related to all project management circumstances, Top Management oversight of unique or high risk projects ensures that decades of experienced decision-making authority is applied to any unique circumstances

8.1.1 Operational Risk Management

VERIDIAM has established, implemented, and maintains a process for managing risk to the achievement of applicable requirements.

The process includes, as appropriate to the organization and the product:

a) Assignment of responsibilities for risk management

b) Definition of risk criteria (e.g. likelihood, consequences, risk acceptance)

c) Identification, assessment and communication of risks throughout product realization

d) Identification, implementation and management of actions to mitigate risks that exceed the defined risk acceptance criteria

e) Acceptance of risks remaining after implementation of mitigating actions

8.1.2 Configuration Management

Veridiam plans, implements, and controls configuration management activities as appropriate to its products in order to ensure the identification and control of physical and functional attributes throughout the product lifecycle. This includes document control for configuration documents, and change control for configured items.

VERIDIAM has established, documented, and maintains a configuration management process appropriate to the product. Configuration management includes, as appropriate, the following.

a) Configuration management planning is conducted through contract review, production planning, traveler, inspection and all applicable quality documents.

b) Configuration identification is flowed down from customer contract. VERIDIAM adheres to all flowed-down Configuration Identification. Furthermore, VERIDIAM implements robust internal control of identification of controlled documents, data, records, equipment, tooling, materials, work-flow, etc. This is all configured as part of planning and control of product realization.

c) Change control is managed through planning and control of production realization. This includes any customer contract flow-down requirements for change control.

d) Configuration status accounting is conducted through inspection processes (receiving, first article, in-process, final inspection, including verification recording on our traveler and other documents as part of our Job Folder (traveler with accompanying related documents such as PO, drawing, specification, computer programming, inspection and testing records, certificate of conformance, etc.).

- Product configuration is maintained using the customer purchase order number and part number and revision, which are associated with a unique VERIDIAM work order number and assigned Sales Order number.
- The Customer PO Number, Part Number and revision, and (where applicable) Sales Order number are all included on the Shipping documents (packing slip) for configuration management of shipped product.
- Configuration of the product is specified in the Customer PO. Changes to the configuration require a change to the Customers PO.

8.1.3 Product Safety

Operational controls shall be implemented to assure product safety during the entire product life cycle, where this is appropriate relative to Veridam's products. These activities may include:

a) assessment of hazards and management of associated risks;

b) management of safety critical items;

c) analysis and reporting of occurred events affecting safety;

d) communication of these events and training of persons.

8.1.4 Prevention of Counterfeit Parts

Operational controls shall be implemented to assure the prevention of counterfeit or suspect counterfeit part use and their inclusion in product(s) delivered to the customer.

8.2 Requirements for Products and Services

8.2.1 Customer Communication

Veridiam has implemented effective communication with customers in relation to:

a) providing information relating to products;

b) handling enquiries, contracts or orders, including changes;

c) obtaining customer feedback relating to products and services, including customer complaints;

d) handling or controlling customer property;

e) establishing specific requirements for contingency actions, when relevant.

8.2.2 Determining the Requirements Related to Products and Services

During the intake of new business Veridiam captures:

a) the requirements for the products and services, including any applicable statutory and regulatory requirements and other requirements deemed necessary by Veridiam

b) requirements not stated by the customer but necessary for specified or intended use, where known

c) special requirements (see 8.5.1 below)

d) operational risks (new technologies, capability and capacity, delivery time frames, etc.)

8.2.3 Review of Requirements Related to Products and Services

Once requirements are captured, Veridiam reviews the requirements prior to its commitment to supply the product. This review ensures that:

a) product requirements are defined

b) contract or order requirements differing from those previously expressed are resolved

c) the organization has the ability to meet the defined requirements, and/or the claims for the products and services it offers

d) special requirements can be met

e) risks have been identified and considered

8.2.4 Changes to Requirements for Products and Services

Veridiam updates all relevant requirements and documents when the requirements are changed, and ensures that all appropriate staff are notified following our Change control procedures.

8.3 Design and Development of Products and Services - Excluded

8.4 Control of Externally Provided Processes, Products and Services

Veridam ensures that purchased product or Service conform to specified purchase requirements.

Veridiam evaluates and selects suppliers based on their ability to supply products and services in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation are established.

8.4.1 General

Purchases are made via the release of formal purchase orders and/or contracts which clearly describe what is being purchased. Received products or services are then verified against requirements to ensure satisfaction of requirements. Suppliers who do not providing conforming products or services may be requested to conduct formal corrective action.

The VERIDIAM Procurement Organization:

a) Maintains a register of approved suppliers that includes the scope of the approval;

b) Periodically reviews supplier performance; records of these reviews are used as a basis for establishing the level of controls to be implemented;

c) Defines the necessary actions to take when dealing with suppliers that do not meet requirements;

d) Ensures, where required, that both VERIDIAM and all suppliers use customer-approved special process sources;

e) Defines the process, responsibilities and authority of the approval status decision, changes of the approval status and conditions for a controlled use of suppliers depending on their approval status, and

f) Determines and manages risk when selecting and using suppliers.

8.4.2 Verification of Purchased Product

VERIDIAM establishes and implements verification or other activities necessary to ensure the externally provided processes, products and services do not adversely affect VERIDIAM's ability to consistently deliver conforming products and services to its customers.

In determining the type and extent of verification or other activities to be applied to external providers of products and services, VERIDIAM takes into consideration:

a) The potential impact of the externally provided processes, products and services on VERIDIAM's ability to consistently meet customer and applicable statutory and regulatory requirements;

b) The perceived effectiveness of the controls applied by the external provider.

Processes or functions of the organization, which are outsourced to an external provider, remain within the VERIDIAM Quality Management System scope. VERIDIAM considers a) and b) above and defines

within acceptance plans both the controls it intends to apply to the external provider and those it intends to apply to the resulting process output.

Verification activities may include:

a) Obtaining objective evidence of the quality of the product from suppliers,

b) Inspection and audit at supplier's premises,

c) Review of the required documentation,

d) Inspection/testing of products upon receipt, and

e) Delegation of verification to the supplier, or supplier certification.

Purchased product is not used or processed until it has been verified as conforming to specified requirements unless it is released under a positive-recall procedure.

Where VERIDIAM utilizes test reports to verify purchased product, the data in those reports are reviewed and accepted per applicable specifications.

Where VERIDIAM delegates verification activities to the supplier, the requirements for delegation are defined and a register of delegations is maintained.

Where VERIDIAM or its customer intends to perform verification at the supplier's premises, VERIDIAM states the intended verification arrangements and method of product release in the purchasing information.

8.4.3 Information for External Providers

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

a) Requirements for approval of product, procedures, processes, customer, product safety, equipment and importance of ethical behavior.

b) Requirements for qualification of personnel

c) Quality Management System requirements

d) The identification and revision status of specifications, drawings, process requirements, inspection/verification instructions and other relevant technical data,

e) Requirements for design, test, inspection, verification, use of statistical techniques for product acceptance, and related instructions for acceptance by the organization, and as applicable special requirements, critical items including key characteristics.

f) Requirements for test specimens (e.g., production method, number, storage conditions) for design approval, inspection/verification, investigation or auditing,

g) Requirements relative to:

- *Supplier notification to organization of nonconforming product,*
- *Arrangements for organization approval of supplier nonconforming material,*
- *When required, notification of changes in product and/or process, changes of suppliers,*

change in location, and where required, obtain organization approval, and

- *Requirements for the supplier to flow down to sub-tier suppliers the applicable requirements in the purchasing documents, including key characteristics where required;*

h) Records retention requirements

i) Right of access by the organization, their customer and regulatory authorities to the applicable areas of all facilities, at any level of the supply chain, involved in the order and to all applicable records.

VERIDIAM ensures the adequacy of specified purchase requirements prior to their communication to the supplier.

8.5 Production and Service Provision

8.5.1 Control of Production and Service Provision

To control its provision of products, Veridiam considers, as applicable, the following:

a) the availability of documents or records that define the characteristics of the products as well as the results to be achieved;

b) the availability and use of suitable monitoring and measuring resources;

c) the implementation of monitoring and measurement activities;

d) the use of suitable infrastructure and environment;

e) the appointment of competent persons, including any required qualifications;

f) the validation and revalidation of special processes if applicable (see below);

g) the implementation of actions to prevent human error;

h) the implementation of release, delivery and post-delivery activities.

Where special requirements, key characteristics and/or critical items are identified or deemed appropriate, the processes will be planned and controlled to manage these aspects.

Where appropriate, special statistical techniques may be used to control or monitor operational processes. In such cases, the techniques selected shall be based on known standards or otherwise justified as statistically valid. This includes sampling plans when sampling is used for inspection, testing or other purposes.

Veridiam utilizes some “special processes” where the result of the process cannot be verified by subsequent monitoring or measurement. The special processes in use and the methods of validation of each are defined in Veridiam Internal Procedures.

8.5.1.1 Control of Equipment, Tools and Software Programs

Equipment, tools, and software programs used to automate, control, monitor, or measure production processes are validated prior to final release for production and are be maintained. Special storage

requirements, if applicable, are defined for production equipment or tooling including any necessary periodic preservation or condition checks.

- VERIDIAM verifies production equipment, tools and programs by the First Article Inspection process, which is conducted prior to first production.
- Machine setups are verified at the start of a new job by first article inspection.

Storage requirements, including periodic preservation/condition checks, are established for production equipment or tooling in storage.

8.5.1.2 Validation and Control of Special Processes

Veridiam utilizes some "special processes" where the result of the process cannot be verified by subsequent monitoring or measurement. These processes are controlled per internal procedures.

Some special processes are sent to outside suppliers, these processes are controlled and an outsourced per internal purchasing procedures.

8.5.1.3 Production Process Verification

New Production processes are validated prior to use or implementation. This may include running test product through the new process or equipment, or by performing a First Article Inspection on a part produced by the process, tooling or equipment. First Article is discussed further in section 8.6.4 below.

8.5.2 Identification and Traceability

Where appropriate, Veridiam identifies its product or other critical process outputs by suitable means. Such identification includes the status of the product with respect to monitoring and measurement requirements. Unless otherwise indicated as nonconforming, pending inspection, hold or disposition, or some other similar identifier, all product shall be considered conforming and suitable for use.

Veridiam maintains the identification of the configuration of the products and services in order to identify any differences between the actual configuration and the required configuration.

If unique traceability is required by contract, regulatory, or other established requirement, Veridiam controls and records the unique identification of the product. This shall include, as appropriate:

a) product identification to be maintained throughout the product life

b) the ability to trace all products manufactured from the same batch of raw material, or from the same manufacturing batch, to the destination (e.g., delivery, scrap)

c) for an assembly, the ability to trace its components to the assembly and then to the next higher assembly

d) for a product, a sequential record of its production

8.5.3 Property Belonging to Customers or External Providers

Veridiam exercises care with customer, government or supplier property while it is under the organization's control or being used by the organization. Upon receipt, such property is identified, verified, protected and safeguarded. If any such property is lost, damaged or otherwise found to be

unsuitable for use, this is reported to the customer or supplier and records maintained.

For customer intellectual property, including customer furnished data used for design, production and / or inspection, this is identified by customer and maintained and preserved to prevent accidental loss, damage or inappropriate use.

8.5.4 Preservation

Veridiam preserves conformity of product during internal processing and delivery to the intended destination. This preservation includes cleaning, FOD control, special handling for sensitive products, marking and labeling including safety warnings, shelf life control and stock rotation, and special handling for hazardous materials. Preservation also applies to the constituent parts of a product.

Preservation of product also includes, where applicable in accordance with product specifications and/or applicable regulations, provisions for**:**

a) Cleaning;
b) Prevention, detection and removal of foreign objects;
c) Special handling for sensitive products;
d) Marking and labeling including safety warnings;
e) Shelf life control and stock rotation;
f) Special handling for hazardous materials.

The processes for preservation of product are defined in the applicable work instructions. These include processes for identification (part number); handling (to prevent damage); packaging (best commercial practice or customer specified); storage (in designated storage areas); and protection (including use of appropriate packaging and storage practices).

8.5.5 Post-Delivery Activities

As applicable, Post-delivery activities are conducted in compliance with the management system defined herein. In determining the extent of post-delivery activities that are required, Veridiam considers:

a) statutory and regulatory requirements;
b) the potential undesired consequences associated with its of Products;
c) the nature, use and intended lifetime of its of Products;
d) customer requirements;
e) customer feedback;
f) f) to i) are not applicable per Table 1 – List of exclusions

When problems are detected after delivery, Veridiam takes appropriate action including investigation and reporting; see section 10.2.

8.5.6 Control of Changes

Veridiam reviews and controls both planned and unplanned changes to processes to the extent necessary to ensure continuing conformity with all requirements.

Persons authorized to approve changes to production process shall be identified.

- Changes are made by Planning and reviewed by Quality and others as required including, where applicable, the Customer.

VERIDIAM identifies and obtains acceptance of changes that require customer and/or regulatory authority approval in accordance with contract requirements.

8.6 Release of Products and Services

Products undergo inspection and/or testing to ensure they meet all requirements at critical stages throughout the various processes, and then prior to final delivery.

Measurement requirements are documented; this documentation is part of the work order documentation, and includes:

a) criteria for acceptance and / or rejection,

b) where in the sequence measurement and testing operations are performed,

c) a record of the measurement results, and

d) type of measurement instruments required and any specific instructions associated with their use

Test records will show actual test results data when required by specification or acceptance test plan.

Where required to demonstrate qualification, Veridiam will ensure that records provide evidence that the product meets the defined requirements.

When key characteristics have been identified, they are monitored and controlled as required.

Product is not used until it has been inspected or otherwise verified as conforming to specified requirements, except when released under positive-recall procedures pending completion of all required measurement and monitoring activities.

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

8.6.2 Receiving Inspection and Testing

Incoming raw materials, processed products or other critical received goods undergo inspection and/or testing at receiving, prior to entry into the production processes

8.6.3 In-Process Inspection and Testing

At defined stages throughout Production, inspections and/or tests are conducted to ensure the products satisfy the requirements for that particular process or activity, prior to being released to the next process or activity.

8.6.4 First Article Inspection

First Article Inspections shall be performed at the discretion of Quality and/or when required by customer or contract requirements.

Such First Article Inspections are a complete inspection of a completed part, of all dimensions and criteria, to validate the production processes and equipment. The product used shall be a representative item from the first production run a new part or assembly to verify that the production processes, production documentation and tooling are capable of producing parts and assemblies that meet requirements. This process shall be repeated when changes occur that invalidate the original results (e.g., engineering changes, manufacturing process changes, tooling changes).

8.6.5 Final Inspection and Testing

Final acceptance criteria for products are defined in appropriate subordinate documentation. Reviews, inspections and tests are conducted at appropriate stages to verify that the product requirements have been met. This is done before products are released.

8.7 Control of Nonconforming Outputs

VERIDIAM ensures 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 are defined in a documented procedure.

Nonconforming product includes:

- *Rejected products and/or products results;*
- *Both product returned from a customer and internally generated nonconforming product, and*
- *Nonconformances related to documentation*

VERIDIAM's documented procedure defines the responsibility for review and authority for the disposition of nonconforming product and the process for approving personnel making these decisions.

9.0 Performance Evaluation

9.1 Monitoring, Measurement, Analysis and Evaluation

9.1.1 General

Veridiam has determined which aspects of its quality management system must be monitored and measured, as well as the methods to utilize and records to maintain, within this Quality Management Systems Manual and subordinate documentation.

Monitoring and measurement of the processes, ensure that Veridiam's Top Management evaluates the performance and effectiveness of the quality management system itself

VERIDIAM applies suitable methods 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 is taken, as appropriate, to ensure conformity of the product.

- *Quality System processes, documentation and records are monitored during Internal Audits*
- *The integrity of production documentation is reviewed during Internal Audits*
- *Key processes are monitored by Management using established KPI's and Quality Objectives*
- *The overall suitability, adequacy and effectiveness of the Quality System is measured and monitored at the Management Review meetings*

In the event of process nonconformity, VERIDIAM will:

a) Take appropriate action to correct the nonconforming process,

b) Evaluate whether the process nonconformity has resulted in product nonconformity, and

c) Determine if the process nonconformity is limited to a specific case or whether it could have affected other processes or products, and

d) Identify and control the nonconforming product.

Where applicable, requirements for monitoring and measuring process performance are cascaded down to VERIDIAM Suppliers.

. 9.1.2 Customer Satisfaction

As one of the measurements of the performance of the management system, Veridiam monitors information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information include:

- recording customer complaints
- product rejections or returns
- trends in on-time delivery
- obtain customer scorecards from certain customers
- submittal of customer satisfaction surveys

The corrective and preventive action system shall be used to develop and implement plans for customer satisfaction improvement that address deficiencies identified by these evaluations, and assess the effectiveness of the results.

9.1.3 Analysis and Evaluation

Veridiam analyzes and evaluates the data and information arising from monitoring and measurement in order to evaluate:

a) conformity of products;

b) the degree of customer satisfaction;

c) the performance and effectiveness of the quality management system;

d) if planning has been implemented effectively;

e) the effectiveness of actions taken to address risks and opportunities;

f) the performance of external providers;

g) the need for improvements to the quality management system.

Statistical techniques used may be defined in appropriate documented procedures; in all cases, the methods are based on established standards or are otherwise determined to be statistically valid.

9.2 Internal Audit

Veridiam conducts internal audits at planned intervals to determine whether the management system conforms to contractual and regulatory requirements, to the requirements of ISO 9001, AS9100, ISO13485, Nadcap and others that apply and to management system requirements. Audits also seek to ensure that the management system has been effectively implemented and is maintained.

9.3 Management Review

Veridiam's Top Management reviews the management system, at least annyally, to ensure its continuing suitability, adequacy and effectiveness. The review includes assessing opportunities for improvement, and the need for changes to the management system, including the *Quality Policy* and quality objectives.

Management review frequency, agenda (inputs), outputs, required members, actions taken and other review requirements are defined in the documented procedure.

Records from management reviews are maintained.

10.0 Improvement

10.1 General

Veridiam uses the management system to improve its processes, products and services. Such improvements aim to address the needs and expectations of customers as well as other interested parties, to the extent possible.

Improvement shall be driven by an analysis of data related to:

The results of analysis shall be used to evaluate:

h) conformity of products and services;

i) the degree of customer satisfaction;

j) the performance and effectiveness of the management system;

k) the effectiveness of planning;

l) the effectiveness of actions taken to address risks and opportunities;

m) the performance of external providers;

n) other improvements to the management system.

10.2 Nonconformity and Corrective Action

Veridiam takes corrective action to eliminate the cause of nonconformity in order to prevent recurrence. Likewise, the company takes preventive action to eliminate the causes of potential nonconformities in order to prevent their occurrence.

The documented procedure defines the requirements for:

a) Reviewing nonconformities (including customer complaints);

b) Determining the causes of nonconformity; including, as applicable, those related to human factors;

c) Evaluating the need for action to ensure that nonconformities do not recur;

d) Determining and implementing the action needed;

e) Recording of the results of action taken;

f) Reviewing the effectiveness of the corrective action taken;

g) Flow down of the corrective action requirement to a supplier, when it is determined that the supplier is responsible for the root cause;

h) Specific actions where timely and/or effective corrective actions are not achieved; and

i) Determining if additional nonconforming product exists based on the causes of the nonconformities and taking further action when required.

j) Maintain the documented information of nonconformity and corrective action management processes.

10.3 Continual Improvement

Through the process effectiveness reviews, done as part of Management Review, Veridiam works to continually improve the suitability, adequacy and effectiveness of the quality management system. This includes seeking opportunities for improvement.

Appendix A: Veridiam Overall Process Sequence & Interaction