



# QUALITY MANUAL

## ECO REVISION HISTORY

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## Section 1: Scope

This Quality Manual documented for UHV Sputtering Inc., provides guidance for conducting our business within a quality management system compliant with ISO 9001:2008 and 13485:2003. These policies apply to all segments of our operation.

### 1.1 General - Introduction

- 1.2 UHV Sputtering Inc. (UHV) has developed and implemented a Quality Management System in order to document the company's best business practices, better satisfy the requirements and expectations of its customers and improve the overall management of the company.
- 1.3 The Quality Management System at UHV Sputtering meets the requirements of the international standard ISO 9001:2008 as well as ISO 13485:2003.
- 1.4 The manual is divided into eight sections that correlate to the Quality Management System sections of the ISO 9001:2008 and ISO 13485:2003 formats. Each section begins with a policy statement expressing UHV Sputtering obligation to implement the basic requirements of the referenced Quality Management System section. Each policy statement is followed by specific information pertaining to the procedures that describe the methods used to implement the necessary requirements.
- 1.5 This manual describes the Quality Management System, delegate's authorities, inter-relationships and responsibilities of the personnel responsible for performing within the system. The manual also provides procedures or references for all activities comprising the Quality Management System to ensure compliance to the necessary requirements of the standard.
- 1.6 This manual is used externally to introduce our Quality Management System to our customers and other external organizations or individuals. The manual is used to familiarize them with the controls that have been implemented and to assure them that the integrity of the Quality Management System is maintained and focused on customer satisfaction and continuous improvement.

### 1.2 Application

UHV Sputtering has determined that the following requirements do not apply to the Quality Management System:

- Sub clause 7.3 Design and Development – UHV Sputtering uses customer designs and does not have any design functions. Therefore this has been excluded from the quality system.
- Sub clause 7.5.1.2.1 Cleanliness of product and contamination control
- Sub clause 7.5.1.2.2 Installation Activities-UHV Sputtering as a contract service provider, does not market or sell any product, therefore this sub clause is not applicable to the QMS.
- Sub clause 7.5.1.2.3 Servicing Activities-UHV Sputtering as a contract service provider, does not market or sell any product, therefore this sub clause is not applicable to the QMS.
- Sub clause 7.5.1.3 Particular requirements for sterile medical devices-UHV Sputtering as a contract service provider, does not provide services for the sterilization of medical devices, therefore this sub clause is not applicable to the QMS.
- Sub clause 7.5.2 Validation of Processes for production and service provisions- UHV Sputtering can validate the results of each process through monitoring and measurements; therefore we have excluded this sub clause from the QMS
- Sub clause 7.5.3.2.2 Requirements for active implantable medical devices and implantable medical devices-UHV Sputtering does not contract for any implantable devices, therefore this sub clause is not applicable to the QMS.

- Sub clause 8.2.4.2 Particular requirements for active implantable devices and implantable devices -UHV Sputtering does not contract for any implantable devices, therefore this sub clause is not applicable to the QMS.

## **Section 2: Normative Reference**

### **2.0 Quality Management System References**

The following documents were used as reference during the preparation of the Quality Management System:

- American National Standard ISO 9000:2005, Quality Management Systems - Vocabulary.
- American National Standard ISO 9001:2008, Quality Management Systems – Requirements
- American National Standard ISO 9004:2000, Quality Management Systems- Guidelines for performance improvements.
- International Standard ISO 13485:2003, Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
- International Standard ISO 10012:2003, Measurement management systems-requirements for measurement processes and measuring equipment.
- International Standard ISO 14971:2007, Medical devices-Application of risk management to medical devices.
- International Standard ISO 19011:2011, Guidelines for auditing management systems.

### **3.0 Quality Management System Definitions**

This section is for definitions unique to UHV Sputtering

- Customer intellectual property – proprietary information that is delivered to the engineering department from a customer to assist with design and development.
- Product – The end item result of meeting all contract terms and conditions. (i.e.: manufactured goods, merchandise, services etc.)
- Quality Records – Documentation of those activities wherein records of said activities must be maintained will be specified in the procedure or work instruction level documents, as applicable.

## **4.0 Quality Management System**

### **4.1 General Requirements & Process Management**

#### **4.1.1 General QMS Requirements**

UHV Sputtering has established documented and implemented a Quality Management System (QMS) in accordance with the requirements of ISO 9001:2008 and ISO 13485:2003. The quality system is fully documented, implemented and maintained, and continually improved through the use of corrective action, internal auditing and management review process.

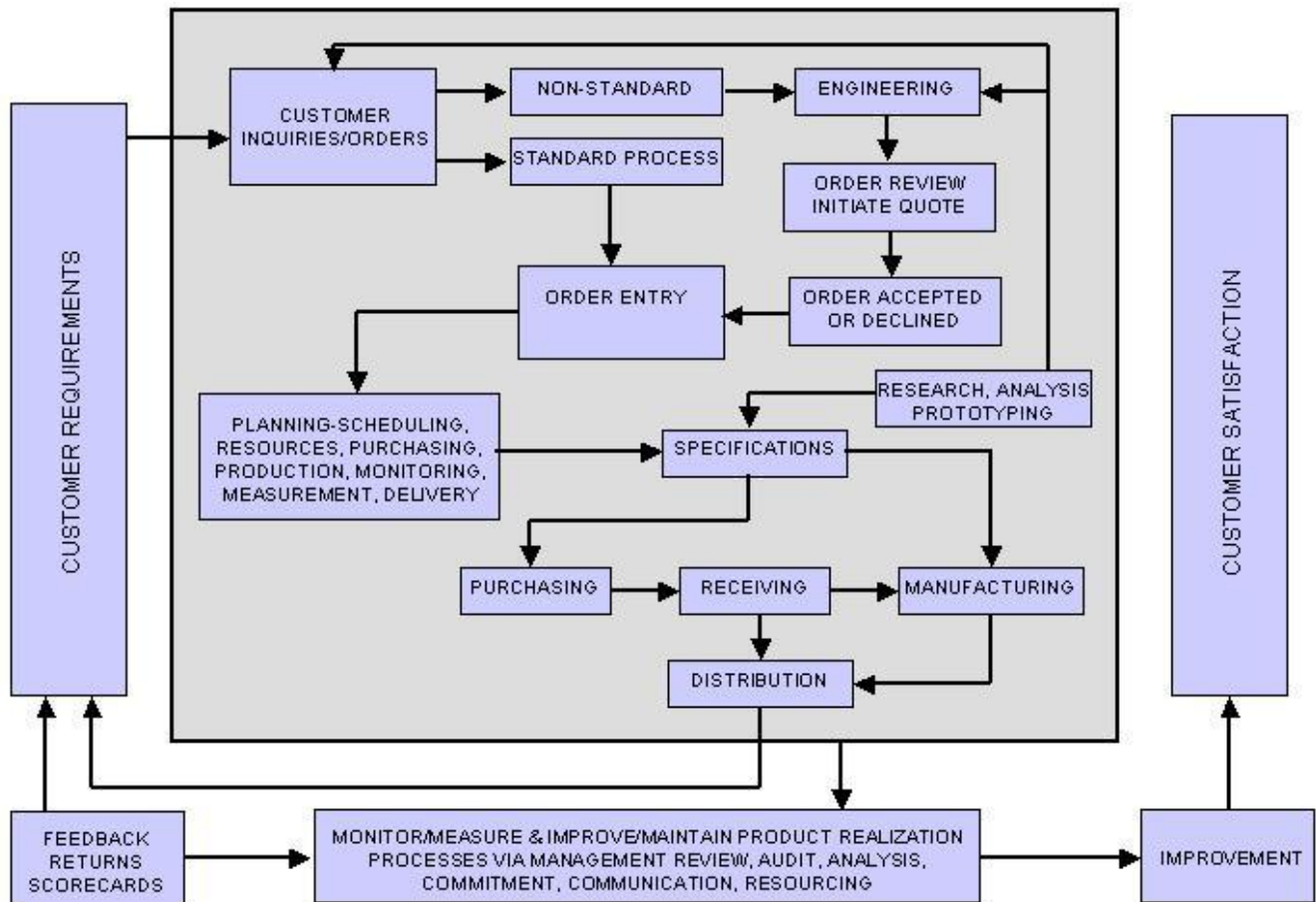
#### **4.1.2 Process Approach Overview**

UHV Sputtering has adopted a process-oriented method of management. For each process identified in use at UHV Sputtering, the sequence and interaction of processes has been determined (see chart below), and the processes

controlled by way of criteria and methods specific to that process. The processes are measured and monitored, and appropriate data gathered and analyzed, to ensure their effectiveness. During Management Reviews, process resources are discussed and allocated by management, as applicable. Corrective and preventive action is taken to ensure the processes achieve the desired results, and continually improve. UHV Sputtering will implement actions as necessary to achieve planned results and maintain the effectiveness of these processes.

**4.1.3 Process Sequence and Interaction**

The following chart represents the sequence and interaction of UHV Sputtering management level processes.



**4.1.4 Methods & Criteria for Control & Monitoring**

All processes at UHV Sputtering are controlled and monitored to ensure ongoing efficiency.

All processes are controlled by the identified documentation on the Master Document List F-423-1. Top level management has identified measurable quality objectives to measuring the efficiency of each process. During each management review meeting top level management will analyze the data from each quality objective to determine if the process is effective or not. If determined not to be effective, a corrective action shall be issued to determine the quality plan to improve the process.

**4.1.5 Resources**

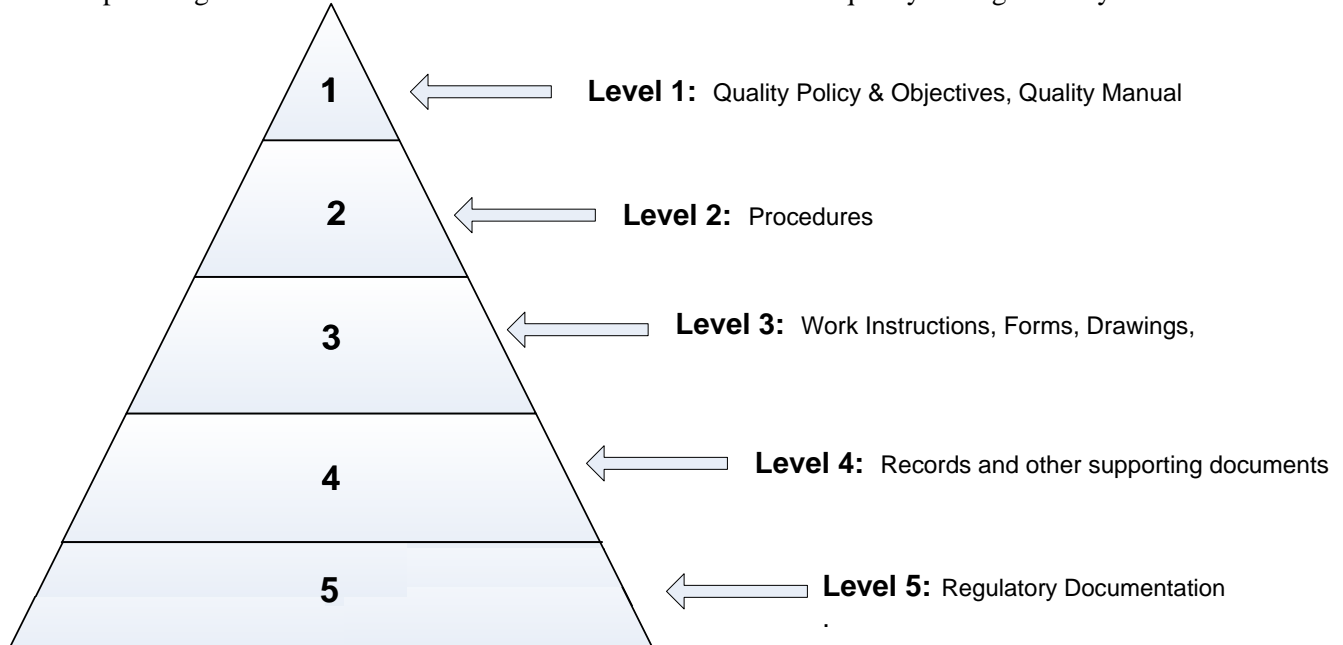
Upper management will ensure the proper allocation of resources needed to support and improve the processes in accordance with section 6.0 of this manual.

**4.1.6 Outsourced Processes**

Where processes are outsourced, these processes shall be controlled by the use of approved suppliers (see section 7.4).

**4.2 Documentation Requirements****4.2.1 General**

UHV Sputtering documentation consists of four levels that define our quality management system and is as follows:



The first level is the Quality Policy statement, accompanying Quality Objectives, and the Quality Manual. The Quality Policy briefly defines our commitment to our customers and continuous improvement. The Quality Objectives are measurable goals established to meet the Quality Policy. The Quality Manual defines *how* UHV Sputtering provides quality to customers, and *how* it meets the requirements of the Quality Policy statement and objectives.

The second level is the documented company and department procedures that define activities in corresponding sections of the Quality Manual. These are management procedures that address quality system related activities.

The third level contains work instructions. These are detailed instructions that are used where needed. Work instructions can be in various formats such as step-by-step written instructions, drawings, pictures, checklists, forms or electronic media.

The fourth level includes the records that result from implementation of the preceding three levels.

The fifth level includes any other documentation specified by national or regional regulations.

All Quality Management System documentation is accessible to appropriate personnel.

**4.2.2 Quality System Manual**

This primary purpose of the Quality System Manual is to describe and document the QMS in place at UHV Sputtering.

Copies of the manual are controlled by the means described in section 4.2.3. Uncontrolled copies may be distributed to organizations as requested. These are current at the date of issue only and will not be subject to amendment action.

This manual has been developed to numerically align with ISO 9001:2008 and ISO 13485:2003.

### 4.2.3 Control of documents

UHV Sputtering controls all QMS documentation, as defined in the Document Control Procedure P-423-1.

“Documents” may be in any form, including electronic files and customer-supplied data. This control ensures:

- Documents are reviewed and approved prior to issue;
- Review and update as necessary and re-approve documents;
- Proper revision level is marked on applicable documents, and that the current revision level is known (via a master list):
- That current revisions are made available in areas requiring them;
- That obsolete revisions of documents are promptly removed from use, and appropriately marked if retained for archival purposes;
- That revisions made to documents undergo the same review and approval process and by the same functions as original issues;
- All documents remain legible and readily identifiable.
- Documents of external origin will be identified and their distribution controlled.

Clarification of written documents shall be made available, through qualified and authorized personnel, for those individuals who may require it.

The Management Representative shall oversee the document control procedures to ensure they are implemented and effective in meeting the requirements of this policy.

### 4.2.4 Control of records

UHV Sputtering identifies “quality records” used to demonstrate required quality and effective QMS operations. These records may be in the form of completed logs, worksheets, forms, data files, or other instruments.

Each department is responsible for maintaining required quality records in accordance with the Control of Records Procedure, P-424-1. This procedure details the specific retention times for quality records, the functions responsible for collecting and indexing them, and the location of their storage.

Records are suitably stored and maintained to ensure their safekeeping and subsequent retrieval. Access to quality related records will be made available to the customer or other concerned parties upon approval of the Management Representative.

The Management Representative is responsible for implementing the procedures that fulfill this policy. It is the responsibility of all personnel to ensure that quality related records are compiled in a complete, legible and accurate manner and are correctly filed and stored in the location provided where applicable.

## **Section 5: Management Responsibility**

### **5.1 Management commitment**

In accordance with the Management Responsibility Procedure, P-510-1, UHV Sputtering’ Top Level Management is committed maintaining the effectiveness and continually improve the QMS. In order to ensure this, management regularly holds meetings with department managers on the status of the company and the QMS, and has provided a process for total internal communications (see section 5.5.3)

All employees are trained on their role in meeting requirements as part of the initial orientation, and ongoing process training. Orientation ensures that all employees are made aware of the company’s quality policy, as well.

During management reviews, specific quality objectives are established, and related goals set. In addition, resource allocation is discussed and analyzed.

**5.2 Customer focus**

Through the quality policy, subordinate procedures, training processes and management reviews, UHV Sputtering executive management applies a customer focus to all its activities, through careful contract review and approval, UHV Sputtering ensures that customer requirements are determined and met, with the aim of enhancing customer satisfaction.

**5.3 Quality policy**

The Quality Policy indicated below has been reviewed and approved by UHV Sputtering’ President. This policy is taught to all new employees, and audited regularly to ensure its distribution and the overall awareness of it by employees. During Management Review, the Quality Policy is reviewed for adequacy.

From the basic requirements of the Quality Policy, company “quality objectives” have been derived that provide a means of measuring the company’s ability to meet requirements and continually improve (see sec. 5.4.1).

**UHV Sputtering Quality Policy**

**“Based on the principles of continuous improvement, UHV Sputtering will maintain the effectiveness of the Quality Management System and meet agreed customer requirements, free from defects, on time, every time.**

**5.4 Planning**

**5.4.1 Quality objectives**

From the Quality Policy above, certain measurable quality objectives have been determined. These are monitored, measure, reported and analyzed by upper management with the intent of using this data to improve the company and the QMS.

Quality Policy Statement	Quality Objective	Metric
Customer Satisfaction	Positive levels of customer satisfaction	Zero Customer Complaints (customer feedback log)
Quality	High quality products	100% Quality Rating (products shipped vs. RMAs)
Customer Support	Positive levels of customer satisfaction	Zero Customer Complaints (customer feedback log)
Continual Improvement	Limited redundant CAR issues	Zero Redundant CAR’s (CAR Log)
	Limited defects	Zero DMR Reports (DMR Log)

**5.4.2 Quality management system planning**

This quality system had been planned in advanced, and its documented policies and procedures reviewed prior to implementation. Subsequent major changes that may affect the performance, quality or reliability of the product are identified, reviewed and approved, and the QMS documentation shall be updated accordingly.

The QMS documentation acts as the overall quality plan for UHV Sputtering as required, specific quality plans may be developed for individual products or technologies; these plans shall include the information given above. In such cases, upper Management shall have the overall responsibility for the development of quality plans, with input from department heads.



## **5.5 Responsibility, authority and communication**

### **5.5.1 Responsibility and authority**

The organization chart defines the basic management structure of UHV Sputtering in all cases, the appropriate person has been granted both the responsibility and authority for his or her position's duties. The responsibility and authority has been communicated to the appropriate person either through training, direct assignment by the immediate supervisor and through reinforcement during management review meetings.

All employees are empowered to request corrective or preventive action in order to prevent the occurrence of nonconformities relating to product, process, or the QMS itself. Top level management shall oversee this effort, and shall make sure that such issues are identified and recorded, that solutions are transmitted to and resolved by the proper functions, and that the solutions are verified for effectiveness.

Department managers are empowered to stop the processing of UHV Sputtering products found to be nonconforming, until that nonconformity has been corrected.

### **5.5.2 Management representative**

The President has appointed the Quality Manager as the management representative. As management representative, s/he has the following responsibility and authority:

- Ensure that processes needed for the quality management system are established and implemented.
- Report to top management on the performance of the quality management system, and note needed improvements.
- Promote awareness of customer requirements and regulatory requirements throughout the organization.
- Act as a liaison with external parties such as customers or auditors on matters relating to the QMS and
- Resolve matters pertaining to quality issues
- Organizational freedom to resolve matters pertaining to quality.

### **5.5.3 Internal communication**

In order to ensure proper communication between and throughout all levels of employees within the company, UHV Sputtering upper management ensures the following:

- All employees are empowered to submit request for corrective or preventive action with regard to quality related issues and suggestions on improving the company and its processes;
- Meetings are held to keep employees informed of current events within the company;
- Quality objectives are prominently posted to keep employees aware of the current standing for each objective, and to ensure their knowledge of the impact of their work on quality.

## **5.6 Management review**

### **5.6.1 General**

Upper management at UHV Sputtering performs formal management reviews of the QMS at a minimum of once per year. The minimum attendance for management reviews shall be the President and the Management Representative; other managers and employees shall attend as needed to meet the requirements of the agenda indicated below:

### 5.6.2 Review input

The Management Review meeting shall include analysis of the following inputs:

- Review of the Quality Policy for adequacy and to ensure it remains consistent with the needs of customers and the industry;
- Reporting on performance of the QMS and changes made to the company that may affect it, or changes made to the QMS that may affect the company;
- Review of Quality Objectives;
- Audit results and trends thereof;
- Review and allocation of resource needs including facilities, equipment, training and other process requirements;
- Review of Corrective & Preventive Action results, status and trends thereof;
- Review of customer returns, complaints, feedback and satisfaction;
- Recommendations for improvement;
- Review of supplier performance;
- Review new or revised regulatory requirements;
- Follow-up activities from previous Management Reviews.

All management review meetings are documented in the form of minutes and action items.

### 5.6.3 Review output

The Management Review members generate Corrective and/or Preventive Actions, or take other recorded actions, as a result of reviewed topics in an effort to improve the QMS, products, processes and services and to address resource needs.

This includes any decision and actions related to the improvement of the effectiveness of the QMS and its processes, improvement of product related to customer requirements, and resource needs.

Minutes of the management review meeting will be kept and retained according to section 4.2.4.

## **Section 6: Resource Management**

### **6.1 Provision of resources**

During management reviews, UHV Sputtering management determines and provides the resources needed to implement and maintain the QMS and continually improve its effectiveness, and to enhance customer satisfaction by meeting customer requirements.

All employees may also submit requests for corrective or preventive action regarding other resource needs or issues.

### **6.2 Human resources**

#### **6.2.1 General**

UHV Sputtering employees are selected, trained and evaluated to ensure that those personnel performing work affecting product quality are competent on the basis of appropriate education, training, skills and experience. As required, personnel shall undergo training to develop or improve these abilities.

### 6.2.2 Competence, awareness and training

UHV Sputtering training processes ensure that:

- Personnel are evaluated for their competency in a way that promotes personal growth and quality.
- Training is adequate for the function involved.
- The relevance of each person's role in quality and relationship to customer satisfaction is understood.

Training programs are evaluated by way of quality auditing to ensure ongoing effectiveness and improvement. Training needs are monitored and reported to management for review. Records of training and other experience are maintained.

Top level management will oversee the overall training efforts; department managers and supervisors are responsible for overseeing department-level training in their areas. Top-level management shall analyze instances of non-conformance for evidence of insufficient skill, job knowledge or training.

Details of UHV Sputtering training program may be found in the Training Procedure, P-622-1 Records of the training are maintained in according to section 4.2.4.

### 6.3 Infrastructure

UHV Sputtering has determined and provided the basic infrastructure needed to achieve conformity to product requirements. Maintenance is employed to ensure the ongoing suitability of such infrastructure. As applicable, documented requirements for maintenance activities, including their frequency will be established if such activities or lack thereof can affect product quality. Infrastructure includes:

- Buildings and workspace;
- Utilities, including pressurized air, electricity, water, waste treatment;
- Process equipment;
- Communication services, such as network connectivity, internet, intranet, etc. Records of the maintenance are maintained according to section 4.2.4.

Infrastructure needs and resources are reviewed regularly during management review.

### 6.4 Work Environment

Upper management has determined and manages the work environment needed to achieve conformity to product requirements. Such management includes:

- Overseeing infrastructure requirements;
- Providing proper lighting, atmospheric controls, etc...
- Providing employee safety equipment when needed.

As applicable, UHV Sputtering will establish documented requirements for the following:

- 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;
- Requirements for work environment conditions and procedures or work instructions to monitor the work environment if work environment conditions could have an adverse affect;
- Requirements for supervision or training of temporary personnel if required to work in special environment conditions; and
- Special arrangements for the control of contaminated or potentially contaminated product in order to prevent contamination of other product, the work environment or personnel.

## **Section 7: Product Realization**

### **7.1 Planning of product realization**

Planning at the product level occurs as defined in the production related procedures identified on the Document Master List, F-423-1 including the Production Control Procedure P-751-1. Such planning includes:

- Identification and acquisition of any required controls, processes, equipment, resources, and skills;
- Verification of the compatibility of the production process, inspection and supporting documentation;
- Updating, as required, of quality control, inspection and testing techniques;
- Identification of suitable verification stages during production of the product;
- Identification of standards of acceptability for all critical product requirements;
- Identification of any product or order-specific quality objectives;
- Identification of any related resource requirements;
- Identification, preparation and retention of quality records;

The applicable traveler or process sheet and associated order documentation acts as the output for the planning of process.

Records of product realization planning are maintained according to section 4.2.4.

Records of risk management are maintained according to section 4.2.4.

### **7.2 Customer-related processes**

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

UHV Sputtering captures all requirements during its quoting and/or contract review processes. Such requirements include those of the customer, as well as regulatory and statutory requirements.

Captured requirements shall specify the product ordered delivery terms, special order considerations, and other criteria.

#### **7.2.2 Review of requirements related to the product**

All orders undergo review prior to the company's commitment to supply a product to the customer per Customer Order Processes Procedure, P-722-1. This review shall:

- Ensure the customer product requirements are adequately defined and documented;
- Ensure that differences between any original request for quote (RFQ) and resulting order are resolved;
- Allow for customer verification of requirements made by verbal means;
- Ensure that UHV Sputtering has the capability to meet all requirements, including product specifications and delivery date.

In addition, every effort will be made to accommodate customer amendments to orders if possible; at certain times along the production process, manufacturing may be stopped to make these accommodations. In cases where such accommodations cannot be met, this condition will be communicated to the customer.

Change to contracts required by UHV Sputtering shall be immediately communicated to the customer, in order to renegotiate terms or requirements.

Records of review are maintained according to section 4.2.4.

**7.2.3 Customer communication**

Communication from customers shall be routed to the appropriate function, and recorded where necessary, in accordance with the following table:

<b>Communication Regarding:</b>	<b>Routed To:</b>	<b>Record Required</b>
Product information	Customer Service/Sales	Product Quotes/PO's
Open orders: status queries	Customer Service/Sales	Product Quotes/PO's
Open orders: other queries	Customer Service/Sales	Product Quotes/PO's
Amendments to active orders	Customer Service/Sales	Product Quotes/PO's
Reports of product nonconformance	Quality Assurance	Corrective Actions
Customer feedback (not product related)	Quality Assurance	Customer Feedback Log
Quality Management System	Quality Assurance	Customer Feedback Log
Advisory Notices	Quality Assurance	Customer Feedback Log

**7.3 Design and Development****7.3. Design and development**

This sub clause has been excluded from the scope of UHV Sputtering quality system. UHV Sputtering uses customer supplied drawings and or specifications to produce product.

**7.4 Purchasing****7.4.1 Purchasing process**

The Purchasing Procedure P-740-1 is followed to ensure that purchased product conforms to the specified purchase requirements. These procedures outline the extent of control required for suppliers. Suppliers are evaluated and selected based on their ability to supply product in accordance with requirements as outlined in the procedure. Criteria for selection, evaluation and re-evaluation are documented in the Purchasing Procedure. Records of the evaluation and any necessary actions are maintained as quality records. The organization is responsible for the quality of all products purchased from suppliers.

**7.4.2 Purchasing information**

UHV Sputtering procedures ensure that purchase orders contain all required information to allow the supplier to properly fill the order, including material identification, quantity, and all appropriate references to standards, specifications, etc... All requirements for approval of product, procedures, processes and equipment, requirements for qualification of personnel, and QMS requirements are to be included.

To the extent required for trace ability, purchasing documents and records are maintained according to section 4.2.4.

**7.4.3 Verification of purchased product**

Incoming product is subject to receiving inspection as defined in section 8.2.4. Records of verification are maintained according to section 4.2.4.

## **7.5 Production and Service Provision**

### **7.5.1 Control of production and service provision**

UHV Sputtering plans and carries out production and service provision in accordance with the production related procedures, Production Process Control Procedure P-751-1, and work instructions. Planning considers, as applicable:

- The establishment of process controls and development of production schedules,
- The identification of in-process verification points on the traveler,

Controlled conditions include, as applicable:

- The availability of information that describes the characteristics of the product
- The availability of work instructions
- The use of suitable equipment
- The availability and use of monitoring and measuring devices
- The implementation of monitoring and measurement
- The implementation of release, delivery and post-delivery activities
- The implementation of defined operations for labeling and packaging

UHV Sputtering will establish and maintain a record for each batch of medical devices that provides traceability to the extent required and identifies the amount manufactured and amount approved for distribution. Batch records will be verified and approved.

### **7.5.1.2 Control of production and service provision – Specific Requirements**

#### **7.5.1.2.1 Cleanliness of product and contamination control**

#### **7.5.1.2.2 Installation activities**

UHV Sputtering as a contract service provider, does not sell or install any product, therefore this sub clause is not applicable to the QMS.

#### **7.5.1.2.3 Servicing activities**

UHV Sputtering as a contract service provider, does not market or sell any product, therefore this sub clause is not applicable to the QMS.

### **7.5.1.3 Particular requirements for sterile medical devices**

UHV Sputtering as a contract service provider, does not provide services for the sterilization of medical devices, therefore this sub clause is not applicable to the QMS.

### **7.5.2 Validation of processes for production and service provision**

Sub clause 7.5.2 Validation of Processes for production and service provisions- UHV Sputtering can validate the results of each process through monitoring and measurements; therefore this sub clause is not applicable to the QMS.

### **7.5.3 Identification and traceability**

#### **7.5.3.1 Identification**

All production materials used by UHV Sputtering will be identified on receipt and during storage, pending issue and use per Identification and Traceability Procedure, P-753-1.

### 7.5.3.2 Traceability

#### 7.5.3.2.1 General

All production materials used by UHV Sputtering will be identified on receipt and during storage, pending issue and use per Identification and Traceability Procedure, P-753-1.

- Records of traceability are maintained according to section 4.2.4.

#### 7.5.3.2.2 Requirements for active implantable medical devices and implantable medical devices.

- UHV Sputtering does not contract for any implantable devices, therefore this sub clause is not applicable to the QMS.

#### 7.5.3.3 Status Identification

The inspection and test status of UHV Sputtering products is identified to ensure nonconforming product is not used, and that only conforming product is passed on to the customer. The mechanisms for such identification are:

- Placement of documentation which shall indicate a product's current status, on or near the product;
- Placement of the product in an area clearly designated for nonconforming product;
- Placement of an accept/reject tag or sticker on the product, as required;
- Records of traceability are maintained according to section 4.2.4.

### 7.5.4 Customer property

When required by the customer, UHV Sputtering will utilize material provided or owned by the customer in the manufacturing of that customer's order per Customer Supplied Product, P-754-1. UHV Sputtering shall:

- Verify incoming customer supplied product at receipt and identify it accordingly;
- Ensure customer-supplied product is not used for any other purpose than that intended by the customer;
- Ensure proper storage and handling of the customer supplied product;
- Report any lost or damaged customer-supplied product immediately to the customer

Customer property includes intellectual property.

Records of customer property are maintained according to section 4.2.4.

### 7.5.5 Preservation of product

UHV Sputtering preserves the conformity of product during internal processing and delivery to the intended destination, per Preservation of Products Procedure, P-755-1. This preservation includes identification, handling, packaging, storage and protection. As applicable, UHV Sputtering will establish documented procedures or work instructions for the control of product with a limited shelf-life or requiring special storage conditions. Special storage conditions will be controlled. Records of storage conditions are maintained according to section 4.2.4.

### 7.6 Control of monitoring and measuring devices

UHV Sputtering has determined per ISO 10012, the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements in accordance with the Calibration Procedure P-760-1. The procedure outlines the process used to ensure that monitoring and measurements are carried out in a manner that is consistent with the monitoring and measurement requirements.

- Calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards.
- Adjusted or re-adjusted as necessary
- Identified to enable the calibration status to be determined
- Safeguarded from adjustments that would invalidate the measurement result
- Protected from damage and deterioration during handling, maintenance and storage
- Be recalled according to a defined method when requiring calibration

In addition, UHV Sputtering assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. UHV Sputtering takes appropriate action on the equipment and any product affected. Records of the results of calibration and verification are maintained in accordance with section 4.2.4, in the form of a corrective action report.

UHV Sputtering maintains a register of these monitoring and measuring devices. The process, if in-house calibration is used, used for their calibration is defined in procedures, work instructions and equipment manuals and includes details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria.

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

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

## **Section 8: Measurement, analysis & improvement**

### **8.1 General**

UHV Sputtering utilizes data gathering and analysis from a variety of sources in order to measure and monitor both the acceptability of product and the effectiveness of processes. Furthermore, this data is reviewed during management review in order to continually improve and maintain the effectiveness of the Quality Management System.

### **8.2 Monitoring and Measurement**

#### **8.2.1 Customer Satisfaction**

UHV Sputtering values customer feedback in all its forms, and shall use such feedback to measure and monitor the ability of the company to meet customer requirements and expectations as defined in the Customer Feedback Procedure P-821-1. Through the use of data gathering, interviews and general communications, UHV Sputtering will convert customer feedback into data capable of being analyzed. This analysis shall then be used to report on UHV Sputtering customer satisfaction levels, which shall be reported to upper management during management review.

#### **8.2.2 Internal audit**

UHV Sputtering ensures that all aspects of its QMS are objectively audited in accordance with ISO 19011 and the Internal Audit Procedure, to ensure that quality activities and related results comply with internal and external requirements, as detailed in the Internal Audit Procedure P-822-1.

Audits are scheduled according to importance of the function audited, as determined by upper management. Trained personnel who are independent of the area being audited conduct audits. External (contract) auditors may be used to ensure this independence.

Audit findings or other results are addressed through corrective or preventive action. In addition, management will review audit results during management reviews to ascertain that the QMS is effective in achieving its objectives. Records of Internal Audit results are maintained according to section 4.2.4.

#### **8.2.3 Monitoring and measurement of processes**

UHV Sputtering 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. In the event of process nonconformity, the organization:

- Takes appropriate action to correct the nonconforming process,
- Evaluates whether the process nonconformity has resulted in product nonconformity, and
- Identifies and controls the nonconforming product in accordance with clause 8.3.

The process for monitoring and measuring of processes is conducted during each internal audit and is analyzed during each management review meeting during the review of the quality objectives.

#### **8.2.4 Monitoring and measurement of product**

UHV Sputtering conducts inspection and testing activities in accordance with the Inspection Procedure P-824-1, in order to verify that product meet all specifications.

##### **8.2.4.1 General Requirements**

For the purposes of this section of the manual, “tests” are included in “inspections.”

- **Receiving inspection** of raw materials and customer supplied product to ensure it meets specified requirements. The level of receiving inspection may be dependent on a supplier’s prior quality history. No material shall be released to production without the required inspection or certification.
- **In-process/final inspection-** UHV Sputtering monitors and measures the characteristics of the product to verify that product requirements are met. Evidence of conformity with the acceptance criteria is maintained as an inspection record. Records indicate the person authorizing release of product. Product release and service delivery does not proceed until all the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority, and where applicable by the customer.

Records of inspection and test activities, such as travelers, process sheets, and inspection reports, are maintained according to section 4.2.4, which identifies specific retention times and authorities for such records.

##### **8.2.4.2 Particular requirements for active implantable devices and implantable devices**

UHV Sputtering does not contract for any implantable devices, therefore this sub clause is not applicable to the QMS.

#### **8.3 Control of Nonconforming Product**

UHV Sputtering ensures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery in accordance with the Control of Non Conforming Procedure, P-830-1. The controls and related responsibilities and authorities for dealing with nonconforming product are defined within this procedure.

Responsibility for review and authority for the disposition of nonconforming product and the process for approving personnel making these decisions is defined in the procedure. Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained are maintained according to section 4.2.4.

#### **8.4 Analysis of Data**

In accordance the Analysis of Data Procedure, P-840-1, and with the review of Quality Objective data (sec. 5.4.1), UHV Sputtering determines, collects and analyzes appropriate data to demonstrate the suitability and effectiveness of the QMS, and to evaluate where continual improvement of the effectiveness of the QMS can be made.

In addition to the Quality Objective data and feedback of customer satisfaction, product conformity and process trend analysis, the status and acceptability of suppliers and vendors will be regularly reviewed during management reviews. Records of the results of the analysis of data are maintained according to section 4.2.4.

## **8.5 Improvement**

### **8.5.1 Continuous improvement**

UHV Sputtering continually improves the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

UHV Sputtering has established a documented procedure, Advisory Notices P-851-1 which can be implemented at any time, should the need arise to issue and implement an advisory notice.

Customer Complaints are handled following Customer Feedback Procedure, P-821-1. Records of customer complaints are maintained according to section 4.2.4.

### **8.5.2 Corrective action**

UHV Sputtering takes action to eliminate the cause of nonconformities in order to prevent recurrence in accordance with the Corrective and Preventive Action Procedure, P-852-1. Corrective actions are appropriate based on the severity of the nonconformities encountered.

The Corrective and Preventive Action Procedure defines requirements for

- Reviewing nonconformities (including customer complaints),
- Determining the causes of nonconformities,
- Evaluating the need for action to ensure that nonconformities do not recur,
- Determining and implementing action needed, including, if appropriate updating documentation,
- Records of any investigation and the results of action taken (see 4.2.4), and
- Reviewing corrective action taken and their effectiveness.
- Flow down of the corrective action requirement to a supplier, when it is determined that the supplier is responsible for the root cause, and specific actions where timely and/or effective corrective actions are not achieved.

### **8.5.3 Preventive action**

UHV Sputtering determines action to eliminate the causes of potential nonconformities in order to prevent their occurrence in accordance with the Corrective and Preventive Action Procedure. Preventive actions are appropriate to the effects of the potential problems.

The Corrective and Preventive Action Procedure, P-852-1 defines requirements for:

- Determining potential nonconformities and their causes
- Evaluating the need for action to prevent occurrence of nonconformities
- Determining and implementing action needed
- Records of results of any investigations and action taken
- Reviewing Preventative Action Taken and its effectiveness.