UHV SPUTTERING INC.
QUALITY MANUAL

DCN REVISION HISTORY

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22-003	K	3/1/2022	M. Clement	W. Ray

Table of Contents

Scope

This Quality System Manual, written and implemented by UHV Sputtering Inc., provides guidance for conducting our business within a quality management system compliant with ISO 9001:2015 and ISO 13485:2016. These policies apply to all segments of our operations within the context of the organization and with a clear understanding of the needs and expectations of all interested parties.

Section 1: General - Introduction

1.1 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 applicable regulatory agencies, and improve the overall management of the company.

1.2 The Quality Management System at UHV Sputtering meets the requirements of the international standards ISO 9001:2015 and ISO 13485:2016.

1.3 The manual is divided into five sections that correlate to the Quality Management System sections of the ISO 13485:2016 formats and corresponding sections of the ISO 9001:2015 standards. Each section begins with a policy statement, which establishes UHV Sputtering's commitment to implement and maintain 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.

1.4 The relationship between the two International Standards referenced in §1.3 is illustrated in the Figure 1.4 below:

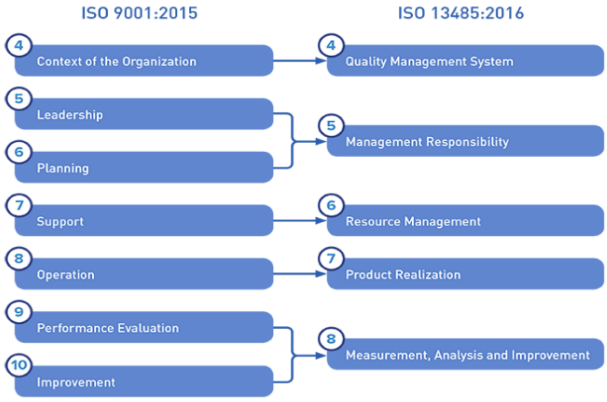

Figure 1.4 ISO Standards Cross Correspondence

1.5 This manual describes the Quality Management System's delegation of authorities, inter-relationships, and responsibilities of the personnel responsible for performing the processes included 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, as well as 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 focuses on customer satisfaction and continuous improvement.

1.7 UHV Sputtering recognizes that the privilege of conducting business in our communities demands excellence in our environmental, health and safety performance. UHV Sputtering is committed to the safe operation of our facility, the welfare of our employees and community, and the protection of the earth's environment. Accordingly, UHV Sputtering will:

- comply fully with the requirements of all applicable laws and regulations, and follow relevant industry standards for safety, engineering, and principles of risk management;
- operate our facility in a manner that continuously improves employee and public safety and environmental protection;
- require, as a condition of employment, that all employees accept personal responsibility and accountability for safe work behavior, and

- provide effective employee environmental, health, and safety training.

1.8 Exclusions - UHV Sputtering has determined that the following requirements of ISO 13485:2016 are not applicable to our Quality Management System, (corresponding clauses of ISO 9001 are cited at the end of each entry as applicable):

- 7.3 **Design and Development** (7.3.1 through (7.3.10 inclusive) – UHV Sputtering uses customer-generated designs, and does not perform in-house design functions; therefore, this requirement is not applicable to the QMS. (ISO 9001:2015 clauses 8.3.1 through 8.3.6)
- 7.5.2 **Cleanliness and contamination control** – (Sections a,b,c and e), UHV Sputtering does not perform cleaning or sterilization of manufactured medical products; therefore, these sections are not applicable to the QMS. Section 7.5.2 d is applicable.
- 7.5.3 **Installation Activities** - UHV Sputtering is a contract service provider only, and does not market or sell any product; therefore, this requirement is not applicable to the QMS.
- 7.5.4 **Servicing Activities** - UHV Sputtering is a contract service provider, and does not market or sell any product; therefore, this section is not applicable to the QMS.
- 7.5.5 **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 requirement is not applicable to the QMS.
- 7.5.7 **Particular requirements for validation of processes for sterilization and sterile barrier systems -** UHV Sputtering does not perform sterilization processes on any products or material.
- 7.5.9.2 **Particular requirements for implantable medical devices** - UHV Sputtering does not perform contract services upon any implantable devices; therefore, this requirement is not applicable to the QMS.
- 8.2.6 **Monitoring and measurement of product**, **with regard to particular requirements for implantable devices** -UHV Sputtering does not perform contract services upon any implantable devices; therefore, this requirement is not applicable to the QMS.

Section 2: Quality Management System References

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

- American National Standard ISO 9000: 2015, Quality Management Systems – Fundamentals and Vocabulary.
- American National Standard ISO 9001: 2015, Quality Management Systems – Requirements
- American National Standard ISO 9004:2000, Quality Management Systems- Guidelines for performance improvements.
- International Standard ISO 13485: 2016, 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.

Section 3: Quality Management System Definitions

This section is for definitions unique to UHV Sputtering's QMS.

- Customer intellectual property – proprietary information that is delivered to UHV Sputtering from a customer to assist with development.
- Product – The end item result of meeting all contractual terms and conditions.
- 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.
  - Advisory Notice: notice issued by the organization, subsequent to delivery of a medical device, to provide supplementary information or to advise on action to be taken in the:
  - return of the medical device to the organization that supplied it, or

- Destruction of a medical device. Issuance of an advisory notice can be required to comply with applicable regulatory requirements.
- Authorized Representative - natural or legal person established within a country or jurisdiction who has received a written mandate from the manufacturer to act on his behalf for specified tasks with regard to the latter's obligations under that country or jurisdiction's legislation.
- Complaint - written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, usability, safety or performance of a medical device that has been released from the organization's control or related to a service that affects the performance of such medical devices. NOTE: This definition of "complaint" differs from the definition given in ISO 9001:2015.
- Distributor - natural or legal person in the supply chain who, on his own behalf, furthers the availability of a medical device to the end user. More than one distributor may be involved in the supply chain. For the purposes of this section, it should be noted that persons in the supply chain who are involved in activities such as storage and transport on behalf of the manufacturer, importer or distributor, are not distributors.
- Importer - natural or legal person in the supply chain who is the first in a supply chain to make a medical device, manufactured in another country or jurisdiction, available in the country or jurisdiction where it is to be marketed.
- Labeling - label, instructions for use, and any other information that is related to identification or technical description, but excluding shipping documents.
- Life-Cycle - all phases in the life of a medical device, from the initial conception to final decommissioning and disposal.
- Manufacturer - natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s).
- Medical device family – Group of medical devices manufactured by or for the same organization and having the same basic design and performance characteristics related to safety, intended use and function.
- Product – Result of a process. Note 2 to entry: Service is the result of at least one activity necessarily performed at the interface between the supplier and customer and is generally intangible. Provision of a service can involve, for example, the following:
    - An activity performed on a customer-supplied tangible product.
- Risk - combination of the probability of occurrence of harm and the severity of that harm
- Risk Management - systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating, controlling and monitoring risk

Refer to ISO 13485: 2016 for notations of further explanations, definitions and terminology.

Section 4 Quality Management System

4.1 General QMS Requirements

UHV Sputtering has established, documented, and implemented a Quality Management System (QMS) in accordance with the requirements of ISO 9001: 2015 § 4.4, 8.4 and ISO 13485: 2016, as well as any applicable regulatory requirements. The quality system is fully documented, implemented and maintained, and continually improved through the use of corrective and preventive action, internal auditing and management review processes as per section 4 of both ISO 9001:2015, and ISO 13485:2016.

Process and Risk-Based Approach Overview

UHV Sputtering has adopted a method of management that promotes the use of the process approach and risk-based thinking. For each process identified in use at UHV Sputtering, the sequence and interaction of processes has been determined (see figure 4.1.3 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. Prior to, and during, the execution of processes, risks that can affect the final outcome/output are considered and analyzed.

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. Refer to Figure 4.1.2 below for an illustration of the sequence of UHV's risk management system, followed by an illustration of the UHV Process Sequence and interaction (Figure 4.1.3).

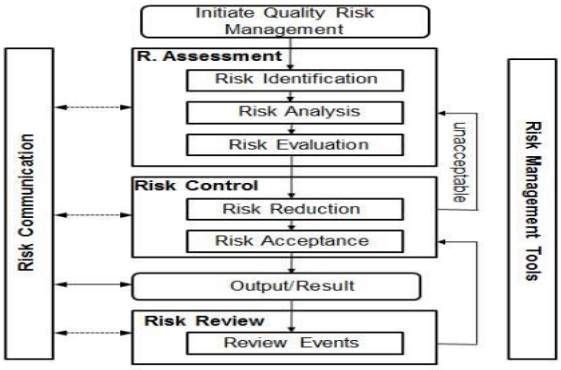

Figure 4.1.2 Risk Management flowchart

4.1.3 Process Sequence and Interaction

The following chart (Figure 4.1.3) represents the sequence and interaction of UHV Sputtering management level processes:

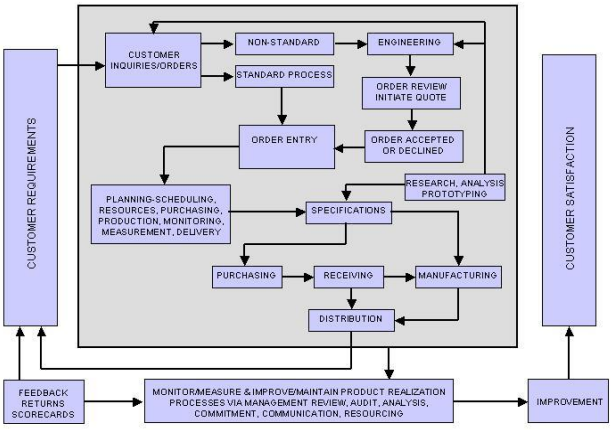

Figure 4.1.3 Process Sequence and Interactions

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 listed on the Master Document List **F-424-1**.Top level management has identified measurable quality objectives that shall be used to measure the efficiency of each process. During each management review meeting, top level management analyzes the data relative to each quality objective in order to determine if the process is effective. If a process is determined to be ineffective, a corrective action shall be issued to devise a plan to improve the process in question.

4.1.5 Resources

Top management will ensure the proper allocation of resources needed to support and improve the processes in accordance with section 6.0 of this manual. All monitoring activities include adherence and conformance to applicable regulatory requirements. In determining controls used, applicable risk factors are analyzed and utilized; as well, these controls include written quality agreements. Any outsourced processes are evaluated with regard to end results and monitored accordingly.

4.1.6 UHV Sputtering Inc. maintains a documented procedure that provides guidance for validating software (where applicable) that is used to maintain the quality management system. Validation is used in particular when said software has undergone any type of functional change. This practice would include "off the shelf" office applications (word processors, email clients, etc...). Records of validation are maintained per UHV procedure **P-425-1**.

4.2 Documentation Requirements (ISO 9001:2015 § 7.5)

4.2.1 General Requirements

The first level is the Quality Policy statement that encompasses the 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. (ISO 9001:2015 §7.5.1)

4.2.2 Quality Manual

UHV Sputtering documentation consists of five levels that comprise our quality management system; they are as follows:

- The first level wherein 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, regional, or industry regulations, and clients.

All Quality Management System documentation is accessible to appropriate personnel. (ISO 9001:2015 § 4.3, 4.4, 7.5.1)

4.2.3 Medical Device File

As a matter of course and record, UHV Sputtering does not provide production, installation, or servicing of installed medical devices. However, per customer and regulatory requirements, for each type or family of medical devices, UHV will maintain files containing all documents generated that demonstrate conformity to international standards and compliance. The contents of the files shall include, but are not limited to:

a) general description of the medical device, intended use/purpose, and labeling, including any instructions for use;
b) specifications for product;
c) specifications or procedures for manufacturing, packaging, storage, handling and shipment;
d) procedures for measuring and monitoring;

All records control activities shall be conducted in accordance with requirements set forth in ISO 13485 § 4.2.5 and ISO 9001 §7.5 *et seq.*.

4.2.4 Control of Documents

UHV Sputtering controls all QMS documentation, as defined in the Document Control Procedure **P-424-1**. Documents can exist in any format or medium, 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) and available to UVH personnel,
- That current revisions are made available in areas requiring them,
- That obsolete revisions of documents are promptly removed from use, and appropriately marked or identified 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,
- Documents, particularly those of a historical nature, are safeguarded against deterioration and loss.

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

Documents of all revisions are retained for a period of time determined by regulatory and/or customer requirements.

The Management Representative shall oversee the document control procedures to ensure they are implemented and effective in meeting the requirements of this policy. (ISO 9001:2015 §7.5.2, 7.5.3)

4.2.5 Control of records

UHV Sputtering identifies 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 records in accordance with the Control of Records Procedure, **P-425-1.** This procedure details the specific retention times for quality records, the functions responsible for collecting and indexing them, and the location of their storage. As applicable, UHV Sputtering retains records for at least the lifetime of the medical device as defined by customer, or as specified by applicable regulatory requirements, but not less than two years from the medical device release by the customer.

Records are suitably stored and maintained to ensure their safekeeping and subsequent retrieval. Changes to a record shall remain readily identifiable. 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. (ISO 9001:2015 § 7.5.2, 7.5.3)

Section 5: Management Responsibility

5.1 Management commitment

In accordance with UHV's Management Responsibility Procedure, **P-510-1**, UHV Sputtering's Top Level Management is committed to maintaining the effectiveness and continued improvement to 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 in their role(s) for 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 as the importance of meeting customer requirements and all applicable regulatory requirements.

During management review meetings, specific quality objectives are established and related goals set. In addition, resource allocation is discussed and analyzed. (ISO 9001:2015 § 5.1.1)

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 and applicable regulatory requirements are determined and met. (ISO 9001:2015 §5.1.2)

5.3 Quality policy

The Quality Policy (see below) has been reviewed and approved by the CEO of UHV Sputtering, Inc. This policy is taught to all new employees, and audited regularly to ensure its distribution and the overall awareness of employees of the Policy's existence and applicability. During Management Review, the Quality Policy is reviewed for continuing suitability.

From the basic requirements of the Quality Policy, company "quality objectives" have been determined and defined, and provide a means of measuring the company's ability to meet requirements and continually improve (see sec. 5.4.1). (ISO 9001:2015 § 5.2, 5.2.1, 5.2.2)

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 and regulatory requirements, free from defects, on time, every time."

5.4 Planning (ISO 9001:2015 § 6.0)

5.4.1 Quality objectives

From the Quality Policy above, certain measurable quality objectives have been determined. These are monitored, measured, reported and analyzed by upper management with the intent of using this data to improve the company and the QMS. (ISO 9001:2015 § 6.2)

Quality Policy Statement	Quality Objective	Metric
Customer Support & Satisfaction	Positive levels of customer satisfaction	Minimal Customer Complaints (customer feedback log); minimum 90% satisfaction
Regulatory Compliance	To meet all applicable regulatory requirements	▪ Maintenance of ITAR registration ▪ Compliance with all applicable regulations
Quality	High quality products	98% Quality Rating (products shipped without DMRs)
On-time Deliveries	To meet all on-time delivery requirements	98% on-time deliveries (customer feedback log)
Continual Improvement	Limited redundant CAR issues	Minimal Redundant CAR's (CAR Log)
	Limited defects	Minimal DMR Reports (DMR Log)
	Limited internal CAR issues	Minimal ICAR's (CAR Log)

Figure 5.4.1 Quality Objectives table

5.4.2 Quality management system planning

This quality system was planned in advance, and its documented policies and procedures were 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. (ISO 9001:2015 §6.0. 6.1, 6.2)

5.5 Responsibility, authority and communication (ISO 9001:2015 § 5)

5.5.1 Responsibility and authority

This organization chart (below) 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 positions' duties. Refer to Figure 5.5.1 below:

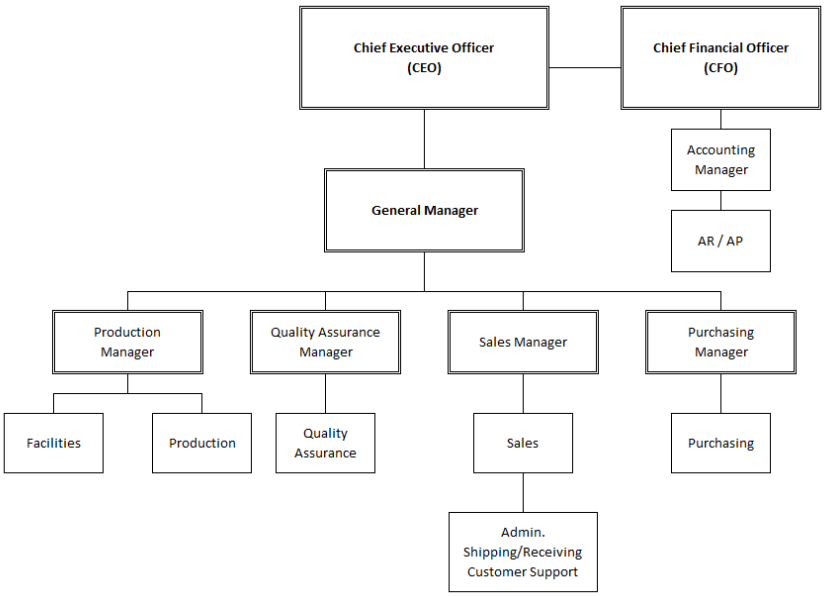

Figure 5.5.1 UHV Sputtering Organization Chart

The responsibility and authority has been communicated to the appropriate person either through training, direct assignment by the immediate supervisor or 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 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. (ISO 9001:2015 §5.3)

5.5.2 Management representative

The CEO has appointed the Quality Manager as the management representative. As management representative, s/he has the following responsibilities and authorities:

- Ensure that processes needed for the quality management system are documented, 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. (ISO 9001:2015 §5.3)

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 conducted periodically to keep employees informed of current events within the company. (ISO 9001:2015 § 7.4)

5.6 Management review (ISO 9001:2015 § 9.3)

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 in 5.62 of this Quality Manual. (ISO 9001:2015 §9.3.1)

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 requirements of customers, regulatory agencies (as applicable), and industry standards;
- 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;
- Monitoring and measurement of processes and products;
- 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. (ISO 9001:2015 §9.3.2)

5.6.3 Review output

The Management Review members may 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,
- services,
- address resource needs, and
- applicable regulatory requirements.

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 recorded and retained according to section 4.2.5 of this Manual. (ISO 9001:2015 §9.3.3)

Section 6: Resource Management (ISO 9001:2015 §7.1)

6.1 Provision of resources

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

All employees may also submit requests for corrective or preventive action regarding other resource needs or issues. (ISO 9001:2015 §7.1.1, 7.1.2)

6.2 Human resources

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.

UHV Sputtering training processes ensure that:

- Necessary competence for personnel performing work affecting product quality is determined,
- Personnel are evaluated for their competency in a way that promotes personal growth and quality,
- Training is adequate for the function involved,
- Personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.

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 according to section 4.2.5 of this Manual. (ISO 9001:2015 §7.2, 7.3)

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 (including both hardware and software);
- Support services, including transport, communication and information (network connectivity, internet, intranet, etc…)

Records of maintenance activities are maintained according to section 4.2.5 of this Manual.

Infrastructure needs and resources are reviewed regularly during management review. (ISO 9001:2015 §7.1.3)

6.4 Work Environment and Contamination Control

6.4.1 Work environment

Top management has determined requirements relative to, and manages said requirements of, 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. (ISO 9001:2015 §7.1.4)

6.4.2 Contamination control

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 effect on processes and/or products.
- Requirements for supervision or training of temporary personnel if required to work in special environment conditions;
- Special arrangements for the control of contaminated or potentially contaminated product in order to prevent contamination of other product, the work environment, or personnel (ISO 9001:2015 §7.1.4)

Section 7: Product Realization (ISO 9001:2015 §8)

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-424-1** 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 and records of risk management are maintained per section 4.2.5 of this Manual. (ISO 9001:2015 §8.1)

7.2 Customer-related processes (ISO 9001:2015 §8.2)

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, either stated or non-stated, but necessary for intended use (as applicable)
- regulatory and statutory requirements,
- any additional requirements determined by UVH Sputtering Inc.

Captured requirements shall specify the product ordered delivery terms, special order considerations, and other criteria. (ISO 9001:2015 §8.2.2)

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 and applicable documents are amended;
- Any and all applicable regulatory requirements,
- 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 4.2.5 of this Manual. (ISO 9001:2015 §8.2.3, 8.2.4)

7.2.3 Communication

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

Communication Regarding:	Routed To:	Record Required
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
Regulatory Requirements	Quality Assurance	Corrective Actions (as applicable)

Figure 7.1 Communications matrix table.
(ISO 9001:2015 §8.2.1)

7.3 Design and Development

This Section has been excluded, (as being non-applicable), from the scope of UHV Sputtering quality system (including corresponding ISO 9001:2015, § 8.3). UHV Sputtering uses customer supplied products, drawings and/or specifications to produce services. See section 1.8

7.4 Purchasing (ISO 9001:2015 §8.4)

7.4.1 Purchasing process

UHV Sputtering's Purchasing Procedure **P-740-1** is maintained to ensure that purchased product conforms to the specified purchase requirements. These procedures outline the extent of control required for suppliers. Suppliers are evaluated, monitored, re-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. The criteria include:

- the supplier's ability to provide product that meets UHV Sputtering's requirements,
- historical performance of the supplier with regard to previous transactions with UHV Sputtering,
- the effect of the purchased product on the quality of the product(s),
- proportionate risk associated with the product(s).

The organization is responsible for the quality of all products purchased from suppliers. Non-fulfillment of purchasing requirements shall be addressed with the supplier:

- proportionate to the risk associated with the purchased product, and
- compliance with applicable regulatory requirements.

Records of the evaluation and any necessary actions are maintained as quality records according to section 4.2.5 of this Manual, as well as applicable UHV documentation. (ISO 9001:2015 §8.4, 8.4.1, 8.4.2)

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 traceability, UHV Sputtering maintains purchasing documents (per 4.2.4) and records (per 4.2.5). (ISO 9001:2015 § 8.4.3,)

7.4.3 Verification of purchased product

Incoming product is subject to receiving inspection as defined in section 8.2.6 of this Manual. In the event that UHV chooses to conduct verification of product at the supplier's facility, all intended verification activities will be communicated via applicable purchasing information. Records of verification are maintained according to section 4.2.5 of this Manual. (ISO 9001:2015 §8.4.2, 8.4.3, 8.6)

7.5 Production and Service Provision (ISO 9001:2015 §8.5)

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:

- documentation of procedures and methods for the control of production
- qualification of infrastructure;
- implementation of monitoring and measurement of process parameters and product characteristics;
- availability and use of monitoring and measuring equipment;
- implementation of defined operations for labeling and packaging;
- implementation of product release, delivery and post-delivery activities

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. (ISO 9001:2015 §8.5)

Sections 7.5.2 – 7.5.7 of ISO13485:2016 are excluded from the UHV Sputtering QMS scope. See section 1.8

7.5.8 Identification

UHV Sputtering maintains a documented procedure that defines requirements, suitable methods, and provides guidance in identification of product as well as inspection status of product throughout all stages of realization. As applicable, UHV Sputtering's documentation specifies methods with which compliance to relevant regulatory requirements is achieved, with particular attention paid to the identification and status of returned material. (ISO 9001:2015 §8.5.2)

7.5.9 Traceability

Traceability at UHV sputtering includes keeping customer's property tagged and isolated from general use. It also entails the tracking and unique identifiers for each job processed at UHV. This includes preservation of finished product as well, this means protecting from alteration, damage and/or contamination. This may also include the packaging used to ship product back to customer, (usually provided by the customer). If special conditions are required by the customer UHV shall ensure that are controlled and recorded. (ISO 9001:2015 has no traceability requirements)

7.5.9.1 General

UHV Sputtering maintains a documented procedure that defines procedures and methods used to maintain traceability. These procedures define the extent of traceability in accordance with applicable regulatory requirements and the records to be maintained per **P- 425-1**).

7.5.9.2 is excluded from QMS scope See section 1.8

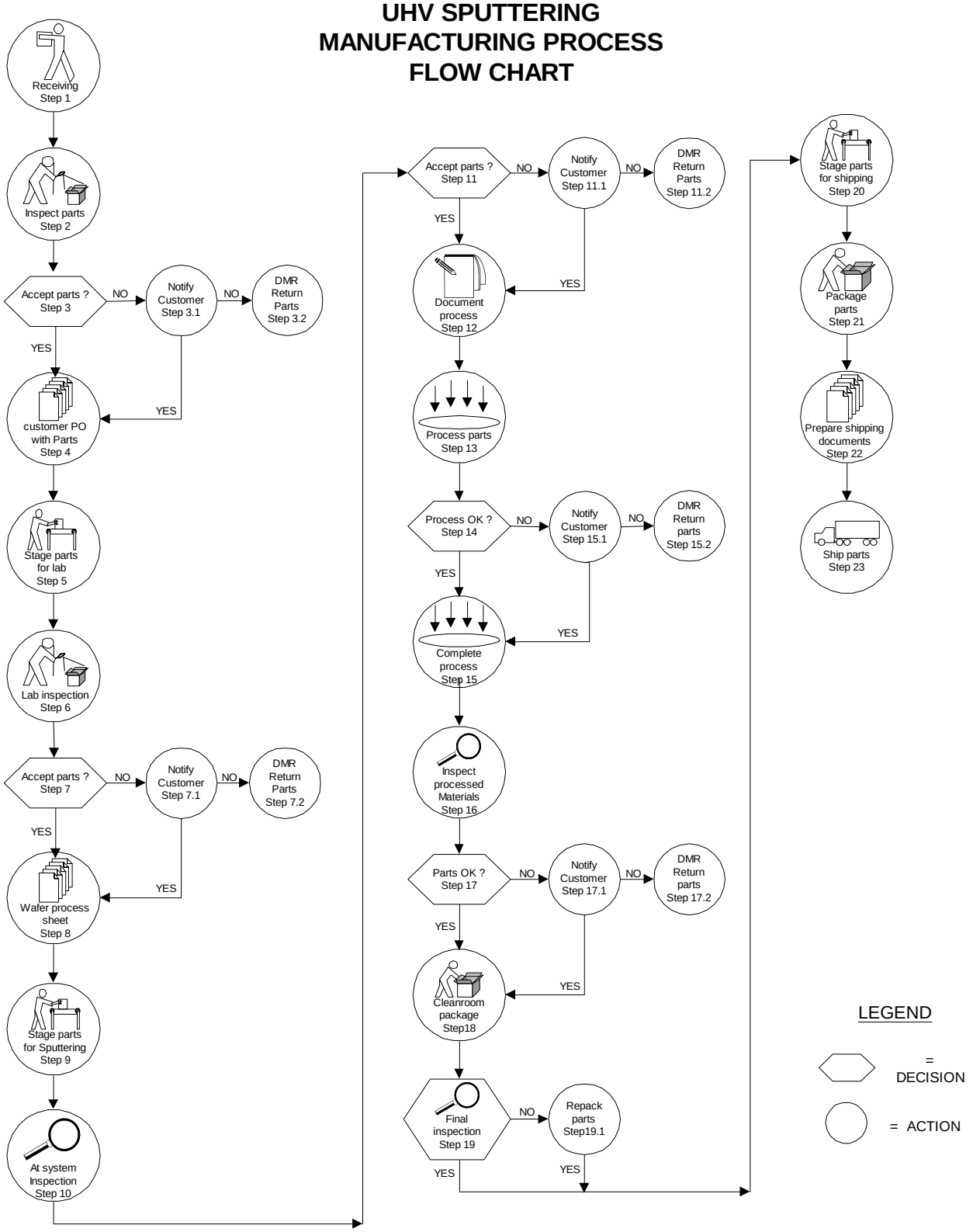

Figure 7.5 UHV Process Flowchart

7.5.10 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 4.2.5 of this Manual. (ISO 9001:2015 §8.5.3)

7.5.11 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 requirements set forth in section 4.2.5 of this Manual. (ISO 9001:2015 §8.5.4)

7.6 Control of Monitoring and Measuring Equipment

UHV Sputtering has determined, per ISO 10012, that the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements are 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 4.2.5 of this Manual, in the form of a corrective action report. **(F-852-1**)

UHV Sputtering maintains a register of these monitoring and measuring devices. The process, if in-house calibration is 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. Methodologies associated with software validation (and revalidations) are proportionate to the risk associated with the use of the software; this includes the effect on the ability of the product to conform to specifications.

UHV Sputtering ensures that environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out. (ISO 9001:2015 §7.5.1)

Section 8: Measurement, analysis & improvement (ISO 9001:2015 §9)

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 effectives of processes. Furthermore, this data is reviewed during management review in order to continually improve and maintain the effectiveness of the Quality Management System. (ISO 9001:2015 §9.1)

8.2 Monitoring and Measurement (ISO 9001:2015 §9.1)

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, as well as regulatory agency, 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, monitoring and maintaining the product requirements, and product realization or improvement processes. This information shall be reported to upper management during management review for the purpose of determination of criteria for corrections and improvements to individual issues as well as the QMS as a whole. (ISO 9001:2015 §8.5.5, 9.1.2)

8.2.2 Customer Complaints
UHV Sputtering maintains a documented procedure for timely complaint handling in accordance with applicable regulatory requirements. This procedure provides guidance and requirements relative to customer complaints, including:
- receiving and recording information;
- evaluating information to determine if the feedback constitutes a complaint;
- investigating complaints;
- determining the need to report the information to the appropriate regulatory authorities;
- handling of complaint-related product;
- determining the need to initiate corrections or corrective actions.

If a customer complaint is not investigated, UHV Sputtering shall document the justification for waiver of investigation. All corrective activities resulting from a customer complaint shall be documented, using UHV Sputtering form **F-821-1**, and in accordance with procedure **P-821-1**.

If an investigation determines activities outside the organization contributed to the complaint, relevant information shall be exchanged via a SCAR (Supplier Corrective Action Report **F-852-3**) between the organization and the external party involved. Complaint handling records shall be maintained per UHV Sputtering Procedure P-425-1, Control of Records (see section 4.2.5 of this Manual) (ISO 9001:2015 §9.1.2)

8.2.3 Reporting to regulatory authorities
In the event that applicable regulatory requirements require notification of complaints that meet specified reporting criteria of adverse events or issuance of advisory notices, UHV Sputtering maintains a procedure (**P-823-1**) that provides guidance with regard to providing notification to appropriate regulatory agencies, as well as other stakeholders. Records of reporting to regulatory authorities are maintained according to section 4.2.5 of this Manual. (ISO 9001:2015 §8.5.5)

8.2.4 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-824-1**.

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 if the QMS is effective in achieving its objectives.
Records of Internal Audit results are maintained according to section 4.2.5 of this Manual. (ISO 9001:2015 §9.2)

8.2.5 Monitoring and Measurement of Processes
UHV Sputtering has established methods which will employ suitable methods for monitoring and measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate. (ISO 9001:2015 §9.1)

8.2.6 Monitoring and Measurement of Product
UHV Sputtering has established a documented procedure (Inspection Procedure **P-826-1**), for the purpose of monitoring and measuring of product characteristics, to verify that stated product requirements have been met. Monitoring activities take place at applicable points during the product processing, per documented plans and arrangements. Conformity to requirements is recorded and records maintained. These records of conformity include (but are not limited to):

- Data that provides basis for acceptance,
- Test equipment used to make acceptance determination,
- identity of the person authorizing release of product.

No product processed by UHV Sputtering will be released without all required steps assuring conformance having been approved and documentation completed. Records are maintained according to section 4.2.5 of this Manual. (ISO 9001:2015 §8.6)
As applicable to this Section, UHV Sputtering has excluded itself from ISO 13485:2016 requirements germane to implantable See section 1.8

8.3 Control of Nonconforming Product (ISO 9001:2015 §8.7)

8.3.1 General
UHV Sputtering ensures that products which do not conform to product requirements are identified and controlled to prevent unintended use or delivery. UHV Sputtering's Control of Discrepant Materials Procedure (**P-830-1**), which defines the controls, responsibilities and authorities relative to identification, documentation, segregation, evaluation and disposition of nonconforming products and materials.

UHV Sputtering shall, determine, as warranted, the need for an investigation and notification of any external party responsible for the nonconformity. The evaluation of nonconformity shall include a determination of the need for an investigation and notification of any external party responsible for the nonconformity. Records of the nature of the nonconformities and any subsequent action taken, including: evaluation, investigation, concessions obtained, and the rationale for decisions shall be maintained according to section 4.2.5 of this Manual. (ISO 9001:2015 §10.2)

8.3.2 Actions in Response to Nonconforming Product Detected Before Delivery
UHV Sputtering takes action with regard to nonconforming product in appropriate fashions, utilizing one or more of the following (but not limited to) methods that:

- take action to eliminate the detected nonconformity;
- take action to preclude its original intended use or application;
- authorize its use, release or acceptance under concession.

UHV Sputtering ensures that nonconforming product is accepted by concession only in the event that:

- justification is provided,
- approval is obtained, and
- applicable regulatory requirements are met.

Records of the acceptance by concession and the identity of the person authorizing the concession are maintained according to section 4.2.5 of this Manual. (ISO 9001:2015 §8.7)

8.3.3 Actions in Response to Nonconforming Product Detected After Delivery

UHV Sputtering has processes and procedures in place to take action in the event that nonconforming product is detected after delivery, or if use has taken place. These procedures ensure that the actions taken are appropriate to the effects, both known or unknown, of the nonconformity.

UHV Sputtering has established a documented procedure (**Advisory Notices P-831-1**,) for the issuance of advisory notices in accordance with applicable regulatory requirements. This procedure is capable of being put into effect at any time, should the need arise.

Records of actions taken with regard to detected non-conformances, and of actions relating to the issuance of advisory notices, are maintained according to section 4.2.5 of this manual. (ISO 9001:2015 §8.7)

8.3.4 Rework

UHV Sputtering has processes and procedures in place which provide guidance in the performance of rework of product. These procedures take into account the potential adverse effect of the rework on the product, and undergo the same review and approval as the original procedure. Products that undergo rework shall be verified to ensure that applicable acceptance criteria and regulatory requirements are met. Records of activities are maintained according to section 4.2.5 of this Manual. (ISO 9001:2015 has no reference to rework)

8.4 Analysis of Data

In accordance with the Analysis of Data Procedure, **P-840-1**, and with the review of Quality Objective data (section 5.4.1 of this Manual), UHV Sputtering determines appropriate methods of collection and processing of input and output data, analyzes the collected data in order to demonstrate the suitability and effectiveness of the QMS, and performs evaluation of areas in which corrective actions and continual improvement of the effectiveness of the QMS can be made.

Inputs for data analysis can include, but are not limited to:

- Customer feedback
- Conformity to product requirements (ex; inspection results)
- Characteristics and trends of processes and product, including opportunities for improvement;
- Supplier performance;
- Audits from internal, customer, or QMS registrars

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 4.2.5 of this Manual. (ISO 9001:2015 § 9.1.3)

8.5 Improvement (ISO 9001:2015 § 10)

8.5.1 Continuous improvement

UHV Sputtering continually improves the suitability and effectiveness of the quality management system through the use of

- the quality policy
- quality objectives
- audit results
- analysis of data
- customer feedback,
- corrective and preventive actions, and
- Management review.

Customer Complaints are handled following guidance provided by UHV Sputtering Customer Feedback Procedure, P-821-1. Records of actions taken with regard to activities performed with the goal of continuous improvement are maintained according to section 4.2.5 of this Manual. (ISO 9001:2015 § 10.1)

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. All corrective actions shall take place in a timely manner, without undue delay. As well, due consideration and care shall be taken to ensure that corrections are appropriate to the issue, and that actions taken shall not cause adverse effects upon relative processes, or upon the QMS as a whole.

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 section 4.2.5 of this Manual), 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. (ISO 9001:2015 § 10.2)

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, and are devised in such a fashion as to not cause adverse effects upon relative processes, or upon the QMS as a whole.

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.
- (ISO 9001:2015 § 0.3.3, 6.1, 10.1, 10.3)