Quality Manual

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1. Company Description

VENTION MEDICAL has more than 30 years of experience partnering with customers to move their complex medical device components and solutions forward. VENTION MEDICAL has created an integrated services solution for the design, engineering and manufacturing of complex medical devices and components.

VENTION MEDICAL is comprised of three business units that possess unique skillsets and capabilities.

The Design & Development business unit is a service provider focused on providing prompt, responsive and creative product development with the capability to deliver finished devices for clinical studies and pilot manufacturing lot sizes. There are three Design Development facilities located in Marlborough, MA, Boulder, CO, and in Sunnyvale, CA.

The Advanced Components business unit provides innovative, high-quality products and components utilized in the manufacture of minimally invasive medical devices, procedures and leading-edge medical technology. This business unit's offerings include but are not limited to heat shrink tubing, balloon catheters and single-lumen, multi-lumen and over-the-wire extrusions. Facilities include Salem, NH, Minneapolis, MN, Chattanooga, TN, and Roscommon, Ireland.

The Molding and Assembly business unit focuses on precision injection molding and full service contract manufacturing of medical devices. This business unit has facilities in:

- West Haven, CT
- Heredia, Costa Rica
- Grand Rapids, MI
- South Plainfield, NJ
- Vega Baja, Puerto Rico
- Kerrville. TX

VENTION MEDICAL provides leading edge technologies, processes and innovation that allow us to have a positive effect on our customers and partners, by advancing their innovations for health.

2. Quality Policy

Quality is important to our business because lives depend on us.

We design and manufacture components and finished devices that are used to save or enhance patients' lives every day.

Consequently, we are committed to achieving the highest standards of quality in everything we do.

To achieve this vision, we pledge to:

- **Think Quality**
  - Bring customers' products to market in a timely, state-of-the-art way
  - Continuously improve the value of our products and services
  - Consistently and proactively fulfill quality and regulatory requirements
  - Maintain the effectiveness of our quality management system
- **Be Quality**
  - Follow our quality management system procedures
  - Understand how what we do affects internal and external customers
  - Take personal responsibility for quality on a day-to-day basis
  - Meet or exceed the expectations of both internal and external customers
- **Go Beyond**
  - Speak up when we see quality concerns
  - Innovate on ways to make quality an integral part of every function
  - Understand the "why's" for our procedures, not just the "what's", and look for ways to improve them
  - Live the quality mantra: "Think Quality. Be Quality. Go Beyond."

3. Quality Objectives

The Management at VENTION MEDICAL develops and establishes measurable Quality Objectives. The progress toward meeting these is presented during Management Review Meetings.

Quality Objectives are also established at the facility level and company performance against the objectives is communicated throughout VENTION MEDICAL facilities.

4. Organization Chart

The organization chart, Attachment 1, represents the top level organization of VENTION MEDICAL.

Business Unit and facility level organization charts are also maintained. See Attachment 2 for the facility specific reference document table.

The organization charts are updated as needed. Organization chart updates do not affect the revision level of the Quality Manual.

5. Scope

5.1 General

The purpose of the Quality Manual is to document the VENTION MEDICAL Quality Management Systems for all employees whose actions affect product quality and to inform customers of the controls that have been implemented to assure product quality.

The VENTION MEDICAL Quality Manual provides an outline for policies, procedures and other documents to comply with the following quality system standard and regulations:

ISO 13485:2003, Medical devices – Quality management systems – Requirements for regulatory purposes

Food and Drug Administration (FDA), 21 CFR Part 820, Quality System Regulation (QSR)

Some facilities may have certification to additional standards and regulations. This is identified in Table 1 below:

TABLE 1, CERTIFICATIONS

Facility	Certifications/Registrations
California/Massachusetts	ISO 13485:2003, ISO 14971:2007 and EN ISO 14971:2012
Connecticut	ISO 13485:2003
Costa Rica	ISO 13485:2003 / JPAL/MHLW Ordinance 169
Ireland	13485:2003
Michigan	ISO 13485:2003/ JPAL/MHLW Ordinance 169
Minnesota	ISO 13485:2003
New Hampshire	ISO 13485:2003
New Jersey	ISO 13485:2003/ JPAL/MHLW Ordinance 169
Puerto Rico	ISO 13485:2003
Tennessee	ISO 9001:2008
Texas	ISO 13485:2003, 9001:2008

The Quality Manual is available as a training tool for all VENTION MEDICAL employees to assist in understanding and implementing the Quality Policy, Objectives, and procedures. This Quality Manual also acts as a guide for internal and external auditors (FDA, registrar, customers, etc.) in their assessment of the system with respect to compliance with regulatory requirements.

The requirements outlined in this Quality Manual apply to all VENTION MEDICAL business units and their respective facilities unless otherwise specified.

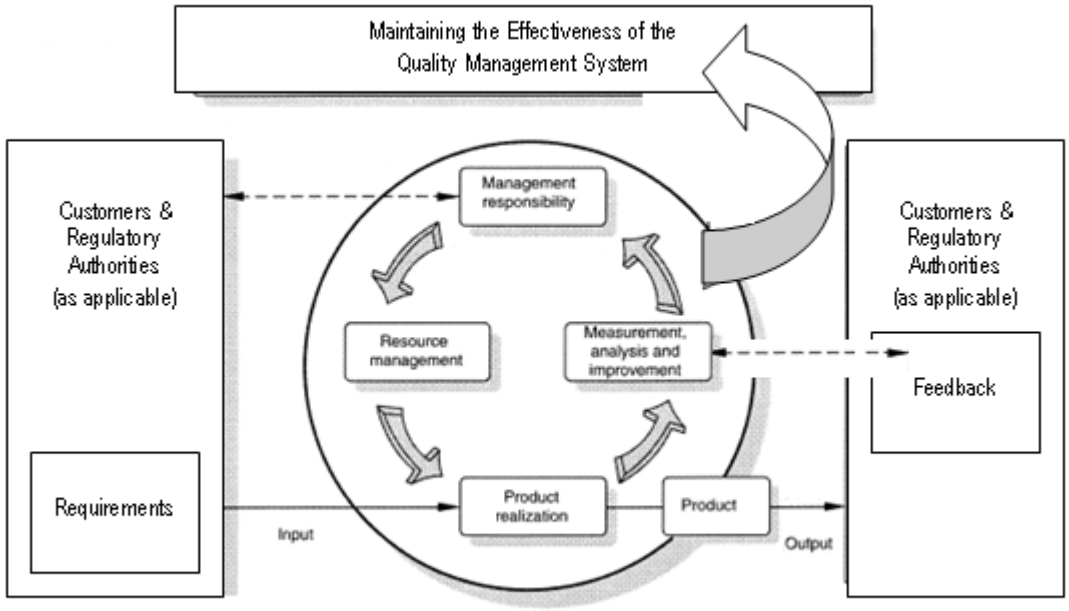
VENTION MEDICAL Senior Quality and Regulatory staff are responsible for developing, implementing, and maintaining VENTION MEDICAL, corporate Quality Manual, company-wide Quality Procedures, Work Instructions, and Forms that are issued to each location and are required for meeting the quality systems requirements described in this manual. The Quality Manual and other company-wide VENTION MEDICAL documents are considered controlled documents and are issued to each location to be released in the local document control system. Changes to the content of the Quality Manual and other company-wide VENTION MEDICAL procedures are maintained through VENTION MEDICAL Document Management System procedure, VM-QS-00001.

Annual review of the Quality Manual is coordinated by the Management Representatives or designee(s) to ensure its continuing suitability and effectiveness. Documentation of the annual review is included in the annual Management Review meeting minutes and/or document change order files.

Each facility is responsible for developing, implementing, and maintaining Quality Procedures, Work Instructions, Forms, Documents, and Records required for meeting the quality systems requirements described in this manual.

Operations performed at suppliers and subcontractors must meet specified criteria as set forth in manufacturing and supplier related processes within the facility's procedures.

Vention Quality System Flowchart



Business Unit and facility level quality system process flow charts are also maintained. See Attachment 2 for the Facility Specific Reference Document Table.

5.2 Regulation Reference Tables

Each facility is responsible for maintaining a Regulation Reference Table, to outline the correspondence between their Quality Management System and the applicable sections of the current versions of ISO 13485 and the FDA Quality System Regulations. See Attachment 2 for the facility specific Regulation Reference Table document.

5.3 Application

VENTION MEDICAL provides integrated services solution for the design, engineering and manufacturing of complex medical devices and components. Each location has specific requirements for the medical device solutions that they provide.

Requirements of the ISO 13485 standard that are not applicable or are documented as exclusions for a facility are listed in Table 2, Application, below.

TABLE 2, APPLICATION

Facility	Exclusions	Non-Applications
California/Massachusetts	None	7.5.1.2.2 Installation, 7.5.1.2.3 Service
Connecticut	7.3 Design Control	7.5.1.2.2 Installation, 7.5.1.2.3 Service
Costa Rica	7.3 Design Control	7.5.1.2.2 Installation, 7.5.1.2.3 Service,
Ireland	None	7.5.1.2.2 Installation, 7.5.1.2.3 Service
Michigan	7.3 Design Control	7.5.1.2.2 Installation, 7.5.1.2.3 Service
Minnesota	None	7.5.1.2.2 Installation, 7.5.1.2.3 Service
New Hampshire	None	7.5.1.2.2 Installation, 7.5.1.2.3 Service, 7.5.1.3 Particular Requirements for sterile medical devices, 7.5.2.2. Particular Requirements for sterile medical devices and 7.5.3.2.2 Particular Requirements for active implantable and implantable medical devices
New Jersey	7.3 Design Control	7.5.1.2.2 Installation, 7.5.1.2.3 Service
Puerto Rico	7.3 Design Control	7.5.1.2.2 Installation, 7.5.1.2.3 Service
Tennessee	7.3 Design Control	7.5.1.2.2 Installation, 7.5.1.2.3 Service
Texas	7.3 Design Control	7.5.1.2.2 Installation, 7.5.1.2.3 Service, 7.5.1.3 Particular Requirements for sterile medical devices, 7.5.2.2. Particular Requirements for sterile medical devices and 7.5.3.2.2 Particular Requirements for active implantable and implantable medical devices

6. Normative References

This Quality Manual defines the VENTION MEDICAL Quality Management System and was prepared using the following as reference materials.

ISO 13485:2003 Medical devices – Quality management systems – Requirements for regulatory purposes

Food and Drug Administration 21 CFR Part 820

ISO 9000:2005 Quality management systems – Fundamentals and vocabulary

ISO/TR 14969:2004 Medical devices – Quality management systems – Guidance on the application of ISO 13485:2003

7. Definitions

Definitions as stated in: ISO 9000:2005 Quality management systems – Fundamentals and vocabulary, ISO 13485:2003 Medical devices – Quality management systems – Requirements for regulatory purposes and Food and Drug Administration 21 CFR Part 820

8. Quality System Requirements

8.1 General Requirements

VENTION MEDICAL through each of its facilities has established, documented, implemented, and maintains a Quality Management System and continually improves the effectiveness of those systems in accordance with the requirements of ISO 13485:2003. The documents defining the quality system are organized into the structure as outlined below:

(a) Quality Manual – (Vention Medical)

(b) Quality Procedures (Standard Operating Procedures) – (Vention Medical, Facilities)

(c) Operational Procedures such as Work Instructions Drawings, Specifications, Documents, and Forms – (Facilities)

(d) Quality Records – (Vention Medical, Facilities)

VENTION MEDICAL has:

- Identified the processes needed for the Quality Management System as well as their application throughout the organization
- Determined the sequence and interaction of these processes and documented them in the Quality System Flow Diagram (Section1.1)
- Specified criteria and methods required to ensure the operation and control of these processes are effective
- Ensured availability of resources and information necessary to support the operation and monitoring of these processes
- Developed methods to monitor, measure, and analyze these processes
- Implemented action(s) necessary to accomplish planned results and preserve the effectiveness and continual improvement of the Quality Management System

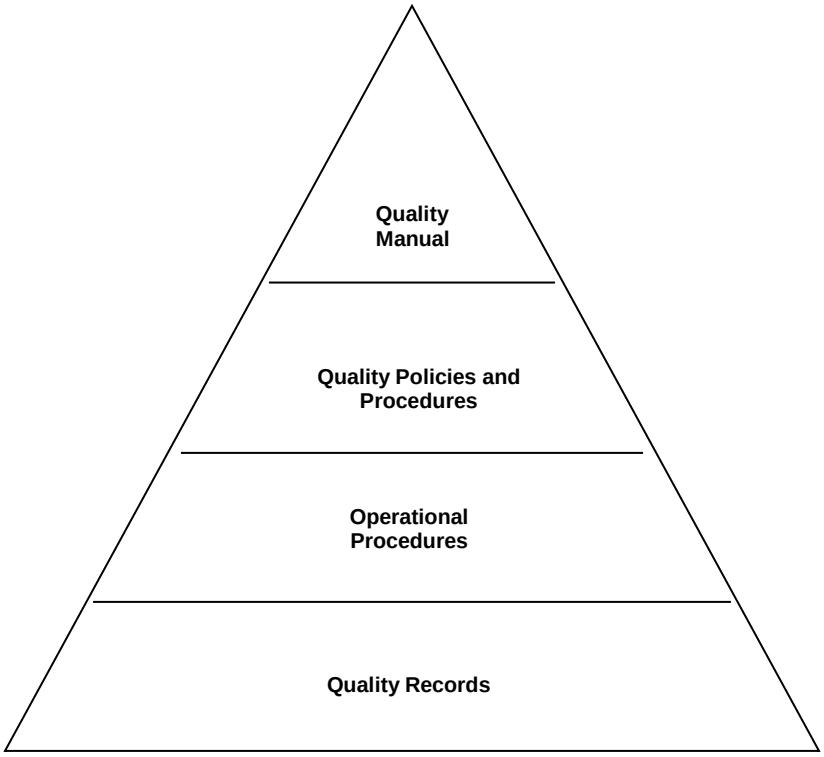
These processes include management activities, provision of resources, product realization and measurement.

VENTION MEDICAL facilities will ensure control over any process that is outsourced which could affect product conformity. Control of such processes is specified within the local Quality Management System. Each facility is responsible for defining the methods to control outsourced activities.

8.2 Documentation Requirements

8.2.1 General

The quality system is defined by documents that encompass all the requirements of the applicable standards and regulations. The documentation allows effective implementation of a consistent quality system. These documents have been organized as outlined in Section 4.1. The extent of the Quality Management System documentation at each facility will depend on the risk, complexity and interaction of the processes at the facility.



8.2.2 Quality Manual

The Quality Manual describes the VENTION MEDICAL Quality Management System including the requirements for a Quality Policy and Quality Objectives. The scope is described in section 1.1. Permissible exclusions of the Quality Management System are tailored to align with the quality management system needs for each facility and are listed in Section 1.2, Table 2, Application.

8.2.3 Control of Documents

The members of VENTION MEDICAL Quality and Regulatory organization are responsible for managing, coordinating, and supervising the document control process for the Quality Manual and the content of any VENTION MEDICAL company-wide procedures. This is done in accordance with VM-QS-00001, Vention Document Management System Procedure.

The Management Representative for each facility is responsible for managing, coordinating, and supervising the document change process for documents applicable to their Quality System. Changes to revision controlled documents may only be made in accordance with the document change control procedure associated with a particular facility. The procedures include steps to ensure review by appropriate personnel with the pertinent background information upon which to base decisions, and to assess and approve documents prior to release.

Documented procedures are established to define the controls needed to:

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

Approved changes are communicated to the appropriate personnel in a timely manner. Change records include a description of the change, approval signatures and date when the change becomes effective.

Documents may be maintained in either hard copy or electronic form. At least one copy of obsolete controlled documents is retained. The retention periods are determined by the facilities in accordance with regulatory requirements and international standards.

8.2.4 Control of Records

Records are established and maintained to provide evidence of conformity to requirements and of the effective operation of the Quality Management System. Records will remain legible, readily identifiable and retrievable. Each facility has documented procedures to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

9. Management Responsibility

9.1 Management Commitment

The VENTION MEDICAL President with other Management is responsible for the establishment and maintenance of the VENTION MEDICAL Quality Management System. Each facility has detailed procedure(s) for management responsibility and authority which delineate their requirements and responsibilities.

Management provides evidence of its commitment to the development of the Quality Management System and continually improving its effectiveness by:

- Communicating to all employees the importance of meeting customer, statutory and regulatory requirements
- Establishing the Quality Policy
- Ensuring that Quality Objectives are established
- Conducting Management Reviews
- Ensuring the availability of resources

The VENTION MEDICAL organization and the interrelation of personnel responsible for quality system implementation at VENTION MEDICAL are defined in the Vention Organization Chart (Attachment 1).

Business Unit and facility level organization charts are also maintained. See Attachment 2 for the facility specific reference document table.

The head of each facility is ultimately responsible for establishing, implementing, and maintaining the quality system within the facility.

9.1.1 Customer Focus

VENTION MEDICAL facilities strive to identify current and future customer needs to meet customer requirements and exceed customer expectations.

9.1.2 Quality Policy

The Quality Policy is implemented through a commitment of all VENTION MEDICAL employees to focus on our customer's needs and desires. This is reflected in our Quality Policy statement that is displayed and effectively communicated to employees.

The Policy provides a framework for establishing Quality Objectives.

Top Management ensures that the Policy is communicated throughout the organization.

The Policy is reviewed for continuing suitability.

9.1.3 Planning

9.1.3.1 Quality Objectives

Quality Objectives, including those to meet requirements for product, are established at relevant functions and levels based on the Quality Policy to support continual improvement and strategic goals. The objectives are reviewed annually for suitability.

Quality Objectives are measurable and performance results are reviewed against goals on a regular basis.

9.1.3.2 Quality Management System Planning

Quality Management System elements and processes are planned to ensure that the system meets the general requirements and Quality Objectives.

Quality Plans are formulated for Quality System related projects as a means to maintain the integrity of the Quality System. Each facility has a process for quality planning that is appropriate for the facility needs and delineates requirements and responsibilities.

9.1.4 Responsibility, Authority and Communication

9.1.4.1 Responsibility and Authority

Top Management ensures the responsibilities and authorities are defined, documented and communicated within VENTION MEDICAL. Interrelationships and independence of personnel who manage, perform, and verify work affecting quality are also established. Departments and functions are defined by each facility in the organization charts. Job descriptions define the responsibilities and authorities of each position.

9.1.4.2 Management Representative

The VENTION MEDICAL Quality and Regulatory organization is responsible for the overall effectiveness and suitability of the Quality Management System.

The head of each facility is responsible for appointing a Management Representative, who, irrespective of other responsibilities, has defined authority to:

- Ensure that a quality system is established, implemented, and maintained in accordance with ISO 13485:2003 and Food and Drug Administration (FDA), 21 CFR Part 820 and other applicable standards and regulations
- Report on the performance of the quality system to management for evaluation and as a basis for improvement of the quality system

- Act as a liaison with representatives from FDA, Registrars, customers, or other 3rd parties on matters relating to the quality system
- Ensure the promotion of awareness of regulatory and customer requirements throughout the organization

The Management Representative(s) may delegate responsibilities for the Quality Management System to others in the organization. The Management Representative may appoint one or more Deputy Management Representative.

9.1.4.3 Internal Communication

Management ensures the appropriate processes are in place to communicate to the organization:

- Quality Policy and Objectives
- Customer and regulatory requirements
- The effectiveness of Quality Management System

Examples of the methods of communication are; the Quality Manual, policies, procedures, reports and regular meetings. Information may be circulated by postings or electronically.

9.1.5 Management Review

Top Management reviews the Quality Management System, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness.

Regular Management Review meetings are held on a schedule established in the quality procedures for each facility. At a minimum, Management Review meetings are held annually.

Input for the Management Review will include: audit results, customer feedback, process performance and product conformity, if applicable, corrective and preventative actions, follow-up actions from previous Management Reviews, performance against Quality Objectives, changes that could affect the Quality Management System, recommendations for improvement, any new or revised regulatory requirements and an assessment of suitability of the Quality Management System.

Output from Management Review will include: possible improvements to the Quality Management System, improvements to customer product and processes, and resource needs.

An annual Vention level Management Review will be held in accordance with VM-QS-00044, Corporate Quality Management Review Process.

Records of the dates of Management Review and the results are documented and maintained.

9.2 Resource Management

9.2.1 Provision of Resources

Management is responsible for ensuring that adequate resources are made available to implement and maintain the effectiveness of the Quality System at all levels of the organization and to ensure consistent fulfillment of customer and regulatory requirements. Resources include personnel, financial, information, infrastructure, and work environment.

9.2.2 Human Resources

9.2.2.1 General

Personnel performing work affecting product quality must be competent on the basis of appropriate education, training, skills, and experience. Records of education, experience, and training are maintained at each facility to demonstrate the suitability of each person for a specific task or position.

9.2.2.2 Competence, Awareness, and Training

The minimum competencies required for each employee are defined in the job descriptions. Each employee has an associated job description. Job descriptions are maintained by each facility. Additional responsibilities may be referenced within specific procedures and work instructions.

Quality Management System awareness training is provided to all employees (regular and temporary) at the start of their employment. Awareness of the requirements, of applicable standards, regulations, guidelines, Quality Policy, companywide policies and procedures, facility policies and procedures, and safety are emphasized in training.

All personnel are made aware of defects or errors which may occur from incorrect performance of their jobs which can affect product quality. Personnel are also made aware of how their actions contribute to the achievement of Quality Objectives. Personnel who perform verification and validation activities are made aware of defects and errors that may be encountered as part of their job. Additional training is required of personnel working in controlled environments.

Effectiveness of training is evaluated. Records of education, training, skills and experience are maintained in accordance with the facility procedures.

Retraining is performed as necessary.

9.2.3 Infrastructure

VENTION MEDICAL provides suitable work environments to perform the operations necessary to meet product and customer requirements. The layouts of the facilities are designed to provide sufficient space and promote the systematic handling and segregation of materials, equipment, and product.

The facilities are furnished with the necessary equipment to enable an efficient operation. The equipment is maintained on a scheduled basis to ensure that manufacturing specifications are met. The maintenance activities are documented and records are maintained.

Each facility is cleaned and maintained by personnel trained to procedures established at the facility.

Software that is used in the Quality System for decision making or automated data processing systems used in production of devices requires software validation activities.

VENTION MEDICAL facilities provide other necessary supporting services such as transport and communication as appropriate.

9.2.4 Work Environment

VENTION MEDICAL facilities will determine and manage the work environment needed to attain conformity to the requirements.

The following requirements will apply:

- The establishment of documented requirements for health, cleanliness, and clothing of personnel if contact between such personnel and the product or work environment could adversely affect the quality of product.
- If work environment conditions can have an adverse effect on product quality, each facility will establish documented requirements for the work environment conditions and documented policies, procedures, and work instructions to monitor and control these work environment conditions.
- Personnel who are required to work temporarily under special environmental conditions will be appropriately trained or supervised by a trained person.
- If appropriate, arrangements will be established and documented for the control of contaminated or potentially contaminated product in order to prevent contamination of other product, the work environment, or personnel.

Management at each facility is responsible for ensuring a suitable working environment for personnel. This includes both human and physical factors.

Manufacturing material that could have an adverse effect on product quality is controlled by procedures to ensure that it is removed or limited to a safe level.

Controlled environments, at each facility, are monitored on a routine basis for compliance to defined specifications as detailed in the procedures at the facility. These activities are documented and reviewed.

10. Product Realization

10.1 Planning of Product Realization

VENTION MEDICAL facilities plan and develop detailed processes needed for product realization. Planning of product realization is scaled appropriately for each project and is based on the customer and the project's complexity and anticipated duration.

Product realization plans include, as applicable at each facility:

- Quality Objectives and product requirements
- Process to ensure the product design is correctly translated into production specifications
- Processes, documentation and provision of resources specific to the product
- Verification, validation, monitoring, inspection and test activities specific to the product to fulfill requirements
- Documented requirements for risk management throughout product realization
- Records needed to provide evidence that the realization processes and resulting product meet requirements are maintained

Product realization plans are created at each facility. The plans are defined in various documents such as product specification, flowcharts, production orders, control plans, quality plans, work instructions, verification and validation reports, risk management files, etc.

10.2 Customer-Related Processes

10.2.1 Determination of Requirements Related to the Product

Customer requirements are determined and documented including:

- Customer specified product requirements
- Statutory and regulatory requirements related to product
- Delivery and post-delivery activities
- Other necessary requirements including those that may not be specified by the customer

10.2.2 Review of Requirements Related to the Product

Each facility reviews the requirements related to the product prior to committing to customer purchase orders or contracts. This ensures that:

- Product requirements are defined and documented
- Contract or order requirements differing from those previously agreed are resolved
- The organization has the ability to meet defined requirements

Records of the review and any actions arising from this review are maintained.

Where requirements are not documented by the customer, they will be confirmed before acceptance. Where product requirements are changed, relevant documents are amended and the personnel affected are made aware of the requirement changes.

10.2.3 Customer Communication

VENTION MEDICAL maintains effective communication with all customers. Each facility has processes in place to assure updated product information is available and to ensure the proper handling of:

- Inquiries, contracts and order handling, including amendments
- Customer feedback including customer complaints
- Advisory notices as appropriate for the facility

10.3 Design and Development

10.3.1 General

Each facility that is involved in the development of new products and/or the modification of existing products must establish design control policies and procedures as well as comply with applicable standards and regulations. Where applicable, procedures must include processes to ensure that the device design or component is properly translated into production specifications.

For facilities with a design and development process the following will be included.

10.3.2 Design and Development Planning

The planning process must be documented, reviewed, updated, approved, and retained as the design process progresses.

These plans identify the design review, verification, validation and design transfer activities that are appropriate at each development stage. The plans outline the responsibilities and authorities and the interfaces among the groups responsible for the design and development processes.

The plans are documented reviewed, updated, and approved as needed.

10.3.3 Design and Development Inputs

The design input process consists of collecting and translating the customer's requirements into design requirements that address the intended use and needs of the customer as well as functional, performance, safety, statutory and regulatory requirements. In addition, there is a mechanism for addressing incomplete, ambiguous, or conflicting requirements.

These inputs may include:

- Customer specifications, including the needs of the user and patient
- Functional, performance and safety requirements, according to the intended use
- Applicable regulatory and legal requirements
- Where applicable, information derived from previous similar designs
- Output(s) of risk management
- Other requirements essential for design and development, such as manufacturability and assembly

Inputs relating to product requirements are defined and documented. Inputs identify design criteria, materials, packaging requirements, labeling requirements, processes requiring development, and analysis including prototype testing and all other requirements to the greatest possible extent. The design input requirements are reviewed for adequacy and approved by a designated individual(s). Requirements must be complete, defined, and not conflict with each other.

The approval, including the date and signature of the individual(s) approving the requirements are documented.

Records are maintained.

10.3.4 Design and Development Outputs

Design outputs are the results of the design effort. The design output identifies those aspects of the design that are crucial to the safe and proper functioning of the product. Outputs include, but are not limited to drawings, BOMs, Routings, inspection instructions, process documentation, packaging, labeling, etc. Design and development outputs must permit verification against the design and development inputs.

The outputs will:

- Meet the input requirements for design and development
- Provide appropriate information for purchasing, production, and for service provision (where applicable)
- Contain or reference product acceptance criteria
- Specify the characteristics of the product that are essential for its safe and proper use

Outputs include but are not limited to, product specification, manufacturing procedures, packaging/labeling and engineering drawings.

Prior to release, design output documentation must be reviewed and approved. The approval, including the date and signature of the individual(s) approving the output are documented.

Records are maintained.

10.3.5 Design and Development Review

Design review meetings are planned according to the complexity, criticality and nature of the work under review. A design review covering the technical aspects of a project shall be held at suitable stages of the project, to evaluate the ability of the results of design and development to meet requirements and to identify any problems and propose necessary actions. Participants in design reviews shall include representatives of functions concerned with the design and development stage being reviewed, a person independent from the project, and any specialist personnel.

The results of design reviews, including the identification of the design, the date, and individuals performing the review are documented. Records of these design reviews and any necessary actions are maintained.

10.3.6 Design and Development Verification

Design verification activities are performed in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements. The results of the design verification, including identification of the design method(s), any required actions, the date, and the individual(s) performing the verification are maintained.

Records of the results of the verification and any necessary actions shall be maintained.

10.3.7 Design and Development Validation

Design validation are planned and performed to ensure that devices conform to defined user needs and intended uses under actual or simulated use conditions. Design validation includes risk analysis, where appropriate. Clinical evaluation required by national or regional regulations, may be conducted and may also be used to satisfy the requirements of design validation. The results of the design validation activities that VENTION MEDICAL is responsible for based on customer agreements, as well as any necessary actions, the date, and the individual(s) performing the validation are maintained.

10.3.8 Design Transfer

Procedures detail design transfer activities to ensure a device design is adequately translated from development specifications into a Device Master Record for manufacturing purposes.

10.3.9 Control of Design and Development Changes

Design change records are maintained for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation. Changes to the design must be controlled to ensure the changes do not adversely affect the quality and/or safety of the product. This review includes evaluation of the effect of the changes on inventoried parts and product already delivered.

Records of the results of the review of changes and any necessary actions are maintained.

10.4 Purchasing

10.4.1 Purchasing Process

VENTION MEDICAL facilities have procedures to ensure that purchased product conforms to specified purchase requirements. The procedures outline the extent of control applied to the suppliers and are dependent upon the effect of the purchased product on subsequent product or the final product.

VENTION MEDICAL evaluates and selects suppliers based on their ability to supply the required specified product. Criteria for selection, evaluation, and reevaluation, including quality requirements, are established by the procedures.

Approved Suppliers Lists are maintained by each business unit or facility. Facilities may share results of supplier evaluations, such as supplier audits, to complete the specific requirements for supplier files and maintenance of the Approved Suppliers Lists as described in those facilities procedures.

Records of the results or evaluations, and any required actions will be maintained.

10.4.2 Purchasing information

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

- Requirements for approval of product, procedures, processes, and equipment
- Requirements for qualification of personnel
- Quality Management Systems requirements

Facilities ensure the adequacy of specified requirements prior to their communication to the supplier.

Purchasing documents must be approved per facility procedures. Each facility maintains relevant purchasing documents and records for traceability.

10.4.3 Verification of Purchased Product/Service

Each facility establishes and implements the inspection or other activities necessary to ensure that purchased product meets specified purchase requirements.

The extent of verification depends upon the status of the suppliers and the criticality of the part.

When verification of purchased product is to be performed at the supplier's premises, purchasing documents must specify the intended verification arrangements and methods of product release.

Records of verification are maintained.

10.5 Production and Service Provision

10.5.1 General

VENTION MEDICAL facilities will plan and carry out production under controlled conditions to ensure devices conform to specifications. Controlled conditions will include, as applicable:

- Information that describes and methods to control the characteristics of the product
- Documented procedures, requirements, work instructions, and reference materials (external standards, codes, etc.) that define and control the manner of production and control of process parameters, as well as criteria for workmanship
- The use of suitable facilities and equipment
- The implementation of monitoring and measurements using appropriate tools and equipment
- The implementation of defined operations for labeling, packaging and lot traceability
- The implementation of release, delivery, and post-delivery activities (VENTION MEDICAL's customers are usually responsible for post-delivery activities for medical devices.)

Records of each lot or batch of manufactured product including the dates of manufacture, quantity accepted and released for distribution to customers, and acceptance records are verified and maintained.

10.5.2 Cleanliness of Product and Contamination Control

Each facility establishes documented requirements for cleanliness of product as required by the product being produced and specific customer requirements.

10.5.3 Installation Activities

If applicable at a business unit or facility, to meet customer requirements, procedures will be put in place to control installation activities.

10.5.4 Servicing Activities

If applicable at a business unit or facility, to meet customer requirements, procedures will be put in place to control servicing activities.

10.5.5 Particular Requirements for Sterile Medical Devices

Each facility, as applicable, will maintain records of the process parameters for the sterilization process which was used for each sterilization batch. Sterilization records will be traceable to each production batch of medical devices.

10.5.6 Validation of Processes

VENTION MEDICAL facilities establish procedures for the validation of processes. Any process where the resulting output cannot be verified by subsequent monitoring, measurement, or test must be validated. This includes processes where deficiencies become apparent only after the product is in use.

Validation demonstrates the ability of these processes to achieve planned results.

Validation plans include, as applicable:

- Defined criteria for review and approval of processes
- Approval of equipment and qualification of personnel
- Use of specific methods and procedures
- Requirements for records
- Revalidation assessment criteria

10.5.7 Software Validation

Vention Medical facilities have established procedures for the validation of application software and changes to such software and/or its application.

Software applications that affect product or are used as part of the quality system are validated prior to use. Validation protocols define the scope of validation requirements for “out-of the box”, modified, or custom software.

Records of the date and the personnel performing validation and revalidation activities are maintained.

10.5.8 Particular Requirements for Sterile Medical Devices

Each facility, as applicable, has procedures for the validation of sterilization process prior to initial use. VENTION MEDICAL participates in the sterilization validation and routine processing according to the specified customer agreement or contract.

Records of the validation are maintained.

10.5.9 Identification and Traceability

VENTION MEDICAL facilities establish documented procedures for identification and traceability. The procedures define the degree of product traceability and the records required.

Processes identify the product by appropriate means throughout product realization including the product status with respect to monitoring and measuring. The acceptance status of the product is maintained to indicate the conformance or non-conformance with acceptance criteria.

The identification of product status is maintained throughout production and storage of product to make certain that only product that has passed the required inspections and tests is dispatched or used. Identification of returned product is maintained to distinguish the returned product from conforming product.

Where traceability is a requirement, each facility has procedures to control and record the unique identification of the product. This includes procedures for implantable and active implantable product as directed by our customers.

10.5.10 Customer Property

VENTION MEDICAL facilities establish documented procedures for control of customer property.

Care is exercised with customer property while it is under a facility's control or being used by the facility. Facilities identify, verify, protect, and safeguard the customer property provided for use or incorporation into the product. If any customer property is lost, damaged, or otherwise found to be unsuitable for use, it is reported to the customer and records are maintained.

Intellectual property and/or confidential health information belonging to a customer will be safeguarded by VENTION MEDICAL.

10.5.11 Preservation of Product

VENTION MEDICAL facilities establish documented procedures for preserving product including handling, storage, packaging, labeling, and delivery.

Processes preserve conformity of product during internal processing and delivery to the intended destination. This preservation includes identification, handling, packaging, storage, and protection. Preservation also applies to the constituent parts of a product.

There are established documented procedures or documented work instructions for the control of product with a limited shelf life or requiring special storage conditions. Such storage conditions will be controlled and recorded.

10.6 Control of Monitoring and Measuring Devices

VENTION MEDICAL facilities establish documented procedures for controlling monitoring and measuring devices.

Each facility determines the monitoring and measurement to be undertaken and the monitoring and measuring device needed to provide evidence of conformity of product to specified requirements.

Processes are established to ensure that monitoring and measurement can be carried out and is carried out in a manner that is consistent with the monitoring and measurement requirements. Procedures describe the methods for the unique labeling of monitoring and measuring tools and equipment including calibration status and due date.

Where necessary to ensure valid results, measuring equipment will:

- Be calibrated or verified at specific intervals, or prior to use, against measurement standards traceable to international or national standards
- Where no such standard exists, the basis used for calibration or verification will be recorded
- Be adjusted or re-adjusted as necessary
- Be identified to enable the calibration status to be determined
- Be safeguarded from adjustments that would invalidate the measurement result
- Be protected from damage and deterioration during handling, maintenance, and storage

An assessment of the validity of the previous measuring results is documented when the equipment is found not to conform to the requirements. The records will document action taken on the equipment and any product affected. Calibration records include: equipment identification, calibration dates, individual performing the calibration, and next calibration due date. Records of the results of calibration and verification are maintained.

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

11. Measurement, Analysis, and Improvement

11.1 General

VENTION MEDICAL facilities have procedures for the measuring and monitoring activities required to ensure product conformity, to facilitate continual improvement to processes and the Quality Management System, and to continually improve the effectiveness of the quality management system.

Processes include determination of appropriate methods, including statistical techniques used for analyzing quality measurement data and the extent of their use to ensure valid results.

11.2 Monitoring and Measurement

11.2.1 Customer Feedback

Each facility monitors, collects and analyzes information from its customers. The procedures detail the methods for collecting information on customer satisfaction. Possible sources of customer feedback are:

- Customer Complaints
- Customer Audits
- Customer Surveys
- Customer Supplied Performance Metrics

The customer feedback analysis will be documented to provide early warning of quality problems and may provide input into the corrective and preventive action system.

11.2.2 Internal Audit

Internal audits are conducted at planned intervals to determine the effectiveness of the Quality Management System. Each facility has procedures for planning, conducting, and documenting the results of the audits within the facilities. These audits are scheduled on the basis of the status, importance, results of previous audits and potential risk of the process to be audited.

Personnel performing the audits must be qualified and independent of the area being audited.

Internal quality audit results might generate, action items, corrective or preventative actions, and follow-up activities to ensure the actions were taken and are effective.

Corrective actions are issued to the appropriate managers for any deficiencies detected during audits. Managers will ensure that actions are taken to eliminate detected nonconformities and their cause in a timely matter. Follow-up verification is required to verify the effectiveness of the corrective actions.

11.2.3 Monitoring and Measurement of Processes

Appropriate methods for monitoring and where applicable, measurement of the Quality Management System is in place at each facility. These methods will demonstrate the ability of the processes to achieve planned results. Corrective action will be taken as appropriate to ensure conformity of the product when planned results are not achieved.

11.2.4 Monitoring and Measurement of Product

Inspection and testing activities are performed to verify that the specified product requirements are met. Procedures are in place for inspection and testing that define requirements and responsibilities.

Records of inspections are maintained to provide evidence of conformity with the acceptance criteria. Records include:

- Identification of the person(s) performing inspection and tests
- Acceptance activities performed, the results, signature and the dates of those activities, and where appropriate the equipment used
- Identification of the person(s) authorizing the release of the product

Incoming, in-process product and final product are inspected and tested, as appropriate, to documented procedures to ensure conformance to specified requirements.

Final inspection and testing are performed to verify the finished product meets specified requirements. All inspection and testing requirements are completed, documented, and accepted prior to authorizing the release of the product for shipment.

11.3 Control of Nonconforming Product

Procedures are in place at each facility for the control of nonconforming product or process. These procedures define requirements and responsibilities needed to ensure that product not meeting specification is prevented from unintended use or delivery.

The control of nonconforming product provides for the identification, documentation, evaluation, segregation, and disposition of material that does not meet specification. Functions affected by nonconforming product are identified and notified.

Nonconforming product is handled in one or more of the following ways:

- By taking action to eliminate the detected nonconformity
- By authorizing its use and release or acceptance under concession
- By taking action to prevent its original intended use or application

Product can be accepted by concession only if regulatory requirements are met. The identity of the person authorizing the concession is recorded.

Unless otherwise specified by the customer, on customer supplied product, the customer is contacted for acceptance of nonconforming product.

When nonconforming product is detected after delivery or use has commenced, the organization takes action appropriate to the effects, or potential effects of the nonconformity. The customer is notified.

If product needs to be reworked, the rework is documented and product is re-inspected in accordance with the original specification. Rework instructions must be authorized in a manner consistent with the original work instruction. Prior to rework approval, a determination of any potential adverse effects of the rework upon the product must be reviewed and documented. Records of rework and re-evaluation activities are maintained.

Records of nonconformities and subsequent actions taken will be maintained.

11.4 Analysis of Data

Each facility compiles and analyzes data and information in their records to determine trends in the performance of product, effectiveness of the Quality Management System, and to identify areas for improvement. Each facility will coordinate these activities and use the data to provide input for management review.

When required, recognized statistical methods are used in support of design, product, or process validation, component or product release, or monitoring product or process performance.

Valid statistical rationale is the basis for choosing a particular sampling plan. Sampling plans are chosen relative to the need. Changes to sampling plans are reviewed and documented.

The analysis of data provides information relating to:

- Customer satisfaction
- Conformance to product requirements
- Characteristics and trends to processes and products including opportunities for preventive action
- Supplier performance

Records of the results of the analysis are maintained.

11.5 Improvement

11.5.1 General

Management fosters a continual improvement philosophy throughout the organization. Improvement to the effectiveness of the Quality Management System are driven through the Quality Policy, Quality Objectives, audit results, analysis of data, corrective and preventative actions, customer feedback, and Management Review.

Each facility utilizes established procedures for handling customer complaints including requirements for uniform and timely processing of complaints. Investigations of customer complaints are documented and maintained.

VENTION MEDICAL informs its customers, in accordance with facility procedures, and aids in actions if it is felt that a situation might warrant advisory notice reporting.

11.5.2 Corrective Action

VENTION MEDICAL facilities will take action to eliminate the cause of nonconformities in order to prevent recurrence.

Each facility establishes documented procedures to define requirements for:

- Reviewing nonconformities (including customer complaints)
- Determining the root 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
- Recording the results of any investigation and actions taken
- Reviewing the corrective action taken and its effectiveness

Corrective action policies and procedures for each facility include customer complaint handling, nonconformance investigation, the determination of subsequent corrective action, and verification that the corrective action was effective.

11.5.3 Preventive Action

VENTION MEDICAL facilities will determine actions to eliminate the causes of potential nonconformities in order to prevent their occurrence.

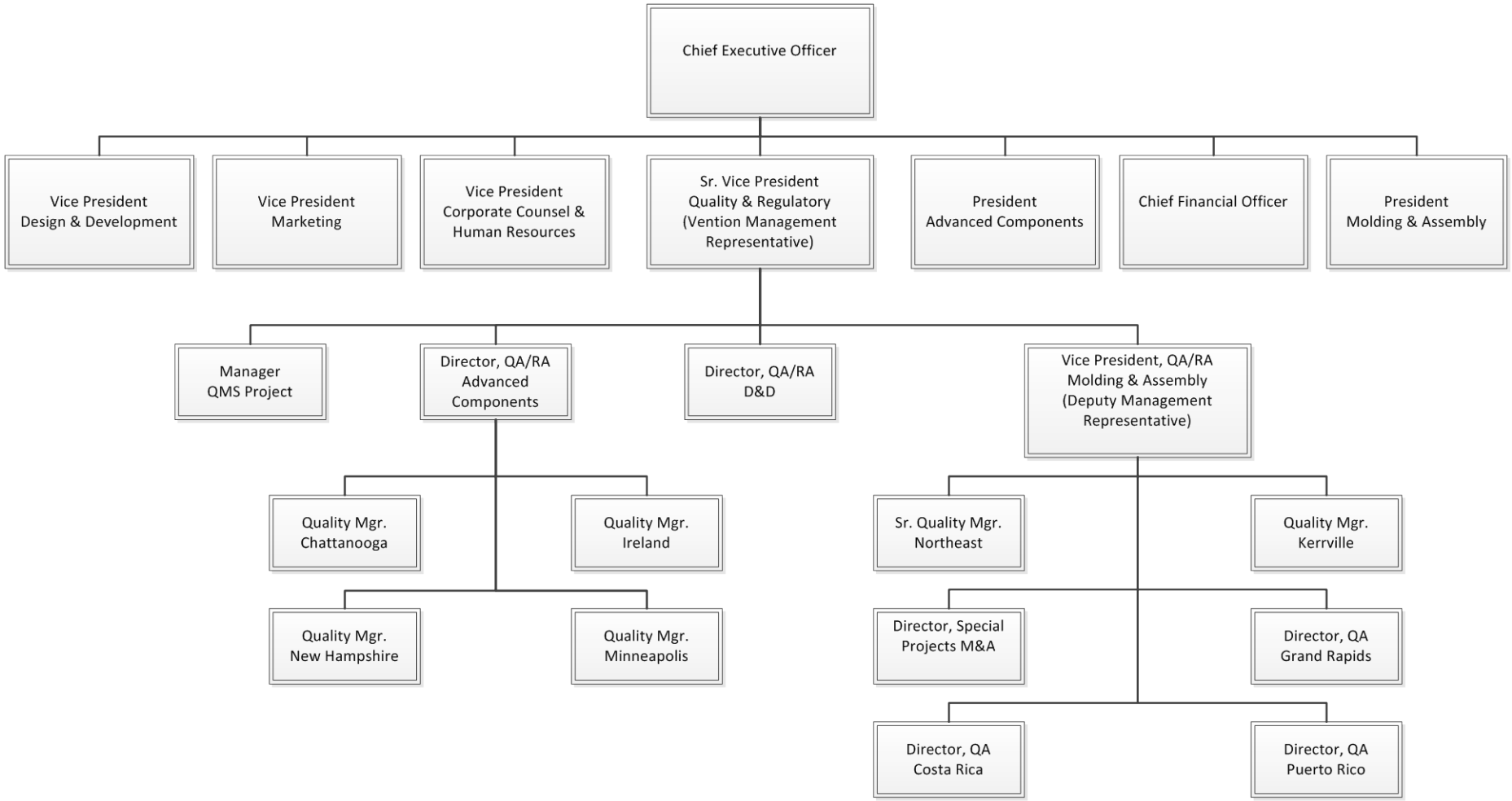
Each facility establishes a documented procedure to define requirements for:

- Determining potential nonconformities and their causes
- Evaluating the need for action to prevent occurrence of nonconformities
- Determining and implementing action needed
- Recording of results of any investigations and of action taken
- Reviewing preventive action taken and its effectiveness

Preventive action policies and procedures include the use of appropriate data to detect, analyze, and eliminate potential causes of problems, determination of the steps needed to deal with any problems requiring preventive action, determination of effectiveness of the preventive action, and submittal of the actions for review. Unfavorable trends in the above data can lead to taking preventive action.

Attachment 1

VENTION MEDICAL Organization Chart



Attachment 2

Facility Specific Reference Document Table

Each Facility maintains an Organization Chart, a Quality System Process Flow Chart and a Regulations Reference Table/Procedure Listing. See Table 3 below for applicable document references.

TABLE 3, REFERENCED DOCUMENTS

Facility	Quality System Process Flow Chart	Regulations Reference Table/Procedure Listing	Organization Chart
California/Massachusetts	101-00001	101-00001-01	101-00001
Connecticut	QM-QSF-NEC	QM-REG-NEC	QM-ORG-CT
Costa Rica	QAM-CR	QAP-039-CR	CR100-248
Ireland	AQM-001	AQM-002	AQM-003
Michigan	ATM-001	ATM-001	ATM-005
Minnesota	16862	16863	16861
New Hampshire	PRO0002	PRO0002	HR0006
New Jersey	QM-QSF-NEC	QM-REG-NEC	QM-ORG-NJ
Puerto Rico	QAMPR-03	QAMPR-01	QAMPR-02
Tennessee	QM-01	S-05-02	S-05-01
Texas	F1112-01	F1112-02	F1009-04

** NOTE: Each of the references in the table is at the current revision at each of the facilities.