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# Humanetics

**FOR INTERNAL DISTRIBUTION ONLY**

QUALITY SYSTEM

QUALITY MANUAL

THIS MANUAL SUPERSEDES  
ALL PREVIOUS QUALITY MANUALS

This description of the established and management approved quality system is to be used to ensure the conformance to specified requirements of all products manufactured and distributed by Humanetics.

**When revisions or changes are required to the contents of this Quality Manual, the complete document will be released with the Revision Level for the document incremented. Individual pages will not be separately revised or released.**

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## 1 INTRODUCTION

Humanetics is located in:

1700 Columbian Club Drive  
Carrollton, TX 75006

12918 Beltex Drive  
Manor, TX 78653

7021 S Bentsen  
McAllen, TX 78503

No. 37, Zhong Nan Road  
Wuxi, Jiang Su, China  
Post 214024

The Company serves its customers by providing precision sheet metal and machined product. The company's Corporate Headquarters is located in Carrollton, Texas.

## 2. SCOPE

The Scope of the TL 9000 R3.0 program includes the following:

***Manufacture of fabricated metal products specializing in the precision fabrication of metals and alloys to customer documented specifications – including sheet metal works, machining, welding, hardware installation and mechanical assembly.***

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### 3.0 DEFINITIONS

**Calibration:**

The comparison of a measurement or system of unverified accuracy to a measurement instrument or system of a known accuracy to detect and correct any variation from the required performance specification.

**CEO:**

Abbreviation for Chief Executive Officer.

**CFO:**

Abbreviation for Chief Financial Officer

**Corrective Action:**

Measures taken to rectify condition(s) adverse to quality and minimize recurrence.

**Documentation:**

Recorded Information.

**EPD:**

Abbreviation for Enterprise Process Definition flow charts.

**Executive Management:**

Comprised of the CEO, Sr. VP, Directors and Managers

**MRP:**

Abbreviation for Materials Requirements Planning.

**Problem Severity:**

Critical: Problem in which the part will not perform the function intended.

Major: Problem which can cause conditions that seriously affect the parts ability to perform the intended function.

Minor: Problem that do not significantly impair the function of the part to perform its intended function.

**QMS:**

Abbreviation for Quality Management System

**Quality:**

The totality of features and characteristics of an entity that bear on its ability to satisfy stated or implied needs.

**Quality Assurance:**

All those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality.

**Quality Audit:**

A systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

**Quality Control:**

The operational techniques and activities that are used to fulfill requirements for quality.

**Quality Management:**

That aspect of the overall management function that determines and implements the quality policy.

**Quality Manual:**

A document setting out the specific quality practices and resources.

**Quality Program:**

An established, documented system to ensure quality.

**Quality System:**

The organizational structure, responsibilities, procedures, processes and resources for implementing quality management.

**Manufacture Number:**

A unique number assigned by Humanetics that is traceable to a combination of raw materials processed by Humanetics into a final product from a specific bill of materials at a specific time of manufacture. The serial number represents a specific manufactured item.

**Specified Requirements:**

Those requirements, including performance requirements, set forth in the applicable product specifications and those specified by Humanetics are necessary to meet client and/or regulatory requirements.

**TL 9000 R3.0:**

The Quality Management System Requirements Handbook, Release 3.0 prepared in a cooperative effort by the members of the Quality Excellence for Suppliers of Telecommunications (QuEST) Forum.

**Traceability:**

The ability to trace the history, application or location of an item or activity, or similar

items or activities, by means of recorded identification.

**Vendor:**

Any individual or organization that furnishes materials, products or services to Humanetics

**Verify:**

To determine conformance to specified requirements.

**Work Instructions:**

Detailed instructions for a Standard Operating Procedure.

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## 4 Quality Management System

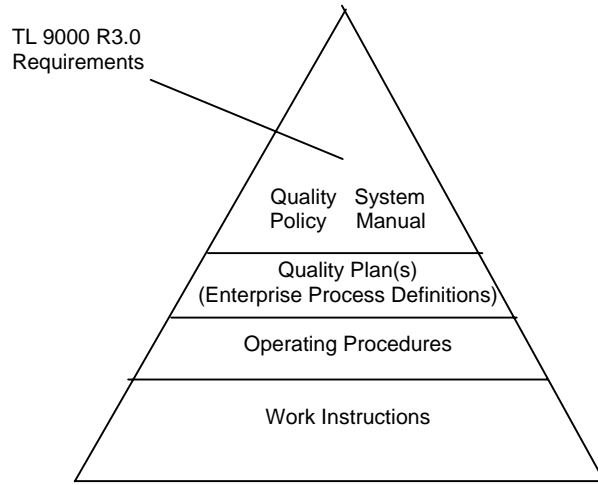
### 4.1 General Requirements

Humanetics Executive Management team establishes, documents, maintains, and implements a documented Quality Management System as a means of ensuring that product conforms to specified requirements. This Quality Management System Manual covers the requirements of TL 9000 R3.0 as a means to manage all processes. This Manual makes reference to the Quality Management System and makes reference to the Standard Procedures for each section of the standards as indicated in appendix A. The manual outlines the structure of the documentation used in the Quality Management System. This documentation consists, but is not limited to:

- The Quality Manual and Enterprise Process Definitions (see Figure 4.1-2) identify and define the processes needed for the quality management system, how processes are applied throughout the organization as well as the sequence and interaction of all processes.
- Standard Procedures, Reference Documents, Work Instructions, Corrective Action Reports, Management Reviews, Job Descriptions, Training Records, Internal and External Audits, and Instruction Manuals provide criteria and methods to ensure effective operation and control of all processes.
- Humanetics' GSS ERP system as well as the MIS Intranet system provides availability of resources and information necessary to support the operation and monitoring of all processes.
- Processes are measured, monitored and analyzed utilizing documented procedures and processes are corrected and improved via the corrective and preventive action systems in order to achieve planned results and continual improvement.
- The structure of Humanetics' Quality Management System is illustrated in Figure 4.1-1.
- Outsourcing of processes which affect product conformity with requirements are controlled via the purchasing processes as defined in the Enterprise Process Definitions and documented procedures.

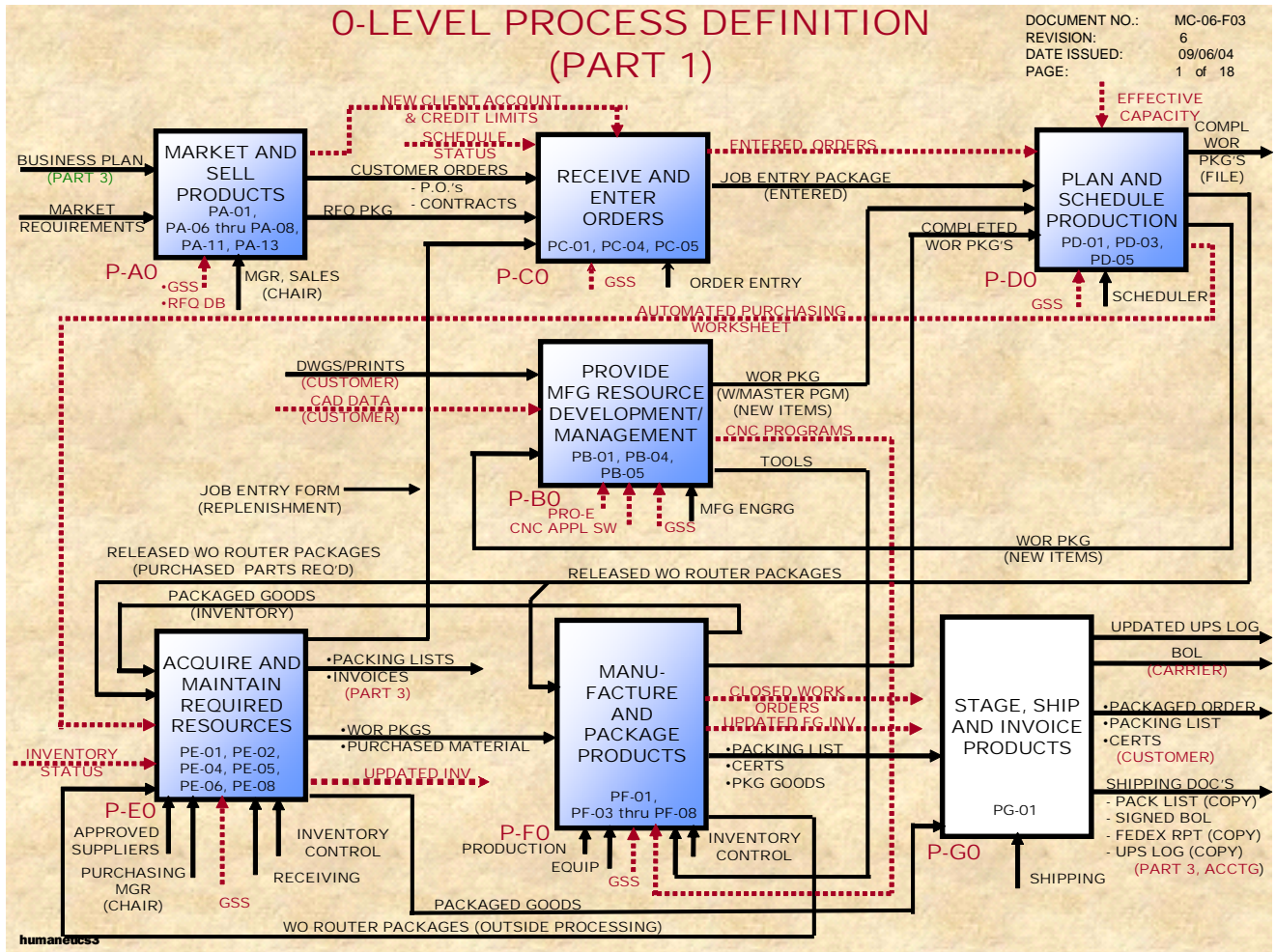
Humanetics does not presently have any factored items. If factored items are added in the future, procedures will be generated.

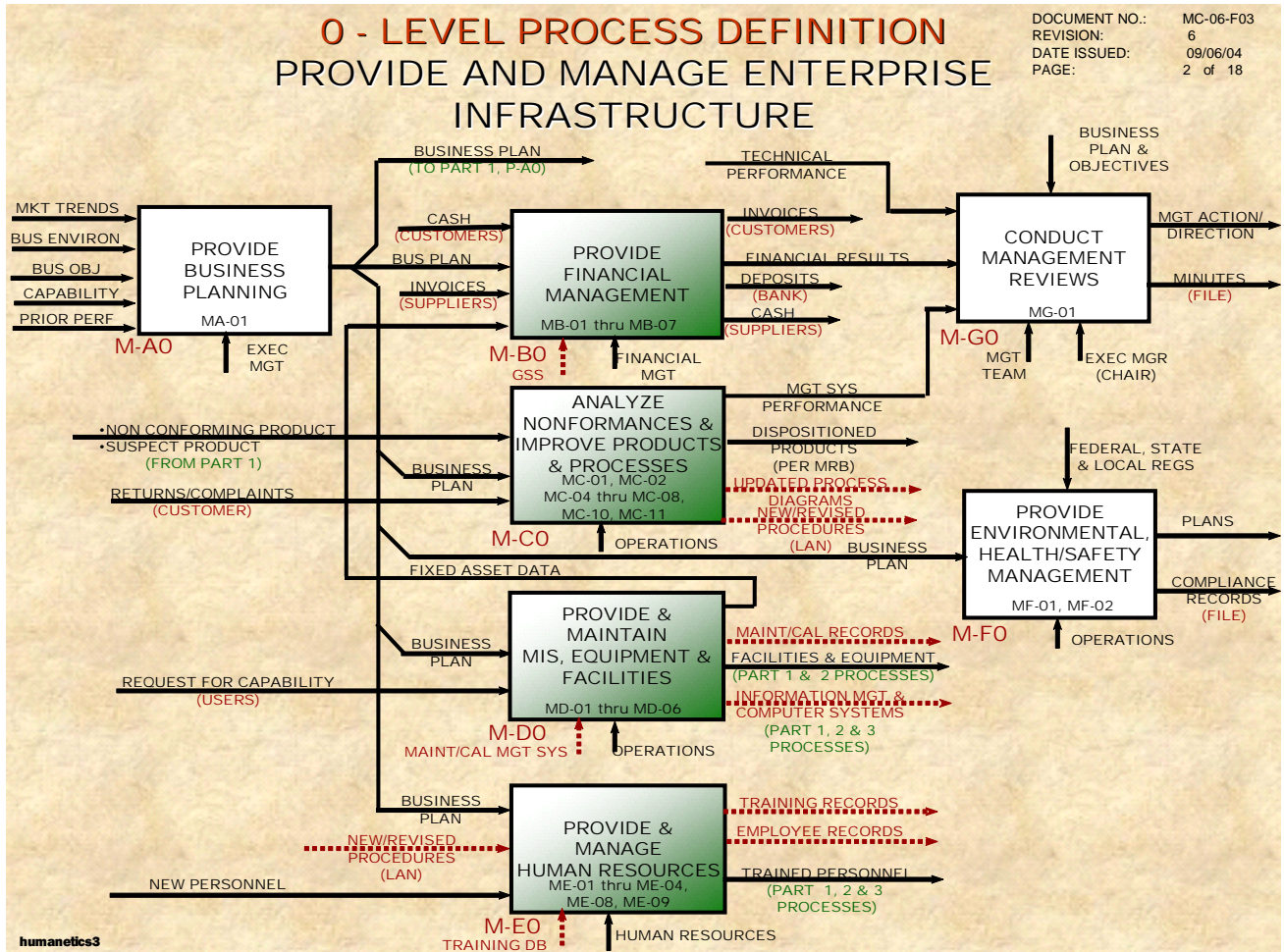
The Humanetics Quality Management System excludes Paragraph 7.3 and all "S" and "V" paragraphs which are not applicable because Humanetics does not perform Design & Development nor does Humanetics deliver any software or services as defined in TL 9000 and certain (as noted in the following paragraphs) "C" paragraphs which are not applicable with respect to this Standard TL 9000 R3.0.



**Quality Management System Structure  
Figure 4.1-1**

## HUMANETICS QMS Process Sequences and Interaction Figure 4.1-2





## 4.2 Documentation Requirements

### 4.2.1 General

Humanetics prepares documented procedures consistent with the requirements of TL 9000 R3.0 and Humanetics' documented Quality Policy and quality objectives. Humanetics effectively implements the Quality System and documentation for that system through a Quality Manual and the execution of processes as defined by the Enterprise Process Definitions and further defined in documented procedures and work instructions and recorded in quality records as defined in each procedure and as required by TL 9000 R3.0. The range and detail of the documentation depends on the complexity of the work, the methods used, and the skills, competence, and training needed by personnel involved in carrying out the activity in order to ensure the effective planning, operation, and control of all processes.

### 4.2.2 Quality Manual

The Humanetics Director of Corporate Quality leads Executive Management and other Managers in establishing, documenting, and maintaining a documented Quality Management System as a means of ensuring that product conforms to specified requirements. This Quality Manual covers the requirements of TL 9000 R3.0 and the scope of this quality management system as defined in paragraph 2. This Manual makes reference to the Standard Operating Procedures for each section of the standards as indicated in appendix A. The manual outlines the structure of the documentation used in the Quality Management System. This documentation consists, but is not limited to, the Quality Manual, Enterprise Process Definitions (describes the sequence and interaction of Quality Management System processes, Refer to Figure 4.1-2), Standard Procedures, Reference Documents, Work Instructions, Corrective Action Log, Management Reviews, Job Descriptions, Training Records, Internal and External Audits, instruction manuals and any other reports required-by the standards.

The Humanetics Quality Management System excludes Paragraph 7.3 and all "S" and "V" paragraphs which are not applicable because Humanetics does not perform Design & Development nor does Humanetics deliver any software or services as defined in TL 9000 and certain (as noted in the following paragraphs) "C" paragraphs which are not applicable with respect to this Standard TL 9000 R3.0.

The structure of Humanetics' Quality Management System is illustrated in Figure 4.1-1.

The Director of Corporate Quality controls this Quality Manual via a documented procedure.

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### 4.2.3 Control of Documents

Humanetics VP's, Directors, and Managers or designees establish and maintain documented procedures and work instructions to control all documents and data that relate to the requirements of TL 9000 R3.0.

Currently released editions of documents and data are received and maintained in either hard copy or electronic media and are available at locations defined in the procedures.

Reference documents can consist of but are not limited to:

- a. Engineering drawings;
- b. Engineering standards;
- c. Inspections instructions;
- d. Test procedures;
- e. Work instructions;
- f. Operations sheets;
- g. Quality Manual;
- h. Operational procedures;
- i. Quality assurance procedures;
- j. Material specifications;
- k. User documentation;
- l. TL 9000 Release 3.0;
- m. Standard Forms.
- n. CAD Electronic files

The documents and data are reviewed and approved for adequacy by personnel identified in documented procedures prior to issue or revision. Document master lists(s) or equivalent(s) are established and maintained by VP's, Directors, Managers, Supervisors or persons designated in the documented procedures. These master list(s) or equivalent(s) identify procedure number, title, date issued, and revision number of documents and are readily available, at locations defined in procedures, in order to preclude the use of invalid and/or obsolete documents.

Document Control Procedures ensure that:

- a. Current or pertinent issues of controlled documents are available at areas where the work is being performed and are legible, readily identifiable and retrievable;
- b. Invalid and/or obsolete documents are promptly removed from all points of issue or use, or otherwise marked to assure against unintended use, by the person designated as responsible;

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- c. Any obsolete documents retained for legal and/or knowledge preservation purposes are marked to identify them as obsolete by the person designated as responsible;
  - d. Documents of internal and external origin (including document updates) are reviewed, distributed and implemented by the person designated as responsible in a manner which ensures timely handling;
  - e. Managers establish procedures to assure the timely review, distribution and implementation of all customer engineering standards/specifications and changes.
  - f. Managers maintain a record of the date on which each change is implemented in procedures according to documented procedures (subject to record control, refer to Section 5.5.7). Implementation includes updates to all appropriate documents.
  - g. Previous versions of controlled documents are kept in the History file according to documented procedures.
  - h. Revisions to controlled documents are noted according to documented procedures.
  - i. The Managers are responsible for removing or marking as obsolete any copies of obsolete controlled documents from the work area according to documented procedures.

#### **4.2.3.C.1 Control of Customer Supplied Documents and Data**

The Sr. VP or designee establishes and maintains documented procedures to control all customer-supplied documents and data (e.g., customer part drawings, customer electronic drawing files, etc.) for documents and data that influence the verification, validation, inspection and testing the product. This is done in conjunction with the Director of Corporate Quality.

#### **4.2.4 Control of Records**

Humanetics' Procedure Owners establish and maintain documented procedures for identification, collection, indexing, retrieval, filing, storage, protection, retention time, and disposition of records.

Each procedure has a matrix to define (identification and collection) records, where they are filed, how they are indexed, and who has responsibility for them (including access/retrieval restrictions, archiving, and final disposition). Information for performance of this activity is defined in documented procedures.

Records are defined in each procedure and maintained to demonstrate conformance to specified requirements and the effective operation of the quality management system and is the responsibility of the Procedure Owner for that procedure. Pertinent records

from vendors are maintained by the Purchasing Department.

All records are legible and are stored in a safe environment to prevent damage or loss and retained in such a way that they are readily available for evaluation.

Records of internal Quality System Audits and Management Reviews are retained for as defined in the procedures. These requirements are minimums and do not supersede any government or customer requirements.

Copies of documents from superseded products required for new product qualifications are retained in the History file per documented procedures.

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## 5 Management Responsibility

### 5.1 Management Commitment

Executive Management defines and documents the commitment for quality management in the quality policy as stated in the quality management system manual and the objectives for quality and commitment to quality management in the company business plan.

Executive Management and all other Managers and Supervisors ensure that employees understand, implement and maintain the development and continual improvement of the quality management system by:

- a. Communicating the importance of meeting customer as well as regulatory and legal requirements at all levels of Humanetics organization via memos, employee reviews and company meetings. Objectives for quality are defined in the Humanetics documented business plan.
- b. Establishing the quality policy and quality objectives via memos, employee reviews and company meetings.
- c. Conducting management reviews in accordance with documented procedures.
- d. Ensuring the availability of necessary resources, as defined in the company plan, by review of the resource requirements at management reviews and taking appropriate actions.

### 5.2 Customer Focus

Executive Management and other Managers or designees ensure that customer needs and expectations are determined, converted into requirements and fulfilled with the aim of enhancing customer satisfaction via the “Market, Sell, & Manufacture Precision Metal Products to Meet Customer Manufacturing & Cost Objectives (P-x)” and the “Provide and Manage Enterprise Infrastructure (M-x)” processes defined in the Enterprise Process Definitions and the associated documented procedures (see 7.2.1 and 8.2.1).

#### 5.2.C.1 Customer Relationship Development

The Sr. VP or designee demonstrates active involvement in establishing and maintaining Customer-Humanetics relationships via the “Market & Sell Products (P-A0)” process and its associated documented procedures.

#### 5.2.C.2 Customer Communication Procedures

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The Sr. VP and Sales Manager or designees establish and maintain documented procedures for communicating with selected customers via the “Market & Sell Products (P-A0)” process and its associated procedures. The procedures include:

- a) A strategy and criteria for customer selection;
- b) A method for sharing customer and Humanetics joint expectations and improving the quality of products; and
- c) A joint review with the customer at defined intervals covering the status of Customer-Humanetics shared expectations and including a method to track the resolution of issues.

### 5.3 Quality Policy

Executive Management and each Manager defines and documents the policy for quality, which is:

“Humanetics pledges to manufacture Quality products that exceed our customer’s expectations by continuously striving for improvement and total customer satisfaction.”

The Quality Policy is reviewed for continuing suitability and effectiveness at management reviews by Executive Management and is a controlled document as defined in documented procedures.

The Quality Policy is communicated to employees at all levels of Humanetics organization via memos, employee reviews, and company meetings. Employee reviews and internal audits are used to ensure that the Quality Policy is understood.

### 5.4 Planning

#### 5.4.1 Quality Objectives

Executive Management establishes quality objectives in the company business plan via “Provide Business Planning” (M-A0). Quality objectives (including those needed to meet requirements for product – Refer to Section 7.1) and continual improvement, and results achieved, are measured and reported during management reviews and are compared with the Quality policy via presentations presented at management reviews as defined in documented procedures.

##### 5.4.C.1 Quality Objectives

Objectives for quality, as defined in the business plan by the Executive Management

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Team, include targets for the TL 9000 metrics defined in the TL 9000 Quality Management System Measurements Handbook.

## 5.4.2 Quality Management System Planning

Humanetics' Management utilizes the Organizational Charts (Figure 5.4.2-1), Job Descriptions, Enterprise Process Definitions, Standard Operating Procedures, Reference Documents, Work Instructions and Instruction Manuals as tools to ensure that trained personnel are planned and hired for management, performance of work and verification of activities including internal quality audits.

In the preparation of the Business Plan which includes the Budget / 3-Year Strategic Plan, management identifies and provides resources that will meet the requirements to achieve its quality objectives including:

- a. Trained personnel assigned for management, performance of work and verification of activities including quality audits;
- b. Facilities and equipment;
- c. Materials and supplies;
- d. Technology and systems;
- e. Continual improvement of the Quality Management System.

Quality Management System change is conducted in accordance with the corrective action system procedures (by personnel identified in the documented procedures) by utilizing procedures under corrective action control during change to ensure that the integrity of the quality management system is maintained during the change.

### 5.4.2.C.1 Long- and Short-Term Quality Planning

Executive Management or designees maintains long- and short-term planning with goals for improving quality and customer satisfaction as well as monitoring and reporting those goals, in the "Establish Client Account & Develop/Execute Account Management Plans for Key Accounts (P-A3)" process and its associated procedures.

The planning addresses:

- a) Cycle time;
- b) Customer service;
- c) Training;
- d) Cost;
- e) Delivery commitments; and
- f) Product reliability

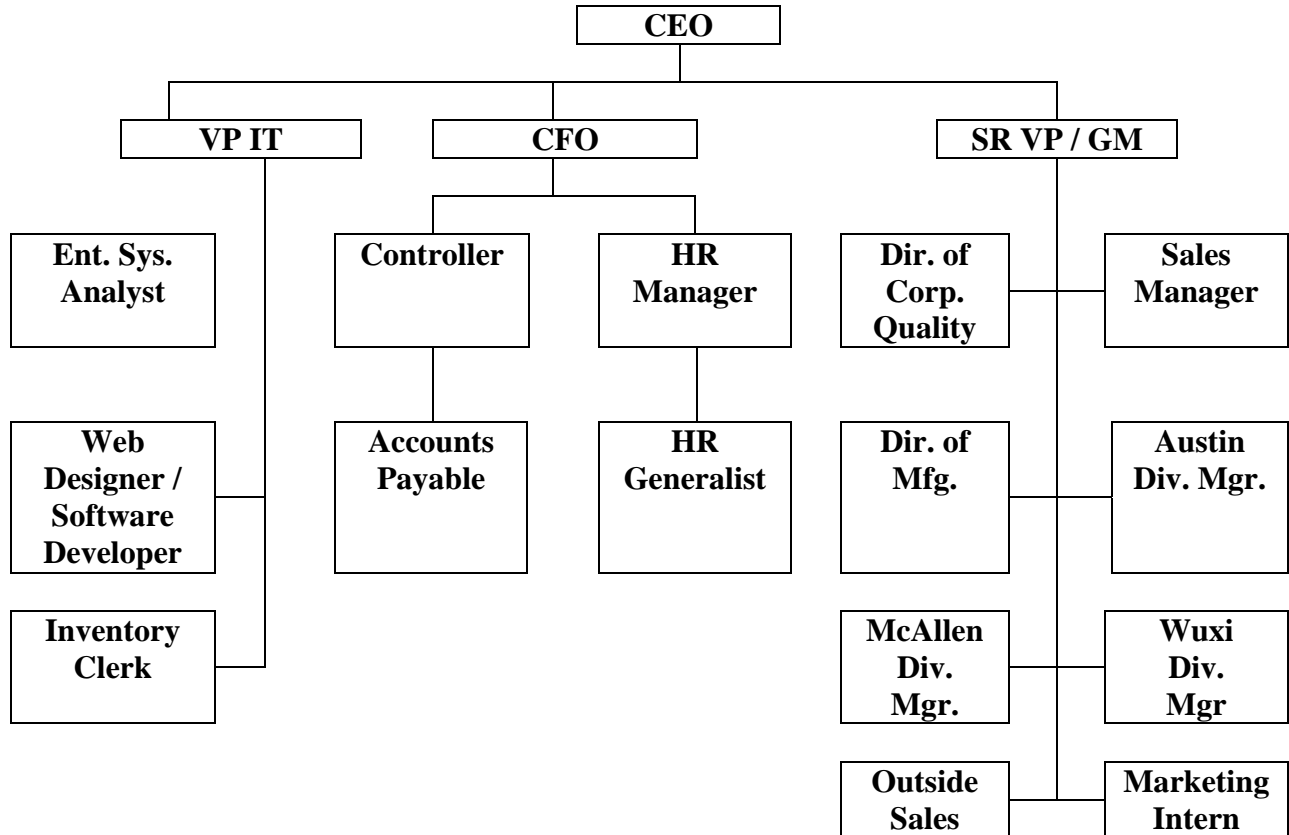
### 5.4.2.C.2 Customer Input

The Sr. VP and Sales Manager and/or designee establishes and maintains methods for soliciting and considering customer input for quality planning activities via the “Market & Sell Products (P-A0)” process and its associated procedures. Consideration is given to establishing joint customer-Humanetics quality improvement programs via the “Market & Sell Products (P-A0)” process and its documented procedures

#### **5.4.2.C.3 Supplier Input**

The Sr. VP and Sales Manager and/or designee establishes and maintains methods for soliciting and using subcontractor input for quality planning activities in the “Market & Sell Products (P-A0)” process and its associated procedures.

**Figure 5.4.2-1  
 HUMANETICS Organization Chart**



Management Representative – Director of Corporate Quality  
 Deputy Management Representative – Quality Manager

Departmental Organization Charts are located on the company intranet.

## **5.5 Responsibility, Authority & Communication**

### **5.5.1 Responsibility and Authority**

The responsibility, authority, and the interrelation of personnel who manage, perform and verify work affecting quality is defined and documented through Organizational Charts, Enterprise Process Definitions, Standard Operating Procedures, reference documents and work instructions.

#### **Listing of Humanetics Positions**

Current Corporate job descriptions are available on the Company Hiiserver to each employee through the Human Resource department.

### **5.5.2 Management Representative**

Humanetics CEO has appointed the Director of Corporate Quality as the management representative for TL9000. Humanetics' Director Corporate Quality has appointed the Quality Manager as the TL 9000 Coordinator, and irrespective of other responsibilities, has defined authority for ensuring that a Quality Management System processes are established, implemented and maintained in accordance with the TL 9000 R3.0. The Quality Manager reports to the Director of Corporate Quality, during management review:

- a. On the performance of the Quality Management System;
- b. Needs for the improvement of the Quality Management System;
- c. Acts as a liaison with external parties on matters relating to the Quality Management System;
- d. Promoting awareness of customer requirements throughout the organization via the "Market & Sell Products (P-A0)" processes and associated procedures as carried out by the Sr VP, Sales Manager, Account Managers and/or Sales Engineers.

### **5.5.3 Internal Communication**

Executive Management and all Managers ensures communication between departments and their personnel via the Enterprise Process Definitions, documented procedures, and management reviews regarding processes of the quality management system as well as its effectiveness. Internal communication is also supported via the company intranet, emails, employee newsletters, company meetings, and new

employee orientations.

### **5.5.3.C.1 Organizational Performance Feedback**

The Quality Manager or designees informs employees of the quality and delivery performance via weekly reports posted in the company along with email distribution to Executive Management.

The Sales Manager or designees informs employees of customer survey results and level of customer satisfaction via customer surveys performed on a periodic basis via a web-based customer survey portal for customer communication and trouble reporting/resolution.

## **5.6 Management Review**

### **5.6.1 General**

The CEO leads Executive Management in reviewing the Quality system through Management Reviews via “Conduct Management Reviews” (M-GO) in accordance with documented procedures. The Management Reviews are conducted at defined intervals, per documented procedures, sufficient to ensure its continuing suitability, adequacy, and effectiveness in satisfying the requirements of TL 9000 R3.0 and the stated Quality Policy and objectives. The strategy for Quarterly Business Review Meetings is:

- a. Review all TL 9000 R3.0 elements at least once a year through internal audit summary reports of the defined enterprise process which includes applicable TL 9000 R3.0 elements.
- b. Decide on the suitability, adequacy, and effectiveness of the Quality System in meeting TL 9000 R3.0 and Humanetics’ business objectives.
- c. Document the basis for the decision on the suitability and effectiveness and adequacy made during the management review process.
- d. Evaluate the opportunities for improvement and the need for changes to the quality management system including quality policy and quality objectives.

Records of these Review Meetings are recorded, which include any action items, in the Review Minutes by the Meeting Secretary.

### **5.6.2 Review Input**

Inputs to the management review are provided by documented procedures and include current performance and improvement opportunities. These inputs include and are not limited to:

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- a. Results of audits;
- b. Customer feedback;
- c. Process performance and product conformance;
- d. Status of preventive, continuous improvement, and corrective actions;
- e. Follow-up actions from earlier management reviews;
- f. Planned changes that could affect the quality management system, and
- g. Recommendations for improvement.

### **5.6.3 Review Output**

Executive Management members provide outputs of the management review per documented procedures. These outputs include, but are not limited to, decisions and actions related to:

- a. Improvement of the effectiveness of the quality management system and its processes;
- b. Improvement of product related to customer requirements;
- c. Resource needs.

## **6 Resource Management**

### **6.1 Provision of Resources**

Humanetics' Executive Management utilizes the Business Plan, Organizational Charts, Job Descriptions, Enterprise Process Definitions, Standard Operating Procedures, Reference Documents, Work Instructions and Instruction Manuals as tools to ensure that trained personnel are planned and hired for management, performance of work and verification of activities including internal quality audits in a timely manner.

In the preparation of the Business Plan, which includes the Budget / 3-Year Strategic Plan, management identifies and provides resources that will meet the requirements to implement and improve the processes of the quality management system as well as address customer satisfaction.

### **6.2 Human Resources**

#### **6.2.1 General**

Executive Management or designees establish and maintain documented procedures via "Provide and Manage Human Resources" (M-E0) for identifying process skills

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requirements as defined in job descriptions. Personnel assigned to process tasks are qualified on the basis of education, skills, training and/or experience by criteria set on the Job Description and when they are interviewed and subsequently hired as an employee.

### **6.2.2 Competence, Awareness and Training**

Executive Management or designees establish and maintain documented procedures for identifying competency needs, as defined in job descriptions, and provide for the training of all personnel performing activities affecting quality to satisfy the identified needs.

- a. Training for each person's assigned duties is the responsibility of the applicable Sr. VP, Directors, Managers or Supervisors who utilize the Quality Manual, Enterprise Process Definitions, Standard Operating Procedures, Work Instructions, Reference Materials, Forms, Reference Manuals and any other means deemed appropriate for training.
- b. Training effectiveness is evaluated by assigned supervision per documented procedures during each employee's review.
- c. Supervision ensures that employees are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives via documented procedures, during employee performance reviews, and via memos and periodic meetings.
- d. Training records (including education, experience, and qualifications) as defined in procedures are the responsibility of the appropriate Director, Manager, Supervisor or Process Owner and are maintained and retained as indicated in the documented procedure (Refer to Section 5.5.7).

#### **6.2.2.C.1 Internal Course Development**

The Director of Corporate Quality or designee establishes and maintains the "Developing / Maintaining Training Courses & Materials" (M-E9) and Provide General & Ongoing & Employee Development Training (M-E3)" processes and their associated procedures to plan, develop, and implement internally developed training courses.

#### **6.2.2.C.2 Quality Improvement Concepts**

The Director of Corporate Quality or designee and the process owners via the "Developing / Maintaining Training Courses & Materials" (M-E9) and Provide General & Ongoing & Employee Development Training (M-E3)" processes provides training in the fundamental concepts of continual improvement, problem solving, and customer satisfaction to all positions that have a direct impact on the quality of the product, including top management.

### **6.2.2.C.3 Training Requirements and Awareness**

Training requirements are defined by the applicable process owner for all positions that have a direct impact on the quality of products via the “Provide and Manage Human Resources (M-E0)” and “Provide Procedure Training (M-E3)” processes and their applicable procedures. The applicable process owner makes employees aware of the training opportunities.

### **6.2.2.C.4 ESD Training**

Humanetics has no processes which require ESD and therefore excludes this paragraph of TL 9000.

### **6.2.2.C.5 Advanced Quality Training**

The Director of Corporate Quality or designee and Quality Manager and applicable process owners via the “Provide General & Ongoing & Employee Development Training (M-E3)” process and its applicable procedures, offer appropriate levels of advanced quality training. Examples of this training are statistical techniques, process capability, statistical sampling, data collection and analysis, problem identification, problem analysis, and corrective and preventive action.

### **6.2.2.C.6 Training Content**

The Director of Manufacturing or designee provides, where hazardous conditions exist, training via the “Provide Environmental & Health/Safety Management (M-F0)” processes and its applicable procedures, training which has a content of:

- a) Task execution;
- b) Personal safety;
- c) Awareness of hazardous environment; and
- d) Equipment protection.

### **6.2.2.HV.1 Operator Qualification (Hardware Only for Humanetics)**

Process owners and the Director of Corporate Quality or designee establish operator qualification and re-qualification requirements for all applicable processes via the “Provide Environmental, Approve, Record, and Validate Special Processes” (M-E8) process and its associated procedures. These requirements, as a minimum, address employee experience, training, and demonstrated skills for special processes. The process provides for communication of this information to all affected employees.

### **6.3 Infrastructure**

The Facilities Manager or designee (using documented procedures) via “Provide and Maintain MIS, Equipment, & Facilities” (M-D0) identifies, provides, and maintains facilities and process equipment needed to achieve the conformity of product to requirements. This includes:

- a. Buildings, workspace and associated utilities;
- b. Process equipment, both hardware, and software;
- c. Supporting services including transport and communications.

### **6.4 Work Environment**

The Sr VP, Directors, and Managers or designees identify the human and physical factors of the work environment needed to achieve conformity of product during project planning and business planning activities. Management of the human and physical factors of the work environment is accomplished via use of documented procedures during performance of work activities in order to achieve conformity of product to requirements.

#### **6.4.C.1 Work Areas**

The Director of Manufacturing or designee ensures that areas used for handling, storage, and packaging of products are clean, safe, and organized in order to ensure that they do not adversely affect quality or personnel performance via the “Provide Environmental and Health/Safety Management (M-F0)” and the “Provide and Maintain MIS, Equipment, and Facilities (M-D0)” processes and their associated procedures.

## 7 Product Realization

### 7.1 Planning of Product Realization

Humanetics' Sr. VP, Directors, and Managers or designees, plans and develops the realization processes via the Enterprise Process Definitions (sequence of processes and sub-processes required to achieve the product), Business Plan, as well as meetings of Executive Management.

In planning product realization, Executive Management and other Managers determine the following, as appropriate:

- a. That a Quality Plan, in the form Job Entry Packages and Work Packages is prepared for each customer order in order to determine quality objectives and requirements for the product. Quality plans are prepared in accordance with the "Receive & Enter Orders (P-C0)" process, the "Plan & Schedule Production (P-D0)" process, and the "Provide Manufacturing Resource Development/Management (P-B0)" process and their associated documented procedures;
- b. The identification, generation, and/or acquisition of any controls (including any CNC programs), processes, equipment (including inspection and test equipment), fixtures, resources and skills that may be needed to achieve the required product quality and objectives is planned during the "Provide Manufacturing Resource Development/Management (P-B0)" process and its associated documented procedures;
- c. Required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance is prepared during performance of the "Market and Sell Products" (P-A0) and "Receive & Enter Orders (P-C0)" process and their associated procedures by personnel designated in those procedures;
- d. The identification and preparation of records (Refer to Section 4.2.4) necessary to provide evidence that the realization processes and resulting product meet requirements

#### 7.1.C.1 Life Cycle Model

The Sales Manager or designee establishes and maintains an integrated set of guidelines that covers the life cycle of Humanetics products via the "Develop Joint Goals & Objectives with Customers with Key Accounts (P-A32)" process and its associated documented procedure. This framework contains, as appropriate, the processes, activities, and tasks involved in the concept, definition, development,

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manufacturing, operation, maintenance and (as required) disposal of products, spanning the life of the products.

### **7.1.C.2 New Product Introduction**

The Sales Manager or designee establishes and maintains documented procedures for introducing new products for General Availability via the “Develop Joint Goals & Objectives with Customers with Key Accounts (P-A32)” process and its associated documented procedure.

### **7.1.C.3 Disaster Recovery**

Executive Management establishes and maintains methods for disaster recovery to ensure the ability to recreate and service the product throughout the product life cycle via the “Provide and Maintain MIS, Equipment, & Facilities (M-D0)” processes and its applicable procedures.

### **7.1.C.4 End of Life Planning**

The EVP Product Operations or designee establishes and maintains documented procedures for the discontinuance of manufacturing and/or support of products by the operation and service organizations via the “Develop Joint Goals & Objectives with Customers with Key Accounts (P-A32)” process and its associated documented procedure. These procedures provides for:

- a) Cessation of full or partial support after a certain period of time;
- b) Archiving product documentation and software;
- c) Responsibility for any future residual support issues;
- d) Transition to the new product, if applicable; and
- e) Accessibility of archive copies of data.

### **7.1.HS.1 Configuration Management Plan (Hardware Only for Humanetics)**

The Sales Manager or designees establish and maintain a configuration management plans via the “Develop Joint Goals & Objectives with Customers with Key Accounts (P-A32)” process and its associated documented procedure which includes:

- a) Identification and scope of the configuration management activities;
- b) Schedule for performing these activities;
- c) Configuration management tools;
- d) Configuration management methods and documented procedures;
- e) Organizations and responsibilities assigned to them;
- f) Level of required control for each configuration item; and
- g) Point at which items are brought under configuration management

### **7.1.S.1 Estimation**

Not Applicable

### **7.1.S.2 Computer Resources**

Not Applicable

### **7.1.S.3 Support Software and Tools Management**

Not Applicable.

### **7.1.V.1 Service Delivery Plan**

Not Applicable

## **7.2 Customer-Related Processes**

### **7.2.1 Determination of Requirements Related to the Product**

The Sr. VP, Sales Manager Account Managers, and/or Sales Engineers determine customer requirements, utilizing the “Market & Sell Products (P-A0)” process and its associated documented procedures, which include determination of:

Product requirements specified by the customer, including the

- a. Requirements specified by the customer, including the requirements for delivery and post delivery activities;
- b. Product requirements not specified by the customer but necessary for specified use or known and intended use;
- c. Obligations related to product, including regulatory and statutory requirements;
- d. Any additional requirements as determined by the Humanetics management team.

### **7.2.2 Review of Requirements Related to the Product**

The Sales Manager or designee “Market & Sell Products (P-A0)” process and the “Receive & Enter Orders (P-C0)” process and their associated procedures for the review of contracts and purchase orders from customers. Methods of establishing a

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means of communication with the customer are defined in the documented procedures.

Before submission of a tender or acceptance of a contract or order, it is reviewed per documented procedures to ensure that:

- a. Customer/product requirements are adequately defined and documented where no written statement of the requirement is available for an order received by verbal means, the Account Manager or Sales Engineer takes the order and follows documented procedures to ensure that the order requirements are agreed upon before acceptance;
- b. Any differences between the contract or accepted order requirements and those in the proposal are resolved by the Account Manager;
- c. Humanetics has the ability to meet the requirements of the customer's order or contract.

Records of purchase orders and contract reviews and review actions are recorded and maintained as defined in the documents procedures by the employee identified in documented procedures, in accordance with Section 4.2.4.

The documented procedures define how amendments to purchase orders or contracts are made and how (and by who) such amendments are communicated to all affected functions throughout the organization. This is the responsibility of the Sr. VP and/or Account Managers.

### **7.2.3 Customer Communication**

The Sales Manager, Account Managers, and/or Sales Engineers, via the "Market & Sell Products (P-A0)" process and the "Receive & Enter Orders (P-C0)" process and their associated procedures, identifies and implements arrangements for communication with customers relating to:

- a. Product information;
- b. Inquiries, contracts or order handling, including amendments and;
- c. Customer feedback, including customer complaints.

#### **7. 2.3.C.1 Notification About Problems**

The Sales Manager, Account Managers, Sales Engineers or designee utilizes the "Market & Sell Products (P-A0)" process and its associated procedures to notify all customers who may be affected by a reported problem that is service affecting.

#### **7.2.3.C.2 Problem Severity**

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Humanetics' Sales Manager, Account Managers, and Sales Engineers assign severity levels to customer reported problems based on the impact to the customer via the "Market & Sell Products (P-A0)" process and its associated procedures and in accordance with the definitions of critical, major, and minor problem reports (see definitions). The Account Manager/Sales Engineers uses the severity levels in determining the timeliness of Humanetics' response per the process procedures.

### **7.2.3.C.3 Problem Escalation**

Sales Engineers, Account Managers or designee utilizes the "Market & Sell Products (P-A0)" process and its associated escalation procedures to resolve customer reported problems.

### **7.2.3.C.4 Customer Feedback**

Sales Engineers, Account Managers or designee establishes and maintains documented problem reporting procedures to provide customers with feedback on their problem reports in a timely manner via the "Market & Sell Products (P-A0)" process and its associated procedures.

### **7.2.3.H.1 Humanetics' Recall Process**

Sales Engineers, Account Managers or designees establish and maintain documented procedures to identify and recall products that are unfit to remain in service via the "Market & Sell Products (P-A0)" process, the "Identify, Analyze and Disposition Nonconforming Products (M-C2)" processes and its associated procedures.

## **7.3 Design & Development**

Paragraph 7.3 is not applicable due to the fact that Humanetics only builds parts to customer drawings and performs no design and development tasks.

## **7.4 Purchasing**

### **7.4.1 Purchasing Process**

The Purchasing Manager or designee establishes and maintains documented procedures via the "Acquire & Maintain Required Resources (P-E0)" process to ensure that purchased product and contracted services conform to specified requirements. Various persons within the organization initiate requests for purchased product and services. The requesting party submitting an approved Purchase Requisition to the

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Purchasing Manager or designee in accordance with Humanetics' documented purchasing procedures accomplishes this.

The Purchasing Manager or Buyer and Quality Manager:

- a. Evaluates and selects suppliers on the basis of their ability to meet Humanetics' requirements including the Quality System and specific quality assurance requirements per documented procedures;
- b. Defines and enforces the criteria for selection, evaluation and re-evaluation of suppliers. This is dependent upon the type of product, the impact of purchased product on the quality of the final product, and where applicable, on the internal and external audit reports, Management Reviews and/or records of the previously demonstrated capability and performance of suppliers.
- c. Establishes and maintains records of acceptable supplier evaluation and any necessary actions arising from the evaluation per documented procedures (see 4.2.4).

#### **7.4.1.C.1 Purchasing Procedures**

The Purchasing Manager or designee and Quality Manager provides documented purchasing procedures via the "Acquire & Maintain Required Resources (P-E0)" process and its associated procedures which include:

- a) Product requirements definition;
- b) Risk analysis and management
- c) Qualification criteria;
- d) Contract definition;
- e) Proprietary, usage, ownership, warranty and licensing rights are satisfied;
- f) Future support for the product is planned;
- g) Ongoing supply-base management and monitoring;
- h) Supplier selection criteria; and
- i) Supplier re-evaluation, and;
- j) Feedback to key suppliers based on data analysis of supplier performance.

#### **7.4.2 Purchasing Information**

The Purchasing Manager or designee is responsible for preparation of purchase order documents in accordance with the "Acquire & Maintain Required Resources (P-E0)" process and its associated procedures. Purchase requirement documents submitted by requestor and purchase orders contain data clearly describing the product ordered, including:

- a. The type, class, grade or other precise identification;

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- b. Description of product or service, including issues of drawings, specifications, process requirements, inspection instructions, test requirements and other relevant technical data, including requirements for approval or qualification of product, processes, procedures, process equipment and personnel as required;
  - c. Quality Management System requirements;
  - d. Description of any certifications that are required;
  - e. The requesting party is responsible to provide the above information (where applicable) to the Purchasing Manager/Buyer and to secure approval of the Purchase Requisition according to documented procedures.

The Purchasing Manager or Buyer prepares purchase order documents and reviews and approves purchasing documents for adequacy of the specified requirements prior to their communication to the supplier.

### **7.4.3 Verification of Purchased Products**

The requesting Manager & Quality Manager establishes and implements inspection activities necessary for ensuring that purchased product meets specified purchase requirements via the "Acquire & Maintain Required Resources (P-E0)" process and its associated procedures.

Where Humanetics' proposes to verify purchased product at the vendor's premises, the Purchasing Manager specifies verification arrangements and the method of product release in the purchasing documents in accordance with documented procedures.

Where specified in the contract or purchase order, customer or the customer's representative is offered the right to verify at suppliers' premises and/or Humanetics' premises that purchased product conform to specified requirements. When such verification at the suppliers' premises is a requirement for the initiation of business with Humanetics, it is so specified in the purchase order per documented procedures.

## **7.5 Production and Service Provision**

The Service Provision of section 7.5.1 & 7.5.2 is not applicable at Humanetics since Humanetics does not perform any activities after the product is shipped to the Customer other than responding to customer complaints & support inquires.

### **7.5.1 Control of Production and Service Provision**

The Director of Manufacturing or designee identifies and plans the production which

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directly affects quality and ensures that these processes are carried out under controlled conditions via the “Plan & Schedule Production (P-D0)” process, the “Manufacture & Package Products (P-F0)” process, and the “Stage, Ship, & Invoice Products (P-G0)” process and their associated procedures. Controlled conditions include the following:

- a. The availability of information that specifies the characteristics of the product in work packages and Work Order (WO) Router Packages;
- b. Documented procedures/work packages/WO router packages defining the manner where the absence of such instructions could adversely affect quality;
- c. Use of suitable production equipment;
- d. Compliance with reference standards/codes, work packages/WO router packages (quality plans), and/or documented procedures;
- e. Monitoring and control of suitable process parameters and product characteristics per documented procedures/work instructions/work packages, by personnel identified in documented procedures using applicable monitoring and measuring devices.
- f. Criteria for workmanship stipulated in the clearest practical manner as defined in work packages (e.g. written standards, representative samples or illustrations), by personnel identified in documented procedures.
- g. Suitable maintenance of equipment to ensure continuing processing capability per documented procedures, by personnel identified in documented procedures.
- h. Implementation of defined processes for release, delivery and applicable post-delivery activities by personnel identified in documented procedures.

#### **7.5.1.C.1 Humanetics’ Support Program**

The Sales Manager, Sales Engineers and Account Managers ensure that customers are provided support to resolve product related problems via the “Establish Client Account & Develop/Execute Account Management Plans for Key Accounts (P-A3)” process and its associated procedures.

#### **7.5.1.C.2 Service Resources**

The Sales Manager, Sales Engineers, Account Managers provide customer contact employees with appropriate tools, training, and resources necessary to provide effective and timely customer service via the “Establish Client Account & Develop/Execute Account Management Plans for Key Accounts (P-A3)” process and its associated procedures.

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### **7.5.1.HS.1 Emergency Service (Hardware Only for Humanetics)**

The Sales Manager, Sales Engineers, and Account Managers ensure that services and resources are available to support recovery from emergency failures of product in the field throughout its expected life via the “Establish Client Account & Develop/Execute Account Management Plans for Key Accounts (P-A3)” process and its associated procedures.

### **7.5.1.HS.2 Installation Plan**

This paragraph is not applicable for Humanetics since Humanetics does not install any of its products for or at a customer.

### **7.5.1.S.1 Patching Procedures**

Not applicable

### **7.5.1.S.2 Patch Documentation**

Not Applicable

### **7.5.1.S.3 Replication**

Not Applicable

### **7.5.1.V.1 Software Used in Service Delivery**

Not Applicable

### **7.5.1.V.2 Tool Changes**

Not Applicable

## **7.5.2 Validation of Processes for Production and Service Provision**

The Director of Manufacturing, Scheduler, and Quality Manager establish and maintain documented procedures (via “Provide Manufacturing Resource Development / Management (P-B0)” process, the “Plan & Schedule Production (P-D0)” process and the “Manufacture & Package Products (P-F0)” process, and the “Provide & Manage Human Resources (M-E0)” and their associated procedures) to control processes where the results of processes cannot be verified by subsequent monitoring or measurement. This

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includes any processes where deficiencies become apparent only after the product is in use or has been delivered.

Validation demonstrates, via production records, the ability of these processes to achieve planned results.

The Scheduler and Quality Manager establishes arrangements via work packages, WO router packages, and operator training for these processes including, as applicable

- a) Defined criteria for review and approval of the processes,
- b) Approval of equipment and qualification of personnel
- c) Use of specific methods and procedures
- d) Requirements for records (see 4.2.4), and
- e) Revalidation.

### **7.5.2.HV.1 Operational Changes (Hardware Only for Humanetics)**

The Director of Manufacturing or designee utilizes the “Provide Manufacturing Resource Development/Management (P-B0)” process and the “Manufacture Product (P-F2)” process and their associated procedures each time a significant change is made in the established operation (e.g., a new operator, new machine, or new technique), a critical examination is made of the first unit(s) processed after the change.

### **7.5.3 Identification and Traceability**

The Director of Manufacturing or designee utilizes the “Plan & Schedule Production (P-D0)” process, the “Manufacture & Package Products (P-F0)” process and the “Stage, Ship & Invoice Products (P-G0)” process and their associated procedures for identifying the product by suitable means throughout product realization. Personnel as defined in documented procedures accomplish product identification.

Documented procedures and work packages/WO router packages provide for identification of the status of product with respect to measurement and monitoring requirements.

Where and to the extent that traceability is a specified requirement, Humanetics establishes and maintains documented procedures for the unique identification of individual products. This identification is recorded. (Refer to Section 4.2.4)

### **7.5.3.HS.1 Product Identification (Hardware only for Humanetics)**

Executive Management or designees establishes and maintains a process for the identification of each product and the level of required control via the “Market & Sell

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Products (P-A0)” process, “Provide Manufacturing Resource Development / Management (P-B0) process, and the “Receive & Enter Orders (P-C0)” process and their associated procedures. These processes identify as appropriate, for each product and its versions, the following:

- a) Product documentation
- b) Development or production tools essential to repeat product creation;
- c) Interfaces to other products; and
- d) Hardware environment.

#### **7.5.3.H.1 Traceability for Recall**

Humanetics parts are traceable throughout the product life cycle in a way that helps Humanetics and customers to identify products being recalled, needing to be replaced or modified via the “Receive & Enter Orders (P-C0)” and “Plan & Schedule Production (P-D0)” processes and their associated procedures.

#### **7.5.3.H.2 Traceability of Design Changes**

The Sales Manager or designee establishes and maintains documented procedures which provide traceability of design changes to identifiable manufacturing dates, lots, or serial numbers via the “Prepare & Submit Quotes (P-A2)” process, “Develop/Verify Pro-E Models & Flat Patterns & Load, Verify Customer Provided Pro-E Models (P-B2)” process, and the “Receive & Enter Orders (P-C0)” process and their associated procedures.

#### **7.5.4 Customer Property**

The Sales Manager or designee via the “Market & Sell Products (P-A0)” process, “Receive Resources (P-E2)” process, and the “Maintain Resource Inventory (P-E3)” process and their associated procedures for the control of identification, verification, storage, protection, and safeguarding of customer supplied product provided for incorporation into Humanetics’ products. Any such product that is lost, damaged, or is otherwise unsuitable for use are recorded and reported to the customer by the Sales Engineers or Account Managers (Refer to Section 4.2.4) as defined in the documented procedures.

Verification by Humanetics does not absolve the customer of the responsibility to provide acceptable product.

#### **7.5.5 Preservation of Product**

The Director of Manufacturing or designee utilizes the “Acquire & Maintain Required

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Resources (P-E0)” process, the “Manufacture & Package Products (P-F0)” process and the “Stage, Ship, & Invoice Products (P-G0)” process and their associated documented procedures for identification, handling, storage and inventory, packaging, preservation, protection, and delivery of products.

Personnel identified in the procedures, establish handling methods per documented procedures to ensure raw materials and finished products are handled in a manner that prevents damage or deterioration.

The Inventory Management System is established and documented by the Purchasing Manager. Inventory Control Clerk - designates storage or stock areas for raw materials and finished product and authorization of receipt and delivery per documented procedures. For product that is subject to shelf life as well as all other product, the condition of the product is assessed during physical inventory. Such product is stored in designated storage areas to prevent damage or deterioration pending use or delivery.

Personnel identified in the procedures control the necessary markings of materials used to ensure conformance to specified requirements. The packing, packaging and labeling system assures all materials shipped are per documented procedures in the guidelines of the customer's specified requirements. Personnel identified in procedures provide for unique customer packaging standards including applicable service part packaging standards. Documented procedures, establishes a system to ensure that all materials shipped are labeled according to customer requirements if such is required by contract.

The Shipping Manager or designee applies packaging methods to preserve and segregate in process and finished product while under Humanetics' control.

The personnel identified in the procedures establish a system to protect product after final Inspection and testing including delivery to destination when contractually specified.

#### **7.5.5.C.1 Anti-Static Protection**

Not Applicable since Humanetics manufactures no products which have electrical components. If Humanetics begins manufacturing of products which have electrical components and require anti-static then procedures will be added at that time.

#### **7.5.5.HS.1 Packaging and Labeling Audit (Hardware Only for Humanetics)**

The Quality Manager or designee includes a packaging and labeling audit in the quality plan or documented procedures via the “Stage, Ship, & Invoice Products (P-G0)” process, “Conduct Out-of-Box Audit (P-F38)”, and their associated documented procedures. The process may include for example, marking, labeling, kitting,

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documentation, customer-specific marking, and correct quantities as defined by the procedures.

#### **7.5.5.H.1 Deterioration**

The Purchasing Manager or designee, where the possibility of deterioration exists, ensure materials in storage are controlled (i.e., date stamped/coded) and materials with expired dates are deemed nonconforming via the “Acquire & Maintain Required Resources (P-E0)” process and its associated procedures.

#### **7.5.5.S.1 Software Virus Protection**

Not applicable.

### **7.6 Control of Monitoring and Measuring Devices**

The Quality Manager or designee utilizes the “Provide & Maintain MIS, Equipment, and Facilities (P-D0)” process and its associated documented procedures to control, calibrate and maintain inspection, measuring, test equipment and fixtures used by Humanetics to evidence of conformity of product to the determined requirements (see 7.2.1). Personnel identified in documented procedures using documented procedures ensure inspection, measuring, test equipment and fixtures are used in a manner that will ensure that measurement uncertainty is known and is consistent with the required monitoring and measurement requirements.

The Quality Manager or designee, where necessary to ensure valid results ensures the measuring equipment will:

- a. Determine the measurements to be made and the accuracy required and select the appropriate inspection, measuring and test equipment that is capable of the accuracy and precision necessary per documented procedures;
- b. Ensure that each inspection, measuring and testing device that can affect product quality is calibrated and verified at specified intervals prior to use, against certified equipment having a known valid relationship to international or nationally recognized standards per documented procedures. If no standard exists, the basis used for calibration is documented according to documented procedures by engineering or quality personnel;
- c. Define the process employed for the calibration of inspection, measuring, test equipment and fixtures including details of equipment type, unique identification, location, frequency of checks, check method, acceptance criteria and the action to be taken when the results are unsatisfactory

- according to documented procedures by the Manufacturing Engineering Manager;
- d. Be adjusted or re-adjusted as necessary;
  - e. Identify inspection, measuring and test equipment with a suitable indicator or approved identification record to show the calibration status according to documented procedures by personnel as identified in the documented procedures.
  - f. Maintain calibration records for inspection, measuring and test equipment according to documented procedures.
  - g. Assess and document the validity of previous inspection and test results when inspection, measuring, and test equipment is found to be out of calibration and take appropriate action on the equipment and any product affected including recording the results of calibration and verification (see 4.2.4) per documented procedures.
  - h. Ensure that environmental conditions are suitable for the calibration, inspections, measurements, and tests being carried out according to documented procedures.
  - i. Ensure that the handling, maintenance, and storage of inspection, measuring and test equipment is such that the accuracy and fitness for use are protected from damage and deterioration according to documented procedures.
  - j. Safeguard inspection, measuring and test facilities, including both test hardware and test software, from adjustments which would invalidate the calibration setting according to documented procedures.

The Quality Manager utilizes documented procedures to validate the ability of software, used for monitoring and measurement of specified requirements, to satisfy the intended application to be confirmed prior to initial use as well as reconfirming validation as necessary.

## **7.6.H.1 Identified Equipment**

The Quality Manager ensures that monitoring and measuring devices that are either inactive or unsuitable for use are visibly identified and are not used for production via the “Provide & Maintain MIS, Equipment, and Facilities (M-D0)” process and its associated procedures. The Quality Manager identifies all monitoring and measuring devices that do not require calibration via the “Provide & Maintain MIS, Equipment, and Facilities (M-D0)” process and its associated procedures.

## **8 Measurement, Analysis and Improvement**

### **8.1 General**

The Director of Corporate Quality and Quality Manager utilize the Process Definitions and their associated procedures for planning and implementation of monitoring, measurement, analysis and improvement process needed:

- a) To demonstrate conformity of product;
- b) To ensure conformity of the quality management system; and
- c) To continually improve the effectiveness of the quality management system.

The Quality Manager identifies the need for statistical techniques and the extent of their use required during the creation or revision of procedures for establishing, controlling and verifying process capability and product characteristics.

### **8.2 Monitoring and Measurement**

#### **8.2.1 Customer Satisfaction**

The Sr. VP and Sales Manager or designees establishes and maintains documented procedures to monitor information on customer perception, satisfaction and/or dissatisfaction as one of the measurements of performance of fulfilling customer requirements. Documented procedures define the methodology for obtaining and using this information by personnel identified in documented procedures.

##### **8.2.1.C.1 Customer Satisfaction Data**

The Sales Manager or designee establishes and maintains a method to collect data directly from customers concerning their satisfaction with provided products via the “Establish Client Account & Develop/Execute Account Management Plans for Key Accounts (P-A3)” process and the “Handling Customer Complaints & Customer

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Satisfaction (M-C9)” process and their associated procedures. The Sales Manager or designee also, collects customer data on how well Humanetics meets commitments and its responsiveness to customer feedback and needs via the same processes. The information is collected and analyzed, and the trends kept via the “Measure Enterprise Performance (M-C8)” process and its associated procedures.

### **8.2.2 Internal Audit**

The Quality Manager utilizes the “Plan & Conduct Internal Audits (M-C1)” process and its documented procedures for planning and implementing internal quality audits to verify whether quality activities and related results comply with planned arrangements, conforms to the requirements of TL 9000 R3.0, and to determine the effectiveness of the implementation and maintenance of the quality management system. Internal Quality Audits are the responsibility of the Quality Manager who is assisted by other trained auditors as detailed in documented procedures.

The Internal quality audits are scheduled by the Quality Manager on the basis of the status and importance of the processes and areas to be audited, as well as results of previous audits, and are conducted by personnel independent of those that have direct responsibility for the activity being performed. Audits are conducted, per documented procedures, by selection of auditors to ensure objectivity and impartiality of the audit process.

The results of the Internal Quality Audits are recorded and brought to the attention of responsible managers, process owners and zero process owners, Quality Manager, and the Director of Corporate Quality for the area audited as outlined in documented procedures. In addition, results of Internal Quality Audits are reported during management reviews.

The VP's, Directors, Managers and/or Process Owners are responsible for the area of nonconformance and takes timely corrective action on deficiencies found during the audit (see 8.5.2). Suitable working environment is considered as part of the internal audit process as evidenced in documented procedures.

Follow-up activities verify and record the implementation and effectiveness of the internal audit corrective actions, as well as provide for reporting of verification results, and is the responsibility of the person assigned by the Corrective Action System as outlined in documented procedures.

### **8.2.3 Monitoring and Measurement of Processes**

The Quality Manager and/or Director of Corporate Quality via the “Improve Products & Processes (M-C0)” process and its documented procedures to implement and control

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the application of statistical techniques identified in 8.1 to measure and monitor those realization processes necessary to meet customer requirements and planned results. When planned results are not achieved, correction and corrective actions are taken, as appropriate, per documented procedures to ensure conformity of the product.

### **8.2.3.C.1 Process Measurement**

Executive Management or designees develop, document, and monitor process measurements at appropriate points to ensure continued suitability and promote increased effectiveness of processes via the “Provide Business Planning (M-A0)”, “Measure Enterprise Performance (M-C8)”, and “Conduct Management Reviews (M-G0)” processes and their associated procedures.

### **8.2.4 Monitoring and Measurement of Product**

The Purchasing Manager or designee ensures that incoming product is not used or processed (except in circumstances described in 8.3) until it has been inspected or otherwise verified as conforming to specified requirements. Verification of the specified requirements is in accordance with the “Receive Resources (P-E2)” process and its associated documented procedures.

The incoming product receiving inspection is documented according to documented procedures by receiving personnel.

In determining the amount and nature of receiving inspection, consideration is given by the Quality Manager to the control of the product exercised by the supplier prior to its receipt at Humanetics

Incoming product is not released for production purposes prior to verification.

During production and shipping, production, shipping, and/or Quality personnel via the “Manufacture & Package Products (P-F0)” process and the “Stage, Ship, & Invoice Products (P-G0)” process and their associated procedures:

- a. Inspect and test product as required by documented procedures and work packages.
- b. Hold product until the required inspection and tests are completed or necessary reports have been received and verified. Product is not released under until planned arrangements (see 7.1) have been satisfactorily completed unless otherwise approved by a relevant authority and, where applicable by the customer.

Production, Shipping, and/or Quality personnel carry out all final inspection and testing

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In accordance with the Manufacturing Process Instructions and/or documented procedures to complete the evidence of conformance of the finished products to specified requirements.

Documented procedures for final inspection and testing require that all specified inspection and tests, including those specified either on receipt of product or in process, have been carried out and that the results meet specified requirements.

No product is dispatched until all the activities specified in the Manufacturing Process Instructions and/or documented procedures are satisfactorily completed and the associated data and documentation are available and authorized as defined by personnel identified in documented procedures and in the production package unless otherwise approved by the customer.

Production, Shipping, and/or Quality personnel establish and maintain records as defined in documented procedures that provide evidence that the product has been inspected and/or tested. These records show clearly whether the product has passed or failed the inspections and/or tests according to defined acceptance criteria. Where the product fails to pass any inspection and/or test, the procedures for the control of nonconforming product apply (Refer to Section 8.3).

Documented procedures identify the inspection authority responsible for the release of the product including customer where applicable. (Refer to Section 4.2.4).

#### **8.2.4.HV.1 Inspection and Test Documentation (Hardware Only for Humanetics)**

The Sales Engineers / Account Managers and or Quality Manager or designee develops detailed documentation for each inspection or testing activity via the "Prepare & Submit Quotes (P-A2)" process and the "Provide Manufacturing Resource Development & Management (P-B0)" and their associated procedures. The Account Manager in conjunction with personnel identified in the procedures develops detailed documentation for each manufacturing inspection or testing activity via the "Provide Manufacturing Resource Development & Management (P-B0)" processes and its associated procedures. These procedures and their associated records include:

- a) Parameters to be checked with acceptable tolerances;
- b) The use of statistical techniques, control charts, etc;
- c) Sampling plan, including frequency, sample size, and acceptance criteria;
- d) Handling of nonconformances;
- e) Data to be recorded;
- f) Defect classification scheme;
- g) Method for designating an inspection item or lot, and
- h) Electrical, functional, and feature testing.

## **8.2.4.HV.2 Inspection and Test Records (Hardware Only for Humanetics)**

Personnel identified in the procedures ensure that inspection and test records include, via the “Manufacture & Package Products (P-F0)” process and its associated procedures:

- a) Product identification;
- b) Quantity of product inspected;
- c) Documented inspection procedures followed;
- d) Person performing the test and inspection;
- e) Date of inspection and/or test; and
- f) Number, type, and severity of defects found.

### **8.2.4.H.1 Periodic Retesting**

The Quality Manager and personnel identified in the procedures establishes and maintains documented procedures, as part of the “Improve Products & Processes (M-C0)” process and the “Manufacture & Package Products (P-F0)” process, that ensures products are periodically retested to assess the product’s ability to continue to meet design requirements.

### **8.2.4.H.2 Content of Testing**

The tests performed, initially and during periodic retests, as defined by the “Improve Products & Processes (M-C0)” process and the “Manufacture & Package Products (P-F0)” process, are more extensive than routine quality tests. The initial tests include those that are contained in the customer and/or Humanetics prints, specifications and/or contracts. The results of these tests are documented per the “Manufacture & Package Products (P-F0)” process and the “Receive and Enter Orders (P-C0) process and their associated procedures.

### **8.2.4.H.3 Frequency of Testing**

The Quality Manager or designee establishes and documents the frequency for test/periodic retest via the “Improve Products & Processes (M-C0)” process and the “Manufacture & Package Products (P-F0)” process and their associated procedures. This process, when determining the test frequency, includes the following:

- a) Product complexity and service criticality;
- b) Number of design, engineering and/or manufacturing changes made to the product and whether the changes affect form, fit, and/or function;
- c) Changes to the manufacturing process;
- d) Manufacturing variations, (e.g., tooling wear);

- e) Material and/or component substitutions and failure rates; and
- f) The field performance record of the product (when provided by the Customer).

#### **8.2.4.H.4 Testing of Repair and Return Products**

The Quality Manager and Director of Manufacturing or designees ensure that repair and return products are subjected to the appropriate evaluations and/or tests to ensure functionality to the product's specification via the "Improve Products & Processes (M-C0)" and its associated procedures.

#### **8.2.4.S.1 Test Documentation**

Not applicable.

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

The Quality Manager utilizes the "Improve Products & Processes (M-C0)" process and its associated documented procedures, the Receiving Inspector utilizes the "Receive Resources (P-E2)" process and its associated procedures, and Manufacturing Personnel utilize the "Manufacture & Package Products (P-F0)" process and its associated procedures to ensure that product that does not conform to specified requirements is prevented from unintended use or installation. This control provides for identification, documentation, evaluation, segregation (when practical), and disposition of nonconforming product and for notification to the functions concerned.

The responsibility for review and authority for the disposition of nonconforming product is defined in documented procedures. Nonconforming product is reviewed in accordance with documented procedures by personnel identified in documented procedures. Under the direction of the "Identify, Analyze, & Disposition Nonconforming Products (M-C2)" process and its associated procedure, product may be:

- a. Reworked or Repaired to meet the specified requirements and eliminate the detected nonconformity in house either by Humanetics or Supplier personnel;
- b. Accepted with or without rework or repair by concession;
- c. Rejected, Returned to Supplier or Scrapped.

When required by the contract, the proposed use or rework of product which does not conform to specified requirements is reported for concession to the customer or customer's representative per documented procedures. The description of nonconformity that has been accepted, and of any rework or revisions done, is recorded to denote the actual condition (Refer to Section 4.2.4) per documented procedures by personnel identified in documented procedures.

Revised or reworked product is re-inspected to demonstrate conformity to requirement in accordance with documented procedures by personnel identified in documented procedures.

When nonconforming product is detected after delivery or use has started, the corrective action process (Refer to Section 8.5.2) is used to implement appropriate action regarding the consequences of the nonconformity by personnel identified in documented procedures.

## **8.4 Analysis of Data**

The Quality Manager or designee utilizes the “Improve Products & Processes (M-C0)” process and its associated documented procedures to collect and analyze appropriate data to determine the suitability and effectiveness of the quality management system and to identify improvements that can be made. This includes data generated by measuring and monitoring activities and other relevant sources.

Personnel identified in documented procedures analyze this data to provide information on:

- a. Customer satisfaction and/or dissatisfaction (see 8.2.1);
- b. Conformance to product requirements (see 7.2.1);
- c. Characteristics of processes, product and their trends including opportunities for preventive action; and,
- d. Suppliers.

### **8.4.C.1 Trend Analysis of Nonconforming Product**

The Quality Manager performs trend analysis of discrepancies found in nonconforming product on a defined, regular basis and the results are utilized as input for corrective and preventive action via the “Identify, Analyze, and Disposition Nonconforming Products (M-C2)” process and its associated procedures.

#### **8.4.H.1 Field Performance Data**

The Quality Manager or designee collects and analyzes field performance data (when available) which can be used to help identify the cause and frequency of equipment failure via the “Improve Products & Processes (M-C0)” process and its associated procedures. In addition, this process maintains no trouble found (NTF) data. The analysis information is provided to the appropriate organizations to foster continual improvement per the process and its procedures.

#### **8.4.V.1 Service Performance Data**

Not applicable.

### **8.5 Improvement**

#### **8.5.1 Continual Improvement**

Executive Management plan and manage the processes necessary for the continual improvement of the quality management system via the “Improve Products & Processes (M-C0)” process and its associated documented procedures. The Quality Manager facilitates, with assistance from Directors and Managers, continual improvement of the quality management system through the use of the quality policy, objectives, audit results, analysis of data, corrective and preventive action, and management review.

##### **8.5.1.C.1 Quality Improvement Program**

The Quality Manager establishes and maintains a Quality Improvement Program via the “Improve Products and Processes (M-C0)” process and its associated procedures to improve:

- a) Customer satisfaction;
- b) Quality and reliability of the product; and
- c) Other processes/product/services used within Humanetics.

##### **8.5.1.C.2 Employee Participation**

Process owners provide methods for encouraging employee participation in the continual improvement process via the “Identify/Implement Improvements & Preventive Actions (M-C5)” process and its associated procedure.

#### **8.5.2 Corrective Action**

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The Quality Manager utilizes the “Improve Products & Processes M-C0)” process and its associated documented procedures for implementing corrective actions. The Quality Manager is responsible for maintaining corrective action records.

Any corrective action taken to eliminate the causes of actual nonconformities are appropriate to the magnitude of problems and commensurate with the risks encountered.

Documented procedures define responsibility for implementation and recording of changes to the documented procedures resulting from corrective action.

Documented procedures for corrective action utilize disciplined problem-solving methods for internal or external nonconformance to specifications or requirements. When external non-conformances occur, response meets any customer prescribed requirements.

The procedures for corrective action include:

- a. The effective handling/review of customer complaints and reports of product nonconformities and is the responsibility of the Logistics and Sales notified of the complaint;
- b. Investigation of the cause of nonconformities relating to product, process and Quality System, and recording the results of the investigation and is the responsibility of the Process Owner notified of the corrective action activity (Refer to Section 4.2.4);
- c. Determination of the corrective action needed to eliminate the cause/recurrence of nonconformities and is the responsibility of the Process Owner notified of the complaint; the corrective action can consist of, but is not limited to, adjustments in a procedure, adjustments to existing materials and/or equipment, training or retraining of personnel;
- d. Application of controls to ensure that corrective action is taken and that it is effective and is the responsibility of the Process Owner notified of the corrective action activity;
- e. Recording the results of action taken (see 4.2.4) and,
- f. Reviewing the corrective action taken.

The Quality Manager or designee analyzes product returned from the customer. Records of these analyses are kept and made available upon request. Humanetics performs effective analysis and initiates corrective action and process changes to prevent recurrence.

### **8.5.2.S.1 Problem Resolution**

Not applicable.

### **8.5.3 Preventive Action**

The Quality Manager utilizes the “Improve Products & Processes (M-C0)” process and its associated documented procedures for implementing preventive actions. The Quality Manager is responsible for maintaining preventive action records.

Any preventive action taken to eliminate the causes of potential nonconformities are appropriate to the magnitude of problems and commensurate with the risks encountered.

The procedures for preventive action include:

- a. The use of appropriate sources of information, to determine potential nonconformities and their causes, such as processes and work operations which affect product quality, concessions, audit results, quality records, service reports, and customer complaints to detect, analyze and eliminate potential causes of nonconformities;
- b. Determination of the steps needed to deal with any problems requiring preventive action is the responsibility of the personnel identified in documented procedures notified of the preventive action activity;
- c. Initiation of preventive action and application of controls to ensure that it is effective is the responsibility of the personnel identified in documented procedures notified of the preventive action activity;
- d. Confirmation that relevant information on actions taken (such as cost savings, process improvements, cycle time reduction, and preventive activities presently in process and those completed) is submitted for management review on a regular basis at Manager Meetings. It is the responsibility of the TL 9000 Quality Engineer according to documented procedures.
- e. Reviewing preventive actions taken.

## Appendix A

### Applicable Procedures

Applicable Paragraph	Procedure Number	Procedure Title
4.1	MC-05	Identifying and Implementing Preventative Actions and Continual Improvements
	MC-06	Developing and Maintaining the Enterprise Process Definitions
	MD-01	Receiving, Evaluating, & Installing New Equipment & Systems
	MD-04	Maintaining / Monitoring Security and Providing System Maintenance / Administration
	MD-05	Providing Back-up and Disaster Recovery
	MG-01	Conducting Reviews of the Management System
	4.2	ALL
4.2.2	QM-01	Quality Manual
4.2.3	PA-06	Reviewing RFQ Packages for Completeness & Revision Changes
4.2.4	PC-05	Preparation of the Master Print File and Verifying / Establishing Material Codes (New Items)
	PD-05	Processing Work Order Router Packages for Release and Closure
	MC-07	Preparing and Maintaining Standard Procedures and Work Instructions
	PA-06	Reviewing RFQ Packages for Completeness & Revision Changes
	PA-13	Establishing Joint Objectives with Customers and Conducting Periodic Account Reviews
	PB-05	Developing and Managing Tooling
	PC-04	Entering Orders and Inventory Codes
	PD-03	Scheduling Jobs to Work Centers and Processing Job Changes / Cancellations
	PD-05	Processing Work Order Router Packages for Release and Closure
	PE-01	Preparing and Issuing Purchase Orders
	PE-02	Establishing and Maintaining the Approved Vendor List and Monitoring Vendor Performance
	PE-05	Conducting Incoming Quality Inspections (Receiving Inspection)
	PF-03	Set-up Workcenter & Run and Monitor Production
	PF-04	Conduct First Article Inspection and Periodic Retests
	PF-07	Conduct Final Inspection
	MC-01	Planning and Conducting Internal Audits of the Management System
	MC-04	Identifying & Implementing Corrective Actions
MC-07	Preparing and Maintaining Standard Procedures and Work Instructions	
MC-10	Handling Customer Complaints and Customer Satisfaction	
MC-11	Identifying, Qualifying and Maintaining Inspection Stamps	
ME-01	Hiring, Transferring, Promoting, Assessing Employee Performance and Terminations	
ME-08	Establishing, Approving, Recording, and Revalidating Special Processes	
4.3	PB-01	Establishing and Maintaining Pro-E (3D) Models and Flat Patterns
	PB-05	Developing and Controlling CNC Programs
5.1	MA-01	Providing Business Planning
	MG-01	Conducting Reviews of the Management System
5.2	PA-01	Develop Market Analysis and Conducting Marketing and Sales

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	PA-07	Input Manufacturing / Production Data and Preparing Estimates
	PA-13	Establishing Joint Objectives with Customers and Conducting Periodic Account Reviews
	MA-01	Providing Business Planning
	MC-10	Handling Customer Complaints and Customer Satisfaction
	MG-01	Conducting Reviews of the Management System
5.3	MA-01	Providing Business Planning
	MG-01	Conducting Reviews of the Management System
5.4	PA-07	Input Manufacturing / Production Data and Preparing Estimates
	MA-01	Providing Business Planning
	MG-01	Conducting Reviews of the Management System
5.4.1	MC-08	Measuring Enterprise Performance
5.4.2	MC-08	Measuring Enterprise Performance
	MG-01	Conducting Reviews of the Management System
5.5	ALL	All Procedures Reference this Paragraph
5.5.1	MC-11	Identifying, Qualifying and Maintaining Inspection Stamps
5.5.2	MG-01	Conducting Reviews of the Management System
5.5.3	PA-13	Establishing Joint Objectives with Customers and Conducting Periodic Account Reviews
	MC-04	Identifying & Implementing Corrective Actions
	MC-10	Handling Customer Complaints and Customer Satisfaction
	ME-01	Hiring, Transferring, Promoting, Assessing Employee Performance and Terminations
	MG-01	Conducting Reviews of the Management System
5.6	PA-13	Establishing Joint Objectives with Customers and Conducting Periodic Account Reviews
	MC-01	Planning and Conducting Internal Audits of the Management System
	MC-04	Identifying & Implementing Corrective Actions
	MC-05	Identifying and Implementing Preventative Actions and Continual Improvements
	MC-10	Handling Customer Complaints and Customer Satisfaction
	MG-01	Conducting Reviews of the Management System
5.6.1	MG-01	Conducting Reviews of the Management System
5.6.2	PA-13	Establishing Joint Objectives with Customers and Conducting Periodic Account Reviews
	MC-10	Handling Customer Complaints and Customer Satisfaction
	MG-01	Conducting Reviews of the Management System
5.6.3	MG-01	Conducting Reviews of the Management System
6.1	PD-01	Establishing and Maintaining Work Center Loadable Hours
	PE-08	Establishing Part Stocking Decisions
	MA-01	Providing Business Planning
	ME-08	Establishing, Approving, Recording, and Revalidating Special Processes
	ME-09	Developing and Maintaining Training Courses and Materials
	MG-01	Conducting Reviews of the Management System
6.2	ALL	All Procedures Reference this Paragraph
6.2.1	ME-08	Establishing, Approving, Recording, and Revalidating Special Processes
6.2.2	ME-01	Hiring, Transferring, Promoting, Assessing Employee Performance and Terminations
	ME-03	Initial Training / Orientation and General Training Requirements
6.3	PB-05	Developing and Managing Tooling

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	MA-01	Providing Business Planning
	MD-01	Receiving, Evaluating, & Installing New Equipment & Systems
	MD-04	Maintaining / Monitoring Security and Providing System Maintenance / Administration
	MD-05	Providing Back-up and Disaster Recovery
	MD-06	Providing Technical User Support
6.4	MA-01	Providing Business Planning
	MD-03	Assessing Equipment Initial Maintenance Requirements, Planning, & Managing Equipment Maintenance
	MF-01	Providing Environmental, Health, and Safety Management
	MG-01	Conducting Reviews of the Management System
7.1	PA-07	Input Manufacturing / Production Data and Preparing Estimates
	PB-05	Developing and Managing Tooling
	PD-03	Scheduling Jobs to Work Centers and Processing Job Changes / Cancellations
	PD-05	Processing Work Order Router Packages for Release and Closure
	PE-05	Conducting Incoming Quality Inspections (Receiving Inspection)
7.2	PA-01	Develop Market Analysis and Conducting Marketing and Sales
	PA-06	Reviewing RFQ Packages for Completeness & Revision Changes
	PA-07	Input Manufacturing / Production Data and Preparing Estimates
	PA-08	Estimate Approval, Establishing Price and Delivering and Following Up of Quotes
	PA-11	Establishing New Client Accounts
	PC-01	Preparing Job Packages
	PC-04	Entering Orders and Inventory Codes
	PC-05	Preparation of the Master Print File and Verifying / Establishing Material Codes (New Items)
7.2.1	PA-08	Estimate Approval, Establishing Price and Delivering and Following Up of Quotes
	PB-05	Developing and Managing Tooling
	PF-04	Conduct First Article Inspection and Periodic Retests
7.2.2	PA-08	Estimate Approval, Establishing Price and Delivering and Following Up of Quotes
	PF-04	Conduct First Article Inspection and Periodic Retests
	MC-11	Identifying, Qualifying and Maintaining Inspection Stamps
7.2.3	PA-08	Estimate Approval, Establishing Price and Delivering and Following Up of Quotes
	PA-13	Establishing Joint Objectives with Customers and Conducting Periodic Account Reviews
	PB-05	Developing and Managing Tooling
	PF-04	Conduct First Article Inspection and Periodic Retests
	MC-04	Identifying & Implementing Corrective Actions
	MC-10	Handling Customer Complaints and Customer Satisfaction
7.3	EXCLUDED	
7.4	PE-01	Preparing and Issuing Purchase Orders
	PE-02	Establishing and Maintaining the Approved Vendor List and Monitoring Vendor Performance
	PE-08	Establishing Part Stocking Decisions
	MD-01	Receiving, Evaluating, & Installing New Equipment & Systems

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	ME-09	Developing and Maintaining Training Courses and Materials
7.4.1	PE-01	Preparing and Issuing Purchase Orders
	PE-02	Establishing and Maintaining the Approved Vendor List and Monitoring Vendor Performance
7.4.2	PE-01	Preparing and Issuing Purchase Orders
	PE-02	Establishing and Maintaining the Approved Vendor List and Monitoring Vendor Performance
	PE-05	Conducting Incoming Quality Inspections (Receiving Inspection)
	PF-04	Conduct First Article Inspection and Periodic Retests
7.4.3	PE-04	Verifying Purchased Items and Returning Materials and Parts to Suppliers
	PE-05	Conducting Incoming Quality Inspections (Receiving Inspection)
7.5	PA-06	Reviewing RFQ Packages for Completeness & Revision Changes
	PB-01	Establishing and Maintaining Pro-E (3D) Models and Flat Patterns
	PB-05	Developing and Controlling CNC Programs
	PF-03	Set-up Workcenter & Run and Monitor Production
	MC-01	Planning and Conducting Internal Audits of the Management System
	MC-02	Identifying, Analyzing & Dispositioning Nonconforming Products
	MC-07	Preparing and Maintaining Standard Procedures and Work Instructions
7.5.1	PD-01	Establishing and Maintaining Work Center Loadable Hours
	PF-01	Review Dispatch List and Assign Operators and Workcenters
	PF-05	Package, Label, and Stage / Stock Product
	PF-06	Verify / Close Work Order Router Packages
	PF-07	Conduct Final Inspection
	PF-08	Conduct Out-of-Box Audit
	PG-01	Stage, Invoice, and Ship Product
	MD-02	Assessing Equipment Initial Metrology Requirements, Planning, & Managing Equipment Maintenance
7.5.2	PF-03	Set-up Workcenter & Run and Monitor Production
	ME-08	Establishing, Approving, Recording, and Revalidating Special Processes
7.5.3	PF-01	Review Dispatch List and Assign Operators and Workcenters
	PF-03	Set-up Workcenter & Run and Monitor Production
	PF-05	Package, Label, and Stage / Stock Product
	PF-06	Verify / Close Work Order Router Packages
	PF-08	Conduct Out-of-Box Audit
	PG-01	Stage, Invoice, and Ship Product
	MC-11	Identifying, Qualifying and Maintaining Inspection Stamps
7.5.4	PA-07	Input Manufacturing / Production Data and Preparing Estimates
	PC-05	Preparation of the Master Print File and Verifying / Establishing Material Codes (New Items)
	PE-05	Conducting Incoming Quality Inspections (Receiving Inspection)
7.5.5	PE-06	Establishing ABC Parameters, Conducting ABC Cycle Counts and Maintaining Inventory
	PF-05	Package, Label, and Stage / Stock Product
	PF-07	Conduct Final Inspection
	PF-08	Conduct Out-of-Box Audit
7.6	MC-02	Identifying, Analyzing & Dispositioning Nonconforming Products
	MD-02	Assessing Equipment Initial Metrology Requirements, Planning, & Managing Equipment Maintenance
	ME-08	Establishing, Approving, Recording, and Revalidating Special Processes

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8.1	MA-01	Providing Business Planning
	MG-01	Conducting Reviews of the Management System
8.2	PA-13	Establishing Joint Objectives with Customers and Conducting Periodic Account Reviews
	MC-10	Handling Customer Complaints and Customer Satisfaction
	MC-11	Identifying, Qualifying and Maintaining Inspection Stamps
	MD-02	Assessing Equipment Initial Metrology Requirements, Planning, & Managing Equipment Maintenance
8.2.1	PA-13	Establishing Joint Objectives with Customers and Conducting Periodic Account Reviews
	MC-10	Handling Customer Complaints and Customer Satisfaction
	MG-01	Conducting Reviews of the Management System
8.2.2	MC-01	Planning and Conducting Internal Audits of the Management System
	MG-01	Conducting Reviews of the Management System
8.2.3	PE-06	Establishing ABC Parameters, Conducting ABC Cycle Counts and Maintaining Inventory
8.2.4	PE-06	Establishing ABC Parameters, Conducting ABC Cycle Counts and Maintaining Inventory
	PF-03	Set-up Workcenter & Run and Monitor Production
	PF-04	Conduct First Article Inspection and Periodic Retests
	PF-07	Conduct Final Inspection
	PF-08	Conduct Out-of-Box Audit
	MC-02	Identifying, Analyzing & Dispositioning Nonconforming Products
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	MC-02	Identifying, Analyzing & Dispositioning Nonconforming Products
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	MC-05	Identifying and Implementing Preventative Actions and Continual Improvements
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8.5	MC-04	Identifying & Implementing Corrective Actions
	MC-05	Identifying and Implementing Preventative Actions and Continual Improvements
	MG-01	Conducting Reviews of the Management System
8.5.1	MC-04	Identifying & Implementing Corrective Actions
8.5.2	MC-02	Identifying, Analyzing & Dispositioning Nonconforming Products
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8.5.3	MC-02	Identifying, Analyzing & Dispositioning Nonconforming Products
	MG-01	Conducting Reviews of the Management System