0. Table of Contents

1. Scope

1.1 General

Carter Process Control GmbH has based the Quality Management System (QMS) described in this manual to demonstrate our capability to consistently provide products/services that meet customer and applicable regulatory requirements, and to operate with increased effectiveness and efficiency with the overall aim of enhancing customer satisfaction.

Our QMS utilizes the process approach and quality management principles contained in the international standards: *ISO 9000:2005*, *ISO 9001:2008* and *ISO 9004:2000* to enhance our ability to continually improve.

1.2 Application

Our QMS complies with all applicable requirements contained in *ISO 9001:2008*, covers the design and provision of all company products, and encompasses all operations at our facilities in Austria.

2. Reference Documents.

The following external documents contain provisions which, through reference in this manual, constitute provisions of our QMS:

ISO 9000:2005, Quality management systems – Fundamentals and vocabulary
ISO 9001:2008, Quality management systems – Requirements
ISO 9004:2000, Quality management systems – Guidelines for performance improvements

- ☐ Customer Specific Requirements
- ☐ Customer Reference Manuals

Appendix A contains a List of Key QMS documents referenced in this manual and defines the key top level processes for implementing our quality policy. Note: documents are referenced throughout this manual only by document number; see *Appendix A* for complete titles.

3. Terms and Definitions.

Our QMS uses the same internationally recognized terms, vocabulary and definitions given in *ISO 9000:2005*. Acronyms, terms, vocabulary and definitions unique to our organization, customers, industry and region and referenced throughout our QMS are contained in *Appendix B*, Terms and Definitions

4. Quality Management System

4.1 General requirements

Our QMS is that part of our overall management system which establishes, documents and implements our quality policy, and related processes for providing products and services which meet or exceed customer requirements, and satisfies QMS requirements of *ISO 9001:2008*.

We have adopted the process approach advocated by *ISO 9000:2005*, by defining and managing:

- process inputs, controls, and outputs to ensure desired results are achieved, and
- interfaces between interrelated processes to ensure system effectiveness is achieved.

Our ‘core’ business processes are what we call ‘Customer Oriented Processes’, or COPs, which are in place to meet the specific needs of our external customers, which directly relate to requirements contained in Clause 7 of *ISO 9001:2008*, Product Realization processes (i.e. things we ‘do’).

Techniques and tools for process management are discussed in *Section 8*.

Specific responsibilities for and the sequence and interaction of our key QMS processes are detailed in Operating Procedures (OPs), many of which contain or reference deployment flow charts depicting the process or procedure described in the narrative OP; *Appendix A* contains a List of Key QMS Documents, including all OPs and other key top level QMS documents.

We recognize the significant role that subcontractors play in achieving desired results and recognize that we must ensure proper control over outsourced QMS processes (*Section 7.4.1.2*).

4.2 **Documentation requirements**

4.2.1 General

This manual contains documented statements of our quality policy and quality objectives and references documented procedures required by *ISO 9001:2008* and other documents needed to ensure effective planning, operation and control of our key QMS processes.

The level and type of QMS documentation established for our business is continually reviewed to ensure it remains appropriate for the complexity and interaction of our processes and the competence of our employees. QMS documents and data may be in hard copy or electronic media. QMS documentation includes this quality manual, OPs, and other internal and external documents and data needed to manage, perform or verify work affecting product quality.
We use OPs to document and define the key QMS processes.

4.2.2 **Quality manual**

This manual is that part of our QMS that defines the scope of our QMS and documents the policy, procedures and processes needed to implement our quality policy and achieve our quality objectives. This manual also documents justifications for exclusions from *ISO 9001:2008* requirements *(Section 1.2*).

4.2.3 **Control of documents**

The Managing Director has overall responsibility for ensuring that all QMS documents, including forms used to create quality records, are controlled per procedures detailed in *OP 4.2.3* and summarized below:

a) Approve documents for adequacy prior to issue.
b) Review, update as necessary and re-approve documents.
c) Identify the current revision status of documents.
d) Ensure that relevant versions of applicable documents are available at points of use.
e) Ensure that documents remain legible, readily identifiable and retrievable.
f) Ensure that documents of external origin (including customer engineering standards/specifications) are identified and their distribution controlled.
g) Prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

The Operations and Technical Director oversees our process for assuring the timely review, distribution and implementation of all customer engineering standards/specifications and changes based on customer-required schedule;

Requirements for the establishment and maintenance of Master Lists of internal and external QMS documents are defined in *OP 4.2.3*

4.2.4 Control of records

The Managing Director has overall responsibility for ensuring that all records required for the QMS (including customer-specified records) are controlled and maintained to provide evidence of conformance to requirements and effective operation of the QMS. Records are retained for a period defined by the customer, applicable regulatory requirements and/or Carter Process Control GmbH management, as applicable, and then disposed of in accordance with applicable requirements. Records may be in the form of hard copy or electronic media. *OP 4.2.4* details procedures necessary to control QMS records that, as a minimum, are prepared to document:

a) Results of processes performed, including identification of the individual performing the activity.
b) Product/process evaluation/acceptance criteria.
c) Procedures, drawings or instructions used to perform an activity, including revision or date of document.
d) Identification of material, parts, or equipment used in the making of the product.
e) Personnel, material or equipment qualifications.
f) Pertinent technical records from sub-contractors.

5. Management Responsibility

5.1 Management commitment

Top Management provides evidence of its commitment to the development, implementation and improvement of our QMS in very tangible ways:

Our quality policy statement (*Section 5.3*) documents and communicates the importance of meeting or exceeding all applicable requirements (including customer, regulatory and legal requirements) through continual improvement of our processes, products, and services.

We ensure that our quality policy is understood, implemented, and maintained at all levels of the organization through widespread printed distribution of our quality policy statement, and through periodic management review of the quality policy statement and corporate level improvement objectives (*Section 5.6*). In addition, our quality policy and objectives are communicated and deployed throughout the organization through individual performance objectives established and reviewed during employee performance reviews (*Section 6.2.2.4*).

All managers demonstrate their commitment to the development and improvement of the QMS through the provision of necessary resources (*Section 6.1*), through their involvement in the internal audit process (*Section 8.2.2*), and through their proactive involvement in our continual improvement activities (*Section 8.5.1*) – where emphasis is placed on improving both effectiveness and efficiency of our key QMS processes.

5.2 Customer focus

Top management ensures a proper customer focus is established and maintained through the following activities:

Customer complaints and other customer input/feedback are continually monitored and measured to identify opportunities for improvement (*Section 8.2.1*).

We continually look for other ways to interact directly with individual customers to ensure a proper focus to their unique needs/expectations is established and maintained: e.g. customer audits, customer visits, trade shows, joint planning sessions, etc.

In addition, we have established an interactive web site: www.carterprocess.com to provide customers with quick access to information and points of contact within our organization (*Section 7.2.3*).

These customer focused communications and interactions ultimately yield clear, explicit customer requirements and expectations in the form of a contractual agreement or customer order (*Section 7.2*).

5.3 Quality policy

"We will achieve customer satisfaction by continually improving processes, products and services to ensure they consistently meet or exceed customer requirements"

Our quality policy statement indicates our commitment and focuses on what is important to us as an organization: *achieving customer satisfaction*; and it prescribes the method by which we accomplish this: *by continually improving processes, products, and services to ensure they consistently meet or exceed requirements.* Moreover, our quality policy statement acts as a compass in providing the direction and a framework for establishing key corporate level performance measures and related improvement objectives (*Section 5.4.1*).

We ensure that our quality policy is communicated and understood at all levels of the organization through documented training, regular communication, and reinforcement during annual employee performance reviews (*Section 6.2.2.4*).

Our quality policy statement is controlled by inclusion in this manual, and along with all policies contained in this manual, is reviewed for continuing suitability during management review meetings (*Section 5.6.2*).

5.4 **Planning**

5.4.1 Quality objectives

Our overall quality goal is to achieve our quality policy, and maintain the integrity of and continually improve a QMS compliant with *ISO 9001:2008*. Further, we establish both corporate level and operational level improvement objectives that are measurable and achievable within a defined time period. Corporate level improvement objectives, derived from our Business Plan and customer goals/targets are documented on a Management Action Request Form (*Doc 369-2)*, and reviewed for achievement during management reviews (*Section 5.6.2*). All managers of key QMS processes monitor and measure performance of processes within their area(s) of responsibility and, where appropriate, establish measurable operational level improvement objectives consistent with our quality policy and corporate level improvement objectives.

Corporate and operational level improvement objectives are reviewed for consistency, accomplishment and clarity through our management review process (*Section 5.6*) and may include any/all of the following possible measures:

- Customer Satisfaction: Managing Director; *Section 8.2.1*.
- Supplier Performance: Operations and Technical Director; *Section 7.4.1.2*.
- QMS Effectiveness: Managing Director; *Section 8.5.1*.
- Overall Operational Efficiency and Manufacturing Process Efficiency: Managing Director; *Section 6.1* and *Section 5.1.1*.
- Training Effectiveness and Employee Awareness: Managing Director with input from the Operations and Technical Director; *Section 6.2.2.4*.
- Product Performance: Operations and Technical Director ; *Section 7.3*.
- Effectiveness of Manufacturing Processes: Operations and Technical Director; *Section 7.5.1*.
- Product Quality: Operations and Technical Director; *Section 8.2.4*.

a) Achievement of ZERO DEFECTS (*Section 8.2.3.1*) and 100% on time delivery (*Section 7.5.1.6*) performance.

b) Manage and control facilities, processes, quality systems and personnel to consistently and cost effectively produce products and furnish services that meet customer needs (*Section 7.5.1*).

c) Be committed to continuous process improvement (*Section 8.5.1.2*) by emphasising reduction of part-to-part variation and the elimination of all waste.

d) Conduct operations in conformance with, or to exceed, all applicable environmental laws and regulations of the jurisdictions in which we do business (*Section 6.4*).

5.4.2 **Quality management system planning**

The QMS planning process involves the establishment and communication of our quality policy (*Section 5.3*) and objectives (*Section 5.4.1*) through issuance of this manual and its associated procedures, and through the provision of resources needed for its effective implementation (*Section 6.1*). Accordingly, this manual constitutes our overall plan for establishing, maintaining and improving an effective QMS. Our management review process (*Section 5.6*) and internal audit process (*Section 8.2.2*) ensure the integrity of our QMS is maintained when significant changes are planned and implemented that affect our key QMS processes.

The Managing Director also develops appropriate quality planning documents for specific products, projects or contracts whenever customer requirements exceed the capability or intent of the product/service realization and support processes described in our QMS (*Section 7.1*).

5.5 **Responsibility, authority and communication**

5.5.1 Responsibility and authority

The Managing Director sets direction and ensures the success of our business through the clear definition and communication of QMS responsibilities and authorities. Other members of Top Management include: the Operations and Technical Director, and the Executive Assistant. The interrelationship of Top Management and other key personnel is depicted in our Organization Chart (*Doc 369-1*).

- Top Management – Members of Top Management are ultimately responsible for the quality of Carter Process Control GmbH's products and services since they control the systems and processes by which work is accomplished. Top Management is responsible for Business Planning, development and communication of our quality policy (*Section 5.3*), QMS Planning (*Section 5.4.2*) including the establishment and deployment of objectives (*Section 5.4.1*), the provision of resources needed to implement and improve the QMS (*Section 6.1*) and management reviews (*Section 5.6*).

- Management – All managers are responsible for execution of the Business Plan and implementation of the policy, processes and systems described in this manual. All managers are responsible for planning and controlling QMS processes within their area(s) of responsibility, including the establishment and deployment of operational level objectives (*Section 5.4.1.1*), and the provision of resources needed to implement and improve these processes (*Section 6.1*). Managers also conduct employee performance reviews (*Section 6.2.2.4*). Management with responsibility and authority for corrective action are notified promptly of non-conformities (*Section 8.5.2*).

- Employees - All employees are responsible for the quality of their work and implementation of the policy and procedures applicable to processes they perform (*Section 8.2.3*). Personnel responsible for product quality have the authority to stop production to correct quality problems (*Section 8.3*). Employees are motivated and empowered (*Section 6.2.2.4*) to identify and report any known or potential problems and recommend related solutions through internal audits (*Section 8.2.2*) and/or the continual improvement and corrective/preventive action processes (*Section 8.5*).

Detailed responsibilities and authorities for QMS implementation and improvement are contained in lower level documents referenced throughout this manual and other QMS documents including procedures, flow charts, job descriptions, work instructions, etc.

5.5.2 Management representative

The Managing Director is appointed as Carter Process Control GmbH's management representative with delegated responsibilities for ensuring that an *ISO 9001:2008* compliant QMS is established, implemented, and maintained; for promoting awareness of customer requirements throughout the organization (*Section 5.5.3*); and for ensuring that the performance of the QMS is reviewed by Top Management for effectiveness, continuing suitability and the need for improvement (*Section 5.6*).

5.5.3 Internal communication

We communicate information regarding QMS processes and their effectiveness through documented training (*Section 6.2.2*), the internal audit process (*Section 8.2.2*), continual improvement and corrective/preventive action processes (*Section 8.5*), and regular formal and informal communications: *OP 5.5.3*

All managers and supervisors, are responsible for establishing internal communications as needed to convey to their employees the relevance and importance of their activities; typically this information is conveyed through production team meetings and cross-functional improvement projects (*Section 8.5.1*). Communications regarding how employees contribute to the achievement of objectives is also conveyed and reinforced during employee performance reviews (*Section 6.2.2.4*).

5.6 **Management review**

5.6.1 General

Top Management conducts a management review meeting at least once annually to ensure the continuing suitability, adequacy, and effectiveness of our QMS in accordance with procedures detailed in *OP 5.6*. The primary inputs reviewed include data that measures the conformance and performance of our QMS and recommendations based on analysis of such data. Conformance is primarily assured through internal audits (*Section 8.2.2*) and demonstrated through a review of internal audit results and our demonstrated ability to correct/prevent problems. Performance is primarily assured through the deployment of corporate/operational level objectives (*Section 5.4.1*) and demonstrated through a review of our demonstrated ability to achieve desired results. The primary outputs of management review meetings are management actions taken (*Section 8.5*) to make changes or improvements to our QMS and the provision of resources needed to implement these actions.

5.6.2 Review input

The management review meeting includes a review of our quality policy (*Section 5.3*), all applicable requirements of the QMS, related performance trends and opportunities for improvement, follow-up actions from earlier management reviews, results of self assessments (*Section 8.4*), and strategic or operational changes that could affect the QMS.

At a minimum, corporate level improvement objectives (*Section 5.4.1*) documented in prior management reviews are reviewed for status and continuing suitability:

5.6.3 Review output

At a minimum, outputs from management review meetings include new/revised corporate level improvement objectives and any related actions required for improvement of the QMS and its processes, improvement of product related to customer requirements, and provision of resource needs. Results of management review meetings are recorded and maintained by the Managing Director per *OP 5.6*

6. Resource Management

6.1 Provision of resources

The Managing Director with input from all responsible managers, ensures, appropriate resources, including trained employees and appropriate equipment, facilities, support services and work environment needed to implement, manage and improve an effective/efficient QMS and enhance customer satisfaction, are identified and provided through our budgeting and other business management processes including but not limited to:

Section 5.4.2, QMS Planning
Section 6.2.2, Human Resource Planning
Section 6.3, Plant, Facility, Equipment and other Infrastructure Planning
Section 6.4, Work Environment and Safety Planning
Section 7.1, Product Quality Planning
Section 7.2, Planning of Customer-related Processes
Section 7.3.1, Design and Development Planning
Section 7.4, Planning of Purchased Product (Materials, Services and Suppliers)
Section 7.5.1, Production and Service Provision Planning
Section 7.6, Measurement Systems Planning
Section 8.1, Measurement, Analysis and Improvement Planning
Section 8.5.1, Continual Improvement Planning

The Managing Director, with input from other responsible managers, monitors and measures overall operational efficiency and provides related input and recommendations that may affect QMS effectiveness to Top Management for review and action (*Section 5.6*).

6.2 **Human resources**

6.2.1 General

We believe that our employees are our most valuable resource and we do our best to help them achieve their full potential through continual education and training.

6.2.2 Competence, training, and awareness

The competency of people assigned responsibilities defined in the QMS is determined on the basis of documented criteria for appropriate education, training, skills, and experience for each required competency or work assignment. The Managing Director has overall responsibility for administering Carter Process Control GmbH's Human Resource Management programs in accordance with procedures detailed in *OP 6.2* and the following policies.

6.2.2.a *Need Determination.* We determine competency needs, including employee training and awareness needs, through the following actions:

Top Management identifies emerging competency needs during management reviews (*Section 5.6*). Emergent competency needs are converted into job descriptions for the type and number of positions that need to be filled through external recruitment, internal reassignment/promotion, and/or outsourcing actions.

The Managing Director, with input from responsible managers, evaluates and qualifies applicants for specific job openings on the basis of documented or demonstrated competencies. Where possible, we help existing employees qualify for new/changed jobs through the provision of appropriate education and training, including on-the-job-training (OJT).

The Managing Director, with input from responsible managers, establishes and maintains job descriptions for each position held at Carter Process Control GmbH to document the specific competencies needed to ensure the quality of Carter Process Control GmbH's products and services.

6.2.2.b *Provision.* Training needs identified as a result of the need determination activities discussed above are passed on to the Managing Director for appropriate planning and timely provision.

6.2.2.c *Effectiveness.* We evaluate the effectiveness of all actions taken to meet competency needs. Training provided is evaluated through immediate feedback from the employee and the manager, officer, or supervisor who identified the training requirement. Training effectiveness is collected and documented by the responsible manager for each training event. The Managing Director, with input from other responsible managers, monitors and measures the overall effectiveness of training and other actions taken to meet competency needs and provides related recommendations to Top Management for review and action (*Section 5.6*).

6.2.2.d *Employee Awareness.* We ensure that our employees are aware of customer requirements (*Section 5.5.2*), the relevance and importance of their activities and how they contribute to the achievement of our quality policy (*Section 5.3*) and objectives (*Section 5.4.1.1*). This is accomplished through awareness training, employee performance reviews (*Section 6.2.2.4*), and employee participation in our internal audit (*Section 8.2.2*) and improvement (*Section 8.5*) processes.

6.2.2.e *Records.*. We maintain appropriate records of education, training, skills and experience in accordance with provision of *Section 4.2.4*. Employee qualification/competency review records and annual performance review results are maintained by the Managing Director.

6.3 Infrastructure

The Managing Director has overall responsibility for planning, providing and maintaining the resources needed to achieve product conformance, including buildings, workspace and associated utilities; process equipment (hardware and software); and supporting services (such as internal transportation and material handling systems and communications systems).

The Operations and Technical Director has overall responsibility for managing our sub supplier infrastructure to ensure total effectiveness.

6.4 Work environment

We provide employee benefits, job and schedule flexibility, interesting work, and involvement of our employees in an empowered environment of continual improvement. We engender total participation by involving employees in internal audit (*Section 8.2.2*) and improvement (*Section 8.5*) activities. The Managing Director has overall responsibility for identifying, implementing and maintaining effective employee benefit and workforce involvement programs.

The Managing Director has overall responsibility for identifying, implementing and maintaining safety and environmental management systems, processes and controls needed to ensure product conformance and meet customer, statutory or regulatory requirements; We monitor and improve workplace safety, health, and ergonomics through adherence to good manufacturing practices, and through safety team meetings and training (*Section 6.2.2*).

7. Product Realization

7.1 Planning of product realization

Our QMS identifies, plans for and documents our product and service realization processes to ensure consistency with all applicable requirements, including customer requirements and related quality objectives and requirements for specific products/services, and any/all applicable statutory/legal requirements. The outputs of product/service realization planning include the specific methods, facilities, equipment, people and materials/support services needed to achieve all desired results for a particular product, service, or contract. Essentially, the outputs of the quality planning process applicable to all products/services are the work instructions and other data included in the purchase order (*Section 7.5.1.2*).

When requirements are not adequately addressed in the standard job pack documentation/data, or as required by the customer, the Managing Director has overall responsibility for developing and implementing a quality control plan to address additional requirements or controls needed to verify work for the specific process, product or contract in question.

The outputs of quality planning (i.e. job packs, control plans, etc.) are carried out in accordance with planned monitoring and measurement activities (*Section 8.2*), which may also include the use of appropriate statistical techniques (*Section 8.1*).

7.2 Customer-related processes

Achieving our quality policy "to meet or exceed customer requirements" requires that we determine, understand, and consistently meet or exceed our customers' requirements and expectations, and that we establish effective communication systems with our customers with regards to product information, inquiries, contract or order handling and related changes, and customer feedback, including complaints. These efforts are described below. The Managing Director has overall responsibility for developing and implementing effective customer-related processes in accordance with the policies in this section and *Section 8.2.1*. *OP 7.2*

7.2.1 Determination of requirements related to the product

Sales personnel generate quotes and negotiate final contracts/orders; Requirements for most major customers are identified in contracts documented and reviewed annually. In other cases, a customer order constitutes a contract, and we ensure that the customer's requirements are clearly identified and confirmed prior to acceptance. *OP 7.2.1*

Product requirements specified by the customer, including the requirements for availability, delivery and support including any after-sales product service and/or post-delivery servicing (*Section 7.5.1.8*) provided as part of the customer contract or purchase order.

Product requirements not specified by the customer but necessary for intended or specified use and obligations related to product, including regulatory and legal requirements; this may include recycling, environmental impact, and characteristics identified as a result of Carter Process Control GmbH's knowledge of the product and related production processes.

All applicable government, safety, and environmental regulations applied to the acquisition, storage, handling, recycling, elimination or disposal of materials.

7.2.2 Review of requirements related to the product (Order review)

Sales personnel review customer requirements identified during the determination process (*Section 7.2.1*) to ensure that they are clearly stated, understood, and recorded. Our process for reviewing all applicable requirements to ensure:

- all applicable product requirements are defined, understood and confirmed with the customer prior to acceptance
- manufacturing feasibility of proposed (new or changed) products is investigated, confirmed and documented prior to making a commitment to supply
- contract or order requirements differing from those previously expressed are resolved
- records of the review and actions resulting from the review are maintained (*Section 4.2.4*)

The Operations and Technical Director investigates, confirms and documents the manufacturing feasibility of proposed products or services in accordance with customer-specific requirements.

Where product requirements are changed, we ensure relevant documents are amended and relevant personnel are made aware of the changed requirements;

7.2.3 Customer communication

Customers are provided information for the following 'key' customer contact personnel: Executive Assistant, Managing Director, and Operations and Technical Director.

Customers can also be provided points of contact for the following key functions, if requested: Manufacturing / Production, Sales and Logistics, and Purchasing.

Customer communications are established through a variety of channels:

- Sales personnel provide *product information* directly to customers including verbal and printed information on our standard product offerings as well as customized information for unique customer applications.
- *Enquiries* are handled by our Sales personnel depending on the nature of the inquiry or who made initial contact; *Section 7.2.1*. Engineering personnel provide *technical assistance* and related information as needed.

- We pay particular attention to customer feedback, including *customer complaints* and customer satisfaction. We have a 24hr hotline number and a wide sales network to encourage and address customer feedback, particularly customer complaints. *Customer satisfaction* is evaluated on an on-going basis by customer contact personnel, i.e. Sales and Top Management; see *Section 8.2.1*.

- We maintain a user/customer friendly web site, www.carterprocess.com which contains extensive product information, a list of contacts of use to both customers and suppliers, and an electronic customer feedback form.

7.3 **Design and development.**

Design and development processes are employed at Carter Process Control GmbH to transform customer requirements into specifications, products, processes or systems. The Operations and Technical Director maintains a list of products/services for which Carter Process Control GmbH has design responsibility, i.e. the authority to establish a new, or change an existing, product specification; this responsibility includes testing and verification of design performance within customer specified applications. The Operations and Technical Director has overall responsibility for managing product design and development activities in accordance with *OP 7.3* and summarized in the following sections.

7.3.1 Design planning. The Operations and Technical Director serves as the Design Team Leader for design projects for new/changed products or services. The Design Team Leader utilizes project management planning tools (available software etc.) to establish a Design Plan that, at a minimum, identifies design stages, predetermined design reviews, scheduled verification and validation activities. The Design Team Leader prepares all engineering requirements for product realization.

7.3.2 Design inputs. The Operations and Technical Director identifies, documents (*Section 4.2.4*) and reviews *design inputs*; and, before finalizing documentation of required inputs, resolves any incomplete, ambiguous or conflicting requirements (*Section 7.2.2*):

- the functional and performance requirements as derived from customer input, legal and regulatory requirements which apply
- useful information or experience from previous similar design efforts
- targets for product quality, life, reliability, durability, maintainability, timing and cost

7.3.3 Design outputs. The Operations and Technical Director ensures that design outputs comply with the design input requirements; include information needed for production and service provision; include or reference acceptance criteria; indicate design characteristics critical to the safe and proper operation of the product; and are approved before issuance.

7.3.4 Design review

During the evolution of each design project, the Operations and Technical Director conducts design reviews as planned and records results and any necessary actions. All functions concerned with the stage being reviewed are represented at the planned review(s). Design reviews are intended to assure that requirements are being fulfilled; when they are not, the Operations and Technical Director utilizes input from those involved in the review to propose a remedy for each identified problem.

7.3.5 Design verification

The Operations and Technical Director ensures design verification activities are carried out as planned (per the Design Plan) and records results and any necessary actions. Design verification activities are intended to determine if design output meets design input requirements; design reviews can be a form of design verification.

7.3.6 Design validation

The Operations and Technical Director ensures design validation is carried out as planned (per the Design Plan) and records results and any necessary actions. Design validation is performed to ensure the product or service resulting from design efforts performs as intended for all specified or known uses/applications. As applicable, the Operations and Technical Director plans and carries out or oversees:

7.3.7 Control of design changes

The Operations and Technical Director ensures all design changes are identified, documented, reviewed, approved, communicated to all affected organizations and functions, and results and any necessary actions are recorded throughout the product program. Design change control includes an assessment of the impact of changes upon component parts and completed products, including those that may have already been delivered. Control also includes the determination of treatment required for each change, which may include verification or validation.

7.4 **Purchasing**

We work in partnership with our suppliers to ensure that purchased products and services meet all applicable requirements. The processes applicable to the planning, acquisition and verification of all products and services that affect customer requirements (such as subassembly, sequencing, sorting, rework and calibration services) are defined in*OP 7.4.1* and *OP 8.2.4* in accordance with the policies outlined in this section.

7.4.1 Purchasing process

The type and extent of control applied to our suppliers and purchased product is dependent upon the effect on subsequent realization processes and their output, as well as consideration of other characteristics including: the type of product; the potential impact of the product on our processes, products, or services; the results of supplier evaluations; and past performance.

Purchased products are verified (*Section 7.4.3* and *Section 8.2.4*) to ensure conformity to specified purchase requirements (*Section 7.4.2*).

The Operations and Technical Director defines and documents the supplier approval process, including criteria for selection, the extent of control to be exercised, and periodic evaluation; *OP 7.4.1*. Suppliers are evaluated and selected based on their ability to supply products or services in accordance with our requirements.

Where specified (by contract, customer engineering drawing, or specification) we purchase products, materials or services from customer-approved sources.

A master list of approved suppliers is maintained to ensure we only purchase product from Carter Process Control GmbH qualified sources or customer-approved sources. The results of evaluations and follow/up actions are recorded.

Supplier performance is monitored by the Operations and Technical Director per *OP 7.4.1* through one or more of the following indicators: delivered product quality; customer disruptions including field returns; delivery schedule performance (including incidents of premium freight); and special status customer notifications related to quality or delivery issues.

7.4.2 Purchasing information

The Executive Assistant ensures the adequacy of specified purchase requirements prior to communication to the supplier per procedures defined in *OP 7.2.1* and the following policies:

Purchasing information communicated to our suppliers contains the appropriate data needed to clearly and fully describe requirements for purchased materials and services; including, where appropriate, requirements for approval/qualification of product, procedures, processes/systems, equipment; qualification of personnel; and quality management system requirements.

7.4.3 Verification of purchased product

The Operations and Technical Director has overall responsibility for ensuring the quality of purchased products using one or more of the following methods: receipt and evaluation of statistical data; receiving inspection and/or testing (such as sampling based on performance); second or third party audits of supplier sites (when coupled with records of acceptable delivered product quality); part evaluation by a designated laboratory; and/or another method agreed with the customer. Receiving inspection is performed per *Section 8.2.4*.

The Operations and Technical Director plans and implements appropriate sampling plans and/or other statistical techniques to verify purchased product per *Section 8.1*.

All requirements for approval of purchased product and/or supplier procedures, processes, equipment, personnel, and/or quality systems are reviewed for adequacy prior to communication to the supplier per *Section 7.4.2*.

As applicable, the Operations and Technical Director documents and communicates the intended verification arrangements and method of product release related to verification activities performed at our suppliers' premises.

7.5 **Production and service provision (Excluded)**

7.5.1 Control of production and service provision

We do not carry out any manufacturing ourselves but rely on our approved sub suppliers for all manufacturing. It is the responsibility of the Operations and Technical Director to ensure that the products bought for supply to our customers meets the exacting demands as expressed in our purchasing procedures.

7.5.1.a Information. The Operations and Technical Director, through communication with the sub suppliers, ensures that all appropriate information including final product/service specifications, raw material characteristics and the required product parameters, is provided to production personnel throughout the product/service provision process.

7.5.1.b Work Instructions. (Excluded)

7.5.1.c Equipment. (Excluded)

7.5.1.d Monitoring and Measurement Devices. (Excluded)

7.5.1.e Release, Delivery, and Post-Delivery Processes. Release of product is dependent on its compliance with all technical specifications and its ability to meet additional customer requirements including packaging, shipping, and delivery, as identified in the contract or order. The Managing Director, through the Executive Assistant, and the Operations and Technical Director, ensures that records of product approval are maintained and clearly indicate the supplier; *Section 7.5.3.1*.

The Managing Director periodically reviews operational data as well as progress towards achievement of corporate level product/service performance objectives (*Section 5.4.1.1*) and provides related recommendations for review by Top Management; *Section 5.6.1*.

7.5.2. Validation of processes for production and service provision

We define processes in which results cannot be verified by subsequent monitoring or measurement as “Special Processes”; this includes any processes where deficiencies may become apparent only after the product is in use or the service has been delivered. The Operations and Technical Director has overall responsibility for ensuring ‘Special Processes” are validated in accordance with procedures. As applicable, arrangements are established for: defining criteria for review and approval of the processes; approval of equipment and qualification of personnel; use of specific methods and procedures; requirements for records; and revalidation.

7.5.3 Identification and traceability

The Operations and Technical Director has overall responsibility for establishing and maintaining product identification throughout all stages of design, production, installation and delivery in accordance with procedures. Where product traceability is a customer-specified requirement, appropriate controls and records are established and maintained.

We establish and maintain product monitoring and measurement status through the use of both physical identification tags/labels and electronic records. Additionally, physical location in clearly designated hold area is an indicator of product status; however, physical location in production process areas may serve as an indicator of product status only where product identification and inspection status is inherently obvious, e.g. in the automated production transfer process. The Managing Director, through the Operations and Technical Director, ensures that all incoming, in-process, and final product is suitably identified and the current status is appropriately tracked and displayed.

Where contractually required, the Operations and Technical Director plans for, establishes and maintains appropriate traceability records in accordance with customer requirements; *Section 7.1*.

7.5.4 Customer property

Customer property includes customer-owned material, tools (including returnable packaging), tooling (including test/inspection tooling and equipment), and intellectual property. We identify, verify, protect and maintain customer property provided for use or incorporation into the product, by applying the same process controls as we do to purchased product (*Section 7.4*).

Whenever customer-specified requirements for property management are beyond the control or capability of our established QMS, the Operations and Technical Director has overall responsibility for planning, documenting and communicating such requirements to all appropriate personnel as a part of product quality planning; *Section 7.1*.

The Operations and Technical Director ensures that lost, damaged or unsuitable customer property is recorded and immediately reported to the customer; *Section 8.3.3*.

7.5.5 Preservation of product

The Managing Director, through the Operations and Technical Director, and the Executive Assistant, has overall responsibility for establishing and implementing a material management system to ensure product conformity is preserved during internal processing and delivery to the intended destination. This system, includes the handling, storage, packaging, delivery, and protection of final product as well as raw materials and in-process constituents of the final product, to ensure:

- Components and products are handled and stored in a manner that prevents damage or deterioration pending use or delivery.
- Each department ensures controls are implemented to prevent mixing conforming and non-conforming materials.
- Packing ensures specified or original manufacturing packaging is utilized.
- All components and products are suitably packed to prevent deterioration or damage during storage and delivery.

In order to detect deterioration, the condition of stock is periodically assessed. Further, obsolete product (including expired age dated material, e.g.), and unidentified or suspect stock is controlled as nonconforming product; *Section 8.3.1*.

7.5.6 Invoice and Delivery

This is the responsibility of the Executive Assistant to prepare and send the appropriate documentation to the customer at the time of delivery according to the purchase order terms and conditions. *OP 7.5.6*

7.6 Control of monitoring and measuring equipment (Excluded)

This is the responsibility of the manufacturing sub supplier and is controlled through their own QMS and is checked and audited during our normal sub supplier evaluation procedure.

8. Measurement, Analysis and Improvement

8.1 General

This section describes how we define, plan, and implement the monitoring, measurement, analysis and improvement activities needed to assure product and QMS conformity and achieve continual QMS improvement. These activities include assessment of customer satisfaction, conduct of internal audits, process monitoring and measurement, and product monitoring and measurement.

The Managing Director ensures that statistical tools used to monitor QMS processes are identified during quality planning and included in control plans, as applicable; *Section 7.1*. Statistical techniques for on-going process control and improvement are established per *OP 8.1* and applicable customer specific requirements documents.

Employees utilizing statistical tools to manage, verify or perform work will attend an overview on basic concepts to ensure they are understood and properly utilized throughout the organization; see *Section 6.2.2*.

8.2 Monitoring and measurement

8.2.1 Customer Satisfaction

Customers are the reason we exist and drive our quality policy “to meet or exceed customer requirements.” The Managing Director has overall responsibility for identifying and reviewing customer requirements (see *Section 7.2.1* and *Section 7.2.2)* and for monitoring and measuring customer satisfaction per procedures contained in *OP 8.2*, summarized as follows:

Data collected by customer contact personnel during routine communications (*Section 7.2.3*)

provide our primary basis for assessing customer satisfaction and is documented and advised to management via the Management Action Request (MAR) Form (*Doc 369-2*).
Customer complaints (whether received in writing, verbally or electronically through our web site customer contact form) are immediately forwarded to the Managing Director for action. The complaint is transferred to the appropriate person or function for resolution. Customer complaints are documented and monitored through resolution through our continual improvement system; *Section 8.5*.

Customer survey data along with other customer feedback (including written or verbal complaints and information collected from our web site's customer feedback form) is reviewed to initiate any improvement or corrective/preventive actions needed; *Section 8.5*.

The Managing Director periodically reviews customer satisfaction survey data and other customer feedback (including complaints), as well as progress towards achievement of corporate level customer satisfaction improvement objectives (*Section 5.4.1*) and provides related recommendations for review by Top Management; *Section 5.6*.

8.2.2 Internal audit

Internal audit results are critical inputs to aid in assessing the effectiveness of our QMS, in identifying opportunities for improvement, and in promoting awareness of customer requirements and effectiveness of the QMS to our workforce.

We conduct QMS audits to determine conformity to *ISO 9001:2008* and any additional QMS requirements that may apply (*ISO 14001:2004*, for example). Our overall measure of QMS effectiveness is the absence of repeat problems/findings, as an indicator that our QMS was effective in eliminating the cause of such problems.

Internal audits are conducted in accordance with a published schedule that identifies the audit scope and frequency. Each of our key QMS processes, with a special emphasis on our 'core' customer oriented processes (*COP 4.1*) and our unique product realization processes (Section 8.2.3.1), is reviewed to determine effectiveness. The schedule is updated on the basis of status and importance of the activity to be audited and previous audit results.

The QMS process, function or quality system element under review is effective if it is achieving the desired results or established objectives; *Section 5.4.1.* In addition, employee involvement in identifying process effectiveness or efficiency improvements is actively sought during internal audits. Internal audit results are used to determine the scope, nature and frequency of future internal audits of processes, products, functions or quality system elements where ineffectiveness or inefficiency is most likely to be found.

The Managing Director has overall responsibility for managing the internal audit process as summarized below and is documented in *OP 8.2.2*

Audits are carried out by qualified personnel (*Section 6.2.2*) who do not have direct responsibility for the activity being audited. Auditors record audit results and submit findings to management personnel with responsibility for the process, function or quality system element audited.

Management responsible for the area audited implement timely corrective action to eliminate detected non-conformances and their causes, and initiate other appropriate action in response to opportunities for improvement identified by process participants or managers. Follow-ups are conducted to verify timely and effective implementation of the proposed action.

The Managing Director maintains all internal audit records, including internal auditor training records, results of internal audits and related follow-ups; periodically reviews internal audit results as well as progress towards achievement of corporate level objectives aimed at improving overall QMS effectiveness (*Section 5.4.1*); and provides related recommendations for review by Top Management; *Section 5.6*.

8.2.3 Monitoring and measurement of processes

We apply suitable methods for monitoring and measuring all QMS processes. QMS processes are documented measured, controlled and evaluated to ensure they are effective (i.e. achieve desired results) and to identify opportunities for improvement. At a minimum, managers with overall responsibility for carrying out a QMS process, analyzes process performance (*Section 8.4*) and takes appropriate improvement, corrective or preventive action (*Section 8.5*).

We conduct process oriented internal audits (*Section 8.2.2*) to verify QMS process conformance and identify opportunities for improvement.

8.2.4 Monitoring and measurement of product (Excluded)

We do not carry out any manufacturing ourselves but rely on our approved sub suppliers for all manufacturing. It is the responsibility of the Operations and Technical Director to ensure that the products bought for supply to our customers meets the exacting demands as expressed in our purchasing procedures.

8.3 Control of nonconforming product (Excluded)

We do not carry out any manufacturing ourselves but rely on our approved sub suppliers for all manufacturing. It is the responsibility of the Operations and Technical Director to ensure that the products bought for supply to our customers meets the exacting demands as expressed in our purchasing procedures.

8.4 Analysis of data

Top Management and other officers, managers and supervisors collect and analyze data using appropriate statistical techniques (*Section 8.1*) to determine the suitability and effectiveness of key QMS processes applicable to their area(s) of responsibility and to identify opportunities for improvement. At a minimum, data is analyzed to assess achievement of the corporate level quality objectives (*Section 5.4.1*).

A process is effective if desired results are achieved. Effectiveness can be measured in terms of product quality, process accuracy, delivery/schedule performance, cost/budget performance, employee/function performance against established objectives, and/or customer satisfaction.

A process is efficient when resource utilization is optimal. Efficiency can be measured in terms of total resource utilization, productivity indicators, and or the cost of poor quality (such as waste/rework costs or hours).

We also conduct an annual self-assessment against the criteria established in Annex A of *ISO 9004:2000*. On an annual basis the Managing Director, with input from Top Management and other key personnel, performs a self-assessment against these criteria, and uses the results, to identify current strengths and weaknesses, and to identify opportunities for improvement, and provide related recommendation to Top Management through our management review process (*Section 5.6.1*).

8.5 Improvement

8.5.1 Continual improvement

At Carter Process Control GmbH, the continual improvement process begins with the establishment of our quality policy (*Section 5.3*) and objectives for improvement (*Section 5.4.1*), based on objectives contained in our Business Plan and customer targets/goals. Customer satisfaction, internal audit, process and product performance data, and the cost of poor quality are then compared to progress against objectives to identify additional opportunities for improvement; *Section 8.4*. Appropriate improvement initiates are established, supported and monitored for achievement through the use of a Management Action Request (MAR) (*Doc 369-2)* and our management review process (*Section 5.6*). We also consider corrective and preventive actions a vital part of our continual improvement program. Corrective actions are initiated when desired results are not achieved and preventive actions are initiated to prevent the occurrence of problems or to implement other improvement actions. Management Action Requests (MARs), are used to document improvement, corrective and preventive actions; all management actions are prioritized and implemented on the basis of data analysis (*Section 8.4*): the impact of failures/problems is used to prioritize needed corrective actions; risks are evaluated to identify and prioritize needed preventive actions; and cost/benefit analyses are performed to identify and prioritize needed improvement actions.

The overall effectiveness of continual improvement program (including corrective and preventive actions taken as well as the overall progress towards achieving corporate level improvement objectives) is assessed through our management review process (*Section 5.6*).

Essentially, such actions are effective if the problems corrected do not reoccur, potential problems identified do not occur, and other improvement actions accomplish the desired results or objectives. Inputs to the management review process are used to establish new/changed improvement objectives and to initiate/prioritize additional improvement actions; *Section 5.6*.

The Managing Director has overall responsibility for establishing and implementing an effective continual improvement system which includes improvement actions, as outlined in *Section 8.5.1* above, and corrective and preventive actions as outlined in *Section 8.5.2* and *Section 8.5.3* following.:

8.5.2 Corrective action

The Managing Director has overall responsibility for managing our corrective action process defined and summarized below:

Evidence of nonconforming product, customer dissatisfaction, or ineffective processes is used to drive our corrective action system because a problem exists requiring immediate correction and possible additional action aimed at eliminating or reducing the likelihood of its recurrence. Management with responsibility and authority for corrective action are notified promptly of product or process non-conformities. Investigating and eliminating the root cause of these failures is a critical part of our continual improvement process.

Follow-ups are conducted (through the internal audit process; *Section 8.2.2)* to ensure that effective corrective action is taken appropriate to the impact of the problem encountered. In addition, the Managing Director summarizes and analyzes corrective action data to identify trends needed to assess overall effectiveness of the corrective action system and to develop related recommendations for improvement. The corrective action system is considered effective if specific problems are corrected and data indicates that the same or similar problems have not recurred. Results of this analysis and related recommendations are presented to Top Management for review and action during management reviews; *Section 5.6*.

8.5.3 Preventive action

The Managing Director has overall responsibility for managing our preventive action process defined and summarized below:

Data from internal audits, customer feedback, employee suggestions, and other appropriate data is collected and analyzed (*Section 8.4*) to identify the actions needed to eliminate the causes of potential problems and thereby prevent their occurrence. Investigating and eliminating the root cause of potential failures is a critical part of our continual improvement process. We review and initiate preventive actions through our preventive action process.

We apply controls and follow-up to ensure that effective preventive action is taken appropriate to the risk and impact of potential problems and losses. In addition, the Managing Director summarizes and analyzes preventive action data to identify trends needed to assess overall effectiveness of the preventive action system and to develop related recommendations for improvement. The preventive action system is considered effective if potential losses were avoided. Results of this analysis and related recommendations are presented to Top Management for review and action during management reviews; *Section 5.6*.

Appendix A

List of Key Internal QMS Documents Referenced in this Manual

(master lists for these and other QMS Documents are defined in *OP 4.2.3*)

Document No.	**Title**
QM	*Quality Manual*
OP 4.2.3	*Control of Documents*
OP 4.2.4	*Control of Records*
OP 5.5.3	*Internal Communication*
OP 5.6	*Management Review*
OP 6.2	*Competence, Training and Awareness*
OP 7.2	*Enquiry Procedure*
OP 7.2.1	*Order review, purchasing and Acknowledgement*
OP 7.3	*Design and Development*
OP 7.4.1	*Supplier Evaluation*
OP 7.5.6	*Invoice and Delivery*
OP 8.1	*Measurement, Analysis and improvement*
OP 8.2	*Customer Satisfaction*
OP 8.2.2	*Internal Audit*
Doc 369-1	*Carter Process Control GmbH Organization Chart*
Doc 369-2	*Management Action Request (MAR)*
Doc 369-3	*Internal Trainings*
Doc 369-4	*Training Record*
Doc 369-5	*Job Description*
Doc 369-6	*Internal Audit Report*
Doc 369-7	*Document Check Sheet*
Doc 369-8	*Lieferantenbewertung*

Appendix B

Terms and Definitions

Acronyms:

QMS – Quality Management System
OP – Standard Operating Procedure

Terms and Definitions. Terms and definitions contained *ISO 9000:2005*; contact the Quality Manager to obtain or view copies of this document. Terms and definitions contained in this manual and unique to our organization or business are listed below; when there is a difference, the definitions given in *ISO 9000:2005* apply. Customer definitions will take precedence over all other definitions.