



# **ACTCO TOOL & MANUFACTURING COMPANY, INC**

## **Quality Assurance Manual**

Revision B

Issued 12-Feb-21

Conforms to ISO 9001:2015

(c) 2020 Actco Tool & Manufacturing Company, Inc.; all rights reserved. This document may contain proprietary information and may only be released to third parties with approval of management. Document is uncontrolled unless otherwise marked; uncontrolled documents are not subject to update notification.

## TABLE OF CONTENTS

0.0	Revision History and Approval .....	3
1.0	Welcome to Actco Tool & Manufacturing Company, Inc. ....	4
2.0	About The Actco Quality Manual.....	4
3.0	Terms and Definitions .....	4
4.0	The Scope and Context of the Actco QMS .....	5
4.1	Determining Our Strategic Direction .....	5
4.2	Scope of the Management System .....	5
4.2.1	Scope Statement.....	5
4.2.2	Facilities Within the Scope .....	6
5.0	Quality Policy.....	6
6.0	Management System Processes .....	6
6.1	Process Identification .....	6
6.2	Process Controls & Objectives.....	7
6.3	Outsourced Processes .....	8
7.0	Documentation & Records .....	8
7.1	General.....	8
7.2	Control of Documents .....	8
7.3	Control of Records .....	8
8.0	Management & Leadership .....	9
8.1	Management Leadership and Commitment.....	9
8.2	Customer Focus.....	9
8.3	Quality Policy.....	10
8.4	Organizational Roles Responsibilities & Authorities .....	10
8.5	Internal Communication .....	10
8.6	Change Management.....	11
8.7	Risks and Opportunities .....	11
8.8	Management Review .....	11
8.9	Quality Objectives and Planning to Achieve Them .....	11
8.10	Planning of Changes .....	12
9.0	Resources .....	12
9.1	Provision of Resources .....	12
9.2	Human Resources .....	12
9.3	Infrastructure .....	12
9.4	Work Environment.....	13
9.5	Monitoring and Measuring Resources .....	13
9.6	Organizational Knowledge .....	13
9.7	Competence .....	13
9.8	Awareness.....	14
9.9	Communication .....	14
9.10	Documented Information.....	14
10.0	Operation.....	15
10.1	Operational Planning and Control .....	15
10.2	Customer Communication.....	15
10.3	Determining the Requirements Related to Products and Services.....	15
10.4	Review of Requirements Related to Products and Services .....	16
10.5	Receiving and Processing of Purchase Orders .....	16
10.6	Changes to Requirements for Products and Services .....	16
10.7	Design and Development.....	17
10.8	Control of Externally Provided Processes, Products & Services, Purchasing.....	17
10.10	Provision of products and services .....	17
10.10.1	Control of Provision of products and services.....	17

10.10.2	Identification and Traceability.....	18
10.10.3	Property Belonging to Third Parties .....	18
10.10.4	Preservation .....	18
10.10.5	Post-Delivery Activities.....	18
10.10.6	Process Change Control .....	19
10.11	Measurement and Release of products and services.....	19
10.12	Control of Nonconforming Outputs.....	19
11.0	Performance Evaluation .....	19
11.1	Monitoring, Measurement, Analysis and Evaluation .....	19
11.1.1	General.....	19
11.1.2	Customer Satisfaction .....	19
11.1.3	Analysis and Evaluation .....	20
11.1.4	Internal Audit .....	20
11.1.5	Management Review .....	20
12.0	Improvement .....	20
12.1	General.....	20
12.2	Corrective and Preventive Action.....	21
12.3	Continual Improvement .....	21
Appendix A:	Overall Process Sequence & Interaction .....	22
Appendix B:	ISO 9001:2015 Cross Reference .....	23

## 0.0 Revision History and Approval

Rev.	Nature of changes	Approval	Date
A	Original release.	Tara Heffern	1-Jan-21
B	Section 10.3 (e) Location of Standards/Specifications/Quality Clauses Section 10.4 Review of Requirements for Products and Services Section 10.4 (f) Quote Processing Work Instruction <b>Checklist</b>	Tara Heffern	12-Feb-21

## 1.0 Welcome to Actco Tool & Manufacturing Company, Inc.

Established in 1966 Actco Tool & Mfg Co provides computer numerical control (CNC) machining services to a wide variety of industries including; Aerospace, Automotive, Medical, Green Energy, Farming, Construction & Recreational Vehicles. We are a 3<sup>rd</sup> generation family owned business and continually improve our internal processes to provide our partners and clients with the highest quality of products.



## 2.0 About The Actco Quality Manual

This manual is prepared for the purpose of defining the company's interpretations of the ISO 9001:2015 international standard, as well as to demonstrate how the company conforms to that standard.

This manual is not aligned with the clause numbering scheme of ISO 9001; instead, Appendix B provides a cross-reference table that shows where, in the manual, each ISO 9001 requirement is addressed.

This manual presents "Notes" which are used to define how Actco has tailored its management system to suit its purposes. These are intended to clarify implementation approaches and interpretations for concepts which are not otherwise clearly defined in ISO 9001:2015. *Notes appear in italics, with gray background.*

Where subordinate or supporting documentation is reference in this manual, these are indicated by **bold italics**.

## 3.0 Terms and Definitions

Actco adopts the following terms and definitions within its Quality Management System. Where no definition is provided, the company typically adopts the definitions provided in **ISO 9000: Quality Management – Fundamentals and Vocabulary**. In some cases, specific procedures or documentation may provide a different definition to be used in the context of that document; in such cases, the definition will supersede those provided for in this Quality Manual or ISO 9000.

### General Terminology

**Actco** – Actco Tool & Manufacturing Company, Inc.

**Actco Tool & Mfg Co** – Actco Tool & Manufacturing Company, Inc.

**Document** – written information used to describe how an activity is done.

**Record** – captured evidence of an activity having been done.

### **Risk-Based Thinking Terminology**

**Risk** – Negative effect of uncertainty

**Opportunity** – Positive effect of uncertainty

**Uncertainty** - A deficiency of information related to understanding or knowledge of an event, its consequence, or likelihood. (Not to be confused with measurement uncertainty.)

### **Nonconforming Product Terminology**

**Rework:** Efforts to bring nonconforming product into conformance through additional operations that *do not* alter the original design of the product.

**Repair:** Efforts to bring nonconforming product into conformance through additional operations that alter the original design of the product; this may be through the addition of material not specified in the original design, or through altering pre-existing design features.

**Scrap:** The discard of nonconforming product in lieu of rework or repair.

## **4.0 The Scope and Context of the Actco QMS**

### **4.1 Determining Our Strategic Direction**

Actco has reviewed and analyzed key aspects of itself and its stakeholders to determine the strategic direction of the company. This involves:

- Understanding our core products and services, and scope of management system (see 4.2 below).
- Identifying “interested parties” (stakeholders) who receive our products and services, or who may be impacted by them, or those parties who may otherwise have a significant interest in our company. These parties are identified in the document **Context of the Organization**.
- Understanding internal and external issues that are of concern to Actco and its interested parties; also identified in the document **Context of the Organization**. Many such issues are identified through an analysis of risks facing either Actco or the interested parties. Such issues are monitored and updated as appropriate, and discussed as part of management reviews.

This information is then used by senior management to determine the company’s strategic direction. This is defined in records of management review, and periodically updated as conditions and situations change.

### **4.2 Scope of the Management System**

#### **4.2.1 Scope Statement**


Based on an analysis of the above issues of concern, interests of stakeholders, and in consideration of its products and services, Actco has determined the scope of the management system as follows:

Actco Tool & Mfg Co is a manufacturer for the aerospace, automotive, Medical, Green Energy, Farming, Construction & Recreational Vehicle industries. Actco Tool & Mfg Co conforms to the ISO

9001:2015 standard as well as with all customer requirements flowed down on purchase orders or other such customer documents.

#### 4.2.2 Facilities Within the Scope

The quality system applies to all processes, activities and employees within the company. The facility is located at:

<p>11421 Baldwin St. Ext. Meadville PA 16335-0675 Phone: (814) 336-4235 Fax: (814) 337-0101 Web: <a href="https://www.actcotool.com">https://www.actcotool.com</a></p>	
--	--

## 5.0 Quality Policy

The Quality Policy of Actco is as follows:

### Customer Satisfaction, Continuous Improvement, & Committed to Excellence

We at Actco Tool & Mfg Co working as a team, will provide solutions to our customers' needs in the most expedient manner. Our company will maintain the highest standards of continuous improvement and efficient streamlining of our methods and facility. We are committed to providing the highest quality products at a fair and honest price, delivered on-time.

## 6.0 Management System Processes

### 6.1 Process Identification

Actco has adopted a process approach for its management system. By identifying the top-level processes within the company, and then managing each of these discretely, this reduces the potential for nonconforming products and services discovered during final processes or after delivery. Instead, nonconformities and risks are identified in real time, by actions taken within each of the top-level processes.

*Note: not all activities are considered "processes" – the term "process" in this context indicates the activity has been elevated to a higher level of control and management oversight. The controls indicated herein are applicable only to the top-level processes identified.*

The following top-level processes have been identified for Actco:

- Calibration of Equipment
- Change Management
- Context of the Organization
- Control of Documents
- Control of Records
- Control of Third-Party Property
- Corrective and Preventive Action
- Design Control
- Hiring and Training
- Identification and Traceability
- Management Review
- Nonconforming Product
- Order Processing
- Organizational Chart
- Outsourced Process
- Preservation of Product
- Preventive Maintenance
- Process Definition *Template*
- Purchasing
- Quality Policy
- Quoting Process Work Instruction / *Checklist*
- Receiving
- Risk and Opportunity Management
- Validation of Equipment

Each process may be supported by other activities, such as tasks or sub-processes. Monitoring and control of top level processes ensures effective implementation and control of all subordinate tasks or sub-processes.

Each top-level process has a **Process Definition** document which defines:

- applicable inputs and outputs
- process owner(s)
- applicable responsibilities and authorities
- applicable risks and opportunities
- critical and supporting resources
- criteria and methods employed to ensure the effectiveness of the process

The sequence of interaction of these processes is illustrated in Appendix A.

*Note: Appendix A represents the typical sequence of processes, and may be altered depending on customer or regulatory requirements at the job or contract level, as needed.*

## 6.2 Process Controls & Objectives

Each process has at least one objective established for it; this is a statement of the intent of the process. Each objective is then supported by at least one “metric” or key performance indicator (KPI) which is then measured to determine the process’ ability to meet the quality objective.

*Note: some processes have multiple objectives and multiple metrics. This is determined by the nature of the process, it’s impact on products and services, and associated risks.*

*Note: Whereas ISO 9001 discusses process measurements and “quality objectives” as separate concepts, Actco combines them; i.e., quality objectives are used to control the processes. Additional objectives for products and services may be assigned, but these will also be used to measure process effectiveness.*

Throughout the year, metrics data is measured and gathered by process owners or other assigned managers, in order to present the data to Senior Management Team. The data is then analyzed by Senior Management Team in order that Senior Management Team may set goals and make adjustments for the purposes of long-term continual improvement.

The specific quality objectives for each process are defined in the minutes of Management Review, per section 8.8.



Metrics, along with current standings and goals for each objective, are recorded in records of management review.

When a process does not meet a goal, or an unexpected problem is encountered with a process, the corrective and preventive action process is implemented to research and resolve the issue. In addition, opportunities for improvement are sought and implemented, for the identified processes.

### 6.3 Outsourced Processes

Any process performed by a third party is considered an “outsourced process” and must be controlled, as well. The company’s outsourced processes, and the control methods implemented for each, are defined in **Outsourced Processes**.

The type and extent of control to be applied to the outsourced process take into consideration:

- a) the potential impact of the outsourced process on the company’s capability to provide product that conforms to requirements,
- b) the degree to which the control for the process is shared,
- c) the capability of achieving the necessary control through the purchasing contract requirements.

## 7.0 Documentation & Records

### 7.1 General

The management system documentation includes both documents and records.

*Note: the ISO 9001:2015 standard uses the term “documented information”; Actco does not use this term, but instead relies on the terms “document” and “record” to avoid confusion. In this context the terms are defined per section 3.0 above. Documents and records undergo different controls as defined herein.*

The extent of the management system documentation has been developed based on the following:

- a) The size of Actco
- b) Complexity and interaction of the processes
- c) Risks and opportunities
- d) Competence of personnel

### 7.2 Control of Documents

Documents required for the management system are controlled in accordance with procedure **Control of Documents**. The purpose of document control is to ensure that staff have access to the latest, approved information, and to restrict the use of obsolete information.

All documented procedures are established, documented, implemented and maintained.

### 7.3 Control of Records

A documented procedure **Control of Records** has been established to define the controls needed for the identification, storage, retrieval, protection, retention time, and disposition of quality records. This procedure also defines the methods for controlling records that are created by and/or retained by suppliers.

These controls are applicable to those records which provide evidence of conformance to requirements; this may be evidence of product and service requirements, contractual requirements, procedural

requirements, or statutory/regulatory compliance. In addition, quality records include any records which provide evidence of the effective operation of the management system.

## 8.0 Management & Leadership

### 8.1 Management Leadership and Commitment

Senior Management Team of Actco provides evidence of its leadership and commitment to the development and implementation of the management system and continually improving its effectiveness by:

- a) taking accountability of the effectiveness of the management system;
- b) ensuring that the **Quality Policy** and quality objectives are established for the management system and are compatible with the strategic direction and the context of the organization;
- c) ensuring that the quality policy is communicated, understood and applied within the organization;
- d) ensuring the integration of the management system requirements into the organization's other business processes, as deemed appropriate (see note);
- e) promoting awareness of the process approach;
- f) ensuring that the resources needed for the management system are available;
- g) communicating the importance of effective quality management and of conforming to the management system requirements;
- h) ensuring that the management system achieves its intended results;
- i) engaging, directing and supporting persons to contribute to the effectiveness of the management system;
- j) promoting continual improvement;
- k) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

*Note: "business processes" such as accounting, employee benefits management and legal activities are out of scope of the QMS.*

### 8.2 Customer Focus

Senior Management Team of Actco adopts a customer-first approach which ensures that customer needs and expectations are determined, converted into requirements and are met with the aim of enhancing customer satisfaction.

This is accomplished by assuring:

- a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met;
- b) the risks and opportunities that can affect conformity of product and service and the ability to enhance customer satisfaction are determined and addressed;
- c) the focus on enhancing customer satisfaction is maintained.

### 8.3 Quality Policy

Senior Management Team has developed the **Quality Policy**, defined in section 5.0 above, that governs day-to-day operations to ensure quality.

The **Quality Policy** is released as a standalone document as well, and is communicated and implemented throughout the organization.

### 8.4 Organizational Roles Responsibilities & Authorities

Senior Management Team has assigned responsibilities and authorities for all relevant roles in the company. These are communicated through the combination of the **Organizational Chart** and Position Descriptions.

The Senior Management Team accepts responsibility and authority for:

- a) ensuring that the management system conforms to applicable standards;
- b) ensuring that the processes are delivering their intended outputs;
- c) reporting on the performance of the management system;
- d) providing opportunities for improvement for the management system;
- e) ensuring the promotion of customer focus throughout the organization;
- f) ensuring that the integrity of the management system is maintained when changes are planned and implemented.

The VP has been assigned the role of QMS Management Representative when having a single point of contact to represent the Actco quality system is useful or required by customer or regulations. Other duties of the QMS Management Representative may be defined herein or within other documented procedures.

### 8.5 Internal Communication

Senior Management Team of Actco ensures internal communication takes place regarding the effectiveness of the management system. Internal communication methods include:

- a) use of corrective and preventive action processes to report nonconformities or suggestions for improvement
- b) use of the results of analysis of data
- c) meetings (periodic, scheduled and/or unscheduled) to discuss aspects of the QMS
- d) use of the results of the internal audit process
- e) regular company meetings with all employees
- f) internal emails
- g) memos to employees
- h) Actco's "open door" policy which allows any employee access to Senior Management Team for discussions on improving the quality system

## 8.6 Change Management

When Actco determines the need for changes to the management system or its processes, these changes planned, implemented, and then verified for effectiveness; see the document **Change Management**.

Documents are changed in accordance with procedure **Control of Documents**.

## 8.7 Risks and Opportunities

*Note: Actco deviates slightly from the approach towards risk and opportunity presented in ISO 9001. Instead, Actco views "uncertainty" as neutral, but defines "risk" as a negative effect of uncertainty, and "opportunity" as a positive effect of uncertainty. Actco has elected to manage risks and opportunities separately, except where they may overlap. Formal risk management may not be utilized in all instances; instead, the level of risk assessment, analysis, treatment and recordkeeping will be performed to the level deemed appropriate for each circumstance or application.*

Actco considers risks and opportunities when taking actions within the management system, as well as when implementing or improving the management system; likewise, these are considered relative to products and services. Risks and opportunities are identified as part of the "Context of the Organization Exercise" defined in **Context of the Organization**, as well as throughout all other activities of the QMS.

Risks and opportunities are managed in accordance with the document **Risk and Opportunity Management**. This procedure defines how risks are managed in order to minimize their likelihood and impact, and how opportunities are managed to improve their likelihood and benefit.

## 8.8 Management Review

The Senior Management Team reviews the management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. The review includes assessing opportunities for improvement, and the need for changes to the management system, including the **Quality Policy** and quality objectives.

Management review frequency, agenda (inputs), outputs, required members, actions taken and other review requirements are defined in the documented procedure **Management Review**.

Records from management reviews are maintained.

## 8.9 Quality Objectives and Planning to Achieve Them

As part of the adoption of the process approach, Actco utilizes its process objectives, as discussed in 6.0 above, as the main quality objectives for the QMS. These include overall product-related quality objectives; additional product-related quality objectives may be defined in work instructions or customer requirements.

The process objectives have been developed in consideration that they:

- a) be consistent with the quality policy;
- b) be measurable;
- c) take into account applicable requirements;
- d) be relevant to conformity of products and services and to enhancement of customer satisfaction;
- e) be monitored;
- f) be communicated;
- g) be updated as appropriate.

Process quality objectives are defined in the minutes of management review per section 8.8 above.  
The planning of process quality objectives is defined in section 6.0 above.

### **8.10 Planning of Changes**

Changes to the quality management system and its processes are carried out in a planned manner per the procedure ***Change Management***.

## **9.0 Resources**

### **9.1 Provision of Resources**

Actco determines and provides the resources needed:

- a) to implement and maintain the management system and continually improve its effectiveness
- b) to enhance customer satisfaction by meeting customer requirements

Resource allocation is done with consideration of the capability and constraints on existing internal resources, as well as needs related to supplier expectations.

Resources and resource allocation are assessed during management reviews.

### **9.2 Human Resources**

Senior management ensures that it provides sufficient staffing for the effective operation of the management system, as well its identified processes.

Staff members performing work affecting product quality are competent on the basis of appropriate education, training, skills and experience. The documented procedure ***Hiring and Training*** defines these activities in detail.

Training and subsequent communication ensure that staff are aware of:

- a) the quality policy;
- b) relevant quality objectives;
- c) their contribution to the effectiveness of the management system, including the benefits of improved performance;
- d) the implications of not conforming with the management system requirements.

*Note: the management system does not include other aspects of Human Resources management, such as payroll, benefits, insurance, labor relations or disciplinary actions.*

### **9.3 Infrastructure**

Actco determines, provides and maintains the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable:

- a) buildings, workspace and associated facilities;
- b) process equipment, hardware and software;
- c) supporting services such as transport;
- d) information and communication technology.

Equipment is validated per the procedure **Validation of Equipment** and maintained per the procedure **Preventive Maintenance**.

Where equipment is used for critical measurement activities, such as inspection and testing, these shall be subject to control and either calibration or verification; see the procedure **Calibration of Equipment**.

*Note: Calibration and measurement traceability is not employed for all measurement devices. Instead, Actco determines which devices will be subject to calibration based on its processes, products and services, or in order to comply with specifications or requirements. These decisions are also based on the importance of a measurement, and considerations of risk.*

#### 9.4 Work Environment

Actco provides a clean, safe and well-lit working environment. The Senior Management Team of Actco manages the work environment needed to achieve conformity to product requirements. Specific environmental requirements for products are determined during quality planning and are documented in subordinate procedures, work instructions, or job documentation. Where special work environments have been implemented, these shall also be maintained per 9.3 above.

Human factors are considered to the extent that they directly impact on the quality of products and services.

*Note: Social, psychological and safety aspects of the work environment are managed through activities outside of the scope of the management system. Only work environment aspects which can directly affect process efficiency or product and service quality are managed through the management system.*

#### 9.5 Monitoring and Measuring Resources

Where equipment is used for critical measurement activities, such as inspection and testing, these shall be subject to control and either calibration or verification; see the procedure **Calibration of Equipment**.

*Note: Calibration and measurement traceability is not employed for all measurement devices. Instead, Actco determines which devices will be subject to calibration based on its processes, products and services, or in order to comply with specifications or requirements. These decisions are also based on the importance of a measurement, and considerations of risk.*

#### 9.6 Organizational Knowledge

Actco also determines the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This may include knowledge and information obtained from:

- a) internal sources, such as lessons learned, feedback from subject matter experts, and/or intellectual property;
- b) external sources such as standards, academia, conferences, and/or information gathered from customers or suppliers.

This knowledge shall be maintained, and made available to the extent necessary.

When addressing changing needs and trends, Actco shall consider its current knowledge and determine how to acquire or access the necessary additional knowledge.

#### 9.7 Competence

Staff members performing work affecting product quality are competent on the basis of appropriate education, training, skills and experience. The documented procedure **Hiring and Training** defines these activities in detail.

*Note: the management system does not include other aspects of Human Resources management, such as payroll, benefits, insurance, labor relations or disciplinary actions.*

## 9.8 Awareness

Training and subsequent communication ensure that staff are aware of:

- e) the quality policy;
- f) relevant quality objectives;
- g) their contribution to the effectiveness of the management system, including the benefits of improved performance;
- h) the implications of not conforming with the management system requirements.

## 9.9 Communication

The Senior Management Team of Actco ensures internal communication takes place regarding the effectiveness of the management system. Internal communication methods:

- i) use of corrective and preventive action processes to report nonconformities or suggestions for improvement
- j) use of the results of analysis of data
- k) meetings (periodic, scheduled and/or unscheduled) to discuss aspects of the QMS
- l) use of the results of the internal audit process
- m) regular company meetings with all employees
- n) internal emails
- o) memos to employees
- p) Actco's "open door" policy which allows any employee access to Senior Management Team for discussions on improving the quality system

## 9.10 Documented Information

The management system documentation includes both documents and records.

*Note: the ISO 9001:2015 standard uses the term "documented information"; Actco does not use this term, but instead relies on the terms "document" and "record" to avoid confusion. In this context the terms are defined by Actco as provided for in section 3.0 above. Documents and records undergo different controls as defined herein.*

The extent of the management system documentation has been developed based on the following:

- e) The size of Actco
- f) Complexity and interaction of the processes
- g) Risks and opportunities
- h) Competence of personnel

Documents required for the management system are controlled in accordance with procedure **Control of Documents**. The purpose of document control is to ensure that staff have access to the latest, approved information, and to restrict the use of obsolete information. All documented procedures are established, documented, implemented and maintained.

A documented procedure **Control of Records** has been established to define the controls needed for the identification, storage, retrieval, protection, retention time, and disposition of quality records. This

procedure also defines the methods for controlling records that are created by and/or retained by suppliers.

These controls are applicable to those records which provide evidence of conformance to requirements; this may be evidence of product and service requirements, contractual requirements, procedural requirements, or statutory/regulatory compliance. In addition, quality records include any records which provide evidence of the effective operation of the management system.

## **10.0 Operation**

### **10.1 Operational Planning and Control**

Actco plans and develops the processes needed for product and service realization. Planning of product and service realization is consistent with the requirements of the other processes of the management system. Such planning considers the information related to the context of the organization (see section 2.0 above), current resources and capabilities, as well as product and service requirements.

Such planning is accomplished through:

- a) determining the requirements for the products and services ;
- b) establishing criteria for the processes and the acceptance of products and services ;
- c) determining the resources needed to achieve conformity to the product and service requirements;
- d) implementing control of the processes in accordance with the criteria;
- e) determining, maintaining and retaining documented information to the extent necessary to have confidence that the processes have been carried out as planned and to demonstrate the conformity of products and services to their requirements.

Changes to operational processes are done in accordance with the document ***Change Management***.

Outsourced processes and the means by which Actco controls them are defined in the documented procedure ***Outsourced Processes***.

### **10.2 Customer Communication**

Actco has implemented effective communication with customers in relation to:

- a) providing information relating to products and services;
- b) handling inquiries, contracts or orders, including changes;
- c) obtaining customer feedback relating to products and services, including customer complaints;
- d) handling or controlling customer property;
- e) establishing specific requirements for contingency actions, when relevant.

### **10.3 Determining the Requirements Related to Products and Services**

During the intake of new business Actco captures:

- a) requirements specified by the customer, including the requirements for delivery and post-delivery activities;



- b) requirements not stated by the customer but necessary for specified or intended use, where known
- c) statutory and regulatory requirements related to the product and service;
- d) any additional requirements determined by Actco.

Once requirements are captured, Actco reviews the requirements prior to its commitment to supply the product and service. This review ensures that:

- a) product and service requirements are defined,
- b) contract or order requirements differing from those previously expressed are resolved,
- c) the organization has the ability to meet the defined requirements, and/or the claims for the products and services it offers, and
- d) risks have been identified and considered.
- e) Review of applicable Standards/Specifications, Material/Heat Treat Certifications, First Article Inspection information (if applicable), Quality Clauses, Special Notes, and documentation required (to include drawings & Request For Quote). Any exceptions to the drawings should be noted at the time of quote. Location of Standards/Specifications/Quality Clauses; Network/act-srv1/Scans/Jobs/Specs.

These activities are defined in greater detail in the procedures ***Quoting Process Work Instruction and Quoting & Order Acceptance***.

#### **10.4 Review of Requirements Related to Products and Services**

Once requirements are captured, Actco reviews the requirements prior to its commitment to supply the product and service. This review ensures that Actco has the capability and capacity to:

- a) meet all requirements specified by the customer, including requirements for delivery and post-delivery activities;
- b) meet any requirements not stated by the customer, but which Actco knows as being necessary;
- c) meet all requirements determined necessary by Actco itself;
- d) meet all related statutory and regulatory requirements;
- e) meet any contract or order requirements differing from those previously expressed (i.e., from a previous Actco quote).
- f) Usage and completion of the ***Quoting Process Work Instruction Checklist***.

These activities are defined in greater detail in the procedure ***Quoting and Order Acceptance***.

#### **10.5 Receiving and Processing of Purchase Orders**

Actco has established a procedure for consistently and accurately processing orders for products & services, see the documented procedure ***Order Processing***.

#### **10.6 Changes to Requirements for Products and Services**

Actco updates all relevant requirements and documents when the requirements are changed, and ensures that all appropriate staff are notified; see the documented procedure ***Change Management***.

## **10.7 Design and Development**

For new designs and for significant design changes, Actco ensures the translation of customer needs and requirements into detailed design outputs. These address performance, reliability, maintainability, testability, and safety issues, as well as regulatory and statutory requirements.

This process ensures:

- a) Design planning is conducted
- b) Design inputs (requirements) are captured
- c) Design outputs are created under controlled conditions
- d) Design reviews, verification and validation are conducted
- e) Design changes are made in a controlled manner.

These activities are further defined in the document ***Design Control***.

## **10.8 Control of Externally Provided Processes, Products & Services, Purchasing**

Actco ensures that purchased product and service conform to specified purchase requirements. The type and extent of control applied to the supplier and the purchased products or services are dependent on the effect on subsequent product and service realization or the final product.

Actco evaluates and selects suppliers based on their ability to supply products and services in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation are established.

Purchases are made via the release of formal purchase orders and/or contracts which clearly describe what is being purchased. Received products or services are then verified against requirements to ensure satisfaction of requirements. Suppliers who do not providing conforming products or services may be requested to conduct formal corrective action.

These activities are further defined in the documents ***Purchasing*** and ***Receiving***.

## **10.10 Provision of products and services**

### ***10.10.1 Control of Provision of products and services***

To control its provision of products and services, Actco considers, as applicable, the following:

- a) the availability of documents or records that define the characteristics of the products and services as well as the results to be achieved;
- b) the availability and use of suitable monitoring and measuring resources;
- c) the implementation of monitoring and measurement activities;
- d) the use of suitable infrastructure and environment;
- e) the appointment of competent persons, including any required qualifications;
- f) the implementation of actions to prevent human error;
- g) the implementation of release, delivery and post-delivery activities.

At this time, Actco does not utilize any in-house "special processes" where the result of the process cannot be verified by subsequent monitoring or measurement. Any such special processes are sent to

outside suppliers, and controlled and an outsourced process per **Outsourced Processes**.

#### **10.10.2 Identification and Traceability**

Where appropriate, Actco identifies its product and service or other critical process outputs by suitable means. Such identification includes the status of the product and service with respect to monitoring and measurement requirements. Unless otherwise indicated as nonconforming, pending inspection or disposition, or some other similar identifier, all product and service shall be considered conforming and suitable for use.

If unique traceability is required by contract, regulatory, or other established requirement, Actco controls and records the unique identification of the product and service.

The documented procedure **Identification and Traceability** defines these methods in detail.

#### **10.10.3 Property Belonging to Third Parties**

Actco exercises care with customer or supplier property while it is under the organization's control or being used by the organization. Upon receipt, such property is identified, verified, protected and safeguarded. If any such property is lost, damaged or otherwise found to be unsuitable for use, this is reported to the customer or supplier and records maintained.

For customer intellectual property, including customer furnished data used for design, production and / or inspection, this is identified by customer and maintained and preserved to prevent accidental loss, damage or inappropriate use.

This activity is defined in greater detail in the document **Control of Third-Party Property**.

#### **10.10.4 Preservation**

Actco preserves conformity of product or other process outputs during internal processing and delivery. This preservation includes identification, handling, packaging, storage, and protection. Preservation also applies to the constituent parts of a product.

The documented procedure **Preservation of Product** defines the methods for preservation of product.

#### **10.10.5 Post-Delivery Activities**

As applicable, Actco conducts the following activities which are considered "post-delivery activities":

- Provide tracking information to the customer regarding shipment delivery (if applicable).
- Provide customer invoice documentation, electronically.

Post-delivery activities are conducted in compliance with the management system defined herein. In determining the extent of post-delivery activities that are required, Actco considers:

- a) statutory and regulatory requirements;
- b) the potential undesired consequences associated with its of products and services;
- c) the nature, use and intended lifetime of its of products and services;
- d) customer requirements;
- e) customer feedback.

### **10.10.6 Process Change Control**

Actco reviews and controls both planned and unplanned changes to processes to the extent necessary to ensure continuing conformity with all requirements.

Process change management is defined in the document **Change Management**.

Documents are changed in accordance with procedure **Control of Documents**.

### **10.11 Measurement and Release of products and services**

Acceptance criteria for products and services are defined in appropriate subordinate documentation. Reviews, inspections and tests are conducted at appropriate stages to verify that the product and service requirements have been met. This is done before products and services are released or delivered.

Each process utilizes different methods for measuring and releasing products and services. These methods are defined in **Process Definitions**.

### **10.12 Control of Nonconforming Outputs**

Actco ensures that products and services or other process outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

The controls for such nonconformances are defined in the document **Control of Nonconforming Product**.

## **11.0 Performance Evaluation**

### **11.1 Monitoring, Measurement, Analysis and Evaluation**

#### **11.1.1 General**

Actco has determined which aspects of its quality management system must be monitored and measured, as well as the methods to utilize and records to maintain, within this Quality Assurance Manual and subordinate documentation.

Monitoring and measurement of the processes, as defined in 8.8 above, ensure that the Senior Management Team evaluates the performance and effectiveness of the quality management system itself.

#### **11.1.2 Customer Satisfaction**

As one of the measurements of the performance of the management system, Actco monitors information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information include:

- recording customer complaints
- product rejections or returns
- repeat orders for product
- changing volume of orders for product
- trends in on-time delivery

- obtain customer scorecards from certain customers
- submittal of customer satisfaction surveys

The corrective and preventive action system shall be used to develop and implement plans for customer satisfaction improvement that address deficiencies identified by these evaluations, and assess the effectiveness of the results.

### 11.1.3 Analysis and Evaluation

Actco analyzes and evaluates the data and information arising from monitoring and measurement in order to evaluate:

- a) conformity of products and services;
- b) the degree of customer satisfaction;
- c) the performance and effectiveness of the quality management system;
- d) if planning has been implemented effectively;
- e) the effectiveness of actions taken to address risks and opportunities;
- f) the performance of external providers;
- g) the need for improvements to the quality management system.

Statistical techniques used may be defined in appropriate documented procedures; in all cases, the methods are based on established standards or are otherwise determined to be statistically valid.

### 11.1.4 Internal Audit

Actco conducts internal audits at planned intervals to determine whether the management system conforms to contractual and regulatory requirements, to the requirements of ISO 9001, and to management system requirements. Audits also seek to ensure that the management system has been effectively implemented and is maintained.

These activities are defined in the document *Internal Audits*.

### 11.1.5 Management Review

The Senior Management Team reviews the management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. The review includes assessing opportunities for improvement, and the need for changes to the management system, including the *Quality Policy* and quality objectives.

Management review frequency, agenda (inputs), outputs, required members, actions taken and other review requirements are defined in the documented procedure *Management Review*.

Records from management reviews are maintained.

## 12.0 Improvement

### 12.1 General

Actco uses the management system to improve its processes, products and services. Such improvements aim to address the needs and expectations of customers as well as other interested

parties, to the extent possible. Actco has determined which aspects of its quality management system must be monitored and measured, as well as the methods to utilize and records to maintain, within this Quality Assurance Manual and subordinate documentation.

Monitoring and measurement of the processes, as defined in 6.0 above, ensure that the Senior Management Team evaluates the performance and effectiveness of the quality management system itself.

Improvement shall be driven by an analysis of data related to:

The results of analysis shall be used to evaluate:

- a) conformity of products and services;
- b) the degree of customer satisfaction;
- c) the performance and effectiveness of the management system;
- d) the effectiveness of planning;
- e) the effectiveness of actions taken to address risks and opportunities;
- f) the performance of external providers;
- g) other improvements to the management system.

## **12.2 Corrective and Preventive Action**

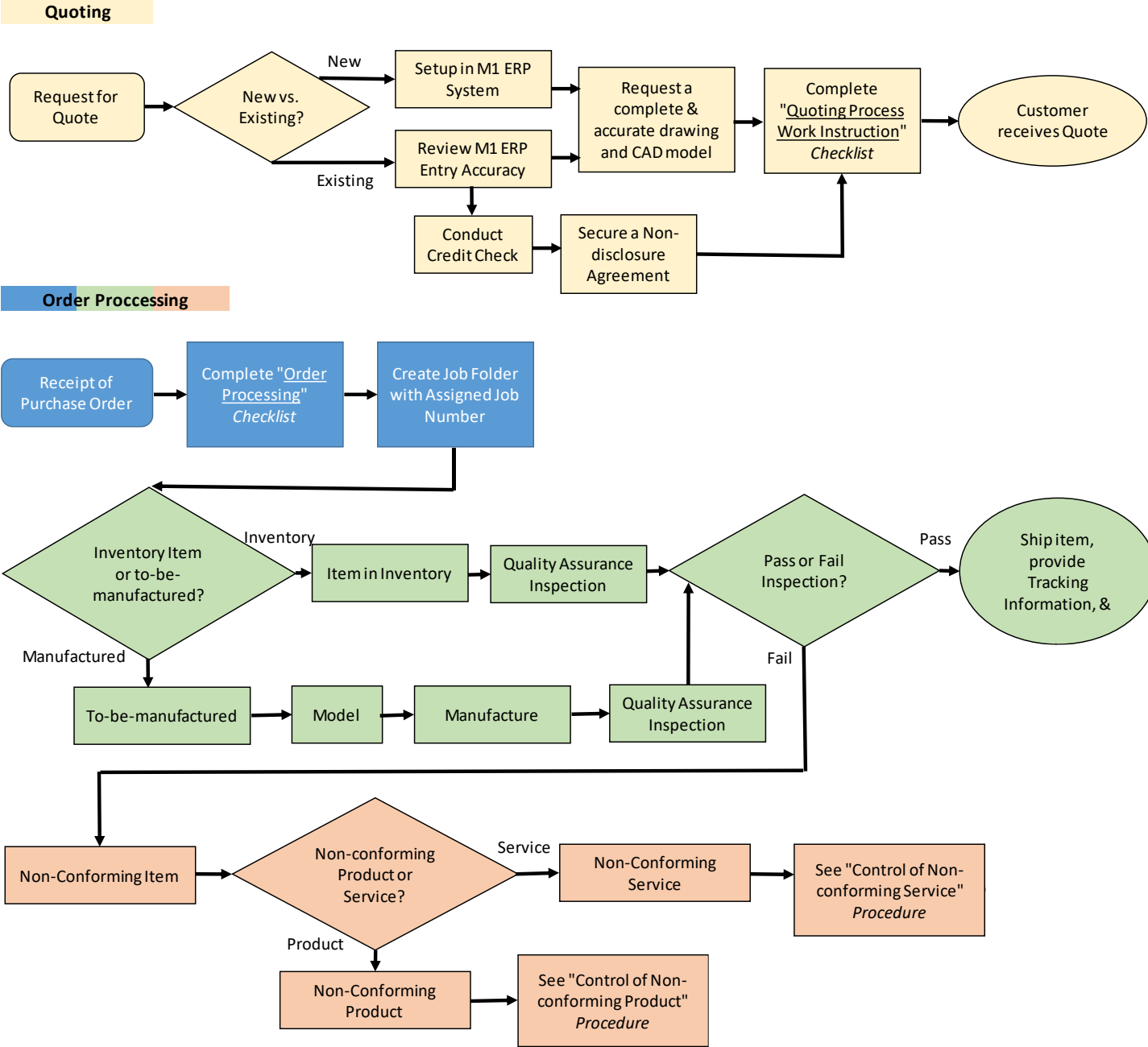
Actco takes corrective action to eliminate the cause of nonconformity in order to prevent *recurrence*. Likewise, the company takes preventive action to eliminate the causes of potential nonconformities in order to prevent their *occurrence*.

These activities are done through the use of the formal Corrective Action (CAR) system, and are defined in the document ***Corrective and Preventive Action***.

## **12.3 Continual Improvement**

Through the process effectiveness reviews, done as part of Management Review, Actco works to continually improve the suitability, adequacy and effectiveness of the quality management system. This includes seeking opportunities for improvement.

## Appendix A: Overall Process Sequence & Interaction



## Appendix B: ISO 9001:2015 Cross Reference

ISO 9001:2015 Clause	Section in Manual
4.0 Context of the Organization (all)	
4.1 Understanding the Organization & Its Context	4.1 Determining Our Strategic Direction
4.2 Understanding the needs & expectations of interested parties	4.1 Determining Our Strategic Direction
4.3 Determining the scope of the QMS	4.2 Scope of the Management System
4.4 Management system and its processes	6.0 Management System Processes
5.0 Leadership	
5.1 Leadership & Commitment	8.1 Management Leadership and Commitment
5.1.1 General	8.1 Management Leadership and Commitment
5.1.2 Customer focus	8.2 Customer Focus
5.2 Policy	5.0 Quality Policy 8.3 Quality Policy
5.3 Organizational Roles Responsibilities and Authorities	8.4 Organizational Roles and Responsibilities and Authorities
6.0 Planning	
6.1 Actions to address risks and opportunities	8.7 Risks and Opportunities
6.2 Quality objectives and planning to achieve them	6.2 Process Controls & Objectives
6.3 Planning of changes	8.6 Change Management
7.0 Support	
7.1 Resources	
7.1.1 General	9.1 Provision of Resources
7.1.2 People	9.2 Human Resources
7.1.3 Infrastructure	9.3 Infrastructure
7.1.4 Environment for the operation of processes	9.4 Work Environment
7.1.5 Monitoring and measuring resources	9.3 Infrastructure
7.1.6 Organizational knowledge	9.5 Organizational Knowledge
7.2 Competence	9.2 Human Resources
7.3 Awareness	9.2 Human Resources
7.4 Communication	8.5 Internal Communication
7.5 Documented information	7.0 Documentation & Records
8.0 Operation	
8.1 Operational planning and control	10.1 Operational Planning and Control
8.2 Requirements for products and services	
8.2.1 Customer communication	10.2 Customer Communication
8.2.2 Determining the requirements related to products & services	10.3 Determining the Requirements Related to Products and Services
8.2.3 Review of requirements related to products & services	
8.2.4 Changes to requirements for products and services	
8.3 Design and development of products and services	10.7 Design and Development
8.4 Control of externally provided processes, products & services	10.9 Purchasing
8.5 Production and service provision	



<b>ISO 9001:2015 Clause</b>	<b>Section in Manual</b>
8.5.1 Control of production and service provision	10.10.1 Control of Externally Provided Processes, Products and Services
8.5.2 Identification and traceability	10.10.2 Identification and Traceability
8.5.3 Property belonging to customers or external providers	10.10.3 Property Belonging to Third Parties
8.5.4 Preservation	10.10.4 Preservation
8.5.5 Post-delivery activities	10.10.5 Post-Delivery Activities
8.5.6 Control of changes	10.10.6 Process Change Control
8.6 Release of products and services	10.11 Measurement and Release of products and services
8.7 Control of nonconforming outputs	10.12 Control of Nonconforming Outputs
9.0 Performance evaluation	
9.1 Monitoring, measurement, analysis and evaluation	
9.1.1 General	12.1 Improvement: General
9.1.2 Customer satisfaction	11.1.2 Customer Satisfaction
9.1.3 Analysis and evaluation	12.1 Improvement: General
9.2 Internal audit	11.1.4 Internal Audit
9.3 Management review	11.1.5 Management Review
10.0 Improvement	
10.1 General	12.1 Improvement: General
10.2 Nonconformity and corrective action	12.3 Corrective and Preventive Action
10.3 Continual improvement	12.1 Improvement: General