



direct components
INCORPORATED

Quality Manual

Rev 15

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This manual complies with the requirements of the AS9120:2016 International Standard.



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1 Introduction

Our Quality Management System Commitment

As the President of Direct Components, Inc. I am committed to the quality management system, taking full accountability, and supporting other roles of leadership. Management uses the process approach and risk-based thinking to ensure the management system is integrated into our business processes to achieve intended results.

I am committed to provide the resources and training needed to ensure an effective quality management system that is necessary for our success and improvement. We provide a work environment that allows our employees to be successful in meeting our customers' needs.

The Quality Policy is established to be the driving force behind our quality management system, and I will continue to ensure that it remains compatible with the context and strategic direction of our organization.

Aaron Nursey

President/CEO

Direct Components, Inc

Quality Policy

Direct Components is committed to customer satisfaction by supplying quality products and services on time, while maintaining unsurpassed levels of ethical standards. Our quality goals are achieved through continual process improvement, adhering to applicable requirements, innovation, ongoing training, and teamwork.



2 Management System Approach

Our approach to our quality management system is based on the Plan, Do, Check, Act cycle (PDCA). The basis of our business beliefs is represented in **three** pillars:

Customer Focus

Our customers are the reason we exist. We aim to meet or exceed their needs and expectations to make them successful. We will even try to anticipate their needs and introduce solutions they've not seen before in the spirit of true partnership. Our success depends upon our customers' success.

Process Approach

To deliver on our commitment to total customer focus we constantly work on our internal processes to maximize their effectiveness and efficiency. We recognize that it takes countless individual activities to deliver our products and services and that the process approach ties them all together. Our business is a process that transforms several inputs (customer requirements, resources, skilled employees, etc.) into an output that meets our customer's needs. Within our business are several key processes that make it all work. Our processes are dependent upon one another and individually need continual attention and improvement. We are constantly challenging ourselves to refine and change how we do things to reduce the time it takes to get something done with the least errors. When errors do occur, we use them as opportunities to learn and improve. We are never satisfied with how things are working now and strive to raise our game every day.

PROCESS VALUE ●●●●



Risk-based Thinking

Looking ahead to anticipate what could happen is the reason we employ risk-based thinking throughout our organization. At several points in our process we purposely stop and ask two probing questions:

- “What could go wrong?”
- “Is there a way to improve?”

This perspective of constantly watching for risks and opportunities leads us to action which we carefully manage to ensure timely implementation and effective results. This gives us an attitude of being proactive to take advantage of every opportunity to improve.

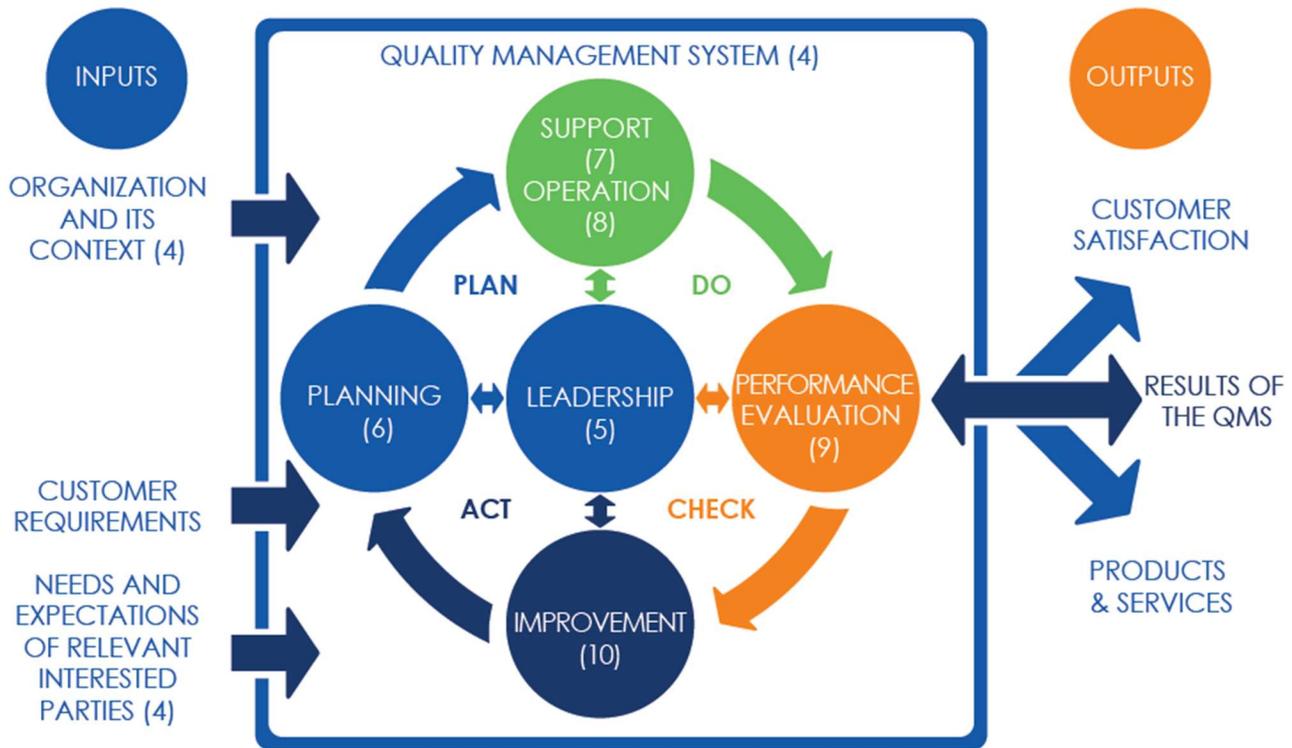
We intend these three basic beliefs to cause our customers to stand up and take notice the difference we provide to them daily. Our quality management system described in this Quality Manual has been carefully crafted to make these three pillars a real part of what makes us work.



3 Quality Manual Structure

This Quality Manual is presented in a PDCA manner and describes our approach to the AS requirements. The manual is divided into four sections with all applicable sub-clauses represented in each section as below:

NOTE: In the sections that follow, **Bold Blue Text** refers to related documentation where additional documentation is maintained and/or records are retained.





SECTION 1: PLAN

With an ever-changing world, we are faced with new challenges on a continuing basis. The issues, changes and trends within our industry and the broader economy present us with risks and opportunities from cultural, technological, competitive, regulatory, market, economic and social factors. Not only can these factors affect our business, but there are also other interested parties and organizations that we deal with on a day-to-day basis and these present additional requirements that we must account for.

These factors may affect our business negatively (risks) or positively (opportunities). The risks may be relevant to us and have the potential to affect our business or our customers in a negative way. These aspects of our business environment may also create opportunities for us to improve our organization or take advantage of expanded current or new business ventures.

Planning other aspects of our organization is also very important. Our planning process also includes people, their knowledge and training, infrastructure, environment, documentation, and communication. All planning efforts are structured, include decision-makers, and are documented when required.

Our extensive planning process puts us in the best position possible to forecast these challenges and take actions when necessary. It also establishes the needed foundations for us to provide our products and services.





4 Context of the Organization

4.1 Understanding the organization and its context

Requirement: Determine the external and internal issues that are relevant to the purpose and strategic direction and that affect the ability to achieve the intended result(s) of the quality management system.

Our Approach: Issues (4.1) stemming from trends and changes in our industry may affect our business purpose and strategic direction. Those that present risks and/or opportunities are initially addressed by top management, documented on the **QMS Plan**, then monitored and reviewed at planned intervals during management review.



4.2 Understanding the needs and expectations of interested parties

Requirement: Determine the interested parties, and their requirements that are relevant to the quality management system.

Our Approach: Requirements from interested parties (4.2) that impact our ability to meet customer and applicable statutory and regulatory requirements may present risks and/or opportunities. These are reviewed to determine relevance and necessary actions and documented on the **QMS Plan**. Subsequently, they are also monitored and reviewed at planned intervals during management review.

4.3 Determining the scope of the quality management system

Requirement: Determine the boundaries and applicability of the quality management system to establish the scope, considering:

- external and internal issues;
- requirements of relevant interested parties;
- products and services.

The scope is available and documented stating the:

- products and services covered by the quality management system;
- justification for any instance where a requirement of the AS standard cannot be applied.

Our Approach: The contextual issues and interested party requirements are considered to determine the scope (4.3) of our quality management system:

Considering these external and internal issues and requirements, we have established the scope of our quality management system as:



Scope

Direct Components Inc. is a distributor of electronic components.

This quality management system pertains to processes relating to the independent stocking and distribution of electronic components and describes the policies, requirements, and the processes, including their interactions that have been implemented at Direct Components, Inc. This manual and its supporting procedures are structured along a process model approach.

The following requirements do not apply;

8.3 Design and Development

Justification: This clause is not applicable because this organization has no capability to design products, this organization only buys and sells products, we have no contractual requirements to perform this function, and we design our processes in the Operations Planning Process making this clause not applicable.

4.4 Quality management system and its processes

Requirement: *Establish, implement, maintain, and continually improve the quality management system, including the processes needed and their interactions. Address customer-specific and applicable statutory and regulatory quality management system-related requirements.*

For the processes needed, determine:

- the inputs required and the outputs expected;*
- their sequence and interaction;*
- the criteria, methods, including monitoring, measurements and related key performance indicators (KPIs) needed to ensure their effective operation, and control;*
- the resources needed and their availability;*
- the assignment of the responsibilities and authorities;*
- the risks and opportunities, and plan and implement the appropriate actions to address them;*
- the evaluation and, if needed, the changes to processes to ensure that they achieve intended results;*
- and improvement.*

Establish and maintain a document(s) regarding the quality management systems processes that includes:

- description of relevant interested parties;*
- scope of the quality management system, including boundaries and applicability (see 4.3);*
- description of the processes needed and their application throughout the organization;*
- the sequence and interaction of the processes;*
- assignment of responsibilities and authorities.*

Our Approach: The processes (4.4) needed to achieve intended outcomes, results and to continually improve our quality management system are identified on the **QMS Plan**, and are



maintained on the **Process Map**, **Process Plans**, and **Process KPI Plan** and reviewed during Management Review.

5 Leadership

5.1 Leadership and commitment

Requirement: *Demonstrate leadership and commitment with respect to the quality management system by:*

- *taking accountability of its effectiveness;*
- *establishing a quality policy and objectives that are compatible with the context and strategic direction;*
- *integrating the QMS requirements into business processes;*
- *promoting the use of the process approach and risk-based thinking;*
- *ensuring that the resources needed are available;*
- *communicating its importance and conforming to its requirements;*
- *achieving intended results;*
- *engaging, directing and supporting people to contribute to the QMS;*
- *promoting improvement;*
- *supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.*



Our Approach: Our top management holds the ultimate responsibility for the quality management system. Our top management is dedicated and committed (5.1) to ensuring that our quality management system is effective, understood and improved.

Top management includes the following members by title:

- President/CEO
- Chief Operating Officer / Chief Financial Officer

5.1.2 Customer focus

Requirement: *Demonstrate leadership and commitment with respect to customer focus by ensuring that:*

- *applicable requirements are determined, understood and consistently and met;*
- *risks and opportunities that can affect conformity of products, services and enhancement of customer satisfaction are determined and addressed*
- *focus on enhancing customer satisfaction is maintained;*
- *product and service conformity (quality) and on-time delivery performance are measured and action taken if results and not or will not be achieved.*

Our Approach: Top management demonstrates leadership and commitment to ensure that all applicable requirements are met, risks and opportunities are addressed, and the focus on



customer satisfaction is maintained (5.1.2) through our **QMS Plan, Process Plans** and **Quality Policy**.

5.2 Policy

Requirement: *Establish, implement and maintain a quality policy that:*

- *is appropriate to the purpose and context and supports the strategic direction;*
- *provides a framework for setting quality objectives;*
- *includes a commitment to satisfy applicable requirements;*
- *includes a commitment to continual improvement of the QMS.*
- *is available and documented;*
- *is communicated, understood and applied;*
- *is available to relevant interested parties.*

Our Approach: The top-level requirement that directs our entire quality management system is our **Quality Policy**. The quality policy (5.2) is maintained, available, communicated, and reviewed as planned per the **Management Review Plan**. It is made available to interested parties at www.directics.com or upon request.

5.3 Organizational roles, responsibilities and authorities

Requirement: *Ensure that the responsibilities and authorities for relevant roles are assigned, communicated, documented and understood.*

Assign quality management system responsibilities and authority for:

- *ensuring that it conforms to the requirements of AS9120:2016;*
- *ensuring that processes are delivering their intended outputs;*
- *reporting on its performance, and opportunities for improvement, to top management;*
- *ensuring the promotion of customer focus;*
- *ensuring that its integrity is maintained when changes are planned and implemented.*
- *appointing a specific member of the organization's management, identified as the management representative, who has the responsibility and authority for oversight of the above requirements.*

The management representative has the organizational freedom and unrestricted access to top management to resolve quality management issues.

Our Approach: Responsibilities and authorities (5.3) for our process owners are assigned, communicated, and understood on our **Process Plans**. The Director of Quality Management has been appointed as the **Management Representative** of our QMS.

6 Planning

6.1 Actions to address QMS risks and opportunities (For Operational risk management, see 8.1.1)

Requirement: *When planning for the QMS, consider the issues (4.1) and the requirements (4.2) and determine the risks and opportunities that need to be addressed to:*

- *assure that the QMS can achieve its intended result(s);*
- *enhance desirable effects;*



- *prevent, or reduce, undesired effects;*
- *achieve improvement.*

Plan:

- *actions to address these risks and opportunities.*
- *how to:*
 - *integrate and implement the actions into our processes;*
 - *evaluate their effectiveness.*

Our Approach: We address the risks and opportunities (6.1) identified in the **QMS Plan** and **Process Plans**, as well as other situations through Management Review and Traction L10 Meetings. The actions will be integrated into our quality management system process and will be evaluated for effectiveness during reviews

6.2 Quality objectives and planning to achieve them

Requirement: *Establish objectives at relevant functions, levels and processes that:*

- *are consistent with the quality policy;*
- *are measurable;*
- *consider applicable requirements;*
- *are relevant to conformity of products and services and the enhancement of customer satisfaction;*
- *are monitored;*
- *are communicated;*
- *are updated as appropriate.*

Quality objectives are documented.

Plan actions to achieve quality objectives, including:

- *What will be done;*
- *What resources will be required;*
- *Who will be responsible;*
- *When the plan(s) will be completed;*
- *How results will be evaluated.*

Our Approach: We establish objectives (6.2) at relevant functions, levels, and processes, and have plans to achieve them on our **Quality Objective Measurement Plans**. The results of these objectives and plans are reviewed per the **Management Review Plan** and retained on the **Management Review Minutes**.

6.3 Planning of changes

Requirement: *Where needed, carry out changes to the QMS in a planned manner considering:*

- *the purpose of the change and any of its potential consequences;*
- *the integrity of the quality management system;*
- *the availability of resources;*
- *the allocation or reallocation of responsibilities and authorities.*



Our Approach: Changes (6.3) that are needed are planned and carried out carefully considering the consequences, the integrity of our QMS, resources and associated responsibilities. The changes are managed and are recorded in the **Management Review Minutes, Meeting agendas and notes, Traction Tools, and/or Process Plans and Audit records**, as appropriate for the change.

7 Support

7.1 Resources

7.1.1 General

Requirement: *Determine and provide resources needed for maintenance and continual improvement of the QMS considering:*

- *capabilities, constraints and existing resources;*
- *needs from external providers.*

Our Approach: During our Management Reviews, our top management discuss all internal and externally provided resources needed (7.1.1) for maintenance and continual improvement of our quality management system and ensures that they are provided.

7.1.2 People

Requirement: *Determine and provide the people necessary to effectively implement the QMS and for the operation and control of processes.*

Our Approach: During our Management Reviews, our top management determines the persons necessary (7.1.2) for the effective implementation of our QMS and for the operation and control of our processes and ensures that the resources are provided.

7.1.3 Infrastructure

Requirement: *Provide and maintain the infrastructure for the operation of processes and conformity of products and services.*

Our Approach: To ensure that our infrastructure resources remain adequate, they are reviewed and discussed during Management Reviews.

7.1.4 Environment for the operation of processes

Requirement: *Provide and maintain the environment necessary for the operation of processes and to achieve conformity of products and services.*

Our Approach: Our top management ensures that our work environment (7.1.4) is sufficient to achieve conformity of our products and services as discussed during Management Reviews.



7.1.5 Monitoring and measuring resources

7.1.5.1 General

Requirement: *Provide the resources needed to ensure results when monitoring and measuring is used to verify conformity of products and services.*

Ensure these resources are:

- *suitable for the specific type of monitoring and measurement activities;*
- *maintained to ensure fitness for purpose.*



Our Approach: We have determined, and provide the resources needed to monitor and measure (7.1.5.1) our products and services to ensure that they continue to meet requirements and specifications. This is documented in the **Quality Objective and Process KPI Measurement Plans**.

7.1.5.2 Measurement Traceability

Requirement: *If measurement traceability is required or considered essential to provide confidence in the validity of the measurement results, measuring/monitoring equipment shall be:*

- *calibrated or verified;*
- *identified as to calibration/verification status;*
- *safeguarded from adjustments, damage or deterioration.*

Determine the validity of previous measurement/monitoring results, when equipment is found to be out of tolerance. Establish, implement and maintain a recall process for monitoring and/or measurement equipment requiring calibration or verification. Calibration and/or verification is carried out under suitable environmental conditions. Provide a list of monitoring and measurement equipment, including:

- *equipment type and identification;*
- *location;*
- *calibration/verification method, frequency and acceptance criteria.*

Our Approach: Measurement traceability is essential to providing confidence in the validity of the measurement results. Details of this process are maintained within the Direct establishes processes to ensure that monitoring and measurement can be carried out in a manner that is consistent with the monitoring and measurement requirements. See **Control of Monitoring & Measuring Equipment Procedure**

7.1.6 Organizational Knowledge

Requirement: *Determine the knowledge necessary for the operation of processes and to achieve conformity of products and services. Maintain this knowledge and, make it available to the extent necessary.*

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



Our Approach: All current knowledge (7.1.6) sources, requirements, changes, needs, and trends are determined by top management, maintained and discussed during Management Reviews.

7.2 Competence

Requirement: Determine the necessary competence of people doing work under organizational control that affects the performance and effectiveness of the QMS and:

- ensure they are competent based on education, training, or experience;
- where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;
- retain appropriate records as evidence of competence.

Our Approach: We determine the required competencies (7.2) for our employees, whose work may impact the effectiveness and performance of our QMS. We hire employees with specific knowledge, skills and education that best fit our needs and provide training to fulfill any missing competencies.

Evidence of this process is retained in **employee training records** and maintained by per the **Control of Documents & Records Procedure and the Record Control Plan**. As of the initial release of this document, all current employees are competent.

7.3 Awareness

Requirement: Make people doing work under organizational control aware of:

- the quality policy;
- relevant quality objectives;
- their contribution to the QMS and the benefits of an improved system;
- the implications of not conforming to the QMS requirements;
- relevant QMS documentation and related changes;
- their contribution to product and service conformity;
- their contribution to product safety;
- the importance of ethical behavior.

Our Approach: People doing work under our control are made aware (7.3) of all the requirements noted above as defined on the **Communication and Awareness Plan** which is reviewed during Management Review.

7.4 Communication

Requirement: Determine all elements of internal and external communications relevant to the quality management system.

Our Approach: Communication (7.4) is very important to our operation's success. Our communication methods are maintained on the **Communication and Awareness Plan**, which is reviewed periodically during Management Review.

7.5 Documented Information

Requirement: Determine the documents and records necessary for an effective QMS, and apply controls to ensure it is:

- available and suitable, where and when it's needed;



- *protected from loss of confidentiality, integrity and improper use;*
- *properly identified;*
- *used in the proper format and media;*
- *reviewed for suitability and adequacy.*

Control the documents and records, including necessary external documents, with regards to (as applicable):

- *distribution, access, retrieval and use;*
- *storage and preservation, including preservation of legibility;*
- *control of changes (e.g. version control);*
- *retention and disposition;*
- *prevention of unintended use of obsolete documents by removal or, if needed for any purpose, by application of suitable identification or controls*

Protect all retained documentation used as evidence of conformity from unintended alterations. Defined data protection processes when documents and records are managed electronically. When applicable, retain records of product origin, conformity, and shipment.

Our Approach: We have determined which internal and external documents and records (7.5) are necessary for the effectiveness of our quality management system. This documented information is created, approved, and controlled according to applicable requirements primarily using our **CORE ISO Compliance Platform®**. To ensure data protection, the CORE ISO Compliance Platform has the following security features:



Server and network security:

- encryption, where appropriate hardened operating systems and firewalls;
- regular security audits;
- rigorous systems reviews;
- state-of-the-art security related upgrades;
- a full time, dedicated security staff for software system maintenance, research and troubleshooting;
- secure facilities locations;
- tightly controlled and supervised server access.

ISO Compliance Platform security:

- unique usernames and passwords;
- encrypted transactions (including username and password submittals);
- company-specific company database realms (associated by username) with a limited database authority level based on customer defined roles;
- specific nature of user session and user authority control and encryption methods cannot be released.

Where records are stored in an electronic form on our server, back-up procedures are defined. Electronic records shall be secured to prevent unauthorized alteration or change and shall not be corrupted due to software or system changes. (See **Control of Documents & Records Procedure**)



SECTION 2: DO

Providing our customers with products and services that meet their requirements and expectations and, if applicable, regulatory/statutory requirements, is why we are in business. This takes planning, reviewing, as well as execution of these processes to ensure that all requirements are identified and met.

In this section of the handbook, we will be describing our methods for conforming to the operational planning, requirements determination and review, design and development, purchasing, product and service provision, post-delivery activities, and what we do when something doesn't go quite as we expected.

8 Operation

8.1 Operational Planning and Control

Requirement: *Plan, implement and control the processes needed to meet requirements for products and services and to implement the actions determined in 6.1, by:*

- *determining requirements for the product and services;*
- *establishing criteria for the processes and for the acceptance of products and services;*
- *determining the resources needed to achieve product and service conformity and to meet on-time delivery;*
- *implementing control of the processes in accordance with the criteria;*
- *maintaining and retaining documents and records to the extent necessary to have confidence that the processes have been carried out as planned and to demonstrate conformity of products and services to requirements;*
- *engaging impacted organizational representatives for operational planning and control;*
- *determining the needed products and services to be obtained from external providers;*
- *establishing controls needed to prevent delivery of nonconforming products and services.*

The output of this planning is suitable for the organization's operations. Control planned changes, review the consequences of unintended changes, and act to mitigate any adverse effects.

Plan and manage product and service provision in an appropriately structured and controlled manner, including scheduled events, performed in a planned sequence, to meet requirements at acceptable risk and within resource and schedule constraints.

Establish, implement, and maintain a process a process to control temporary and permanent work transfers to ensure continuing conformity to requirements, including identification and management of work transfer impacts and risks.

Our Approach: The processes, including outsourced processes that affect our products and services are controlled (8.1). The details and evidence of our processes are maintained within the **QMS Plan** and **Process Plans**. All planned changes are controlled, un-planned changes are reviewed and actions to mitigate are taken for any adverse effects.

Our approach to structured planning and managing the provision of our products and services is: **Customer Service and Configuration Management Procedure.**



Our approach to planning and managing work transfers is described in the **Purchasing Procedure**.

8.1.2 Configuration Management

Requirement: *Plan, implement and control an appropriate configuration management process to ensure identification and control of physical and functional attributes throughout the product life cycle. The process shall:*

- *control product identity and requirements traceability, including change control;*
- *ensure product and service documentation reflects the actual product and service attributes.*

Our Approach: Product and service features, functions and attributes are documented in appropriate configurations. There is a change control process to ensure that changes to configurations are not introduced unknowingly. Product and service configurations are managed through operational processes to control traceability to requirements. The details of our operational configuration management and configuration change control process is maintained within the **Customer Service and Configuration Management Procedure**.

8.1.4 Prevention of Counterfeit Parts

Requirement: *Plan, implement and control appropriate processes for prevention of counterfeit or suspect counterfeit parts use and their inclusion in the product delivered to the customer.*

Our Approach: We take proactive steps to prevent counterfeit or suspect counterfeit parts from entering our system via controls and traceability of our externally provided parts, and incoming receiving inspections. Our counterfeit parts program is described in our **Counterfeit Parts Procedure** along with appropriate sections of our **Purchasing, Inspection, & Receiving Procedures & Work Instructions**.

8.1.5 Prevention of Suspect Unapproved Parts

Requirement: *Plan, implement and control appropriate process, appropriate to the organization and product, that identifies and prevents the release of unapproved or suspect unapproved parts.*

Our Approach: We take proactive steps to prevent the release of unapproved or suspect unapproved parts from entering our system via controls and traceability of our externally provided parts, and incoming receiving inspections. Our unapproved parts process is integral to our counterfeit parts program and is described in our **Counterfeit Parts Procedure** along with appropriate sections of our **Purchasing Procedure**.

8.2 Requirements for Products and Services

8.2.1 Customer communication

Requirement: *Communication with customers includes:*

- *information relating to products and services;*



- *inquiries, contracts or order handling, including changes;*
- *obtaining customer feedback relating to products and services, including customer complaints;*
- *the handling or controlling of customer property, if applicable;*
- *specific requirements for contingency actions, when relevant.*

Our Approach: Open, and efficient communication with our customers (8.2.1) is very important for communicating information relevant to products and services, contract information, customer complaints, changes, property, requirements and contingency actions.

8.2.2 Determining the requirements for products and services

Requirement: *When determining the requirements for the products and services to be offered to customers, ensure that:*

- *the requirements for the products and services are defined, including; applicable statutory and regulatory requirements, and those the organization considers necessary;*
- *the organization has the ability to meet the claims for the products and services offered;*

Our Approach: Using **Customer Service and Configuration Management Procedure** we determine the requirements (8.2.2) for our current or new products and services to ensure that all applicable customer, organizational, regulatory, and statutory requirements are identified to ensure that we can meet the claims and requirements. This method includes steps to identify and “special high risk” requirements, and any associated operational risks.

8.2.3 Review of the requirements for products and services

Requirement: *Ensure that the ability to meet the requirements for products and services to be offered to customers is present. Conduct a review before committing to supply products and services to a customer, to include:*

- *customer requirements, including requirements for delivery and post-delivery activities;*
- *requirements not stated by the customer, but necessary for the customers' specified or intended use, when known;*
- *requirements specified by us;*
- *statutory and regulatory requirements applicable to the products and services;*
- *contract or order requirements differing from those previously expressed.*

Ensure that contract or order requirements differing from those previously defined are resolved.

Coordinate the review across applicable organization functions.

Negotiate a mutually acceptable requirement with the customer if the review results in a determination that some requirements cannot be met or can only be partially met.



Our Approach: Using **Customer Service and Configuration Management Procedure** we review all requirements (8.2.3) to ensure that we can meet the product and service requirements prior to offering the product or service. If our customer does not provide us with any documented statement of requirements, we will confirm requirements prior to acceptance. Requirements generated from the product or service, the organization, statutory, regulatory and requirements that are differing from previous ones are reviewed. The review is coordinated across organization functions, as needed. Should it be determined that not all requirements can be fully met, a mutually agreeable solution is negotiated with the customer prior to acceptance. The results of the review are retained in the appropriate folder on the server and in the database.

8.2.4 Changes to requirements for products and services

Requirement: *Ensure relevant documentation is amended and that relevant persons are aware of changes.*

Our Approach: When the requirements for products and services are changed (8.2.4), the Order processor and/or CSR ensures that relevant documentation is amended and that relevant personnel are made aware of the changed requirements.

8.4 Control of externally provided processes, products, and services (Purchasing)

8.4.1 General

Requirement: *Ensure that externally provided processes, products, and services conform to requirements, including from sources defined by the customer. Utilize customer-designated or approved external providers, including process sources, when required.*

Identify and manage the risks associated with external provision of processes, products, and services, as well as the selection and use of external providers.

Apply controls to externally provided processes, products, and services when:

- *products and services are provided for incorporation into the organization's products and services;*
- *products and services are provided directly to the customer(s) on behalf of the organization;*
- *a process, or part of a process, is provided because of our decision.*

Require external providers to apply appropriate controls to their direct and sub-tier external providers to ensure requirements are met.

Establish and apply criteria for the evaluation, selection, monitoring of performance and re-evaluation of external providers based on their ability to provide processes or products and services in accordance with specified requirements.



Maintain a list of external providers that includes approval status and approval scope.

Define the processes, responsibilities and authorities for approval status decisions, changes of the approval status, and conditions for a controlled use of external providers depending on their approval status,

Periodically review external provider performance, including process, product and service conformity and on-time delivery performance. Define the necessary actions to take when dealing with external providers that do not meet requirements. Retain records of the results of the evaluations, monitoring of the performance and re-evaluations.

Define the requirements for controlling documents or records created by and/or retained by external providers.

Our Approach: We ensure that all our external providers of processes, products, and services (8.4), including those defined by our customers, conform to all applicable requirements. We apply sufficient controls to any provider of products or services that:

- are directly incorporated into our products or services;
- are provided directly to the customer on our behalf; or
- provide a process, or part of a process requested by us.

Our criteria for selection, evaluation, and re-evaluation practices, our external provider evaluation practices, our applicable responsibilities and authorities regarding external provider selection and approval status designations, our external provider risk management practices and flow down requirements and our external provider documentation control practices are described in our **Purchasing Procedure** and associated Work Instructions.

As of the initial release of this document, all current external providers in good standing are approved.

8.4.2 Type and extent of control

Requirement: *Ensure that externally provided processes, products and services do not adversely affect the ability to consistently deliver conforming products and services to customers by:*

- *ensuring that externally provided processes remain within the control of the QMS;*
- *defining both the controls that are intended to be applied to an external provider and those intended to be applied to the resulting output;*
- *taking into consideration;*
 - *the potential impact of the externally provided processes, products and services on the ability to consistently meet customer and applicable statutory and regulatory requirements;*
 - *the effectiveness of the controls applied by the external provider;*
 - *the results of the periodic review of their performance*
- *determining the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.*



Perform verification activities of externally provided processes, products, and services, according to the identified risks, including, if applicable, inspection or periodic testing where there is a high risk of nonconformities including counterfeit parts.

Implement a process to evaluate data in test reports that are used to verify externally provided products to ensure product requirements are met. Verify the accuracy of test reports where a customer or the organization has identified raw material as an operational risk or critical item(s.)

Our Approach: The controls (8.4.2) that we apply to our external providers are decided on an individual basis. We ensure all external providers remain in control in our quality management system and apply other controls as necessary by product, service, or situation. Our controls are defined in our **Purchasing & Receiving Procedures** and Work instructions.

8.4.3 Information for external providers

Requirement: *Ensure adequate requirements prior to communicating to the external provider, and communicate the requirements for:*

- *the processes, products and services to be provided, including the identification of relevant technical data;*
- *approval or release of products and services, methods, processes or equipment;*
- *competence of external provider's personnel, including necessary qualification;*
- *their interactions with the QMS;*
- *the control and monitoring of the external provider's performance to be applied;*
- *verification or validation activities that the organization, or customers, intend to perform at the external provider's premises;*
- *the use of statistical techniques for product acceptance and related instructions for acceptance by the organization;*
- *the need for the external provider to:*
 - *implement a QMS;*
 - *use customer-designated or approved external providers, including process sources;*
 - *notify the organization of changes to processes, products or services including changes to their external providers or location of manufacture, and obtain the organization's approval;*
 - *flow down to external providers applicable requirements including customer requirements;*
 - *prevent the use of counterfeit parts, suspect unapproved and unapproved parts*
 - *notify the organization of nonconforming processes, products or services and obtain their approval for the disposition;*
- *retain records, including retention periods and disposition requirements;*
- *the right of access by the organization, their customer and regulatory authorities to the applicable areas of facilities and to applicable documentation, at any level of the supply chain;*
- *ensuring that external providers' persons are aware of:*
 - *their contribution to product and service conformity;*
 - *their contribution to product safety;*
 - *the importance of ethical behavior.*

Ensure the adequacy of specified requirements prior to communicating to the external provider.

Our Approach: Prior to communicating with external providers, we ensure that all applicable requirements are clearly identified. These may include requirements relating to products, services, externally provided processes, certifications or personnel, and any verification or validation that the external provider provides at their premises.



The purchasing information (8.4.3) is communicated to external providers via purchase orders, contracts, or agreements & purchase order terms and conditions.

8.5 Production and Service Provision

8.5.1 Control of production and service provision

Requirement: *Implement product and service provision under controlled conditions, including, as applicable:*

- *the availability of documents that defines the characteristics of the products and services, and the results to be achieved;*
- *ensuring the availability of suitable monitoring and measuring resources*
- *documented monitoring and measurement activities at appropriate stages to verify that criteria for control of processes and process outputs, and acceptance criteria for products and services, have been met. Documentation to include:*
 - *acceptance and rejection criteria;*
 - *where in the process sequence verifications are to be made;*
 - *measurement results to be retained (minimum is acceptance or rejection);*
 - *any specific equipment required and instructions for use*
- *use of statistically sound monitoring and measurement sampling plans which are appropriate for their use*
- *the use, and control of suitable infrastructure and process environment;*
- *the competence and, where applicable, required qualification of people;*
- *the validation, and periodic revalidation, of the ability to achieve planned results of any process for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement;*
- *the implementation of actions to prevent human error;*
- *the implementation of products and services release, delivery and post-delivery activities;*
- *establishment of workmanship criteria;*
- *accountability for all products during production (e.g., part/material quantities, split orders, nonconforming product, etc.);*
- *evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized;*
- *provision for foreign object (FOD) prevention, detection and removal;*
- *control and monitoring of utilities and supplies to the extent they impact product conformity;*
- *the consequences of obsolescence (e.g., materials, components, equipment, etc.)*

Our Approach: We control all phases of our product or service realization (8.5.1). These controls may include, as appropriate: documented characteristics, monitoring and measurement, validations, or reviews of products and/or processes, workmanship criteria, foreign object detection, utility and supplies control, and release and post-delivery activities.

Lab & Warehouse Manager is responsible for controlling all phases of product and service provision and for maintaining appropriate records.



8.5.1.1 Control of equipment, tools, and software programs

Requirement: *Validate and maintain equipment, tools and software programs used to automate, control, monitor or measure production processes prior to release into live production.*

Define storage requirements for production equipment or tooling, including any necessary preservation or condition checks.

Our Approach: We validate all equipment, tools, and software prior to live production use. In addition, we provide adequate storage for equipment and tooling when not in use to ensure it is not damaged and have specific methods for ensuring suitability. These methods are defined in **Control of Monitoring & Measuring Equipment Procedure.**

8.5.2 Identification and traceability

Requirement: *Use suitable means to identify outputs when it is necessary to ensure the conformity of products and services. Identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision. Control the unique identification of the outputs when traceability is a requirement and retain the records necessary to enable traceability.*

Maintain the applicable product or service configuration identification to identify any differences between the actual and required configurations.

Establish controls for any acceptance authority media (stamps, passwords, etc.)

Control unserviceable product and physically segregate from service able product.

Maintain product identification and traceability by suitable means (e.g., labels, bar codes, etc.) during splitting, storage, packaging and preservation until delivery This includes during outsourced handling or packaging operations, as well.

Retain records of the following information when delivering split orders:

- *Amount delivered versus the amount received from the external provider;*
- *PO number(s);*
- *Customer name(s)*

Our Approach: Where traceability (8.5.2) is a requirement, we use methods suitable to identify outputs to ensure conformity of our products or services. The method(s) used for traceability is determined by the Lab & Warehouse Manager, Lab Supervisor, and/or Receiving & Warehouse Supervisor as appropriate and is accomplished through the use of our database.

8.5.3 Property belonging to customers or external providers

Requirement: *Exercise care with property belonging to the customer or external providers while it is under organizational control or being used. Also, identify, verify, protect, and safeguard the customer's or external provider's property provided for use or incorporation into our products and services.*



Property of the customer or external provider which is lost, damaged, or found to be unsuitable, is reported to the customer or external provider and retain records of what occurred.

Our Approach: There may be times that we use property belonging to customers or external providers (8.5.3). When this occurs, we identify, verify, and protect the provider's property. The Lab & Warehouse Manager is responsible for controlling and recording customer property. In the rare occurrence of customer or provider's property becoming lost, damaged, or unusable, the Lab & Warehouse Manager will contact the provider. The outcomes are retained on the **Nonconformance Form**

8.5.4 Preservation

Requirement: *Ensure preservation of process outputs during production and service provision, to the extent necessary to maintain conformity to requirements. Include provisions for the following, as applicable:*

- *cleaning;*
- *prevention, detection and removal of foreign objects (FOD);*
- *special handling and storage for sensitive products;*
- *marking and labeling, including safety warnings for precautions;*
- *shelf life control and stock rotation;*
- *special handling and storage for hazardous materials.*

Our Approach: We use methods necessary to ensure that our product or service maintains conformance to the requirements. The Lab & Warehouse Manager is responsible for ensuring adequate preservation of our products and services.

8.5.5 Post-delivery activities

Requirement: *Meet requirements for post-delivery activities associated with products and services, considering:*

- *customer requirements;*
- *the nature, use and intended lifetime of the products and services;*
- *customer feedback;*
- *statutory and regulatory requirements;*
- *the potential, undesired consequences associated with its products and services*

Post-delivery activities could include, as applicable, product/customer support. Take appropriate action, including investigation and reporting, for problems detected after delivery.

Our Approach: Post-delivery activities (8.5.5) include, RMA Management, Customer Satisfaction Surveys, Customer Feedback, warranty activities, authentication of a product, etc. These activities are developed considering applicable requirements, product/service use and support requirements, customer support and feedback and potential risks.



8.5.6 Control of changes

Requirement: Review and control changes for production or service to the extent necessary to ensure conformity with specified requirements. Identify persons authorized to approve production or service provision changes. The personnel authorizing the change, and any necessary actions arising from the review.

Our Approach: Any changes that occur during our product or service provision are controlled by Director of Customer Service, Director of Quality Management, and/or appropriate management and may be reviewed during management review and documented in the management review minutes, Traction Tools, or may result in the issue of a new purchase order, notes in the sales order, or other documentation to identify the changes.

8.6 Release of products and services

Requirement: Implement planned arrangements at appropriate stages to verify that product/service requirements have been met.

Release of products/services to the customer does not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer. Retain records on the release of products/services includes:

- evidence of conformity with acceptance criteria
- traceability to the person(s) authorizing the release.

Ensure all documents and/or records required to accompany products and services are available at delivery.

Our Approach: The release of our product/service (8.6) is indicated by means of issuance of a Certificate of Conformance, generation of an invoice, and test report, (when required), and does not occur until all planned arrangements have been completed and is only released by authorized persons.

The Lab & Warehouse Manager is responsible for ensuring any product qualification requirements are met and records retained.



8.7 Control of nonconforming process outputs, products, and services

Requirement: Ensure process outputs that do not conform to requirements are identified and controlled to prevent unintended use or delivery. Maintain a documented procedure for Control of Nonconformances, including the provisions for:

- Defining the responsibility and authority for review and disposition and the process for approving such persons;
- Taking necessary actions to contain the effect of the nonconformance on other processes, products or services;
- Timely reporting of nonconformances of delivered products and services to the customer and other relevant parties;
- Defining impact-appropriate corrective actions for nonconforming products or services detected after delivery



Take action based on the nature of the nonconformity and its effect on the conformity of products/services. This applies also to nonconforming products/services detected after delivery of the products or during or after the provision of the service.

As applicable, deal with nonconforming outputs in one or more of the following ways:

- correction;
- segregation, containment, return or suspension of products and services;
- informing the customer;
- obtaining authorization for acceptance under concession by a relevant authority, and, when applicable, the customer.



Conspicuously and permanently mark or positively control scrap until rendered unusable. Control counterfeit or suspected counterfeit parts to prevent reentry into the supply chain.

For AS9120, nonconforming product dispositions are limited to:

- scrap;
- rejection for return to the external provider;
- rejection for revalidation by the manufacturer;
- submittal to the customer or design authority for use-as-is disposition, as applicable

Where nonconforming outputs are corrected, conformity to the requirements is verified.

Retain records that:

- describes the nonconformity;
- describes the actions taken;
- describes any concessions obtained;
- identifies the authority deciding the action in respect of the nonconformity.

Our Approach: Any output that does not conform (8.7) to requirements is identified and controlled to prevent unintended use or delivery. We take appropriate informal or formal action to deal with the nonconformity. We take appropriate action to deal with the nonconformity. Details are described in the **Control of Nonconformances Procedure**. Resolutions are described on the **Nonconformance Form**.



SECTION 3: CHECK

We make great efforts to be data-driven decision makers. This can only be accomplished by ensuring that we maintain accurate data and that the data is properly interpreted.

We take the time to analyze data from various areas that supplies us with data on:

- customer satisfaction;
- process effectiveness;
- product/service conformity;
- effectiveness of our QMS;
- external providers;
- our planning efforts;
- external providers; and
- the associated risks and opportunities.

Our thorough “checking” process allows us to have confidence in our quality management system and identify improvement areas.

9 Performance Evaluation

9.1 Monitoring, measurement, analysis, and evaluation

Requirement: Determine:

- *what needs to be monitored and measured;*
- *the methods for monitoring, measurement, analysis and evaluation to ensure valid results;*
- *when the monitoring and measuring will be performed;*
- *when the results from monitoring and measurement will be analyzed and evaluated. Evaluate the performance and effectiveness of the quality management system through the Management Review process and retain records as evidence of the results.*



Our Approach: Our method of monitoring, measurement, analysis, and evaluation is maintained within our **Measurement Plans**. The review of this plan is retained in our **Management Review** minutes.

9.1.2 Customer satisfaction

Requirement: *Monitor customer perceptions of the degree to which their needs and expectations have been fulfilled.*

Monitor the following information at a minimum, develop and implement improvement plans to address deficiencies, and assess the effectiveness of the results:

- *product and service conformity;*
- *on-time delivery;*
- *customer complaints;*
- *customer -initiated corrective action results.*



Our Approach: We obtain and, monitor customer perception by means of Quality Objectives, Customer surveys, customer complaints, acquiring through email communications, customer - initiated corrective action results. The customer satisfaction data is discussed during Management Reviews.

9.1.3 Analysis and evaluation

Requirement: *Analyze and evaluate appropriate data and information arising from monitoring, measurement, and other sources to evaluate:*

- *conformity of products and services;*
- *the degree of customer satisfaction;*
- *the performance and effectiveness of the QMS;*
- *planning implementation;*
- *the effectiveness of actions taken to address risks and opportunities;*
- *the performance of external provider(s);*
- *need or opportunities for improvements to the QMS.*

Our Approach: Our sources and evaluations (9.1.3) are described within our **Measurement Plans** and retained within our **Management Review meeting minutes**.

9.2 Internal audit

Requirement: *Conduct internal audits at planned intervals to provide information on whether the QMS conforms to requirements, is implemented and maintained.*

The organization shall:

- *plan, establish, implement and maintain an audit program(s) including the frequency, methods, responsibilities, planning requirements and reporting, which takes into consideration, the importance of the processes concerned, changes affecting on the organization, and the results of previous audits;*
- *define the audit criteria and scope for each audit;*
- *select auditors and conduct audits to ensure objectivity and impartiality of the audit process;*
- *ensure that the results of the audits are reported to relevant management;*
- *take appropriate correction and corrective actions without undue delay;*
- *retain records as evidence of the implementation of the audit program and audit results.*

Our Approach: Our internal audit program is implemented and maintained and is used to ensure that our QMS is maintained and effective. Our internal audits are planned according to importance on our **Internal Audit Plan and Schedule**. Our auditors are objective and impartial and report the results to management. Corrective Actions resulting from internal audits are taken without undue delay. The

Management Representative is responsible to oversee the internal auditing system and for retaining appropriate records. Internal audit results and status are discussed during Management Review.





9.3 Management review

Requirement: Top management conduct planned reviews of the QMS to ensure its suitability, adequacy, effectiveness, and alignment with the strategic direction considering:

- the status of actions from previous management reviews;
- changes in external and internal issues that are relevant to the QMS;
- information on the performance and effectiveness of the quality management system, including trends in:
 - customer satisfaction and feedback from relevant interested parties;
 - the extent to which quality objectives have been met;
 - process performance and conformity of products and services;
 - on-time delivery performance;
 - nonconformities and corrective actions;
 - monitoring and measurement results;
 - audit results;
 - the performance of external providers;
 - the adequacy of resources;
 - the effectiveness of actions taken to address risks and opportunities;
 - opportunities for improvement.

The outputs of management review are to include decisions and actions related to:

- opportunities for improvement;
- any need for changes to the quality management system;
- resource needs;
- risks identified.

Retain records as evidence of the results of management reviews.

Our Approach: Our management reviews are planned via the **Management Review Plan**. At a minimum, these reviews are attended by:

- President / CEO
- Chief Operating Officer / Chief Financial Officer
- Director of Quality Management
- Director of Sales
- Director of Customer Service

The **Management Review Agenda & Minutes** includes all required inputs & outputs including the actions and decisions relating to any opportunities for improvement, needed changes to the QMS and resource needs.





SECTION 4: ACT

This final step within our Plan, Do, Check and Act quality management system serves two purposes. First, it is the step which is used to make the decision of taking or not taking action based on the analysis and evaluations that occur during the “check” step. Whether we decide to take action or not, the decision will always be metric-driven, and risk-based.

The second purpose of the “Act” step is that it serves as the pivoting step that guides our QMS back to the Plan phase to begin the PDCA cycle and support continual improvement.

This last section of our manual covers our approach to improvements and corrective actions.

10 Improvement

10.1 General

Requirement: Determine and select opportunities for improvement and implement actions to meet customer requirements and enhance customer satisfaction, including (as appropriate):

- improving products and services to meet requirements as well as to address future needs and expectations;
- correcting, preventing or reducing undesired effects;
- improving the performance and effectiveness of the quality management system.



Our Approach: We select opportunities relating to:

- improve our products and services;
- correct, prevent or reduce undesired effects;
- improve our QMS.

We retain the records regarding improvements on our **Measurement Plans** and **Corrective Action Forms**.

10.2 Nonconformity and corrective action

Requirement: When a nonconformity occurs, including those arising from complaints:

- react to the nonconformity, and as applicable:
 - act to control and correct it;
 - deal with the consequences;
- evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere:
 - review and analyze the nonconformity;
 - determine the causes of the nonconformity, including those related to human factors;
 - determine if similar nonconformities exist, or could potentially occur;
- implement any action needed;
- review the effectiveness of any corrective action taken;
- update risks and opportunities determined during planning, if necessary;
- make changes to the quality management system, if necessary;
- flow down corrective action requirements to an external provider when they are determined responsible for the nonconformity;
- take specific actions when timely and effective corrective actions are not achieved.



Corrective actions are appropriate to the effects of the nonconformities encountered.

Maintain a documented procedure describing the nonconformity and corrective action process.

Retain records as evidence of:

- *the nature of the nonconformities and any subsequent actions taken;*
- *the results of any corrective action.*

Our Approach: Nonconformities are taken seriously and are reacted to as applicable. We take any actions necessary to ensure that the nonconformity does not recur or occur elsewhere. Corrective actions are submitted to external providers, when appropriate. The details of our corrective action process are documented in our **Corrective Action Procedure**. Nonconformities are documented on our **Nonconformance Form** and/or **Corrective Action Form** and discussed during Management Review.

10.3 Continual improvement

Requirement: *Continually improve the suitability, adequacy, and effectiveness of the QMS.*

Monitor improvement activity implementation and evaluate the effectiveness of results.

Our Approach: We consider the results of analysis and evaluation, and the outputs from Management Review, to confirm if there are needs or opportunities to be addresses as part of continual improvement.

