Rockwell Automation Quality Management System

Overview and Answers

Rockwell Automation

1.0 PURPOSE

To demonstrate and provide a public summary of the top-level Rockwell Automation (RA) Quality Management System (QMS) and RA internal documents (primarily the corporate 900 manual) that support the RA Quality Policy 900-20-01, as well as to give a general company overview and to answer questions commonly asked regarding our Quality Management System. It is not always feasible to respond immediately and individually to every questionnaire. This document allows us to quickly provide the general management system information that is typically requested.

This document is meant only as a high-level overview of the structure and content of the Quality Management System. It is not a policy or procedure to be followed. The actual RA Quality Manual is not a single document. The documentation of the QMS is spread across a collection of documents at various levels of detail and is company confidential. Specific internal documents, such as those referenced in this document, are available for review during audits with appropriate non-disclosure agreements, but copies are typically not shared in accordance with our policy on Safeguarding Sensitive Information.

For general Rockwell Automation information or audit requests, please contact customerinquiry@ra.rockwell.com

This document can be viewed online at:
http://literature.rockwellautomation.com/idc/groups/literature/documents/ct/qms-ct001_-en-e.pdf

2.0 SCOPE

The scope of the Quality Management System encompasses all activities, locations, and people within Rockwell Automation. This includes, but is not limited to the design, development, manufacture, remanufacture, repair, integration, and support of industrial automation components, software, systems, solutions, and services. Everyone has the potential to impact quality, whether directly or indirectly involved in the activities described in this document.

The Quality Management System is based on ISO 9001. Many sites within RA are ISO 9001 certified and the Quality Management System requires conformance to ISO 9001-based requirements regardless of certification. Implementation of specific tasks may be at an overall RA level or at any appropriate level within RA.

3.0 RESPONSIBILITY

3.1 Top Leadership

Has ultimate responsibility for the management system.

3.2 Vice President of Quality

Has the delegated authority and responsibility for ensuring that all QMS requirements are documented, implemented, and maintained.

3.3 Global Quality Management Systems

Has the delegated responsibility and authority for promoting the use of and adherence to the management system.

3.4 Business Units/Functions/Departments

Have the responsibility for developing and implementing processes and procedures to support the QMS and the completion of duties specified in support of the QMS.

3.5 Local QMS Coordinator

Has the responsibility for implementing and managing the QMS at a facility or other defined level.

4.0 ROCKWELL AUTOMATION'S COMMITMENT TO QUALITY

Commitment to Quality

Since 1987, when the first facility was registered to ISO 9001, Rockwell Automation locations worldwide have been continuously ISO 9001 certified. Rockwell recognizes the importance ISO 9001 certification brings and it further exemplifies the worldwide recognition of Rockwell Automation's consistent and superior quality in customer service as well as assurance of high-quality products that include the leading brands of Industrial Automation.

Rockwell Automation Quality Policy

Quality is our Culture

Rockwell Automation is committed to making our customers more productive. We apply our unique expertise and technology to understand and consistently address their Industrial Automation and Connected Enterprise needs.

We fulfill the requirements of our customers and other interested parties by challenging ourselves, our suppliers, and our partners to continually improve the quality, simplicity, and value of our processes, products, services, and solutions. (900-20-01)

Quality Management System Registration

Our management system is registered to the ISO 9001 standard and our products and services are provided by processes that conform to all applicable clauses of the ISO 9001 standard such as Purchasing, Design, and Manufacturing. Rockwell Automation facilities are audited to these standards by an internationally recognized registrar. As evidenced by our continuing registration, we continue to meet or exceed all requirements.

Statement of Conformance

Rockwell Automation's well-established policies and procedures ensure the quality and reliability of our products. Products are developed, produced, and delivered under processes controlled by the Quality Management System and meet internal and external standards, specifications published in product literature, and customer requirements per purchase order or contract.

Throughout the manufacturing process, appropriate tests and inspections are performed per applicable standards. Many products are built in batches on automated electronic assembly equipment. Individual units are not necessarily physically observed by Quality personnel at each step, but data on every unit is collected at each stage and that data is monitored and acted upon by Quality personnel to continually improve.

This statement of conformance applies to all genuine Rockwell Automation products sold through and purchased from Rockwell Automation-authorized channels.

A certificate of conformance can be requested through Customer Inquiry (customerinquiry@ra.rockwell.com) or your Customer Quality representative.

4.1 Certifications

Many Rockwell sites, including the Milwaukee headquarters and 100% of the principal manufacturing sites as listed in our 10-K report, representing the majority of our manufacturing operations, are ISO 9001 registered and audited by third-party registrars. The Milwaukee headquarters and several other sites are on a common, multi-site certificate, while others may be on separate certificates while sharing a common QMS.

Copies of our current ISO 9001 certificates can be viewed at:

https://www.rockwellautomation.com/en-us/support/documentation/technical-data/iso9001ansiesd2020qua20180213-1749.html

Our current product certifications and technical documentation can be viewed at:

https://www.rockwellautomation.com/global/support/technical-documentation/overview.page

5.0 QMS SUMMARY

The RA Quality Management System is based on ISO 9001 and all clauses are considered applicable.

The purpose of the Quality Management System is to:

- Consistently provide products and services that meet customer and applicable statutory and regulatory requirements
- Enhance customer satisfaction

Evidence that the QMS is working effectively is demonstrated by:

- Having clearly documented or understood expectations
- Acting in accordance with expectations
- Achieving the desired results and/or acting on discrepancies

The way the QMS approaches this is to:

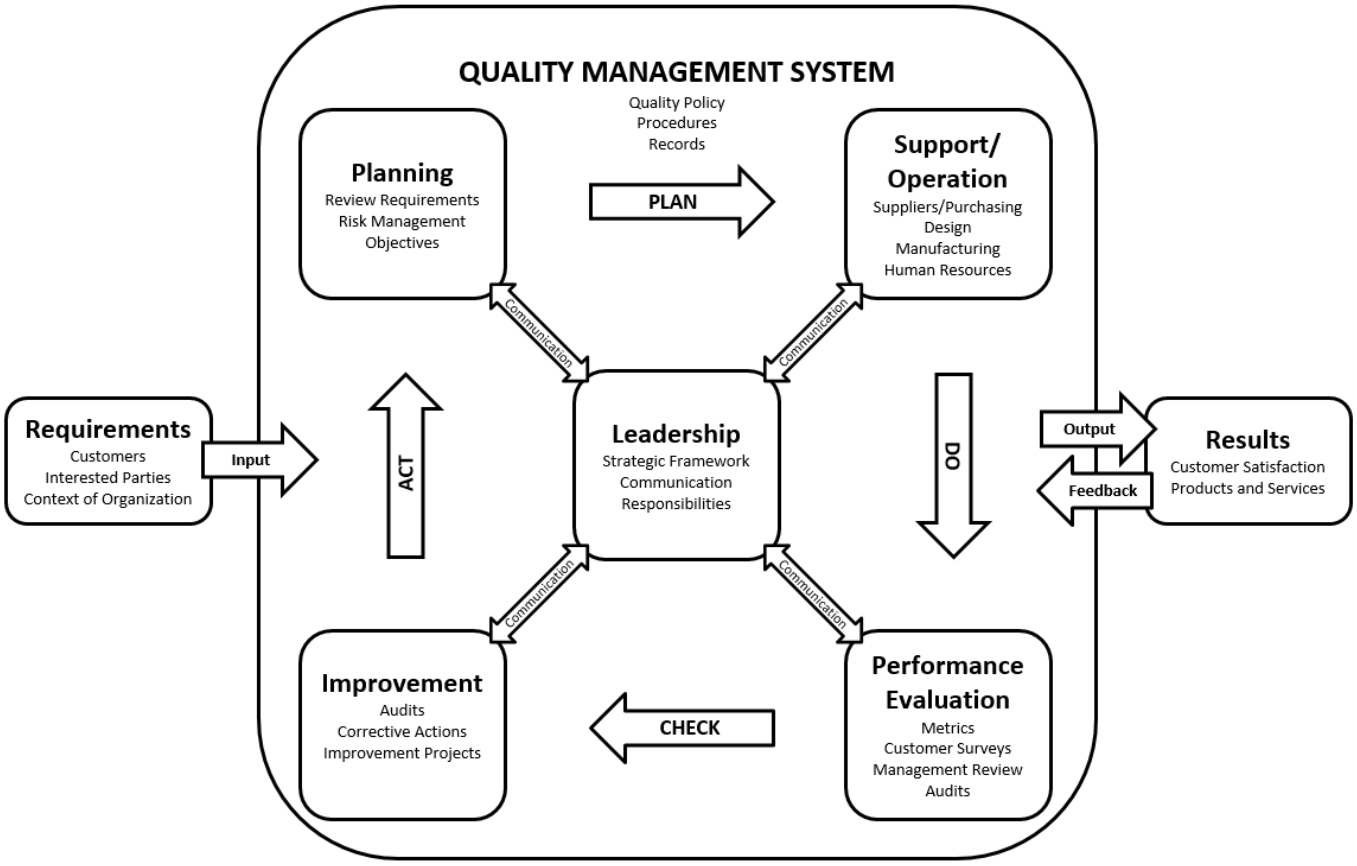
- Identify requirements and risks - what are the needs and what could prevent meeting those needs?
- Put things in place to address the requirements and risks - could include procedures, processes, goals, people, information, physical materials, etc.
- Plan for what to do when expectations are not met, and act to correct and/or improve

This can be captured in the key concepts of risk-based thinking and the plan-do-check-act cycle. Risks and opportunities are identified and acted upon. When risks are identified, they must be accepted, transferred, or mitigated. Plans are implemented and verified, and the results are used as in input to the next cycle of planning.

Processes intended for the entire organization may be defined in internal documents with a global scope. Otherwise, 900-20-02, Quality Management System Overview will provide the organization with the basic requirements and direction for further defining supporting processes at business/regional/local/other level. Supporting processes may include more requirements but may not be less restrictive than global processes.

The quality management system as a whole includes all of the processes defined at every level to support it.

The interconnectedness of processes must be considered; the input of one process may be the output of another, and the customer of one process may be a supplier to another. The Plan-Do-Check-Act cycle represents this at a high level.



The collection of procedures, their reference to each other, and the references to ISO clauses within procedures or the manual tables of contents demonstrate the connections.

Though each element of the QMS may impact others, the QMS is structured in a logical order to flow through the process of providing products and services that meet customer requirements:

- Scope of the QMS is defined
- Leadership establishes the QMS
- Plans are made to support the QMS
- Resources (people, documents, equipment, etc.) are put in place to facilitate the QMS
- Product requirements are determined
- Products are developed
- Suppliers are identified and controlled
- Products are built and delivered
- Performance is reviewed
- Improvement efforts are made

6.0 ORGANIZATION AND COMPANY INFORMATION

Current publicly available information is posted on our website, http://www.rockwellautomation.com

Company Overview:
http://www.rockwellautomation.com/global/about-us/company-overview.page

Investor Relations/Financial Reports:
https://ir.rockwellautomation.com/investors/

Capabilities:
https://www.rockwellautomation.com/global/capabilities/overview.page?

Corporate Responsibility:
https://www.rockwellautomation.com/en-us/company/about-us/integrity-sustainability/corporate-responsibility.html

Terms of Sale:
https://www.rockwellautomation.com/en-us/company/about-us/legal-notices/terms-and-conditionsofsale.html

Terms of Purchase:
https://www.rockwellautomation.com/en-us/company/about-us/legal-notices/terms-of-purchase.html

Product Catalog:
https://www.rockwellautomation.com/en-us/products.html

Ethics & Compliance *(Anti-Corruption, Trade Policy, Supply Chain/Conflict Minerals)*
https://www.rockwellautomation.com/en-us/company/about-us/integrity-sustainability/ethics-compliance.html

Rockwell Automation YouTube Channel:
https://www.youtube.com/channel/UC0q6j_EisHf1o_olWCvUHdA

Other Contacts:
For general Rockwell Automation information, please contact: customerinquiry@ra.rockwell.com

For Product Certification/Compliance Inquiries, please contact:
ProductCertification@ra.rockwell.com

For Product Environmental Compliance Inquiries, please contact:
ProductStewardship@ra.rockwell.com

For Country of Origin/NAFTA Certificates or Tariff Code Inquiries, please contact:
RAEXIMClassification@ra.rockwell.com

7.0 LEADERSHIP

Top management can be viewed online at:
https://ir.rockwellautomation.com/corporate-governance/executive-leaders/default.aspx
(this is the only publicly shared org chart)

Co Nguyen is Rockwell Automation's Vice President of Quality, reporting to the Senior VP of Integrated Supply Chain.

8.0 FACILITIES & EMPLOYEES

Rockwell Automation Headquarters is located at:
1201 South Second Street
Milwaukee, WI 53204

The business operates facilities in 80+ countries and more than 400 locations staffed by approximately 20,000 employees. For information about specific sites, contact customerinquiry@ra.rockwell.com

9.0 FREQUENTLY ASKED QUESTIONS

The following are common questions regarding our quality system and how we meet the requirements. In general, any question regarding the applicability of an ISO 9001 requirement can be answered "yes." Rather than listing every ISO 9001 requirement and the standard response of any ISO 9001 company, we focus on the Rockwell-specific implementation.

These answers reflect the overall Rockwell Automation QMS, and though we have standard process regardless of location or type pf product, there are details that may differ depending on the specific scope. For example, if we are providing custom engineered solutions, there are many factors that are governed by the specific contract, and if we're providing commercial off the shelf products we're governed by our standard terms and conditions of sale. And even with standard products, the details for a service may be different than software and that may be different than hardware, a controller has different design and manufacturing considerations than a pushbutton, a specific version of software may have been developed under a previous process, or one site may have special local conditions and requirements.

We need to fully understand the scope of the business and we need to confirm expectations about current and/or proposed business before we can fully address some questions. A standard checklist may not be answerable if it doesn't match the products and services we supply. The more detail you can provide regarding the scope/agenda, the easier it will be to address your questions efficiently and completely.

In addition to the FAQ below, there is a Software Development Process Overview Questions & Answers available at:
https://literature.rockwellautomation.com/idc/groups/literature/documents/ct/qms-ct027_-en-e.pdf

Any questions not answered in this document can be addressed to our Global Quality Management Systems group via our Customer Inquiry team. Please contact customerinquiry@ra.rockwell.com if further information is required.

Question	Answer	Internal Corporate Procedure Reference
Context of the Organization		
How does Rockwell determine the context of the organization, determine internal and external issues, and understand the needs of interested parties?	The Strategic Framework and the management review processes establish the context, issues, and interested parties of the organization. Business Units may further define their context, but they may not reduce the RA context or scope and they cannot contradict requirements or say that requirements of the QMS are not applicable if it could impact their ability to meet the needs of the QMS.	900-20-02, Quality Management System Overview
What is the scope of Rockwell's QMS?	The scope of the Quality Management System encompasses all activities, locations, and people within Rockwell Automation. This includes, but is not limited to the design, manufacture, re-manufacture, distribution, support, and service of automation components and systems. Everyone has the potential to impact quality, whether directly or indirectly involved in QMS activities, though not all activities occur at every site.	900-20-02, Quality Management System Overview
How is Rockwell's QMS defined?	The QMS is defined using the process approach, identifying inputs, outputs, sequence, interaction, resources, responsibilities, risks, evaluation, and improvement. At the corporate level, the 900 manual defines the global QMS processes. 900-20-02, Quality Management System Overview, states all ISO 9001 requirements as Rockwell requirements.	900-20-02, Quality Management System Overview
Leadership		
How does top management demonstrate leadership and commitment to the QMS?	Leadership demonstrates this through planning and communication, and direct involvement with quality management activities such as management review, developing the Strategic Framework, and setting objectives.	900-20-02, Quality Management System Overview
How does top management demonstrate customer focus?	Risks and opportunities that could affect customers are addressed in the Enterprise Risk Management process. Customer surveys are performed at top management's request and the results trigger actions from top management.	900-20-02, Quality Management System Overview
What is the Quality Policy and how is it communicated?	See section 4.0 above. This is the single quality policy for the entire organization, and it is documented in a corporate procedure, featured on posters and cards, included in various training modules and regular quality presentations, and reviewed during management reviews.	900-20-01, Quality Policy

Question	Answer	Internal Corporate Procedure Reference
How are roles, responsibilities, and authorities communicated?	Roles, responsibilities, and authorities are determined by job descriptions, position in the organization chart, in the responsibilities section of procedures, and by business and individual goals.	900-20-02, Quality Management System Overview
Planning		
How are risks and opportunities addressed?	Risks and opportunities and actions to address them are determined when considering the context of the organization and during regular business planning, such as the Enterprise Risk Management process. Risks can be accepted, transferred, or mitigated. There is no single, all-inclusive risk/change management process.	900-20-02, Quality Management System Overview
How are quality objectives set?	RA sets quality objectives at multiple levels. Some may apply to everyone while others apply to a narrow scope. Top management establishes the Strategic Framework to set the top-level priorities which are cascaded down. Business Units prepare quality plans and objectives as appropriate to meet their business requirements and the requirements of the Quality Management System. Continual improvement of the Quality Management System itself is an objective.	900-20-02, Quality Management System Overview
How are changes to the QMS handled?	Business needs may change, and the Quality Management System must adapt. However, changes must not impact the overall ability of the Quality Management System to meet the aims of promoting continual improvement and awareness of customer requirements and improving customer satisfaction.	900-20-02, Quality Management System Overview 900-20-47, QMS Document Management
Support		
How are resources determined and allocated?	It is the responsibility of Business Unit Management to provide and maintain adequate resources and competent personnel to perform activities and meet requirements as defined in the Quality Management System. These resources include workspace, equipment, personnel, supplies and supporting services such as information systems, along with any other human or physical factors that would affect the ability to comply with the procedures or quality plans.	900-20-02, Quality Management System Overview
How are monitoring and measuring resources controlled?	There is no single, universal system across all of RA, but each Business Unit has established effective systems to maintain accuracy and suitability of monitoring and measuring equipment, tooling, and software, and to control the selection, identification, maintenance, and calibration of equipment used to verify that products, services, and/or processes conform to specifications.	900-20-39, Calibration and Validation
How is organizational knowledge documented and shared?	Knowledge may be formally documented or informally understood. It can be made up of internal and external sources. The primary source is the collection of policies, procedures, work instructions, job aids, and training.	900-20-02, Quality Management System Overview

Question	Answer	Internal Corporate Procedure Reference
How is competence assured?	Interview criteria and performance reviews are used to verify that new and existing employees are competent and qualified to perform required tasks. There is not necessarily a specific list of training for every role – it is primarily the manager's responsibility to review and track training needs. Training, in various forms, is deployed as required to meet the identified needs or the general needs of the job or company.	Manual 800, Human Resources
How are QMS awareness and relevant information communicated?	There are communication processes between the various levels and functions to share relevant information. This includes information regarding the Quality Policy and the Quality Management System and its effectiveness, including the importance of meeting the Business Unit's goals and objectives as well as customer and legal requirements. This communication can take the form of all employee meetings or e-mails, down to one-on-one discussions.	900-20-02, Quality Management System Overview
How are procedures controlled?	Each Business Unit is responsible for meeting all requirements of the QMS and the supporting 900-level documents. The 900-level documents may require the Business Unit to establish supporting procedures, forms, or work instructions. The Business Unit may also create additional local documents to support or clarify the requirements of the 900-level documents. Business Units do not need to restate any requirements of 900-level or other higher-level procedures. Documents may be maintained either in hard copy or electronic form. Control of the 900-level procedures, as well as guidance for how to control all QMS procedures, is also defined in a 900-level procedure. All standard ISO control elements are addressed.	900-20-47, QMS Document Management
How are records controlled?	The need for specific records is detailed within each procedure and there is a master record retention policy and schedule for all RA. All standard ISO control elements are addressed.	900-20-33, Records Retention Procedure
What is the overall IT security control plan?	We have an Information Security Policy that defines the key elements related to the secure management of Rockwell Automation's information assets. It includes backup/recovery, disaster recovery, and security procedures.	Global Corporate Policy 980-04, Information Security Policy
What is the backup and recovery process?	Servers are backed up, backed up data is secured, backup failures logged and resolved, restores (recovery) are periodically tested for integrity and, if appropriate, follow the record retention policy.	IT Backup and Restore Process
What is the IT disaster recovery process?	We have a disaster recovery program, and annually, an IT system recovery test is performed to review the accuracy and completeness of the disaster recovery procedures of critical business systems.	IT Disaster Recovery Exercises

Question	Answer	Internal Corporate Procedure Reference
What is the procedure for IT security regarding: physical access, logical access, virus control?	Physical access to data centers or server rooms is restricted and monitored. Periodic review of log activity and Data Center access list are performed by Data Center management staff for any unauthorized access. Logical access consists of role-based access control with segregation of duties, and physical and virtual network segmentation. For virus control, end-point protection software is installed on all capable servers, desktop, and portable PCs.	Global Corporate Policy 980-04, Information Security Policy
Operation		
How are operational processes planned and controlled?	The groups that bring a product from an idea to an offering all work together within the same value stream to ensure smooth and complete hand offs from one process to the next. This includes product management, design, industrialization, manufacturing, quality and others.	900-20-02, Quality Management System Overview
How is customer communication handled?	Products are either sold based on published specifications or there are specific contracts for specific orders. Sales can be made through distribution channels or directly depending on the product and market. Product information is available on-line. Customers may be notified of changes, either by choice or as required. Customers can also contact tech support, distributors, or sales.	I2O-04-04, Product Change Management
How are customers' product and service requirements determined and reviewed?	The development process ensures that customer requirements are gathered and translated into specifications and confirms that expected specifications can be met, either working with product management and market expectations or by contract review directly with the customer.	100-11-02, Sales Contracts Review and Approval
How are product and service changes documented and communicated?	Changes may have internal and/or external impact. Changes to form, fit, or function require a catalog number change. Other changes would be communicated differently depending on the impact of the change. Changes are documented in updated specifications, drawings, and procedures.	I2O-04-04, Product Change Management
How is the design process controlled?	The Common Product Development (CPD) process is a standard design and development project methodology within RA. Business Units may define variations of CPD or may define their own unique process. In all cases, the requirements of ISO 9001 are met. Progress of activities is reviewed at appropriate intervals, including a final check at the completion of a project to ensure that all activities are completed or addressed, and that the product meets defined requirements. These requirements apply regardless of whether the work is performed internally by RA personnel or externally by suppliers or contractors under the direction of RA. Design activities themselves including the persistence of product requirements are addressed by the Rockwell Automation Product Lifecycle (RAPL) processes.	900-20-36, Common Product Development 900-20-72, RA Product and Solution Lifecycle I2O-04-10, Common Engineering Change Process

Question	Answer	Internal Corporate Procedure Reference
How are suppliers controlled?	Materials, products, and services purchased by Business Units must conform to specified requirements. Selected and approved suppliers are included on an approved supplier list. Suppliers are qualified based on their continuing ability to meet quality, cost, and delivery requirements, as well as the strength of their business.	900-20-25, Supplier Evaluation and Approval Process 900-20-68, Service and Process Supplier Approval and Evaluation Process
Is there a process for addressing suspect counterfeit parts?	Rockwell Automation (RA) has processes and procedures in place to mitigate supply chain risk. All suppliers to RA are evaluated and qualified. This process requires representatives from RA Supplier Quality and Sourcing to assess and monitor supplier capability and performance. This can include analysis of sample parts and on-site audits. Standard purchases can only be made from approved suppliers. If a non-standard purchase must be made from a broker, we follow a process that evaluates the potential broker and the specific parts and includes further analysis by RA's Component Engineering. This process requires the broker to declare that parts are genuine and can include anti-counterfeit inspections by the broker. If there is any reason to further inspect any parts when they arrive at a RA facility, the RA Supplier Quality group can create inspection criteria. This will flag incoming parts and provide inspection instructions. Receiving personnel are trained according to multiple local work instructions on how to respond to inspection requests. If anything does not pass inspection, it is processed as potentially non-conforming material and segregated. If the parts are determined to be counterfeit, corrective action would be taken with the supplier and any suspect products would be treated as non-conforming material. Production personnel are trained to look for appropriate labeling and packaging before use. They are also trained to not use parts that appear damaged.	900-20-70 Counterfeit Component Prevention 900-20-52, Independent Distributor Procurement Process 900-20-25, Supplier Evaluation and Approval Process

Question	Answer	Internal Corporate Procedure Reference
How are products and services manufactured and/or provided under controlled conditions?	Documented procedures are prepared for processes where the absence of such instruction would adversely affect quality. Unless otherwise required for specific, documented reasons, the latest revision of procedures must be used. Products passing through the manufacturing process are be inspected, tested, and identified at pre-determined points as defined by the Quality Plan, documented procedures and contractual requirements. Documented procedures exist that specify the qualification requirements for new and revised processes, products, services and equipment. Workmanship standards exist and apply to RA products and services, except as required by contract or documented exception. Acceptance standards for workmanship and product characteristics are defined in written standards, representative samples, or by other means. Production equipment that directly affects product conformance is controlled, maintained, and calibrated in accordance with an established control and maintenance system, to ensure continuing process capability.	900-20-32, Manufacturing Change Management and Initial Process/Equipment Validation 900-20-59, Preventive and Autonomous Maintenance
How are outputs identified?	Business Units establish systems to positively identify, and indicate the status of, materials and product at all stages of production, packaging, installation, servicing, repair, modification, and/or use as required to evaluate performance or when required by customer and/or contract. This can include computer-based systems based on machine-readable identification such as bar codes.	900-20-02, Quality Management System Overview
How is property owned by customers or external providers controlled?	Unless specified by contract, RA treats customer or external provider property with the same care as company property. This includes physical property as well as intellectual property. The customer or external provider is notified if there are any issues with their property.	900-20-02, Quality Management System Overview
How are outputs preserved and protected?	The specific preservation requirements may vary by Business Unit. Business Units are responsible for ensuring that systems exist to control the preservation of material to prevent and detect damage or deterioration. Requirements could include shelf life, temperature, humidity, ESD sensitivity, physical limitations, or other customer/industry standards. The status (pass/fail, expired, time exposed to temperature/humidity, etc.) of parts and products are identified in such a way as to prevent unintended use. FIFO or other inventory control methods are used to ensure that parts and products that degrade over time are used prior to their expiration date. Any suspected damaged parts or product must be considered as nonconforming until determined otherwise. Parts and products must be handled, stored, and transported (internally and to the customer) in a way that prevents physical and electronic damage. This includes using appropriate packaging.	900-20-29, Electrostatic Discharge (ESD) Control Program 900-20-38, Control of Material Affected by Shelf Life
How are post-delivery requirements met?	Business Units establish and maintain processes to ensure that customer support and service requirements are defined and implemented if such services are specified, implied, or required by contract. Field Service provides reactive, preventive, and proactive onsite support around the world.	900-20-02, Quality Management System Overview

Question	Answer	Internal Corporate Procedure Reference
How are production and service provision changes controlled?	Business Units establish processes to implement and control temporary (limited in time and/or scope) and permanent process changes. This could include processes like "Process Change Notices" and "Manufacturing Change Management and Initial Process/Equipment Validation." The change and its impact are considered and documented. Procedures are updated as necessary and training on the new process is provided.	900-20-32, Manufacturing Change Management and Initial Process/Equipment Validation
How is the release of product and services controlled?	Acceptance criteria is established when the process is defined. This could include inspection or test or authorization by a person.	900-20-32, Manufacturing Change Management and Initial Process/Equipment Validation
How are nonconforming outputs controlled?	Nonconforming outputs can be discovered and controlled to prevent unintended use by various processes. RA-wide processes may exist for certain situations. Nonconforming material is marked/identified as such and segregated to a separate area to avoid accidental use. Material is reviewed by cross-functional teams to determine disposition.	900-20-05, Stop Order Process 900-20-15, Assessment of Post Release Product Anomalies 900-20-43, The Preparation and Use of the Product Quality Waiver 900-20-61, Material Review Board (MRB)
Performance Evaluation		
What is monitored and measured?	Monitoring and measurement needs may vary, but there are some common metrics such as: Outgoing Quality, Warranty Claims to Sales, Past Due Shipments to Customer Want and Schedule/Promise Date, Purchased Material Quality Performance, Manufacturing Process Quality, Rolled Throughput Yield Loss, Initial Return Rate (IRR), MRB Cycle Time Metric, Field MTBF Calculations	900-25 series of metrics procedures
How is customer satisfaction monitored?	There are many customer touch points. Customer Care, Remote Support Services, Customer Experience, Customer Quality, and Sales are all possible sources of customer feedback within RA ranging from individual customer interactions up to a global customer survey.	900-20-02, Quality Management System Overview

Question	Answer	Internal Corporate Procedure Reference
How is data analyzed and evaluated?	Data collection systems exist to provide data to the function/department responsible for analyzing and reporting issues related to the effectiveness of the Quality Management System and overall quality improvement. The systems include methods for analyzing the information collected and extracting specific details. SAP is the primary source of enterprise data, though other data systems exist. Where appropriate, statistical techniques may be employed. Data is presented objectively so that well-informed decisions can be made. To facilitate transparency, full disclosure of assumptions, gaps, and exceptions are documented wherever possible.	900-20-50, Measurement System Analysis
How are internal audits managed?	There is a corporate procedure to outline the quality audit program for Rockwell Automation and to describe the method used for conducting first-party (Internal) Quality Audits. The audit process meets and exceeds the requirements of ISO 9001. There is also a standard internal auditor training class.	900-20-30, Internal Quality Audits
How is management review conducted?	Formal Management Review is only required by top management of the company overall and it addressed with a combination of regular meetings and specific presentations; however, internal communication is established at all levels of Rockwell Automation management as necessary to communicate relevant information regarding the quality management system.	900-20-03, Quality Management Review
Improvement		
How are corrective actions managed?	Anyone can begin the corrective action process. Depending on the processes involved, different corrective action methods may be employed. Business Units establish, document, and maintain systems for identifying nonconformities and initiating corrective actions. The formality of the corrective action process depends on the risk involved. Simple issues may be addressed on the spot, while others may require more in-depth problem-solving methodologies and the involvement of multiple functions.	900-20-27, 8-Disciplines (8-D) Problem Solving Process 900-20-71, Corrective Action
How is the QMS continually improved?	There is no separate, continual improvement program. Continual improvement is part of each element of the QMS. Every requirement for analysis and action contributes to the continual improvement of the QMS. Metrics are continually reviewed and drive longer-term strategic planning as well as more immediate corrective actions and improvement projects.	900-20-02, Quality Management System Overview

Question	Answer	Internal Corporate Procedure Reference
Additional Questions		
Are your processes and products 21 CFR Part 11 compliant?	Our commercial off the shelf products may include 21 CFR Part 11 functionality, but they must be configured appropriately to provide compliance. It is not compliant of the box. A custom solution may be compliant if specified by contract.	White Paper: https://literature.rockwellautomation.com/idc/groups/literature/documents/wp/secur-wp005_-en-p.pdf
Do you follow GAMP and GxP practices?	Where required by industry, personnel are trained in GxP practices and solution providers may validate systems with a GAMP approach, but we do not necessarily make any overarching claims regarding GxP adherence.	
Will you allow regulatory agencies to audit you?	Typically, we do not open ourselves to regulatory audits for regulations we are not directly required to meet or make any claims about meeting.	