ISO 9001:2015 Translated into Plain English

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4. Context

4.1 Understand your organization and its context (cont)

- Identify and understand your organization's **context**
  - Consider internal and external issues that affect your ability to achieve the intended **QMS outcomes/results** (context issues)
  - Consider the organization's purpose, its strategic direction, its internal and external issues, and its ability to achieve what it has planned to do (strategic direction, internal issues, external issues, ability to achieve what is planned)
  - Consider the interest groups that are relevant to your organization's **QMS** and the relevant requirements of those interest groups (interest groups, interest groups that are relevant to the QMS and their requirements)
- Monitor and review information about these issues (monitor and review)
  - Consider the overall context of your organization's quality management system (QMS)

4.2 Identify the needs and expectations of interested parties

- Identify the parties who affect or could affect your QMS
  - Consider interested parties that affect or could affect your QMS (interested parties that affect or could affect the QMS)
  - Consider how interested parties could affect your ability to provide products and services that meet customer and applicable statutory and regulatory requirements (how interested parties affect ability to meet customer and applicable statutory and regulatory requirements)

4.3 Define the scope of your quality management system

- Clearly document and know what your QMS should apply to
  - Key boundary and applicability information to define your scope
  - Consider your organization's context when you define your scope
- Document the scope of your quality management system (QMS)
  - Document your organization's QMS scope, including details of what organization's QMS will and doesn't apply to
  - Document why your organization's QMS doesn't apply to parts of the standard that are included in your scope of QMS
  - Document how your organization's QMS meets the intent of those parts of the applicable standard you excluded from your scope of QMS
- Maintain this document that defines the scope of your QMS
  - Control your organization's QMS scope document

4.4 Develop a QMS and establish documented information

- Develop your organization's QMS and its processes
  - Develop a **business-focused quality management system (QMS)**
    - Determine the **processes** that your QMS needs
    - Determine the sequence of your QMS processes
    - Determine methods needed to manage processes
    - Determine resources needed to support processes
    - Determine responsibilities for processes and QMS
    - Determine **risks** and opportunities for each processes
    - Determine methods needed to evaluate processes
    - Determine how to measure and evaluate processes
    - Apply criteria needed to operate and control your processes
    - Apply methods needed to operate and control your processes
  - Maintain your processes based quality management system
  - Improve your processes based quality management system
- Maintain documented information that supports your QMS
  - Maintain documented information to support processes
    - Control documents which support processes operations
    - Retain records which show that you are being followed
    - Control records which show that plans are being followed

5. Leadership

5.1 Provide leadership by focusing on quality and customers

- Demonstrate your leadership by encouraging a focus on quality
  - Accept responsibility for your QMS
  - Ensure your quality management system (QMS) is effective
  - Ensure that **quality policy** and **quality objectives** are established
  - Ensure that **QMS** achieves its intended results
  - Ensure that your QMS achieves its intended results
  - Promote your **quality culture** to stakeholders
  - Promote the **quality** of your products and services
  - Promote the **quality** of your processes and QMS
  - Ensure that your QMS achieves its intended results
  - Communicate your commitment to the QMS
  - Enable quality management to improve
  - Expect managers to be accountable for their QMS
  - Expect managers to be accountable for their QMS
  - Promote the use of **process approach**
- Demonstrate your leadership by encouraging a focus on customers
  - Expect personnel to focus on customers
  - Expect personnel to manage all relevant requirements
  - Expect personnel to focus on enhancing customer satisfaction
  - Expect personnel to focus on enhancing customer satisfaction

5.2 Provide leadership by establishing a suitable quality policy

- Establish your organization's **quality policy**
  - Develop an appropriate **quality policy**
    - Make sure that it supports your organization's purpose
    - Make sure that it deals with your **organization's context**
    - Make sure that it supports your strategic direction
    - Make it a commitment to satisfy applicable requirements
    - Make it a commitment to continual QMS improvement
  - Implement your organization's quality policy
  - Maintain your organization's quality policy
- Communicate your organization's quality policy
  - Communicate your organization's quality policy
  - Communicate your organization's quality policy
  - Apply your organization's quality policy

5.3 Provide leadership by defining roles and responsibilities

- Assign QMS roles, responsibilities, and authorities
  - Communicate QMS roles, responsibilities, and authorities

6. Planning

6.1 Define actions to manage risks and opportunities

- Consider risks and opportunities when you plan your **QMS**
  - Plan the development of your organization's QMS
    - Plan how your organization will address its risks and opportunities (how your organization's QMS will address its risks and opportunities)
    - Plan how your organization will address its risks and opportunities (how will its QMS will be actions integrated into its processes and how will its QMS evaluate the effectiveness of these actions)
    - Figure out what you need to do to address the risks and opportunities that affect your ability to achieve the intended results of your QMS (what do it to address the risks and opportunities affecting its intended results)
- Plan how you're going to manage risks and opportunities
  - Plan how you're going to manage risks and opportunities
    - Define actions to address risks and opportunities
    - Define actions that you need to undertake the risks and opportunities that affect your ability to achieve the intended results of your QMS (it's actions to manage its risks)

6.2 Define quality objectives and develop plans to achieve them

- Establish quality objectives for all relevant areas
  - Clarify criteria for setting **quality objectives**
  - Establish your organization's quality objectives
  - Communicate your quality objectives
  - Document your quality objectives
  - Control your quality objectives
  - Update your quality objectives
- Develop plans to achieve objectives and evaluate results
  - Establish plans to achieve quality objectives
    - Plan how you're going to evaluate your results

6.3 Plan changes to your quality management system

- Plan changes to your quality management system
  - Consider why your organization needs to make changes
  - Consider consequences that unintended changes could cause
  - Consider the consequences that changes could potentially produce
  - Consider the availability of resources whenever you make changes
  - Consider the integrity of your QMS whenever you make changes

7. Support

7.1 Support your QMS by providing the necessary resources

- Provide internal and external resources for your **QMS**
  - Determine the resources that your QMS needs
  - Provide the resources that your QMS needs
- Provide suitable people for your QMS and your processes
  - Provide the people that your QMS needs to be effective
    - Provide the people that you need in order to operate processes
    - Provide the people that you need in order to control processes
- Provide the infrastructure that your processes need have
  - Determine the **infrastructure** that your processes need
    - Determine what infrastructure your organization needs to operate its processes (what infrastructure does your organization need to operate its processes)
    - Provide the infrastructure that your processes need
- Provide the appropriate environment for your processes
  - Determine the environment that your processes need
    - Determine what environment your organization needs to operate its processes (what environment does your organization need to operate its processes)
    - Provide the environment that your processes need
- Provide monitoring, measuring, and traceability resources
  - Provide suitable measurement traceability resources
    - Determine what measurement traceability resources your organization needs to operate its processes (what measurement traceability resources does your organization need to operate its processes)
    - Provide suitable measurement traceability resources
- Provide organizational knowledge for your processes
  - Determine the knowledge that your organization needs to have
  - Acquire the knowledge that your organization needs to have
  - Make organizational knowledge available to the extent required
  - Maintain required levels and manages it knowledge and information
  - Address changes and trends in knowledge and information

7.2 Support your QMS by ensuring that people are competent

- Identify those under your control who do work that affects quality
  - Clarify your organization's quality competence requirements
  - Acquire competence whenever shortcomings are discovered
  - Develop competence when it's cost effective to do so
  - Evaluate the effectiveness of actions taken to acquire competence

7.3 Support your QMS by instilling your culture into people

- Support your QMS by instilling QMS communications
  - Make your organization's QMS communications effective
  - Figure out how internal communication will be handled
  - Figure out how external communications will be handled

7.4 Support your QMS by controlling documented information

- Develop documented information that your QMS needs
  - Control documents that your organization's QMS needs
    - Control documents that your organization's QMS needs
    - Consider personnel when you establish documents and records
    - Consider processes when you establish documents and records
    - Consider products when you establish documents and records
    - Consider services when you establish documents and records
    - Consider what you establish documents and records
    - Select all the documents and records that your QMS needs
    - Select all documents that your organization's QMS needs
    - Select all essential documents and records that your QMS needs
- Manage the creation and updating of documented information
  - Make sure that your organization's QMS documents and records are identified and described
  - Make sure that your organization's QMS documents and records are in a suitable format and media
  - Make sure that your organization's QMS documents and records are reviewed and approved
- Control the management and use of documented information
  - Control your QMS documents and records so they are available
    - Control Your QMS documents and records are available
    - Control Your QMS documents and records are suitable
    - Control Your QMS documents and records are adequate
    - Control Your QMS documents and records are protected
    - Control Your QMS documents and records are accessible
    - Control Your QMS documents and records are adequate
    - Control Your QMS documents and records are protected
    - Control Your QMS documents and records are adequate
    - Control Your QMS documents and records are protected
    - Control Your QMS documents and records are protected
  - Control how your QMS documents and records are controlled
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8. Operations

8.1 Develop, implement, and control your operational processes

- Plan the implementation and control of operational **processes**
  - Plan your processes to implement and control operational processes
  - Plan your plans to implement and control operational processes
  - Control planned operational processes changes and modifications
  - Review suitable operational processes documents and records

8.2 Determine and document products and service requirements

- Communicate with customers and manage customer property
  - Communicate with customers
    - Provide customer information
    - Obtain information from customers
  - Manage customer property
    - Control property supplied by customers

8.3 Clarify all product and service requirements and develop it

- Clarify your product and service requirements and requirements
  - Verify that you can clearly state product and service requirements
- Review product and service requirements and record results
  - Review the requirements before you accept orders from customers
    - Review product & service requirements before accepting orders
    - Verify differences between original product and final order
    - Review product & service requirements before accepting orders
  - Review product and service requirements when they change
    - Document results of product and service requirements reviews
    - Document new or changed product and service requirements

8.4 Control documents when product and service requirements change

- Control of relevant documented information to reflect changes in product and service requirements (control of documented information)
  - Review and approve documents and records that describe product and service requirements before they are issued

8.5 Establish a process to design and develop products and services

- 8.5.1 Create an appropriate design and development process
  - Establish an appropriate design and development process
  - Implement an appropriate design and development process
- 8.5.2 Plan product and service design and development activities
  - Plan your design and development stages and events
    - Consider design and development processes complexities
    - Consider design and development process complexities
    - Consider design and development process requirements
    - Consider design and development process participation
    - Consider design and development process participation
    - Consider design and development process responsibilities
    - Consider design and development process responsibilities
    - Consider design and development process resources
- 8.5.3 Determine product and service design and development inputs
  - Clarify your product and service design and development inputs
  - Define product and service design and development inputs needs
  - Consider product and service design and development inputs needs
- 8.5.4 Identify how design and development process will be controlled
  - Control product and service design and development activities
    - Control how design and development results are defined
    - Control how design and development reviews are carried out
    - Control how design and development reviews are carried out
    - Control how design and development verifications are done
    - Control how design and development validations are done
    - Document product and service design and development activities
- 8.5.5 Clarify how design and development outputs will be produced
  - Control product and service design and development outputs
    - Control that design and development outputs are adequate
    - Ensure that outputs are capable of supporting product processes
    - Ensure that outputs include or refer to acceptance criteria
    - Ensure that outputs can be used for validation purposes
    - Control design and development output documents and records
    - Control design and development output documents and records
- 8.5.6 Identify how changes will be managed in design and development
  - Control changes during or subsequent to design and development
  - Control changes during or subsequent to design and development
  - Control changes during or subsequent to design and development
- 8.6 Monitor and control external processes, products, and services
  - 8.6.1 Confirm that external products and services meet requirements
    - Establish controls for external processes, products, and services
    - Establish controls for external processes, products, and services
    - Determine criteria where reliable, if outside national providers
    - Use criteria to control external process, product, and providers
    - Use criteria to monitor the performance of an external provider
    - Use criteria to evaluate your organization's external providers
  - 8.6.2 Control how to manage purchased products and services
    - Control how to manage purchased products and services
    - Control how to manage purchased products and services
    - Control how to manage purchased products and services
    - Control the control that external process, product, and service provides to your organization's QMS and the control that it exists in your QMS
    - Develop criteria for external providers
    - Develop criteria for external providers
    - Implement controls for external process, product, and service
  - 8.6.3 Discuss your organization's requirements with external providers
    - Clarify what you expect from external providers
    - Clarify your organization's process requirements
    - Clarify your organization's product requirements
    - Clarify your organization's service requirements
    - Clarify your organization's equipment requirements
    - Clarify your organization's transport requirements
    - Clarify your organization's packaging requirements
    - Clarify your organization's methodological requirements
    - Clarify your organization's monitoring and control requirements
    - Clarify your organization's verification or validation requirements
    - Discuss your organization's requirements with external providers
- 8.7 Manage and control production and service provision activities
  - 8.7.1 Establish controls for production and service provision
    - Implement controlled conditions for production
    - Implement controlled conditions for service provision
    - Implement controlled conditions for delivery process
    - Implement controlled conditions for service provision
  - 8.7.2 Identify your needs and control that unique identity
    - Use suitable means to identify outputs
    - Identify outputs throughout processes
    - Identify outputs throughout service provision
    - Control unique identity of outputs
    - Control unique identity if traceability is required
  - 8.7.3 Protect property owned by customers and external providers
    - Identify property belonging to customers and external providers
    - Verify property belonging to customers and external providers
    - Protect property belonging to customers and external providers
    - Monitor property belonging to customers and external providers
    - Document property belonging to customers and external providers
  - 8.7.4 Preserve outputs during production and service provision
    - Preserve outputs during production and service provision
    - Consider using identifying, handling, packaging, storing, and protecting outputs during production or service provision
    - Consider using identifying, handling, packaging, storing, and protecting outputs during production or service provision
    - Consider using identifying, handling, packaging, storing, and protecting outputs during production or service provision
    - Consider using identifying, handling, packaging, storing, and protecting outputs during production or service provision
  - 8.7.5 Develop and control post-delivery activities
    - Clarify your organization's post-delivery requirements
    - Clarify your organization's post-delivery requirements
    - Clarify your organization's post-delivery requirements
    - Identify activities that need to be carried out after service delivery
    - Identify activities that need to be carried out after service delivery
    - Comply with your organization's post-delivery requirements
  - 8.7.6 Control changes for production and service provision
    - Control changes for production and service provision
    - Control changes for production and service provision
    - Control changes for production and service provision
    - Evaluate the need to control changes
    - Evaluate the need to control changes
- 8.8 Implement arrangements to control product and service release
  - Establish planned arrangements to verify products or each stage
  - Verify that product requirements are met at appropriate stages
  - Verify that product requirements are met at appropriate stages
  - Document the verification of product requirements
  - Document the verification of product requirements
- 8.9 Control nonconforming outputs and document actions taken
  - 8.9.1 Identify and control nonconforming outputs to prevent unintended use
    - Identify outputs that do not conform to their requirements
    - Evaluate nonconforming outputs and examine their impact
    - Control nonconforming outputs to prevent unintended use
    - Notify nonconforming outputs nonconforming impacts are concerned
  - 8.9.2 Document nonconforming outputs and the actions that are taken
    - Document your organization's nonconforming outputs
    - Document the actions and the decisions taken to prevent nonconforming outputs from being used or delivered

9. Evaluation

9.1 Monitor, measure, analyze, and evaluate QMS performance

- 9.1.1 Plan how to monitor, measure, analyze, and evaluate
  - Plan how you're going to monitor, measure, analyze, and evaluate your organization's QMS (how your organization's QMS will be monitored, measured, analyzed, and evaluated)
- 9.1.2 Find out if customer needs and expectations are being met
  - Establish methods that can be used to monitor perceptions
  - Establish methods that can be used to monitor customer satisfaction
- 9.1.3 Evaluate performance, effectiveness, conformity, and satisfaction
  - Analyze your monitoring and measurement results
    - Analyze and evaluate appropriate data and information
    - Use your analytical results to evaluate performance
    - Use your analytical results to evaluate conformity
    - Use your analytical results to evaluate conformity
    - Use your analytical results to evaluate satisfaction

9.2 Conduct audits to examine conformance and performance

- 9.2.1 Audit your quality management system of planned intervals
  - Conduct internal conformance audits at planned intervals
    - Determine if your organization's QMS meets requirements
    - Determine if your organization's QMS is effective
- 9.2.2 Develop an internal audit program for your organization
  - Plan the development of your internal audit program arrangements
    - Develop a program that can focus on it QMS's main concerns
    - Develop it program that can determine if your QMS is effective
    - Develop it program that can determine if your QMS is effective
    - Establish internal audit planning requirements
    - Establish internal audit requirements
    - Establish internal audit schedules
    - Establish internal audit schedules

9.3 Perform top management reviews and document your results

- 9.3.1 Review suitability, adequacy, effectiveness, and direction
  - Review your organization's QMS at regular intervals
  - Review the suitability of your organization's QMS
  - Review the adequacy of your organization's QMS
  - Review the effectiveness of your organization's QMS
  - Review the direction of your organization's QMS
- 9.3.2 Use and perform management reviews of planned intervals
  - Plan your organization's management review activities
  - Schedule your organization's reviews of planned intervals
  - Review your organization's quality management system

9.3 Demonstrate management review outputs and document results

- Document outputs management review results
  - Document outputs management review results

10. Improvement

10.1 Determine improvement opportunities and make improvements

- Consider ways of enhancing customer satisfaction
  - Consider opportunities to support innovation
  - Consider opportunities to take corrective action
  - Consider opportunities to transition your operations
  - Consider opportunities to improve your operations
  - Determine and select opportunities for improvements
    - Identify opportunities to meet customer requirements
    - Identify opportunities to address customer complaints
    - Make various improvements and enhance satisfaction

10.2 Control nonconformities and take corrective action and consequences

- React to your organization's **nonconformities**
  - Control and correct your nonconformities
  - Evaluate the need to eliminate causes
  - Evaluate the need to eliminate causes
  - Implement corrective actions to eliminate causes
  - Review the effectiveness of your corrective actions
- 10.2.2 Document your nonconformities and the actions that are taken
  - Document your organization's nonconformities
  - Document your organization's corrective actions
  - Document your organization's corrective actions results

10.3 Review the suitability, adequacy, and effectiveness of your QMS

- Consider innovation, analysis, and management review results
- Use results to confirm that your QMS needs must be addressed
- Improve the suitability, adequacy, and effectiveness of your QMS

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