



This checklist is for Process Approach based internal auditing. It is divided into sections corresponding to the quality system processes defined in the Process Map. In this checklist the Process Map is included on the first page, but in an integrated documentation the Process Map should only be included in the Quality Manual. The Process Map and this audit checklist must call out the same processes. When you edit the Process Map to fit your company, remember to also make corresponding changes in the checklist.

This is also an ISO 9001 compliance checklist. The requirements for each process are paraphrased from ISO 9001 and there is a reference to the corresponding clause of the standard (first column). The checklist is carefully designed to completely cover all requirements of the ISO 9001 standard. If, when customizing the Process Map, you delete or add processes, make sure that you re-associate the corresponding clauses in ISO 9001 and don't leave any out (e.g., maintain completeness of the checklist in regard to compliance with ISO 9001).

You should customize this checklist on three levels: 1) align it with any changes in the Process Map, 2) further develop the "Requirements" column to add other relevant requirements (if any), and 3) edit the "What to look for and how" column to make it appropriate to the products, operations, practices and issues that are relevant in your company. The third item in particular will require the most customizing.

Product Realization Process PRP 01 – Sales and Order Processing				
ISO 9001	Requirements	What to look for and how	Comply	Auditor notes and evidence
7.2.1	Determine product requirements <ul style="list-style-type: none"> ▪ specified by the customer (including delivery and post-delivery); ▪ not stated by the customer, but necessary for specified or intended use; ▪ statutory and regulatory requirements related to the product; and ▪ any additional requirements determined by the company. 	<i>How are customer requirements determined and communicated? Are they documented? Who processes this information and how is it done? Are there written procedures/instructions and/or training? Are there any requirements that are not stated by the customer but are necessary? Are there any regulatory requirements? Who determines, and how, what these additional requirements might be? Are they documented? How?</i> Check a sample of orders to verify that procedures, instructions and/or training are being followed. Interview employees and review customer complaints to find out whether there is history of order requirements that were misunderstood and/or incomplete.	Note "Yes" for compliance and "No" for noncompliance.	
7.2.2	Prior to the commitment to supply product, review requirements related to the product to ensure that <ul style="list-style-type: none"> ▪ requirements are defined, ▪ any discrepancies and ambiguities are resolved, and ▪ company is able to meet the requirements. Maintain review records.	<i>How are customer requirements reviewed, and by whom? Are there written procedures, instructions, checklists, and/or training. Are there records demonstrating that the required reviews are being conducted for every order?</i> Check a sample of orders to verify that procedures, instructions and/or training are being followed. Interview employees and review customer complaints and on-time delivery records to find out any cases of orders that were shipped late due to lack of adequate capacity to fulfill these orders.		
7.2.2	Where product requirements are not	<i>Is it permissible to take and accept verbal orders? If so,</i>		

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	documented (not communicated in writing), confirm the requirements before accepting the order.	<i>are these orders confirmed? How are such orders confirmed? Ask for records (copies) of the confirmations. Interview personnel to find out whether they were consistently trained/instructed to confirm verbal orders.</i>		
7.2.2	When changing or amending orders, ensure that relevant documents are amended and that changes are communicated to relevant personnel.	<i>How are change orders processed? Is there a system for amending documents? Are there written instructions, procedures and/or training? How is information about order changes communicated to relevant departments/personnel within the company? Review a sample of change orders to verify that procedures, instructions and/or training are being followed. See if you can uncover any past problems caused by mishandling of change orders.</i>		
7.2.3.a 7.2.3.b	Determine and implement arrangements for <ul style="list-style-type: none">▪ communicating product information,▪ handling enquiries, orders and change orders.	<i>Are processes for communicating with customers adequately defined, to include policies, assignment of authorities and responsibilities, and methods (procedures, instructions, training)? Are these processes consistently implemented? Verify that product brochures/specifications and other product information (including the internet site) are current.</i>		

Product Realization Process PRP 02 – Purchasing				
ISO 9001	Requirements	What to look for and how	Comply	Auditor notes and evidence
7.4.1	Control suppliers and the purchased product to ensure that the product conforms to specified purchase requirements.	<i>How are suppliers controlled: initial selection evaluations, ongoing monitoring, audits of supplier's QMS and/or manufacturing processes, requests for corrective actions? How is purchased product controlled: review of quality records (SPC charts, inspection reports, lab test results, etc.), receiving inspection? Who makes these decisions?</i>		
7.4.1	Evaluate and select suppliers based on their ability to supply products conforming to specified requirements. Establish evaluation and selection criteria. Maintain records or supplier evaluations and related actions.	<i>Are suppliers evaluated and reviewed before they are approved? What are the scope, extent and criteria for evaluating and approving suppliers? Who decides? How is the approval documented (an approved vendor list)? Are there records of initial supplier evaluations? Select randomly and review a sample of supplier evaluation and monitoring files. Is their approval status clearly authorized? Is their performance consistently monitored? In the event of nonconforming deliveries, are they required to implement corrective actions? Is there a follow up?</i>		
7.4.2	In purchasing specifications include, where appropriate <ul style="list-style-type: none"> ▪ requirements for approval of product, procedures, processes and equipment; ▪ requirements for approval of personnel, and ▪ quality management system requirements. 	<i>Where appropriate, are there requirements for certificates, inspection reports, SPC data, approval of samples, etc. included in purchasing documents? Are there any requirements with regard to supplier's quality management system? Review a sample of purchase orders, especially those where the product is expected to come with certificates.</i>		
7.4.2	Ensure adequacy of purchasing specifications before they are forwarded to suppliers.	<i>How is adequacy of purchasing documents ensured? Are the documents reviewed before release? Are there standard, pre-approved, specifications in the system? What other methods are used? See if you can uncover any past problems caused by errors or omissions in purchasing documents.</i>		

Product Realization Process PRP 03 – Receiving

ISO 9001	Requirements	What to look for and how	Comply	Auditor notes and evidence
7.4.3	Establish and implement activities for ensuring that purchased products meet specified purchase requirements.	<i>What is being done to ensure purchased product conformity: certificates or inspection reports from supplier or independent labs, SPC records, Cpk or Ppk requirements, in house receiving inspection, supplier's QMS certification? Select a sample of purchased product categories and investigate for each what activities or arrangements are planned to ensure their conformity, how this plan is documented and communicated, and whether it is consistently implemented.</i>		
7.4.3	When intending to perform product verification at supplier premises, define verification arrangements and methods in the purchasing documents.	<i>Is this relevant? If so, review a sample of purchase orders or contracts to ascertain that product verification and release methods are defined in the purchasing documents.</i>		

Checklists for the remaining 16 processes listed below are not included in the DEMO version of the software.

Product Realization Process PRP 04 – Inventory Management**Product Realization Process PRP 05 – Production****Product Realization Process PRP 06 – Delivery****Product Realization Process PRP 07 – Inspection, Test and Metrology****Product Realization Process PRP 08 – Production and Quality Planning****Product Realization Process PRP 09 – Product Design**

Measurement and Improvement Process MIP 01 – Control of Nonconforming Product

Measurement and Improvement Process MIP 02 – Internal Audits and Analysis of Data

Measurement and Improvement Process MIP 03 – Corrective and Preventive Action

Measurement and Improvement Process MIP 04 – Customer Complaints & Satisfaction

Management Responsibility Process MRP 01 – Planning and Objectives

Management Responsibility Process MRP 02 – Management Review

Management Responsibility Process MRP 03 – Continual Improvement

Resource Management Process RMP 01 – Personnel Competence and Skills

Resource Management Process RMP 02 – Information, Document Control and IT

Resource Management Process RMP 03 – Facilities, Equipment and Work Environment