

OVERVIEW OF DOCUMENTS & RECORDS REQUIRED BY ISO 9001: 2015

Disclaimer:

The procedures, records, templates, examples and guidelines provided on this website are for **educational and reference purposes only**. They serve as practical illustrations to support understanding of ISO 9001:2015 requirements and are **not guaranteed to ensure compliance** with the standard or any regulatory requirements.

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Certification success depends on proper implementation, internal audits, management commitment and third-party certification body assessment

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Mandatory Documents & Records Required			
Clause No.	Documents / Records	Example(s)	Reference(s)
4.3	Scope of the Quality Management System	<ul style="list-style-type: none">One-paragraph description of activities, locations and exclusions for ISO 9001 certification	
5.2	Quality Policy	<ul style="list-style-type: none">One-page statement of commitment to customer satisfaction, compliance and continual improvement	Annex 1 – Sample Quality Policy
6.2	Quality Objectives and Plans for Achieving Them	<ul style="list-style-type: none">Excel tracking, quarterly objective report, action plan tracking	

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7.1.5.1	Record of Maintenance and Calibration of Monitoring and Measuring Equipment	<ul style="list-style-type: none"> • Calibration certificates • Laboratory reports • Equipment tags 	
7.2	Competence Records	<ul style="list-style-type: none"> • Training certificates • Skills matrix • Licenses held by a personnel 	
8.2.3.2	Product/Service Requirements Review Record	<ul style="list-style-type: none"> • Contract review form • Quotation • Purchase order/ Letter of award from client 	Annex 2 - Contract Review Form
8.3.2	Record about design and development outputs review	<ul style="list-style-type: none"> • Design review minutes • Design output verification checklist • Design drawings • Prototypes specification 	
8.3.3	Design and Development Inputs Record	<ul style="list-style-type: none"> • Customer specifications sheet, • Blueprint, Source file from previous projects or customer 	
8.3.4	Record of Design and Development Control	<ul style="list-style-type: none"> • Verification test results, • Validation report 	
8.3.5	Design and Development Outputs Record	<ul style="list-style-type: none"> • Approved drawings • Final specification documentation 	
8.3.6	Record of Design and Development Changes	<ul style="list-style-type: none"> • Engineering Change request form (ECN) • Impact assessment 	Annex 3 – Engineering Change Notice (ECN)
8.4.1	Record of Evaluation of External Provider (supplier)	<ul style="list-style-type: none"> • Supplier scorecard • Audit report • Approved Supplier (Vendor) List 	Annex 4 – Supplier Scorecard

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8.5.1	Record of Product/Service Characteristics	<ul style="list-style-type: none"> • Bill of Material (BOM) • Standard Operating Procedures • Work Instructions • Work / Job Sheet 	
8.5.3	Record of Changes on Customer's Property	<ul style="list-style-type: none"> • Consignment form • Loan agreement • Return receipt 	
8.5.6	Record of Changes in Production/Service Provision	<ul style="list-style-type: none"> • Production change notice (PCN) • Revised / updated WI 	
8.6	Evidence of Product/Service Conformity	<ul style="list-style-type: none"> • Inspection record (e.g. test report, certificate of analysis) • OK / NOK stamp, tag 	
8.7.2	Record of Nonconformity	<ul style="list-style-type: none"> • Non-conforming report/ form • NCR register • Scrap tag • Photo of defective or discrepancies 	
9.1.1	Monitoring Performance Information	<ul style="list-style-type: none"> • KPI dashboard • Trend charts • Survey results, feedback from • Tabulated data, reports 	
9.2	Results of Internal Audit	<ul style="list-style-type: none"> • Audit report • Audit checklist • Audit summary • Audit Findings Log 	
9.3	Management Review Records	<ul style="list-style-type: none"> • Minutes of Meeting 	
10.2	Record of Nonconformities and Corrective Action	<ul style="list-style-type: none"> • Corrective action report (e.g 8D problem solving report) 	Annex 5 – 8D Problem Solving Report

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		<ul style="list-style-type: none"> • Root cause studies (e.g. 5-whys, fishbone diagram) • Effectiveness check (e.g revised WI, updated procedures, re-training records, etc) 	
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Common Documents & Records – Non-Mandatory (Good to have)

Clause No.	Documents / Records	Example(s)	Sample Template
4.1, 4.2	Determining Context of the Organization and Interested Parties	<ul style="list-style-type: none"> • Systematically identifies internal and external issues that impact ability to achieve quality objectives, maps interested parties and their specific requirements/expectations, documents top management commitment to customer satisfaction, compliance and continual improvement 	Annex 6 – Context of Organization Template
6.1	Procedure for Addressing Risks and Opportunities	<ul style="list-style-type: none"> • Establishes structured methodology to identify, assess likelihood/impact of risks and opportunities, prioritizes treatment actions, assigns process owners with timelines, integrates actions into quality objectives and planning for effective implementation and monitoring. 	
7.1.2 7.2 7.3	Competence, Training and Awareness Procedure	<ul style="list-style-type: none"> • Defines competence requirements for roles affecting quality performance, conducts gap analysis against current skills, develops/delivers targeted training programs, verifies effectiveness through practical 	

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		assessments and maintains qualification records for audit evidence	
7.1.5	Procedure for equipment maintenance and measuring equipment	<ul style="list-style-type: none"> Maintains complete inventory of monitoring/measuring equipment with location/specifications, establishes calibration and maintenance schedules based on manufacturer recommendations, documents all service activities performed by qualified personnel with traceability. 	
7.5	Procedure for Control of Documents and Records	<ul style="list-style-type: none"> Establishes complete rules for document creation, approval by authorized personnel, periodic review/updating cycles, version control identification, controlled distribution lists and defined retention/disposal periods per regulatory requirements 	
8.2	Sales Procedure	<ul style="list-style-type: none"> Defines complete workflow from customer enquiry receipt through quotation preparation and technical review, contract review ensuring all requirements are specified/achievable, formal customer acceptance via PO or award letter 	Annex 7 – Sale Procedure Template
8.3	Procedure for Design and Development	<ul style="list-style-type: none"> Controls full design process through defined stages: requirements input collection, technical design reviews with minutes, output verification against input requirements, final validation confirming fitness for intended purpose 	

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8.5	Procedure for Production and Service Provision	<ul style="list-style-type: none"> Specifies detailed work instructions for each process step, identifies critical control parameters and monitoring points, defines acceptance criteria for inspections/tests, documents complete results for traceability 	
8.5.4	Warehousing Procedure	<ul style="list-style-type: none"> Governs systematic receipt, storage under defined preservation conditions, inventory tracking, handling/packing procedures, dispatch processes and stock movement documentation to prevent deterioration or loss 	
8.7 10.2	Procedure For Management of Nonconformities and Corrective Actions	<ul style="list-style-type: none"> Documents immediate identification of nonconformities, implements containment actions, performs structured root cause analysis, determines/implements appropriate corrective actions, verifies effectiveness through follow-up activities 	
9.1.2	Procedure for Measuring Customer Satisfaction	<ul style="list-style-type: none"> Establishes defined methods for obtaining customer feedback including surveys and direct communication, analyzes satisfaction trends and performance against expectations, identifies opportunities linked to continual improvement processes 	Annex 8 – Customer Satisfaction Measurement Template
8.2	Procedure for Internal Audit	<ul style="list-style-type: none"> Develops annual audit programme covering all processes, selects independent competent auditors, prepares detailed checklists aligned to standard clauses, systematically documents findings and verifies corrective action implementation 	

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8.3	Procedure for Management Review	<ul style="list-style-type: none">• Convenes top management to systematically review QMS performance against objectives, evaluate continuing suitability and effectiveness, identify improvement needs, determine necessary resource allocations and changes	
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Annex 1 – Sample Quality Policy

Quality Policy

[Company Name], established in [Year] and headquartered at **[Address]**, is fully committed to operating an effective Quality Management System that consistently delivers products and services exceeding customer expectations. We maintain a strong customer focus by systematically understanding, meeting and exceeding requirements through structured processes and continuous feedback mechanisms, while ensuring full adherence to all applicable statutory, regulatory and contractual obligations.

Our approach emphasizes process excellence through robust, documented procedures with defined performance metrics and regular reviews, alongside proactive risk management that identifies, assesses and treats risks and opportunities impacting quality objectives. We develop personnel competence through structured training and qualification programs, and pursue continual improvement through regular evaluation of QMS effectiveness with documented actions pursued at Management Review meetings.

Scope: This policy applies to all processes, products and services as defined in our QMS Scope Statement. It is communicated to all employees and interested parties via notice boards and company portal, and reviewed annually for continuing suitability.

Approval:

.....
[Name of Top Management]
[Title: Managing Director / CEO]
Date: [Insert Date]

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Annex 2 - Contract Review Form

Form Reference:

Review Date:

1. Enquiry & Quotation Information

Customer	
Quotation Reference	
Estimated Contract Value	
Proposed Project Duration/ Lead Time	
Contact Person	Name : Email : Contact No:

2. Review Checklist

2.1 Customer Requirements: <ul style="list-style-type: none"><input type="checkbox"/> Specifications clearly defined and achievable<input type="checkbox"/> Delivery timeline/capacity realistic<input type="checkbox"/> Pricing/payment terms confirmed correct<input type="checkbox"/> Scope matches quoted proposal<input type="checkbox"/> Post-delivery activities understood (warranty/support)	2.2 Organizational Capability: <ul style="list-style-type: none"><input type="checkbox"/> Technical resources/competencies available<input type="checkbox"/> Production/service capacity confirmed<input type="checkbox"/> Subcontractor needs identified
2.3 Risks & Compliance: <ul style="list-style-type: none"><input type="checkbox"/> Key risks identified (delivery/quality/financial)<input type="checkbox"/> Statutory/regulatory requirements met<input type="checkbox"/> Terms & conditions acceptable	2.4 Environmental & Safety Considerations <ul style="list-style-type: none"><input type="checkbox"/> Environmental impacts assessed<input type="checkbox"/> Occupational safety requirements identified<input type="checkbox"/> Sustainability clauses reviewed (green procurement, energy efficiency)<input type="checkbox"/> Customer environmental/safety specifications achievable

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3. Review Notes

Technical	[comment on feasibility, resources gaps, lead-time, etc]
Commercial	[comment on profitability, payment terms]
Risks and Compliance	[comment on project, legislation risks and the mitigation plans to be taken]
Environmental & Safety	[comment on risk treatment and mitigation plans]

4. Review Outcome

- Approved** – Procedure to quote
- Conditional Approved** – Proceed to quote after resolution with terms and service agreement
- Reject** – [please indicate reason(s)]

5. Review Signatures

Sales Representative : _____ Date: _____

Technical Review : _____ Date: _____

Operations Review : _____ Date: _____

Managing Director : _____ Date: _____

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Annex 3 – Engineering Change Notice (ECN)

ECN Reference: ECN-[YYYY-XXX]

Date Initiated: [DD/MM/YYYY]

1. Production Information

Production Part Number	
Affected batch / lot	
Proposed Revision	
Description of Engineering Change	
Reason for Change	<input type="checkbox"/> Quality Issue <input type="checkbox"/> Customer Change Request <input type="checkbox"/> Cost Reduction <input type="checkbox"/> Process Improvement <input type="checkbox"/> Others:

2. Impact Analysis

Change Impact Analysis	Status
Design Drawing	<input type="checkbox"/> Updated <input type="checkbox"/> Not Applicable
Bill of Materials	<input type="checkbox"/> Updated <input type="checkbox"/> Not Applicable
Work Instructions / Work Procedures	<input type="checkbox"/> Updated <input type="checkbox"/> Not Applicable
Quality Control	<input type="checkbox"/> Updated <input type="checkbox"/> Not Applicable
Customer Notification	<input type="checkbox"/> Updated <input type="checkbox"/> Not Applicable
Inventory / Stock	Affected Quantity: [] <input type="checkbox"/> Scrap <input type="checkbox"/> Rework <input type="checkbox"/> Return to Vendor

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3. Change Description

Before Change	After Change
<i>[Sketch/description or attach current drawing]</i>	<i>[Sketch/description or attach proposed drawing]</i>
Supporting Documents <input type="checkbox"/> Drawing <input type="checkbox"/> Specifications <input type="checkbox"/> Test Data <input type="checkbox"/> Others:	

4. Implementation Plan

Effective Date	
Action Required	<input type="checkbox"/> Modify existing parts <input type="checkbox"/> New Part Creation <input type="checkbox"/> Scrap inventory <input type="checkbox"/> Obsolescence of parts
Person-in-Charge [Name / Department]	
Remarks	

5. Approval

Functional Team	Name	Signation	Date
Requestor			
Design Authority			
Production Authority			
Quality Control Authority			
Director			

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6. ECN Outcome

Approved

On-Hold

Reject – [please indicate reason(s)] _____

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Annex 4 – Supplier Scorecard

1. Supplier Information

Supplier / Company : _____

Period of Evaluation : _____

2. Evaluation Scores

Criteria	Weightage	Score Achieved	Percentage
Quality level	40%	[] /100	
Delivery performance	20%	[] /100	
Service level	20%	[] /100	
Environmental, health performance	15%	[] /100	
Price	5%	[] /100	
Total	100%	[] /100	[] %

Scoring Guide:

Grade A – 90 to 100% ; Grade B – 80 to 89%; Grade C – 60 to 79% ; Grade D – Below 60% (Not acceptable)

3. Supplier Classification

- Approved** – Remain in Approved Supplier List
- Conditional** – Improvement Plan required
- Reject** – To seek alternative source

4. Reviewed and Approval

	Name	Signation	Date
Procurement			
Quality Control Authority			
Director			

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Annex 5 – 8D Problem Solving Report

Report No:

Date:

D0: Emergency Response Action	
Problem Summary	
Containment Actions Taken:	
Date Initiated	

D1: Team Formation		
Roles	Name	Department
Team Leader		Management
Member 1		Quality Control
Member 2		Production
Member 3		Engineering
Member 4		Logistics

D2: Problem Description	
Who was affected	[Describe who and what processes was affected]
What happened	[Describe what is the problem, defects, quantity]
When it happened or detected	[Describe when it was first detected; period of duration that had been affected]
Where did it happened	[Describe the location of where defect was found or process been carried out]
Why did it happen	[Describe initial symptoms]
What is the impact	[Describe the impact encountered by user or customer]

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D3: Interim Containment Actions

What action(s) was taken	[Describe who and what processes was affected]
What the effectiveness of containment action(s)	[Describe what is the problem, defects, quantity]

Responsible:

Completion: [DD/MM/YYYY]

D4: Root Cause Analysis

Method Used	<input type="checkbox"/> 5-Why <input type="checkbox"/> Fishbone <input type="checkbox"/> DOE
Root Cause(s)	[Describe in specific what is the cause]
Verification	[Describe test or methods to confirm the root cause]
Where did it happened	[Describe the location of where defect was found or process been carried out]
Why did it happen	[Describe initial symptoms]
What is the impact	[Describe the impact encountered by user or customer]

D5: Corrective Actions (Permanent)

Planned Corrective Action(s)	[Describe in what actions will be implemented]
Implementation Plan	[Describe what will be done, timeframe and the methods/ steps]
Verification Method	[Describe how the effectiveness will be measured]

D6: Implement and Validate

Implementation Date	
Results	[Describe what the before and after data/ observation after implementing corrective actions]
Standard Work Updated	<input type="checkbox"/> Yes <input type="checkbox"/> No

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D7: Prevention of Recurrence	
Change(s)	<input type="checkbox"/> Process instruction revised <input type="checkbox"/> Training conducted <input type="checkbox"/> Controls added to FMEA <input type="checkbox"/> Similar process reviewed <input type="checkbox"/> Risk / Impact Assessment revised <input type="checkbox"/> Others:

D8: Team Recognition & Closure			
Lesson Learnt	[Describe what experience gained / lesson learnt]		
Team Recognition			
Closed By		Date	
Management Approval		Date	

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Annex 6 – Context of Organization Template

Document Ref: _____ Review Date: _____ Next Review: _____

1. Internal Issues (Our Strengths/Challenges)

Internal Issue	Impact on quality management process	Owner
Skilled technical staff	Can deliver complex projects	HR Manager
Limited production capacity	Restricts large volume orders	Operations
Modern calibration equipment	Ensures measurement accuracy	QA Manager

2. External Issues (Market & Environment)

Internal Issue	Impact on quality management process	Owner
Industry 4.0 competition	Must improve delivery speed	Sales Director
New environmental regulations	Additional compliance costs	EHS Manager
Economic slowdown	Price pressure from customers	MD

3. Interested Parties & Requirements

Interested Party	Key Requirements	Priority
Customers	On-time delivery, zero defects	High
Suppliers	Consistent quality materials	Medium
Employees	Safe workplace, fair pay	High

4. Top Management Commitment

"[Company Name] commits to understanding our business context and meeting the requirements of all interested parties through our ISO 9001:2015 Quality Management System."

Signed: _____

[Name of Director] | [Date]

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Annex 7 – Sale Procedure Template

1. Purpose

This procedure establishes the systematic process for the determination, review, and confirmation of customer requirements prior to the organization's commitment to deliver products or services, ensuring capability to meet specified needs in accordance with ISO 9001:2015 Clause 8.2.

2. Scope

This procedure applies to all customer enquiries, communications, quotations, contract negotiations, and order confirmations processed through sales and customer service functions.

3. Responsibilities

a) Sales Manager shall be accountable for:

- Overall governance and continual improvement of the sales process
- Ensuring timely logging and progression of all customer enquiries
- Preparation, review, and authorization of customer quotations
- Maintenance of customer relationship management records

b) Technical Manager shall be accountable for:

- Verification of technical feasibility and resource availability for proposed contracts
- Identification of technical risks and development of appropriate mitigation measures
- Participation in contract review meetings for complex requirements

c) Quality Manager shall be accountable for:

- Confirmation that customer requirements are compatible with Quality Management System capabilities
- Oversight of contract review documentation completion and retention
- Verification of compliance with applicable statutory and regulatory requirements

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4. Procedure

4.1 Receipt and Logging of Customer Enquiries

4.1.1 All customer enquiries shall be formally logged within four (4) hours of receipt.

4.1.2 Enquiry records shall capture customer identification, contact details, preliminary requirements, delivery expectations, and source.

4.2 Clarification of Requirements

4.2.1 Sales personnel shall contact customers within twenty-four (24) hours to clarify specifications, quantities, commercial terms, and compliance requirements.

4.2.2 All communications shall be documented systematically.

4.3 Contract Review Process

4.3.1 Formal Contract Review shall verify requirements definition, organizational capability, and risk mitigation prior to quotation issuance or order acceptance.

4.3.2 Contract Review records shall be approved before customer commitment.

4.4 Preparation and Issue of Quotations

4.4.1 Quotations shall specify scope, pricing (valid 30 days), delivery, payment terms, and quality commitments.

4.4.2 Sales Manager approval required prior to customer issue.

4.5 Customer Acceptance and Order Confirmation

4.5.1 Acceptance evidenced by signed quotation, purchase order, or documented confirmation.

4.5.2 Order Confirmation issued within twenty-four (24) hours documenting final terms.

4.6 Order Handover to Operations

4.6.1 Complete documentation package transferred including Contract Review record, requirements specification, and risk assessment.

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Annex 8 – Customer Satisfaction Measurement Template

1. Purpose

This procedure establishes the systematic process for obtaining, analyzing, and acting upon customer feedback to monitor satisfaction levels and drive continual improvement, as required by ISO 9001:2015 Clause 9.1.2.

2. Scope

Applicable to all customers receiving products or services from the organization, covering post-delivery feedback collection and analysis.

3. Responsibilities

3.1 Customer Satisfaction Coordinator shall be accountable for:

- Implementation of feedback collection methods across all customer segments
- Collation, analysis, and reporting of customer satisfaction data
- Communication of findings to relevant process owners

3.2 Sales Manager shall be accountable for:

- Obtaining feedback during customer interactions and contract reviews
- Escalation of critical customer concerns to senior management
- Implementation of sales-related improvement actions

3.3 Quality Manager shall be accountable for:

- Verification that customer feedback analysis aligns with quality objectives
- Integration of satisfaction trends into Management Review inputs
- Oversight of corrective actions arising from dissatisfaction trends

3.4 Managing Director shall be accountable for:

- Review of customer satisfaction performance during Management Review meetings

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- Approval of resources required for significant improvement initiatives
- Authorization of strategic responses to systemic customer concerns

4. Procedure

4.1 Feedback Collection Methods

4.1.1 Customer feedback shall be obtained through multiple channels including:

- Post-delivery satisfaction surveys (target response rate: 30%)
- Direct customer meetings and telephone interviews
- Complaint records and resolution feedback
- Net Promoter Score (NPS) questioning during contract closeout

4.1.2 Surveys shall be issued within five (5) working days of project/service completion using the Customer Satisfaction Survey Form.

4.2 Data Collation and Analysis

4.2.1 All feedback data shall be logged in the Customer Feedback Register within three (3) working days of receipt.

4.2.2 Quarterly analysis shall determine:

- Overall satisfaction trends (rating scale 1-5 or NPS)
- Common themes in positive and negative feedback
- Comparison against previous periods and industry benchmarks
- Correlation with specific products, services, or processes
-

4.3 Trending and Performance Indicators

4.3.1 Key performance indicators shall include:

- Average satisfaction score (target: $\geq 4.2/5.0$)
- NPS score (target: ≥ 50)
- Percentage of customers rating 'Very Satisfied' (target: $\geq 70\%$)
- Repeat business rate (target: $\geq 80\%$)

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4.4 Corrective and Improvement Actions

4.4.1 Individual customer complaints shall be addressed per the Nonconformity Procedure.

4.4.2 Systemic issues identified through trend analysis shall generate:

- Corrective action requests assigned to process owners
- Improvement opportunities for Management Review consideration
- Process changes verified through subsequent feedback cycles

4.5 Reporting and Communication

4.5.1 Quarterly Customer Satisfaction Reports shall be prepared containing:

- Quantitative performance data and trends
- Qualitative feedback themes and verbatim comments

Action status updates from previous period

4.5.2 Reports shall be presented at Management Review meetings.