

ISO 9001:2000 Explained and Exhibits List of Files

File name	Directory where file is located	PDF in ISO Explained	To be Used	Name of document / What used for	Relates to Clause
				ISO 9001 Explained and Exhibits - Part 1	
				<p>The "ISO 9001:2000 Auditor Training Course and Forms" includes:</p> <ol style="list-style-type: none"> 1. ISO 9001:2000 Requirements Explained - An Adobe PDF File for Use on a Network System 2. Manual 1 Requirements Explained - a printout of the PDF file explanation of the standard (used to train auditors) The Auditor Training Course also includes ISO 9001 Explained. 3. Manual 2 Exhibits - a printout of the PDF file Exhibits that illustrate the requirements of the standard (used for training auditors) 4. Trainer Manual - tells how to set up and management an audit program and train auditors 5. Auditor Manual - how to conduct and report an ISO 9001:2000 process audit 	
iso 9001-2000 explained rev 3-1-04.pdf	ISO 9001 Explained			<p>ISO 9001:2000 Requirements Explained - An Adobe PDF File for Use on a Network System</p> <p>This 294 page Adobe PDF document explains what each sentence in the ISO 9001:2000 standard means. The Adobe file has links to 98 Exhibits (listed below) that illustrate the ISO requirements. The written explanation of the standard may be placed on a network system for access by auditors and employees at the site license location.</p>	all
				<p>Manual 1 Requirements Explained</p> <p>This manual is a printout of <u>the written explanation of the standard</u> (the Adobe PDF file). The Manual printout is used as part of the Auditor Training Course. A photocopy of this manual is made for each auditor.</p>	all
				<p>Manual 2 Exhibits</p> <p>This manual is a <u>printout of the Exhibits</u> that are used to illustrate the explanation of the standard.</p>	
				<p>List of Exhibits</p> <p>Following is a list of the charts, documents, forms and databases that are used to illustrate the requirements of the Standard. This product includes these documents as Microsoft Word and Excel files. These documents may be edited and used as part of your ISO quality system documentation and employee training programs.</p>	
				<p>TO: Organizations implementing the standard</p> <p>This product should be purchased at the beginning of an ISO implementation project to obtain the most benefit from the materials. The written explanation of the standard explains what each sentence in the standard means and assumes no prior knowledge of quality systems and management systems. All of the forms in this product were designed to include the requirements of the standard. It is likely that you will want to incorporate some of the Exhibit forms and documents as part of your quality management system.</p>	

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				Key: An "X" in column 3 indicates that the PDF written explanation of the standard has a link to this illustration document. The numbers in the last column identify the clause(s) of the standard to which the exhibit applies.	
				4 Quality management system (title only)	
				4.1 Quality management system - General	
				Flowchart Basics Introduces basic flowchart symbols, a process flowchart and deployment flowchart.	4.1
flowchart basics.doc	Sample Documents	x			
				Typical Sequence and Interaction of Processes for a Manufacturing Company Sample flowchart showing the sequence and interaction of key processes.	4.1
flowchart 1 - key processes S & I.doc	Sample Documents	x			
				DFC 4.1 Sequence and Interaction of Key QMS Processes Sample flowchart showing the sequence and interaction of key processes.	4.1
flowchart 2 - seq and interaction of key processes.doc	Sample Documents	x			
				Corrective and Preventive Action A sample process flowchart.	4.1
flowchart 3 - process flowchart.doc	Sample Documents	x			
				DFC 6.2.2 - Competence, Awareness and Training System A sample deployment flowchart.	4.1
flowchart 4 - deployment flowchart.doc	Sample Documents	x			
				Elements of a Process Description This document defines what should be known about a process. This may be used to introduce "WHAT A PROCESS IS" during a training session and to determine if a process has been adequately planned and documented.	4.1 5.4.1 5.4.2 7.1
elements of a process description.doc	Forms	x			
				Input Output Chart A process planning tool used to identify: 1. process inputs and outputs 2. process objectives 3. reference documents, forms, and records used by the process Resulting chart can be used: 1. to establish minimal documentation for an undocumented process 2. as an insert to a procedure, work instruction or other document format to show (at a glance) inputs/outputs and objectives of the process	4.1 5.4.1 5.4.2 7.1 b 8.2.3
input output chart.doc	Forms	x			
				Input Output Chart Instructions Instructions for how to complete an Input Output Chart.	same as above
input output chart instuctions.doc	Forms	x			
				Input Output Chart Example (a file only) A completed Input Output Chart.	
input output chart example.doc	Sample Documents	On CD			
				Input Output Chart - Related to ISO Clauses (a file only) Identifies where an Input Output Chart can be used to satisfy requirements in the ISO 9001:2000 standard.	4.1 8.2.3
input output chart - related to ISO clauses.doc	Sample Documents	On CD			

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supplier customer agreement.doc	Forms	x		Supplier Customer Agreement <i>(a standard form)</i> An Agreement between an in-house Supplier process and an in-house Customer process. The agreement defines the acceptance criteria for the service, material, or information that the Supplier process delivers to the Customer process. This form is used to establish the expected inputs and outputs for a process.	4.1
supplier customer agreement template.doc	Forms			Supplier Customer Agreement <i>(template version of this form)</i>	
supplier customer agreement example.doc	Forms	x		Supplier Customer Agreement Example Example of a complete form.	4.1
process planning formula chart.doc	Forms	x		Process Planning Formula Chart This chart may be used for planning activities to ensure 4.1 requirements are met. The chart lists the 7 requirements in clause 4.1 that must be met when 1. planning any new process 2. defining a plan to meet a quality objective 3. defining an improvement plan 4. planning a change to the QMS (new equipment, new computer system, etc.)	4.1 5.4.1 5.4.2 7.1
				4.2 Documentation requirements (title only)	
				4.2.1 Documentation requirements - General	
				Operating Procedure document formats The purpose of the sample documents for clause 4.2.1 is to show how documents can differ from one organization to another and to provide sample document formats.	4.2.1
OP 4.2.4 Records sample.doc	Sample Documents	x		OP 4.2.4 Records Sample This sample Operating Procedure format is provided by West Management Services. This example uses a simple layout and short sentences that are easy to understand.	4.2.1
	Sample Documents			Documentation Format Examples from IsoQual, Inc. The following flowchart, Standard Operating Procedure (SOP) and Process Assessment Worksheet are presented to provide examples of these types of documents. The Process Assessment Worksheet is a new type of document that assists process owners and auditors to assess the performance of a process.	4.2.1
flowchart 4 - deployment flowchart.doc	Sample Documents	x		DFC 6.2.2 - Competence, Awareness and Training System A flowchart provides an overall picture of a process.	4.2.1
SOP format sample.doc	Sample Documents	x		SOP Format Sample Organizations define a standard format that they will use for a written procedure. This is an example of a format template. Compare the format template to the next document on this list which is a completed SOP.	4.2.1

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SOP 6.2.2 Competence Awareness and Training - Rev 1-1-03.doc	Sample Documents	x		SOP 6.2.2 – Competence, Awareness and Training This is an example of a Standard Operating Procedure. It is included here so you can compare a completed document to the SOP standard format (above).	4.2.1
process assessment worksheet example.doc	Sample Documents	x		Process Assessment Worksheet Example This is a new type of document (developed by IsoQual, Inc.) that is used assess a process. A completed worksheet (such as this example) may be used by the process manager and auditors to assess the performance of a process. The worksheet identifies: 1. the process Objective and Baseline Performance against which the process is measured 2. improvement objectives (when defined for the process) 3. process inputs and outputs 4. what controls the process 5. key measures (what is used to measure if the process is achieving its objective(s))	4.2.1
process assessment worksheet.doc	Sample Documents	x		Process Assessment Worksheet Form A blank Process Assessment Worksheet form and instructions for completing the form. Also see the above example of a completed form.	4.2.1
				4.2.2 Quality manual	
quality manual numbering.doc	Sample Documents	x		Quality Manual Numbering Most organizations number the topics in the quality manual to correspond to the numbering of the ISO 9001:2000 standard. This makes it easier to discuss the standard and to audit the quality management system.	4.2.2
				4.2.3 Control of documents	
master list.xls	Sample Documents	x		Master List (an Excel file used to maintain an electronic Master List of documents) The Quality Manual should identify the Directory and file name location of this list when this file is used.	4.2.3
doc chg request form.doc	Forms	x		Document Change Request Form (a standard form) Used to request a change to a document.	4.2.3
doc chg request template.doc	Forms	On CD		Document Change Request (a data entry template) The data entry template version of this form. Used to request a change to a document.	4.2.3
doc chg request instructions.doc	Forms	x		Document Change Request Instructions Instructions for completing the DCR form and template.	4.2.3
	DCR Doc Change Requests - file here			DCR Doc Change Requests - file here A Directory for filing Document Change Requests submitted on a data entry template.	4.2.3

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DCR Log.xls	Forms	x		DCR Log (Document Change Request Log) <i>a database</i> Used to list and track the status of Document Change Requests. A DCR Log database is likely to be used when there are a large number of documents or when changes to documents occur frequently.	4.2.3
DCR Log instructions.xls	Forms	On CD		DCR Log Instructions <i>(a file only)</i> Additional information related to using the DCR Log.	4.2.3
doc chg review form.doc	Forms	x		Document Change Review Form This form is used to track the review of a proposed document change that could impact other documents. This form is appropriate for organizations that have a small number of documents and changes to documents do not happen frequently.	4.2.3
doc chg notice.doc	Forms	x		Document Change Notice (DCN) <i>(a standard form)</i> Form used to inform document users of what changes have been made to a revised document.	4.2.3 7.3.7
doc chg notice template.doc	Forms	On CD		Document Change Notice (DCN) <i>(a date entry template)</i> Form used to inform document users of what changes have been made to a revised document.	4.2.3 7.3.7
				4.2.4 Control of records	
records matrix.xls	Sample Documents	x		Records Matrix Used to list records maintained by the organization and the controls that apply to each type of record.	4.2.4
records matrix sample.xls	Sample Documents	x		Records Matrix Sample Completed matrix sample document.	4.2.4
				5 Management responsibility (title only)	
				5.1 Management commitment	
				5.2 Customer focus	
				5.3 Quality policy	
				5.4 Planning (title only)	
				5.4.1 Quality objectives	
setting objectives.doc	Sample Documents	x		Setting Objectives This document presents an example of objectives set by top management of a typical manufacturing company.	5.4.1
establish and review objectives.doc	Sample Documents	x		Establishing and Reviewing Quality Objectives This article by Christopher Paris of Oxbridge Quality Resources, Inc. provides an example of a quality policy and objectives that support statements in the quality policy. The article also shows how a chart can be used to identify top-level objectives and objectives for key processes.	5.4.1 5.3

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quality objective mgt review table.doc	Forms	x		Quality Objective Management Review Table This table may be used to list quality objectives, what will be used to measure if the objective is achieved (the metric), the current goal, current standing at the time of the review, and a revised goal if a revision is made.	5.4.1
top-level quality objective plan.doc	Forms	x		Top-Level Quality Objective Plan This form is used to define the plan for a Top-Level quality objective that will be achieved by contributions from more than one department or functional area.	5.4.1
quality objective dept plan.doc	Forms	x		Quality Objective Department Plan This form is used to define the plan for a department or functional area quality objective.	5.4.1
quality objective assignment.doc	Forms	x		Quality Objective Assignment This form is used by a Department Manager to assign activities to personnel who will contribute to a Department Quality Objective Plan.	5.4.1
	Quality Objective Plans - file here	x		Quality Objective Plans - file here <i>(a Directory)</i> This directory is used to file Top-Level Quality Objective Plans, Quality Objective Department Plans, and Quality Objective Assignment forms.	5.4.1
				5.4.2 Quality management system planning	
project plan log.doc	Forms	x		Project Plan Log <i>(a form)</i> This form may be used to assign who is responsible for activities when planning is done for a project or for a new process or group of processes.	5.4.2
project plan assignment.doc	Forms	x		Project Plan Assignment <i>(a form)</i> This form is used to assign activities to those who will contribute to achieving quality management system plans.	5.4.2
	Project Plans - file here			Project Plans - file here <i>(a Directory)</i> This directory can be used to file the Project Plan Log form and Project Plan Assignments that originate from Management Review meetings.	5.4.2
				5.5 Responsibility, authority and communication (title only)	
				5.5.1 Responsibility and authority	
organization chart structure.doc	Sample Documents	x		Organization Chart Structure Shows the standard conventions used to design an Organization chart.	5.5.1
				5.5.2 Management representative	
				5.5.3 Internal communication	

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				5.6 Management review - All of the forms that relate to Management Review are included with the written explanation of the standard. Printouts of these forms are in the Trainer Manual.	5.6
framework to support the quality policy.doc	Mgt Review forms	x		A Framework to Support the Quality Policy A diagram that shows how quality objectives defined for the organization must be traceable to the commitments and goals stated in the Quality Policy. Management Reviews determine where quality objectives are needed to meet quality policy commitments and goals.	5.6 5.3
management review report.doc	Mgt Review forms	On CD		Management Review Report A form for recording the minutes of Management Review	5.6 5.3
action number form.doc	Mgt Review forms	x		Action Number Form An Action Number Form is completed for each potential action that is discussed during Management Review. The item is described, time and resources estimated, a preliminary Priority identified, and the item is listed on the Management Review Result Chart (an Excel sheet form).	5.6
management review result chart.xls	Mgt Review forms	x		Management Review Result Chart An Excel form Used to list potential actions as they are discussed during Management Review. The database is sorted by Priority to determine which items are selected for action. The printout and computer file serve as a record of all items discussed during the meeting. The chart may be copy/pasted to the Opportunities Log to provide an on-going record of Management Review action decisions and items that can be selected for improvement at a future date.	5.6
management review result chart instructions.xls	Mgt Review forms	On CD		Management Review Result Chart Instructions Instructions for completing the above Excel chart.	5.6
1 results of audits.doc	Mgt Review forms	On CD		1 Results of audits A report on the effectiveness of the system and the ability of the audit program to detect and correct problems.	5.6
2 customer feedback.doc	Mgt Review forms	On CD		2 Customer Feedback Topics for discussion related to customer feedback.	5.6
3 process performance.doc	Mgt Review forms	On CD		3 Process performance This is a comparison of process objectives to current performance. Managers report on the performance of processes they own.	5.6
4 product conformity.doc	Mgt Review forms	On CD		4 Product Conformity This is a review of products and services to determine if they meet specification as advertised and if there is a need to change product design, materials, technology, or improve the product in some way.	5.6
5 status of corrective actions.doc	Mgt Review forms	On CD		5 Status of Corrective Actions An analysis of corrective action closure time, degree of recurrence, and the adequacy of problem resolution techniques.	5.6

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6 status of preventive actions.doc	Mgt Review forms	On CD		6 Status of Preventive Actions An analysis of preventive action activities including planning, training, research, and analysis methods used to determine if improvement is needed.	5.6
7 follow-up actions from mgt reviews.doc	Mgt Review forms	On CD		7 Follow-up actions from management reviews A report on whether closed actions remain effective. A report on the status of open actions and what action should be taken on actions that are not meeting targets or calendar goals.	5.6
8 changes affecting the mgt system.doc	Mgt Review forms	On CD		8 Changes affecting the management system A report on changes that can affect the management system.	5.6
9 recommended improvements.doc	Mgt Review forms	On CD		9 Recommended improvements A review of suggestions for improvement that can originate from anyone. See next entry on this chart.	5.6
improvement suggestions from personnel.doc	Mgt Review forms	On CD		Improvement Suggestions from Personnel Information related to establishing an Improvement Committee comprised of several members of management. The Committee reviews suggestions for improvement, presents these items during management review and management meetings. A Committee member maintains the Opportunities Log database and the Opportunities Log 3-Ring Binder that contains all suggested improvement items submitted by employees and the Action Number Forms generated during Management Reviews.	5.6 8.5.1
planning assignment.doc	Forms	On CD		Planning Assignment The standard requires that there is a plan to achieve quality objectives and that needed resources are provided. This document lists forms that can be used to plan a top-level quality objective and a department objective where incremental targets are set. Corrective Preventive Action Request forms are identified when planned actions should correct a problem. Project planning forms are identified when the plan is a large project or when new processes must be planned. The Management Representative should become familiar with these forms and can identify the type of planning format that should be used. You may also identify your own planning document, method, or planning software that should be used.	5.6
1 opportunities log.xls	Opportunities Log	x		Opportunities Log Used to list all potential actions discussed during Management Review. Items not selected for action during Management Review may be selected as improvement actions at a future date when resources become available.	5.6
1 opportunities log instructions.xls	Opportunities Log	x		Opportunities Log Instructions Instructions for the Opportunities Log.	5.6
				6 Resource management (title only)	
				6.1 Provision of resources	
				6.2 Human resources (title only)	
				6.2.1 General	

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				6.2.2 Competence, awareness and training	
	Competence Evaluation Forms			Competence Evaluation Forms Directory A directory for filing Competence Evaluation Forms that define the units of competence for specific activities and how competence is evaluated. Original forms are filed in this directory. Completed forms with data related to employees are maintained by Department Managers (?). (See next listed document.)	6.2.2
competence evaluation for (name activity).doc	Forms	x		Competence Evaluation Form for (Name Activity) Used to: 1. identify units of competence for a type of work or activity 2. define performance standard 3. identify training or other action needed to achieve competency 4. evaluate results of action taken 5. assign additional action if person is not yet competent	6.2.1 6.2.2 7.5.2
personal development plan.doc	Forms	x		Personal Development Plan Defines training needed for an employee. This form identifies the activities (or units of competence within an activity defined on the Competence Evaluation Form) for which a development plan/ training is needed. The form identifies planned training, when an evaluation will be made to determine the effectiveness of the training, and if the person has achieved the competence requirements for identified activities.	6.2.2
qualified personnel database.xls	Forms	x		Qualified Personnel Database A database that lists the activities performed in the organization and who has qualified to perform these activities. There should be a Competence Evaluation Form for each activity listed in the database. Do a sort by Department / Function name to locate activities that apply to specific departments or areas and who is qualified to perform those activities.	6.2.2
training record.doc	Sample Documents	x		Training Record This form identifies training requirements, the date training occurred, when effectiveness will be assessed, and the date of assessment.	6.2.2
training matrix.xls	Sample Documents	x		Training Matrix This form shows how a matrix can be used to identify the Standard Operating Procedures and Work Instructions that should be included in the employee's training.	6.2.2
OJT training matrix.doc	Sample Documents	x		OJT Training for Manufacturing and Shipping This form identifies activities to be included in an On-the-Job training program.	6.2.2
semi annual training assessment.doc	Sample Documents	x		Semi Annual Assessment of Training Effectiveness and Needs A form used to perform a 6 month review of the effectiveness of employee training and to identify training needs that should take place in the next 6 months.	6.2.2
				6.3 Infrastructure	
				See Part 2 for Exhibits that illustrate clauses 6.4 through 8.5.3	
				Click Browser Back button (in top left corner) to Return	