

## ISO 9001:2008 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 |
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|   |                                 |                      |            | <b>ISO 9001:2008 Explained and Exhibits - PART 1</b>  |                   |
| iso 9001-2008 explained rev 2-20-09.pdf                       | ISO 9001 Explained              |                      |            | <b>ISO 9001:2008 Requirements Explained - An Adobe PDF File for Use on a Network System</b> by Jane M. Birkenstock<br>This 300 page Adobe PDF document explains what each sentence in the ISO 9001:2008 standard means. The Adobe file has links to <b>103</b> 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.   | all               |
| ISO 9001 Explained and Exhibits List of Files Rev 2-20-09.xls |                                 | File                 |            | <b>ISO 9001 Explained and Exhibits List of Files - (THIS FILE)</b><br>This is a list of all the documents in this product.  |                   |
|   |                                 |                      |            | <b>Key:</b> An "X" in column 3 indicates that the PDF written explanation of the standard has a link to this illustration document. The word "File" in column 3 means there is a computer file of the document, but it does not appear as an exhibit in the written explanation of the standard. The numbers in the last column identify the clause(s) of the standard to which the exhibit applies.  |                   |
| uses for iso 9001-2008 explained.doc                          | <b>Introduction - README</b>    | File                 |            | <b>Uses for ISO 9001:2008 Requirements Explained</b><br>Uses for this product include:<br>1. Reference and training source when implementing an ISO 9001 quality system<br>2. Training Internal Auditors on ISO 9001 requirements and how you meet requirements<br>3. Employee Training<br>4. Reference source for all employees - when PDF file placed on your computer system   |                   |
| using iso 9001 explained when implementing the standard.doc   | <b>Introduction - README</b>    | File                 |            | <b>Using ISO 9001 Explained When Implementing the Standard</b><br>How ISO 9001 Explained can be used when setting up and maintaining an ISO 9001 quality management system. Using ISO 9001 as a reference document and for employee training.   |                   |
|   |                                 |                      |            | <b>TO: Organizations implementing the standard</b><br><b>This product should be purchased at the beginning of an ISO implementation project to obtain the most benefit from the materials.</b> 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. You may want to use some of the forms and documents in this product as part of your quality management system. |                   |
| making changes on documents and forms.doc                     | <b>Introduction - README</b>    | File                 |            | <b>Making Changes on Documents and Forms</b><br>Topics include: revision identification, comparing forms to your existing forms, page breaks, using the Forms Toolbar, protecting documents, and making changes on data entry templates.  |                   |

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| using Adobe Reader.doc                              | Introduction - README               | File                 |            | <b>Using Adobe Reader</b><br>This file relates to setting User Preferences and Toolbar settings for viewing pdf files.  |                   |
|   |                                     |                      |            |   |                   |
|   | <b>Print and Assemble Manual</b>    | File                 |            | <b>Print and Assemble Manual Instructions</b><br>Instructions for making a printed copy of <i>ISO 9001:2008 Requirements Explained</i> . Includes the type of binders, index tabs and paper to order from your office supply provider. <a href="#">The Management Representative, the ISO Coordinator and Internal Auditors should have a printed copy of ISO 9001 Explained.</a>   |                   |
| Table of Contents for Tabs.doc                      | <b>Print and Assemble Manual</b>    | File                 |            | <b>Table of Contents for Tabs</b><br>This is the Table of Contents for the index tabs used in the printed manual.   |                   |
| spine insert Manual 1 - requirements.doc            | <b>Print and Assemble Manual</b>    | File                 |            | <b>Spine Insert Manual 1 - Requirements Explained</b><br>Spine insert for the manual.   |                   |
| outside and inside title pages.doc                  | <b>Print and Assemble Manual</b>    | File                 |            | <b>Outside and Inside Title Pages</b><br>Outside and inside title pages and introduction for the manual.  |                   |
|   |                                     |                      |            |   |                   |
|   |                                     |                      |            | <b>ISO 9001:2008 Requirements Training</b><br>ISO 9001 Explained can be used for references purposes only. It can also be used to train those who need to have an in-depth knowledge of the Standard or specific clauses in the standard. The next document provides instructions for 3 methods that can be used for ISO 9001 Requirements Training.  |                   |
| instructions for iso 9001 requirements training.doc | ISO Training, Test and Answer Sheet | File                 |            | <b>Instructions for ISO 9001 Requirements Training</b><br><ol style="list-style-type: none"> <li>1. Content of ISO 9001:2008 Requirements Explained <ol style="list-style-type: none"> <li>1.1 Using ISO 9001 Explained when Implementing the Quality System</li> </ol> </li> <li>2. Those Who Need In-depth Knowledge of the ISO 9001 Requirements</li> <li>3. Three Methods for Teaching the ISO 9001 Requirements as a Course</li> <li>4. Course Materials Chart</li> <li>5. Dividing the Course into Sections</li> <li>6. Trainer Preparation</li> <li>7. Classroom Method</li> <li>8. FAST Method</li> <li>9. Self-Learning Method (<a href="#">ISO Project Leader uses this method to obtain a Training Certificate before teaching this course.</a>)</li> <li>10. Classroom Method Agenda</li> <li>11. FAST Method Agenda</li> <li>12. Self-Learning Method Agenda</li> <li>13. Certificate</li> </ol> |                   |

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| iso requirements training CEU chart.doc               | ISO Training, Test and Answer Sheet | File                 |            | <p><b>ISO 9001 Requirements Training CEU Chart</b> (used when training Internal Auditors)<br/> <a href="#">The time the Trainer spends reading materials in preparation for training others qualifies for CEU credits and a Training Certificate under the Self-Learning Method.</a><br/>           Continuing Education Units (CEUs) are awarded for continuing adult education training. 10 hours = 1 unit. Trainees keep track of all the time that they spend related to ISO 9001 Requirements training, including classroom time, reading assignments, reviews and test time. This also includes time spent preparing documentation when these materials are used in conjunction with an ISO implementation project. The number of CEUs appears on the course certificate.</p>  |                   |
|   |                                     |                      |            | <p><b>Trainees receive a printed copy of ISO 9001 Requirements Explained</b><br/>           Use the "Print and Assemble Manual Instructions" to make a printed copy of <i>ISO 9001 Requirements Explained</i> for each trainee.</p>  |                   |
| questions on the iso 9001 requirements.doc            | ISO Training, Test and Answer Sheet | File                 |            | <p><b>Questions on the ISO 9001 Requirements</b><br/>           This document identifies an ISO Clause (a topic in the standard) and then asks several questions about what the requirements in that clause mean. There are 52 clauses in the standard. This document focuses on comprehension and is used when providing training related to the requirements of the ISO 9001 standard. 2 of the 3 methods for presenting this course have reading assignments. Trainees answer the questions that correspond to the reading assignment. These questions also serve as a verification that the Trainee actually read the assignment.</p>  |                   |
| questions on the iso 9001 requirements - answers.doc  | ISO Training, Test and Answer Sheet | File                 |            | <p><b>Questions on the ISO 9001 Requirements - Answers</b><br/>           Answer sheet for the above document.</p>   |                   |
| how we meet iso requirements forms - instructions.doc | How We Meet ISO Requirements        | File                 |            | <p><b>How We Meet ISO Requirements Forms - Instructions</b><br/>           The "How We Meet ISO Requirements" forms may be used to track the status of an ISO 9001 implementation project.</p>   |                   |
|   |                                     |                      |            | <p><b>How We Meet ISO Requirements - Forms</b> (used to provide ISO requirements training to auditors)<br/>           The 5 "How We Meet ISO Requirements" forms were designed to be used as part of Internal Auditor Training to identify how the organization meets the ISO 9001 requirements. Auditors must understand what the ISO requirements mean and how your organization meets the requirements. Publicly offered Auditor Training Courses do not have the time to explain (in detail) what the requirements mean and cannot explain how <u>your organization</u> meets the requirements. Your Audit Program Manager must provide this information. <i>ISO 9001 Explained</i> explains what the requirements mean in detail. The following forms are used to 1) identify your organization's document that tells how ISO requirements are met, and 2) to write a note that tells the method that is used to meet the requirements in each ISO numbered clause.</p> |                   |
| clause 4 how we meet ISO requirements.xls             | How We Meet ISO Requirements        | File                 |            | <p><b>Clause 4 How We Meet ISO Requirements</b> (a form) 1 page</p>  |                   |

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| clause 5 how we meet ISO requirements.xls                                    | How We Meet ISO Requirements        | File                 |            | <b>Clause 5 How We Meet ISO Requirements</b> (a form) 1 page  |                   |
| clause 6 how we meet ISO requirements.xls                                    | How We Meet ISO Requirements        | File                 |            | <b>Clause 6 How We Meet ISO Requirements</b> (a form) 1 page  |                   |
| clause 7 how we meet ISO requirements.xls                                    | How We Meet ISO Requirements        | File                 |            | <b>Clause 7 How We Meet ISO Requirements</b> (a form) 4 pages   |                   |
| clause 8 how we meet ISO requirements.xls                                    | How We Meet ISO Requirements        | File                 |            | <b>Clause 8 How We Meet ISO Requirements</b> (a form) 1 page  |                   |
| test on iso 9001 requirements.doc  | ISO Training, Test and Answer Sheet | File                 |            | <b>Test on ISO 9001:2008 Requirements</b><br>This test has 50 questions and is used as a final test when training is provided on the ISO 9001 standard. This is a 20 to 30 minute open book test.   |                   |
| test on iso 9001 requirements - answers.doc                                  | ISO Training, Test and Answer Sheet | File                 |            | <b>Test on ISO 9001:2008 Requirements - Answers</b><br>Answer sheet to the test. A passing score is 75%.  |                   |
| Certificate of Achievement - ISO 9001 Requirements Training.doc              | ISO Training, Test and Answer Sheet | File                 |            | <b>Certificate of Achievement - ISO 9001 Requirements Training</b><br>This certificate is awarded upon successful completion of training on the ISO 9001:2008 standard using the materials in this product.   |                   |
| certificate of achievement instructions - iso 9001 requirements training.doc | ISO Training, Test and Answer Sheet | File                 |            | <b>Certificate of Achievement Instructions - ISO 9001 Requirements Training</b><br>Instructions for completing the certificate.   |                   |
| Certificate of Achievement - blank.doc                                       | ISO Training, Test and Answer Sheet | File                 |            | <b>Certificate of Achievement - blank</b><br>A blank certificate that can be awarded in recognition of any type of training provided by the organization.   |                   |
| iso 9001:2008 - changes between the 2000 and 2008 versions.doc               | <b>Introduction - README</b>        | File                 |            | <b>ISO 9001:2008 - Changes between the 2000 and 2008 Versions</b><br>The ISO 9001:2000 standard was updated in 2008. This document identifies where changes were made in the text of the year 2000 version of the standard.   |                   |
|  |                                     |                      |            | <b>Exhibits that Illustrate the ISO 9001:2008 clauses begin here:</b>   |                   |
|  |                                     |                      |            | <b>List of Exhibits</b><br>Following is a list of the charts, documents, forms and databases that are used to illustrate the requirements of the Standard. <a href="#">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.</a> |                   |
|  |                                     |                      |            | 4 Quality management system (title only)  |                   |
|  |                                     |                      |            | <b>4.1 Quality management system - General</b>  |                   |
| flowchart basics.doc   | Sample Documents                    | x                    |            | <b>Flowchart Basics</b><br>Introduces basic flowchart symbols, a process flowchart and deployment flowchart.  | <b>4.1</b>        |
| flowchart 1 - key processes S & I.doc  | Sample Documents                    | x                    |            | <b>Typical Sequence and Interaction of Processes for a Manufacturing Company</b><br>Sample flowchart showing the sequence and interaction of key processes.   | <b>4.1</b>        |

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| flowchart 2 - seq and interaction of key processes.doc | Sample Documents                | x                    |            | <b>DFC 4.1 Sequence and Interaction of Key QMS Processes</b><br>Sample flowchart showing the sequence and interaction of key processes.   | 4.1                                     |
| flowchart 3 - process flowchart.doc                    | Sample Documents                | x                    |            | <b>Corrective and Preventive Action</b><br>A sample process flowchart.  | 4.1                                     |
| flowchart 4 - deployment flowchart.doc                 | Sample Documents                | x                    |            | <b>DFC 6.2.2 - Competence, Awareness and Training System</b><br>A sample deployment flowchart.  | 4.1                                     |
| elements of a process description.doc                  | Forms                           | x                    |            | <b>Elements of a Process Description</b><br>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<br>5.4.1<br>5.4.2<br>7.1            |
| input output chart.doc                                 | Forms                           | x                    |            | <b>Input Output Chart</b><br>A process planning tool used to identify:<br>1. process inputs and outputs<br>2. process objectives<br>3. reference documents, forms, and records used by the process<br>Resulting chart can be used:<br>1. to establish minimal documentation for an undocumented process<br>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<br>5.4.1<br>5.4.2<br>7.1 b<br>8.2.3 |
| input output chart instructions.doc                    | Forms                           | x                    |            | <b>Input Output Chart Instructions</b><br>Instructions for how to complete an Input Output Chart.   | same as above                           |
| input output chart example.doc                         | Sample Documents                | File                 |            | <b>Input Output Chart Example</b> <i>(a file only)</i><br>A completed Input Output Chart.   |   |
| input output chart - related to ISO clauses.doc        | Sample Documents                | File                 |            | <b>Input Output Chart - Related to ISO Clauses</b> <i>(a file only)</i><br>Identifies where an Input Output Chart can be used to satisfy requirements in the ISO 9001:2008 standard.  | 4.1<br>8.2.3                            |
| supplier customer agreement form.doc                   | Forms                           | x                    |            | <b>Supplier Customer Agreement</b> <i>(a standard form)</i><br>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                           | File                 |            | <b>Supplier Customer Agreement</b> <i>(template version of this form)</i>   | 4.1                                     |
| supplier customer agreement example.doc                | Forms                           | x                    |            | <b>Supplier Customer Agreement Example</b><br>Example of a complete form.   | 4.1                                     |

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| process model.doc                      | Audit Forms                     | x                    |            | <b>Process Model</b><br>This is a Process Model (a picture of a process). List items a) through f) in clause 4.1 tell what should be considered when a process (an activity) is first set up. This is the basis for setting up an effective process.  | 4.1                          |
| process model explanation.doc          | Audit Forms                     | x                    |            | <b>Process Model Explanation - Requirements of 4.1</b><br>This chart has a more detailed explanation of the picture of a process. The first column on the chart identifies items on the Process Model. The 2nd column tells what each item on the Process Model means.  | 4.1                          |
| process planning formula chart.doc     | Forms                           | x                    |            | <b>Process Planning Formula Chart</b><br>This chart may be used for planning activities to ensure 4.1 requirements are met.<br>The chart lists the 7 requirements in clause 4.1 that must be met when<br>1. planning any new process<br>2. defining a plan to meet a quality objective<br>3. defining an improvement plan<br>4. planning a change to the QMS (new equipment, new computer system, etc.) | 4.1<br>5.4.1<br>5.4.2<br>7.1 |
|  |                                 |                      |            | 4.2 Documentation requirements (title only)   |                              |
|  |                                 |                      |            | <b>4.2.1 Documentation requirements - General</b>   |                              |
|  |                                 |                      |            | <b>Operating Procedure document formats</b><br>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                    |            | <b>OP 4.2.4 Records Sample</b><br>This sample Operating Procedure format is provided by West Management Services.<br>This example uses a simple layout and short sentences that are easy to understand.   | 4.2.1                        |
|  | Sample Documents                |                      |            | <b>Documentation Format Examples from IsoQual, Inc.</b><br>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                    |            | <b>DFC 6.2.2 - Competence, Awareness and Training System</b><br>A flowchart provides an overall picture of a process.   | 4.2.1                        |
| SOP format sample.doc                  | Sample Documents                | x                    |            | <b>SOP Format Sample</b><br>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                    |            | <b>SOP 6.2.2 – Competence, Awareness and Training</b><br>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).  | <b>4.2.1</b>      |
| process assessment worksheet example.doc                     | Sample Documents                | x                    |            | <b>Process Assessment Worksheet Example</b><br>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:<br>1. the process Objective and Baseline Performance against which the process is measured<br>2. improvement objectives (when defined for the process)<br>3. process inputs and outputs<br>4. what controls the process<br>5. key measures (what is used to measure if the process is achieving its objective(s))  | <b>4.2.1</b>      |
| process assessment worksheet.doc                             | Sample Documents                | x                    |            | <b>Process Assessment Worksheet Form</b><br>A blank Process Assessment Worksheet form and instructions for completing the form. Also see the above example of a completed form.   | <b>4.2.1</b>      |
|  |                                 |                      |            | <b>4.2.2 Quality manual</b>   |                   |
| exhibit 5 - document pyramid.doc                             | Audit Training                  | x                    |            | <b>Exhibit 5 Document Pyramid</b><br>This Document Pyramid shows a commonly used 3 Level structure for the Quality Manual. Level 1 is the Quality Manual (usually around 30 pages) that identifies the processes that comprise the quality management system. The Level 1 Quality Manual will describe the process or refer to Level 2 Operating Procedures that describe processes in more detail. Operating Procedures may refer to Level 3 Work Instructions that describe process steps at work centers. The Exhibit also identifies the ISO 9001:2008 requirements for documentation. The box at the bottom of the page describes the composition of the Quality Manual. | <b>4.2.2</b>      |
| quality manual numbering.doc                                 | Sample Documents                | x                    |            | <b>Quality Manual Numbering</b><br>Most organizations number the topics in the quality manual to correspond to the numbering of the ISO 9001:2008 standard. This makes it easier to discuss the standard and to audit the quality management system.  | <b>4.2.2</b>      |
|  |                                 |                      |            | <b>4.2.3 Control of documents</b>   |                   |
| master list.xls  | Sample Documents                | x                    |            | <b>Master List</b> (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.   | <b>4.2.3</b>      |
| doc chg request form.doc                                     | Forms                           | x                    |            | <b>Document Change Request Form</b> (a standard form)<br>Used to request a change to a document.  | <b>4.2.3</b>      |
| doc chg request template.doc                                 | Forms                           | File                 |            | <b>Document Change Request</b> (a data entry template)<br>The data entry template version of this form. Used to request a change to a document.   | <b>4.2.3</b>      |

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| doc chg request instructions.doc | Forms                               | x                    |            | <b>Document Change Request Instructions</b><br>Instructions for completing the DCR form and template.   | <b>4.2.3</b>          |
|                                  | DCR Doc Change Requests - file here |                      |            | <b>DCR Doc Change Requests - file here</b><br>A Directory for filing Document Change Requests submitted on a data entry template.   | <b>4.2.3</b>          |
| DCR Log.xls                      | Forms                               | x                    |            | <b>DCR Log</b> (Document Change Request Log) <i>a database</i><br>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.  | <b>4.2.3</b>          |
| DCR Log instructions.xls         | Forms                               | File                 |            | <b>DCR Log Instructions</b> <i>(a file only)</i><br>Additional information related to using the DCR Log.  | <b>4.2.3</b>          |
| doc chg review form.doc          | Forms                               | x                    |            | <b>Document Change Review Form</b><br>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.  | <b>4.2.3</b>          |
| doc chg notice.doc               | Forms                               | x                    |            | <b>Document Change Notice (DCN)</b> <i>(a standard form)</i><br>Form used to inform document users of what changes have been made to a revised document.  | <b>4.2.3</b><br>7.3.7 |
| doc chg notice template.doc      | Forms                               | File                 |            | <b>Document Change Notice (DCN)</b> <i>(a data entry template)</i><br>Form used to inform document users of what changes have been made to a revised document.  | <b>4.2.3</b><br>7.3.7 |
|                                  |                                     |                      |            | <b>4.2.4 Control of records</b>   |                       |
| records matrix.xls               | Sample Documents                    | x                    |            | <b>Records Matrix</b><br>Used to list records maintained by the organization and the controls that apply to each type of record.  | <b>4.2.4</b>          |
| records matrix sample.xls        | Sample Documents                    | x                    |            | <b>Records Matrix Sample</b><br>Completed matrix sample document.   | <b>4.2.4</b>          |
| records matrix 2.xls             | Sample Documents                    | File                 |            | <b>Records Matrix</b> <i>(2nd sample)</i><br>Used to list records maintained by the organization and the controls that apply to each type of record. <a href="#">The first column has an ISO clause number to indicate that it is a record required by the ISO 9001 standard. This helps auditors to check that the records required by ISO clauses are maintained. The second column identifies the type of required record and makes it easy to collect the information needed to complete this matrix (chart).</a> | <b>4.2.4</b>          |
| records matrix sample 2.xls      | Sample Documents                    | File                 |            | <b>Records Matrix Sample</b> <i>(2nd sample)</i><br>Completed matrix sample document.   | <b>4.2.4</b>          |
|                                  |                                     |                      |            | 5 Management responsibility (title only)  |                       |
|                                  |                                     |                      |            | 5.1 Management commitment   |                       |

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|  |                                     |                      |            | 5.2 Customer focus  |                     |
|  |                                     |                      |            | 5.3 Quality policy  |                     |
|  |                                     |                      |            | 5.4 Planning (title only)   |                     |
|  |                                     |                      |            | <b>5.4.1 Quality objectives</b>   |                     |
| setting objectives.doc                 | Sample Documents                    | x                    |            | <b>Setting Objectives</b><br>This document presents an example of objectives set by top management of a typical manufacturing company.  | <b>5.4.1</b>        |
| establish and review objectives.doc    | Sample Documents                    | x                    |            | <b>Establishing and Reviewing Quality Objectives</b><br>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. | <b>5.4.1</b><br>5.3 |
| quality objective mgt review table.doc | Forms                               | x                    |            | <b>Quality Objective Management Review Table</b><br>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.  | <b>5.4.1</b>        |
| top-level quality objective plan.doc   | Forms                               | x                    |            | <b>Top-Level Quality Objective Plan</b><br>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.  | <b>5.4.1</b>        |
| quality objective dept plan.doc        | Forms                               | x                    |            | <b>Quality Objective Department Plan</b><br>This form is used to define the plan for a department or functional area quality objective.   | <b>5.4.1</b>        |
| quality objective assignment.doc       | Forms                               | x                    |            | <b>Quality Objective Assignment</b><br>This form is used by a Department Manager to assign activities to personnel who will contribute to a Department Quality Objective Plan.  | <b>5.4.1</b>        |
|  | Quality Objective Plans - file here | x                    |            | <b>Quality Objective Plans - file here</b> <i>(a Directory)</i><br>This directory is used to file Top-Level Quality Objective Plans, Quality Objective Department Plans, and Quality Objective Assignment forms.  | <b>5.4.1</b>        |
|  |                                     |                      |            | <b>5.4.2 Quality management system planning</b>   |                     |
| project plan log.doc                   | Forms                               | x                    |            | <b>Project Plan Log</b> <i>(a form)</i><br>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.  | <b>5.4.2</b>        |
| project plan assignment.doc            | Forms                               | x                    |            | <b>Project Plan Assignment</b> <i>(a form)</i><br>This form is used to assign activities to those who will contribute to achieving quality management system plans.   | <b>5.4.2</b>        |

## ISO 9001:2008 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 |
|---|---------------------------------|----------------------|------------|---|-------------------|
|   | Project Plans - file here       |                      |            | <b>Project Plans - file here</b> ( <i>a Directory</i> )<br>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)  |                   |
|   |                                 |                      |            | <b>5.5.1 Responsibility and authority</b>   |                   |
| organization chart structure.doc                | Sample Documents                | x                    |            | <b>Organization Chart Structure</b><br>Shows the standard conventions used to design an Organization chart.   | 5.5.1             |
|   |                                 |                      |            | 5.5.2 Management representative   |                   |
|   |                                 |                      |            | 5.5.3 Internal communication  |                   |
|   |                                 |                      |            | <b>5.6 Management review</b> All of the forms that relate to Management Review are included in this product.  | 5.6               |
| framework to support the quality policy.doc     | Mgt Review forms                | File                 |            | <b>A Framework to Support the Quality Policy</b> ( <i>in text and a separate file</i> )<br>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<br>5.3        |
| management review report.doc                    | Mgt Review forms                | File                 |            | <b>Management Review Report</b><br>A form for recording the minutes of Management Review  | 5.6<br>5.3        |
| action number form.doc                          | Mgt Review forms                | x                    |            | <b>Action Number Form</b><br>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                    |            | <b>Management Review Result Chart</b><br>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                | File                 |            | <b>Management Review Result Chart Instructions</b><br>Instructions for completing the above Excel chart.  | 5.6               |
| 1 results of audits.doc                         | Mgt Review forms                | File                 |            | <b>1 Results of audits</b><br>A report on the effectiveness of the system and the ability of the audit program to detect and correct problems.  | 5.6               |

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|--|---------------------------------|----------------------|------------|---|---------------------|
| 2 customer feedback.doc                    | Mgt Review forms                | File                 |            | <b>2 Customer Feedback</b><br>Topics for discussion related to customer feedback.   | 5.6                 |
| 3 process performance.doc                  | Mgt Review forms                | File                 |            | <b>3 Process performance</b><br>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                | File                 |            | <b>4 Product Conformity</b><br>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                | File                 |            | <b>5 Status of Corrective Actions</b><br>An analysis of corrective action closure time, degree of recurrence, and the adequacy of problem resolution techniques.  | 5.6                 |
| 6 status of preventive actions.doc         | Mgt Review forms                | File                 |            | <b>6 Status of Preventive Actions</b><br>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                | File                 |            | <b>7 Follow-up actions from management reviews</b><br>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                | File                 |            | <b>8 Changes affecting the management system</b><br>A report on changes that can affect the management system.  | 5.6                 |
| 9 recommended improvements.doc             | Mgt Review forms                | File                 |            | <b>9 Recommended improvements</b><br>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                | File                 |            | <b>Improvement Suggestions from Personnel</b><br>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. | <b>5.6</b><br>8.5.1 |

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|---|---------------------------------|----------------------|------------|--|-------------------------|
| planning assignment.doc                       | Forms                           | File                 |            | <b>Planning Assignment</b><br>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                    |            | <b>Opportunities Log</b><br>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                    |            | <b>Opportunities Log Instructions</b><br>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  |                         |
|   |                                 |                      |            | 6.2.2 Competence, training and awareness   |                         |
|   | Competence Evaluation Forms     |                      |            | <b>Competence Evaluation Forms Directory</b><br>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                    |            | <b>Competence Evaluation Form for (Name Activity)</b><br>Used to: <ol style="list-style-type: none"> <li>1. identify units of competence for a type of work or activity</li> <li>2. define performance standard</li> <li>3. identify training or other action needed to achieve competency</li> <li>4. evaluate results of action taken</li> <li>5. assign additional action if person is not yet competent</li> </ol>   | 6.2.1<br>6.2.2<br>7.5.2 |
| personal development plan.doc                 | Forms                           | x                    |            | <b>Personal Development Plan</b><br>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                   |

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| qualified personnel database.xls    | Forms                           | x                    |            | <b>Qualified Personnel Database</b><br>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                    |            | <b>Training Record</b><br>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                    |            | <b>Training Matrix</b><br>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                    |            | <b>OJT Training for Manufacturing and Shipping</b><br>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                    |            | <b>Semi Annual Assessment of Training Effectiveness and Needs</b><br>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   |                   |
|                                     |                                 |                      |            | <i>(continued in Part 2)</i>   |                   |
|                                     |                                 |                      |            | <a href="#">Click Browser back button (in upper left corner) to return.</a>  |                   |