

ISO 9001:2008 Checklist Package List of Files

File name	Directory where file is located	List Item	ISO 9001:2008 Checklist Package List of Files Name of document / What used for
US format	Use these directory names or name your own directory. If you rename the Directory, you must change the Directory name on the document.		Note: The document footers of the files listed below identify the Directories in column B. You will need to create these Directories if they do not already exist as part of computer system.
			This product is provided by: ISO 9000 Checklist , 3575 S. Bascom Ave. #2, Campbell, CA 95008 USA Phone: (408) 371-9995 Email: Jane Birkenstock <janebirk@iso9000checklist.com>
ISO 9001 CHECKLIST PACKAGE LIST OF 35 FILES Rev 3-8-09.xls	Audit Forms	1	ISO 9001:2008 Checklist Package List of 35 Files
FOR EACH AUDITOR, PLACE THESE 2 DOCUMENTS INTO A PLASTIC SHEET PROTECTOR			The "Audit Steps Card" and the document titled "Auditing a Process - ISO 9001:2008" (BELOW) are study guides for Auditors. Place these two documents back to back in a plastic sheet protector for each Auditor.
audit steps card for color printer Rev 2-20-09.doc	Audit Forms	2	Audit Steps Card This document identifies the steps that an auditor takes to perform an audit. This file is for use with a color printer.
audit steps card for standard printer Rev 2-20-09.doc	Audit Forms	3	Audit Steps Card This is the same as the above document. Red often does not print well on a standard printer.
auditing a process Rev 2-20-09.doc	Audit Forms	4	Auditing a Process - ISO 9001:2008 This single page has all the interview questions found on the "Universal Items Checklist." This provides auditors with an overview of what they are looking for when they check for the requirements (located throughout the standard) that apply to the process under audit. You may provide this document to every employee so they will know the basic questions that will be included in every audit.
list of audit forms Rev 2-20-09.doc	Audit Forms	5	List of Audit Forms Provide Auditors with this chart that identifies audit forms and what they are used for.
what forms to use chart Rev 2-20-09.doc	Audit Forms	6	What Forms to Use Chart This chart identifies which forms to use depending on what you are assigned to audit.
document review Rev 2-20-09.doc	Audit Forms	7	Document Review This document explains how to complete the Audit Plan Form and prepare forms that are used to conduct the audit. This is a detailed document that tells new auditors exactly how to perform Document Review and set up their paperwork. The auditor follows the audit plan when conducting the audit. (This is an excerpt from the ISO 9001:2008 Auditor Training Course and Forms)

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manager interview Rev 2-20-09.doc	Audit Forms	8	Manager Interview Auditors interview the people who actually perform the work. In most situations, Managers do not perform work activities. This document is included in this package so auditors understand why they usually do not spend a great deal of time interviewing managers. Use the Manager Interview Form to interview the manager. (This is an excerpt from the ISO 9001:2008 Auditor Training Course and Forms)
audit by clause method Rev 2-20-09.doc	Audit Forms	9	Audit by Clause Method A chart telling how to perform a Clause Method Audit. Audit by Clause Method is used when you want to audit every location where the requirements of an ISO clause applies. As defined in this product, this is not a process audit.
audit by process method Rev 2-20-09.doc	Audit Forms	10	Audit by Process Method A chart telling how a process audit is identified, how it could be documented, how to do document review, and how to perform the audit of a documented or undocumented process. Audit by Process Method can be used to audit a process that identifies how the organization meets the requirements of an ISO clause.
audit plan form Rev 2-20-09.doc	Audit Forms	11	Audit Plan Form The Audit Program Manager enters the information on this form that identifies the Scope of the Audit. When first assigning audits, the Audit Program Manager also completes the form "ISO Requirements for This Process" that identifies the ISO requirements that apply to the process. (See the form "ISO Requirements for This Process.") When identifying the process to be audited, you identify the document <u>that most fully describes the process</u> . This will be either the paragraph location in the Quality Manual (when only the Quality Manual identifies the process) or an Operating Procedure or other document (or software) that describes how the process is performed. Auditors will identify any lower level documents that are referenced by the higher level document.
audit plan form - audit assignment explained Rev 2-20-09.doc	Audit Forms	12	Audit Plan Form - Audit Assignment Explained This document explains how the audit assignment is defined on the Audit Plan Form.
9001-2008 checklist Rev 2-20-09.doc	Audit Forms	13	ISO 9001:2008 Checklist A 61-page Checklist that contains checklist questions for each requirement clause of the standard. This Checklist is used to audit a documented or undocumented process that identifies how the requirements of an ISO clause are met. Blue text underlined and in italics identifies where 2008 revision changes appear.
ISO 9001 2008 - Changes between the 2000 and 2008 versions Rev 2-20-09.doc		14	ISO 9001 2008 - Changes between the 2000 and 2008 Versions This document identifies where changes appear in the text of the ISO 9001:2008 Standard and why the changes were made.
checklist instructions Rev 2-20-09.doc	Audit Forms	15	Checklist Instructions Instructions on how to use the ISO 9001:2008 Checklist.

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universal items checklist - all Rev 3-1-04.doc	Audit Forms	16	<p>Universal Items Checklist - All</p> <p>There are two versions of the Universal Items Checklist. <u>A service company is more likely to use this version of the form.</u> This version (that has the word ALL in the name of the form) has items that apply to ALL processes and is the shorter version. Auditors check the form titled, "ISO Requirements for This Process" (completed by the Audit Program Manager for each process) to determine which version of this form to use. <u>This Checklist is used to audit a documented or undocumented process or procedure. This Checklist includes checking for the requirements of other processes that apply to the process under audit. When auditing an Operating Procedure, the auditor uses a separate Universal Items Checklist for each person identified in the Operating Procedure who is interviewed. If an individual performs more than one step of an OP, all interview responses are recorded on the single Universal Items Checklist that is used to interview that person.</u></p>
universal items checklist Rev 2-20-09.doc	Audit Forms	17	<p>Universal Items Checklist</p> <p>There are two versions of the Universal Items Checklist. This version has items that apply to all processes <u>plus additional items that are more likely to apply to manufacturing production processes.</u> This is the longer version. Auditors check the form titled, "ISO Requirements for This Process" (completed by the Audit Program Manager for each process) to determine which version of this form to use. This Checklist is used to audit a documented or undocumented process or procedure. <u>This Checklist includes checking for the requirements of other processes that apply to the process under audit. When auditing an Operating Procedure, the auditor uses a separate Universal Items Checklist for each person identified in the Operating Procedure who is interviewed. If an individual performs more than one step of an OP, all interview responses are recorded on the single Universal Items Checklist that is used to interview that person.</u></p>
NOTE TO USER			<p>What is the difference between the 2 versions of the Universal Items Checklist?</p> <p>Universal Items Checklist - All - (Version 1) This Checklist has the questions that will apply to any process that is audited. It does not contain questions related to equipment maintenance, traceability and calibration. <u>It is more suitable for a front office activity or to a service company.</u></p> <p>Universal Items Checklist - (Version 2) This Checklist has all the questions on Version 1 PLUS questions that are more likely to apply to a manufacturing activity. The additional questions on Version 2 relate to equipment maintenance, traceability and calibration.</p> <p>Which version to use: If in doubt, use Version 2 and write N/A (Not Apply) when a question does not apply.</p>

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ISO requirements for this process Rev 2-20-09	Audit Forms	18	<p>ISO Requirements for This Process</p> <p>The Audit Program Manager completes this form for every process. The form identifies which ISO clauses contain one or more requirements that apply to a specific process. All the clauses in column 1 apply to every process. Audit Program Manager: In column 2, place an X in front of any numbered clause that contains requirements that apply to the process. Identify any other clauses that contain requirements that apply to the process at the bottom of the page. In Directory: Audit Forms/ create a Sub-Directory named: ISO Requirements for Each Process. File all completed forms in the Sub-Directory. Auditors will look for the completed form for a process in this Sub-Directory - and print out the form. The Auditor checks the completed form for a process to find out which questions on the Universal Items Checklist apply to the process assigned for audit.</p>
universal items list Rev 2-20-09.doc	Audit Forms	19	<p>Universal Items List</p> <p>Some ISO requirement clauses contain requirements that apply to many other processes. When any process is audited, the Auditor also checks to see that requirements of other processes that apply to the process are being followed. The Universal Items List has a summary statement of the requirements of the clauses that contain requirements that apply to all processes and clauses that apply so frequently to other processes that they are included on this list. This document assists the Audit Program Manager in completing the form "ISO Requirements for This Process" that identifies which requirements of the ISO standard apply to each process assigned for audit. This document can also be used for auditor training.</p>
notes form Rev 3-1-04.doc.doc	Audit Forms	20	<p>Notes Form</p> <p>Used to plan a checklist of what to look for during an audit and to record the results of interviews and observation. See the document titled "Document Review" for how to use this form.</p>
long notes form Rev 3-1-04.doc	Audit Forms	21	<p>Long Notes Form</p> <p>This form may be used to plan a checklist of what to look for during an audit. See the document titled "Document Review" for how to use this form. The form can also be used to record audit evidence if other forms do not have sufficient writing space.</p>
manager interview form Rev 2-20-09.doc	Audit Forms	22	<p>Manager Interview Form</p> <p>Auditors use this form to interview the area manager. See the document titled "Manager Interview" that explains what is included in a manager interview.</p>
records review form Rev 3-1-04.doc	Audit Forms	23	<p>Records Review Form</p> <p>This form is used to list the records reviewed when reviewing a sampling of records.</p>
audit results memo Rev 3-1-04.doc	Audit Forms	24	<p>Audit Results Memo</p> <p>Auditors must provide a verbal summary of the audit results to the area manager before leaving the area audited. This form is used to summarize the audit results if the Manager is not present when the audit is completed. The Auditor can also use this form to list the items to include in the verbal summary to the Manager. This ensures that all items were included.</p>

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audit results memo template Rev 3-1-04.doc	Audit Forms	25	Audit Results Memo <i>(data entry template)</i> A data entry template that is the same as the above form. The template allows the auditor to complete the form and send it as an email to the area manager.
exhibit 4 - iso 9001 - content of clauses Rev 2-20-09.doc	Audit Training	26	Exhibit 4 - ISO 9001 - Content of Clauses This document has a summary statement of the content of the clauses of the ISO 9001:2008 standard. This document is helpful when determining which requirements of the standard apply to a specific process (activity). Audit Program Manager: When completing the form "ISO Requirements for This Process," all the clauses with an X in column 1 will apply to every process. When using the "Content of Clauses" document, you look at a named ISO clause and ask the question, "Is the identified process affected by the requirements of this clause?"
process model Rev 2-20-09.doc	Audit Forms	27	Process Model The process Model (picture of a process) identifies the requirements in clause 4.1 that apply to every process (activity). Auditors must MEMORIZE this picture in order to understand what they are looking for when they audit a process. Questions on page 1 of the Universal Items Checklist relate to this Process Model. Note: When an Operating Procedure (OP or SOP) is used to describe a process, each activity that someone must do that is listed in that procedure is just a step of the larger process (the Operating Procedure). When you use the Universal Items Checklist to interview each person who is listed in the Operating Procedure, the check for inputs and outputs is a check to see if the person gets what is needed for the work and knows the one or more steps that he or she must do. If a person does more than one step in an OP, all interview responses are recorded on the Universal Items Checklist that is used to interview that person.
process model explanation Rev 3-1-04.doc	Audit Forms	28	Process Model Explanation - Requirements of 4.1 This document provides a more detailed explanation of the requirements of clause 4.1 and explains what auditors look for when they ask the questions on page 1 of the Universal Items Checklist. Auditors should review this document before they perform an audit.
exhibit 7 - grouping related clauses Rev 2-20-09.doc	Audit Training	29	Exhibit 7 - Grouping Related Clauses This document can be used when planning audits to identify clauses that have related content.
9001-2008 list of all clauses Rev 2-20-09.doc	Audit Forms	30	ISO 9001:2008 List of all Requirement Clauses A 1-page document that lists the requirement clauses of the standard.

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work order audit form Rev 2-20-09.doc	Audit Forms	31	Work Order Audit Form Form to use to conduct the audit of a Work Order. You may conduct this type of audit or audit organization-specific processes separately. The standard does not state that you must conduct this type of audit. This type of audit checks to see that all system processes used to deliver a specific product, contract, or order are properly connected. This is a process audit of each activity performed. The audit also checks to see if the ISO requirements that apply to each process are being followed. This type of audit is best performed by an experienced auditor who knows the standard very well.
work order audit instructions Rev 2-20-09.doc	Audit Forms	32	Work Order Audit Form Instructions Detailed instructions for how to perform the audit of a Work Order.
auditor qualifications and training record Rev 2-20-09.doc	Audit Forms	33	Auditor Qualifications and Training Record Defines the personal attributes, qualifications and skills that you require for the position of auditor. The form provides space to record the training provided for the auditor and to evaluate the Trainee's performance for 2 supervised / evaluated audits.
vocabulary - quality related terms Rev 2-20-09.doc	Audit Forms	34	Vocabulary - Quality Related Terms This document contains terms that are used by manufacturing and service organizations and terms used in auditing. You may edit this document and add terms that are specific to your industry. This document does not contain the vocabulary found in the ISO 9000:2008 standard.
license agreement Rev 2-20-09.doc		35	License Agreement for the ISO 9001:2008 Checklist This product is sold as a site license for a single site with up to 400 employees. You may request a quote for use of this product at a site with more than 400 employees and for multiple site locations.
			Customer Service: Call 408.371.9995 with any questions regarding this product.
			Email: Jane Birkenstock <janebirk@iso9000checklist.com>
			Click Browser Back Button (in upper left corner) to Return