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
				ISO 9001:2008 Explained and Exhibits - PART 2	
ISO 9001 Explained and Exhibits List of Files Rev 2-20-09.xls		File		**ISO 9001 Explained and Exhibits List of Files - (THIS FILE)** This is a list of all the documents in this product.	
				6.4 Work environment	
				7 Product realization (title only)	
				7.1 Planning of product realization	
				7.2 Customer-related processes (title only)	
				7.2.1 Determination of requirements related to the product	
				7.2.2 Review of requirements related to the product	
				7.2.3 Customer communication	
				7.3 Design and development (title only)	
design requirements exercise.pdf design requirements exercise.doc	Training	x		**Design Requirements Exercise** Use the PDF version of this file to perform the Exercise. **(Approximate time: 20 minutes if using a computer to view documents. Add 10 minutes if you have printed out all documents and the exercise is done by a group with discussion.)** This exercise helps to understand the ISO requirements for design input requirements, design stages, reviews, verification, validation, and design changes. Concepts and terms related to these requirements may not be known to people who have not participated in a structured design project. This exercise is a review of sample forms that meet the requirements of the ISO 9001:2008 standard. You may replace the sample documents with your own documents when they contain similar content. The sample forms in this exercise appear again in the 7.3.1 - 7.3.7 design clauses.	7.3.1 7,3.2 7.3.3 7.3.4 7.3.5 7.3.6 7.3.7
design requirements exercise - answer key.pdf design requirements exercise - answer key.doc	Training	x		**Design Requirements Exercise - Answer Key** Answer Key to the Design Requirements Exercise. Personnel doing this exercise by self-study can use the PDF version of this file to check the Exercise.	
				7.3.1 Design and development planning	
design and dev planning - reviews.doc	Sample Documents	x		**Design and Development Planning - Reviews** Information related to design and development reviews.	**7.3.1 7.3.4**
product and service design flow charts.doc	Sample Documents	File		**Product and Service Design Flow Charts** *(in text and a file)* Example showing typical stages included in a design for a product that will also be serviced. A training document.	**7.3.1**
				7.3.2 Design and development inputs	

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File name	Directory where file is located	PDF in ISO Explained	To be Used	Name of document / What used for	Relates to Clause
design input checklist.doc	Forms	x		**Design Input Checklist** This checklist may be used when determining design input requirements for a product or service.	**7.3.2**
				7.3.3 Design and development outputs	
				7.3.4 Design and development review	
design and dev review report.doc	Forms	x		**Design and Development Review Report** This form is used to create a record of design and development reviews.	**7.3.4**
				7.3.5 Design and development verification	
verification matrix.xls	Sample Documents	x		**Verification Matrix** A verification matrix is used to list the requirements for the product or service, state these requirements in terms that are measurable, and provide the details related to how these requirements will be verified. Product and service characteristics are verified during design and development. Characteristics subject to variation are also verified during product and service realization.	**7.3.5** 7.1 7.3.2 7.3.6 7.4.3 8.2.4
verification matrix instructions.doc	Sample Documents	x		**Verification Matrix Instructions** Instructions for completing a verification matrix.	same as above
verification matrix instructions applied to design 7.3.5.doc	Sample Documents	File		**Verification Matrix Instructions Applied to Design 7.3.5** This has the same information as the verification matrix instructions. The blue text in this document points out the verification activities that should take place during the design and development of a product.	**7.3.5**
verification plan - input req.doc	Forms	x		**Verification Plan for an Input Requirement** The organization must determine how each design and development input requirement will be verified. This form lists items that should be considered when defining a verification activity and the record that must be maintained as evidence of validation.	**7.3.5**
				7.3.6 Design and development validation	
validation plan - use req.doc	Forms	x		**Validation Plan for a Use Requirement** The organization must determine how each input use requirement will be validated. This form lists what should be considered when defining a validation activity, and the record that must be maintained as evidence of verification.	**7.3.6**
				7.3.7 Control of design and development changes	

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File name	Directory where file is located	PDF in ISO Explained	To be Used	Name of document / What used for	Relates to Clause
design doc chg request.doc	Forms	x		**Design Document Change Request - DDCR** A form / In manufacturing, this form is called an Engineering Change Request (ECR). Used to request a 1. Product or service requirement change 2. Design in-process change (when the change affects a document approved by a design review) 3. Modification / revision to an existing product or service Form is used to identify the requested change, identify affected documents, changes required and estimate the total time and cost to implement the change.	7.3.7
design doc chg request instructions.doc (not included in course printouts)	Forms	x		**Design Document Change Request Instructions** Instructions for completing this form.	7.3.7
design doc chg request affected doc.doc (not included in course printouts)	Forms	x		**Design Document Change Request Affected Document** Used in association with the Design Document Change Request - DDCR form. This form is used to evaluate what the affect of a requested design change will be (if any) on other components, component parts and systems that interact with the item that is requesting the change.	7.3.7
rev instructions for production products.doc	Forms	x		**Revision Instructions for Production Products** *(a standard form)* A form used to provide revision instructions for production products, the tests and inspections to perform, and records to generate.	7.3.7
rev instructions for production products template.doc	Forms	File		**Revision Instructions for Production Products** *(a data entry template)* A data entry template for the above form.	7.3.7
				7.4 Purchasing (title only)	
				7.4.1 Purchasing process (relates to suppliers)	
supplier capability rating.doc (not included in course printouts)	Sample Documents	File		**Supplier Capability Rating** A rating scale used to classify your present relationship with suppliers.	7.4.1
Approved Supplier List - ASL.xls	Forms	x		**Approved Supplier List** An example of an Approved Supplier List. Suppliers are listed based on a capability ranking using letters A through G.	7.4.1
supplier questionnaire.doc	Sample Documents	x		**Supplier Questionnaire** A form used to obtain supplier information including company name, products and services provided, and information on the supplier's quality system. This is a minimal information form.	7.4.1
SCAR.doc	Forms	x		**Supplier Corrective Action Request** *(form)* Form sent to supplier requesting corrective action related to receipt of discrepant materials or product.	7.4.1
	SCAR Log	x		**A directory for the Supplier Corrective Action Request Log**	

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File name	Directory where file is located	PDF in ISO Explained	To be Used	Name of document / What used for	Relates to Clause
1SCAR Log.xls	SCAR Log	x		**SCAR Log** (Supplier Corrective Action Request Log - *a database*) A log used to monitor requests for corrective action sent to suppliers. This Excel database allows you to monitor the types of problems you have with a supplier. You can also sort by supplier and the number of days required to resolve a request for corrective action.	**7.4.1**
1about the SCAR Log.xls	SCAR Log	x		**About the SCAR Log** (Supplier Corrective Action Request Log) Information about using this Log to monitor supplier performance.	**7.4.1**
1SCAR Log instructions.xls	SCAR Log	x		**SCAR Log Instructions** Explains how to sort the Supplier CAR Log to determine which suppliers are most responsive to your requests for corrective action.	**7.4.1**
supplier re-evaluation rating.xls	Forms	x		**Supplier Re-evaluation Rating** Excel form used to re-evaluate suppliers on a periodic basis. Excel computes the total score for items considered in the rating. The form has space for entries on multiple dates which allows you to see performance trends over an extended period of time.	**7.4.1**
supplier re-evaluation form.xls (not included in course printouts)	Sample Documents	File		**Supplier Re-evaluation Form** Form used to re-evaluate suppliers on a periodic basis.	**7.4.1**
				7.4.2 Purchasing information	
				7.4.3 Verification of purchased product	
				7.5 Production and service provision (title only)	
				7.5.1 Control of production and service provision	
				7.5.2 Validation of processes for production and service provision	
validation of special process - criteria.doc	Forms	x		**Validation of Special Process - Criteria** *(form and template)* This form is a work sheet used to identify the requirements for a special process.	**7.5.2**
				7.5.3 Identification and traceability	
				7.5.4 Customer property	
customer-owned property form.doc	Forms	x		**Customer-Owned Property Form** *(form)* Used to describe customer-owned property kept on the organization's site. The form may be used as a receipt, a report of nonconformities, and a record.	**7.5.4**
customer-owned property template.doc (not included in course printouts)	Forms	File		**Cutomer-Owned Property Template** *(a data entry template)* Data entry template version of this form.	**7.5.4**
	Customer-Owned Property Log and Records			**Customer-Owned Property Log and Records** *(an empty Directory)* This Directory may be used as the file location for the Excel Customer-Owned Property Log and for data entry template files that contain records of customer-owned property.	**7.5.4**

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Customer-Owned Property Log.xls	Forms	x		**Customer-Owned Property Log** An Excel file used to list the file names where customer property is described when the property records are kept in the form of data entry template forms. This file can be sorted by customer name to locate property records.	7.5.4
Customer-Owned Property Log Handwritten.xls (not included in course printouts)	Forms	File		**Customer-Owned Property Log Handwritten** *(a file only)* A standard form used to maintain a handwritten property log.	7.5.4
				7.5.5 Preservation of product	
				7.6 Control of monitoring and measuring equipment	
Calibration Verification Database.xls	Forms	x		**Calibration Verification Database** Database used to list measurement devices that require calibration or verification of their accuracy and the date that the next calibration or verification is due.	7.6
				8.1 Measurement, analysis and improvement - General	
				8.2 Monitoring and measurement (title only)	
				8.2.1 Customer satisfaction	
				8.2.2 Internal audit	
audit steps card for color printer.doc	Audit Forms	x		**Audit Steps Card** *(use with a color printer)* This 1-page document lists each step an auditor takes to perform an audit. The Auditor Manual that is part of the full *ISO 9001:2008 Auditor Training Course and Forms* provides a detailed description for every statement on this page. The numbered steps correspond to the numbered descriptions in the Auditor Manual.	8.2.2
audit steps card for standard printer.doc	Audit Forms	File		**Audit Steps Card** *(use with a standard printer)* Same as the above document.	8.2.2
auditing a process.doc	Audit Forms	x		**Auditing a Process - 9001:2008** This 1-page document has questions that an Auditor asks when any process is audited. This document may be distributed to everyone in the organization.	8.2.2
				8.2.3 Monitoring and measurement of processes	
input output chart.doc	Forms	File		**Input Output Chart** First introduced in clause 4.1. Repeated here (in the written explanation of the standard) to identify a method that can be used for the monitoring of processes. A process planning tool used to identify process objectives and the criteria for acceptable process inputs and outputs.	8.2.3 4.1 5.4.1 5.4.2 7.1 b

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input output chart instuctions.doc	Forms	File		**Input Output Chart Instructions** Instructions for how to complete an Input Output Chart.	same as above
process assessment worksheet.doc	Sample Documents	File		**Process Assessment Worksheet Form** First introduced in clause 4.2.1. Repeated here (in the written explanation of the standard) to identify a method that can be used for the monitoring of processes. A blank Process Assessment Worksheet form plus instructions for completing the form. The next entry on this chart is an example of a completed worksheet.	**8.2.3**
process assessment worksheet example.doc	Sample Documents	File		**Process Assessment Worksheet Example** This is a new type of document 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	**8.2.3**
				4. what controls the process 5. key measures (what is used to measure if the process is achieving its objective(s) This worksheet format was developed by IsoQual, Inc.	**8.2.3**
				8.2.4 Monitoring and measurement of product	
verification matrix.xls	Sample Documents	X		**Verification Matrix** A verification matrix is used to list the requirements for the product or service, state these requirements in terms that are measurable, and provide the details related to how these requirements will be verified. Product and service characteristics are verified during design and development. Characteristics subject to variation are also verified during product and service realization.	7.35 7.1 7.3.2 7.3.6 7.4.3 **8.2.4**
verification matrix instructions.doc	Sample Documents	X		**Verification Matrix Instructions** Instructions for completing a verification matrix.	same as above
verification matrix instructions applied to 8.2.4.doc	Sample Documents	File		**Verification Matrix Instructions Applied to 8.2.4 Monitoring and measurement of product** This has the same information as the verification matrix instructions Exhibit presented in 7.3.5. The blue text in this document points out the verification activities that should take place when purchased product is verified and during product realization (when the product is made).	**8.2.4**
				8.3 Control of nonconforming product	
discrepant material report.doc	Forms	x		**Discrepant Material Report - DMR** Form used to report defects in: 1. incoming materials from suppliers, and 2. product that did not pass in-house inspection activities.	**8.3**
DMR Log.xls	Forms	x		**Discrepant Material Report Log** Log used to identify nonconforming material and product, its location and disposition.	**8.3**

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				8.4 Analysis of data	
analysis of data - possible sources chart.doc	Forms	x		**Analysis of Data - Possible Sources Chart** List of possible sources of data that can be analyzed to determine where improvement can be made.	**8.4**
pareto analysis training.doc	Training	x		**Pareto Analysis Training** (Includes the 5 documents within the dark border.) This is a training document, **or instructions can just be read**. 1. Wherever possible, train personnel at data collection locations to enter data onto the Excel Pareto analysis file. This prepares data for the Analyst. 2. The Analyst investigates items for a proposed solution and what resources are needed to correct the problem and presents findings to Top Management. 3. Top Management determines the Severity Ranking of nonconformances, selects actions to implement, and approves needed resources.	**8.4** **8.5.1**
pareto analysis service sample.xls	Training	x		**Pareto Analysis Service Sample** Example of a completed Pareto Analysis; used in Pareto Analysis Training.	**8.4** **8.5.1**
pareto item investigation.doc	Forms	x		**Pareto Item Investigation** *(a standard form)* The person who analyzes the results of a Pareto analysis may send this form to the process owner who confirms if a problem exists, states the preferred solution, and estimates the time and cost to correct the problem. This information is used by management when determining Pareto analysis items selected for action.	**8.4** **8.5.1**
pareto analysis mfg sample.xls	Training	x		**Pareto Analysis Manufacturing Sample** Example of a completed Pareto Analysis; used in Pareto Analysis Training.	**8.4** **8.5.1**
pareto analysis training - review answer key.doc	Training	x		**Pareto Analysis Training - Review Answer Key** The answer key to the Review at the end of the Pareto Analysis Training document.	**8.4**
pareto item investigation template.doc	Forms	File		**Pareto Item Investigation** *(a data entry template)* The data entry template version of this form.	**8.4** **8.5.1**
WI (assigned number) - Pareto Analysis Instructions.doc (printout included in Trainer Manual)	Forms	File		**WI (assigned number) - Pareto Analysis Instructions** This document is a detailed Work Instruction for those who contribute to completing a Pareto Analysis, including instructions for: 1. The Data Entry Person - successful completion of "Pareto Analysis Training" and the "Pareto Analysis Data Entry Exercise" qualifies a person to be a Pareto Analysis Data Entry Person. 2. The Analyst - the person who performs the analysis, investigates items, and reports results to top management 3. The Review Team comprised of Top Management - who determine the disposition of each item included in the analysis.	**8.4** **8.5.1**

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pareto analysis form.xls (printout included in Trainer Manual)	Forms	x		**Pareto Analysis Form** Used to analyze a large amount of collected data to determine what to fix to get the greatest benefit. Includes data entry of items, investigation of data, assigning 1 to 10 Critical Ranking, preparation of information for management review, selection of actions to implement, and assignment of actions. Items not selected that merit future action are entered in the Opportunities Log.	**8.4** 8.5.1
				The purpose of the following exercise is to train personnel to perform the data entry part of a Pareto Analysis. This is done so more people contribute to the analysis - and the analyst is not doing all of the work.	
pareto analysis data entry exercise.doc (printout included in Trainer Manual)	Training	File		**Pareto Analysis Data Entry Exercise** Successful completion of this exercise qualifies a person to be a Pareto Analysis Data Entry Person. The exercise includes: 1. Naming an analysis and the file name (3 examples) 2. Entering data for 2 analyses	**8.4**
pareto analysis data entry exercise - answer key.doc (printout included in Trainer Manual)	Training	File		**Pareto Analysis Data Entry Exercise - Answer Key** The answer key to the above exercise. The answer key includes the following two files: **Directory**: Training/ file: 01-02-01 customer complaints for dec 2000.xls **Directory**: Training/ file: 01-04-03 4th Q 2002 customer complaints - 7 hotels.xls	**8.4**
01-02-01 customer complaints for dec 2000.xls (printout included in Trainer Manual)	Training	File		**Part of the "Pareto Analysis Data Entry Exercise - Answer Key" (above)** This is the answers to a data entry exercise that is used to qualify as a data entry person. The trainee's data entry is compared to this document.	**8.4**
01-04-03 4th Q 2002 customer complaints - 7 hotels.xls (printout included in Trainer Manual)	Training	File		**Part of the "Pareto Analysis Data Entry Exercise - Answer Key" (above)** This is the answers to a data entry exercise that is used to qualify as a data entry person. The trainee's data entry is compared to this document.	**8.4**
				8.5 Improvement (title only)	
				8.5.1 Corrective action	
corrective action checklist.doc	Forms	x		**Corrective Action Checklist** A checklist that summarizes the requirements of clause 8.5.2. The Checklist can be used as a training document related to corrective action.	**8.5.2**
what is a pareto analysis.doc (not included in printed documents)	Training	x		**What is a Pareto Analysis?** A one-page document that introduces Pareto Analysis. Pareto analysis will show what to fix first to get the most improvement.	**8.5.2** 8.4
pareto analysis training - Instructor READ ME.doc	Training	File		**Pareto Analysis Training - Instructor READ Me** *(a file only)* A note to the Trainer regarding Pareto analysis training.	

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review nonconformities using pareto analysis.doc	Training	File		**Review Nonconformities Using Pareto Analysis** *(a file only)* A two-page document that introduces how Pareto Analysis can be used to identify the most significant nonconformities out of a large number of nonconformities of different types. This document shows that the Pareto 80/20 ratio does not always occur, but will still indicate the most significant items to consider for corrective action.	**8.5.2**
nonconformity review and evaluation form.doc	Forms	x		**Nonconformity Review and Evaluation Form** The answers to the questions on this form provide the information needed to evaluate if corrective action is needed related to a specific type of nonconformity. The Quality Assurance Manager and/or Top Management evaluate if action is needed related to the nonconformity. This form may be used to create a record of the review and evaluation.	**8.5.2** 8.5.1 8.5.3
nonconformity review and evaluation template.doc	Forms	File		**Nonconformity Review and Evaluation Template** *(a file only)* A data entry template of the above form.	**8.5.2** 8.5.1 8.5.3
cpar form.doc	Forms	x		**Corrective Preventive Action Request** *(a form for hand-written reporting)* 1. Used to request a corrective or preventive action and as a record of the action taken. 2. May be used to suggest an Opportunity for Improvement or preventive action. 3. May be used to report a customer complaint that originates outside of Customer Service reporting.	**8.5.2**
cpar template.doc	Forms	File		**Corrective Preventive Action Request** *(a data entry template)* Same as the above form.	**8.5.2**
cpar instructions.doc	Forms	x		**Corrective Preventive Action Request Instructions** Insructions for completing CPAR form and template.	**8.5.2**
cpar about form.doc	Forms	File		**Corrective Preventive Action Request - About Form** *(no printout - a file only)* Terms used on the form and changes you may want to make to the form and template.	**8.5.2**
corrective action plan.doc	Forms	x		**Corrective Action Plan** A form that may be used to prepare a corrective action plan when the Corrective Preventive Action Plan form does not have sufficient writing space. The user completes entry boxes on this form and deletes entry items that do not apply to the situation.	**8.5.2**
cpar activity assignment.doc	Forms	x		**CPAR Activity Assignment** (form) Used to assign activities that that are part of the corrective action plan. Form defines activity requirements and what measures success.	**8.5.2**
corrective action team log.doc	Forms	x		**Corrective Action Team Log** (form) A form used to list and track the completion of activities when there are multiple departments or functional areas that participate in a corrective action.	**8.5.2**
corrective action team log instructions.doc	Forms	x		**Corrective Action Team Log Instructions** Defines authorities and responsibilities related to a corrective action carried out by a team.	**8.5.2**

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	CPAR Directory			**CPAR Directory -** a directory for filing Corrective Preventive Action Requests submitted using the CPAR data entry template form. When the "Corrective Action Plan" form, the "Corrective Action Team Log," and "Activity Assignments" are filed in this directory they will be found after the CPAR template number entry. This sequencing will occur when you identify audit file names as indicated on the original template forms.	**8.2.2** 8.52
cpar log database.xls (printout is in the Trainer Manual)	Forms	x		**CPAR Log Database** Corrective Preventive Action Log Database Used to track the status of corrective actions, preventive actions, and improvement actions. The list of CPARs from auditor reports can be copy/pasted into this log when auditors use the data entry template to list CPARs. Sorts can be performed to: 1. Assign follow-up for effectiveness of closed actions (part of an audit assignment) 2. determine which departments/areas/clauses require more frequent audit 3. determine trends to report to Management Review See comment notes in heading cells for what to enter in cells.	**8.2.2** 8.52
cpar log database instructions.xls (printout included in Trainer Manual)	Forms	x		**CPAR Log Database Instructions** Instructions on how to sort the database.	**8.2.2** 8.52
				8.5.3 Preventive action	
preventive action checklist.doc	Forms	File		**Preventive Action Checklist** *(in text and a file)* This Checklist may be used as a general planning guide when determining and evaluating what actions are needed to prevent or detect the causes of potential nonconformities. The form applies to any type of planning situation and applies when evaluating if there is a need for preventive action.	**8.5.3**
failure modes effects analysis intro.doc	Forms	File		**Failure Modes Effects Analysis Introduction** Explains that a Failure Modes Effects Analysis can be used for 1. any type of planning event 2. to evaluate the need for preventive action, and 3. as a training document for those involved in planning activities	**8.5.3** 5.4.2 7.3.2 7.3.4 8.5.2
failure modes effects analysis - FMEA.doc	Forms	File		**Failure Modes Effects Analysis - FMEA** A Failure Modes Effects Analysis looks for inherent characteristics of products and processes that will eventually result in problems or a failure to meet requirements. A FMEA identifies product/service requirements or process objectives, critical success factors, possible failures, the likelihood of their occurrence, root cause, and what to do to prevent failure when provisions are not adequate.	**8.5.3** 5.4.2 7.3.2 7.3.4 8.5.2
				End of the Exhibits that illustrate the written explanation of the ISO 9001:2008 Standard	

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known issues.doc	**Introduction - READ ME**	File		**Known Issues** Information relates to saving Read Only files, how dates appear on Excel files (applies to non-US countries), and small numbers used on the Corrective Preventive Action Request form.	
ABOUT THIS PRODUCT	Sold as a download			**ISO 9001:2008 Requirements Explained** is a pdf file that you place on your organization's computer system. It has links to all the Exhibit documents listed on this page. Users report that this product creates a consensus within an organization related to what the ISO requirements mean and helps to determine how to correct nonconformances.	
	Included in the full Auditor Course			**ISO 9001:2008 Requirements Explained** is part of the larger product titled, *ISO 9001:2008 Auditor Training Course and Forms*. This training course allows you to train your own internal auditors. The content of *ISO 9001:2008 Requirements Explained* is Manual 1 Requirements and Manual 2 Exhibits when purchased as part of the full auditor course.	
	Included in the full Auditor Course			**Manual 1 - Requirements Explained**. This is a printout of the written explanation of the standard. You make a photocopy of this manual for each auditor.	
	Included in the full Auditor Course			**Manual 2 - Exhibits**. This is a printout of all the Exhibit documents. You make a photocopy of this manual that is used when training auditors. You may insert your own documents as Exhibits when you have similar documents.	
	Reduced price for the full Auditor Training Course.			**Reduced Price for the Full Auditor Training Course** The full auditor course can be purchased at a reduced price if you have purchased *ISO 9001:2008 Requirements Explained* and then want to purchase the full auditor course. The price of your prior purchase will be deducted from the price of the full Auditor Course.	
				Site License: This product is subject to the terms of the Site License Agreement. The present List Price for a single location with up to 400 employees is found on the iso9000checklist.com website. You may request a quote for a multiple site license or for a location with more than 400 employees.	
				This product is offered by: **ISO 9000 Checklist** 3575 S. Bascom Ave. #2 Campbell, CA 95008 USA Web site: http://www.iso9000checklist.com contact: Jane Birkenstock <janebirk@iso9000checklist.com> Phone: (408) 371-9995	
				Click Browser back button (in upper left corner) to return.	