

ISO COMPLIANCE WHITEPAPER

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HOW CAN FILEHOLD SYSTEMS HELP WITH ISO COMPLIANCY?

The process of becoming ISO compliant begins with an Organization's decision to adhere to a set of international quality management standards. ISO compliancy is not compulsory; however, following quality standards when developing and producing products and/or services is good for business. Staying compliant and maintaining accreditation and/or certification requires the Organization follow certain rules and regulations set out by the ISO. While ultimately the Organization is responsible for defining and enforcing quality management processes, FileHold Systems ('FileHold') feature-rich document and lifecycle management software can assist by efficiently monitoring, organizing, accessing and distributing artifacts in a manner consistent with ISO standards.

1.1. ISO 9001 PRINCIPLES

The table shows the eight ISO 9001 Principles and discusses how FileHold features may be used to address those particular ISO points.¹

ISO 9001 Principles	How FileHold Can Help
Customer focus: Understanding the customer's needs and providing a method for them provide feedback.	The feature-rich workflow module, electronic forms, and Guest (Self-Service) Portal, and Courier ² , allow Organizations to securely interact with their external Customers. This access makes it easy to exchange information such as surveys, checklists and other pertinent feedback information. Feedback documents can be securely stored and routed to appropriate personnel within the organization.
	Would you like to know more?
	http://www.filehold.com/blog/15/03/integrating-pdf-forms-automatic-document-importation
	http://www.filehold.com/features/optional/workflow
	http://www.filehold.com/search/node/workflow
	http://www.filehold.com/resources/whitepapers/guest-user-accounts-self-service-portal
Leadership: Understanding the Organizations mission. Encourage and develop a culture where employees know what to do to satisfy customers.	Using workflow templates, managers can easily disseminate vital customer/supplier relationship information to employees. Electronic signatures can be used to verify that users have read corporate policies, mission statements, and customer satisfaction goals.
	Document and calendar notifications allow employers to observe customer relationship tasks to ensure employees are following relationship standards.

² Courier will be available in FileHold v. 15.



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¹ This document does not discuss all features available with FileHold. The extensive API allows FileHold to be customized to resolve more complex business process that cannot be done with out of the box features http://www.filehold.com/features/custom/web-services-api. Refer to the FileHold website for more information: www.filehold.com.

ISO 9001 Principles	How FileHold Can Help
Involvement of people: Ensuring that everyone has and maintains skills to contribute to the company's success.	FileHold can be easily configured to track and retain information about employees' training and skills.
	Training material and\or training videos may be stored securely in FileHold ensuring that users have up to date access to the latest material.
	Scheduled workflow tasks for mandatory training can be monitored by managers via the workflow dashboard ensuring that employees complete required courses. The Electronic Signature option offers a way to tract course completion.
	Users can personalize views for quick access to calendar event, document alerts and reminders as well as workflow reviews and approvals making it easy for users to follow internal policies and procedures.
	FileHold can integrate with Learning Management Systems. Certifications and student data can be imported and used within the document management system.
	Would you like to know more?
	http://www.filehold.com/help/user/my-filehold
	http://www.filehold.com/help/user/inbox
	http://www.filehold.com/optional/electronic signatures
Process approach: use processes rather than individual tasks for better efficiency.	FileHold can be useful in streamlining the Organization's processes for better productivity and efficiency. Organizations can translate many of their processes into FileHold workflows, which ensures consistency and accountability.
	The workflow dashboard allows administrators to easily view and assess workflow activity. Workflows can be collaborative and allow for review and approval cycles as required by the process.
	Users can see list of all workflow tasks assigned to them through the document management system My Tasks area.
	The logical structure of the FileHold Library makes it easy for users to understand and follow processes defined by their managers.

ISO 9001 Principles	How FileHold Can Help
Systems approach to management: having consistent methods to manage tasks.	FileHold was designed with ISO in mind. The FileHold Library may be configured for the Organization's business models with pre-defined lexicons as required for different models. This ensures assets are tagged (classified) in a meaningful and consistent way when added or checked into the software.
	There is no limit to the number of schemas that can be defined. Each schema can have its own set of metadata tags and security. Workflow templates can be defined and assigned to different schemas. Workflow templates ensure that tasks follow pre-defined rules and routes for review and approval.
	User and group security is pre-defined; thus users will only see those assets to which they have access.
	The Auto-filing feature is useful for customers who have similar and/or repetitive documents. Auto-filing allows the software to be configured to file documents intelligently and automatically based on the lexicon.
	Users may define Watched folders as a way to automatically upload documents to FileHold with correct metadata values.
	Enhanced scanning features allow a quick way to go from unmanaged paper to electronically-managed in just a few easy steps.
	Would you like to know more?
	http://www.filehold.com/resources/faq/library-and-metadata-structure
	http://www.filehold.com/help/user/watched-folders
	http://www.filehold.com/help/library/auto-filing-documents
	http://www.filehold.com/help/scanning/scanning-overview
Continual improvement: make improvement an on-going objective.	FileHold can assist Organizations by ensuring that improvement and/or enhancement requests are tracked and properly disseminated to the correct personnel. Improvement requests can come from any in form: digitized video, photos, whiteboard diagrams, sketches, Visio or PowerPoint diagrams, etc. These improvement suggestions can be routed for review and approval. A Continual Improvement schema can be implemented for working documents. Approved documents can be transferred to portal locations for viewing by appropriate audiences.
	By using specific metadata tags, managers can quickly view these requests and act upon them accordingly.
	Additionally, workflows can be configured to manage change orders for improvements.

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ISO 9001 Principles	How FileHold Can Help
Factual approach to decision making: make decisions based on facts.	Using a FileHold Library to centrally manage physical as well as electronic artifacts means that users have quick access to critical information. Once the data is found, it may be saved and used for reporting. Reports may be extracted into manipulative format for further analysis and charting.
	Robust searching mechanisms make it easy for users to locate documents. Users can do simplistic searches from a Google-like toolbar to complex advanced searches using search operator selectors. Searches can be on metadata or document content. Searches may be saved for later use and/or for sharing.
	Saved searches may be saved as Quick Searches. Quick searches are a type of search template. When a user runs a quick search, they are required to enter a single search term value. The search results that are returned meet all preset search criteria plus the quick search term the user entered.
	An additional benefit of a saved quick search is that it may be invoked through a URL from an external application. When the URL for the quick search is clicked from an external application, the saved quick search runs and displays the search results in the selected UI type option. Therefore, a user who uses a supply chain management software application, can have links to relevant FileHold documents.
	Would you like to know more?
	http://www.filehold.com/features/standard/reporting
	http://www.filehold.com/help/user/advanced-searches
	http://www.filehold.com/help/users/saved-searches
	http://www.filehold.com/help/user/url-builder
	http://www.filehold.com/help/user/export-folder-list-csv
	http://www.filehold.com/blog/15/02/how-integrate-filehold-search-web- page
	http://www.filehold.com/blog/15/11/integrating-filehold-salesforce-accounts-page
Mutually beneficial supplier relationships: understand your suppliers so that you can better work with them.	The guest portal and Courier features allows Organizations to effectively and securely share information with suppliers. This can be in the form of surveys, checklists, improvements, and other electronic forms for obtaining supplier feedback.
	Electronic forms can be downloaded by a supplier and when completed, they can then be submitted back and added to the library for data extraction and storage. The entire form is stored electronically and can be put into a workflow for further review and approval such as the case with expense reports.
	Would you like to know more?
	http://www.filehold.com/blog/15/03/integrating-pdf-forms-automatic-document-importation

1.2. ISO 17025 ELEMENTS

The five ISO 17025 elements are shown in the table below and discusses how FileHold features may be used to address those particular ISO points.

ISO 17025 Elements	How FileHold Can Help
Scope: understand what equipment is involved and what the environmental conditions are.	FileHold can be used to track the Organization's physical (offline) and electronic assets, as well as all pertinent formation about those assets. This information may be stored with relevant metadata tags that allow it to be easily and logically searched. The metadata results may also be converted into a manipulative format, such as Microsoft® Excel® for further analysis.
	Document notifications can ensure that users have the most current data regarding assets. Saved searches allow quick access to all relevant information regarding assets.
	Mobile FileHold ensures that field employees have access to the most current information on equipment.
	Would you like to know more?
	http://www.filehold.com/products/mobile-filehold
	http://www.filehold.com/help/user/search-overview
	http://www.filehold.com/help/user/export-folder-list-csv
Normative References: maintain documents on processes that give the most recent information about every area of the process and equipment standards.	The robust document management capabilities allow organizations to maintain critical process documents in a secure fashion. Users have easy access to current documents and, if applicable, historical versions. The easy to use interface provides for a familiar and logical means for users search and retrieve documents.
	Workflows and document notifications ensure users know when artifacts have been added, updated, approved, etc.
	When working with documents in FileHold, users are only able to modify, view, or search for the most recent version of a document. If older versions of documents need to be viewed or searched, then special settings need to be used. This ensures only the most recent document information is used.
	Document status icons and version property information inform users if documents have been checked out or undergoing a workflow process. This allows users to have a quick understanding of what is happening with the document.

ISO 17025 Elements	How FileHold Can Help
Terms & Definitions: Ensure that there is a mechanism to track and label equipment, instruments, workstations, employees, and a method for providing defined instructions, protocol, procedure, and safety measures.	By using offline document schemas and relevant metadata tags, FileHold can assist in tracking physical as well as electronic artifacts. These tags may also be used to associate relevant instructions as well as for reporting.
	The FastFind feature allows Organizations to configure FileHold searching from within third party applications such as a CRM or Supply Chain system. Pre-defined hotkeys may be configured in the third-party application that when selected allowing the user to search and view relevant FileHold documents.
	Scheduled workflows and document notifications will ensure that employees are current on changes made to FileHold managed assets.
	FileHold may also be integrated with barcode label printers to enable efficiently labelling and tracking equipment.
	Would you like to know more?
	http://www.filehold.com/help/library/schemas-offline-documents
	http://www.filehold.com/features/optional/fastfind

ISO 17025 Elements

Management Requirements: provide document control, service to clients,

contract reviews, preventative actions, internal audits, management reviews, etc.

How FileHold Can Help

Enhanced workflow capabilities can be defined to automate the movement of internal and external company documents such as policies, procedures, and so on, in a secure manner.

Library Administrators have central control of the structure and the user authorization rights to each area of the library. Controlled document filing ensures that authorized users can easily browse for documents that are stored in a logical and well-organized fashion. A full audit trail and audit reports allow administrators to track use trends.

The FileHold Web Client allows authorized users to access the central repository from virtually anywhere, and since the Web Client runs on Mobile devices, field workers also have access to current information.

The extensive API and Web Client can be configured to link to other quality control systems throughout the organization.

FileHold provides for five levels in the hierarchy including the Library and files themselves. This is in compliance with industry best practices.

Email and/or document alerts can be sent to recipients to notify them of an important date or event. For example, for policies that must be updated or reinstated at least once every three years, the policy team wants to set up a notification on the policies' expiry dates 60 days before the three year anniversary. The alert repeats every three years. No action is taken upon the document itself.

The FileHold calendar allows the user to see a summary daily tasks and reminders.

Workflow templates allow managers to define processes for many organization activities such as reviews, audits, etc.

FileHold has extensive scanning and OCR'ing functionality that expedites digitizing paper assets into electronic format. This allows the Organization to reduce the amount of paper being stored, and provides both additional controls over the Organizations assets as well as centralized location for searching for information.

With the Brava viewer, users have even more control over their documents such as adding watermarks, annotations, redactions. The viewer also allows document comparison, collaborative markups, and electronic signatures. CAD engineers can view AutoCAD drawings, and there is an Engineering Edition for viewing other formats such as Microstation, Myriad, Solidworks and others.

The Records Management feature allows Administrators to define retention polices in ensure physical and electronic assets are correctly and stored and disposed based on internal business practices.

Would you like to know more?

http://www.filehold.com/features/standard/records-management

http://www.filehold.com/resources/faq/library-and-metadata-structure

http://www.filehold.com/features/standard/records-management

http://www.filehold.com/help/user/brava-viewer-overview

http://www.filehold.com/features/scanning-imaging

ISO 17025 Elements	How FileHold Can Help
Technical Requirements: provide safe working conditions, functional equipment, proper calibration of devices, handling of tests and substances, result reporting etc.	Organizations can use FileHold to securely store functional and technical requirements data, offline documents allow tracking of physical assets, and relevant metadata tagging allows for easy searching and reporting.
	Workflows and alerts can ensure that employees are notified of changes to equipment specifications, test results, etc.
	Using Mobile FileHold, field employees can use mobile devices to access to current information as well as workflow notifications.
	Would you like to know more?
	http://www.filehold.com/products/mobile-filehold