



M-Files QMS

Out-of-the-Box Solution for Daily Quality Management

Topics

- How we see Quality Management
- Benefits of a dedicated QMS
- M-Files QMS system essentials
- Built-in electronic and digital signing
- QMS use scenarios with screenshots

Three Approaches to Quality

- Meet quality certification requirements
 - ISO 9001, ISO 13485, CE labeling, etc.
- Must comply with law or regulations
 - Pharmaceutical, healthcare, aviation, petrochemical, etc.
 - Rigorous quality processes and dedicated quality personnel
 - Audited repeatedly
- Internal reasons
 - Demanding, quality-intensive products or services
 - Quality flaws bring risks of financial loss, missed timelines or reputation damage

Why a Dedicated Quality Management System?

- Share all quality information
 - Essential QM data not buried in spreadsheets, emails communications or paper files
 - Share calendar and database data
- Control essential documents
 - Make sure everyone uses the correct versions
- Get quality tasks done on time
 - SOP reviews, mandatory trainings, maintenance due dates, CAPA deadlines etc.
 - Make system aware of key dates so they appear on common calendar, and reminders can be sent automatically

Why a Dedicated Quality Management System (Cont.)

- Get evidence about your policies are actually being followed
 - Document Control is just the first step!
 - Easily record all completed tasks
- Get accurate and up-to-date information on your quality performance
 - Open issues, overdue tasks, average time needed for corrective actions etc.
- Survive personnel changes
 - Find past personnel's documents, emails, responsibilities and open tasks

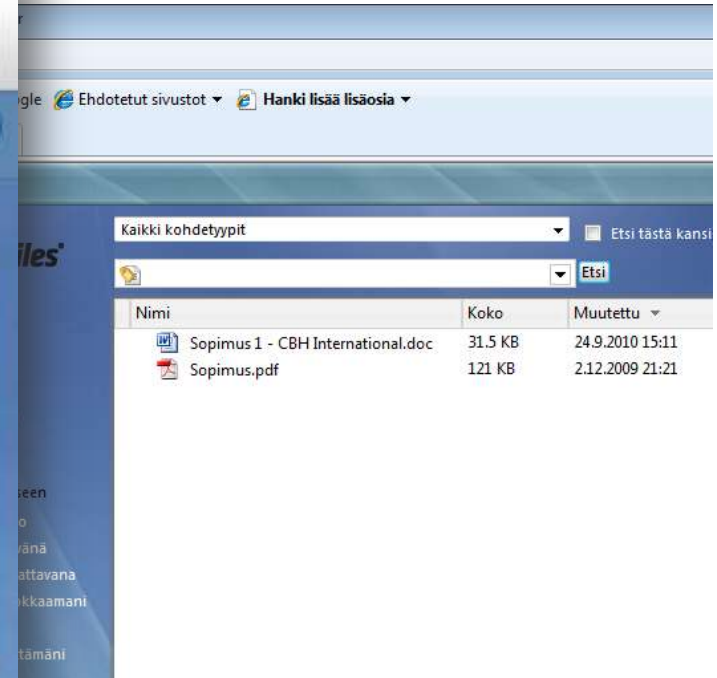
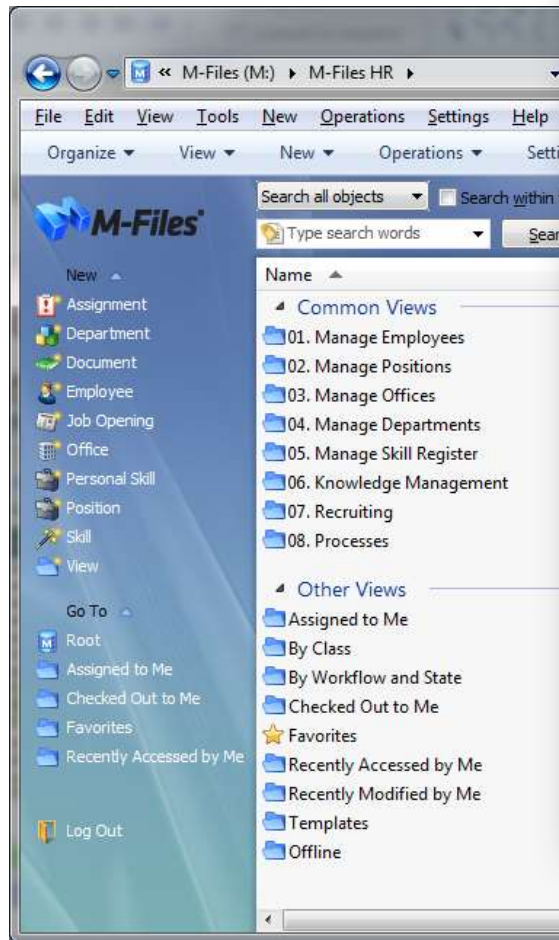
M-Files QMS

- A solution for ***daily*** quality management
 - Not just a static quality manual or SOP publishing system
- All typical quality processes out-of-the-box
 - Quickly tailored to each client during implementation
- Repository for all related documents and emails
 - Award-winning M-Files technology
- Combine documents and database data in one system

Make sure you follow your ***own*** quality policy

Three Ways of Connecting to M-Files QMS

M-Files Mobile Access



M-Files Web Access

M-Files Windows Client

Different Connection Options: Expected Use

- M-Files Client
 - For the 'power users'
 - Unmatched performance and user experience
 - Off-line use without any network connection
- M-Files Web Access
 - Search, read and ad-hoc use
 - Easy access for clients, suppliers and other 'trusted outsiders'
 - Works on any web browser
- M-Files Mobile Access
 - All content and tasks on smartphones and tablets
 - Handy for viewing personal task list of signing off tasks
 - Major mobile platforms supported

Superior usability over any web-browser-only solution!

M-Files QMS Hosting Options

- QMS Cloud Vault
 - Hosted in Microsoft's Windows Azure data centers
 - System maintenance and data backup by provider
- Traditional on-premise hosting
- Hybrid: Integrations to existing Windows domain or production systems possible with both hosting models.

M-Files QMS Key Processes

1. Document control
2. Personnel database
3. Audits and findings follow-up
4. Deviations and CAPA processing
5. Customer feedback processing
6. Repeating quality control tasks
7. Keep inventories and database listings

Document Control Sub-categories

- Quality Manual
- Controlled Documents
 - Major & minor version, training requirements, and more
 - SOPs, instructions etc.
- External Documents
 - 3rd party key documents used in manufacturing, training etc
- Personnel files
- Training documents
- Quality Control task specific documents
 - E.g. audit certificates, deviation specific files or photos, customer feedback related email etc. etc.
- Database item -specific documents
 - Product documents, files linked to equipment etc. etc.

M-Files QMS Key Features

- Simple and intuitive Windows user interface
 - High quality work with moderate training
- Comes with built-in electronic and digital signing
- Set of awareness tools
 - Automatic email notifications
 - **M-Files Reporting** for a quality overview
 - **M-Files Calendar** for intuitive overview of activities

M-Files QMS Security Features

- Full time-stamped audit trail log of all activities
 - Change recording includes also
- Compulsory version history of all content
 - Tracks all activities, not just file versions
- Mandatory workflows
- Enforce naming conventions
- Unique numeric ID for each document and record
- Best permissions management on the market
 - Metadata-driven automatic permissions!
- Built-in backup solution
 - Excellent support for Disaster Recovery

Employee point of view:

What is expected from me?

- Quality work is typically not in employee's focus
- Each employee needs a simple and clear to-do list
 - Figuring out pending tasks from various documents and emails will not work!
- M-Files QMS simplistic approach
 - All employee tasks appear in ***Tasks assigned to Me*** view
 - Employee attempts to keep this folder empty at all times
 - Email reminder sent when something new on to-do list or if the employee forgets to do something

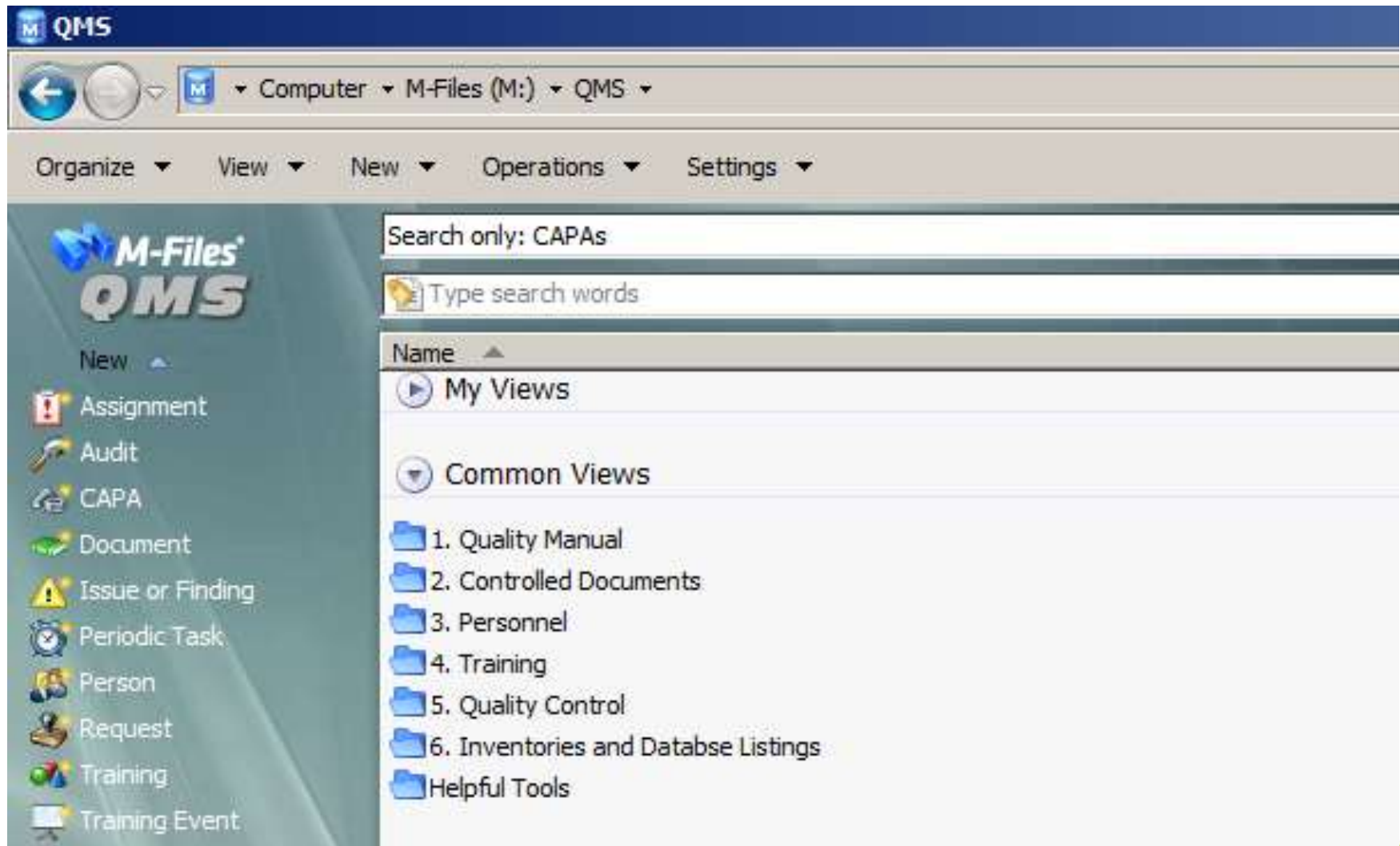
Database listings clarified

- M-Files QMS can contain all necessary database listing and inventories
 - Replace spreadsheets or homegrown data silos
- QMS can be the ***master database***
 - Several departmental databases and inventories accessible with one login
 - Under strict access control

or...

- QMS can ***synchronize live*** with existing systems
 - Sync one-way or two-way
 - Bring customers from your CRM, products from ERP, personnel from HR system, users from MS Active Directory etc.
 - Alternatively, use QMS to manage only quality tasks or as a document repository

M-Files QMS User Interface



Built-in eSigning

- Suitable for legally & regulatory binding internal documents
 - SOPs, training certificates, HR files, maintenance records, CAPA records, etc.
- No 3rd party software or service needed
- Very easy to use
- One or several signatures per document
 - Each with its own purpose and signature manifestation
- Auto-convert MS Office documents to PDF when signed
 - Auto-create a signature page or signature section
 - Render any information or add watermarks and stamping
 - Insert signing certificate to "lock" its contents
- Complies with known eSigning standards
 - E.g. 21 CFR Part 11 and GMP Annex 11 (2011)

Two signing methods included

Either one can be used, or both combined

M-Files Electronic Signing

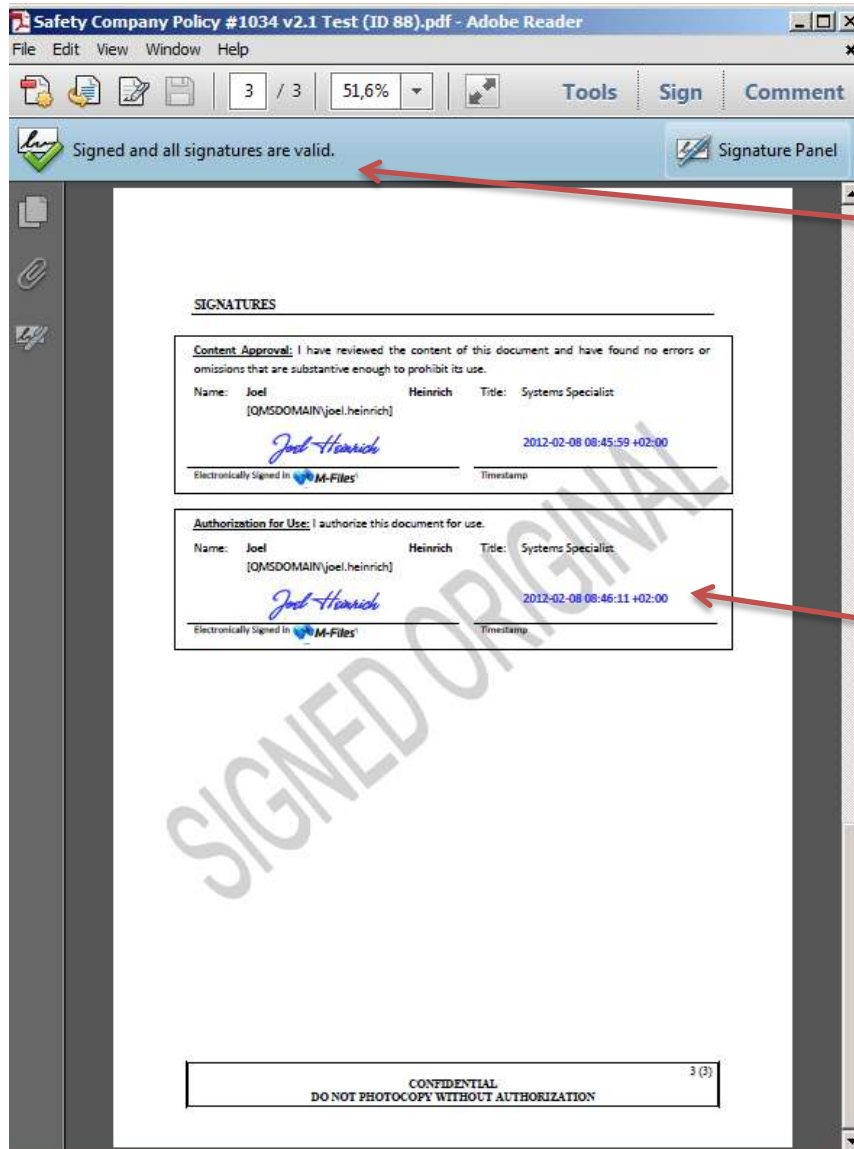
- Proof of signature remains in M-Files system
- Links the document or database record to a **person(s)** who signed
- One or several signatures per document
- Both for printable documents and database records

M-Files Digital Signing

- Proof of signature embedded in the signed document
- Links the document to **originating company**, even when a copy is sent out of the company
- One signature per document
- Only for printable documents

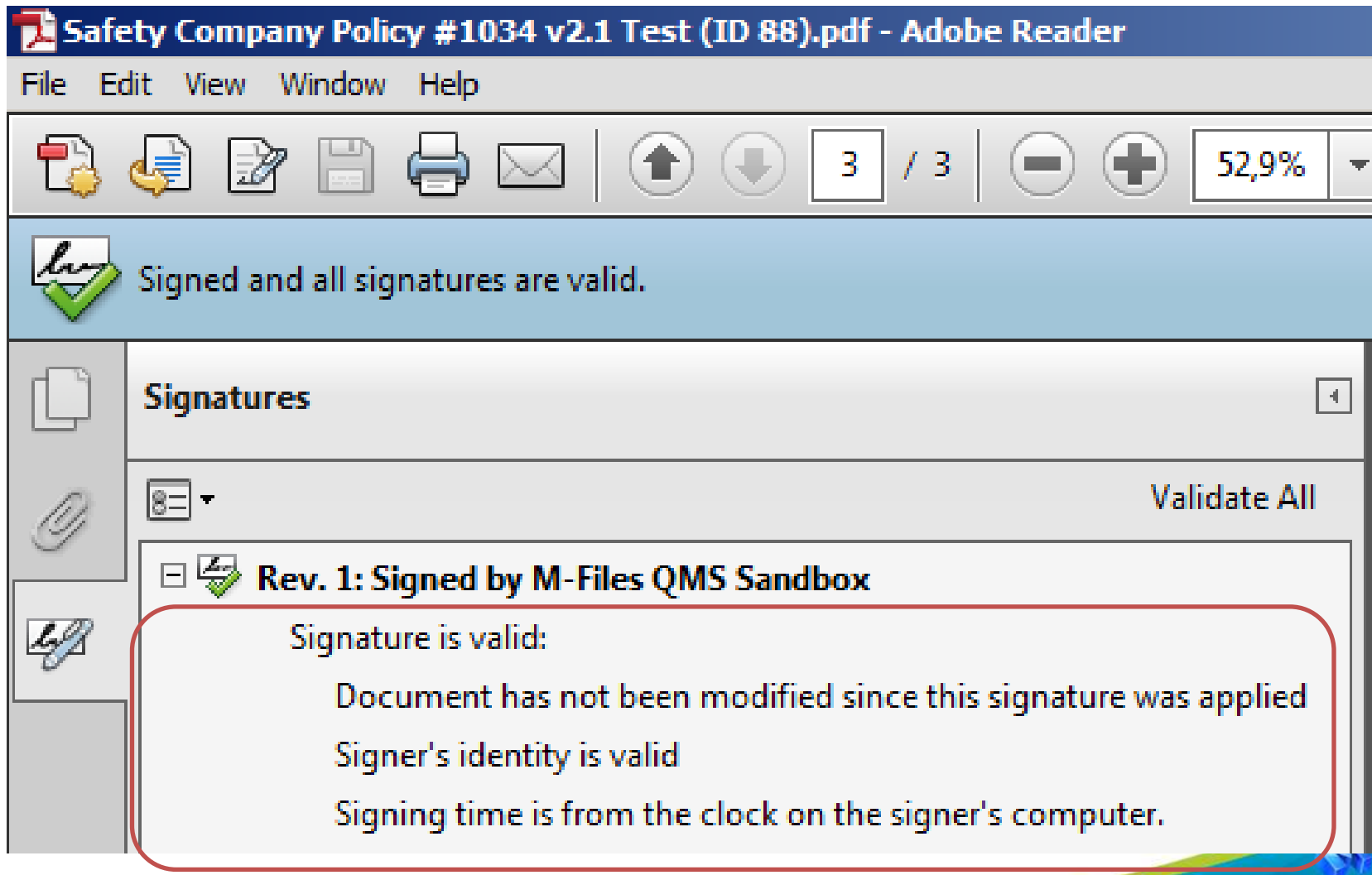
M-Files QMS supports both!

Sample PDF File with Electronic and Digital Signatures

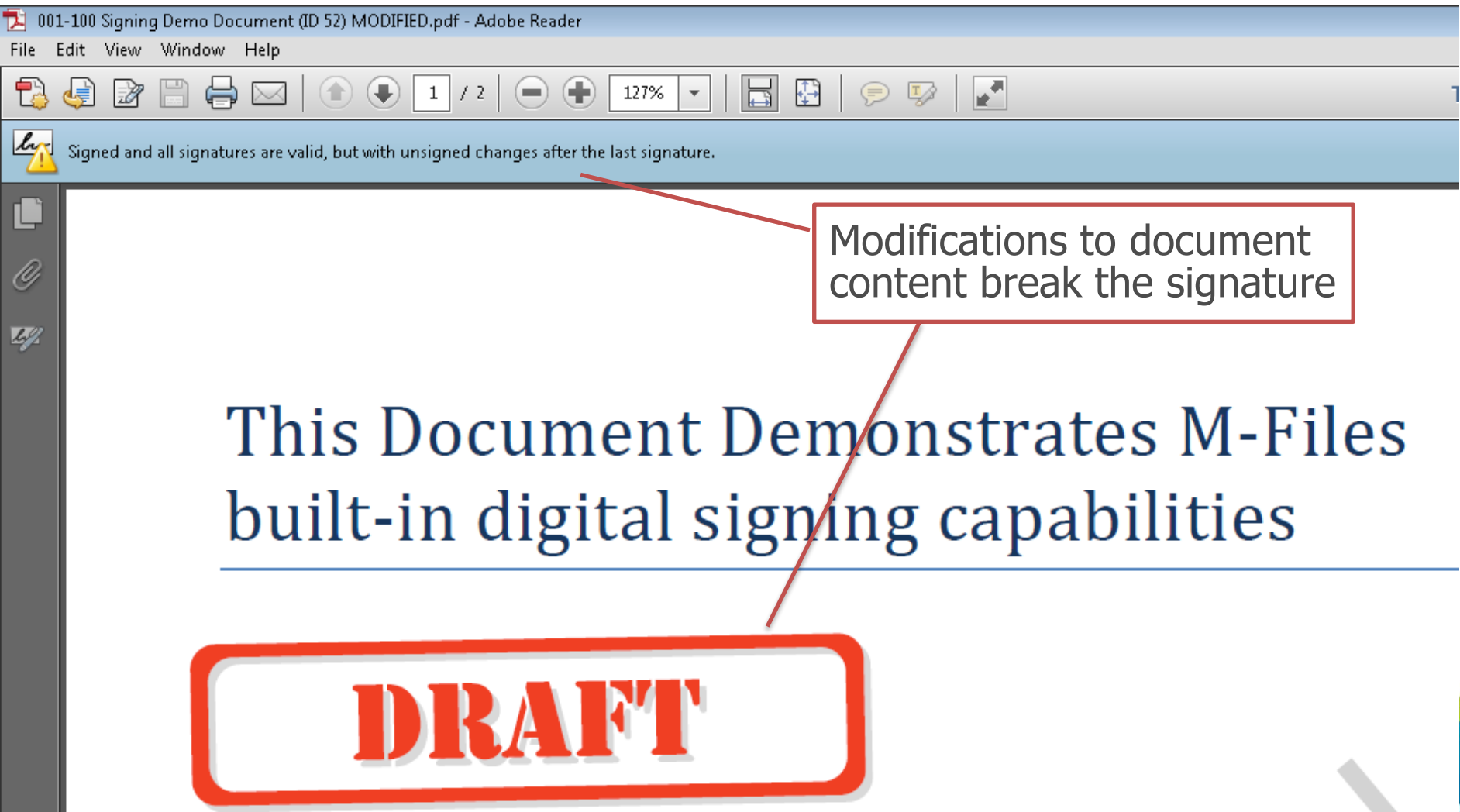


- **Digital signature says:**
"This original document can only have come from **Our Company**. No one inside or outside our company has modified it after signing"
- **Electronic signature says:**
"This document is approved by this **signer** (or signers). All relevant signing information is visible on the document"

Standard PDF Readers Detect Digital Signatures



Falsified Signed Documents Detected by PDF Readers



M-Files eSigning: Benefits Over Paper and Pen

- Save time and automate processes
 - Sign online 24/7
 - No scanning
 - Find all the signed originals because they never leave M-Files
- Better quality
 - Protect signed document contents
 - No more fake timestamps
 - Better reading quality
- Avoid the risk of document archive disaster
 - Given that your backups or data replication is in order!
 - Each backup copy is also ***The Signed Original***

Another eSigning demo later in this slide set: how to create a new SOP

M-Files QMS Validation

Wikipedia definition: "**validation** is the process of checking that a product, service, or system meets specifications and that it fulfills its intended purpose. These are critical components of a quality management system such as ISO 9000"

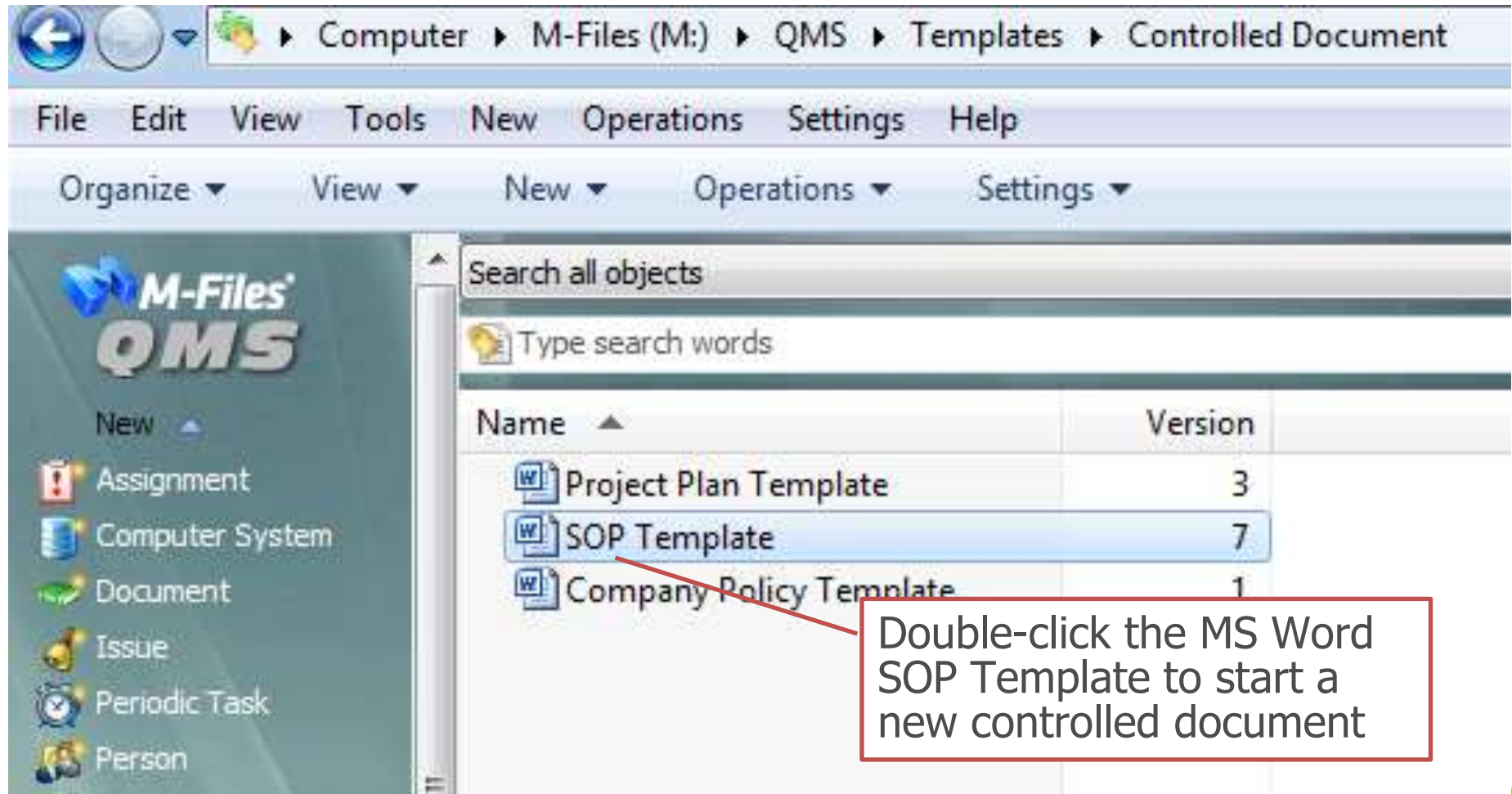
- relevant to some clients, not all
- in some industries electronic records can replace signed paper originals only when system formally validated
- each validation is done locally
 - based on local implementation, use processes and personnel
- M-Files can be validated against known regulatory requirements, ask us for details

Example Use Cases

1. Author, sign and publish a new SOP
2. Get the newly approved SOP learned by staff
3. Do a classroom training and provide certificates
4. Build an equipment inventory
5. Follow-up a quality deviation
6. Process customer feedback
7. Performing an audit and process its findings

USE CASE 1: AUTHOR, SIGN AND PUBLISH A NEW SOP

Creating new SOP's from Templates



The screenshot shows the M-Files QMS application window. The address bar indicates the path: Computer > M-Files (M:) > QMS > Templates > Controlled Document. The menu bar includes File, Edit, View, Tools, New, Operations, Settings, and Help. Below the menu bar are sub-menus for Organize, View, New, Operations, and Settings. On the left, the M-Files QMS logo is displayed above a 'New' button and a list of object types: Assignment, Computer System, Document, Issue, Periodic Task, and Person. The main pane shows a search bar and a table of templates.

Name	Version
Project Plan Template	3
SOP Template	7
Company Policy Template	1

A red arrow points from the 'SOP Template' row to a text box containing the instruction: Double-click the MS Word SOP Template to start a new controlled document.

Specify SOP Properties, Including Two Signers

New Document

General

Class: Controlled Document

☒ Use template: SOP Template.docx

☐ Create an empty multi-file document

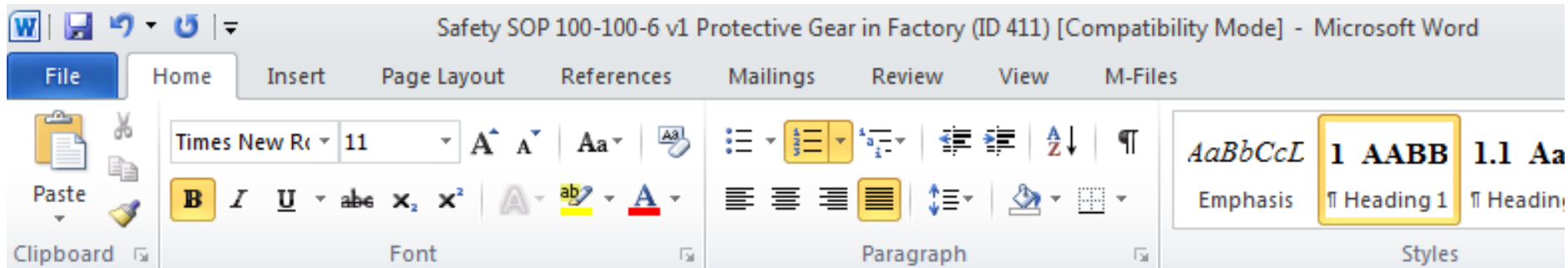
☐ Create an empty single-file document

File extension:

Properties:

Title - Controlled Document:	(automatic)
Controlled Document Type:	SOP
Document Area:	Safety
Document Id:	100-100-6
Document Name:	Protective Gear in Factory
Major Version:	1
Country:	
Effective Date:	<input checked="" type="checkbox"/> 17. 1.2012
Author(s):	Mika Salonoja
Reviewer(s):	Mika Salonoja Joel Heinrich
Content Approver:	Mika Salonoja
Authorizer:	Joel Heinrich

Smart Templates with Dynamic Content



XYZ inc.

SAFETY SOP 100-100-6 v1 Protective Gear in Factory

Author: Mika Salonoja

Major Version: 1

Effective Date: 17.1.2012

M-Files fills in document properties to the template









1 PURPOSE

This section should state the purpose of the SOP; What is it for?

2 SCOPE

This section should state the scope of the SOP; What does it apply to?

Intuitive UI to Control Documents

Name ▲	Major Version	State	Document Area	C
 Safety SOP 100-100-6 v1 Protective Gear in Factory	1	 1. Draft	Safety	-
>  Author(s) (1)				
└  Authorizer (1)				
 Joel Heinrich	-	-	-	-
>  Content Approver (1)				
 Mika Salonoja			-	-
>  Reviewer(s) (2)				

Document state

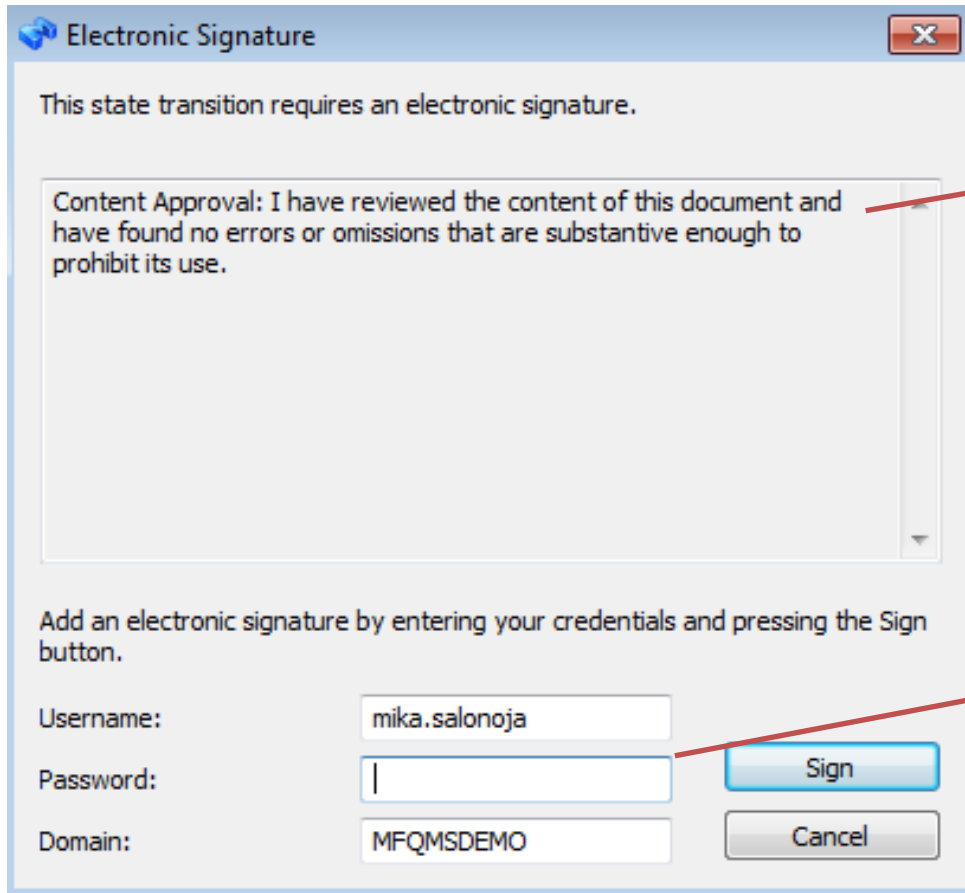
Responsible persons

Initiating Electronic Signature

The screenshot displays the M-Files application window. The address bar shows the path: Computer > M-Files (M:) > QMS > 1. Controlled Documents > 1. Document Authoring. The menu bar includes File, Edit, View, Tools, New, Operations, Settings, and Help. Below the menu bar are tabs for Organize, View, New, Operations, and Settings. The left sidebar contains a 'View' section with options like View and Modify, Check Out, Properties, History, Make Copy, and Calendar. A red box highlights the 'Move into State' button, which is labeled '4. Content Approved'. A callout box points to this button with the text: 'The first signature is initiated by hitting 'Move into state: Content Approved' (the button only visible for the person that has signing privileges)'. The main pane shows a table with columns for Name, Major Version, and State. The table contains one entry: 'Safety SOP 100-100-6 v1 Protective Gear in Factory' with Major Version '1' and State '3. Finalized, awaits Approval'.

Name	Major Version	State
> [W] Safety SOP 100-100-6 v1 Protective Gear in Factory	1	3. Finalized, awaits Approval

Applying author signature



The dialog box is titled "Electronic Signature" and contains a text area for content approval, a section for adding an electronic signature with input fields for username, password, and domain, and "Sign" and "Cancel" buttons.

Electronic Signature

This state transition requires an electronic signature.

Content Approval: I have reviewed the content of this document and have found no errors or omissions that are substantive enough to prohibit its use.

Add an electronic signature by entering your credentials and pressing the Sign button.

Username: mika.salonoja

Password: |

Domain: MFQMSDEMO

Sign

Cancel

Legal manifestation

Signing Password

Approved Document in M-Files QMS

Safety SOP 100-100-6 v1 Protective Gear in Factory

Controlled Document ID 411, version 4

Created: 15.1.2012 19:32, Mika Salonoja
Last modified: 23.1.2012 10:52, (M-Files Server)

Controlled Document... SOP

Document Area: Safety

Document Id: 100-100-6

Document Name: Protective Gear in Factory

Major Version: 1

Country:

Effective Date: 17.1.2012

Author(s): Mika Salonoja

Reviewer(s): Mika Salonoja

Joel Heinrich

Content Approver: Mika Salonoja

Authorizer: Joel Heinrich

Required Readers:

Signature manifestation:

Reason: Content Approval

Meaning: I have reviewed the content of this document and have found no errors or omissions that are substantive enough to prohibit its use.

Signed By: Mika Salonoja
(MFQMSDEMO\mika.salonoja)
Signing Time: 23.1.2012 10:52:59

Signature(s): Content Approval: Mika Salonoja,
23.1.2012

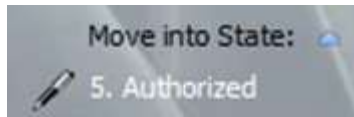
Workflow: [Controlled Document Workflow](#)

State:  [4. Content Approved](#)

Assigned to: Joel Heinrich

Content approved, waiting
for authorization

Authorizing SOP




Authorizer selects the SOP in her task list and moves it to Authorized state.

A screenshot of a Windows-style dialog box titled 'Electronic Signature'. The dialog contains the following elements:

- A title bar with a close button (X).
- A message: 'This state transition requires an electronic signature.'
- A text area with the text: 'Authorization for Use: I authorize this document for use.'
- A message: 'Add an electronic signature by entering your credentials and pressing the Sign button.'
- Three input fields: 'Username:' with the value 'heijoe', 'Password:' with masked characters '.....', and 'Domain:' with the value 'MFQMSDEMO'.
- Two buttons: a blue 'Sign' button and a grey 'Cancel' button.

Authorized SOP


Name ▼	Controlled Document T...	Document
>  Safety SOP 100-100-6 v1 Protective Gear in Factory	SOP	Safety

Safety SOP 100-100-6 v1 Protective Gear in Factory
Controlled Document ID 431, version 8

Created: 23.1.2012 11:03, Administrator
Last modified: 23.1.2012 11:42, (M-Files Server)

Controlled Document T... SOP
Document Area: Safety
Document Id: 100-100-6
Document Name: Protective Gear in Factory
Major Version: 1
Country:
Effective Date: 24.1.2012
Author(s): Mika Salonoja
Reviewer(s): Mika Salonoja
Joel Heinrich
Content Approver: Mika Salonoja
Authorizer: Joel Heinrich
Required Readers:

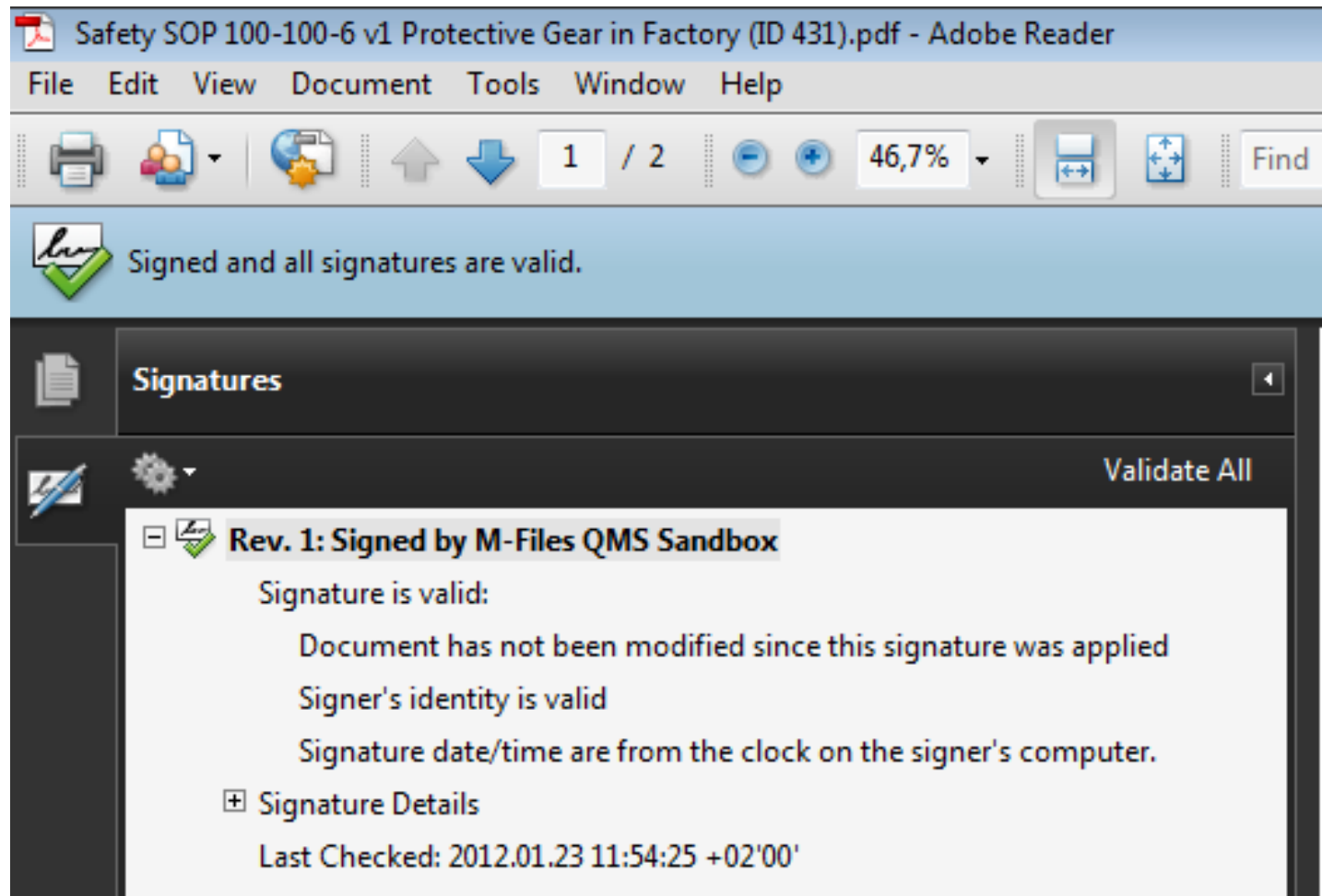
Signature manifestation:
Reason: Authorization for Use
Meaning: I authorize this document for use
(heijoe)
Mika Salonoja, 23.1.2012
Authorization for Use: Joel Heinrich, 23.1.2012

Workflow: Controlled Document Workflow
State:  6. Available For Training

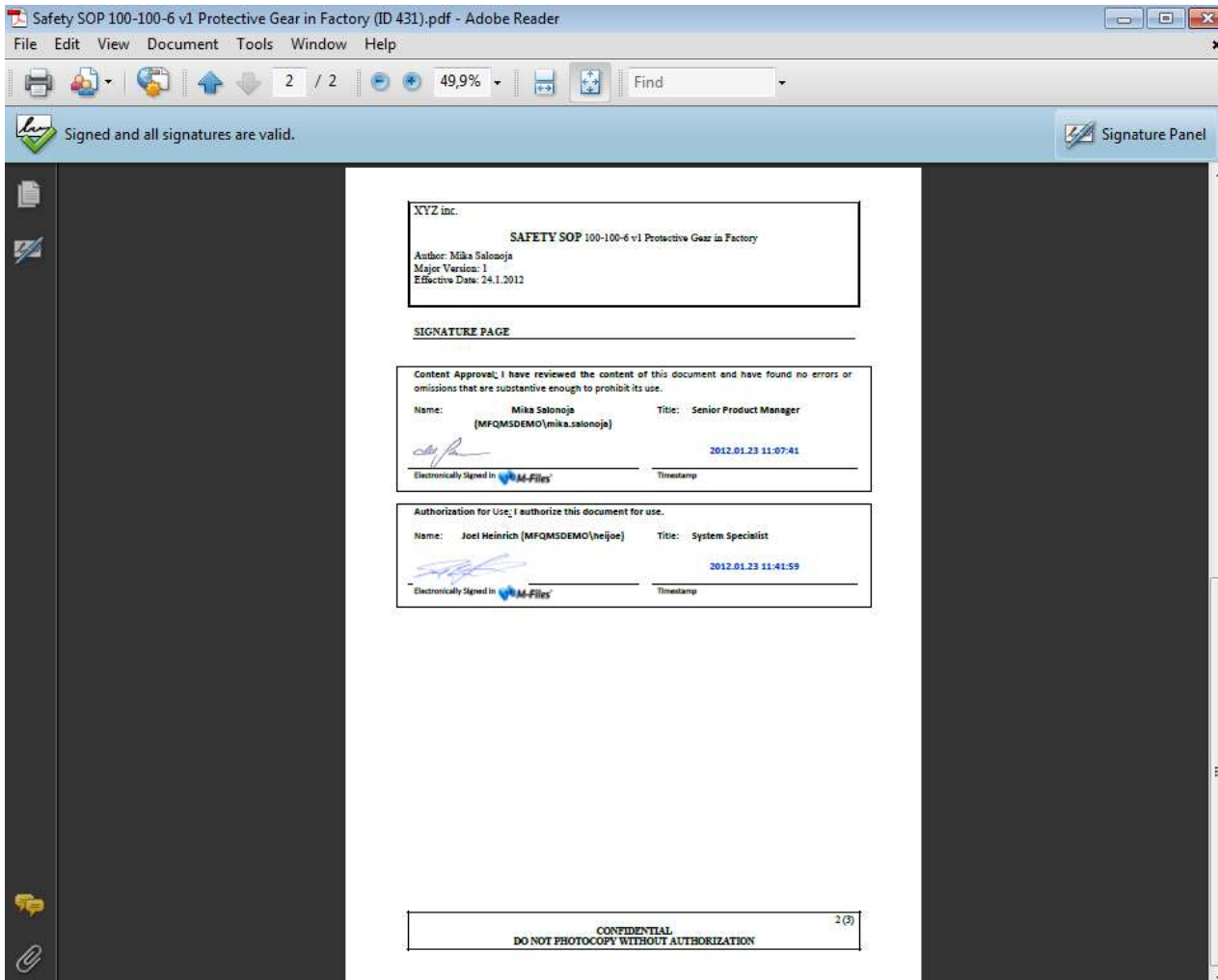
File automatically
converted to PDF

SOP is now Available
for Training

Digital Signature in Place



Electronics Signature Page automatically added (Signature layout is customizable)



Electronic Signatures

Content Approval: I have reviewed the content of this document and have found no errors or omissions that are substantive enough to prohibit its use.

Name: **Mika Salonoja**
(MFQMSDEMO\mika.salonoja)

Title: **Se** Manifest



Signature proven with
signing password

2012.01.23 11:07:41

Electronically Signed in  **M-Files®**

Timestamp

Timestamp from
the system

Authorization for Use: I authorize this document for use.

Name: **Joel Heinrich (MFQMSDEMO\heijoe)**

Title: **System Specialist**

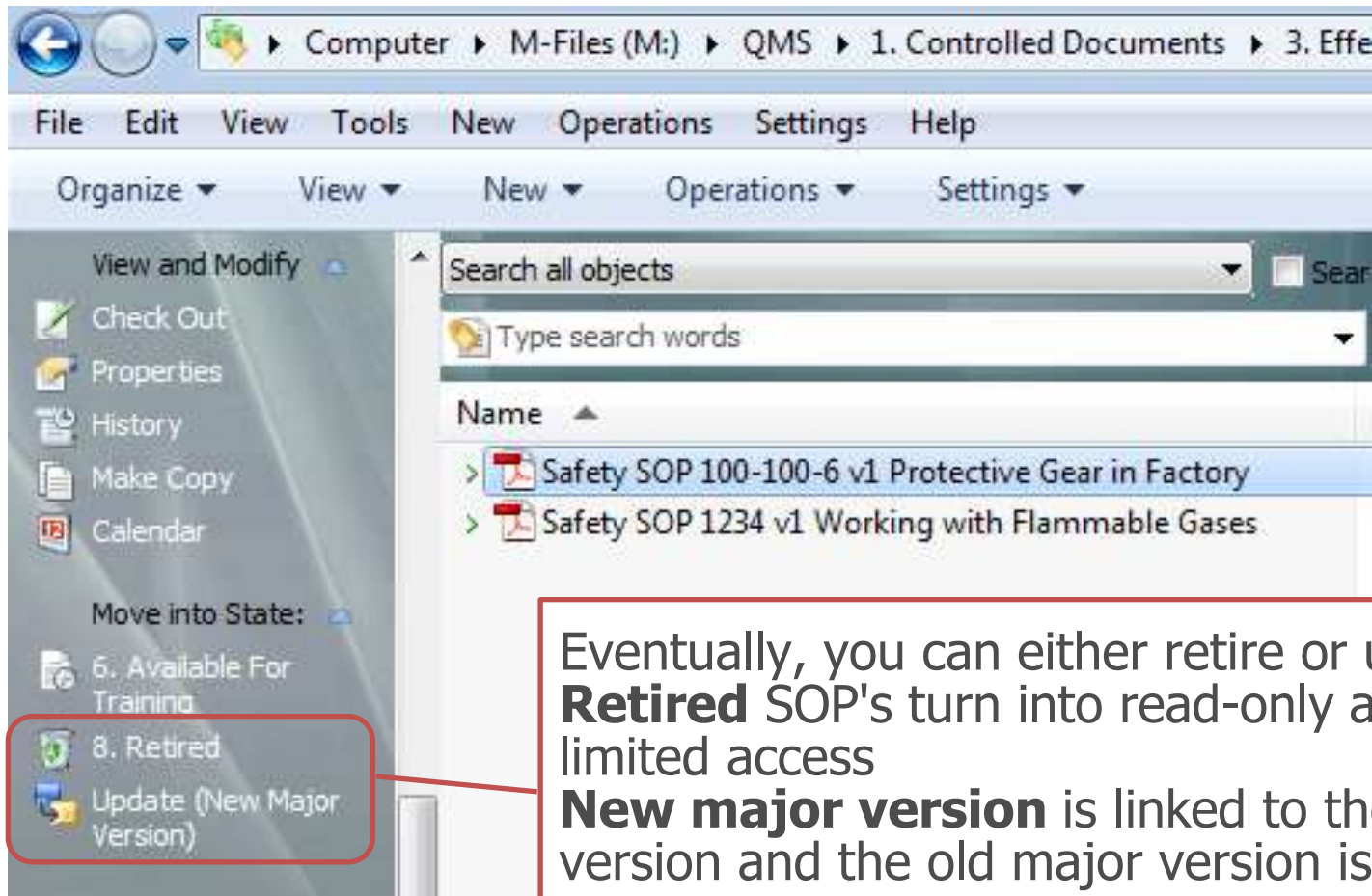


2012.01.23 11:41:59

Electronically Signed in  **M-Files®**

Timestamp

Updating SOP's



Eventually, you can either retire or update the SOP. **Retired** SOP's turn into read-only archive with limited access

New major version is linked to the old major version and the old major version is retired

USE CASE 2: GET THE NEW SOP TRAINED TO STAFF

Define the people to whom the new SOP is mandatory

Properties - Safety SOP 100-100-6 v1 Protective Gear in Factory.pdf (Docum... X

General Properties Workflow Comments Permissions Notifications

Class: Controlled Document ▼

☐ Multi-file document

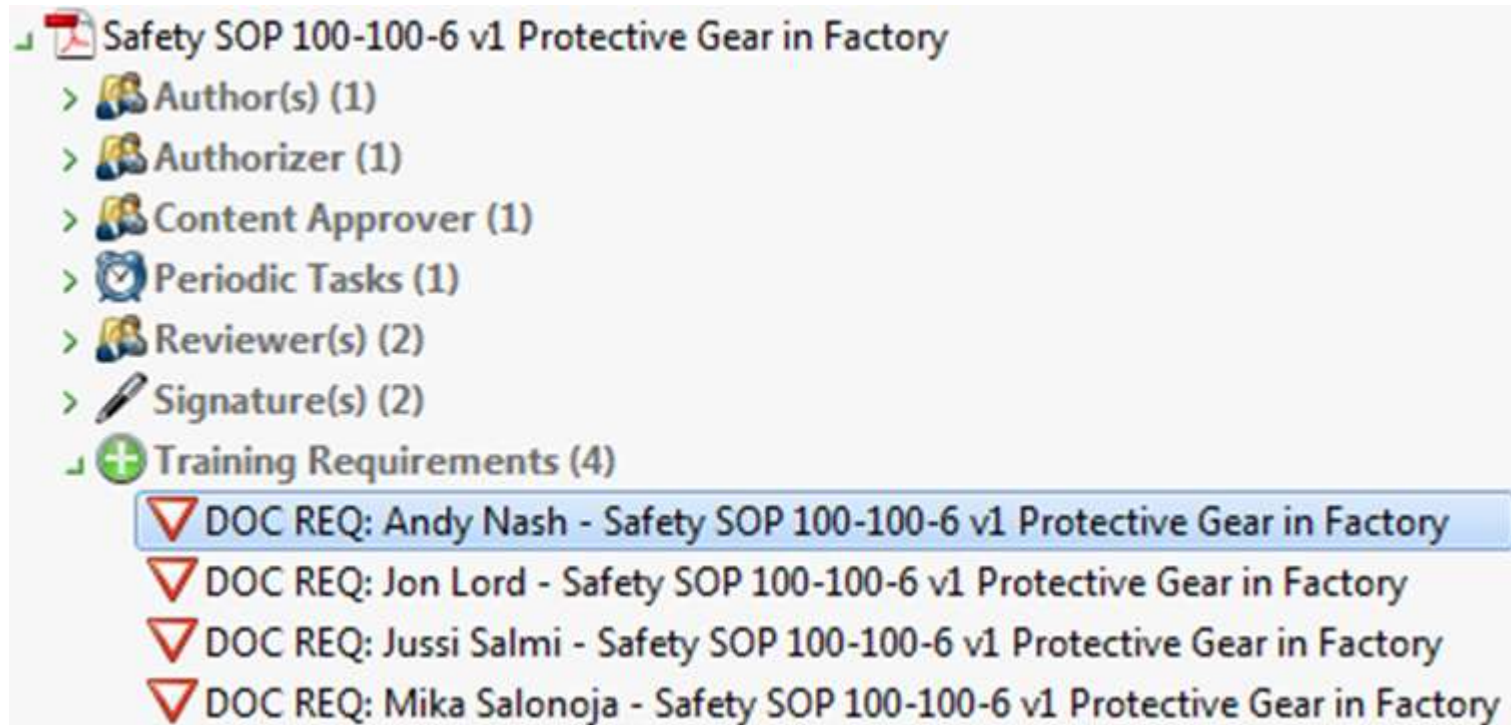
☒ Single-file document

File extension: pdf ▶

Properties:

Reviewer(s):	Mika Salonoja ▼	- ▶ ▲
	Joel Heinrich ▼	+ ▶
Content Approver:	Mika Salonoja ▼	▶
Authorizer:	Joel Heinrich ▼	▶
Required Readers:	Andy Nash ▼	- ▶
	Jon Lord ▼	- ▶
	Mika Salonoja ▼	- ▶
	Jussi Salmi ▼	+ ▶

A pending training requirement to each person is created

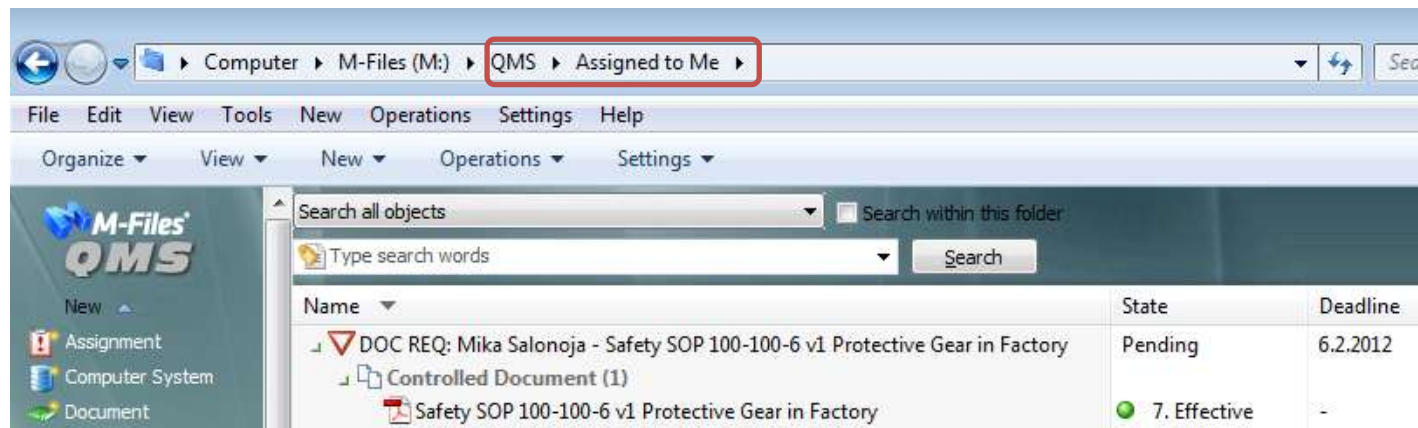


Safety SOP 100-100-6 v1 Protective Gear in Factory

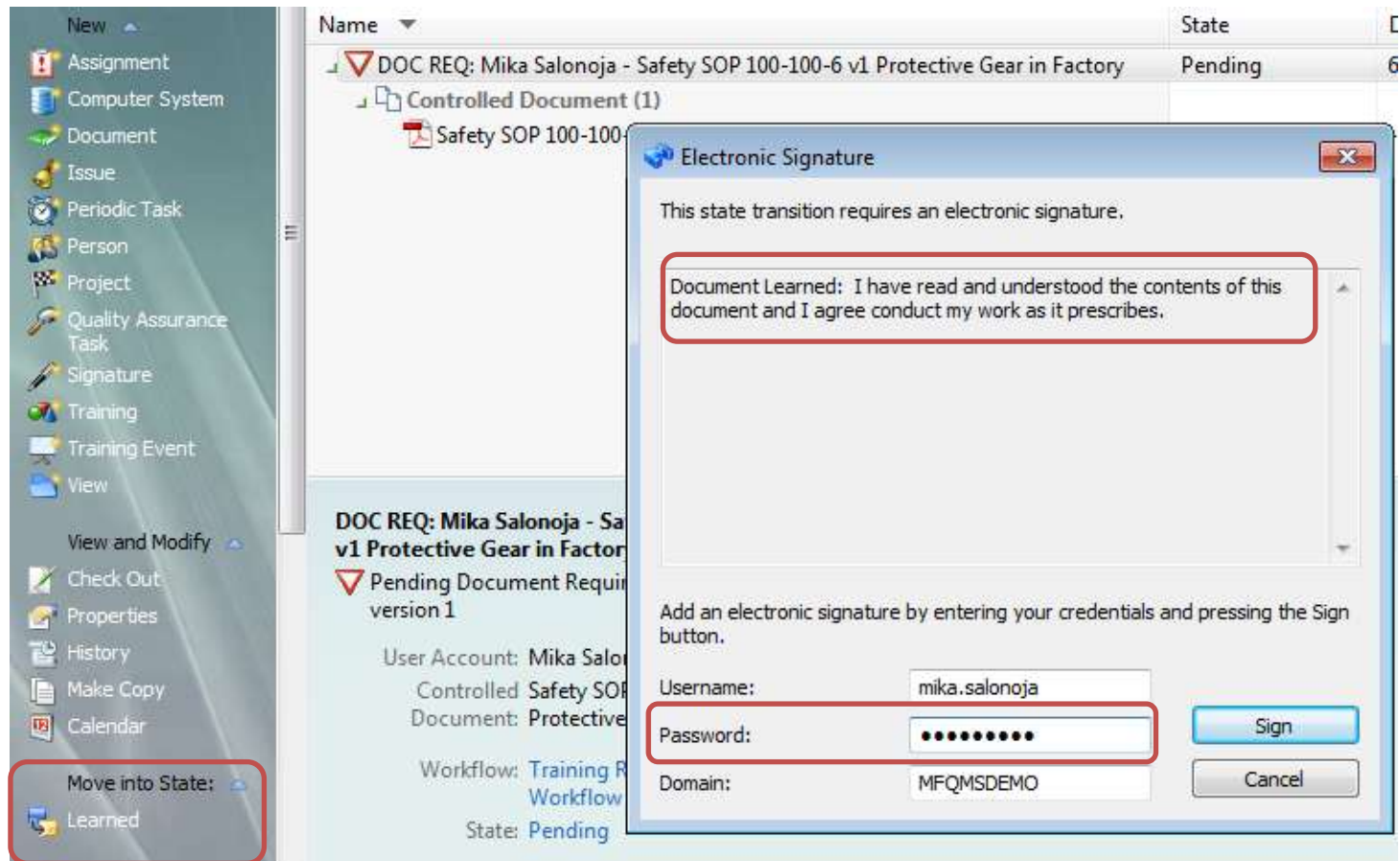
- > Author(s) (1)
- > Authorizer (1)
- > Content Approver (1)
- > Periodic Tasks (1)
- > Reviewer(s) (2)
- > Signature(s) (2)
- + Training Requirements (4)
 - ▼ DOC REQ: Andy Nash - Safety SOP 100-100-6 v1 Protective Gear in Factory
 - ▼ DOC REQ: Jon Lord - Safety SOP 100-100-6 v1 Protective Gear in Factory
 - ▼ DOC REQ: Jussi Salmi - Safety SOP 100-100-6 v1 Protective Gear in Factory
 - ▼ DOC REQ: Mika Salonoja - Safety SOP 100-100-6 v1 Protective Gear in Factory

User's to-do list

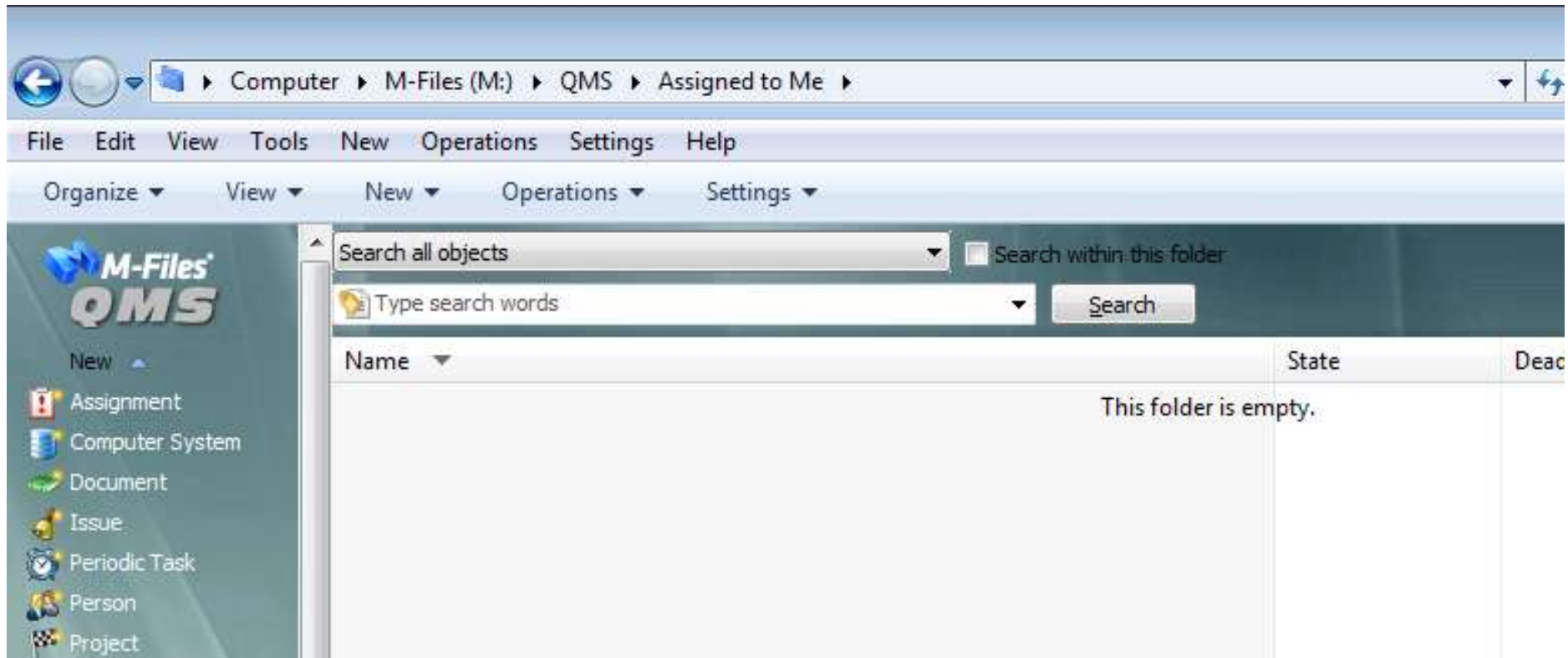
- Training requirements appear on person's to-do list with deadline
- Additionally, an email reminder is automatically sent to the user



Once document is learned, it's training is requirement is closed with eSignature



Once training requirement is satisfied, employee's To-Do list is again empty



Following-up with the training results

Search all objects ☐ Search within this folder

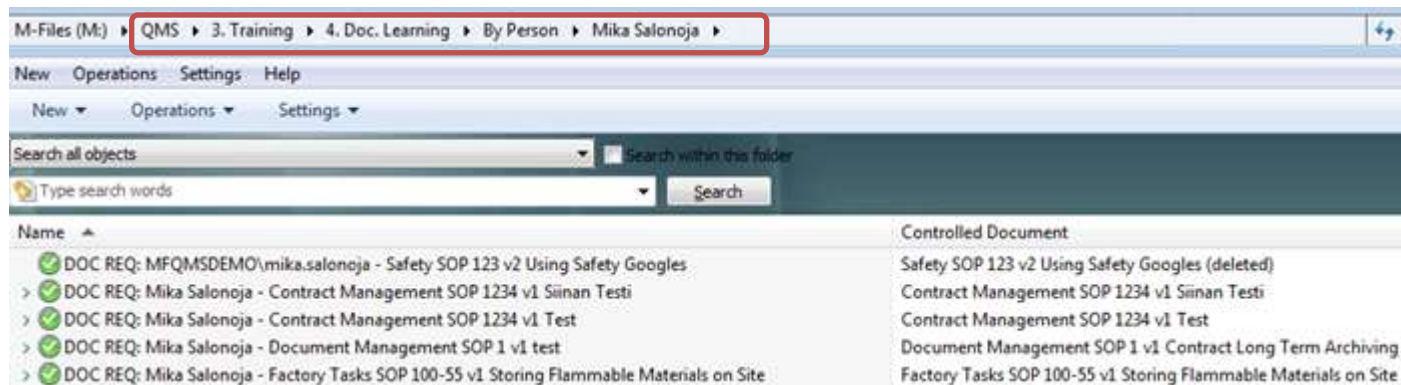
Type search words

Name	Assigned to	Deadline
> ▼ DOC REQ: Andy Nash - Safety SOP 100-100-6 v1 Protective Gear in Factory	Andy Nash	6.2.2012
> ▼ DOC REQ: Jon Lord - Safety SOP 100-100-6 v1 Protective Gear in Factory	Jon Lord	6.2.2012
> ▼ DOC REQ: Jussi Salmi - Safety SOP 100-100-6 v1 Protective Gear in Factory	Jussi Salmi	6.2.2012
> ✓ DOC REQ: Mika Salonoja - Safety SOP 100-100-6 v1 Protective Gear in Factory	-	-

Four people needed to learn this SOP
Only one has done that so far

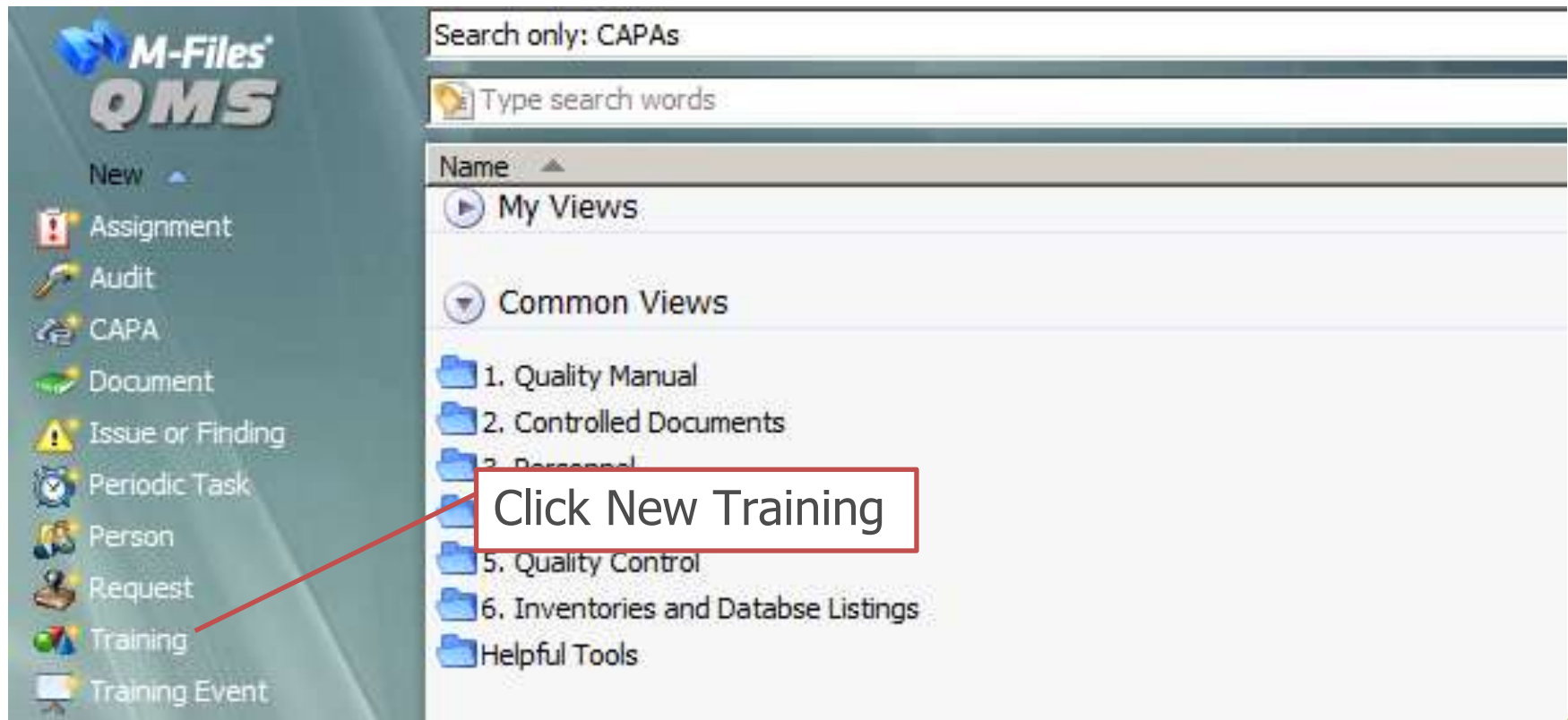
Employee's Training Records

- You can view each employee's training records to review pending Training tasks.



USE CASE 3: CLASSROOM TRAINING

Creating a new Training



Specify the training or course

Possible to specify SOPs covered in the training

Properties - Basic Safety Training (Training)

General | **Properties** | Workflow | Comments | Permissions | Notifications

Class: Training

Properties:

Name or title: Basic Safety Training *

Description: This course covers basic safety in factory operations. This course covers attached SOPs.

Controlled Document(s):

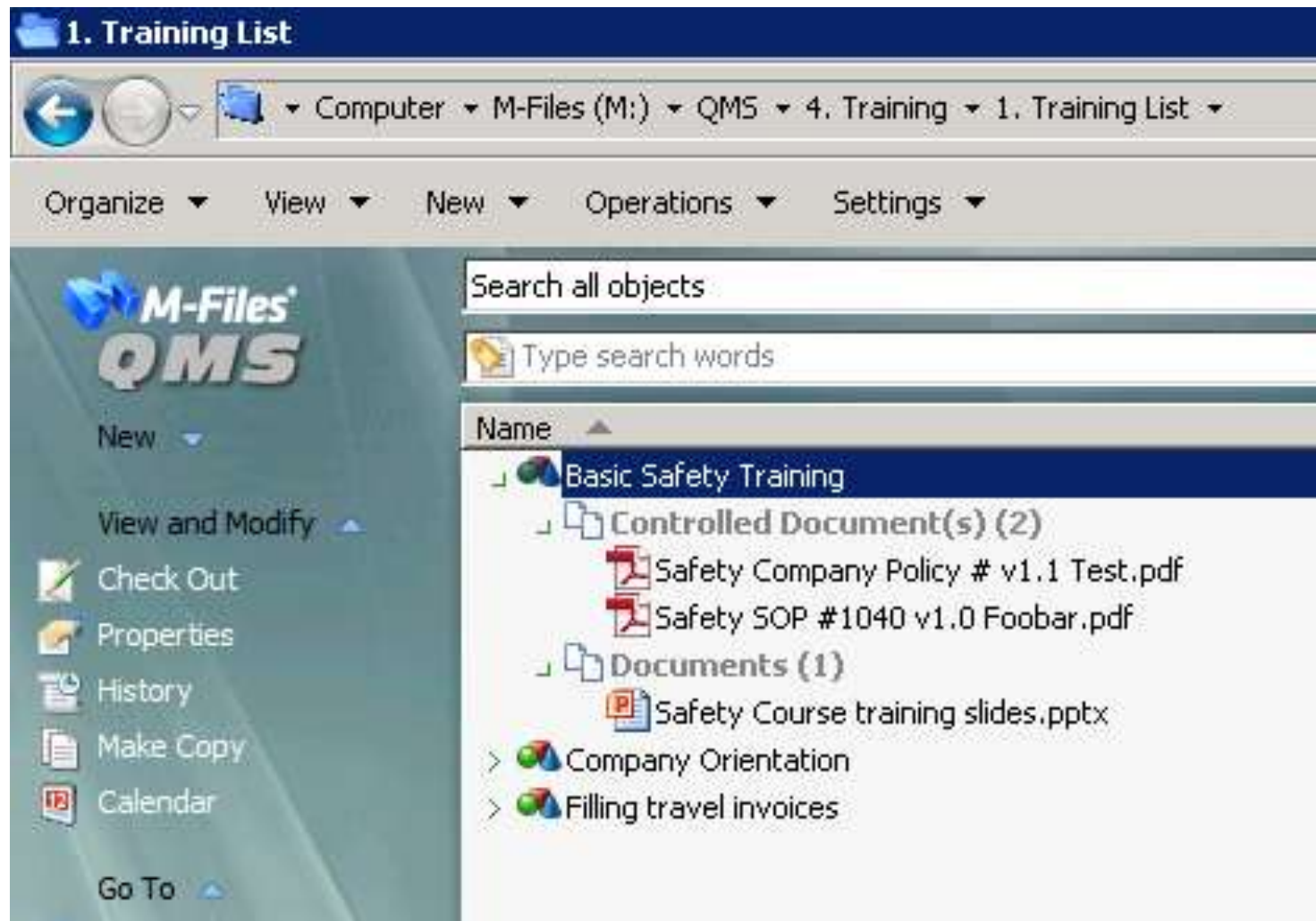
- Safety SOP #1040 v1.0 Fooobar
- Safety Company Policy # v1.1 Test

Add some training material to M-Files QMS

The screenshot shows the Microsoft PowerPoint application window. The 'File' menu is open, and the 'Save to M-Files (QMS)' option is highlighted with a red rectangle. The 'New Document' task pane is visible on the right, showing the 'General' tab with the following settings:

New Document	
Class:	Training Material
Save as type:	PowerPoint Presentation (*.pptx)
Properties:	
Name or title:	Safety Course training slides
Training:	
Training Event:	Basic Safety Training
Created:	Company Orientation Dummy Training

New training is now fully defined and visible on company course list



Adding new training sessions in Calendar View

The screenshot displays the M-Files Calendar application interface. The title bar reads "M-Files Calendar - v1.0.3.0". The menu bar includes "File", "Edit", "View", "Tools", "New", "Operations", and "Help". On the left, there is a sidebar with a calendar for February 2012, where the 16th is highlighted. Below this is a sidebar with a tree view showing "Periodic Tasks", "Training Events", "Effective Documents", "Training Events", "Training Records", and "Self Learning". The main area shows a calendar grid for the week of February 12-18, 2012. The 16th is highlighted in orange. A context menu is open over the 16th, with options: "New", "Refresh", "Show Properties Pane", "Deviation...", "Training Event...", "Customer Audit...", "Internal Audit...", "Supplier Audit...", "Management Quality Review...", and "Regulatory Inspection...". A red box with a white border and a red arrow points to the "Training Event..." option. The text inside the box reads: "Mark the training slot, right-click and select New Training Event".

Mark the training slot, right-click and select New Training Event

Filling in the training event details

The screenshot shows the M-Files software interface. On the left is a sidebar with a navigation tree containing 'Audits', 'Issues', 'Periodic Tasks', 'Training Events' (selected), 'Effective Documents', 'Training Events', 'Training Records', and 'Self Learning'. The main area displays a calendar for February and March 2012. In the February calendar, the 16th is highlighted with a red border. To the right of the calendar is a vertical timeline with time slots from 08 AM to 14 00. Overlaid on the right is a 'New - Training Event' dialog box with the following fields:

General

Class: Training Event

☒ Use template: Dummy Training Event

Properties:

Title - Training Event: (automatic) *

Training: Basic Safety Training *

Trainer: Mika Salonoja *

Start Date: ☒ 25. 1.1998 *

Start Time: ☒ 9:00:00

End Time: ☒ 12:00:00

End Date: ☒ 13. 2.2012

Location: Auditorium 1

Participants:

Relationships... More Properties...

Permissions: Full control for all internal users

Workflow: Training Event State

First training is now scheduled

M-Files Calendar - v1.0.3.0

File Edit View Tools New Operations Help

M-Files

12 - 18 February 2012

February 2012

S	M	T	W	T	F	S
29	30	31	1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29			

March 2012

S	M	T	W	T	F	S
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31
1	2	3	4	5	6	7

Basic Safety

Location: Auditorium 1
Trainer: Mika
Salonoja
Participants:

Audits
Issues
Periodic Tasks
Training Events
Effective Documents
Training Events
Training Records
Self Learning

Add participants after the training session

Properties - Basic Safety Training 13.2.2012 Auditorium 1 (Training Event)

Properties | Workflow | Comments | Permissions

Class: Training Event

Properties:

Title - Training Event:	Basic Safety Training 13.2.2012 Auditorium 1	*
Training:	Basic Safety Training	* + ▸
Trainer:	Mika Salonoja	* + ▸
Start Date:	<input checked="" type="checkbox"/> 13. 2.2012	*
Start Time:	<input checked="" type="checkbox"/> 9:00:00	
End Time:	<input checked="" type="checkbox"/> 12:00:00	
End Date:	<input checked="" type="checkbox"/> 13. 2.2012	
Location:	Auditorium 1	+ ▸
Participants:	Andy Nash April March Clark Kent Gillian Campbell	+ ▸
Signature(s):	Training Confirmation: ,	
Created:	16.2.2012 20:47	*
Created by:	Mika Salonoja	*

Trainer now signs off the training event with eSignature

The screenshot shows a web application interface with a search bar at the top. Below it, a list of training events is displayed, with 'Basic Safety Training 13.2.2012 Auditorium 1' selected. The details for this event are shown on the left, including training name, trainer, dates, times, location, and participants. On the right, an 'Electronic Signature' dialog box is open, prompting the user to sign off on the training event. The dialog contains a text area with a confirmation statement, a username field, a password field, a domain field, and 'Sign' and 'Cancel' buttons.

Type search words

Name

> Basic Safety Training 13.2.2012 Auditorium 1

Basic Safety Training 13.2.2012 Auditorium 1
Training Event ID 8, version 4

Training: Basic Safety Training
Trainer: Mika Salonoja
Start Date: 13.2.2012
Start Time: 9:00
End Time: 12:00
End Date: 13.2.2012
Location: Auditorium 1
Participants: Andy Nash
April March
Clark Kent
Gillian Campbell
Signature(s): Training Confirmation: ,
Workflow: Training Event State
State: Training Held

Electronic Signature

This state transition requires an electronic signature.

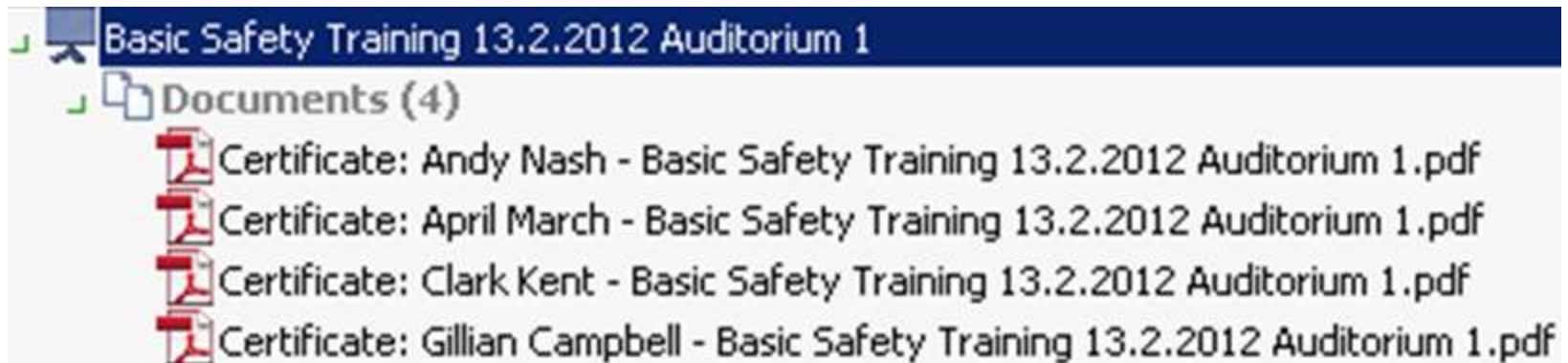
Training Confirmation: I have reviewed the content of this Training Event and have found no errors or omissions. The listed participants attended the event and have been sufficiently instructed on the relevant topics.

Add an electronic signature by entering your credentials and pressing the Sign button.

Username: mika.salonoja
Password:
Domain: QMSDOMAIN

Sign
Cancel

Training certificates are automatically created




Training Certificates



- Based on a MS Word template
→ Easily customizable with your logos etc.
- Digitally signed PDF's document (M-Files batch signing)
- Certificates automatically appear under QMS personnel files
- Can be printed on paper and mailed, or sent via email

USE CASE 4: BUILDING AN EQUIPMENT INVENTORY

Highly Customizable Data models

- [-]  Equipment
 - ☐ Title - Equipment
 - ☐ Equipment Type
 - ☐ Title
 - ☐ Description
 - ☐ Serial Number
 - ☐ Manufacturer's Product Code
 - ☐ Location
 - ☐ Date of implementation
 - ☐ Responsible Person
 - ☐ User Account
 - ☐ User Groups

- Easy to implement without programming
- Different data types supported:
 - Text
 - Date
 - Drop-down lists
 - Numbers
 - etc.

Adding new records manually

- M-Files creates forms to fill-in data automatically.
→ Changed properties are updated on the fly.

The screenshot shows a software window titled "New - Equipment" with a "General" tab. The form contains the following fields and values:

Field	Value
Class:	Equipment
Use template:	<input type="checkbox"/> (unchecked)
Properties:	
Title - Equipment:	(automatic)
Equipment Type:	Laboratory Equipment
Title:	Clean room
Description:	XYZ here
Serial Number:	
Manufacturer's Product Code:	
Location:	
Date of implementation:	<input type="checkbox"/> 16. 2.2012
Responsible Person:	
Created:	16.2.2012 14:12
Created by:	OMSDOMAIN\mika.salonoja

Adding new records from an exiting database

Object Type Properties - Equipment

General | Advanced | Permissions | **Connection to External Database**

☒ Use a connection to an external database to import and modify objects that reside in the external database.

OLE DB connection string (from server):

Define... ?

SELECT statement:

?

Refresh Columns





Columns:

Source Column	Target Property	Update	Insert	

If you want to allow users to modify the data in the external database from within M-Files, specify the SQL statements that M-Files Server can use to create, modify, or delete records in the external database:

- Synchronize data live from an existing system (e.g. ERP or LIMS)
 - M-Files data in sync automatically
- Mass-import data from Excels

The same familiar UI to access equipment data and other QMS records

Name ▲	State	Equipment Type	Date of implementation
>  Analysis Unit XYZ Laboratory Equipment	 2. In Production Use - OK	Laboratory Equipment	16.2.2012
>  Fork Truck Vehicle	 2. In Production Use - OK	Vehicle	16.2.2012

Analysis Unit XYZ Laboratory Equipment

Equipment ID 1, version 3

Created: 1.2.2012 17:07, Mika Salonoja
Last modified: 16.2.2012 14:19, Mika Salonoja

Equipment Type: Laboratory Equipment

Title: Analysis Unit XYZ

Description:

Serial Number:

Manufacturer's Pro...

Location:

Date of implement... 16.2.2012


Responsible Person: Clark Kent

Necessary documents can be attached to any database item

Search all objects ☐ Search within this folder Reset All

Type search words Advanced Search

Name	State	Equipment Type
Fork Truck Vehicle	2. In Production Use - OK	Vehicle
> Responsible Person (1)		
> Locations (1)		
> Issues and Findings (1)		
> Documents (1)		
forklifttruckguide.pdf		
> Analysis Unit XYZ Laboratory Equipment	2. In Production Use - OK	Laboratory Equipment



forklifttruckguide
Equipment Document ID 115, version 1
Created: 16.2.2012 14:21, Mika Salonoja
Last modified: 16.2.2012 14:21, Mika Salonoja
Equipment: Fork Truck Vehicle

Forklift truck guide

Some notes by Stephen Tibbick, Harrow Council Environmental Health Services
partly based on the fact-sheet from www.NuneatonandBedworthbusiness/healthsafety.

17/11/2003

Index

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Introduction	1
The Forklift Truck	1
Checking the truck	2
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Schedule 1 to the Lifting Operations and Lifting Equipment Regs 1998	5
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Training of Operators	7
Authorisation of Operators	8
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Employers Checklist - Forklift Trucks	11
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Introduction

Forklift trucks (FLT) feature prominently in workplace accidents. Every year there are about 8000 lift truck accidents resulting in injury, and about 10 fatalities. Even if people are not injured in FLT accidents there is often damage to buildings, storage systems or stock. The main causes of FLT accidents are:

- ♦ lack of operator training
- ♦ inadequate premises
- ♦ poor FLT maintenance

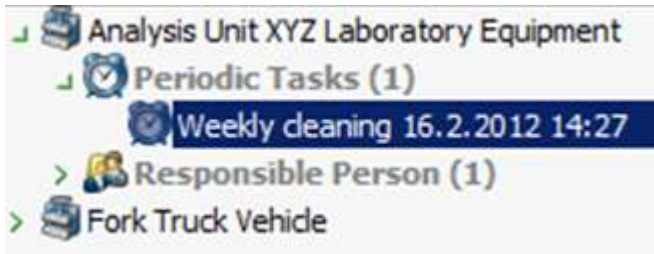
It is the responsibility of management to assess FLT operations and ensure that safe system of work are implemented and maintained. Subsequent responsibilities for safe use will also lie with line managers, supervisors and operators.

Equipment can be linked to any quality control task



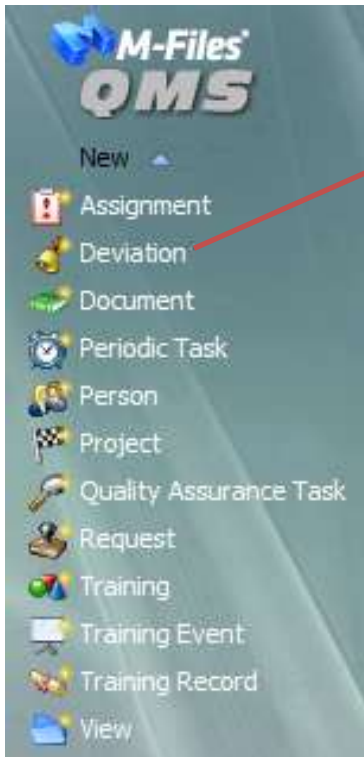
Maintenance tasks

- M-Files QMS comes with built-in features to add recurring maintenance tasks to the equipment

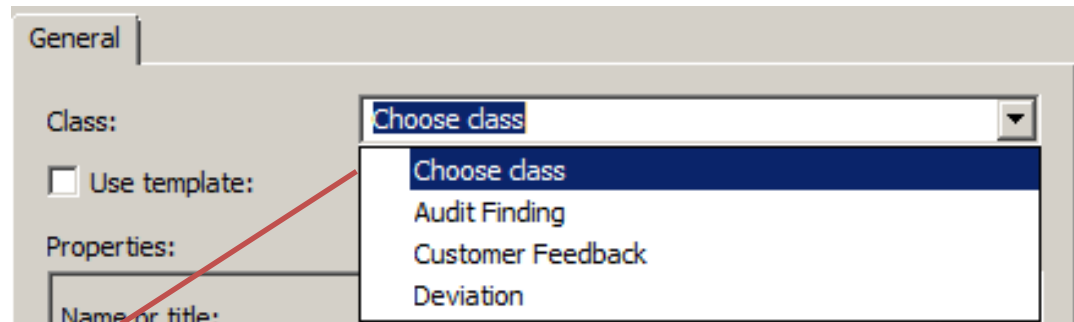


USE CASE 5A: FOLLOWING UP A QUALITY DEVIATION (SIMPLE OPTION)

Creating a New Deviation



Create a new Deviation



Three deviation types to choose from:
Audit finding: linked to an audit or inspection event
Customer feedback: linked to a customer and product
Deviation: an internal quality issue or non-conformity

Fill in the deviation form

New - Deviation

General

Class: Deviation

☐ Use template:

Properties:

Deviation Type: Safety Issue

Short Description: Gas Leakage in Laboratory

Date of Issue: ☒ 1. 2.2012

Due Date: ☒ 8. 2.2012

Product:

Supplier: Supplier Company A

Equipment: Analysis Unit XYZ Laboratory Equipment

Responsible Person:

Issue Number: (automatic)

Description: A small amount of pressurized flammable gas leaked because valve was not closed as instructed

Recommended Action: Re-training of relevant SOPs

Corrective Action (actual):

Overview of ongoing deviations

Responsible Person

Issue and Deviations

Computer > M-Files (M:) > QMS > 4. QA Activities > Issue and Deviations

Organize View New Operations Settings

M-Files QMS

Search only: People

Type search words

Name	Deviation Type	Date of Issue	Due Date	State	Assigned to
> Deviation #116 Gas Leakage in Laboratory Analysis Unit XYZ Laboratory Equipment - 1.2.2012	Safety Issue	1.2.2012	8.2.2012	2. Awaits resolution	Mika Salonoja
> Deviation #117 Not wearing eye protection - 31.1.2012	Issue with Personal Protection	31.1.2012	16.2.2012	1. Start	-
> Deviation #118 Failed to read mandatory SOPs - 2.2.2012	Lack of Training	2.2.2012	16.3.2012	3. Resolved - Unverified	-

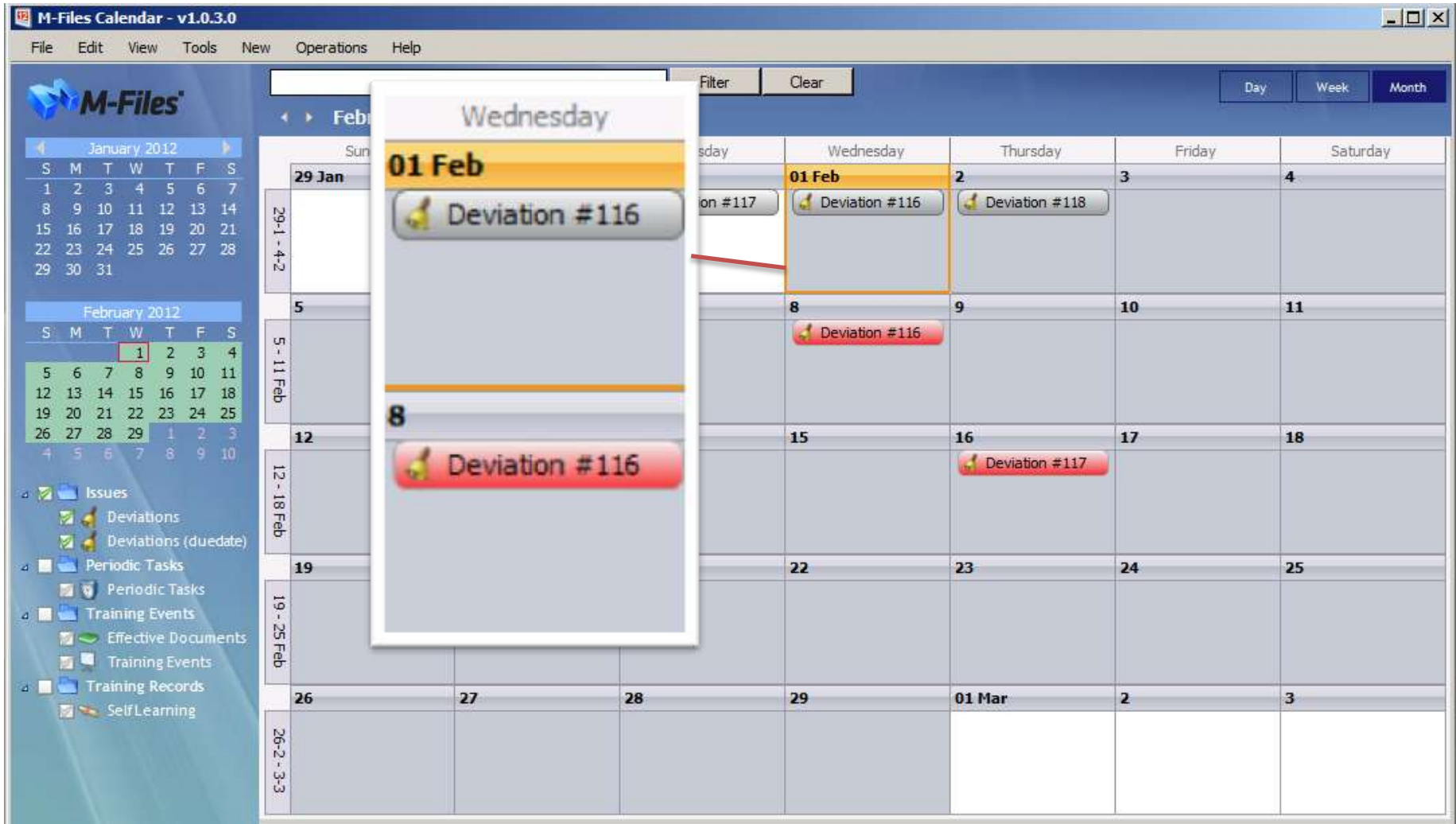
New

- Assignment
- Deviation
- Document
- Periodic Task
- Person
- Project
- Quality Assurance Task
- Request
- Training
- Training Event
- Training Record
- View

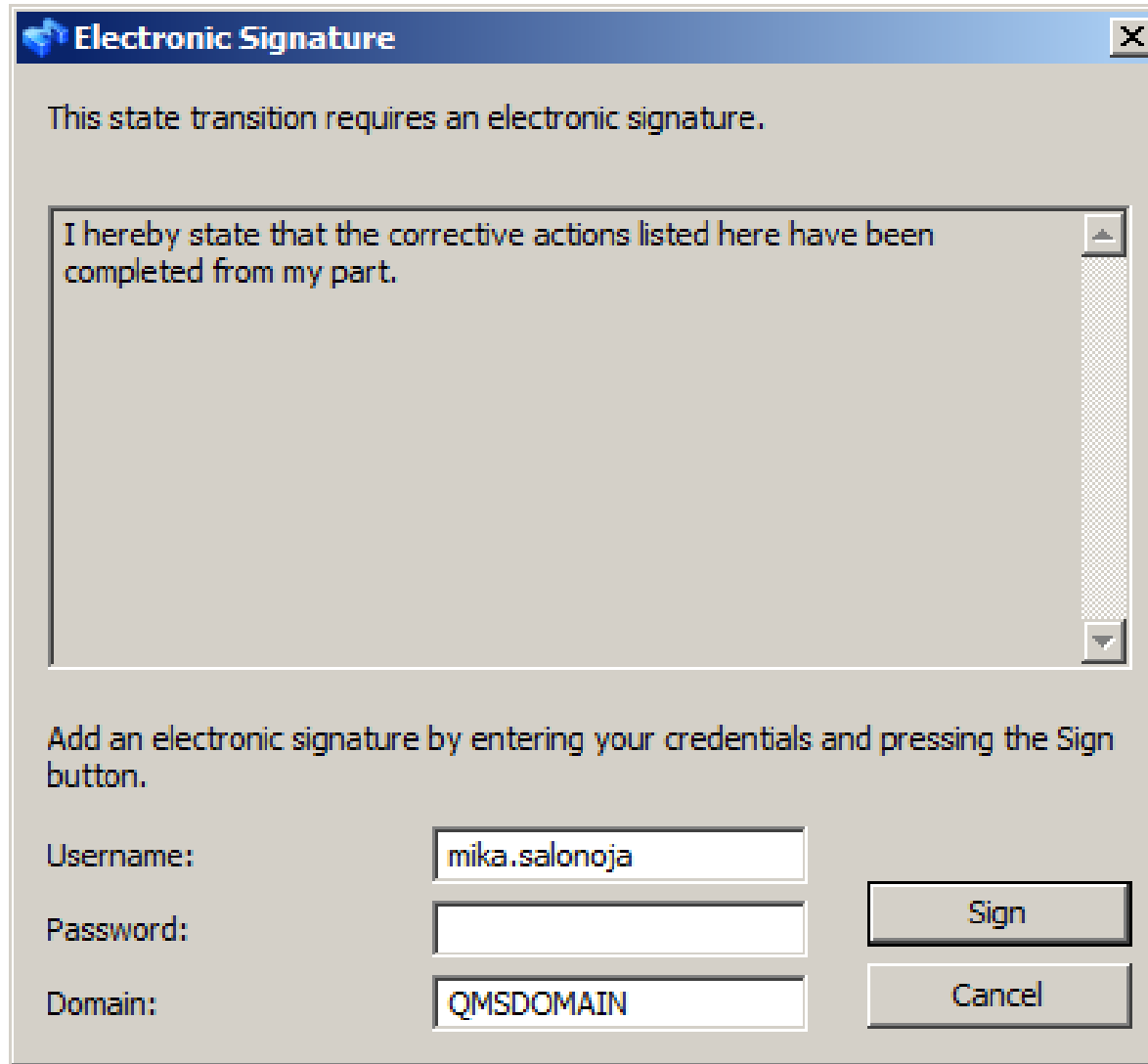
Due Date

State

to browse deviations by and their due dates



The deviation is closed with eSignature after corrective actions



Electronic Signature

This state transition requires an electronic signature.

I hereby state that the corrective actions listed here have been completed from my part.

Add an electronic signature by entering your credentials and pressing the Sign button.

Username:

Password:

Domain:

The image shows a standard Windows-style dialog box titled "Electronic Signature". It has a blue header bar with a close button (X) in the top right corner. The main content area is light gray and contains a message: "This state transition requires an electronic signature." Below this is a large text box with a vertical scrollbar on the right, containing the text: "I hereby state that the corrective actions listed here have been completed from my part." At the bottom of the dialog, there is a section for adding an electronic signature. It includes a label "Add an electronic signature by entering your credentials and pressing the Sign button." followed by three input fields: "Username:" with the value "mika.salonoja", "Password:" with an empty field, and "Domain:" with the value "QMSDOMAIN". To the right of these fields are two buttons: "Sign" and "Cancel".

Full audit trail reveals who has done what and when

History

History:

Name	Version	Status Time	State	User
> Deviation #116 Gas Leakage in Laboratory Analysis Unit XYZ Laboratory Equipment - 1.2.2012	7	1.2.2012 17:34	4. Resolved - Closed	Mika Salonoja
> Deviation #116 Gas Leakage in Laboratory Analysis Unit XYZ Laboratory Equipment - 1.2.2012	6	1.2.2012 17:31	3. Resolved - Unverified	Mika Salonoja
> Deviation #116 Gas Leakage in Laboratory Analysis Unit XYZ Laboratory Equipment - 1.2.2012	5	1.2.2012 17:29	2. Awaits resolution	Mika Salonoja
> Deviation #116 Gas Leakage in Laboratory Analysis Unit XYZ Laboratory Equipment - 1.2.2012	4	1.2.2012 17:12	2. Awaits resolution	Mika Salonoja
> Deviation #116 Gas Leakage in Laboratory Analysis Unit XYZ Laboratory Equipment - 1.2.2012	3	1.2.2012 17:11	1. Start	Mika Salonoja
> Deviation #116 Gas Leakage in Laboratory Analysis Unit XYZ Laboratory Equipment - 1.2.2012	2	1.2.2012 17:11	1. Start	(M-Files Server)
> Deviation #116 Gas Leakage in Laboratory Analysis Unit XYZ Laboratory Equipment - 1.2.2012 ...	1	1.2.2012 17:10	1. Start	Mika Salonoja

Deviation #116 Gas Leakage in Laboratory Analysis Unit XYZ Laboratory Equipment - 1.2.2012
Deviation ID 1, version 7

Created: 1.2.2012 17:03, Mika Salonoja
Last modified: 1.2.2012 17:34, Mika Salonoja

Deviation Type: Safety Issue
Short Description: Gas Leakage in Laboratory
Date of Issue: 1.2.2012
Due Date: 8.2.2012
Product:
Supplier: Supplier Company A
Equipment: Analysis Unit XYZ Laboratory Equipment
Responsible Person: Mika Salonoja
Issue Number: 116

Description:
A small amount of pressurized flammable gas leaked because valve was not closed as instructed
Recommended Action: Re-training of relevant SOPs
Corrective Action (actual):
We replaced the valve completely and put new warning sign on the wall next to the unit
Signature manifestation:
1.2.2012 17:34:01 Mika Salonoja
(QMSDOMAIN\mika.salonoja): '3. Resolved - Unverified' -> '4. Resolved - Closed'

Workflow: [Deviation State](#)
State: 4. Resolved - Closed

Add Label to This Version...
Modify Version Details...
Roll Back
Close

Type: Deviation (0 files)
Checked In
0 bytes
QMSDOMAIN\mika.salonoja

USE CASE 5B: FOLLOWING UP A QUALITY DEVIATION (ADVANCED USE CASE)

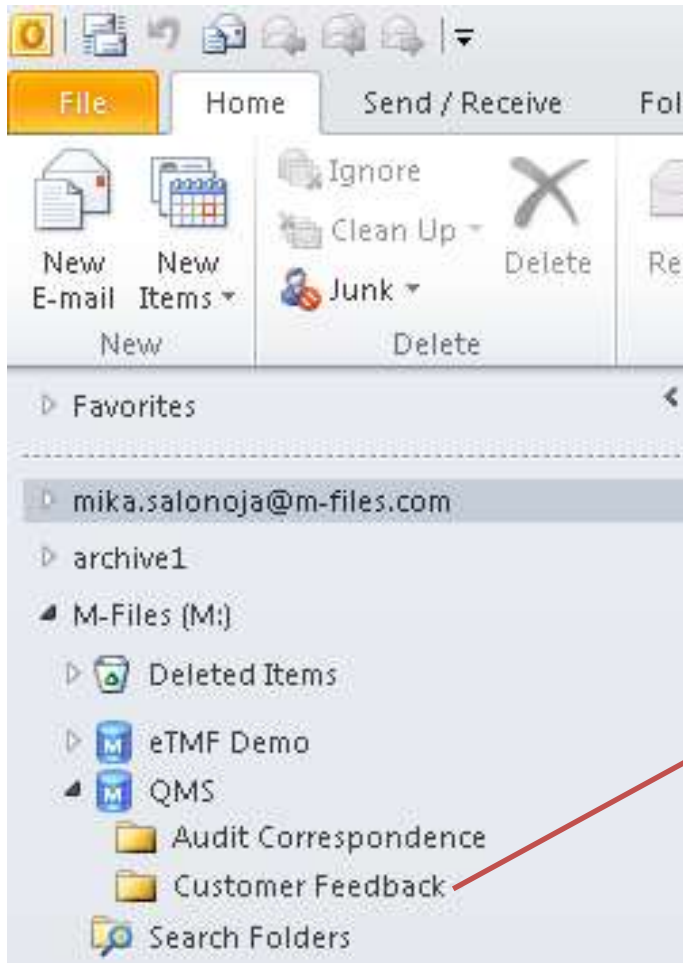
Advanced Use case: separate deviations and CAPAs

- More complex deviations can be split into multiple CAPA's
 - Each CAPA can be assigned to different people with its own due date
 - Once all CAPA's are closed the deviation entry can be closed with eSignature

⚠ Deviation #117 Not wearing eye protection 31.1.2012	?	2. Awaits resolution	Not wearing eye protection	Gillian Campbell	16.2.2012
📁 CAPAs (2)					
📁 CAPA #1003 Deviation #117 Not wearing eye protection 31.1.2012	➡	1. Start - CAPA Recorded	Get more gear	Gillian Campbell	15.2.2012
📁 CAPA #1004 Deviation #117 Not wearing eye protection 31.1.2012	➡	1. Start - CAPA Recorded	Update SOP	Joel Heinrich	1.3.2012

USE CASE 6: PROCESSING CUSTOMER FEEDBACK

Option 1: feedback by Email



Drag the mail to Customer Feedback folder in Outlook

Fill in the metadata card in Outlook

New Document

General

Class: Customer Feedback Document

Save as type: Outlook message (*.msg)

Properties:

Name or title: Reclamation!

Customer Feedback - Open:

Email From: mika.salonoja@m-files.com

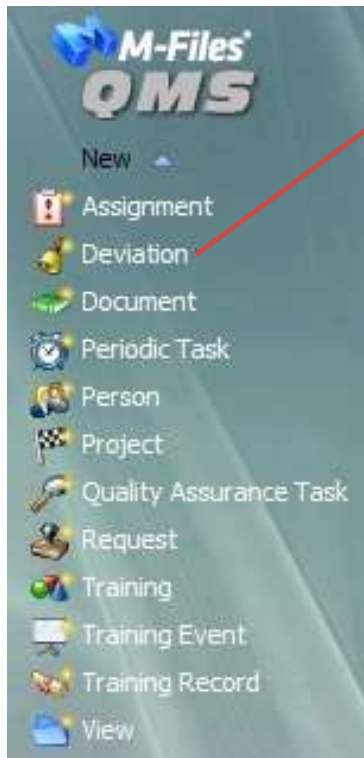
Email To: mika.salonoja@m-files.com

Email Subject: Reclamation!

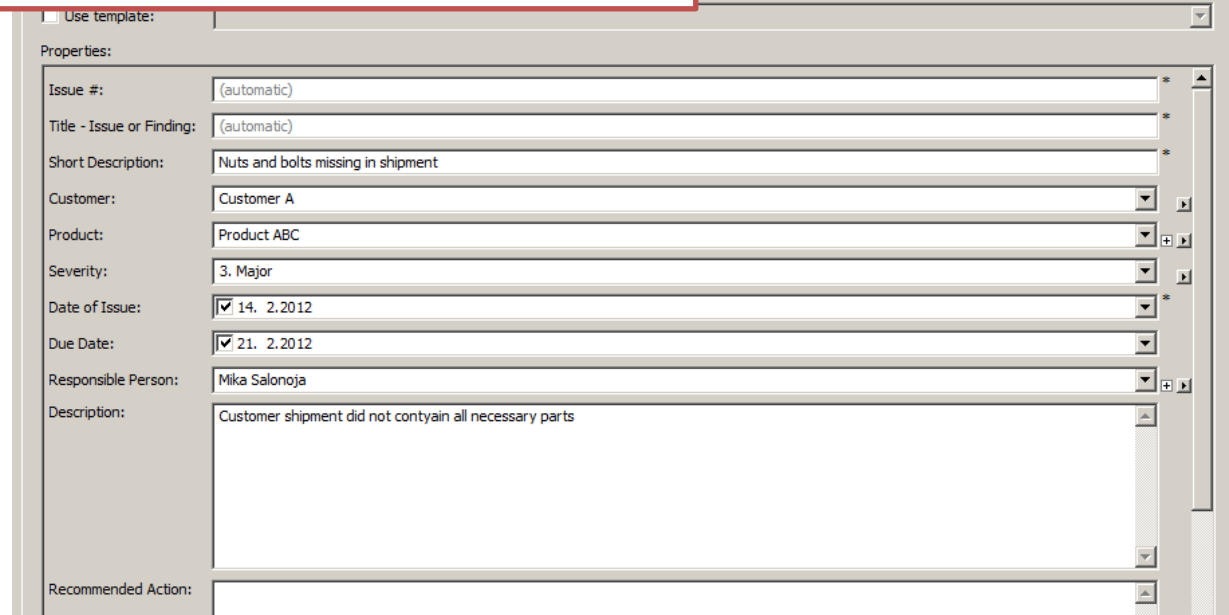
Email Date: ☒ 16. 2. 2012

Most properties are automatically filled

Option 2: feedback by phone or in a meeting



Create a new Deviation and fill in the metadata card



The image shows the 'New Deviation' form in the M-Files QMS application. The form is titled 'Properties:' and contains several fields for entering deviation data. A red arrow points from the 'Deviation' option in the sidebar to this form.

Use template:	
Issue #:	(automatic)
Title - Issue or Finding:	(automatic)
Short Description:	Nuts and bolts missing in shipment
Customer:	Customer A
Product:	Product ABC
Severity:	3. Major
Date of Issue:	<input checked="" type="checkbox"/> 14. 2.2012
Due Date:	<input checked="" type="checkbox"/> 21. 2.2012
Responsible Person:	Mika Salonoja
Description:	Customer shipment did not contain all necessary parts
Recommended Action:	

Ongoing customer feedback cases are visible in 'All open cases' view

▼ M-Files (M:) ▼ QMS ▼ 5. Quality Control ▼ 2. Customer Feedback ▼ 1. All Open Cases ▼

w ▼ Operations ▼ Settings ▼

Search only: CAPAs ▼ ☐ Search within this folder

Type search words ▼ Search

Name ▲	State	Customer	Date of Issue	Product	Responsible Person
> ⚠ Customer Feedback #126 16.2.2012 Failed to meet customer specifications	➡ 1. Start	Customer B	16.2.2012	Product XYZ	
> ⚠ Customer Feedback #127 9.2.2012 Wrong Colour Delivered	❓ 2. Awaits resolution	Customer A	9.2.2012	Product ABC	Clark Kent
> ⚠ Customer Feedback #128 14.2.2012 Nuts and bolts missing in shipment	➡ 1. Start	Customer A	14.2.2012	Product ABC	Mika Salonoja

Customer Feedback #128 14.2.2012 Nuts and bolts missing in shipment

Customer Feedback ID 13, version 1

Issue #: 128

Short Description: Nuts and bolts missing in shipment

Customer: Customer A

Product: Product ABC

Severity: 3. Major

Date of Issue: 14.2.2012

Due Date: 21.2.2012

Responsible Person: Mika Salonoja

Description: Customer shipment did not contain all necessary parts

Created: 16.2.2012 12:58, Mika Salonoja

Last modified: 16.2.2012 12:58, Mika Salonoja

Customer feedback now awaits corrective action

The screenshot displays the M-Files software interface. On the left is a vertical navigation pane with icons and labels for various functions: Assignment, Audit, CAPA, Document, Issue or Finding, Periodic Task, Person, Request, Training, Training Event, Training Record, View, View and Modify, Check Out, Properties, History, Make Copy, Calendar, Move into State, 3. Resolved - Closed, Go To, and Root. The main area is divided into two sections. The top section shows a list of three customer feedback issues, each with a yellow warning icon, a date, a description, and a status icon. The third issue, 'Customer Feedback #128 14.2.2012 Nuts and bolts missing in shipment', is highlighted. The bottom section provides a detailed view of this issue, including its title, ID, version, creation and modification dates, and a list of attributes such as Issue #, Short Description, Customer, Product, Severity, Date of Issue, Due Date, Responsible Person, and Description. A 'Recommended Action' section is also present. At the bottom, a red-bordered box highlights the 'Workflow' and 'State' information.

Customer Feedback #128 14.2.2012 Nuts and bolts missing in shipment

Customer Feedback ID 13, version 2

Created: 16.2.2012 12:58, Mika Salonoja
Last modified: 16.2.2012 13:00, Mika Salonoja

Issue #: 128
Short Description: Nuts and bolts missing in shipment
Customer: Customer A
Product: Product ABC
Severity: 3. Major
Date of Issue: 14.2.2012
Due Date: 21.2.2012
Responsible Person: Mika Salonoja
Description: Customer shipment did not contain all necessary parts
Recommended Action: ...
Corrective Action (...): ...

Workflow: [Issue Processing](#)
State: [2. Awaits resolution](#)
Assigned to: Mika Salonoja

Feedback appears on responsible person's to-do list Together with other pending tasks awaiting my action

Assigned to Me

Computer > M-Files (M:) > QMS > Assigned to Me

Organize View New Operations Settings

M-Files QMS

New

- Assignment
- Audit
- CAPA
- Document
- Issue or Finding
- Periodic Task
- Person
- Request

Search only: CAPAs

Type search words

Name
> ⚠ Audit Finding #121 Document Control Missing signature
> ⚠ Customer Feedback #128 14.2.2012 Nuts and bolts missing in shipment
> ⚠ DOC REQ: Mika Salonoja - Equipment SOP #1031 v1.0 Mika
> ⚠ DOC REQ: Mika Salonoja - Personnel Form # v1.0 Test
> ⚠ DOC REQ: Mika Salonoja - Safety Company Policy #1034 v2.1 Test
> ⚠ DOC REQ: Mika Salonoja - Safety SOP #1032 v2.0 Help!
> ⚠ DOC REQ: Mika Salonoja - Safety SOP #1041 v2.0 Fooobar

Any further email discussions about the case can be stored under the feedback case for later reference

- └  Customer Feedback #128 14.2.2012 Nuts and bolts missing in shipment
 - >  Customer (1)
 - └  Documents (2)
 -  RE: Redamation!.msg
 -  Redamation!.msg
 - >  Prodcuts (1)
 - >  Responsible Person (1)

Once all tasks done, feedback case is closed

The screenshot displays a software interface for managing customer feedback. On the left, a tree view shows a hierarchy: Customer (1) > Customer A > Documents (2) > RE: Reclamation!.msg > Reclamation!.msg > Prodcuts (1) > Product ABC > Responsible Person (1) > Mika Salonoja. The main area shows a list of three customer feedback cases. The first case is highlighted: Customer Feedback #128, dated 14.2.2012, with the description 'Nuts and bolts missing in shipment'. The status is '2. Awaits resolution' and the customer is 'Customer A'. Below the list, a detailed view for 'Customer Feedback #128' is shown, including the issue number, short description, customer, product, severity, date of issue, due date, responsible person, and description.

Case ID	Date	Description	Status	Customer
Customer Feedback #126	16.2.2012	Failed to meet customer specifications	1. Start	Customer B
Customer Feedback #127	9.2.2012	Wrong Colour Delivered	2. Awaits resolution	Customer A
Customer Feedback #128	14.2.2012	Nuts and bolts missing in shipment	2. Awaits resolution	Customer A

Customer Feedback #128 14.2.2012 Nuts and bolts missing in shipment
Customer Feedback ID 13, version 2

Issue #: 128
Short Description: Nuts and bolts missing in shipment
Customer: Customer A
Product: Product ABC
Severity: 3. Major
Date of Issue: 14.2.2012
Due Date: 21.2.2012
Responsible Person: Mika Salonoja
Description: Customer shipment did not contain

Electronic Signature

This state transition requires an electronic signature.

I hereby state that this issue is now processed and related corrective actions have been completed

Add an electronic signature by entering your credentials and pressing the Sign button.

Username:
Password:
Domain:

USE CASE 7: PERFORMING AN AUDIT AND FOLLOWING UP ITS FINDINGS

A new audit event is scheduled in Calendar view

M-Files Calendar - v1.0.3.0

File Edit View Tools New Operations Help

Filter Clear

Day Week Month

February 2012

S M T W T F S

29 30 31 1 2 3 4

5 6 7 8 9 10 11

12 13 14 15 16 17 18

19 20 21 22 23 24 25

26 27 28 29

March 2012

S M T W T F S

1 2 3

4 5 6 7 8 9 10

11 12 13 14 15 16 17

18 19 20 21 22 23 24

25 26 27 28 29 30 31

1 2 3 4 5 6 7

Audits

- Customer Audit
- Internal Audits
- Management Review
- Regulatory Inspection
- Supplier Audit

Issues

- Deviations
- Deviations (duedate)
- Periodic Tasks
- Periodic Tasks
- Training Events
- Effective Documents
- Training Events

29 Jan

Equipment

30

31

Deviation

01 Feb

Equipment

Personnel

9:09 AM Doc

2

Safety

3

4

5

6

Safety SOP

7

8

7:17 AM Doc

9

Customer

Safety

Safety

10

Equipment

11

12

19:35 PM An

Deviation

13

Safety SOP

Safety SOP

12:37 PM Do

14

15

Safety SOP

16

11:01 AM Do

Deviation

Deviation

17

18

19

20

21

22

23

24

25

26

27

28

29

30

31

New

Refresh

✓ Show Properties Pane

Deviation...

Training Event...

Customer Audit...

Internal Audit...

Supplier Audit...

Management Quality Review...

Regulatory Inspection...

List of Audits

> 🔍 Customer Audit #101 Test 9.2.2012	Customer Audit	2. Completed - Closed
> 🔍 Internal Audit #102 Test2 9.2.2012	Internal Audit	➡ 1. Open - Ongoing
> 🔍 Other QA Event #103 Test3 9.2.2012	Other QA Event	➡ 1. Open - Ongoing
> 🔍 Regulatory Inspection #104 Test 4 9.2.2012	Regulatory Inspection	➡ 1. Open - Ongoing
> 🔍 Supplier Audit #105 Test 5 9.2.2012	Supplier Audit	➡ 1. Open - Ongoing
> 🔍 Management Quality Review #106 Test MGMT 12...	Management Quality Review	➡ 1. Open - Ongoing
> 🔍 Customer Audit #107 Annual Inspection 20.2.2012	Customer Audit	➡ 1. Open - Ongoing

Automatic numbering

State

Customer Audit #107 Annual Inspection 20.2.2012

Customer Audit ID 8, version 1

Audit #: 107

Customer: Customer A

Title: Annual Inspection

Start Date: 20.2.2012

End Date: 20.2.2012

Subsidiary:

Product:

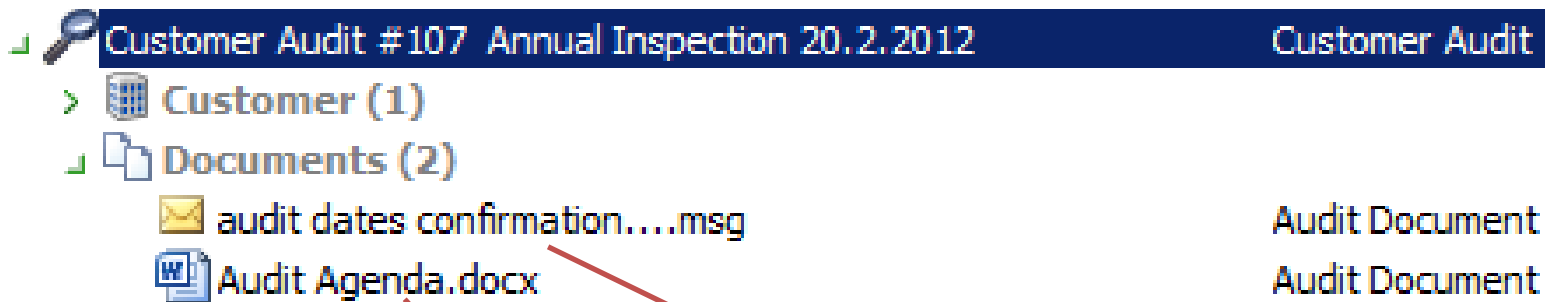
Description: Recurring annual audit

Responsible Person: Mika Salonoja

Created: 16.2.2012 13:52, Mika Salonoja

Last modified: 16.2.2012 13:52, Mika Salonoja

Audit Documents



Emails saved via Outlook drag & drop

Add documents to the audit before, during and after the audit event

Audit Findings

Customer Audit #107 Annual Inspection 20.2.2012	Customer Audit	-
Customer (1)		
Documents (2)		
Issues and Findings (3)		
Audit Finding #131 Human Resources Third Finding	Audit Finding	Human Resources
Audit Finding #130 Facilities Second Finding	Audit Finding	Facilities
Audit Finding #129 Document Control First Problem	Audit Finding	Document Control
Responsible Person (1)		

In the sample case 3 findings are added on 3 different areas

Audit Finding Workflow

Customer Audit #107 Annual Inspection 20.2.2012	Customer Audit	-	1. Open - Ongoing
> Customer (1)			
> Documents (2)			
> Issues and Findings (3)			
! Audit Finding #131 Human Resources Third Finding	Audit Finding	Human Resources	? 2. Awaits resolution
! Audit Finding #130 Facilities Second Finding	Audit Finding	Facilities	? 2. Awaits resolution
! Audit Finding #129 Document Control First Problem	Audit Finding	Document Control	? 2. Awaits resolution
> Responsible Person (1)			

Recommended Actions

Audit Finding #129 Document Control First Problem
Audit Finding ID 14, version 3

Issue #: 129
Short Description: First Problem
Audit - Open: Customer Audit #107 Annual Inspection 20.2.2012
Area: Document Control
Severity: 2. Minor
Responsible Person: Mika Salonoja
Due Date: 23.2.2012
Description: Necessaru documents could not be located during the audit
Recommended Action: Fix basic control procedures and provide additional training
Corrective Action (...)

Workflow: [Issue Processing](#)
State: ? 2. Awaits resolution
Assigned to: Mika Salonoja

State

Alternatively Audit Finding can trigger multiple CAPA's that all have a workflow

<div> Audit Finding #131 Human Resources Third Finding</div> <div> Audit - Open (1)</div> <div> CAPAs (3)</div> <div><div> CAPA #1005 Audit Finding #131 Human Resources Third Finding</div><div> CAPA #1006 Audit Finding #131 Human Resources Third Finding</div><div> CAPA #1007 Audit Finding #131 Human Resources Third Finding</div></div> <div> Responsible Person (1)</div>	Human Resources	<div> 3. Resolved - Closed</div> <div> 4. Resolved - Closed</div> <div> 4. Resolved - Closed</div> <div> 4. Resolved - Closed</div>
---	-----------------	--

Takeaways

- M-Files QMS: a practical tool for daily quality management
- Superior document control capabilities
- Superior connectivity and usability over any web-browser-only solution
- Lot of processes in one package & one login
- Flexible and easy built-in digital signing
- Quality awareness via M-Files reporting and built-in calendar

*"Make sure you actually follow **your** quality policies"*