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

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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

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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

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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

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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
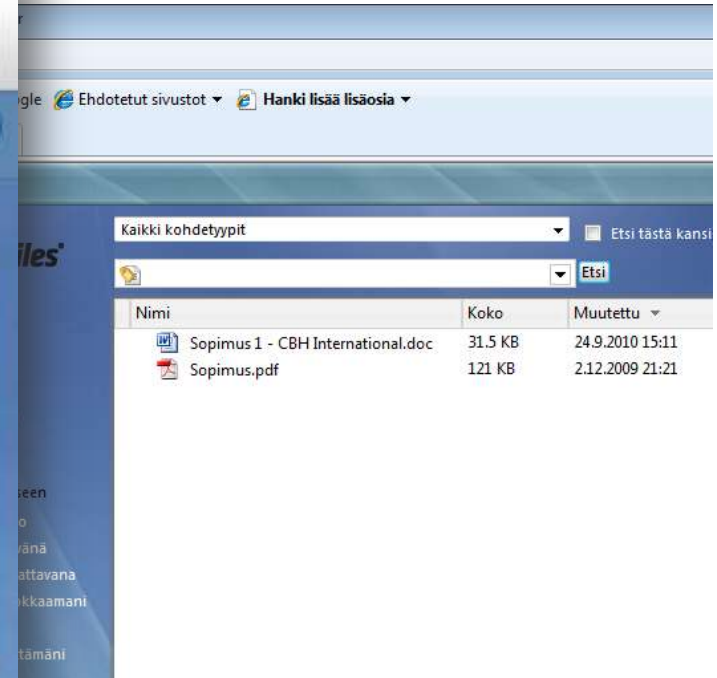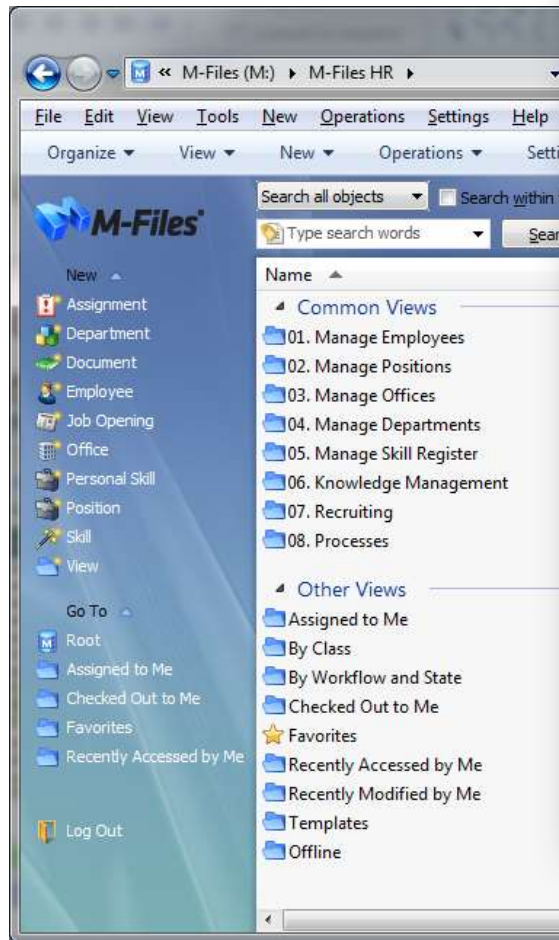
M-Files Web Access

M-Files Windows Client

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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!

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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.

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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 etcc

- 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.

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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

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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

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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

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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

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M-Files QMS User Interface
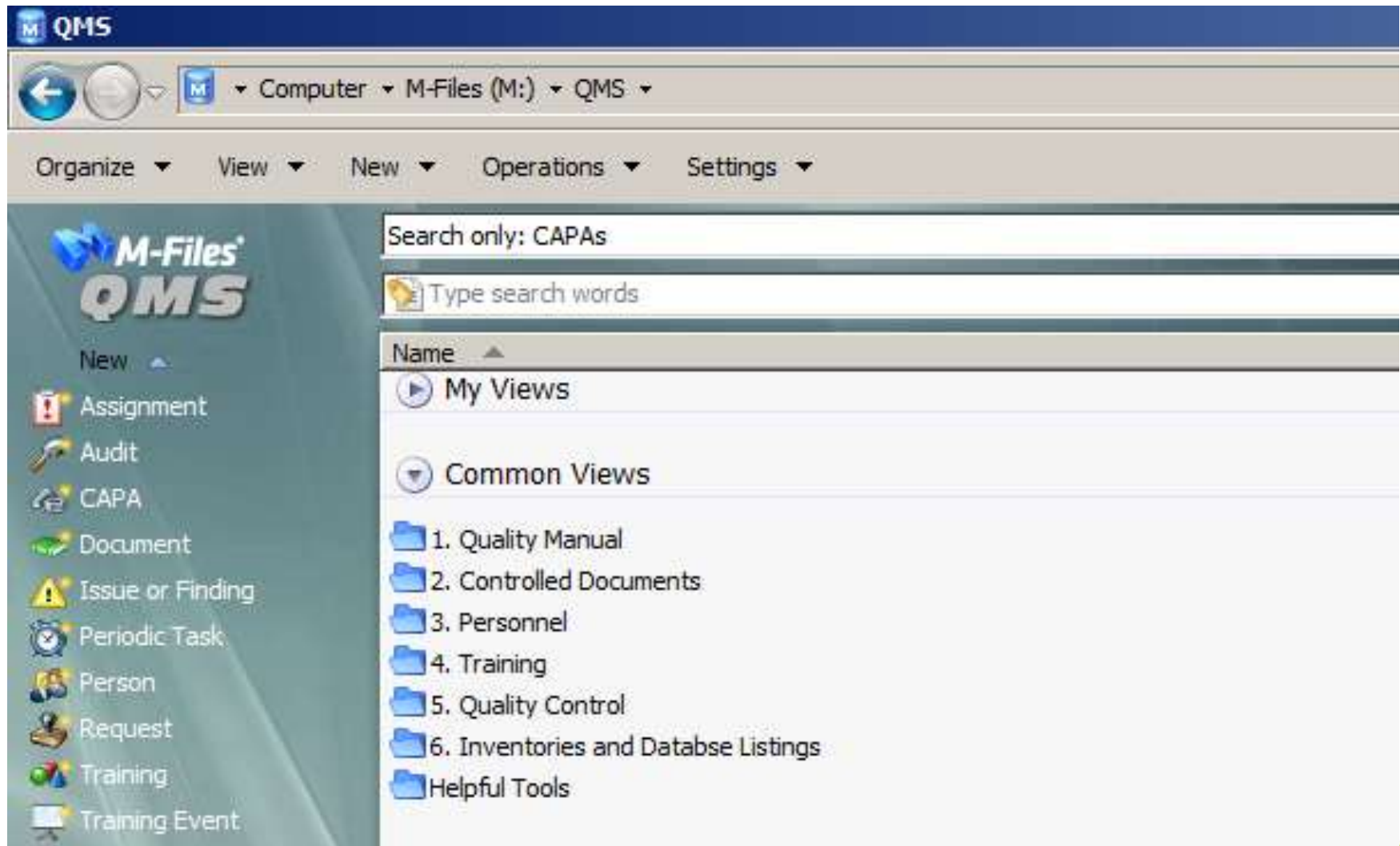
Built-in eSigning

- 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)

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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!

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Sample PDF File with Electronic and Digital Signatures
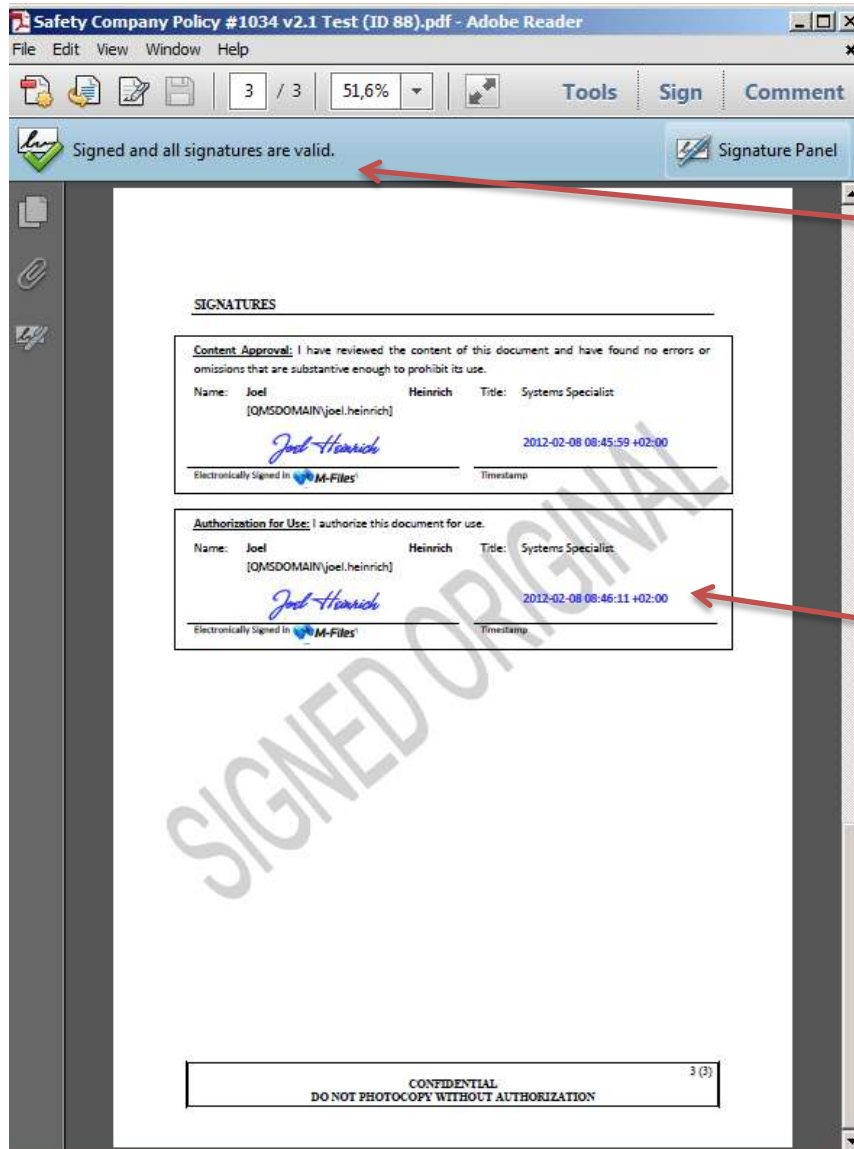
- **_Digital signature says_**: "This original document can only have come from **Our Company.** No one inside or outside our company has modified it after signing"

- **_Electronic signature says_**: "This document is approved by this **signer** (or signers). All relevant signing information is visible on the document"

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Standard PDF Readers Detect Digital Signatures
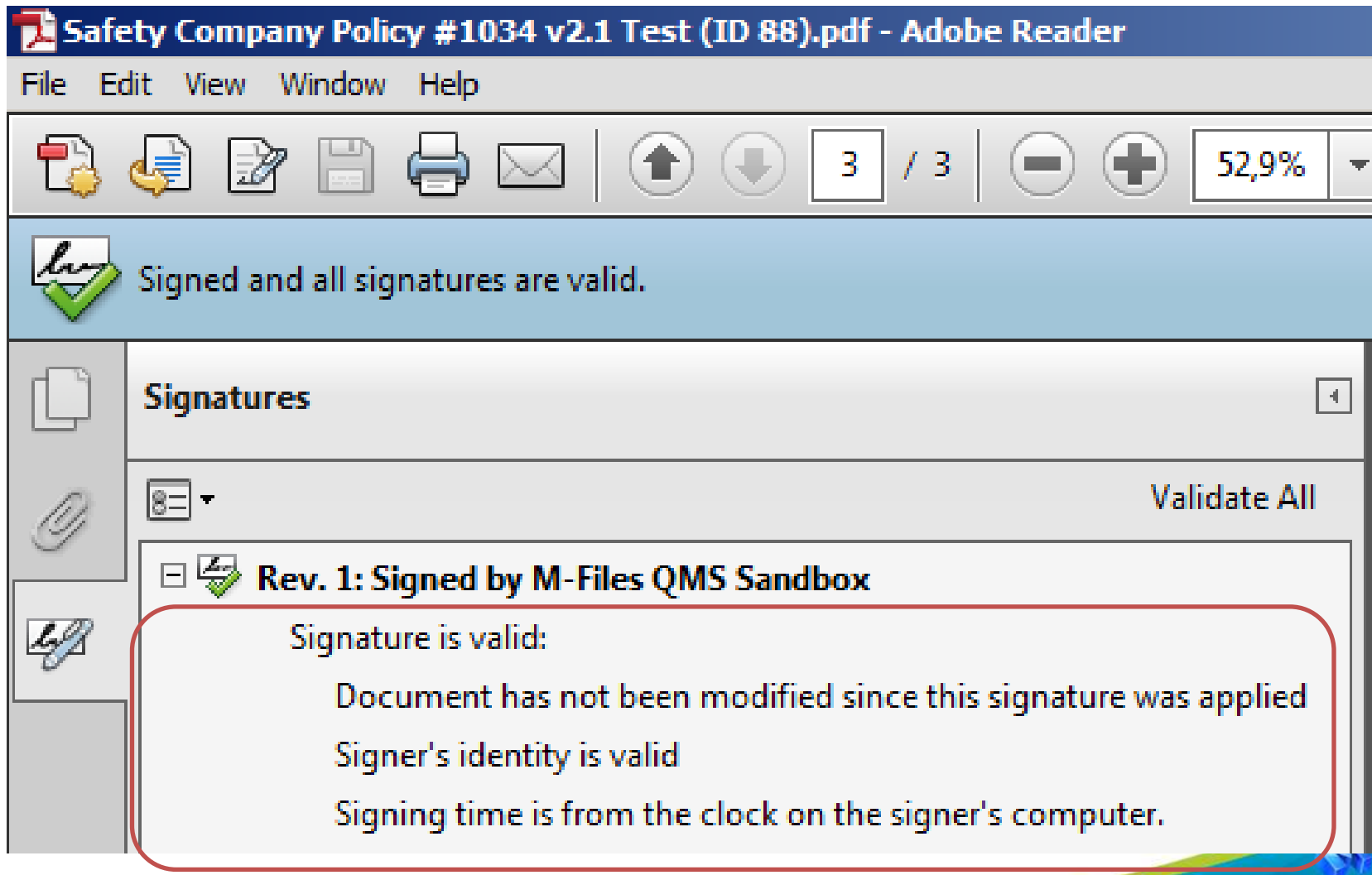
Falsified Signed Documents Detected by PDF Readers

001-100 Signing Demo Document (ID 52) MODIFIED.pdf - Adobe Reader

File   Edit   View   Window   Help

1 / 2   127%

Signed and all signatures are valid, but with unsigned changes after the last signature.

Modifications to document content break the signature

This Document Demonstrates M-Files built-in digital signing capabilities

DRAFT
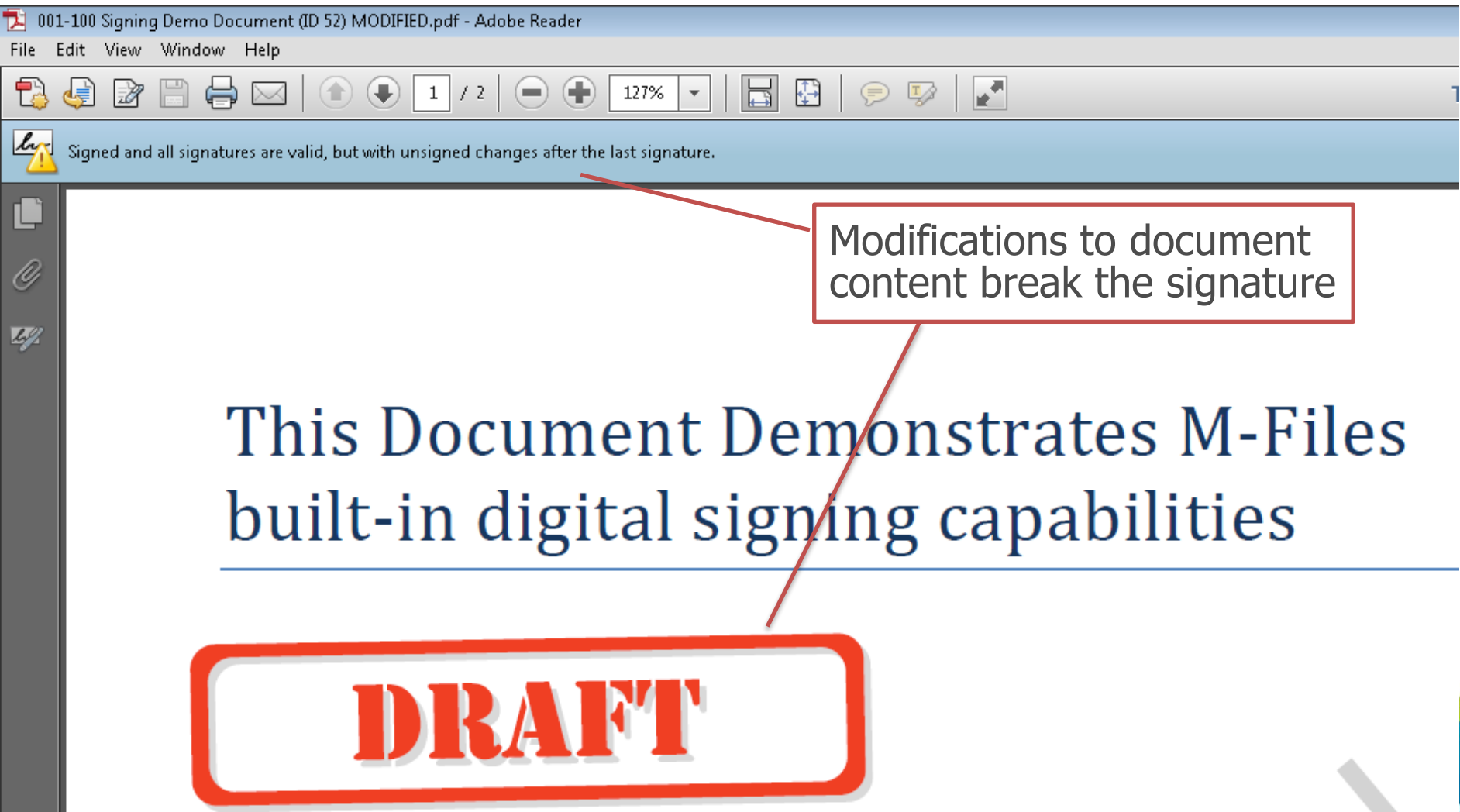
M-Files eSigning:
Benefits Over Paper and Pen

- 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

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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"
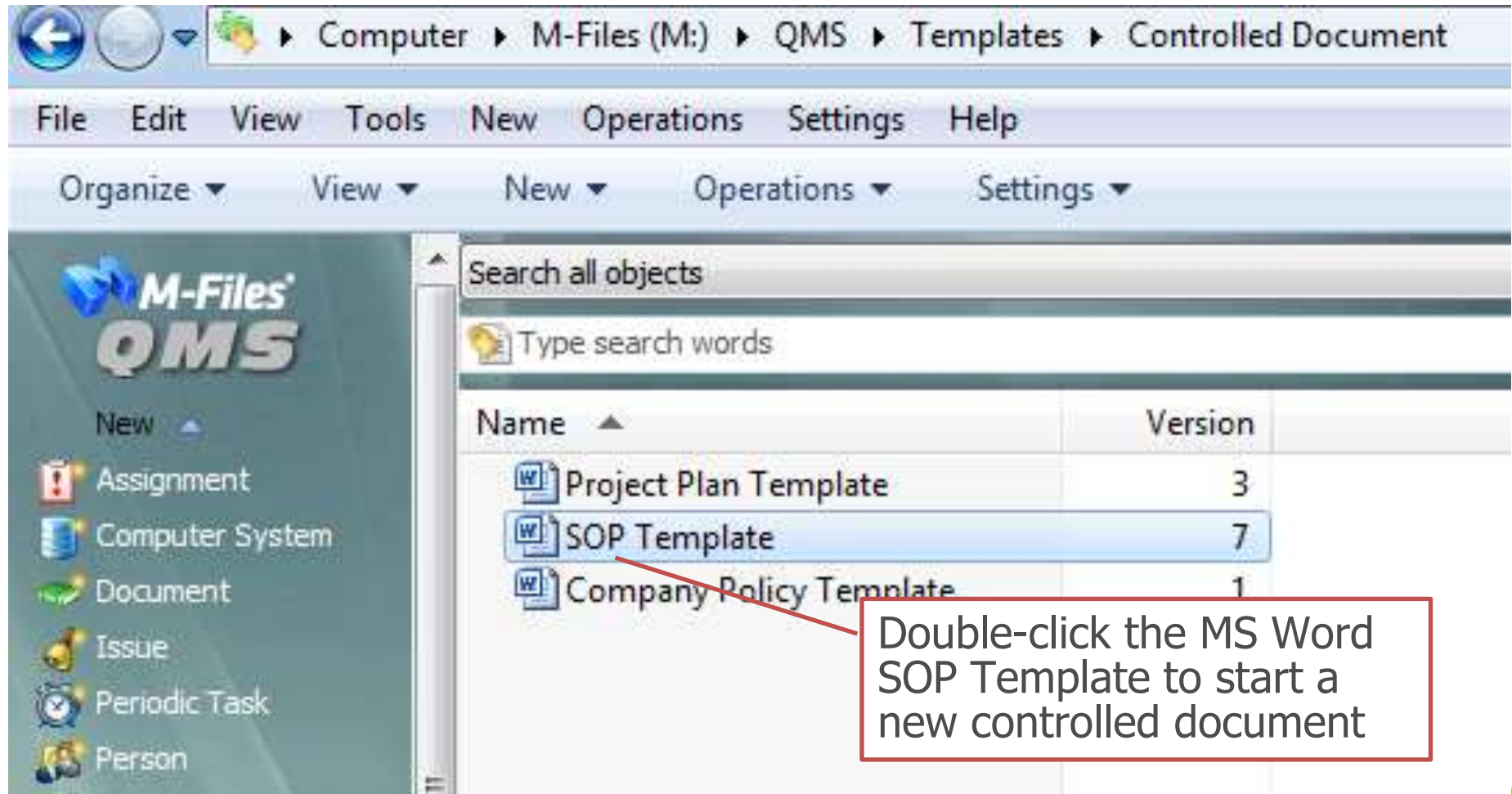
- relevant to some clients, not all

- 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

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

Creating new SOP's from Templates

Computer ▸ M-Files (M:) ▸ QMS ▸ Templates ▸ Controlled Document

File   Edit   View   Tools   New   Operations   Settings   Help

Organize ▾   View ▾   New ▾   Operations ▾   Settings ▾

M-Files
QMS

Search all objects

Type search words

New ▲

Assignment
Computer System
Document
Issue
Periodic Task
Person

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

Double-click the MS Word SOP Template to start a new controlled document

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Specify SOP Properties, Including Two Signers

Smart Templates with Dynamic Content
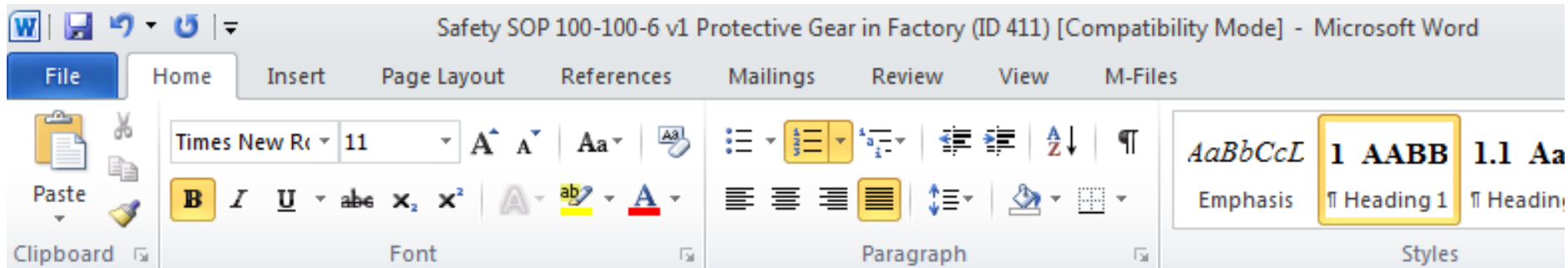
Intuitive UI to Control Documents

Initiating Electronic Signature

The first signature is initiated by hitting 'Move into state: Content Approved'
(the button only visible for the person that has signing privileges)

Applying author signature

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 Docume... **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

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Authorizing SOP

Move into State:
5. Authorized
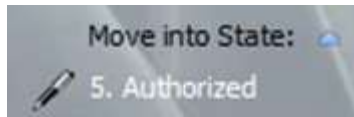
Authorizer selects the SOP in her task list and moves it to Authorized state.

Electronic Signature

This state transition requires an electronic signature.

Authorization for Use: I authorize this document for use.

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

Username: heijoe

Password: ●●●●●●●●●●

Domain: MFQMSDEMO

Sign

Cancel

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Authorized SOP

File automatically converted to PDF

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)

ika Salonoja, 23.1.2012
Authorization for Use: Joel Heinrich, 23.1.2012

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

SOP is now Available for Training

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Digital Signature in Place
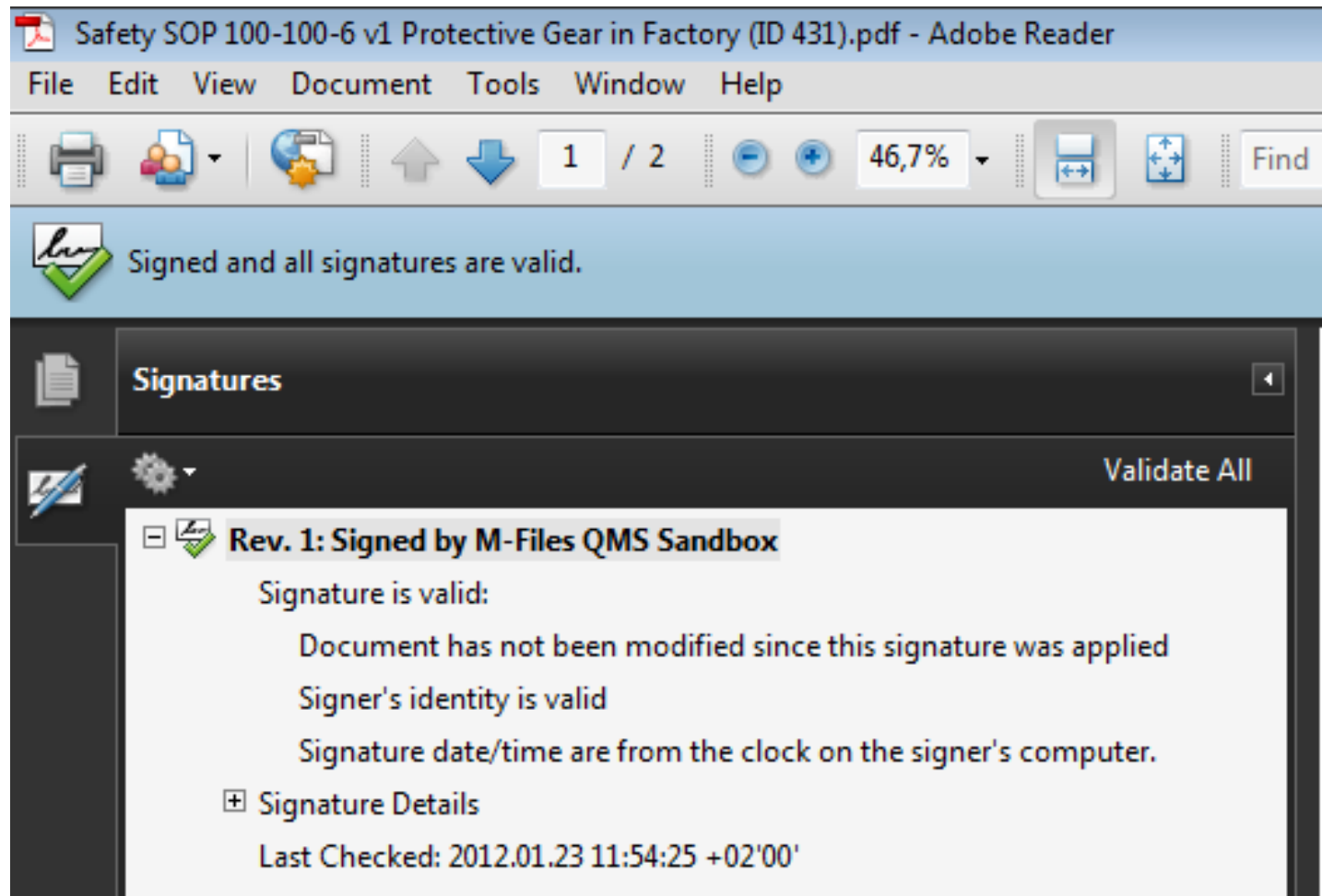
Electronics Signature Page automatically added (Signature layout is customizable)
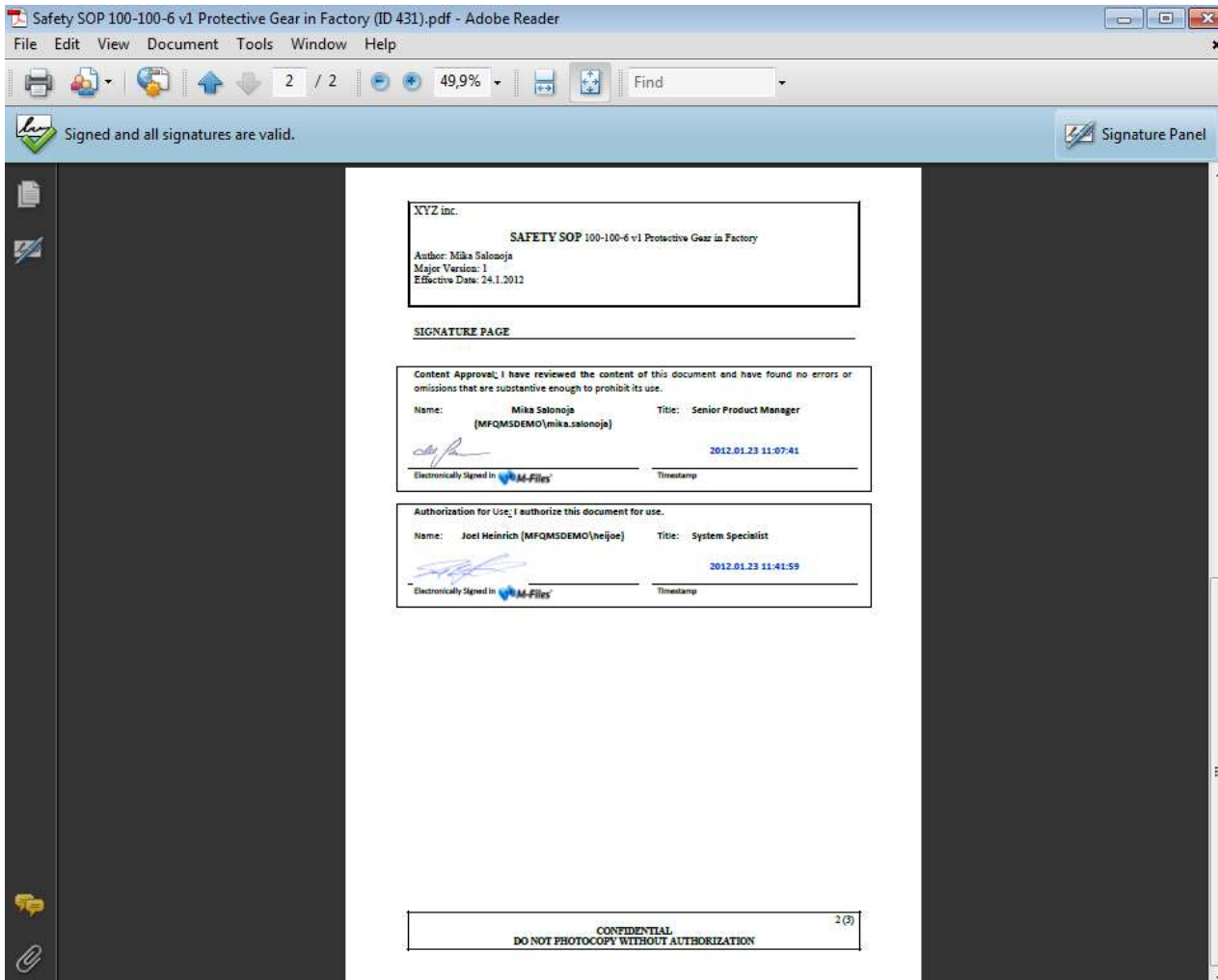
Electronic Signatures

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

M-Files

Updating SOP's
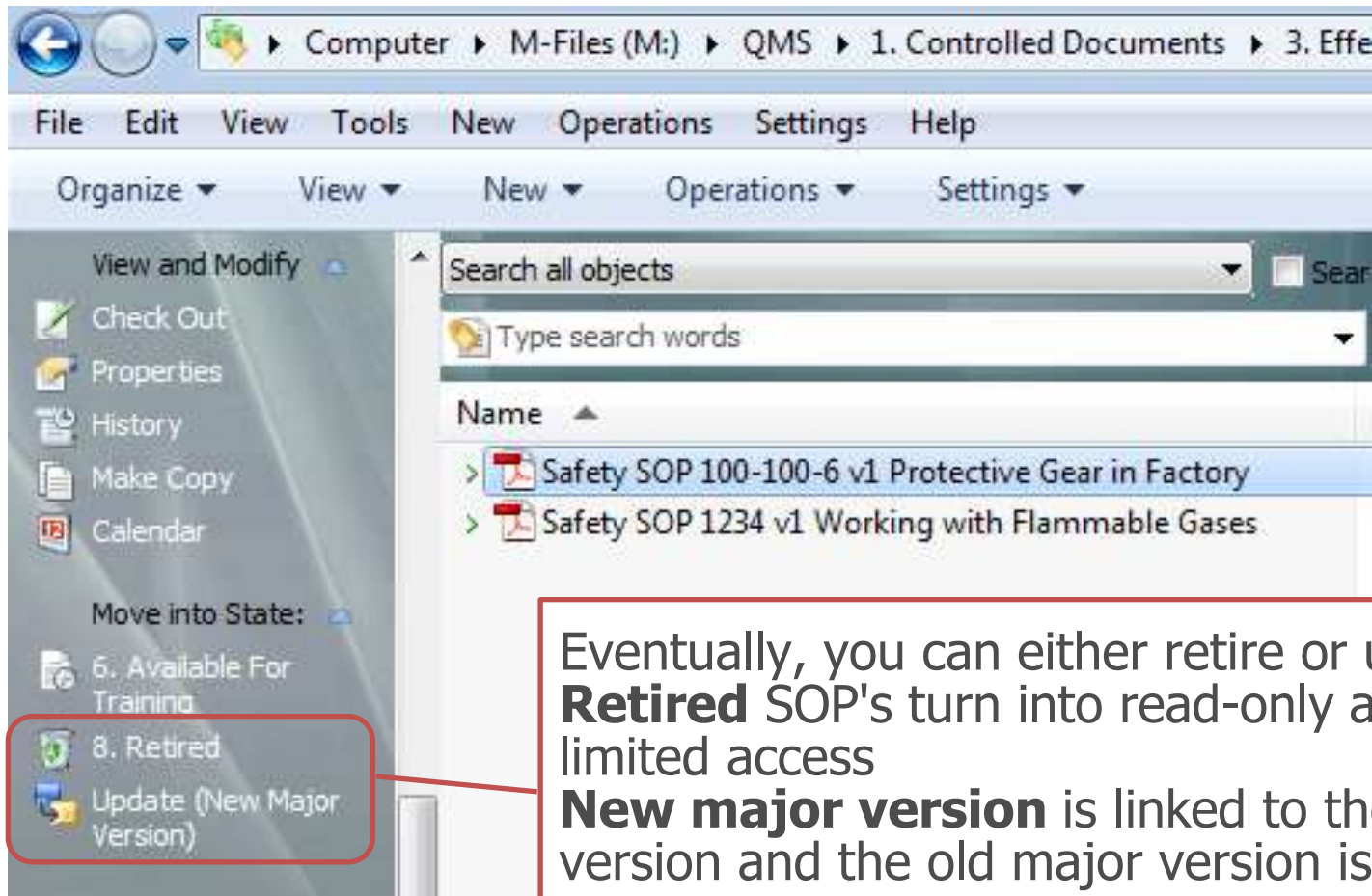
Eventually, you can either retire or update the SOP.
Retired SOP's turn into read-only archive with limited access
New major version is linked to the old major version and the old major version is retired

USE CASE 2: GET THE NEW SOP TRAINED TO STAFF

Define the people to whom the new SOP is mandatory
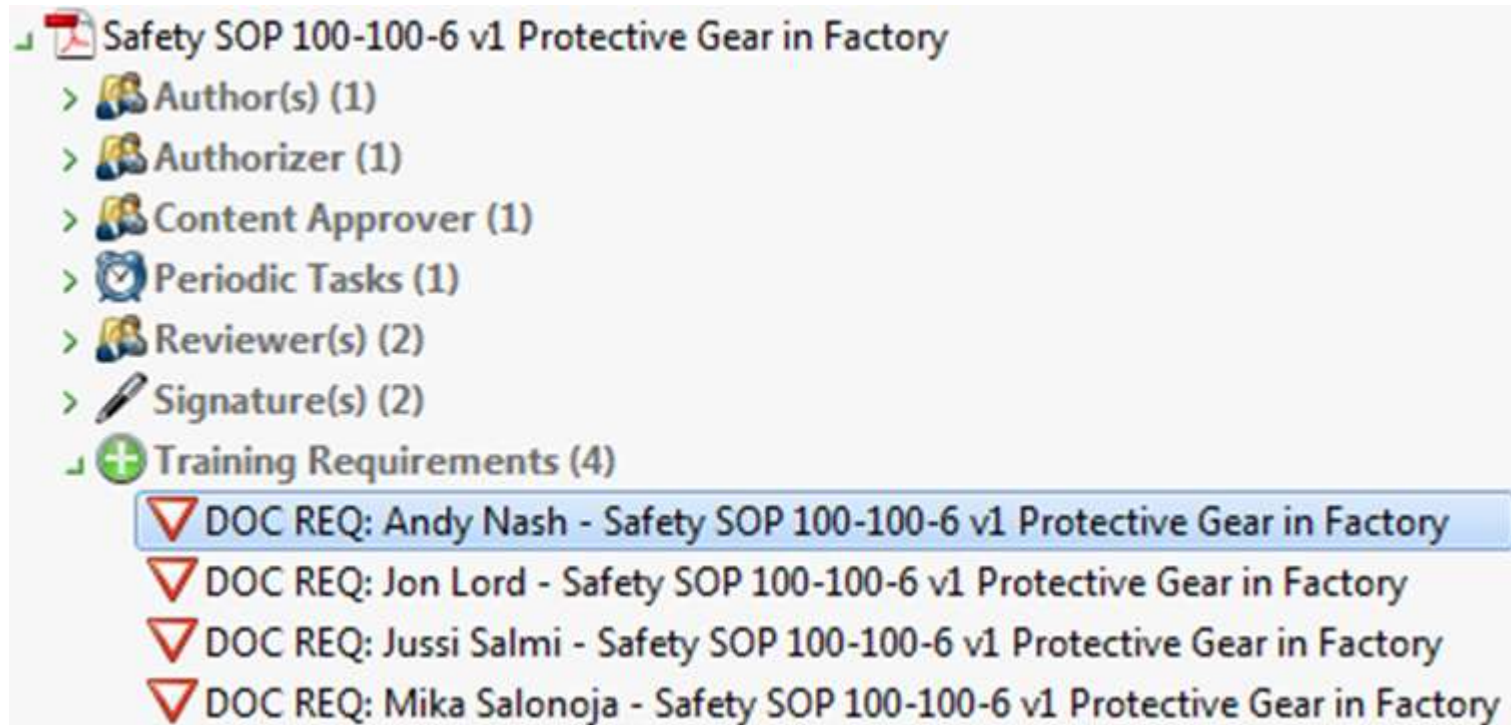
A pending training requirement to each person is created

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
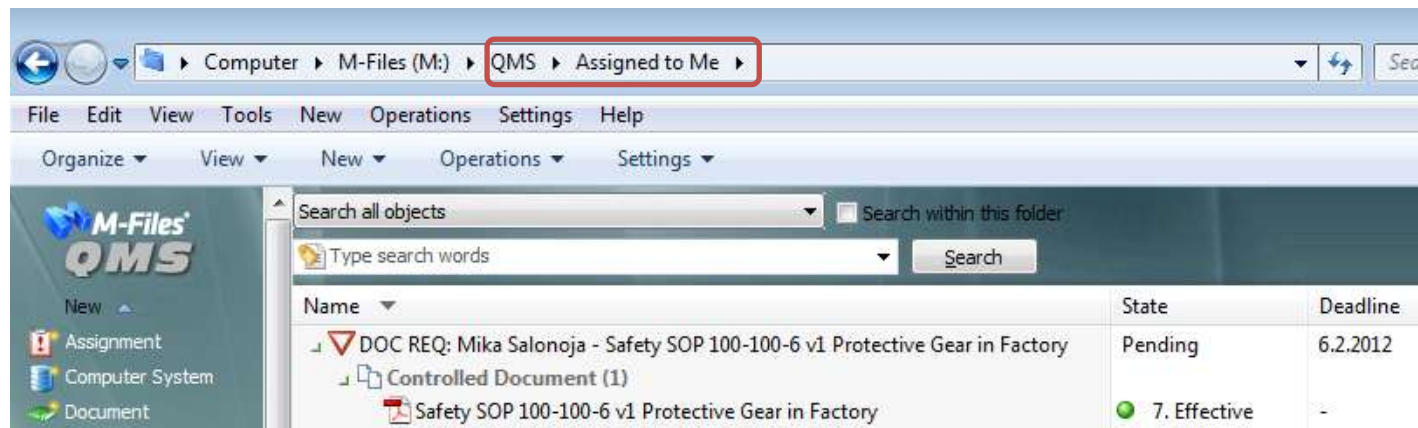
Once document is learned, it's training is requirement is closed with eSignature
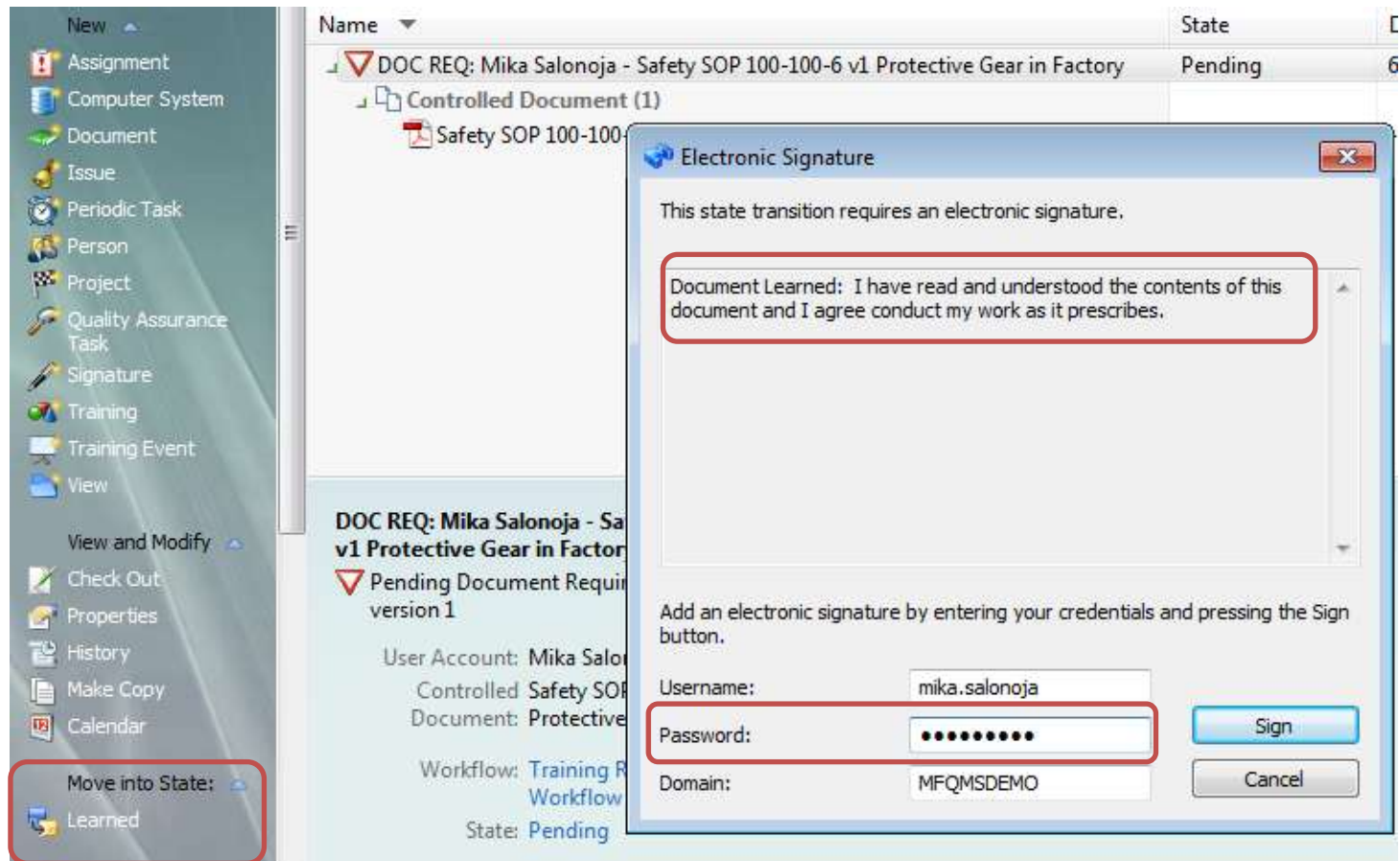
Once training requirement is satisfied, employee's To-Do list is again empty
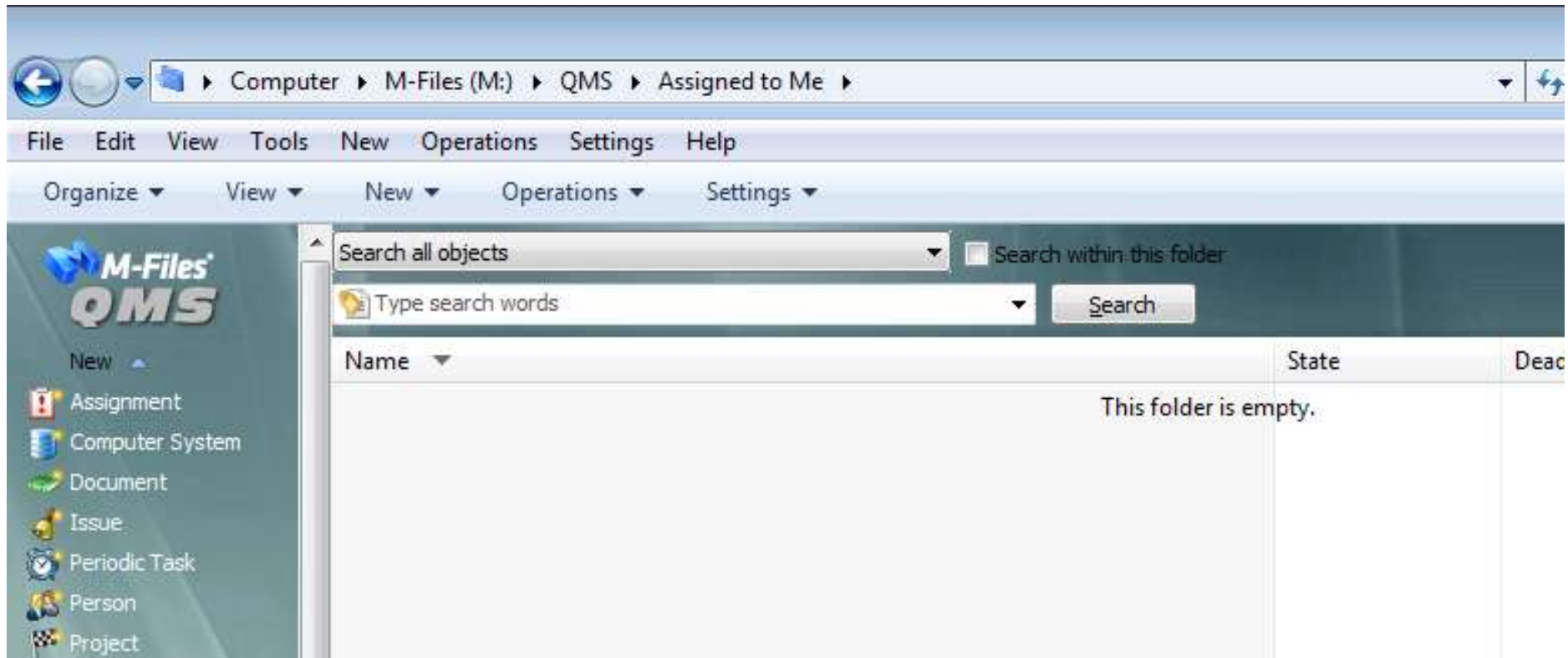
Following-up with the training results

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.
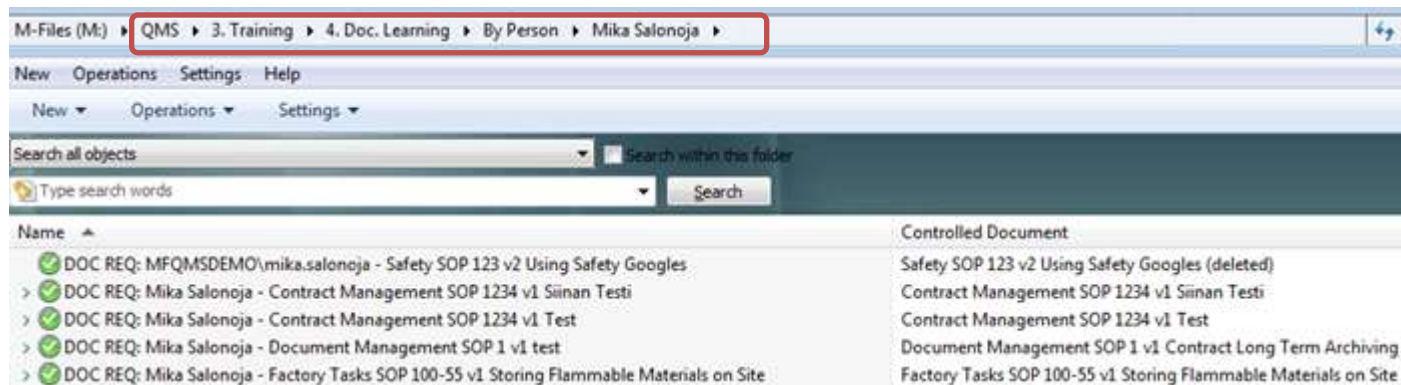
USE CASE 3: CLASSROOM TRAINING

Creating a new Training

Click New Training
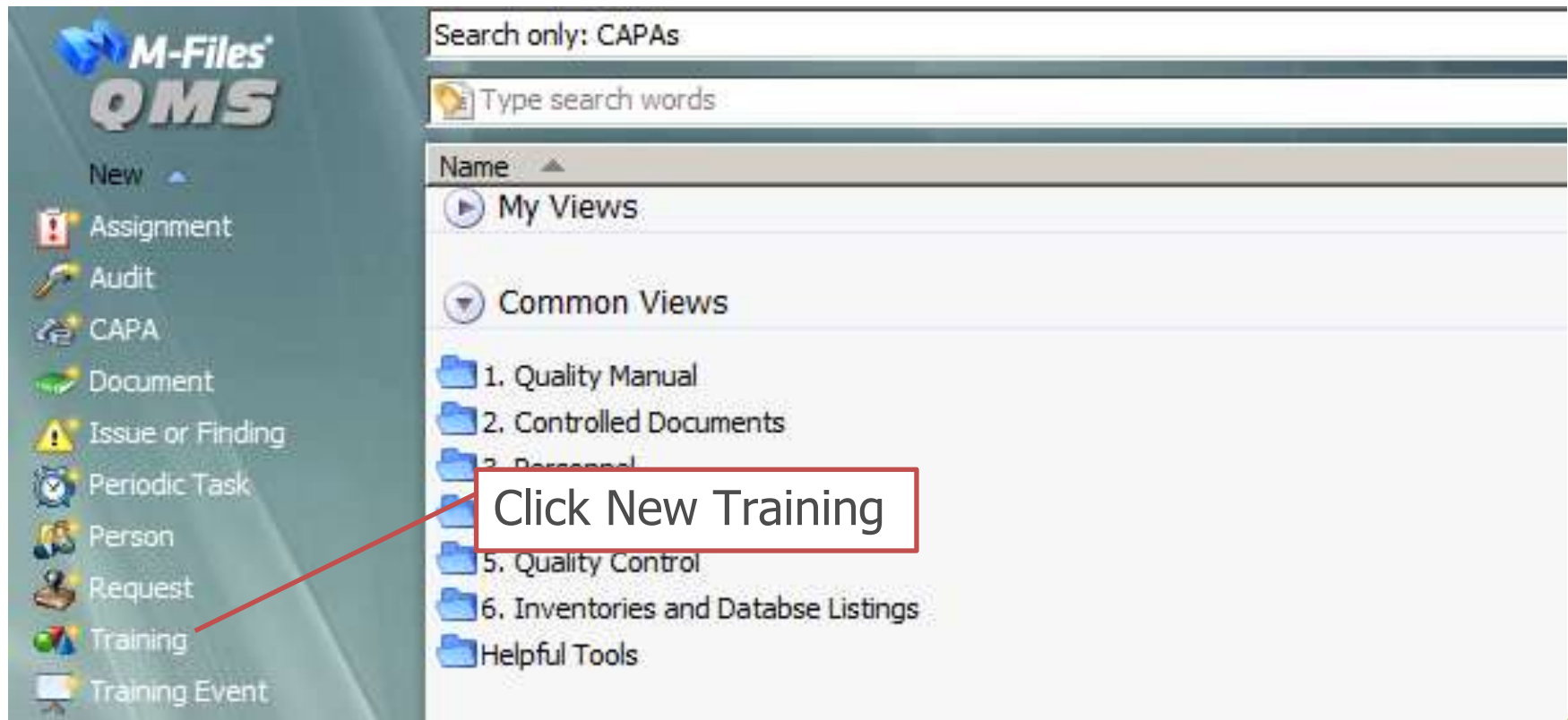
Specify the training or course
Possible to specify SOPs covered in the training

Add some training material to M-Files QMS

New training is now fully defined and visible on company course list
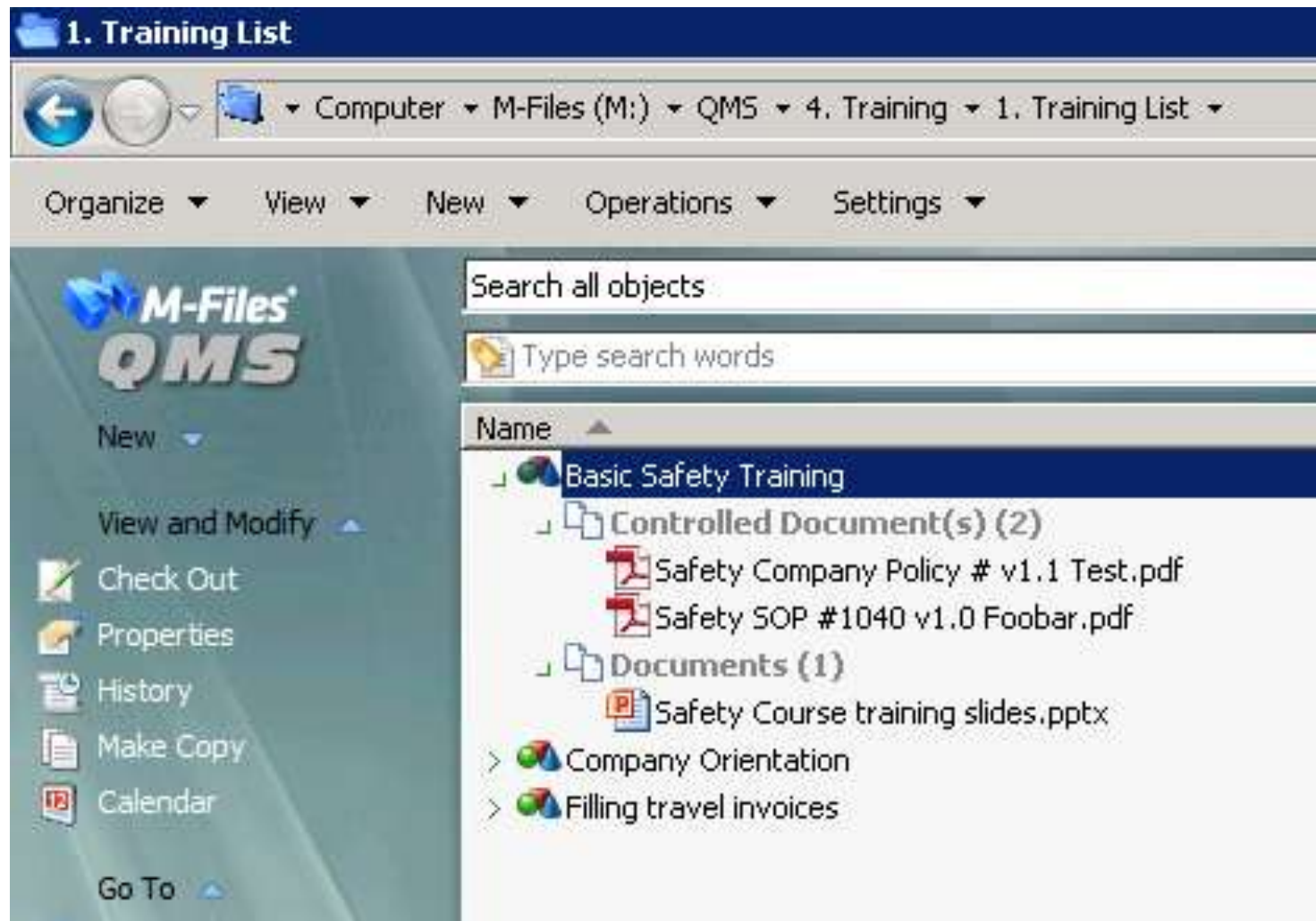
Adding new training sessions in Calendar View

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

Filling in the training event details

First training is now scheduled

Add participants after the training session

Trainer now signs off the training event with eSignature

Training certificates are automatically created

Basic Safety Training 13.2.2012 Auditorium 1
Documents (4)
Certificate: Andy Nash - Basic Safety Training 13.2.2012 Auditorium 1.pdf
Certificate: April March - Basic Safety Training 13.2.2012 Auditorium 1.pdf
Certificate: Clark Kent - Basic Safety Training 13.2.2012 Auditorium 1.pdf
Certificate: Gillian Campbell - Basic Safety Training 13.2.2012 Auditorium 1.pdf

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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.

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Adding new records manually

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

Adding new records from an exiting 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**

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Necessary documents can be attached to any database item

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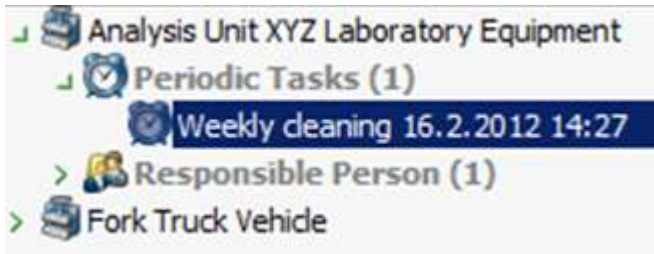
USE CASE 5A: FOLLOWING UP A QUALITY DEVIATION (SIMPLE OPTION)

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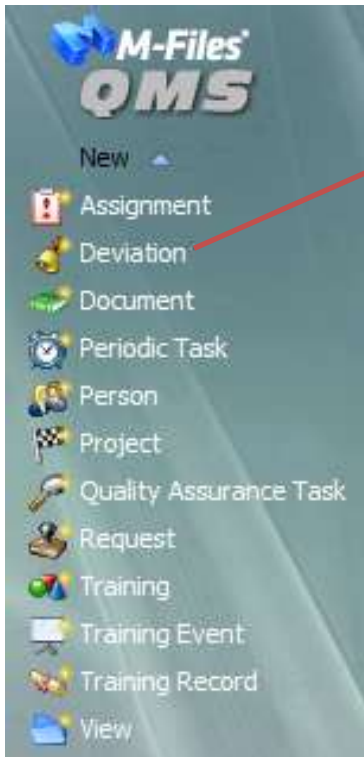
Create a new Deviation
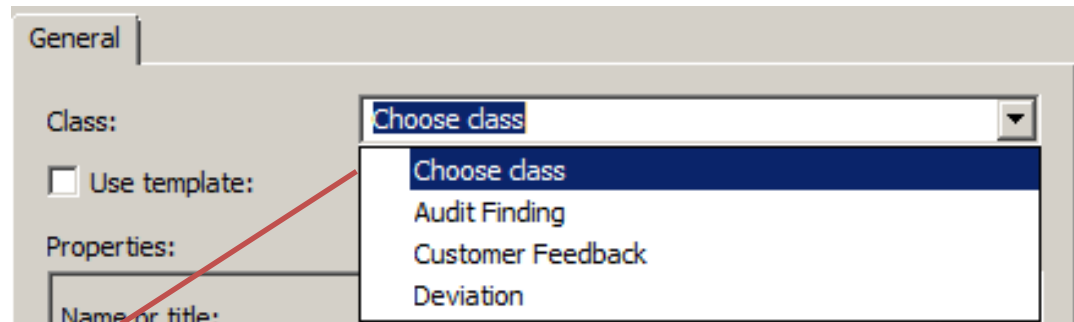
Three deviation types to choose from:
Audit finding: linked to an audit or inspection event
Customer feedback: linked to a customer and product
Deviation: an internal quality issue or non-conformity

Fill in the deviation form

Overview of ongoing deviations

Built-in calendar view
to browse deviations by and their due dates

The deviation is closed with eSignature after corrective actions

Full audit trail reveals who has done what and when

# 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

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USE CASE 6: PROCESSING CUSTOMER FEEDBACK

Option 1: feedback by Email
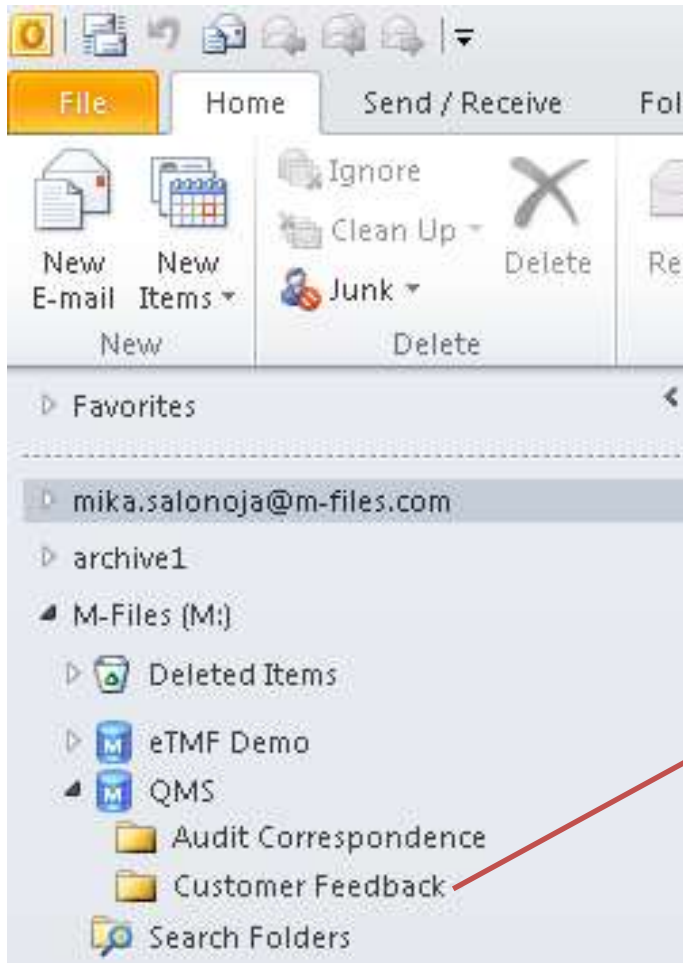
Drag the mail to Customer Feedback folder in Outlook

Fill in the metadata card in Outlook
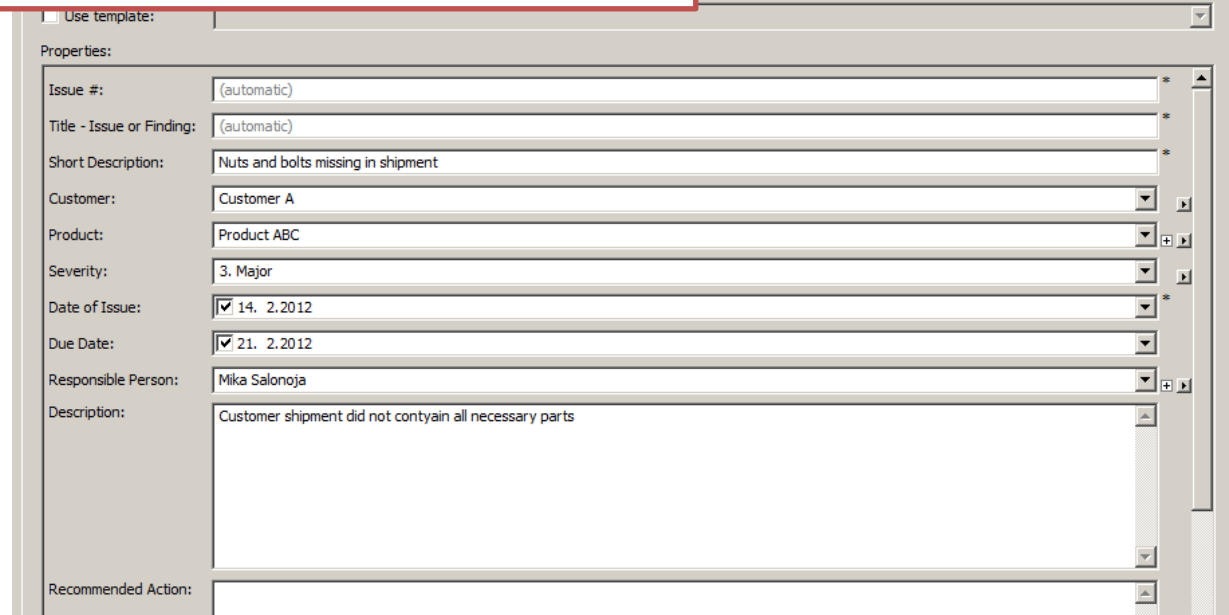

Most properties are automatically filled

Option 2: feedback by phone or in a meeting
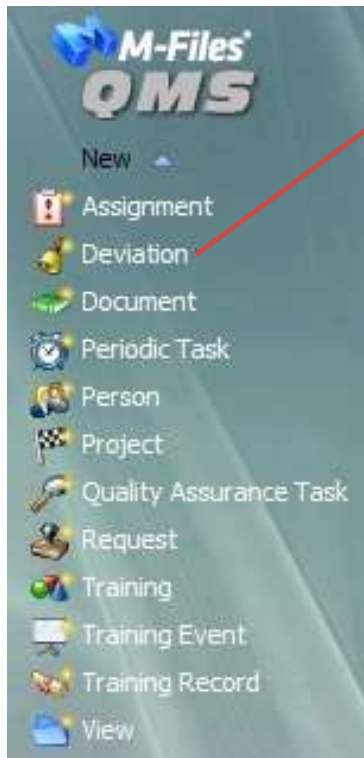
Create a new Deviation and fill in the metadata card

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

Customer feedback now awaits corrective action

- > ⚠ Customer Feedback #126 16.2.2012 Failed to meet customer specifictions — ➡ 1. Start
- > ⚠ Customer Feedback #127 9.2.2012 Wrong Colour Delivered — ❓ 2. Awaits resolution
- > ⚠ Customer Feedback #128 14.2.2012 Nuts and bolts missing in shipment — ❓ 2. Awaits resolution

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
Root

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 contyain all necessary parts

Recommended Acti…
Corrective Action (…

Workflow: Issue Processing
State: ❓ 2. Awaits resolution
Assigned to: Mika Salonoja

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

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

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

Once all tasks done, feedback case is closed

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

A new audit event is scheduled in Calendar view

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

Created: 16.2.2012 13:52, Mika Salonoja
Last modified: 16.2.2012 13:52, Mika Salonoja

Audit #: 107
Customer: Customer A
Title: Annual Inspection
Start Date: 20.2.2012
End Date: 20.2.2012
Subsidiary:
Product:
Description: Recurring annual audit
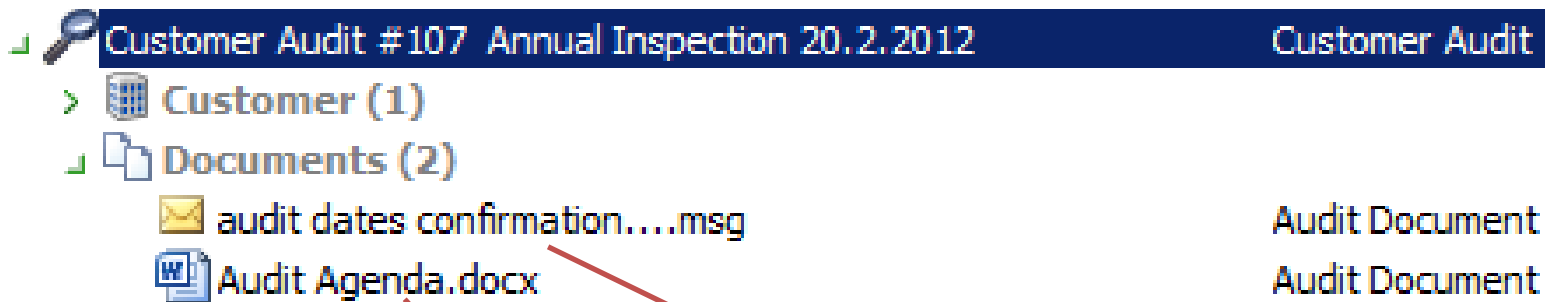Responsible Person: Mika Salonoja

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Audit Documents

Customer Audit #107 Annual Inspection 20.2.2012   Customer Audit

> Customer (1)

Documents (2)

✉ audit dates confirmation....msg   Audit Document

📄 Audit Agenda.docx   Audit Document

Emails saved via Outlook drag & drop

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

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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

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Audit Finding Workflow

Recommended Actions

State

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

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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"*

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