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Workflow for electronic approval

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Apply and review data

Audit Trail

– In the regulated field of medical engineering (*GxP*), *computer-based systems* (here: IQ Software) must comply with the following four requirements:

(1) Defined access:
Access is possible for authorized persons only, whereas the assigned role defines the permitted editing authorizations.

(2) Computer-generated change log (so-called **Audit Trail**):
Including reasons and signature: *Who* did *when* do *which* changes *where* and *why*?

(3) Archiving of all revision states including version control:
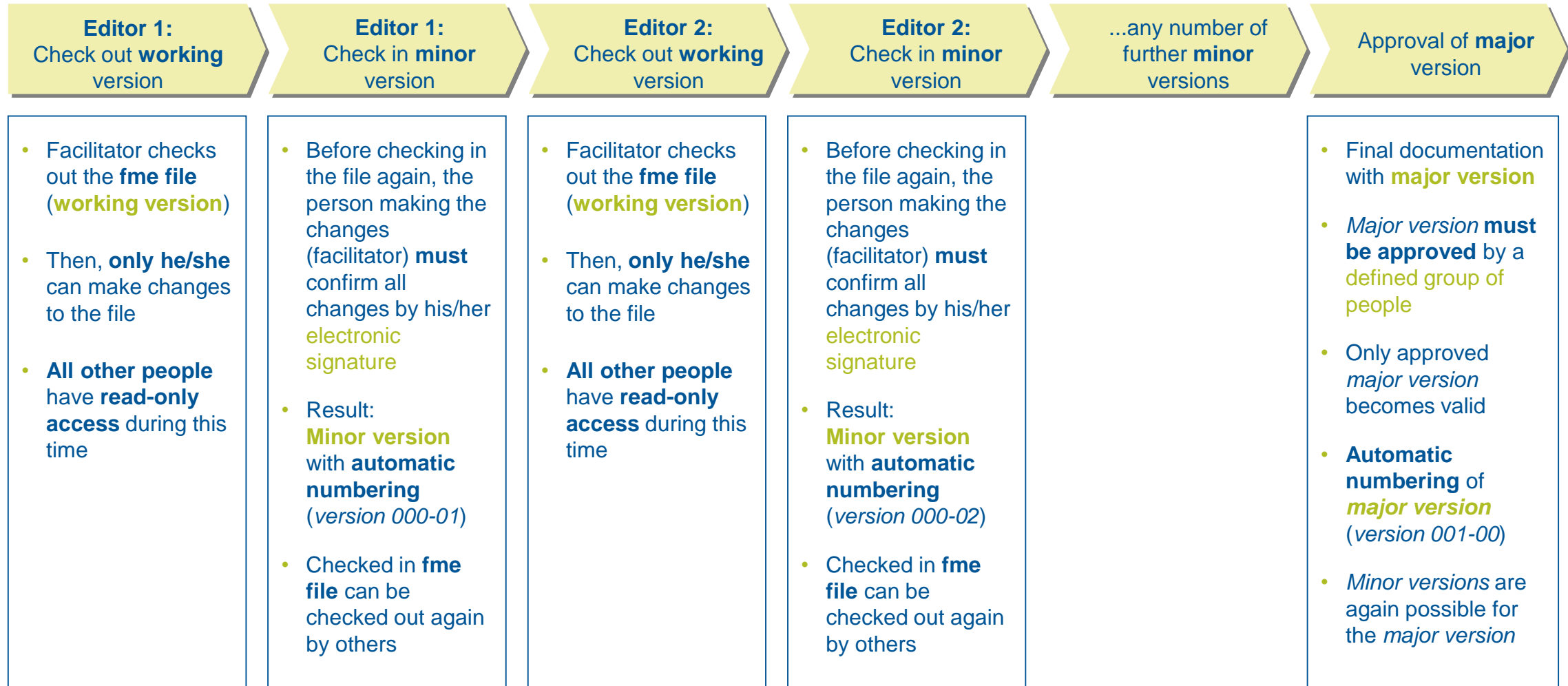Only authorized changes are possible and permitted. Only checked out working versions can be edited. Every *working version* will be converted into a documentation version in the end, which provides for **read-only access**.

(4) Electronic approval procedure for documentation versions:
With electronic signatures (*who including role, date, and time*)

Process overview

| Editor 1: Check out **working** version	Editor 1: Check in **minor** version	Editor 2: Check out **working** version	Editor 2: Check in **minor** version	...any number of further **minor** versions	Approval of **major** version
• Facilitator checks out the **fme file** (**working version**) • Then, **only he/she** can make changes to the file • **All other people** have **read-only access** during this time	• Before checking in the file again, the person making the changes (facilitator) **must** confirm all changes by his/her electronic signature • Result: **Minor version** with **automatic numbering** (*version 000-01*) • Checked in **fme file** can be checked out again by others	• Facilitator checks out the **fme file** (**working version**) • Then, **only he/she** can make changes to the file • **All other people** have **read-only access** during this time	• Before checking in the file again, the person making the changes (facilitator) **must** confirm all changes by his/her electronic signature • Result: **Minor version** with **automatic numbering** (*version 000-02*) • Checked in **fme file** can be checked out again by others		• Final documentation with **major version** • *Major version* **must be approved** by a defined group of people • Only approved *major version* becomes valid • **Automatic numbering** of *major version* (*version 001-00*) • *Minor versions* are again possible for the *major version*

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Automatic version control

–   Starting point: name of document.fme

–   Further nomenclature for file names: name of document_Vxxx-yy_zzzzz.fme

   •   **_Vxxx-yy_zzzz** is automatically added or changed by the IQ Software

   •   **V** = Version

   •   **yy** = Two digits for **minor versions**

   •   **xxx** = Three digits for **major versions**

   •   **zzzz** = Indicates the status of a **read-only file**:
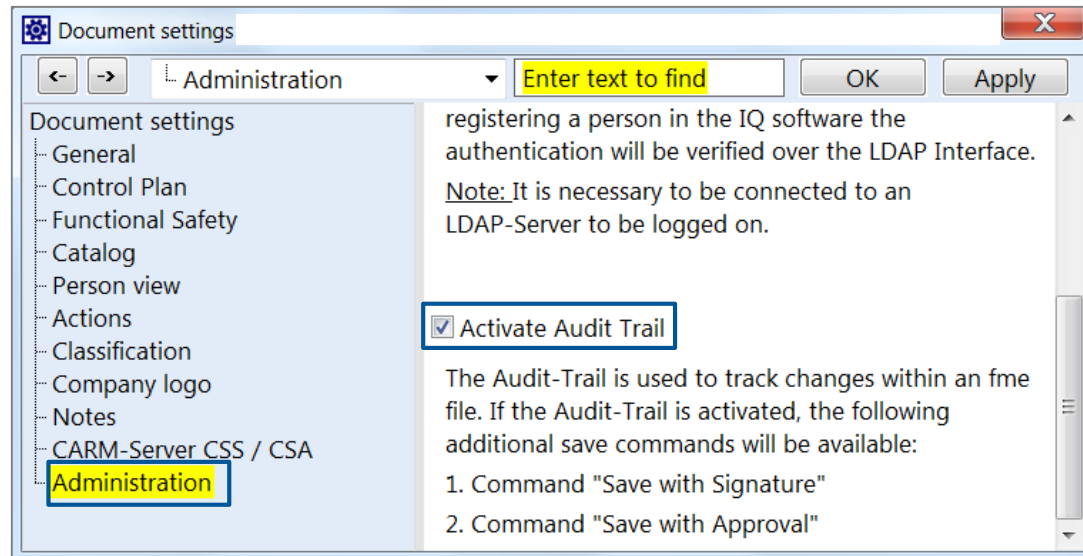   –   _signed, _in_approval, _canceled, _rejected or _approved

Step 0: Preparations in the fme file

–   Activate Audit Trail for the **fme file**: Only the **supervisor** or a person with **administrator rights** is allowed to do that.
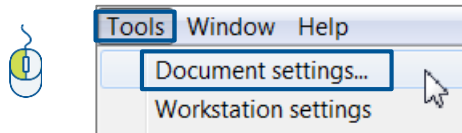
1. Open the **Document settings**.

2. In the **Document settings**, select the category **Administration** on the left and then activate the **Audit Trail** option.

Tools Window Help
Document settings...
Workstation settings

Document settings

← → | Administration ▼ | Enter text to find | OK | Apply

Document settings
- General
- Control Plan
- Functional Safety
- Catalog
- Person view
- Actions
- Classification
- Company logo
- Notes
- CARM-Server CSS / CSA
- Administration

registering a person in the IQ software the authentication will be verified over the LDAP Interface.

Note: It is necessary to be connected to an LDAP-Server to be logged on.

☑ Activate Audit Trail

The Audit-Trail is used to track changes within an fme file. If the Audit-Trail is activated, the following additional save commands will be available:

1. Command "Save with Signature"
2. Command "Save with Approval"

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Audit Trail

Step 0: Preparations in the fme file

– Teams and persons: Create authorized persons and their roles with associated rights. Only the **supervisor** and later the **IT staff** are allowed to do that.

Team	Name	First name	Job title	User name	Create persons	Password	Admini-strator	QA
	Supervisor				☑	*****	☑	☐
Role 1: IT	Peach	Marcel	IT staff	Pea1	☑	*****	☑	☐
Role 2: Moderator	Bonewski	Hans	FMEA moderator	Bon1	☐	*****	☐	☐
	Hehre	Claudia	FMEA moderator	Heh1	☐	*****	☐	☐
Role 3: Review and approval	Kasper	Detlef	Head of Engi-neering	Kas3	☐	*****	☐	☐
	Schranz	Franz	Manager	Sch7	☐	*****	☐	☐
Role 4: Final approval	Mayer	Thomas	QA staff	May5	☐	*****	☐	☑
	Seetzen	Gudrun	QA staff	See1	☐	*****	☐	☑
Role 5: Team member	Meier	Max	Engineering staff	Mei8	☐		☐	☐
	Müller	Detlef	Production staff	Mül9	☐		☐	☐
	Zickler	Thomas	Production staff	Zic4	☐		☐	☐

2. In concluding, you should *write* the *catalog of persons* into the *template* (menu **Tools | Write template**) so that it is available in all **new fme files**.

Note:
For the **administration of persons** with *user name* and *password*, the connection to an **LDAP server** can be carried out.

1. In **Teams and persons**, you configure *roles* in the form of *teams* and assign persons to them. Activating the **Audit Trail** provides you with two additional columns, **Administrator** and **QA** (Quality Assurance). **At least one person** must be classified into **QA** for the later approval procedure.

Audit Trail

Step 0: Preparations in the fme file

– Teams and persons: Create authorized persons and their roles with associated rights. Only the **supervisor** and later the **IT staff** are allowed to do that.

| Role	Rights
IT	User administration
Facilitator	Implement the changes
Review and approval	Approval of changes by department
Final approval	Approval of changes by QA
Team member	Participants in sessions / experts

Important:
All persons from *IT* and *facilitator* as well as the **two approval** roles must be assigned with a **password** to prevent **unauthorized** persons from granting approval.

Step 1: Log-in to an fme file

– To generate a **reliable change log**, it is very important that every **editor logs in as himself/herself**.

– If your *Windows user name* is the **user name** registered in Teams and persons, you will be logged in automatically when you open the fme file. As an alternative, you can also log in via an **LDAP server**.
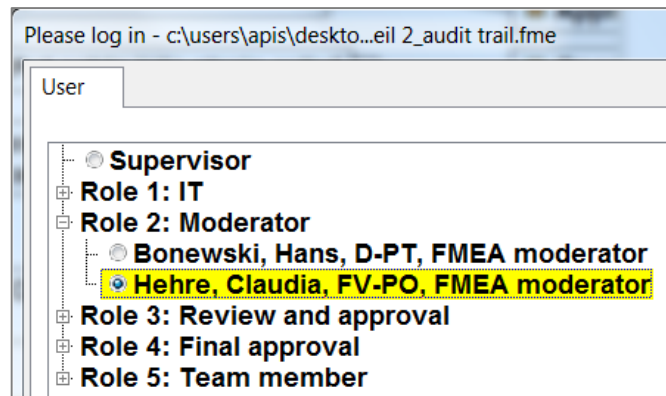
Step 2: Check out file *for individual person*

– When the fme file is saved **for the first time**, the currently logged in user (facilitator) **checks** the file **out** as a **working version**. Only he/she can edit the file from now on. All other persons have read-only access.
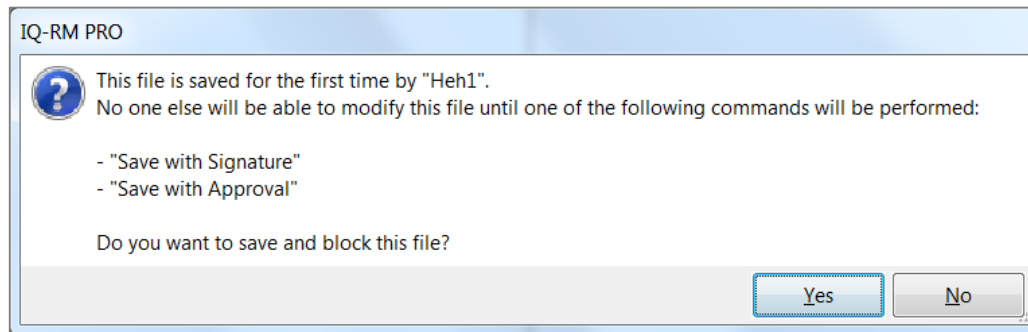
In the example, the logged in facilitator **Hehre, Claudia** checks the *fme file* out for editing.

– The following entry is created in the Audit Trail log:
Document blocked – work in progress plus various other details like editor, date, and time

Audit Trail

Step 3: Save changes as *minor version*

- After the facilitator has implemented the required changes, he/she has to save them as a **minor version** with his/her signature.
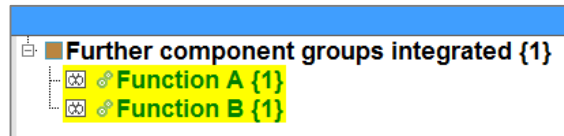
Examples of changes
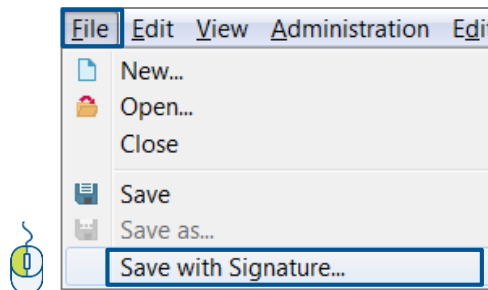
1. The implemented changes are at first saved as a **minor version** by means of the corresponding command from the **File** menu.

Step 3: Document reason for change

IQ-RM PRO: Save with Signature

File name

D:\part 2_audit trail_V000-01_signed.fme

Comment

In this version, a new component group with various functions was integrated.

View Audit Trail

OK   Cancel   Help

part 2_audit trail_V001-01_signed.fme

part 2_audit trail_V001-02.fme
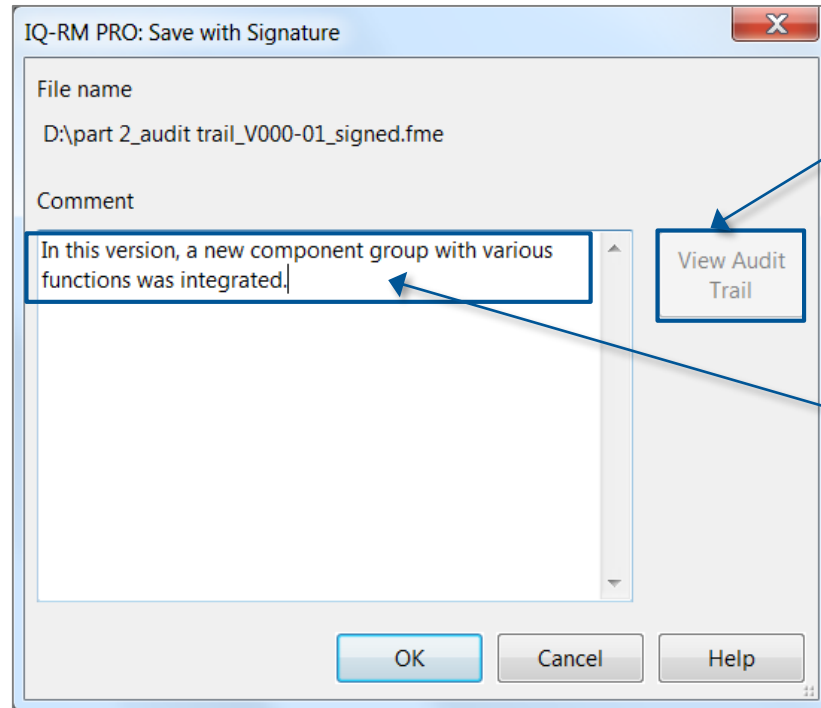
4. **Audit Trail** shows the comparison of changes only as of the **second signed minor version**. Click this button to view this comparison.

2. The facilitator should describe the changes briefly by means of a comment for the **Audit Trail log**.
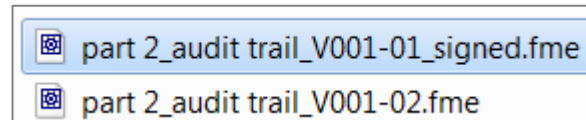
3. As a result, the **first minor version** is saved as signed in *read-only mode* and a new **minor version 2** is created automatically. This second minor version can be opened by another facilitator, who can check it out as a **working version** by **saving** it personally.

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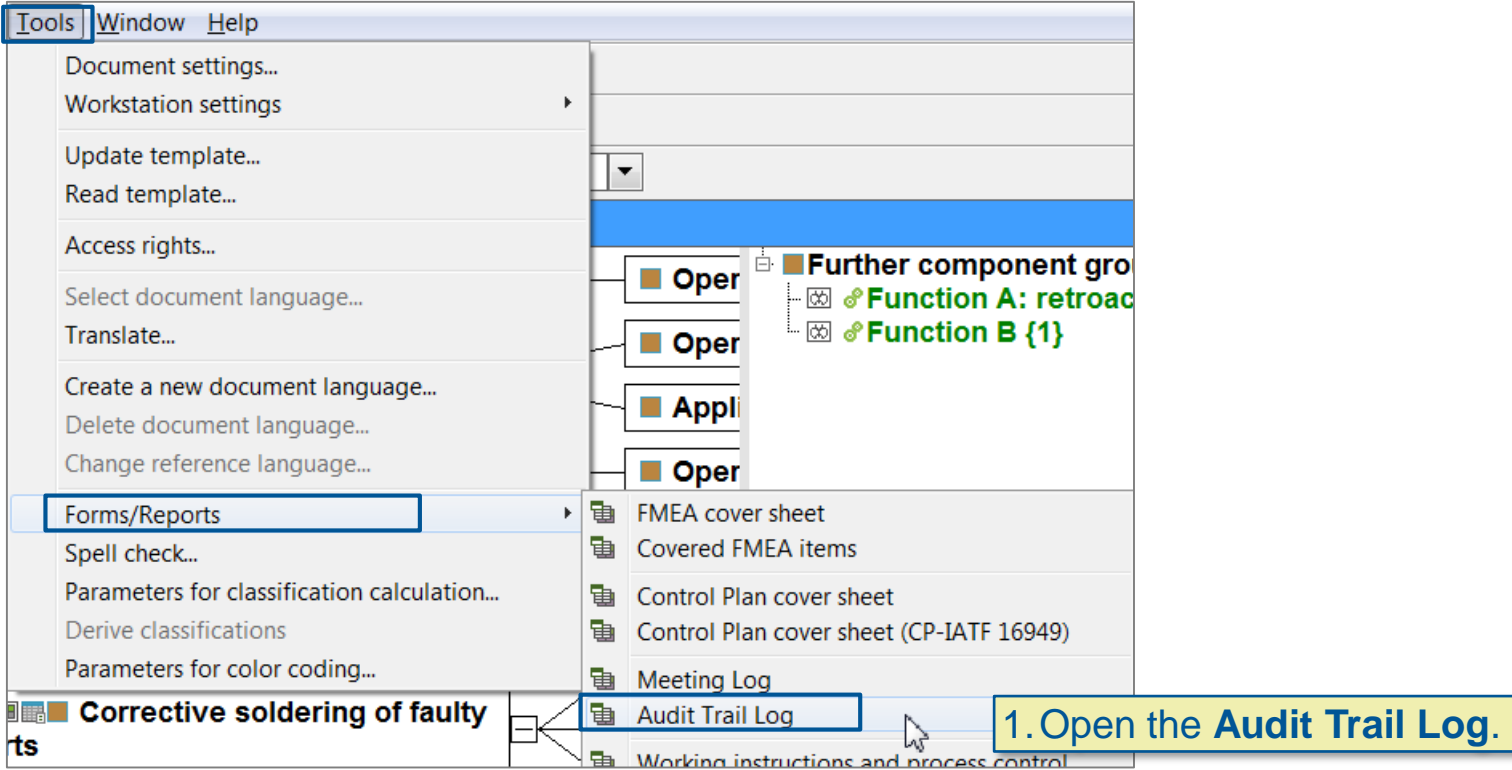Informationstechnologien GmbH

Step 3: View comparison of changes

– When you have signed the **second minor version**, you can view a comparison of the **change logs** of the *status when signing* and the *status when checking out* this minor version in the **Audit Trail**.

– Comparison of changes in XPS viewer:

Minor version

Step 3: View history of changes

– You can see the **entire history of changes** in the Audit Trail Log.

1. Open the **Audit Trail Log**.

Minor version

Step 3: View history of changes

– You can see the **entire history of changes** in the Audit Trail Log.

| Audit Trail Log:					
Title/Document name	Action	Note	User ID	Date	Time

Use this hotclick icon to view the corresponding version comparison in the XPS viewer.

Title/Document name	Action	Note	User ID	Date	Time
part 2_audit trail_V000-03.fme	Created		Bon1	25-Jun-2019	11:35:50
part 2_audit trail_V000-02_signed.fme	Created	Function A was modified.	Bon1	25-Jun-2019	11:35:50
part 2_audit trail_V000-02.fme	Version comparison		Bon1	25-Jun-2019	11:35:50
part 2_audit trail_V000-02.fme	Document blocked - work in progress		Bon1	25-Jun-2019	11:32:02
part 2_audit trail_V000-02.fme	Created		Heh1	25-Jun-2019	11:30:19
part 2_audit trail_V000-01_signed.fme	Created	In this version, a new component group with various functions was integrated.	Heh1	25-Jun-2019	11:30:19
part 2_audit trail.fme	Document blocked - work in progress		Heh1	25-Jun-2019	11:29:07

2. The **Audit Trail Log** shows the **entire history of changes** across all *minor versions* and *major versions*.

Audit Trail

Step 4: Save changes as *major version*

– After the facilitators have implemented all changes via the various minor versions, the changes are finally documented by saving the major version.

– A major version must be approved by a defined group of people by their signature.
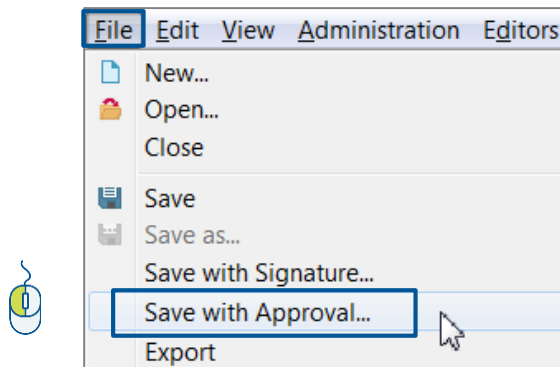
1. In concluding, the implemented changes are passed onto the approval process as a **major version** by the facilitator using the corresponding command from the **File** menu.

Step 4: Complete the approval coversheet

- At first, fill in the *upper section* (header data) of the coversheet.

2. All five header data fields are mandatory fields to be completed by the **author** (facilitator).

The currently logged in user is automatically entered as the **author**.

Step 4: Complete the approval coversheet

– Then, define the persons required for the approval of the major version in the *bottom section*.

Review and approval			
Schranz, Franz, D-PT, Manager Sch7 Manager		Approve	Reject
Kasper, Detlef, RD-S, Head of Engineering Kas3 Head of Engineering		Approve	Reject
n/a			

3. Mandatory field: Choose at least **one** and maximally **three** persons from the **Review and approval** role.

Final approval			
Mayer , Thomas, QA staff May5 QA staff		Approve	Reject

4. Mandatory field: Choose **one** person from *quality assurance (QA)* from the **Final approval** role.

Step 5: Initiate approval process

– After having completed the mandatory fields, the author initiates the approval process.

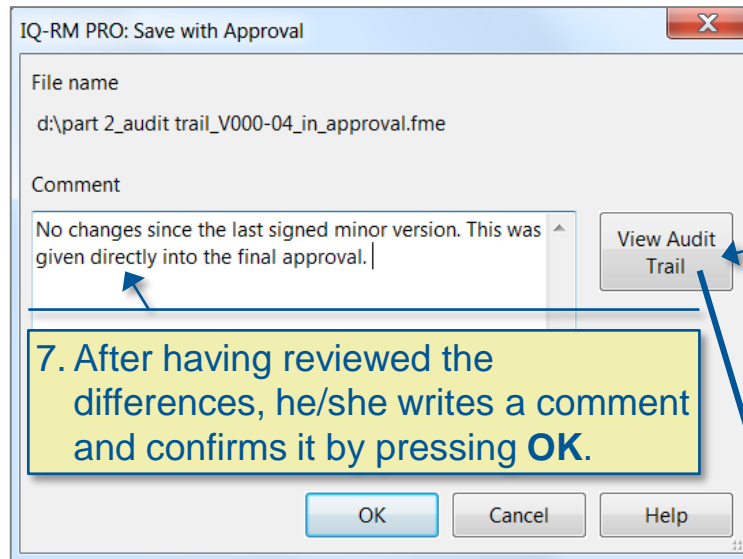| Author		
Hehre, Claudia, FV-PO, FMEA moderator Heh1 FMEA moderator	Initiate approval	
Review and approval		
Schranz, Franz, D-PT, Manager Sch7 Manager	Approve	Reject
Kasper, Detlef, RD-S, Head of Engineering Kas3 Head of Engineering	Approve	Reject
n/a		
Final approval		
Mayer , Thomas, QA staff May5 QA staff	Approve	Reject

5. The **author** clicks to **initiate the approval process**. The process can be initiated only with all mandatory fields filled in.

Major version

Step 5: Approval by the author

– At first, the comparison with the last signed minor version is done.

IQ-RM PRO: Save with Approval

File name

d:\part 2_audit trail_V000-04_in_approval.fme

Comment

No changes since the last signed minor version. This was given directly into the final approval.

View Audit Trail

6. The approval window opens. The **author** clicks the right button to open at first the **version comparison** (see figure below) to the last signed **minor version**.

7. After having reviewed the differences, he/she writes a comment and confirms it by pressing **OK**.

OK   Cancel   Help

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Full list of differences

Older Document: File name: d:\part 2_audit trail_V000-03_signed.fme
Creation date: 28.10.2000 14:58:32.
Modification date: 25.06.2019 11:40:07.
Newer Document (most recently changed): File name: D:\part 2_audit trail_V000-04.fme
Creation date: 28.10.2000 14:58:32.
Modification date: 25.06.2019 12:15:25.

No differences found!

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Step 5: Approval by the author

– Then, the comparison with the last signed major version is done.

8. Then, the **version comparison** to the last signed **major version** opens automatically. To review the differences, the **author** clicks again the right button. This opens the **version comparison** (see figure below).

9. After having reviewed the differences, he/she writes a comment and confirms it by pressing **OK**.

Major version

Step 5: Approval by the author

– The approval by the **author** is documented by his/her electronic signature.

Author	
Hehre, Claudia, FV-PO, FMEA moderator Heh1 FMEA moderator	Approval initiated: Signed by Heh1 on 25.06. 2019 13:38:10 This signature is valid electronically.
	Cancel approval

Electronic signature of the **author**

If required, the **author** may cancel the approval process by clicking **Cancel approval**.
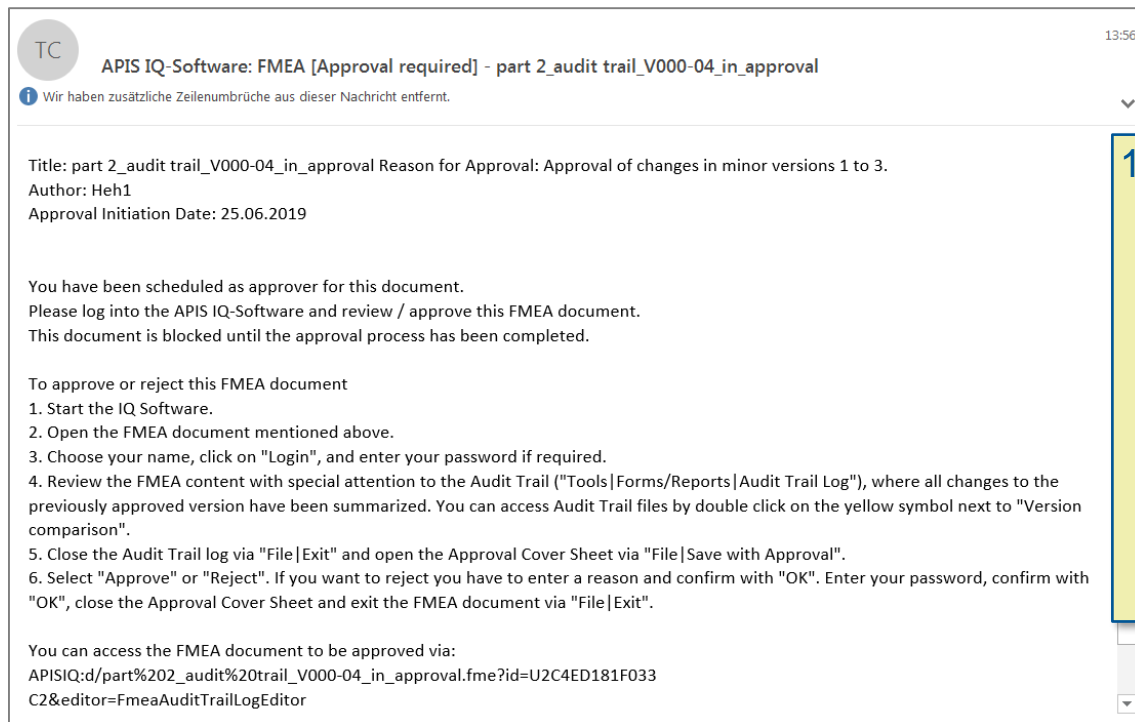
The approval by the **author** including his/her comments is recorded in the **Audit Trail Log**.

Title/Document name	Action	Note	User ID	Date	Time
part 2_audit trail_V000-04_in_approval. fme	Approved		Heh1	25-Jun-2019	13:43:25
part 2_audit trail_V000-04_in_approval. fme	Created		Heh1	25-Jun-2019	13:43:25
part 2_audit trail_V000-04.fme	▤ Version comparison (to previous approved version)	All changes are plausible and will therefore be accepted.	Heh1	25-Jun-2019	13:43:25
part 2_audit trail_V000-04.fme	▤ Version comparison	No changes since last minor version. This was given directly into the final approval.	Heh1	25-Jun-2019	13:39:10
part 2_audit trail_V000-04.fme	Created		Heh1	25-Jun-2019	13:35:31

Major version

Step 6: Further approvals

– Every person named as approver receives the following e-mail.

TC
APIS IQ-Software: FMEA [Approval required] - part 2_audit trail_V000-04_in_approval   13:56

ℹ Wir haben zusätzliche Zeilenumbrüche aus dieser Nachricht entfernt.

Title: part 2_audit trail_V000-04_in_approval Reason for Approval: Approval of changes in minor versions 1 to 3.
Author: Heh1
Approval Initiation Date: 25.06.2019

You have been scheduled as approver for this document.
Please log into the APIS IQ-Software and review / approve this FMEA document.
This document is blocked until the approval process has been completed.

To approve or reject this FMEA document
1. Start the IQ Software.
2. Open the FMEA document mentioned above.
3. Choose your name, click on "Login", and enter your password if required.
4. Review the FMEA content with special attention to the Audit Trail ("Tools|Forms/Reports|Audit Trail Log"), where all changes to the previously approved version have been summarized. You can access Audit Trail files by double click on the yellow symbol next to "Version comparison".
5. Close the Audit Trail log via "File|Exit" and open the Approval Cover Sheet via "File|Save with Approval".
6. Select "Approve" or "Reject". If you want to reject you have to enter a reason and confirm with "OK". Enter your password, confirm with "OK", close the Approval Cover Sheet and exit the FMEA document via "File|Exit".

You can access the FMEA document to be approved via:
APISIQ:d/part%202_audit%20trail_V000-04_in_approval.fme?id=U2C4ED181F033
C2&editor=FmeaAuditTrailLogEditor

10. The approval by the author **automatically** triggers an **e-mailing**. All named approvers receive an e-mail requesting them to grant approval and including instructions how to grant approval as well as a link to the respective fme file.

Note:
The e-mail addresses must be stored with the persons concerned in the **Data Manager** under **Teams and persons** to be able to carry out the mailing.

Major version

Step 6: Further approvals

– The approver can view the comparisons of differences in the **Audit Trail Log**.

11. Open the respective **fme file** and log in personally with your password.

12. Open the **Audit Trail Log** via **Tools | Forms/Reports**.

Audit Trail Log:					
Title/Document name	Action	Note	User ID	Date	Time
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13. Use the **hotclick icon** for the version comparison to open both comparisons and to view the differences in detail.

Title/Document name	Action	Note	User ID	Date	Time
part 2_audit trail_V000-04_in_approval. fme	Approved		Heh1	25-Jun-2019	13:43:25
part 2_audit trail_V000-04_in_approval. fme	Created		Heh1	25-Jun-2019	13:43:25
part 2_audit trail_V000-04.fme	Version comparison (to previous approved version)	All changes are plausible and will therefore be accepted.	Heh1	25-Jun-2019	13:43:25
part 2_audit trail_V000-04.fme	Version comparison	No changes since last minor version. This was given directly into the final approval.	Heh1	25-Jun-2019	13:39:10

Major version

Step 6: Further approvals

– The approval or rejection is done on the approval coversheet. In case of rejection, the reasons must be recorded.

14. Open the **approval coversheet** by closing the **Audit Trail Log** and choosing the command **Save with approval** from the **File** menu.

Review and approval		
Schranz, Franz, D-PT, Manager Sch7 Manager	Approve	Reject

15. On the coversheet, click either **Approve** or **Reject** in the row bearing your name.

Review and approval	
Schranz, Franz, D-PT, Manager Sch7 Manager	Approved: Signed by Sch7 on 25.06.2019 14:07:29 This signature is valid electronically.
Kasper, Detlef, RD-S, Head of Engineering Kas3 Head of Engineering	Approved: Signed by Kas3 on 25.06.2019 14:20:50 This signature is valid electronically.

16. The approvals are documented with electronic signature and the rejections, if applicable, with reasons.

Step 6: Further approvals

– Finalize the approval process:

17. The last person to grant approval will be shown a message informing about the successful approval of the **major version**. Thereupon, all approvers will receive an automatic e-mail informing them about the new **major version**.

Major version

Step 7: Possible new minor versions

– The new major version (V001-00_approved) again is the basis of new minor versions (V001-01 to –XX), until another major version (V002-00_approved) is finally approved.

– The first minor version is automatically created when the approved major version is saved.

Approved **major version** saved with **read-only** access

part 2_audit trail_V001-00_approved.fme	25.06.2019 14:26
part 2_audit trail_V001-01.fme	25.06.2019 14:26

Minor version 1, *which can be checked out*, of the new **major version**
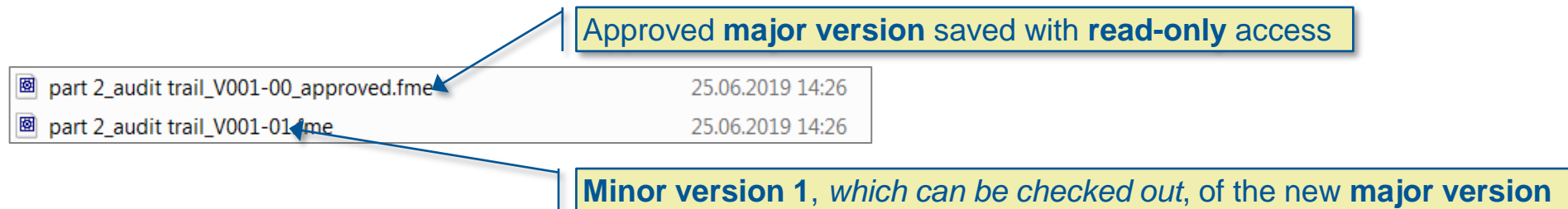
Major version

History in Audit Trail Log

– The Audit Trail Log comprises the complete history:

Extract from Audit Trail Log:
History of entire approval process for **major version 1**

Title/Document name	Action	Note	User ID	Date	Time
part 2_audit trail_V001-01.fme	Created	Minor version 1, *which can be checked out*, of the new **major version**	May5	25-Jun-2019	14:26:34
part 2_audit trail_V001-00_approved. fme	Created	Approved major version (read-only access)	May5	25-Jun-2019	14:26:25
part 2_audit trail_V000-04_in_approval. fme	Approved	Approval by QA	May5	25-Jun-2019	14:26:24
part 2_audit trail_V000-04_in_approval. fme	Approved	Approvals by both reviewers	Kas3	25-Jun-2019	14:20:50
part 2_audit trail_V000-04_in_approval. fme	Approved		Sch7	25-Jun-2019	14:07:29
part 2_audit trail_V000-04_in_approval. fme	Approved	Approval by the author (facilitator)	Heh1	25-Jun-2019	13:43:25
part 2_audit trail_V000-04_in_approval. fme	Created		Heh1	25-Jun-2019	13:43:25
part 2_audit trail_V000-04.fme	Version comparison (to previous approved version)	All changes are plausible and will therefore be accepted.	Heh1	25-Jun-2019	13:43:25
part 2_audit trail_V000-04.fme	Version comparison	No changes since last minor version. This was given directly into the final approval.	Heh1	25-Jun-2019	13:39:10

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Automatic e-mail notification

– All the named approvers will be automatically sent an e-mail, when the approval process is:

  • Started by the author (file extension_in approval)

  • Canceled by the author (file extension_canceled)

  • Rejected by one of the approvers (file extension_rejected)

  • And if the approval process was successful (file extension_approved)

– **Unapproved** major versions must be improved by means of new minor versions and then again run through the approval process as major versions.