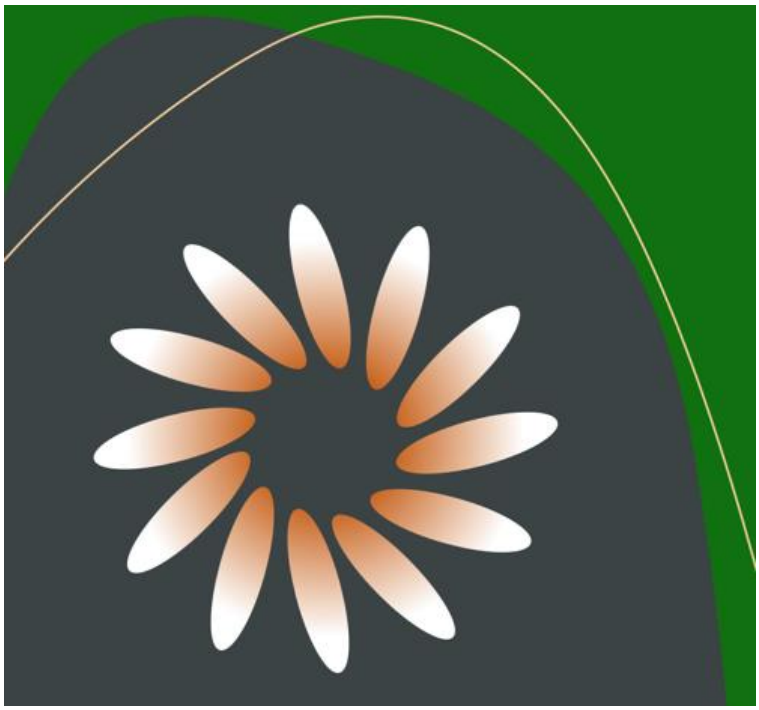
HALOPV

PROHALO

PSMF Module



HALOPV
USER GUIDE

This is an end-user guide for the **PSMF Module** of the drug safety solution **HALOPV**.

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1. HALOPV PSMF Module User Manual

User Manual - Release 4.X (4.2 released March 2023)

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2. Preface

The information in this user manual is based on the standard package of the PSMF Management Module and functionalities, which are subject to change. The latest product information, including release notes for HALOPV and multi-tenant HALOPV, is available at:

https://insife.com/halopv

2.1 Insife Support

The Insife Support team can be reached at support@insife.com 24/7, depending on the agreed terms. Furthermore, the Insife Support team handles upgrades related to modules requiring MedDRA codes, EDQM codes, WHO Drug dictionary, etc.

3. Introduction

3.1 Purpose of this document

This User Manual describes the PSMF Module features of HALOPV. It is intended as a module guide, which should be considered one of the general manuals. You will find a manual for each Module separately at https://insife.com/halopv-user-guides-tutorials.

The overall guide for using general features is available online on General features (insife.com)

3.2 Modules of HALOPV

At the time of writing this manual, HALOPV modules comprise:

- Aggregate Reporting
- Agreements
- Clinical Trials
- Complaints

- Data Collection Programs
- Device Incidents Processing
- Entities
- ICSRs (Medicine and Vaccine Incidents)
- Literature Monitoring
- Labelling
- Medical Information and Communications
- Pharmacovigilance System Master File (PSMF)
- Products
- Quality
- Requirements Intelligence
- Risks
- Signals
- Submissions

Besides the modules, you will also find a separate manual for application administration and user administration in Admin Guide (insife.com).

3.3 About HALOPV

HALOPV is a cloud-based system. Internet connectivity is required. You can use your computer, tablet, or smartphone to access the system. Your organization should have provided you with the correct link to access your instance of HALOPV.

4. Navigating the PSMF Module

Once you log into HALOPV with your user credentials, on the left Menu, you will find the list of Modules to which your user has access. To review HALOPV access and general features, please refer to our **General Features User Manual** and **User Guide Introduction and Main Features**.

The **PSMF Module** will show if your user has the role to access the Module.

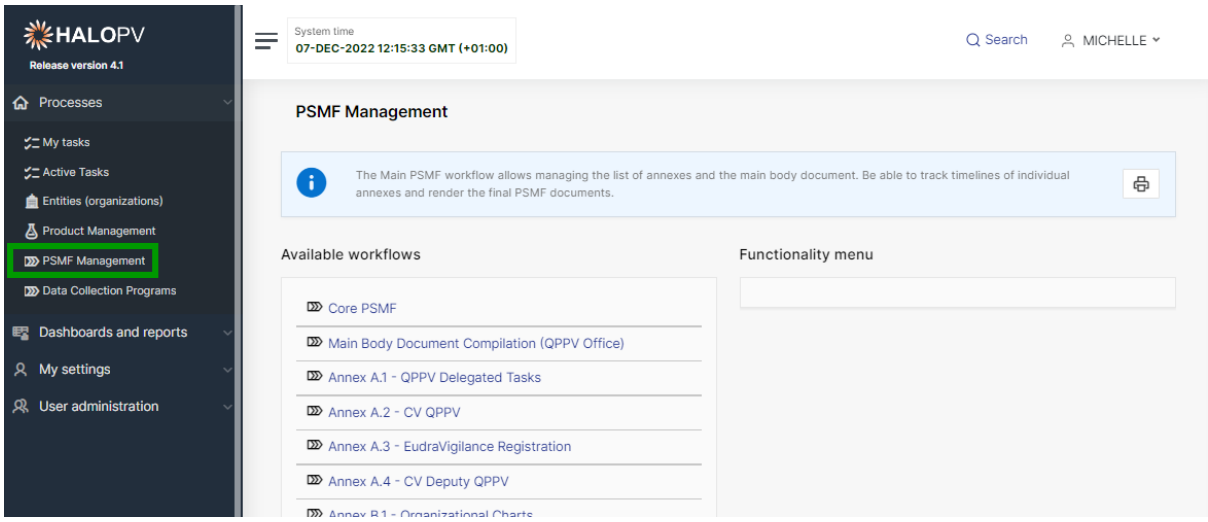

Figure 1 In the left menu, the PSMF Module is available for users with the appropriate access role

4.1 Module Main Screen

The Main Screen displays the list of workflows available in the Module PSMF – including the Functionality Menu.

It is important to note that the workflows may be configured to local requirements in your HALOPV setup. Hence the workflows may look different from the standards, and some workflows and menus might not be available to the user view.

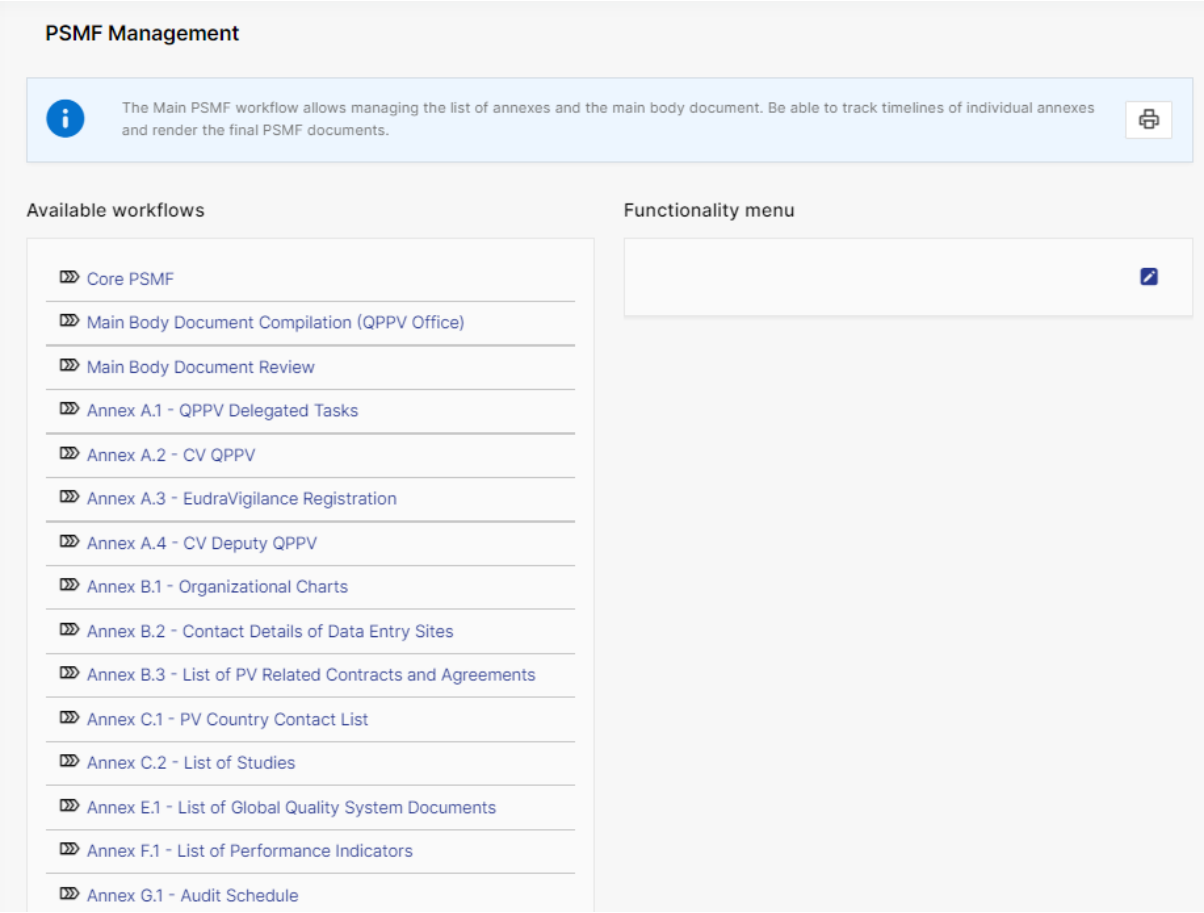

Figure 2 The standard list of Workflows and Functionality Menu items for the PSMF Module

4.2 Standard Workflows

Users can access the record worklist by clicking on one of the available workflows. **E.g., Main body document review, Annex A.1**. The view will display the record(s) created in the process workflow.

The Records worklist may have different columns, depending on the selected workflow. However, the principle is the same for all workflows. The standard list displays the ***Record ID, Title of the record, the Type, Current task, Overall Due date*** *(the date the task is due to comply with set timelines),* etc.

It is important to note that the workflows may be configured to local requirements in your HALOPV setup. Hence the workflows may look different from the standard.

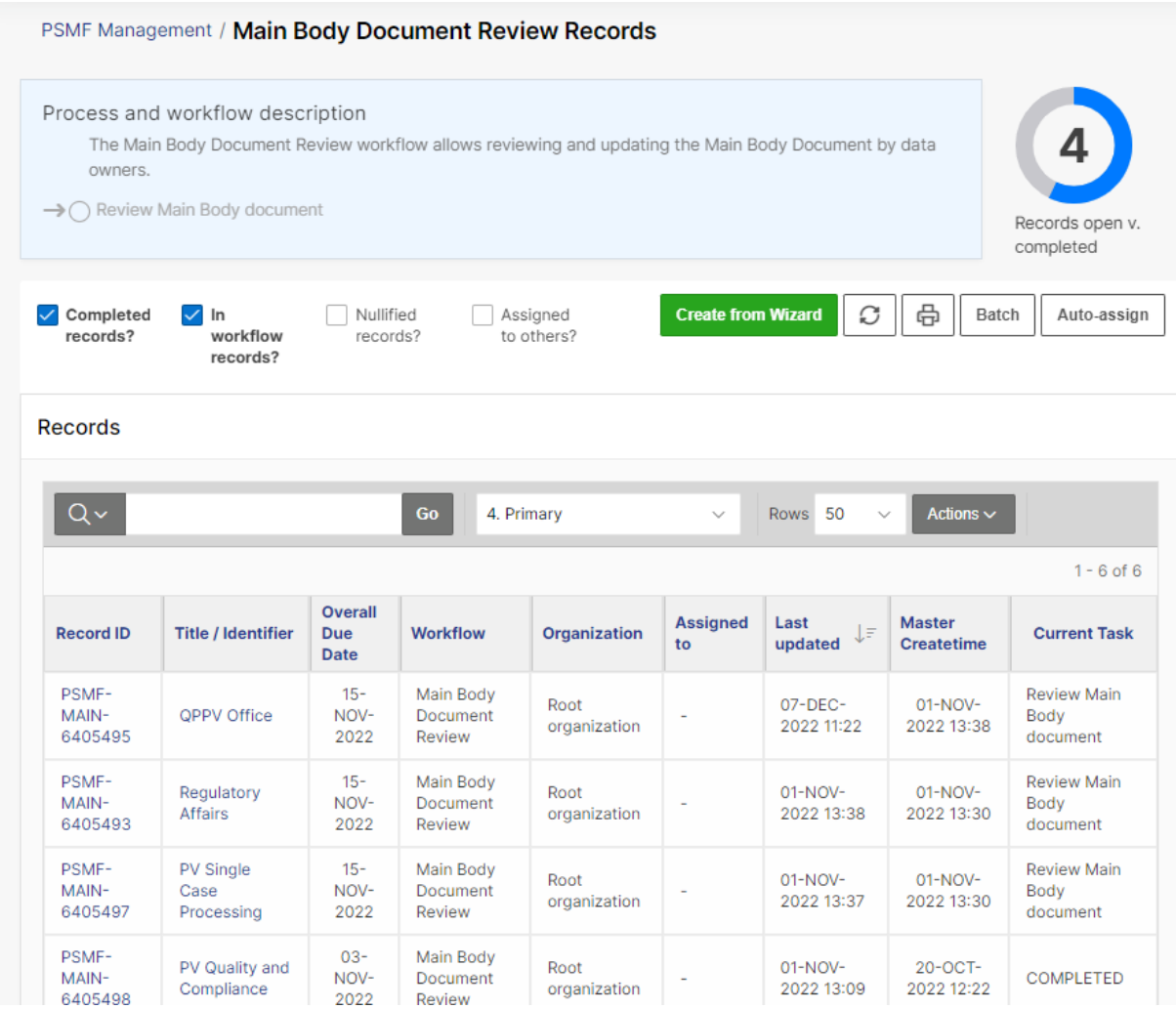

Figure 3 When clicking on a workflow, the following screen displays the Process workflow description, current tasks (if configured,) and a worklist of records, where the Record ID or Title/Identifier can be clicked to access the individual record.

The columns' names may vary depending on your system configuration. Annexes may contain only one record, e.g., Annex A.

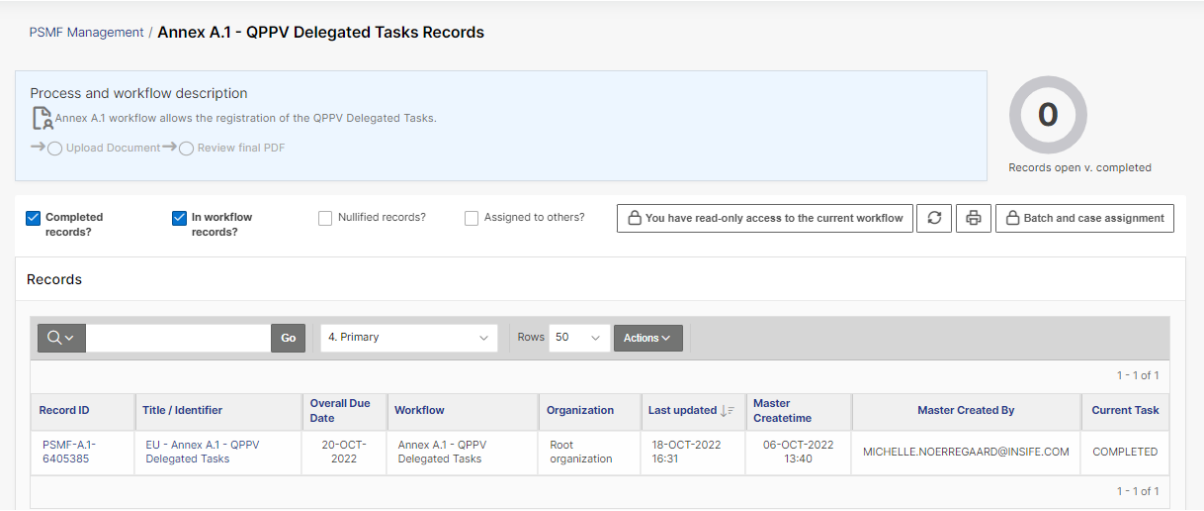

Figure 4 The screen displays the Process workflow description and a worklist of records. In this case, only one record is listed for Annex A.1 List of Delegated tasks.

End users can update reports using the **Actions** button**.** Please consult the User Guide on Interactive Reports.

Please note that access to Records is restricted to the user role assigned to you, e.g., 'You have read-only access to the current workflow' means that the user cannot create or nullify a record but can execute the task(s) assigned within the record if the role has been assigned.

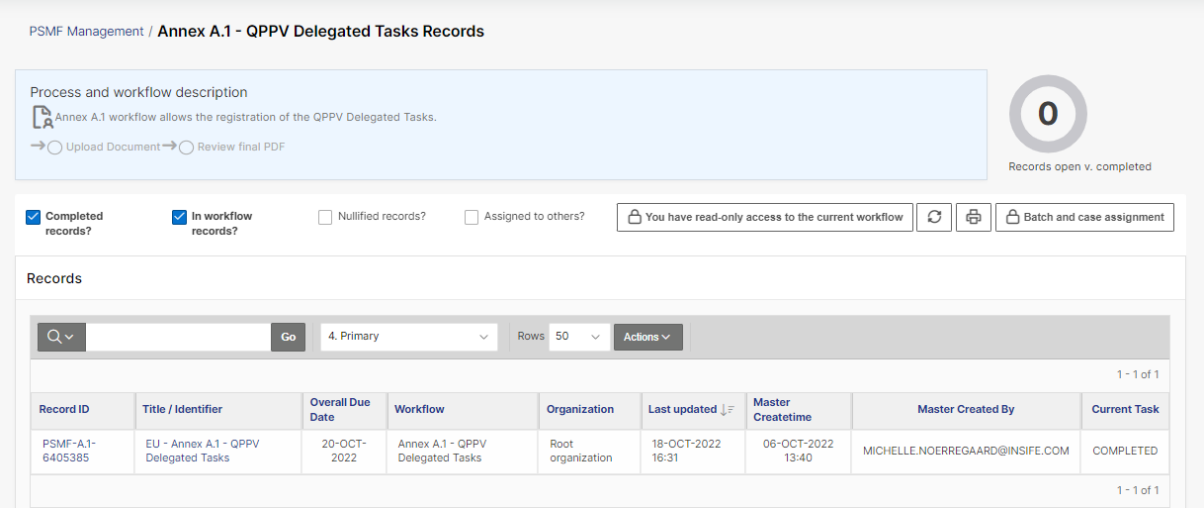

Figure 5 The screen displays the user's restriction to create new records.

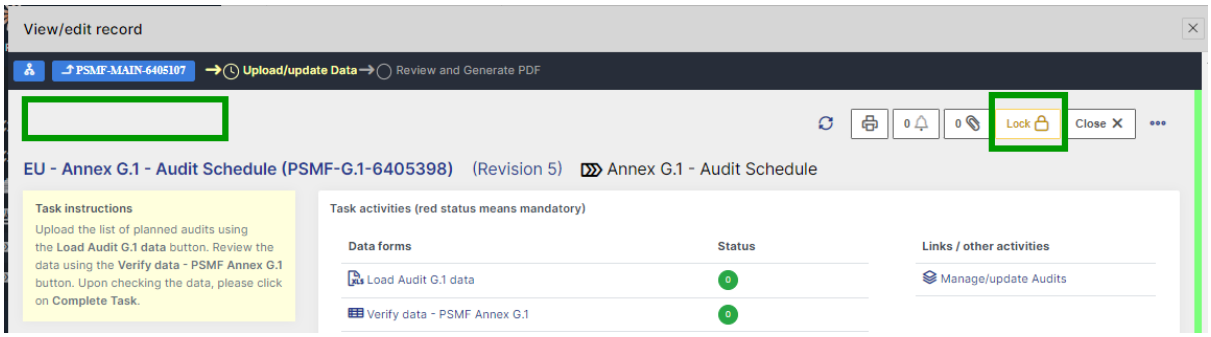

Figure 6 The screen displays an example of a record where the user has 'Read-only' access. The record is locked, and the 'Complete Workflow' button is missing.

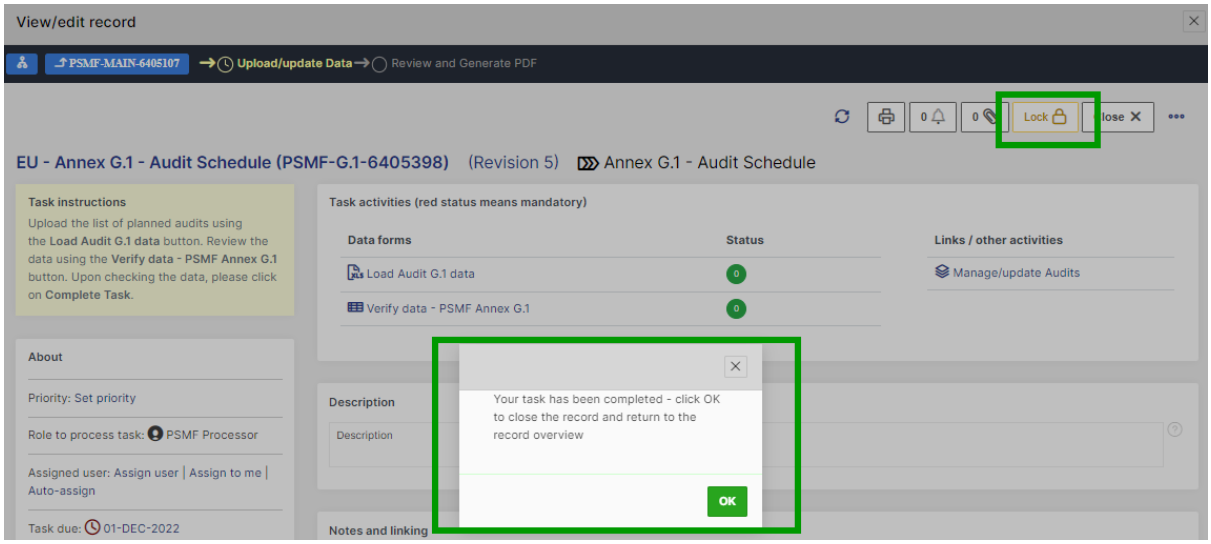

Figure 7 The screen displays an example of a user missing the role to access the workflow's step.

4.3 Workflows Structure

Clicking on the **"Record ID"** or **"Title/Identifier"** takes you to the individual record, as shown below.

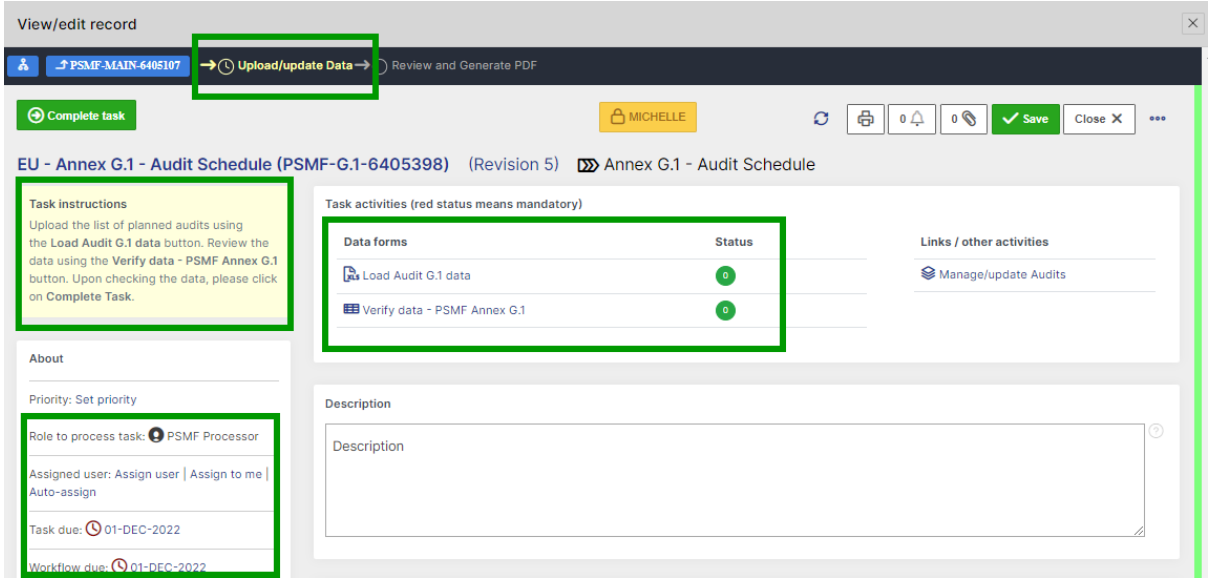

Figure 8 The screen displays an example of a user with the role of accessing the first step.

A Workflow shows a graphical representation of an active and inactive step, your role, the tasks assigned to that role, and the due date.

No other user can perform activities in the record when a user has a record open. The record will be in a locked state.

The **Task instructions** are shown in the application on the left side of the screen, highlighted in yellow. Follow the task instruction for further information about the step.

The **About** section shows the role requires to access the step, the due task date, and the overall due date of the workflow.

The record view also displays the current user in the step. This means no other user can perform any task in the current step.

The **Task activities** and **Link/other activities** sections contain all required tasks buttons to execute in the step.

The top part of the view shows a link to the parent record '***Core PSMF***'. The current process step is highlighted in bold.

A workflow step may have task actions. The status is marked with colors:

- **Green mark:** the task is not mandatory.
- **Red mark:** the task action is mandatory, and the task cannot be completed before it is done.
- **Pending actions:** the task has activated validation rule(s). This is usually linked to a mandatory task (red mark) that requires your attention.

If an existing record should be moved to a further step, **e.g.,** from **Upload/Update Annex** to **Approve**, the user can use the *change* Workflow standard functionality located on the left corner of the record view. This applies to workflows that have more than two steps.

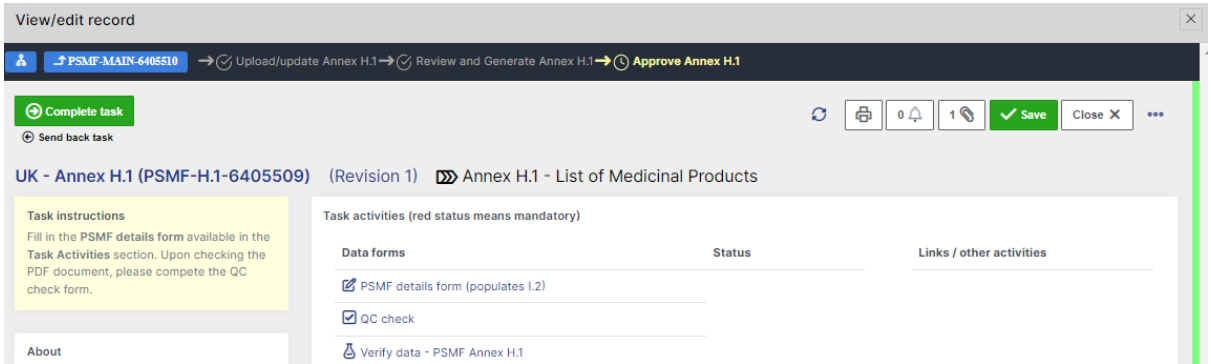

Figure 9 Example of an Annex with three steps

The Annexes' workflows aim to manage either **Global/Core PSMF** or versioning for other regions or countries, e.g., UK, China**,** France, Malaysia, etc.

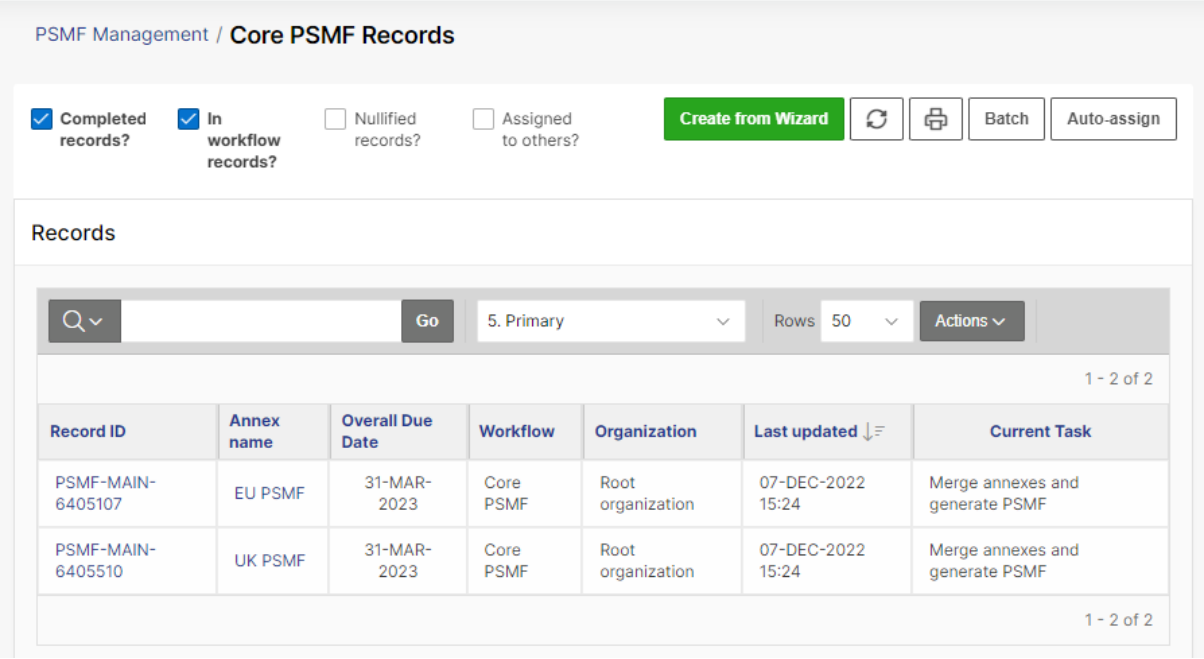

Figure 10 Example of Core PSMFs for EU and UK

4.3.1 Annexes Available in PSMF Management Module

The workflow structure of the Annexes depends on the business processes. Therefore your HALOPV system configuration might vary regarding the number of steps, titles, descriptions, and task actions. Below is an example of the HALOPV Standard package for the PSMF Module.

- **Core PSMF -** Core PSMF is the parent record of all the workflows listed below. Annexes' compliance can be tracked. The workflow allows users to compile and merge the Main Body and Annexes into a PDF document.
    - **Main Body Document Compilation (QPPV Office) -** The workflow documents the changes made to the Main Body. Entries are later rendered into Annex I.1
    -
        - **Main Body Document Review -** The process workflow is a child process of the '*Main Body Compilation (QPPV Office)*' that contains a list of child records assigned to individual roles or users to update the Main Body. It allows data owners to review and update the Main Body Document.
    - **Annex A.1 - QPPV Delegated Tasks –** The workflow allows the registration of the QPPV Delegated Tasks.
    - **Annex A.2 - CV QPPV -** The workflow allows the registration of the CV QPPV.
    - **Annex A.3 - EudraVigilance Registration -** The workflow allows storing the EudraVigilance Registration.
    - **Annex A.4 - CV Deputy QPPV -** The workflow allows the registration of the CV Deputy QPPV.
    - **Annex B.1 - Organizational Charts -** The workflow allows registering and managing organizational charts.
    - **Annex B.2 - Contact Details of Data Entry Sites -** The workflow allows registering and managing Contact Details of Data Entry Sites.
    - **Annex B.3 - List of PV-Related Contracts and Agreements -** The workflow allows managing and updating agreements and rendering content for reports.
    - **Annex C.1 - PV Country Contact List -** The workflow allows managing and updating PV Country Contact List and rendering content for reports.

- **Annex C.2 - List of Studies -** The workflow allows uploading and filtering the List of Studies, managing sites, and ethics committees.
- **Annex E.1 - List of Global Quality System Documents -** The workflow allows managing and updating the Global Quality System Documents list and rendering content for reports.
- **Annex F.1 - List of Performance Indicators -** The workflow provides the capability to manage and update the list of KPIs and render content for reports.
- **Annex G.1 - Audit Schedule -** The workflow allows managing and updating the list of Planned Audits.
- **Annex G.2 - List of Conducted Audits -** The workflow provides the capability to manage and update the list of Conducted Audits and render content for reports.
- **Annex G.3 - List of Critical and Major Audit Findings -** The workflow allows managing and updating the list of Critical and Major Audit Findings and rendering content for reports.
- **Annex G.4 - List of Critical and Major Non-conformities -** The workflow allows updating the list of Critical and Major Non-conformities and rendering content for reports.
- **Annex H.1 - List of Medicinal Products -** The workflow provides the capability to manage and update the list of Medicinal Products and render content for reports.
- **Annex H.2 - Safety Monitoring Requirements -** Review and edit safety monitoring requirement records.
  - **Annex H.2 - Content Update -** The process workflow is a child process of the '*Safety Monitoring Requirements'* Content update includes a list of child records assigned to individual roles or users.
- **Annex I.1 – Logbook -** The workflow can process Main Body document comments and render the logbook content registered in the '*Main Body Document Compilation (QPPV Office)'* workflow.
- **Annex I.2 - History of Changes for Annex Contents** - The workflow process changes made to annexes in the *'PSMF Details form'* and renders content for reports.

The workflow usually consists of a **create/update** step, a **review** step, and an **approval step**. It might be that your local business requirement only requires two steps, '**Update/Upload**' and **'Review/Approve**,' as shown in the example above.

Figure 11 Example of a workflow with two steps.

If you create a new Annex e.g. 'UK-Annex H.1' remember to assign a parent record e.g., 'UK PSMF'; otherwise, no dependencies will be created between parent and child records.

The following section will explain some of the annexes' workflows in further detail. The annexes below represent examples of unique functionalities that can be used across workflows.

Thus, in this Manual, we will list only the relevant workflows that cover most of the functionalities across HALOPV related to the PSMF Management Module.

- Annex A
- Annex G.1
- Main Body Compilation (QPPV Office)
- Annex I.1
- Annex I.2

- Core PSMF

4.3.2 User Roles Relevant to the PSMF Management Module

Users must be assigned roles to access the relevant modules. Furthermore, user roles can allow access or editing rights for a record in a specific workflow task step. Please consult the table below for standard user roles provided by the system. Your administrator may have configured other user roles. For a description of how to administer users and user roles, please refer to the [Admin Guide (insife.com)]

Defined Usergroup name (Role)	Description
Generic PSMF processing	Required to access the Module
PSMF Module	The role can create records and assign a due date.
PSMF Processor	Users with this role can process the information/data in the workflow step.
PSMF Reviewer	Users with this role can review the information/data in the workflow step.
PSMF Approval	Users with this role can approve the information/data in the workflow step.

4.4 Workflow: Annex A

Annexes A.1, A.2, A.3, A.4 have a similar configuration. The workflow is composed of two steps. Users must upload a document into the attachment area in the first step. Users can either upload documents to the **GxP area** or the **Working files (Sharepoint/OneDrive)**.

The second step is the review step, where the document is reviewed and generated in PDF format if needed. Generally, in the last steps, the data form **PSMF details form (populates I.2)** is required as a mandatory form. Entries in **PSMF details form (populates I.2)** are later rendered into **Annex I.2**

Tools to attach documents and generate PDFs are available to users.

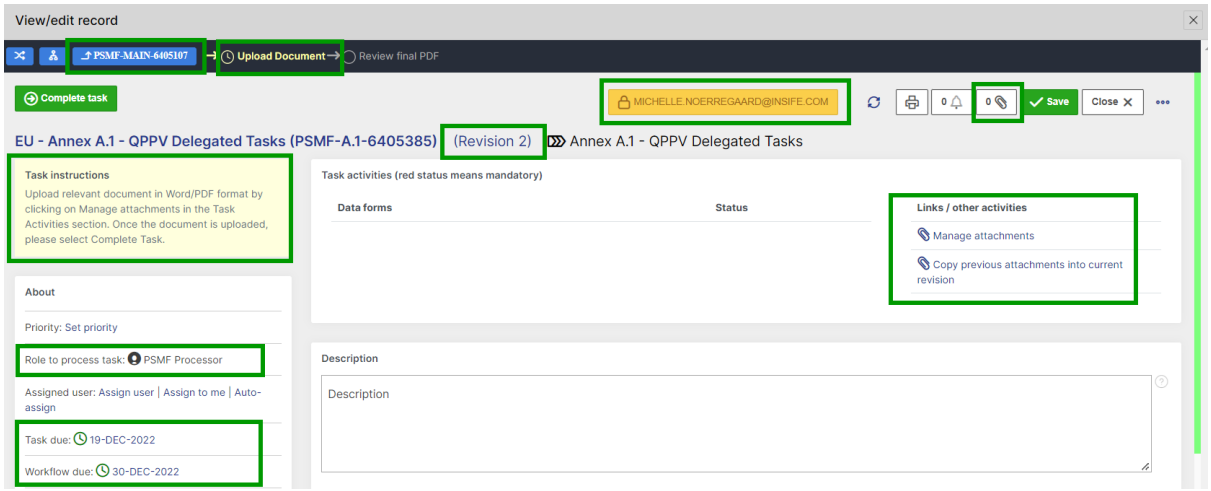

Figure 12 Functionality across HALOPV Records

4.4.1 Upload Document (Step 1)

The **Upload Document** step in the workflow allows users to upload documents.

As with any other task in the application, you must have the corresponding role assigned to process the record in the task step.

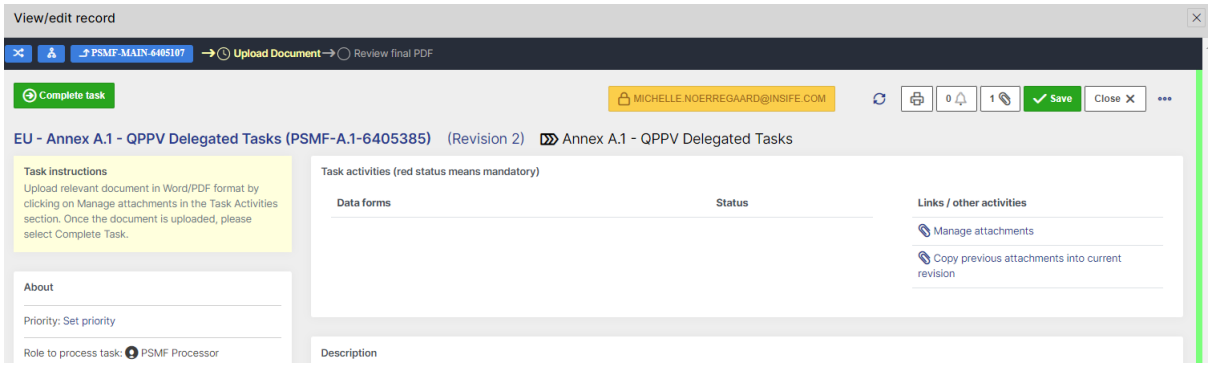

Figure 13 Annex A.1, step 1

The task step instructions are shown in the application on the left side of the screen, highlighted in yellow. Please follow the task instruction for further information about the step.

Role to process task: PSMF Processor

Task instructions (as shown in the application): Upload relevant document in Word/PDF format by clicking on Manage attachments in the Task Activities section. Once the document is uploaded, please select Complete Task.

The task step contains the following activities:

Data form action	Description
Manage attachments	This form allows attaching the required documentation or reviewing existing documentation. Annex A requires that the user upload documentation in Word or PDF Format. **Note:** The attachment icon can be used as an alternative to the ***Manage attachments*** form. The attachment (paper clip) icon is in the record's upper right corner.
Copy previous attachments into current revision	This form allows users to re-utilize previously uploaded documentation on the latest revision. The functionality is commonly used for records where information does not change quite often, like CVs in Annex A.2 and A.4. Once documents are selected, the documentation will be available in the attachment icon 1

Users can attach or review documents using the **Manage attachment** task or clicking on the paper clip icon in the upper right corner of the record.

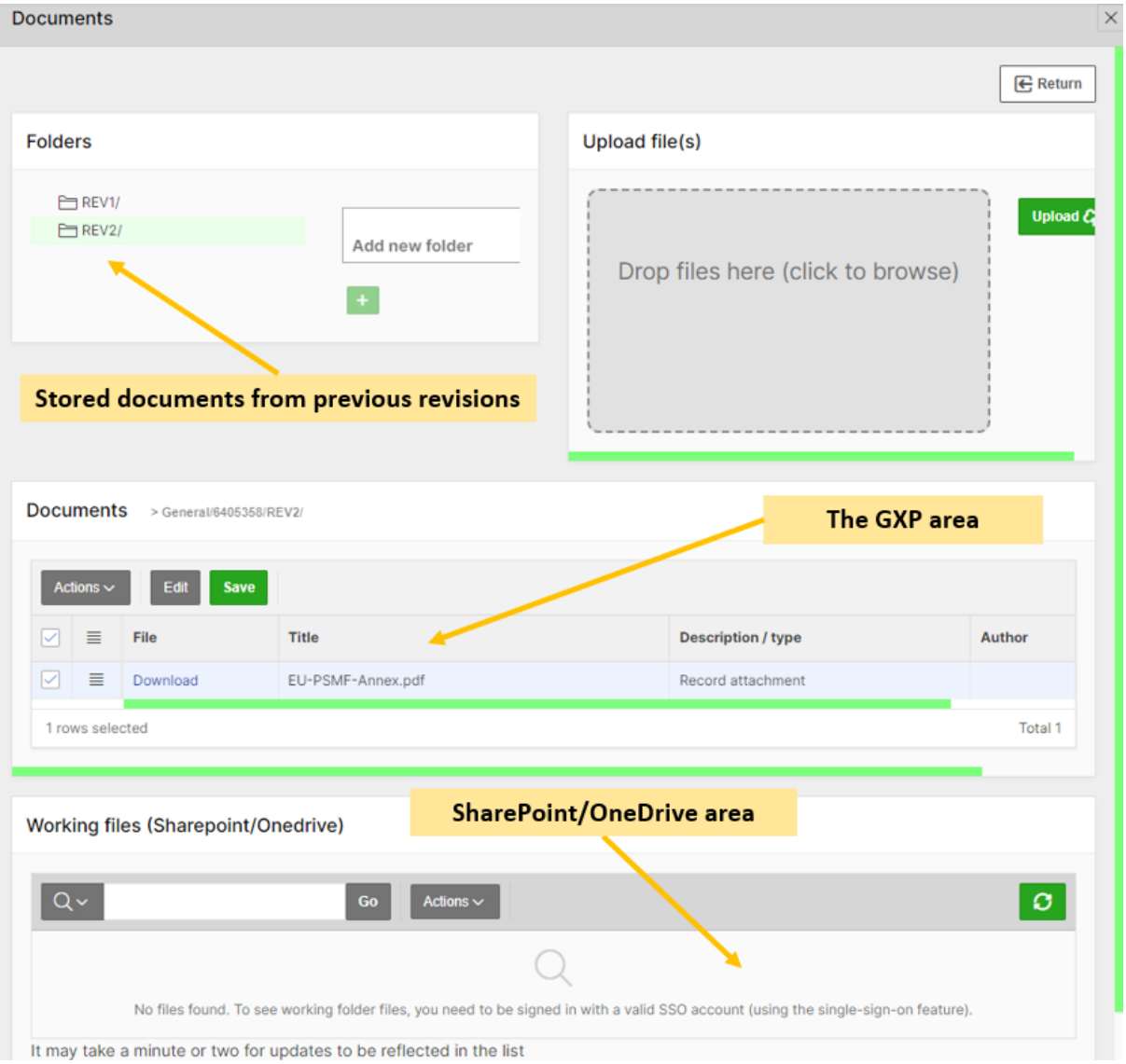

Figure 14 Attachment section areas

If you want to use the same document from the last revision, click on **Copy previous attachments into current revision form** and select the document from the last revision**.**

Once your task is completed, please click on '**Close X**' to close the record session. Otherwise, the record will be locked by your user, and the role in the next step will not be able to perform any task.

4.4.2 Review Final PDF (Step 2)

The **Review/ Approve** step allows document review by a different user role. Depending on your configuration, a **QC Check** form might be available.

As with any other task in the application, you must have the corresponding role assigned to process the record in the task step.

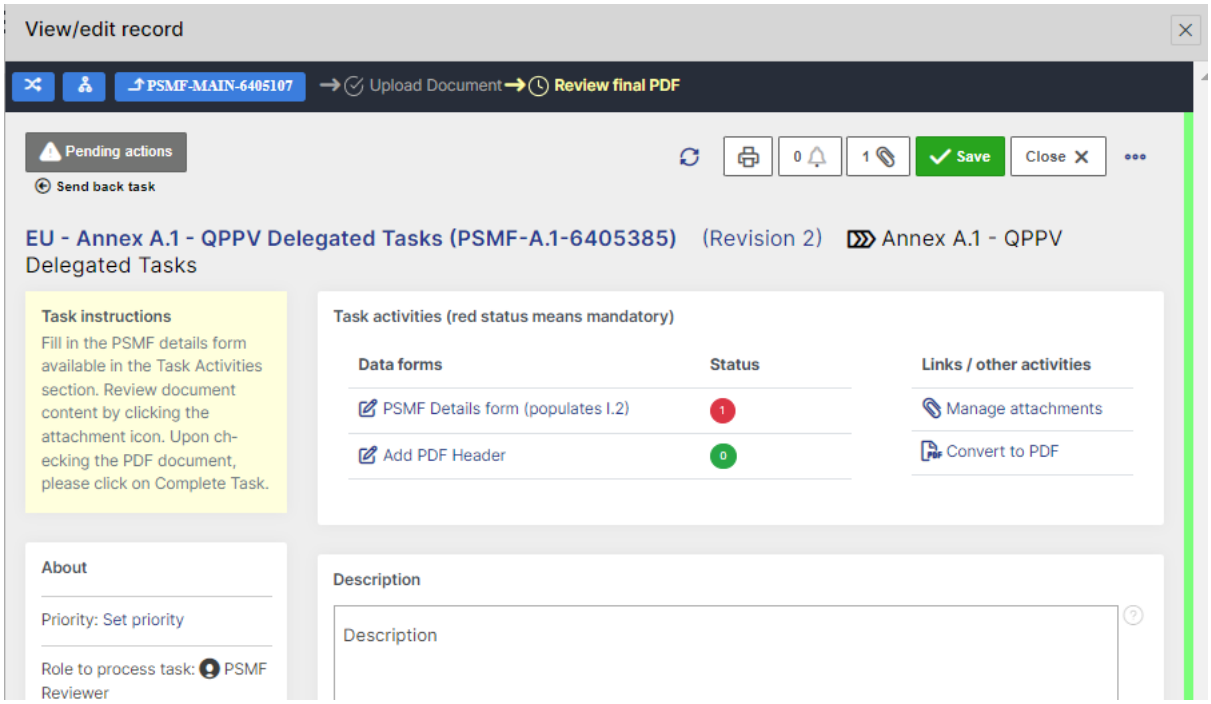

Figure 15 Annex A.1, step 2

Please note that a red status in the form means that a validation rule is active. Unless it is fulfilled, users cannot complete the step. Click on **Pending actions** to review the validation rules that apply to the form.

The task step instructions are shown in the application on the left side of the screen, highlighted in yellow. Please follow the task instruction for further information about the step.

Role to process task: PSMF Reviewer.

Task instructions (as shown in the application): Fill in the PSMF details form available in the Task Activities section. Review document content by clicking the attachment icon. Upon checking the PDF document, please click on Complete Task.

The task step contains the following activities:

Data form action	Description
PSMF Details form (Populates I.2)	This data form (mandatory) allows registering **Data lock Point, Audit log notes,** and **Responsible**. These entries are required to populate and render **Annex I.2** Users can exclude the Annex revision by ticking the box **Exclude from PSMF Log (Annex I.2)** ***Note:*** *Entries in the* ***PSMF Details form*** *for active records will not be transferred to Annex I.2 unless the workflow is completed.*
Manage attachments	This form allows attaching the required documentation or reviewing existing documentation. **Note:** The attachment icon can be used as an alternative to the ***Manage attachments*** form. The attachment (paper clip) icon is in the record's upper right corner.
Convert to PDF	For documents located in HALO GxP area, you can use this form to convert Word or PowerPoint documents into PDF format.
Add PDF Header	This form can be used for PDF documents that are missing a header or a footer, e.g., EudraVigilance

The **PSMF Details form** requires mandatory data points for Annex I.2. Therefore, ensure you fill in the data lock point, the audit log notes, and the responsible. Depending on your system configuration, the annex version can be aligned with the HALO record revision. If not, ensure you also fill in the 'Version (manual)' field.

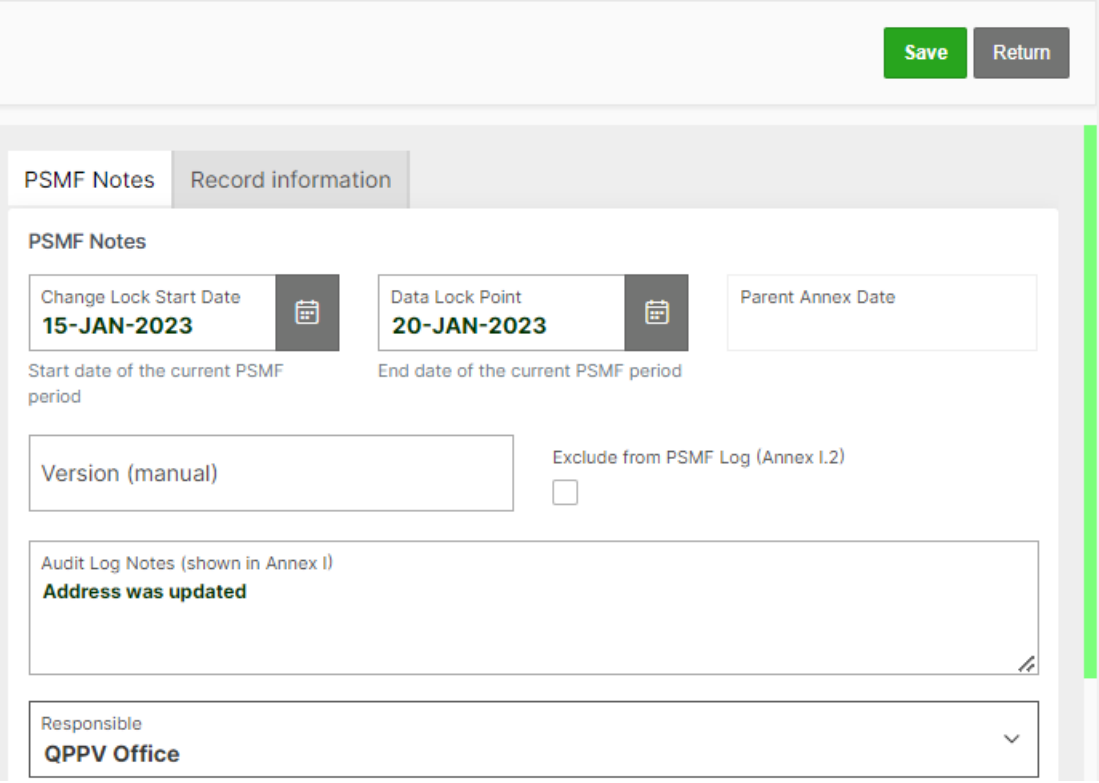

*Figure 16 Mandatory fields in the **PSMF Details form** required for Annex I.2*

Access the document by clicking on the **Manage attachment** task or the paper clip icon in the upper right corner of the record. On the attachment area, '**Documents**' folder, click **Download** to review the document.

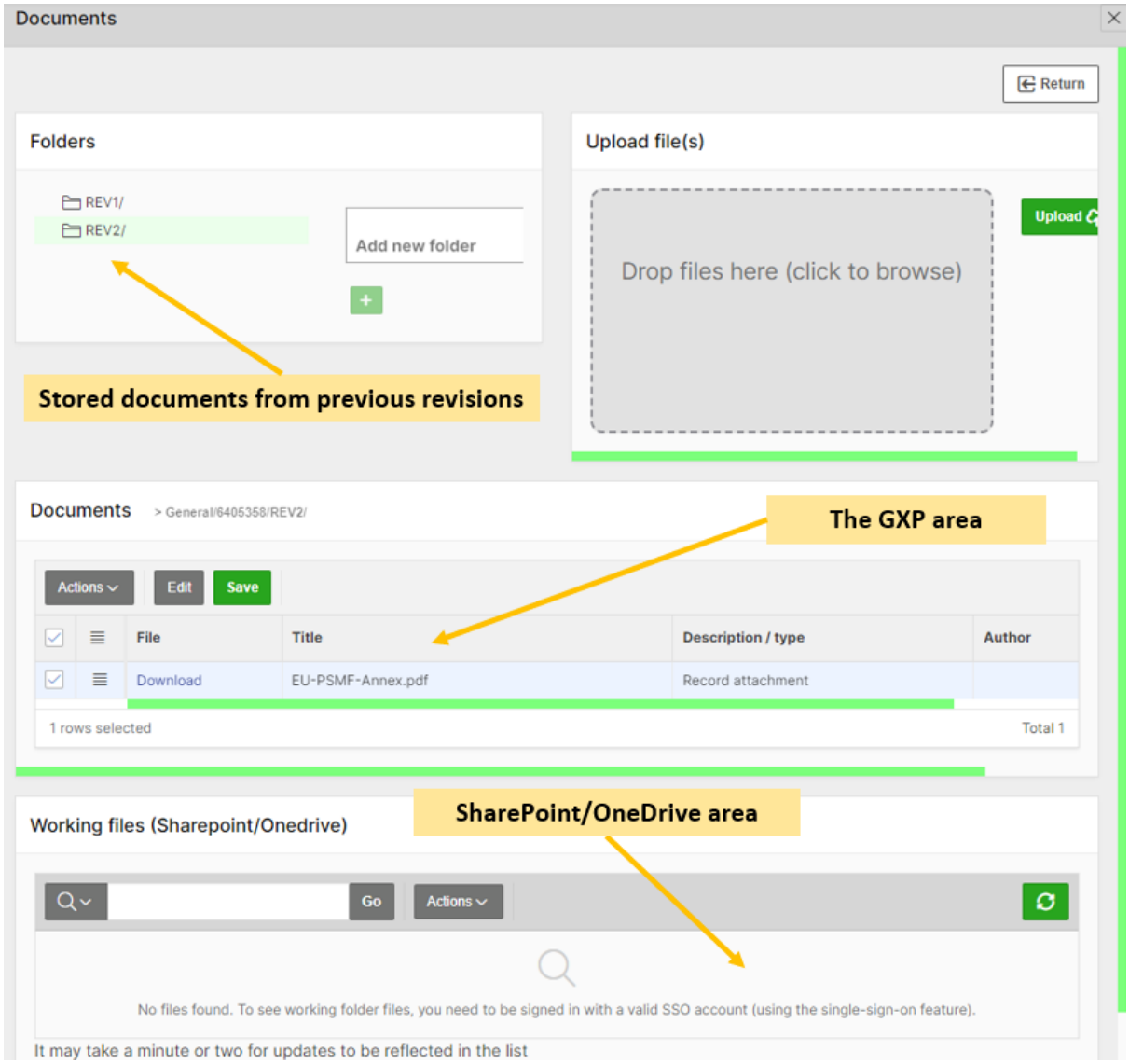

Figure 17 Attachment section areas

Additional tasks might be available in the step if you need to update the document.

Once task actions are completed, click on **Complete task**. The Annex is now finalized, and the workflow is at rest.

4.5 Workflow: Annex G.1

Annex G.1 is an example of HALOPV capabilities regarding data loading. The same structure can be used for Annexes C.1, C.2, B.3, E.1, G.2, G.3, G.4, H.1, or H.2.

HALOPV Data loader converts and loads Excel documents into HALO data forms. Users can also update data in records or nullify existing records.

The example workflow is composed of two steps. In the first step, users can upload data using an excel document(s) or review existing data in records. Records corresponding to conducted or scheduled Audits are stored in the **Quality Management** Module.

The second step is the review step, where the document is reviewed and generated in Word or PDF format. Generally, in the last steps, the data form **PSMF details form (populates I.2)** is required as a mandatory form. Entries in **PSMF details form (populates I.2)** are later rendered into **Annex I.2**

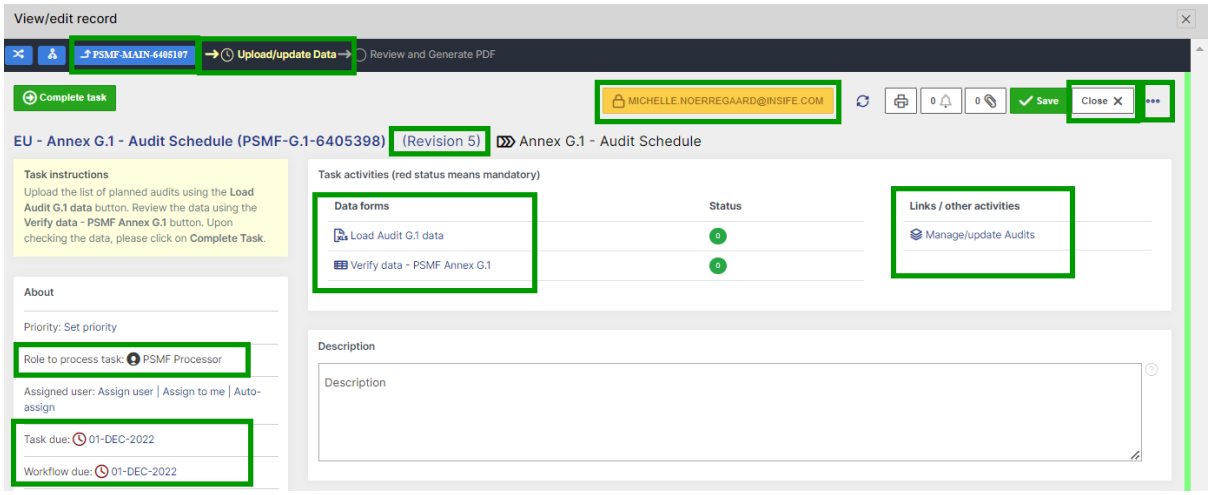

Figure 18 Annex G.1 workflow

4.5.1 Upload/Update Data (Step 1)

The **Upload/Update Data** step allows users to upload Excel files or manage/update audit records.

As with any other task in the application, you must have the corresponding role assigned to be able to process the record in the task step.

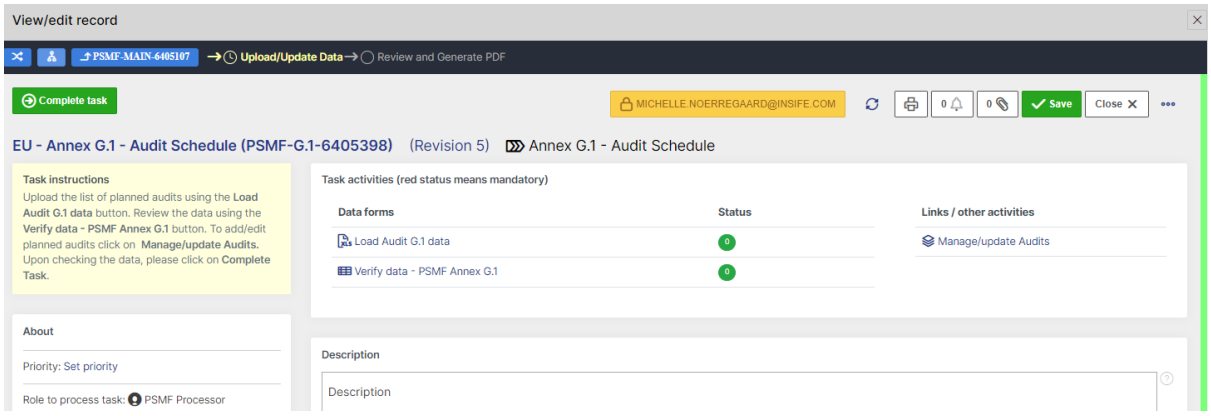

Figure 19 Annex G.1, step 1

The task step instructions are shown in the application on the left side of the screen, highlighted in yellow. Please follow the task instruction for further information about the step.

Role to process task: PSMF Processor

Task instructions (as shown in the application): Upload the list of planned audits using the **Load Audit G.1 data** button. Review the data using the **Verify data - PSMF Annex G.1** button. To add/edit planned audits click on **Manage/update Audits.** Upon checking the data, please click on **Complete Task**.

The task step contains the following activities:

Data form action	Description
Load Audit G.1 data	This page allows the user to load data into HALO from Excel documents. Formatting applied to the Excel document is removed before loading data. Data is uploaded in the Audit details form; entries like Audit Report ID, Auditees, Type of Auditee, Include in PSMF, PV related main findings, and scheduled and execution dates.
Verify data – PSMF Annex G.1	This form allows users to verify the list of records in the Quality Management Module, Audit process workflow.
Manage/update Audits	This form allows users to manage and update audit records in the Quality Management Module.

To upload data into HALOPV a data loader template should be configured for your columns in excel to match the fields in the HALOPV **Audit details form**.

Load Audit G.1 data form is configured with pre-defined values based on the Annex requirements *(Please do not change pre-defined values.)*

Data loading options > Nullify (delete) obsolete records:

- **Per default:** No
- **No:** Updates the entries in the system according to the uploaded file, BUT entries will not get removed in the system in case they are not available in the Excel
- **All records in target workflow:** deletes all entries in the system's table, and the new data gets transported.
- **Obsolete records (not in Excel):** Updates the data in the system according to the uploaded Excel file and removes the entries from the database which are not included in the Excel file

Once your task is completed, please click on '**Close X**' to close the record session. Otherwise, the record will be locked by your user, and the role in the next step will not be able to perform any task.

4.5.2 Review and Approve (Step 2)

The **Review/ Approve** step allows document review by a different user role. Depending on your configuration, a **QC Check** form might be available.

As with any other task in the application, you must have the corresponding role assigned to process the record in the task step.

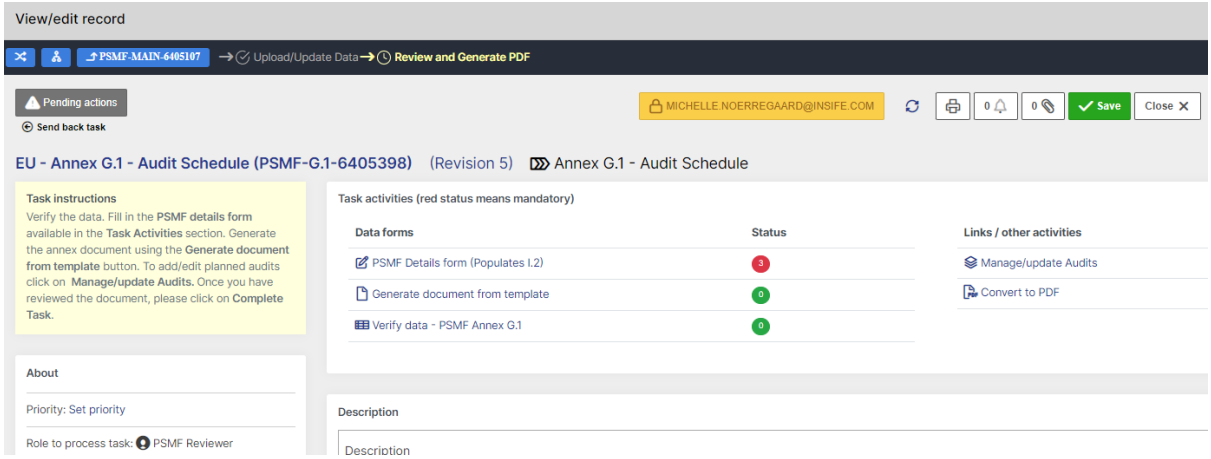

Figure 20 Annex G.1, step 2

Please note that a red status in the form means that a validation rule is active. Unless it is fulfilled, users cannot complete the step. Click on **Pending actions** to review the validation rules that apply to the form.

The task step instructions are shown in the application on the left side of the screen, highlighted in yellow. Please follow the task instruction for further information about the step.

Role to process task: PSMF Reviewer.

Task instructions (as shown in the application): Verify the data. Fill in the **PSMF details form** available in the **Task Activities** section. Generate the annex document using the **Generate document from template** button. To add/edit planned audits click on **Manage/update Audits.** Once you have reviewed the document, please click on **Complete Task**.

The task step contains the following activities:

Data form action	Description
PSMF Details form (Populates I.2)	This data form (mandatory) allows registering **Data lock Point, Audit log notes,** and **Responsible**. These entries are required to populate and render **Annex I.2** Users can exclude the Annex revision by ticking the box **Exclude from PSMF Log (Annex I.2)** ***Note:*** *Entries in* ***PSMF Details form*** *for active records will not be transferred to Annex I.2 unless the workflow is completed.*

Data form action	Description
Generate document from template	This form provides features to link a document template to a process record. Users can then select a document on a drop-down list. The document will be generated in Word or PDF and attached to the record. **Interactive report (Optional)** This option allows the selection of the interactive report for generation instead of the pre-defined interactive report configured in the Document generation template. This option requires that only one Interactive report placeholder is configured in the template **Template file (Optional)** This option allows the selection of the WORD template file to use for generation instead of the pre-defined template configured in the Document generation template **Template file from work (Optional)** This option allows the selection of the WORD template file to use for generation instead of the pre-defined template configured in the Document generation template **Upload to working folder** This option allows upload to the Working folder attachment area instead of the default attachment storage. This option is only available if a Working folder is configured (System configuration > OneDrive integration)
Verify data – PSMF Annex G.1	This form allows users to verify the list of records in the Quality Management Module, Audit process workflow.
Manage/update Audits	This form allows users to manage and update audit records in the Quality Management Module.
Convert to PDF	For documents located in HALO GxP area, you can use this form to convert Word or PowerPoint documents into PDF format.

Use the task action **Generate document from template** to generate the Annex. Select Word or PDF as the output format. If you click 'Upload working folder,' the document will be uploaded into HALO SharePoint (*Please ensure your company is subscribed to this service.)* SharePoint functionality can be used for the online reviewing of documents.

As data is stored in the system, ensure you update the data entries in records, as an alteration to rendered documents in the GxP area will not affect the next revision rendering.

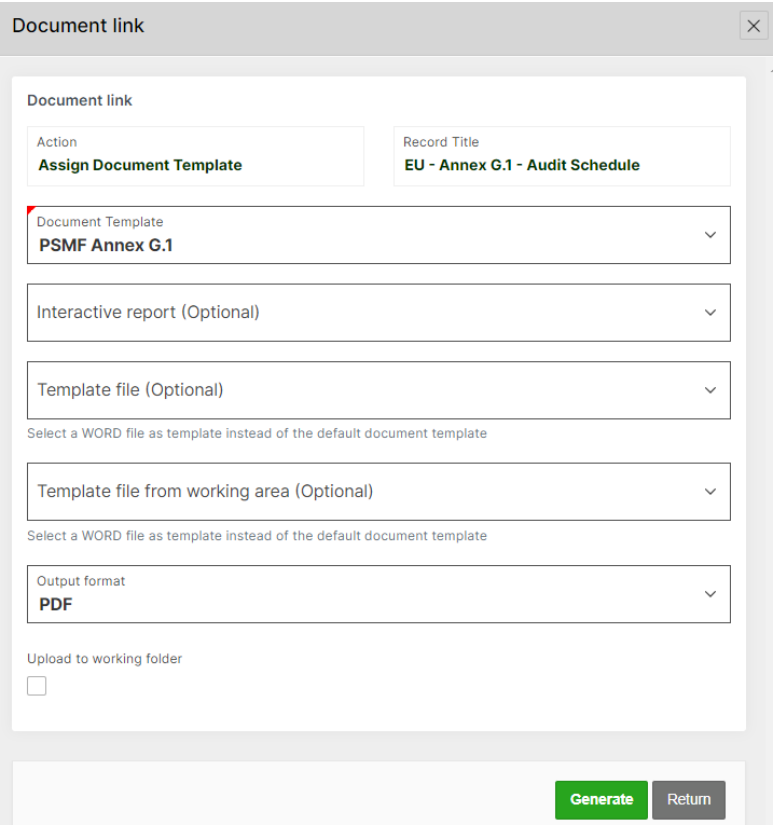

Figure 21 Example of the functionality 'Generate document from template' – how to select a HALOPV template and render Annex G.1

Access the document by clicking on the **Manage attachment** task or the paper clip icon in the upper right corner of the record. On the attachment area, '**Documents'** folder, click **Download** to review the document.

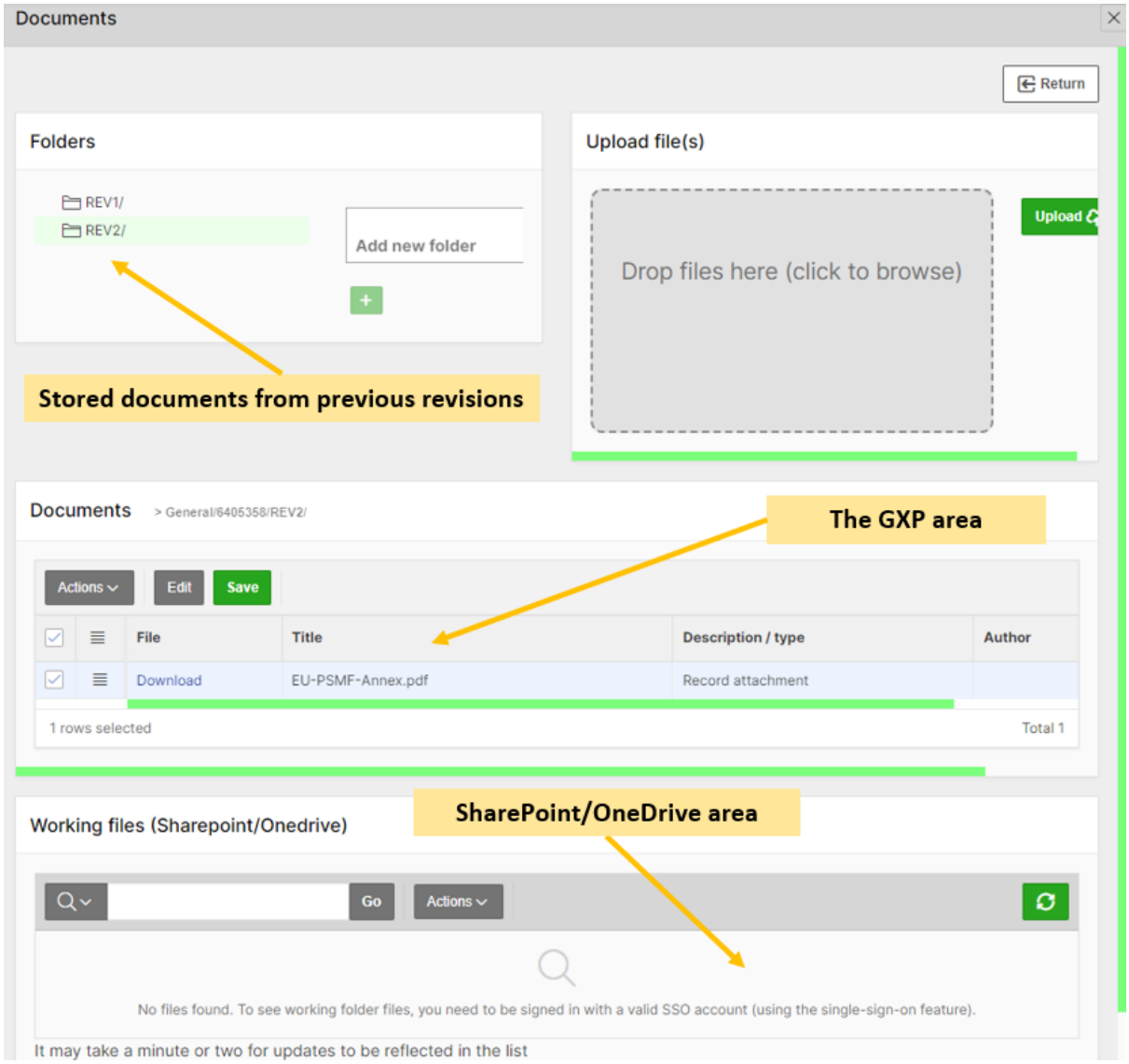

Figure 22 Attachment section areas

The **PSMF Details form** requires mandatory data points for Annex I.2. Therefore, ensure you fill in the data lock point, the audit log notes, and the responsible. Depending on your system configuration, the annex version can be aligned with the HALO record revision. If not, ensure you also fill in the 'Version (manual)' field.

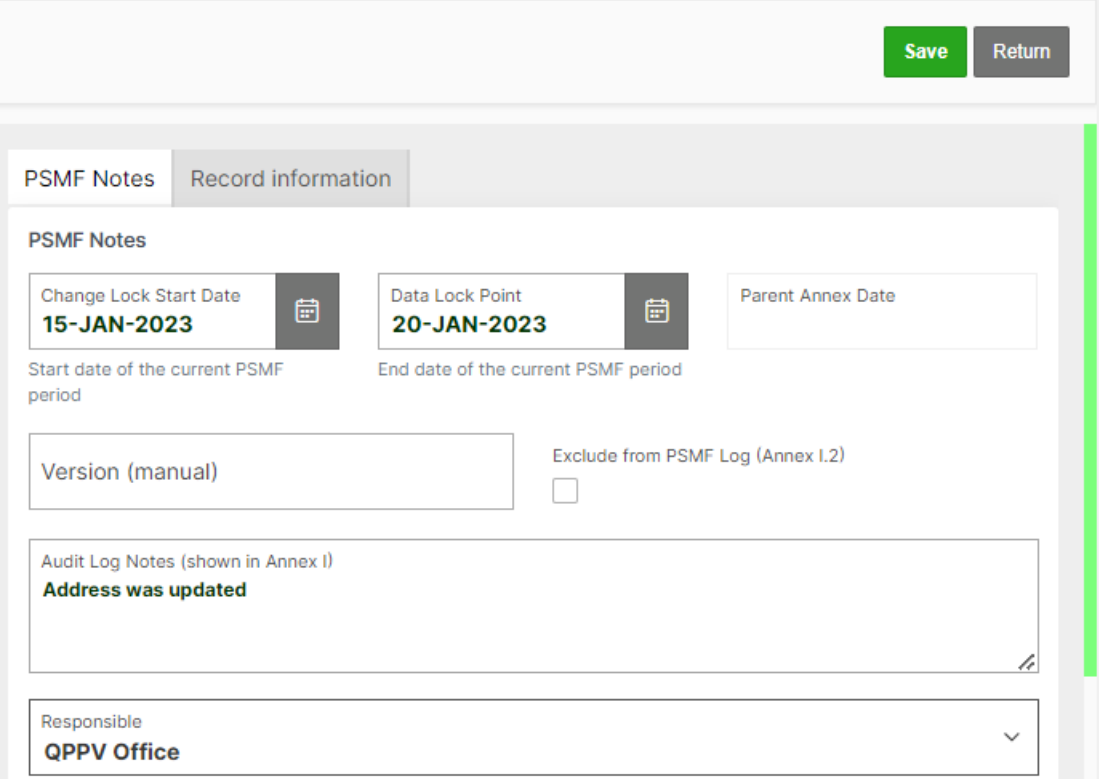

*Figure 23 Mandatory fields in the **PSMF Details form** required for Annex I.2*

Additional tasks might be available in the step if you need to update the document.

Once task actions are completed, click on **Complete task**. The Annex is now finalized, and the workflow is at rest.

4.6 Workflow: Main Body Compilation (QPPV Office)

The workflow is composed of four steps. In the first step, users must review the Main Body document in the attachment area. In this example, the document is located in the **Working files (Sharepoint/OneDrive)**.

The second step is the review step, where the document is reviewed, **PSMF Details form (Populates I.2)** is filled in to be later rendered into **Annex I.2,** and Main Body Comments are registered. The third step is the approval step of the document by the QPPV.

The fourth step (automatic) ensures all child records are completed and ready for the next revision.

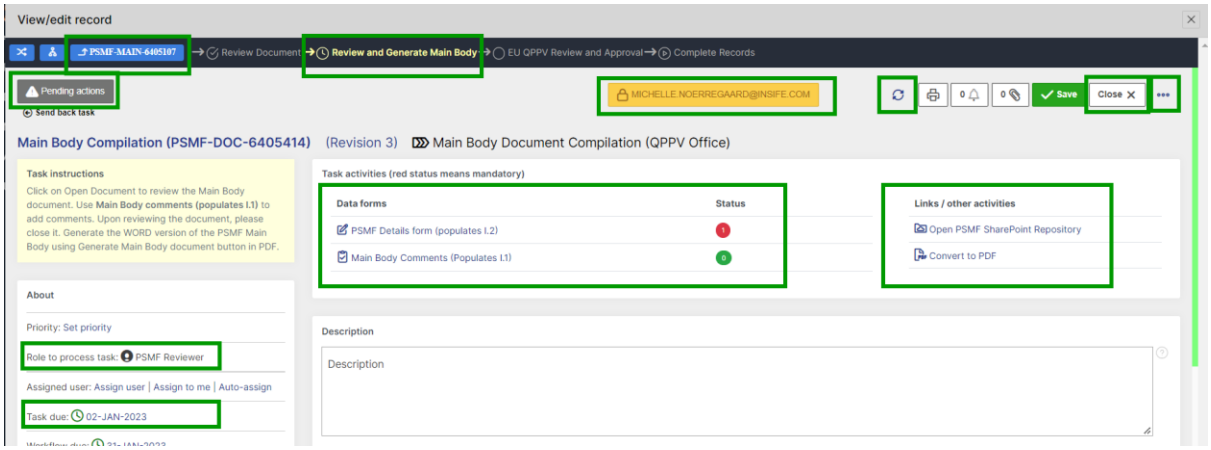

Figure 24 Example of Main Body Document Compilation (QPPV Office) workflow

4.6.1 Review Document (Step 1)

The **review** step allows users to access the SharePoint repository.

As with any other task in the application, you must have the corresponding role assigned to process the record in the task step.

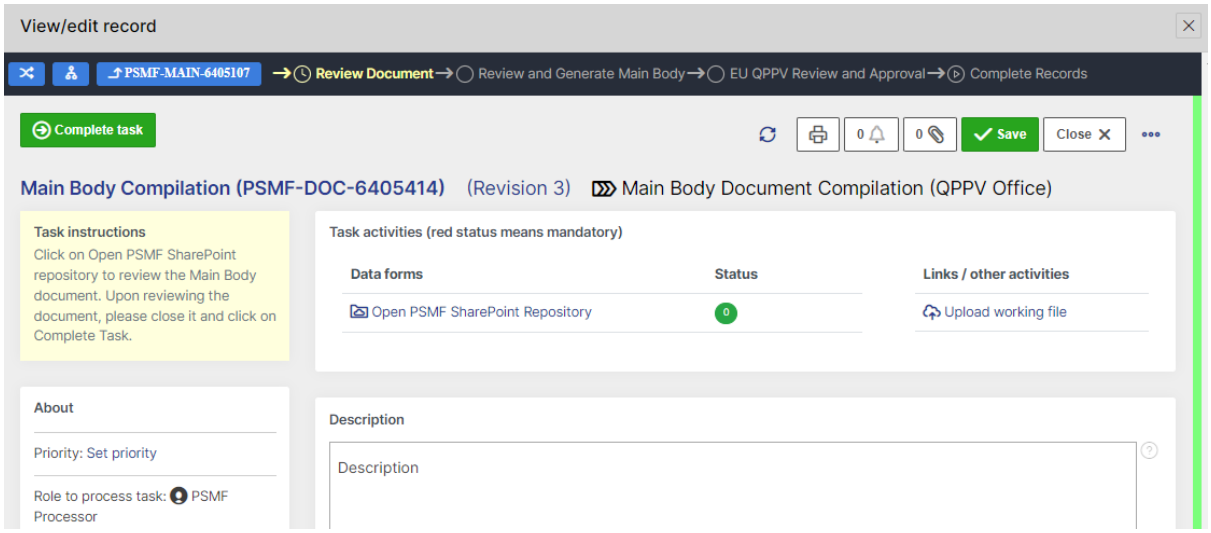

Figure 25 Main Body Document Compilation (QPPV Office), step 1

The list of child records includes the records listed in the workflow **Main Body Document Review**. The workflow can be scheduled to inform data owners periodically via email to update the Main Body document. The link in the email redirects the Data Owner to the respective record.

Related Records

Go | 1. Primary Report | Actions

Title	Workflow	Organization	Status	Link Type	Created
PV Regions (6405494)	Main Body Document Review	Root organization	COMPLETED	Child record	17-OCT-2022 05:58AM
PV Risk Management (6405496)	Main Body Document Review	Root organization	COMPLETED	Child record	17-OCT-2022 06:00AM
PV Quality and Compliance (6405498)	Main Body Document Review	Root organization	COMPLETED	Child record	20-OCT-2022 12:22PM
PV Single Case Processing (6405497)	Main Body Document Review	Root organization	Review Main Body document	Child record	01-NOV-2022 01:30PM
Regulatory Affairs (6405493)	Main Body Document Review	Root organization	Review Main Body document	Child record	01-NOV-2022 01:30PM
QPPV Office (6405495)	Main Body Document Review	Root organization	Review Main Body document	Child record	01-NOV-2022 01:38PM

1 - 6

Figure 26 List of Child records linked to the Main Body Document Compilation (QPPV Office) workflow

The task step instructions are shown in the application on the left side of the screen, highlighted in yellow. Please follow the task instruction for further information about the step.

Role to process task: PSMF Processor

Task instructions (as shown in the application): Click on **Open PSMF SharePoint repository** to review the Main Body document. Upon reviewing the document, please close it and click on **Complete Task**.

The task step contains the following activities:

Data form action	Description
Open PSMF SharePoint Repository	This form allows users to access documents stored in SharePoint/Onedrive folder configured in the workflow. When a new record revision is created, existing DOCX documents in the attachment area are copied into the Working folder area. The HALO user can only open and work with files in the Working folder if the user has access to the configured OneDrive folder.
Upload working file	This functionality can be used if the document in the SharePoint folder needs to be replaced or additional documents must be shared with data owners.

The SharePoint repository allows users to open and work online with multiple users (if access to the OneDrive folder is configured for the working folder attachment area). Once the document is loaded into the HALOPV GxP area, users will no longer be able to edit the document.

Once task actions are completed, click on **Complete task**. And remember to click on **Close X;** otherwise, the user role in the next step will not be able to perform any actions.

4.6.2 Review and Generate Main Body (Step 2)

The **Review and generate** step allows a different user role to review the Main Body document.

As with any other task in the application, you must have the corresponding role assigned to process the record in the task step.

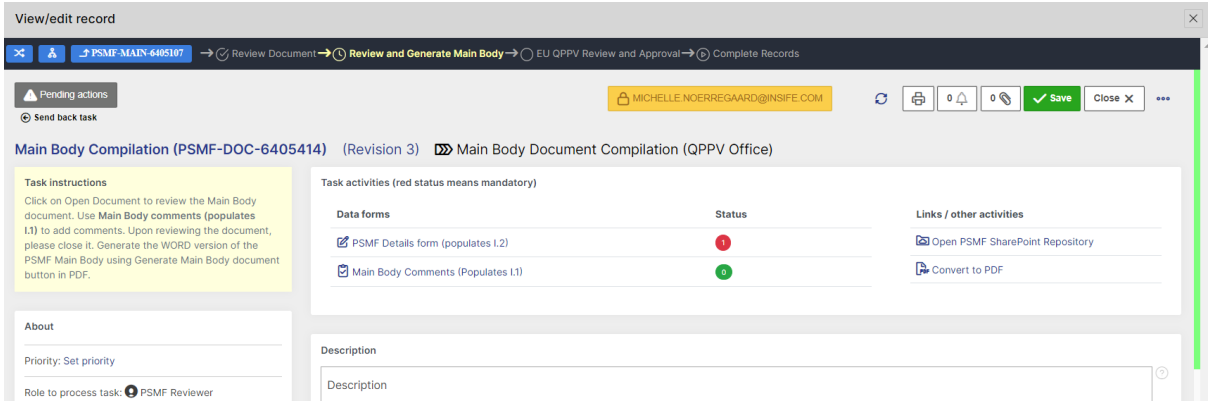

Figure 27 Main Body Document Compilation (QPPV Office), step 2

The task step instructions are shown in the application on the left side of the screen, highlighted in yellow. Please follow the task instruction for further information about the step.

Role to process task: PSMF Reviewer.

Task instructions (as shown in the application): Click on **Open PSMF SharePoint Repository** to review the Main Body document. Use **Main Body comments (populates I.1)** to add comments. Upon reviewing the document, please close it.

Populate the **PSMF Details form (Populates I.2)** and upload the Main body from the **Working folder (SharePoint/OneDrive)** to the **Document** folder (GxP area).

Render the PDF version using the **Convert to PDF** button. Upon reviewing the document, please complete the workflow.

The task step contains the following activities:

Data form action	Description
Open PSMF SharePoint Repository	This form allows users to access documents stored in SharePoint/Onedrive folder configured in the workflow. When a new record revision is created, existing DOCX documents in the attachment area are copied into the Working folder area. The HALO user can only open and work with files in the Working folder if the user has access to the configured OneDrive folder.
PSMF Details form (Populates I.2)	This data form (mandatory) allows registering the **Data lock Point, Audit log notes,** and **Responsible**. These entries are required to populate and render **Annex I.2** Users can exclude the Annex revision by ticking the box **Exclude from PSMF Log (Annex I.2)** ***Note:*** *Entries in **the PSMF Details form** for active records will not be transferred to Annex I.2 unless the workflow is completed.*
Main Body Comments (Populates I.1)	The form allows the logging of the PSMF Main Body review comments from multiple reviewers. Users can edit review comments. And add inputs regarding 'Chapter,' 'Reason' for alteration, 'Old,' 'New,' Responsible for alteration,' or if 'No adjustments required.' The timestamp is logged, but Annex I.1 is defined by the data lock point in the 'PSMF Details form' located in Annex I.1
Convert to PDF	For documents located in HALO GxP area, you can use this form to convert Word or PowerPoint documents into PDF format.

Before rendering **Annex I.1 – Logbook** and proceeding to PSMF compilation, ensure comments are included using the button **Main Body Comments (Populates I.1).**

Main Body Comments (Populates I.1) form allows the user to register comments as entries for the Main Body, which later are transferred and rendered into Annex I.1 (*Review the example comment further in the section Annex I.1 – Logbook*). After using the **Add comment** button, the comment is listed in the view and transported to Annex I.1. Users can edit comments in this form as long as the workflow is not completed.

Note: the date considered for all comments in Annex I.1 is the one included in the **PSMF Details form** available in the current step.

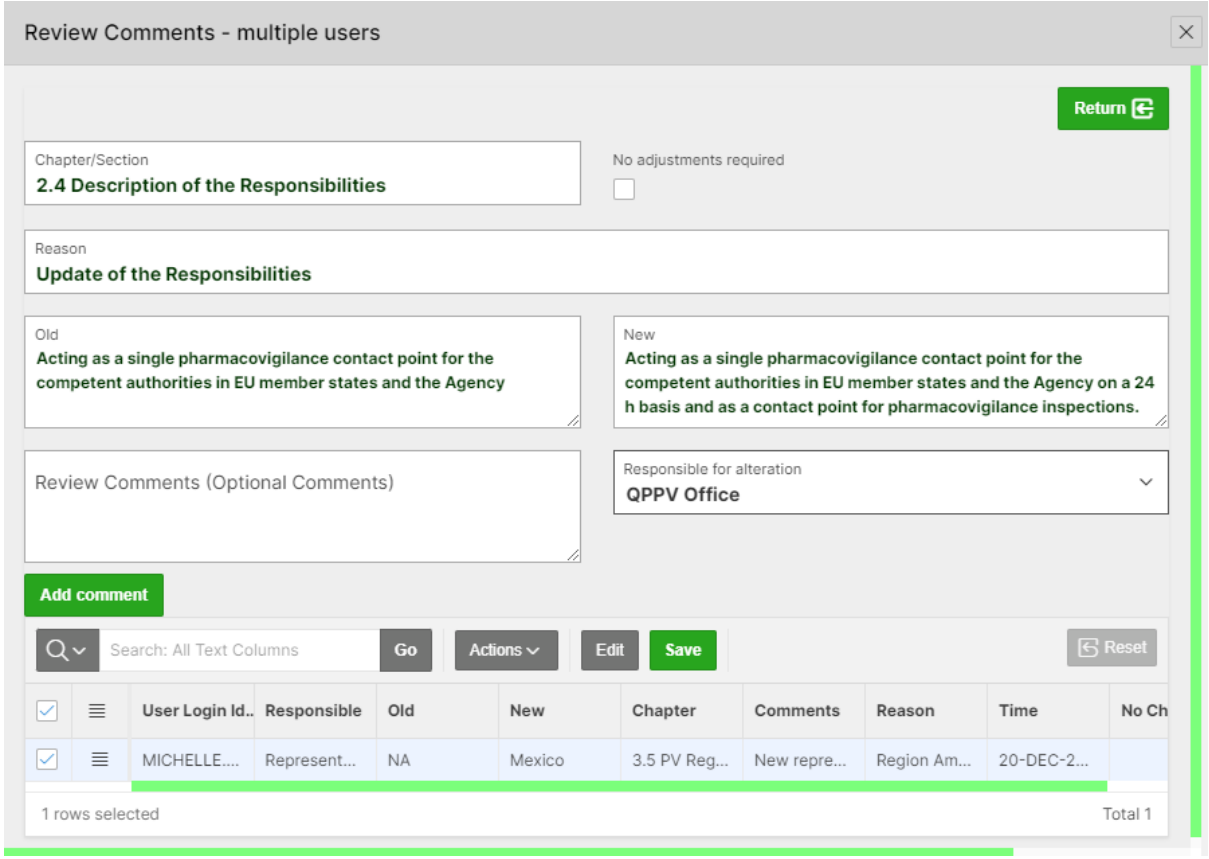

*Figure 28 Example of an entry in the form '**Main Body Comments (Populates I.1)**'*

The **PSMF Details form** in the workflow is a mandatory task as the data lock point is required for **Annex I.2** and **Annex I.1.** Additionally, for **Annex I.1,** the **version** is mandatory as it renders into the Annex I.1 template for the new revision. ***(Please note that this logic regarding the data lock point and version for Annex I.1 only applies to this workflow)***.

A red status in the **PSMF Details form** means that a validation rule is active. Unless it is fulfilled, users cannot complete the step. Click on **Pending actions** to review the validation rules that apply to the form.

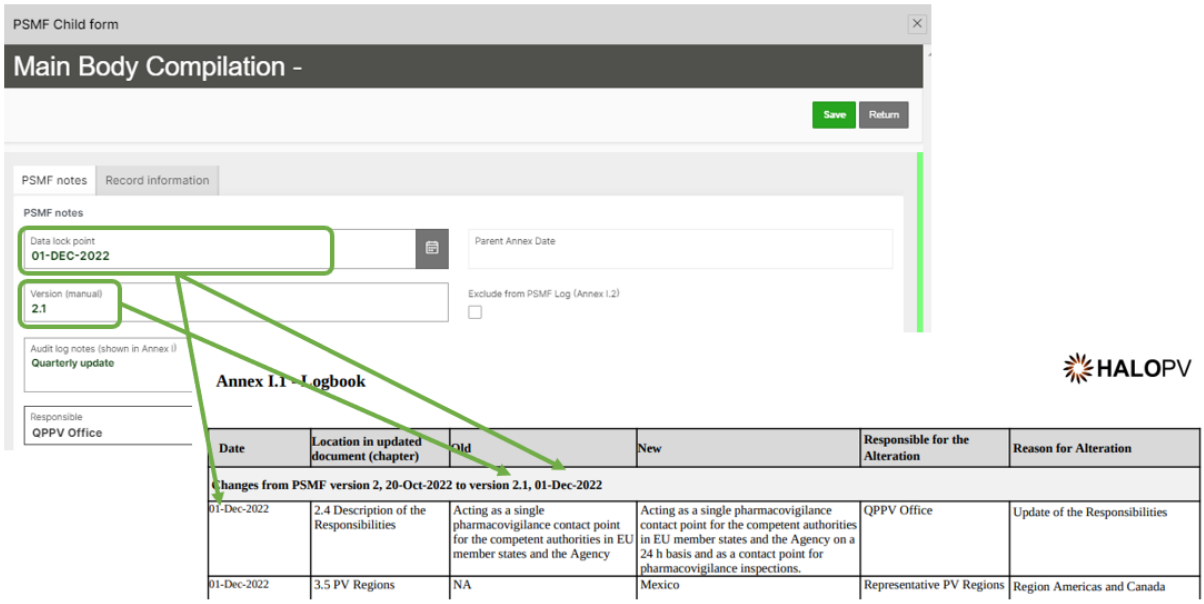

*Figure 29 Example of the mandatory fields in the **PSMF Details form** required for Annex I.1 and its mapping in Annex I.1*

The example above illustrates the two fields required in the **PSMF Details form** for Annex I.1. So ensure these fields are filled in before completing the workflow.

After completing the **PSMF Details form**, users should move the Main Body document from the **'Working files (SharePoint/OneDrive)**' to the GxP area '**Documents**' folder. Click on the paperclip icon to access the attachment section.

Please, ensure the **Main Body** Document is closed before moving it to the GxP area or rendering the final PDF version.

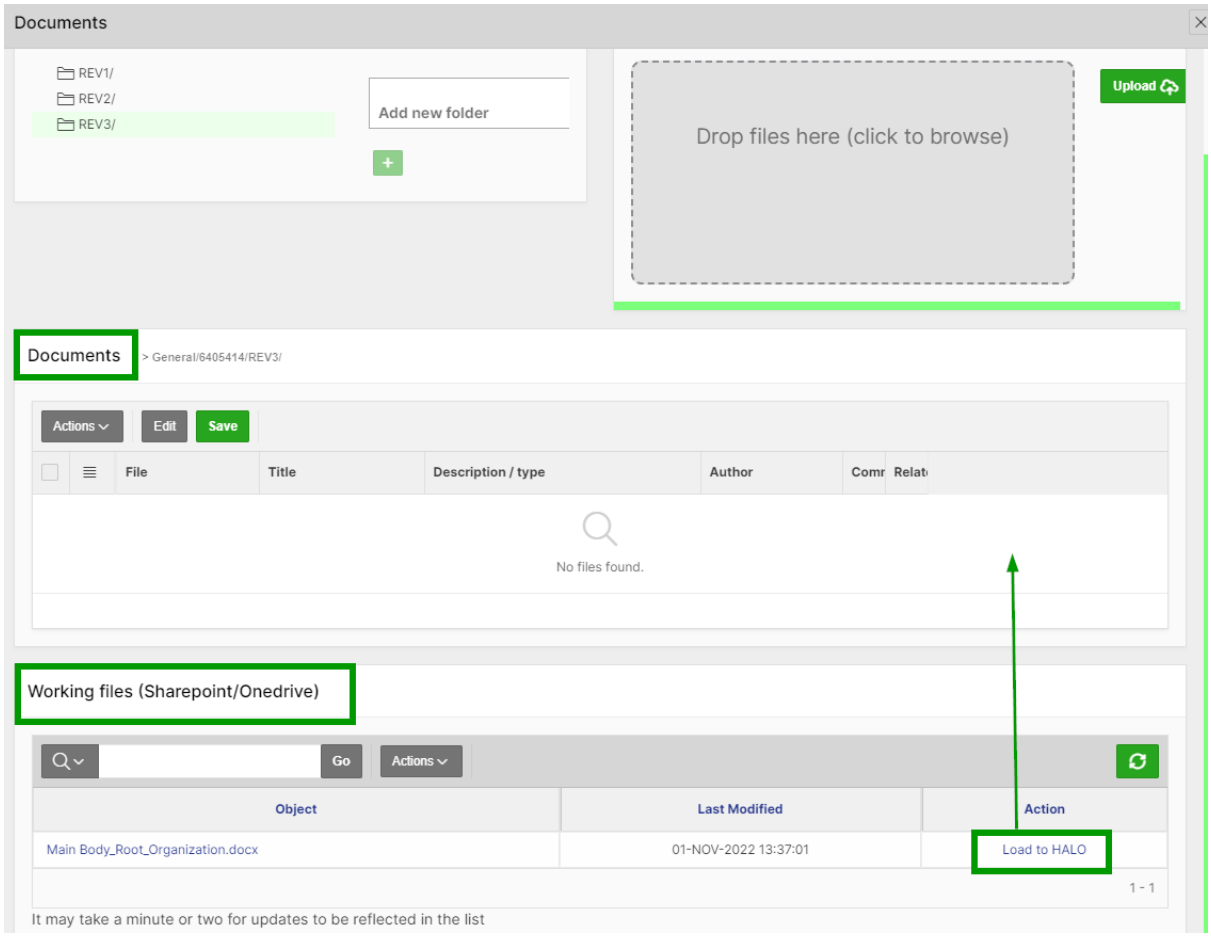

Figure 30 Example of how to upload a document from the 'Working files' area into the 'Documents' GxP area

Once the document is loaded into the HALOPV GxP area, users will no longer be able to edit the document.

Additional tasks might be available in the step if you need to update the document, e.g., attach new documents and convert them to PDF. So, remember to convert the word document into PDF using the **PDF Converter** button. Otherwise, the document will not be available for final rendering in the **Core PSMF** workflow

After completing all task actions and preparing the document for QPPV review, click on **Complete task**. Remember to click on **Close X;** otherwise, the QPPV role cannot perform any actions on the next step.

4.6.3 EU QPPV Review and Approval (Step 3)

The **Review and approval** step allows reviewing of the Main Body document in the GxP area by the EU QPPV role.

As with any other task in the application, you must have the corresponding role assigned to process the record in the task step.

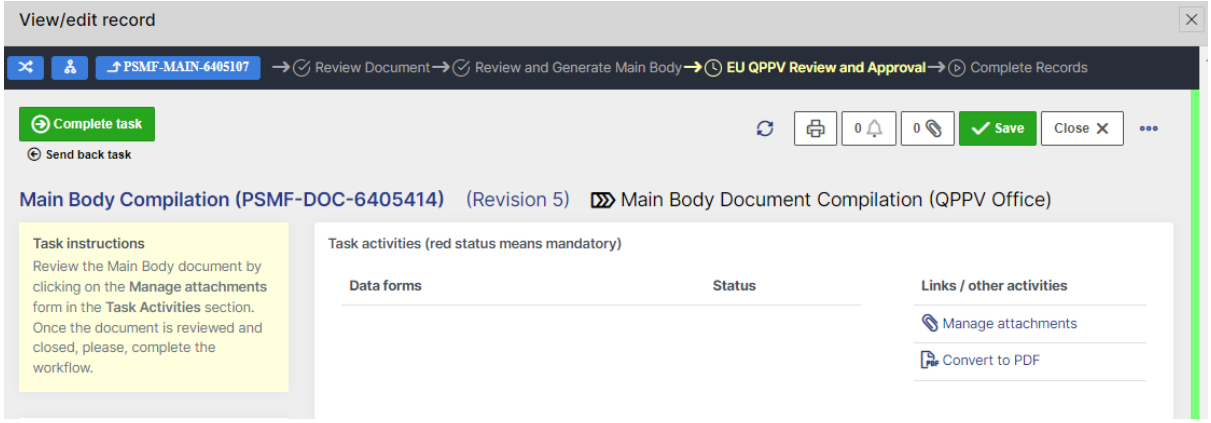

Figure 31 Review step 'EU QPPV Review and Approval'

The task step instructions are shown in the application on the left side of the screen, highlighted in yellow. Please follow the task instruction for further information about the step.

Role to process task: PSMF Approver.

Task instructions (as shown in the application): Review the Main Body document by clicking on the **Manage attachments** form in the **Task Activities** section. Once the document is reviewed and closed, fill out the **QC form**.

Please, note that once the user clicks on '**Approve**,' in the **QC form** the workflow automatically completes.

The task step contains the following activities:

Data form action	Description
Manage attachments	This form allows attaching the required documentation or reviewing existing documentation. **Note:** The attachment icon can be an alternative to the ***Manage attachments*** form. The attachment (paper clip) icon is in the record's upper right corner.
Convert to PDF	For documents located in HALO GxP area, you can use this form to convert Word or PowerPoint documents into PDF format.
QC Check	The page allows the QC reviewer to acknowledge the review and enter review comments. **Note:** The user completing the QC form cannot be the same user who completed the workflow's previous step. Please, note that once the user clicks '**Approve**,' the workflow automatically completes.

Access the document by clicking on the **Manage attachment** task or the paper clip icon in the upper right corner of the record. On the attachment area, '**Documents**' folder, click **Download** to review the document.

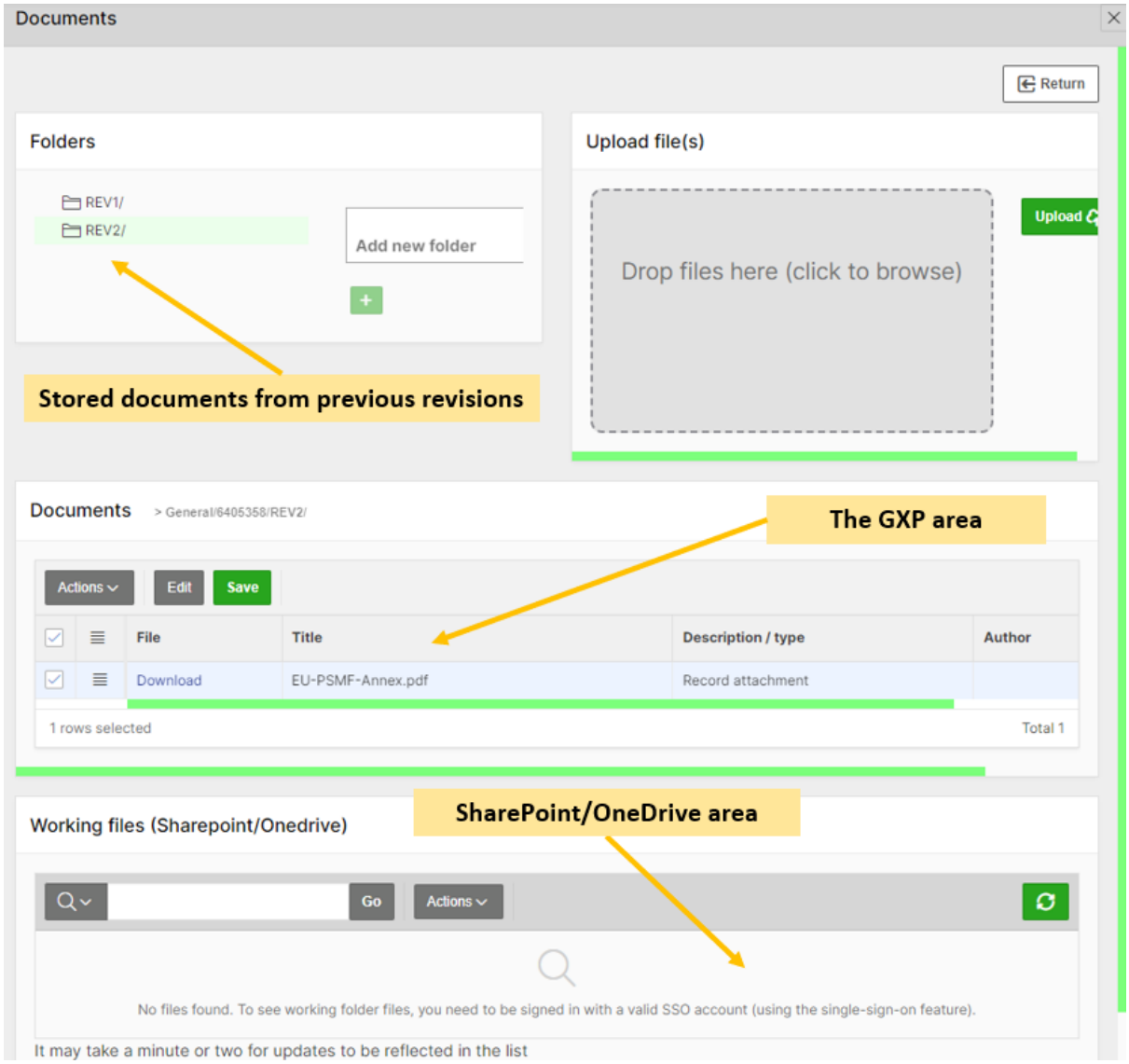

Figure 32 Attachment section areas

Once task actions are completed, fill in the **QC Check** form, this will automatically complete the step in the workflow. The Annex is now finalized and will proceed to the next step, **Complete records.**

4.6.4 Complete Records (Step 4)

Complete records is an automatic step that will close child records. No further action is required.

The child records of the **Main Body Document Compilation (QPPV Office)** workflow will show with status **COMPLETED** on the list of **Related Records.**

As standard, the **PSMF Details form** is available for review as 'Read-only' on completed workflows.

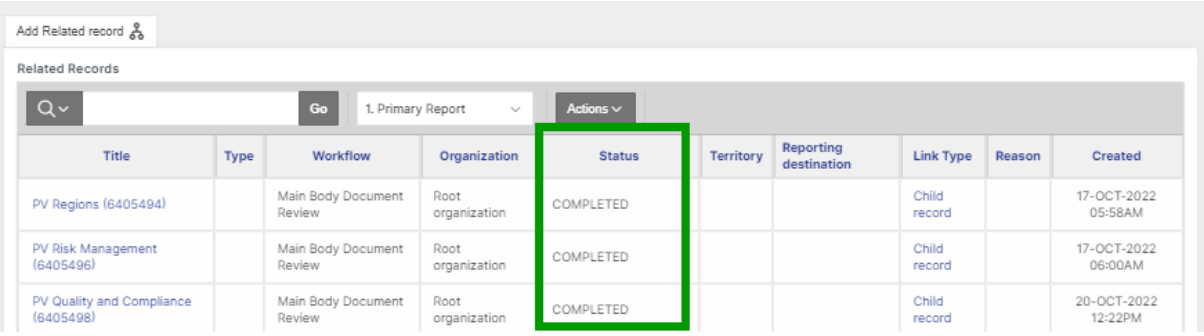

Figure 33 Related records after the Automator run in the automatic step 'Complete Records'

4.7 Workflow: Annex I.1 – Logbook

The workflow is composed of two steps. In the first step, users must fill in the **PSMF Details form** and generate Annex I.1 using a HALOPV document template for Annex I.1.

The second step is the approval step of the Annex I.1 document by the QPPV Office.

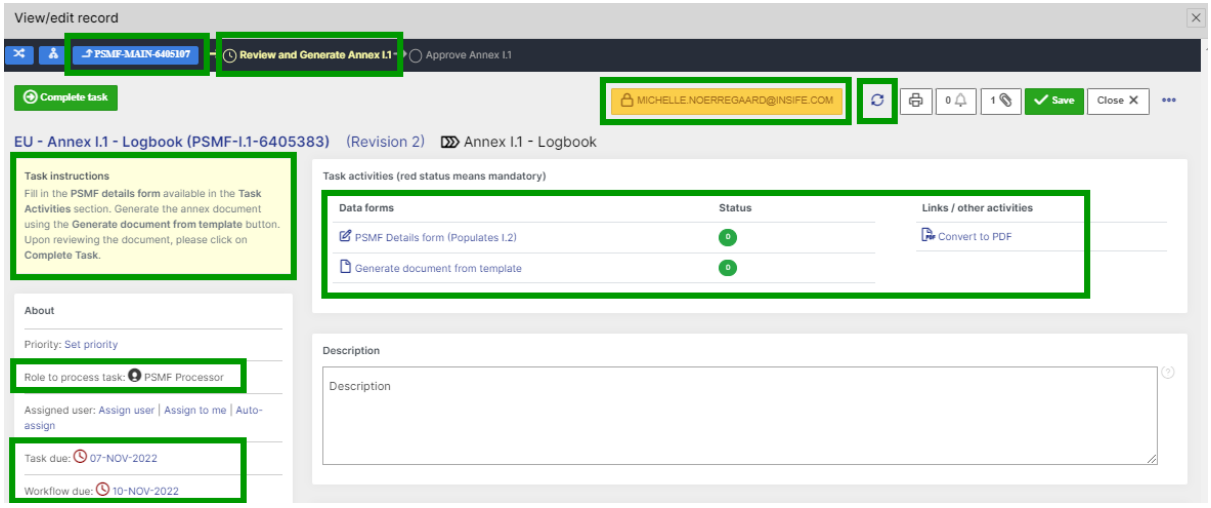

Figure 34 Example of Annex I.1 workflow

4.7.1 Review and Generate Annex I.1 (Step 1)

The **Review and Generate** step allows users to render Annex I.1 in Word or PDF format.

As with any other task in the application, you must have the corresponding role assigned to process the record in the task step.

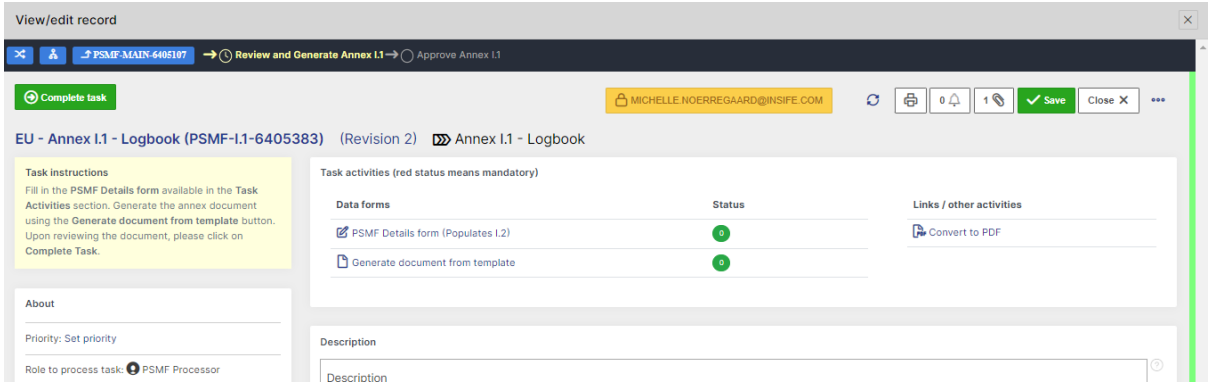

Figure 35 Review and Generate Annex I.1 (Step 1)

The task step instructions are shown in the application on the left side of the screen, highlighted in yellow. Please follow the task instruction for further information about the step.

Role to process task: PSMF Processor.
Task instructions (as shown in the application): Fill in the **PSMF Details form** available in the **Task Activities** section. Generate the annex document using the **Generate document from template** button. Upon reviewing the document, please click on **Complete Task**.

The task step contains the following activities:

Data form action	Description
PSMF Details form (Populates I.2)	This data form (mandatory) allows registering the **Data lock Point, Audit log notes,** and **Responsible**. These entries are required to populate and render **Annex I.2** Users can exclude the Annex revision by ticking the box **Exclude from PSMF Log (Annex I.2)** ***Note:*** *Entries in* ***the PSMF Details form*** *for active records will not be transferred to Annex I.2 unless the workflow is completed.*
Generate document from template	This form provides features to link a document template to a process record. Users can then select a document on a drop-down list. The document will be generated in Word or PDF and attached to the record. **Interactive report (Optional)** This option allows the selection of the interactive report for generation instead of the pre-defined interactive report configured in the Document generation template. This option requires that only one Interactive report placeholder is configured in the template **Template file (Optional)** This option allows the selection of the WORD template file to use for generation instead of the pre-defined template configured in the Document generation template **Template file from work (Optional)** This option allows the selection of the WORD template file to use for generation instead of the pre-defined template configured in the Document generation template **Upload to working folder** This option allows upload to the Working folder attachment area instead of the default attachment storage. This option is only available if a Working folder is configured (System configuration > OneDrive integration)

Data form action	Description
Convert to PDF	For documents located in HALO GxP area, you can use this form to convert Word or PowerPoint documents into PDF format.

The **PSMF Details form** requires mandatory data points for Annex I.2. Therefore, ensure you fill in the data lock point, the audit log notes, and the responsible. Depending on your system configuration, the annex version can be aligned with the HALO record revision. If not, ensure you also fill in the 'Version (manual)' field.

Please note that a red status in the form means a validation rule is active. Unless it is fulfilled, users cannot complete the step. Click on **Pending actions** to review the validation rules that apply to the form.

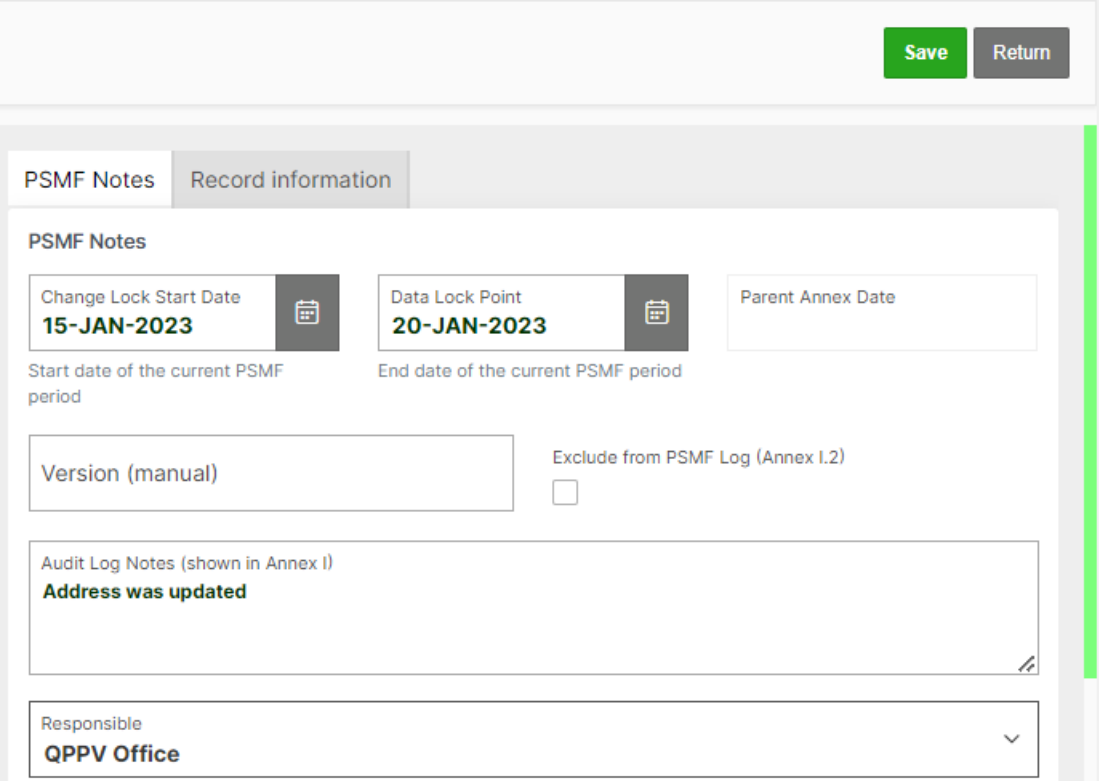

*Figure 36 Mandatory fields in the **PSMF Details form** required for Annex I.2*

Use the task action **Generate document from template** to generate the Annex. Select Word or PDF as the output format. If you click 'Upload working folder,' the document will be uploaded into HALO SharePoint (*Please ensure your company is subscribed to this service.)* SharePoint functionality can be used for the online reviewing of documents. In the case of Annex I.1, this is not required as data is stored in the system, and alteration to a rendered document will not affect the next revision rendering. So, ensure all entries in the Main Body Compilation are reviewed and no missing data points.

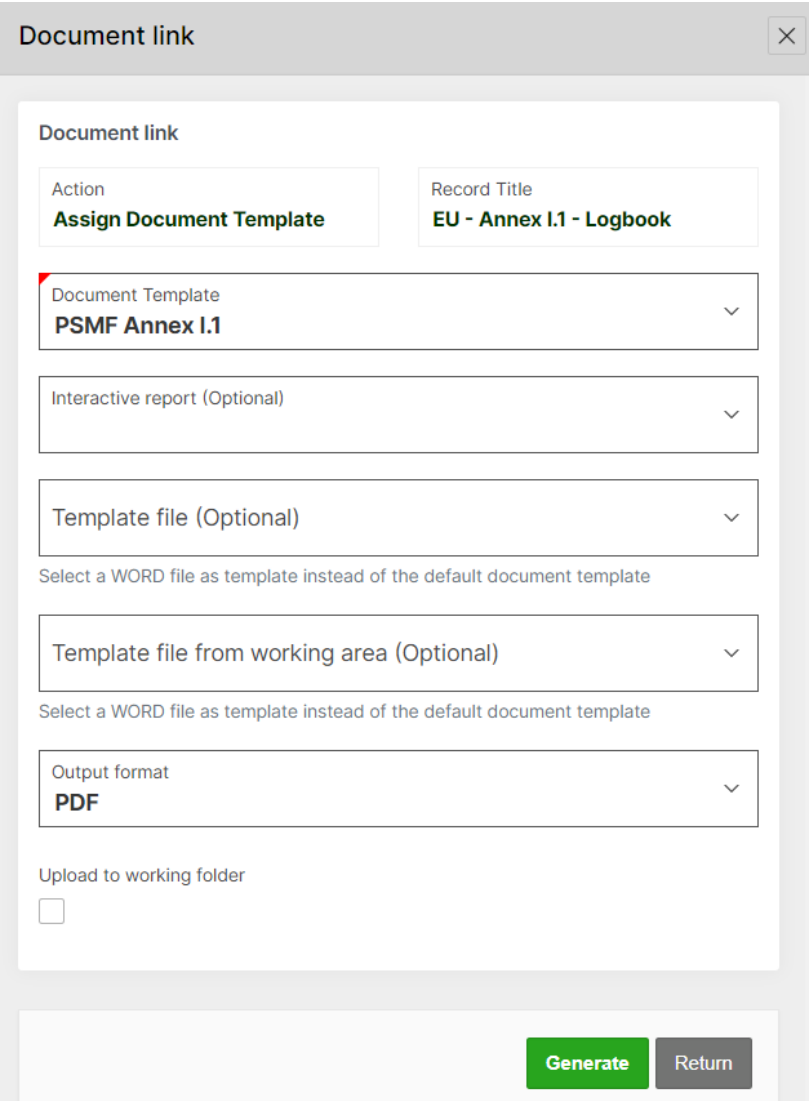

Figure 37 Example of the functionality 'Generate document from template' – how to select a HALOPV template and render an Annex

Access the document by clicking on the **Manage attachment** task or the paper clip icon in the upper right corner of the record. On the attachment area, '**Documents**' folder, click **Download** to review the document.

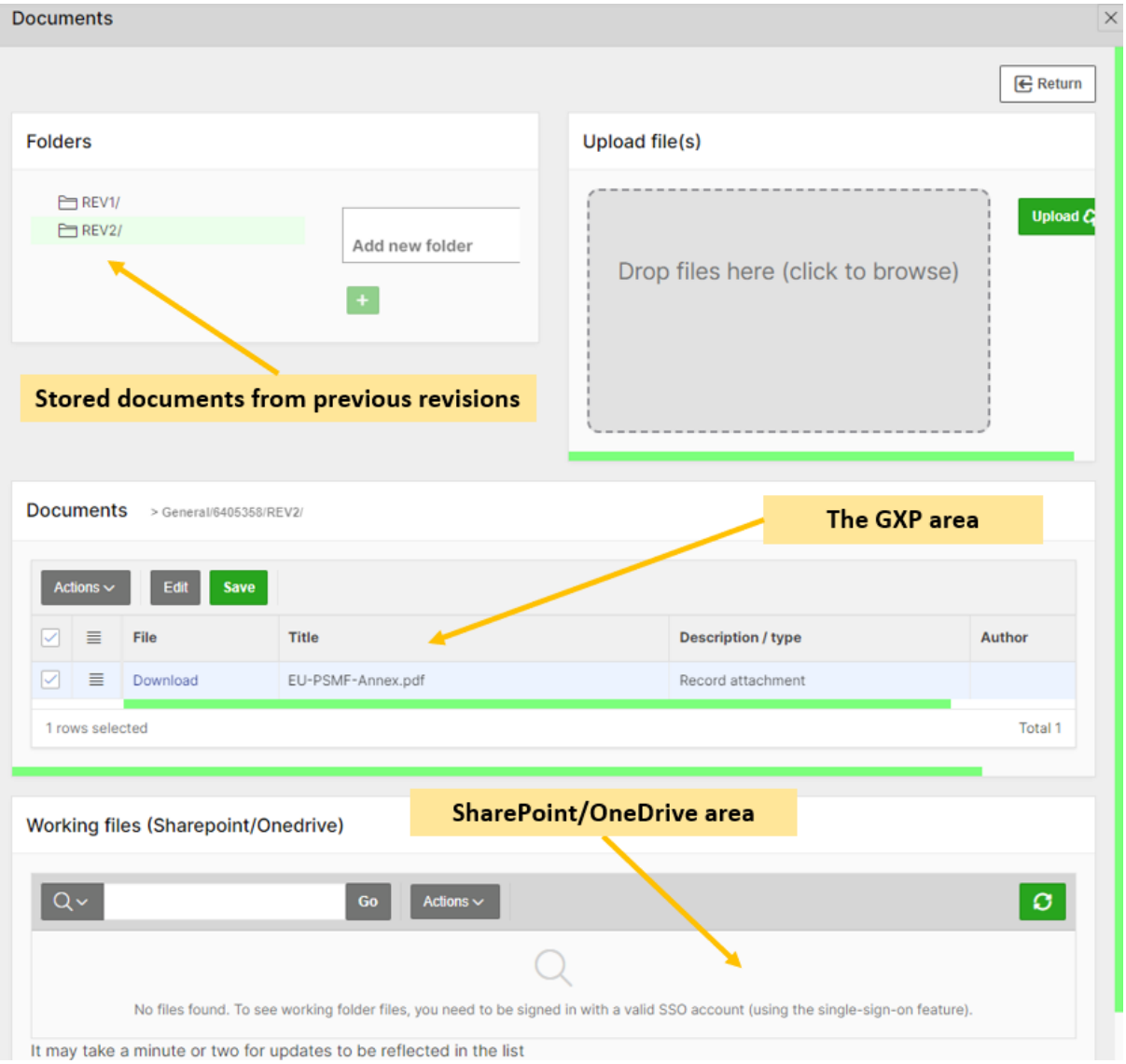

Figure 38 Attachment section areas

Additional tasks might be available in the step if you need to update the document, e.g., attach new documents and convert them to PDF.

Once task actions are completed, click on **Complete task**. And remember to click on **Close X;** otherwise, the user role in the next step will not be able to perform any actions.

4.7.2 Approve Annex I.1 (Step 2)

The **approval** step allows users to review the document in the attachment section. Click on the paper clip icon to review the document.

As with any other task in the application, you must have the corresponding role assigned to process the record in the task step.

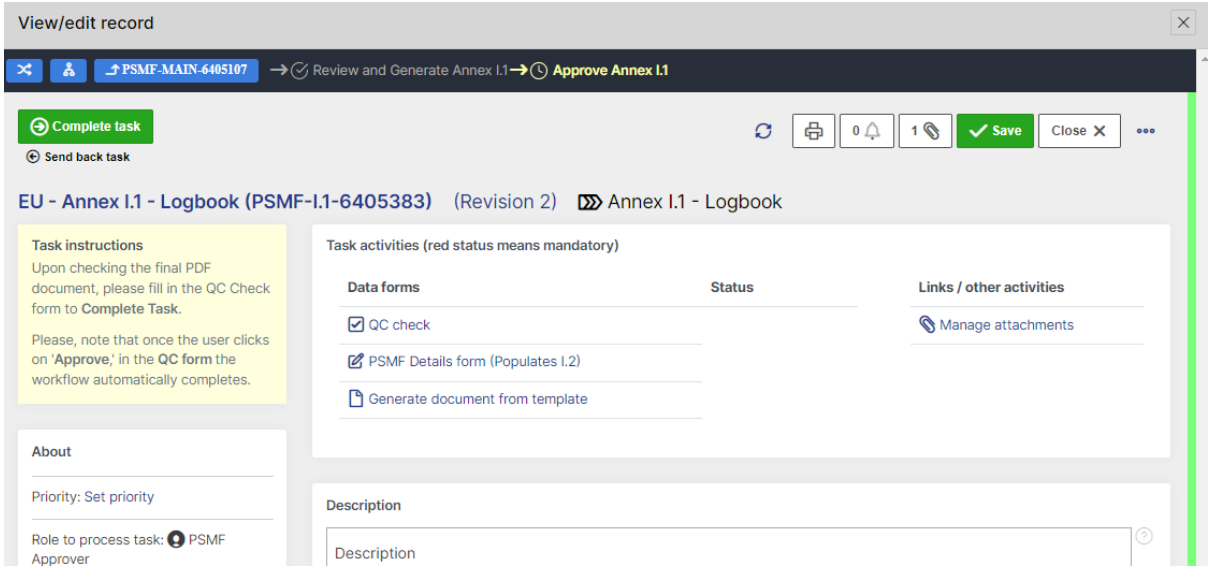

Figure 39 Approve Annex I.1 (Step 2)

The task step instructions are shown in the application on the left side of the screen, highlighted in yellow. Please follow the task instruction for further information about the step.

Role to process task: PSMF Approver.

Task instructions (as shown in the application): Upon checking the final PDF document, please fill in the **QC Check** form to Complete Task.

Please, note that once the user clicks on '**Approve**,' in the **QC form** the workflow automatically completes.

The task step contains the following activities:

Data form action	Description
QC Check	The page allows the QC reviewer to acknowledge the review and enter review comments. **Note:** The user completing the QC form cannot be the same user who completed the workflow's previous step. Please, note that once the user clicks on '**Approve**,' the workflow automatically completes.
Manage attachments	This form allows attaching the required documentation or reviewing existing documentation. **Note:** The attachment icon can be used as an alternative to the ***Manage attachments*** form. The attachment (paper clip) icon is in the record's upper right corner.
PSMF Details form (Populates I.2)	This data form (mandatory) allows registering the **Data lock Point, Audit log notes,** and **Responsible**. These entries are required to populate and render **Annex I.2** Users can exclude the Annex revision by ticking the box **Exclude from PSMF Log (Annex I.2)** ***Note:*** *Entries in **the PSMF Details form** for active records will not be transferred to Annex I.2 unless the workflow is completed.*

Data form action	Description
Generate document from template	This form provides features to link a document template to a process record. Users can then select a document on a drop-down list. The document will be generated in Word or PDF and attached to the record. **Interactive report (Optional)** This option allows the selection of the interactive report for generation instead of the pre-defined interactive report configured in the Document generation template. This option requires that only one Interactive report placeholder is configured in the template **Template file (Optional)** This option allows the selection of the WORD template file to use for generation instead of the pre-defined template configured in the Document generation template **Template file from work (Optional)** This option allows the selection of the WORD template file to use for generation instead of the pre-defined template configured in the Document generation template **Upload to working folder** This option allows upload to the Working folder attachment area instead of the default attachment storage. This option is only available if a Working folder is configured (System configuration > OneDrive integration)

The **PSMF Details form** requires mandatory data points for Annex I.2. Therefore, ensure you fill in the data lock point, the audit log notes, and the responsible. Depending on your system configuration, the annex version can be aligned with the HALO record revision. If not, ensure you also fill in the 'Version (manual)' field.

Please note that a red status in the form means a validation rule is active. Unless it is fulfilled, users cannot complete the step. Click on **Pending actions** to review the validation rules that apply to the form.

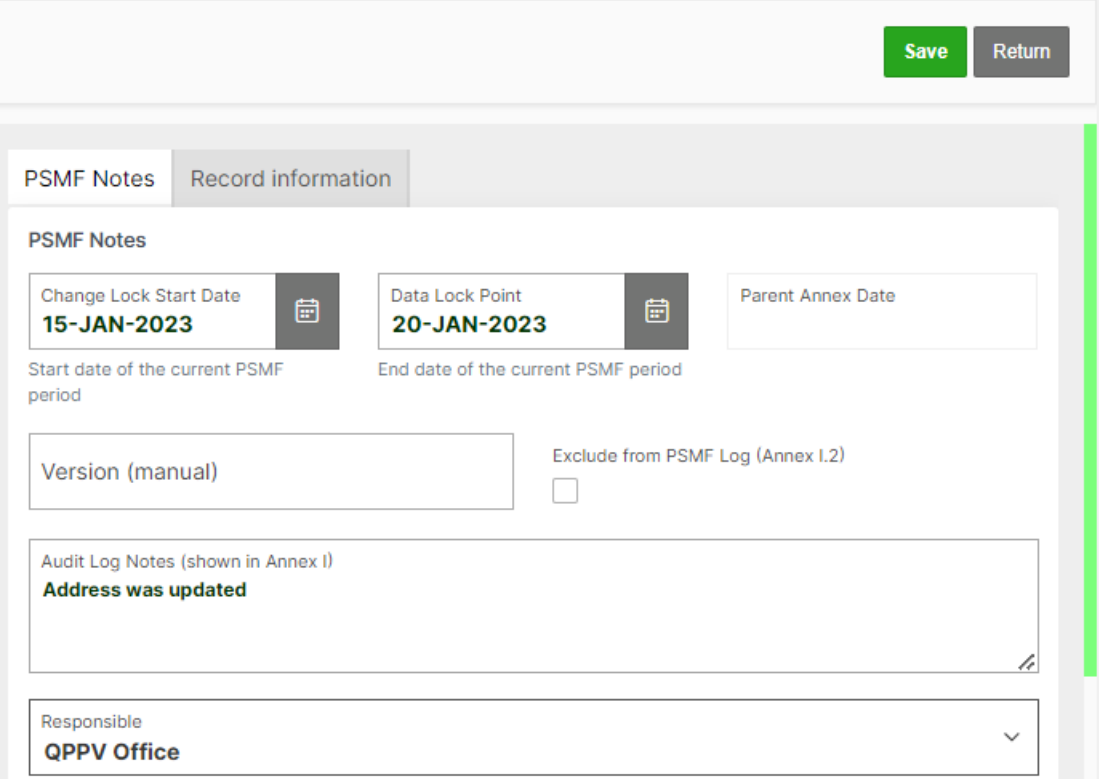

*Figure 40 Mandatory fields in the **PSMF Details form** required for Annex I.2*

Access the document by clicking on the **Manage attachment** task or the paper clip icon in the upper right corner of the record. On the attachment area, '**Documents**' folder, click **Download** to review the document.

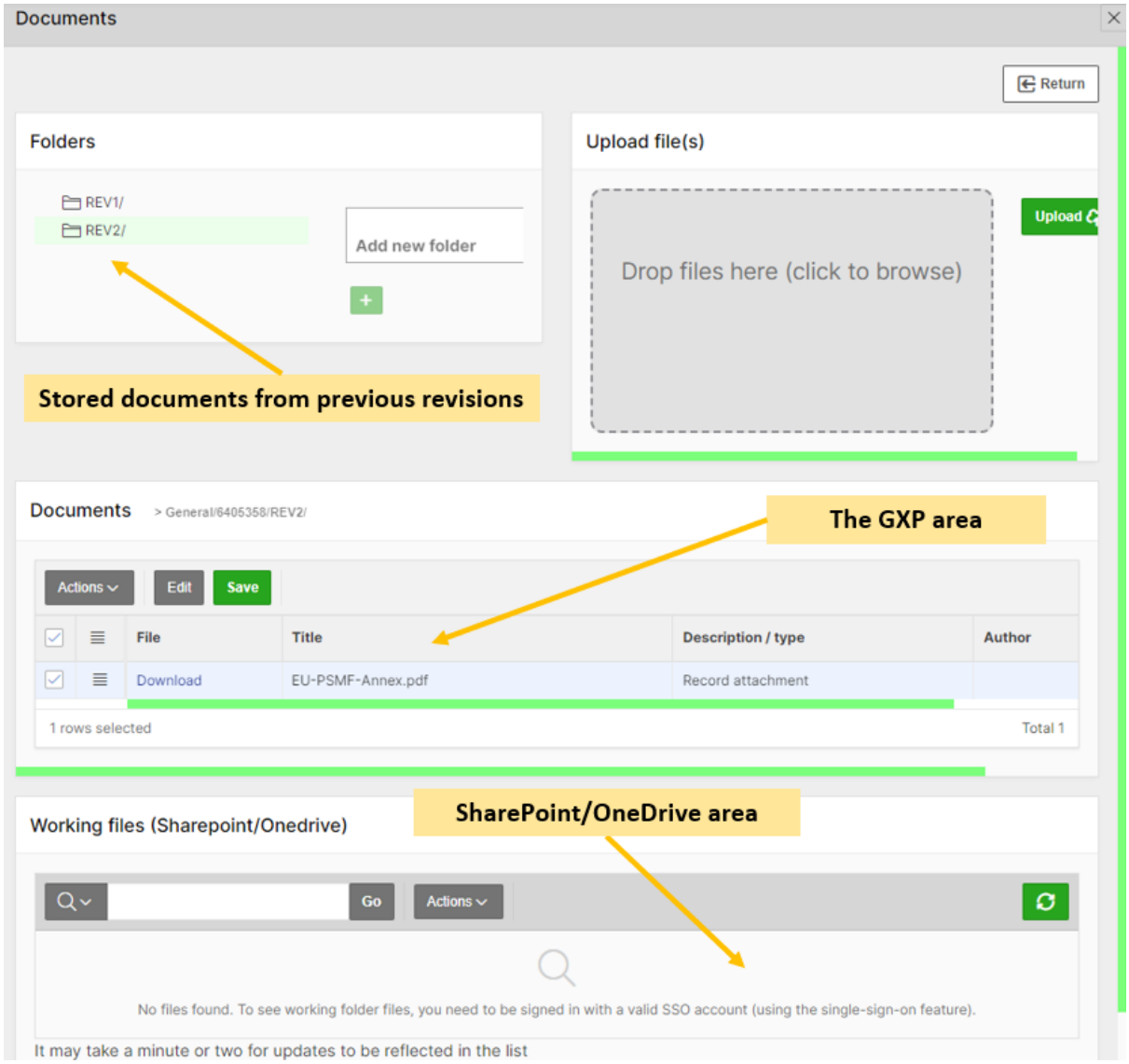

Figure 41 Attachment section areas

Additional tasks might be available in the step if you need to update the document, e.g., render the latest version.

After reviewing the document, please complete the **QC Check** form. This form will automatically complete the workflow. The Annex is now finalized, and the workflow is at rest.

4.8 Workflow: Annex I.2 – History of Changes for Annex Contents

The workflow is composed of two steps. In the first step, the user must generate Annex I.2 in Word or PDF format using the HALOPV document template for Annex I.2.

The second step is the approval step of the Annex I.2 document. The user must fill in the **PSMF Details form** and ensure Annex I.2 is in PDF format.

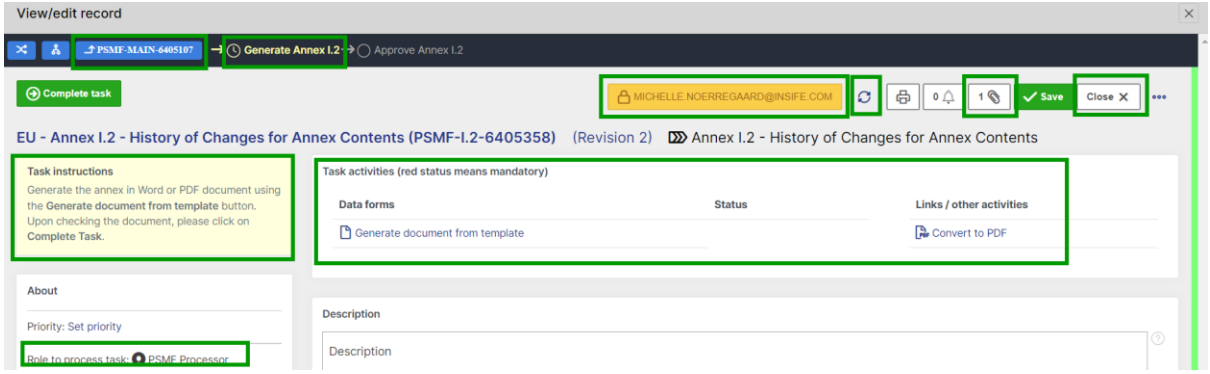

Figure 42 Example of Annex I.2 workflow

4.8.1 Generate Annex I.2 (Step 1)

The first step allows users to generate the Annex.

As with any other task in the application, you must have the corresponding role assigned to process the record in the task step.

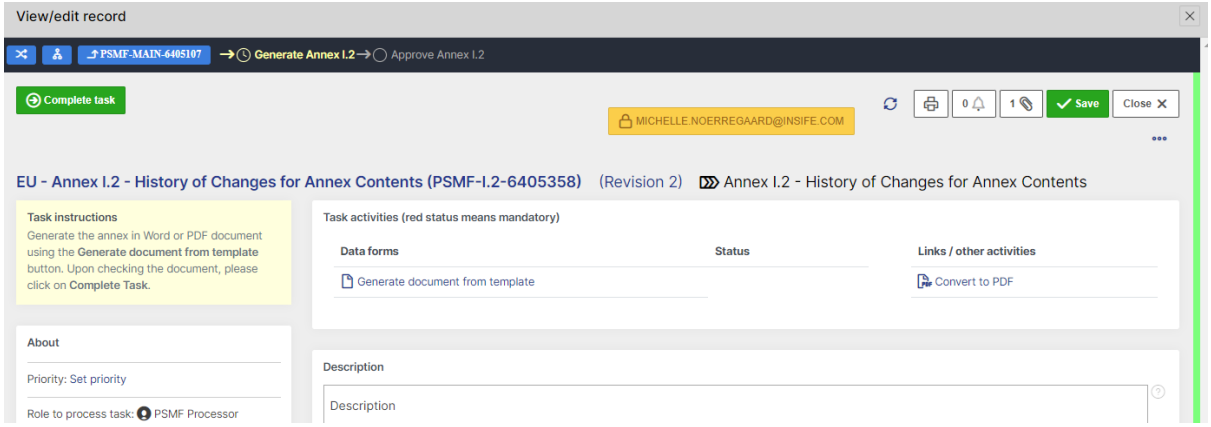

Figure 43 Approve Annex I.2 (Step 1)

The task step instructions are shown in the application on the left side of the screen, highlighted in yellow. Please follow the task instruction for further information about the step.

Role to process task: PSMF Processor.

Task instructions (as shown in the application): Generate the Annex in Word or PDF document using the **Generate document from template** button. Upon checking the document, please click on **Complete Task**.

The task step contains the following activities:

Data form action	Description
Generate document from template	This form provides features to link a document template to a process record. Users can then select a document on a drop-down list. The document will be generated in Word or PDF and attached to the record. **Interactive report (Optional)** This option allows the selection of the interactive report for generation instead of the pre-defined interactive report configured in the Document generation template. This option requires that only one Interactive report placeholder is configured in the template **Template file (Optional)** This option allows the selection of the WORD template file to use for generation instead of the pre-defined template configured in the Document generation template **Template file from work (Optional)** This option allows the selection of the WORD template file to use for generation instead of the pre-defined template configured in the Document generation template **Upload to working folder** This option allows upload to the Working folder attachment area instead of the default attachment storage. This option is only available if a Working folder is configured (System configuration > OneDrive integration)
Convert to PDF	For documents located in HALO GxP area, you can use this form to convert Word or PowerPoint documents into PDF format.

Use the task action **Generate document from template** to generate the Annex. Select Word or PDF as the output format. If you click 'Upload working folder,' the document will be uploaded into HALO SharePoint (*Please ensure your company is subscribed to this service.)* SharePoint functionality can be used for the online reviewing of documents. In the case of Annex I.2, this is not required as data is stored in the system, and alteration to a rendered document will not affect the next revision rendering. So, ensure all entries in the Main Body Compilation are reviewed and no missing data points.

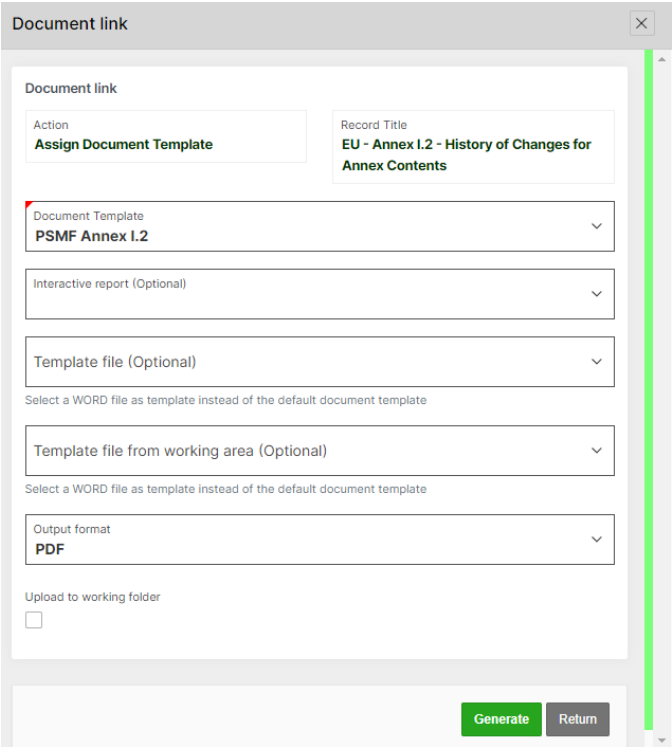

Figure 44 Example of the functionality 'Generate document from template' – how to select a HALOPV template and render an Annex

Access the document by clicking on the **Manage attachment** task or the paper clip icon in the upper right corner of the record. On the attachment area, '**Documents'** folder, click **Download** to review the document.

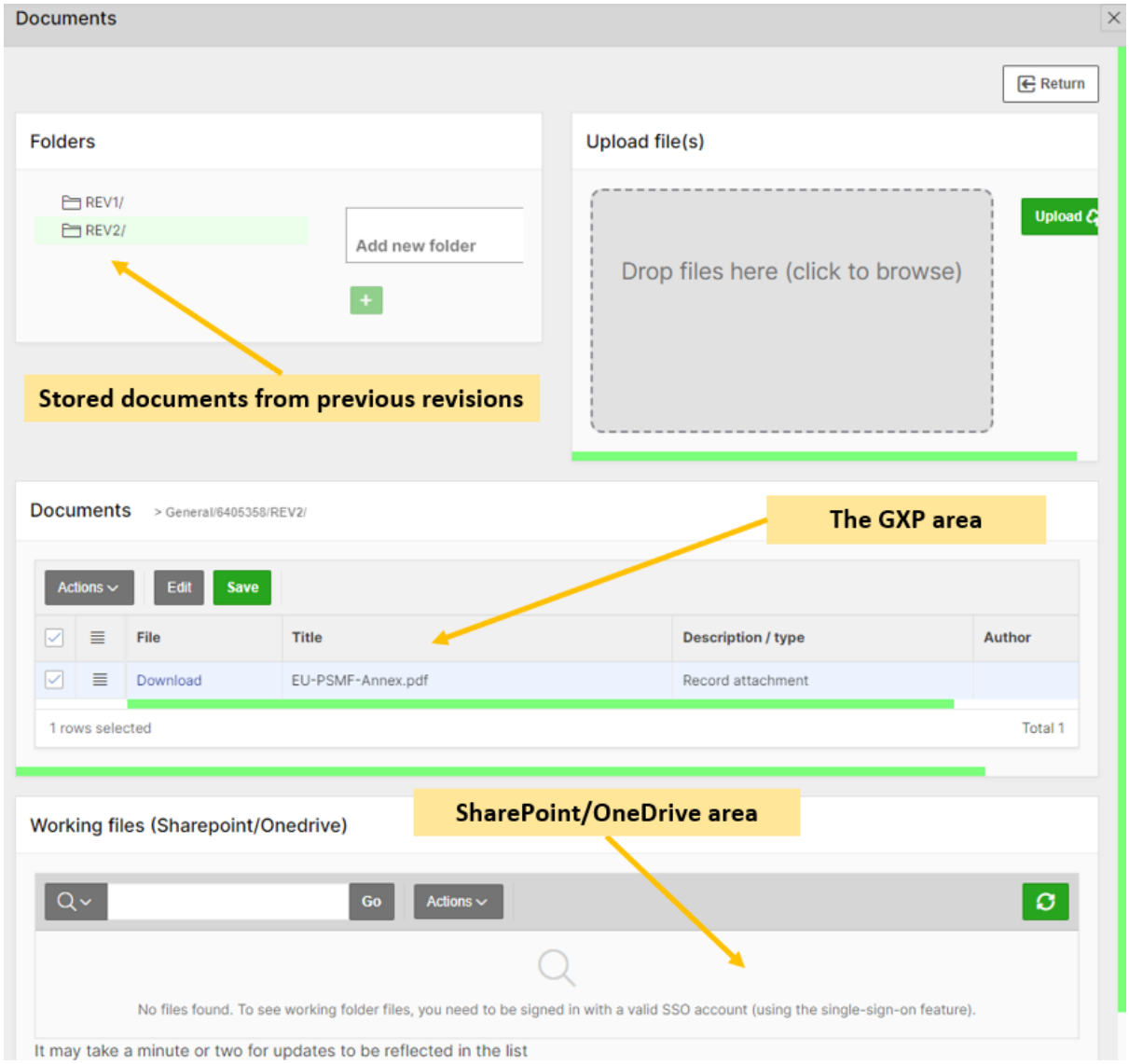

Figure 45 Attachment section areas

Additional tasks might be available in the step if you need to update the document, e.g., attach new documents and convert them to PDF.

Once task actions are completed, click on **Complete task**. And remember to click on **Close X;** otherwise, the user role in the next step will not be able to perform any actions.

4.8.2 Approve Annex I.2 (Step 2)

The **approval** step allows users to review the document in the attachment section, and fill in the PSMF Details form.

As with any other task in the application, you must have the corresponding role assigned to process the record in the task step.

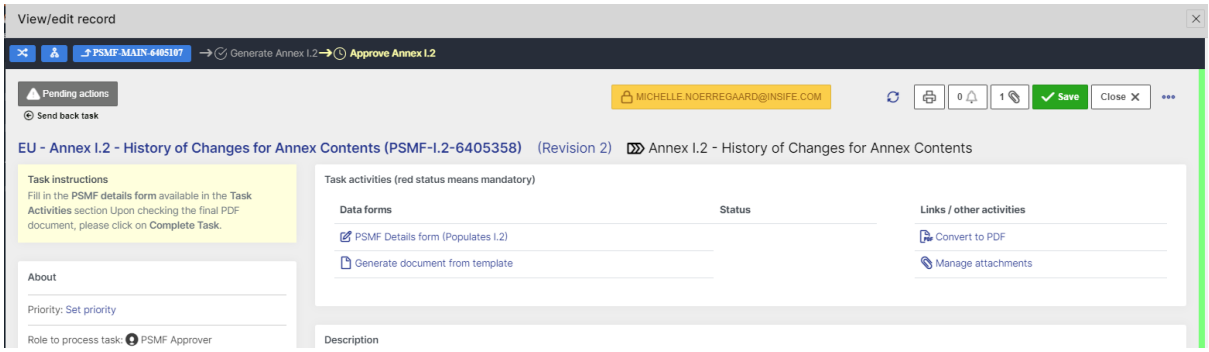

Figure 46 Approve Annex I.2 (Step 2)

The task step instructions are shown in the application on the left side of the screen, highlighted in yellow. Please follow the task instruction for further information about the step.

Role to process task: PSMF Approver.

Task instructions (as shown in the application): Fill in the **PSMF details form** available in the **Task Activities** section Upon checking the final PDF document, please click on **Complete Task**.

The task step contains the following activities:

Data form action	Description
PSMF Details form (Populates I.2)	This data form (mandatory) allows registering **Data lock Point, Audit log notes,** and **Responsible**. These entries are required to populate and render **Annex I.2** Users can exclude the Annex revision by ticking the box **Exclude from PSMF Log (Annex I.2)** ***Note:*** *Except in Annex I.2. Entries in* ***PSMF Details form*** *for active records will not be transferred to Annex I.2 unless the workflow is completed.*
Generate document from template	This form provides features to link a document template to a process record. Users can then select a document on a drop-down list. The document will be generated in Word or PDF and attached to the record. **Interactive report (Optional)** This option allows the selection of the interactive report for generation instead of the pre-defined interactive report configured in the Document generation template. This option requires that only one Interactive report placeholder is configured in the template **Template file (Optional)** This option allows the selection of the WORD template file to use for generation instead of the pre-defined template configured in the Document generation template **Template file from work (Optional)** This option allows the selection of the WORD template file to use for generation instead of the pre-defined template configured in the Document generation template **Upload to working folder** This option allows upload to the Working folder attachment area instead of the default attachment storage. This option is only available if a Working folder is configured (System configuration > OneDrive integration)
Convert to PDF	For documents located in HALO GxP area, you can use this form to convert Word or PowerPoint documents into PDF format.

Data form action	Description
Manage attachments	This form allows attaching the required documentation or reviewing existing documentation. **Note:** The attachment icon can be used as an alternative to the ***Manage attachments*** form. The attachment (paper clip) icon is located in the upper right corner of the record.

The **PSMF Details form** requires mandatory data points for Annex I.2. Therefore, ensure you fill in the data lock point, the audit log notes, and the responsible. Depending on your system configuration, the annex version can be aligned with the HALO record revision. If not, ensure you also fill in the 'Version (manual)' field.

Please note that a red status in the form means that a validation rule is active. Unless it is fulfilled, users cannot complete the step. Click on **Pending actions** to review the validation rules that apply to the form.

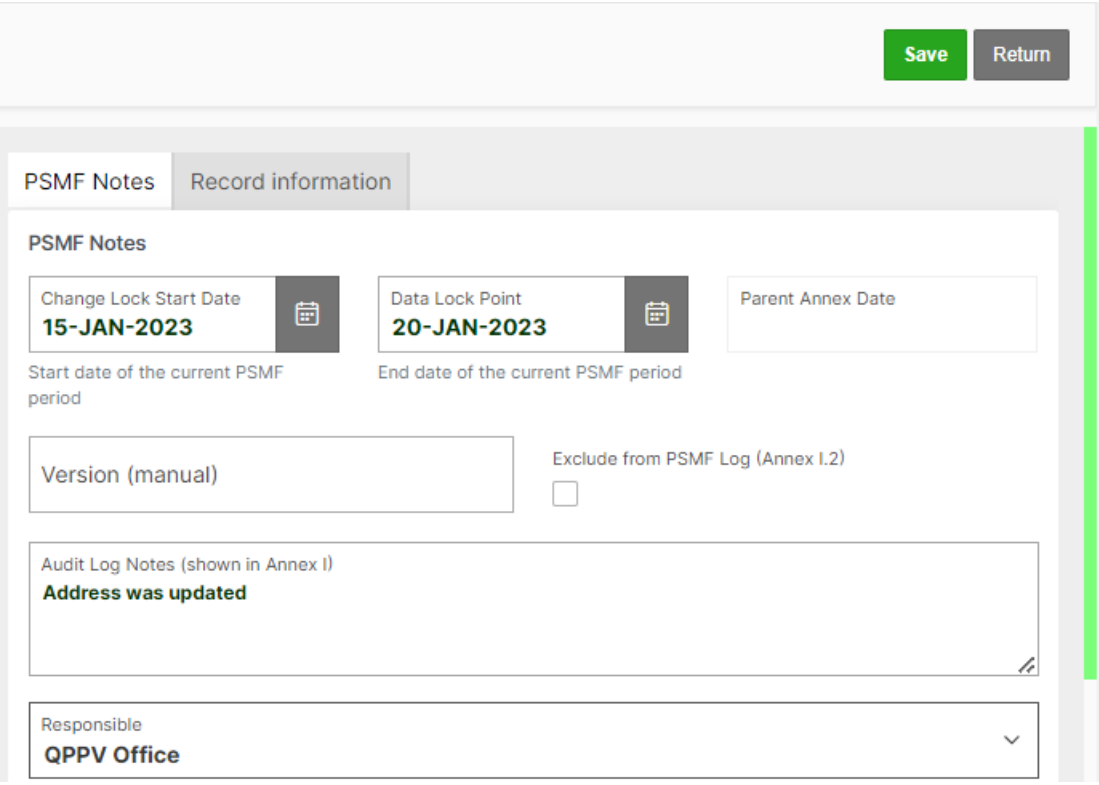

*Figure 47 Mandatory fields in the **PSMF Details form** required for Annex I.2*

Access the document by clicking on the **Manage attachment** task or the paper clip icon in the upper right corner of the record. On the attachment area, '**Documents'** folder, click **Download** to review the document.

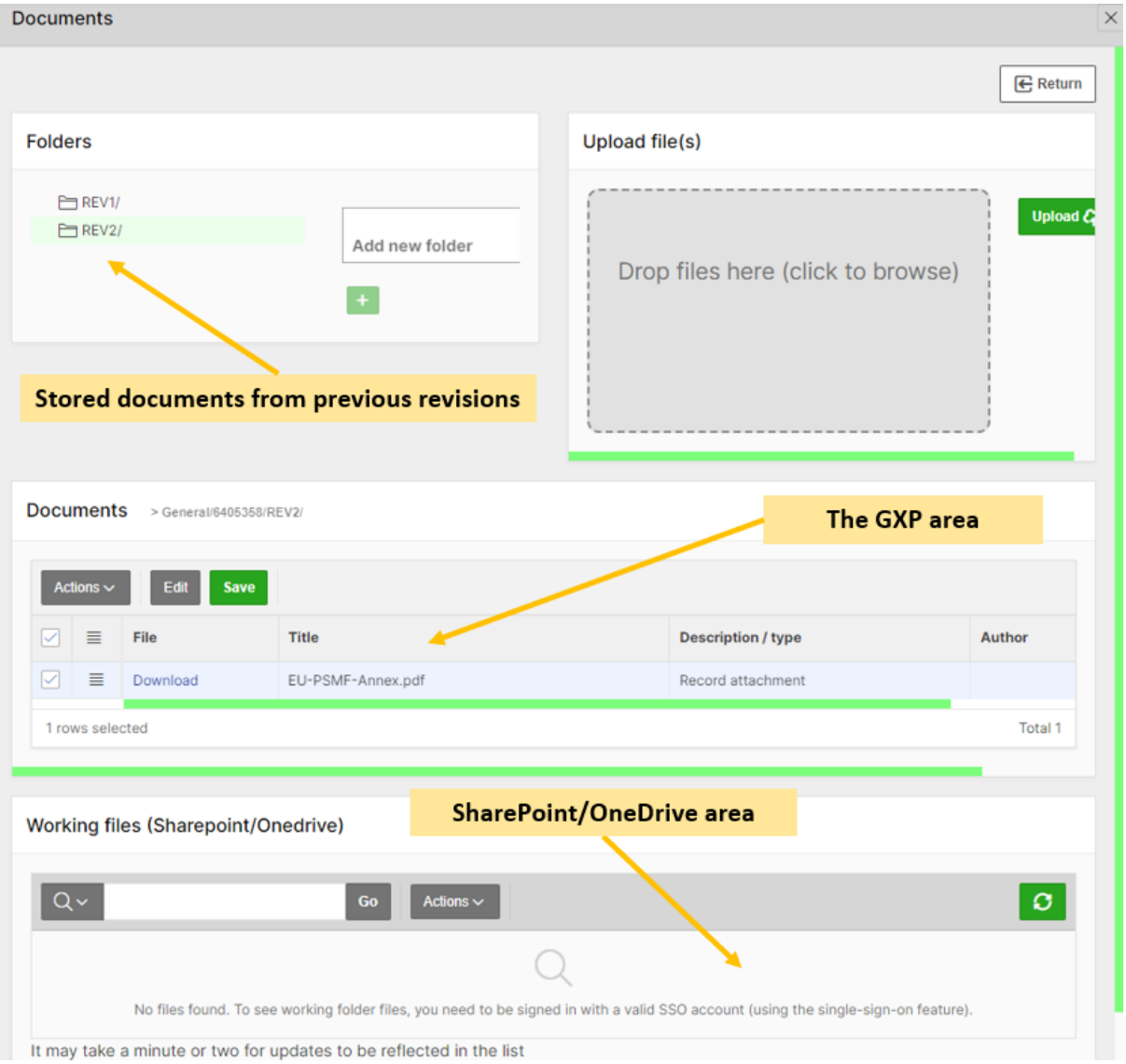

Figure 48 Attachment section areas

Additional tasks might be available in the step if you need to update the document, e.g., attach new documents and convert them to PDF.

Once task actions are completed, click on **Complete task**. The Annex is now finalized, and the workflow is at rest.

4.9 Workflow: Core PSMF

The workflow allows users to compile and merge the Main Body and Annexes into a PDF document.

The **Core PSMF** workflow is composed of three steps. In the first step, the user must merge all required annexes. In the second step, the user Review the final version of the PSMF, and in the third step, the user approves and finalizes the overall PSMF creation process.

In this user manual, we use the configuration of the EU PSMF as a reference. But additional PSMF can also be managed (as shown below), e.g., UK PSMF, FR PSMF, etc. New Core PSMFs can be stored as individual parent workflows with dedicated child records, segregated by country and organizational entity.

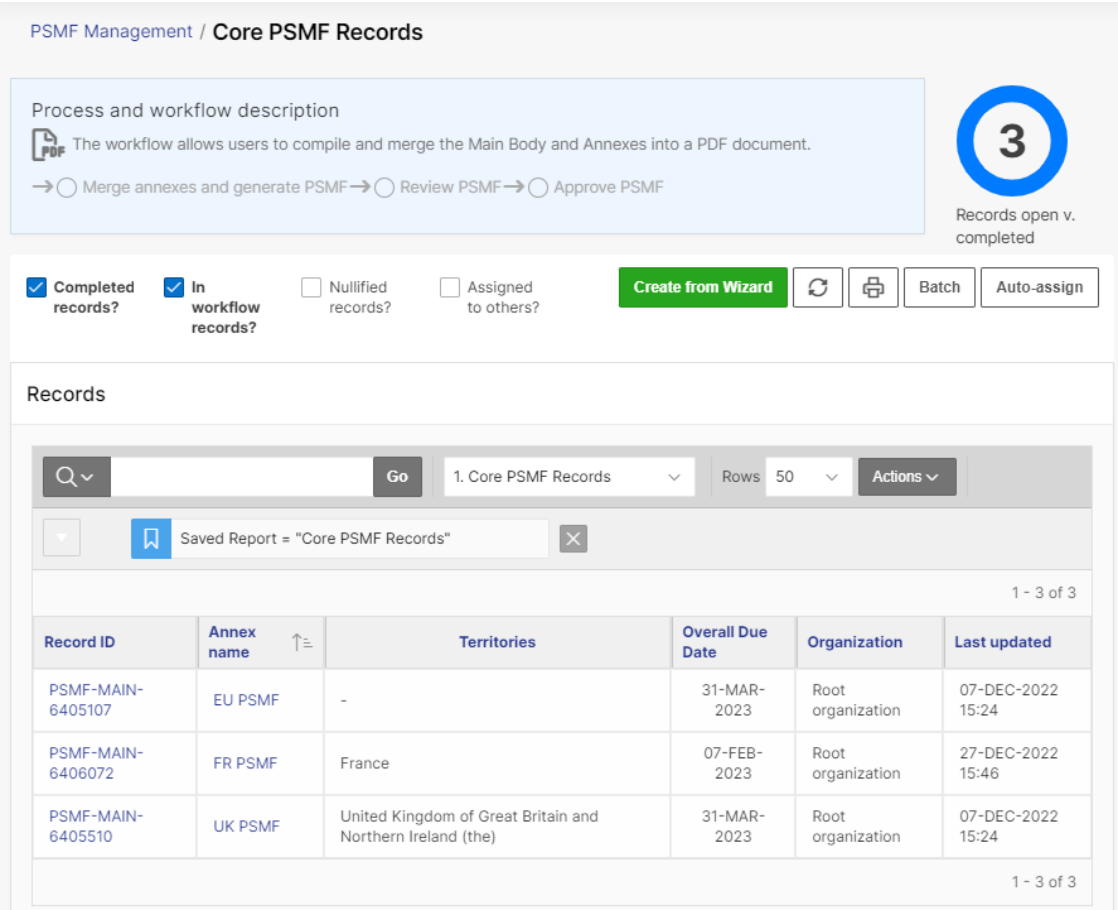

Figure 49 Example of the Core PSMF – List of records

Users can upload previous document compilations to the current PSMF.

- To review attachments in previous workflow revisions, click on the attachment icon in your current version and go to the section **Folders**. To review specific revision documentation, click on the **Revision** next to the record title, select the revision number you want to inspect, and then click on the attachment icon of the record. **Download** it if needed, and upload it to the current record revision.

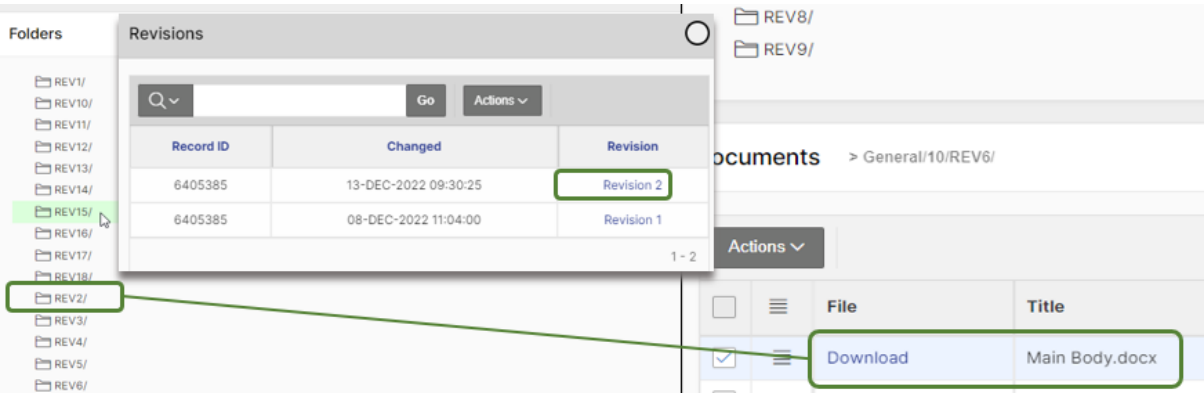

Figure 50 Example of how to access old revisions and download documents from previous revisions

4.9.1 Merge Annex and Generate PSMF (Step 1)

The first step allows users to merge the Main Body and annexes.

As with any other task in the application, you must have the corresponding role assigned to process the record in the task step.

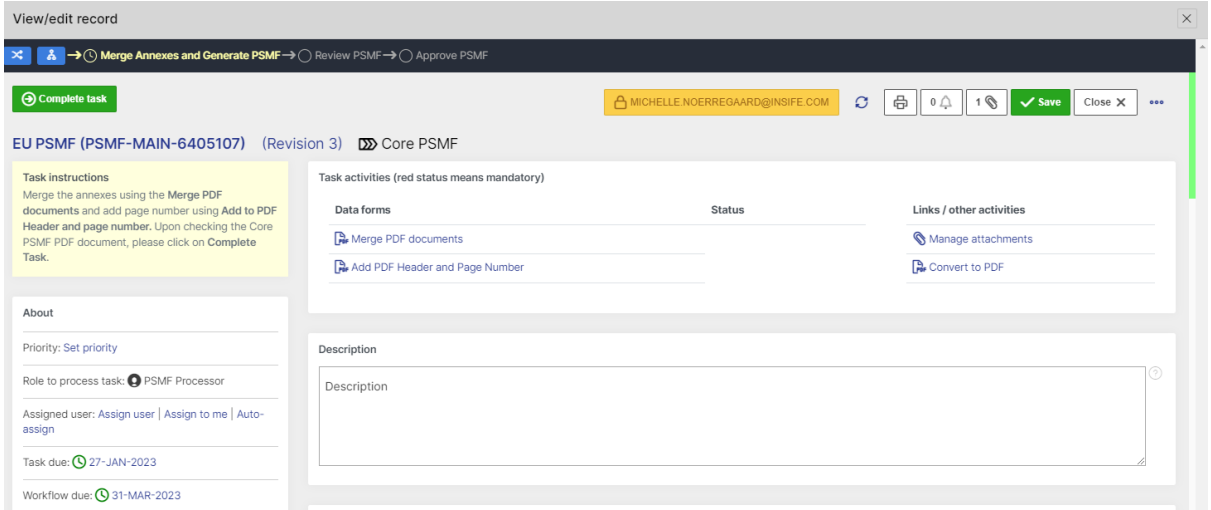

Figure 51 Example of the Core PSMF- EU PSMF (Step 1)

Please, ensure all annexes workflows are completed before merging the final PSMF. You can check the current **Status** of the Annexes by going to the button of the record and reviewing the section **Related Records,** as shown below.

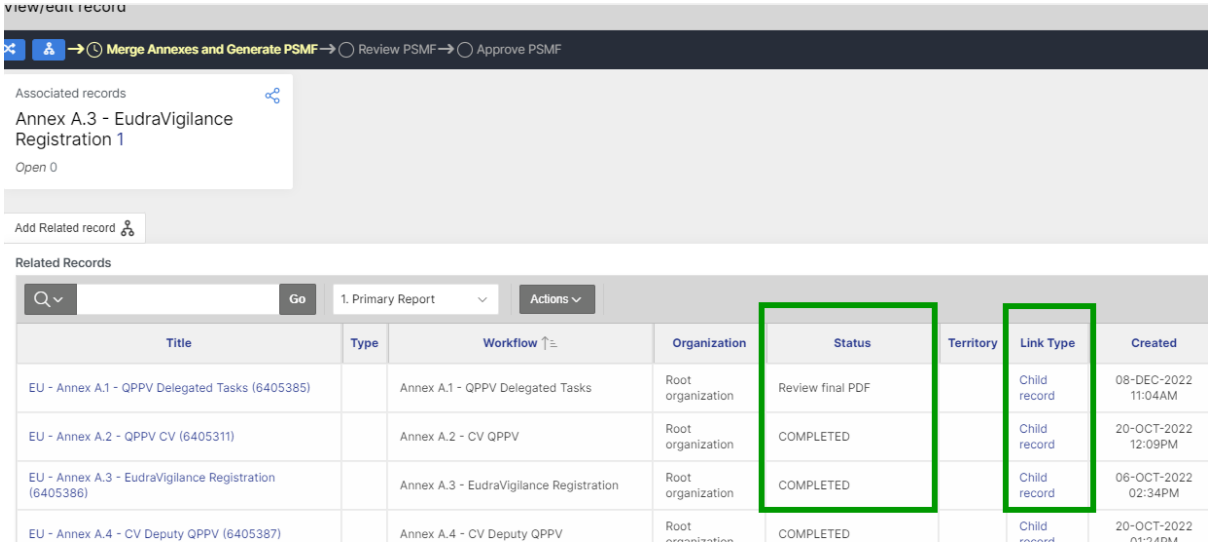

Figure 52 EU PSMF – List of child/related records indicating 'Status'

The task step instructions are shown in the application on the left side of the screen, highlighted in yellow. Please follow the task instruction for further information about the step.

Role to process task: PSMF Processor.

Task instructions (as shown in the application): Merge the annexes using the **Merge PDF documents** and add page number using **Add to PDF Header and page number.** Upon checking the Core PSMF PDF document, please click on **Complete Task**.

The task step contains the following activities:

Data form action	Description
Merge PDF documents	This form allows merging multiple PDF files from the current record and child records (latest approved revision). The selected files will be merged, and the final, merged document will be available for download or upload directly into the record.
Add PDF Header and Page Number	This form provides features to add headers, and footer - including page numbers to PDF documents.
Manage attachments	This form allows attaching the required documentation or reviewing existing documentation. **Note:** The attachment icon can be an alternative to the ***Manage attachments*** form. The attachment (paper clip) icon is in the record's upper right corner.
Convert to PDF	For documents located in the HALO GxP area, you can use this form to convert Word or PowerPoint documents into PDF format.

Merge the PDFs for Main Body and all required Annexes to create the overall PSMF document.

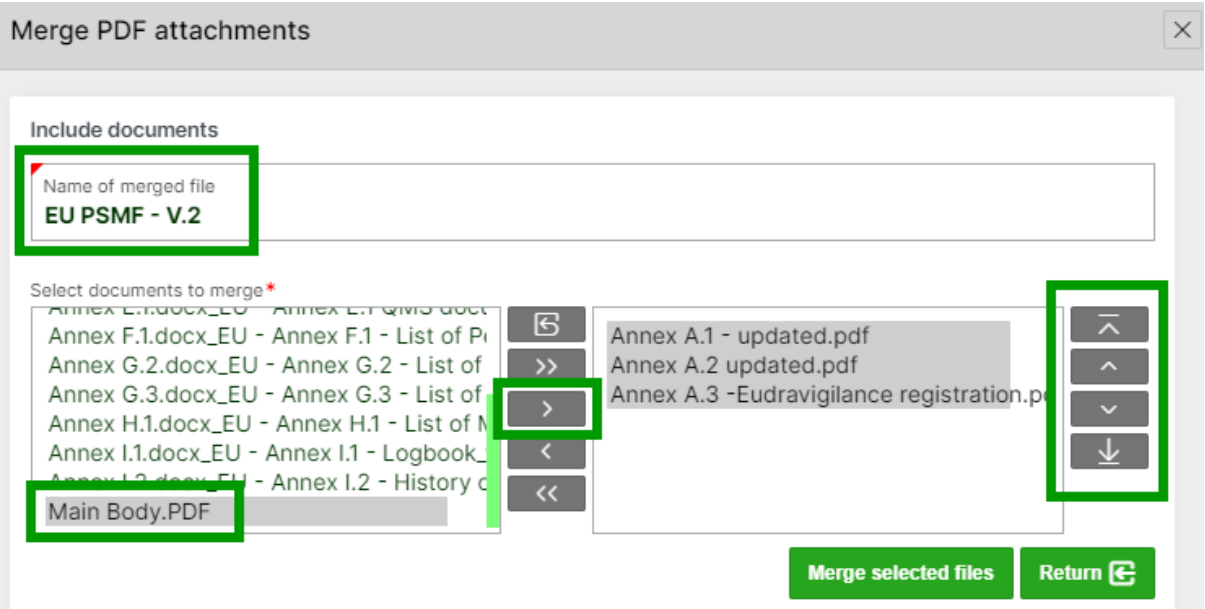

Figure 53 Merge PDF documents using the arrows to select available PDFs in current annexes

1. Start by selecting all relevant documents which should be included in the PSMF. Use the arrows to shift the documents to the PSMF relevant box (right).
2. Add a name for the overall PSMF document
3. Define the sequence of the Annexes by selecting the document and selecting the arrows to shift the document in the correct order.
4. Click on **Merge selected files**. The compiled PSMF document is saved in the HALOPV GxP attachment area.

Access the document by clicking on the **Manage attachment** task or the paper clip icon in the upper right corner of the record. On the attachment area, '**Documents'** folder, click **Download** to review the document.

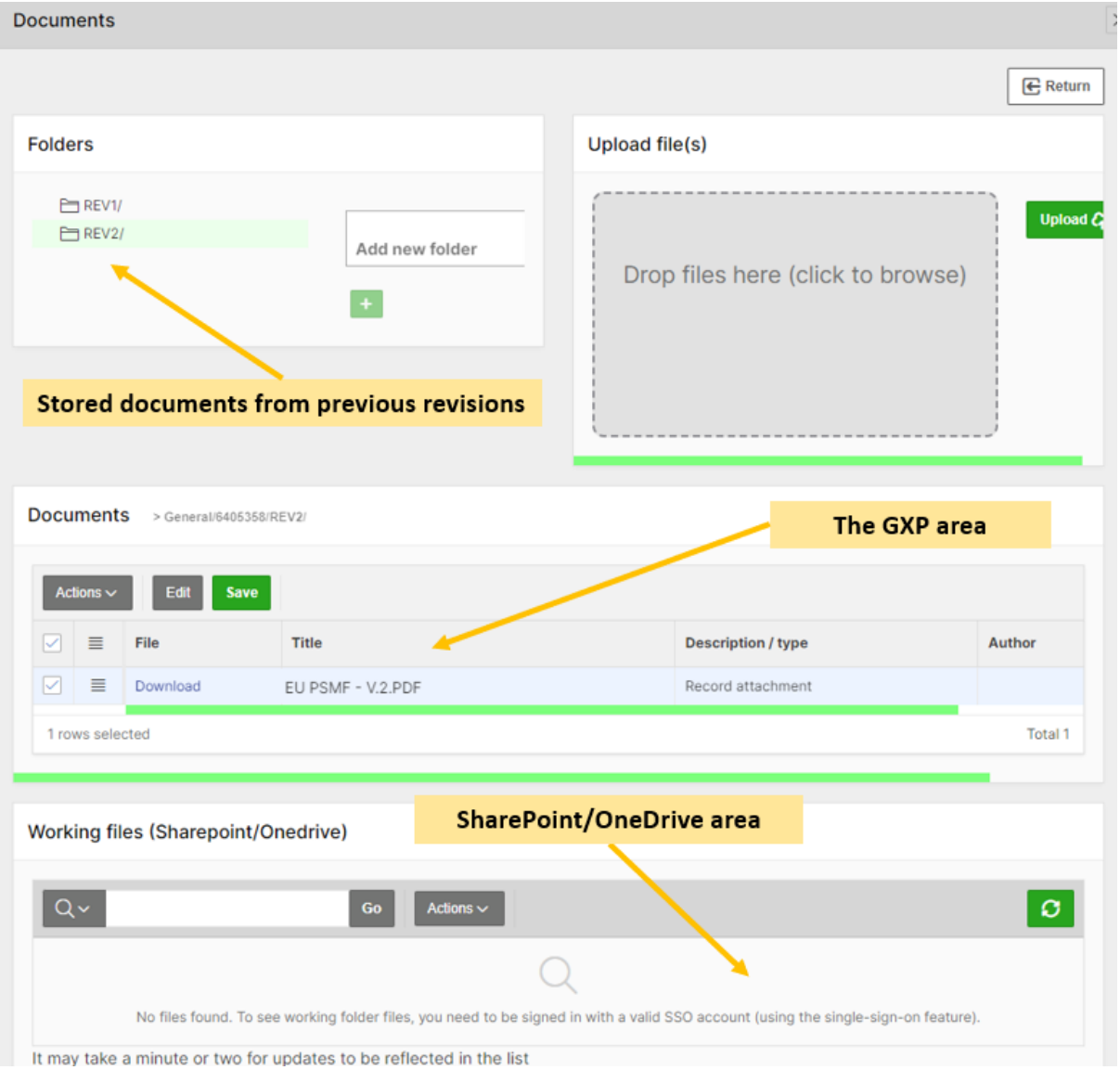

Figure 54 Attachment section areas

Include the page numbers for all pages of the PSMF using **Add PDF Header and Page Number.**

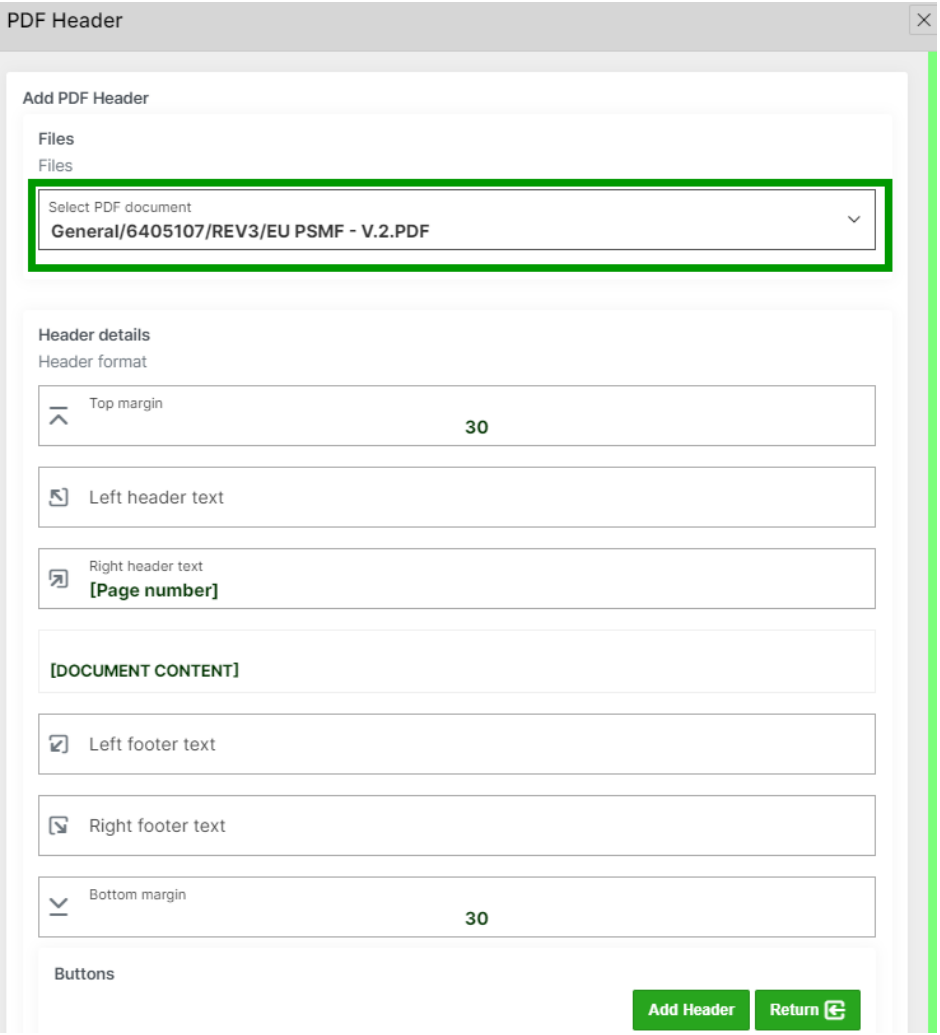

Figure 55 'Add PDF Header and Page Number' data form

1. Select the created PSMF document as PDF, in this case 'EU PSMF – V. 2.PDF'
2. If needed, add Header and Footer. But remember that HALO templates already contain both.
3. Click on **Add Header** to generate the page number. The document is now stored in the attachment area of HALOPV.

Additional tasks might be available in the step if you need to update the document, e.g., attach new documents and convert them to PDF.

Once task actions are completed, click on **Complete task.** And remember to click on **Close X**; otherwise, the user role in the next step will not be able to perform any actions.

4.9.2 Review PSMF (Step 2)

The second step allows users to review the compiled PSMF document.

As with any other task in the application, you must have the corresponding role assigned to process the record in the task step.

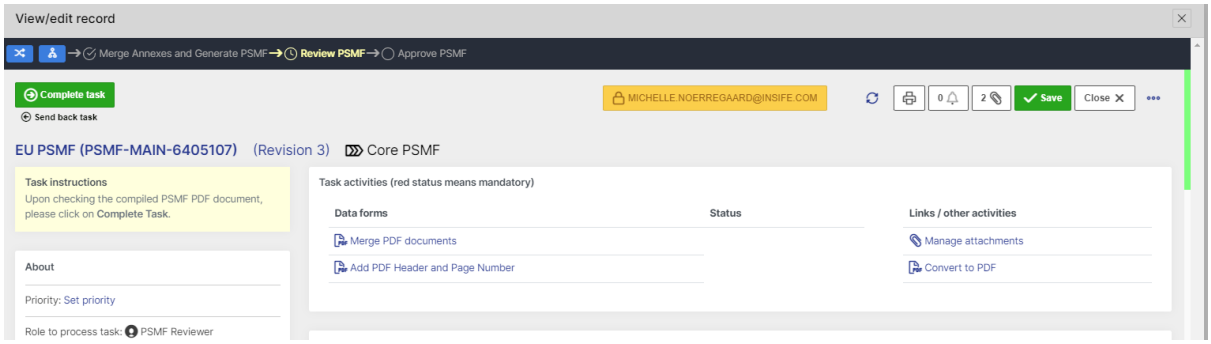

Figure 56 Example of the Core PSMF- EU PSMF (Step 2)

The task step instructions are shown in the application on the left side of the screen, highlighted in yellow. Please follow the task instruction for further information about the step.

Role to process task: PSMF Reviewer.

Task instructions (as shown in the application): Upon checking the compiled PSMF PDF document, please click on **Complete Task**.

The task step contains the following activities:

Data form action	Description
Merge PDF documents	This form allows merging multiple PDF files from the current record and child records (latest approved revision). The selected files will be merged, and the final merged document will be available for download or upload directly into the record.
Add PDF Header and Page Number	This form provides features to add headers and footer - including page numbers, to PDF documents.
Manage attachments	This form allows attaching the required documentation or reviewing existing documentation. **Note:** The attachment icon can be an alternative to the ***Manage attachments*** form. The attachment (paper clip) icon is in the record's upper right corner.
Convert to PDF	For documents located in the HALO GxP area, you can use this form to convert Word or PowerPoint documents into PDF format.

Additional tasks might be available in the step if you need to update the document, e.g., attach new documents and convert them to PDF.

Access the document by clicking on the **Manage attachment** task or the paper clip icon in the upper right corner of the record. On the attachment area, '**Documents**' folder, click **Download** to review the document.

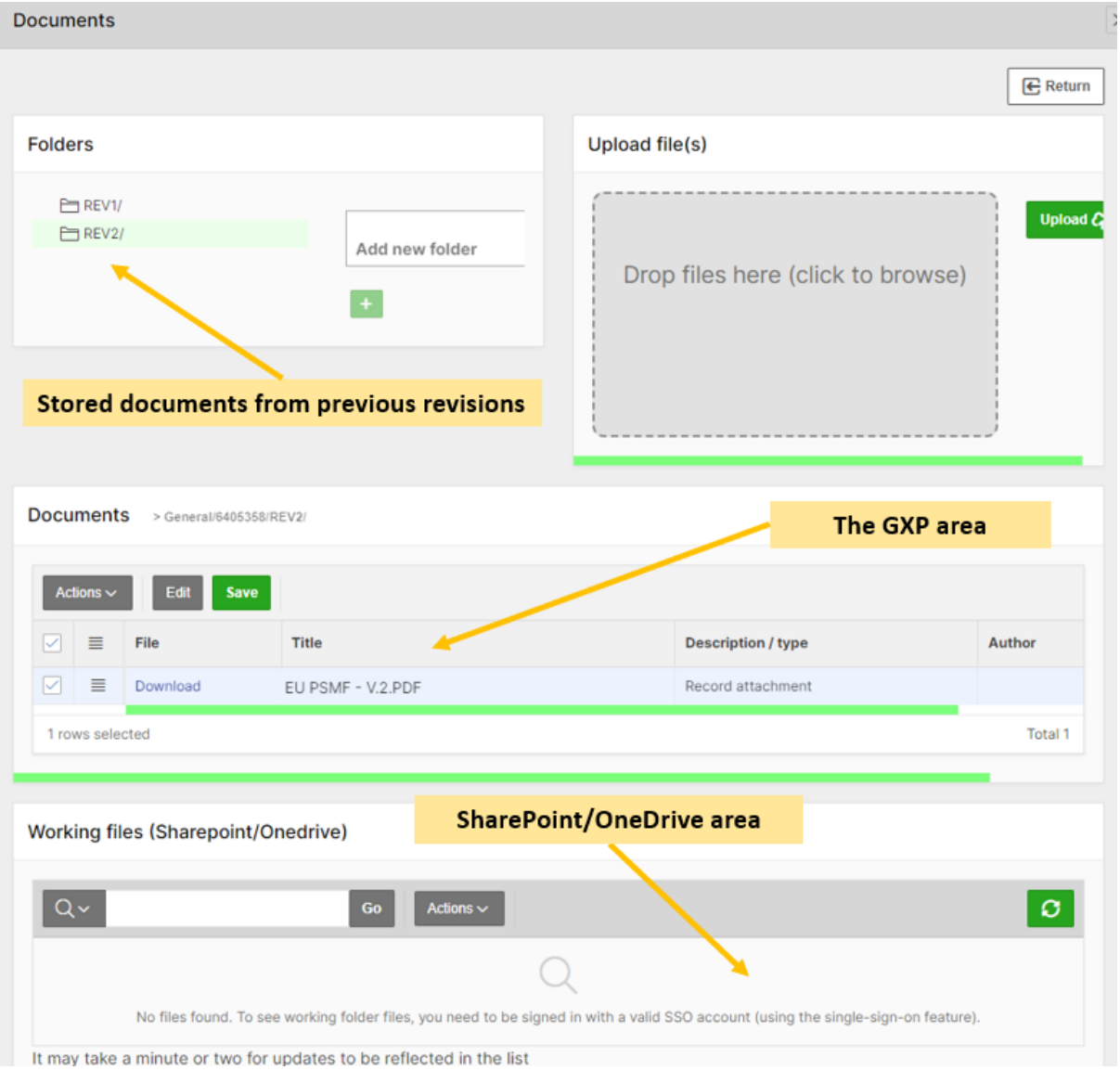

Figure 57 Attachment section areas

Once the review is completed, click on **Complete task.** And remember to click on **Close X**; otherwise, the user role in the next step will not be able to perform any actions.

4.9.3 Approve PSMF (Step 3)

The third step allows users to **Approve** the document and complete the record revision.

As with any other task in the application, you must have the corresponding role assigned to process the record in the task step.

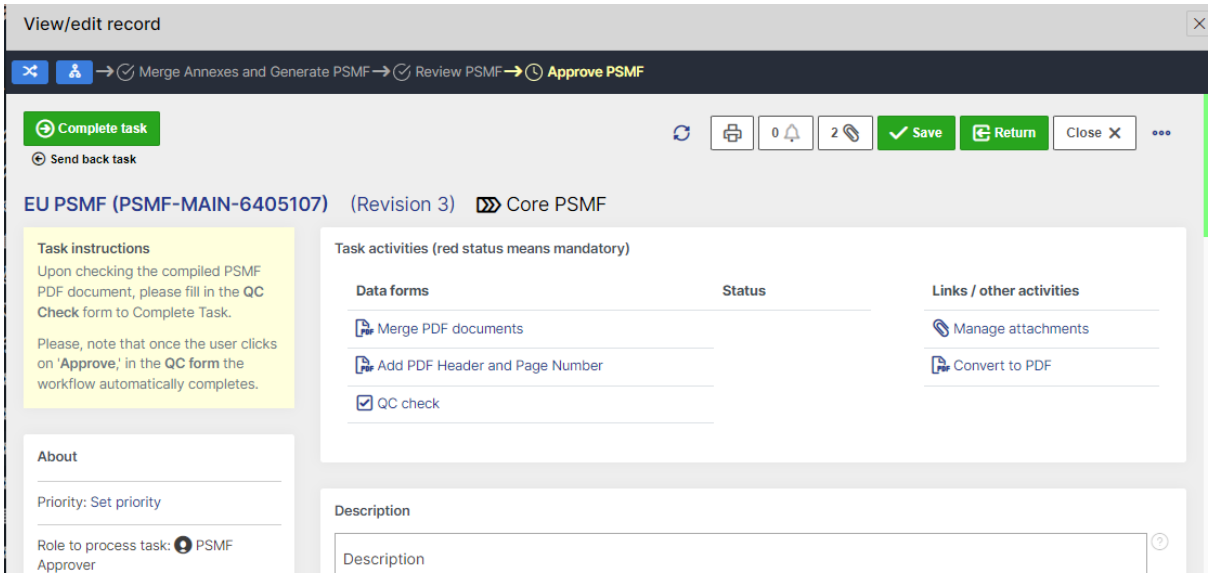

Figure 58 Example of the Core PSMF- EU PSMF (Step 3)

The task step instructions are shown in the application on the left side of the screen, highlighted in yellow. Please follow the task instruction for further information about the step.

Role to process task: PSMF Approver.

Task instructions (as shown in the application): Upon checking the compiled PSMF PDF document, please fill in the **QC Check** form to Complete Task.

Please, note that once the user clicks on **'Approve,'** in the **QC form** the workflow automatically completes.

The task step contains the following activities:

Data form action	Description
Merge PDF documents	This form allows merging multiple PDF files from the current record and child records (latest approved revision). The selected files will be merged, and the final, merged document will be available for download or upload directly into the record.
Add PDF Header and Page Number	This form provides features to add headers, and footer - including page numbers to PDF documents.
QC Check	The page allows the QC reviewer to acknowledge the review and enter review comments. **Note:** The user completing the QC form cannot be the same user who completed the workflow's previous step. Please, note that once the user clicks on '**Approve**,' the workflow automatically completes.
Manage attachments	This form allows attaching the required documentation or reviewing existing documentation. **Note:** The attachment icon can be used as an alternative to the ***Manage attachments*** form. The attachment (paper clip) icon is in the record's upper right corner.
Convert to PDF	For documents located in the HALO GxP area, you can use this form to convert Word or PowerPoint documents into PDF format.

Additional tasks might be available in the step if you need to update the document, e.g., attach new documents and convert them to PDF.

Access the document by clicking on the **Manage attachment** task or the paper clip icon in the upper right corner of the record. On the attachment area, '**Documents**' folder, click **Download** to review the document.

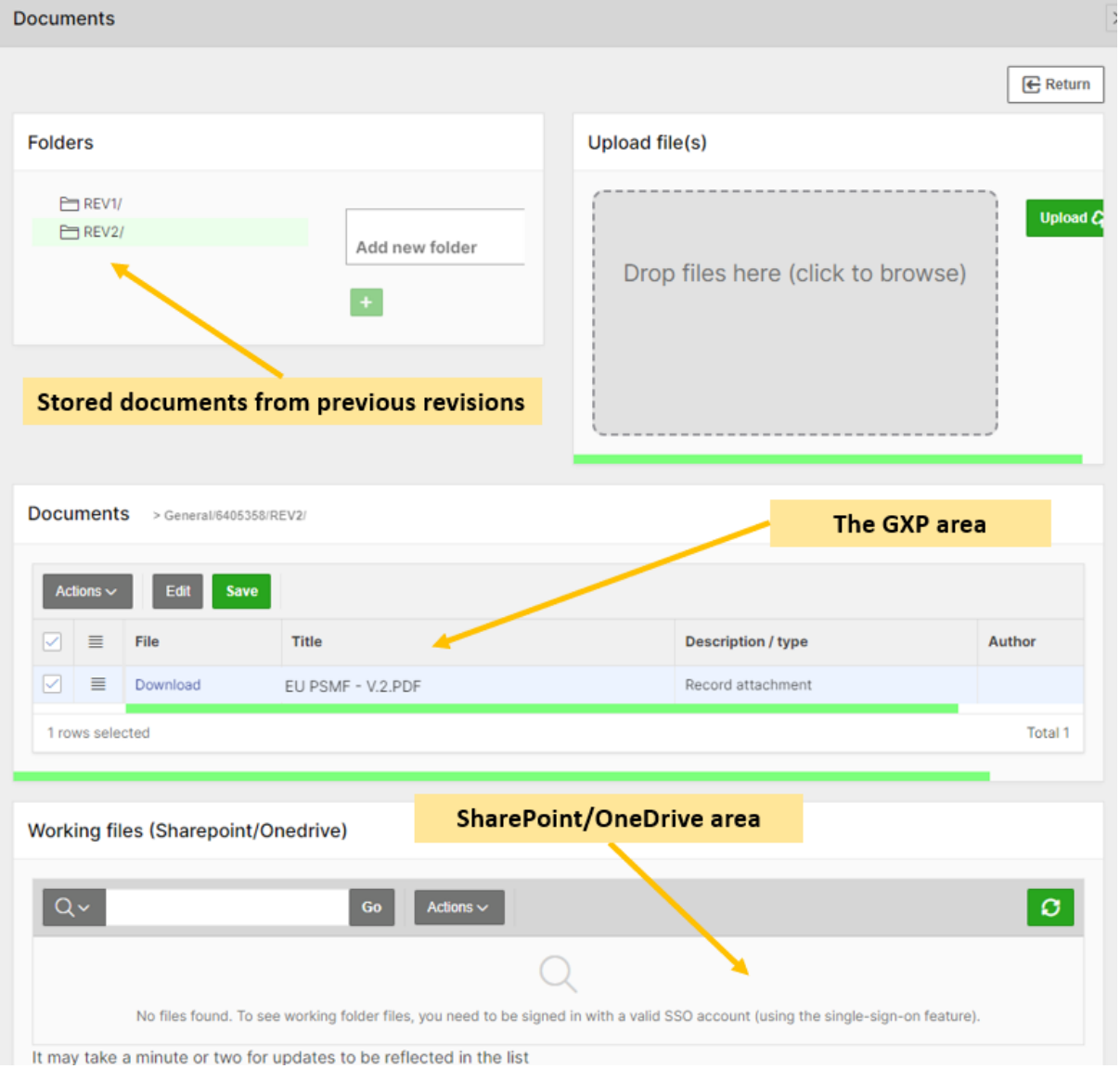

Figure 59 Attachment section areas

After reviewing the document, please complete the **QC Check** form. This form will automatically complete the workflow**.**

The PSMF Compilation is now finalized, and the workflow is at rest.

To review additional HALOPV **User Guides** and **User Manuals** please visit our website https://insife.com/halopv-user-guides-tutorials or contact your system administrator.