Management of SOPs through Q-Pulse Guide

Contents

1. Introduction

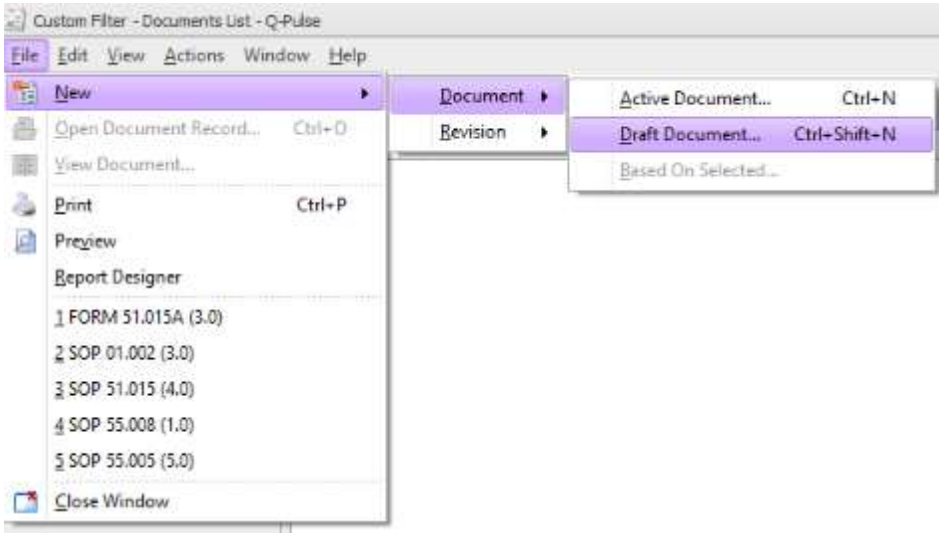
A large number of the functions detailed within the document will be completed centrally by the relevant Quality Assurance representative. For R&I in general this will be the Quality Assurance Manager and Quality Officer with delegated authorities within the GCRF and Bio-Repository as an example. For those functions carried out centrally (QA) will appear in the title of the section, however interaction with staff will still take place to complete the functions within Q-Pulse.

Specific work instructions will be presented to staff in any instructions they receive from Q-Pulse as well as any Q-Pulse training they may receive.

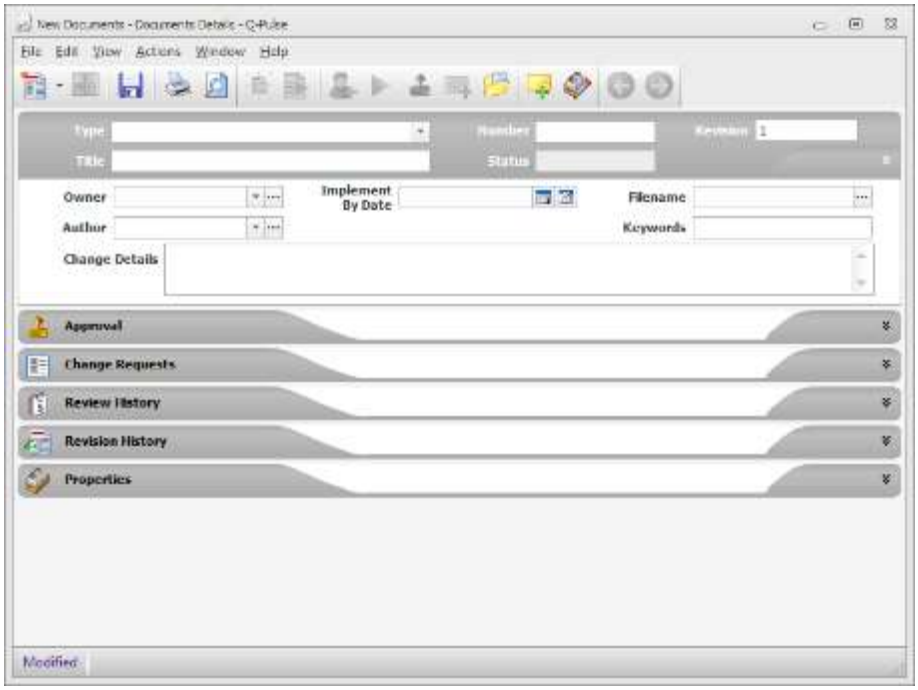
2. Creating a new SOP record (QA)

When there is a requirement to create a new document in Q-Pulse which must be signed by the relevant approvers, this is achieved through the actions detailed within this section. This functionality is carried out by the Quality Assurance Manage, Quality Officer or appropriate designee. Firstly, to begin the process of creating the relevant document record you must open the documents module from Q-Pulse. This is achieved by selecting the documents ribbon in the home screen which will in turn open a new window for the documents module.

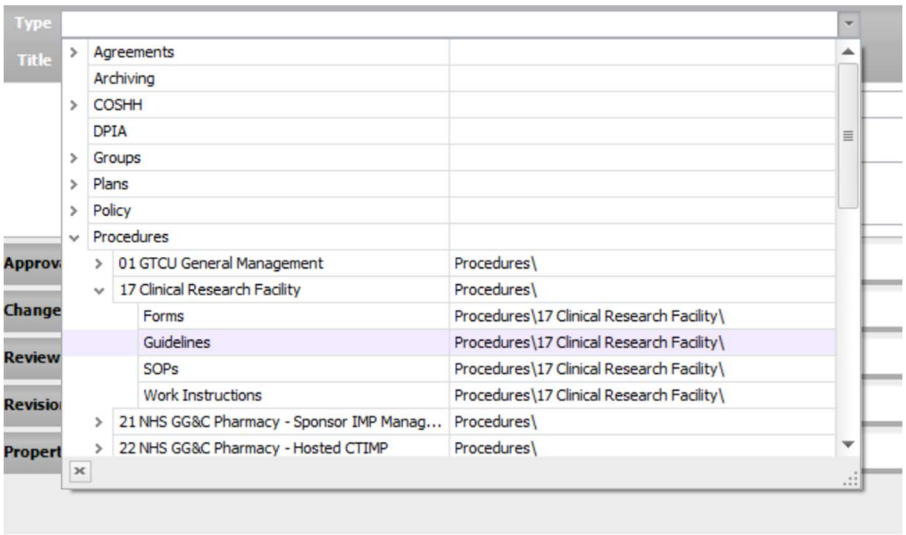
From within the documents module in Q-Pulse, select "File > New > Document > Draft Document"



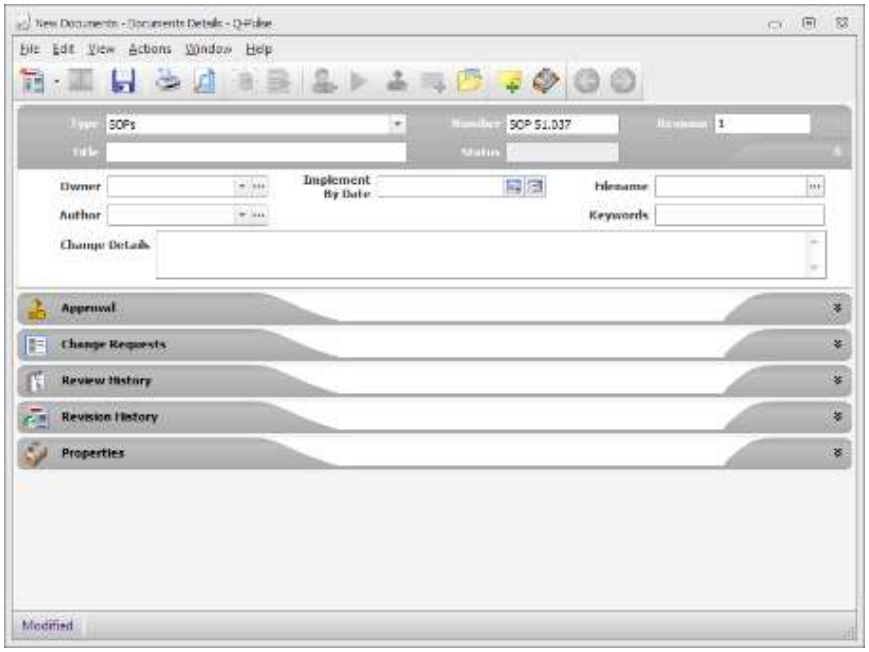
This will in turn open a new window which is an individual record for a draft document, this will not be an active document until appropriate signatures are in place and the document is then made active.



There are multiple fields to be completed within this document record, the first is to make an appropriate selection from the available options on the type of document. From the image below it is shown that numerous document types are available, SOPs, Forms, Guidelines and Work Instructions are contained within the each Chapter listed under the "Procedures" drop down option.

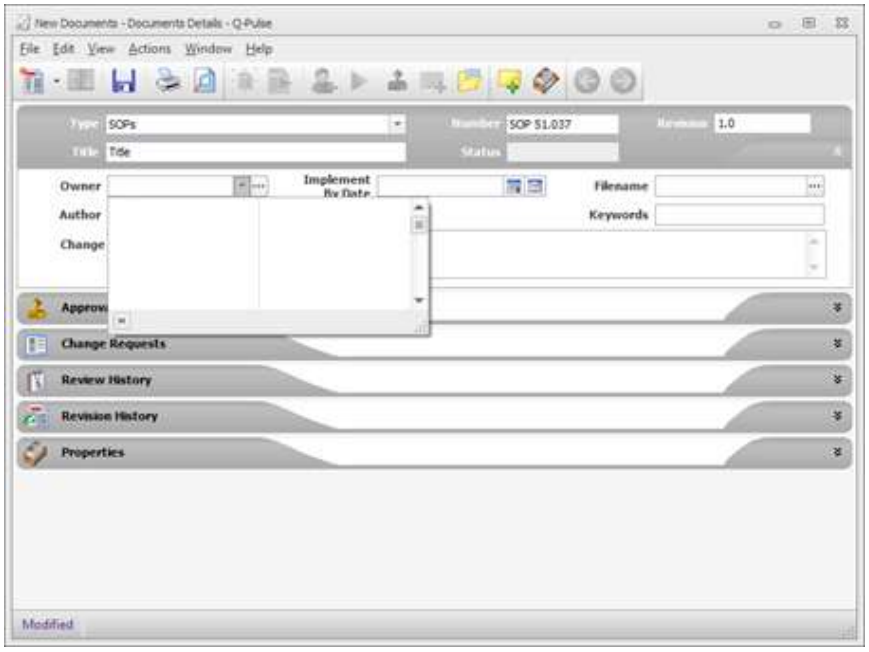


When the appropriate selection has been made, the "Number" field will auto-populate with the appropriate prefix and select the next number available in the stack. **<u>If this number is to be changed, it can be overtyped.</u>**

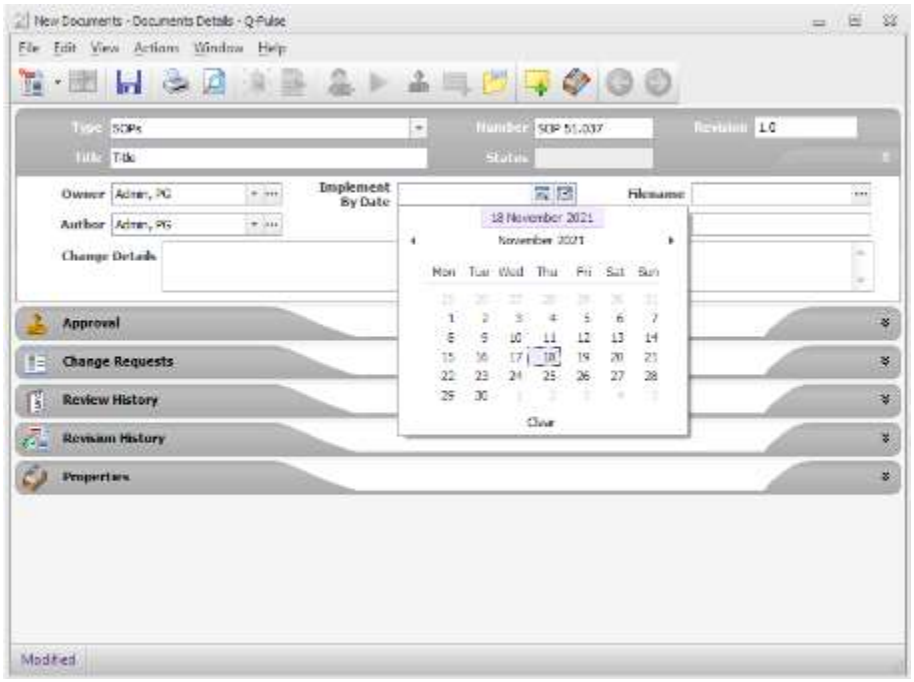


The next fields are the revision number which will default to 1, **<u>this must be expanded to include the decimal point and may not always begin at 1.0</u>**. This can be changed if required. The next field is the Title, this is the name given to the document in question and must be typed in.

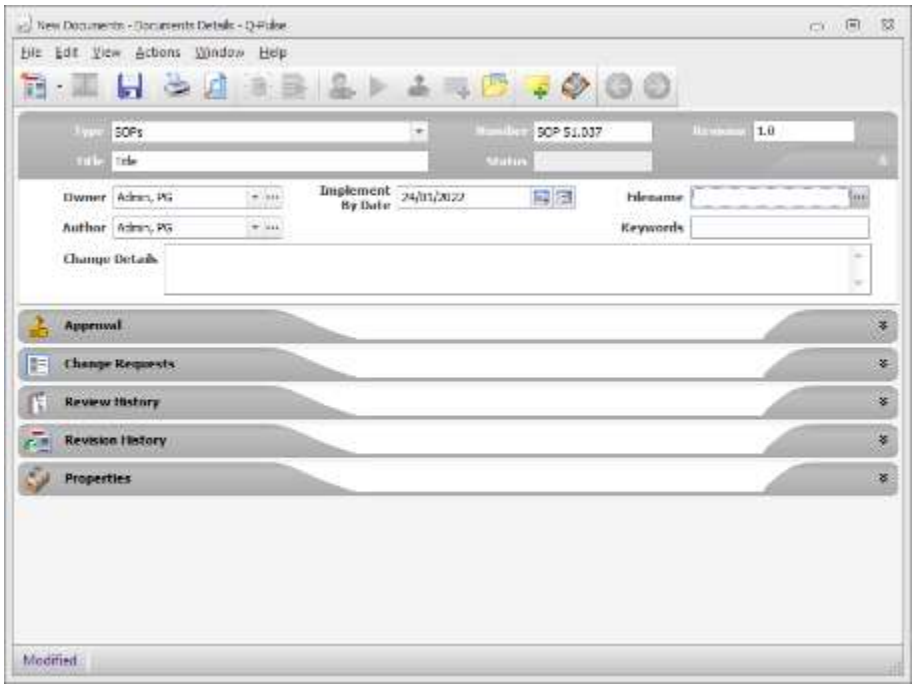
Following this, both the "Owner" and "Author" fields can be populated. Generally these names will be the same and will be reflective of the individual responsible for writing and updating the document in question. In some instances further into the lifecycle of a document these names may diverge to capture a change of ownership in the event the assigned author is no longer in post for example. The names for both fields can be selected from the list of all names entered into Q-Pulse.



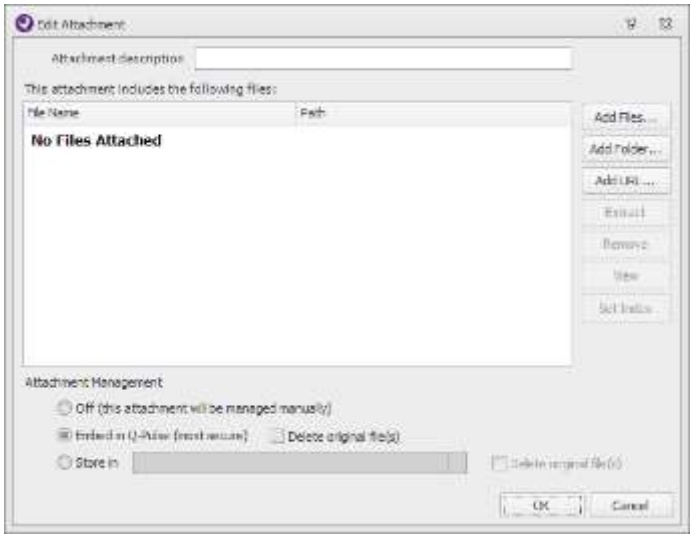
The next field which can be populated is the "Implement By Date", in the event it is a requirement to meet a deadline for the release of a document this field can be used to track progress. **This is not a mandatory field and if approval and release of the SOP is not time sensitive then this can be left blank**.



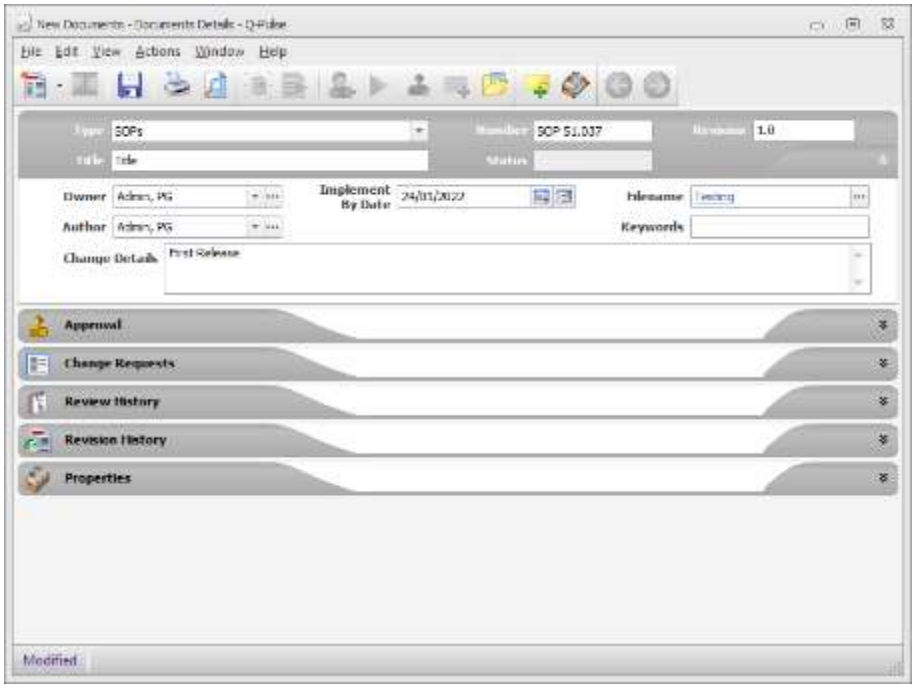
The next field "Filename" is where the document itself is attached to the record, to achieve this select the button with 3 dots beside the field to open the document selection window.



This will open the following window which can be used to navigate through your local machines file structure and select the appropriate document. When this has been attached, select OK to add the document to the record. The filename must be in a standard format of the document number and version number, all extra details such as "final" or "draft" must be removed, i.e. "SOP XXX – VX", "Form XXX – VX" and not "SOP XXX – VX – Final copy". For Forms, as they will be used to capture information and will commonly form documentation for the TMF or ISF, 2 copies must be added. One copy with the document history and signature section and the end and one with them removed. They may be labelled as "with signature page" and "without signature page" at the end. The copy with the signature page removed must be indexed to the front so that the copy staff download removes this information for them to use for filing in the TMF/ISF. This is achieved by selecting the document from the list and then pressing the "Set Index" button at the bottom.

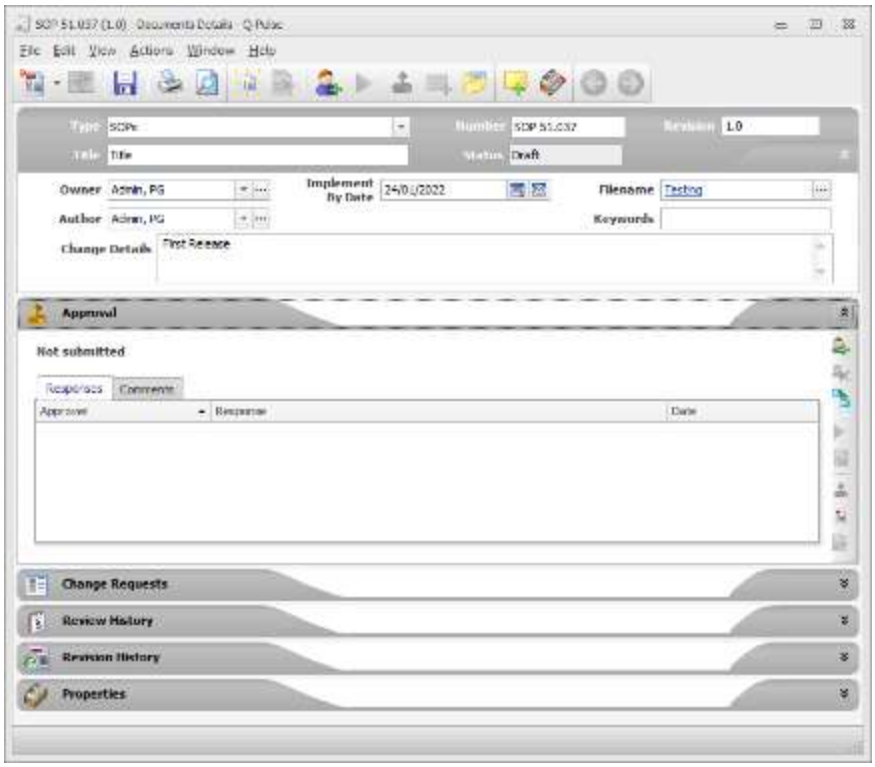


The final field for completion in this section is "Change Details", this will become more relevant through the life cycle of the document and can be used to explain how this document differs from previous versions. In the event of a first release, used the words "First Release" for example.

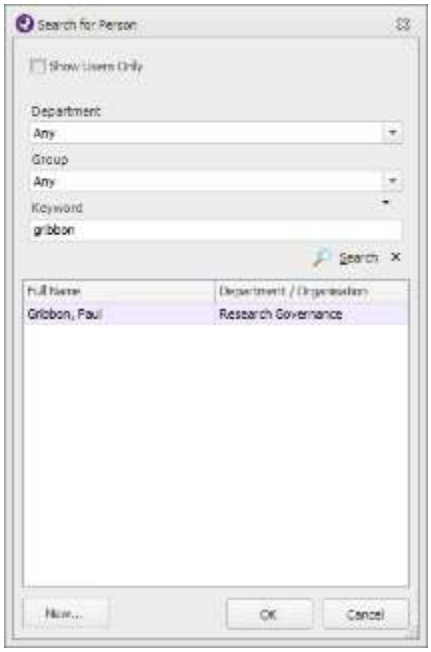


The next section is to then set up the approvals and sign off of the document, **before this is achieved you must save the document record as completed so far. To do this select the save button at the top of the record**.

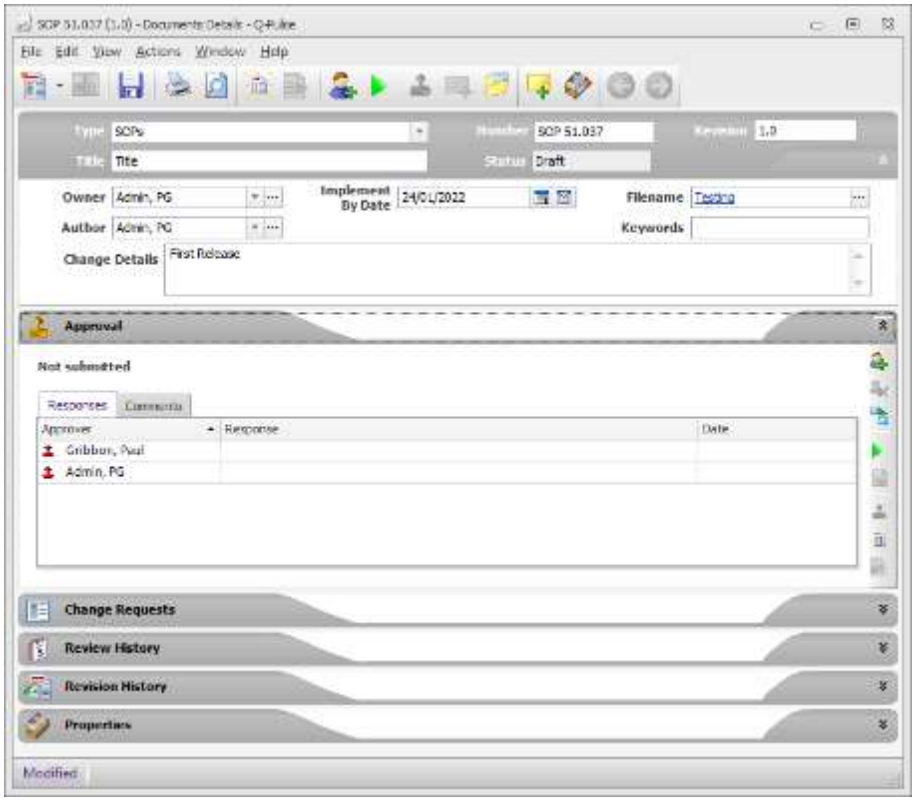
When saved, expand the "Approval" ribbon in Q-Pulse and from here you can add the names of approvers as required. This is achieved by selecting the button to the right hand side with the picture of the person with the green plus symbol.



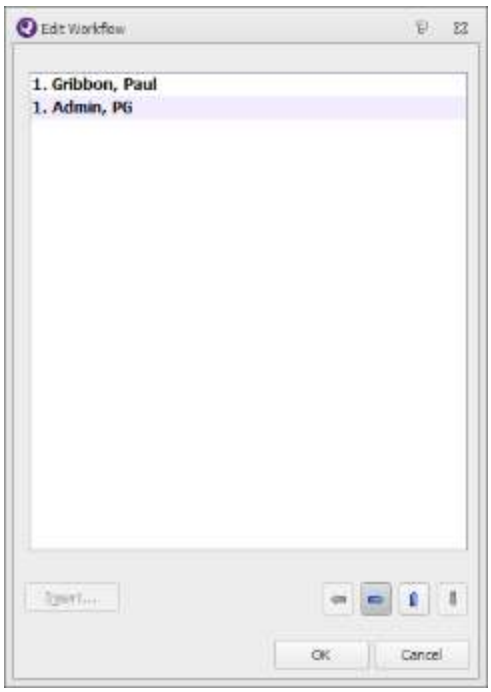
By selecting this, a new window will open from which **you can search for users within Q-Pulse as shown below. Repeat this process until all required approvers have been added**.



This will add all of the named approvers to the record as shown below, **<u>from here you must then select the order in which the approvals are conducted by select the workflow order button.</u>**

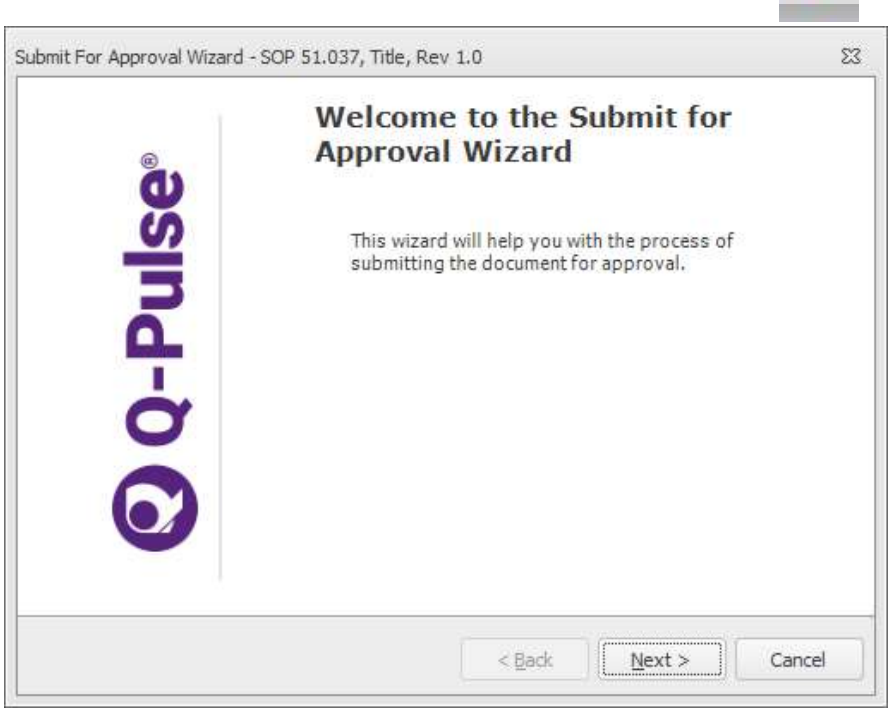


<u>This will then open the following window, you can stagger the approval order for those assigned by selecting the name and using the side arrow as shown below to change the order of approvals.</u>

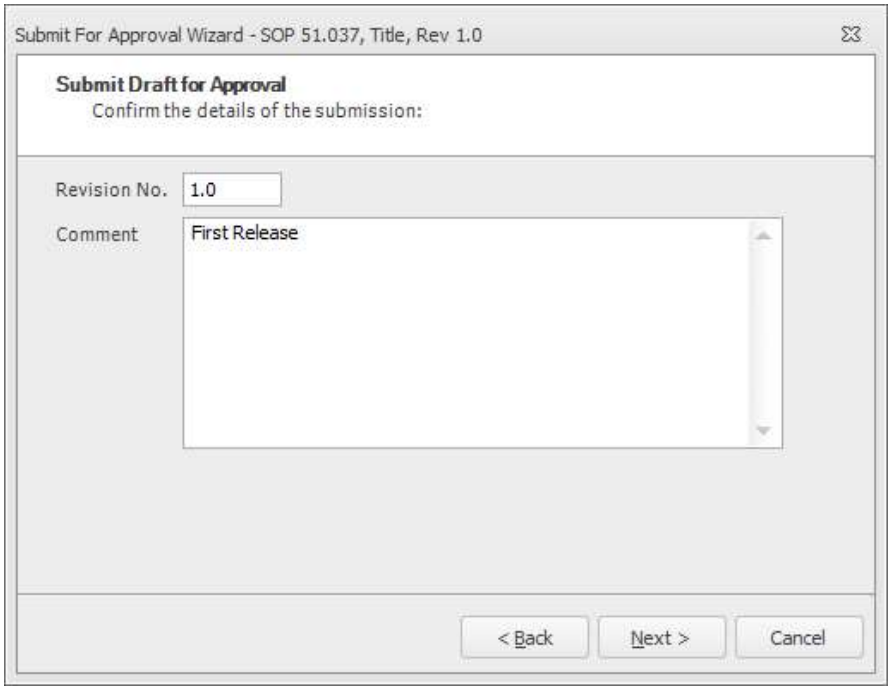


In the example shown, this has changed the 2nd approval to have a number 2 beside the name which means they will be the 2nd to sign after number 1 has completed their approval. This can be expanded as required to as many approvers as required.

When the appropriate approvers and workflow have been assigned, **you can then return to the document record and release the document for approvals. This is achieved by selecting the green play button to open the approval wizard. Once opened, select next to progress**.

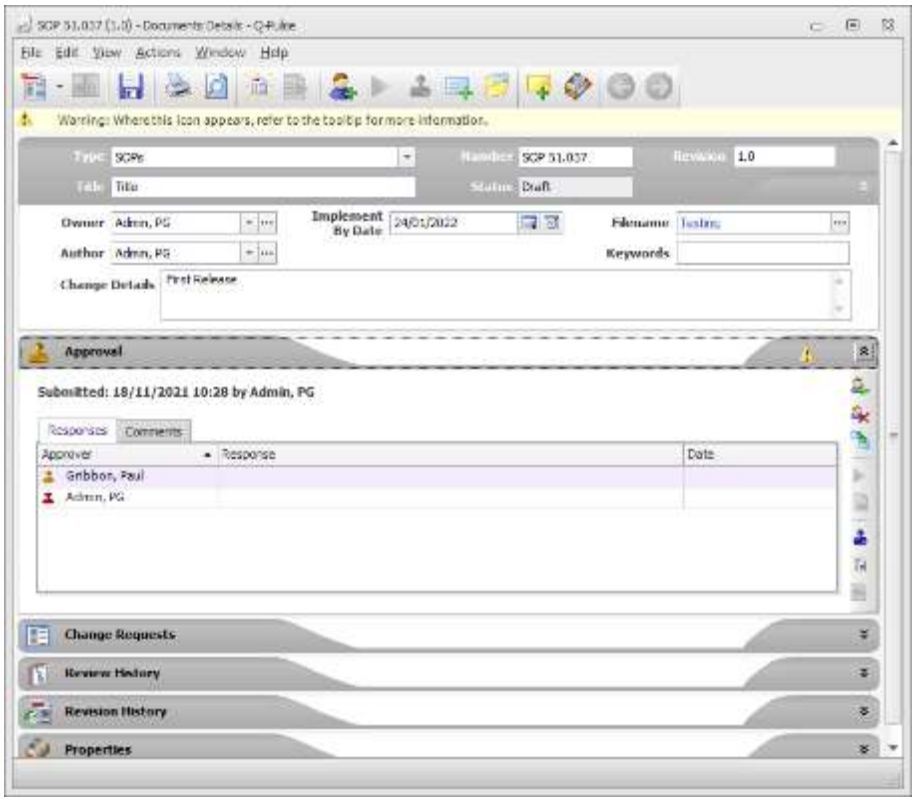


The next window then confirms the version number of the document and room for comment to the approvers, in this case you can add "first release" or any relevant details for the approvers. Select Next to continue.



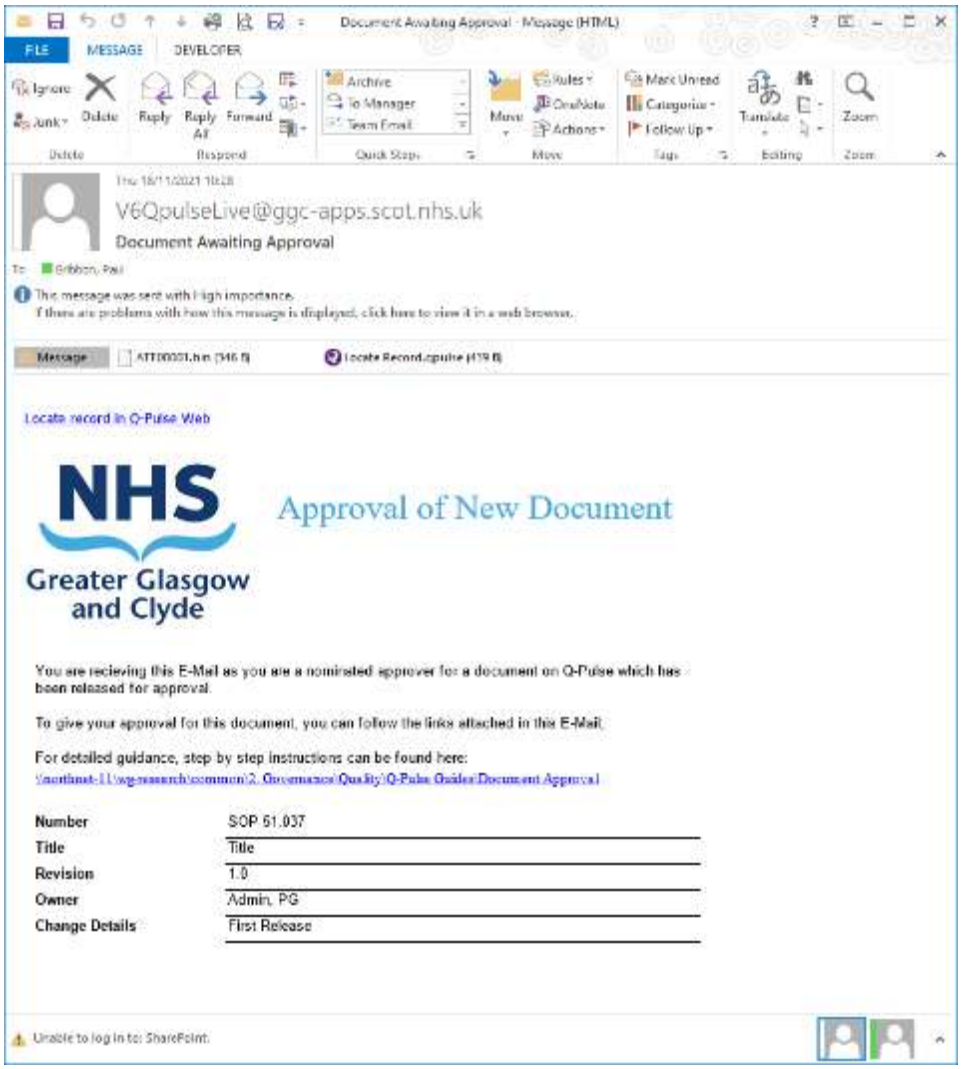
The final page will provide a summary of what the actions will be in relation to the approvals, if this is all correct then select "Finish" to begin the approval process.

Once the approval process has begun, it shows as a statement that it has been submitted for approval and the approvers will be colour coded. Yellow shows that the approval action is with the individual, red shows it is pending and they have not yet been notified and green shows they have submitted their approval response. This can be misleading as it will appear as green even if the decision was to reject so must be reviewed.



When an assigned approver has been notified of an approval action, Q-Pulse will send them an E-Mail to detail the required action. An example of this is detailed below.

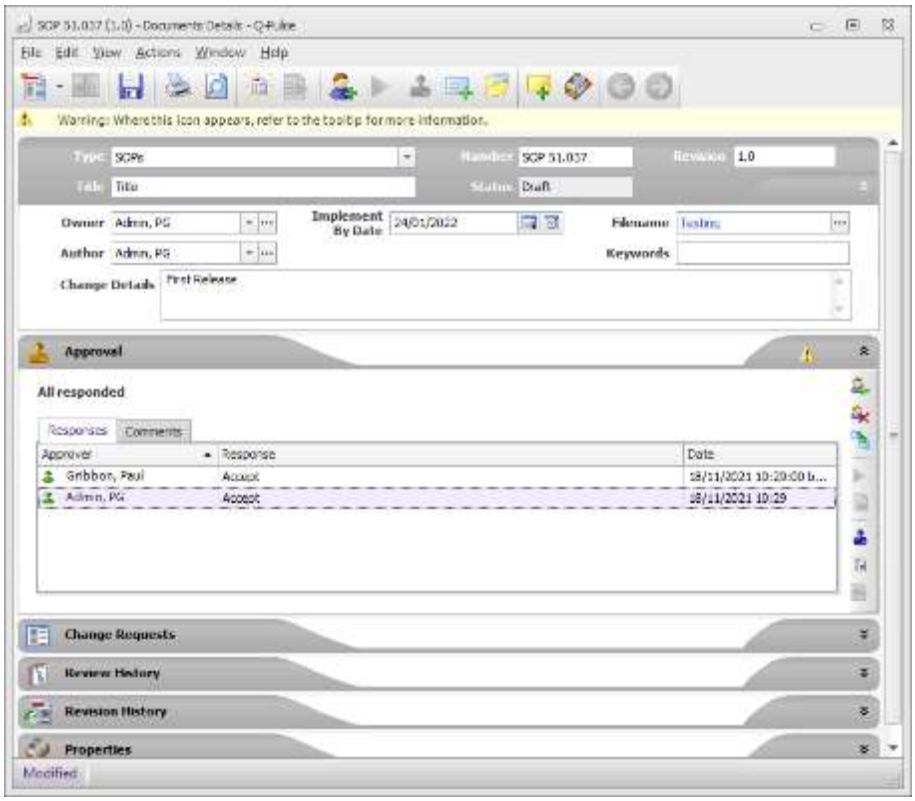
This E-Mail will contain some basic instructions and a link to a how to guide to complete the required actions.



The following guide is provided to users to show them how to complete the required actions in either the application or the web client.

https://www.nhsggc.scot/downloads/approving-a-document/

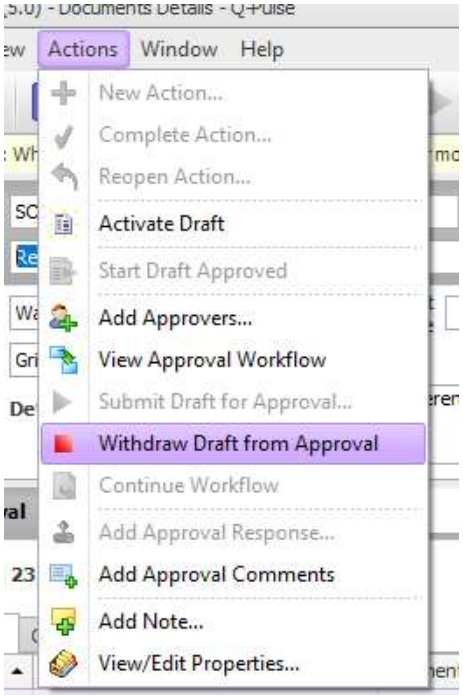
When all approvers have responded, the record will update to show all have responded and their icon will appear as green.



When all approvals have been returned, if they have all accepted then the document will be made active by selecting the "Activate Document" button which appears at the top of the window, and also under the "Actions" button at the top.

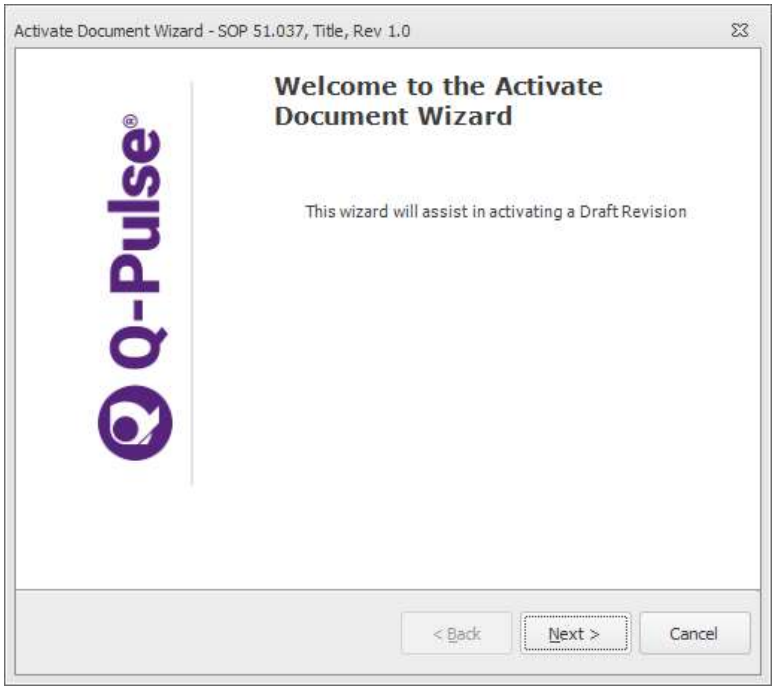
If anyone has rejected the document then the reasons for their rejection should be addressed and an updated version of the document added. They may give the reasons for the rejection in the comments section of the approval or failing this they can be contacted by E-Mail. When the issues have been addressed and the new document added, the approval cycle can then be restarted. To do this, selection "Actions > Withdraw Draft from Approval".

The author and QA will both be notified in the event of a rejection, QA will contact the author to make sure they are aware and ask that they address the issues highlighted.

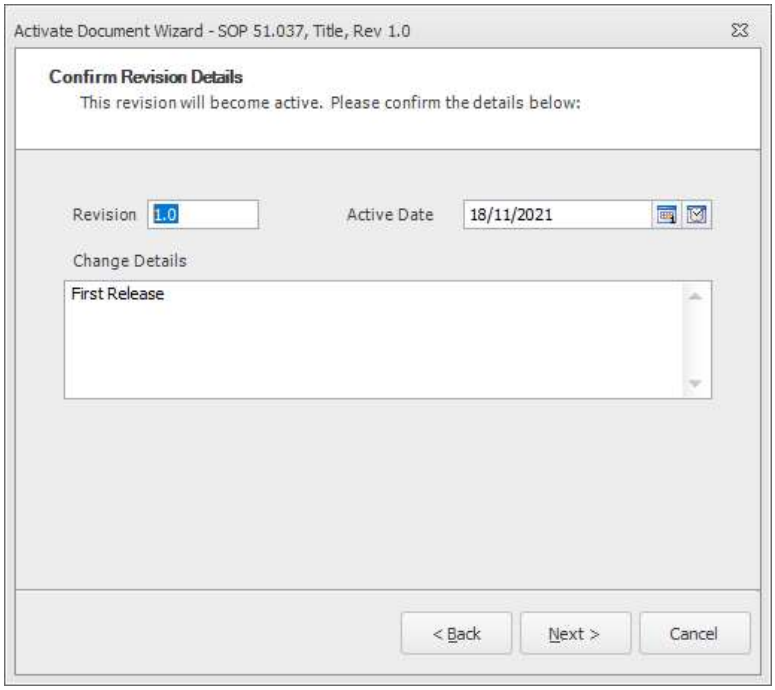


Then follow the previous steps to send the document back through approvals, the list of names should still be present and it is just required to select "Submit Draft for Approval". At this time you can add a comment to state the issues have been addressed and can also email the approvers to let them know.

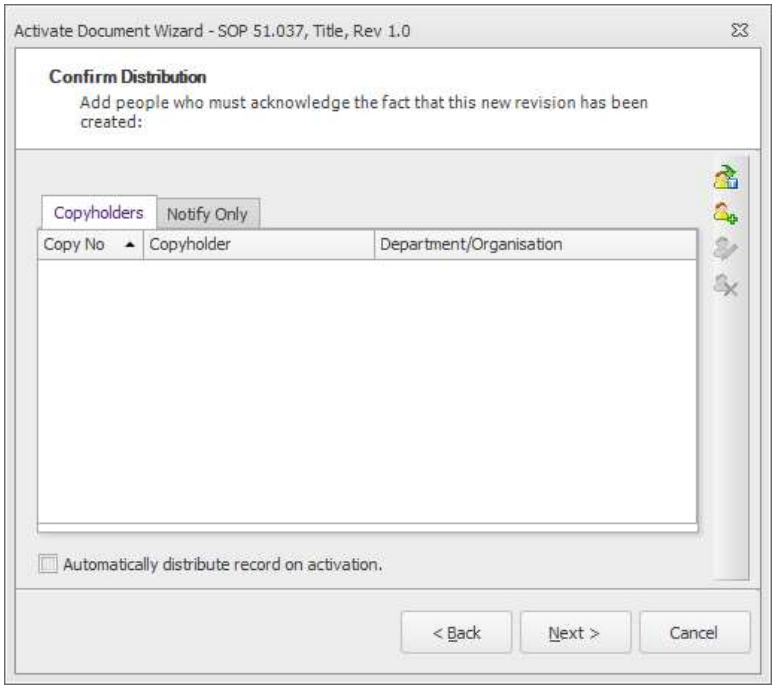
Assuming the document has been accepted in the previous steps and you have selected "Activate Draft", this will then open the following wizard to make the document active, to continue select the "Next" button.



The next window will then confirm several details, the "Active Date" field will default to the current date but can be overtyped to reflect a different date if required, when completed, select "Next".

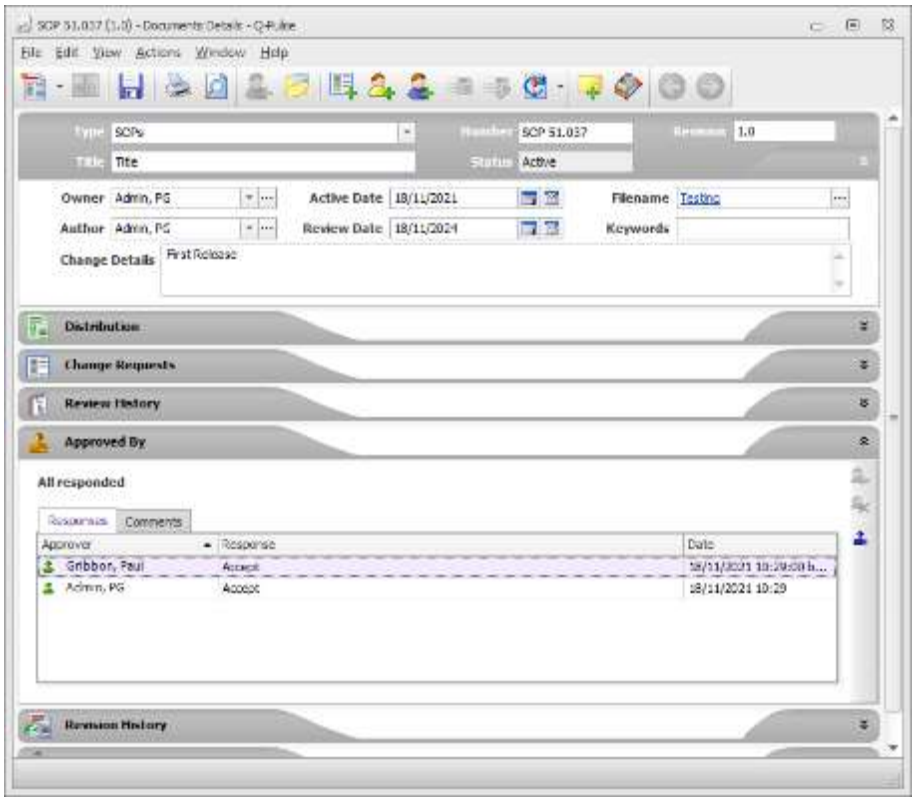


The next section is to then assign the appropriate names for the "Read and Comprehend" and "Notification" process for documents detailed in section 7. The option to automatically distribute is not selected so this action must be completed manually after, select "Next" to continue.



The final page will be a confirmation of the actions to be taken, if correct select "Finish".

This will then result in an active copy of the document being available on Q-Pulse, the "Implement By" date will now have changed to an "Active Date" and "Review Date". **The review date must then be changed to the last day of the year shown, i.e. "31/12/XXXX" where XXXX represents the year already present in the review date field.**



<u>Once this is complete, the document will be downloaded and the "Document History" section at the end will have the active date added for the relevant version number and the file replaced with this copy in Q-Pulse</u>. To do this, press the button with the 3 dots beside the filename field, select the document and press "remove", then select "add file" and attach the copy with the active date now added and then save the document record.

For Chapters 17, 21-23, 50-59 & 61 (SOPs, Forms and Guidelines only)
<u>Once complete, the approvals record of the document must be</u> printed by selecting "File>Print" and then selecting "Document Approvals" from the drop down, select "Print" and then using PDF writer to save a PDF file. Use the name "Document Approvals - <Doc Number> - <Doc Version>. A copy of the document with the active date added and the approvals will be sent to RCB for release on the CTU website (rcbdoco@glasgowctu.org). The document must then also be saved as a PDF if an SOP or the original file format for all others, removing the signature page if a Form, and uploaded to the R&I website as detailed in Section 9.

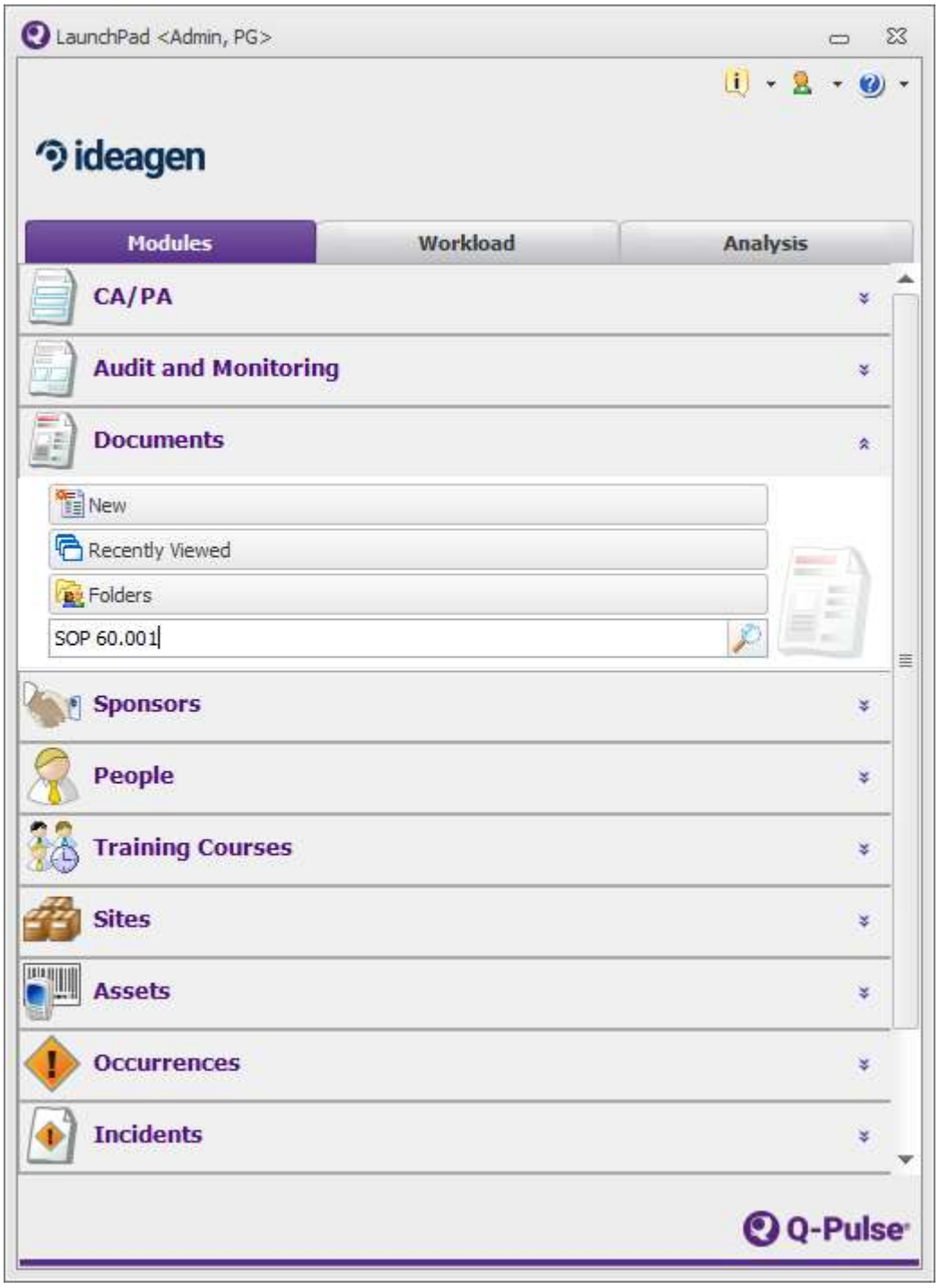
For SOPs, the document references must also be updated to link the document to all other relevant documents and highlight if an Investigator relevant SOP as detailed in Section 8.

2.1. Multiple Documents

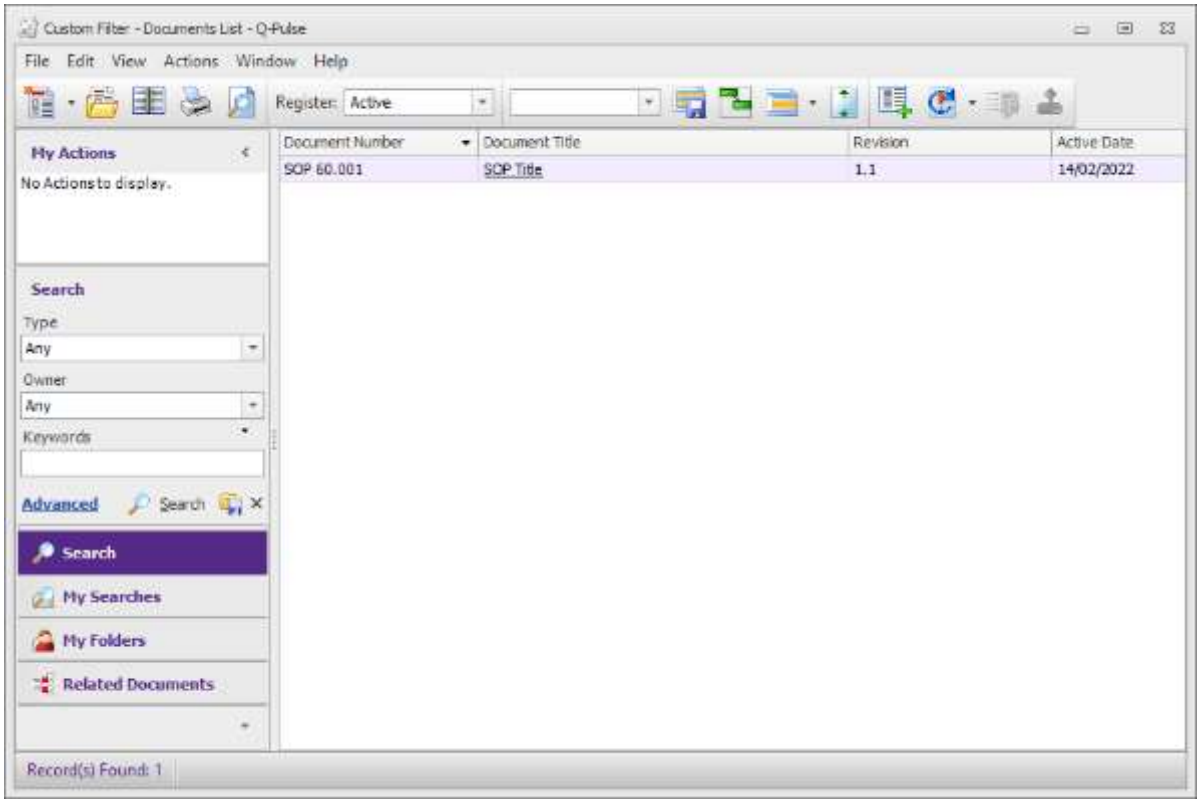
In the event multiple documents associated to the same SOP (i.e. share a base number) are going through approval at once, all documents should be released at the same time. To this end, approvals for all of the documents must be completed before any of them are made active.

3. Creating a new Version of SOP record (QA)

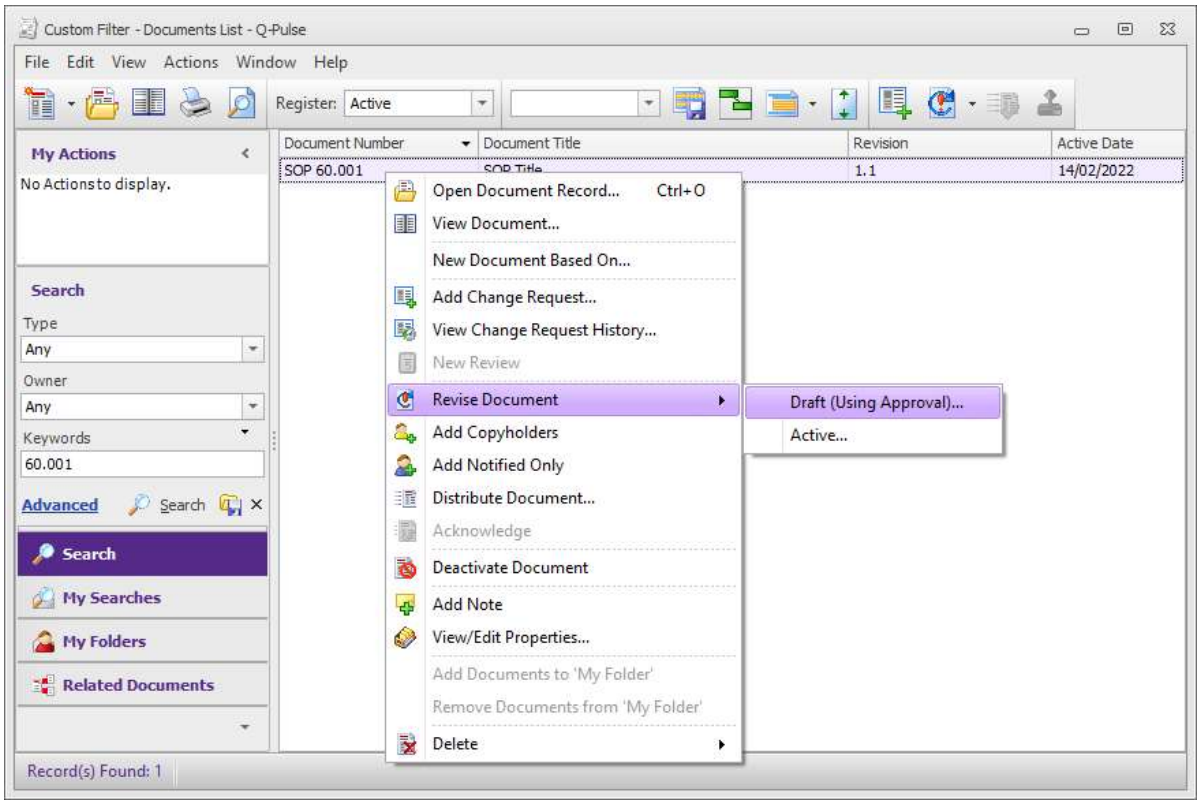
To create a new revision of a document in Q-Pulse, the first step is to locate the record of the document in question. If it is a known or specific document, it can be searched for under the document tab from the front launch screen. To achieve this, expand the document tab and search for the document using either its number or title.



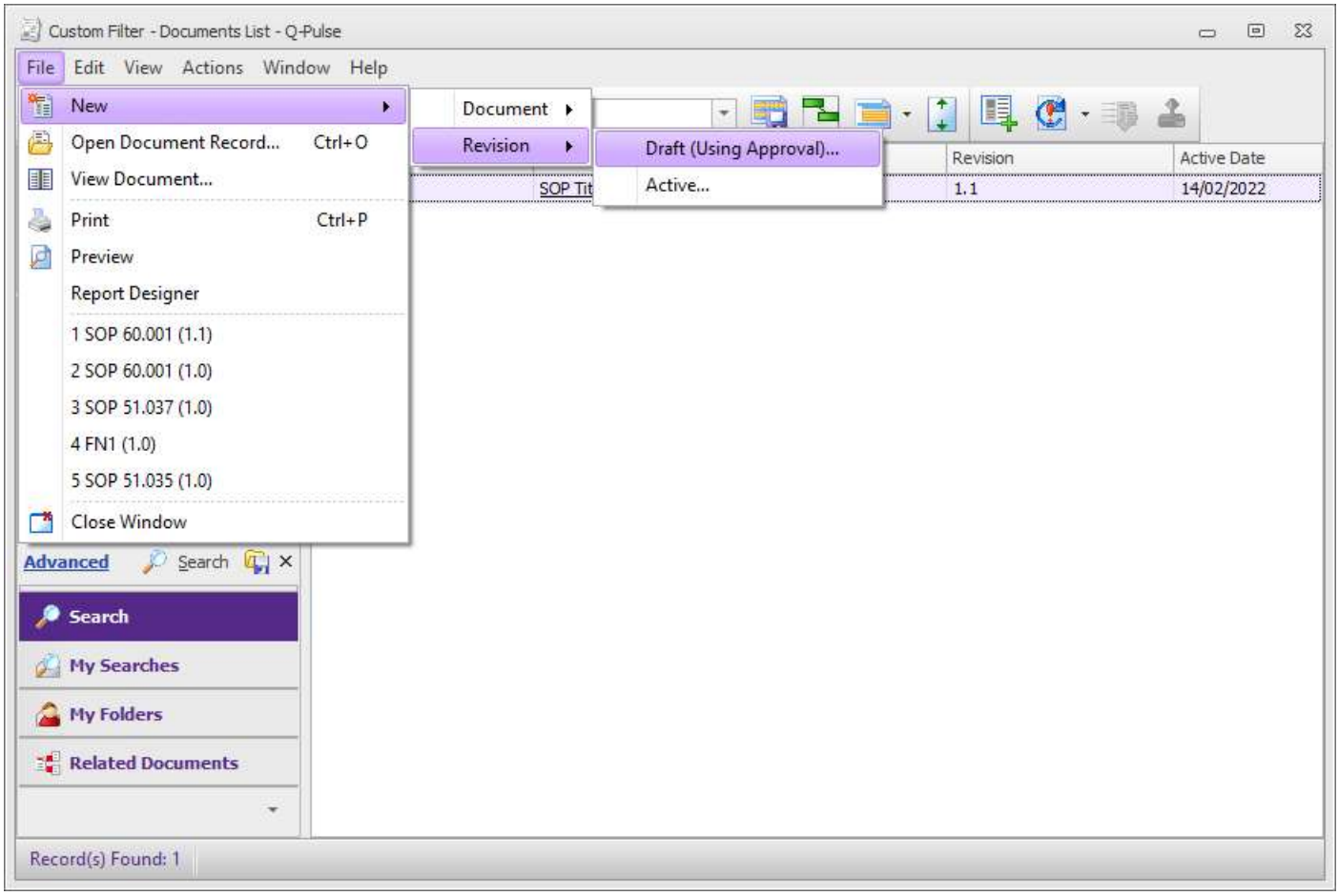
This will open a new window with a list of the returned documents. When the document record has been located, there are a number of ways to then create a new revision of the document.



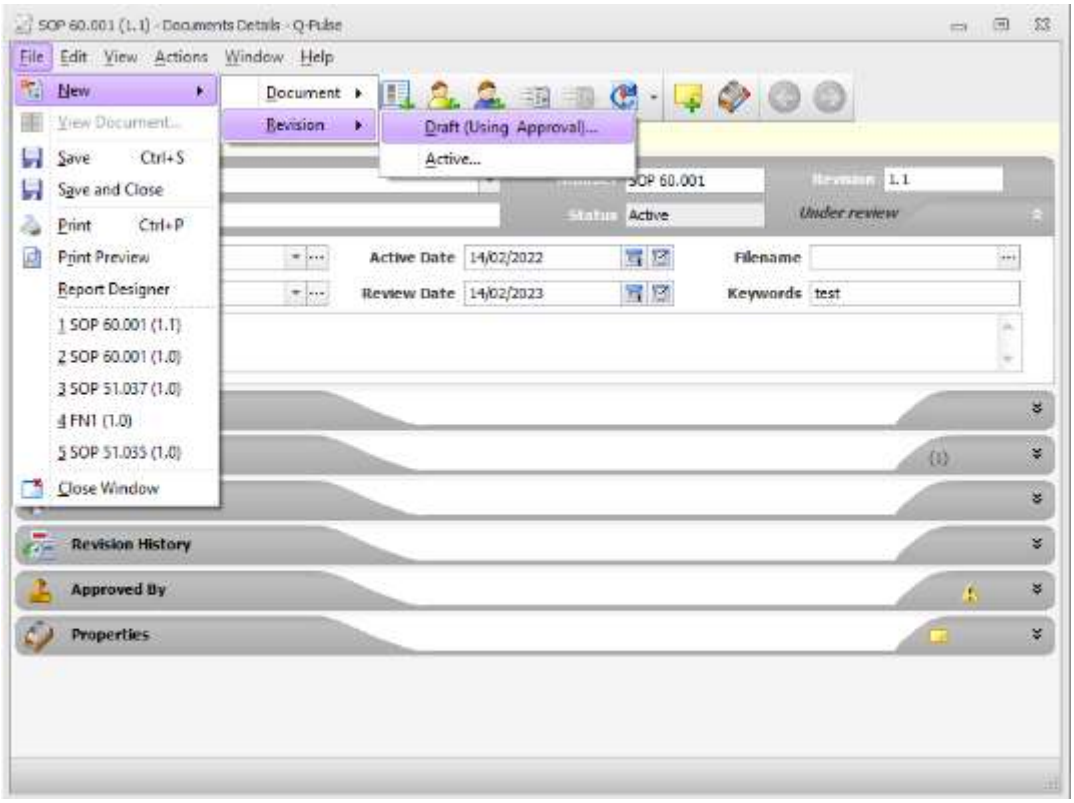
The first option, when the record has been located you can right click on the line listing and select "Revise Document >Draft (Using Approval)". **Do not select "Active" or it will be released without approvals.**



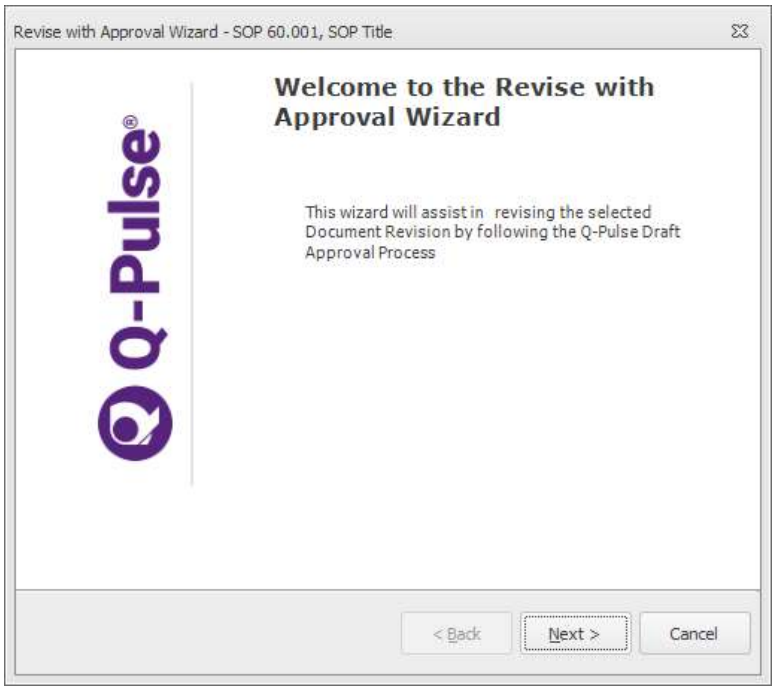
Alternatively, from the same location when the document in question is highlighted you can select "File > New > Revision > Draft (Using Approval). **Do not select "Active" or it will be released without approvals.**



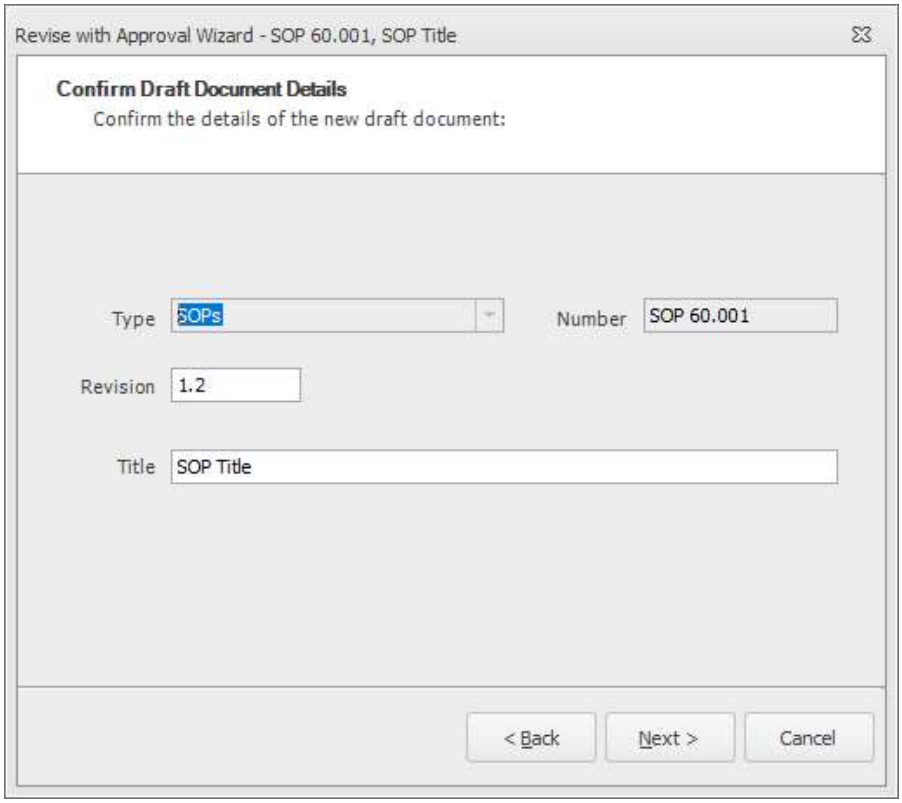
The final option is to first open the record for the document question, from here select "File > New> Revision > Draft (Using Approval). **Do not select "Active" or it will be released without approvals.**



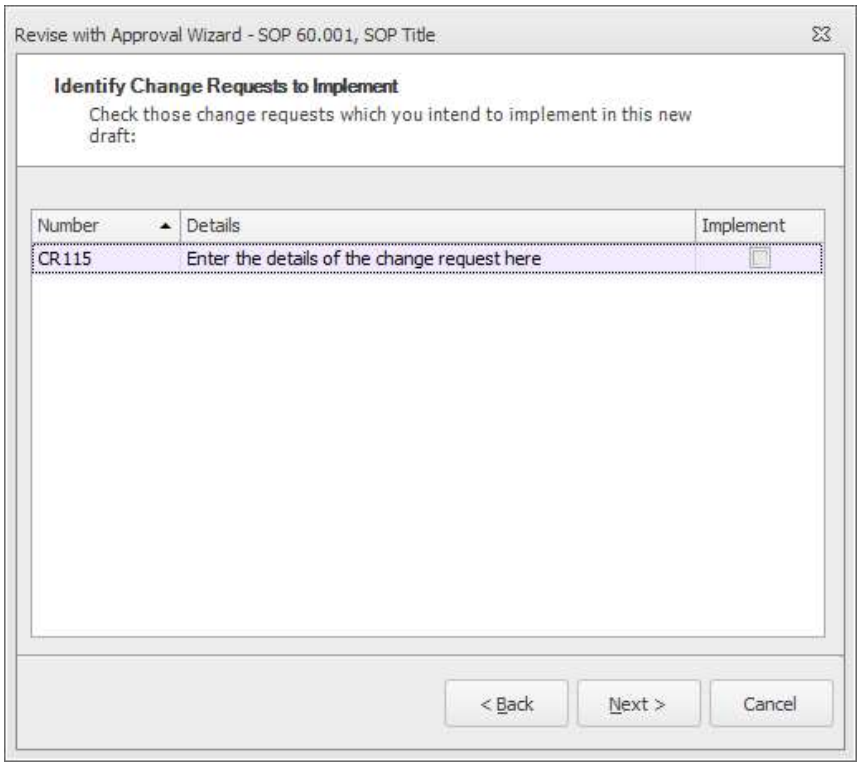
All of these options will result in the following window being opened to start the wizard which will guide you through the process. Select Next to continue.



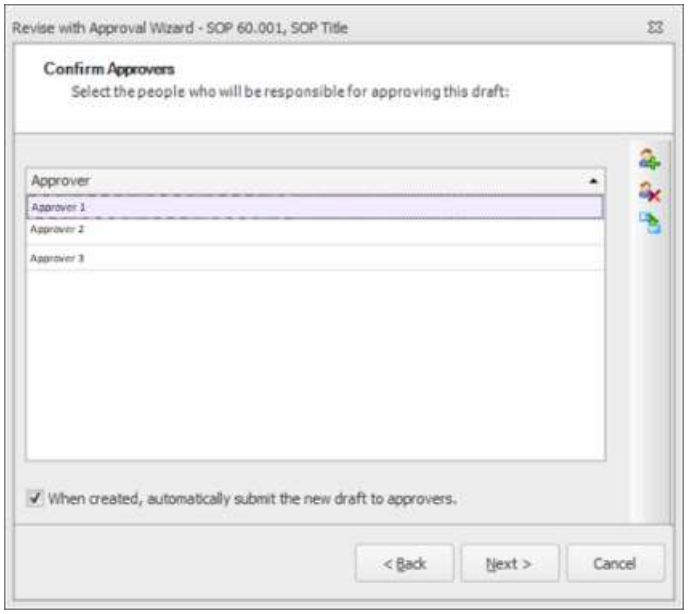
The next page will present you with a new window in which the details for the document can be updated, this includes the revision number and the title. Increase the revision number to the next in sequence. Select Next to continue.



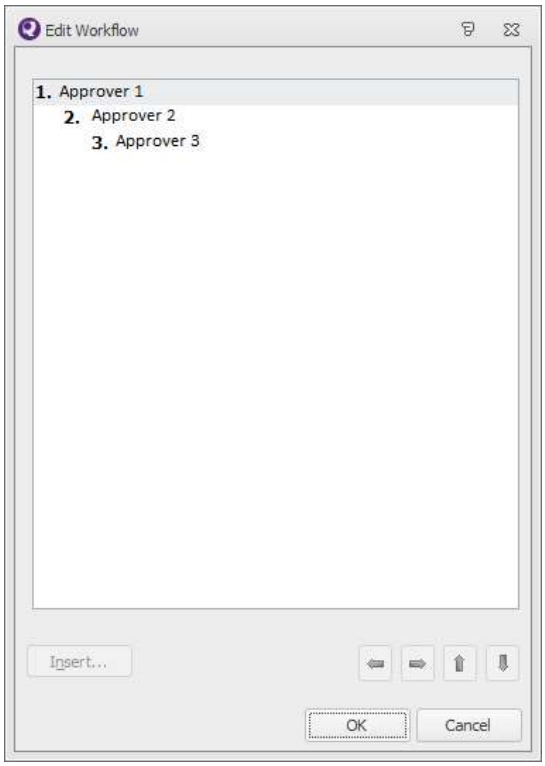
If any change requests are raised against the document which are still pending implementation a window will appear asking if you wish to implement them in this revision. Select any that are appropriate at this stage and select Next, this is covered in more detail in Section 5. **Ideally, all pending change requests will be addressed when the document is released, if any have not been go back to the author and request it is addressed.**



The next page will contain the list of assigned approvers for the document, if no change requests were present the previous section would have been skipped directly to this. If approvers have already been assigned to the existing version of the document they will be carried forward, they may no longer be accurate due to changes in staff.

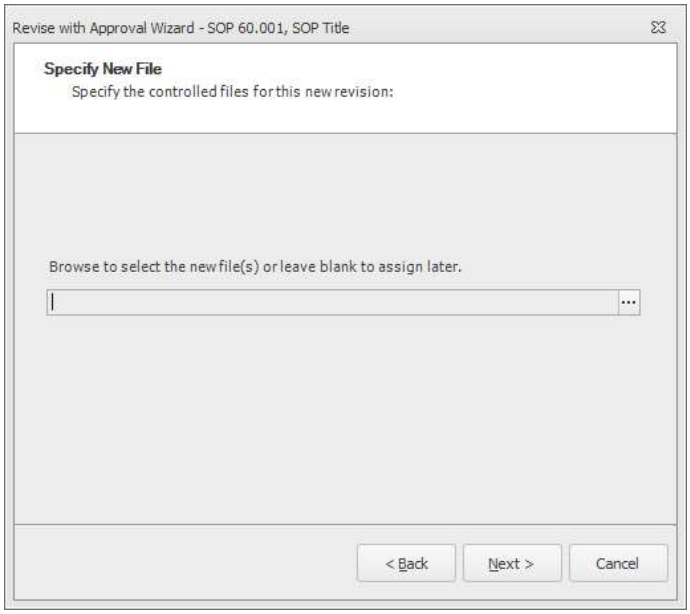


The list of approvers can be updated by using the add and remove approver buttons on the right hand side. The workflow must be set appropriately to ensure the approvals happen in sequence. **The left and right arrows can be used when a name is highlighted to ensure they are stacked appropriately.**



When the approvers have been appropriately assigned, select Next to continue the process. At the bottom of the page there is an option to automatically submit for approval when created, if this is selected the approvers will be contacted as soon as the document is created to approve. Otherwise this must be completed manual at the end of this process.

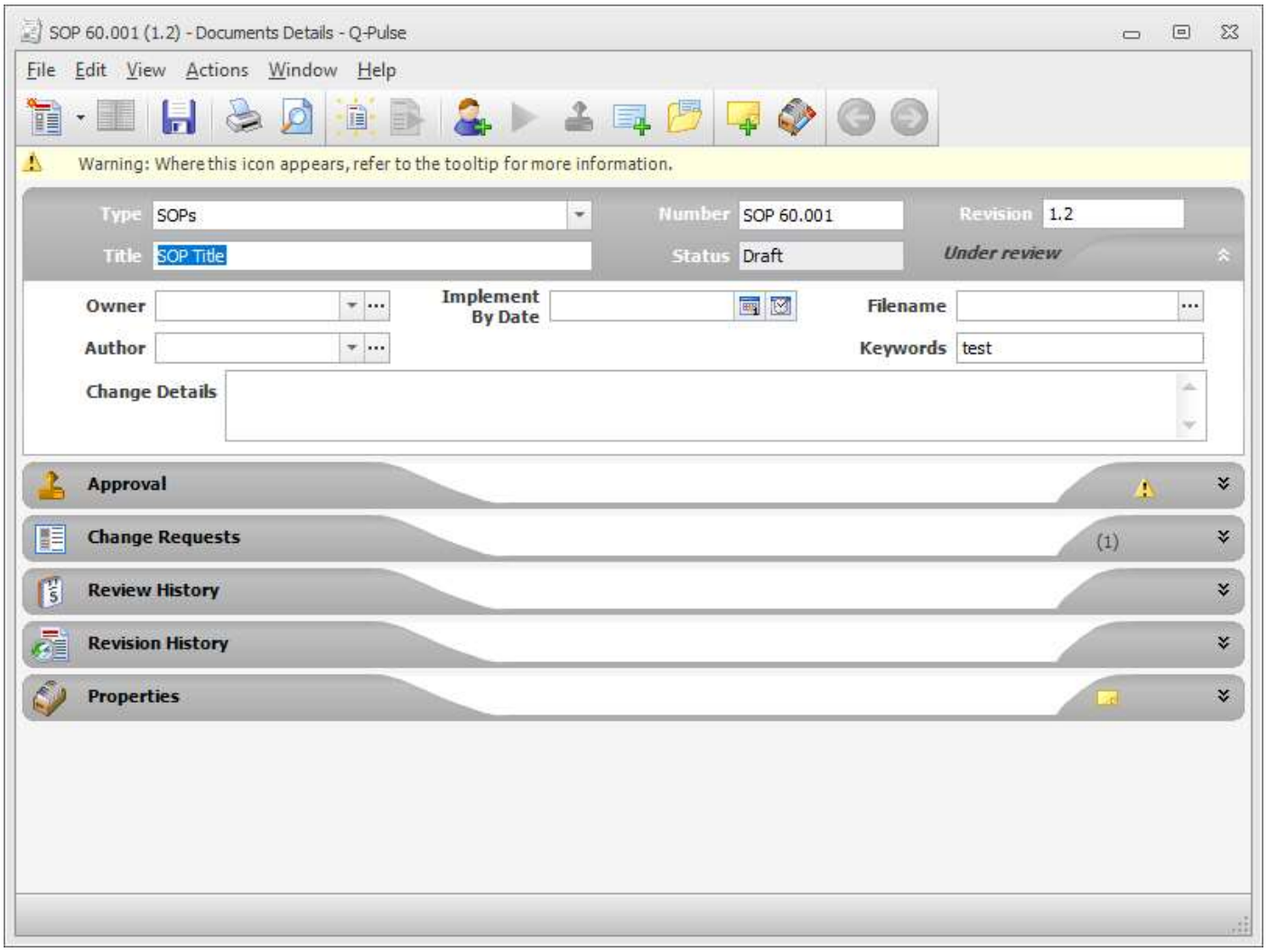
The next page will allow you to upload the appropriate updated document, this is achieved by selecting the button with the 3 dots to the right of the field. This will open a standard document selection window, locate the document and attach. **Make sure the file name is in the format of "<Doc Number> - <Version Number> and all extraneous details are removed, such as "final", "draft" or "track changes" etc. Also ensure it is a clean version of the document with no comments or track changes.**



When the document is attached, select "Next" to continue.

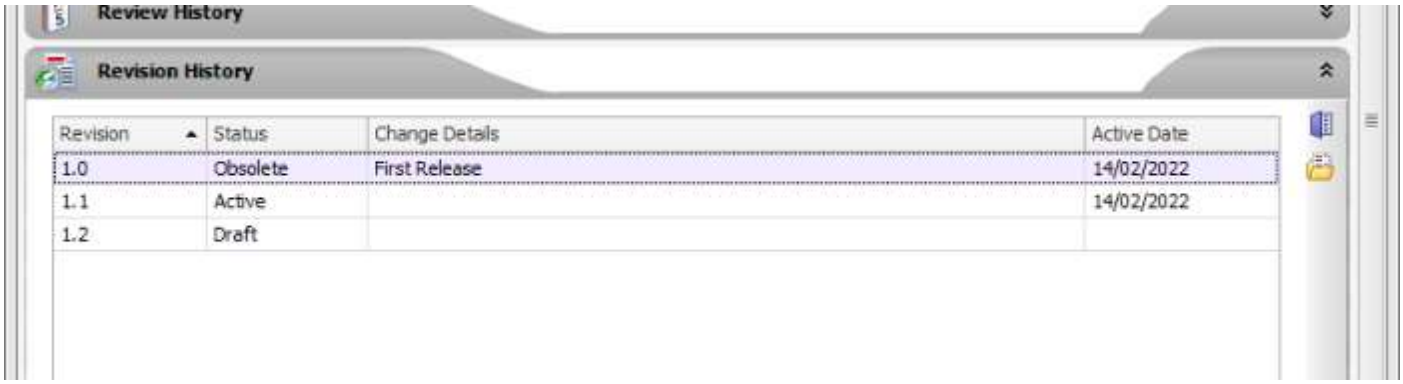
The final page will act as a confirmation of all the details entered, if all correct then select "Finish"

This will open a new window with updated document record.



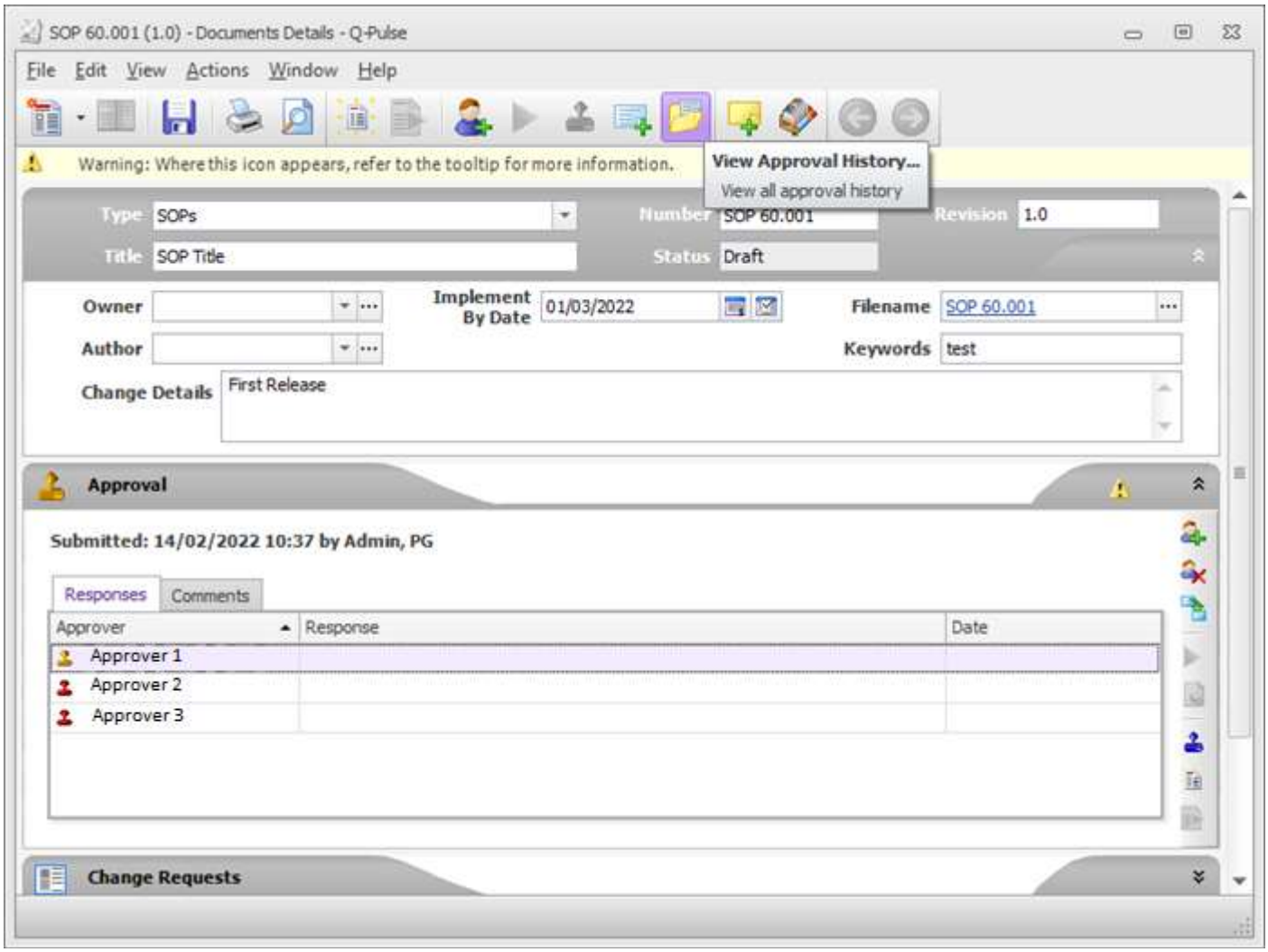
<u>When the new revision window is opened, enter the appropriate "Change Details" with an explanation of the difference from the previous version. This is contained in the document history section of the document.</u>

When an updated document has been created, the previous version history is visible from the "Revision History" tab.

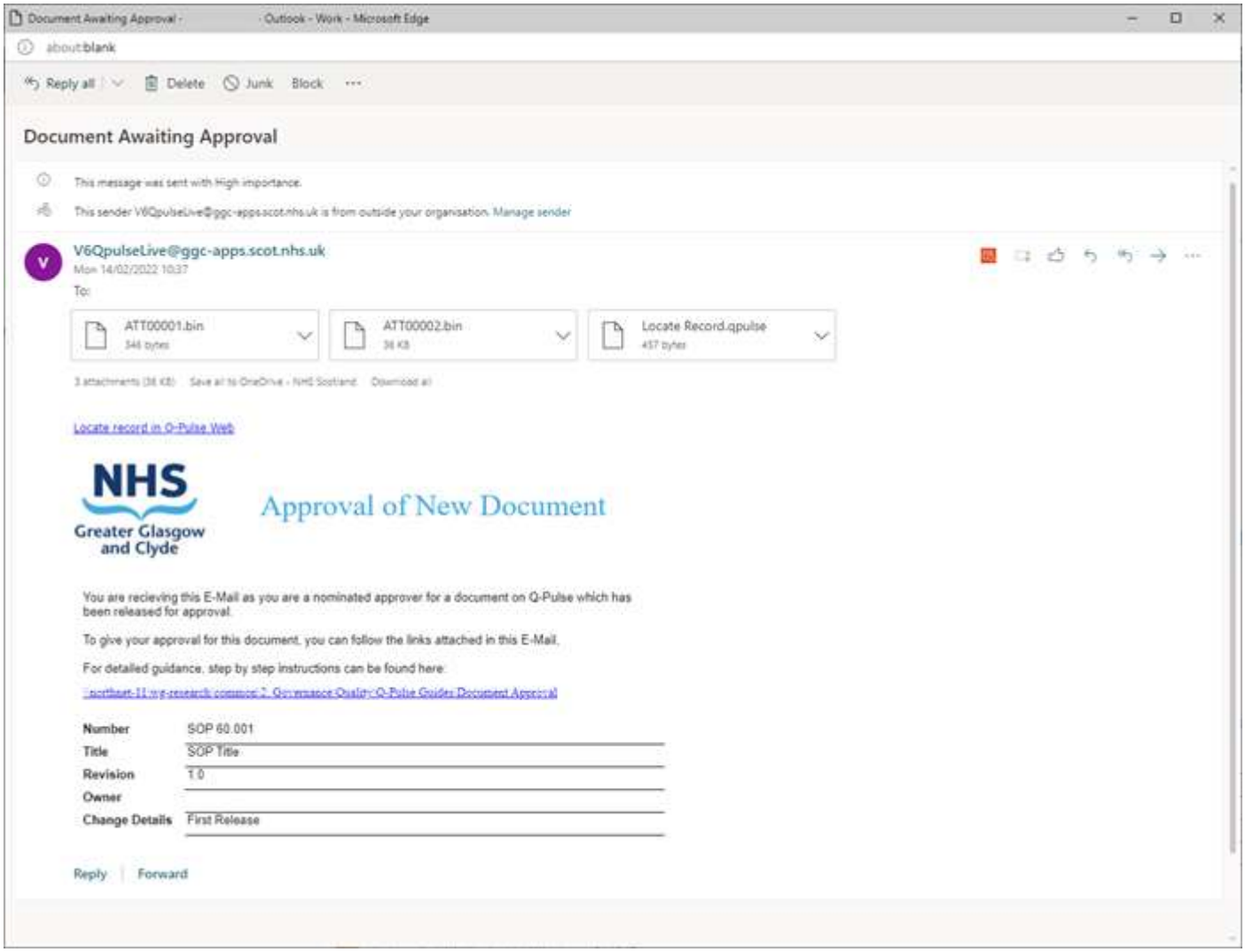


If the box to automatically submit the document for approvals was not selected during set up, it may be submitted at this stage. To submit a document for approval, expand the approval tab from within the document record and select the submit for approval button on the right hand side. This also appears at the top of the document window.

When submitted for approvals, the icon beside the names will change colour as it moves through the process. The first user will appear as yellow to show the action is with them, the other will remain red as they cannot yet complete an action. Once an approver completes their approval action the icon will change to green.



When a user has been requested to complete an approval action they will get an E-Mail notification which contains a how to guide on completing.



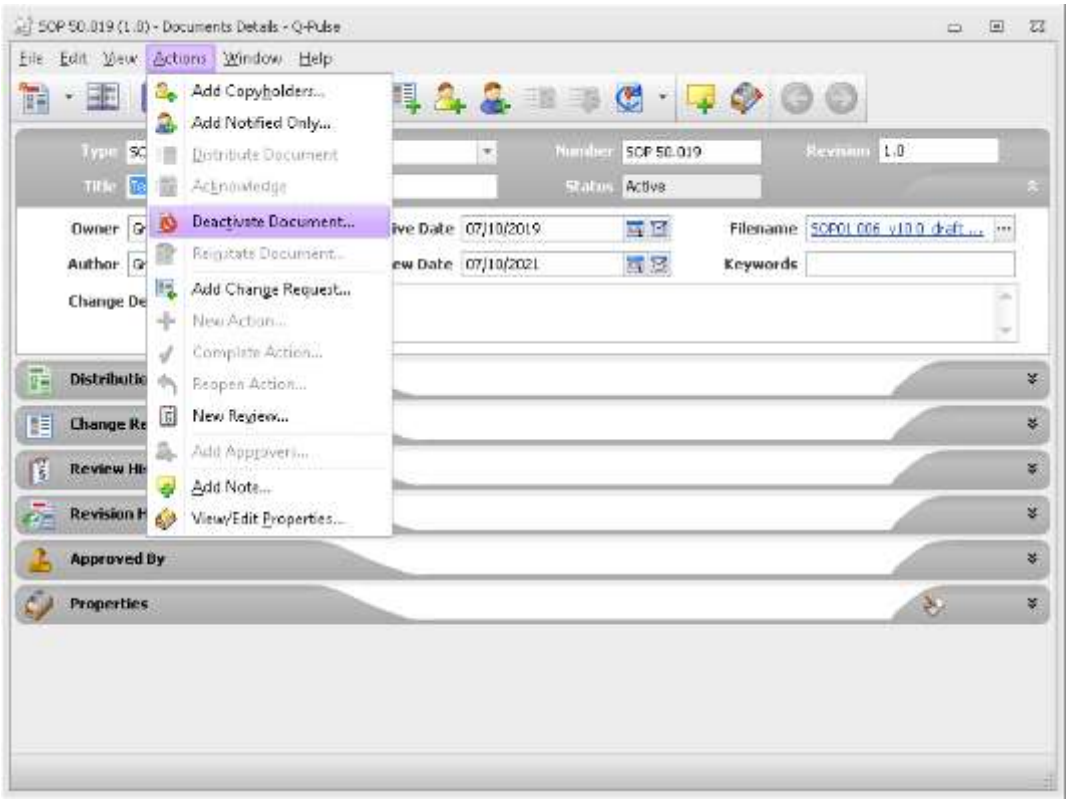
When all approvals have been completed, follow the same process as detailed in Section 2, page 13-16, to make the document active or resubmit if rejected.

3.1. Multiple Documents

In the event multiple documents associated to the same SOP (i.e. share a base number) are going through approval at once, all documents should be released at the same time. To this end, approvals for all of the documents must be completed before any of them are made active.

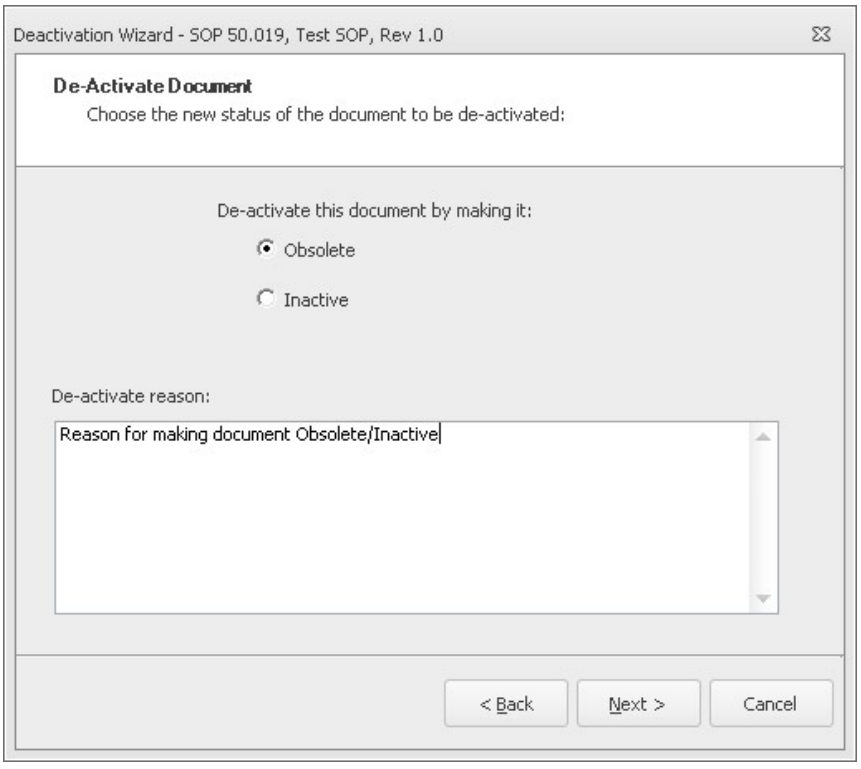
4. Make Document Obsolete (QA)

During the review of documents it may be required to remove a document from Active status as it is no longer required. Before a document is removed, its links to other documents must be considered, this can be done by reviewing the document links as detailed in Section 8. Making the document obsolete is achieved by completing Form 01.006C and actioned by the Quality Assurance Manager or appropriate designee. To carry out this action, navigate to the record in question and select "Actions >Deactivate Document", this will then launch a wizard to guide you through this process.

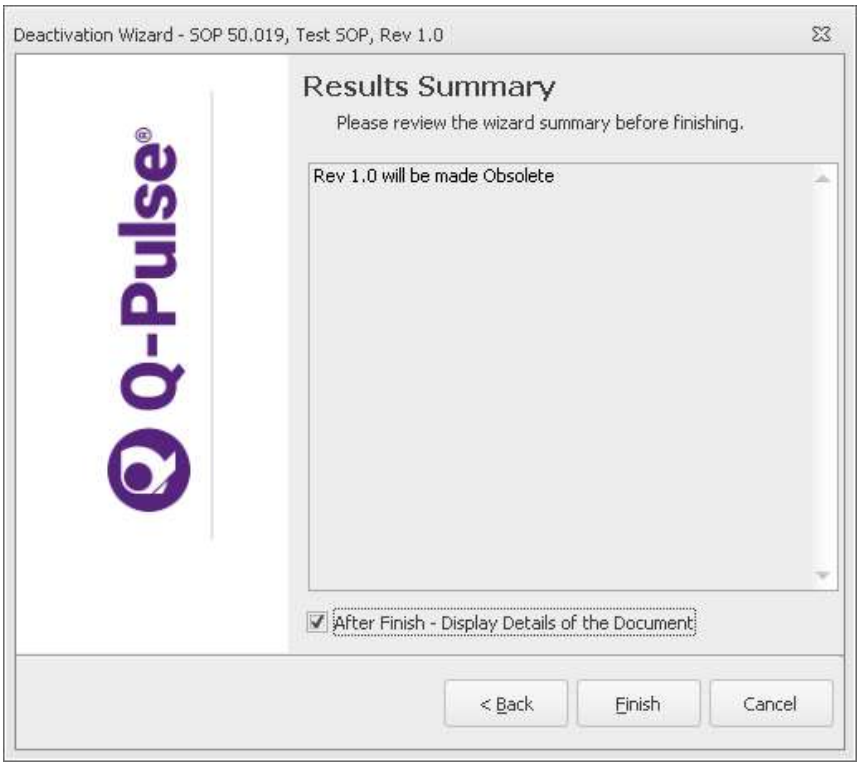


The first page of the wizard is a confirmation of the action to be taken, to proceed with this process select "Next".

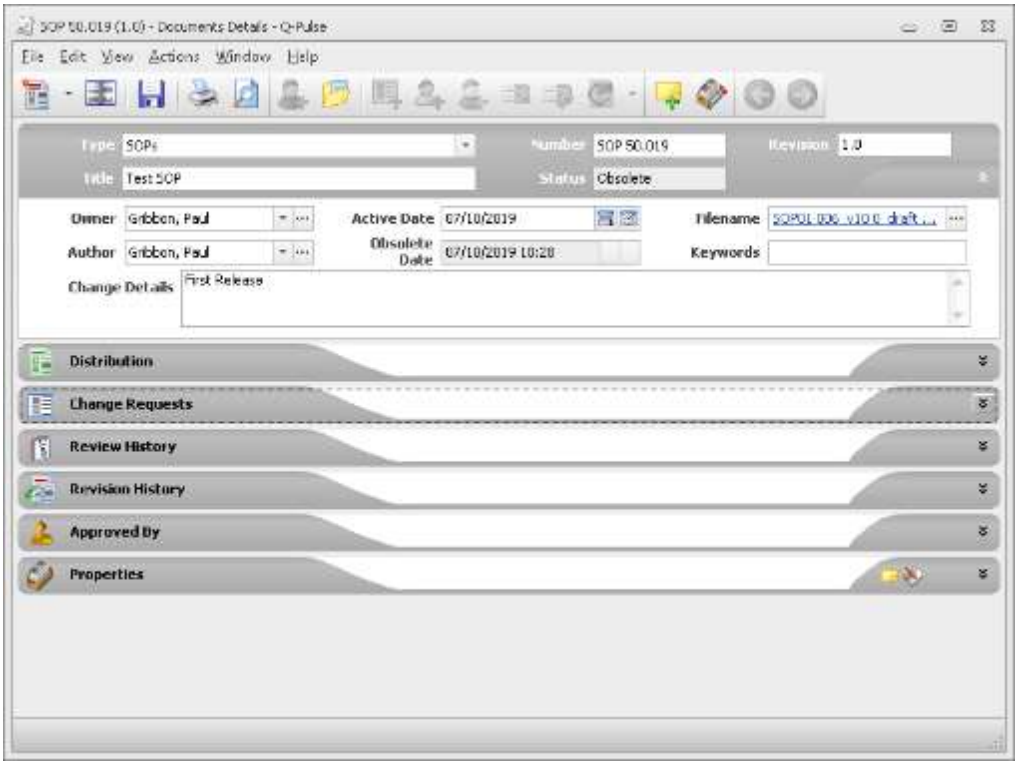
The next page is to select whether the document is to become Obsolete or Inactive and state the reasons for this. Either option will remove the document from Active status and can be selected dependent on the circumstances. Once this is completed, select Next.



The final page is a confirmation of the action to be taken, if this is correct then select Finish to confirm.



Once this has been completed, the status of the document will be changed to reflect. The record itself will still be accessible to act as evidence if ever required.



The document must then be removed from the R&I website and a copy of Form 01.006C sent to RCB for it to be removed from the GCTU website also.

5. Change Requests

A Change Request is a record held against a document within Q-Pulse to act as a reminder for actions to be taken during its review, as a notification process for issues with a document by a stakeholder or for the purpose of seeking clarification. All Q-Pulse users with access to the document module will have the ability to raise Change Requests against a document.

5.1. Raising a Change Request

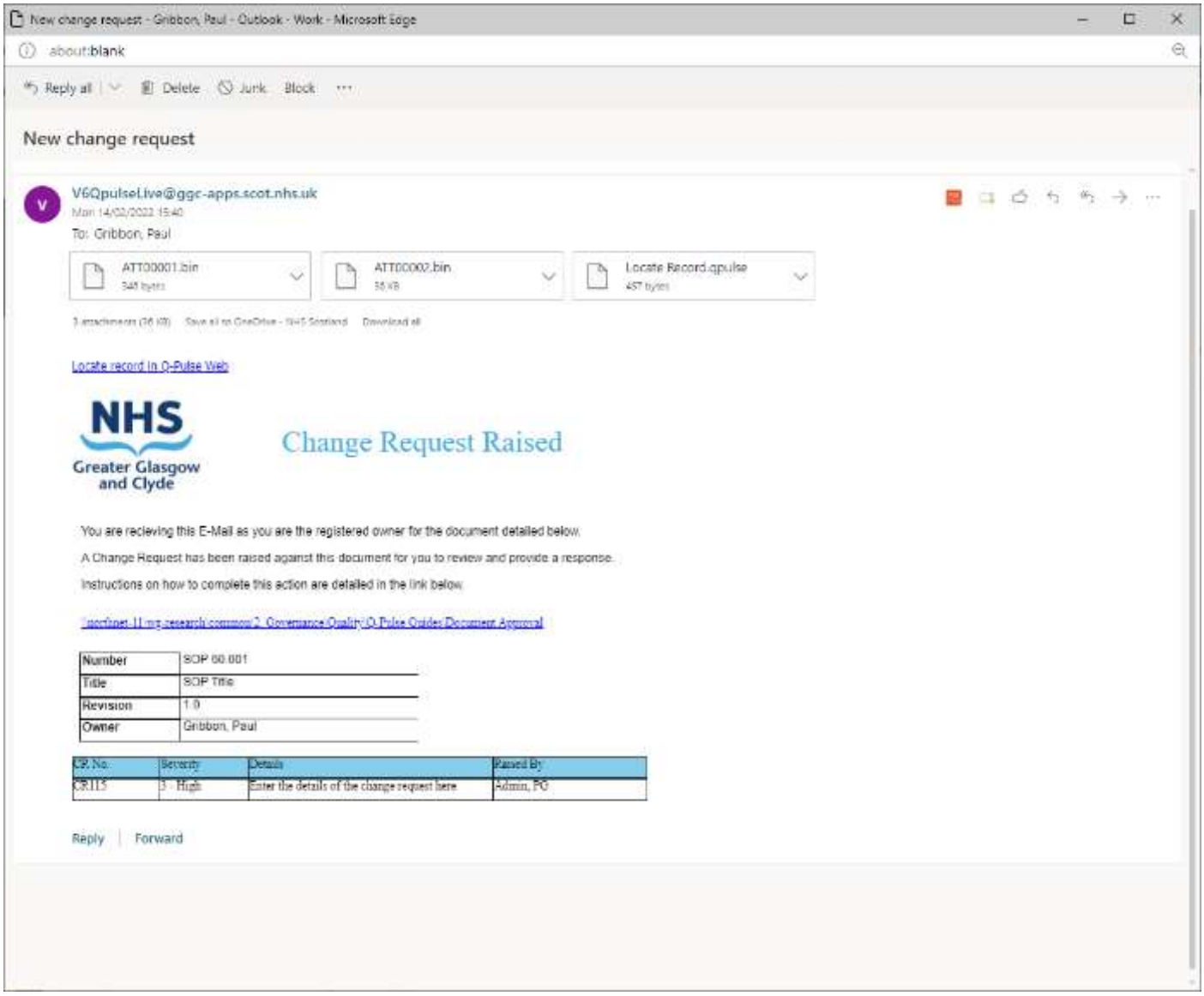
A change request can be raised against an SOP, Form, Guideline or Work Instruction by any Q-Pulse user with access to that document.

The following How To Guide can be used to raise a Change Request, all users are given a link to this when they first get a Q-Pulse Account.

https://www.nhsggc.scot/downloads/creating-a-change-request/

5.2. Review a Change Request

When a change request has been created, the document owner will get a notification with a basic overview of the details as seen below.



This will contain a link to a How To Guide on responding to the change request.

https://www.nhsggc.scot/downloads/Responding-to-a-change-request/

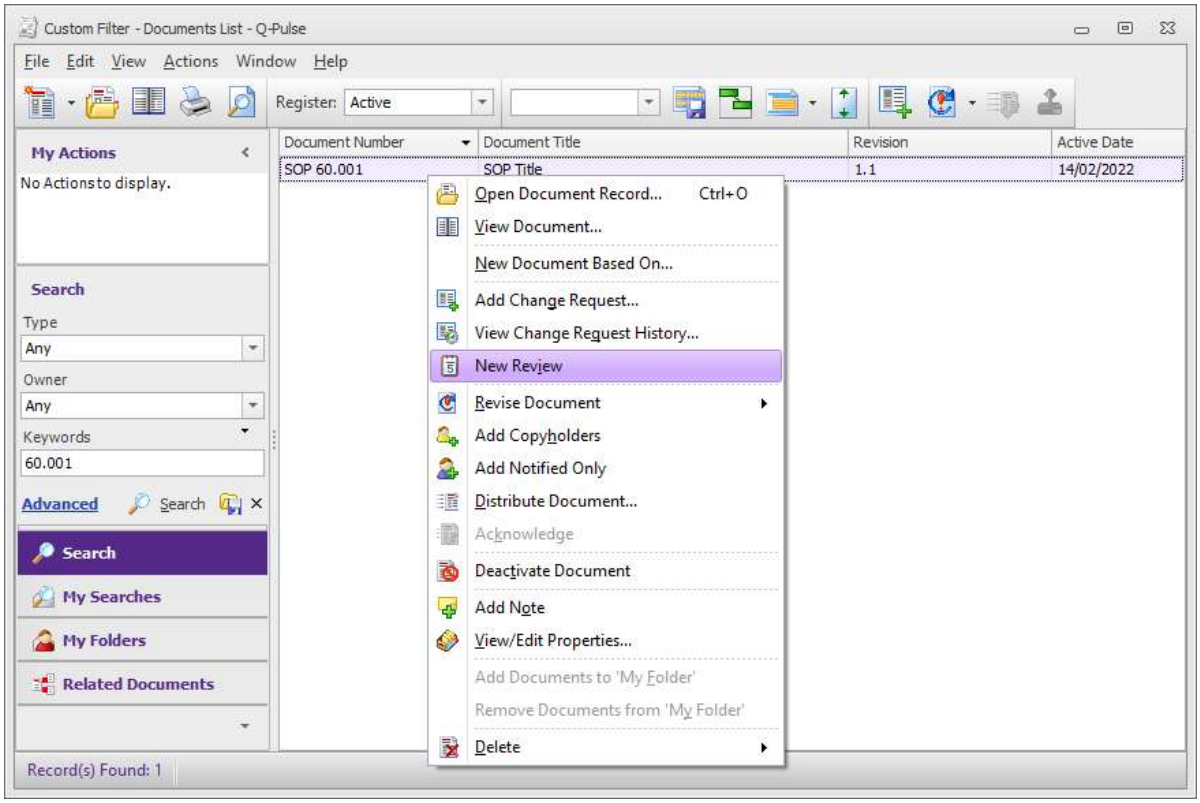
6. Document Review

6.1. Creating a Document Review (QA)

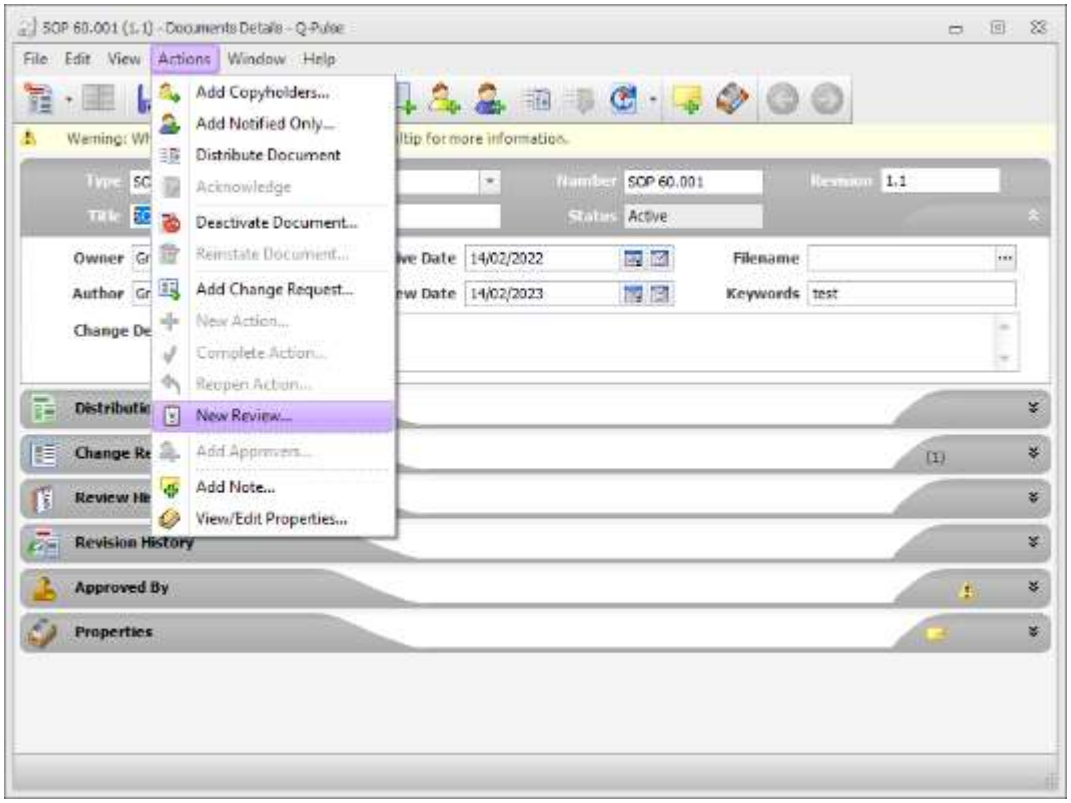
Q-Pulse has the functionality to record the review of a document, this is not essential if the document is known to require an update as the document being updated will act as the evidence of this process. However, in the event an update of the document is not required this process can be used to record the fact that the document has been reviewed and its content are acceptable. To update a document without using this functionality, refer to section 6.4.

To create a document review record in Q-Pulse, the first step is to locate the record of the document in question. If it is a known or specific document, it can be searched for under the document tab from the front launch screen. To achieve this, expand the document tab and search for the document using either its number or title.

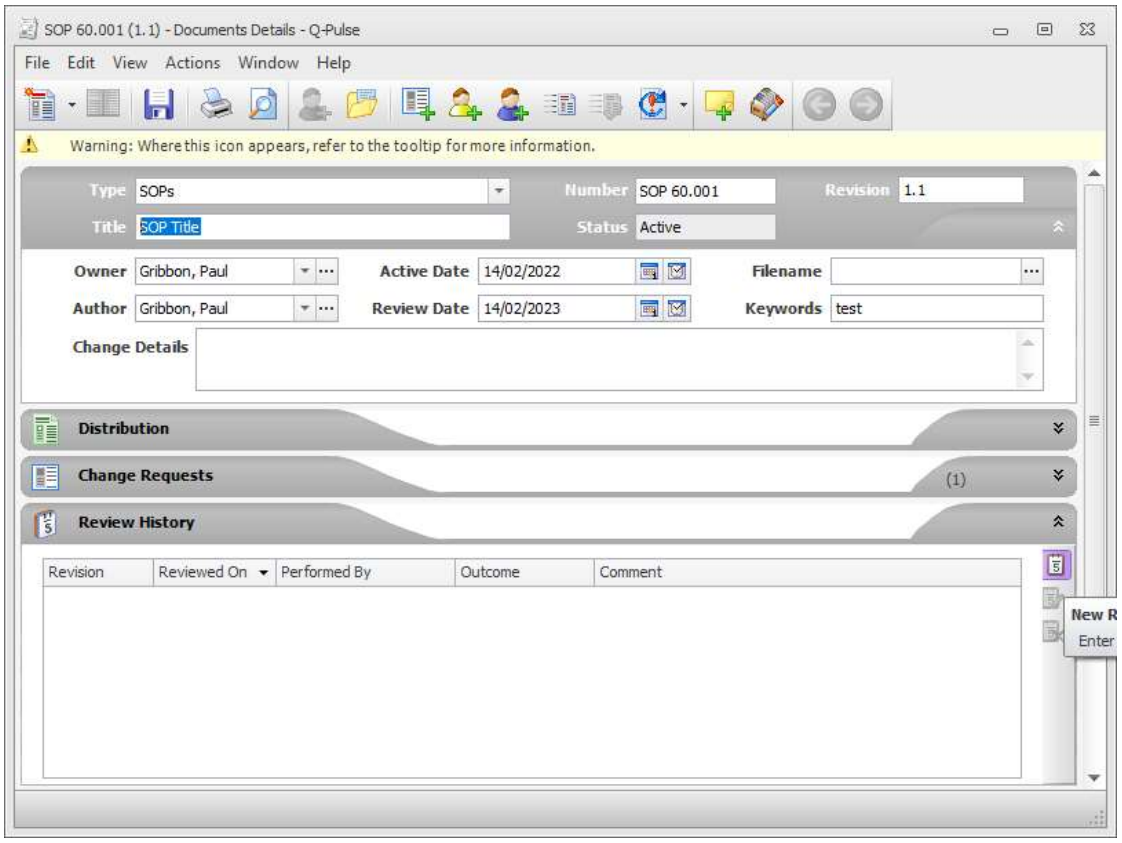
When the required documents have been identified there are 3 different options for creating a new review. The first is to right click on the document record from the search list and select "New Review".



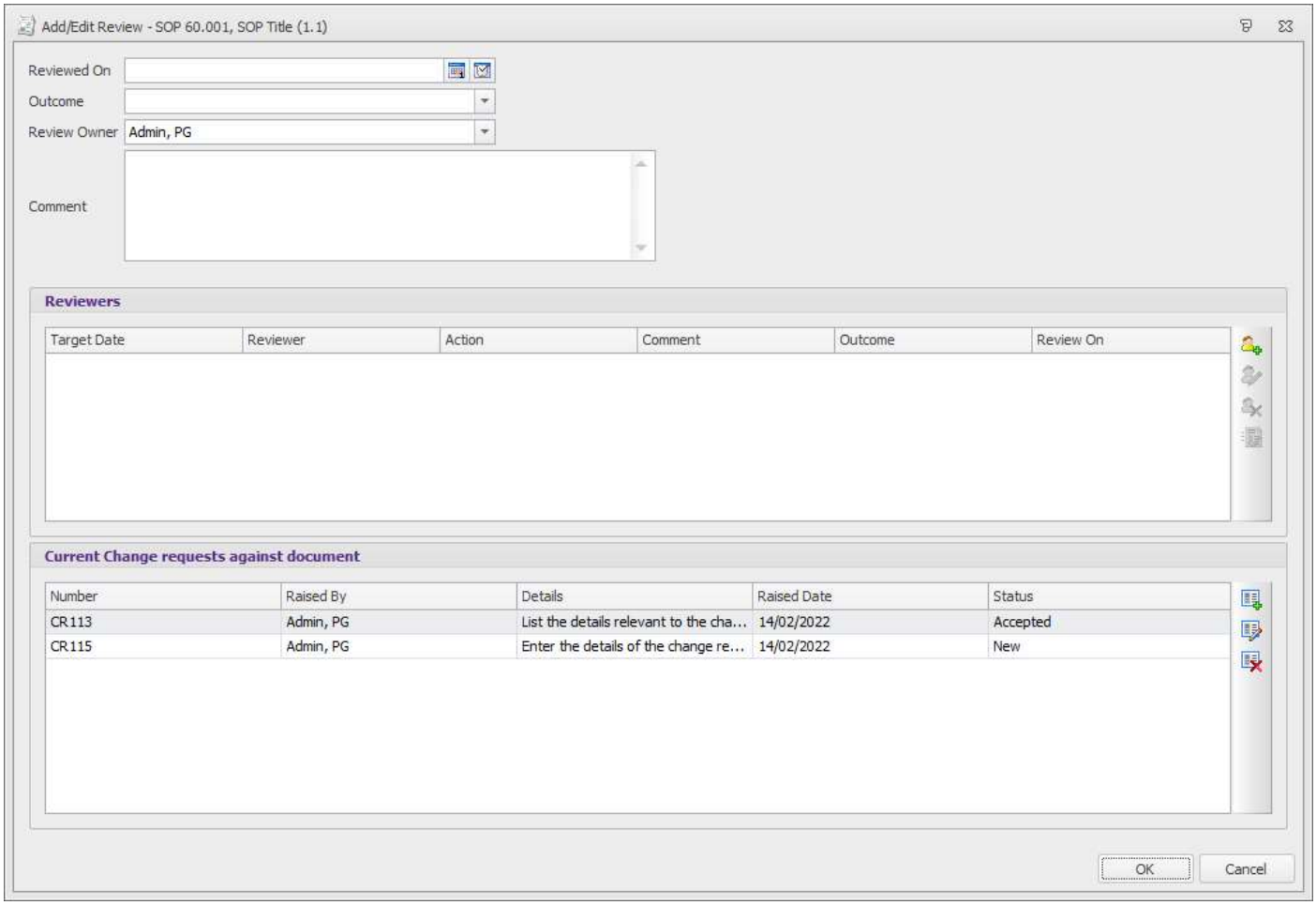
The 2nd option is to open the document record and select "Actions > New Review"



The 3rd option is to expand the "Review History" tab in the document record and select the "New Review" button on the right hand side.



All of these options will result in a new window being opened from which users can be tasked with reviewing the document. The review owner tab will be prepopulated based on the account creating the review, this can be changed and should be the document owner. The bottom of this window will have details of all existing change requests which can be considered by all the reviewers when conducting the review, the review owner should update the Change Request status as appropriate if this has not already been completed.

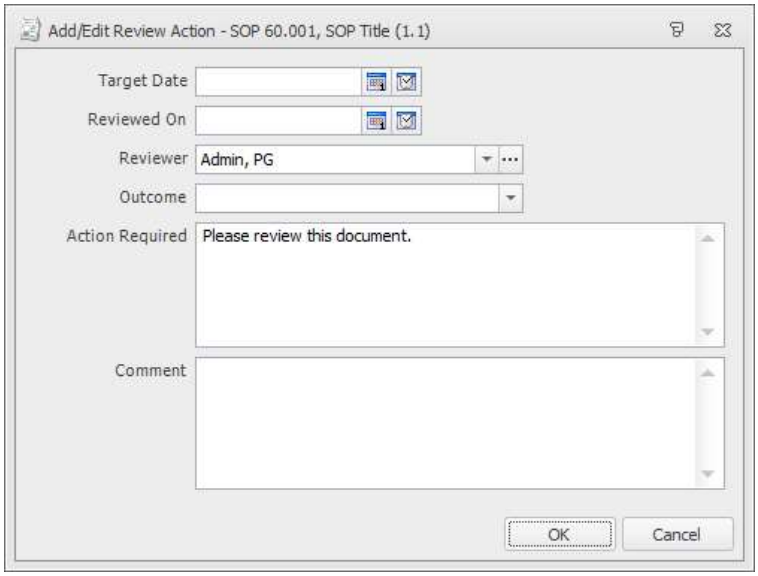


6.1.1. Adding Reviewers

Named individuals can be added to the review to act as a record that they have fed in to the process, the actual method for conducting this review may vary for each scenario. A group meeting to review the SOP may work best, or users to feed in remotely and individually can also be used. Alternatively the review can be left with just the review owner and details of those involved listed in the comment section. If each individual involved is to be recorded in this review record to act as evidence of their involvement, click the "add new reviewer" button on the right to add each of them.

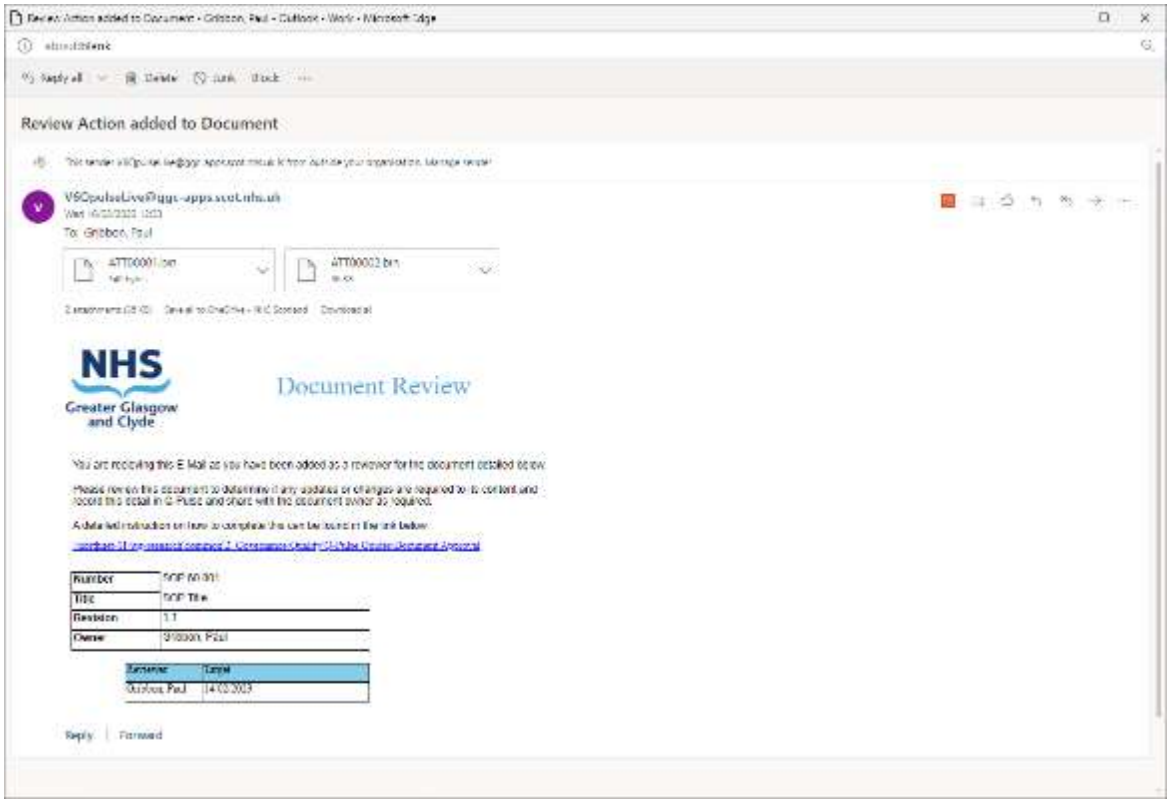
This action can be completed by the Quality Assurance Manager or designated Authority if they are informed of the required names, or by the individual responsible for the review.

This will open a new window in which the details of a reviewer can be added. A target date can be set in the top field which is the required date for any responses by the reviewer. The reviewers name can be selected from the "Reviewer" tab by either typing and selecting from the drop down or searching by pressing the button with 3 dots to open a search window. The text in the "Action Required" field is default but can be updated with specifics of what is required from the reviewer. The remaining fields should be left blank and are for the Reviewer to complete.



When you have entered the details for the reviewer, select Ok on this window and repeat this process as required to add the relevant reviewers. Once this is complete, select Ok to close the review window and save the document record.

All reviewers named will then receive an automated e-mail message to notify them that they have been added as a reviewer.



6.1.2. Responding to a Document Review

Each reviewer will receive an E-Mail notification which will contain a link to a How To Guide on completing the required actions.

https://www.nhsggc.scot/downloads/Responding-to-a-Document-Review

6.2. Scheduled and Unscheduled Review

Document can be reviewed on a Scheduled and Unscheduled basis. For scheduled reviews, this is linked to the "Review Date" held for each document, a central report is generated and distributed to all departments informing them of what documents require a review in that given year, an email will be sent to the author, approver and any relevant members of staff for that area on a quarterly basis and then monthly in the final quarter of the year.

Progress on this activity will be monitored in Monthly reports sent to each department and an overview sent to the Director and Senior Manager. In addition the SOP Committee will maintain oversight on a Quarterly basis and reported annually to GHSP RAG.

All document reviews will be led by the Author for the SOP, it is their responsibility to review the contents of the documents (SOPs and all associated documents) and ensure that the appropriate stakeholders feed into the process. The stakeholders can be identified from the RACI for the SOP. If the document is updated, this will act as evidence of the review and section 6.1 is not required. This can be managed in several different ways and will depend on the document itself, the stakeholders and the complexity. Some options include:

- Group Meeting – Virtual or in Person
- E-Mail Distribution
- Sharepoint/Teams

The use of track changes to record any updates and comments should be used and the input of all stakeholders considered. **No action should be given to any group of staff without their agreement and buy in.** The ultimate decision on content falls to the Author and Approver and areas of conflict or disagreement may be escalated to the appropriate level to agree a resolution.

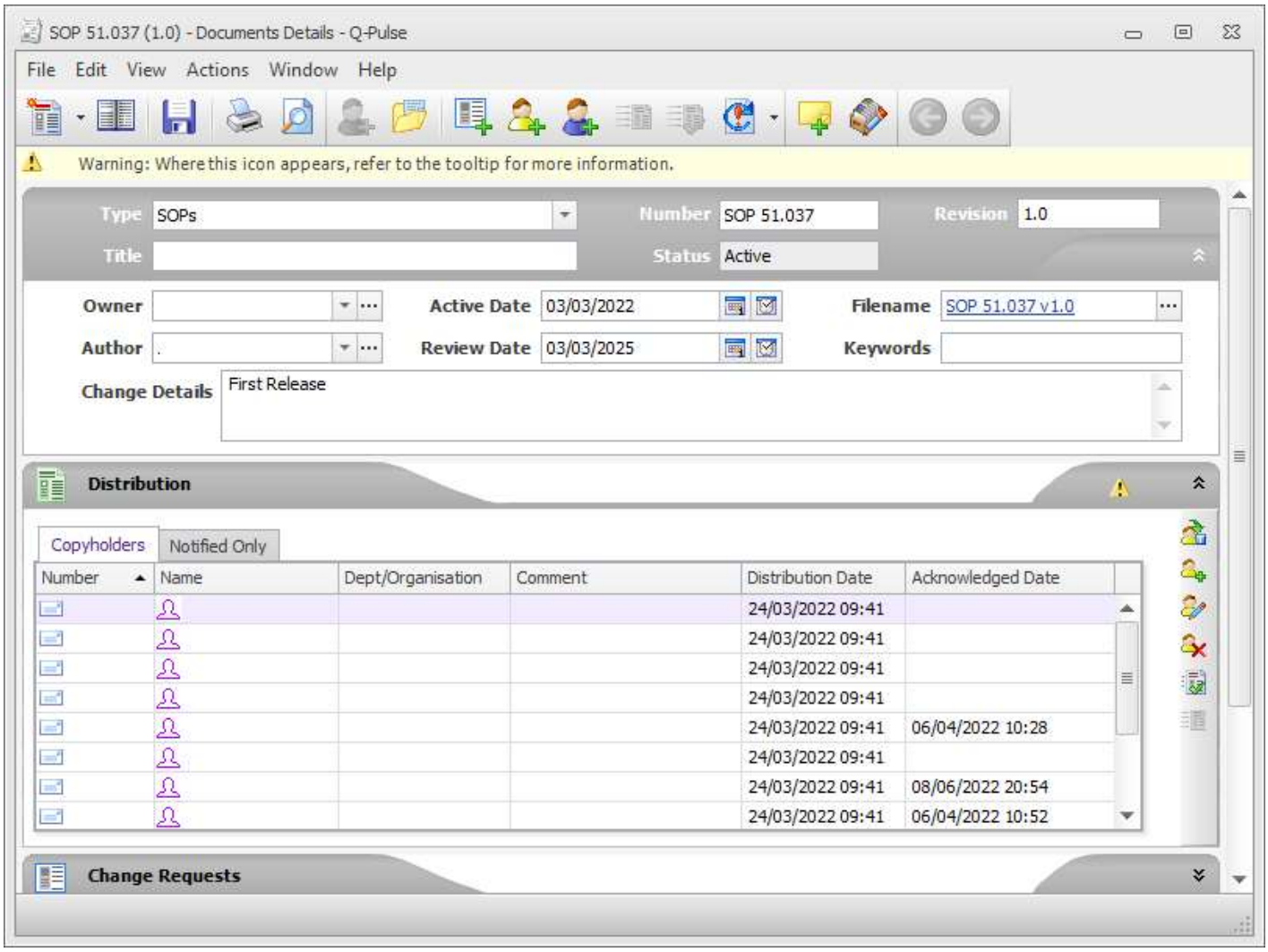
Clear timelines should be given of when responses are required to ensure timely progress is made, in the event you do not receive feedback from a group of stakeholders you may ask again for them to feed in but are not required to wait for this feedback as long as they have been given the opportunity to reply.

If an unscheduled review is required, the same process will be followed but it will not be time dependent as with the scheduled reviews.

7. Read and Comprehend (QA)

As described in SOP 50.023, the requirement for Staff to Read and Comprehend certain SOPs associated to their Staff Category is detailed within each SOP. This is reflected and recorded in Q-Pulse as each staff member will be issued with the relevant SOPs to Read and acknowledge they comprehend its contents through Q-Pulse.

This has been mentioned previously in Section 2 and 3 and only appears as an option for Active documents or when documents are being made active. The records relating to this for Active documents can be found under the "Distribution" tab.



As can be seen in the example above, a list of staff will have a record of the document having been distributed to them and a record of when they have acknowledged they have read this document.

Reports are run centrally by the Quality Assurance Manager or the appropriate designated authority to ensure staff are responding in a timely manner as well as automated reminders being sent.

In the event a document is to be added as new or updated which changes the staff groups associated to the SOP, this will be reflected in the records by the Quality Assurance Manager or the appropriate designee at this time which is detailed in Section 2 and 3.

In the event new members of staff join R&I or change role within, the Quality Assurance Manager or the appropriate designee must be notified to ensure they are set up with the appropriate Q-Pulse account and the correct documents distributed.

When distributing a large number of documents to a member of staff, to avoid them receiving an email per document you can turn off the notification E-Mails within Q-Pulse while you distribute them.

To achieve this, from the Administration Module in Q-Pulse, select the "Messaging" option and then disable "Notification Only" and "Notify Copy Holders" before distributing the document. You can distribute all but one document where they are either Notified only or a Copy Holder before re-enabling and sending one email for each type.

The required reading list of documents will be assigned to their account and available when they log in.

The distribution of the documents is dependent on an individual's job role and is reflective of that which is detailed within the RACI of the document.

Some considerations for this process:

When Project Managers are referenced in the RACI, the staff groups are:

- All of the PMU unit making up project managers within R&I
- Industry Collaboration Project Managers in Innovation
- ⊗ Do not send to RCB or GU project Managers

In general, do not send to GU staff as this process is controlled by GU themselves, a weekly notification of new or updated SOPs is sent which GU then use to appropriately train staff.

Do not add a staff member as a copyholder if they are the author or approver, instead add them as notified only.

7.1. Responding to Read and Comprehend Action

When a document is distributed, an E-Mail will be sent to all Copyholders and Notified individuals. This will include a file to locate the record in the desktop application and a link to open the record in the web version.

The following document has been updated and it is required that you acknowledge that you have received, read and comprehend its content.

If you do not know your log in details for Q-Pulse, check for a previous email from Q-Pulse with the subject "New User Added to Q-Pulse GG&C Research and Innovation". Failing this, contact the QA Manager.

Number	SOP 17.006
Title	Refrigerator and Freezer Unit Use and Monitoring
Revision	5.0
Active Date	01/04/2025
Author	

If you do not have access to the GG&C network, you may access the above mentioned document on the Glasgow CTU website.

https://www.glasgowctu.org/Home/sops/

It may take time for this update to filter through to the website so confirm the correct version number is in place before reading. Form 01.008B can be used to record you have read the documents and returned to the R&I Quality Manager (paul.gribbon@ggc.scot.nhs.uk) for update on Q-Pulse

If you are on the GG&C network, you can log in to Q-Pulse directly and acknowledge this document.

To open this document in Q-Pulse web, there is a link at the top of this E-Mail to locate the record.

To complete the required actions, the following How To Guide is available.

Read and Comprehend Documents - Web

Read and Comprehend Documents - Application

This E-Mail will include links to How To Guides to complete the required actions in both the application and on web.

https://www.nhsggc.scot/downloads/read-and-comprehend-application/

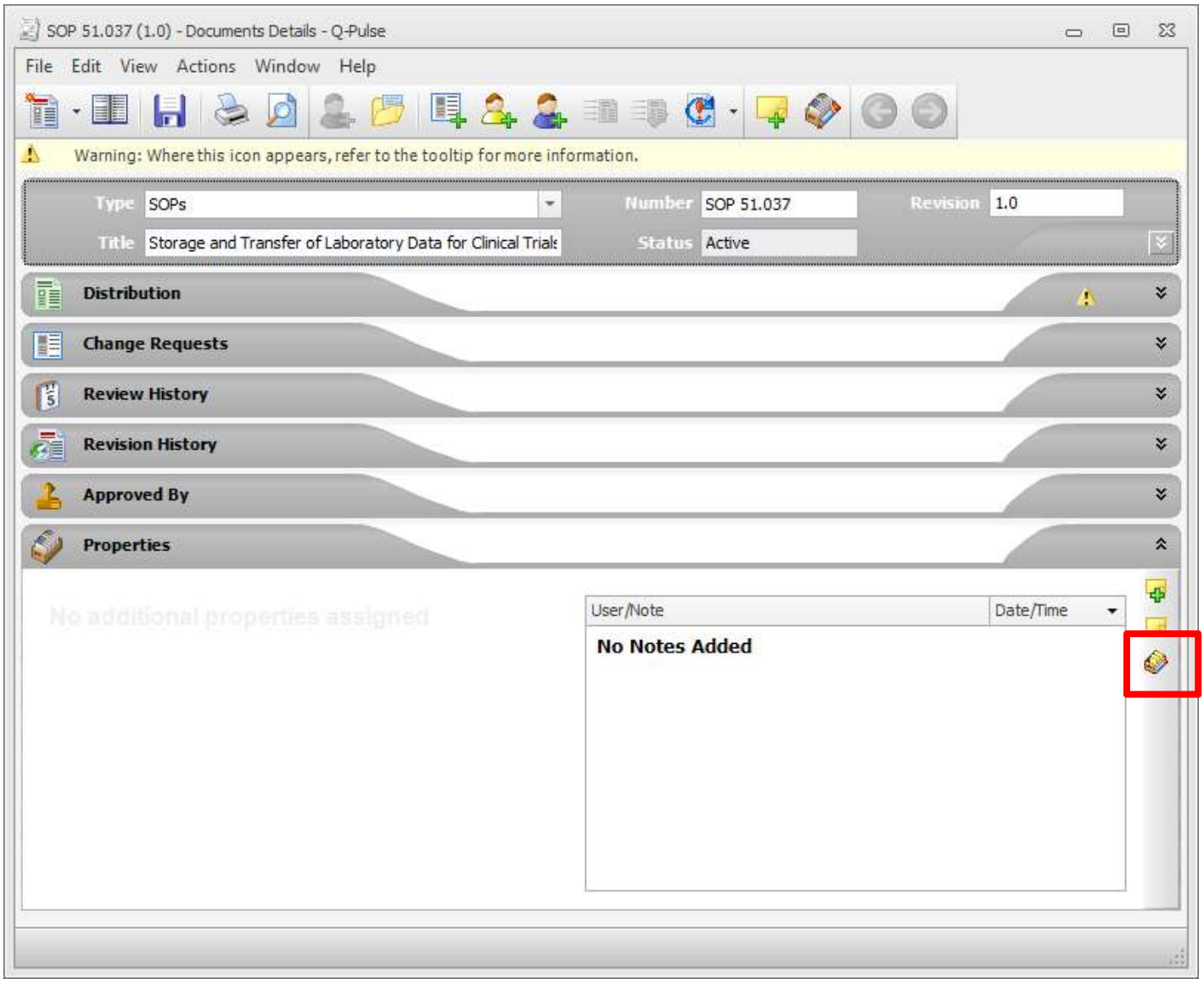
https://www.nhsggc.scot/downloads/read-and-comprehend/

As some investigators may not be on the NHSGGC network, links to the SOPs are made available on the R&I website and staff may confirm back to QA by E-Mail that the documents have been read and request that Q-Pulse is updated for them.

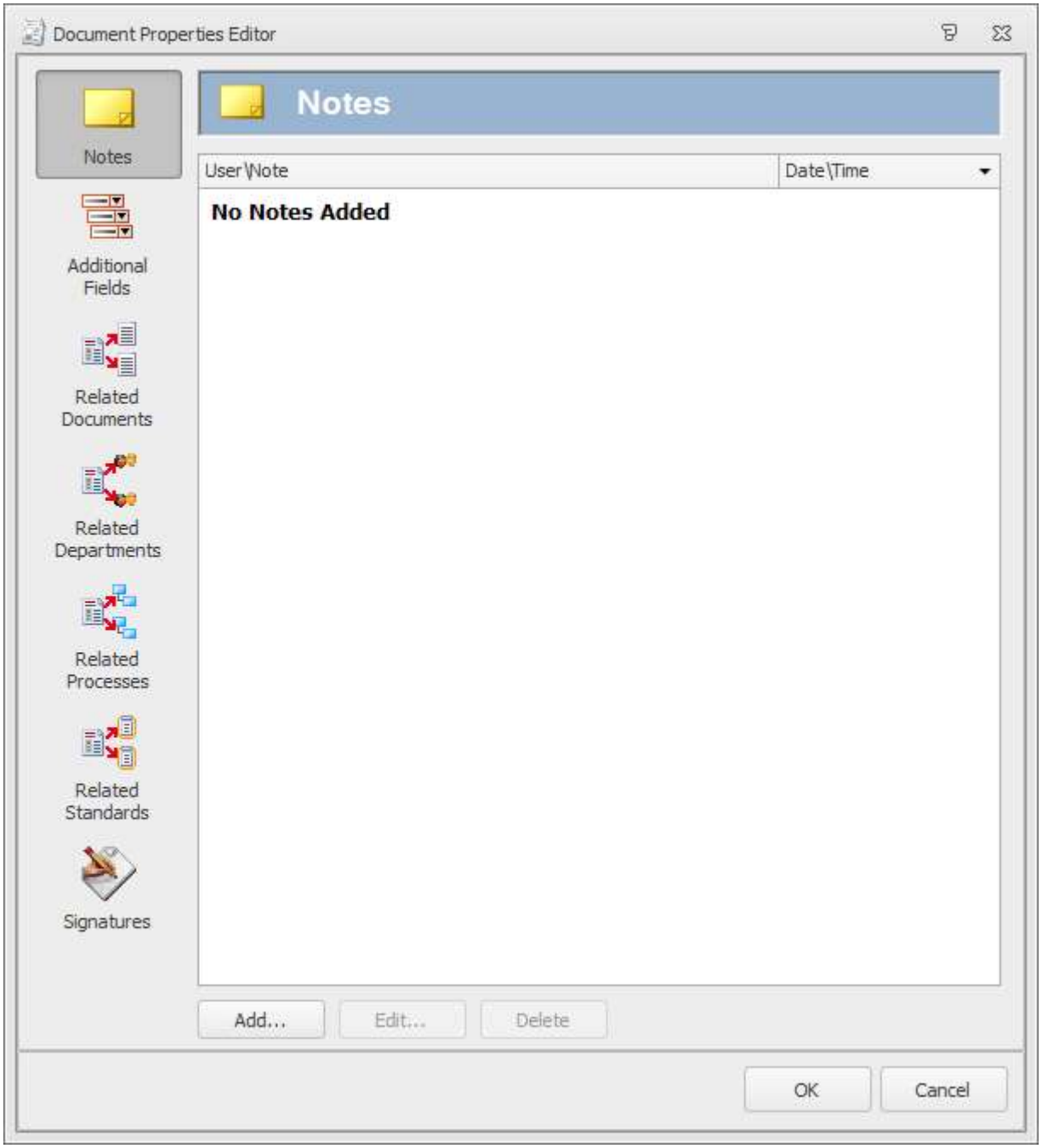
8. Related Documents and Processes(QA)

SOPs, Forms, Guidelines and Work Instructions can be interconnected in their nature and reference other processes. This relationship which is detailed in section 4, Referenced Documents, of the SOP template can then be represented within Q-Pulse by forming these links.

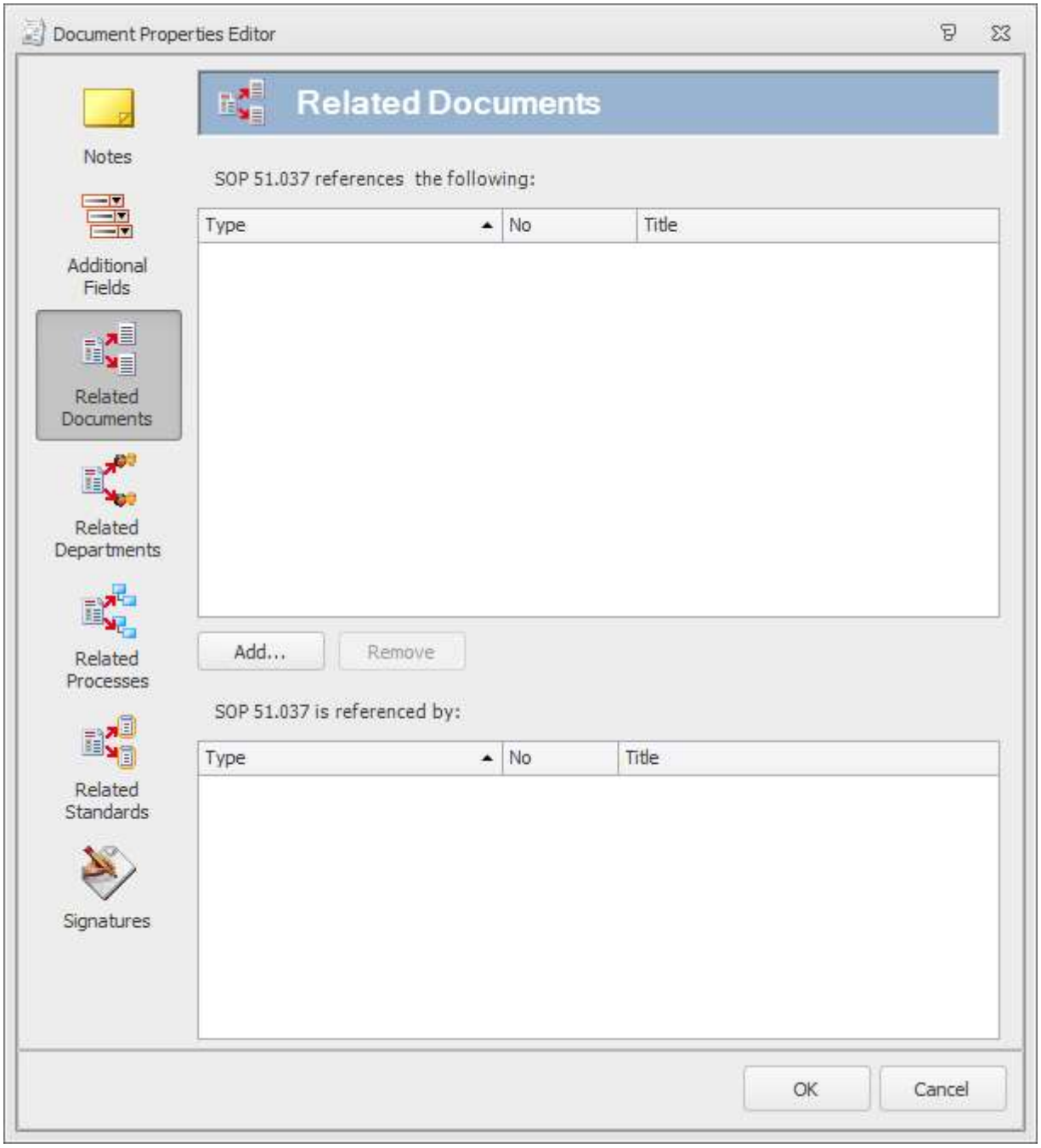
This action will be taken by the Quality Assurance Manager or the appropriate designee, to achieve this, during the release of a new SOP or update of an existing SOP detailed in section 2 and 3, the properties tab of the document can be expanded and the document properties option selected. This action is only required to be completed for SOPs.



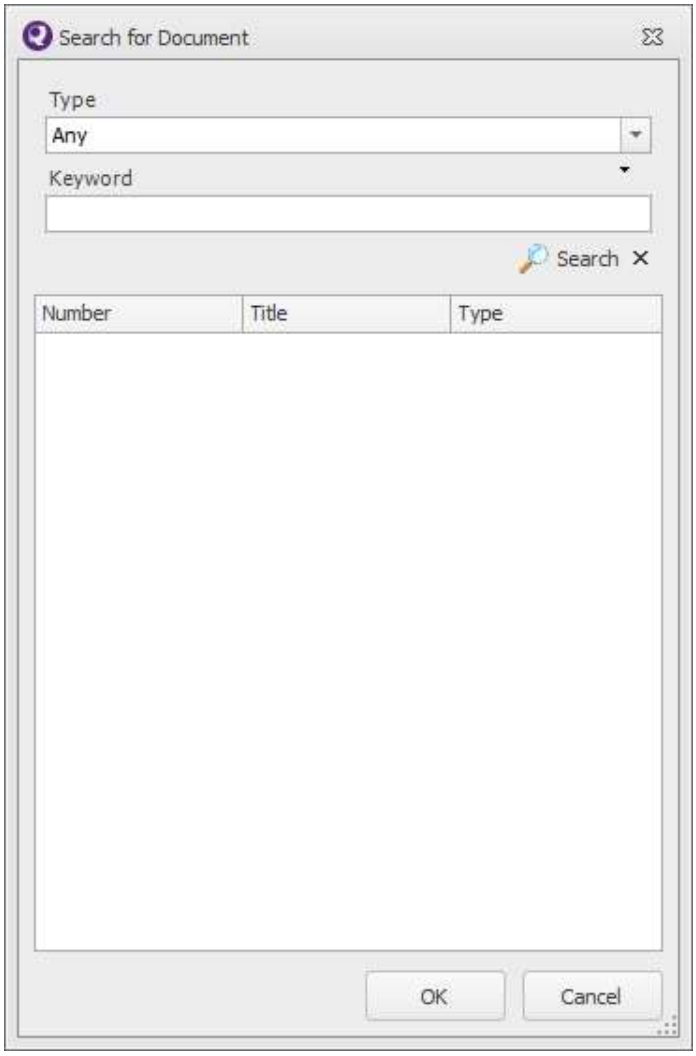
This will open a new window which has a number of different options in which associations can be formed to the document. In this instance it is the "Related Documents" option which is of interest, select this option to change the displayed screen.

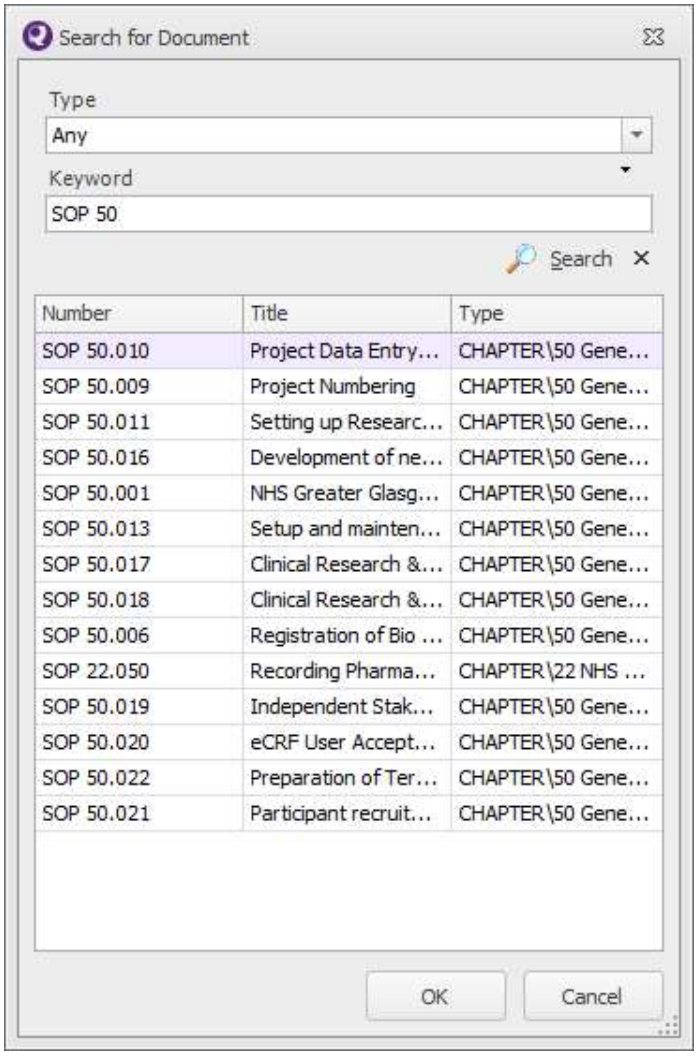


In this screen there is the ability to "Add" a link to another document, this allows to link any document held in Q-Pulse to this document record.



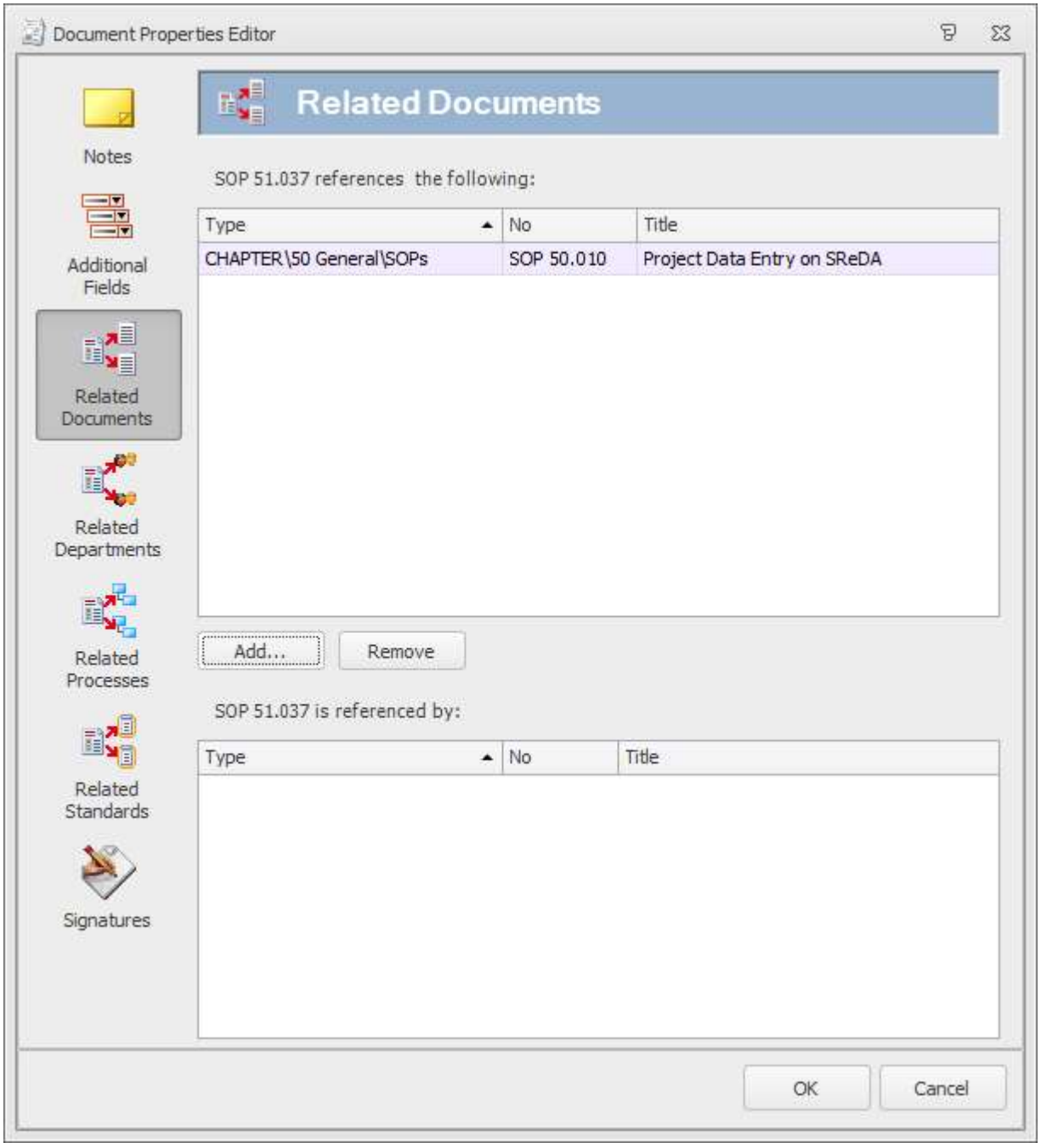
By selecting Add, a new window will open and allow you to search based on a keyword which can be the document number or title.





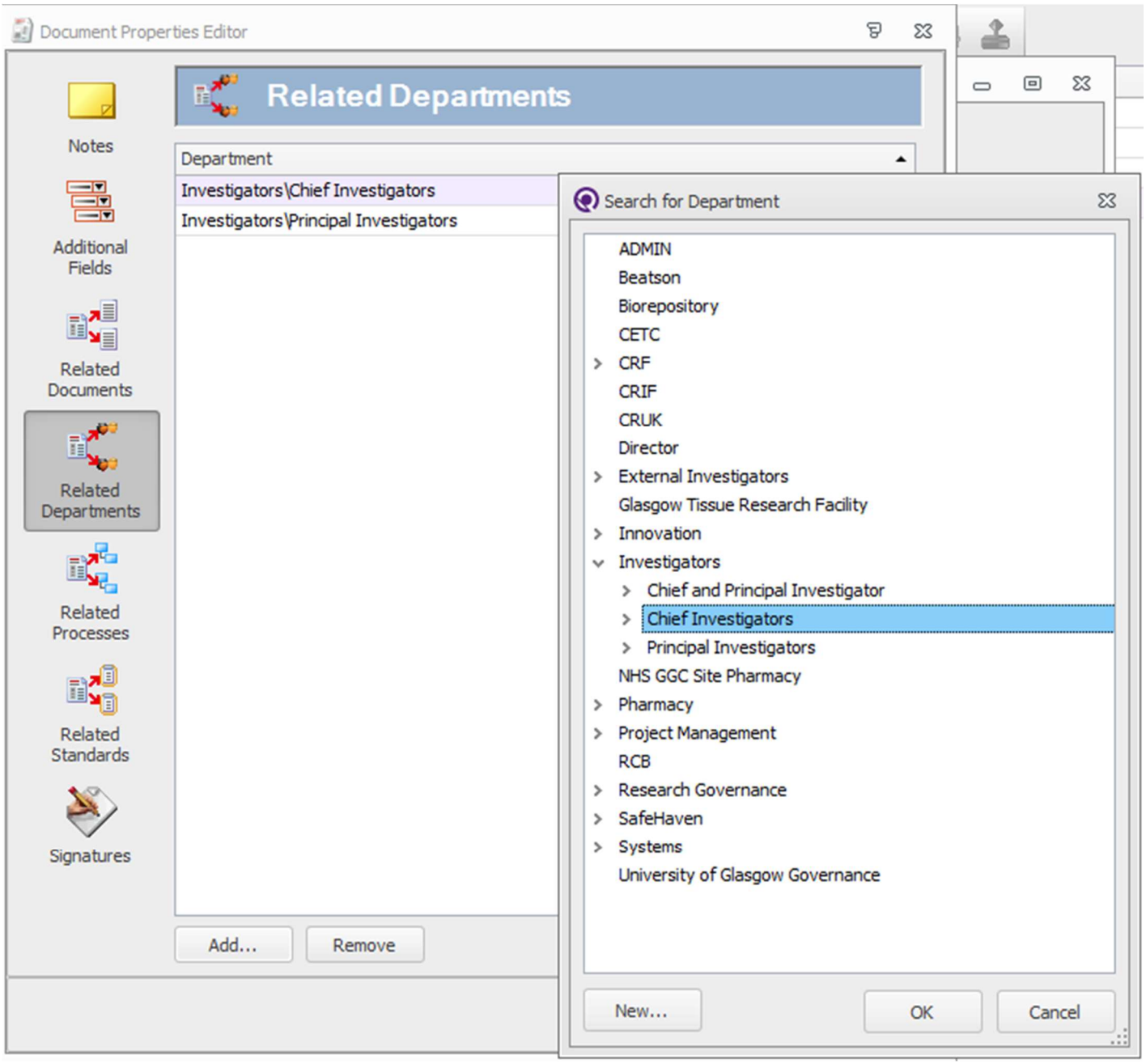
From the presented list of options, select the relevant SOP, Form or Guideline to add this link.

This process can be repeated as many times as is required to form all the appropriate links. With these links in place, it will allow you to view all the associated documents to an SOP when it is undergoing review and help to manage the potential ripple through impact of any changes.



In addition to linking documents, when an SOP is relevant to Investigators, either a CI or PI as detailed within the RACI matrix, it must be marked as having a link to that department within this section in order to ensure that changes to these documents are appropriately managed and updated on the R&I website.

To achieve this, on the same screen as above, select "Related Department" and from here you can select "Add" to make the link.



When you select Add, the list of all relevant departments will be displayed, under "Investigators", select "Chief Investigators" and "Principal Investigators" as appropriate.

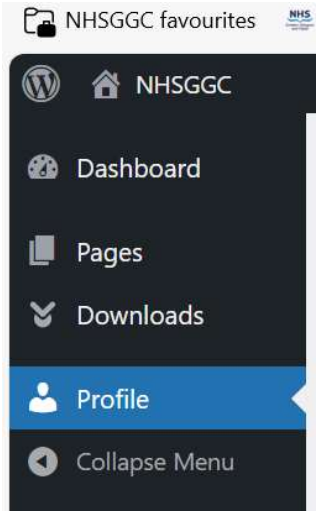
9. Updating the R&I Website (QA)

To update the R&I website you must have completed the relevant Learn Pro session for the use of wordpress and have been given an account for wordpress.

The SOP page for R&I will be maintained in line with the documents available on Q-Pulse for Chapters 17, 21-23 & 50-58. SOPs, Forms and Guidelines will be maintained but Work Instructions will be maintained on Q-Pulse only.

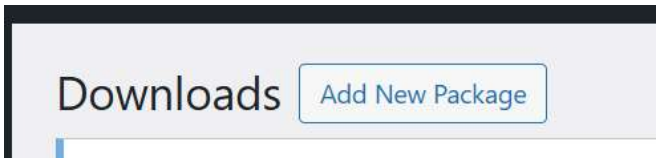
You will have 2 scenarios of either adding a brand new document or updating an existing document, first log in to your wordpress account.

From here you will have the main screen and be presented with the option for “Downloads” on the left hand side. Select this to see a list of available documents.

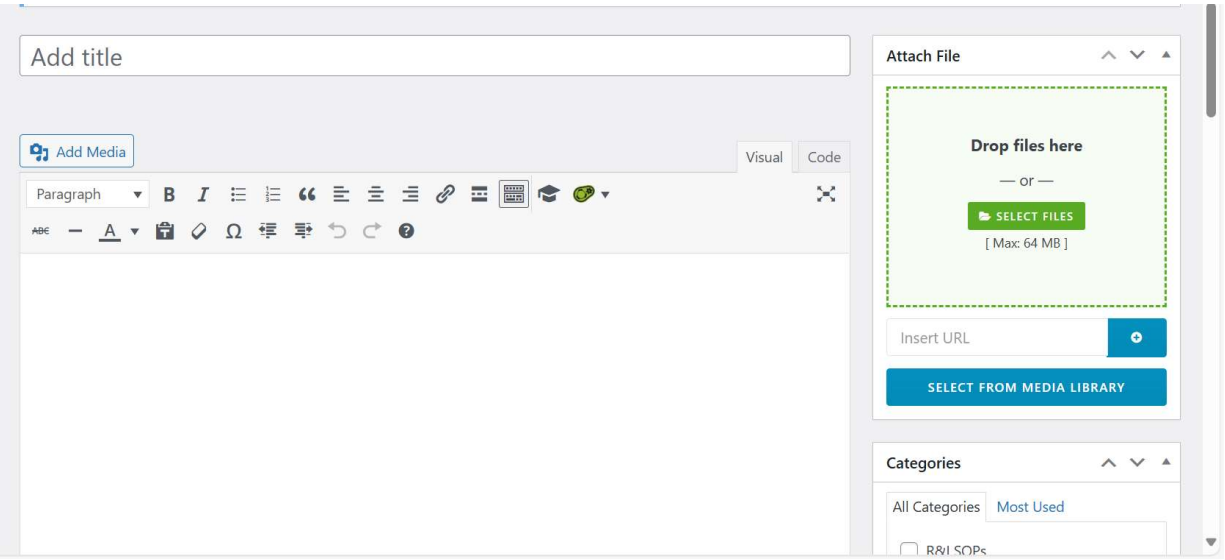


9.1. Adding New Document

If a brand new document is to be added that has no previous versions available, at the top of the Downloads page there will be an option for “Add New Package”. Select this to open a new window to add a document.



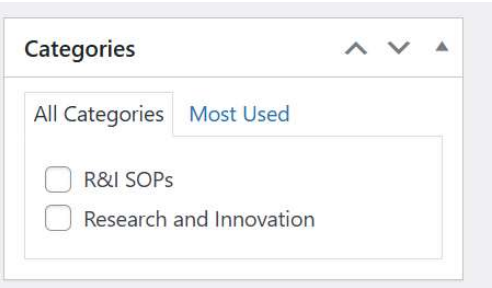
There will be several fields that need to be completed, the first is the title of the document which reflects the number given in Q-Pulse, i.e. SOP XXX, Form XXX, GUI XXX etc



In the large text field below, add the title of the document as it appears in Q-Pulse.

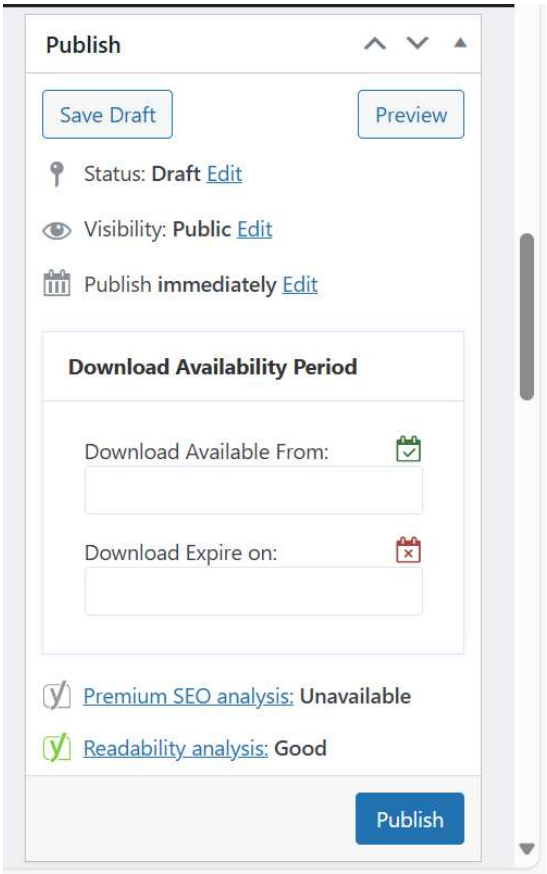
On the right hand side, there is an option to attach files, select the green button to select the document which has the completed active date as discussed previously.

Below this on the right hand side, select the category as “R&I SOPs”



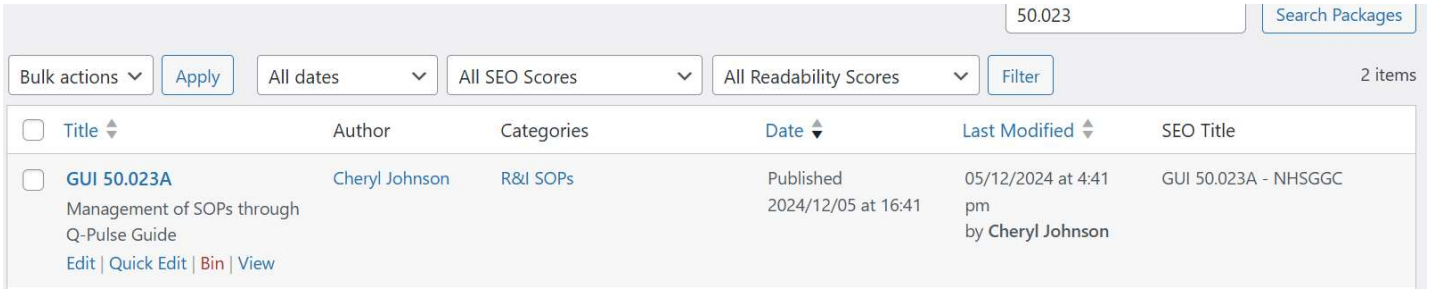
If password protection is required for the document, scroll down to “Package Settings” and then select “Lock Options”, from here select the option “Enable Password Lock” and follow the instructions to create passwords.

The final action is to then publish the document which appears as a button on the right hand side.



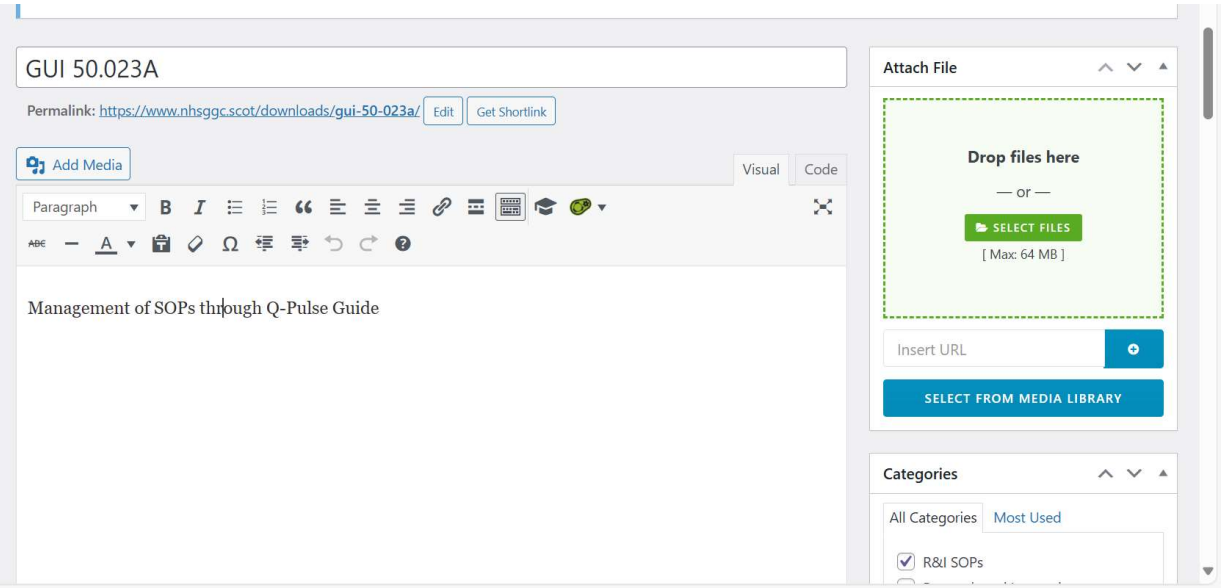
9.2. Update Document

If a version of a document already exists you can search for it using the search bar on the top right.



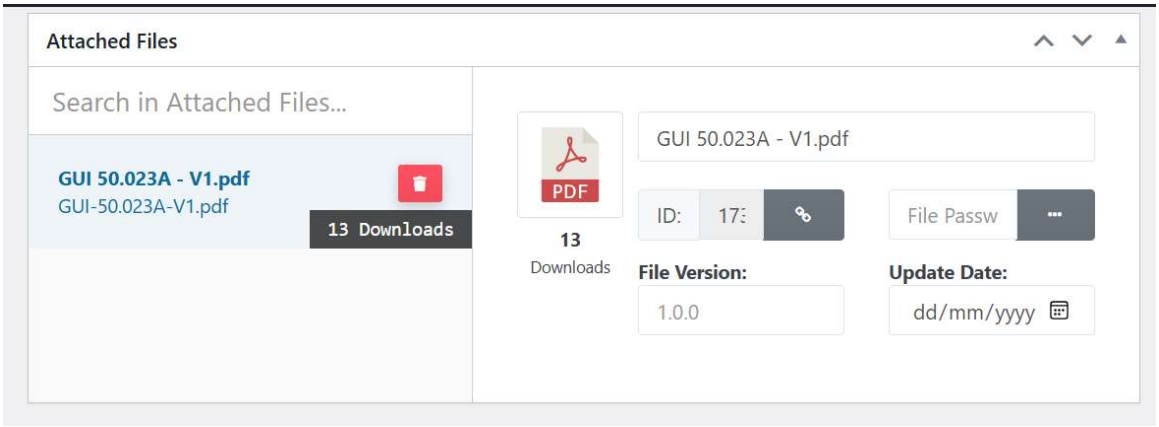
You can open the record by click on the blue text of the document title.

This will open a screen with the relevant information for the document.

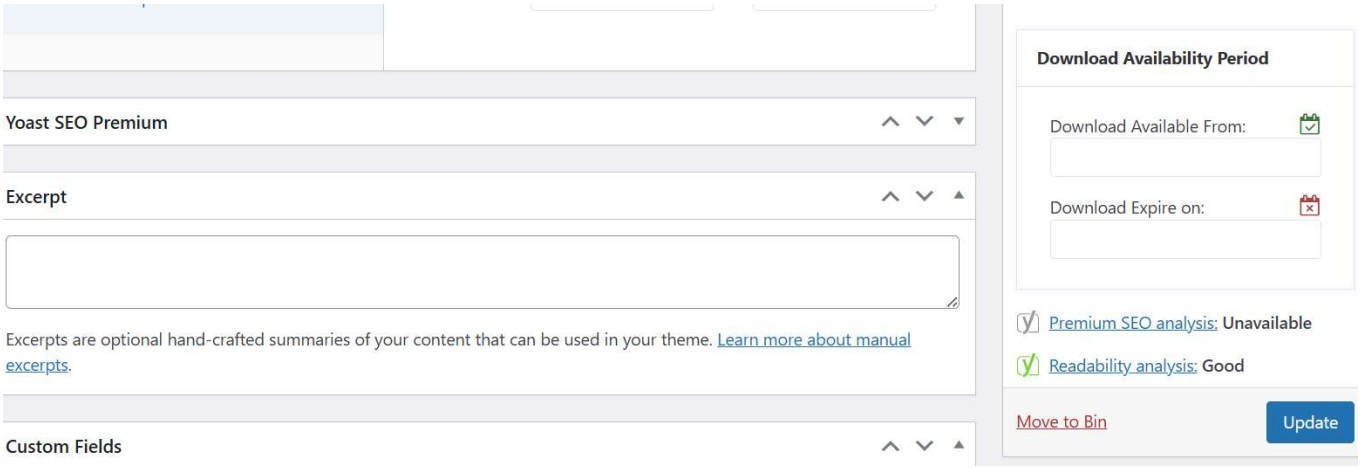


You can change the title of the document in the text field available if required, the version number is not recorded and so it is only changes of title that need to be updated.

By scrolling further down you will find an “Attached Files” section, by hovering over the file you will be presented with the option to delete the existing document. Delete this existing document before uploading the new one.



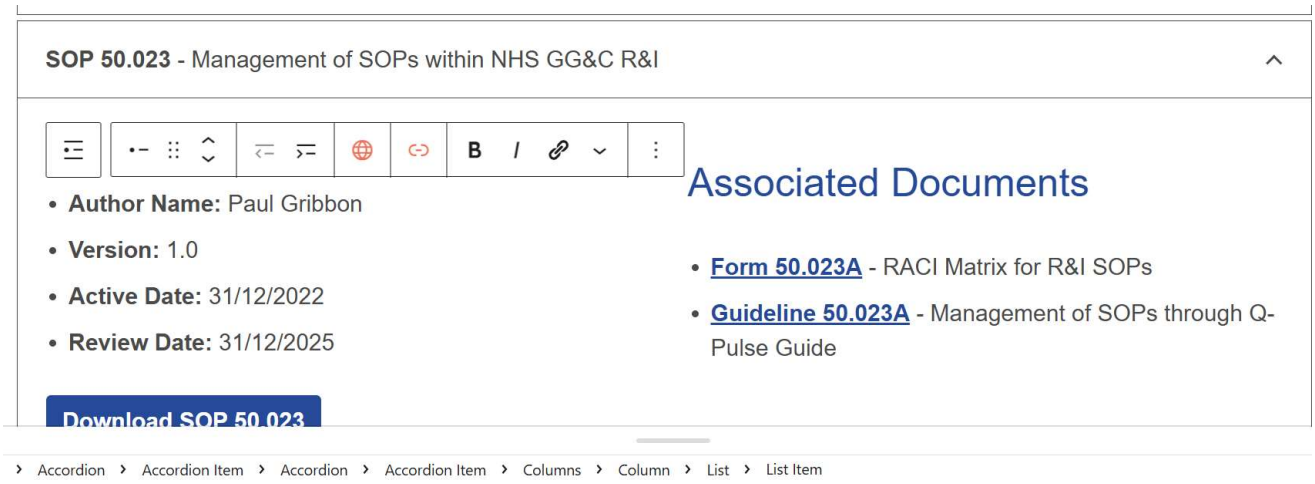
Once deleted, scroll back up to the “Attach Files” option on the top right and select the green “Select Files” button. Select the updated version of the document with the added active dates as discussed previously. When completed, the new file will be in place and the record can be updated. To do this, scroll down to beside the attached files section and a button with the title “Update” will be present. Select this to update the record.



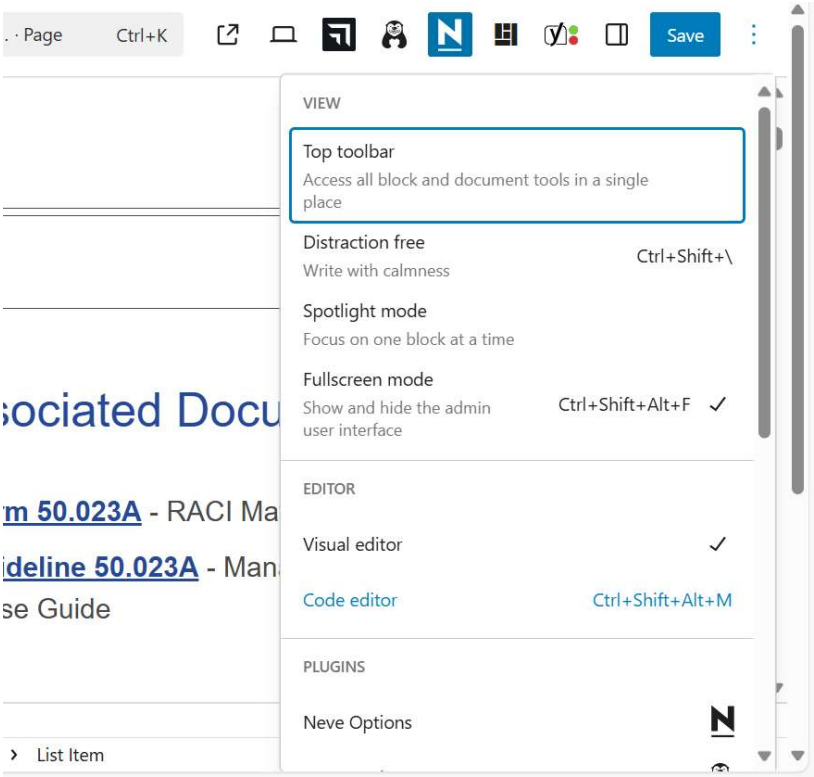
9.3. Updating SOP Page

In addition to updating the Documents, the SOP Page must be update to reflect changes to version numbers, authors, titles and the creation or removal of documents. To do this, select the “Pages” option from the left above “Downloads”. This will show a list of pages available, the one of interest is “Standard Operating Procedures (SOPs)”.

The web page can be updated in one of two ways depending on the extent of the changes. If a change to a single document is needed and it is just the Version, Author or Title then this can be done by navigating to the required area and updating by selecting and overtyping. All links will remain the same and do not need to be updated unless a new document is being introduced.



In the event of updating several documents or adding/removing documents the page can be updated through HTML. To access this, on the same page in the top right hand corner select the 3 dots beside save and then select “Code Editor”, alternatively you can press “Ctrl+Shift+Alt+M”.



This will change the view to the HTML for the webpage, you are not expected to know how to edit the HTML, instead a tool is available on the common drive to produce HTML for the page based off an extract from Q-Pulse that can replace the existing code and update the page.

The tool can be located here:

\\northnet-11\wg-research\common\2. Governance\Quality\Website Code

Instructions are available in the Macro enabled file “WEB SOP generator” on extracting data from Q-Pulse and updating the webpage. As this requires an update to a large amount of data the web interface may freeze or time out, allow this to run and update as it may take some time.

In both cases, when the updates are complete. Select the “Save” button in the top right hand side when finished.

Glasgow Clinical Trials Unit Guideline

Guideline signatories

Prepared by	Paul Gribbon
Approved by	Caroline Watson

Document history

Version	Date	Description	Retrospective Implementation
1.0	25/08/2022	First Release	No
2.0	22/09/2025	Clarifications and extra details added, inclusion of R&I website instructions	No