

# **NJRO Document Preparation, Creation and Approval using Q-Pulse**

**NJRO-GEN-SOP-024**

## Contents

1. Introduction
2. Scope of document
3. Responsibilities
4. Procedure
5. Appendices

## Background/Introduction

This procedure will outline the steps required to create a new draft document record in the NJRO Q-Pulse system and submit it through the approvals process. It is expected that the document has already been drafted in the correct template at this stage. Only members of the Document Management group can create draft documents within the system. If the document author is not a document manager then they should notify the document manager in their team or the Q-Pulse system administrator to create the draft record and ask to be assigned as the document author.

## Scope of the Document

This procedure should be followed for all new documentation created in the NJRO that requires document management within the Q-Pulse system.

## Responsibilities

Within The Newcastle upon Tyne Hospitals NHS Foundation Trust (NuTH FT) the NJRO team are responsible for the development and management of sponsor level research SOPs as well as Policies, Work Instructions, Guidance documents and Templates (Forms etc.)

This SOP is applicable to all members of the NJRO who are involved in preparing, reviewing or controlling NJRO Documentation

SOPs and documents concerned with NJRO procedures appropriate for use across all research project work will be written by a member of the NJRO team, depending on who is best qualified by experience or competency to do so.

This procedure will be followed by any members of the Document Managers group adding a new draft document to the system.

It is the responsibility of document managers to add document records to the system. They should add the member of their team who has authored the document as staff who are not in this group cannot create document records on the system.

## Procedure

When drafting NJRO documentation, the guidelines set out in the [Document Control SOP NJRO-GEN-SOP-001](#) should be followed.

### Initial Review of a New Document

Once a document has been drafted, the author will send the document electronically for initial sense check according to the table in Appendix 1.

The check process is designed to ensure the document content is understandable and there are no omissions. It is NOT intended to be a formatting check at this stage.

### Format Check

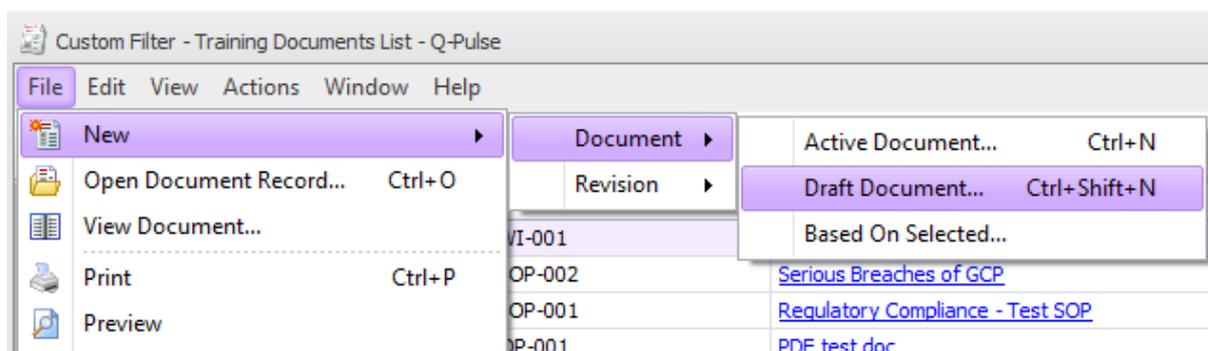
Once the document has been sense checked it should then be sent to the Informatics Mailbox [nuth.njro.informatics@nhs.net](mailto:nuth.njro.informatics@nhs.net) for final formatting checks. If no issues are identified during the formatting review a draft document record can then be created within the Q-Pulse system by a Document Manager.

If the initial sense check or formatting review identifies issues with the document, the document author can decide to incorporate or reject the comments and should liaise with the reviewer/formatter to finalise a draft document suitable for use.

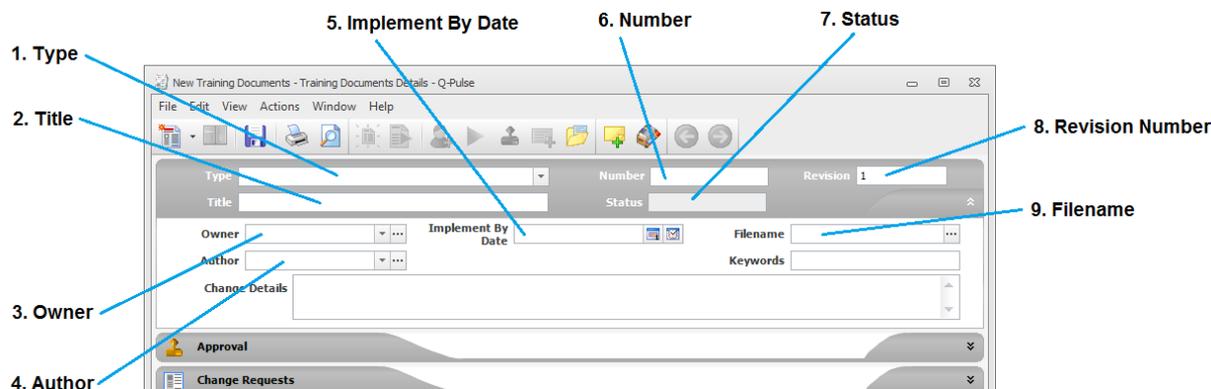
### Creation of a draft record in the Q-pulse system

#### 1. Procedure

- Log into the system using your credentials
- Open the Documents Module
- Select **File > New > Document > Draft Document** (see image below)



Complete the fields on the 'Document details' screen as shown in the image and described below;



**1. Type** - Select the appropriate document type from the tree structure by clicking the down arrow  at the right hand side of the 'Type' field to display the structure and expand the tree to navigate down to the appropriate 'suite' and then 'document type' (Policy, SOP, WI, Template or Guide)

Ensure you select the document type (Policy, Standard Operating Procedure, Working Instruction, Template or Guide) as below or the document number will not populate automatically;

i.e. **NJRO > General > Standard Operating Procedure**

1. NJRO	
> Funding Development	1. NJRO\
> General	1. NJRO\
Standard Operating Proce...	1. NJRO\General\
Template	1. NJRO\General\
Working Instruction	1. NJRO\General\

**2. Title** – Enter the Title of the document

**3. Owner** – Use the drop-down list to select the appropriate document owner according to the table in Appendix 2. **\*Note that this should not be the same person as the Author\***. In instances where the listed assigned owner below is the same person as the author, an alternative owner should be chosen from the listed deputy's below;

**4. Author** – Use the drop-down menu to select the name of the person who wrote the document

**5. Implement By Date** – Enter the date you would like the document to come into use (not mandatory)

\*\*\*Now save the record to create the draft using the disk icon in the top panel\*\*\*

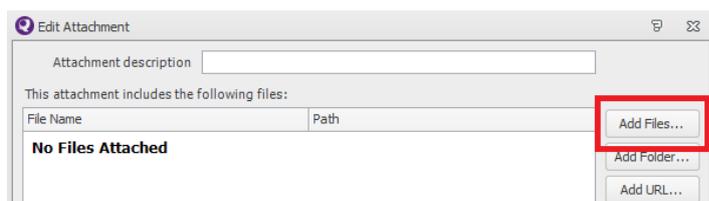


**6. Number** – This field will be automatically populated after the document type is selected and the save button is pressed. If the field is still blank at this point, please email the informatics mailbox [nuth.njro.informatics@nhs.net](mailto:nuth.njro.informatics@nhs.net) to inform the system manager.

**7. Status** – This field will be automatically populated after the document type is selected and the save button is pressed

**8. Revision number** – The revision number should automatically populate with revision 1

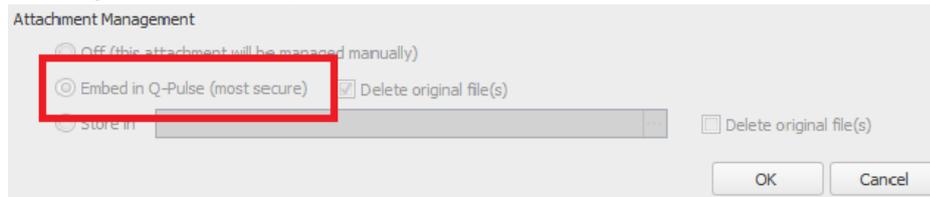
**9. Filename** – Use the  button at the right hand side of the file name field to open the 'edit attachment' screen. Click 'Add files' and browse to the location of the document you wish to add.



- a. If the document is categorised as an 'SOP', 'WI', 'GUIDE' or 'POL' then you will need to upload both an editable (Microsoft word) version **and** a PDF version of the document (see ['How to save a file as a pdf'](#) if you are unsure of how to do this). Once the files are selected click 'Open'  
*\*For templates/forms etc. where you want the end user to be able to download an editable version, you only need to upload the editable version\**
- b. Once the files appear on the 'Edit Attachment' pane, single click the PDF file and click the 'Set Index' button – this ensures the end user only has access to the un-editable version



- c. If the document is categorised as a 'Template' and therefore the end user requires an editable version (a form to be completed etc.), select only the editable (Word/Excel etc.) version of the document and click 'Open'.
- d. By default the file should be set to 'Embed in Q-Pulse' on saving. If this is not the case, you will see an 'Attachment Management' section at the bottom of the page; select the option to 'Embed in Q-Pulse'



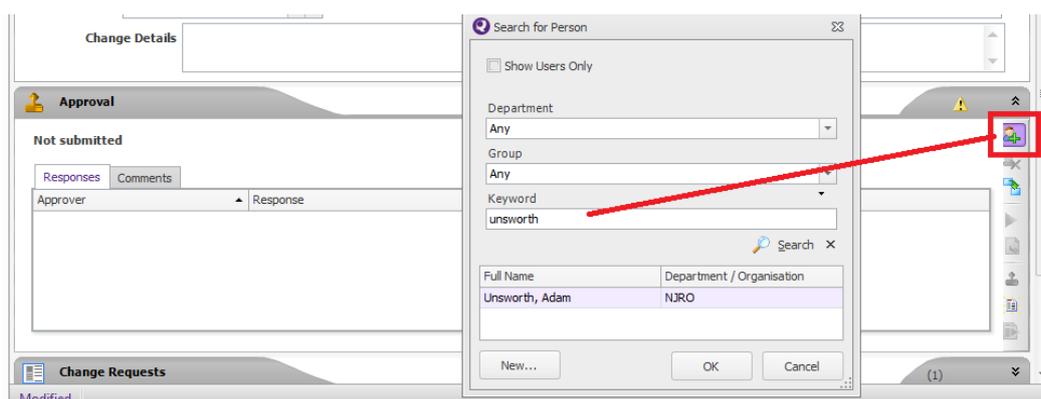
- e. Click OK to return to the main screen



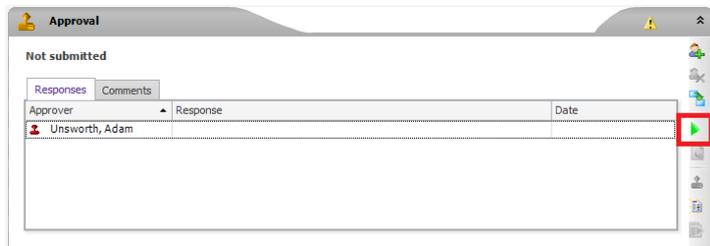
Save the document record. Any errors or omissions will be highlighted; correct any problems and repeat the save as necessary

### Adding Approvers and submitting for Approval

Click on the 'Approval' tab and then on the 'Add Approver' button (Little person with the '+' next to them) Add the appropriate approvers for the type of document by referring to the table in Appendix 3



Finally click the green arrow on the approval tab to 'Submit Draft for Approval'



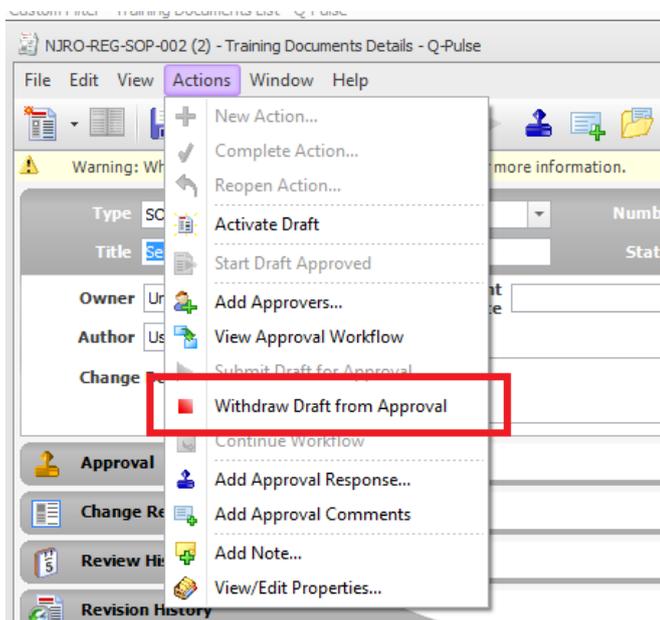
Save the document record and exit back to the main menu



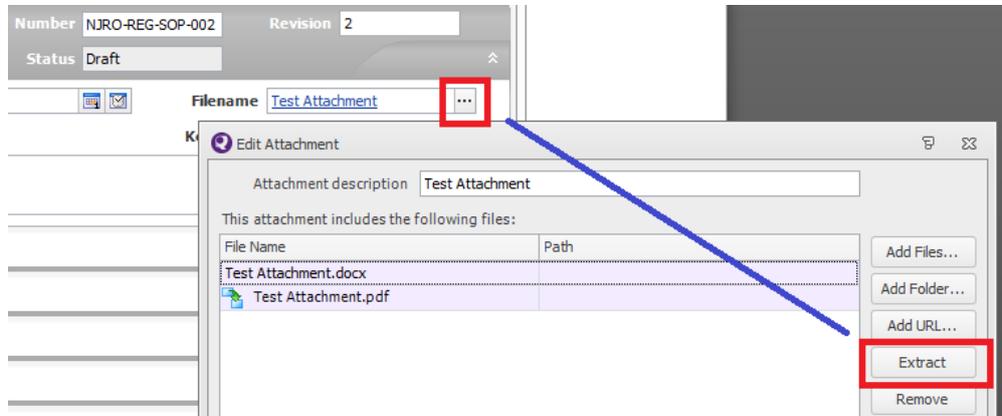
### Document rejected at the Approval stage

If the document gets rejected at the approval stage, follow the process below;

- Author to take note of Rejection comments
- Withdraw draft from approval



- Extract document and make necessary changes



- Re-upload corrected attachment/s
- Resubmit for approval

## Document Activation and Distribution

### Activating a draft document

The Q-Pulse system manager will get a notification when all approvers have responded and the document has been fully approved. At this stage the system administrator will send the owner and author a 'Q-Pulse distribution Pro forma' to be completed before the document can become active. Once this pro forma is returned to the system manager the document will be activated and will move from the draft to the active register.

### Distribution

The system administrator will then distribute the document according to information provided on the distribution pro forma to ensure it reaches the intended audience.

## Appendix 1

### Initial Review

#### Sense Check Process for all NJRO documentation (Policies, SOPs, WI's and Templates)

Q-Pulse Suite	Member of own team	QA	Other Team/s involved in the process	Formatter
General	Yes	Yes	Yes	Yes
Regulatory Compliance	Yes	Yes	Yes	Yes
Governance	Yes	Yes	Yes	Yes
Quality Assurance	Yes	No	Yes	Yes
Informatics	Yes	No	Yes	Yes
Grants & Contracts	Yes	No	Yes	Yes
Funding Development	Yes	No	Yes	Yes

## Appendix 2

### Owner to be assigned

Q-Pulse Suite	Owner	Deputy To be used when the Owner listed in the 'Owner' column authored the document
General	Document Manager of Authors team	Regulatory Compliance Manager, RM&G Manager, Deputy Regulatory Compliance Manager or Quality Assurance Manager
Regulatory Compliance	Regulatory Compliance Manager	Deputy Regulatory Manager or Regulatory Compliance Specialist
Governance	RM&G Manager	Regulatory Compliance Manager or Research Governance Specialist
Quality Assurance	Quality Assurance Manager	Regulatory Compliance Manager
Informatics	Information Manager	Information Specialist
Grants & Contracts	Grants and Contracts Manager	Funding Development Manager
Funding Development	Funding Development Manager	Grants & Contracts Manager

### Appendix 3

**Approval Process – this process applies to SOPs, Working Instructions and Policies only** (Templates and Guidance documents only require 1 approver – use the 1<sup>st</sup> Approver)

Q-Pulse Suite	1 <sup>st</sup> Approver	2 <sup>nd</sup> Approver
General	Document Manager in own team*	QA Manager
Regulatory Compliance	Document Manager (Regulatory Compliance) or Deputy	QA Manager
Governance	Document Manager (Governance) or Deputy	QA Manager
Quality Assurance	Document Manager (Quality Assurance) or Deputy	Regulatory Compliance or Governance Manager
Informatics	Document Manager (Informatics) or Deputy	Regulatory Compliance/Governance Manager or Information Specialist
Grants & Contracts	Document Manager (Grants & Contracts) or Deputy	Funding Development Manager
Funding Development	Document Manager (Funding Development) or Deputy	Grants & Contracts Manager

\* Normally the document owner