Guideline number	**50.023B**	Version	**1.0**
Title	**Review of QMS Documents**		

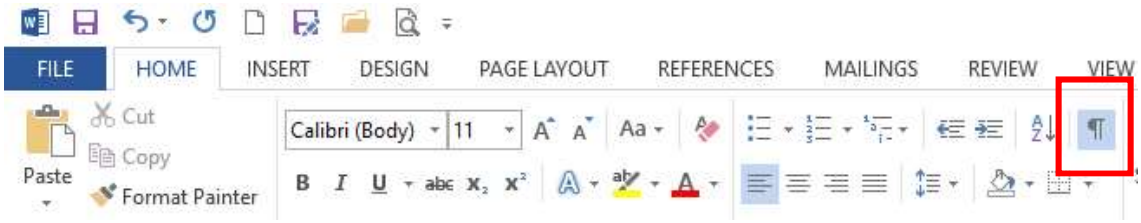
1. Introduction

2. Format

It is preferred to have uniform formatting for all QMS documents released within R&I, below are a number of formatting guidelines to consider for the aim of producing a uniform output of documents within the QMS.

2.1 Viewing Document Formatting

Microsoft Word has built in functionality to show the formatting settings used in the document. This can assist when reviewing the document to understand how it is formatted.



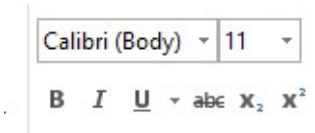
This will make a number of formatting features visible in the form of symbols:

¶	Paragraph break
↵	Manual line break
→	Tab
·	space
°	Non-breaking space
¬	Optional hyphen
⚓	Object anchor
¤	End of cell/row
–	Non-breaking hyphen

2.2 Font

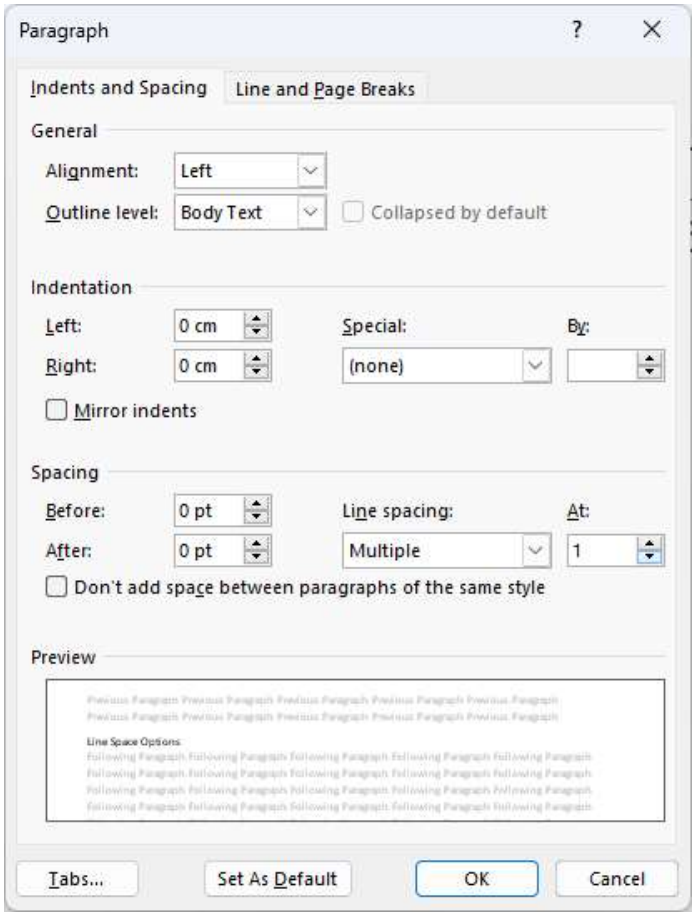
All font within QMS documents should use the below settings, heading will have additional requirements outlined later.

Style – Calibiri
Size – 11



2.3 Line Space Options

The line spacing options can sometimes vary between documents, it is preferred to have a uniform setting of no additional spacing applied to all text as shown below. On some occasions it may be required to apply spacing to improve the final appearance of a document.

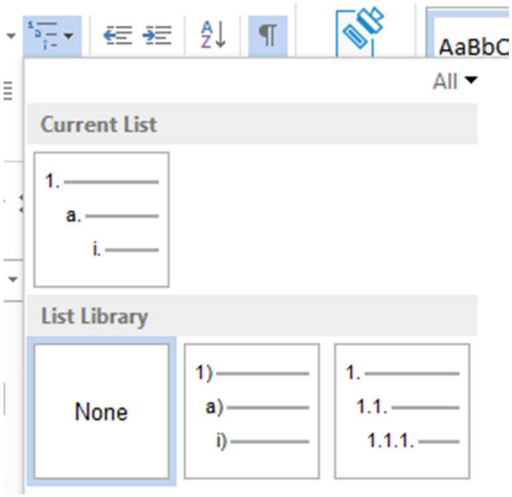


2.4 Headings

Documents should use the built in styles function of Microsoft word to create headers, this makes the process of changing a document and adjusting headers easier as well as improving navigation of the document.

The styles used should be the default styles of Heading 1, Heading 2, Heading 3, etc. which will be updated to be calibri – 11 with **Bold** enabled.

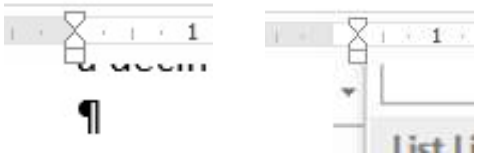
Each heading should use the numbering function shown below so that each Heading Level moves up a decimal point. This should be used in place of typing the header numbers as if a number changes then it is required to manually update every number following this, whereas this process automatically adjusts them.



For example,

1. Heading 1
1.1. Heading 2
1.1.1. Heading 3
1.1.1.1. Heading 4

As shown above, Heading 1 and Heading 2 will have no indent, Heading 3 upwards will have an indent of a quarter mark on the ruler at the top of the page.



There should be no carriage return between a heading and the text below, and no carriage return between 2 levels of heading if no text between. At the end of a section there should be a carriage return before moving on to the next, as shown in the example below.

1. Heading 1
1.1. Heading 2
Body of text

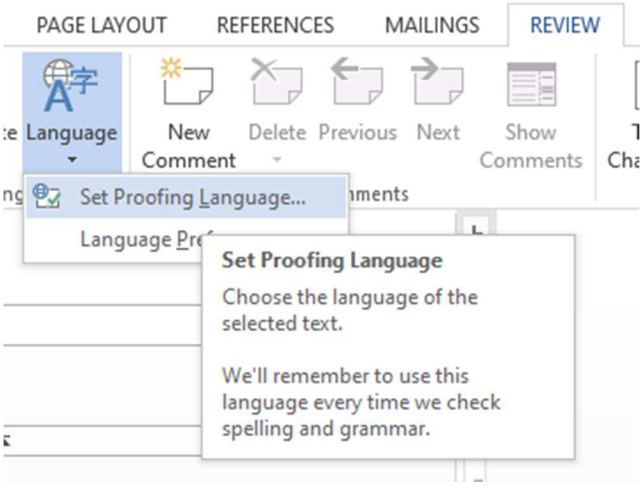
1.1.1. Heading 3
Body of Text

1.1.1.1. Heading 4

2.5 Proofing Language

The language of the document should be defaulted to English UK to ensure appropriate spelling is used, the language settings can sometimes be defaulted to English US resulting in Americanised spelling being introduced.

First, select all text within the document before setting the Proofing Language.



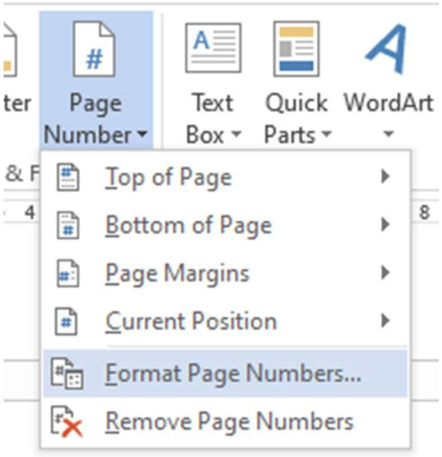
(Click the set as Default button and then OK)

2.6 Page Numbers

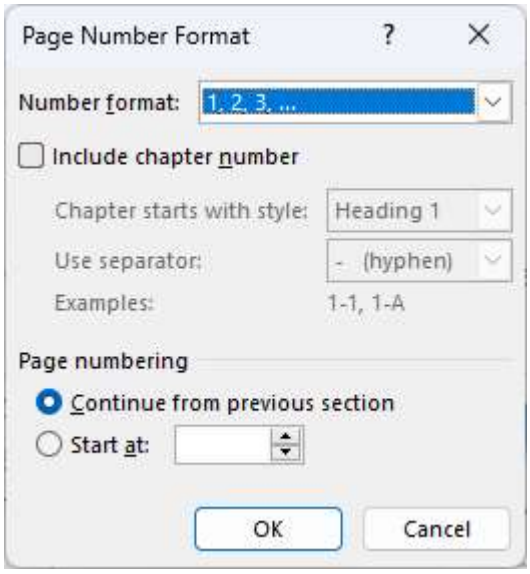
All documents are required to have page numbers in the format of “Page x of x”, sometimes chapters can be introduced which distorts the format.

Page·2·1·of·4¶

If this happens, under the “Insert” tab, select the “Page Numbers” option.



From here, ensure that “Include chapter number” is not selected.



2.7 Split of text between pages

Consideration should be given to how text is split between pages, for example if a title appears at the bottom of a page with little to no text on that page before moving on to the next, this should be moved in its entirety onto the next page to improve the flow.

Where possible, avoid having lists, tables or paragraphs split between 2 pages.

2.8 Document Headers and Footers

All SOPs, Forms and Guidelines have a default template that have specific requirements for headers and footers to be used.

Headers

SOP - Glasgow Clinical Trials Unit Standard Operating Procedure
Form - Glasgow Clinical Trials Unit Form
Guideline - Glasgow Clinical Trials Unit Guideline

In addition, the top of the templates have boxes for information to describe the document. For SOPs and Guidelines these should always be used. In some instances, Forms which are to be completed and retain information for the TMF it may not be suitable to make use of these boxes and so they can be removed. All of the control information will appear in the footer. All of the information provided in these boxes should have the font set as **bold**.

Footers

SOPs

SOP <number> version X.0 Page X of X

SOP template version 2.0

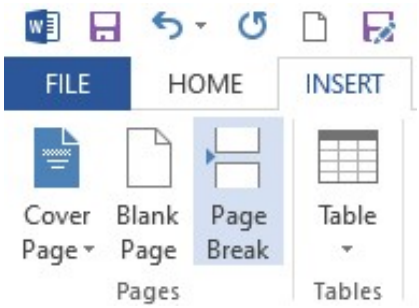
Forms of Guidelines

<Doc Type> <number> version X.0 Page X of X

<Doc Type> template version 1.0

2.9 Use of Carriage Return and Page Break

When using carriage return to make a gap between either paragraphs or sections within a document, it should only be a single carriage return. In some circumstances, when information will split between pages as mentioned in 2.6 and you need to move text to avoid this, you can use the page break functionality to have text move to the next page without the need for several carriage returns.



2.10 Placement of RACI Matrix and Contents

When placing a RACI matrix in an SOP, it requires placing a table within a cell of a table on the document. In order to make the RACI matric sit correctly, place a single carriage return above the table and then a single carriage return below. As the table will automatically try and fit to contents it will remove the carriage return at the bottom if no text is present. To make this space stay, press the space bar once to enter a single space.

When completing the RACI, the order of the groups should be in order. The top line should be the staff group listed as accountable, then in order those as Responsible, Consulted and then Informed. This will assist in reading the roles and their involvement.

2.11 Related and Referenced Documents

All documents listed under the related and referenced sections should appear as bullet points, ideally each document number should have a hyphen to separate the title as shown below:

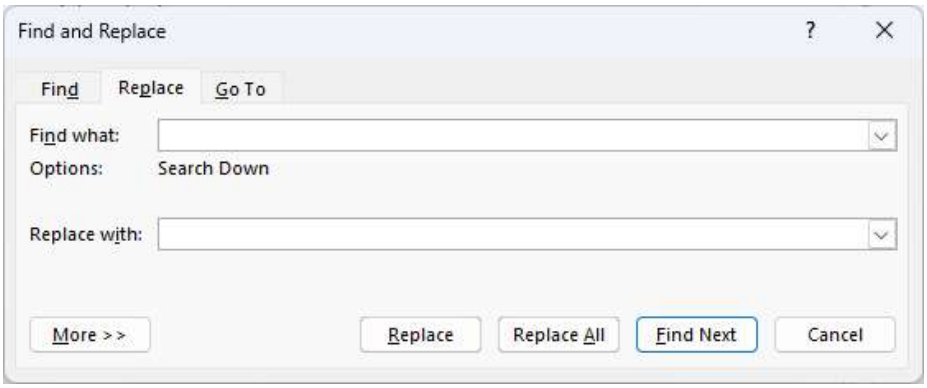
SOP XXX – Title

2.12 Double Spacing

Quite often double spacing can be used between words, this can be visible when the document formatting visibility is enabled. This is when the space bar was pressed twice between words, this will typically show as a formatting error during a spelling and grammar check.

A quick way to correct this is to press “CRTL+F” and then select “Replace” as shown below.

This will open a search bar where you can say what you want to find and what you want to replace it with, here if you enter a double space in the find and a single space in replace and then select replace all.



3. Considerations

When reviewing a document that will form part of the QMS a number of considerations must be made, some of these will be detailed below but this list is not exhaustive as there will always be additional considerations to be made.

3.1 Use of Language

The language used in a document is very important as the choice of words can have a big impact on what the document means. A common error is the use of "should", this is when the author is trying to outline what they expect to happen but the use of this word implies that it is not essential. Other words such as "must" or "will" are more definitive.

Shall, must, will – these words are all requirements and indicate that the activity has to happen.

Should – this word indicates that it is advisable to do so, but not essential

May – gives permission to carry out an activity

Can – shows that it is possible to do a thing

3.2 Who, What, Where and When?

The detail within the document should always be of a sufficient level that those reading are able to see:

Who – Who is responsible for carrying out the activity? Is the list complete? With CTIMPs and CIMDs does it cover both as Innovation staff will cover CIMDs. It is not enough to say an activity must happen but also who is expected to do it.

What – There must be sufficient detail on what the actual activity is and how to do it, the intention is that the SOP should be possible to follow in the absence of additional training. If training is required along with the SOP then this must be in place.

Where – This can cover many aspects, where can the required information be found, where should outputs be stored? Where can required applications or websites be found?

When – Consider the timing of events and actions, are there set timelines of when it should be completed and if so what are they? If given in days, is it calendar days or working days? What are the consequences and actions if the timelines are not met?

Guideline signatories

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Document history

Version	Date	Description	Retrospective Implementation
1.0	22/09/2025	First Release	No