Independent Stakeholder Assessment Guidance

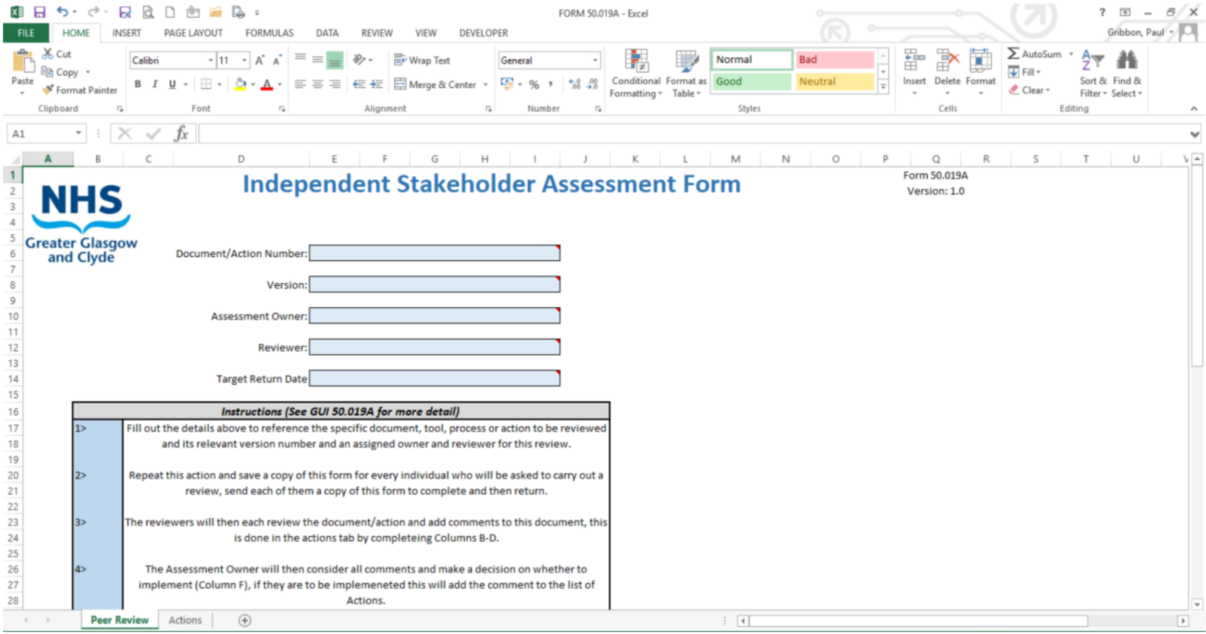
GUI 50.019A

Version: 1.0

Preparing The Assessment

The Independent Stakeholder Assessment will be prepared by the owner of the Document, tool, process or action to be assessed, the first step in preparing the assessment will be to download Form 50.019A from either the Glasgow CTU website or from Q-Pulse. Care must be taken to ensure that the latest version is being used and not an older version stored locally, this is why it is best to always download directly from these two sources.

When the form is downloaded and first opened, it will look like the screenshot below. At this stage, there will be 5 boxes to complete. There are basic instructions on the process detailed on the form itself, and comments above each box which has to be completed.



Independent Stakeholder Assessment Guidance

GUI 50.019A

Version: 1.0

Document/Action Number

This serves as a reference to the item which is to be assessed, if it is an SOP being assessed then use the SOP number, if it is a specific action then use the action number. In the event it is a tool or process that does not have a specific number, you can use a title. For example, "eCRF for Trial X".

Document/Action Number: DOC01

This is a reference number or title to the document, tool or process being reviewed.

Version

In this box, record the Version of the Document/Action which is under assessment. It is essential to be able to trace the exact version being assessed, the majority of items to be assessed will be under Version control. The event may arise that something must be assessed which does not have version control, in this instance it can be recorded as NA.

Version: 1

This is the relevant Version number of the above which is currently under review.

Owner

This box is used to record the name of the individual who is organising the Independent Stakeholder Assessment, this will generally be the person who is responsible for the item which is under assessment, although an assessment can be called by someone else if required. This is the person who will be responsible for sending out the Independent Stakeholder Assessment forms, receiving completed forms and making judgements on what is to be implemented and making the required changes.

Review Owner: Owner

This is the name of the individual who has created the review and completed forms should be returned to.

Reviewer

This is the name of the individual who will be asked to complete a review, appropriate reviewers should be selected to ensure that all relevant stakeholders are involved in the process. If their particular expertise are involved, it is wise to consult them if only to get assurance that everything is ok.

Reviewer: Reviewer

This is the name of the individual who is being asked to carry out the peer review and provide feedback.

Target Return Date

This is the date by which the Assessment Owner expects the completed reviews to be returned, this should be discussed with the individual reviewers in advance to ensure that they are able to meet the deadline.

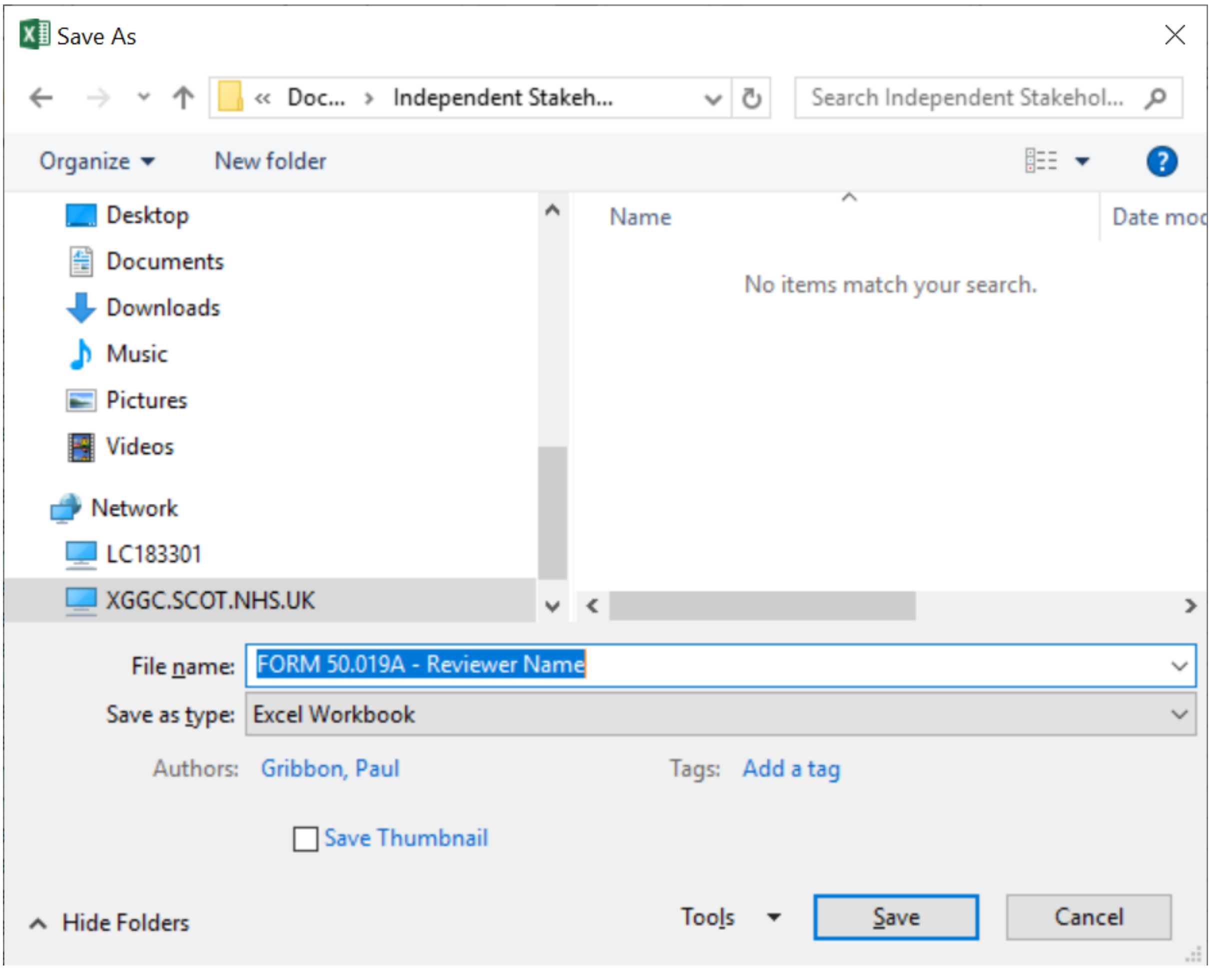
Independent Stakeholder Assessment Guidance

GUI 50.019A

Version: 1.0

Target Return Date | 01 August 2020 | **This is the date by which the reviews should be completed and returned.**

The above details will be completed and a form created for every individual who needs to complete an assessment. This means that an assessment involving 6 reviewers will require 6 forms. When the above details have been completed, select “Save As (F12)” and save a copy of the form for each reviewer changing only the reviewer name in each.



When all forms have been created, they must then be E-Mailed to the reviewers along with a copy of the item under review or instructions on how to access. The reviewers should then complete their reviews and aim to return by the target date, it is the responsibility of the Assessment Owner to ensure completed reviews are returned and chase up if required.

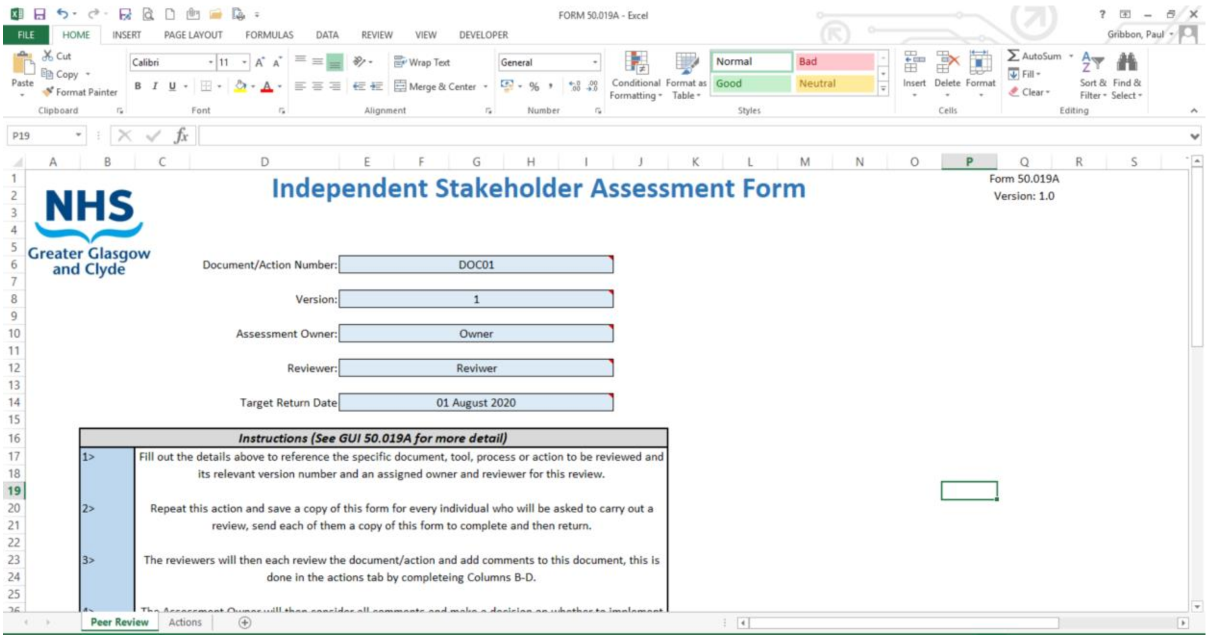
Independent Stakeholder Assessment Guidance

GUI 50.019A

Version: 1.0

Completing Review

As a reviewer, you should receive the form with the front page completed. This will give you details of what it is you are expected to review and by what date. It also lets you know who must receive the completed form in the Assessment Owner box. At this stage, you should carry out a review of the item you are being asked to assess, you can complete this form at the same time or following the complete review, whichever is easier for you to do.

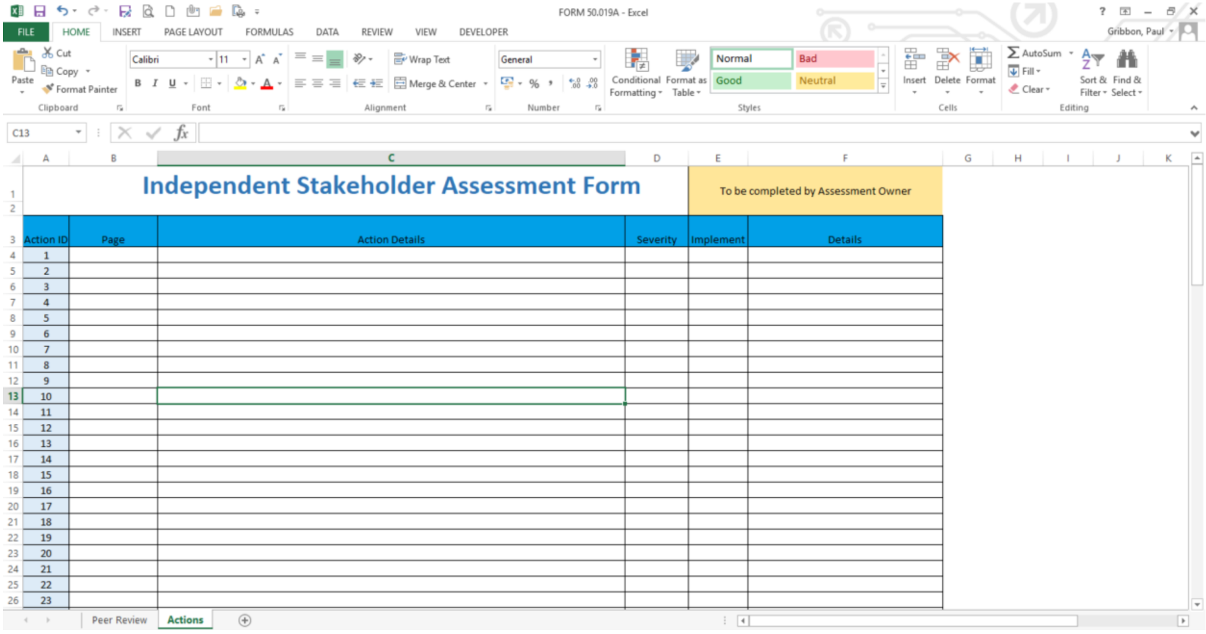


Independent Stakeholder Assessment Guidance

GUI 50.019A

Version: 1.0

When you receive the form, you must select the “Actions” tab at the bottom, this will open the following tab where you will add any comments you may have.



Independent Stakeholder Assessment Guidance

GUI 50.019A

Version: 1.0

There are a number of different columns on this tab, only 3 of which need to be completed by the reviewer.

Action ID: This is a predefined number sequence to help separate and identify individual actions. This column is prefilled and does not require any input.

Page: This is a reference to the location of the observation being raised, if it is a document then it will be the page number, appropriate description of the location can be used in the event page number is not appropriate.

Action Details: This is where details are added about the observation being made, enough detail should be added in this field for the assessment owner to understand what the issue is and how to correct it. For example if there is a typo, highlight what has been spelled incorrectly, if incorrect details have been used highlight this and also, if known, what the correct details are.

Severity: This field should be used to help highlight to the reviewer the importance of the observation being made. A typo by itself is a minor issue, but if there is a large number or it could result in the detail being misunderstood it can become more important. If something isnt as clear as it should be, this may be an intermediate observation. Or, if there are incorrect details present this could be listed as a Major observation. This is selected from a drop down list with these predefined levels.

Implement: This field is to be completed by the assessment owner when a completed review is returned to them, this will record the decision on whether or not to implement the comment made by the reviewer. This will be a drop down field allowing for Yes or No to be entered.

Details: This field is also completed by the assessment owner, this is a space to allow them to add detail to their decision on wether or not to implement the observation. This will assist in understanding what has happened during the review if it is revisited at a future date.

Independent Stakeholder Assessment Guidance

GUI 50.019A

Version: 1.0

Below is an example of a populated Assessment, the level of detail can be as much as is required and will act as evidence of the assessment process. A completed assessment can be returned with as many or as few comments as required. In the event a review is completed and no comments are to be added then the form should still be returned to the assessment owner explaining that no comments are to be added. The form will still need to be recorded as evidence of the review.

Independent Stakeholder Assessment Form

To be completed by review Owner

Action ID	Page	Action Details	Severity	Implement	Details
1	2	Typo the word "the" is spelt "th"	Minor		
2	2	Not enough detail in explanation of process A	Intermediate		
3	4	Information is incorrect for turn around time, should be 7 days rather than 14.	Major		
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					

Peer Review | Actions

Independent Stakeholder Assessment Guidance

GUI 50.019A

Version: 1.0

When the completed form is returned to the assessment owner, they can then look at the observations raised by each reviewer and make decisions on whether to implement or not. This must be recorded in the form using columns E and F. As can be seen below, there is a drop down allowing for a Yes/No decision to be made on each. If required, the assessment owner can discuss the observations with the reviewer to determine the best course of action before making a decision.

Independent Stakeholder Assessment Form — To be completed

Action ID	Page	Action Details	Severity	Implement
1	2	Typo the word "the" is spelt "th"	Minor	
2	2	Not enough detail in explanation of process A	Intermediate	Yes / No
3	4	Information is incorrect for turn around time, should be 7 days rather than 14.	Major	
4				
5				
6				

This process must be completed for each form completed by a reviewer, it may be that several reviewers come back with the same comments so the decision to implement or not must be recorded against each and updated as required in the item under assessment.

Independent Stakeholder Assessment Form — To be completed by review Owner

Action ID	Page	Action Details	Severity	Implement	Details
1	2	Typo the word "the" is spelt "th"	Minor	Yes	Typo corrected
2	2	Not enough detail in explanation of process A	Intermediate	Yes	More detail added
3	4	Information is incorrect for turn around time, should be 7 days rather than 14.	Major	No	Review of turn around times, 14 days is correct.
4					
5					
6					
7					

When all of the reviews have been completed and any required changes made, it may be required to make a 2nd round of reviews if the changes were extensive. It may be possible to just check with the individual reviewer who made the comments that the correction is sufficient. It is good practice to make sure that the implemented fixes are sufficient, but are not essential for minor issues such as typos etc.

When completed, the Independent Stakeholder Assessment forms should be saved in the appropriate locations to act as evidence of the assessment process. Where the assessment is specific to a trial, this should be saved in the TMF and in most cases they should be recorded in Q-Pulse.

Independent Stakeholder Assessment Guidance

GUI 50.019A

Version: 1.0

Document Details

Prepared by:	Signed	Date
Approved by:	Signed	Date

Document History

Version	Date	Description
1.0	02/10/2020	