

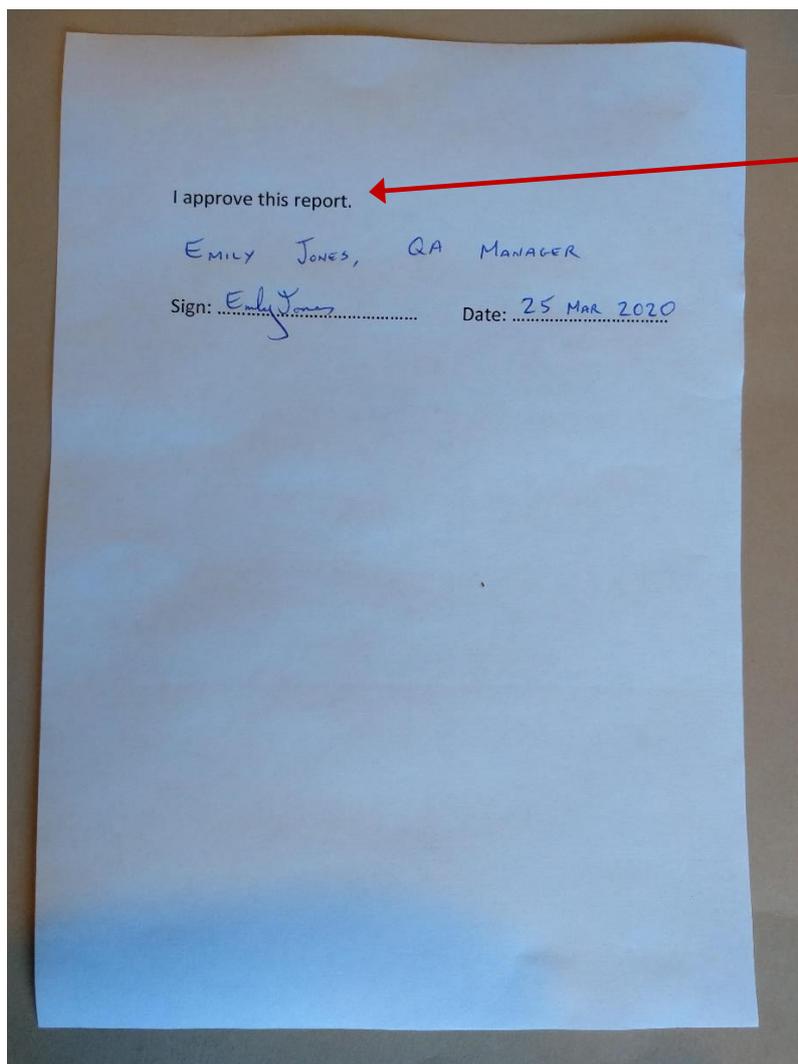


### Examples to illustrate aspects to consider when performing remote approval, e.g. in a homeworking situation.

The examples have been created for this guidance but are based on real situations seen on inspection.

They are not exhaustive but identify common issues that can be encountered if the distribution and approval process when approving documents in a homeworking environment are not clearly defined and assessed.

#### Example 1 – Document number/version not included on the approval page



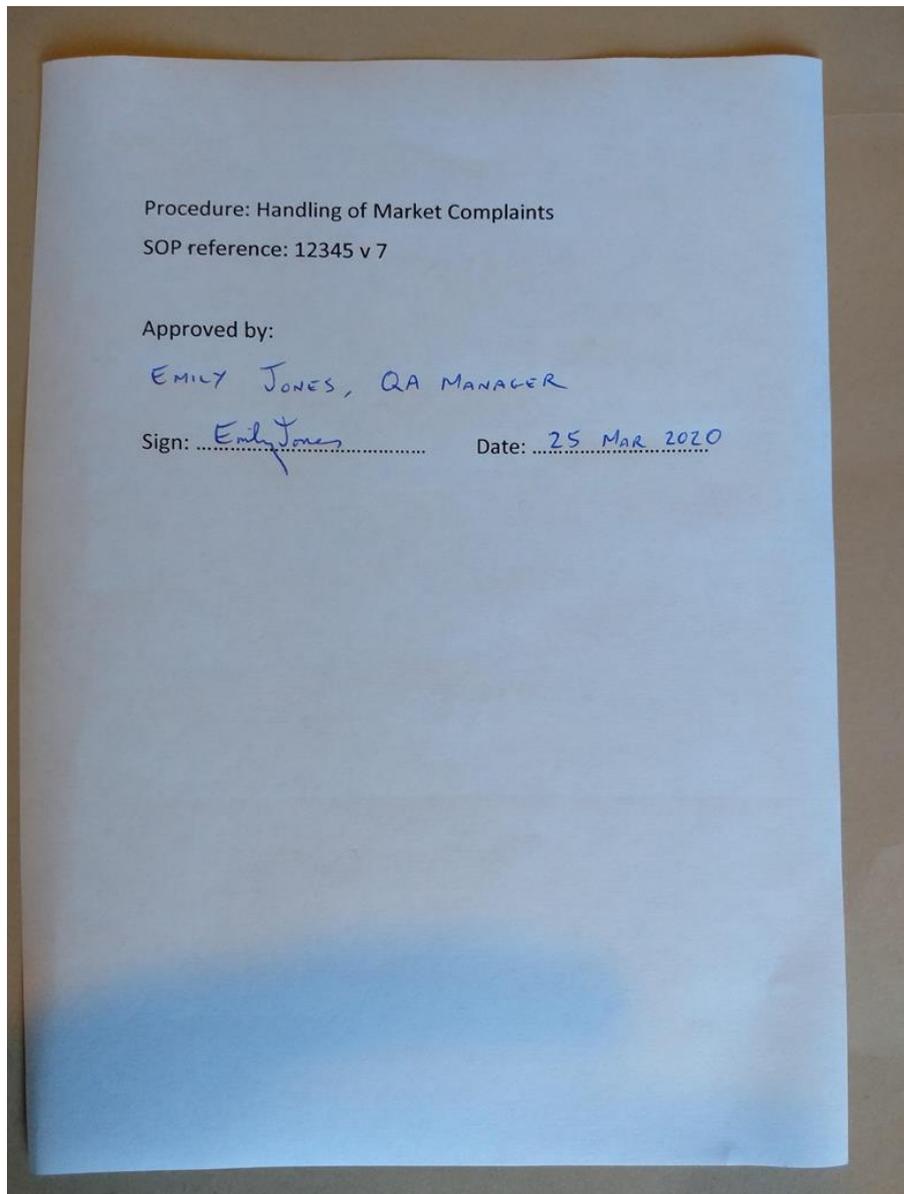
It is ambiguous what document is being referred to.

In the example above, the document approval page was printed, signed/dated and scanned.

However, because it does not include the document number/version on the approval page, it is unclear which document has been approved.



**Example 2: document number/version included**



The example above is better as the scope of the approval is described with the document title, reference and version included on the approval page.

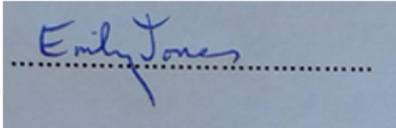
Note: If a home-worker does not have a scanner, taking a photo with a mobile phone of the approval is acceptable, if it is legible.



### Example 3: Inserting signature images to documents

Procedure: Incoming goods checks  
SOP reference: 67890 v 3

Approved by:  
EMILY JONES, QA MANAGER

Sign: ....  Date: 25 March 2020

In the example above the approver has pasted an image of their signature into the document.

This is inappropriate as it can be difficult to control who can do this and therefore how the signature is attributable to the individual. This is not compliant with good documentation or data integrity principles.



#### **Example 4: Approval by email**

In general, for more critical signatures, reliance on only an email to record document approval does not provide adequate control.

An email chain may be appropriate for low risk approvals, for example to record that an update to an internal procedure has been reviewed and approved. However, email generally lacks adequate document control where there is greater criticality such as recording approval of higher risk records that potentially have an impact to product quality.

#### **Example 5 - Approved documents stored in a shared folder**

When approved documents are stored in a shared folder, it is important that there are adequate controls to avoid uncontrolled document changes occurring after approval and that the current version of a document is available.

Controls include but are not limited to:

- There should be access control to the folder location.
- It should be considered how it would be detected if a document was changed after approval, such as:
  - Actions on documents should be attributable.
  - There is an audit trail for the system, and it is backed up.

**Note:** These examples are intended to assist organisations that have had to adopt homeworking at short notice and are involved in the pharmaceutical lifecycle (GMP, GDP, GLP, GCP & GPvP) or GLP studies regulated by MHRA. This document is not intended to replace existing guidance provided by MHRA and in EU GMP.