Background

What is a document?

A document is an information source and its supporting medium. The medium can be paper, electronic, or photographic.

Documents are important because they:

- Make it possible for a large number of people to implement a process in the same way, and get consistent results
- Provide objective evidence of activities and results
- Facilitate training

What does it mean to control documents?

To control documents, or to have an individual document under document control, means to have created a system that ensures that the documents are:

- Current
- Retrievable/accessible
- Approved for adequacy (see next section)

It also means:

- Any obsolete versions of a document are dated, marked as obsolete, and removed from circulation.
- Any abbreviated document – eg, a posted work aid – is consistent with, and corresponds to, the complete procedure.
- The system works so that relevant versions of applicable documents are available at points of use; the user is able to find the document and know that it is complete, relevant, and applicable.

Document control is a set of processes that govern the way documents are:

- Developed
- Approved
- Made available for use
- Revised and reissued
- Taken out of the system and archived

What does it mean for documents to be “approved for adequacy?”

Adequacy means the document meets the needs of the users and the QMS.

Documents must be approved for adequacy by someone who has the expertise to determine it. This means someone with knowledge of the process, the tasks, the environment, and the users.

Here is a list of document attributes to look for in assessing adequacy – the document should be:

- Accurate
- Specific to the task or issue
- Clear
- Well organized
- Easy to navigate and find things in

If a document is not adequate, the performance of the QMS will reflect it. For example:

- There will be complaints and defects.
- Metrics and internal audits will detect the problem.

When individuals create their own versions of a document, this shows that the original was not adequate.

Why is document control important?

Effective document control has significant benefits. For example:

- Ensures consistency
  - Testing is being done the same way among all staff, all shifts, and all locations. This means better patient care.
- Reduces errors and cycle times
  - Staff have ready access to the right documents. They get their work done more efficiently and accurately, taking out the guess work. This means better turn-around times.

David Wolfe on the risk of inconsistency

Christine Christopher on document-related occurrences

- Lowers operating costs
  - With a well-designed system, the process for approving new or revised documents is organized and streamlined. This means new methods can be implemented more quickly and take up less time for the reviewers.
- Lowers compliance costs
  - Preparing for inspections and audits takes less time if the document control system is easy to use and robust.

A lack of document control poses significant risks:

- Wrong document use
  - A single occurrence due to inaccurate or unapproved document can result in a costly liability.
- No defined procedure
  - Lack of guidance for critical steps in a process can lead to inaccurate test results and ultimately poor patient care.
- Inaccessibility of documents
  - Patient safety and employee safety may be at risk during a fire or other disaster if approved instructions are difficult to locate.

What must be controlled?

In determining what documents to control, keep in mind the key goals – to help staff:

- Perform critical tasks in a consistent way
- Get their work done efficiently, with minimal uncertainty and questions

In a nutshell, documents must be controlled if they contain the following:

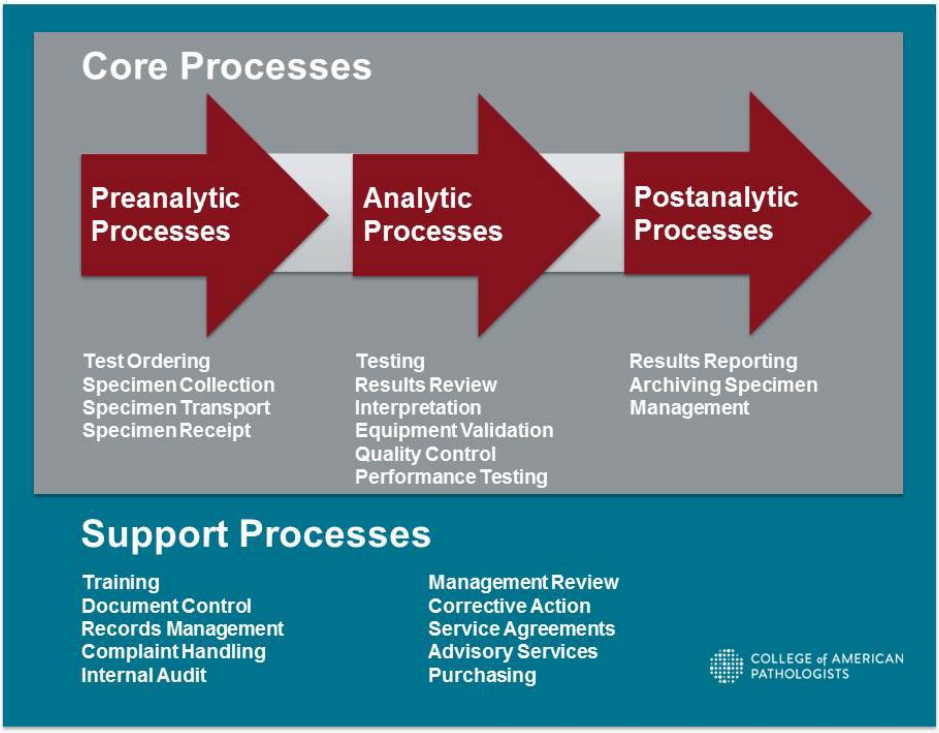
- Key details requiring update
- Details that affect quality of patient care

David Wolfe on using feedback loops to find gaps

Christine Christopher on missing information

Scope of what must be controlled – documents from both core and support processes

The document control system must control all documents that are part of the QMS. This means all documents that describe, or are used in, core processes and support processes.



Types of documents that must be controlled

A quality management system includes the following types of documents:

- Process documents about how the work flows through the laboratory
- Procedure documents about how to perform specific tasks
- Policy documents to guide decisions
- Documents that describe how the QMS is structured, and how processes connect (a good quality manual provides this information)
- Documents that provide technical or scientific references
- Listings/logs of documents
- Regulatory and legal documents that describe policies and requirements that must be followed

Each of these document types will require periodic changes. So each type must be controlled.

Document control is crucial anytime critical documents go through revisions because they directly affect quality and patient care.

Source of documents that must be controlled – both internal and external to the laboratory

Laboratories must control both

- Internal documents such as SOPs and procedures
- Documents of external origin such as regulations, standards, laws, or procedures, such as a manufacturer's instructions

David Wolfe on using internal audit results

General list of documents that do, and do not, need to be controlled

Most documents that laboratory staff create and use need to be controlled.

However, some do not. For example, documents that are created for specific short-term purposes (emails, agendas, and meeting notes) or that are used as part of research and development (journals and/or white papers), do not need to be controlled.

Here is a more comprehensive list of what does and does not need to be controlled.

Need to Control	**No Need to Control**
1. Policies, processes, and procedures, including work aids that instruct on how to perform tasks, eg: a. Hepatitis B Surface Antigen confirmatory test procedure b. Specimen collection process c. Critical result notification policy 2. Secondary documents such as work aids and forms that are drawn from a larger procedure and serve as references for staff while performing a task 3. Communications describing planned deviations from established procedures posted for staff awareness 4. Factual references that support a work process (eg, calibration tables, biological reference intervals) that may change over time 5. Training materials that provide instruction on a process that must be performed consistently (eg, internal standards for doing QC) 6. External documents that impact the QMS: a. Standards, regulations, and laws (eg, ISO 15189, CAP Checklists, CLIA law) b. Equipment manuals and technical bulletins that are used to develop laboratory procedures and that may be changed or updated by the vendor c. Customer agreements that explain requirements for project work 7. Any documents the laboratory states that it will control in its own policies and procedures 8. Documents that must be controlled according to the requirements of regulatory bodies, eg, the CAP checklists 9. Any documents that laboratory management determines must be controlled to achieve the goals of the quality management system	1. Documents with no instructional content created for a short-term purpose (eg, agendas, meeting notes, emails) 2. Background scientific information (eg, textbooks) that will not be part of any procedure 3. Documents regarding noncritical work (eg, administrative procedures, or instructions for ordering office supplies) a. What is critical in one laboratory may not be critical in another. 4. Information that never changes (eg, Fahrenheit to Celsius table) **Note:** These are examples of documents that pose no direct risk to patient care. It would be impractical and unnecessary to control them. Controlling documents takes time and effort. It is important to focus laboratory resources on matters that directly impact quality and patient care.

Is document control the same as record control?

No. A record is a specific type of document. Most documents say what to do. A record says what has been done.

Examples of records:

- Temperature charts
- Instrument maintenance logs
- Patient reports
- Management review reports

A record enables the laboratory to reconstruct what has occurred in the past and ensures critical information is not dependent on the memory or availability of an individual.

Some documents become records. This is true in the case of forms. A form provides a checklist of things to do. Once the procedure is complete and the form has been filled out, it becomes a record.

Records have their own quality requirements and need to be controlled. While not required, it is a best practice for a laboratory to create a records control procedure. The organization needs to state what records it creates, the environment in which they are stored, how long it keeps them, who is responsible for them, and how it disposes of them.

Records need to be controlled because they provide evidence of conformity to requirements and of the effective operation of the quality management system. It helps to define:

- How records are identified, collected, and indexed
- How they are stored to prevent damage, loss, or unauthorized access
- How long they are kept
- How it disposes of them

Records need to remain legible and retrievable.

How should documents be structured?

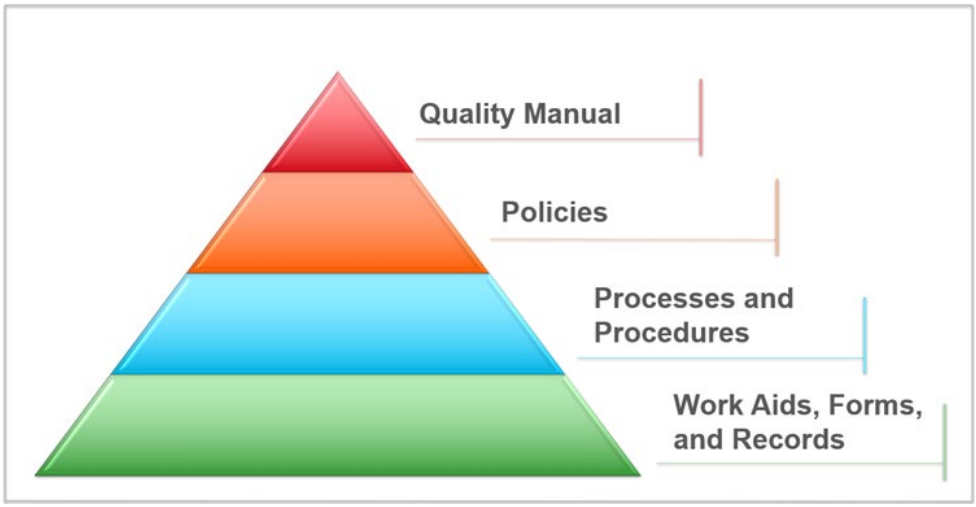
Structure documents into a hierarchy.

High-level documents should describe and help locate low-level documents.

- High-level documents provide a general description of what to do.
- Low-level documents say exactly what to do.

The top document in the hierarchy is the quality manual. This is recommended as a best practice but is not required by the ISO standards.

The quality manual provides an index of key processes, policies, and procedures. It also contains a high-level map of the organization's processes and their interactions. Individual procedures reference more specific work instructions and forms.



Document hierarchy

For more information on quality manual, see QM*Ed* course Quality Manual Development.

What is the difference between a policy, a process, a procedure, a form, and a record?

These terms are confusing because organizations often use the word *procedure* in a vague way to refer to any kind of document.

David Wolfe on the problems caused by poor definitions

But these terms have specific meanings. Here are the definitions:

Term	Definition
Policy	A documented statement of overall intentions, endorsed by management and chosen from among alternatives to guide and determine present and future decisions. Examples: A quality policy statement, a critical result notification policy.
Process	A documented set of interrelated or interacting activities that transform inputs into outputs. These activities occur over time with starts and stops and involve more than one person or group. Example: Test order entry to specimen storage.
Procedure	A documented set of instructions that describe a specified way to perform an activity. A procedure can be done from start to finish by one person or a closely working team in one place and time. Examples: Receiving and processing patient specimens; external documents such as manufacturer's instructions or package inserts **Note:** Often the term procedure is used more generally to refer to a specified way to carry out an activity *or a process*. So, the documented description of a process is sometimes referred to as a "procedure," even though process and procedure are technically two different things.
Work Aid	A procedure, or a portion of a procedure, created to serve as a reference while the worker performs the task.
Form	A blank document that is used to capture results of the performance of a procedure.
Record	A document that captures results or other critical information from the performance of a procedure.

Work Aids and Other Secondary Documents

Staff in the laboratory often do not need the full procedure to do their work. They only need a key portion of the procedure, sometimes called a "recipe card" or a work aid.

David Wolfe on analyzing the need for work aids

Work aids play an important role because it is difficult to remember factual details such as procedure steps – it is better to be able to view the key steps while performing the task.

Christine Christopher on integrating work aids

Sometimes it is convenient to create a note and post it, so it can be read while doing the task. It is not recommended to use documents in this way, but it's acceptable as long as they are controlled. This means they are:

- Identifiable
- Traceable to an approved, current procedure

If documents are identified, linked, and controlled, all documents will reflect any changes to methodology. In this way, practice and results will be consistent.

Note: Sticky notes are not reliable for long-term use. Use laminated sheets or cards as a better approach.

Here are some best practices for work aids.

Best practice #1: Create logs or indexes for secondary documents – this gives you an inventory

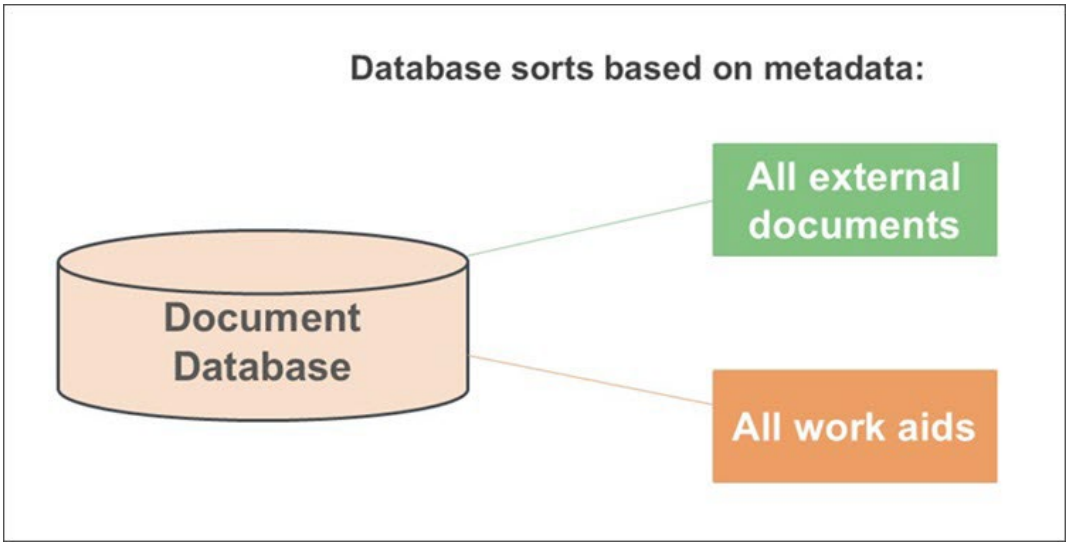
Some work aids are simply copies of existing documents. Here is an example of an approach for controlling such work aids or "secondary documents."

Secondary Document Log Example

Note: Miller-Latif Laboratory is a fictitious example to illustrate best practices and one possible approach.

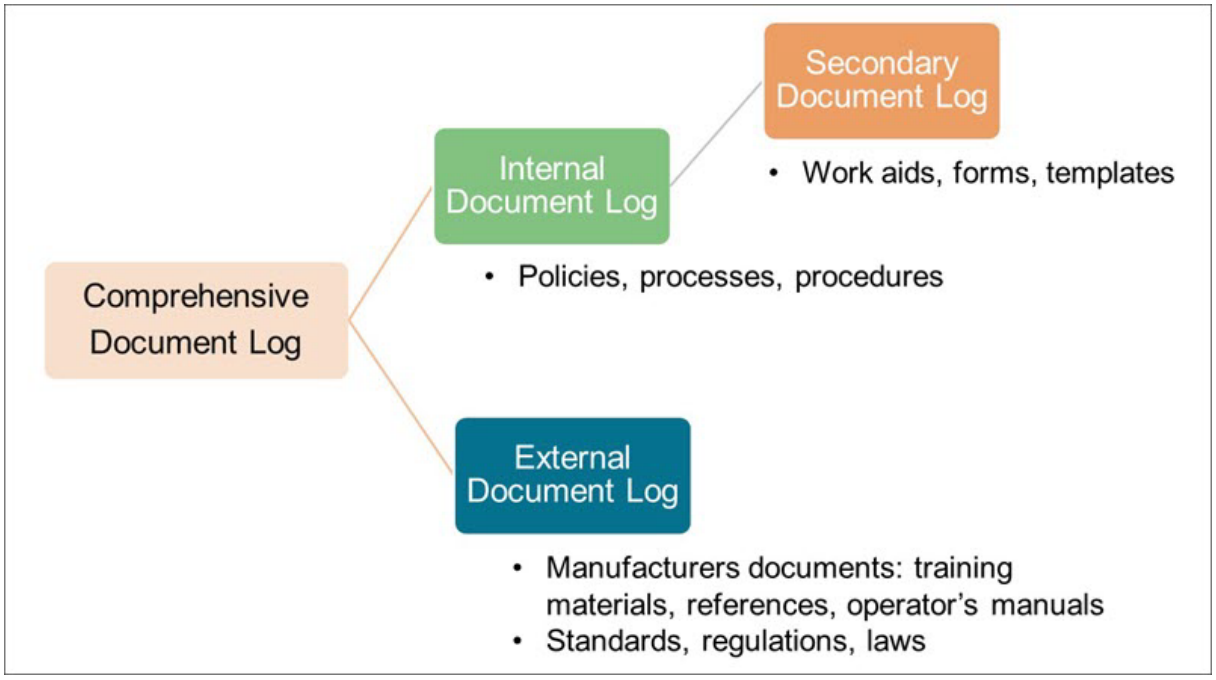
Secondary document logs list document name, key information, and location

You don't need to have a separate log; you can also use metadata to make it easy to sort your database of documents to reveal subcategories.



Database sorting can create virtual document logs

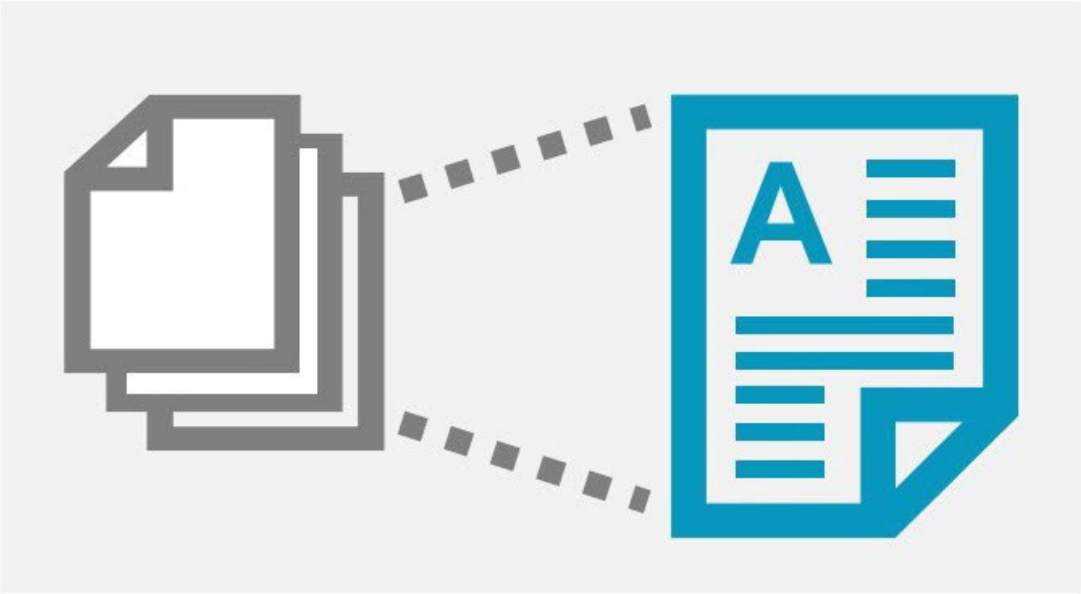
You may want to create different kinds of document logs, for different subsets of your documents.



Hierarchy of document logs

Best practice #2: Integrate work aids into source documents

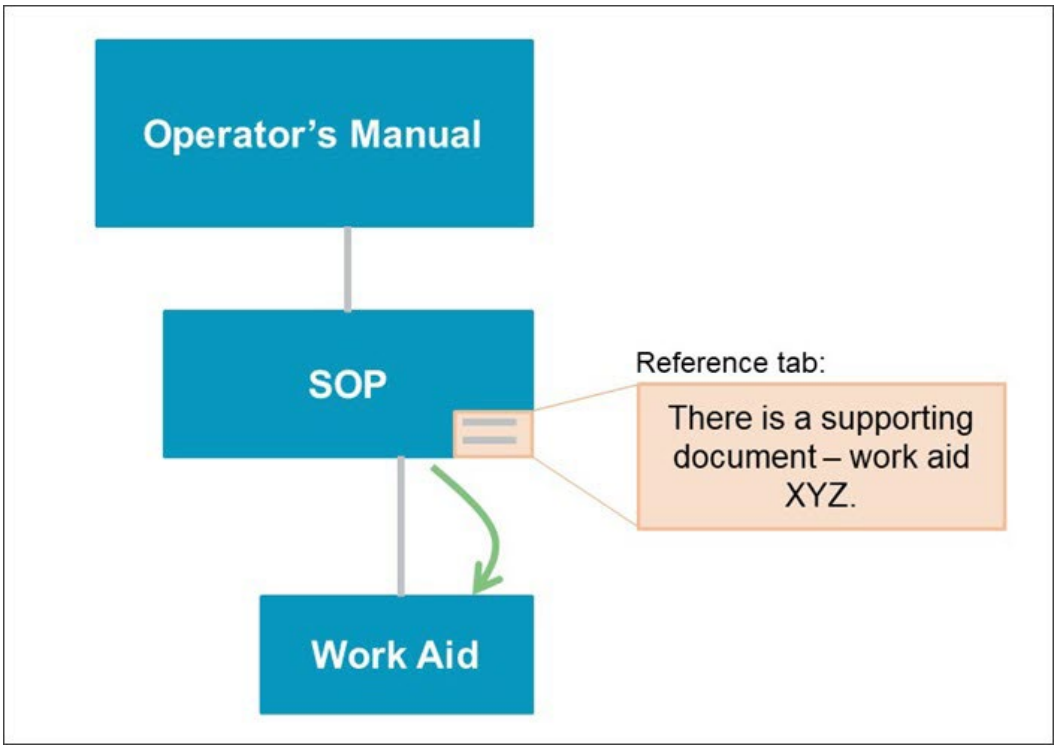
Work aids may be a summary of a procedure, or a visual portrayal of the procedure. One way to help control them is to make them part of the appendix of the source document.



Work aids can be included in the appendix

Best practice #3: Include references or links in source documents to secondary documents, and *vice versa*

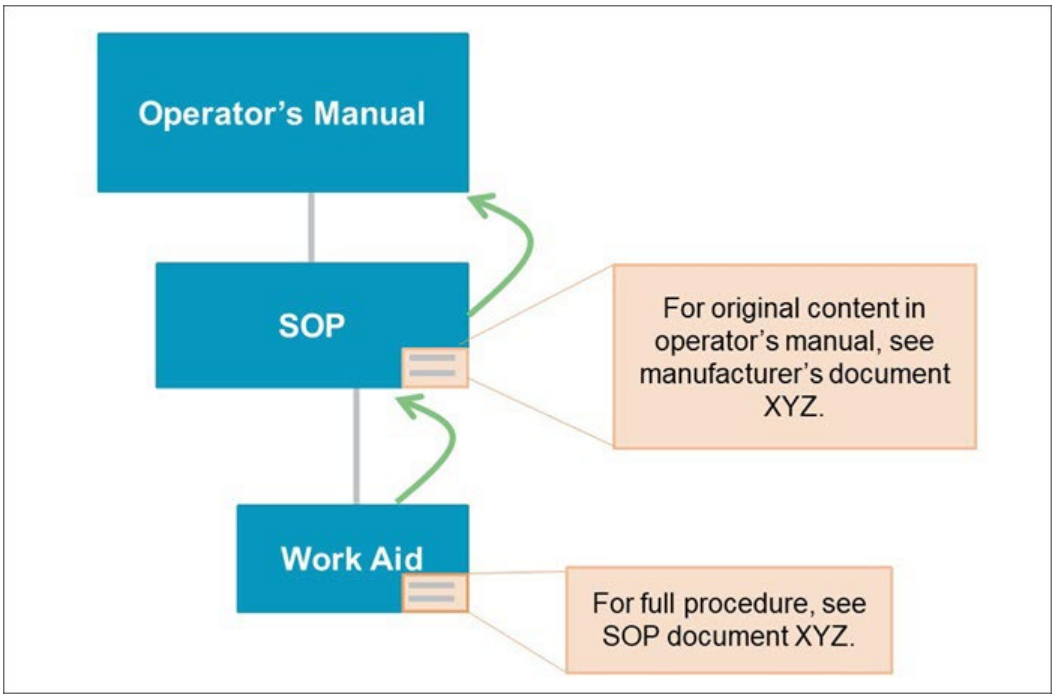
Including references to secondary documents is known as “linking down.”



Linking down technique

Linking down prompts management and staff to update work aids and other secondary documents when they make changes to SOPs.

Including references to source documents is known as “linking up.”



Linking up technique

Linking up helps ensure that secondary documents are traceable to their source document.

It also prompts users to update the source document if staff make a methodology change to a work aid.