

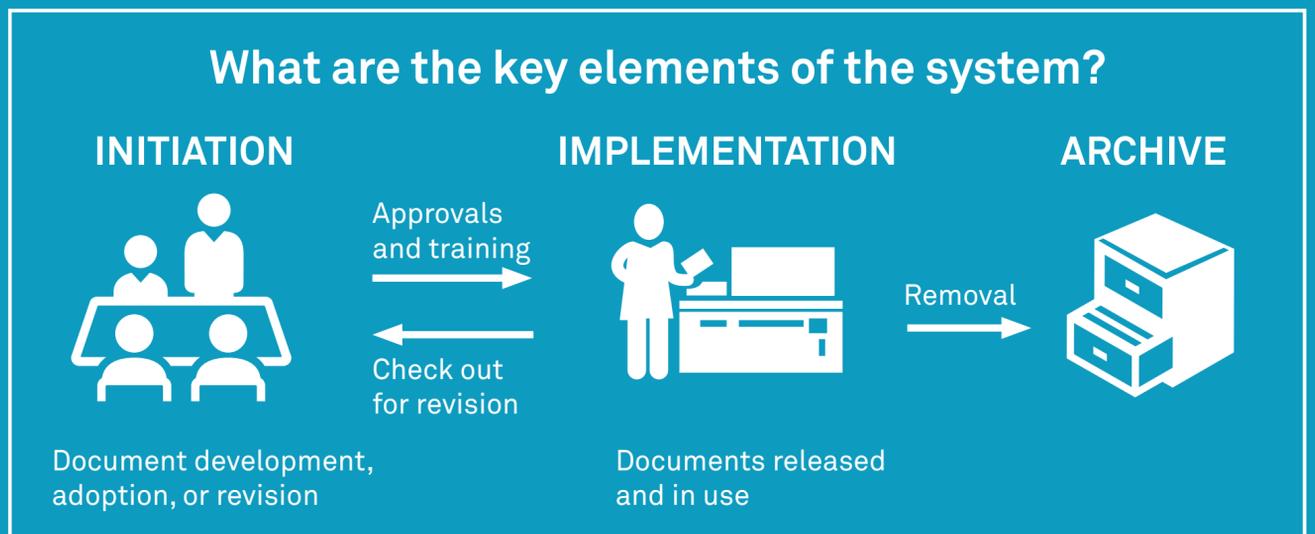


What is the goal of document control?

A system to ensure that

- Everyone sees the same document
- The current version is accurate
- The laboratory performs critical tasks in a consistent way

What are the key elements of the system?



What documents need to be controlled?

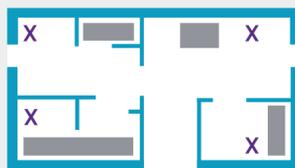
Need to control	No need to control
1. Policies, processes, and procedures that instruct on how to perform work	1. Documents with no instructional content, created for a short-term purpose (eg, agendas, meeting notes, and emails)
2. Factual references that support a work process (eg, calibration tables, biological reference intervals)	2. Documents with background scientific information (eg, textbooks, conference materials)
3. Training materials that provide instruction on a process or procedure	3. Nonwork related documents (eg, lunch menus, phone list)
4. Standards and regulations (eg, ISO 15189, CAP Checklists)	4. Information that never changes (eg, Fahrenheit to Celsius table)
5. Customer agreements that explain requirements for project work	

What are some effective ways to keep work aids under document control?

1. Make the work aid an **APPENDIX** to the larger procedure.
2. Create a secondary document log to track all posted work aids that are copies (or parts) of other documents.



Secondary Documents				
Name	ID	Date	Revision	LOCATION
				X
				X
				X
				X



Key Terms

Policy 	A general guideline or statement of overall intentions. (eg, policy on critical result notification)
Process 	A set of interrelated activities that transform inputs to outputs. Processes typically involve more than one person, starts and stops, and multiple procedures. (eg, preanalytic process) <ul style="list-style-type: none"> • Core process—bears directly on the product or service that the customer purchases (eg, preanalytic, analytic, postanalytic) • Support process—supports a core process (eg, purchasing, complaint handling, corrective action)
Procedure 	Set of instructions that describe a specified way to perform an activity. Can typically be done by one person at one time. (eg, blood gas sample collection)
Work aid/ Job aid 	A procedure, or portion of procedure, created to serve as a visible reference while a worker performs.
Form 	A blank document used to capture results. It provides instruction on what information to gather. Usually classified as a procedure.
Record 	Captures results or other critical information from the documented procedure.

Interested in learning more about document control? The CAP's QMED online course on document control will give you more information about requirements and methods. Earn two CE credits with the completion of the course. For more information, visit cap.org and search QMED.