

# *Why Your Documents Can Make or Break Your QMS and What You Can Do About It*

**Lucia Berte**

*LABORATORIES MADE BETTER!*

# Why Documents Break Your QMS

**Why?**

**Deficiency:**  
Documents don't reflect how the work is actually done.

Training does not use or reflect the approved documents.

**Why?**

Personnel don't use the documents when performing work.

**Why?**

**Why?**

"SOP Drift" due to personal deviations from poorly written documents.

External assessors observe these disconnects and cite deficiencies.

**Uh-oh!**

# Document Demo 1.

## LOCKOUT / TAGOUT ON ELECTRICAL EQUIPMENT

A. For circuit breakers that have lockout capability, you must use locks for each circuit breaker disconnect switch.

- (1) Get the appropriate number of locks and tags.
- (2) Prepare the lockout tags and lockout and tagout the necessary circuit breaker.
- (3) Disconnect the switches.
- (4) Turn disconnect switches to the “Off” position.
- (5) Lockout the switches and attach lockout tags.

B. **IMPORTANT: WHEN DISCONNECTING SWITCHES ALWAYS STAND TO THE HINGED SIDE OF ANY BREAKERS AND FACING THE OPPOSITE DIRECTION BEFORE TURNING THEM OFF.**

C. For circuit breakers that do not have lockout capability, you will need to use tagging.

- (1) If tagging will provide the same level of safety as using a lock, then you can use a tag without a lock as long as you also take supplemental measures to ensure adequate safety. These measures would include removing isolating circuit elements or blocking control switches.
- (2) Stand to the hinged side of any breakers and face the opposite direction before using.
- (3) Turn disconnect switches to the “Off” position.
- (4) Attach tags

**ONLY A QUALIFIED PERSON CAN LOCKOUT AND TAGOUT CIRCUIT BREAKERS. IF YOU ARE NOT QUALIFIED TO PERFORM A LOCKOUT / TAGOUT, YOU MUST FIND A QUALIFIED PERSON TO COMPLETE THE PROCEDURE.**

# How Documents Break Your QMS: CLIA is Not a QMS!

**§493.1251 Standard: Procedure Manual.**

**(a) *A written procedures manual for all tests, assays, and examinations* performed by the laboratory must be available to, and followed by, laboratory personnel.**

## Only Half of a QMS is Testing

***The mindset of the  
CLIA 14 elements  
of a procedure manual  
does not work  
for administrative documents.***

# CLIA 14 Elements and QMS Documents

#	Element	?
1	Patient preparation	NA
2	Microscopic examination	NA
3	Steps, calculations, and interpretations	S
4	Reagent and materials preparation	NA
5	Calibration and verification	NA
6	Reportable range	NA
7	Control procedures	NA

#	Element	?
8	Corrective actions	NA
9	Method limitations	NA
10	Reference intervals	NA
11	Alert or critical values	NA
12	Literature references	NA
13	Result reporting	NA
14	Test system unavailability	NA

## So It's No Wonder Then....

*Half of a QMS is management, for which there are rare requirements for documented processes and procedures.*

*Management documents do not reflect the order in which QMS activities actually happen.*





How many of you still say  
“policyandprocedure”?

# Document Requirements

## CAP

Lab General  
GEN.20375

*“The lab has a document control system to manage policies, procedures and forms...”*

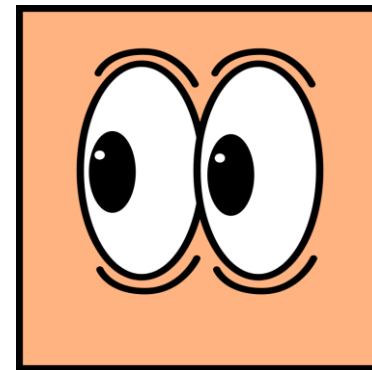
## CAP

All Common  
COM.10000 -  
COM.10500

*“...technical policies and procedures  
”  
...”*

What You Can  
Do About It

**LOOK AT  
OLD THINGS  
IN A NEW  
WAY**



Did You Know That There Are...

## 4 Types of Documents

**Policy**

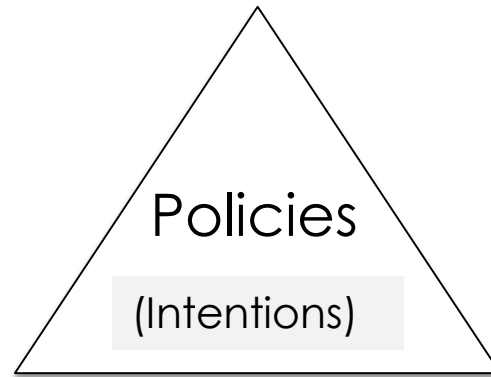
**Process**

**Procedure**

**Form**

The Truth About  
Laboratory  
Documents:

**4 Document Types**



# Policy as a Document

**Policies  
contain  
statements of  
intent.**

**“We maintain  
and manage  
paper-based  
and  
electronic  
documents.”**

# Policies About What?

- ▶ Ethics, impartiality, confidentiality
- ▶ Customers
- ▶ Safety
- ▶ Personnel
- ▶ Suppliers and purchasing
- ▶ Equipment management
- ▶ Document management
- ▶ Records management
- ▶ Information management
- ▶ Nonconforming events management
- ▶ Measurement and monitoring
- ▶ Continual improvement

# Then What Happens?

Policies  
contain  
statements of  
intent.

“We maintain  
and manage  
paper-based  
and  
electronic  
documents.”

***How do we  
turn intent  
into action?***



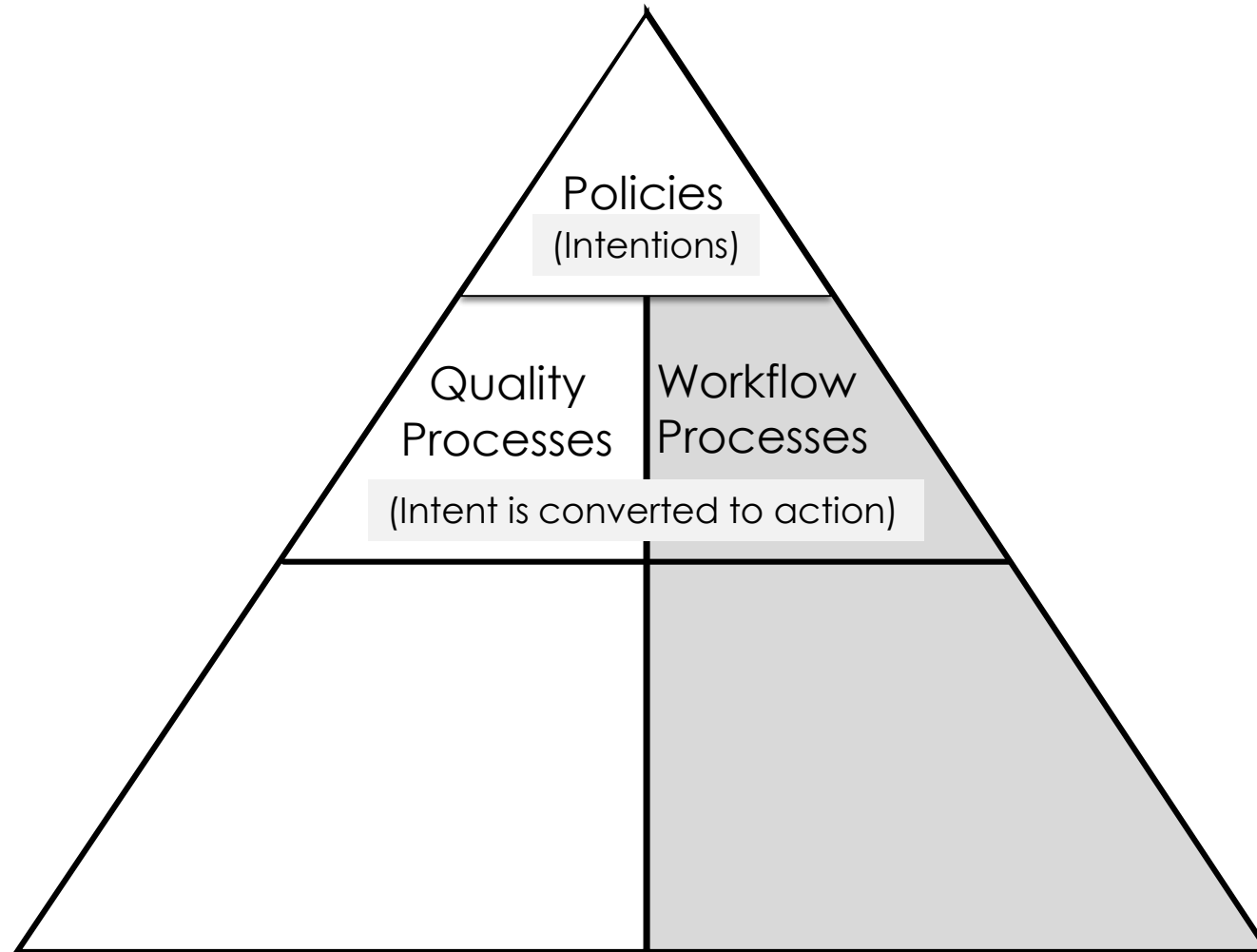
# What's Missing?

**PROCESS**  
– *as a document* –  
not scattered and buried  
inside “CLIA SOPs”

# The Truth About Laboratory Documents:

## 4 Document Types - Processes

18



# Management Process as a Document

## **Policy Statement**

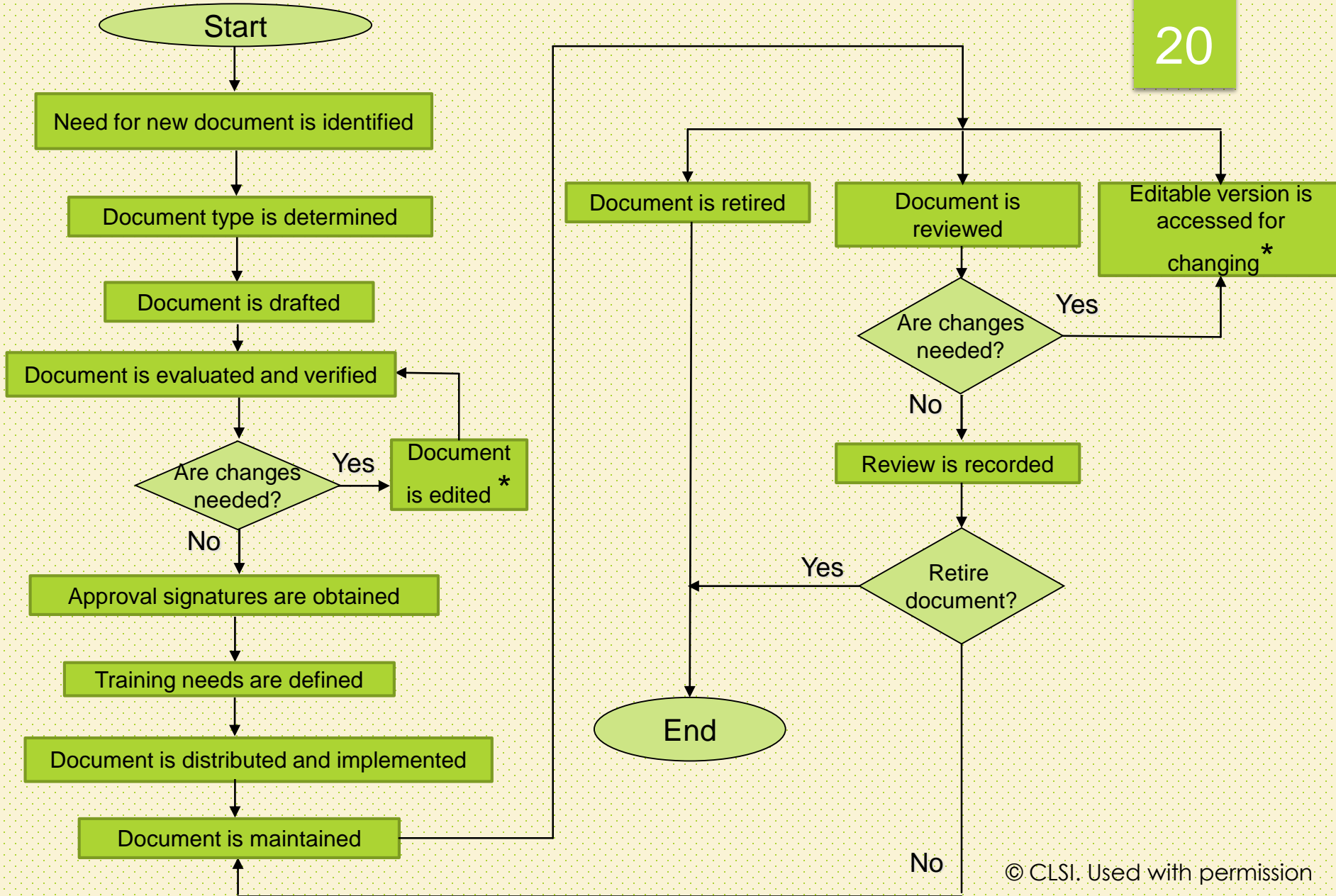
**“We maintain and manage paper-based and electronic documents.”**

**“HOW do we maintain and manage our paper-based and electronic documents?”**

*Who does what and when?*

# Quality Process Example: *Document Management Process*

20



# Technical Process as a Document

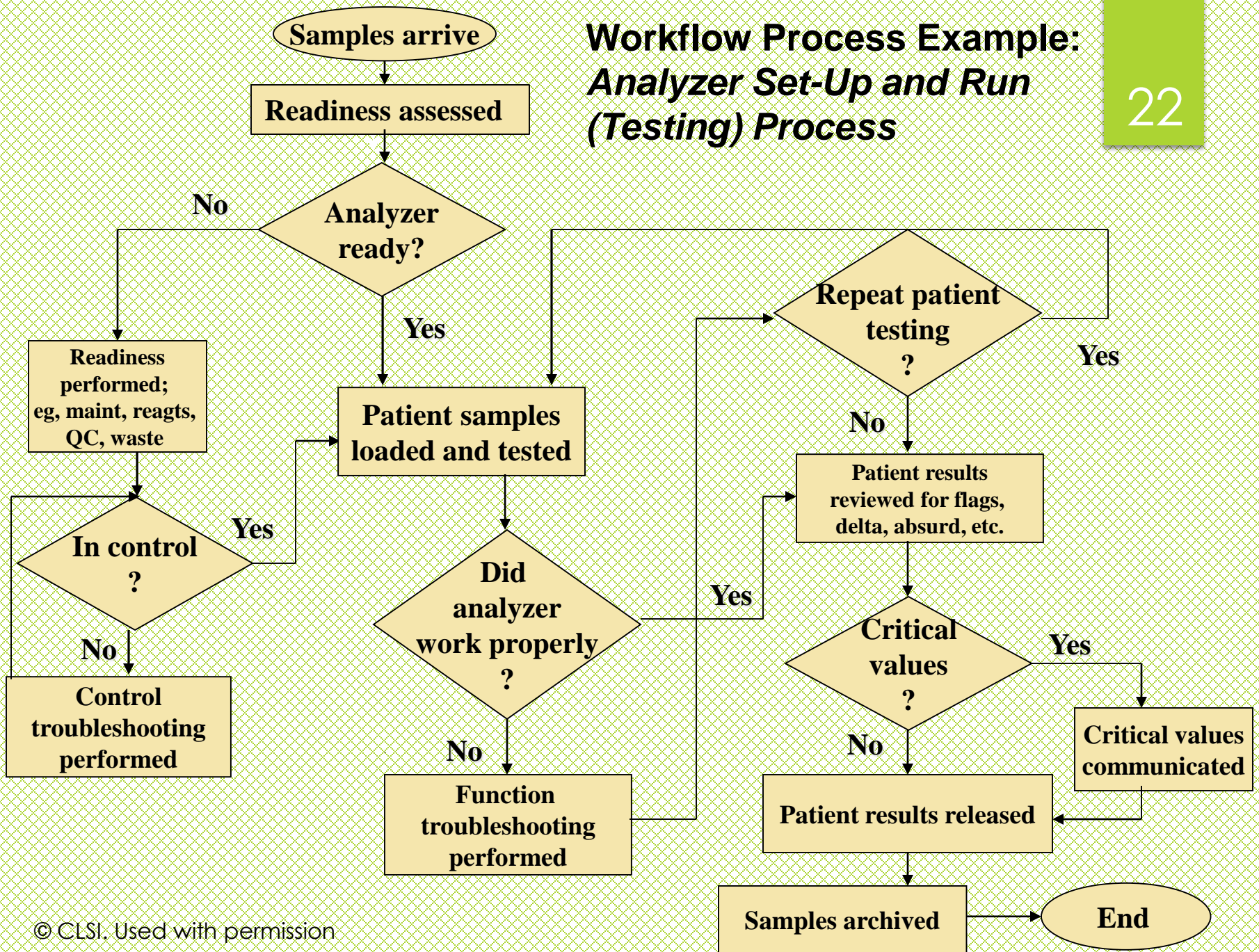
## **Policy Statement**

**“We follow documented and validated processes for laboratory testing.”**

**“HOW does automated testing happen in our laboratory?”**

*Who does what and when?*

# Workflow Process Example: Analyzer Set-Up and Run (Testing) Process



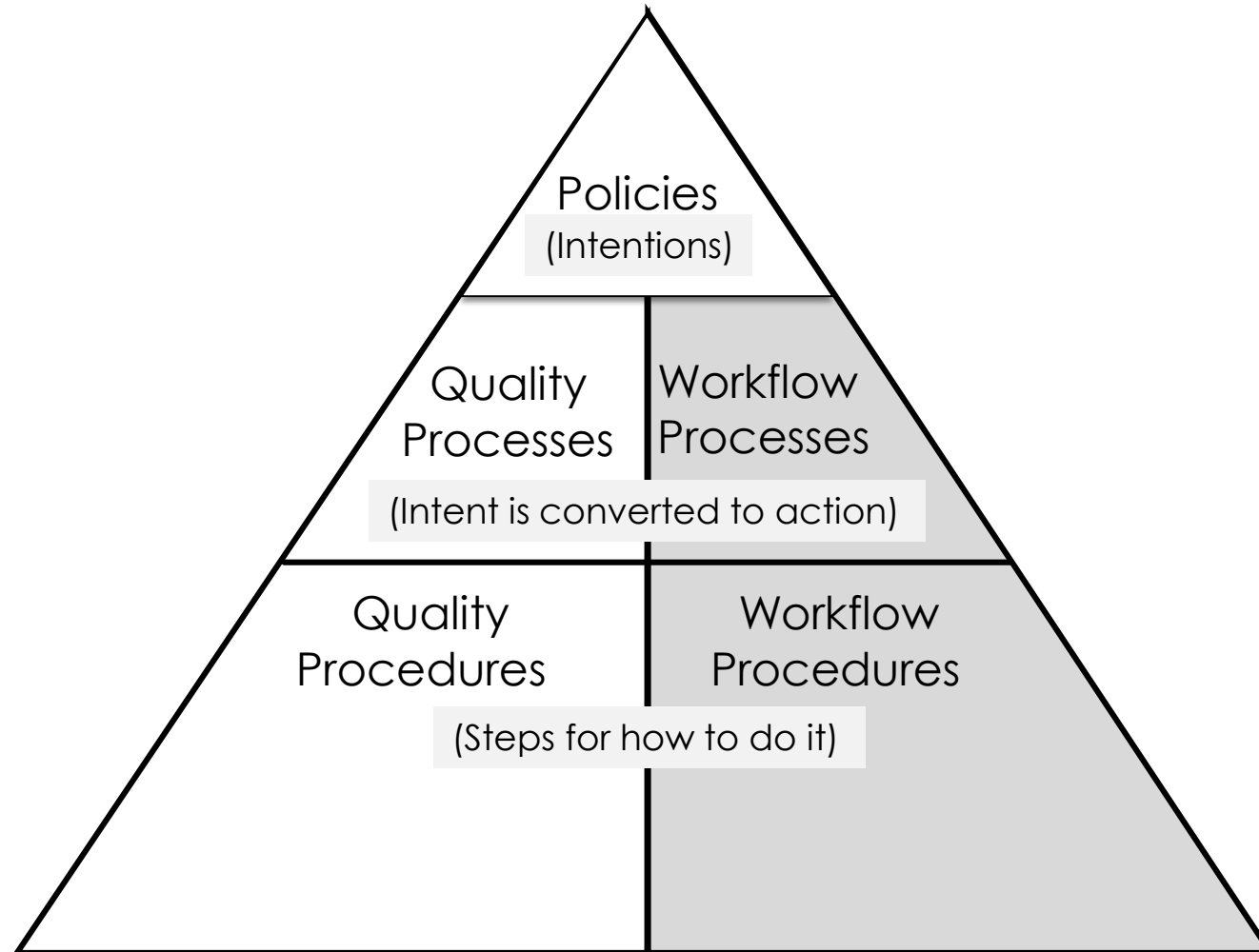
# Analyzer Testing is NOT an SOP!

- ▶ Work truly progresses in the order shown on the flowchart
  - ▶ Not in the CLIA 14-point order
- ▶ Actual work progression is different from the CLIA 14-point SOP
  - ▶ Activities-based vs analyte details
- ▶ Work documents should contain only what is done at that time.
  - ▶ Work done at other times should be in other documents!

# The Truth About Laboratory Documents:

## 4 Document Types - Procedures

24



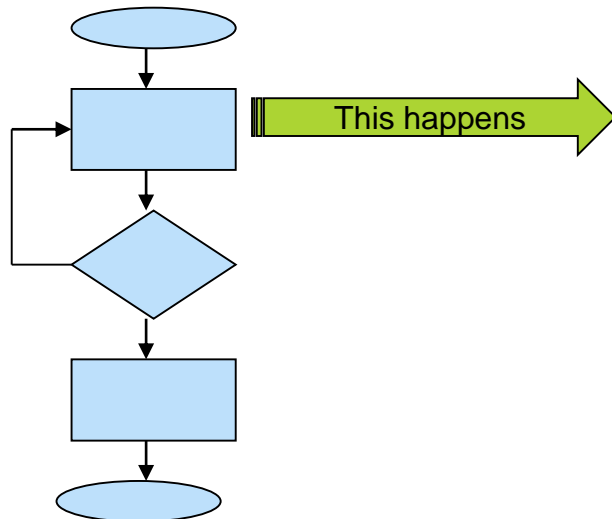


# Process vs. Procedure

How it happens here



How do I do this one thing?



Step	Action
1	Label the tube with the patient's initials.
2	Add 2 drops of patient plasma to the tube.
3	Add 3 drops of Reagent A to the tube.
4	Mix gently by swirling.
5	Incubate for 15 minutes at 37 °C.

# Document Demo 2.

## Performing Lockout/Tagout on Electrical Equipment

### Lockout/tagout procedure

This table describes how to perform lockout/tagout on electrical equipment.

Procedure table makes sequential action steps clear and visible and keeps readers oriented.

Step	Action						
1	Are you qualified to lockout and tagout circuit breakers? If yes, go to the next step. If no, have a qualified person complete the procedure.						
2	Determine whether each circuit breaker associated with the equipment or process to be maintained has lockout capability. <table border="1" data-bbox="734 425 1497 592"> <thead> <tr> <th>If the circuit breaker...</th> <th>Then...</th> </tr> </thead> <tbody> <tr> <td>has lockout capability</td> <td>-- get a lock for each circuit breaker disconnect switch, and -- go to Step 4</td> </tr> <tr> <td>does not have lockout capability</td> <td>--go to Step 3</td> </tr> </tbody> </table>	If the circuit breaker...	Then...	has lockout capability	-- get a lock for each circuit breaker disconnect switch, and -- go to Step 4	does not have lockout capability	--go to Step 3
If the circuit breaker...	Then...						
has lockout capability	-- get a lock for each circuit breaker disconnect switch, and -- go to Step 4						
does not have lockout capability	--go to Step 3						
3	For each circuit breaker that does not have lockout capability, determine whether tagging alone will provide the same level of safety as using a lock. <table border="1" data-bbox="734 782 1497 1039"> <thead> <tr> <th>If tagging will...</th> <th>Then...</th> </tr> </thead> <tbody> <tr> <td>provide the same level of safety as using a lock</td> <td>--take supplemental measures to ensure adequate safety. <b>Examples:</b> remove isolating circuit elements or block control switches.</td> </tr> <tr> <td>not provide the same level of safety as using a lock</td> <td>--shut down <i>all</i> sources of electrical generation</td> </tr> </tbody> </table>	If tagging will...	Then...	provide the same level of safety as using a lock	--take supplemental measures to ensure adequate safety. <b>Examples:</b> remove isolating circuit elements or block control switches.	not provide the same level of safety as using a lock	--shut down <i>all</i> sources of electrical generation
If tagging will...	Then...						
provide the same level of safety as using a lock	--take supplemental measures to ensure adequate safety. <b>Examples:</b> remove isolating circuit elements or block control switches.						
not provide the same level of safety as using a lock	--shut down <i>all</i> sources of electrical generation						
4	Get a tag for each breaker.						
5	Prepare the tags.						
6	Lockout and tagout the necessary circuit breakers and disconnect switches. Stand to the hinged side of any breakers and face in the opposite direction before turning them off. Turn disconnect switches to the "Off" position. Lockout the switches and/or attach the tags.						

Embedded decision tables clarify different types of action.

# Procedure Examples

## Quality Procedures

- ▶ Correcting a result on a
  - ▶ paper document
  - ▶ electronic document
- ▶ Reporting a nonconforming event
- ▶ Conducting an internal audit
- ▶ Delivering training
- ▶ Revising a document

## Technical procedures

- ▶ Performing a venipuncture
- ▶ Accessioning a specimen
- ▶ Performing a manual urinalysis
- ▶ Troubleshooting an instrument problem
- ▶ Reviewing QC results
- ▶ Reporting an alert or critical value

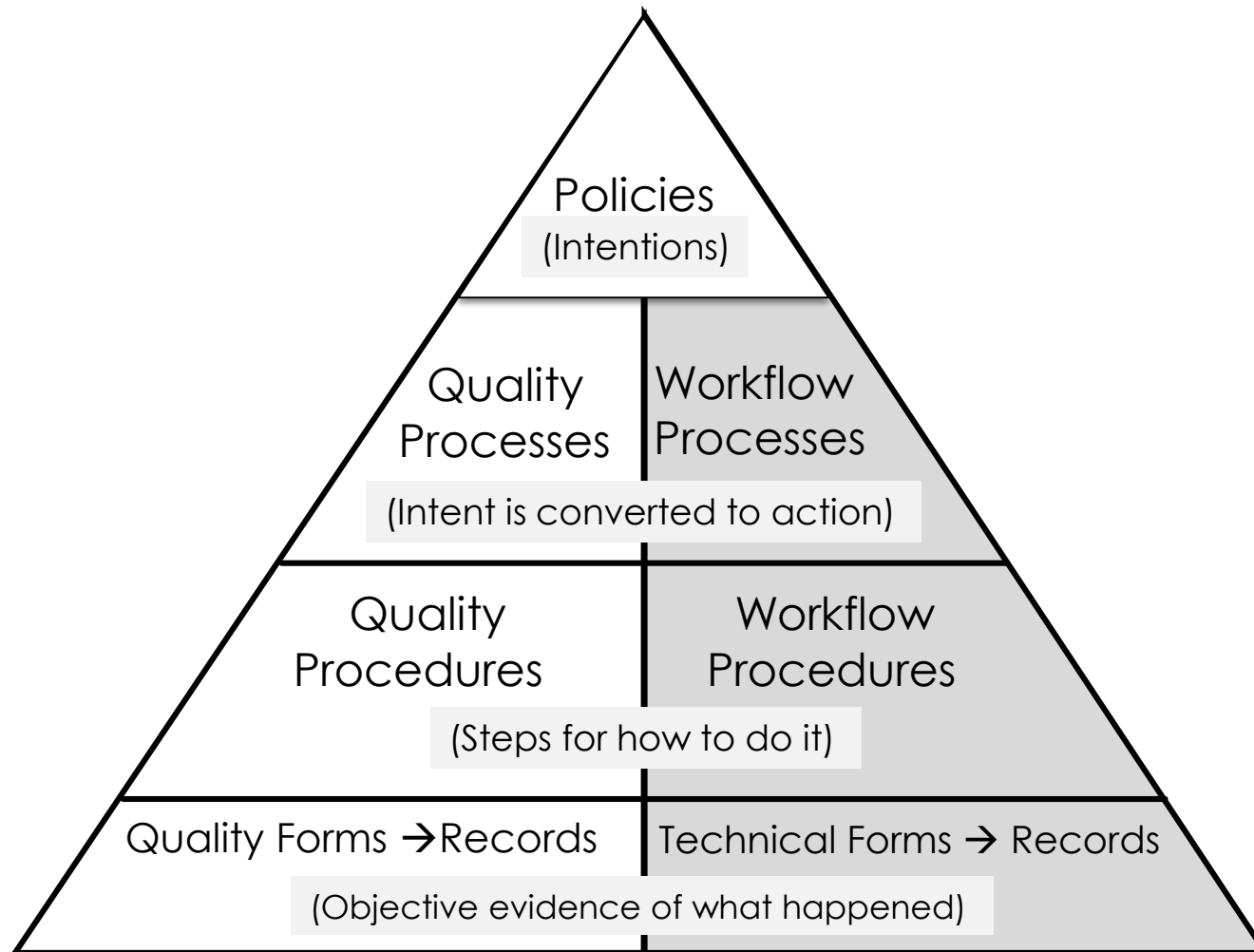
# Why? Why? Why????

- ▶ Why write documents that don't reflect the way work is actually done?
- ▶ Why make it hard for personnel to do the right thing?
- ▶ ***Why is pleasing an inspector more important than providing personnel with clear instructions?***
- ▶ Why can't we understand that the primary users of laboratory documents are its **personnel?**

# The Truth About Laboratory Documents:

## 4 Document Types: Forms → Records

30



# Completed Blank Forms Become Records

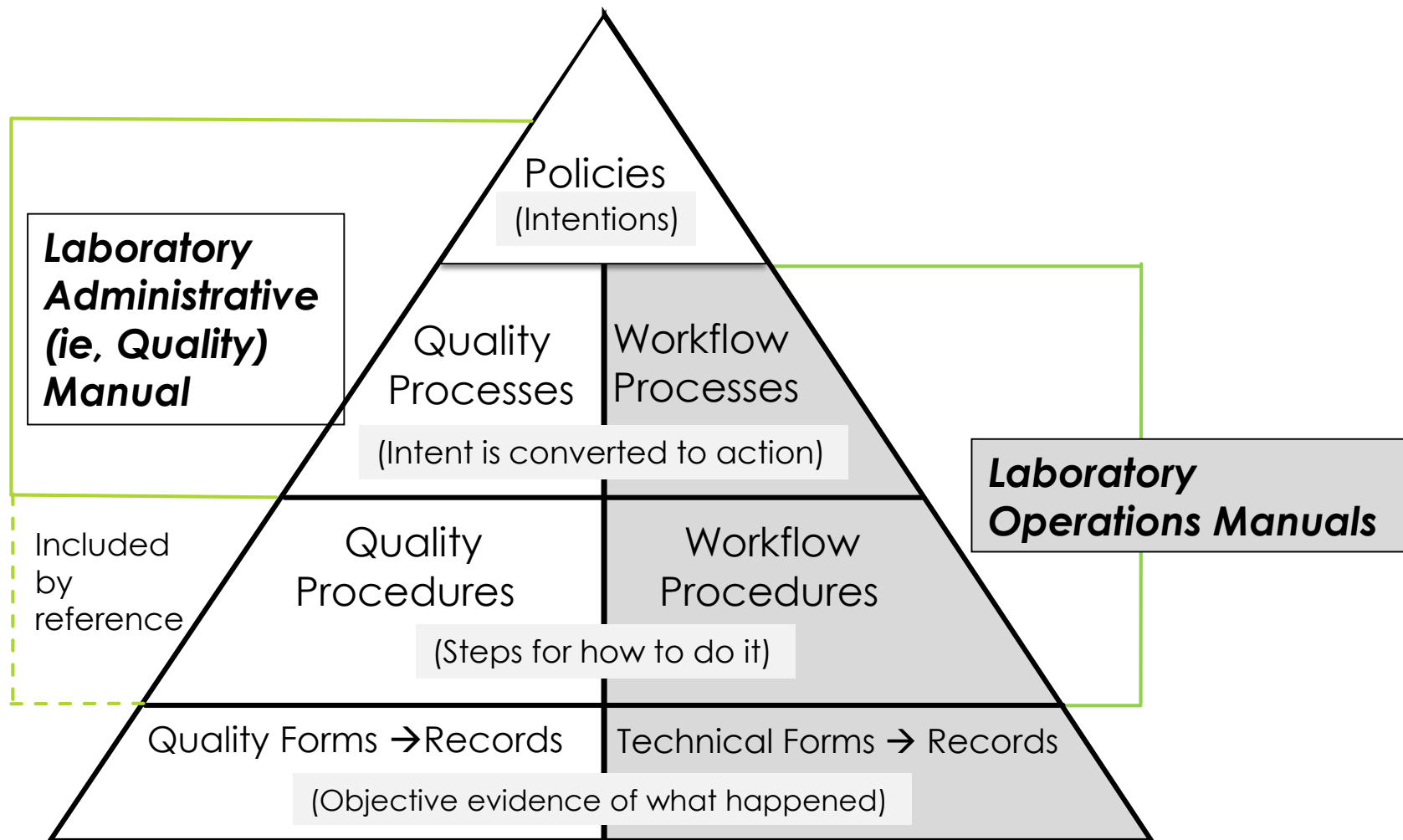
## Forms

- ▶ Should be laid out in the order in which results are obtained
  - ▶ During the process
  - ▶ During a single procedure
- ▶ Include pertinent instructions
- ▶ Be as simple as possible
- ▶ Labels are a type of form

## Records

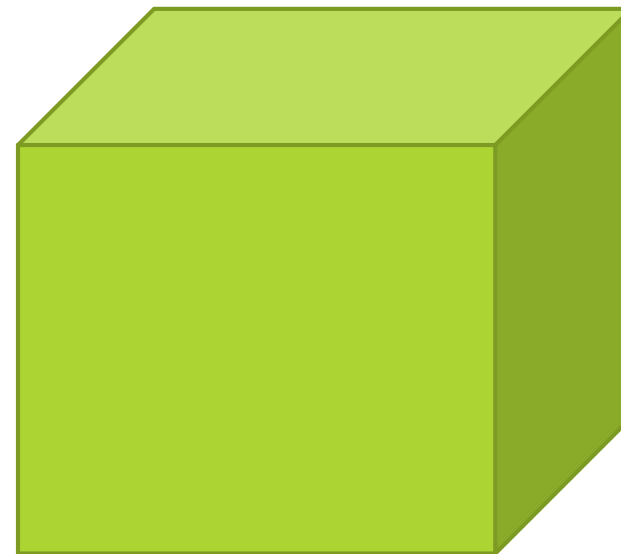
- ▶ Contain results from performing procedures
  - ▶ Paper recording
  - ▶ Electronic entry or transmission
- ▶ Become objective evidence of whether requirements were met
- ▶ Vital tools for internal audits and external assessments

# QMS vs Technical Documents: How to organize in a way that makes sense





What is this slide saying?

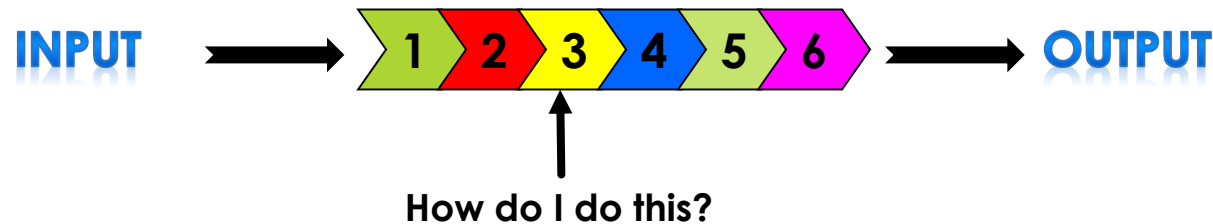


**“Everyone doing his best  
is not the answer.  
It is first necessary that  
people know what to do.”**

**W. Edwards Deming**

*“If you can’t describe what you are doing  
as a process  
then you don’t know what you are doing.”*

W. Edwards Deming



# Resources

- ▶ CLSI. **QMS02, 6<sup>th</sup> edition**  
*Development and Management of Laboratory Documents*
- ▶ CLSI. **QMS18, 1<sup>st</sup> edition**  
*Process Management*
- ▶ CLSI. **QMS01, 5<sup>th</sup> edition**  
*Quality Management System: A Model for Laboratory Services*
- ▶ CLSI. **QMS25, 1<sup>st</sup> edition**  
*Handbook for Developing a Quality Manual*
- ▶ <https://www.informationmapping.com/en/information-mapping/information-mapping/examples>