10 Most Common Laboratory Accreditation Deficiencies: How to Solve and Prevent Recurrences; Measuring the COPQ Associated With Deficiencies

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LABORATORIES MADE BETTER!

Most Common Deficiencies

- Documents and "procedure manual"
- Records of competence assessment
- Problems with PT requirements
- Validation of modifications of FDA approved-cleared tests

Correcting an Inspection Deficiency

"If you always do what you've always done, you'll always get what you've already got!"

The Underlying Problem

Documents do not reflect the order in which work actually happens.

What Causes This Problem?

The mindset of the "CLIA 14 elements" of a "procedure manual."

Interpreting the Regulation

§493.1251 Standard: Procedure Manual.
(a) *A written procedure manual for all* tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel.

Literal interpretation

- "A" - as in "one"
- "Procedure manual" – as in a single manual
- "for all tests, assays, examinations" – as in, "All tests… in one manual"
- No mention of non-testing activities (eg, management or QMS)

CLIA 14 Elements

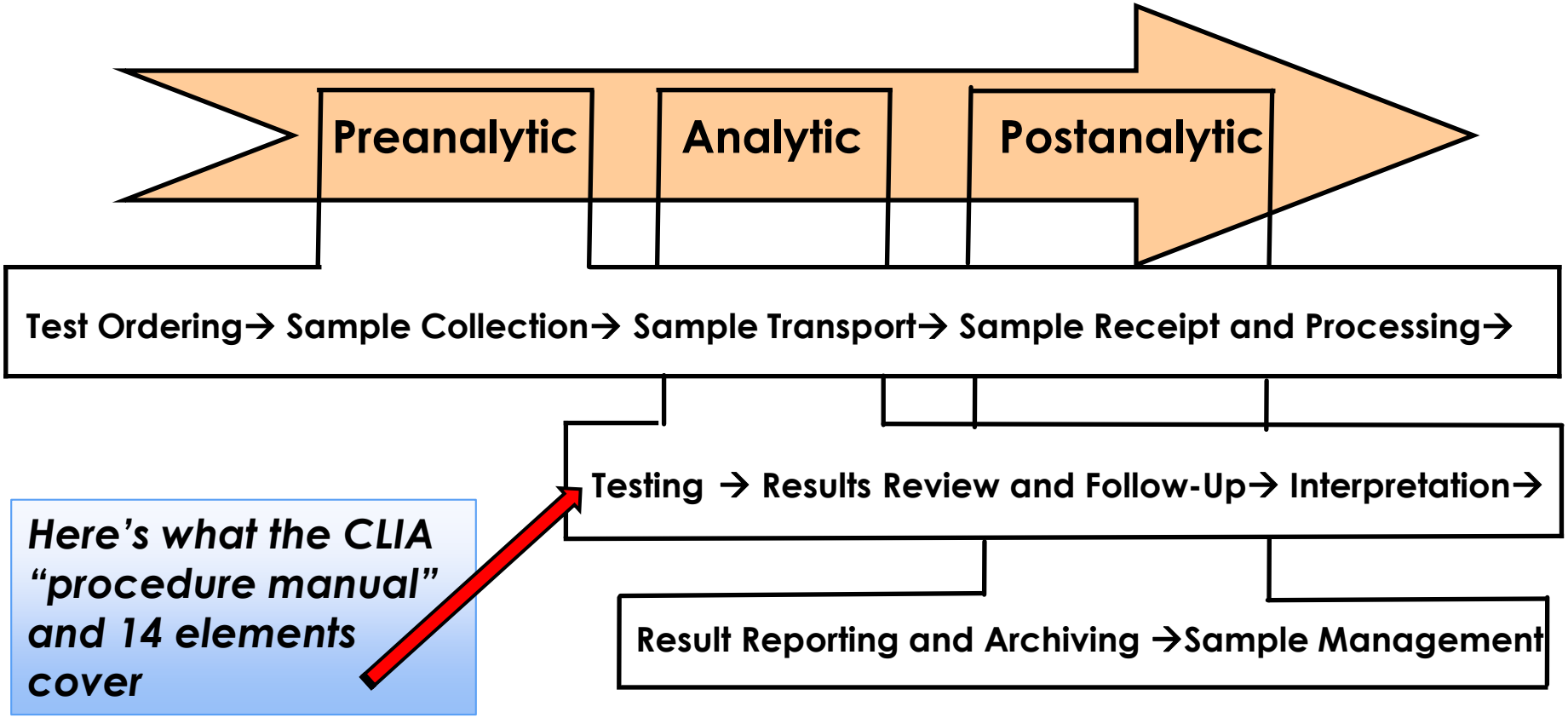
#	Element	
1	Patient preparation	
2	Microscopic examination	
3	Steps, calculations, and interpretations	
4	Reagent and materials preparation	
5	Calibration and calibration verification	
6	Reportable range	
7	Control procedures	

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

"Tests, assays, and examinations"
are only one part of a long series of
processes that comprise laboratory workflow

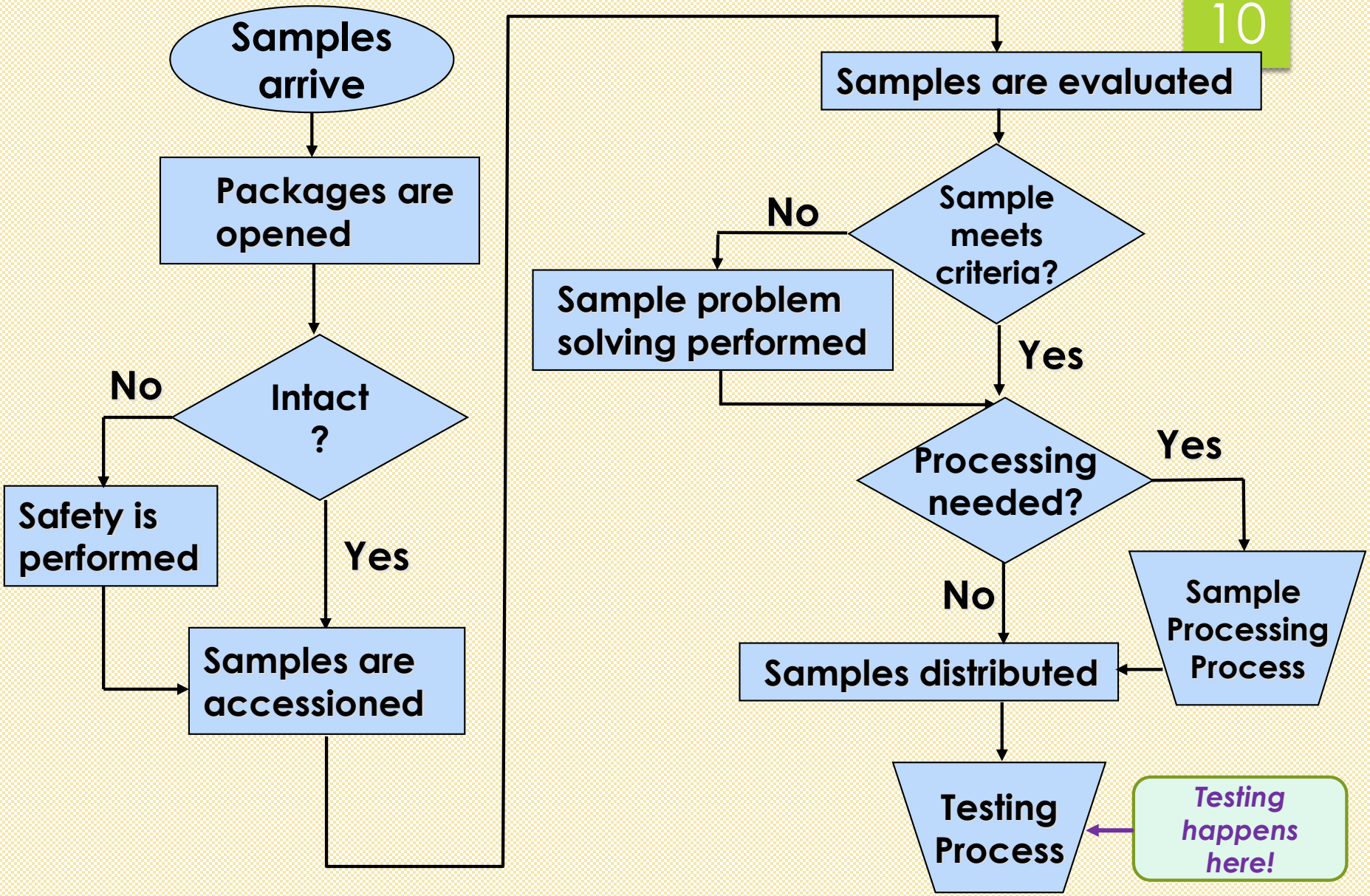
– ***all*** of which are needed to be
performed correctly to reduce
the risks to patient safety.

Here's How Laboratory Work REALLY Happens!

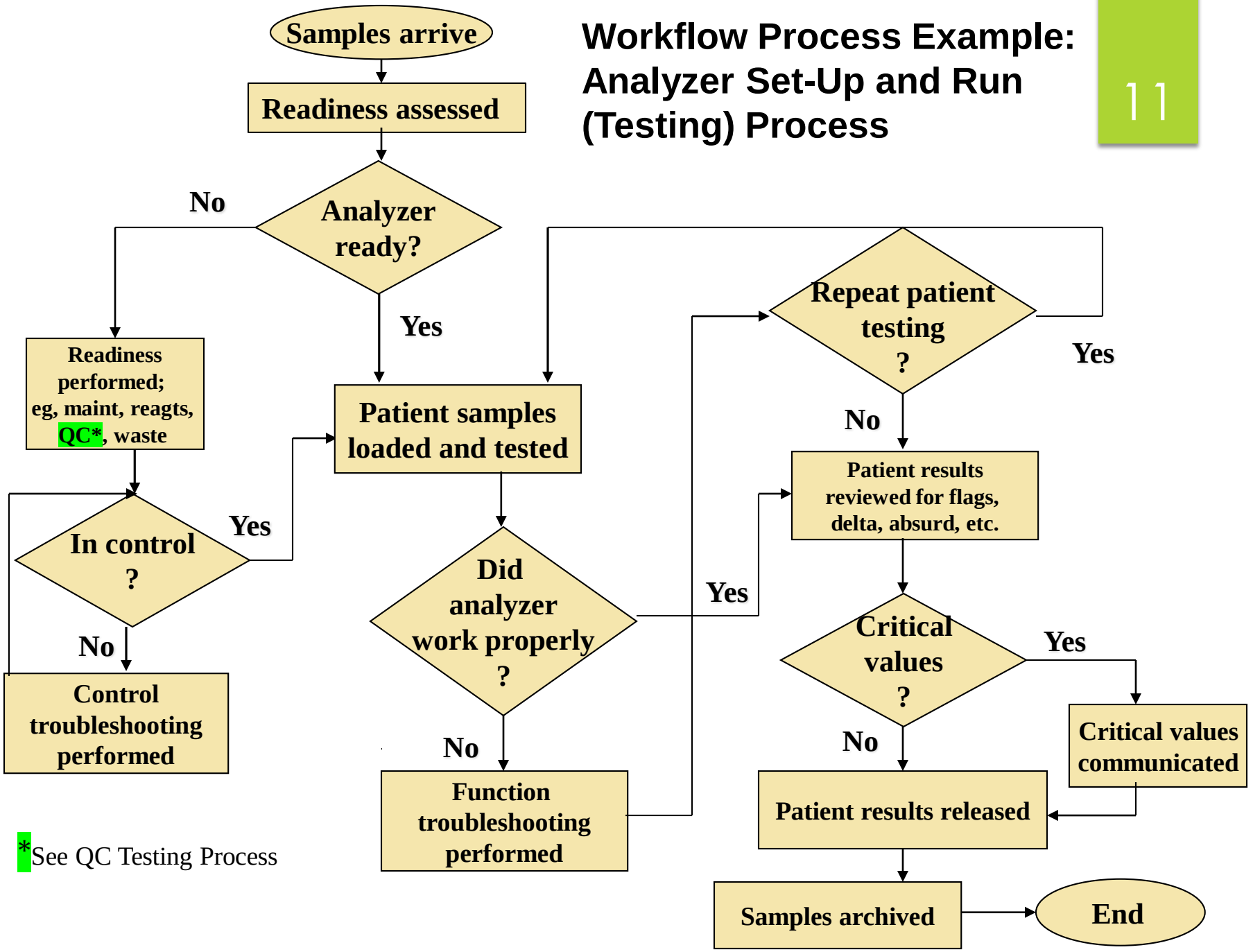


Here's what the CLIA "procedure manual" and 14 elements cover

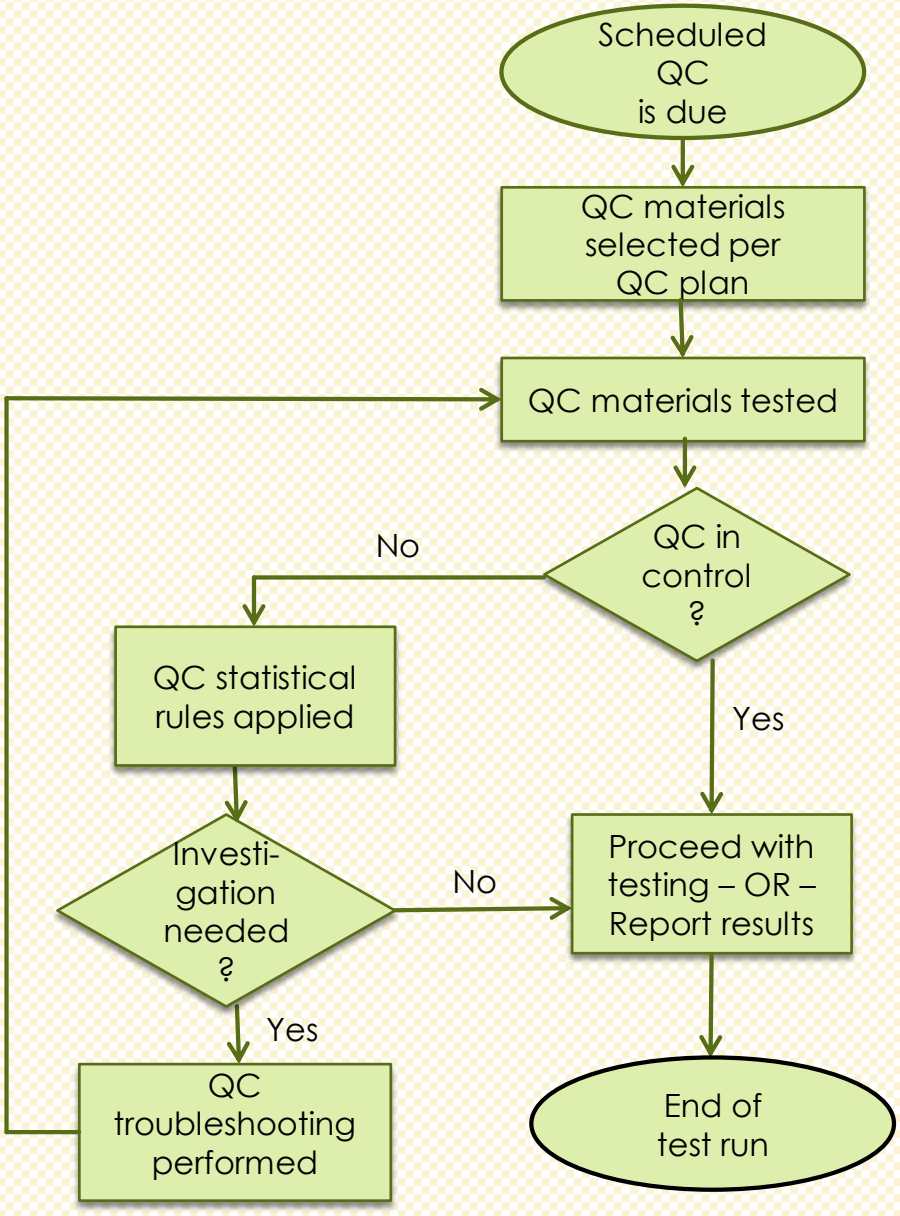
Example: Sample Receiving Process (Non-Testing)



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



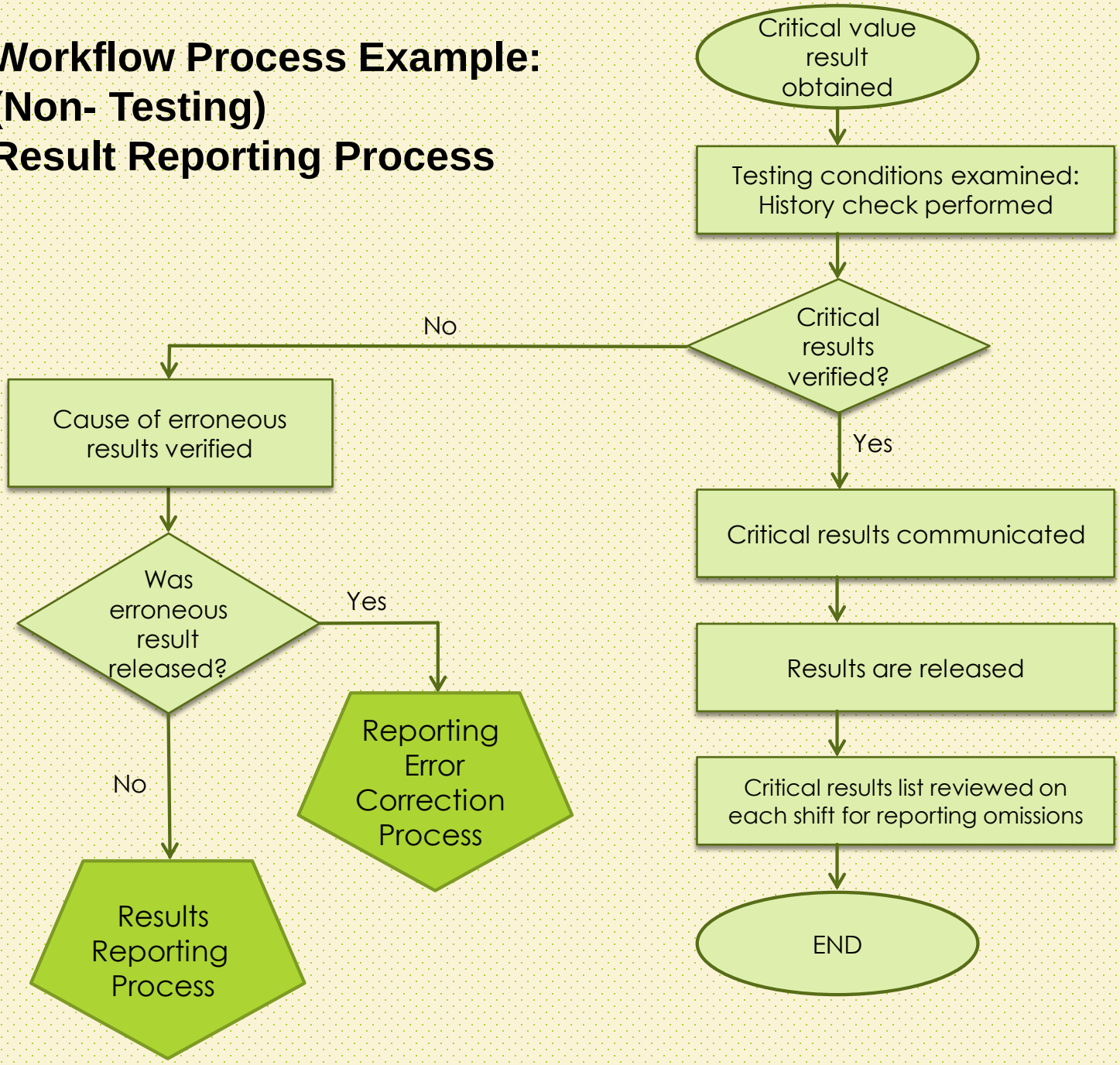
*See QC Testing Process



Workflow Process Example:

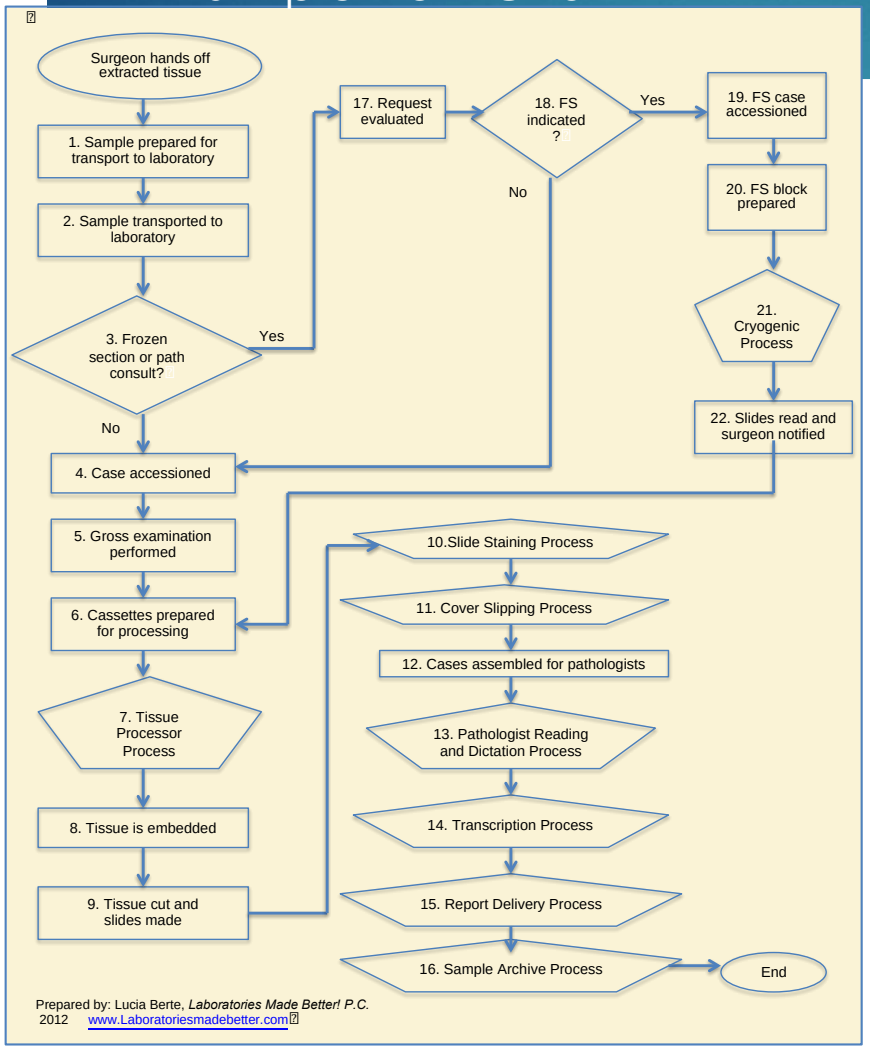
* QC Testing Process

Workflow Process Example: (Non- Testing) Result Reporting Process

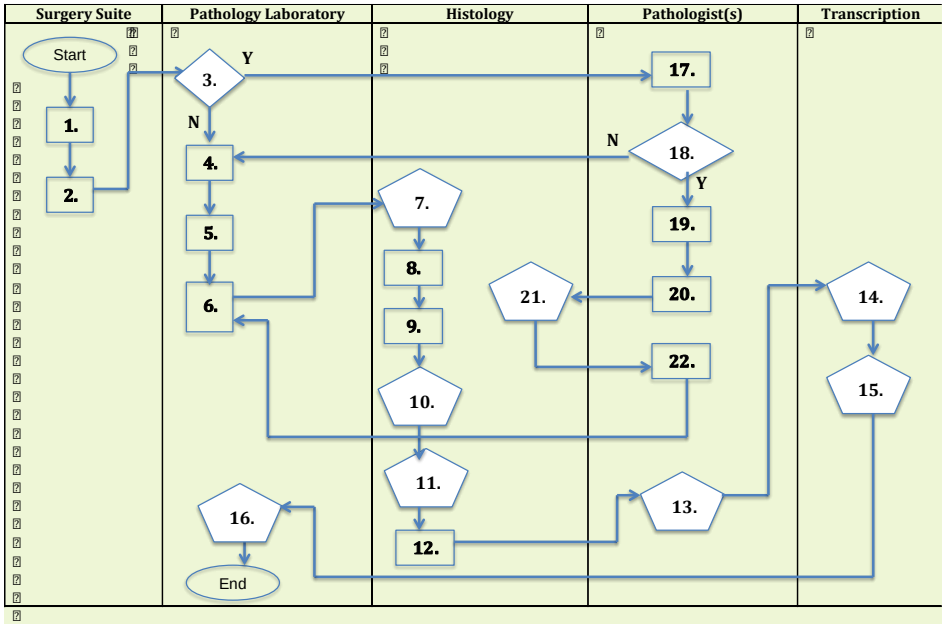


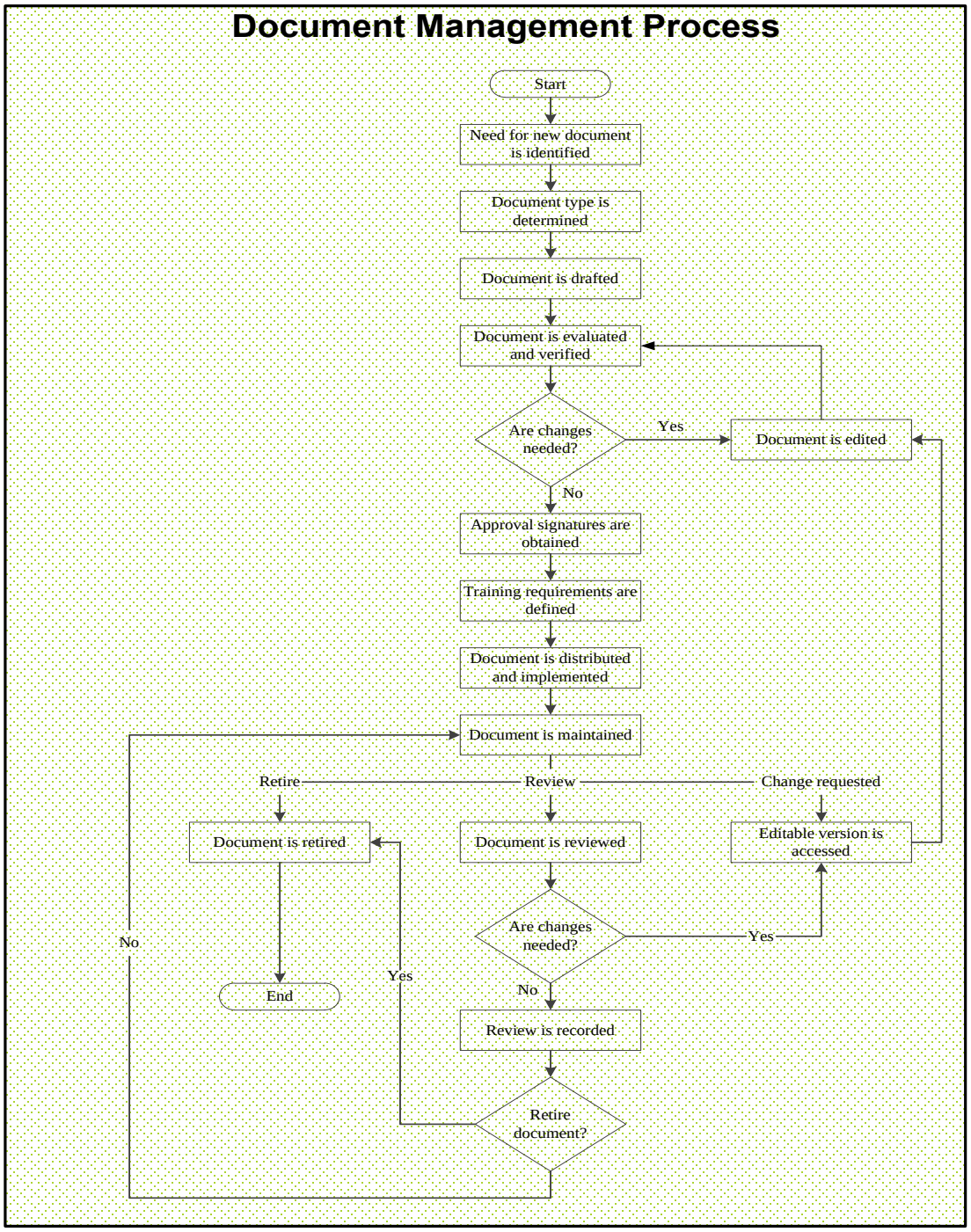
Surgical Pathology Process

Simple Flow Chart



Cross-functional "Swim-lanes" Flow Chart





CLSI Guideline
QMS02, 6th edition

Why Do We Have Problems?

- We try to make the CLIA-A2LA-JC-CAP-COLA inspectors happy
- *Hint: Wrong customer!!*
- We weren't trained to write good documents
- *Hint: CLIA-based SOPs are not good documents*
- We think that one outline or format fits all, when it really doesn't
- *Hint: There are 4 types of documents*
- We don't know how to structure information to be useful for the reader
- *Hint: But we could certainly learn!*

Which Is More Likely to be Read and Understood?

BEFORE: Example of a traditional document

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.

AFTER: The same document

Performing Lockout/Tagout on Electrical Equipment

Lockout/tagout procedure

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

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.

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.

If tagging will...	Then...
provide the same level of safety as using a lock	--take supplemental measures to ensure adequate safety. **Examples**: remove isolating circuit elements or block control switches.
not provide the same level of safety as using a lock	--shut down *all* 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.

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

Embedded decision tables clarify different courses of action.

A New Model for Procedures Manuals

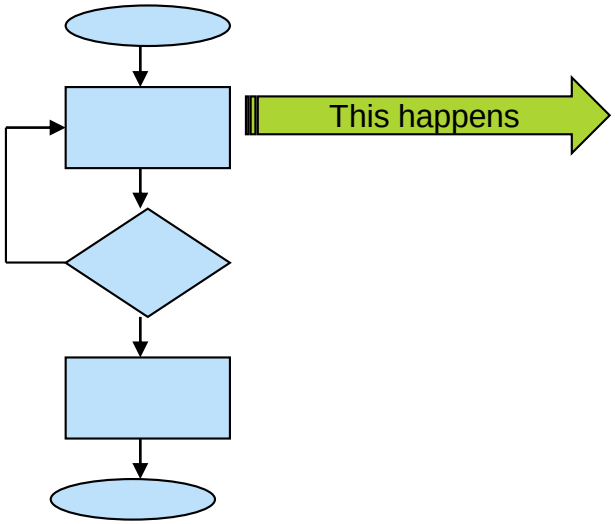
REAL LIFE

- Work does not happen in alphabetical order!
- Work **always** happens in *processes*
- A process outlines the needed procedures (instructions)

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.

Where does process information come from?

People	• Group flow charting is an invaluable experience
Observations	• Be sure to distinguish process from procedure!
Documents	• Most laboratory SOPs are actually verbal descriptions of a process – and usually incomplete!

“People support what they help create.”

Logic for Procedures Manuals

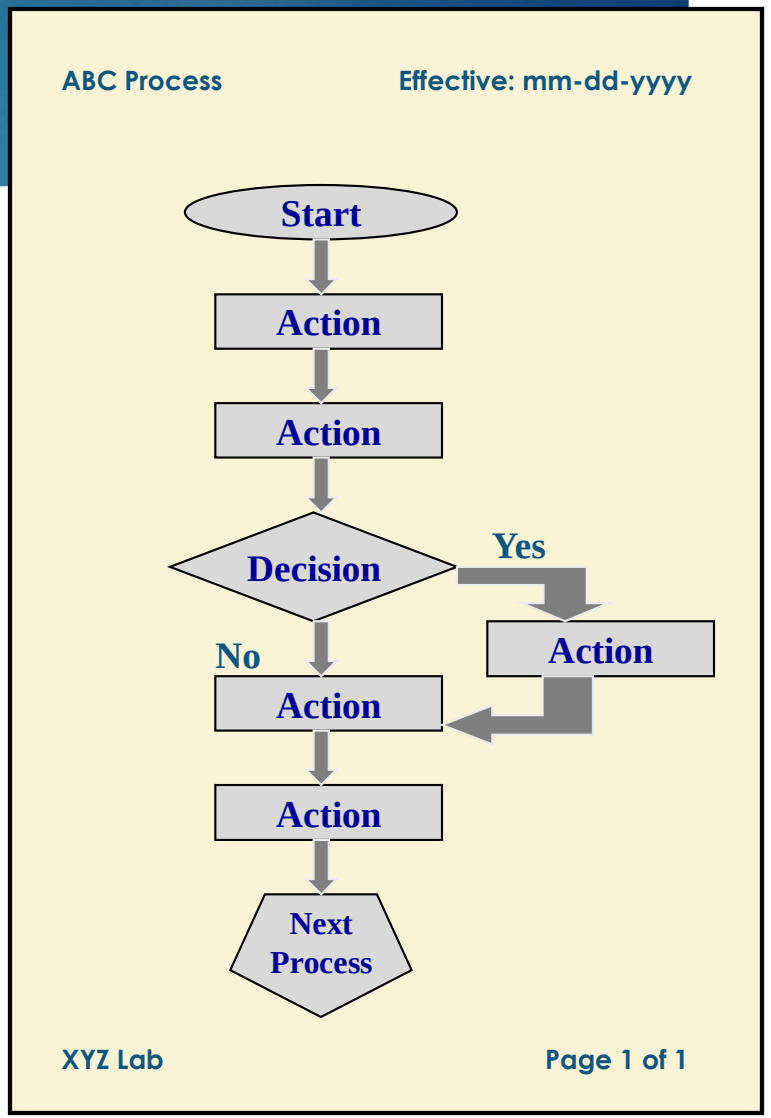
- Put the flowchart first!
- Followed by the much shorter instructions for the one activity, in the order in which they are performed
- OR – Reference to operator's manual or instrument screen shot
- Example of any properly completed form(s)
- Additional needed information

Suggested Table of Contents

- Process flowchart
- Operations Procedures
- Analyte Attribute Table(s), where needed
- Quality Control section (QC Plan)
- Calibration section
- Maintenance section
- Troubleshooting section
- Examples of properly completed forms
- Other? As needed

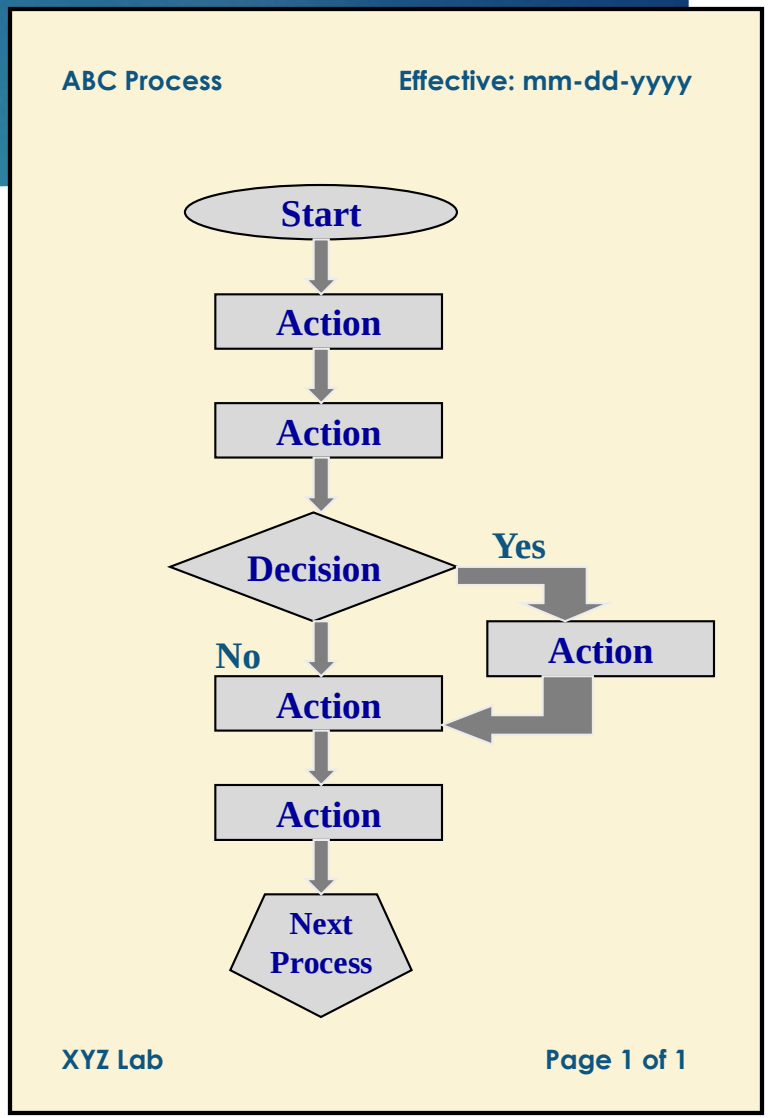
Process Flowchart 1.

- Have blank document template in Word
  - Headers, footers
  - Document control information
- Make flowchart in Visio
- Embed Visio file as Object in Word file



Process Flowchart 2.

- Some labs put next to each box
  - Section number
  - Procedure name/number
- Take advantage of hyperlink feature for electronic documents

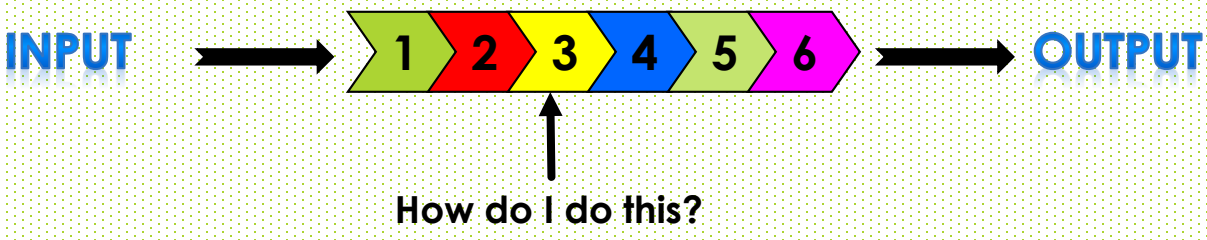


Analyte Attribute Table for Automated Procedures

	Protime	PTT	Thrombin Time
Clinical utility			
Sample Type			
Minimum sample volume			
Method limitations			
Reference range			
Critical values….			

"If you can't describe what you are doing as a process
then you don't know what you are doing."

W. Edwards Deming



Cost Thinking

What is the failure cost of correcting an external assessment deficiency?

Mostly Labor Cost When Correcting a Deficiency

Who	What
Supervisor	(Root cause analysis?)
Supervisor	Drafts response
Manager and/or Lab Director	Reviews and approves response
Supervisor	Finalizes response
(Supervisor)	(Revises response if not accepted)
Supervisor	Redrafts documents

Who	What
Supervisor	Document management
Manager and/or Lab Director	Reviews and approves revised documents
Supervisor and staff	Training on new documents
Supervisor	Competence assessment, as needed

Don't Be A Prisoner!

- **The "14 elements of a procedure manual" are 31 years old, *derived from an outdated guideline (NCCLS GP02) from 40 years ago*.**
- **These elements do not represent laboratory workflow.**

Write for Your Documents' Primary Customer – Your Personnel!

- **Meet the intent of the requirement**
- **In a way that helps personnel get it right**

What Should Happen

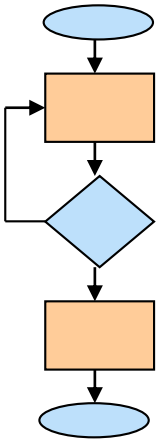
CMS/CLIA-JC-CAP-COLA should make requirements consistent with the way work really happens.

Don't hold your breath –
(NCCLS GP02 → process thinking in 2002)

Be proactive by meeting the intent.

5 Reasons Why "Process"

- All work is sequential ***processes***
- ISO15189 and CLSI QSEs are management and workflow ***process***-based QMSs
- Lean: Reduce ***process*** waste
  Six Sigma: Reduce ***process*** variation
- Engaging with practitioners: Through the test ordering and results interpretation ***processes***
- Change leadership: ***Process*** and cost thinking



Requirements vs Guidance

REQUIREMENTS	GUIDANCE
WHAT must be done	HOW it could be done
NOT how to do it	Recommendations of good practice

Resources

- Andersen B, Fagerhaug T, Henriksen B, Onsoyen LE. ***Mapping Work Processes***, *2nd ed.* Milwaukee, WI: ASQ Quality Press, 2008. www.asq.org
- CLSI. **QMS18**, 1st edition *Process Management*
- CLSI. **QMS02**, 6th edition *Development and Management of Laboratory Documents*
- *https://www.informationmapping.com/en/information-mapping/information-mapping/examples*
- *CLSI. **QMS20**, 1st edition Understanding Cost of Quality in the Laboratory*

"If we don't change our direction we're going to wind up where we're headed."

Native American proverb