Exploring the Essentials of Quality Assurance

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Objectives

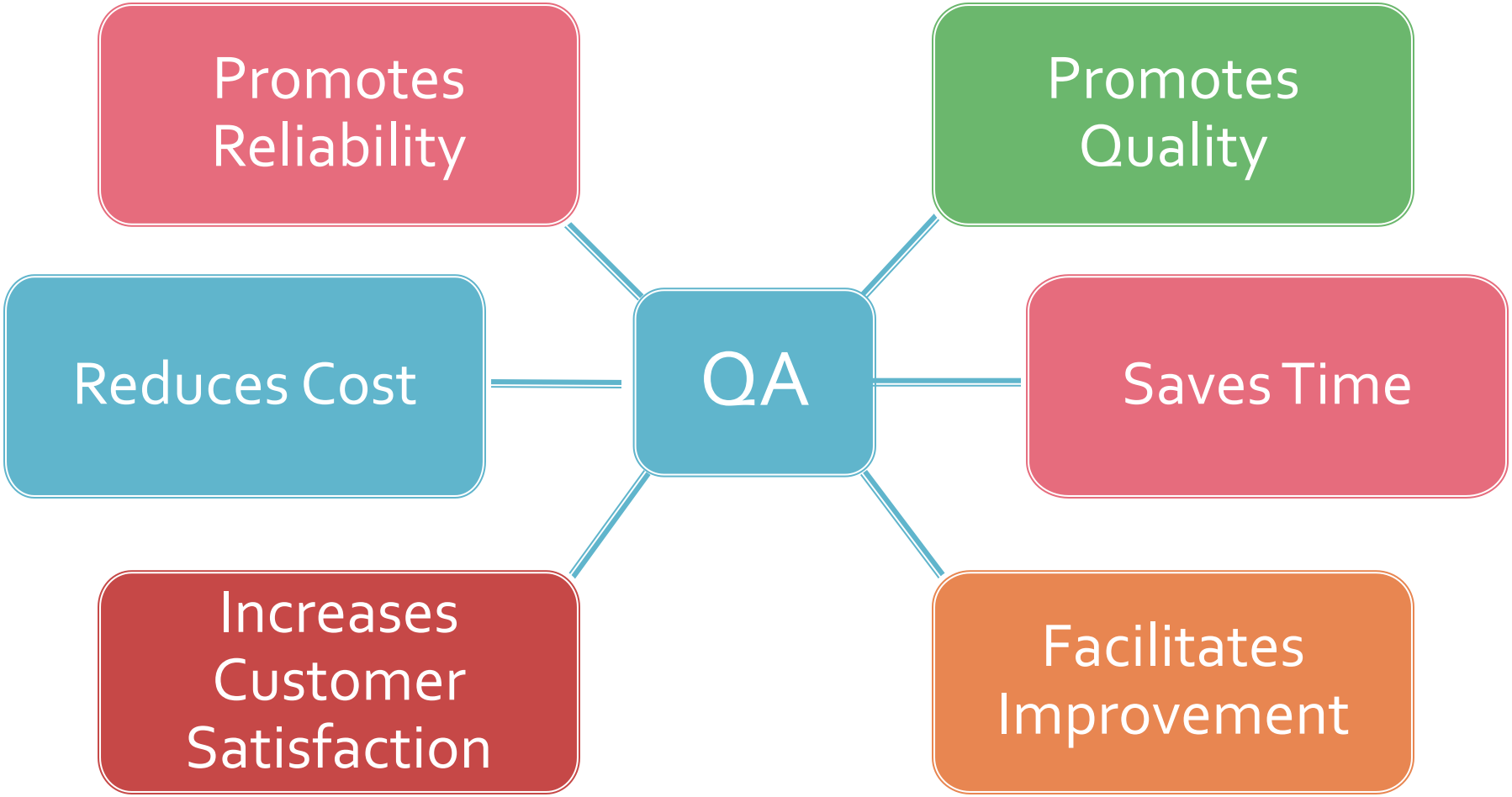
- Discuss:
  - Why Quality Assurance is Important
  - How to Implement a Quality Management System

- Explore the Following Key Elements:
  - Traceability
  - Document Control
  - Root Cause Analysis
  - Corrective Action and Preventive Action

What is Quality Assurance?

- The planned and systematic activities implemented in a quality system so that quality requirements for a product or service will be fulfilled.

Why is QA Important?



The Cost of Not Having Quality Assurance

If inaccurate results are reported:

- Delay treatment/response
- Cause unnecessary treatment

Lower Confidence

Increased Cost, Time, Effort

Quality Assurance is not Quality Control

Quality Assurance	vs.	Quality Control
Process Oriented		Product Oriented
Failure Prevention System		Failure Detection System
Development of the planning processes and procedures to ensure customer requirements are met		Checking the products to ensure that specifications have been met

Okay, QA is Important. What Now?

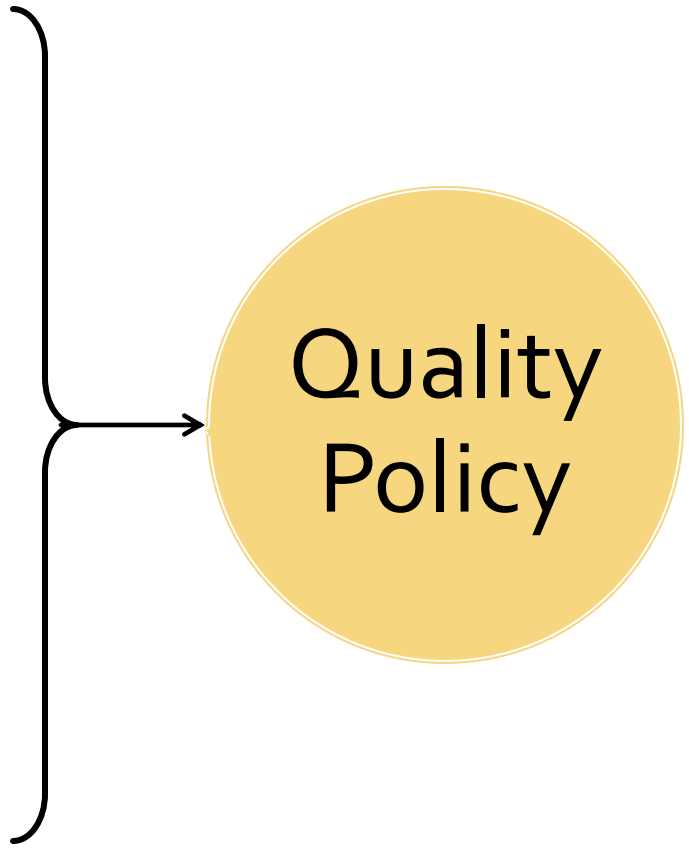
- You now need to implement a Quality Management System!
  - The International Organization for Standardization(ISO) and the Clinical and Laboratory Standards Institute (CLSI) define a quality management system as "*coordinated activities to direct and control an organization with regard to quality.*"

The Quality Management System

The Quality Policy is a Concise Statement

Ensure that the Quality Policy:

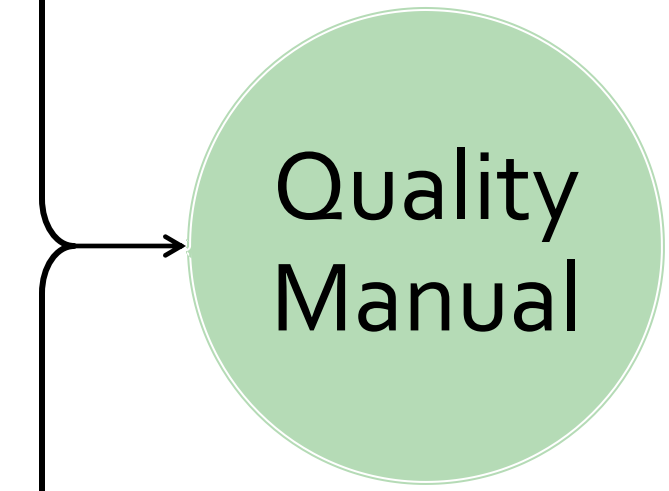
1. is **relevant** to the purpose of the organization
2. includes a **commitment to comply** w/ requirements and **continually improve** the effectiveness of the QMS
3. provides a **framework** for establishing and reviewing quality objectives
4. is **communicated** and understood within the organization
5. is **reviewed** for continuing suitability



The Quality Manual Details how the QMS Operates

Recommend that it includes/addresses:

1. The Quality Policy
2. Organization/Management system
3. Document Control
4. Review of requests, tenders and contracts
5. Subcontracting of tests and calibrations
6. Purchasing services and supplies
7. Service to the customer
8. Complaints
9. Control of nonconforming work
10. Continual Improvement
11. Corrective action
12. Preventive action
13. Control of records

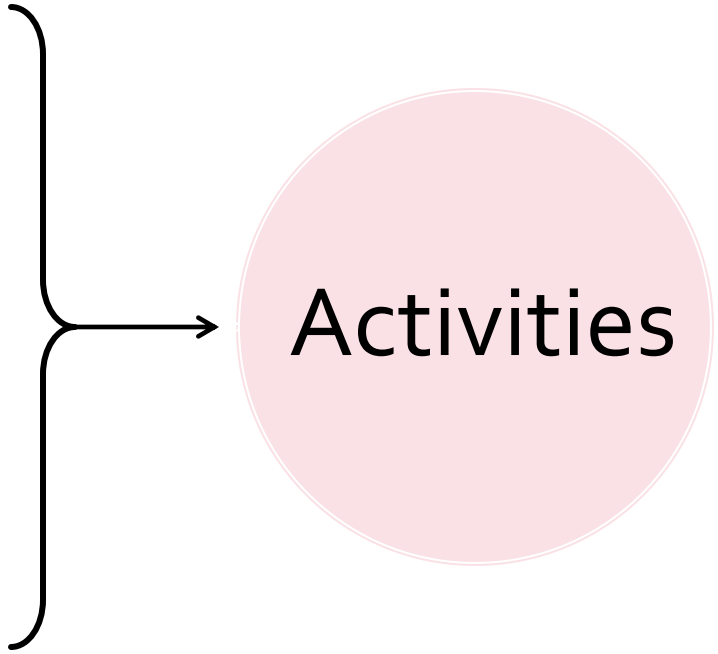


The Quality Manual Details how the QMS Operates (Cont.)

14. Internal audits
15. Management reviews
16. Traceability
17. Inspection and testing
18. Statistical techniques
19. General technical requirements
20. Personnel
21. Accommodation and environmental conditions
22. Calibration methods and method validation
23. Equipment
24. Measurement traceability
25. Sampling
26. Reporting of results
27. Customer satisfaction

Activities-Demonstrate Compliance

1. Policies and Procedures
2. Documenting the Required Elements
3. Training
4. Internal/External Audits
5. Reviews
6. Corrective Action/Preventive Action



Client Feedback is Valuable!

Methods of collection:

1. Customer Complaints
2. Spontaneous Expressions of Satisfaction/Dissatisfaction
3. Issue Log
4. Questionnaires
5. Surveys
6. Focus Groups
7. Awards and Recognitions
8. Repeat Customers

How to Implement a Quality Management System

- Step 1: Planning

1. Assemble a Quality Management Team and/or appoint a QA Lead
2. Review the Standard and Customer Requirements
   - Create a checklist of required elements
3. Conduct a Gap Analysis (Needs Assessment)
4. QMT to agree on Strategy
   - Create an Implementation Checklist
   - Assign due dates or goals
   - Agree on full implementation date

How to Implement a Quality Management Plan (Cont.)

- Step 2: Develop a Quality Manual
- Step 3: Develop the Documentation
  - SOPs, forms, etc.
    - Try to *standardize* these as much as possible
    - Assign form numbers to every document and keep it consistent (ex. SAN-0001.001)
    - Build *traceability* into you documentation
    - Avoid strictness in times and methods
      - Ex. Swab an area 100cm X 100cm using an S-shaped motion

How to Implement a Quality Management Plan (Cont.)

- Step 4: Implementation
- Step 5: Internal Audit
- Step 6: Management Review/Corrective Action
- Step 7: External Audit
- Step 8: Continuous improvement

Key Elements of a Quality Management System

- Traceability
- Document Control
- Root Cause Analysis
- Corrective Action and Preventive Action

What is Traceability?

Traceability	
Metrological	**Operational**
An unbroken chain of measurements and associated uncertainties (NIST)	An unbroken chain of data linking results to applicable methods, reagents, reference materials, equipment, staff, and calibration standards (Signature Science, LLC)

Traceability in the Laboratory

- What does it mean in a laboratory?
  - The ability to interrelate and verify information about all steps in sample handling from sample receipt to reporting
  - Established by records that describe all the elements that can affect the sample or its analytical derivatives (Signature Science, LLC)

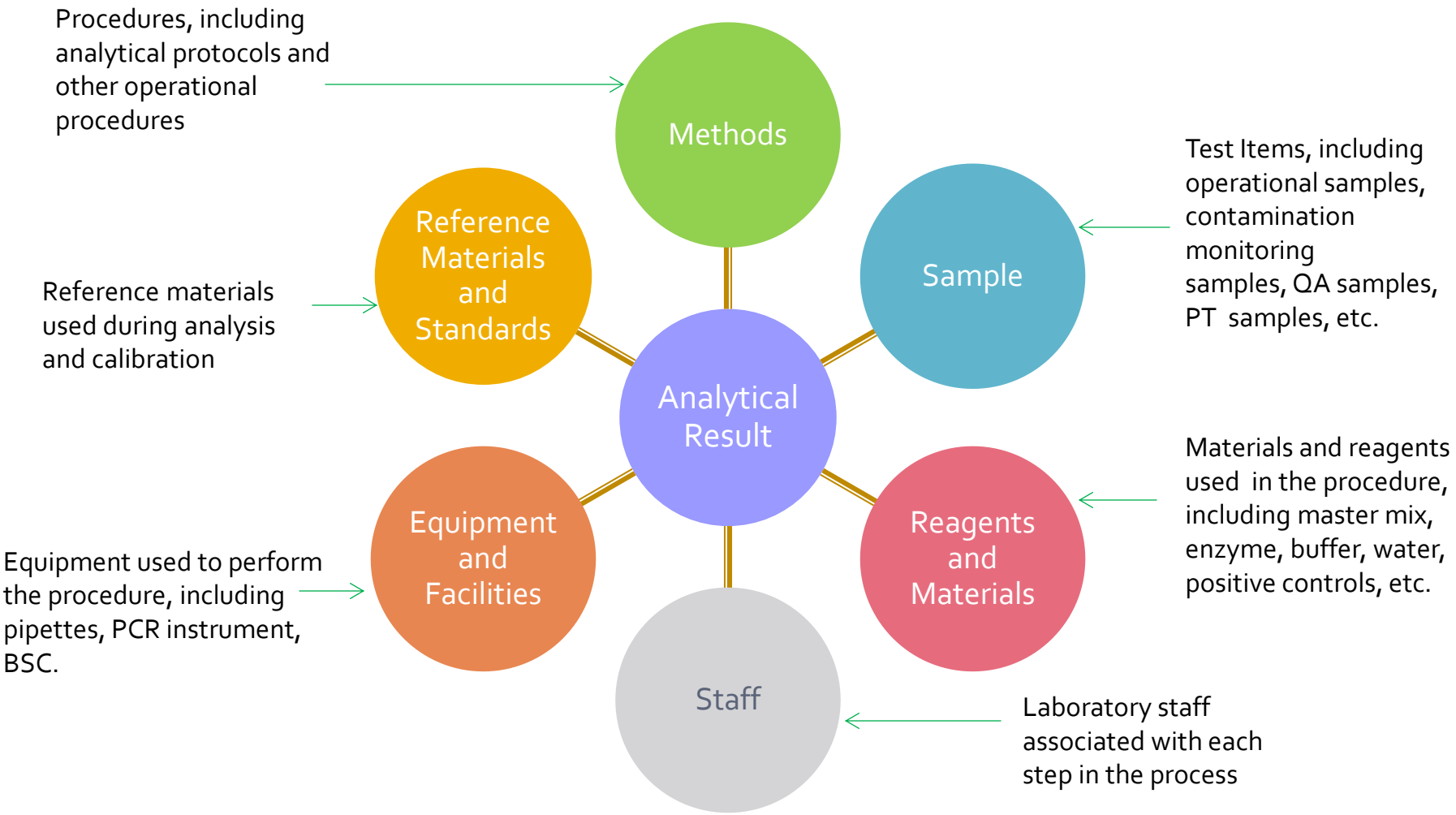
Why is Traceability Important?

1. Supports the defensibility of results
2. Provides the information necessary to repeat the analysis under the same conditions
3. Facilitates root cause investigation and corrective action

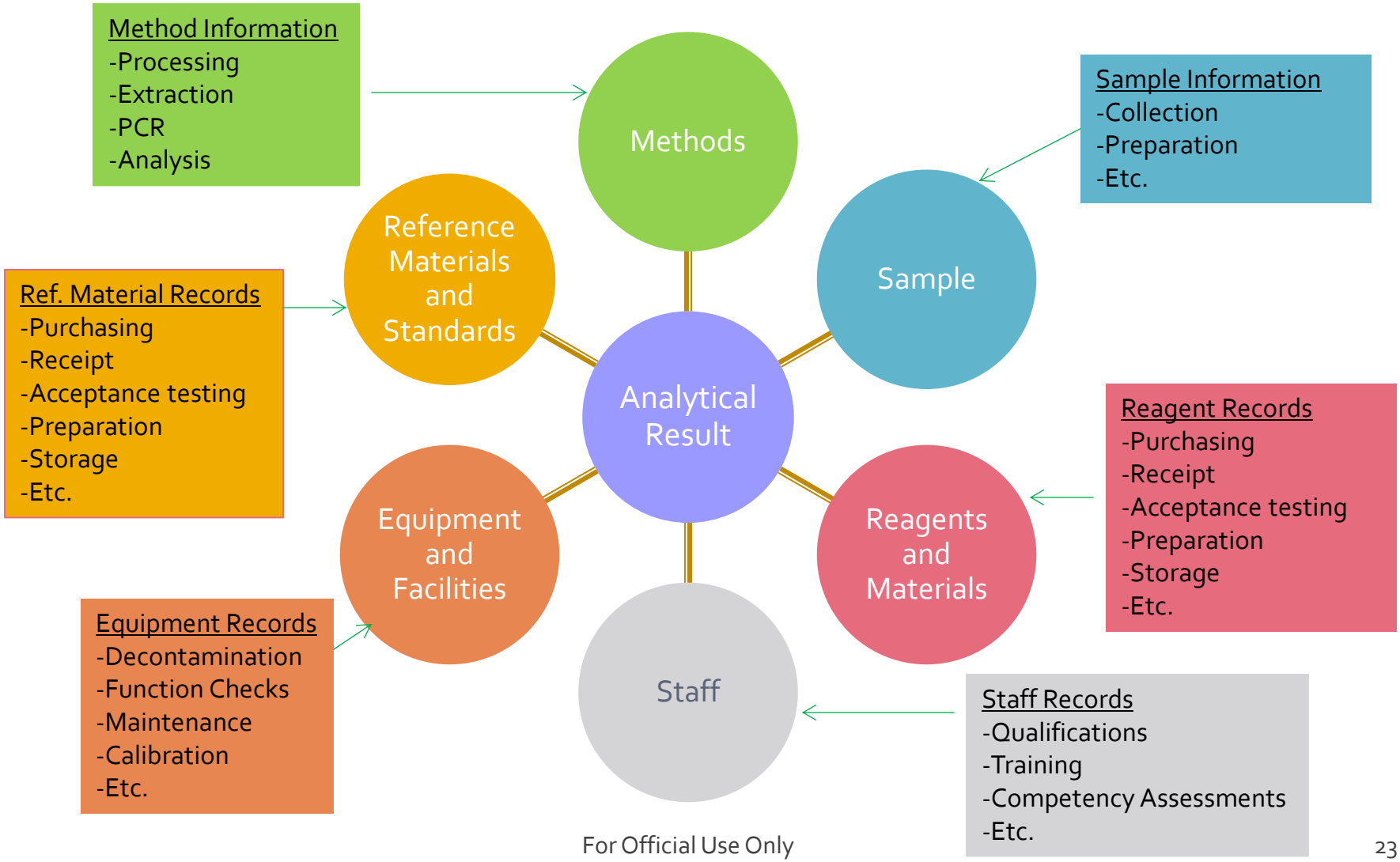
How do we Establish Traceability?

- *Record* all of the details that went into generating the analytical result for a sample
  - Starting with sample receipt through the final result
  - When it comes to traceability, if it's not recorded, it did not happen!
- *Create and maintain* records related to
  - Methods
  - Staff
  - Equipment
  - Samples
  - Standards and reference materials
  - All consumables that may materially affect the analytical process
  - Reagents and Materials

Traceability Concept

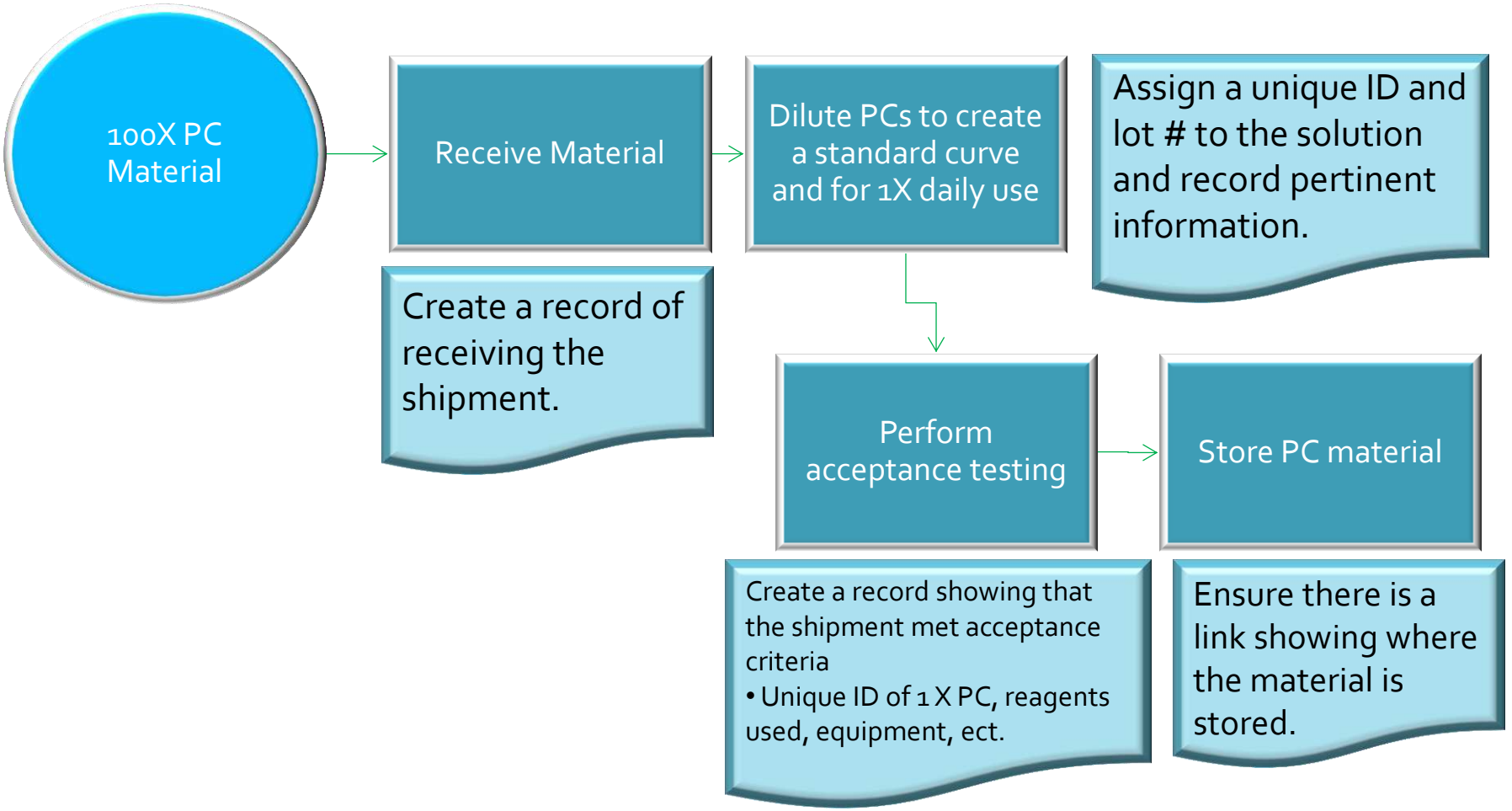


Traceability Concept-Records



Traceability Concept-Single Component

- For each process step, **record** what happened to complete that step.



San Diego-Example of Traceability on a Bench Sheet

PCR Plate Map and MM Prep for Operational Screening Using XXX- Reagents

Technician:
ABI Machine:
Date:
Run Name:
Did technician check vol. of wells? Y N
Did technician check lot numbers? Y N

Master Mix =	N	Pooling Cal. of MM		Vol/well (pool)
	14	N/(µL)	Total Volume	MM=10µL
3X Organism Specific MM		5	**70**	NTC=10µL
PCR Grade Water		5	**70**	Sample=10µL
Plat. Taq		0.25	**3.5**	PC = 5µL+ 5µL Water
Total Volume		10.25	**143.5**	Total vol.= 20µL

			Acceptable Range as of 02Aug13						
Target	Lot # Master Mix	Lot # Positive Control	Athos	Porthos	CT value	Passed?	Name	Lot#	Exp:
T1	060912-05M	GB30May13A	26.12-29.29	25.82-28.36			Taq	1218859	8/31/2014
T2	040612-01M	GB30May13B	26.19-29.95	25.55-29.45			PCR Grade Water	DMJul13A	5/31/2014
T3	040113-04M	GB30May13C	27.00-29.32	26.32-28.96			Adhesive Covers	201208179	n/a
T4	281212-04M	GB30May13D	26.18-29.45	25.49-29.25			ABI 96 Well Plate	I0272QA124	n/a
T5	191212-02M	GB30May13E	27.39-31.72	27.14-.30.66			Edge Plate Sealers	160453	n/a
T6	181212-01M	GB30May13F	25.37-30.33	24.71-30.49			Eppendorf tubes	B147636K	n/a
T7	160513-01M	N/A	31.89-33.96	31.39-33.88			Plate free of cracks?	Yes No	n/a
							Individual ABI plate #		

	1	2	3	4	5	6	7	8	9	10	11	12
A	3700/3708	3701/3709	3702/3710	3703/3711	3704/3712	3705/3713	3706/3714	3707/3715	Neg. Filt.	BLANK	QA 673 A/B	T1-PC
B	3700/3708	3701/3709	3702/3710	3703/3711	3704/3712	3705/3713	3706/3714	3707/3715	Neg. Filt.	BLANK	QA 673 A/B	T2-PC
C	3700/3708	3701/3709	3702/3710	3703/3711	3704/3712	3705/3713	3706/3714	3707/3715	Neg. Filt.	BLANK	QA 673 A/B	T3-PC
D	3700/3708	3701/3709	3702/3710	3703/3711	3704/3712	3705/3713	3706/3714	3707/3715	Neg. Filt.	BLANK	QA 673 A/B	T4-PC
E	3700/3708	3701/3709	3702/3710	3703/3711	3704/3712	3705/3713	3706/3714	3707/3715	Neg. Filt.	BLANK	QA 673 A/B	T5-PC
F	3700/3708	3701/3709	3702/3710	3703/3711	3704/3712	3705/3713	3706/3714	3707/3715	Neg. Filt.	BLANK	QA 673 A/B	T6-PC
G	3700/3708	3701/3709	3702/3710	3703/3711	3704/3712	3705/3713	3706/3714	3707/3715	Neg. Filt.	BLANK	QA 673 A/B	BLANK
H	MM-NTC	MM-NTC	MM-NTC	MM-NTC	MM-NTC	MM-NTC	INH-NTC	BLANK	BLANK	BLANK	BLANK	BLANK

Pipettes	Hood	Equipment	SN#	Cal. Due	Check if used
1	Master Mix	200 µl	1009692	10/31/13	
2	Master Mix	10 µl	4695701	10/31/13	
3	Master Mix	200 µl-multi	E0609106E	11/3/13	
4	Master Mix	20 µl	2960316	10/31/13	
5	Master Mix	1000 µl	1268708	10/31/13	
6	Master Mix	Vortex	BW1001	7/22/14	
7	Master Mix	Centrifuge	51007136	7/22/14	
8	Plate Load	20 µl-multi	J0752689A	11/3/13	
9	Plate Load	10 µl	3149473	10/31/13	
10	Plate Load	200 µl	1198116	10/31/13	
11	Plate Load	200 µl-multi	E0608137E	11/3/13	
12	Positive Control	10 µl	D1327998T	9/30/13	
13	Positive Control	Vortex	87101087	7/23/14	
14	Positive Control	Centrifuge	BW1002	7/23/14	

Cycling parameters
45 cycles for Stage 2
Stage 1: 50C for 2 min, 95C for 20 sec
Stage 2: Step 1: 95C for 3 sec
Step 2: 60C for 30sec
Run Mode: **7500 Fast**

Technician Signature: Date:

Reviewed By: Date:

San Diego-Example of Traceability on a Bench Sheet

San Diego Laboratory
Form # SAN-0019.008
Effective: 01Aug2013

DNA Extraction Worksheet

Start time		
Sample numbers	SD13-3700 to SD13-3715, QA 673 A/B, Swabs or NA	
PBS Tween	Lot # DM02May13a	Exp.Date: 26 Apr 2015
TE buffer	Lot # AK06Aug13A	Exp.Date: 06 Feb 2016
diH2O	Lot # DM30Apr13a	Exp.Date: 31 May 2014
MSNU03050 Plate	Lot # R2NA71230	
MSGVN2250 Plate	Lot # R2NA71213	
96 well extract plate	Lot # 348617-V 22915	
Reservoirs	Lot # 13912022	

Foil Seal	Lot # 132097
Edge Plate Sealers	Lot # 160453
P1000	S/N 4705867
Multi-200	S/N C1102531E
Multi-1000	S/N G1363491T
Centrifuge	S/N J01089
Thermal Cycler	S/N AL100845
Biosafety Cabinet	S/N 80718

Lot numbers verified, connections verified, and ensured that there are no cracks in any of the plates. Yes

The rest of the procedure……

Technician:_____Date:_____**End Time**:_____

Reviewed By:_____ Date:_____

San Diego Lab-Example of Daily Tracking

Daily Reagent & Consumable Tracking - San Diego

Item	Vendor	Lot #-Check X	Exp. Date	Lot #-Check $	Lot #-Check #	Lot #-Check &	Lot #-Check ^	Lot #-Check @	Comments	August 2013 1	2	3	4	5	6	7	8
Sample Processing																	
										X/X	X/X	X/X	X/X				
										X/X	X/X	X/X	X/X				
										X/X	X/X	X/X	X/X				
										X/X	X/X	X/X	X/X				
										X	X	X	X				
										X	X	X	X				
Extraction																	
										X	X	X	X				
										X	X	X	X				
										X	X	X	X				
										X	X	X	X				
										Y	Y	Y	N-C11				
										X	X	X	X				
										X	X	X	X				
										X	X	X	X				
TE Buffer	Sigma	1089-901	30Feb2014	2099-809 exp. 30March2015						X	X	$	$				
										X	X	X	X				
										X	X	X	X				
										X	X	X	X				
										X	X	X	X				
										X	X	X	X				
PCR Screening Analysis																	
										X	X	X	X				
										X	X	X	X				
										X	X	X	X				
										X	X	X	X				
										X	X	X	X				
										X	X	X	X				
										X	X	X	X				
										X	X	X	X				

Key Elements of a Quality Management System

- Traceability
- Document Control
- Root Cause Analysis
- Corrective Action and Preventive Action

Document Control

Documents	vs.	Records
▪ Provide information and instruction for policies, procedures, and processes		▪ Are the <u>data</u> that are generated when staff perform those policies, procedures, and processes
▪ Tell us <u>what to do</u>		▪ Tell us <u>what was done</u>
▪ Need to be revised as information, needs, and situations change		▪ Cannot revise

Document Control Requirements

- 6 Requirements:
  - 1. Currency
  - 2. Staff Review
  - 3. Authorization
  - 4. Management Review
  - 5. Archiving
  - 6. Availability

Ways to Ensure Document Control

- 1. Have a Master List
  - version #, effective date, changes made, location

Master Document List
(Last Updated: Feb 18, 2014)

Process	Document Number	Document Title	Type of Document	Version or Revision	Effective Date	Next Review Date	Responsible Organization	Location

- 2. Common area for accessing docs
- 3. QA Lead obsoletes and archives old versions
- 4. Schedule the Annual Review
- 5. Inspect during Internal Audit

Key Elements of a Quality Management System

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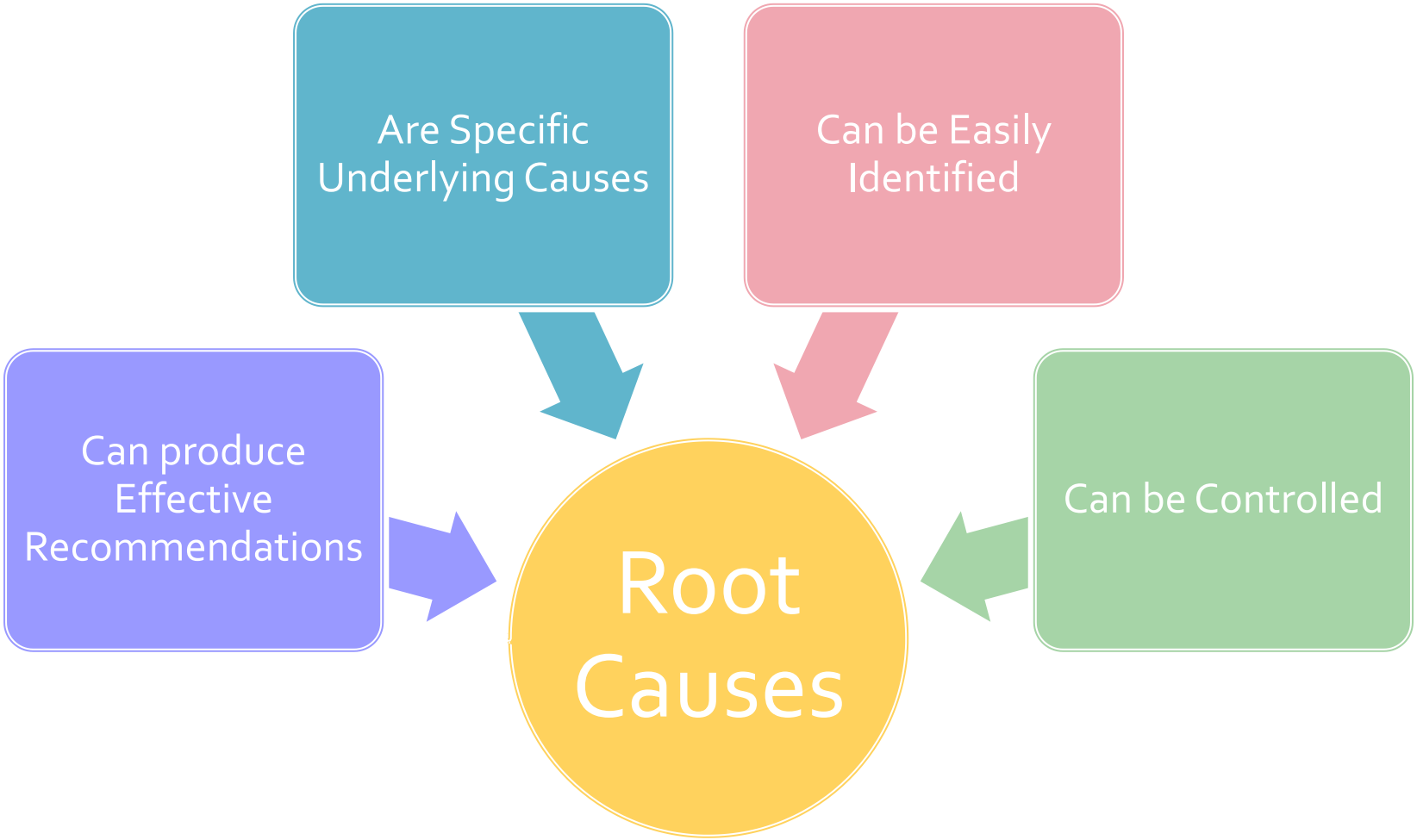
Root Cause Analysis

- What is a Root Cause?
  - A factor that caused a nonconformance and should be permanently eliminated through process improvement
- What is Root Cause Analysis?
  - A class of problem-solving methods aimed at identifying the root causes of problems.

Why is Root Cause Analysis Important?

- Root cause analysis helps identify *what*, *how* and *why* something happened, thus preventing recurrence.
- It is only when the *why* is established that corrective measures can be put in place.
- No RCA leads to only a "correction" and then the problem comes back!

Root Causes…


Are Specific Underlying Causes
Can be Easily Identified
Can produce Effective Recommendations
Root Causes
Can be Controlled

Example A

- Imagine Chris is supposed to pipette sample QA 1 into well A1 but instead pipettes sample QA 2 into the well instead. This is not discovered until after the run is analyzed and the results do not match up with the spiking scheme.
  - Many would use the above to describe “what” happened and the typical investigation would conclude that the cause was operator error therefore the “how” is answered.

Example A Continued

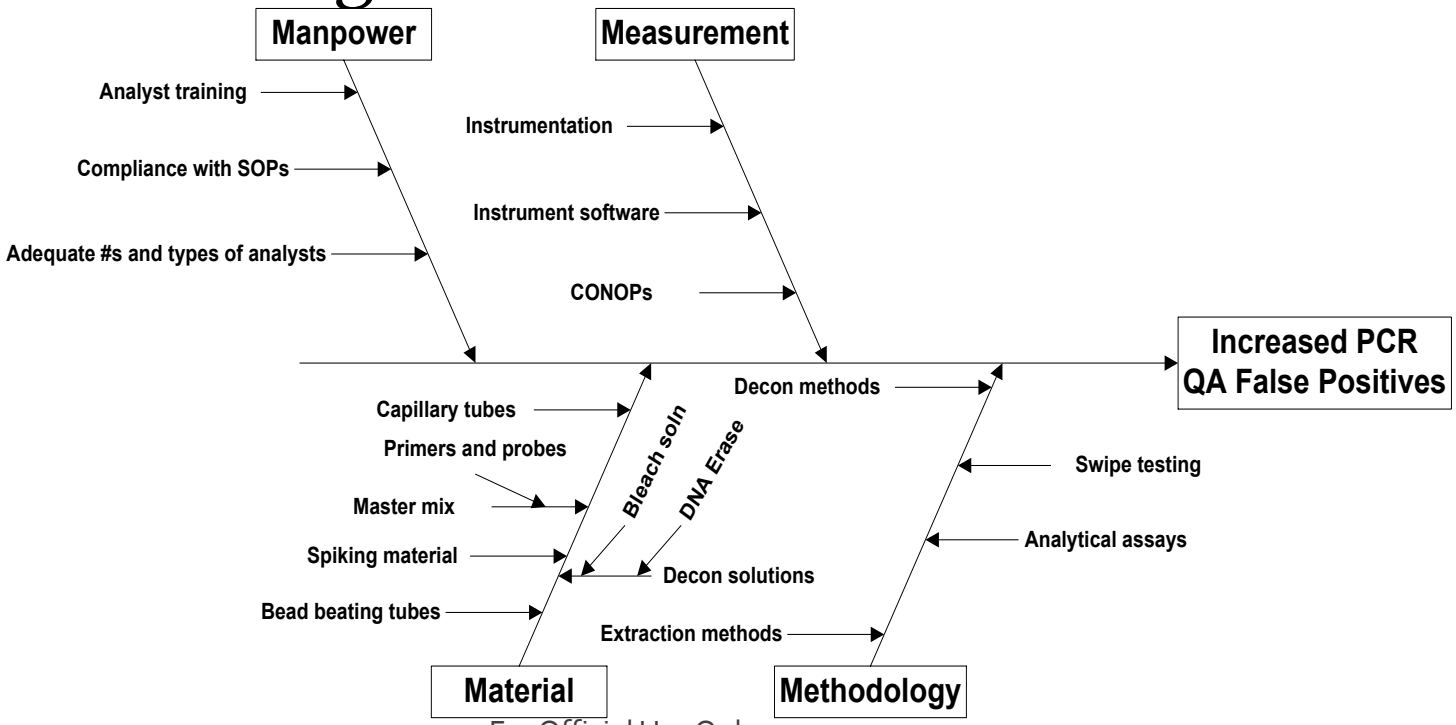
- Many times the investigation stops here.
  - the recommendation ends up being "Retrain the technician".
  - "why" has not been answered.
  - no measure to prevent recurrence.
- The "why" in this case was due to illegible handwriting on the tubes=the root cause!
  - Corrective Action=label the tubes with color-coded labels with the numbers already printed on them.

Tools for Root Cause Analysis

1. Five Whys
   - Begin with a statement of the problem followed by the question “Why did this problem occur?” Each answer now triggers a new problem to which “Why?” is asked again. This process continues until the answer reached is the fundamental cause.

Tools for Root Cause Analysis Cont.

2. Brainstorming, Interviews, or Observation
3. Process Flow Diagram
4. Fishbone Diagram



Root Cause Analysis Steps

Things to Avoid

- Avoid blaming
- Stopping too soon
- The belief that there can only be 1 root cause
- Only having a correction rather than a corrective action
- Incomplete Problem Definitions

Key Elements of a Quality Management System

- Traceability
- Document Control
- Root Cause Analysis
- Corrective Action and Preventive Action

Corrective Action vs. Preventive Action

Corrective Action	vs.	Preventive Action
Process, or series of actions, designed to minimize or eliminate the *recurrence* of a non-conformity		A measure that is put in place in order to avoid an *occurrence* from happening
Uses *root cause analysis*		Can be thought of as *risk analysis*

Both need internal policies!

Correction, Corrective Action, or Preventive Action?

- Checking all candy that a preschooler got from a Halloween party prior to giving it to him/her and throwing out all lollipops?
  - ✓ Preventive Action!
- Throwing out the lollipops after the toddler chocked on one?
  - ✓ Correction!
- The school having a policy in place after the incident to not allow lollipops at school.
  - ✓ Corrective Action!

Corrective Action Request Form

CAR Number:	**Date Initiated:**
PART A: PROBLEM IDENTIFICATION	
Corrective Action Requestor:	
CAR Assignee:	**QA Lead:**
Source: Complaint (Identify Person) Internal or external audit finding Failed proficiency test (lab only) Nonconformity QC Failure **Decision Matrix PAR or CAR?:** **Statement of the Requirement:** **Statement of the Evidence:**	
Description of Issue:	
Initial Correction(s) Taken *(List measures taken to temporarily mitigate the problem)*:	
Client and QA Contractor Notified of Problem? Yes No N/A	
Date Notified:	

Stop Work Required? No Yes	**Date of Stop Work:**	**Date Work Resumed:**
Requested Completion Date for Root Cause Investigation and Corrective Action Identification:		

Corrective Action Request Form

PART B: ROOT CAUSE INVESTIGATION	
Has the problem occurred before? No Yes If yes, how frequently? ___	
Root Cause Analysis Performed: Questioning and Brainstorming Observation Interviews Other ___	
Notes on Root Cause Analysis: *(Describe what has been done to get to the root cause. For example, include proximate and intermediate causes identified, dates of meetings held to discuss the issue, investigation performed, etc.)*:	
Root Cause(s): *(List the possible cause(s) and place an X by the one(s) you believe to be the root cause)*	___ ___ ___ ___ ___

Corrective Action Request Form

PART C: CORRECTIVE ACTION (CA)
Corrective Action(s):
(List the possible corrective action(s) and place an X by the one(s) to be implemented)
Will existing documents need to be changed to address this corrective action? No Yes (If Yes, describe changes)
I, the QA Lead or designee, have reviewed the CA and believe it is likely to resolve the problem and prevent recurrence.

Name:	**Signature:**

PART D: VERIFICATION OF CORRECTIVE ACTION

How long will the corrective action be monitored?	**Who will monitor the corrective action?**

Verification Notes (Describe what was monitored):
I have reviewed the corrective action and ensured its implementation and effectiveness.

Name:	**Signature:**

PART E: FOLLOW UP AUDIT

Follow Up Audit Required? No Yes	**Internal Auditor**

Did audit confirm effectiveness of the Corrective Action (see internal audit records for details)? **No Yes**
PART F: CLOSE OUT OF CAR
This CAR is completed as of this date ___
This CAR is OBE as of this date ___ because of the following ___
PART C: CORRECTIVE ACTION (CA)

Questions?

References

- "Root Cause Analysis and Corrective Actions" version 1.0; A2LA (2011)
- http://onquality.blogspot.com/2011/10/difference-between-qa-and-qc.html by Jimena María Calfa
- "Traceability" webinar; Signature Science, LLC.

Contact Information

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