

UBC Laboratory Quality Management June 2019

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Since we started our course, we have addressed a lot of topics

1. Definitions of Quality
2. Designing your Quality Manual
3. Organizational Charts
4. Setting Policies
5. Costs of Quality
6. Costs of Poor Quality
7. Non-financial Costs of Poor Quality
8. Costs of Waste
9. Managing Risk
10. Failure Mode Effects Analysis (FMEA)
11. Severity and Occurrence Analysis
12. Understanding Error
13. The Essential 8 Quality Monitoring Tools
14. Creating an OFI List
15. Documenting your Corrective Actions
16. Recording and Reporting Complaints
17. Formal and Informal Internal Audit
18. Developing and Monitoring Quality Indicators

And you have done a lot of Assignments

- 1. Failure Mode Effects Analysis (FMEA)**
- 2. Severity and Occurrence Analysis**
- 3. Creating an OFI List**
- 4. Documenting your Corrective Actions**
- 5. Recording and Reporting Complaints**
- 6. Formal and Informal Internal Audit**
- 7. Developing and Monitoring Quality Indicators**

This Week we are going to revisit somethings and do some new things, but they are all on the theme of making your laboratory better.

- Setting a Plan
- Establishing Goals and Objectives / Mission and Vision
- Creating and Maintaining an Organizational Chart.
- Planning your Management Report.

June 17-21 2019

- The Week's Agenda
 - Creating a Plan
 - Establishing Goals and Objectives / Mission and Vision
 - Creating and Maintaining an Organizational Chart.
 - Planning your Management Report.
 - Review and Quiz

Day 1: Create the Plan: Work to the Plan

For the last 80 years,
Quality Improvement through Quality Management
has be based on
ONE SINGLE PRINCIPLE

**MAKE THE PLAN
WORK TO THE PLAN**

W. Edwards Deming



Walter Shewhart



ASK THIS QUESTION...

*What Can We Do To Make
My Laboratory Better?*

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PICK YOUR TOPIC

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Will we NEED to make CHANGES?
Do we Need More Information?

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**GATHER
INFORMATION**

Costs? Staff? Customers?
Time? Organization?
Steps to Take

ASK THIS QUESTION...

What Can We Do To Make My Laboratory Better?

Have a Party!!

MONITOR FOR
CONTINUED
SUCCESS

CHECK THE
RESULTS

DO THE PLAN

PICK YOUR TOPIC

Will we NEED to make CHANGES?
Do we Need More Information?

Did My Mini Trial Work?
Make Adjustments
Another Mini Trial

or...

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**Give it a Try
(mini trial)**

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MONITOR FOR CONTINUED SUCCESS

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ASK THIS QUESTION AGAIN...

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In QUALITY

Every Action Has A Structure

Ask the Question...

Gather Information

Create a Plan

Try a Trial Run

Learn from the Trial Run

Make the Adjustments

Run the Plan

Check the Results and Monitor for Success

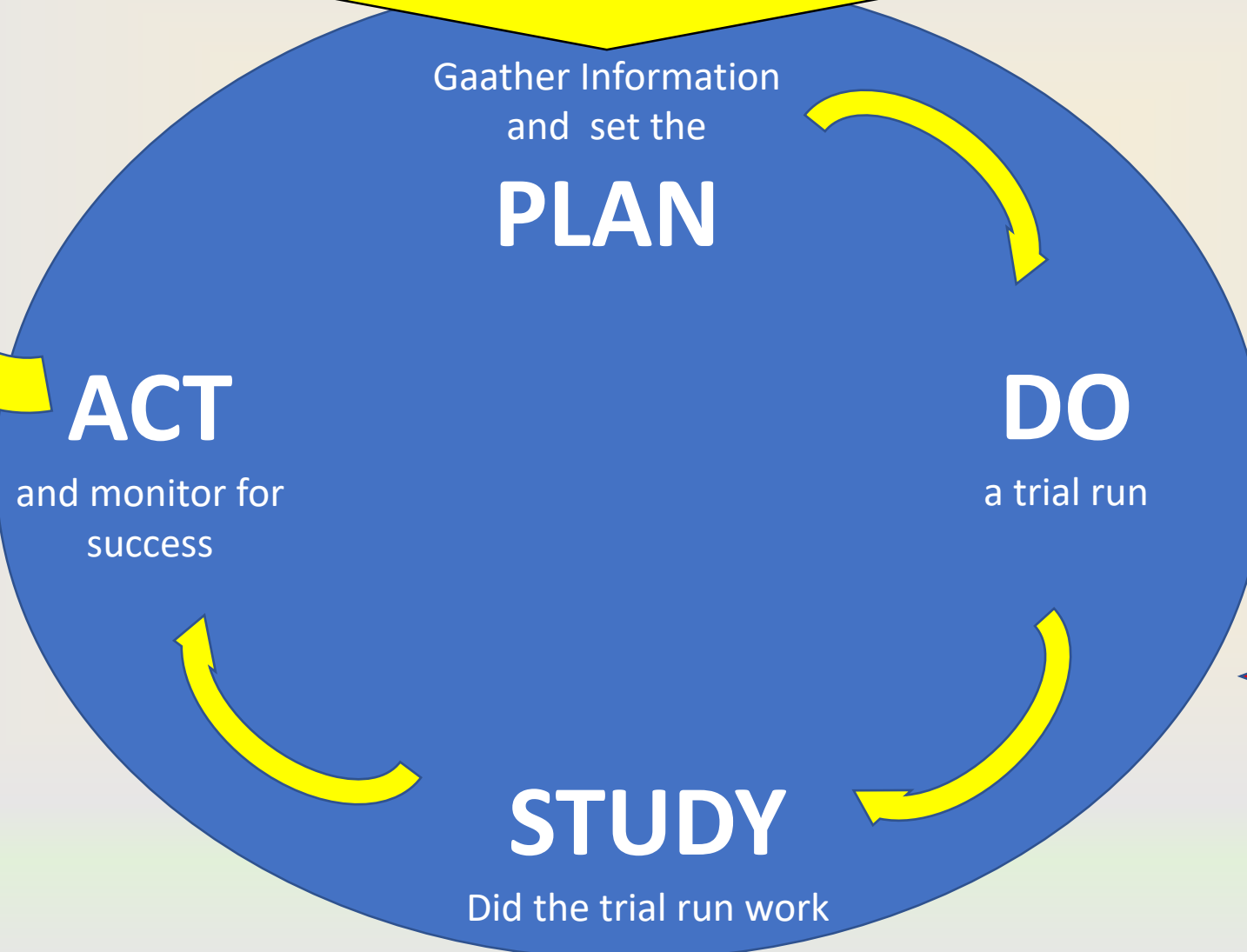
REPEAT

REPEAT

REPEAT

ASK THE QUESTION...

What Can We Do to Make
My Laboratory Better?



A NEW and IMPORTANT COMPONENT IN THE PLANNING PROCESS...

ISO 9001:2015

WHEN CREATING A PLAN YOU MUST CONSIDER...

- **How will I benefit from my new plan?**
- **What are the risks associated with my new plan?**
 - **Will my customers benefit from my new plan?**
- **Are there risks to my customers from my new plan?**

Today's Assignment...

- Scenario
 - Your laboratory has is interested in making changes that will make your laboratory better.
- Your Question is:
 - What specific process or procedure can you implement that will make an improvement in your current laboratory processes.
- Following the PDSA cycle steps, create and Present a PLAN to introduce a new process or procedure .
- Include the possible benefits and risks to you and your customers associated with the PLAN/

Day 2: In My Travels I Get to See Two Distinct Types of Laboratories

Laboratories Going Forward

- Expanding Test Menu
- New Projects
- Staff involvement
- Increasing workflow
- Additional Plans in the works

Laboratories Stalled or Retreating

- No Changes to the Test Menu
- No New Projects on the horizon
- Little Staff Engagement
- Workflow gradually dropping
- No Plans for change being discussed

Progress Does Not Just Happen...
Progress is the Product of Structure and work.

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PLANNING FOR THE LONGER TERM...

- ✓ Setting the Laboratory Goals
- ✓ Setting the Laboratory Objectives

- ✓ Creating the laboratory Mission
- ✓ Creating the Laboratory Vision



Setting Goals and Objectives

Goals:

- Results to be achieved now, or soon.
- What do I want to accomplish by the end of this season?

Objective

- My *ultimate* goal;
- What do I want to accomplish when my plan is in place and complete?
- What is my END GOAL?

About Goals and Objectives...

If you don't set and reach your
GOALS, step after step,
You will NEVER
Reach your OBJECTIVE



About Goals and Objectives...

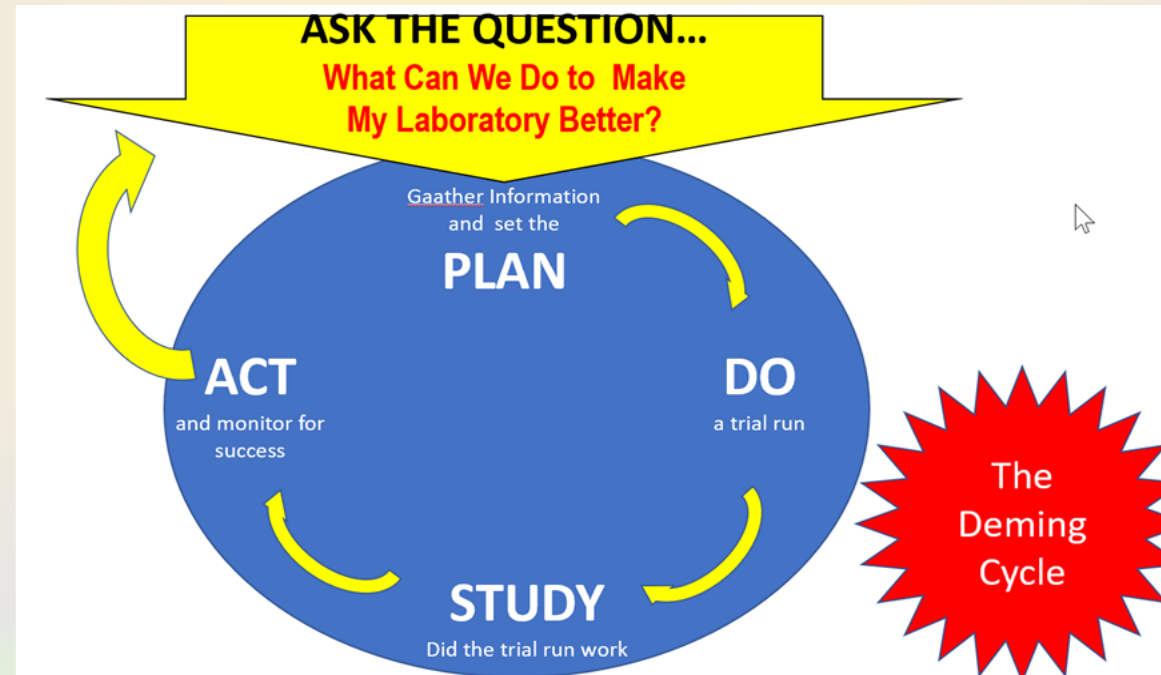
How Can I Increase My Opportunities
To Reach My Goals?

How Can I Increase My Potential
To Reach My Objective?

About Goals and Objectives...

How Can I Increase My Opportunities
To Reach My Goals?

How Can I Increase My Potential
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Ask the Question – Create a Plan – Act on the Plan

Missions and Visions

ISO Defines* Mission and Vision as:

Mission

Organization's purpose for existing as expressed by top management

Vision

Aspiration of what an organization would like to become as expressed by top management

* **ISO9000:2015** : Quality management systems — Fundamentals and vocabulary

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* **ISO9000:2015** : Quality management systems — Fundamentals and vocabulary

What is a Laboratory's Purpose for Existing?

- To test patient samples in order to safely generate timely accurate clinically useful information to assist physicians and patients make health related decisions.
- To hire knowledgeable and trained people in order to safely and efficiently collect samples, accession information, perform tests, create and information that can be reported to the correct persons.
- To provide reference or support to assist other laboratories so they can provide the best laboratory services they are capable of providing.

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* **ISO9000:2015** : Quality management systems — Fundamentals and vocabulary

What might a laboratory ASPIRE to become in the future?

- Aspire to become known as the best laboratory in Cambodia to provide the most clinically useful accurate and timely information.
- Aspire to become the best employer in Cambodia for trained and knowledgeable laboratory scientists and technologists
- Aspire to become the best reference centre in Cambodia for certain specific medical laboratory tests
- Aspire to become the best site for laboratory scientists and technologists to gain knowledge.

What's the difference between having a Mission and living the Mission?

HAVING A MISSION

Write the Mission

Put the Mission in a Pretty frame

Hang the Mission on the wall

Point out the Mission to Visitors
and Dignitaries

What's the difference between having a Mission and living the Mission?

LIVING THE MISSION

Write the Mission

Check the Mission Regularly

AM I WORKING TO MY PLAN?

Am I meeting my Goals?

Am I working to achieve the Progress that I need?

A Word of Caution....

Organizations Sometimes Get Overly Enthusiastic

Setting Goals And Objectives
That Are Unrealistic

Setting Missions And Visions
That Are Unachievable

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In The Long Run
This Is **Not** Helpful

Setting Objectives And Missions
Alongside Your Organization.

Today's Assignment...

Share with us
your Laboratory's
MISSION and **VISION** Statement

Tell us **ONE THING** you do
to ensure your laboratory
meets your **MISSION** goals?

Day 3: Creating and Maintaining an Organizational Chart.

- International Organization for Standardization uses a language that can be difficult to understand.

How do you interpret this?

ISO9001:2015

Organizational roles, responsibilities and authorities

- Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization.

ISO15189:2012

Quality Manual

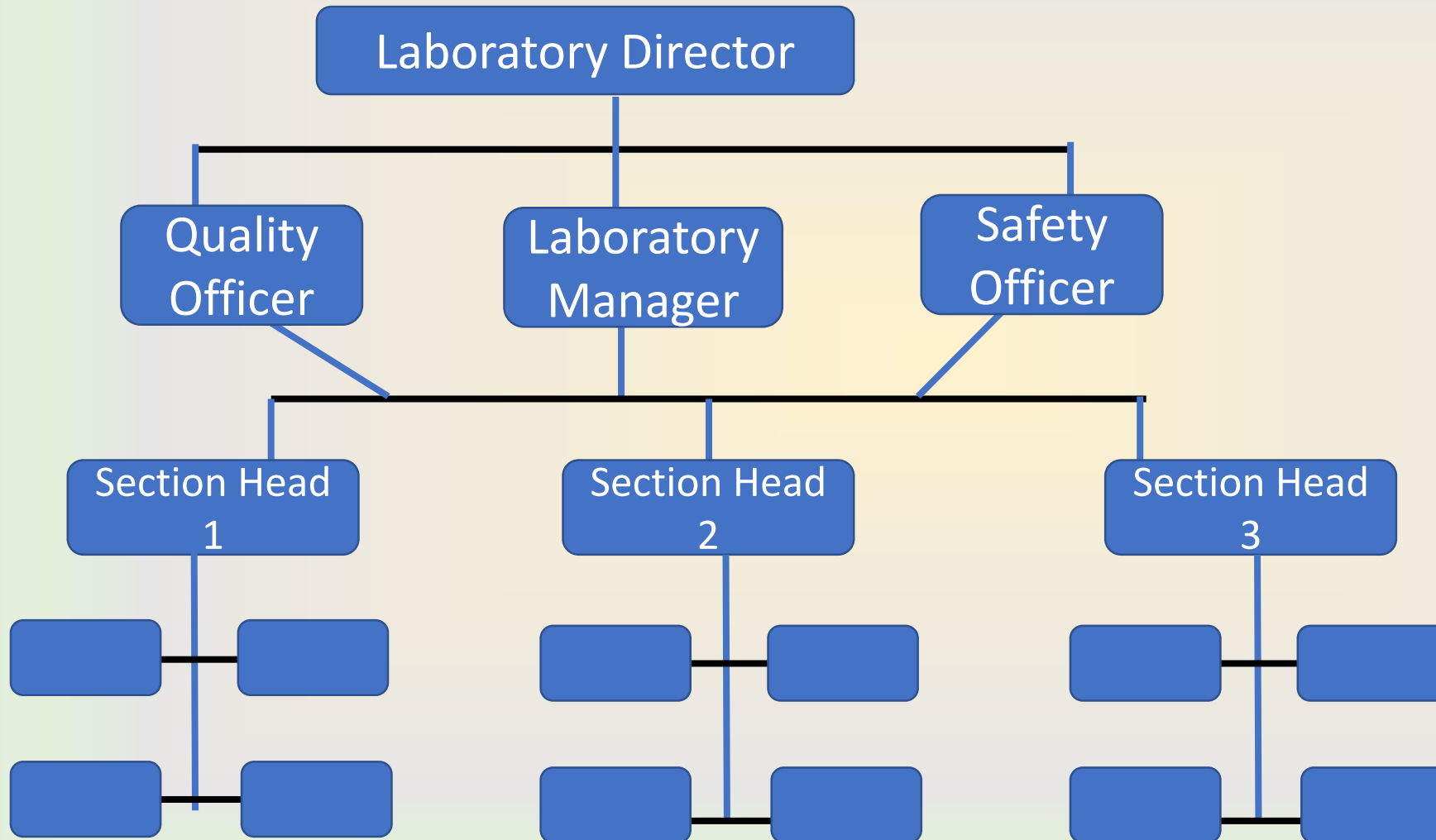
The laboratory shall establish and maintain a quality manual that includes:

- c) a presentation of the organization and management structure of the laboratory and its place in any parent

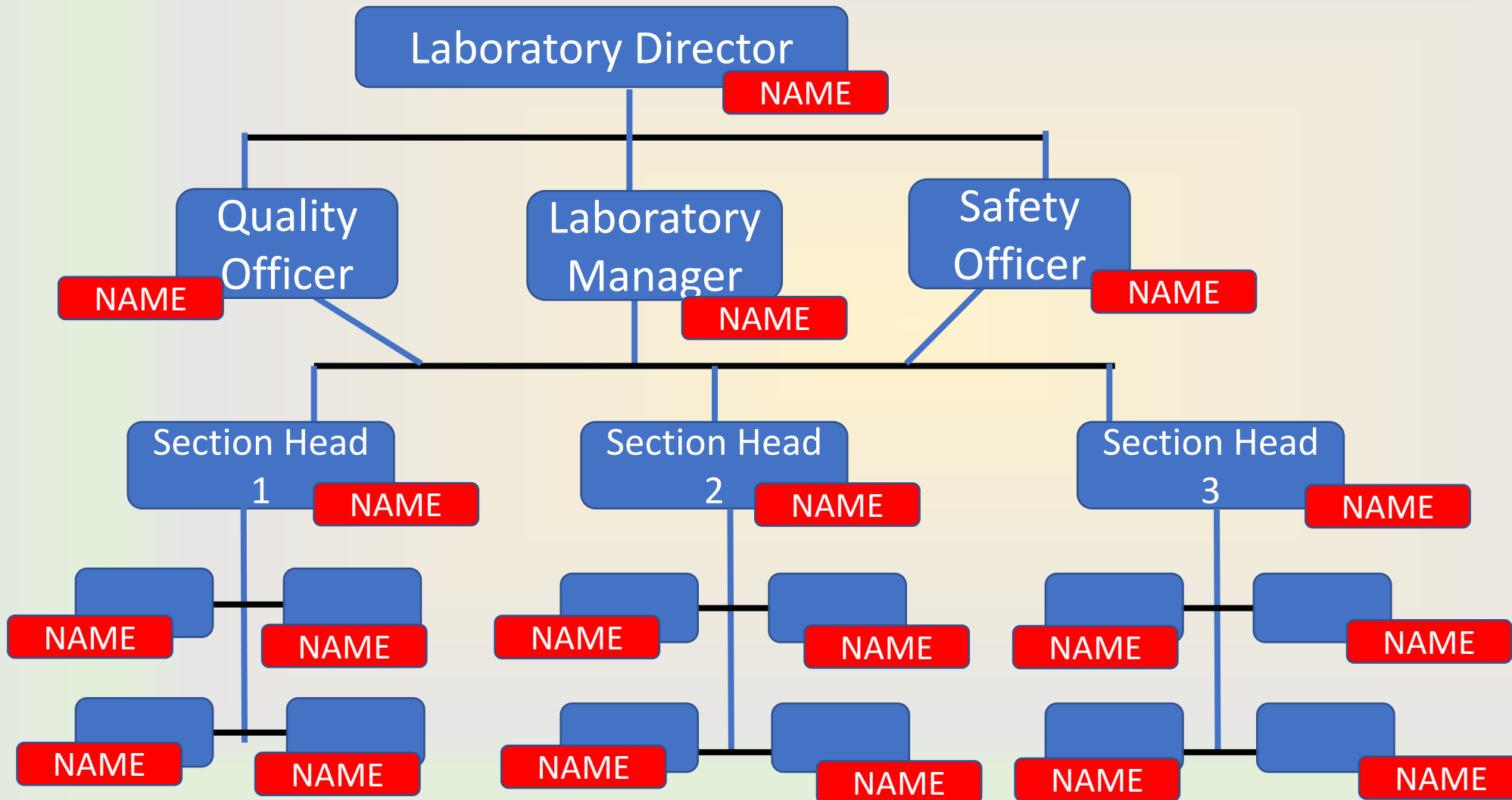
The two views of Organizational Mapping

- Structure Mapping
 - Where do I fit within the organization's structure
 - To whom do I report?
 - Are there people who report to me?
- Project Mapping
 - Where do I fit within the organization's function
 - Whose work come before mine in this project?
 - Whose work follows mine in this project?

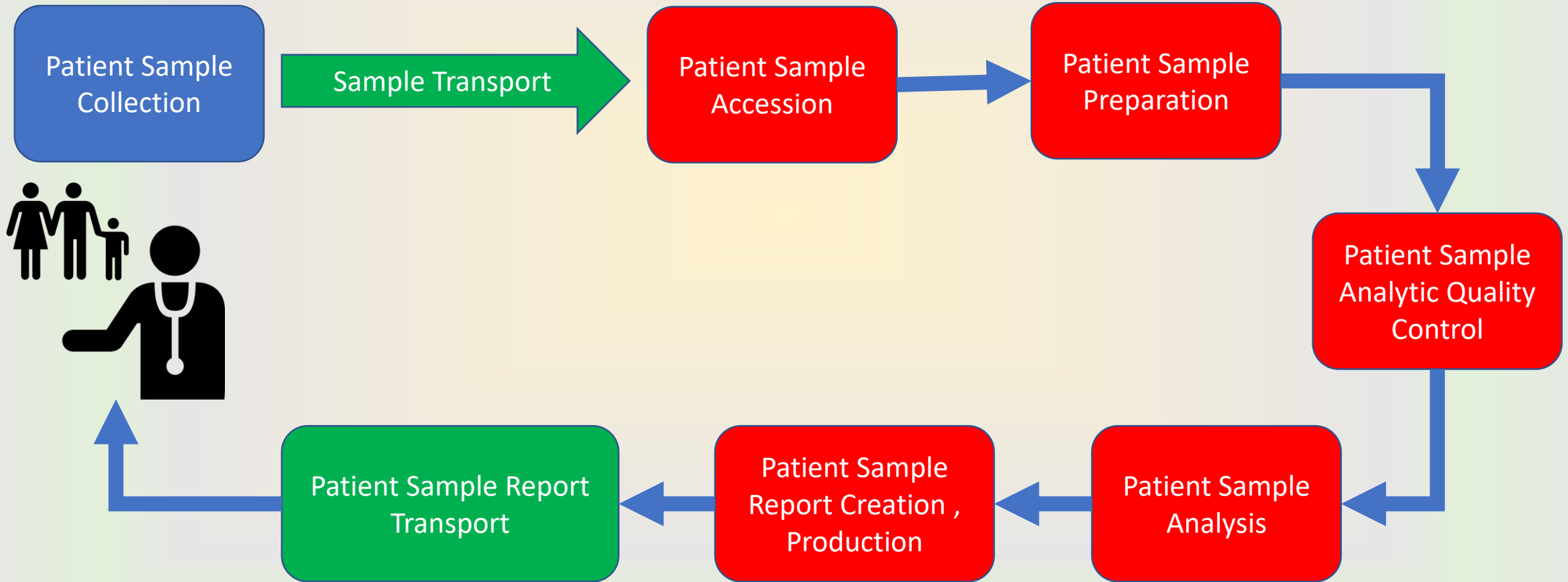
Organizational Structure Map



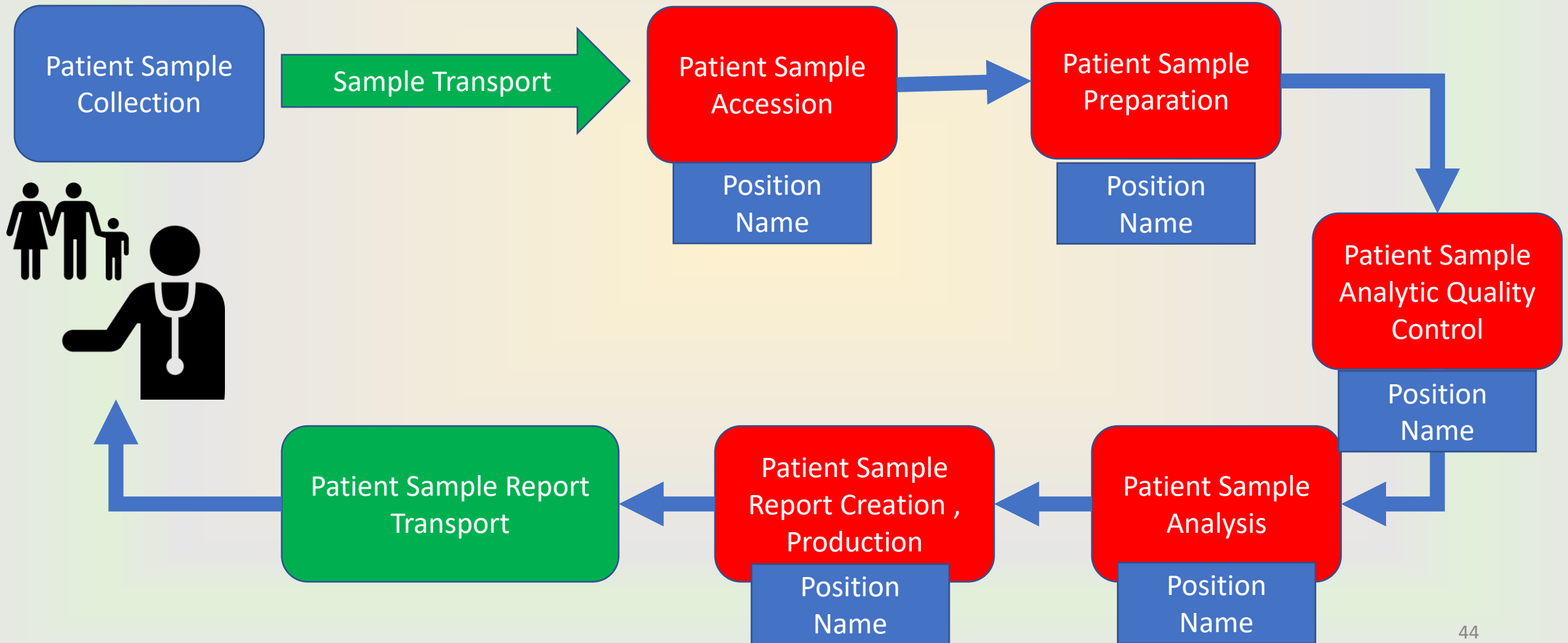
Organizational Structure Map



Organizational Function Map



Organizational Function Map



Today's Assignment...

For EACH Laboratory

Create

A Function Map

and

A Structure Map

that depicts the structure in
YOUR Laboratory

Day 4: Management Reporting

There is an important task that
all Quality oriented organizations
must complete...

Management Reporting

There is an important task that all Quality oriented organizations must complete...

**Completion of a
Management Review
Report**

Why do a Management Review Report

The Management Review Report
is NOT just
an “accreditation exercise”

***It is an essential, indeed critical
measure of an organization’s
Commitment
to their Quality and their Customers.***

Quality Management Review

Review of the laboratory's

Policies and Procedures
Changes: Staffing
Changes: Equipment and Environment.
Changes: Risk
Errors and Opportunities for Improvement
Accreditation and Proficiency Testing
Quality Indicators
Corrective Actions
Preventive Actions
Safety
Customer Satisfaction
Meeting Goals and Objectives
Planning Goals and Objectives

Quality Management Review

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What does ISO 15189:2012 expect?

- a) suitability of procedures and sample requirements
- b) assessment of user feedback;
- c) staff suggestions;
- d) internal audits;
- e) risk management;
- f) use of quality indicators;
- g) reviews by external organizations;
- h) results of participation in (PT/EQA);
- i) monitoring and resolution of complaints;
- j) performance of suppliers;
- k) identification and control of nonconformities;
- l) results of continual improvement including current status of corrective actions and preventive actions;
- m) follow-up actions from previous management reviews;
- n) changes in the volume and scope of work, personnel, and premises that could affect the quality management system;
- o) recommendations for improvement, including technical requirements.

Without a Management Review...

*Everything gets forgotten...
All the mistakes recur...
You never get better...
Your never improve...
Your customers lose interest...*

You always get

WORSE

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***What a waste of
Time – Money - Effort***

We have covered EVERYTHING you need...

- **Review your Policy Manual:**
 - Are you doing what you said you were going to do?
- **Review your OFI list:**
 - Are you repeating the same errors?
 - Did your corrective actions make a difference?
- **Review your Preventive actions, especially around SAFETY**
 - Have you gotten rid of safety hazards?
- **Did your Quality Indicators indicate you are in the right direction?**
 - Did you check on customer satisfaction?
 - Did you do acceptable on your PT/EQA?
 - Does your Quality Control work as expected?
 - Did you address the problems that result in frequent or severe errors?
 - Did your internal audits indicate that you are meeting your requirements?
- **Review you Goals and Objectives?**
 - Did you meet the goals you wanted to meet?

A simple strategy that will ALWAYS lead to success...



Growing Your Management Review



Commit to get started NOW

Commit to track and report one
or two items this year

Next year double your reports

After that do it ALL

Week Summary

- This week we covered several important topics
 - Creating a Plan
 - Consideration of Risks in Planning and Development
 - Setting Goals and Objectives
 - Developing both a Mission and a Vision Statement
 - Creating Organizational Structure and Function Maps.
 - Management Review
- With these items addressed we have covered a full scope of issues important and relevant to Laboratory Quality Management

Since we started our course, we have addressed a lot of topics

1. Definitions of Quality
2. Designing your Quality Manual
3. Organizational Charts
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5. Costs of Quality
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19. Creating a Plan
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21. Setting Goals and Objectives
22. Developing both a Mission and a Vision Statement
23. Creating Organizational Structure and Function Maps.
24. Management Review

There are multiple approaches to Quality...

What we have NOT spent time on...

- Pre-Examination Procedures
- Laboratory Examination (Analytic) Phase
- Quality Control
- Reporting Procedures
- Accreditation
- EQA

What we have spent time on...

- Policy and Procedure
- Customer service (complaints)
- Recognizing your staff
- Understanding Error
- Costs and Waste
- Addressing Risk
- Developing a Plan
- Setting Goals and Objectives
- Management Reporting.

There are multiple approaches to Quality...

What we have NOT spent time on...

- Pre-Examination Procedures
- Laboratory Examination Phase
- Quality Control
- Reporting
- Accreditation
- EQA

What we have spent time

- Complaints)
- Our staff
- Standing Error
- Costs and Waste
- Addressing Risk
- Developing a Plan
- Setting Goals and Objectives
- Management Reporting.

Laboratory Quality is
LARGER in scope and relevance than
PERFORMING AND REPORTING TESTS