Quality begins with 'Me'

Advancing Excellence

College of American Pathologists Accredited

ANVISA

NABL Accredited

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Quality means doing it right when no one is looking.

-Henry Ford

According to Phil Crosby*, Quality is . . .

An attitude:

- Zero Defects
- Continuous Improvement

A measurement:

- Price of Conformance,
- Price of Non-conformance (defects)

*Crosby's name is best known in relation to the concept of **Do It Right First Time** and **Zero Defects**.

Need for maintaining Quality

- Quality systems in large scale laboratories and healthcare organization are evolving. There is tremendous pressure on laboratories to deliver quality reports within the defined economical framework and to fulfill the criteria of accreditation.

- This can be accomplished by maintaining strict quality control program which can be a painful process to start with but with good end result.

Need to transform an Organization

From	To
Motivation through fear and loyalty	Motivation through shared vision
Attitude: "It's their problem"	Ownership of every problem affecting the customer
Attitude: "the way we've always done it"	Continuous improvement
Decisions based on assumptions/ judgment calls	Decisions based on data and facts
Everything begins and ends with management	Everything begins and ends with customers
Crisis management and recovery	Doing it right the first time
Choosing participative OR scientific management	Choosing scientific AND participative management

Total Quality Is…

- Meeting Our Customer's Requirements
- Doing Things Right the First Time- Freedom from Failure (Defects)
- Consistency (Reduction in Variation)
- Continuous Improvement
- Quality in Everything We Do

Accreditation

"Procedure by which an authoritative body gives formal recognition that a body (laboratory) or person (signatory) is competent to carry out specific tasks (scope)."

- Criteria - ISO/IEC 15189,17025
- Assures that the procedures and test results are technically valid
- Recognizes technical competence of laboratory staff
- Endorses that laboratory operates management system effectively

Certification

"Procedure by which a third-party (certification body) gives a written assurance that a product, process or service (of an organisation) conforms to specified requirements."

- Specified requirements - ISO 9001
- Assures that organisation has in place an effective quality or environmental management system
- Does not confer technical or analytical credibility of the test result

Typical Accreditation Body

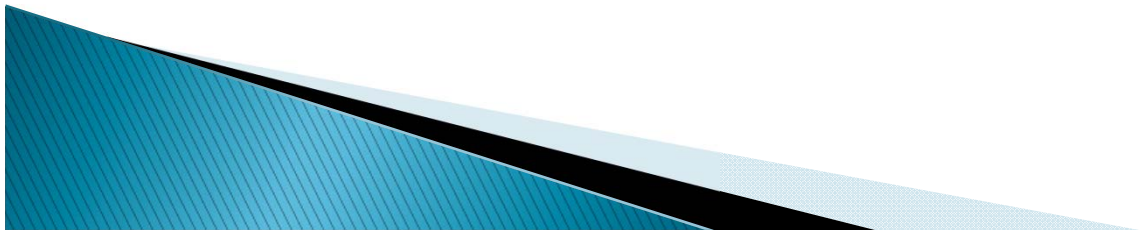
- National accreditation body is a statutory body
- User and/or government funded, “not for profit” organisation
- Third-party
- Internationally recognized
- Accreditation granted per test/ field of service
- In absence of NAB, labs need to seek accreditation internationally

CAP Accreditation "Gold Standard"

- Established in 1961.
- In 1995, it received approval as an accrediting organization under CLIA '88 by the Centers for Medicare and Medicaid Services (CMS).
- Provides a solid foundation for ensuring excellence in patient safety and compliance
- Top rated 100 US Hospitals with laboratories - 97% CAP accredited
- Over 7,000 laboratories accredited worldwide in 45 countries
- Laboratories in 96 countries subscribe to CAP PT
- Field teams - Asia, Middle East, South America, India, Europe, Mexico etc.

International Laboratory Accreditation Cooperation (ILAC)

- International umbrella organisation which covers national & regional accreditation organisations
- To develop the principles and the practice of laboratory accreditation
- To harmonize procedures and criteria for accreditation
- To assist in the development of new programmes
- To facilitate mutual recognition of members' programme
- To reduce technical barriers in trade
- To improve International acceptability of test results

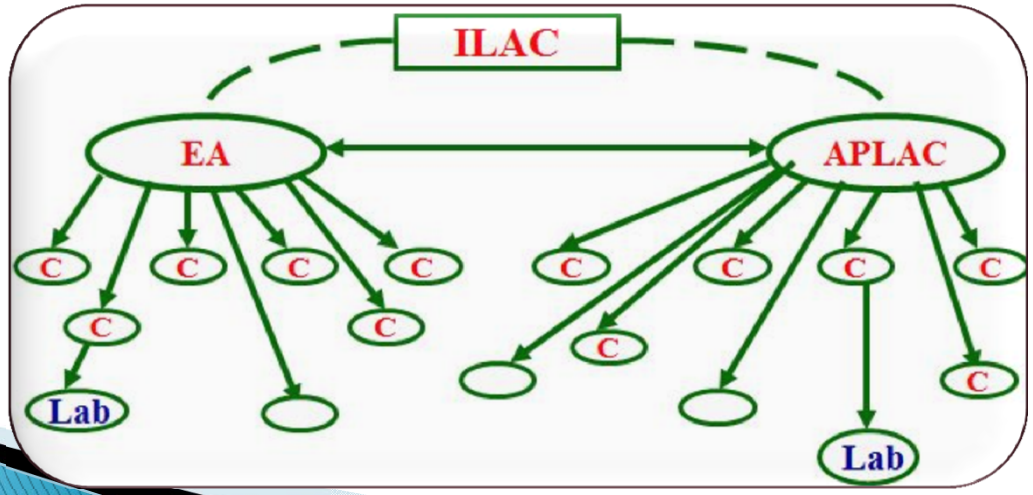


Accreditation Organizations

International – ILAC

Regional – EA ; IAAC; APLAC; SADCA

National – BELAC; SAS; A2LA; NABL…….



International Standards applicable to Laboratories

- **ISO/IEC 17000:** Conformity assessment - Vocabulary and general principles
- **ISO/IEC 17025:** General Requirements for the Competence of Testing & Calibration Laboratories
- **ISO 15189:** Medical Laboratories - Particular Requirements for Quality and Competence

International Standards applicable to Laboratories

- **ISO/IEC Guide 43:** Proficiency Testing by inter laboratory comparisons –Part I & Part II
- **ISO 9000:** Quality Management Systems- fundamentals & vocabulary
- **ISO/IEC 17011:** General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies

(http://www.iso.org)

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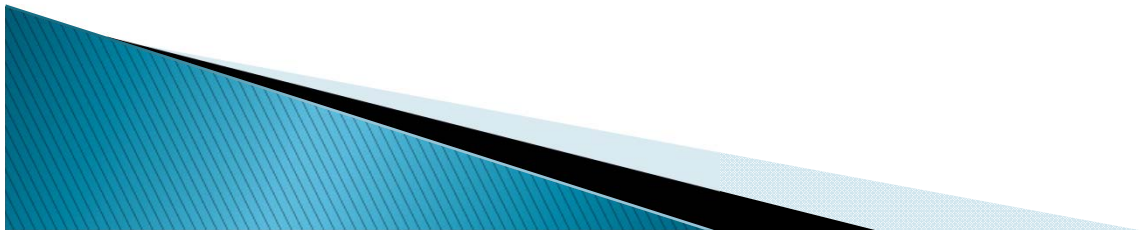
Why Laboratory Accreditation?

- Growing public interest in the quality of health care.
- Demand for accountability because of high cost.
- Increasing public expectations from health care providers.
- Privatization of health insurance and advent of managed health care.
- Business imperatives: CRO, Clinical Trial patients, International
- All expect results that are accurate, obtained in an efficient, effective manner, within a suitable timeframe & at acceptable cost.

Accreditation ….optimal approach to assuring quality in medical testing !



Why Laboratory Accreditation?

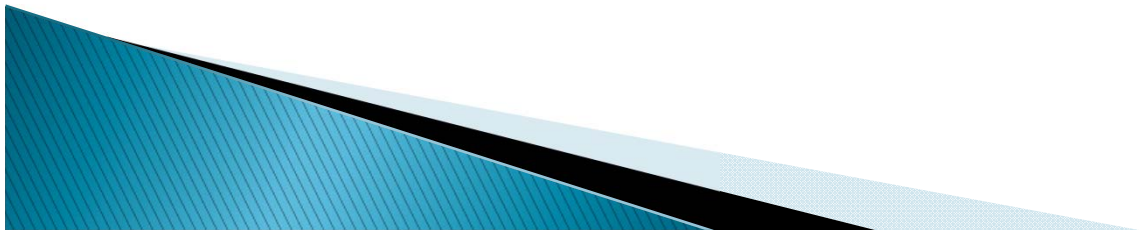
Benefits to the Laboratory

- Makes the lab conscious of **QUALITY**.
- Increase client & decision makers confidence.
- Build staff morale.
- Improves lab performance.
- Saves money by getting it right the first time
- Improves laboratory competitiveness.
- Ensures good support in event of legal challenge.
- National & International recognition.
- Global Equivalence.
- Improves business prospects.

Quality Costs !

Quality includes….

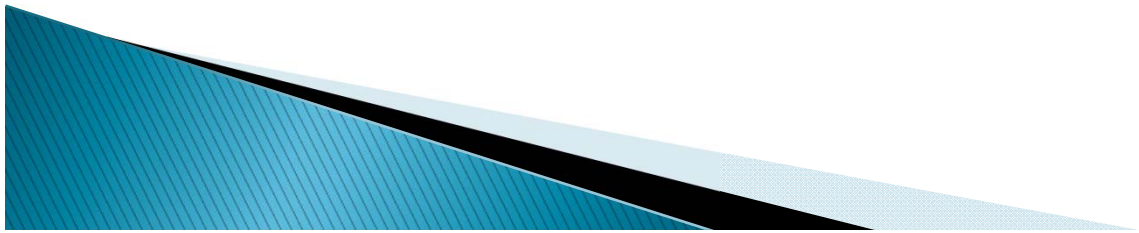
- ✓ Quality Assurance
- ✓ Quality Control
- ✓ Quality Improvement
- ✓ Quality Indicators
- ✓ Quality Management System



Quality Assurance

"part of quality management focused on providing confidence that quality requirements will be fulfilled"

ISO 9000:2000

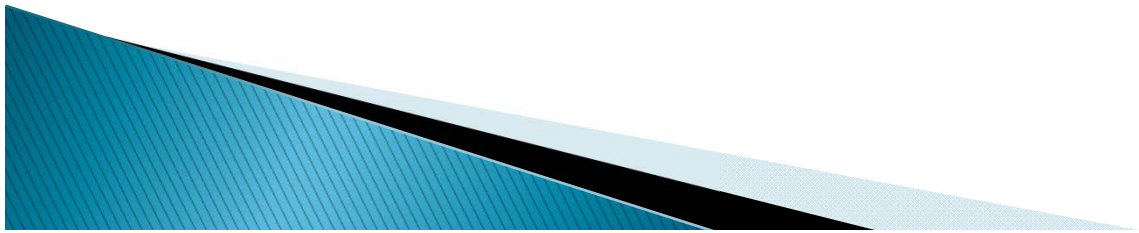


Quality Control

Part of quality management focused on fulfilling quality requirements ISO 9000:2000

Operational activities aimed at monitoring the quality of products and services throughout the testing process, and at identifying unsatisfactory performance.

- IQC – set of procedures for continuously assessing laboratory work and the emergent results; should actually control release of results.
- Proficiency Testing- EQAS



Quality Improvement

- Part of quality management focused on increasing the ability to fulfill quality requirements

  ISO 9000:2000

- Quality improvement is like a race without a finish line

- ISO/IEC 17025 and Accreditation are just the starting points

- All labs should have quality improvement plans which would enable in achieving excellence in all 3 phases: Pre-analytical, Analytical & Post-analytical

Quality Indicators

Measured information that

- Indicates the performance of a process
- determines quality of services
- highlights potential quality concerns
- identifies areas that need further study and investigation, and
- track changes over time

Identifiers of Good Indicators

Measurable	*Can you count it, time it, record it?*
Achievable	*Can you actually capture it?*
Interpretable	*When you've got it, what does it mean?*
Actionable	*Can you do something about it?*
Timed	*Does your set cover both the short and long term?*
Engaging	*Does your set involve all laboratory personnel?*
Balanced	*Does your set cover the full cycle of events?*

Clinical Pathology Quality Management Key Indi

SERVICE MONITOR	Thres-hold	April 2008	March 2008	February 2008	January 2008	December 2007	Nov 2007
Blood culture contamination	3%	2.9%	2.7%	2.9%	2.6%	2.8%	3.2%
	5%						
CAP Survey exception reports	1%	4/673	4/467	0/223	1/126	15/781	0/570
	2%						
TAT Creatinine, stat, Day	45 min	47/83	49/85	48/84	49/84	54/85	50/86
	60 min						
TAT HGB, stat, Day	60 min	39/72	36/72	40/76	39/79	42/79	39/76
	75 min						
TAT Bacterial Vaginosis Gram, ED	60 min	50/90	44/89	43/73	40/78	39/75	42/86
	90 min						
TAT CSF gram stain, ED	60 min	56/198	60/182	50/193	47/207	44/191	48/184
	90 min						
Result corrections all Pathology areas	150	126	113	177	84	113	313
	175						
Specimens rejected from Pathology collection locations	5	6	1	4	22	0	6
	10						
Specimens rejected (clotted) from non-Pathology collections (gen lab)	50	201	213	182	205	188	209
	100						
Specimens rejected (QNS) from non-Pathology collections (gen lab)	50	113	139	104	134	118	125
	100						
Mislabeled specimens w/o blood bank	10	18	26	23	21	15	32
	20						
Mislabeled specimens blood bank	0	2	3	4	2	3	1
Service delivery complaints (valid)	5	6	11	5	7	10	4
	10						

Quality Management System

⇒ ISO 9000:2000

Management system to direct and control an organization with regard to Quality

The Quality Management System comprises all the manuals, procedures, reference standards, other documents and records that:

- Identify the customers requirements
- Control operations and activities
- Record all relevant information
- Deliver the product or service to customer requirements

The Economic value of a report

Lab XYZ
The Cheapest Thyroid Panel

What's the reasonable cost for Lab report ???

- The Cheapest test report with "No clinical value"
  - Can be very expensive to the patient & Clinician

- Relatively expensive report with "Good clinical value"
  - Can Save a lot of cost

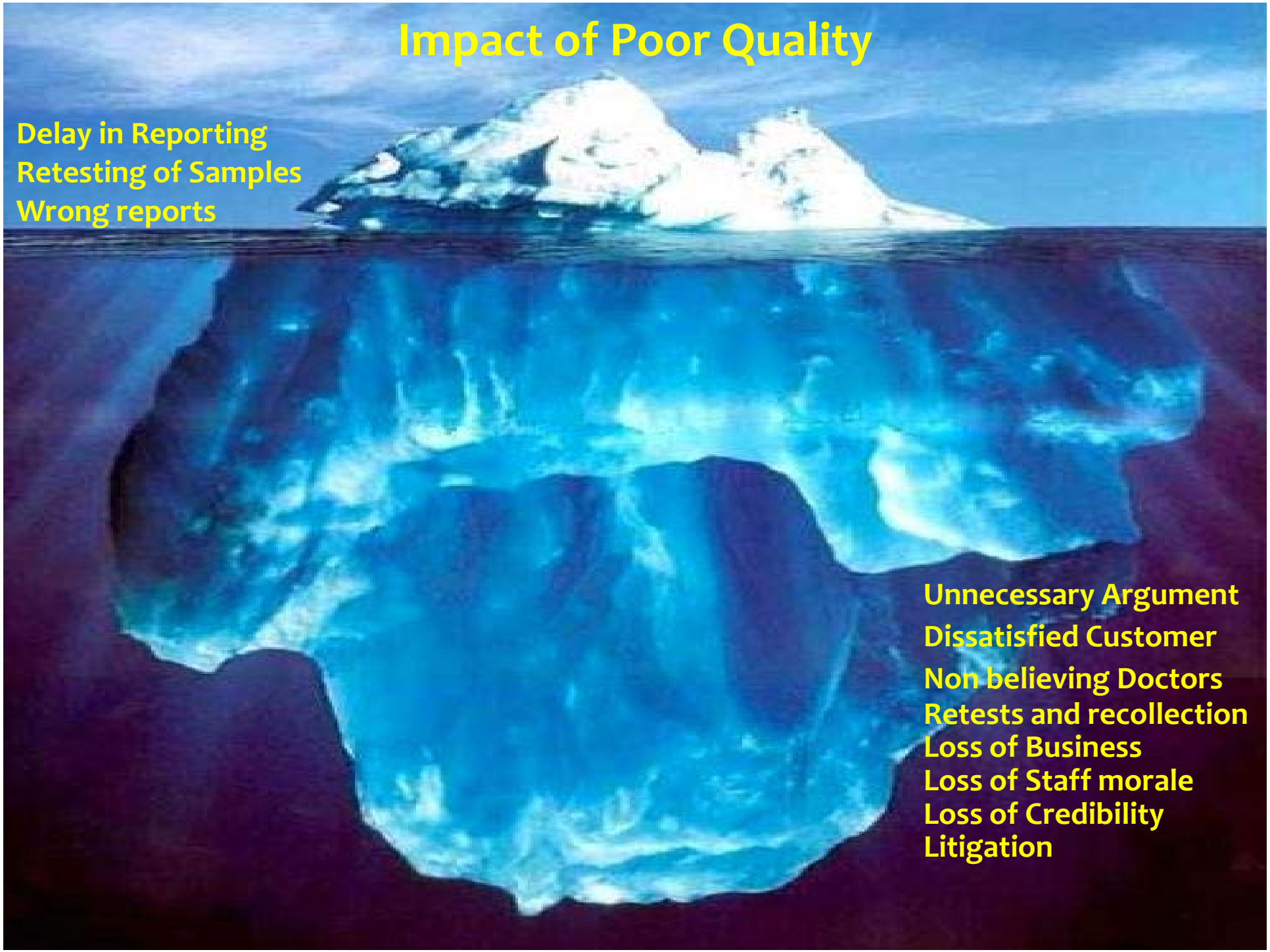
Lab ABC
Thyroid Panel at higher cost from an accredited lab known for quality reporting

The Economic value of a report

Can be measured based on:

- Accuracy & dependability of results
- Clinical value
- Ease of interpretation
- Reported at the right time

Impact of Poor Quality



Quality costs are offset by Quality payoffs.

- Enhanced reputation.
- Loyal clientele.
- Reduced costs of systems failure

eg. machine downtime, retesting for complaints, poor staff performance.

- **More focus on quality will make lab performance more effective and result in decrease in financial wastage**

Key Points for achieving Quality

1. Align with top management's requirements & get their commitment

- Reduce Costs
- Image/Media
- Regulations
- Customer Base
- Staff Management
- Go Green

Management Calculations

Management Awareness towards QMS

2. Communicate your intent to all staff

3. Create Quality Policy

- Management commitment

- Organization Mission and Objectives

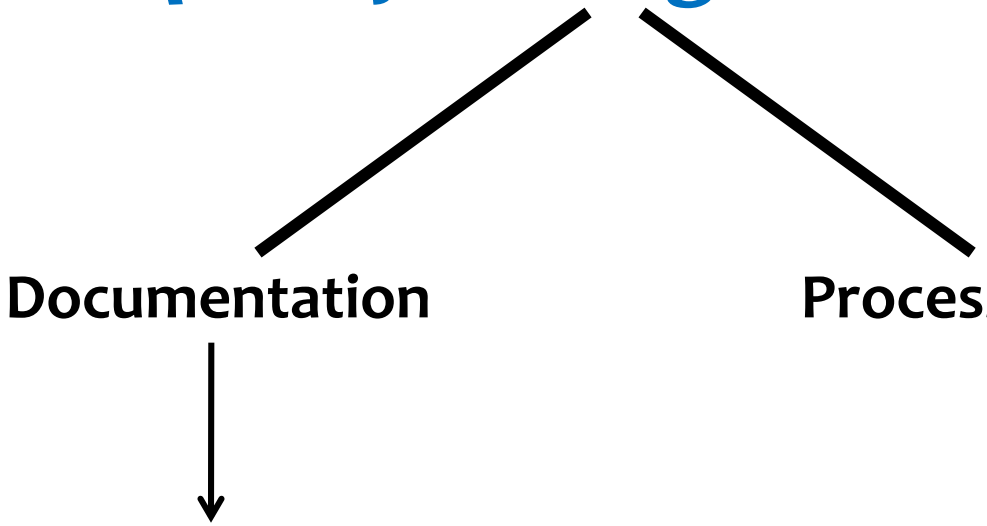
- Scope of services

- How shall you maintain these quality testing

4. Appoint a responsible individual as “Quality Manager”

5. Prepare an implementation plan

6. Quality Management System



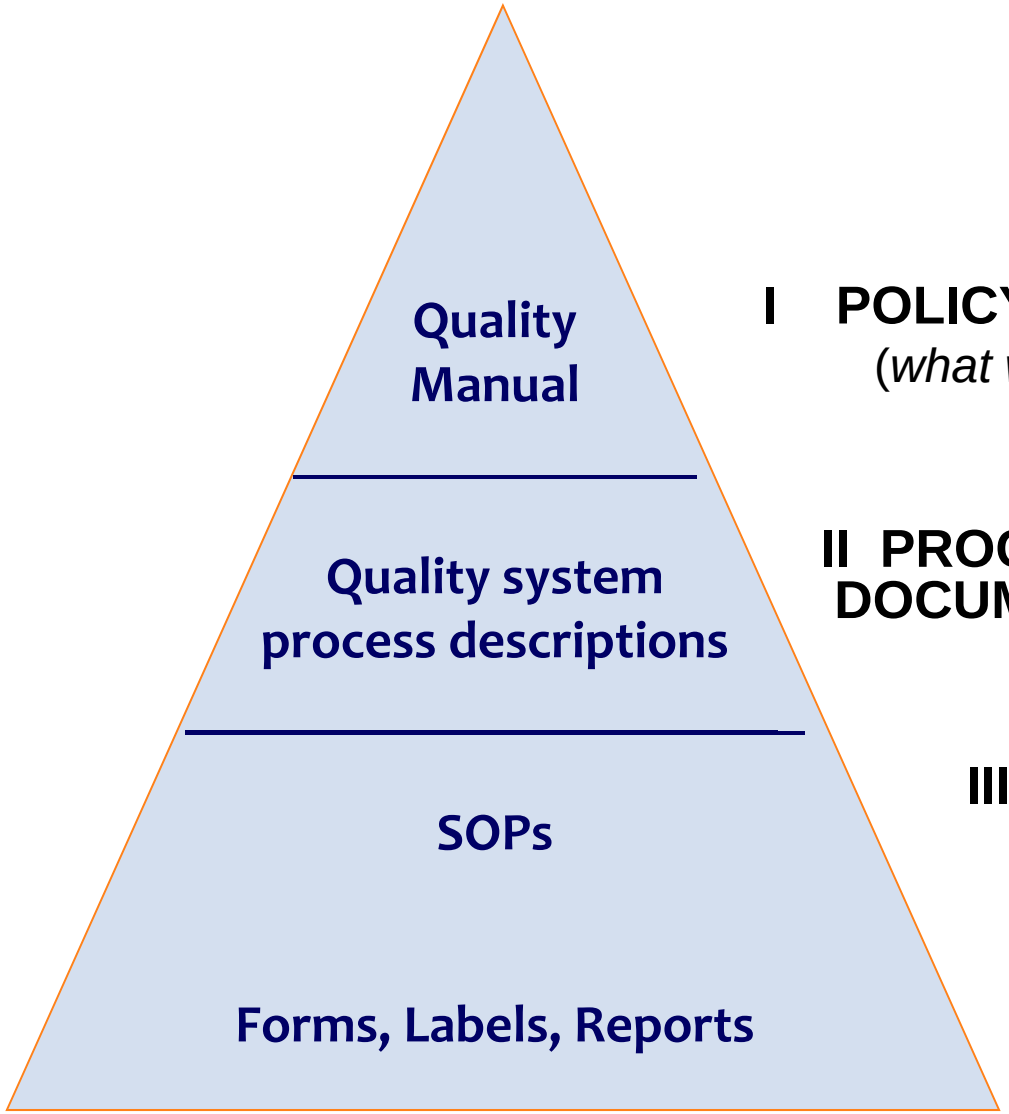
Documentation

A document is a file that contains information that the user can view

Process Control

Implementing all the processes and procedures as we want to do to get the desired outcome.

Quality System Documentation Hierarchy



I POLICY DOCUMENTS
(*what will be done)*

II PROCESS DESCRIPTION DOCUMENTS *(how it happens)*

III PROCEDURE DOCUMENTS
(*how to do it)*

IV RECORDS *(what was done)*

7. Internal Audits

- Recommend conducting once per year
- Planned by the quality manager
- Personnel should not audit their own work
- Reviewed by management
- Corrective or preventive actions identified, documented, and measured

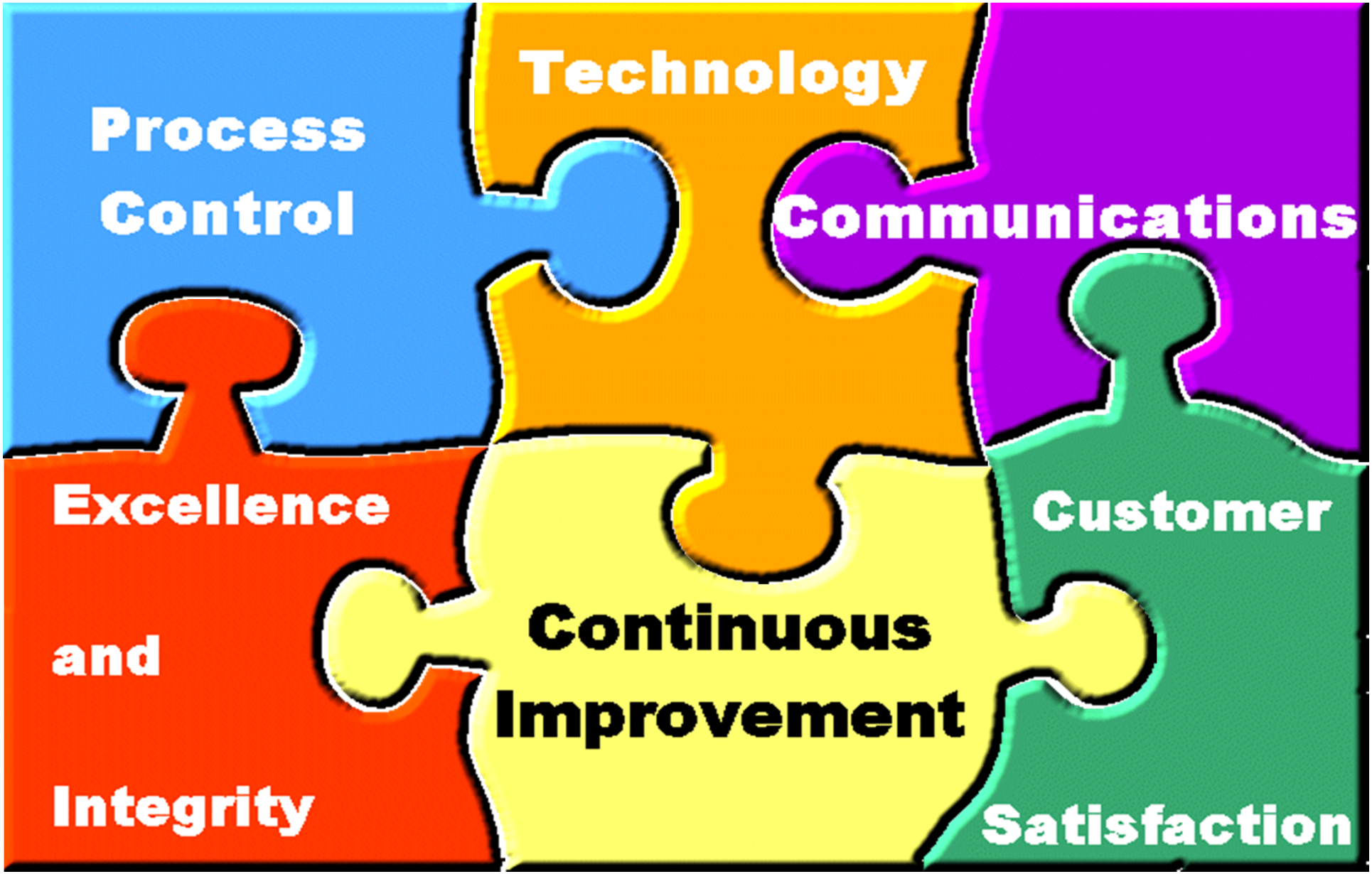
8. Management Review

- QMS documentation be reviewed and signed periodically by laboratory management.
- Review: reports from managerial/supervisory personnel, internal audits, external assessments, non-conformity reports, indicator analyses, feedback, etc.
- Action plans for improvement are appropriately identified, developed, implemented and monitored.

Think GLOBAL about efficiency through automation and computerization

Act local to increase efficiency through creative efforts

Building Quality



Quality is Contagious

This infectious passion activates emotional process and makes quality an obsession.

Who is Responsible???

- Lab Tech-The person who performs testing
- Supervisor-The person who is responsible for day-to-day activities, training, delegation of work
- Quality Officer- The person who monitors QA
- Lab Director-The person who is responsible for entire seamless operation, planning, and control of all activities


QUALITY
STARTS WITH ME

Quality Begins With Me

Personal Responsibility

- All team members are responsible for quality and customer satisfaction, it is part of everything we do, it is central to our values.
- Strive to make continuous improvement a part of every day and every job.
- **Quality is an on-going Process, not an Event.**


Engaging people with a coherent
key message will enable change

Recognition of Good Work

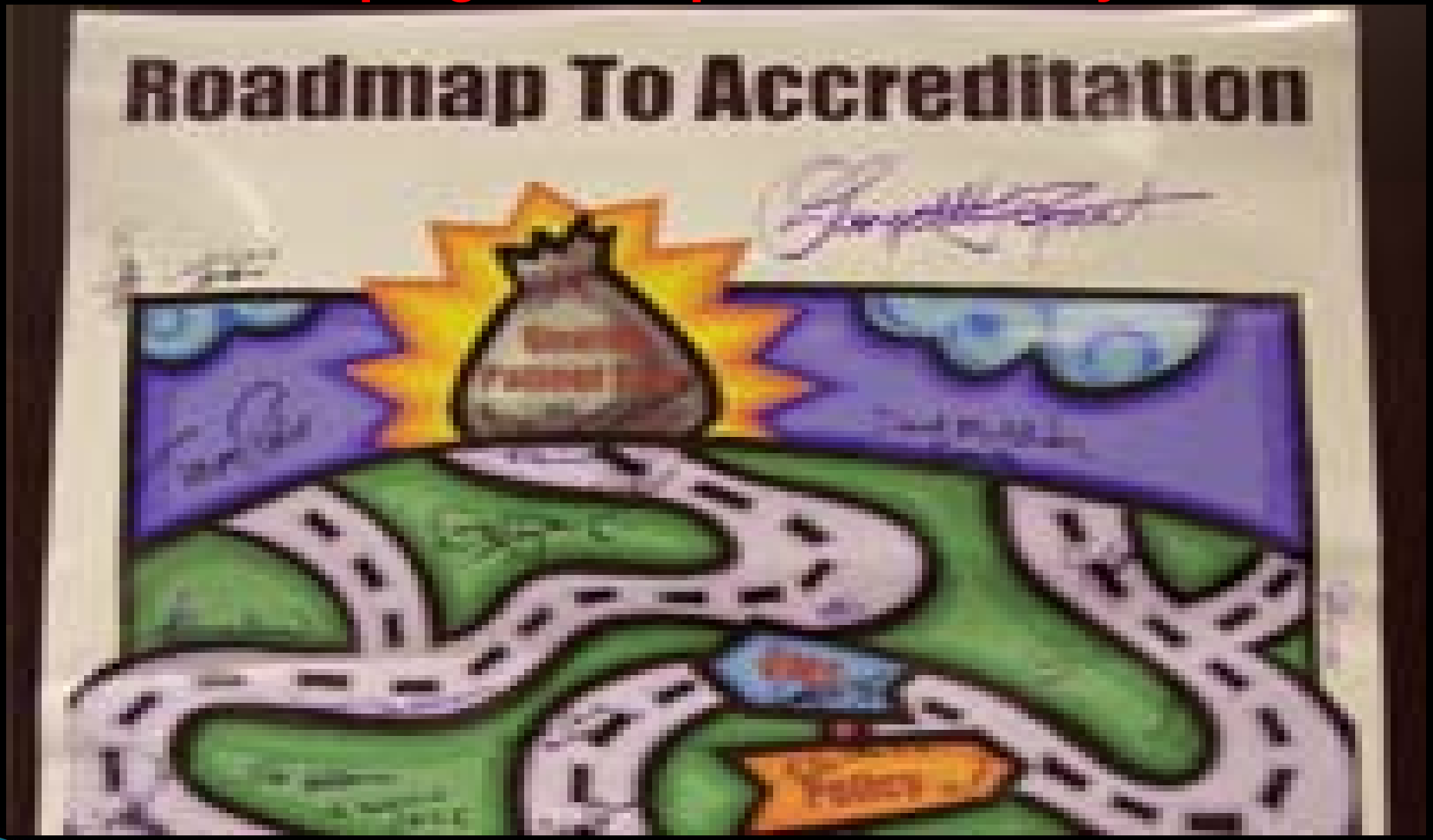
Accreditation is a public recognition of the achievement of accreditation standards by an organization, demonstrated through an independent external peer assessment organization.

Useful Websites……

- CMS CLIA web page: http://www.cms.hhs.gov/CLIA/
- FDA CLIA web Page: http://www.fda.gov/cdrh/clia/index.html
- FDA CLIA test complexity db: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm
- CDC CLIA web page: http://wwwn.cdc.gov/clia/default.aspx
- CAP web page: http://www.cap.org/apps/cap.portal
- TJC web page: http://www.jointcommission.org/
- COLA web page: http://www.cola.org/

THANK YOU

Helping All People Live Healthy Lives



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