

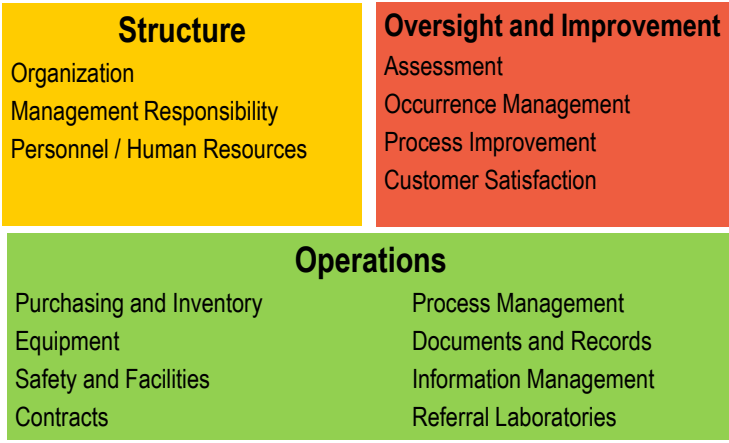
# Applying Quality to the Medical Laboratory

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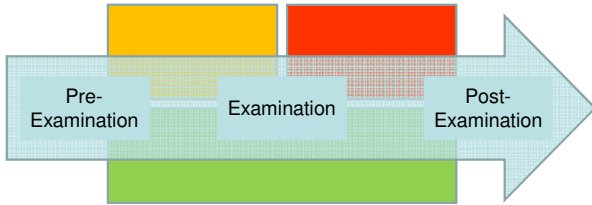
# Resident Quality Management Seminar Series

- Session 2
  - Laboratory Error
    - Significant Error, "Negligible" Error, Invisible Error
    - Significant Error is about 1-3 per 5000 samples.
  - Costs of Poor Quality
    - Prevention, Assessment, Internal Failure, External Failure.
    - Failure costs are hidden, unbudgeted costs.
    - In superlaboratories 8-10 percent of FTE time may be consumed by remediation and correction of error.
  - Standards
    - Quality is the meeting of Requirements.

# Quality Domains



# Quality Cycle



## Structure

**The Organizational Chart tells employees**

- To whom do they report
- Who reports to them.

**The Quality Manual tells employees**

- What is the Quality Policy, Mission and Vision
- What is the Policy on sample acceptance
- What is the Policy on sample rejection
- What is the Policy on Test Validation
- What is the Policy on staff education and training

**If you know the Policy you understand why things are done .**

```

graph TD
    VL[Vancouver Laboratory  
Org Chart 1-2011] --> MD[Med Director]
    VL --> OD[Ops Director]
    MD --> QM[Quality Manager]
    OD --> QM
    QM --> H[Haem]
    QM --> M[Micro]
    QM --> C[Chem]
    QM --> AP[A Path]
    H --> HM[Haem Manager]
    M --> MS[Micro Manager]
    C --> CM[Chem Manager]
    AP --> AMP[A Path Manager]
    HM --> HS[Haem Supervisor]
    MS --> MSUP[Micro Supervisor]
    CM --> CSUP[Chem Supervisor]
    AMP --> APSUP[A Path Supervisor]
    HS --> HT[Haem Technologist]
    MSUP --> MTS[Micro Technologist]
    CSUP --> CST[Chem Technologist]
    APSUP --> APS[AP Technologist]
            
```

## The Quality Tree

- **POLICY** is the foundation of Quality. The nourisher.
- Everything else flows from quality.
- In the absence of **POLICY** there is no explanation for why we do what we do.

## Structure

**Management Responsibility**

- **Establishment of Policy**
- Design and Implementation
- Arrangements to ensure conflict of interest addressed
- Arrangement to ensure confidentiality addressed
- Ensure Continual Improvement
- Authorities and Delegation
- Regular Review to ensure error and complaints addressed
- **Top Management bears 94% of the responsibility for Quality (Deming).**

## Quality and Management

Top Management	Quality Manager
<ul style="list-style-type: none"> <li>• Top Level of Decision Making</li> <li>• <b>Set</b> Policy and Vision</li> <li>• Communicate with Quality Manager</li> <li>• Manage the Laboratory</li> <li>• Drive Quality</li> <li>• Authority to <b>stop</b> activities</li> <li>• Management Review                             <ul style="list-style-type: none"> <li>- Review Reports</li> <li>- Collate Information</li> <li>- Drive PDSA</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Report at Top Level</li> <li>• <b>Operationalize</b> Policy and Vision</li> <li>• Communicate with Top Management</li> <li>• Manage the Quality Team</li> <li>• Drive Quality</li> <li>• Authority to <b>halt</b> activities</li> <li>• Management Review                             <ul style="list-style-type: none"> <li>- Develop / Compile Reports</li> <li>- Collate Information</li> <li>- Responsible for PDSA</li> </ul> </li> </ul>




## Human Resources

**Policy:**  
The laboratory shall have an organizational plan, personnel policies, and job descriptions that define qualifications and duties.

**Human Resources**  
70 percent of your budget  
100 percent of your workforce

The laboratory depends  
on every staff person  
doing their role  
RIGHT  
the first time and every time.




## Structure

**•Job Description**

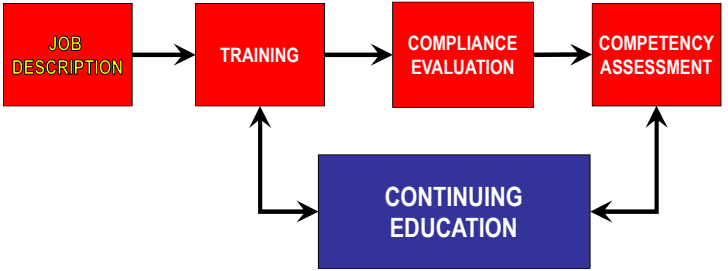
- To whom do I report
- Who reports to me
- Describe the expectations
- Trains to the expectation
- Compliance with the expectation
- Competence with the expectation

**•Personal Record**

- Review of Records
- Health, Safety
- Continuing Education.
- Review of Performance




## Job Descriptions more than just a description




```

graph LR
    JD[JOB DESCRIPTION] --> T[TRAINING]
    T --> CE[COMPLIANCE EVALUATION]
    CE --> CA[COMPETENCY ASSESSMENT]
    CE --> CE2[CONTINUING EDUCATION]
    CE2 --> T
    CE2 --> CA
  
```




## Operations

- **Process Management**
  - Activities should be organized within a Standard Operating Procedure (SOP).
  - The SOP must be clear and readable.
  - The SOP must be followable.
    - Time, Training, Equipment, Reagent, Resources, Safety
  - There is some advantage to SOPs having a consistent format and structure.
  - All people performing an activity should have access to the same SOP.




## Operations

- Document Control
  - Many procedures change from time to time. If people are not aware of the change, they will continue on with the procedure that they have always done.
  - Sometimes individuals make small changes in the way that they interpret and perform a procedure. This results in some people doing the procedure one way and others doing it another.




## Documents that Need Controlling

- Any Document that changes versions over time
  - Policy statements SOPs
  - Job Aids Job Descriptions
  - Forms critical to operations
  - Texts
- Records critical to laboratory quality that change over time
  - Contracts
  - Equipment maintenance schedules
  - Assessment notifications



## How to set up document control

1. Decide which documents are going to be controlled.
2. Set up a numbering system so that the documents can be tracked.
3. Set up a **master document control log**
4. Set the rules on document changes
  - a. Who can make changes?
  - b. How can changes be made?
  - c. How are changes circulated?
  - d. How often are documents reviewed?
5. Set up the document control monitoring system
6. **PDSA**



## Document Control

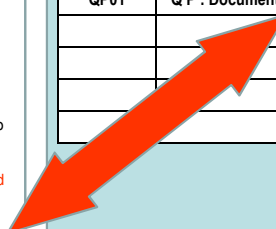
Quality Policy : Document Control


1. All Time and Version sensitive documents and records shall be controlled.
2. The Master Log shall be maintained.
3. The Master Log shall be under the ownership of the Quality Team
4. The Document Control system shall be audited regularly.

QP01-C0111


### Master Control Log

NUMBER	TITLE	VERSION	DATE
QP01	Q P : Document Control	C	Jan '11






## Keeping Document Control under control




**Many Copies**

- Very accessible
- Some strongly prefer paper
- Subject to many different changes
- Requires rigorous audit
- Requires rules




**One Copy**

- May be less accessible
- Some strongly prefer electronic
- Changes more controllable
- Requires regular audit
- Requires rules




## Document Control Audits

1. Walk around the laboratory and find all copies of a specific document.
  - a) Are all copies the same?
  - b) Are there job aids related to a previous version still available and being used?
  - c) Does everyone know where to find the current version of the document?
2. Discard wrong copies and replace with correct copies.
3. Write the report.
4. Plan for the follow-up.
5. Repeat regularly with different documents.




## Operations

- **Contracts**
  - In the medical laboratory contracts represent the closest relationship to general service industry
    - There is a defined customer
    - There is a defined set of expectations
    - Success or failure to meet expectations can be directly measured.
    - Consequences of failure to meet expectations is pre-defined.



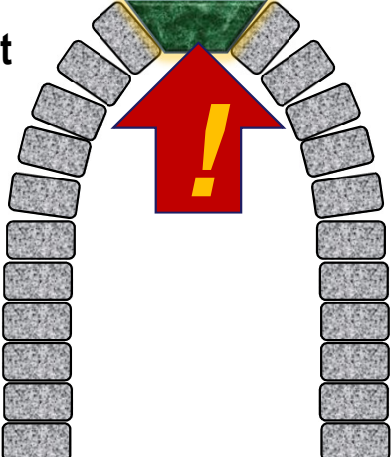

## Operations

- **Referral Laboratories**
  - Referral laboratories are those laboratories with whom the laboratory CHOOSES to interact through submission of samples.
  - Referral laboratories are sub-contracts.
  - Referral laboratories should have a Quality system at least as good as yours because their work reflects on your Quality.
  - You may elect to visit referral laboratory to check their Quality system.
- **Reference Laboratories are not Referral Laboratories**

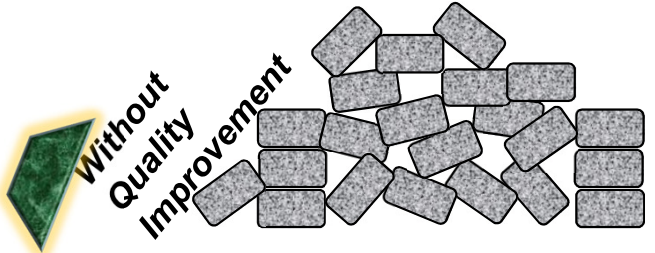



Oversight and Improvement


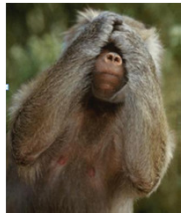
Quality Improvement  
is the  
Quality Keystone



Oversight and Improvement

You can't fix

*What you  
don't know*


The Quality  
Discovery Process

- Assessment
  - Audit
    - Internal
    - External Internal
    - Internal External
    - External
      - Proficiency Testing
      - Accreditation
- Indicators
  - Quality Indicators
  - Key Productivity Indicators
  - Complaints
  - Satisfaction Survey
  - Events / Incidents
  - Injuries and Accidents
  - Opportunities for Improvement
  - Preventive Action Surveys


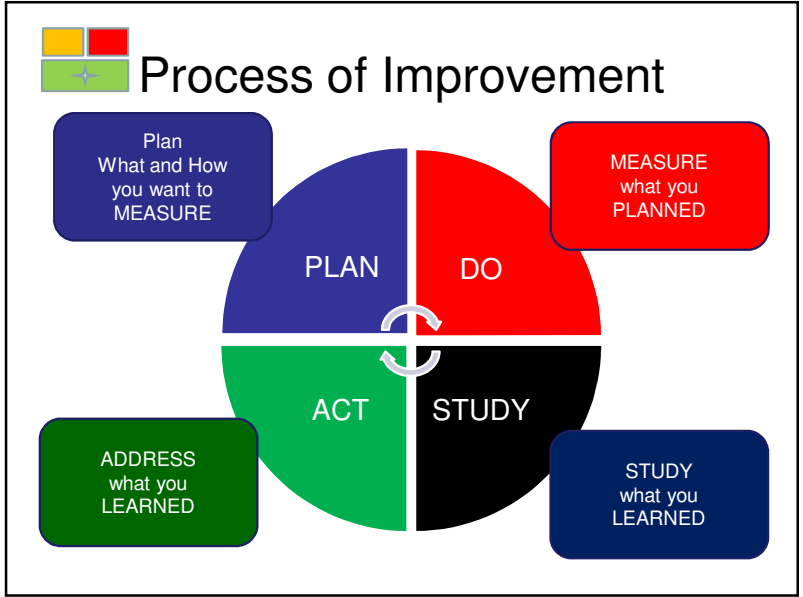
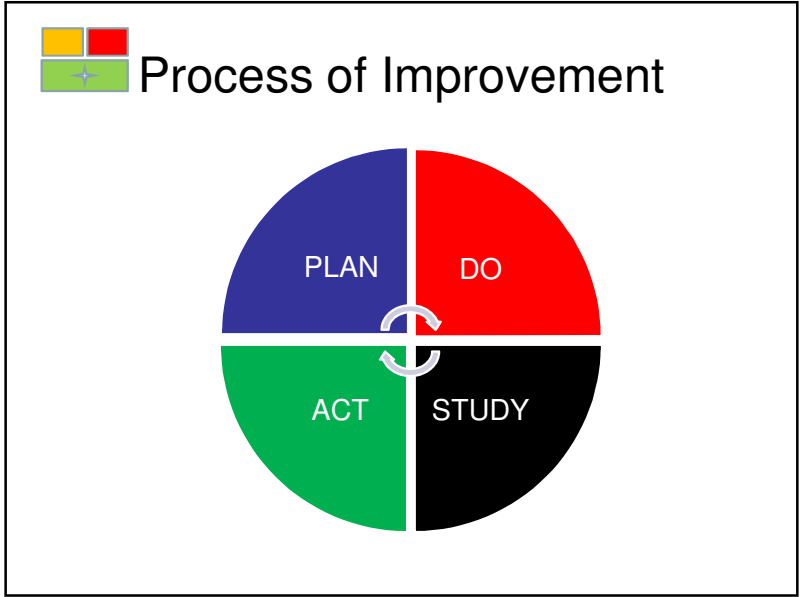



### Quality Discovery

- Be VERY specific
- Be Measurable
- Be Objective
- Be Achievable
- Define your Goals and Expectations
- Be Regular
- Be Reportable
- Be Responsive.



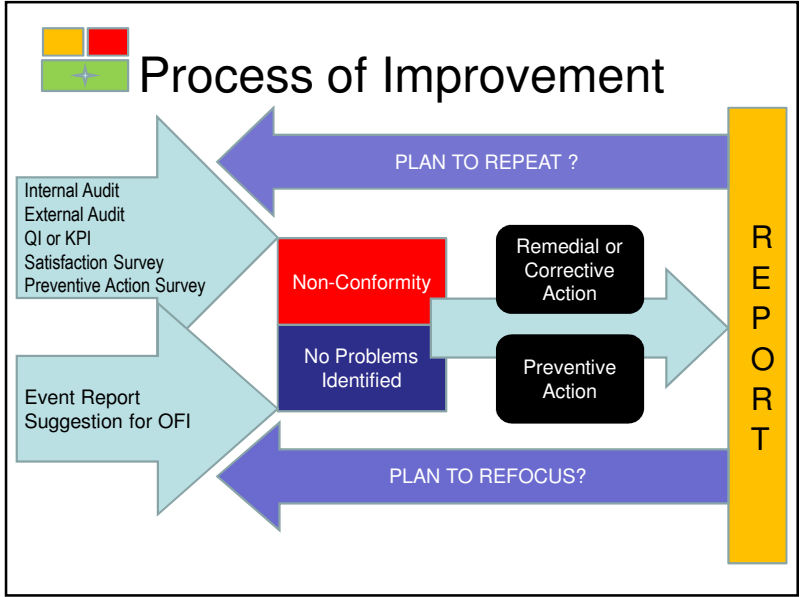

### The Key to Quality



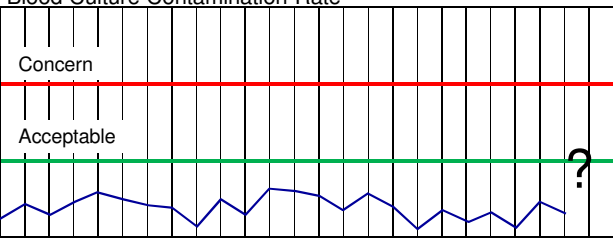
### Internal Audits Lead to Four Steps

- Remedial Actions**
  - Fix the problems that you find.
- Corrective Actions**
  - Fix the steps that lead to the problems.
- Preventive Actions**
  - Seek the steps that might potentially lead to problems in the future
- Action Report**
  - Document the problems and the actions taken

### Re-Focussing Energies

Blood Culture Contamination Rate



When indicator information becomes consistent and predictable, it is time to re-focus your energies.




### Querying Quality

<p><b>Annual Review</b></p> <ul style="list-style-type: none"> <li>Once a year</li> <li>One Major Effort</li> <li>Must be Broad</li> <li>One Year: One Report</li> <li>Two Years: Two Reports</li> <li>Three Years: Three Reports</li> </ul>	<p><b>Mini Review</b></p> <ul style="list-style-type: none"> <li>Once a month</li> <li>Selected moments</li> <li>Targeted</li> <li>One Year: 12 projects</li> <li>Two Years: 24 projects</li> <li>Three Years: Trending studies</li> </ul>
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## Key to Internal Audits

Small  
Tightly Defined  
Frequent  
Focused on Areas  
that are fixable  
Focus on every level  
Use Multiple Approaches



## Reporting Events and OFIs

**Events**

- The event has occurred
  - Accident
  - Non-conformity
  - Complaint
  - Error
- The event did not occur because we caught it early
  - Near Miss

**OFIs**

- Suggestions
- Preventive Action




## Self - Reporting

Encourage ALL staff to report events that resulted in accident, injury, inconvenience, complaint.

Encourage ALL staff to provide ideas that could improve the laboratory operation.

**Self Reporting Program Needs**

1. **Fast & Easy to report**
2. **Blameless**
3. **Non-Threatning**
4. **Confidential**
5. **Traceable**
6. **Reportable**
7. **Actionable**



## Reportable Information

**Information to Report**

1. Date and time of event
2. Location of event
3. Description of event
4. Immediately reported
5. Initial actions taken
6. Name of reporter
7. Contact info of reporter

**Response to Report**

1. Classify Report
2. Identify possible causes
3. Check Remediation
4. Set Corrective Actions
5. Track and Trend Activity
6. Report Activity



## Customer Satisfaction

### Quality is the meeting of Customer needs

The Right Result  
 To the Right Person  
 In the Right Time  
 Every Time



## Customer Satisfaction

### Who are the laboratory's customers

Patients  
 Clinicians  
 Research Collaborators  
 Public Health  
 Internal personnel.



## Customer Satisfaction

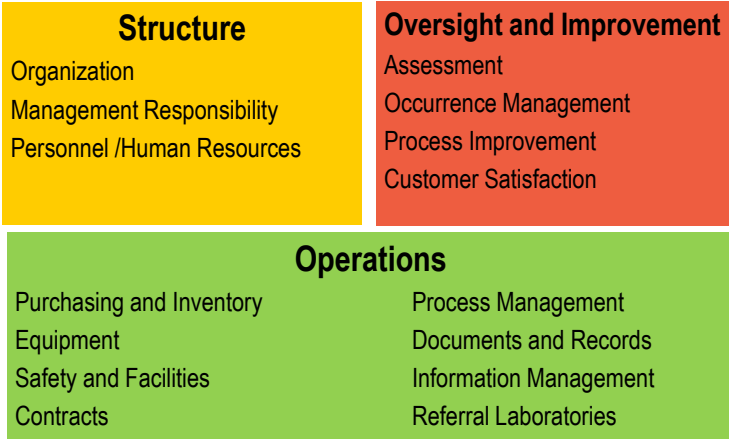
- What happens when laboratory customers are satisfied?
  - **NOTHING**
- What happens when laboratory customers are NOT satisfied?
  - **EVERYTHING**
  - Complaints      Investigation
  - Loss              Consequences
  - Compromised Care**



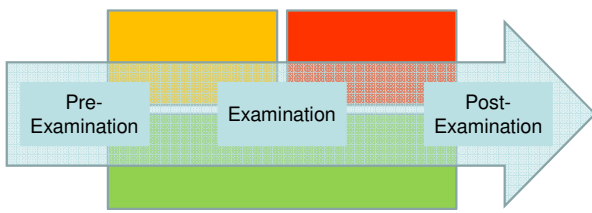
## Addressing Satisfaction

- Communication** *again and again and again*
- Advisory Committees
  - Discussion Groups
  - Notifications and Newsletters
  - Investigate EVERY Complaint
  - Respond to EVERY Complaint
  - Monitor Indicators
    - Surveys can be a valuable asset
    - Research connectivity.
  - **Include within Continual Improvement Process**

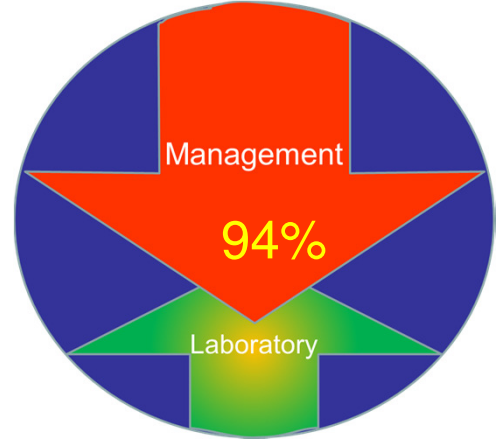
### Quality Domains



### Quality Cycle



### Deming Vision of Management Responsibility



### Process of Improvement

