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# How to Build the Quality Improvement Mindset and Sustained Effort into the Laboratory Organization

Bonnie Messinger  
CPHQ, CMQ/OE (ASQ)  
ARUP Laboratories, Inc.

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“...appreciation of  
context is often  
the crux of  
improvement  
strategies.”

Carr, Susan. "Evidence and Criteria;" Patient Safety and Quality Health Care. September/October 2008

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### Mission

ARUP's mission is to continually  
improve patient care by building  
professional relationships through  
excellence in laboratory testing,  
service, education, and research.


Making the Best Better

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### The JCAHO 10-Step Process

1. Assign Responsibility
2. Delineate Scope
3. Identify Key Aspects of Care/Service
4. Identify Indicators
5. Set Thresholds
6. Monitor
7. Identify Improvement Opportunities
8. Take Action
9. Assess
10. Communicate



**Discovery:**  
Those who own  
data collection,  
own the  
process.

- Medical Director/Director is responsible for all aspects of the departmental indicator monitoring system
- Manager/Supervisor is responsible for oversight of all division/section quality monitoring activities
- Quality Specialist is responsible for division quality activities:
  - PT, audits, occurrence reporting, improvement support, QC, indicator monitoring, instrument validation, SOP's.




## Scope

**Discovery:**  
What gets measured, Improves!

- Anatomic Pathology and Oncology/Genetics
- Business Development
- Chemistry
- Quality & Compliance and Safety
- Human Resources and Institute for Learning
- R & D and Technology Transfer
- Immunology
- Strategic Services and Facilities
- Infectious Diseases
- Support Services
- Transfusion Services
- IT Systems
- University Healthcare Clinical Laboratory and Services

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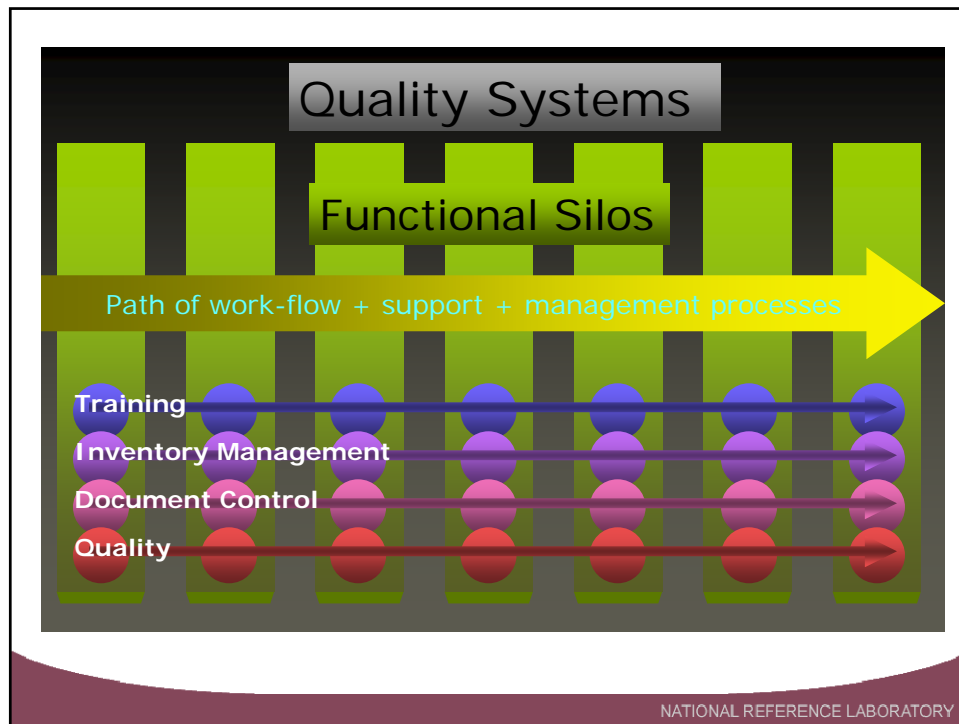


## Identify Indicators

**Discovery:**  
The best choices are measurements that are easy, but telling, or are already being measured, but not stratified.  
Measuring can be expensive; indicators that promise little or no improvement return are poorer choices

- Early Warning
  - Stat testing turn-around time
- Confirmatory
  - Bench-top cleaning log completion
- Critical Services
  - First attempt critical result notification success rate
- Critical Processes
  - Mislabelled specimens by patient care unit
- Latent Error
  - Number of understaffed shifts
- Human Behavior
  - Missed test orders by shift
- Compliance
  - Number of days between competency testing and major error

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## Examples of ARUP Indicators

### Structure Measures

- Accreditation/ licensure issues
- Audits
- Correlation of results/ instruments
- Compliance with policy/ procedure
- Employee safety issues
- Hazardous waste minimization activities
- Instrument/ kit failures
- Performance appraisals
- Personnel competency
- Proficiency testing performance

### Process Measures

- Accuracy/ clarity of laboratory reports
- Appropriateness of samples and labeling
- Appropriateness of transport conditions
- Critical value notification/ documentation
- Incident reports
- Test order accuracy
- Provision of adequate sample/clinical information
- Specimen handling accuracy
- Turn-around time

### Outcome Measures

- Appropriateness of requests
- Client interaction/ consultation
- Clinical correlation
- Employee injuries/ safety issues
- Patient outcome
- Physician/ client feedback
- Lost samples
- Corrected reports

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## Set Thresholds

**Discovery:**  
Standard denominators and thresholds for key indicators are critical to spreading improvement success

- Use current performance as a baseline and challenge the process.
- Use organizational goals.
- Establish criticality (may be 100% is only acceptable threshold).
- Use benchmarking, other organizations, literature, industry standards (Q-Probes).
- Use realistic targets.

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## Monitor

**Discovery:**  
Anything that touches or has the potential to touch the patient, is an improvement imperative.

### Internal

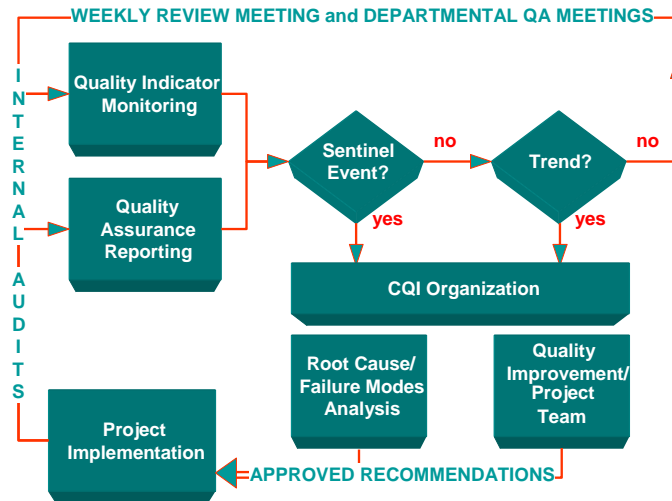
- Has the potential to affect product safety, potency and purity, but is caught and corrected before exiting the system.
- Deviation from standard, norm or established process that does not reach the client or patient.

### External

- Testing not performed
- Result amended
- Reporting delayed
- Complaint

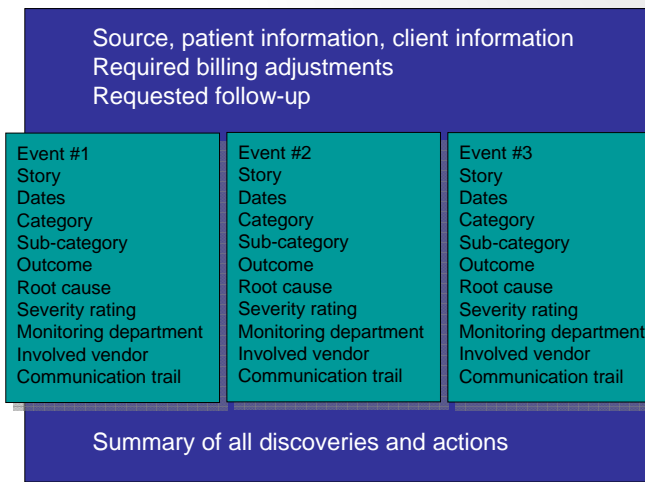
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## ARUP Quality Cycle



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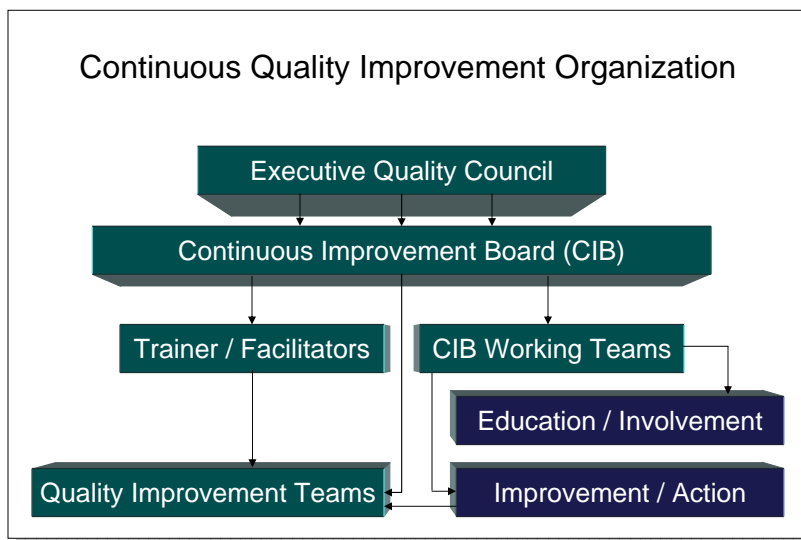
**Discovery:**  
Assigning only one tracking category for each occurrence report robs the organization of the incentive to fix all but the most obvious unsafe systems



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1992

## Continuous Quality Improvement Organization



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## Emphasis on Customers, with focus on patients

1994

**CQI philosophy is based on**

- leadership,
- employee feedback and participation,
- customer needs and expectations,
- emphasis on patient safety.

### Mission

The mission of the Continuous Improvement Board (CIB) is to act as a facilitator to create an environment of quality teamwork at all levels of ARUP which continuously improves services and products we deliver to customers (both internal and external) and ultimately the patient.

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## Continuous Improvement Board

### Discovery:

**An Improvement Board should be composed of 90% committed members and 10% skeptics. With participation, the skeptics become committed.**

- Oversight committee for quality improvement activities Uphold corporate quality philosophy
  - Train workforce members
  - Recognize efforts and reward success
  - Prioritize improvement projects
  - Form and mentor QIT's
  - Support implementation
- Rotating membership ensured broad workforce engagement.

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## CIB Working Teams

### Discovery:

**Throwing a carnival is unparalleled as an advertising strategy.**

**Games, executive participation and popcorn are essential.**

#### Education/Involvement

- Recognition
- Advertising
- Training
- Publications

#### Improvement Action

- QIT Request Approval
- Team Formation
- Team Tracking

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### Discovery:

Formal improvement teams are resource intensive; choose wisely.

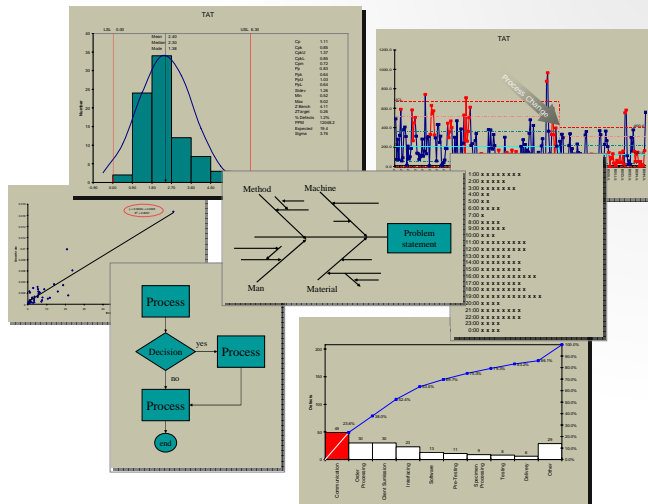
Scaling the team is more important than having broad representation.


A process that is failing or inefficient and is....

- Necessary for customer needs
- Critical for Operation
- Costing money because of poor quality
- Causing grief
- Continually exceeding thresholds
- Very complex
- Involving multiple departments

### Discovery:

For identifying improvement opportunities, the Seven Basic Quality Tools are all you need.






## Act

**Discovery:**  
**The hardest part of improvement is implementing recommendations. Many implementations lead directly to another improvement opportunity.**

- Remedial Action
- Corrective Action
- Preventive Action
- Implementation Teams
- Documentation
- Project Management

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## Assess

1999

**Discovery:**  
**Using peers from other sections to conduct internal audits spreads best practices and opens lines of communication**

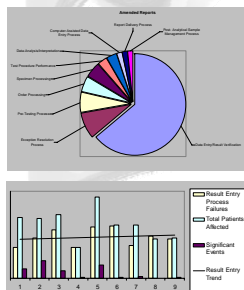
**Internal Audits (Examples)**

- Analytical Measurement
- Corrective Actions
- Equipment and Process Validation
- HIPAA Compliance
- Information Technology
- Labeling Accuracy
- Proficiency Testing
- Record Retention and Archiving
- Safety
- SOP's and Document Control
- Specimen Trackability and Traceability
- QC and Preventive Maintenance
- Quality Program Effectiveness
- Training and Competency

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## Communicate

### Weekly



### Agenda

- Scheduled client visits and start-ups and client visit reports
- Compliments and successes, shared practices
- Discussion of significant issues from the previous week
- Client focus for selected clients or client groups
- Graphical displays of data trends
  - Performance over time for outcomes (misplaced samples, amended reports and significant issues)
  - A 10-week moving window for selected processes
  - Client trends

## Communicate

### Monthly

### Monthly data is reviewed in Section Monthly QA Meetings

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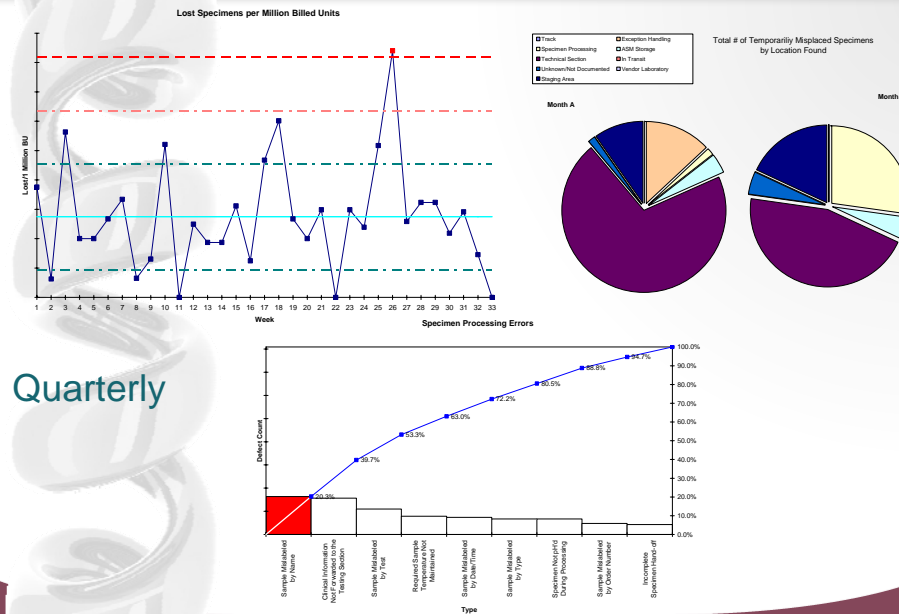
Monthly Quality Assurance/Improvement Meeting Minutes for Central Support Services  
To review data for October 2008  
Meeting date November 10, 2008  
Attending:

Code	Indicator Number	Agenda Item/Indicator Name	Threshold	Actual Value	Description or Discussion	Resp. Party	Status
R	1	Number of Compromised Samples (Any Temperature Violation)	0	#	Automated Specimen Management (ASM) Specimens placed on the fridge, new gel		monitor
R	2	Number of Specimens found in Trash Modules or Sinks	Sampled	#	Corrective Action: When there is a compromised specimen the supervisor or lead investigates the issue to find out the cause. If the issue is the result of human error a variance report is initiated and training of the employee is conducted.		monitor
R	3	Number of Manually Mislabeled Specimens	Monitor Only	#	Corrective Action: The employees have found a more efficient means of reporting this issue. Using a new gel in a bar labeling specimen from dropping off the bench making it easier for processors to capture any specimens that fall. The Bioreengineering department will stay vigilant keeping the track well maintained. The department will increase the frequency of module checks.		monitor

Corrective Action: Physically separating the carts into frozen and refrigerated has simplified the process and reduces the error rate. Also the department supervisor and lead are working hard to get new employees trained. Special attention is the Genetic department's specimens will be emphasized to the group. Each mislabeled specimen is reviewed and handled on a case by case basis by the supervisor or lead with the responsible employee. A variance report is issued in situations when further training is required. The ASM group has been successful with the training of new employees.

Number of manually mislabeled specimens

Confidential. This document may be protected from disclosure by state and federal law.



Annually

Indicator Effectiveness Counts

Number of indicators where monitoring was...	Improve Care	Measure Quality	Measure Outcome
Most Effective	452	428	298
Somewhat Effective	249	267	189
Not Effective	68	67	71
Not Applicable	16	21	222

**Discovery:**  
Transparency promotes collaboration and sharing.

Pairing the ARUP QA report with the client Exception report provides a clearer picture of quality than one or the other alone would provide.

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ARUP CLIENT QUALITY ASSURANCE DATA REPORT

REPORTING PERIOD: [date] to [date] REPORT GENERATED: [date]

A detailed summary for any given index can be requested by e-mailing the Index # to: ARUPQuality@arup.com  
DO NOT INCLUDE PROTECTED HEALTH INFORMATION IN E-MAIL COMMUNICATIONS

[Client#] [Client Name]  
[City, State]

Index: 123456

Submitter: [Patient Name: (Last Name, First Name)] ARUP ID #: [Medical Record No.]  
DOB: [Patient DOB] Alternate Number: [Client ID No.]

DATE ISSUE REPORTED: [Date index was created]

PROCESS: Process name: [Brief description of process failure]  
OUTCOME: When known, any undesired outcome of the process failure

PROCESS: Process name: [Brief description of process failure]  
OUTCOME: When known, any undesired outcome of the process failure

CONCLUSION: Description of ARUP's response based on a brief assessment of the potential outcome for this process failure

**Key to Response Details**  
The following letters are assigned based on outcome or potential outcome for the outcome:  
[Symbol] - Not a problem  
[Symbol] - Minor problem  
[Symbol] - Major problem  
[Symbol] - Critical problem  
[Symbol] - Not a problem  
[Symbol] - Minor problem  
[Symbol] - Major problem  
[Symbol] - Critical problem

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ARUP CLIENT EXCEPTION REPORT

REPORTING PERIOD: [date] to [date] REPORT GENERATED: [date]

[Client#] [Client Name]  
[City, State]

ARUP EXCEPTION: 00-002-12345 [Medical Record No.]  
NAME: [Last Name, First Name] DOB: [Patient DOB]

EXCEPT DATE: [Date order was held] Description of the held order or sample. Description of how the exception was resolved

VERIFY DATE: [Date exception was resolved]

ARUP EXCEPTION: 00-002-12345 [Medical Record No.]  
NAME: [Last Name, First Name] DOB: [Patient DOB]

EXCEPT DATE: [Date order was held] Description of the held order or sample. Description of how the exception was resolved

VERIFY DATE: [Date exception was resolved]

ARUP EXCEPTION: 00-002-12345 [Medical Record No.]  
NAME: [Last Name, First Name] DOB: [Patient DOB]

EXCEPT DATE: [Date order was held] Description of the held order or sample. Description of how the exception was resolved

VERIFY DATE: [Date exception was resolved]

TOTAL EXCEPTIONS DURING PERIOD: 3  
TOTAL TESTS ORDERED BY CLIENT DURING PERIOD: 12,345  
PERCENT EXCEPTIONS TO TESTS ORDERED: 0.02%

Through excellence in laboratory testing, service, education and research, ARUP's mission is to continually improve patient care and support the mission of the University of Utah

ARUP's vision is to be the reference laboratory of choice for community health care systems, as the most responsive source of quality information and knowledge

**Discovery:**

**No single quality model or method will suffice over time to address the quality needs of a growing organization.**

- 7 Basic Quality Tools
- 7 Management Quality Tools
- Automation
- Process Simulation
- Error-proofing/Innovation
- Lean
- Six Sigma
- Agile



ARUP's automation initiative develops, implements and integrates systems, instruments and applications.

- Expert Specimen Processing
- Image Management
- Automated Core Laboratory testing platform
- Track delivery
- Automated Specimen Management
- Automated Endocrinology testing platform
- Shipment Tracking
- Thawing and Mixing Work Cell

## Total Quality Management



### Employee Break Room Improvement

Implemented immediately

- Ice machine
- A promise of continued improvement tied to financial success

Implemented in 1 year

- Larger vending machines with better selections
- Modular tables and chairs to save space

Implemented in 5 years

- Area for personal telephone calls
- Private area for nursing mothers
- Separate meeting rooms
- Recycling

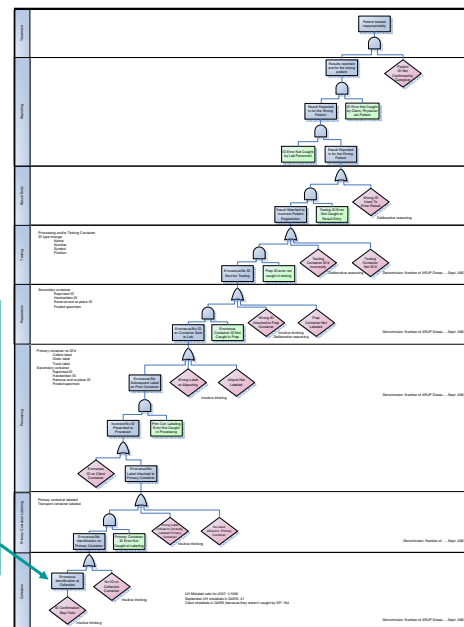
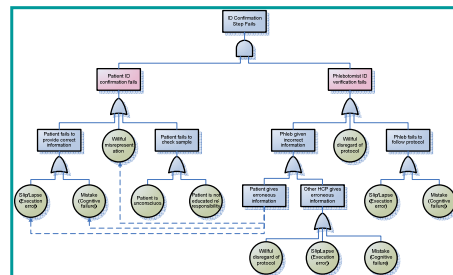
Implemented in 10 years

- Improved ambience
- Cafeteria with subsidized meal options

## Fault Tree Analysis

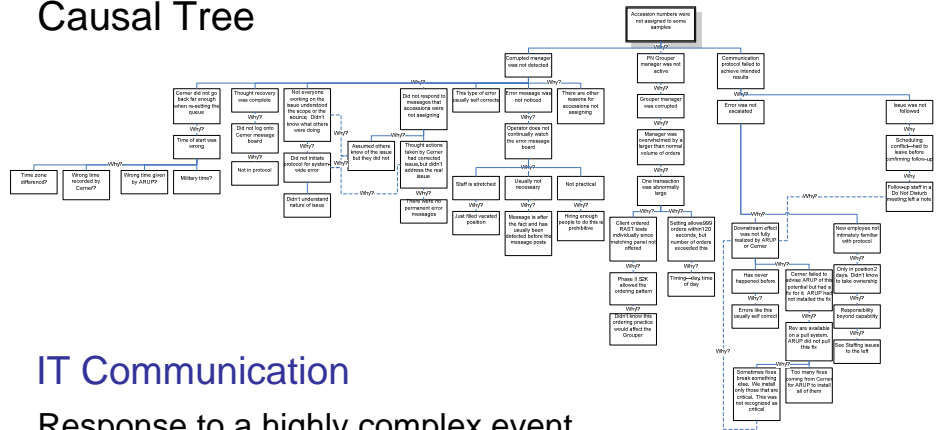
### Identification Error Risk

- Assess event risk
- Assess cumulative risk





## Causal Tree



## IT Communication

### Response to a highly complex event

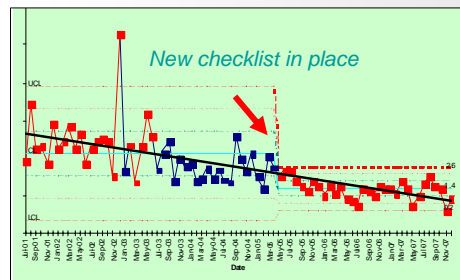
- The time sequence of the events was not linear.
- The communication requirements were complex.
- Each player was choosing downstream actions based on incomplete upstream information

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## Failure Modes and Effects Analysis

### Misplaced Samples



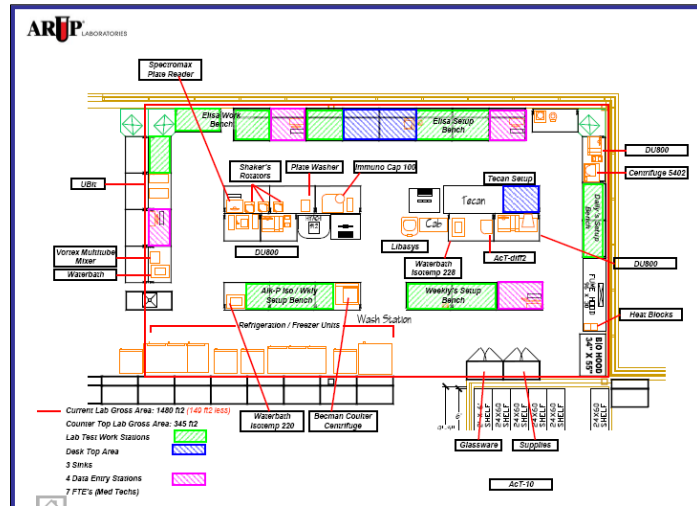
- Revised the standard search checklist for all departments to include all possible locations for samples to “disappear” at each step in the sample delivery and storage process.
- New checklist approved and adopted October 2005.

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## Lean

### Special Chemistry Work Area Redesign

- 31% reduction in distance traveled per test
- Gained 100 sq-ft bench space
- Reduced overall lab size by 10%
- Gained 17% lab bench top
- Increased workstations to add 3-5 FTE
- Created space for a larger capacity piece of equipment



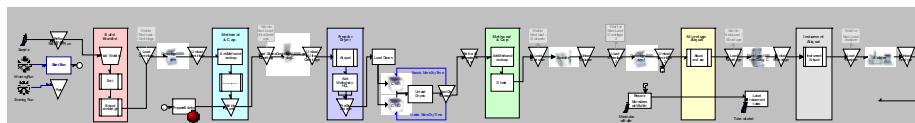
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## Process Simulation

### Meconium Sample Preparation Process

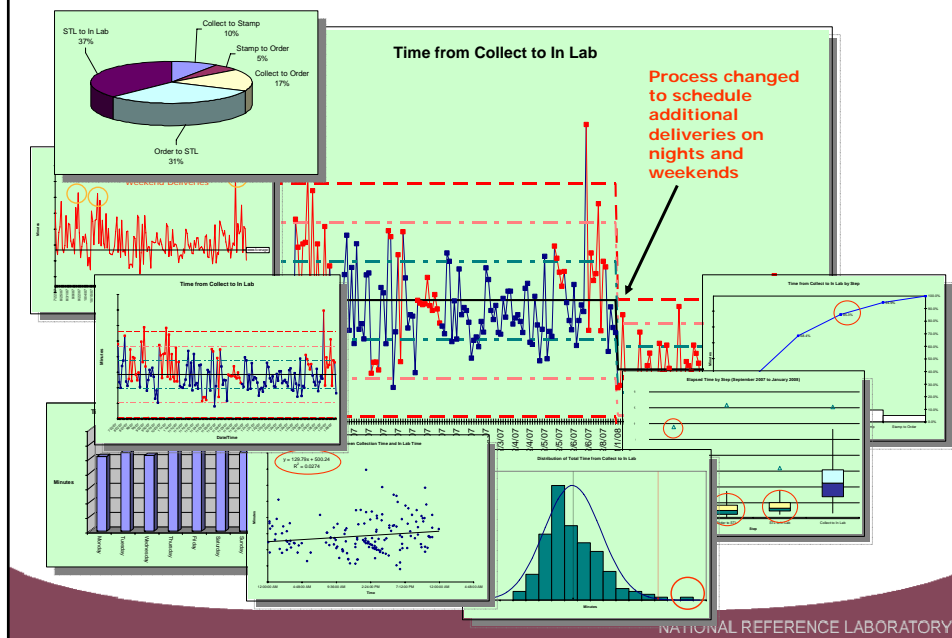
Process simulation VSM showed that travel time and non-standard work processes lengthened processing time.

- Redesigned the work area to improve efficiency and minimize travel time.
- Standardized steps to a best practice model.
- Changed to an alternate platform, eliminating labor intensive and lengthy sample preparation steps.
- Improved sensitivity with the new platform.



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## Six Sigma Gram Stain Turn-around Time Study



## One-page Project Manager

### Department Set-up Process

- Scope
- Business Model
- Objectives, Mission, Goals
- Budget
- Policies, Processes and Procedures
- Forms and Templates
- Evaluation and Monitoring Criteria
- Audits
- Risk Assessments
- Staff and Resources

ARUP PMO - The Project Manager		ARUP Resources hours to date PMO		ARUP	
ARUP Project Management Office 12/2004		ARUP Resources hours to date PMO		ARUP	
Project: ARUP PMO		Project Manager: Paul Lewis PMO		May 15, 2005	
Project Objective: To establish a functional Project Management Office (PMO) at ARUP.					
Objectives	Major Tasks	Task Completed By:	Owner	Priority	
1. Determine scope of PMO	1.1 Determine PMO and project requirements	1.1	1.1	1.1	1.1
2. Justify PMO via business model	2.1 Determine ARUP business objectives	2.1	2.1	2.1	2.1
3. PMO mission defined	3.1 Define goals of PMO	3.1	3.1	3.1	3.1
4. PMO budget	4.1 Communication of PMO role to Management	4.1	4.1	4.1	4.1
5. Define compliance criteria-Policy	5.1 Define reporting requirements-Policy	5.1	5.1	5.1	5.1
6. Define Management priorities (Operational priorities)	6.1 Define Roles and Responsibilities-Policy	6.1	6.1	6.1	6.1
7. Create a project membership/cataloging scheme	7.1 Identify project categories	7.1	7.1	7.1	7.1
8. Project templates and forms, including evaluation templates	8.1 Empower PMO to track/enforce requirements	8.1	8.1	8.1	8.1
9. Establish PMO to track/enforce requirements	9.1 Establish PMO to track/enforce requirements	9.1	9.1	9.1	9.1
10. Establish PMO to track/enforce requirements	10.1 Establish PMO to track/enforce requirements	10.1	10.1	10.1	10.1
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**Phase I: Replace DOS-based product (complete)**

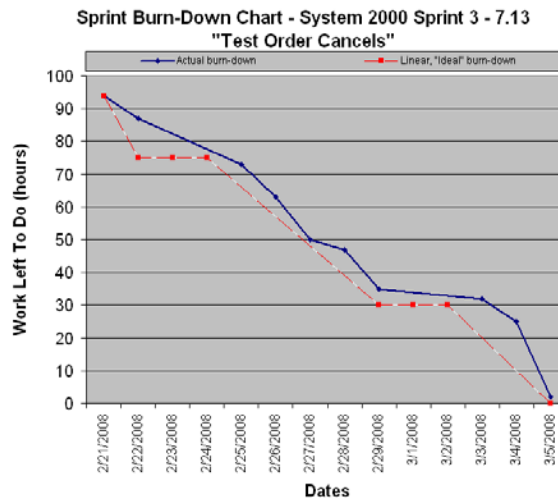
**Phase II: Accessioning in the field (complete)**

**Phase III: Pre-accessioning in the field for interface clients**

**Three sprints completed**

**Phase IV: Web-based System 2000**

## System 2000™ Phase III

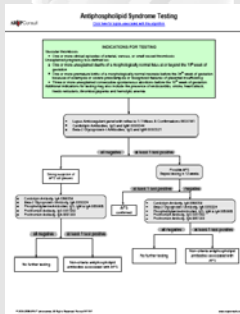


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## ARUP Consult™

Laboratory test selection support tool:

- lab tests categorized into disease-related topics
- clinical background information, test ordering suggestions, and concise diagnostic advice
- direct links to relevant references
- algorithms to support clinical decision-making
- available in both Web and PDA formats



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**Discovery:**

**Most organizations operate from an internalized Quality Plan. That was the case with ARUP. Putting the Plan in writing wasn't so daunting as we imagined.**

**Quality Systems**

- Organization
- Staff & Resources
- Equipment & Supplies
- Purchasing & Inventory
- Contract Management
- Product Development
- Process Control
- Documents & Records
- Information Management
- Occurrence Management
- Assessments & Compliance
- Process Improvement
- Service and Satisfaction
- Facilities and Safety

**ARUP's Five Pillars**

- To Provide Excellent Patient Care by Supporting Clients
- To Create a Good Working Environment
- To Do the Right Thing
- To Improve Continuously
- To Act Responsibly

## Emphasis on Context

### Basic principles

- Simple rules; cultural norms
- Executives as role models

### Holistic quality

- Embracing who we are
- Planning for who we will be

### Collegial relationships

- Patients, practitioners, suppliers and the community as partners

### Organizational learning

- Mistakes as opportunities
- Workforce open to growth

### Empowered Teams

- Characterized by accountability
- Driven by front line champions

“Management systems that conform to a rigid and complex “quality” blueprint in the hope of rubber-stamping success will fail.

The successful strategy is one that creates a unique culture of quality that has the ingenuity and intelligence to continually evolve.”

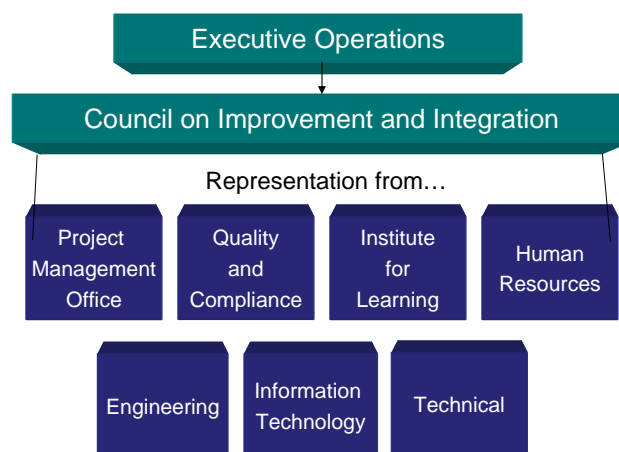
**Discovery:**  
Quality is a  
systems property  
in that it is:

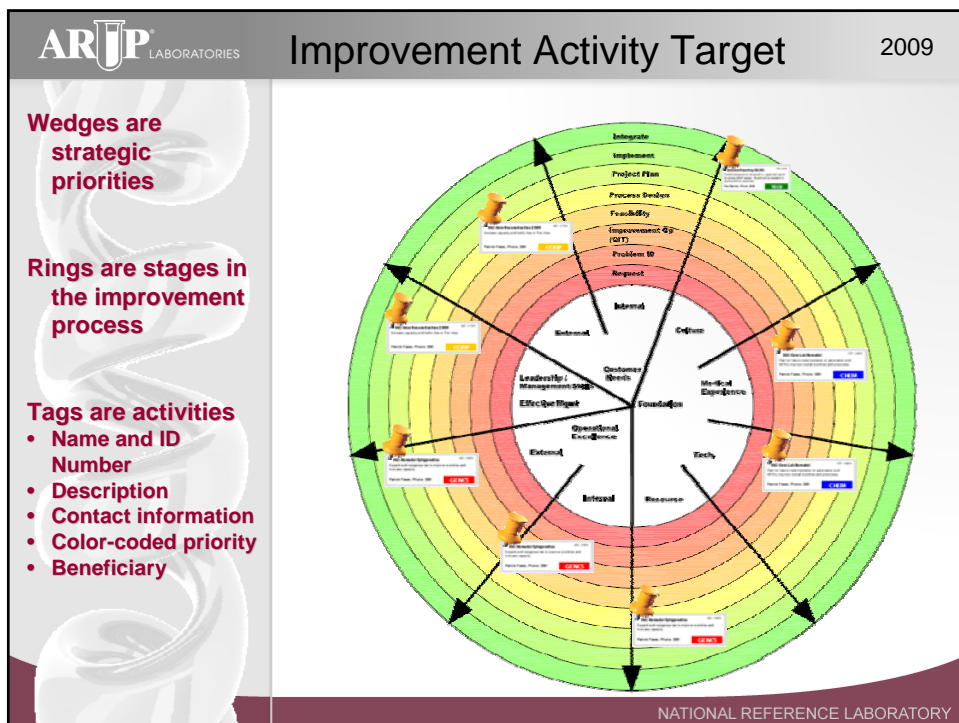
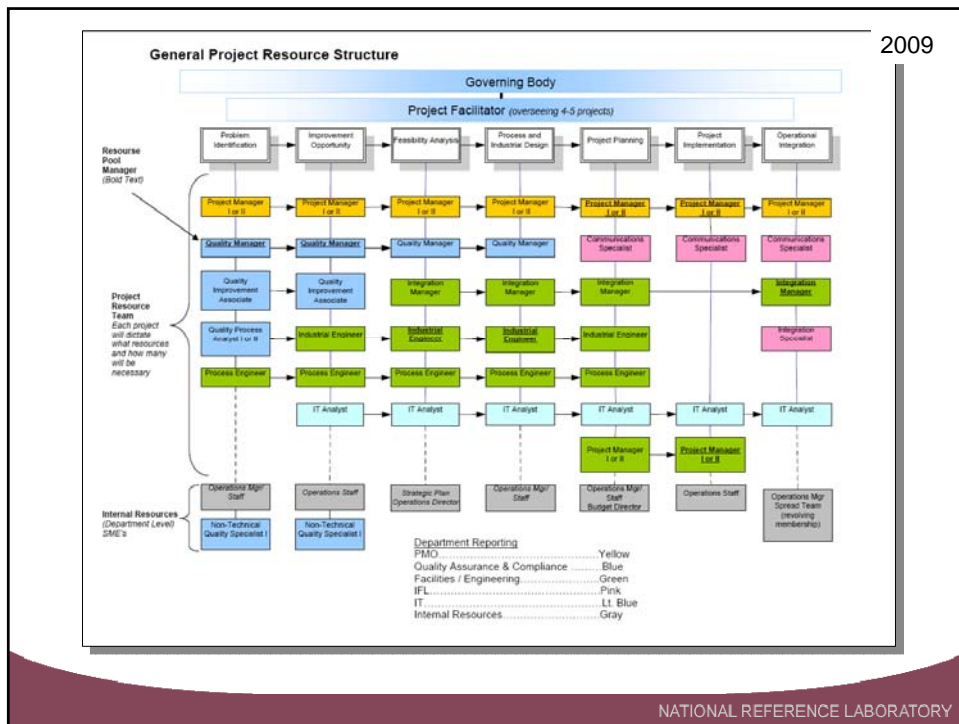
- Evolutionary
- Adaptable
- Embedded
- Emergent and
- Inherently ordered

Needs of the organization evolved beyond those provided by the early organizational structure.

- Continuity
- Agility
- Responsiveness
- Ready and dedicated resources
- Feasibility analyses
- Tracking
- Implementation
- Communication

### Council on Improvement and Integration







## Communication – the 10<sup>th</sup> Step

**Discovery:**

**Communication is the thread that ties all the players together; it ties quality to culture and primes the organization for success**

With employees

With the end user—patients, clients, caregivers, payors

With vendors and suppliers

With peers

About successes

About challenges

About discoveries

Even about heartbreaks

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## And finally, back to context....

**Discovery:**

**Any improvement strategy, no matter how brilliant, has little chance of success if it operates outside the context of our belief about ourselves and our work.**

**“Priority is a function of context.”**

—Stephen R. Covey

“Usually improvement cannot be accomplished or sustained without giving the messy business of social interactions, communication, power and organizational context its due.”

Carr, Susan. “Evidence and Criteria;” *Patient Safety and Quality Health Care*. September/October 2008

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