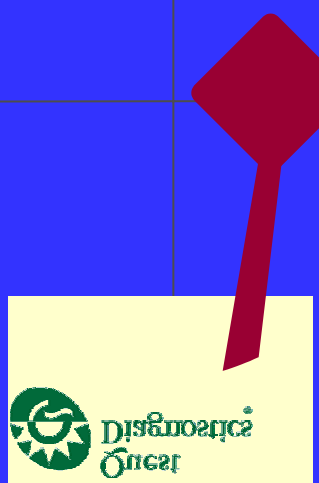
Quest Diagnostics' Experience: Non-Regulatory Quality Standards

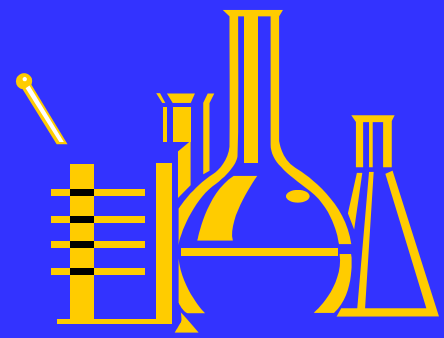
Presented by George Pounds
MT(ASCP), CLS, MBA



Presentation Objectives

The presentation will answer the questions …

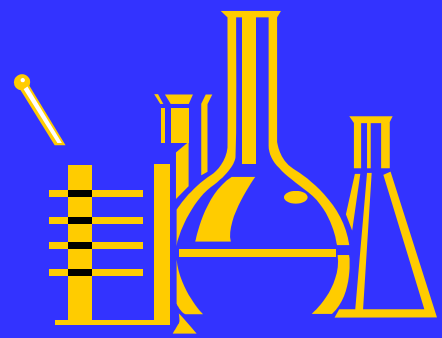
- **Why ISO 9001 & Six Sigma?**
- **How did Quest Diagnostics do it?**
- **What did we learn?**
- **What were the benefits?**
- **What's the difference between all these standards and how do they relate to Quality?**



Why Non-Regulatory Standards?

While Regulatory standards are essential and provide a necessary foundation, compliance to Regulatory Standards were <u>not</u> helping the business;

- **meet customer needs**
  …*the best laboratory services possible*
- **drive productivity and quality improvement**
  …*industry competition*
- **improve employee hiring and retention**
  …*employee market competition*
- **provide assay design standards**
  …*industry leadership*



Quest Diagnostics Non-Regulatory History

1997 Pilot ISO 9001 at Nichols Institute as a Quality framework

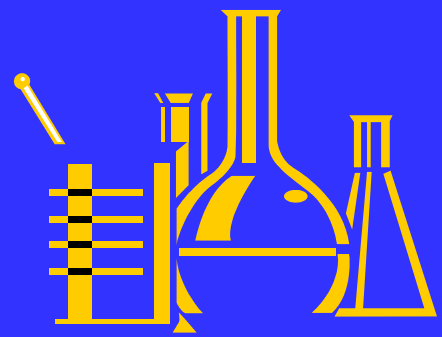
1998 Expanded certification to other clinical and non-clinical facilities.

2000 Initiated Six Sigma as a Quality improvement program within ISO 9001 framework.

- Maintained ISO certification for currently certified labs
- Replicate ISO learnings to the remaining labs through Six Sigma and Corporate Medical Quality.

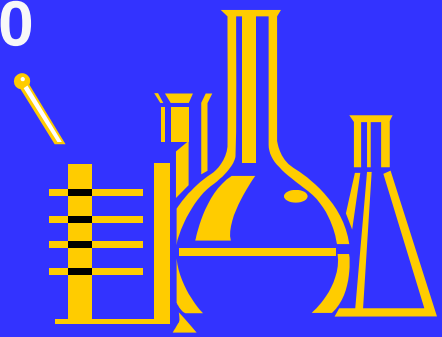
2001 10 facilities Certified (5 clinical labs and 5 non-clinical)

2003 Fully implemented Six Sigma program throughout Quest Diagnostics



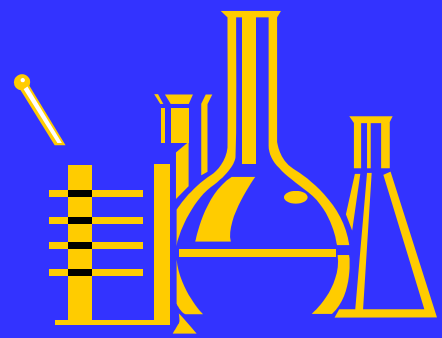
How was ISO implemented?

- Identified a corporate ISO leader.
- Identified an on-site ISO project leader.
- Identified an on-site project team (20 – 40 staff)
- Implemented a standard project plan (approximately 52 steps)
- Performed staff training (just-in-time method).
- First lab took 15 months, subsequent labs took 10 months.
- Cost of Certification: $10,000 - $15,000
- Ongoing annual costs: $8,000 - $12,000



What did we learn from ISO?

- ISO represents a cultural change to the organization.
- Resistance to change is normal … must establish & communicate clear need and benefits.
- Key integrated components for success …
  - Clear and visible management participation is required.
  - Solid tools for process management at all levels of the organization.
  - Solid document management at all levels of the organization.
  - Solid measurement system to know how you are doing.
  - Solid training and competency for all staff.
  - Solid supplier management process.
  - Solid design control process
- Minimal recognition of ISO by Hospital and Physician clients

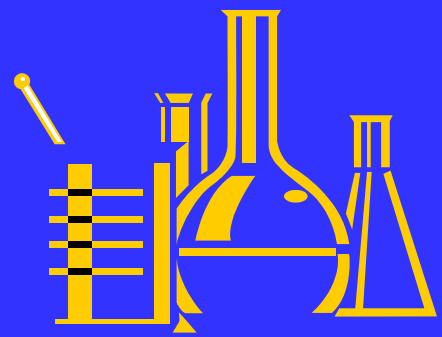


What are the Benefits from ISO?

- **Management Participation!**
  Setting clear organizational goals and alignment around those goals.

- **Quality Planning!**
  Places customer defined outcomes as the goal of the organization!

- **Process Management!**
  This is where most errors and problems occur!
  Removes department barriers!



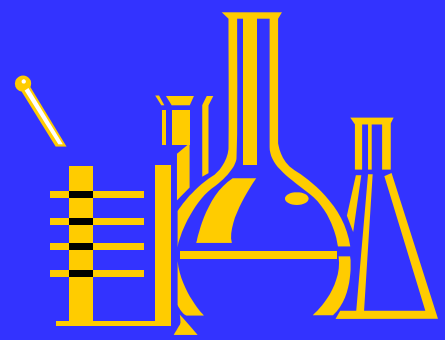
What are the Benefits from ISO?

- **Document Management System!**
  Controls document and records at all levels ... not just SOPs.

- **Measurement and Improvement System!**
  Process and customer measures are embedded in the lab operation.
  Plan, Do, Check, Act!

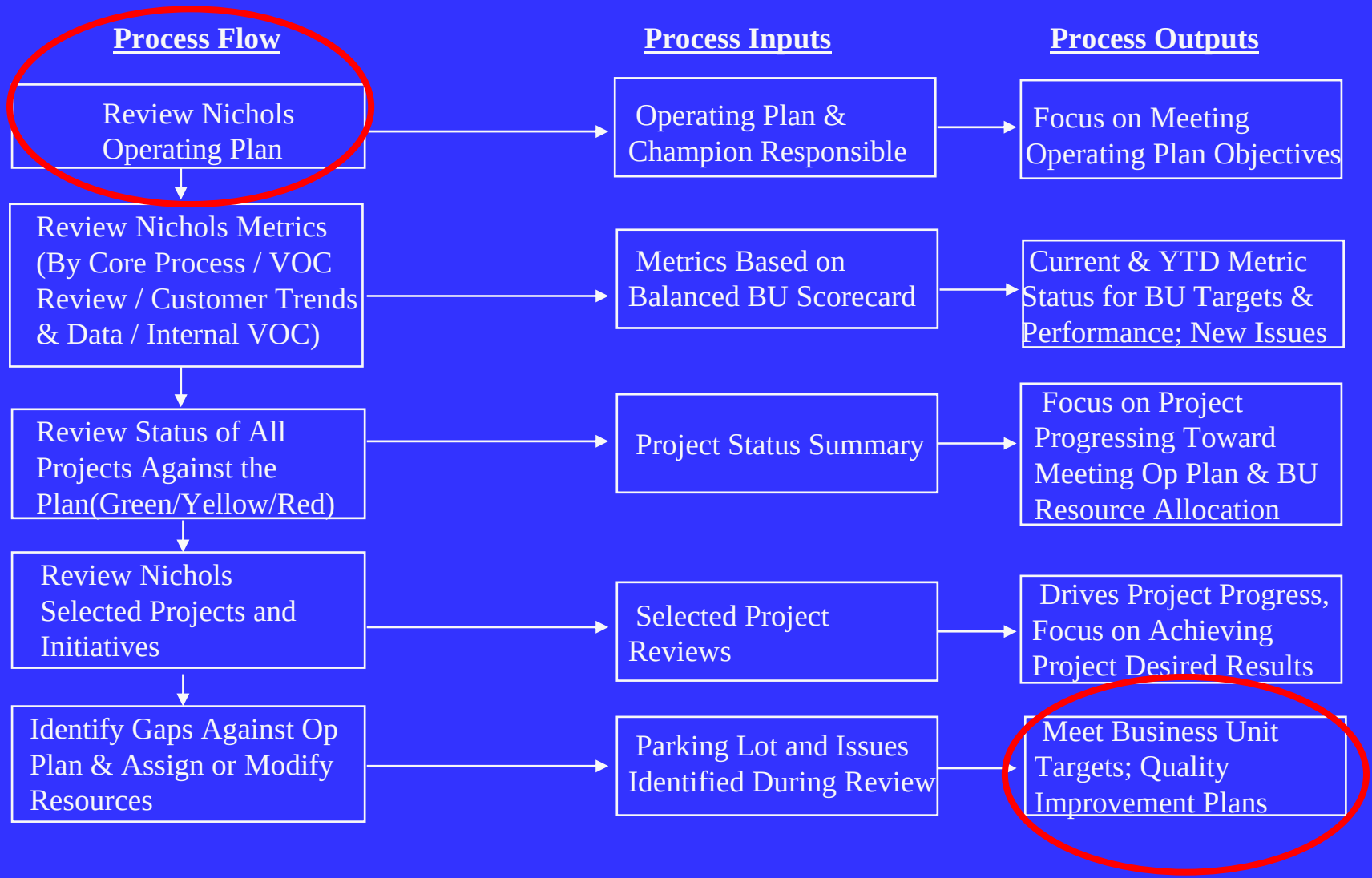
- **Supplier Management System!**
  Supplier performance is monitored and they are accountable to meet quality measures.

- **Design Control System!**



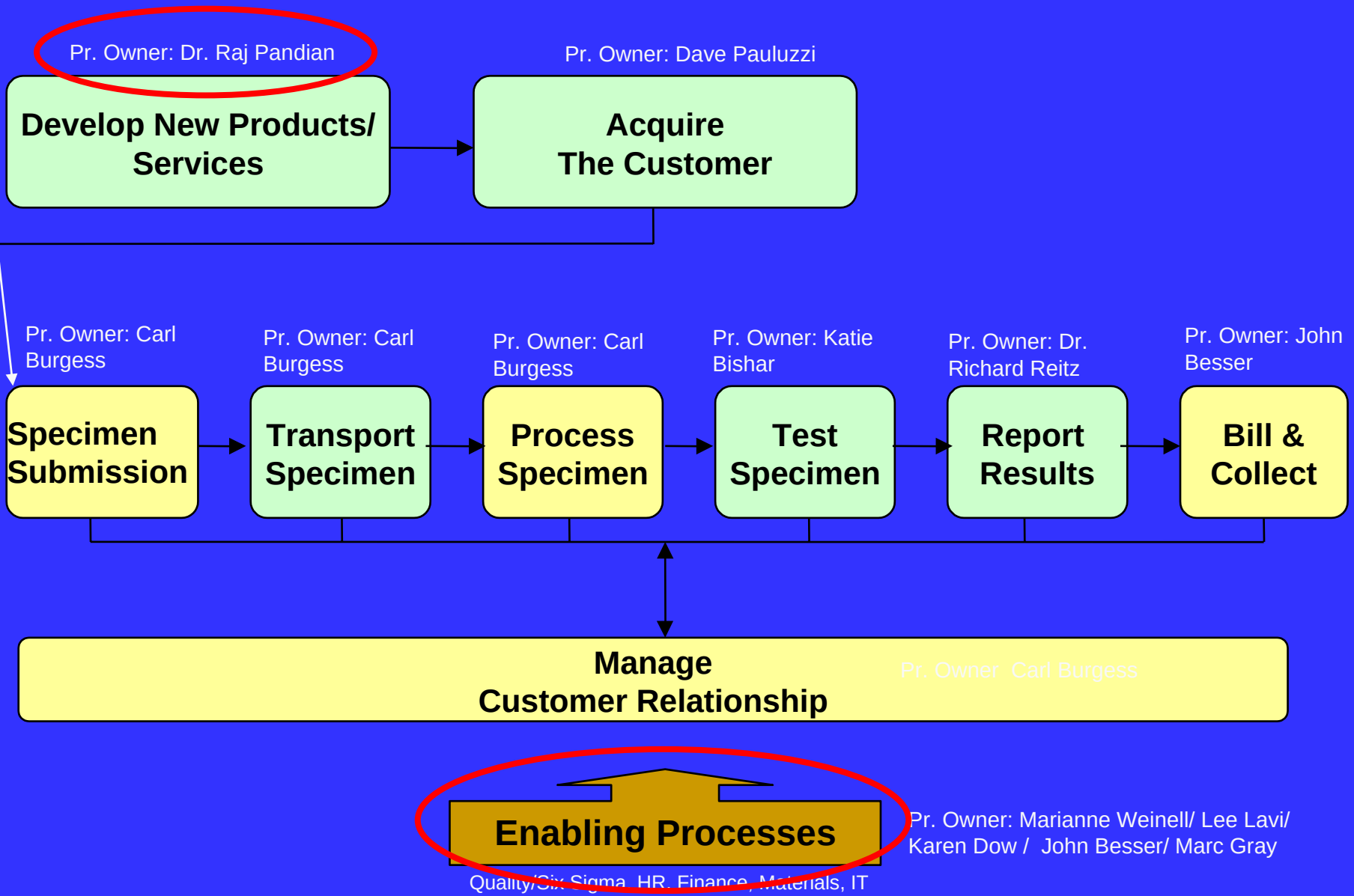
Example: Quality Planning

Business Quality Council, Meeting Process Flow / Input - Output



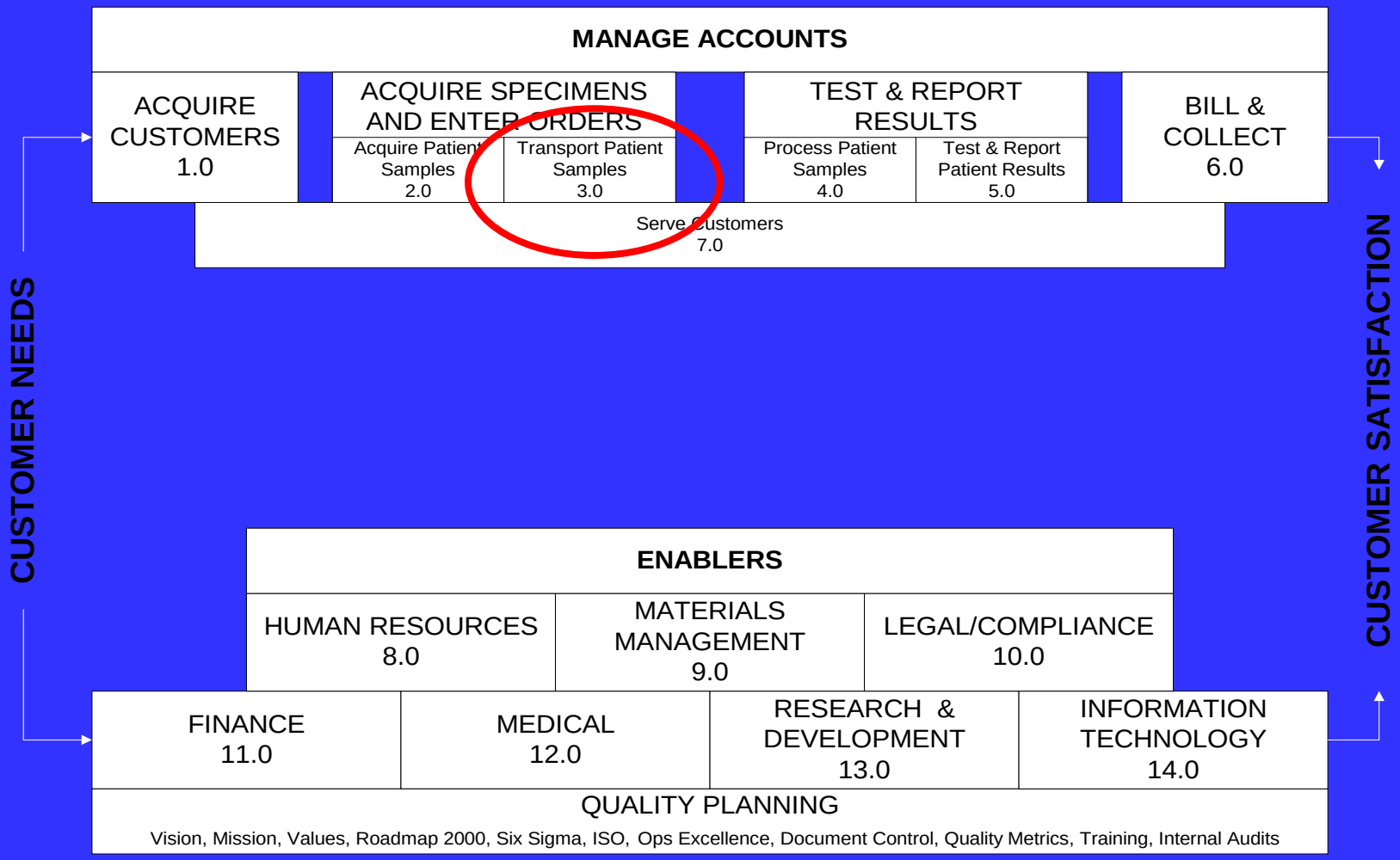
Example: Process Management

Core Process Alignment Nichols-



Example: Process Management

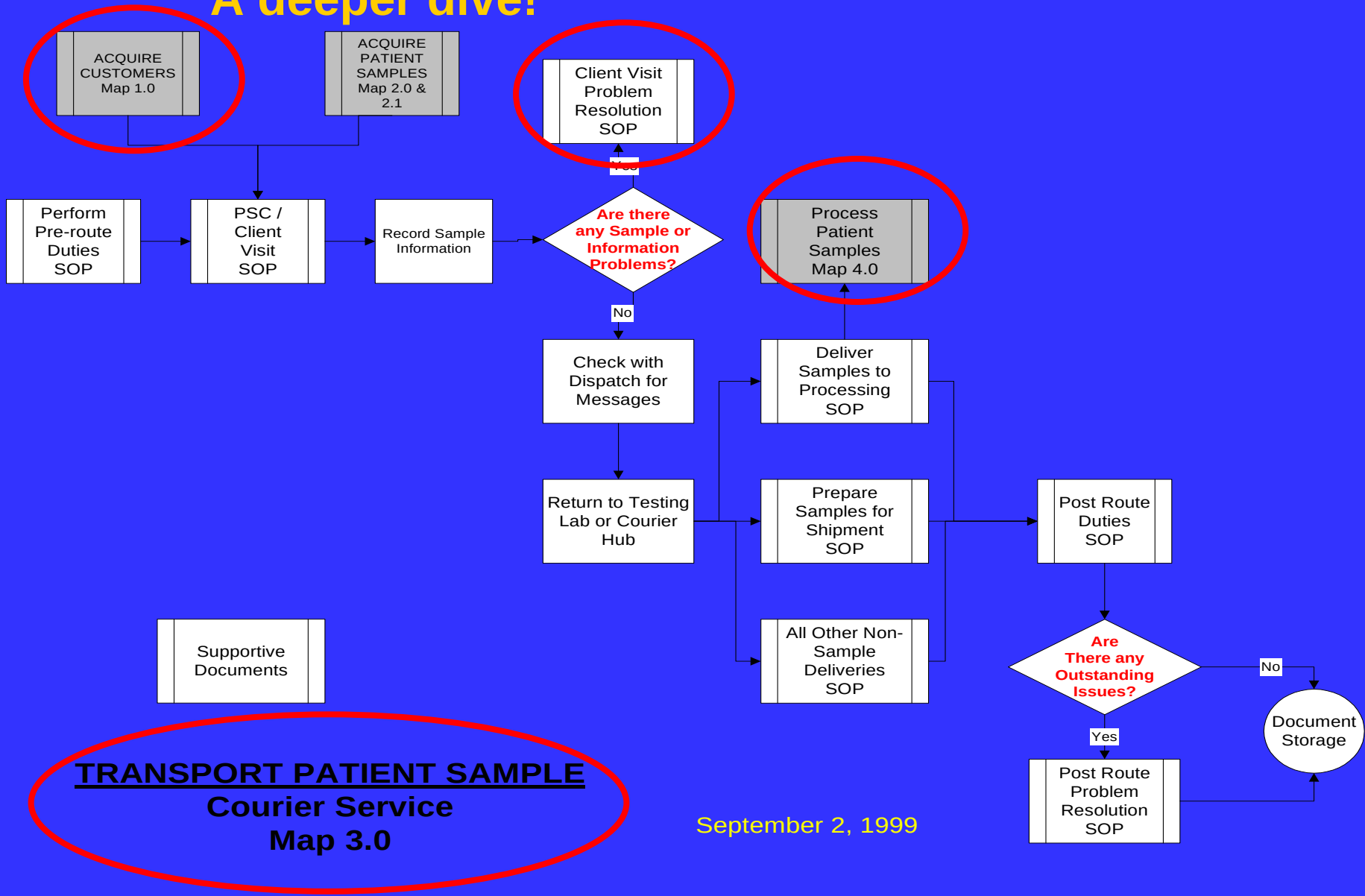
Process Management



MACRO MAP

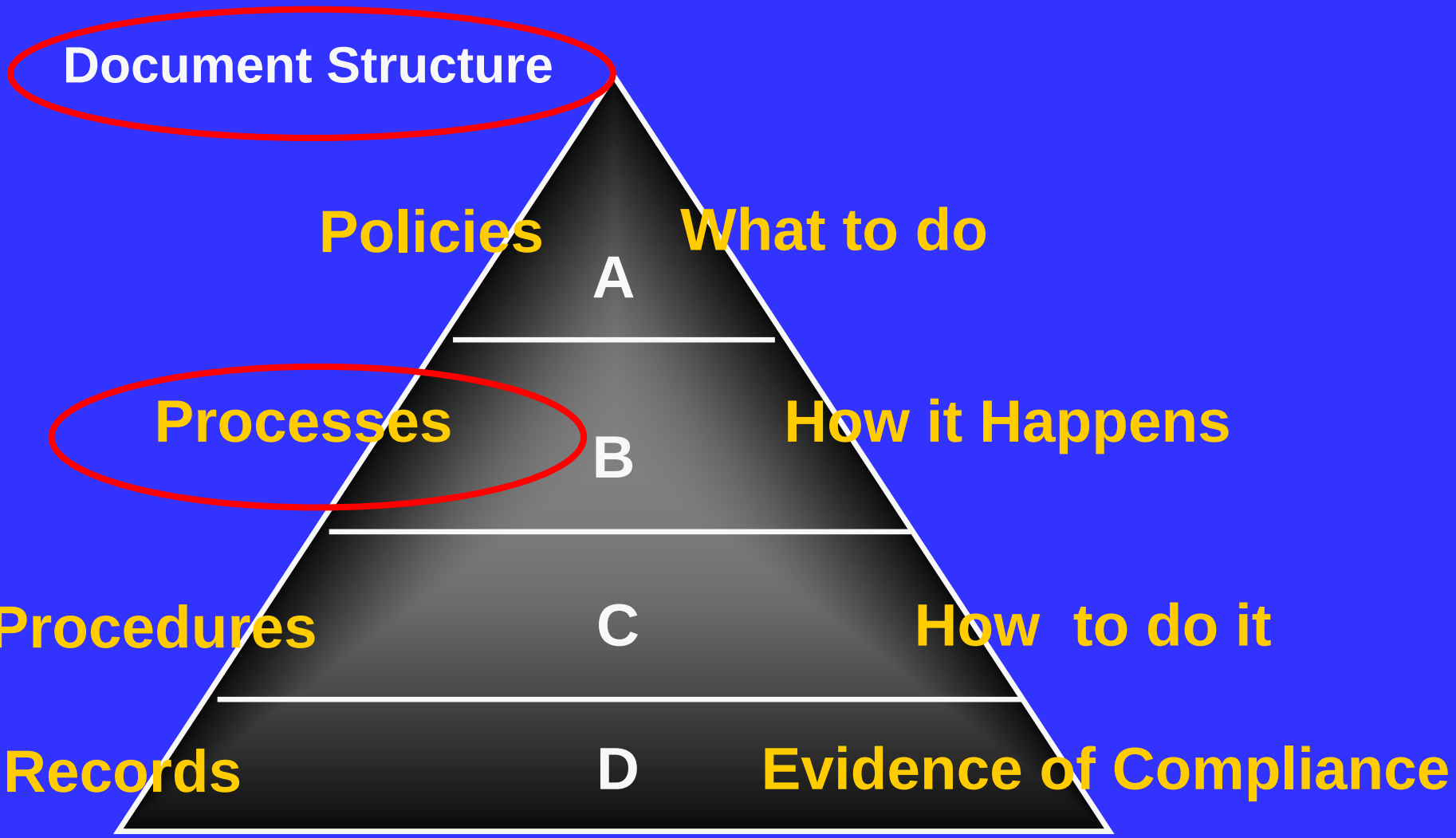
Example: Process Management
A deeper dive!

Process Management



Example: Document Management

Document Management

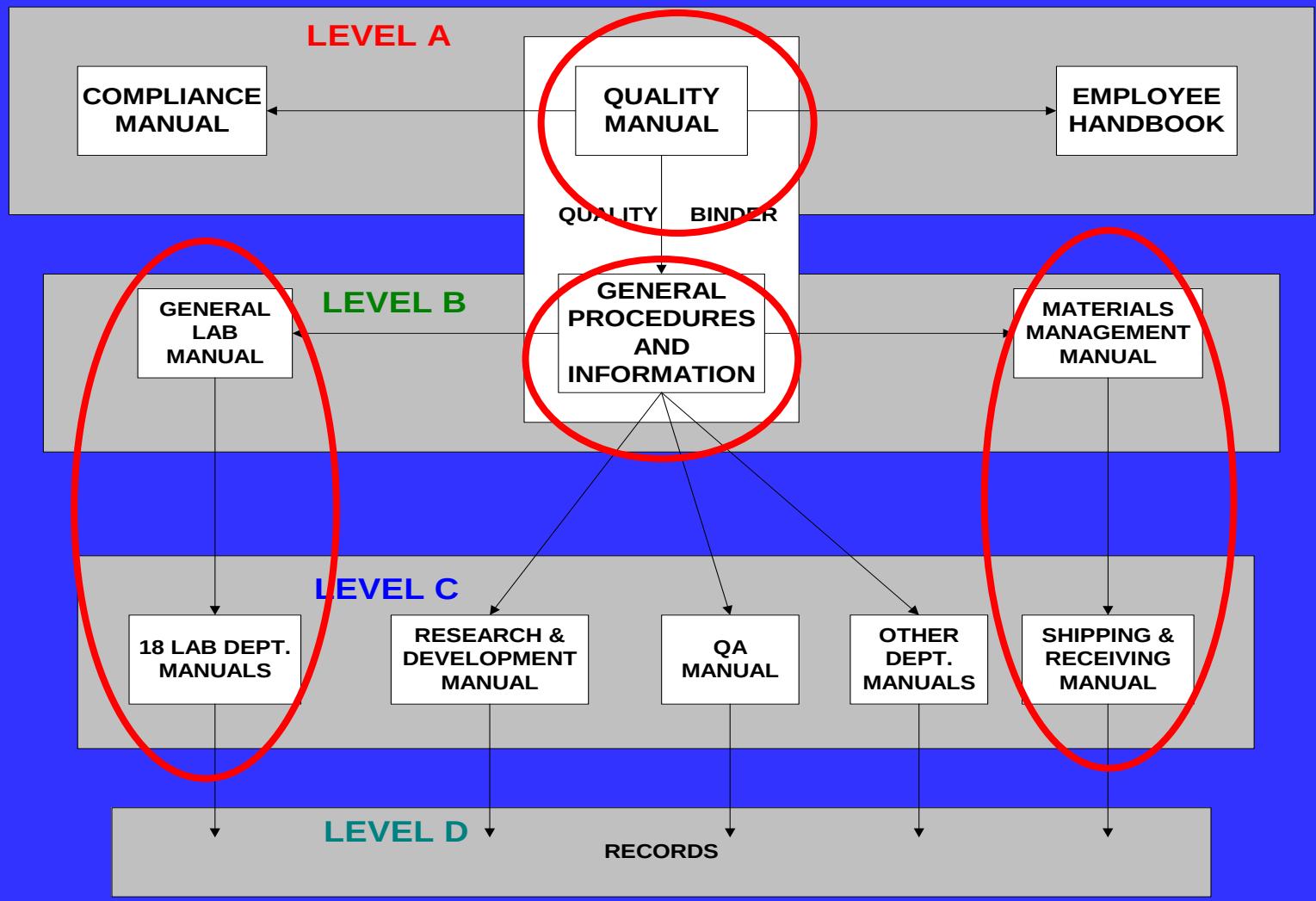


Example: Document Management

Document Management (Quality Manual)

Document Structure

Actual



Example:
Management Responsibility
and Measurement

Management Review

Quality Measures include results of:

- all audits, internal or external
- customer feedback including surveys and complaints
- employee surveys
- key process measures

Then provide for corrective and preventive actions & follow-up actions from previous management reviews

Example: Measurement

Client Retention Team

Client Retention Team in place. Service Solutions Specialists assess Clients At Risk. Top 25 Tests TAT, SF and TNP activity for prior month. Contact Sales Rep and summarize findings.Team members assign action items for improved retention. In addition, will evaluate early intervention data.

Draw to Release	Total Tests	Unit Code	Test Description	Expected Release to Final	Under Expected	Over Expected	Percent Failed
034:34	255	450	Hepatitis B Surface Antigen	021:23	008:07		8%
038:26	167	3701	Hepatitis C Antibody, EIA	033:39	014:16		2%
039:09	145	558	Hepatitis B Core Antibody (IgM)	025:53	006:21		0%
038:22	143	478	Hepatitis A (IgM), Acute Status	025:54	006:22		0%
068:26	108	6960	HIV-1/HIV-2 Antibody Screen	017:06		000:54	35%
028:11	94	4362	T4, Free, Non-Dialysis	049:59	035:40		1%
028:32	47	409	CA 125, MEIA	049:45	021:48		0%
027:23	47	983	CA 27.29	052:27	039:19		0%
023:05	40	4360	LEAD, BLOOD (PT-DEMO)	050:41	026:45		10%
022:18	38	672	WBC/Lymphs	016:08		003:50	5%
032:13	36	514	Alpha-Fetoprotein, Serum	037:48	026:55		0%
028:47	31	6037	Homocysteine (Cardiovascular), Serum, FPIA	056:27	038:25		10%
031:24	31	9199	MATERNAL SERUM SCREEN 4	071:45	030:18		6%
035:20	29	475	CA 19-9, Serum	021:50	009:47		0%
036:03	25	910	Hepatitis B Surface Antibody Quantitation	030:57		006:15	8%
026:08	21	562	PTH, Intact and Calcium	052:57	027:59		0%
031:56	21	6732	Methylmalonic Acid	115:10:00	053:45		5%
034:04	18	295	Thyroid Peroxidase Antibody (Anti-TPO)	051:39	037:21		0%
041:20	18	4210	Vitamin B1, Plasma	071:44		026:05	61%
030:33	17	412	Prolactin	020:26	005:20		0%
036:52	16	218	ANCA Vasculitides	056:38	021:09		19%
252:27:00	16	6309	Estradiol, Ultra Sensitive	018:24		039:06	13%
045:24	15	701	Ceruloplasmin	026:52	006:19		0%
038:29	14	404	Thyroglobulin Antibody	045:23	030:15		0%
026:36	13	406	Thyroglobulin	058:45	042:30		8%
						Average TAT	8%

Example: Measurement

Client Retention Team

Service Event Summary Report
Client 52572
From 01 MAY 2004 to 31 MAY 2004

Service Event Analysis

Origin Desc	Cause Description	Count	Total %
CLIENT	NO SAMPLE RECEIVED	11	24%
STEROIDS	DELAY	9	20%
CLIENT	SPILT ORDER PRIMARY SAMPLE RECEIVED	7	16%
CLIENT	TEST NOT ACCESSIONED	3	7%
CLIENT	BATCH NOT CROSSED	3	7%
CLIENT	ADDITIONAL INFORMATION REQUESTED TO REPORT TEST	2	4%
CLIENT	TEST ADD HOLD	1	2%
CLIENT	INCORRECT SAMPLE TYPE SUBMITTED	1	
CLIENT	STABILITY SAMPLE	1	
CLIENT	TEST CANCELED BY CLIENT	1	
CLIENT	PATIENT VERIFY	1	
SEROLOGY	DELAY	1	
SEROLOGY	MISSING SPECIMEN	1	
TEST SEND OUTS	COMMUNICATION COMPLAINT	1	
ENDOCRINE PEPTIDES	MISSING SPECIMEN	1	
IMMUNOCHEMISTRY	DELAY	1	
		Total 45	

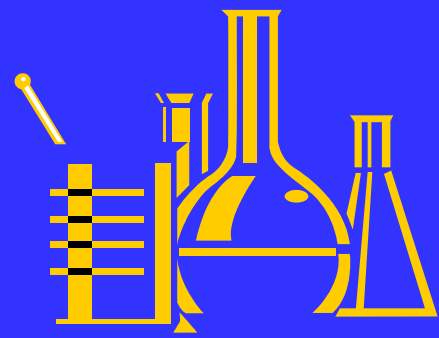
Test Not Performed (TNP) Analysis

TNP Comment Description	
TNP-INTERFERING SUBSTANCE PRESENT. UNABLE TO QUANTITATE. Count	1
TNP-Specimen exceeds Quest Diagnostics, Nichols Institute's recommended; stability range. Please resubmit. Charges have been cancelled. Count	1
TNP-The EDTA blood specimen that we received was too old to yield an accurate; white blood cell count. We are unable, therefore, to calculate or report; absolute values for the lymphocyte subsets. Count	1
TNP-Unable to perform ordered test with sample type submitted. Please contact; Quest Diagnostics Client Services for the sample requirements for this test,; or if an alternative test is desired. Charges have been cancelled. Count	1
TNP-Unable to perform ordered test because the specimen was submitted in an; incorrect transport medium. Please contact Quest Diagnostics, Nichols; Institute Client Services at (800) 553-5445 for the transport medium; requirements for this test, or if a	1
TNP-Duplicate test order. Test has been cancelled. Count	5
TNP-INTERFERING SUBSTANCE PRESENT. UNABLE TO QUANTITATE.; TNP-Unable to calculate due to interfering substance. Count	1
TNP-TEST REQUEST CANCELLED - NO CHARGE. Count	5
TNP-Cancelled per client request. Count	9
TNP-Cancelled per client request.; TNP-NO SAMPLE RECEIVED. Count	1
Grand Count	35

Example: Training Management

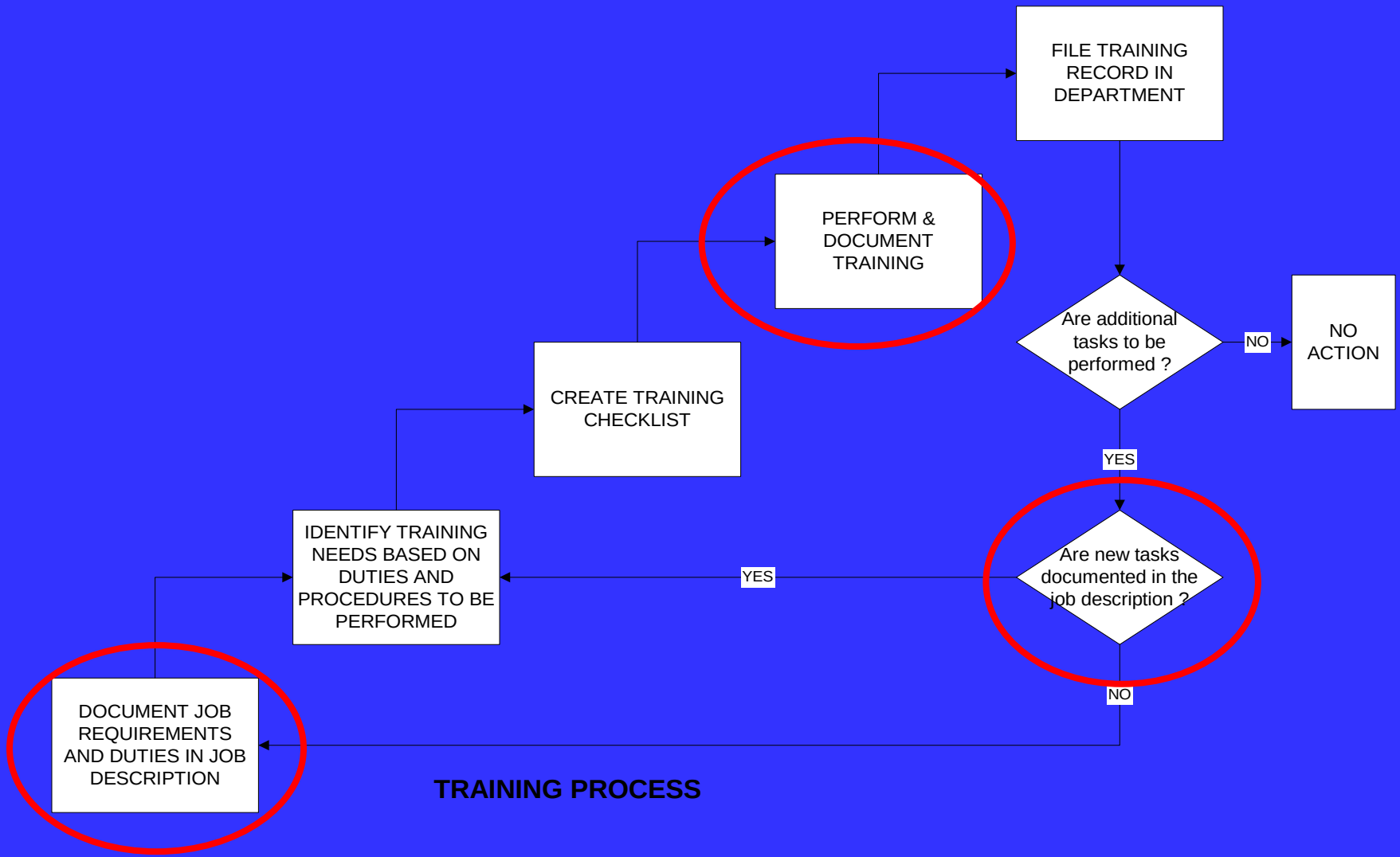
Training Management

- **Job Descriptions -** describe the qualifications and tasks for all job titles.
- **Learning & Development** - formal instruction to enhance overall knowledge or insight related to current or future job positions for all employees.
- **Training** - formal instruction on SOPs or any other document necessary to perform the tasks in the Job Description for all employees.
- **Competency** - periodic assessment of task performance for all employees.



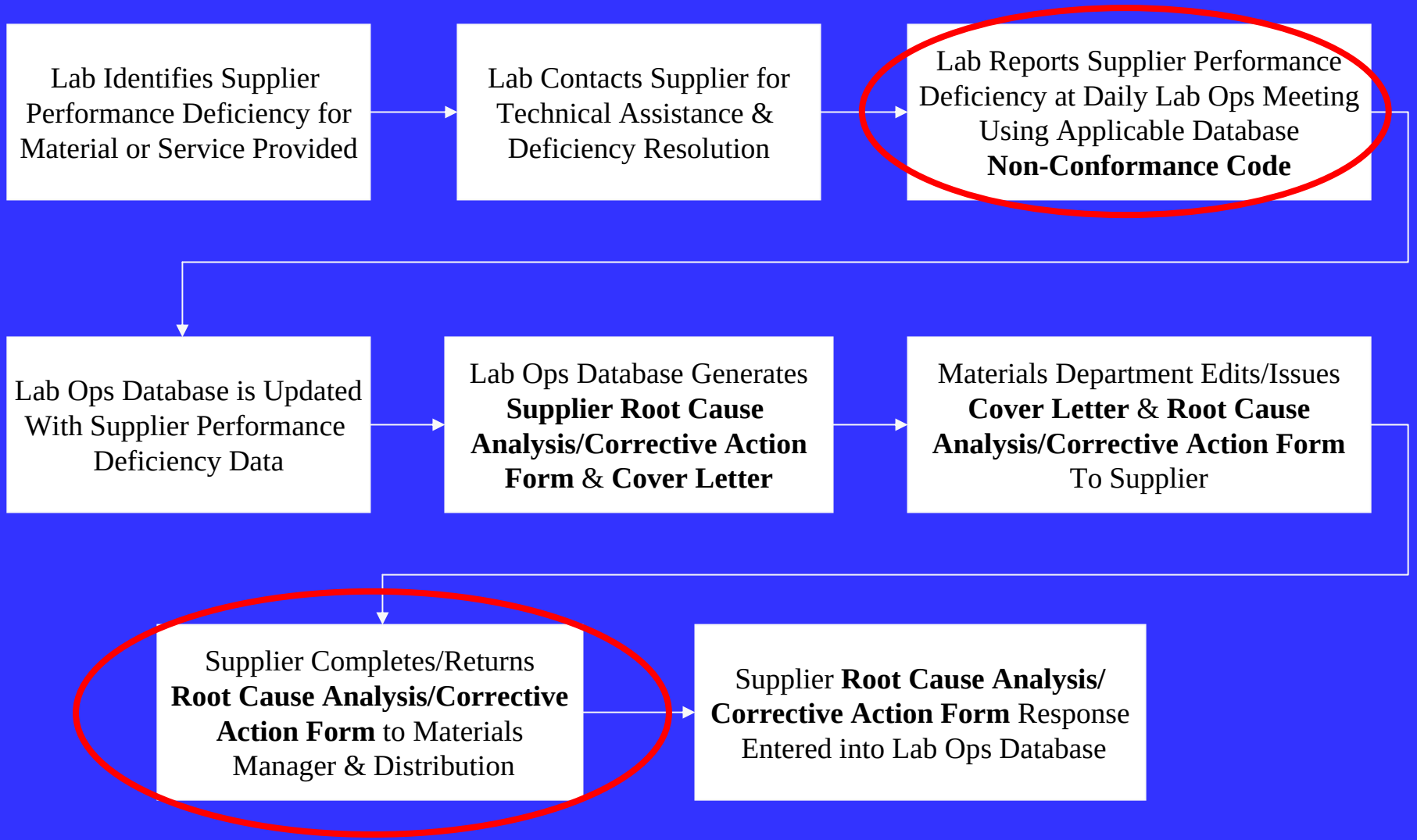
Example: Training Management

Training Management



Example: Supplier Management

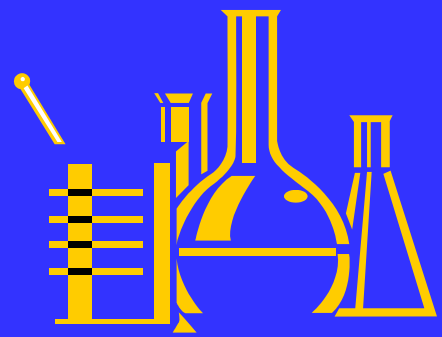
SUPPLIER NON-CONFORMANCE DATA COLLECTION & DOCUMENTATION PROCESS FLOW



How does Six Sigma fit into a Non-Regulatory approach to Quality?

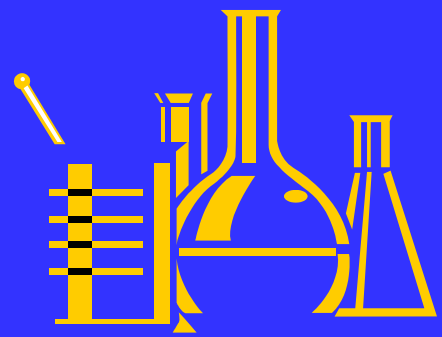
How was Six Sigma implemented?

- Identified a corporate Six Sigma leader.
- Identified Master Black Belts (BB) as on-site project leaders.
- Identified and trained on-site Black Belts.
- Implemented a standard project plan.
- Identified and initiated Six Sigma projects.
- Identified and trained Green Belts (GB).
- 2000 – 2003: 330 BB & 1245 GB projects complete.



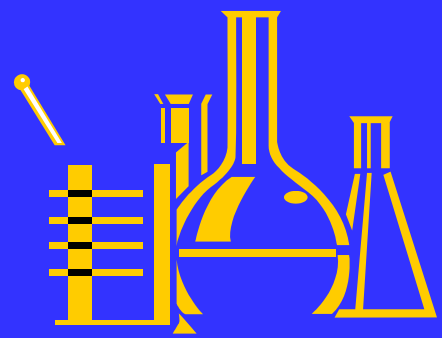
What are we learning from Six Sigma?

- A cultural change to the organization ... expect resistance!
- Better Six Sigma results from ISO certified facilities!
- Management participation required.
- Project selection and alignment required for success.
- Sharing of key learnings essential to overall success.
- Effective and practical statistical and team management tools.
- Hospital and Physician recognition of Six Sigma is growing.



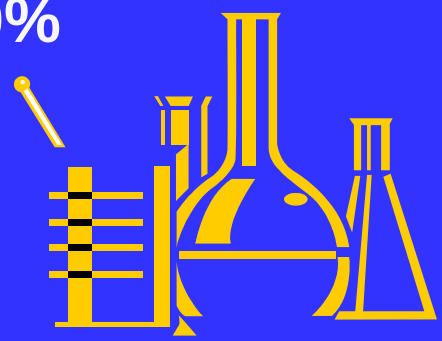
What are the Benefits from Six Sigma?

- **Highly evolved tool (statistical and team management) for improvement!**
  …Best results if there is a well defined infrastructure to support it.
- **Extremely customer focused**
  …get the voice of the customer with specific critical to quality measures!
- **Focus on specific problems!**
  …Don't boil the ocean!
- **Focus on data … not opinion!**
  …Get the right data in the right format!

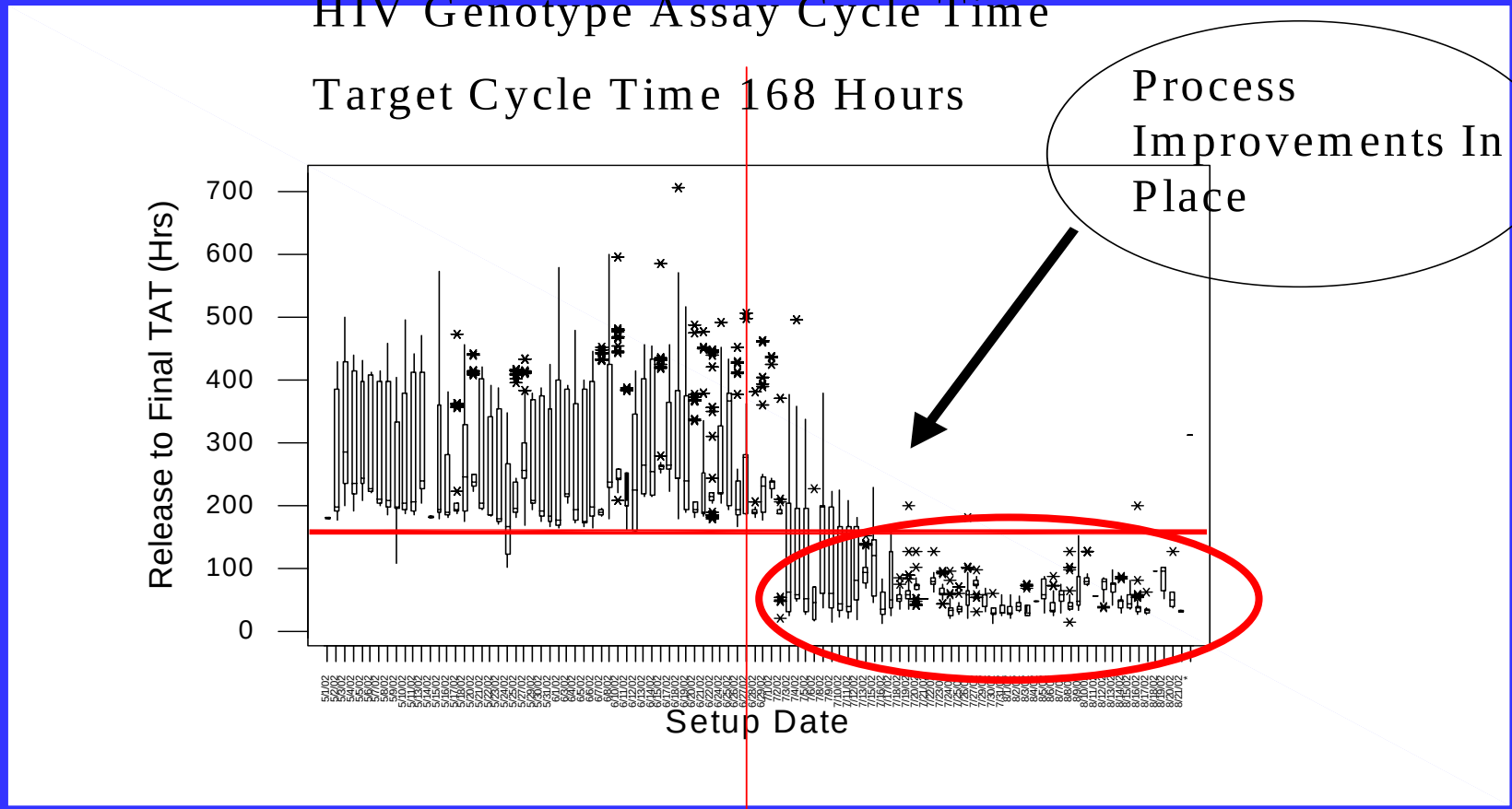


What are the Benefits from Six Sigma?

- **Focus on root cause analysis!**
  …Practical use of statistical tools to understand the root cause of the problem.
- **Focus on sustaining the gain!**
  …The process owner participates in solution design, monitoring and correcting future problems.
- **Focus on risk assessment!**
  …FMEA tool for anticipating problems and identifying solutions prior to incident.
- **Proven Results!**
  …Customer Satisfaction: improved 20%
  Savings: Exponential

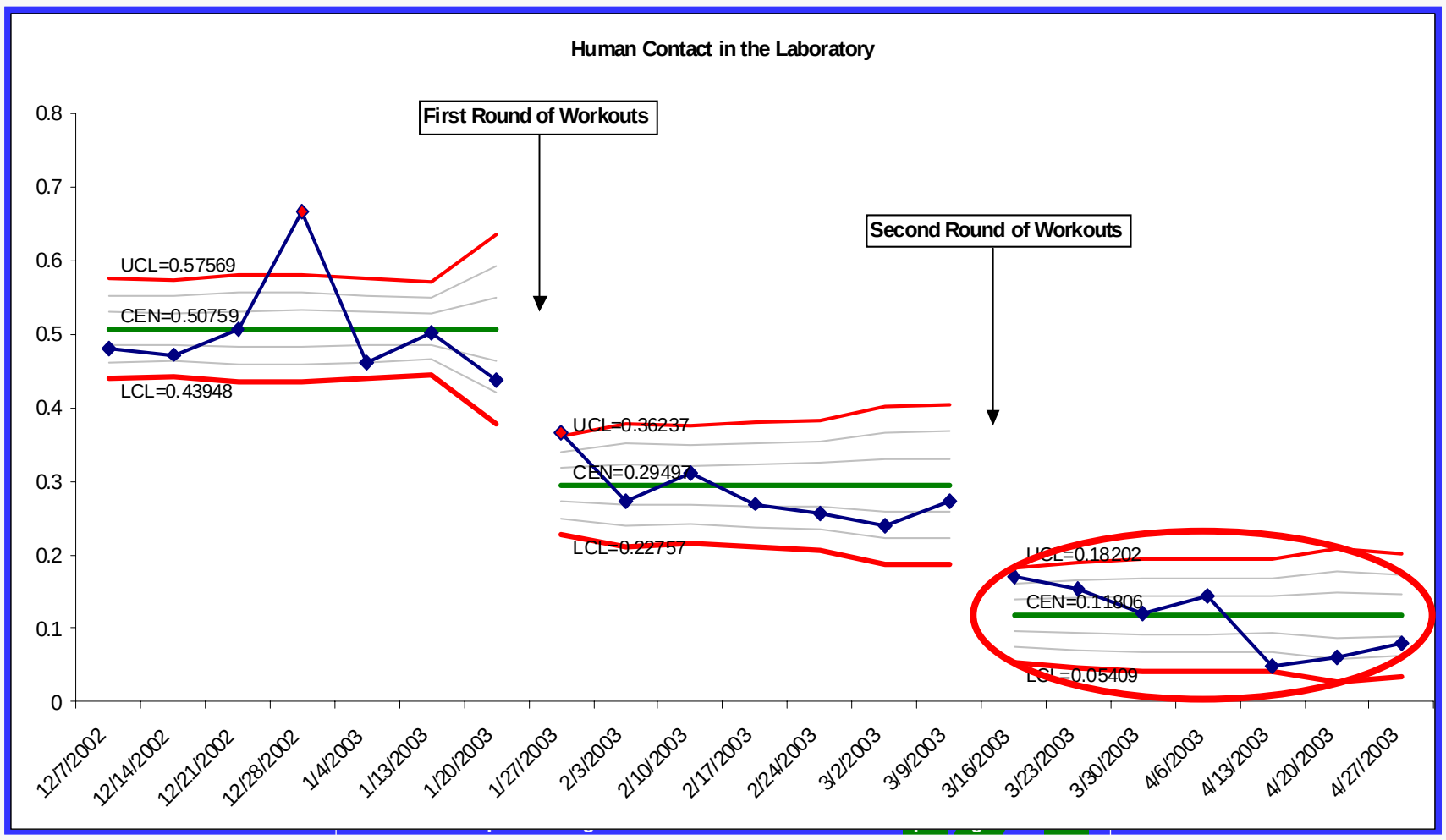


Example: HIV Genotype TAT



Key Tools: VOC, Process Mapping, Time Study, Process Capacity analysis

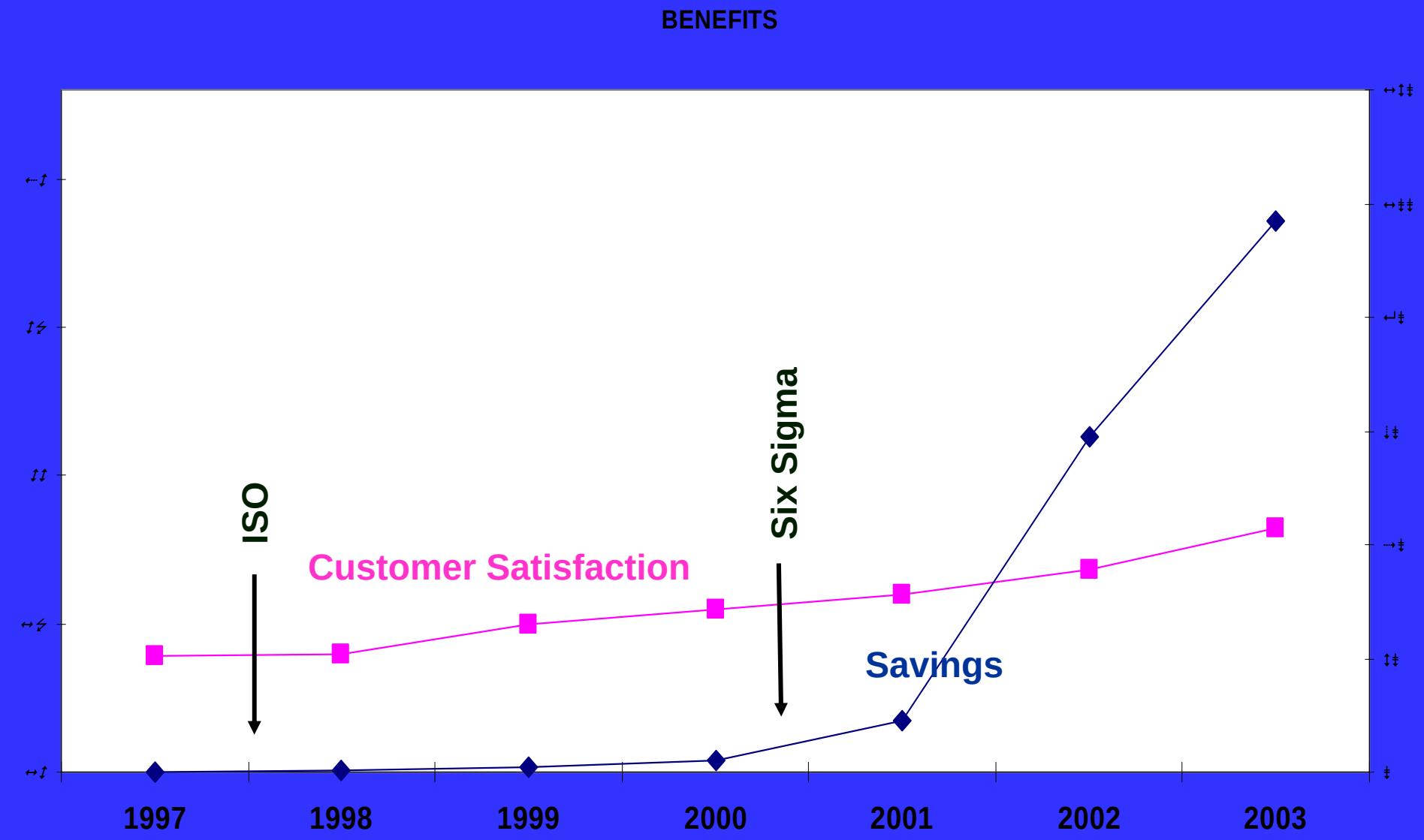
Improvements: Streamlined repeat process & instrument schedules. Implemented IT automation for reviews and reporting



Key Tools: VOC, created a reliable measure and display system

Improvements: wireless head-sets, accurate contact information in the LIS, dedicated staff for answering the phone.

What are the Overall Benefits?



QUALITY EVOLUTION

*wide use by clinical lab industry!

STAGES OF QUALITY

NCCLS Guideline GP26 (based on ISO 9000)

STAGE	ACTIVITIES PERFORMED
Total Quality Management	Total management approach centered around **"Customer Satisfaction"**
Quality Improvement	Formal process to **achieve significant improvements** and **cost savings**
Quality System	**"Comprehensive and Coordinated"** system to meet quality objectives
Quality Assurance	Organized activities to provide **"Confidence"** that the organization meets requirements for quality
Quality Control	Operational techniques applied to **"Specific Tasks"** for quality and regulatory compliance.

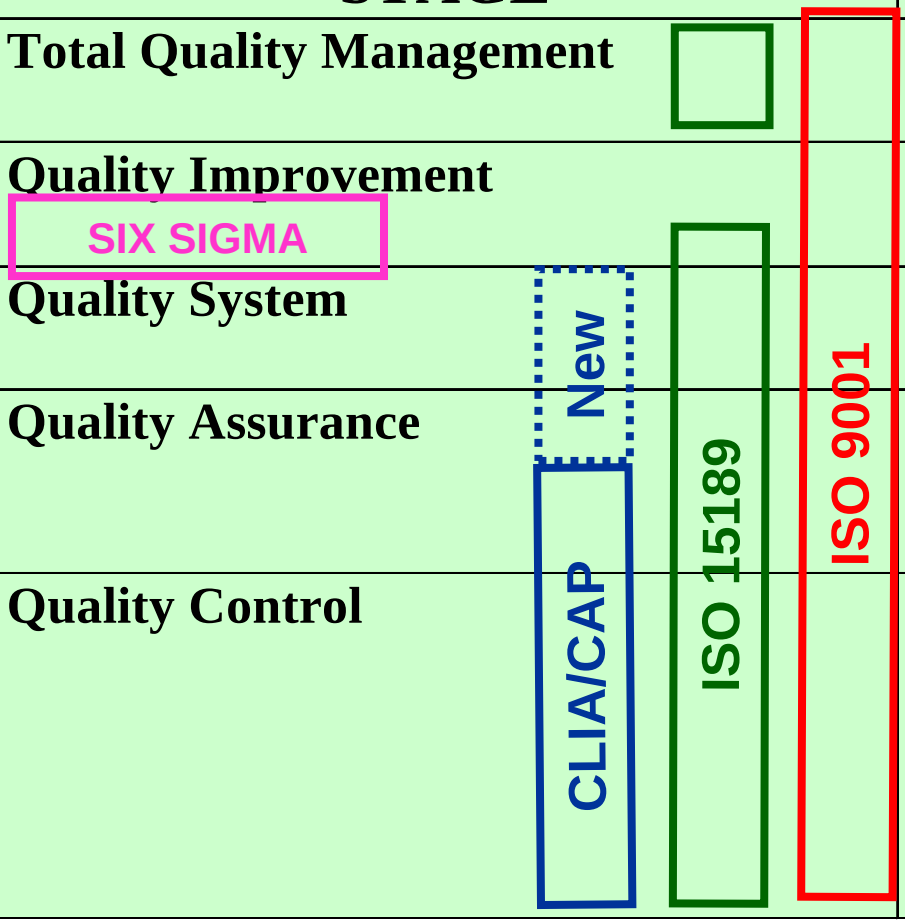
JURAN AND NCCLS

JURAN	NCCLS GP26
Strategic Quality Management	Total Quality Management
	Quality Improvement
Operational Quality Management	Quality System
	Quality Assurance
Work Force Quality Control	Quality Control

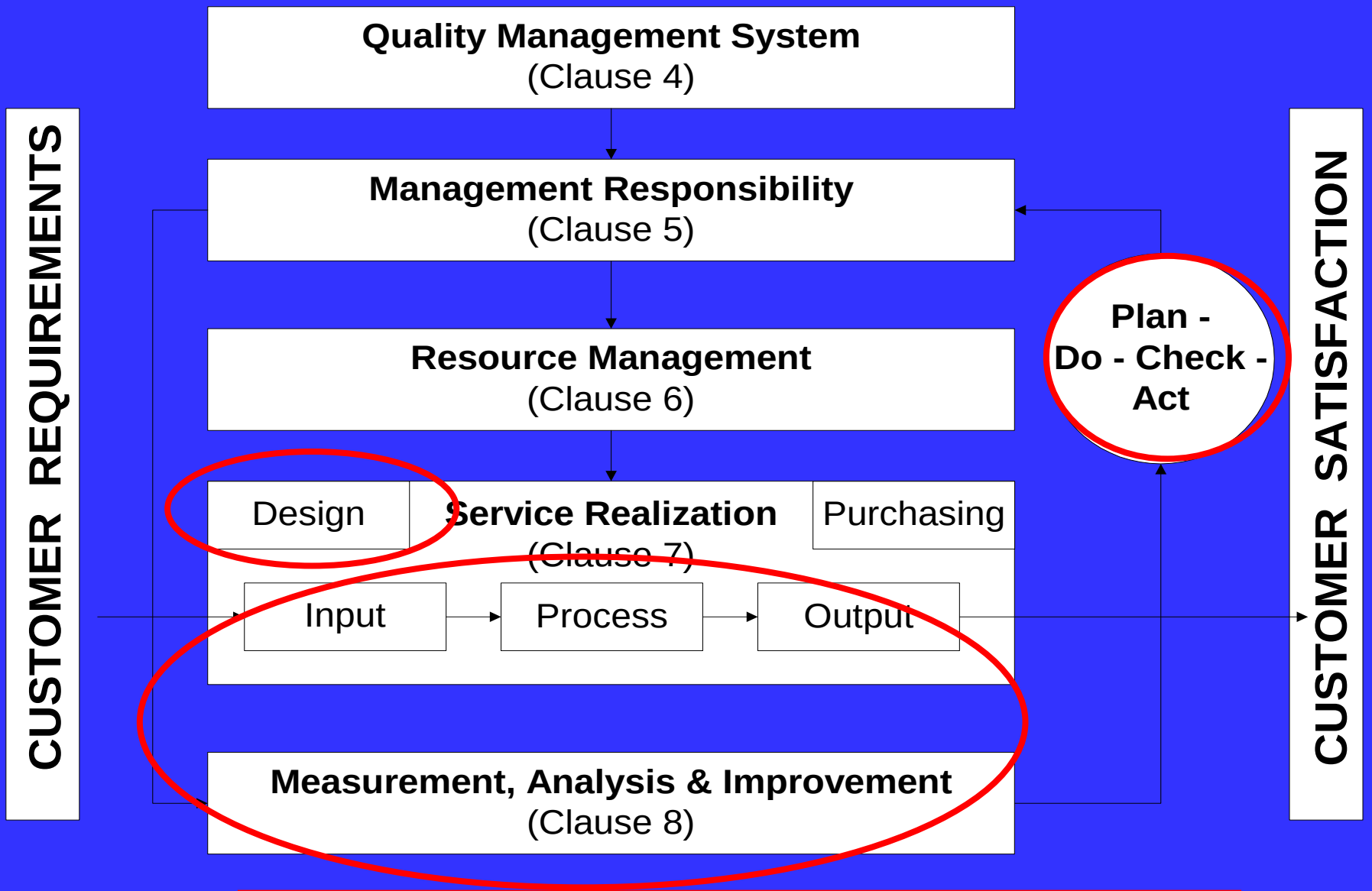
STAGES OF QUALITY

NCCLS Guideline GP26 (based on ISO 9000)

STAGE	ACTIVITIES PERFORMED
Total Quality Management	Total management approach centered around **"Customer Satisfaction"**
Quality Improvement	Formal process to **achieve significant improvements** and **cost savings**
Quality System	**"Comprehensive and Coordinated"** system to meet quality objectives
Quality Assurance	Organized activities to provide **"Confidence"** that the organization meets requirements for quality
Quality Control	Operational techniques applied to **"Specific Tasks"** for quality and regulatory compliance.

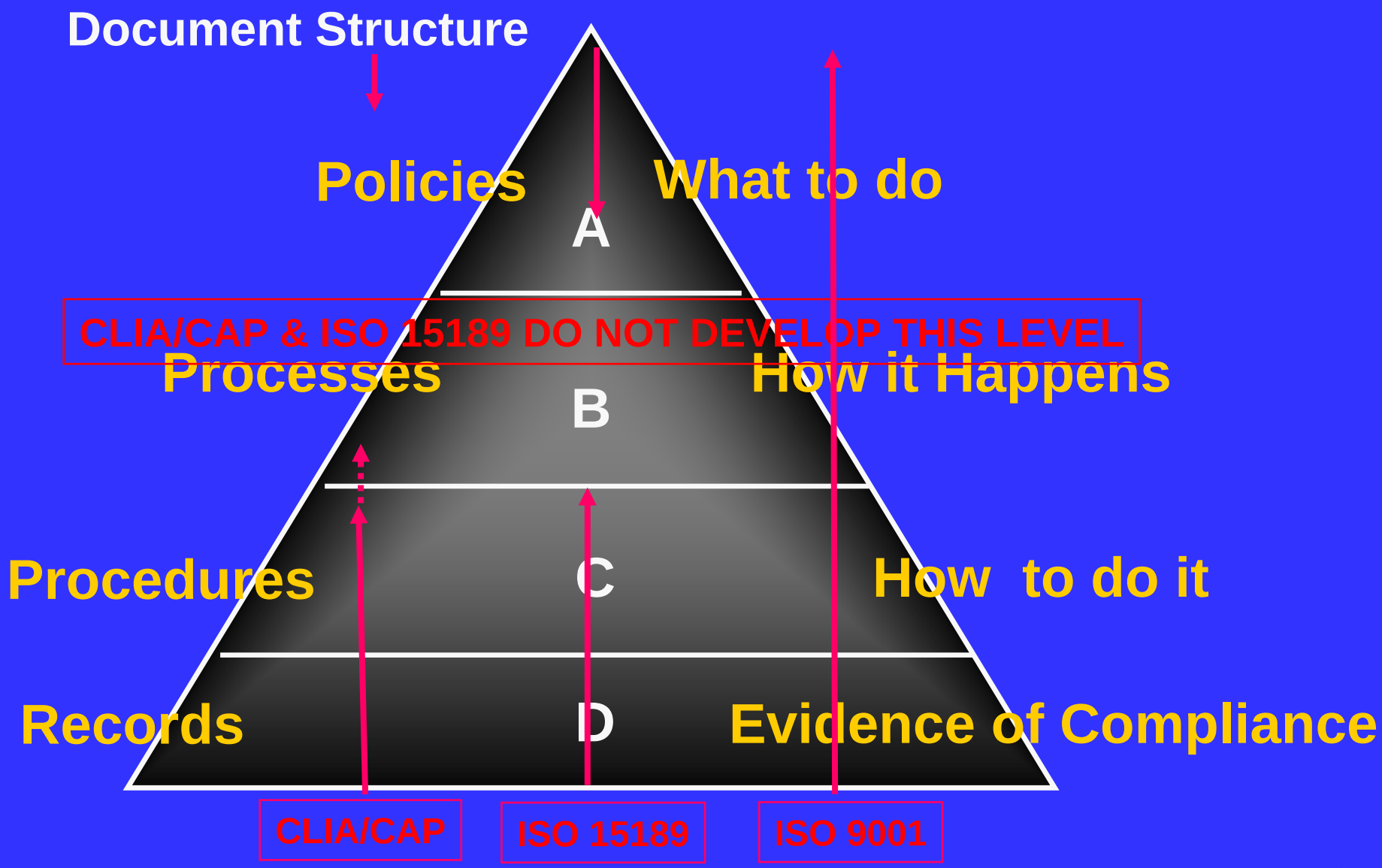


ISO 9001 - 2000 Revision



ISO 15189 does not develop these aspects

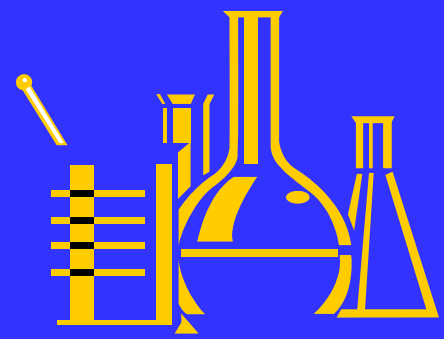
Document Management



Presentation Objectives

The presentation will answer the questions …

- **Why ISO 9001 & Six Sigma?**
- **How did Quest Diagnostics do it?**
- **What did we learn?**
- **What were the benefits?**
- **What's the difference between all these standards and how do they relate to Quality?**



Thank You for Your Time and Attention

Questions?