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 not 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

**Process Flow**

- Review Nichols Operating Plan
- Review Nichols Metrics (By Core Process / VOC Review / Customer Trends & Data / Internal VOC)
- Review Status of All Projects Against the Plan (Green/Yellow/Red)
- Review Nichols Selected Projects and Initiatives
- Identify Gaps Against Op Plan & Assign or Modify Resources

**Process Inputs**

- Operating Plan & Champion Responsible
- Metrics Based on Balanced BU Scorecard
- Project Status Summary
- Selected Project Reviews
- Parking Lot and Issues Identified During Review

**Process Outputs**

- Focus on Meeting Operating Plan Objectives
- Current & YTD Metric Status for BU Targets & Performance; New Issues
- Focus on Project Progressing Toward Meeting Op Plan & BU Resource Allocation
- Drives Project Progress, Focus on Achieving Project Desired Results
- Meet Business Unit Targets; Quality Improvement Plans
Example: Process Management

Core Process Alignment
Nichols-

Pr. Owner: Dr. Raj Pandian

Develop New Products/Services → Acquire The Customer

Pr. Owner: Dave Pauluzzi

Specimen Submission → Transport Specimen → Process Specimen → Test Specimen → Report Results → Bill & Collect

Pr. Owner: Carl Burgess
Pr. Owner: Carl Burgess
Pr. Owner: Carl Burgess
Pr. Owner: Katie Bishar
Pr. Owner: Dr. Richard Reitz
Pr. Owner: John Besser

Manage Customer Relationship

Pr. Owner: Carl Burgess

Enabling Processes

Pr. Owner: Marianne Weinell/ Lee Lavi/ Karen Dow / John Besser/ Marc Gray

Quality/Six Sigma, HR, Finance, Materials, IT
Example: Process Management

**MANAGE ACCOUNTS**

1. **ACQUIRE CUSTOMERS** 1.0
   - Acquire Patient Samples 2.0
   - Transport Patient Samples 3.0
   - Serve Customers 7.0

2. **ACQUIRE SPECIMENS AND ENTER ORDERS**
   - Acquire Patient Samples 2.0
   - Transport Patient Samples 3.0
   - Process Patient Samples 4.0
   - Test & Report Patient Results 5.0

3. **TEST & REPORT RESULTS**
   - Process Patient Samples 4.0
   - Test & Report Patient Results 5.0

4. **BILL & COLLECT** 6.0

**ENABLERS**

- **HUMAN RESOURCES** 8.0
- **MATERIALS MANAGEMENT** 9.0
- **LEGAL/COMPLIANCE** 10.0
- **FINANCE** 11.0
- **MEDICAL** 12.0
- **RESEARCH & DEVELOPMENT** 13.0
- **INFORMATION TECHNOLOGY** 14.0

**QUALITY PLANNING**

**MACRO MAP**
Example: Process Management
A deeper dive!

Perform Pre-route Duties SOP

PSC / Client Visit SOP

Record Sample Information

Client Visit Problem Resolution SOP

Are there any Sample or Information Problems?

Process Patient Samples Map 4.0

Process Patient Samples Map 4.0

Deliver Samples to Processing SOP

Prepare Samples for Shipment SOP

Post Route Duties SOP

Are there any Outstanding Issues?

No

Document Storage

Yes

Supportive Documents

ACQUIRE CUSTOMERS Map 1.0

ACQUIRE PATIENT SAMPLES Map 2.0 & 2.1

ACQUIRE PATIENT SAMPLES Map 2.0 & 2.1

ACQUIRE PATIENT SAMPLES Map 2.0 & 2.1

Process Management

September 2, 1999

ACQUIRE CUSTOMERS Map 1.0

TRANSPORT PATIENT SAMPLE
Courier Service Map 3.0

Record Sample Information

Process Management

Supportive Documents

September 2, 1999

Check with Dispatch for Messages

Return to Testing Lab or Courier Hub

Prepare Samples for Shipment SOP

All Other Non-Sample Deliveries SOP

Supportive Documents

Septemder 2, 1999

Post Route Problem Resolution SOP

Post Route Problem Resolution SOP

Document Storage

No

Yes
Example: Document Management

Document Structure

Policies

What to do

A

Processes

How it Happens

B

Procedures

How to do it

C

Records

Evidence of Compliance

D
Document Structure

Actual

LEVEL A
- COMPLIANCE MANUAL
- QUALITY MANUAL
- EMPLOYEE HANDBOOK
- QUALITY BINDER

LEVEL B
- GENERAL LAB MANUAL
- GENERAL PROCEDURES AND INFORMATION
- MATERIALS MANAGEMENT MANUAL

LEVEL C
- 18 LAB DEPT. MANUALS
- RESEARCH & DEVELOPMENT MANUAL
- QA MANUAL
- OTHER DEPT. MANUALS
- SHIPPING & RECEIVING MANUAL

LEVEL D
- RECORDS

Example: Document Management

Document Management (Quality Manual)
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
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.

### Example: Measurement

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

Average TAT 8%
Service Event Summary Report
Client 52572
From 01 MAY 2004 to 31 MAY 2004

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

Test Not Performed (TNP) Analysis

<table>
<thead>
<tr>
<th>TNP Comment Description</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>TNP-INTERFERING SUBSTANCE PRESENT. UNABLE TO QUANTITATE.</td>
<td>1</td>
</tr>
<tr>
<td>TNP-Specimen exceeds Quest Diagnostics, Nichols Institute’s recommended; stability range. Please resubmit. Charges have been cancelled.</td>
<td>1</td>
</tr>
<tr>
<td>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.</td>
<td>1</td>
</tr>
<tr>
<td>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.</td>
<td>1</td>
</tr>
<tr>
<td>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</td>
<td>1</td>
</tr>
<tr>
<td>TNP-Duplicate test order. Test has been cancelled.</td>
<td>5</td>
</tr>
<tr>
<td>TNP-INTERFERING SUBSTANCE PRESENT. UNABLE TO QUANTITATE.; TNP-Unable to calculate due to interfering substance.</td>
<td>1</td>
</tr>
<tr>
<td>TNP-TEST REQUEST CANCELLED - NO CHARGE.</td>
<td>5</td>
</tr>
<tr>
<td>TNP-Cancelled per client request.</td>
<td>9</td>
</tr>
<tr>
<td>TNP-Cancelled per client request.; TNP-NO SAMPLE RECEIVED.</td>
<td>1</td>
</tr>
</tbody>
</table>

Total 35
Example: 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 PROCESS**

1. **DOCUMENT JOB REQUIREMENTS AND DUTIES IN JOB DESCRIPTION**
2. **IDENTIFY TRAINING NEEDS BASED ON DUTIES AND PROCEDURES TO BE PERFORMED**
3. **CREATE TRAINING CHECKLIST**
4. **PERFORM & DOCUMENT TRAINING**
5. **FILE TRAINING RECORD IN DEPARTMENT**
   - Are additional tasks to be performed? **NO** → NO ACTION
   - Are new tasks documented in the job description? **YES**

**TRAINING MANAGEMENT**
Example: Supplier Management

SUPPLIER NON-CONFORMANCE DATA COLLECTION & DOCUMENTATION PROCESS FLOW

1. Lab Identifies Supplier Performance Deficiency for Material or Service Provided
2. Lab Contacts Supplier for Technical Assistance & Deficiency Resolution
3. Lab Reports Supplier Performance Deficiency at Daily Lab Ops Meeting Using Applicable Database Non-Conformance Code
4. Lab Ops Database is Updated with Supplier Performance Deficiency Data
5. Lab Ops Database Generates Supplier Root Cause Analysis/Corrective Action Form & Cover Letter
6. Materials Department Edits/Issues Cover Letter & Root Cause Analysis/Corrective Action Form To Supplier
7. Supplier Completes/Returns Root Cause Analysis/Corrective Action Form to Materials Manager & Distribution
8. Supplier Root Cause Analysis/Corrective Action Form Response Entered into Lab Ops Database
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).
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

HIV Genotype Assay Cycle Time

Target Cycle Time 168 Hours

Setup Date

Process Improvements In Place

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

**Human Contact in the Laboratory**

**First Round of Workouts**

**Second Round of Workouts**

**Improvements:** wireless head-sets, accurate contact information in the LIS, dedicated staff for answering the phone.
What are the Overall Benefits?

ISO Implemented

BENEFITS

Customer Satisfaction

Savings


QUALITY EVOLUTION

STRATEGIC QUALITY MANAGEMENT (1980s) (2000s*)

OPERATIONAL QUALITY MANAGEMENT (1950s) (1980s*)

WORK FORCE QUALITY CONTROL (1920s) (1950s*)

*wide use by clinical lab industry!
## STAGES OF QUALITY

**NCCLS Guideline GP26 (based on ISO 9000)**

<table>
<thead>
<tr>
<th>STAGE</th>
<th>ACTIVITIES PERFORMED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Quality Management</td>
<td>Total management approach centered around “Customer Satisfaction”</td>
</tr>
<tr>
<td>Quality Improvement</td>
<td>Formal process to achieve significant improvements and cost savings</td>
</tr>
<tr>
<td>Quality System</td>
<td>“Comprehensive and Coordinated” system to meet quality objectives</td>
</tr>
<tr>
<td>Quality Assurance</td>
<td>Organized activities to provide “Confidence” that the organization meets requirements for quality</td>
</tr>
<tr>
<td>Quality Control</td>
<td>Operational techniques applied to “Specific Tasks” for quality and regulatory compliance.</td>
</tr>
<tr>
<td>JURAN</td>
<td>NCCLS GP26</td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>---------------------------------</td>
</tr>
<tr>
<td><strong>Strategic Quality Management</strong></td>
<td><strong>Total Quality Management</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Quality Improvement</strong></td>
</tr>
<tr>
<td><strong>Operational Quality Management</strong></td>
<td><strong>Quality System</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Quality Assurance</strong></td>
</tr>
<tr>
<td><strong>Work Force Quality Control</strong></td>
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## STAGES OF QUALITY

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</tr>
<tr>
<td>Quality Assurance</td>
<td>Organized activities to provide “Confidence” that the organization meets requirements for quality</td>
</tr>
<tr>
<td>Quality Control</td>
<td>Operational techniques applied to “Specific Tasks” for quality and regulatory compliance.</td>
</tr>
</tbody>
</table>
ISO 9001 - 2000 Revision

Quality Management System
(Clause 4)

Management Responsibility
(Clause 5)

Resource Management
(Clause 6)

Design
Service Realization
(Purchasing)

Input → Process → Output

Measurement, Analysis & Improvement
(Clause 8)

Customer Requirements → Plan - Do - Check - Act → Customer Satisfaction

ISO 15189 does not develop these aspects
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?