TriCore’s Journey to ISO15189 Accreditation and Beyond

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Core Laboratory Operations
Services

- 10 hospital laboratories
- Core Reference Laboratory
- > 8.4 million tests performed in 2013
- More than 50 satellite centers
  - Cancer Centers
  - Branch Labs
  - Patient Care Centers

Faculty/staff

- >1100 employees
- 45 Medical/Scientific directors

Founded in 1998 as a unique collaboration between Presbyterian Health System and University of New Mexico Health Science Center.

TriCore Reference Laboratory is an independent not-for-profit corporation.
Management Requirements
(ISO 9001-2000/8)

Technical Requirements
(ISO/IEC 17025:2005)
• Began more than 10 years before ISO accreditation
• Builds on capabilities acquired along the way
• Integrates elements of CLIA / CAP LAP accreditation, Six Sigma, LEAN, Quality System Essentials
• They ultimately all originated in W. Edwards Deming’s Quality Revolution

ISO15189 Standards - Learning along the way
1997-2000 Building TriCore

Laboratory Services merger of UNM, PHS and The Reference Laboratory

- Forced standardization of platforms
- Merger of Cultures
- Large *project management* effort
- Created *Technical Workgroups* – focus on LAP compliance and standardization
- Quality is governed by a committee of site representatives (rotating chair)
1997-2000 Building TriCore

Required Effort

- Board of Directors stood firm
- Outside help from consultants
- Change management
- Let things run their course
Lessons Learned

• Uncovered sections with the most manual processes (i.e. microbiology & histology) posed biggest challenges to standardization efforts

• Differences in engagement persisted for some time but did not derail the effort

• Shared visions provided guidance to overcome differences

• Some people will choose to leave and new leaders emerge
2001-Variation Reduction

Focus on reducing variation in processes
• Mini- Advanced Training Program Quality Courses
• Sponsor Hospital supported and resourced

Document control process emerges
• Manually managed
• Difficult to maintain compliance

ISO15189 Standard 4.3 Document Control
ISO15189 Standard 4.9 Identification and Control of Nonconformities
ISO15189 Standard 4.12 Continual Improvement
Personal Journey
Concept of ISO 9001 introduced

- Started a dedicated system quality department (one Quality manager)
- Annual reviews of quality
- Established purchasing requirements; major vendor business reviews
- Developed electronic document control system
- Developed Risk Reporting System

ISO15189 4.2 Quality Management System
ISO15189 4.4 Review of Contracts
ISO15189 4.6 External Services and Supplies
ISO15189 4.9 Identification and control of nonconformities
ISO15189 4.15 Management Reviews
Lessons Learned

- Hard sell since ISO 9001 is tailored to industrial enterprises, not medical laboratories; no cultural connection
- Viewed as addition to daily work and not relevant
- Executive management support and resourcing is critical
2006-LEAN and Six Sigma at Core Facility

- Vendors utilized to support the effort
- 5S
- Standard work
- Kanban system
- Value stream mapping
- Started internal regularly occurring LEAN audits
- Selected Staff for engagement and enthusiasm

ISO15189 4.11 Preventive Action
ISO15189 4.6 External services and supplies
ISO15189 4.14 Internal Audits
Personal Journey
LEAN extends to Hospital Labs

- Operations Directors receive formal training
- Focus on pre-analytical variation
- Documentation of Clinical Staff input
Established New Quality Plan

- Hospital Feedback
- Quality Manager and one clerk
Management Structure Changes

- Creation of Senior Management Team
- Clinical Pathology Council
- Anatomic Pathology Council
- Pre-Analytical Services Team
2008- A Year of Change

Start of growth and transition

• Addition of two Regional Hospitals
  ➢ Bridge geographic distances
  ➢ New organizational cultures
  ➢ Contracts prevented immediate equipment standardization
  ➢ Standardized quality practices

The Foundation of Quality allowed for easier transition without derailment of Quality process improvement.
New CEO- Quality Champion

- Decide on formal quality development (ISO 15189 or QSE)
- Selected ISO 15189
  - Message “Not Going Away”
  - Right framework for systematic change management
  - External accreditation

Quality department adds process engineering to their skill set
At start of ISO accreditation, we had some experience with:

ISO15189  4.1  Organization and Management
ISO15189  4.2  Quality Management System
ISO15189  4.3  Document Control
ISO15189  4.4  Review of Contracts
ISO15189  4.6  External Services and Supplies
ISO15189  4.7  Advisory Services
ISO15189  4.9  Identification and control of nonconformities
ISO15189  4.11 Preventive Action
ISO15189  4.12 Continual Improvement
ISO15189  4.13 Quality and Technical Records
ISO15189  4.14 Internal Audits
ISO15189  4.15 Management Reviews
ISO15189  5  Technical Requirements largely overlap with CAP-LAP accreditation
But we were missing:

ISO15189 4.5 *Examination by Referral Laboratories*

ISO15189 4.8 *Resolution of Complaints*

ISO15189 4.10 *Corrective Action*
2008- A Year of Change

Lessons Learned

• Quality manager needs ability to manage change and be an implementer - not just understand charts and matrixes

• Resolution of complaints needs a formal process

• First hint of personnel credentialing issue
Three more Regional hospitals acquired

TriQual Formalized

- Authority matrix for Quality developed
- Quality Planning Team
- Research Committee
- IT Governance Committee

ISO15189 4.2 Quality Management System
ISO15189 4.13 Quality and Technical Records
RFP for first major platform standardization across enterprise (10 sites across New Mexico)

- Project Management
- All sites participate
- Standardized procedures and reference ranges
- Completed in 28 months
PERSONAL JOURNEY
ISO 15189 – start of formal accreditation for three sites as a system (Core lab and two tertiary care hospitals)

- Quality hires six sigma black belt with ISO background, trainer with ISO audit credentials
- GAP assessment
- Recognize need for root cause training
Divide and conquer-
Operations Directors formed system wide teams to address assigned clauses.

- Document control
- Equipment
- Competency and training
- Internal audits

And we opened a new Hospital Laboratory!
<table>
<thead>
<tr>
<th>QSE</th>
<th>Element Audited/Reviewed</th>
<th>HOW and WHERE the Audit Information is Captured and WHO is Responsible</th>
<th>Source Doc</th>
<th>Source Procedure</th>
<th>Indicate where the MD Reviews and signs</th>
<th>Indicate if (and what) information for each element gets reported as the deviation, deviation and TriCue</th>
<th>How Monitored</th>
<th>Issue to QOCB?</th>
<th>Where in the System</th>
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</thead>
<tbody>
<tr>
<td>Q</td>
<td>Quality Indicators</td>
<td>No</td>
<td>Weekly Checks</td>
<td>Monthly Dept Audits</td>
<td>DOC Procedure</td>
<td>Monthly QA review</td>
<td>Yes</td>
<td>Exceptions</td>
<td>Yes</td>
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<tr>
<td></td>
<td>High Severity Nonconformities, A, B risk assessments</td>
<td>Reviewed by mgr and assigned to staff thru ITS system</td>
<td>No</td>
<td>Audit ITS for completeness</td>
<td>Quality Assurance Indicators-QIAF</td>
<td>Monthly QA review</td>
<td>Yes</td>
<td>Major exceptions</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>A &amp; B Risk assessments</td>
<td>Reviewed by mgr or designated and assigned to staff thru ITS system</td>
<td>No</td>
<td>Audit ITS for completeness</td>
<td>Incident Tracking System Procedure: Customer Complaint Procedure, Formal Corrective Action Plans</td>
<td>Monthly QA review</td>
<td>Yes</td>
<td>Major exceptions</td>
<td>No</td>
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<tr>
<td></td>
<td>ITS Outstanding</td>
<td>No</td>
<td>Mgr reviews &amp; follows up w/assigned staff</td>
<td>Manager audits ITS for completeness</td>
<td>Incident Tracking System Procedure: Customer Complaint Procedure, Formal Corrective Action Plans</td>
<td>Monthly QA review</td>
<td>No</td>
<td>Major exceptions</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Formal Action Plans</td>
<td>No</td>
<td>Submitted as assigned, as identified in ITS system or as determined by QI action thresholds</td>
<td>Monthly QA review</td>
<td>Yes</td>
<td>Yes</td>
<td>Major only</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

Organized by Quality System Essentials
Quality Review Roll Up
ISO 15189 – Accreditation!

- Kept audits going
- Addressed nonconformities
- Worked on metric standardization, “roll up” capabilities
- Management reviews
  - New risk reporting system
  - Recognized document control system software was inadequate

ISO15189 Standard 4.8 Resolution of Complaints ✅
ISO15189 Standard 4.12 Continual Improvement ✅
2011- ISO Accreditation!

Directory of Service improvements

• Change management processes implemented
• Reduced sources of information to DOS only

Personnel

• Implemented credential verification of ALL staff

ISO15189 Standard 5.1 Personnel
ISO15189 Standard 5.4 Pre-examination Procedures
First Surveillance of System

• Strengths
  - Internal Audit
  - Preventive Action (LEAN)
  - Organization and Management

• Improvements Needed
  - Corrective Actions
  - Quality Manual and Processes-New quality Matrix
Second Platform implemented across the enterprise (10 hospitals, one cancer center and Core Facility)

- RFP written based on requirements
- Evaluations are scored based on requirements
- Project Management
  - Three month RFP
  - Nine Month installation time

Decrease in project completion by 19 months!
2013 Surveillance II

Second Surveillance of System

• Strengths
  - Staff involvement
  - New staff aware of quality processes
  - Implementation of new document control system

• Improvement Needs
  - Need better root cause analysis
  - Space for Hospital Labs
  - Work to improve Kanban systems
Metrics

✓ Decreased lab Cost Per Adjusted Patient Day by 4.7%
✓ Outpatient Satisfaction increased from 95% to 99%
✓ Lab Error rate decreased by greater than 10%
✓ Turn Around Times decreased by 17%
✓ Decrease in send out testing from 23% to 1.8 % of all tests
✓ 230 independent Physicians have written payers requesting TriCore
Total Company
Cost Per Test Actual vs. Annual Medical Care Services CPI
New Accreditation

- First three labs scheduled for May 2014 for re-accreditation
- Adding three Central New Mexico hospital laboratories to ISO Accreditation in October 2014
Personal Journey
What ISO 15189 has given TriCore

- Ability to apply principles to new technology
- Disciplined vendor reviews - saved $$$
- Personnel validation
- Defined quality management system
- Defined project management skills
- Continuous internal audit - always inspection ready
- Improved responsiveness to our clients
2014 And beyond!!

What value ISO brings for years to come:

• Applying validation principles to new and complex testing, in particular
  ➢ genomics/sequencing and interpretation
  ➢ conversion of microbiology into a molecular/proteomics specialty

• Continue to apply techniques and validation principles of the clinical laboratory to histology and anatomic pathology
What value ISO brings for years to come:

- An organized process to tackle the new frontiers
  - “pre-pre-analytic” such as test ordering and utilization,
  - “post-post analytic” which essentially includes all aspects of information management and reporting
  - population management
  - Evidence based genomic testing
Current Challenge – Change Management

- Rapidly changing regulatory environment
- Personnel
- Supply Chain Issues
- Equipment uptime
- Closing the IT gap
Personal Journey
Questions?