Lab Quality Managers Roundtable

Anne T. Daley

MS, CMQOE(ASQ)CSSBB, MT(ASCP) DLM

Quality Officer

ARUP Laboratories

Jean Hammelev

MBA/HCM, CT(ASCP)

Vice President, Operational Excellence

Sonora Quest Laboratories /

Laboratory Sciences of Arizona

Learning Objectives

By the end of this Special Session, you will be able to:

- learn from peers what is working and not working in their laboratories.
- discuss with peers various techniques, approaches, and methods for facilitating continual improvement, creating a culture of quality in the laboratory, implementing a quality management system, and much more!
- develop immediate strategies to address quality issues within the participant's organization.

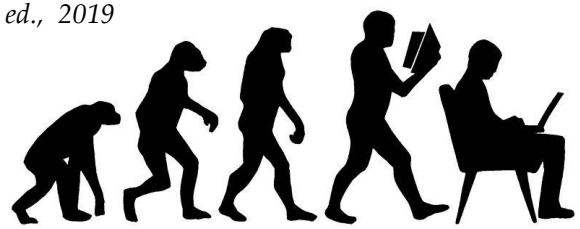
How the Session Will Work

- Session is being recorded, so everyone must speak into a microphone
  - Please wait for a facilitator to provide a microphone before speaking
- Discuss “Hot” Topics In Quality
  - Provided by facilitators
  - Provided by participants
- First topic
  - Where is your laboratory in its evolution of quality?

Evolution of Quality – Where's Your Lab?

Elements	QC	QA	QMS
Focus	Method control	Process management	Laboratory-wide system
Scope	Verified examination method controlled to ensure production of correct results by: • Instrument's internal controls • Manufacturer's control materials • Purchased external control materials	Accuracy and efficiency of: • Preexamination processes • Examination processes • Postexamination processes	Effectiveness and sustainability of the management and technical processes that support and move work through the laboratory
Limitations	Does not prevent preexamination or postexamination errors	Does not prevent errors that occur outside the path of workflow processes listed above	No limitations, by including all aspects of laboratory management and technical operations
Evolution of levels	QC was the beginning of quality measures in the medical laboratory.	QA's process focus is broader than QC's method focus.	A QMS's system-wide focus is broader than QC's method focus and QA's process focus.

Resource: CLSI *A Quality Management System Model for Laboratory Services, QMS01, 5th ed., 2019*



Potential Discussion Topics

2018-19 Top Ten Deficiency Comparison

Deficiency	CAP	COLA	TJC	Comments
Competency Assessment	1	1	1	
Activity Menu	2		2	
Proficiency Testing	6,8	5,7	6,7	Handling and record keeping
Method Comparisons	3		4	
Procedure Manual	4			
Calibration Verification		8	10	
Equipment Maintenance	5,9		5	Function checks and record keeping
Not Meeting Responsibilities of Position		2,3,4,6		LD, TC/TS, Testing Personnel
QC Monitoring		9,10	8	Waived and non-waived
Reagents Labeling and Expiration	7,10			
Complete Lab Report			3	

ISO 15189:2012 Deficiency Trends

A2LA	IQMH	ISO 15189	Citation
8		4.1	Organization and management responsibility (ethical conduct, quality objectives, Lab Director responsibilities)
7		4.3 *	Document Control (documents reviewed/approved before use & periodically, master document list, change control)
6	2,3,4, 10	4.14	Evaluation of audits (internal audits, quality indicators, risk management, external assessment of POCT)
	5	4.15	Management Review (discharging actions)
10	1	5.1	Personnel (training, competency – blood product admin)
9		5.2 *	Accommodation and environmental conditions (control, monitoring, and recording lab environmental conditions)
1,3	6	5.3 ***	Laboratory equipment, reagents, and consumables (maintenance, calibration, inventory records, traceability)
	7	5.4	Pre-examination processes (transport bag evaluation)
4	8,9	5.5	Examination processes (measurement uncertainty, validation, verification, documented procedure)
2,5		5.6	Ensuring quality of examination results (PT, defining QC)

Resource: A2LA data reported by Director of Government Relations on 9/27/2019
IQMH data reported by Director, Centre for Education on 10/8/2019

Moderator's Suggestions

- Regulatory Landscape (CLIA, CAP, COLA, TJC, ISO)
- Approach to Performance Excellence (Culture of Quality)
  - Quality Organizational Structure
  - Continual Improvement Approaches
- Performance Metrics (What to Measure and How)
- Process Automation

Open Discussion

THANK YOU!

Additional Discussion Slides

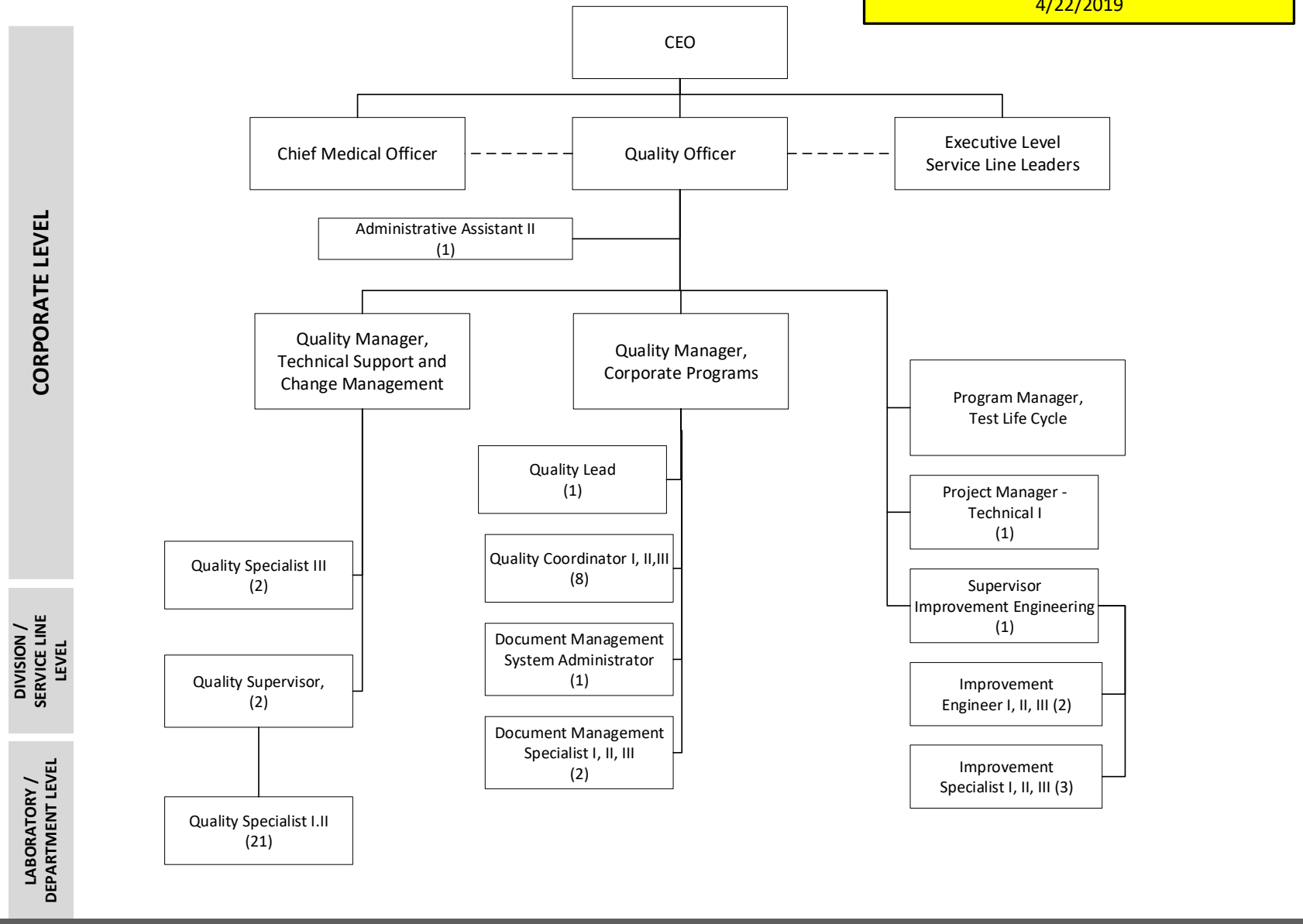
Interpreting the Regulations & Standards

- **Needs to / must / shall / is** – explains an action directly related to fulfilling a regulatory and/or accreditation requirement or is indicative of a necessary step to ensure patient safety or proper fulfillment of a procedure
- **Require** – represents a statement that directly reflects a regulatory, accreditation, performance, product, or organizational requirement or a requirement or specification identified in an approved documentary standard
- **Should / may be** – describes a recommendation provided in laboratory literature, a statement of good laboratory practice, or a suggestion for how to meet a requirement

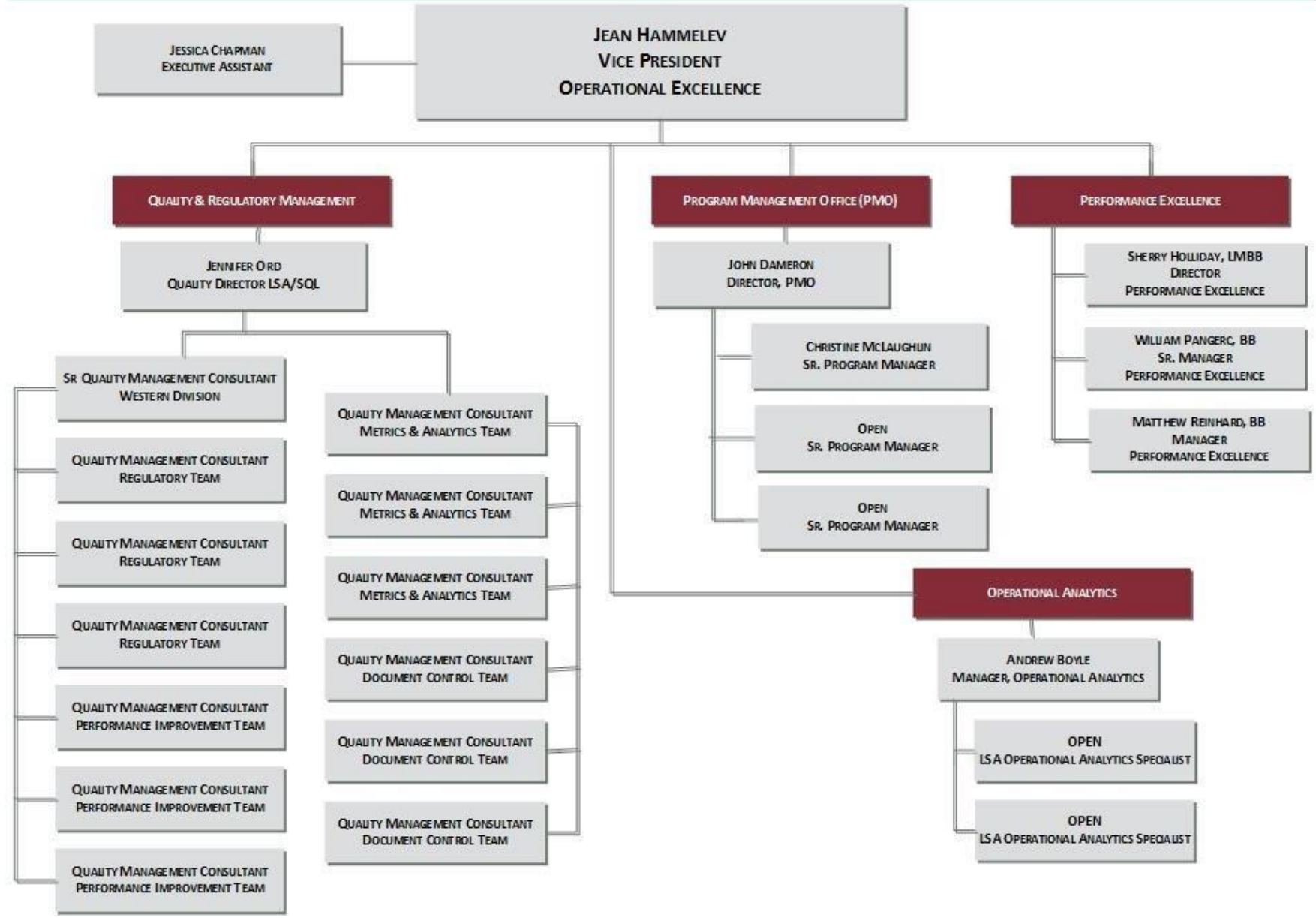
Resource: Modified from CLSI *A Quality Management System Model for Laboratory Services, QMS01, 5th ed., 2019*

Quality Systems and Support

4/22/2019



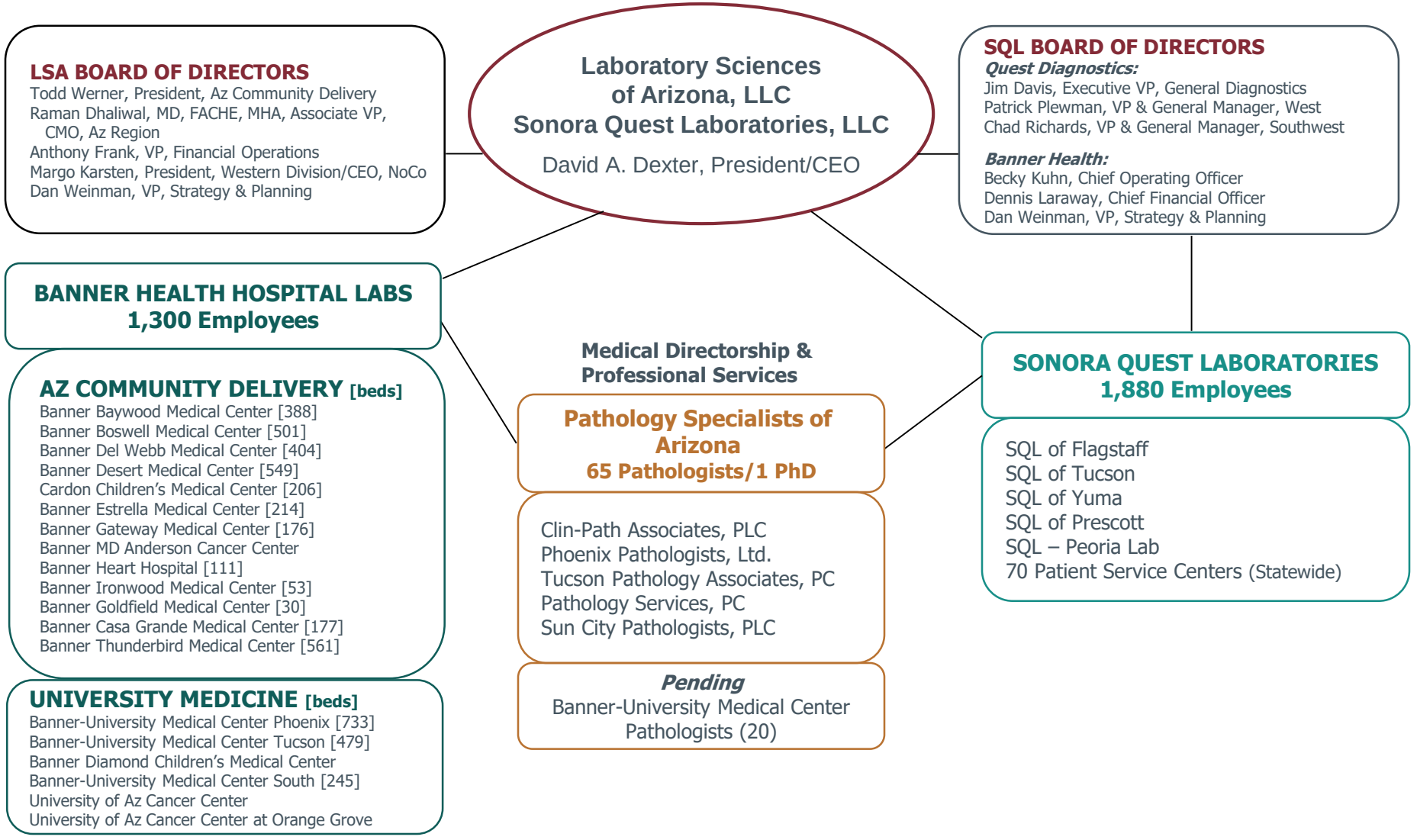
LSA/SQL Operational Excellence (OPEX)
Organizational Chart
2019



Laboratory Sciences of Arizona

Sonora Quest Laboratories™
A Subsidiary of Laboratory Sciences of Arizona

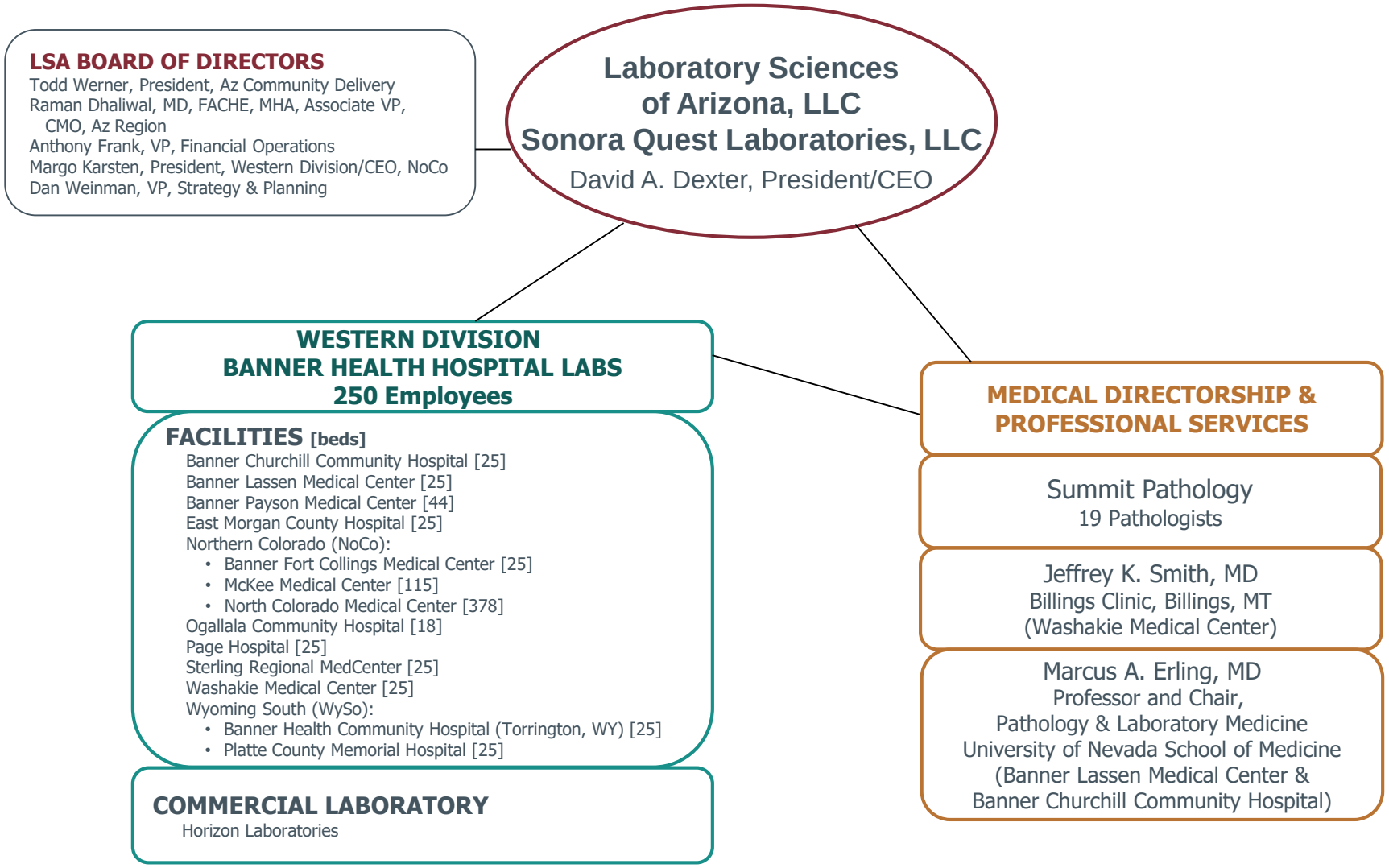
Arizona Integrated Laboratory Network



Laboratory Sciences of Arizona

Sonora Quest Laboratories™
A Subsidiary of Laboratory Sciences of Arizona

Western Division Integrated Laboratory Network



Four Types of Improvement Projects

Project Level	Methodology and Desired Outcome	Scope	Documentation Tool	Sponsor	Examples
Just Do It	Implement a known, obvious, and simple solution	Intra-department	Work Request	Lead	Error proofing, low risk/low impact improvements
Yellow Belt	Reduce waste with Lean using Best in Class method	Intra-department	A3	Supervisor	Staff identified problems: storage, motion, and spatial improvements
Green Belt	20% or $20K improvement, Reduce variation with Lean Six Sigma	Intra-division Inter-division	Charter Storyboard	Manager, Director, Executive if applicable	Sharing of specimens within AP
Black Belt	40% or $50K improvement, Reduce variation with Lean Six Sigma	Inter-division System Wide	Charter Storyboard	Executive Director	Unnecessary Excepts, Test Packet Review

Focused Plan: The Strategy

ROADMAP 2019

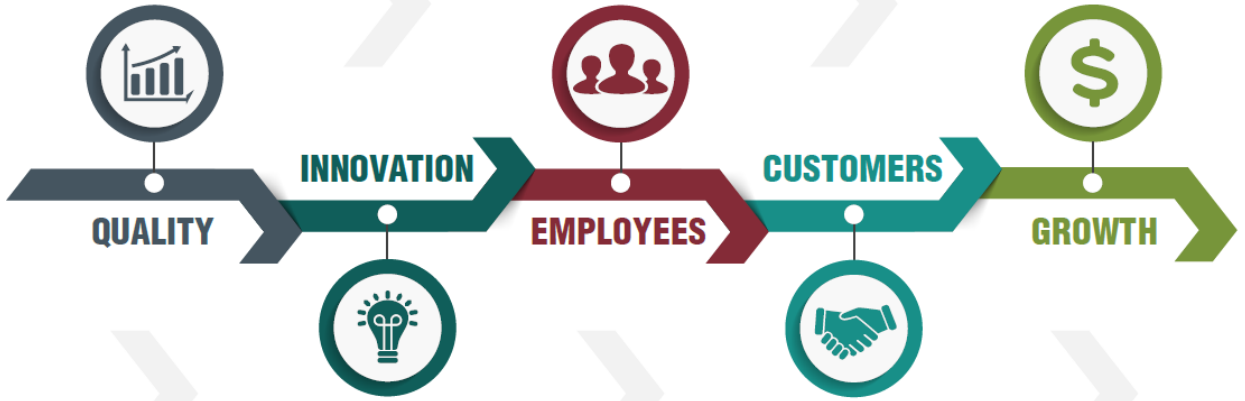
"Differentiate Through Value"

Sonora Quest Laboratories™ | Laboratory Sciences of Arizona

Drive Performance Excellence
- Measure & Manage the Right Things
- Continuously Improve Performance
- Safeguard Diagnostic & Information Assets

Engage & Inspire Each Other
- Attract, Develop & Retain the Best People
- Connect All Employees Via Technological Solutions

Accelerate Growth
- Establish Value Added Revenue Streams
- Support Banner Health & Quest Diagnostics Growth Strategies
- Minimize Cost & Reduce Waste



Invest in Innovative Solutions
- Relocate SQL/Papago Campus On Time & On Budget
- Execute Business Excellence Strategies
- Launch Lab Future State 2.0

Provide an Exceptional Experience
- Build a Customer-Obsessed Culture
- Simplify Customer Interactions Through Technology

Our Mission	Our Vision	Our Values	Our Ethical Behaviors
Drive Exceptional Customer Value Across the Continuum of Care	*Be the Trusted Leader in Diagnostic and Information Services*	*Accountability, Collaboration, Compassion, Integrity, Quality*	*Decent, Fair, Honorable, Truthful*

OUR FOUNDATION

PROPRIETARY INFORMATION - FOR INTERNAL USE ONLY

Sonora Quest Laboratories™ | Laboratory Sciences of Arizona

Terminology Confusion

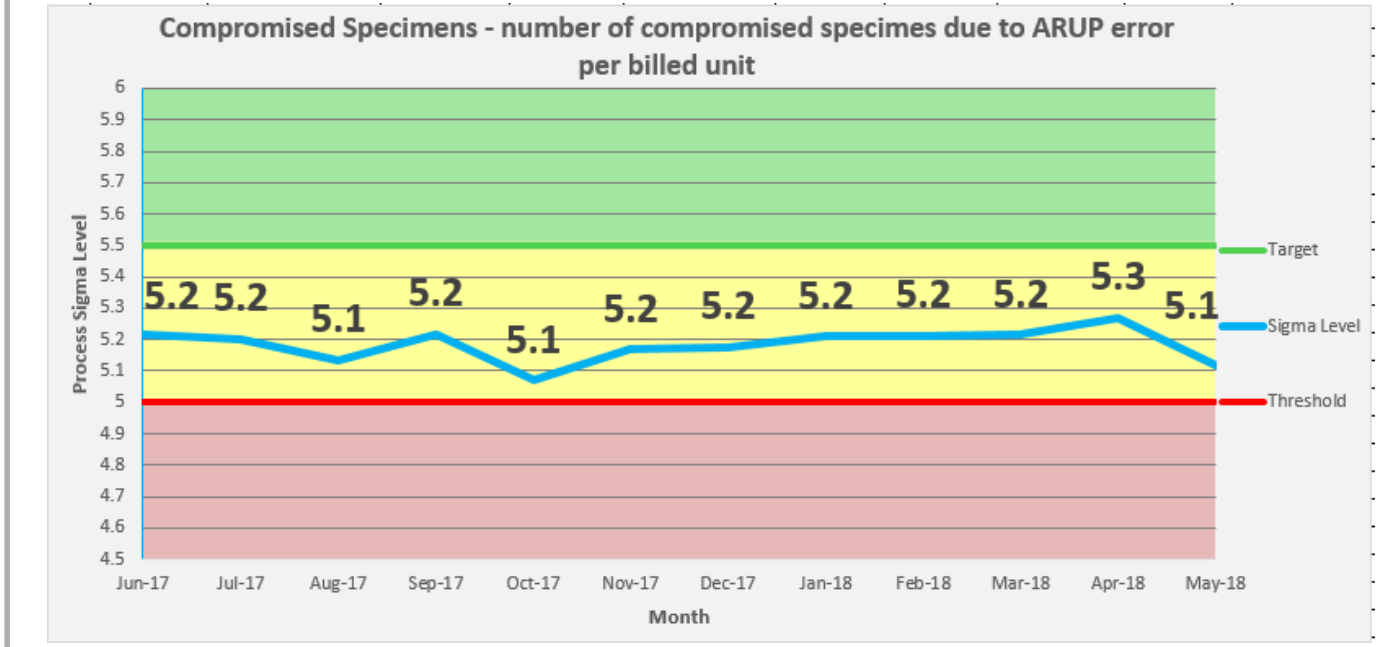
Table 6. Important Relationships in Quality Indicator Development

	Purpose	Question	Example
Goal	States how the strategic plan can be accomplished	"What do we do to achieve our strategic plan?"	Improve customer satisfaction
Objective	Specifies an action that, when achieved, will help fulfill a goal	"How will we know if we are achieving our goals?"	Reduce TAT of cardiac markers to the ED by 30% within 4 months
Indicator	Measures performance of the work process involved in the objective	"How close are we in achieving the objective?"	Data measuring time from specimen collection to release of results
Target	Reflects desired performance or expectations	"What performance level are we trying to accomplish?"	25 minutes or less
Threshold	Triggers an improvement action	"What is the poor performance level that, when exceeded, warrants our taking action?"	More than 35 minutes

Abbreviations: ED, emergency department; TAT, turnaround time.

Resource: CLSI, QMS12 *Developing and Using Quality Indicators for Laboratory Improvement,* 2nd Ed., 2019

Performance Indicators – Two Second Review



Above Threshold, below target. Improvement efforts initiated in Chemistry sections

- Red indicates below threshold – corrective action needed
- Yellow indicates above threshold, below target, no corrective action needed. Process improvement indicated.
- Green indicates above target – continue with process improvements as identified

What is Six Sigma?

A Statistical Measure of a Process's Ability to Meet Customer Requirements

Process Sigma	Process Yield	PPM/DPMO
6	99.9997%	3.4
5	99.98%	233
4	99.4%	6210
3.5	97.7%	22,700
3	93.3%	66,807
2	69.1%	308,537

Healthcare Today?

A "Stretch" Goal
6 Sigma → 3.4 DPMO

6σ Is considered "Virtual Perfection"