APHL Quality Manager Exchange

Marcia Valbracht, MHA - Manager, Quality Systems
Visit to Arizona January 10-11, 2019

Mark Pendergast, Manager, Quality Systems
Visit to New Mexico March 12-13, 2019

May 16, 2019

Quality Manager Exchange

Host: Phoenix, AZ

- Kathryn Wangsness, MHA
- Chief, Office of Laboratory Services
- Quality Assurance Manager
- Arizona State Public Health Laboratory
- 250 North 17th Avenue, Phoenix, AZ 85007

Host: Albuquerque, NM

- Allison Treloar, MS, CBA(ASQ), SLS(ASCP)CM, MBCM
- Director, Office of Quality, Safety, Security, & Emergency Preparedness / RO / RLO
- Scientific Laboratory Division
- 1101 Camino de salud, NE

  Albuquerque, NM 87102

Scope

How was the decision made to determine what topics or areas of focus would be covered during the visit?

The decision on topics was made collaboratively between visiting and hosting quality managers.

Scope - Goals of Exchange

1. Look for commonalities and differences in quality programs
2. What can we learn from one another?
   - What works well?
   - What could use improvement?
3. How can APHL facilitate improvements?

Time & Cost

Location	Airfare*	Hotel	Meals	Transportation	QMS Time (SHL)	QMS Time (Host)	SHL Cost
Arizona	*$351.40*	$218.38	$162.20	$21.00	36 hrs ($1620 @ ~$45/hr)	16 hrs	$2021.58
New Mexico	*$759.01*	$389.81	$200	$54.00	36 hrs ($1620 @ ~$45/hr)	16 hrs	$2263.81
Totals:	*$1110.50*	$608.19	$362.20	$75.00	72 hrs ($3240 @ ~$45/hr)	32 hrs	$4285.39
**APHL paid for airfare.*							

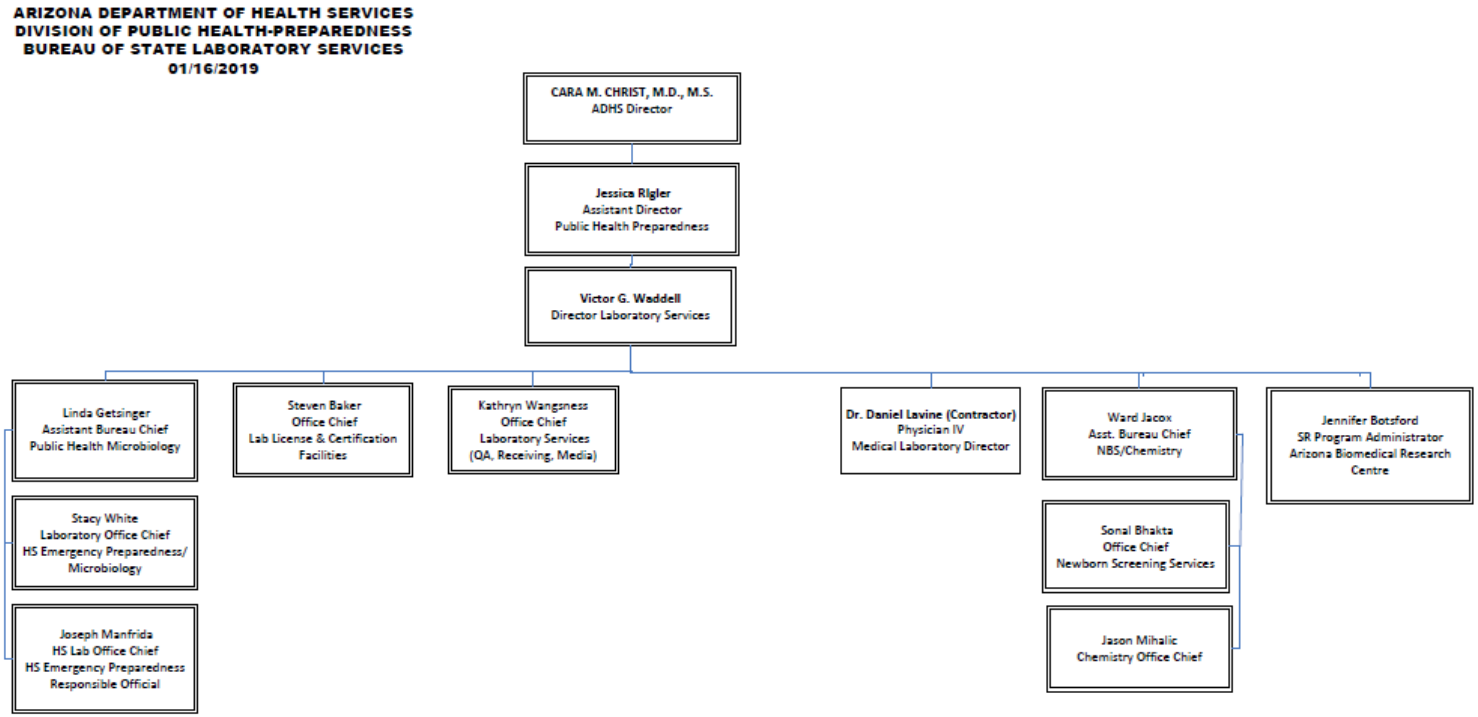
Agenda

Day 1	Day 2
8:00 – 9:30 Arrive at the site/introductions. Site tour	8:00 – 12:00 QA discussions: Quality Assurance Manual (QAM) Clinical Quality Systems Plan (QSP) Integration of multiple regulations (goals) Organization charts with roles and responsibilities
9:30 – 12:00 Quality Management System (QMS) Overview Roles and responsibilities of Quality Management (QM) staff in respective laboratories Accreditation requirements and responsibilities of QM staff Quality Culture Communications (team meetings/huddles)	
12:00 – 1:00 Lunch	12:00 – 1:00 Lunch
1:00 – 5:00 Risk Management/Continuing Improvement/Lean Internal/External audits QA Reviews (monthly reports, tracking/trending of Quality matters) Document (SOPs, etc.) writing and tracking Record retention	1:00 – 5:00 QA discussions: 12 Quality System Essentials (QSE) Management meetings/management review Tracking/Trends

Commonalities

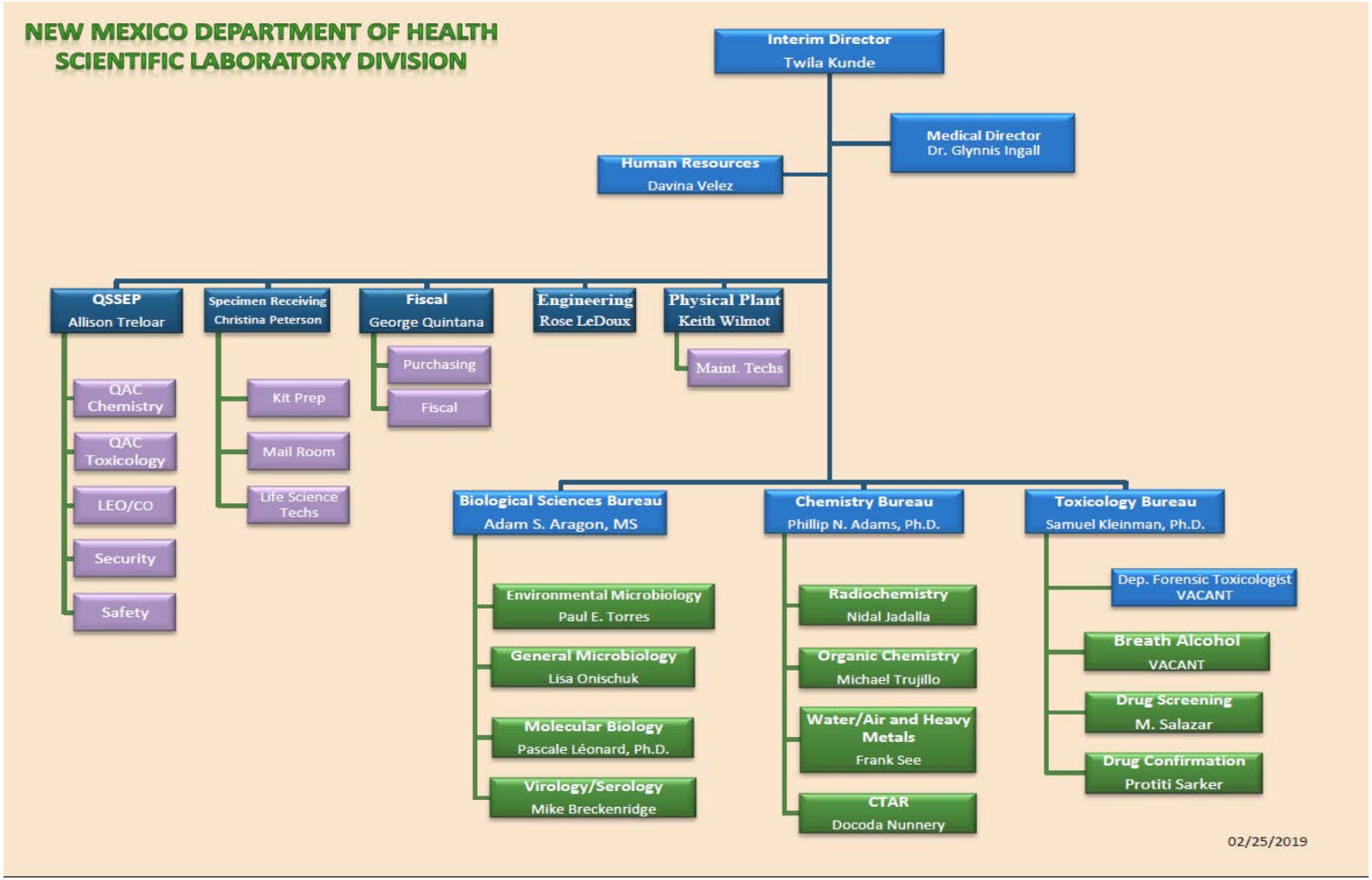
	Arizona	New Mexico	Iowa
Locations	1	1	2
Staff	77	100	156
QMS Staff	2.5	3	2.4
Accreditations/ Certifications	FDA, EPA, CMS	CMS, College of American Pathologists, American Board of Forensic Toxicologists, FSAP, FDA, EPA	CMS, EPA, TNI, AIHA-ISO 17025, Other states
Fee for service work?	NBS only	No	Yes
Document Control	Manual - reviewing software options	iPassport	iPassport

AZ Org Chart

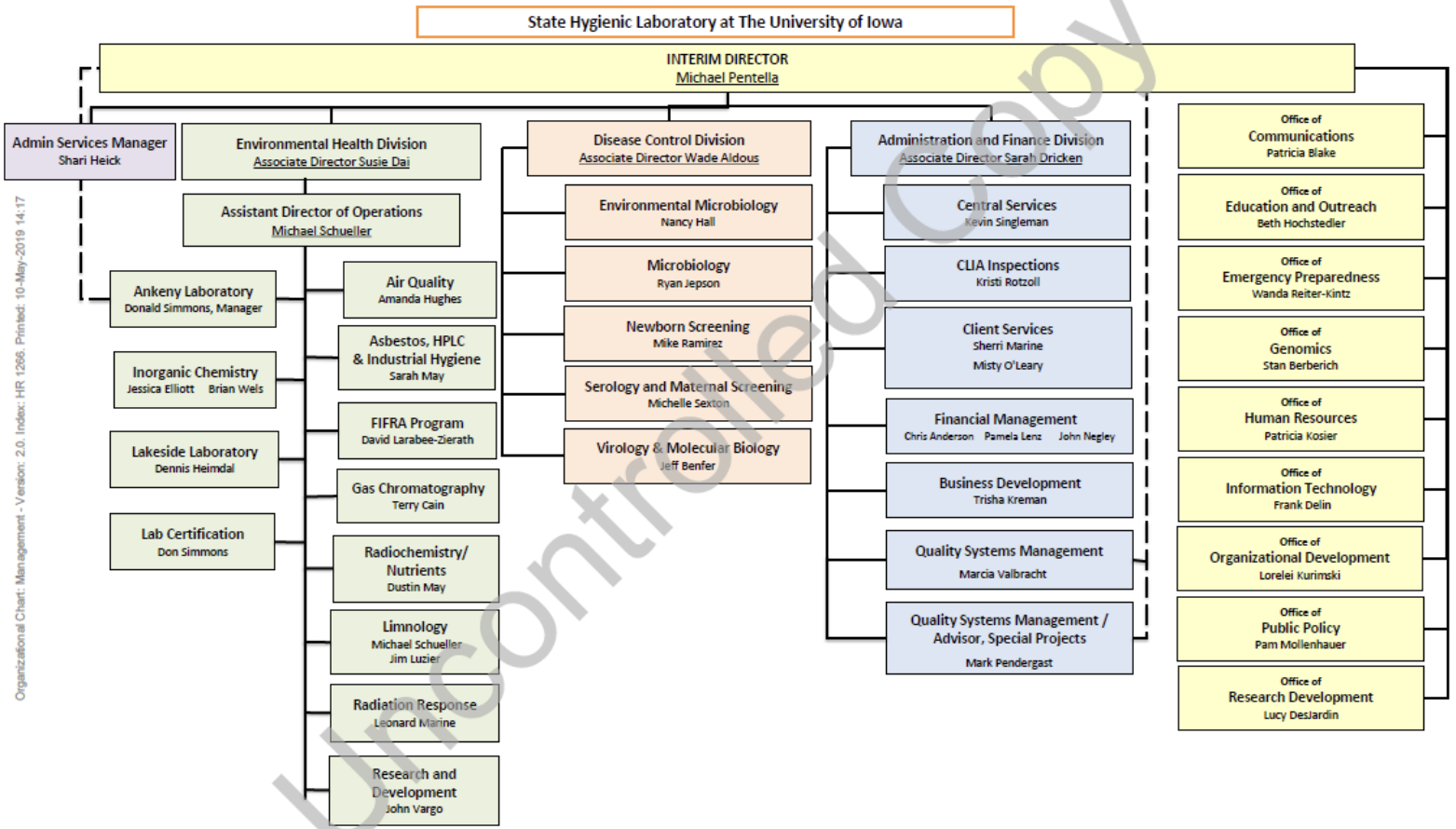


BUREAU OF STATE LAB SVCS CURRENT 01.2019.

NM Org Chart


NEW MEXICO DEPARTMENT OF HEALTH
SCIENTIFIC LABORATORY DIVISION
Interim Director
Twila Kunde
Medical Director
Dr. Glynnis Ingall
Human Resources
Davina Velez
QSSEP
Allison Treloar
QAC Chemistry
QAC Toxicology
LEO/CO
Security
Safety
Specimen Receiving
Christina Peterson
Kit Prep
Mail Room
Life Science Techs
Fiscal
George Quintana
Purchasing
Fiscal
Engineering
Rose LeDoux
Physical Plant
Keith Wilmot
Maint. Techs
Biological Sciences Bureau
Adam S. Aragon, MS
Environmental Microbiology
Paul E. Torres
General Microbiology
Lisa Onischuk
Molecular Biology
Pascale Léonard, Ph.D.
Virology/Serology
Mike Breckenridge
Chemistry Bureau
Phillip N. Adams, Ph.D.
Radiochemistry
Nidal Jadalla
Organic Chemistry
Michael Trujillo
Water/Air and Heavy Metals
Frank See
CTAR
Docoda Nunnery
Toxicology Bureau
Samuel Kleinman, Ph.D.
Dep. Forensic Toxicologist
VACANT
Breath Alcohol
VACANT
Drug Screening
M. Salazar
Drug Confirmation
Protiti Sarker
02/25/2019

IA Org Chart


State Hygienic Laboratory at The University of Iowa
INTERIM DIRECTOR
Michael Pentella
Admin Services Manager
Shari Heick
Environmental Health Division
Associate Director Susie Dai
Assistant Director of Operations
Michael Schueller
Ankeny Laboratory
Donald Simmons, Manager
Inorganic Chemistry
Jessica Elliott Brian Wels
Lakeside Laboratory
Dennis Heimdal
Lab Certification
Don Simmons
Air Quality
Amanda Hughes
Asbestos, HPLC & Industrial Hygiene
Sarah May
FIFRA Program
David Larabee-Zierath
Gas Chromatography
Terry Cain
Radiochemistry/ Nutrients
Dustin May
Limnology
Michael Schueller
Jim Luzier
Radiation Response
Leonard Marine
Research and Development
John Vargo
Disease Control Division
Associate Director Wade Aldous
Environmental Microbiology
Nancy Hall
Microbiology
Ryan Jepson
Newborn Screening
Mike Ramirez
Serology and Maternal Screening
Michelle Sexton
Virology & Molecular Biology
Jeff Benfer
Administration and Finance Division
Associate Director Sarah Dricken
Central Services
Kevin Singleman
CLIA Inspections
Kristi Rotzoll
Client Services
Sherri Marine
Misty O'Leary
Financial Management
Chris Anderson Pamela Lenz John Negley
Business Development
Trisha Kreman
Quality Systems Management
Marcia Valbracht
Quality Systems Management / Advisor, Special Projects
Mark Pendergast
Office of Communications
Patricia Blake
Office of Education and Outreach
Beth Hochstedler
Office of Emergency Preparedness
Wanda Reiter-Kintz
Office of Genomics
Stan Berberich
Office of Human Resources
Patricia Kosier
Office of Information Technology
Frank Delin
Office of Organizational Development
Lorelei Kurimski
Office of Public Policy
Pam Mollenhauer
Office of Research Development
Lucy DesJardin
Organizational Chart: Management - Version: 2.0. Index: HR 1266. Printed: 10-May-2019 14:17
Uncontrolled Copy

Commonalities

1. Quality training need for all staff in a public health laboratory
2. Roles and responsibilities must be defined for quality staff and how that relates to the organization chart.
3. Quality is more than meeting minimum accreditation requirements.
4. Leadership understanding and commitment is critical for an effective QMS.

What Works Well

- LEAN (The AZ governor made Lean training and use mandatory for all state government entities).
- Section Huddles
- Standard work (both laboratories face this within accreditation requirements and good laboratory practice)
- Monthly Section Quality Reports/Checklists (demonstrates supervisors are reviewing the quality systems for their section)

What Works Well

- Monthly meetings with QA group
- APHL QA List serve
- CLSI guidelines
- Membership in professional organizations, e.g., ASQ, TNI, APHL
- Researching quality topics through EPA, TNI, and AIHA websites

Ideas for Improvement

- Funding for Quality Management staff (additional)
- Need to emphasize one organization-one quality management system
- Roles and responsibilities well-defined within the organization

Ideas for Improvement

- Training for Quality staff with the need to know various laws and regulations for accrediting bodies
- Document control is a need for laboratories (manual vs. computer system, e.g., iPassport)
- How to prioritize tasks
  - Usually based on deadlines for accreditations
  - Scheduling items is extremely important, for example: internal and external audits, reporting to management, training for staff

Follow Up @ SHL

1. Discuss with management how we can improve the **quality culture** in the organization (engage management in quality training for all staff)
2. Better **Involve bench staff** in quality discussions
3. Review **model of quality coordinators** identified by division/section to form a unified QA Group and QMS.
4. Review **standardizing risk assessment** to prioritize limited resources and impact to the QMS.

Desired Outcomes - SHL

Further evaluation is necessary to find, recognize, and describe risks that might help or prevent the SHL from achieving objectives in relation to the Quality Management System.

Funding, training, cost of quality, and project management skills are all consistent themes identified during the exchange trip.

Desired Outcomes - SHL

Risk Identification	Treatment
Job descriptions based on the true function and duties provided by the Quality department.	Human Resources evaluating updates to JDs with leadership.
Organization charts need to reflect the objectivity necessary in the Quality Role.	Strategic Plan 2019-2020 - Goal: Redesign Organizational Structure
Management support is key, especially in shaping the Quality Culture.	Quality Management Committee; further discussion & work needed
Quality training is necessary for all staff.	Components in place; further discussion & work needed
Review model of quality coordinators identified by division/section to form a unified QA Group and QMS.	Strategic Plan 2019-2020 - Goal: Redesign Organizational Structure
Review standardizing risk assessment at the SHL to prioritize limited resources and impact to the QMS.	Initiating discussion; base on ISO Risk Mgmt. Guide 31000:2018? APHL assistance?

Project Suggestions for APHL

Training – All Staff

APHL could help facilitate this definition of roles and responsibilities with increased training and awareness by offering workshops at annual meetings and/or webinars geared to all staff (technical and non-technical) in a laboratory.

Project Suggestions for APHL

Training – Quality Managers

APHL training/orientation specific to quality staff (APHL perform training needs assessment for Quality staff)

Project Suggestions for APHL

Training – Directors

APHL training for directors on the roles and responsibilities of quality staff and how they fit into all areas of the lab. Emphasize how they can be effective.

Project Suggestions for APHL

Policy & Process Items

- How to improve the quality culture

Project Suggestions for APHL

Policy & Process Items

- Risk Assessment - Identification, analysis, evaluation, and treatment.

Is it possible to establish a consistent risk analysis model for SPHLs to assist with prioritizing limited resources?

Example: for risk analysis define scoring for severity, likelihood, and detection for QMS identified risks.

Risk Probability Number (RPN) = severity x likelihood x detection

Thank you

marcia-valbracht@uiowa.edu

mark-pendergast@uiowa.edu

Mission: The State Hygienic Laboratory at the University of Iowa protects and improves quality of life by providing reliable environmental and public health information through the collective knowledge and capabilities of our organization.