AAVLD Committee Report

(Note: Please attach any additional pages necessary for the following subtopics and your minutes / narrative)

Quality Assurance Committee	November 20, 2015
Committee	Date
Joseph Kellum	N/A
Committee Chair	Co-chair if applicable
Dr. Kristy Farmer - New Chair	
Nominees for upcoming chair / co-chair	Nominees for upcoming chair / co-chair

Committee Statement of Purpose:

The mission of the Quality Assurance Committee of the American Association of Veterinary Laboratory Diagnosticians is to be the central resource for quality assurance information, communication and support within the AAVLD.

Strategy(ies) for Committee Activity Supporting AAVLD Strategic Plan (Please List):

- To continue serving the AAVLD members who provide quality management to veterinary diagnostic labs.
- To continue to provide committee-style business as started back this year, in addition to the presentation/ informational style that it has evolved into.
- Utilize sub-committees to accomplish charges as they arise for the committee, such as the proficiency guidance document committee this past year.

Items for Review by the Executive Board (Please List):

None.

Action Items for the Committee (Please List):

- Advisory subcommittee to assist the Chair with direction and function of the committee, including other task-based subcommittees.
- Work with the Accreditation Committee in preparation for the 2016 Quality Assurance Symposium.

AAVLD Quality Assurance Committee

Friday, October 23, 2015
Room 551

1:00 – 1:05 PM ..... Welcome & Review of Agenda

1:05 – 1:20 PM ..... NAHLN/NVSL Update (Torchin)

1:20 – 1:35 PM ..... AAVLD AC Update (Loiacono)

1:35 – 2:05 PM ..... Improving Data Integrity and Reliability (Davies)

2:05 – 2:45 PM ..... Real World Nonconformances: Root Cause to Corrective Action (Alexander)

2:45 – 3:00 PM ..... Break

3:00 – 3:30 PM ..... Maintaining a Mature Quality System (Lukens)

3:30 – 4:00 PM ..... Client Shipping Kits and Process Solutions (Raynak)

4:00 – 4:30PM ..... Safety in Quality Requirements (Farmer)

4:30 – 4:45PM ..... Abstract: Automating Auditing Via Electronic QMS (Havens)

4:45 – 5:00 PM ..... Committee Business (Kellum)

- PT Guide Subcommittee Update
- NVSL PT Update
- New Committee Chair Announcement

5:00 PM ..... Closing Remarks & Adjournment

Quality Assurance Committee Meeting Minutes

Joseph Kellum Jr., QA Committee Chair (2013-2015) and Quality Manager / Safety Officer at Mississippi State Veterinary Research & Diagnostic Laboratory System, opens the meeting at 1:00 pm. Mr. Kellum welcomes the group and reviews the meeting agenda (see attached).

- The Committee membership sign up list is passed around and Mr. Kellum requests people write legibly so their name will appear correctly on the AAVLD web site Committee member list.
- Mr. Kellum also discusses the need for members to take an active role in the QA Committee. New people are welcome to get involved. Volunteers for sub-committees that may be formed are encouraged.
- The Committee would like to provide additional guidance information for the AAVLD membership and proposes forming sub-committees in the future to accomplish these goals. As has been done previously, these guidance materials will be reviewed and approved by the Accreditation Committee.
- Also, ideas for topics for future meetings or symposia are welcome.
- Mr. Kellum thanks today's speakers.

1. NAHLN/NVSL Update – presented by Dr. Christina Loiacono, Associate Coordinator with the National Animal Health Laboratory Network (NAHLN) presents the updates from the NAHLN and the National Veterinary Services Laboratory (NVSL)
    - Quality is important to NAHLN; NAHLN audits laboratories and supports training on laboratory quality
    - A NAHLN Approval Committee was created in 2014 with members from reference laboratories and NAHLN program staff and has met 4 times– this group provides review of audit reports to ensure consistency and transparency
    - NAHLN audited 7 labs and did 1 gap analysis in the past year
    - Quality Management System training held in Ames has been in progress since 2010.
        - 12 trainings have been held so far, which includes a wet lab and workshops; 475 people have been trained since it began, including international and Plant Protection Quarantine (PPQ) attendees
        - August 2015 had representatives from 45 NAHLN labs, and 21 international students from 14 countries; this training also included three new trainers "in training"
        - There will be another QMS course in 2016
    - NAHLN Portal
        - Provides electronic management of laboratory information including contact information, SOP distribution, etc.
        - As SOPs come due for review or revision they will be placed on the portal
        - The goal is to provide all proficiency testing through the portal

- When is Quality Most Important?
    - Laboratories MUST maintain a high level of quality during an outbreak
    - The NALHN program office received a large amount of quality-related questions during the outbreak and they answered them as best as possible; they assisted in evaluating options to handle the outbreak testing (including mobile labs); they worked to help labs supplement their staff via staff from other laboratories; revised SOPs or approved deviations as needed; they provided PT materials so staff could be approved for testing quickly
    - Questions received during the surge involved document control, proficiency testing, training and equipment, and use of unauthorized labs
    - If there are areas that need to be addressed by NAHLN (for example, university policies, safety, etc.) bring it to NAHLN attention

2. Accreditation Committee Update – Presented by Ms. Laura Torchin, Quality Manager at the California Animal Health and Food Safety Laboratory, University of California, Davis
    - The AC has a new Chair, Dr. Tim Baszler and Vice-Chair, Ms. Barbara Martin.
    - Meetings of the AC during the last year have involved the review and approval of site visit reports, laboratory responses and follow up responses or update reports
    - The AC had 7 laboratory site visits in 2015 and will have 10 in 2016
    - Because the AC spends a lot of time discussing reports and responses the meetings in February and July have been extended 4-5 hours to allow more time to complete agenda items
    - Committee SOPs on site visits, committee management, audit pool management and member evaluation, etc. are completed or in development and will be placed on the AAVLD web page soon.
    - The AC is also developing templates for reports and laboratory responses to increase consistency
    - The Accreditation Application is being revised
    - The AC and audit pool members will be signing a confidentiality agreement
    - There will be auditor training in February 2016 which will be open to anyone
    - Ms. Torchin requested feedback from the members regarding topics for training in next year's symposium and any other inquiries

3. Improving Data Integrity and Reliability - presented by Dr. Rebecca Davies, Associate Professor and Director of Quality Central at the University of Minnesota
    - Dr. Davies discusses the potential to improve the reliability of research data by implementing quality principles to the research laboratory
    - AAVLD has had a significant impact on the quality of veterinary diagnostic laboratories

- Examination has revealed problems with research data reliability and repeatability which threatens sound science
- QA is not part of the basic researcher's education; newly graduated students have trouble getting hired partially because of their lack of quality training
- We need strategies to provide quality related education
- Dr. Davies worked with a volunteer research laboratory and implemented some basic quality assurance and/or control processes; this project worked well and will be expanded in the future. Lessons learned:
    - Plant seeds of quality in small groups
    - Put money into grants for quality assurance

4. Real World Nonconformances: Root Cause to Corrective Action – presented by Trevor Alexander, Microbiologist II Parasitology/Bacteriology and Quality Assistant at the Washington Animal Disease Diagnostic Laboratory at Washington State University
    - Mr. Alexander discussed the real world process of a root cause analysis and implementation of a corrective action for a failed quality check on new MIC media
    - All factors involved in the process must be examined for the root cause analysis; the example shown used a simplified fishbone diagram
    - Analysis of the factors resulted in the selection of items that could have caused the problem and these were included in the corrective action, as follows:
        - A repeat of the process same as originally performed
        - A change to the sample identification procedure
        - Verification of the reference standard
        - Check on new lot of media
    - How long should monitoring be? It should be long enough to prove your corrective action worked. In this case since the problem appeared to have occurred after six months, so monitoring was done for 8 months
    - The root cause was determined to be a sample identification traceability issue and monitoring revealed the correct root cause was selected as the problem did not reoccur

5. Maintaining a Mature Quality System – presented by Patricia Lukens, Quality System Manager at Washington Animal Disease Diagnostic Laboratory at Washington State University
    - Ms. Lukens discussed aspects of the quality system that must continue to be maintained as laboratory quality systems mature
    - SOPs must continue to be reviewed and revised as needed
    - Training on the quality system must continue periodically for all staff
    - Train the trainers consistently; train internal auditors to carry quality to lab staff

- Maintain regular internal auditing; educate staff about auditing and being audited
- Consistent records, continuous improvement and compliance with procedures and policies
- Basically continue all the programs as required and do not take anything for granted or make assumptions

6. Client Shipping Kits and Process Solutions – presented by Ms. Sarah Raynak, Office Supervisor III, Diagnostic Center for Population and Animal Health at Michigan State University
    - Their laboratory was experiencing more complaints regarding shipping of samples than expected
    - Complaints are opportunities for the laboratory to educate a client on how the laboratory can assist them
        - Complaints included "where are my samples?", "why did it take so long?"
        - Clients were reminded
    - The laboratory performed root cause analysis and evaluated the trends of complaints received about shipping
    - They examined their shipping provider options and came up with solutions negotiated with one provider; these solutions were custom designed for their needs for an exact record of delivery and receipt of packages to the laboratory
    - The result is a large monetary savings for the laboratory and a reduction in complaints about shipping (that also saves staff time and therefore money)

7. Safety in Quality Requirements – presented by Dr. Kristy Farmer, Quality Manager / Safety Officer at the Thompson-Bishop-Sparks State Diagnostic Laboratory and current Chair of the AAVLD Safety Committee
    - Dr. Farmer discussed the meaning and importance of safety, biosafety, biosecurity and biocontainment policies and procedures and their relationship with the AAVLD Requirements
    - Safety involves protection of people from injury, danger or risk
    - Biosafety includes policies and processes used to prevent exposure of people or the environment to potentially infectious agents
    - Biosecurity is procedures used to protect against disease or harmful biological agents, which may include facility security
    - Biocontainment is containment of harmful agents in secure facilities, which may include equipment
    - There are three places in the Requirements that mention these elements
    - AAVLD Requirements Section 5.3 Accommodation and Environmental Conditions, which describes the requirements for safety, biosafety, biosecurity and biocontainment in the laboratory

- Requirements Section 5.3.5 discusses the requirement for policies and procedures for safety, biosafety, biosecurity and biocontainment and includes training for staff on these elements
- AAVLD Requirements Section 5.4.2.3 f) which lists safety and biocontainment considerations required in a SOP

8. Abstract: Automating Auditing Via Electronic QMS – presented by Andrew Havens of Q-Pulse
    - Traditionally auditing has been done "manually" which has challenges
    - Electronic Audit Management can provide the following elements:
        - Electronic scheduling
        - Security – controlled access
        - Scope details, checklists
        - Document information linked
        - Scoring, management of findings
        - Report review and approval
        - Evaluation of trends
        - iPad capabilities
    - This module will interact with other Q-Pulse modules

9. Committee Business – by Mr. Kellum
    - Thank you to the speakers and comments on the value of their presentations
    - Sub-Committee on PT Guide (Patricia Godwin, Lou Simudio and Trevor Alexander) completed their guide to proficiency test providers, which will undergo revision soon to revise some phone numbers
    - Chair requests feedback on topics for future meetings and/or trainings and also business you would like to see the Committee complete
    - The next Quality Assurance Committee Chair has been selected and is Dr. Kristy Farmer the Quality Manager and Safety Officer from the Thompson-Bishop-Sparks State Diagnostic Laboratory. Ms. Farmer is also the immediate past Chair of the AAVLD Safety Committee
    - Mr. Kellum thanks the Committee for the memories and adjourns the meeting at 4:45 pm.