

Contact: Diana Gonzalez

**VETERINARY DIAGNOSTICS LABORATORY ACCREDITATION REPORT
AT IOWA STATE UNIVERSITY**

Action Requested: Receive the accreditation report for the Veterinary Diagnostics Laboratory in the College of Veterinary Medicine at Iowa State University.

Executive Summary: The Veterinary Diagnostics Laboratory (1) underwent a self-study that addressed the standards and criteria defined by the accrediting body; and (2) had an on-site visit by peer evaluators. The program was accredited in 2012 for a period of five years. However, there were a number of standards that were in non-conformance. The program was required to submit a progress report by June 15, 2013. This report addresses the Board of Regents Strategic Plan priority to provide “educational excellence and impact” as well as Goal #8 – “Iowa’s public universities and special schools shall be increasingly efficient and productive.”

Background:

- ◇ **Description of Program.** The Veterinary Diagnostics Laboratory (VDL) is a component of the ISU College of Veterinary Medicine (CVM), and combined with the Food Supply Veterinary Medicine section, forms the Department of Veterinary Diagnostic and Production Animal Medicine (VDPAM) at ISU. The VDL’s funding in FY 2012 (\$15.5 million) represents a combination of service fees (72%); line item State appropriation (21%); allocation from the College of Veterinary Medicine (6%); and USDA National Animal Health Laboratory Network (NAHLN) infrastructure support (1%). During FY 2012, the laboratory conducted approximately 1 million tests, generating \$11.2 million in service fee income. In addition, VDPAM faculty members were principal investigators or co-principal investigators on approximately \$31.2 million in active research grants.

The VDL serves to protect and advance Iowa’s \$12.5 billion animal agriculture industry through comprehensive laboratory services; teaching veterinary students, graduate students, future diagnosticians, and veterinary practitioners; and applied research and development activities. The laboratory provides diagnostic and laboratory support to Iowa and other states for food and fiber animals, avian species, companion animals, wildlife, limited aquaculture, toxicology and nutritional analyses, pharmaceutical testing for animal-based products, Racing Chemistry, and forensic testing of performance animals. The major species served by the laboratory are porcine, poultry, and bovine. The VDL has been an USDA NAHLN core laboratory since initiation of the network in 2002.

A certified clinical pharmacologist and a certified toxicologist were hired in 2012. The veterinary toxicology and analytical chemistry section was restructured in 2012 into *Toxicology and Nutrition*. A new section, *Cyclone Custom Analyte Detection Services (CYCADS)*, formed in 2012 is redirecting the analytical capabilities of the Racing Chemistry laboratory to food animal pharmaceutical and pain biomarker research and diagnostic service applications.

- ◇ Purpose of Accreditation. An accredited educational program is recognized by its peers as having met state and national standards for its development and evaluation. To employers, graduate schools, and licensure, certification, and registration boards, graduation from an accredited program signifies adequate preparation for entry into the profession. In fact, many of these groups require graduation from an accredited program as a minimum qualification. Accreditation is also intended to protect the interests of students, benefit the public, and improve the quality of teaching, learning, research, and professional practice.
- ◇ Accrediting Agency. The accrediting body is the Accreditation Committee of the American Association of Veterinary Laboratory Diagnosticians (AAVLD).
- ◇ Review Process. The self-study prepared by the Veterinary Diagnostics Laboratory contained the responses to the standards required by the accrediting body – administrative requirements (organization, management, and personnel; finance and budget); management requirements (organization and management; quality system; document control; review of request or contract; subcontracting of test services; purchasing services and supplies; complaints; control of non-conforming testing and test results; corrective and preventative action; records; internal audits; management review); and technical requirements (general; personnel; accommodations and environmental conditions; test methods; equipment; measurement traceability; specimens; handling of specimens; ensuring the quality of test results; reporting test results).
- ◇ On-Site Team Report. In August 2012, the visiting team determined that the Veterinary Diagnostics Laboratory was in substantial compliance with the accrediting agency standards although a number of non-conformances were identified.
- ◇ Observations of Site Team. “The limitations of the nearly 40-year old VDL facility are an area of immediate concern. The space, air handling and structural limitations of the aging facility can be expected to have a serious negative impact on the ability of the VDL to continue to develop and incorporate new technologies and state-of-the-art services, ensure separation of incompatible activities, and importantly to efficiently respond to the very real potential of a disease outbreak or large-scale surveillance program in support of business continuity for the state’s animal agriculture industries. The CVM public spaces, including hallways that are shared with or in proximity to laboratory areas cannot be closed off from students and technician traffic or otherwise secured to ensure a high level of biocontainment, biosafety, and laboratory security.

Numerous facility deficiencies noted as impacting biosafety and laboratory biosecurity related to the aging laboratory were also documented in a 2012 External academic Program Review (a seven-year review completed by peers from five institutions). Laboratory self-audit and internal reviews consistently document concerns related to environmental control, including poor air-handling, loss of negative room pressure, humidity, and inadequate space for designated activities. Approximately \$130 million was appropriated by the Iowa legislature to renovate and construct facilities at the CVM; however, only \$1.5 million of that was allocated to the VDL to complete construction of their BSL-3 capable facility. Planning for a new VDL facility was included in the 2012 VDPAM Strategic Plan.”

◇ Requirements Identified by the Visiting Team. (Institutional responses are identified in italics.)

- ⇒ “Respond to the Non-Conformances cited in the report with documentary evidence by June 15, 2013.”

Non-conformance responses, together with records and associated documentary evidence, were provided.

- ⇒ “Revise the current Corrective Action process of the AAVLD Requirements with special attention to (a) recording and tracking all non-conformances regardless of severity; (b) providing a consistent guideline or definition of minor issues/remedial events (those requiring identification, immediate correction, and tracking) versus major non-conformances which additionally require investigation and root cause analysis; and (c) implementation of a laboratory-wide policy and procedures that remove the provision for discretionary use of the Corrective Action and investigative processes.”

The corrective action process and its existing documents were reviewed and extensively revised by the Quality Steering Group. The Policy now states it is the responsibility for all VDL employees to record departures from policies and procedures, and that the corrective action process must be initiated when a single major non-conformance, or three related minor non-conformances, is identified. The non-conformance investigation process now follows a consistent method. The Procedure now describes how to apply revised Q-Pulse templates to assure consistency in information recorded across the lab. The template also assigns responsibility for corrective action, follow-up, and timeframe for resolve. The procedure also requires usage of fields to categorize entries for ease of analysis and identifying trends.

- ⇒ “Review all quality documents for the appropriate use of the terminology ‘shall’ and ‘should.’”

The VDL Quality Manual and its associated policies and procedures were reviewed for ‘should’ and ‘shall,’ and revised to remove unintended discretionary compliance. Documents were also revised to address other non-conformances identified by the site team and consolidated where content allowed.

- ⇒ “Ensure review and trend analysis is a component of all critical quality management activities.”

Revision to the VDL corrective action process now requires the use of entry categorization fields in Q-Pulse, which allows for analysis and identification of trends. This capability will be employed when corrective/preventive action entries are discussed at the management review and to summarize findings of the annual internal audit. Periodic meetings are planned to review existing entries.

- ⇒ “Review and edit where necessary technical and equipment policy and procedures for compliance with the quality standard, with special attention given to environment and equipment maintenance plans, schedules and monitoring; and the provision of acceptable ranges/acceptance limits for assay critical measurements in compliance with AAVLD standards.”

The laboratory developed a lab-wide equipment policy and procedure to address the identified gap. Additional resources have been allocated and are assisting the Bacteriology, CYCADs/Racing Chemistry, and Toxicology and Nutrition sections to achieve full implementation of the Q-Pulse equipment module. This will schedule periodic equipment maintenance and monitoring activities, allow for associated record storage, and facilitate compliance with AAVLD requirements. Technical SOPs will be revised at their next scheduled document review, and acceptable ranges and limits added for measurements deemed assay critical.

◇ Recommendations Identified by Site Team.

- ⇒ “Review internal training program, with the goal of providing additional quality system training on the VDL training manual, system policies, and associated procedures to reinforce VDL quality policies and practices.”

There are a number of steps the lab currently takes to ensure a thorough understanding of the laboratory’s quality system. The laboratory has a centralized onboarding process of new personnel that involves reading the laboratory’s quality manual and its associated quality systems policies and procedures. New employees provide a digital signature in the lab’s electronic quality management software system acknowledging they’ve received, read, and understood the contents of the documents. This understanding is also verified through a comprehensive quiz covering the content of the documents.

The lab’s Quality Management Team is currently reviewing the lab’s onboarding process and quality system training program to ensure its applicability and completeness with current and future lab needs, and is working to improve the process by making it more interactive by using Blackboard Learn as a tool. These improvements will be formally documented in the lab’s corrective and preventive action records as they are made, and these records can be provided in future correspondence if requested by the AAVLD Accreditation Committee.

- ⇒ “Generate laboratory-wide procedures.”

Lab-wide policies and procedures were drafted where repetitive section documents existed, or new documents are currently planned where lab-side quality program deficiencies were identified through a gap analysis.

- ⇒ “Self-assessment of whether a five-year document review is sufficient to best serve the quality and technical practices of the VDL.”

The review period of documents with the quality system was revised; the policy now states that VDL manuals, policies, procedures, and associated references are to be reviewed at least once every two years.

◇ Sample Commendations noted by Site Team.

- ⇒ “Continual improvement activities, including annual audits using metric-based reporting for compliance with all VDL quality manual and AAVLD requirements.

- ⇒ A program of annual proficiency assessment of pipetting skills using the laboratory’s liquid handling pipette calibration equipment (Artel PCS) to determine accuracy and precision. Staff is tested both before and after a training presentation provided by the VDL Quality Team.

- ⇒ Implementation of annual task-specific proficiency/competency evaluation for IT staff.

- ⇒ Bar-code tracking of case material from the initial assignment on the necropsy floor through all stages of necropsy freezer inventory (entered, stored, and removed for disposal).
- ⇒ Housing of histology processors and related equipment associated with noxious fumes under custom hood/air-handlers.”
- ◇ Best Practices Suggested by Site Team.
 - ⇒ “Consider incorporating compliance with the VDL Quality System and quality practices into all employees’ annual performance reviews.
 - ⇒ Consider marking posted Evaluation Plan Maps with a ‘You are here’ for the benefit of persons who are not familiar with the layout of the laboratory.
 - ⇒ Consider as appropriate a back-up generator or uninterruptable power supply to protect critical equipment in the event of a prolonged power failure.
 - ⇒ Review the Pathology Guideline prepared by the AAVLD Pathology Committee for related Best Practices.”
- ◇ Non-Conformances Noted During Site Visit. The site team identified non-conformances in a number of component(s) of the following management and technical requirements: Quality System; Document Control; Review of Request or Contract; Subcontracting of Test Services; Purchasing Services and Supplies; Complaints; Control of Non-Conforming Testing and Test Results; Corrective and Preventive Action; Records; Technical Records; Internal Audits; Management Reviews; Personnel; Accommodation and Environmental Conditions; Test Methods; Control of Data; Equipment; Measurement Traceability; Handling of Specimens; Ensuring the Quality of Test Results; and Reporting Test Results.
ISU provided a written response to each of the non-conformance areas identified in the Site Visit Report.
- ◇ VDL Facility Needs Assessment. The VDL and Facilities Planning and Management worked with a third-party consulting firm (ED2 International) to assess the current and future facility needs of the laboratory. The needs assessment report was not meant to be a master plan of how to satisfy facility needs or to prioritize them. However, the report did point out that the laboratory’s facility challenges have accumulated over 35 years of growth and change in diagnostic medicine and are not consistent with the bio-containment and bio-safety expectations of modern day veterinary diagnostic facilities. The VDL does not presently have either the necessary bio-containment (on a macro laboratory level) or the space required to sustainably respond to an infectious disease crisis affecting Iowa’s animal agricultural industries.
- ◇ Accreditation Status. In November 2012, the American Association of Veterinary Laboratory Diagnosticians, Inc. awarded continued accreditation to the Veterinary Diagnostic Laboratory in the College of Veterinary Medicine at Iowa State University for a period of five years. A satisfactory written response to all non-conformances, including documentary evidence, and a written report demonstrating progress on addressing all Requirements and Recommendations identified in the Site Visit Report were requested by June 15, 2013. Responses will be considered at the July 18, 2013 meeting of the Accreditation Committee of the AAVLD.