White Paper
Laboratory Accreditation Program

American Association of Veterinary Laboratory Diagnosticians

Current and Future Perspectives

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Executive Summary

The American Association of Veterinary Laboratory Diagnosticians (AAVLD) has administered an accreditation program for state-funded veterinary diagnostic laboratories since 1969. Administrative and scientific personnel of accredited diagnostic laboratories serving on the Accreditation Committee of the AAVLD conduct site visits to laboratories seeking accreditation. The Accreditation Committee of the AAVLD is the ruling body for determining the accreditation status of laboratories, and follows written guidelines (*Essential Requirements*) in assessing compliance and physical capabilities to make accreditation decisions. At present, 45 laboratories in the United States (some of which are multiple laboratories included in one state laboratory system) and 2 laboratories in Canada have full AAVLD accreditation status. The program is utilized only in North America.

The attainment and maintenance of healthy herds and flocks in trading nations around the world is dependent upon the accurate diagnosis and reporting of animal diseases. Detection and reporting of the presence of diseases within nations is dependent upon the prompt and accurate testing of their animals and animal products for diseases that may be of socioeconomic importance to other nations receiving those animals or animal products. The importance of standardized testing for animal diseases has been recognized by many trading nations. Some have adopted internationally recognized testing accreditation programs that base laboratory accreditation upon the International Organization of Standards (ISO) 17025 document as their official guide to acceptable standards for laboratory accreditation.

The World Organization for Animal Health (Office International des Epizooties - OIE) released in October 1999 a draft of the *Standard for Management and Technical Requirements for Laboratories Conducting Tests for Infectious Animal Diseases*, written by the Standards Commission of the OIE. This document describes international standards for management and technical competence that should serve as the basis for

accreditation of laboratories that conduct diagnostic tests for infectious animal diseases. It is based on ISO 17025 and other relevant standards, and is intended to be a foundation document from which further interpretations can be made as required.

The time is at hand for the AAVLD accreditation program to adopt internationally recognized standards for measuring veterinary diagnostic laboratory competence to perform prompt, accurate, and reliable testing for animal diseases and disorders. It is anticipated that the outcome of alterations to the AAVLD accreditation program will incorporate those standards that will provide authority for international recognition while maintaining the flexibility to accommodate the varying needs, testing requests, financial means, and administrative structures present in veterinary diagnostic laboratories associated with the AAVLD. As a first step, the Accreditation Committee recommends incorporation of OIE standards into the AAVLD *Essential Requirements* and accreditation process. This will require changes in the standards for accreditation, the site visit, and laboratory operation. It is the intention of the Accreditation Committee that these changes will be incorporated promptly, openly and with guidance from the organization so that all laboratories will have the opportunity to respond as necessary.

The following White Paper provides a background so that all AAVLD members and laboratories will have a common understanding of the rationale for making this decision.

Introduction

Animal disease diagnosis and surveillance in the United States is the combined responsibility of publicly funded state and federal diagnostic laboratories. Ensuring the quality of diagnostic and surveillance efforts is essential to safeguarding the health and well being of our national herds and flocks, companion animals, wildlife, zoo and exotic species, and the general public. Equally critical is assuring our trading partners that importation of animals and live animal products from the United States is safe.

The American Association of Veterinary Laboratory Diagnosticians (AAVLD) laboratory accreditation program has provided the only accreditation service for publicly supported diagnostic laboratories in the United States. The World Organization for Animal Health (Office International des Epizooties - OIE) and our trading partners historically have accepted AAVLD accreditation as prima facie evidence of quality diagnostics. While this acceptance has not wavered, there is no accreditation body in other countries equivalent to AAVLD. As a result, the international community increasingly has relied for accreditation on organizations that use International Organization of Standards (ISO) standards as a guide.

The purpose of this white paper is to address the current status and future of the AAVLD accreditation program, with particular regard to evolving international standards, and to propose an action plan that will ensure the quality and continued acceptance of accreditation for publicly funded laboratories in the United States. The white paper is the culmination of a review process begun five years ago and completed following passage of a resolution by the AAVLD House of Delegates in 2000 that "The Accreditation Committee shall investigate the feasibility of utilizing ISO 17025 as part of the accreditation of AAVLD labs and the feasibility of utilizing an appropriate accreditor to assist with accreditation responsibilities for AAVLD under AAVLD/NVSL advisement." The process has included multiple special meetings of the AAVLD Accreditation Committee, meetings with leaders of the American Association for Laboratory Accreditation on incorporation of ISO 17025 standards into the accreditation process and use of a private organization to accredit AAVLD laboratories, discussions with leaders of the National Veterinary Services Laboratory on accreditation goals for federal labs, ISO 17025 training of two AAVLD leaders, two meetings with OIE in Paris by representatives of AAVLD leadership, and discussions with other countries currently using ISO 17025 standards for laboratory accreditation.

History of AAVLD accreditation program

The AAVLD began a formal accreditation program in 1969. The purpose of this program was to provide an external review process by which state-funded laboratories could assess the quality of their diagnostic services. As a result of the accreditation review and report recommendations, laboratories could establish goals for improvement and obtain funding necessary to address deficiencies. The national animal health climate in which the accreditation program began and subsequently developed was one of formal national and state regulatory disease control programs and disease eradication. Thus, it was essential that animal disease testing meet strict standards so that program diseases (for example hog cholera, brucellosis, and pseudorabies) for which testing was conducted in state laboratories could be eliminated from the United States, and that livestock destined for movement across state and national borders could reliably be

deemed free of national program and other regulated diseases. While formal program diseases aimed at eradication now receive less emphasis as they reach a successful conclusion, the contemporary climate for accreditation is not so different than it was in the beginning. United States producers increasingly rely on export of animals and animal products to prosper. As a result, international acceptance of diagnostic laboratory results from individual animal and population-based testing is critical for maintaining open avenues of trade. Emergence and re-emergence of infectious diseases, including national program diseases such as tuberculosis; rapid global transport that increases the threat of foreign animal disease introduction into the United States; and the use of bioweapons, most of which are zoonotic agents, all impart a heightened sense of importance to reliable, quality diagnostic laboratory results.

Current AAVLD Accreditation Process and Essential Requirements

Largely a self-help process by which colleagues with the common interest of promoting excellence in diagnostic medicine could elevate the discipline, accreditation was based on standards derived by recognized experts with experience in the field. From the beginning, AAVLD accreditation standards were outlined in a document termed *Essential Requirements for An Accredited Veterinary Medical Diagnostic Laboratory*.

On-site review of AAVLD accredited, publicly funded veterinary medical diagnostic laboratories currently occurs every five years and evaluates the degree to which the laboratory meets its own statement of objectives and the established criteria set by the Accreditation Committee (as outlined in the *Essential Requirements*). Each accredited laboratory pays an annual fee of $300 during years in which a site visit does not occur, and a fee of $500 during the site visit year, regardless of whether the laboratory has one primary site or multiple branch laboratories. (*Note added, November, 2002. When this document was written, the previous statement was correct. Starting in 2002, accredited laboratories now pay an additional $300 during the year of the site visit for each branch laboratory in the system.)*

The site visit team, consisting of a minimum of two and typically three members of the Accreditation Committee, is provided with a comprehensive application document prior to the review, and follows a standard operating procedure in conducting the on-site review. Essential requirements are focused on the organization of the laboratory, personnel, physical facilities, equipment, records, communication, laboratory quality assurance, and budget. The last update of these requirements in February 1998 placed increased emphasis on the laboratory quality assurance program, with particular attention to evolving draft OIE and ISO 17025 standards (see below). The general areas of emphasis in the *Essential Requirements* are very similar to the current ISO 17025 standards. Compliance with essential requirements is assessed through section summary forms in the application document, and during the on-site review. During the review, randomly selected records are examined in detail, and case audits conducted. Interviews of laboratory administrators, professional and technical staff, and in many cases clients are used as a means of identifying strengths and weaknesses of the laboratory as they relate to the essential requirements. Assessment of competence at the bench level by observation of technical staff performing test procedures is not done. This is a distinct difference between AAVLD *Essential Requirements* and ISO 17025 standards. General support for the laboratory is assessed through interview of the administrator to whom the laboratory director reports. Site visits typically last two or three days. A written and verbal report by the site visit team is made to the full committee at

one of three annual meetings. The committee may by majority vote accept the report as written, or may accept the report with revisions. After acceptance of the written report, the committee by majority vote acts on a motion for full accreditation, provisional accreditation, or denial of accreditation. Results of the committee action are conveyed to the laboratory director by the chair of the Accreditation Committee along with the final report of the site visit team.

It is important to note that neither the AAVLD nor its Accreditation Committee is officially recognized as an accrediting entity by the International Laboratory Accreditation Cooperation (ILAC) or National Cooperation for Laboratory Accreditation (NACLA). These cooperative groups, which foster multilateral recognition among regional accrediting bodies to facilitate international test data acceptance, promote the use of ISO 58 guidelines when assessing the qualifications of accrediting bodies. The requirements of ISO Guide 58 standards for record keeping, audits, liability coverage, and frequency of site visits, among others, are areas for which the AAVLD accreditation process would need to be substantially modified to be in compliance.

International Standards of Accreditation

Following the last round of negotiations on the General Agreement on Tariffs and Trade in 1994, the World Trade Organization (WTO) selected the OIE as its scientific reference organization in the area of animal health. As such the OIE became the official WTO representative in matters relating to international trade of animals and live animal products. Since animal disease surveillance and laboratory diagnosis are integral to establishing the health status of the national herds and flocks as well as individual animals destined for export, the OIE has developed a set of standards for acceptable laboratory practices (*Standard for Management and Technical Requirements for Laboratories Conducting Tests for Infectious Animal Diseases*). The purpose of this document is to establish laboratory standards that must be met by member countries when producing data for use in establishing infectious disease status. Importantly, the OIE is not, nor does it intend to become, an accrediting organization. That responsibility and function continues to rest with each country. However, the OIE will act on behalf of the World Trade Organization when trade disputes surrounding or including laboratory results arise, and will use their guide for good laboratory practices when adjudicating those disputes. Therefore, it is very important that laboratory practices and accreditation criteria in the United States meet or exceed OIE standards.

The current OIE *Standard for Management and Technical Requirements for Laboratories Conducting Tests for Infectious Animal Diseases* is based on ISO 17025 and other standards, and incorporates parts of the ISO 9000 series that are relevant to the scope of testing. Input into development of the *Standard* was international in scope, and included representatives from the United States. The OIE Standards document is divided into Management and Technical requirements sections, and in general addresses the same areas as the AAVLD *Essential Requirements*, including organization of the laboratory, personnel, physical facilities, equipment, records, communication, and laboratory quality assurance. It differs in scope and detail. Examples of areas covered in the OIE standards that are not specifically addressed in the AAVLD essential requirements are internal audits, control of non-conforming testing and test results, handling of complaints, and assay validation. However, it is important to recognize that the OIE standards, unlike the AAVLD essential requirements, address only infectious disease testing. The standards can, nevertheless, be used as a general

guide for diagnostic tests in addition to infectious diseases. As in the ISO 17025 standards, but unlike the AAVLD essential requirements, the OIE Standards outline laboratory practice requirements with declarative statements and the use of “shall”, “will”, and “should”. Sufficient detail is provided in many sections that little latitude is allowed in interpretation. As one example, in reporting test results the OIE standards specify that each report shall include the following information: title, name and address of the laboratory; location where the test was performed; unique identification on each page of the report and at the beginning and end; name and address of the client; description and identification of the specimen; identification of the assay used; date of receipt and date of performance of the test; test result with units of measurement; reference to sampling procedures used by the laboratory; opinions and interpretations of the test results; and name, function and signatures of the person authorizing the test report. The level of detail in the OIE standard, if adopted as an accreditation standard for AAVLD, would alter the AAVLD accreditation process and the common laboratory practice procedures in accredited laboratories. In many areas, it would require (and promote) increased standardization of laboratory practices among publicly funded diagnostic laboratories in the United States.

Accreditation is addressed in the introduction to the OIE *Standard for Management and Technical Requirements for Laboratories Conducting Tests for Infectious Animal Diseases*. It is worth repeating here. “This document describes the international standards for management and technical competence that serve as the basis for accreditation of laboratories that conduct diagnostic tests for infectious animal diseases. The acceptance between countries of test results and diagnostic interpretations will be facilitated if laboratories comply with this Standard and obtain accreditation from bodies who have entered into mutual recognition agreements with equivalent bodies in other countries using this Standard.” Several important conclusions can be drawn from these statements. [1] The OIE has developed standards that are meant to serve as the basis for accreditation (but as noted above relies on member countries for ensuring adherence to these standards). [2] Compliance to OIE standards is not mandatory but if done will facilitate international acceptance of test results. [3] Accreditation processes among member countries should be formally accepted by mutual recognition agreements. It is the latter conclusion that has in large part influenced the decision of several countries, including Australia, Canada, and the European Union, to develop accreditation processes overseen by ILAC (ISO/IEC Guide 58) approved accrediting bodies using ISO 17025 standards. Importantly, the National Veterinary Services Laboratory has elected to follow suit by establishing a goal of ISO 17025 accreditation for the Center for Veterinary Biologics and individual laboratory tests, and has plans to be reviewed by the American Association for Laboratory Accreditation (A2LA), an agency located in Rockville, Maryland that meets ISO 58 standards.

Accreditation to ISO 17025 standards

The ILAC formally recognizes several accrediting organizations in the United States and abroad. These include but are not limited to the National Voluntary Laboratory Accreditation Program (NAVLAP) (through the National Institute of Standards and Technology) and the American Association for Laboratory Accreditation (A2LA) in the United States, the Standards Council of Canada (SCC), the European Cooperation for Accreditation (EA), the Asian Pacific Laboratory Accreditation Cooperation (APLAC), and the National Association of Testing Authorities (NATA) in Australia. Each of these organizations is formally recognized as accrediting bodies, use ISO 17025 standards,

and adhere to ISO Guide 58 standards for accreditors. In the United States, the A2LA has the most experience accrediting laboratories performing biological testing, and as noted above has been selected by the National Veterinary Services Laboratory as the organization that will assess the Center for Veterinary Biologics and individual NVSL tests for accreditation to ISO 17025 standards. However, A2LA experience in the biological field is limited to food safety microbiological laboratories for which standardized test procedures are specified by the Food and Drug Administration, USDA, or other regulatory agency. There is no ISO Guide 58 accrediting organization within the United States that has experience in accreditation of human or animal diagnostic laboratories. Precedent for accreditation of animal disease diagnostic laboratories exists in other countries in which ISO 17025 standards have been applied by ISO Guide 58 approved accreditors. These include Great Britain, the Netherlands, and Australia. Canadian federal animal health laboratories currently accredit to ISO 17025 on an individual test basis. At least one Provincial diagnostic laboratory is registered to ISO 9002 series standards, and is ISO 17025 accredited for one test. The experience of laboratories and accreditors in these countries can provide valuable guidance for application of ISO 17025 standards to animal disease diagnostic laboratory accreditation in the United States.

ISO Guide 58 accreditors must visit accredited laboratories minimally at three-year intervals. Currently A2LA requires a site visit every two years. This would be a substantial and costly change for AAVLD accredited laboratories. First year costs for A2LA accreditation include a $1000 application fee for the first facility and an additional $800 for each additional facility (for example, branch laboratories), an annual fee of $1,300 for the first facility and $900 each for other facilities, and assessment fees that include $800 per day for assessors plus travel, per diem, and other incidental expenses. (All estimates are based on January 1, 2000 fees.) Thus, for a laboratory with a single facility, the estimated first year cost would be $6,300. Second year costs, which could include an interim surveillance visit, would total approximately $3,300, third year costs with a site visit $5,300, and fourth year costs without a site visit $1,300. These estimates include only one assessor on the site visit. Entire laboratories, individual sections or disciplines within laboratories, or even individual tests within a section can be accredited to ISO 17025 standards. Additional assessors, which likely would be required for accreditation of multiple sections of AAVLD laboratories, would increase this cost proportionally by $800/day/assessor plus travel, per diem, and incidentals. If AAVLD provided trained assessors for A2LA (with no non-AAVLD, A2LA assessors on the site visit), and AAVLD assessors were not remunerated for the site visit beyond per diem (as is currently the case), the total costs could be reduced substantially. However, A2LA may require that at least one non-AAVLD, A2LA-approved assessor be present on each site visit.

ISO 17025 standards are divided in management requirements and technical requirements. As noted above, the OIE standards were derived in large part from ISO 17025, so the general areas covered in each section are very similar and will not be repeated. (In fact, OIE standards are so closely related to ISO 17025 that negotiations for royalties to be paid by OIE to the International Organization of Standards had to be completed before the OIE standards could be offered to the international community.) Most areas covered in ISO 17025 are the same as in the AAVLD Minimal Essentials. Initial indications from A2LA are that AAVLD Minimal Essentials could be incorporated into ISO 17025 standards as program requirements over and above the general requirements specified by ISO 17025 to develop a combined standards document for

A2LA accreditation of diagnostic laboratories. The most substantial changes would occur in the technical requirements sections, with additional details on test and calibration methods, method validation, sampling and reporting. However, in practice some sections of animal disease diagnostic laboratories (for example pathology and diagnostic bacteriology) operate in a substantially different fashion than other microbiological laboratories in which the target of the assay (for example, *Salmonella* or *Campylobacter*) is known. This would require a change in mentality for an organization such as A2LA when assessing competence. It is worth noting again that ISO 17025 uses declarative statements and words such as “shall”, “will”, and “should”, and provides sufficient detail that little latitude is allowed in interpretation. As a result, A2LA site visits would differ substantially from current AAVLD protocol, including an on-site assessment of competence by viewing the performance of assays. Currently, AAVLD site visits include an interview of the administrator to whom the laboratory director reports. Substantial evidence supports the view that this part of the AAVLD site visit can be extremely beneficial to the laboratory in securing additional resources and space. It is not a part of the A2LA assessment.

Following the site visit, A2LA assessors provide a report to the laboratory and to A2LA staff. The laboratory addresses any deficiencies, and the laboratory response to deficiencies is reviewed by A2LA staff. All information is submitted to an Accreditation Council. The decision on accreditation by A2LA rests with the Council, which does not include the assessors. Following accreditation, a laboratory must continuously submit results of proficiency testing, and annually must submit internal audits and management reviews to A2LA.

Recommendation

Based upon an analysis of the available laboratory accreditation options; the varied and unique financial, administrative, and structural features of AAVLD-associated laboratories; the importance of maintaining international trade to the vitality of our agricultural animal industries; and the vital role that a sound and reliable animal health laboratory system has in protecting our animal industries and assuring our trading partners that our national herds and flocks are healthy and free of diseases of international import, the Accreditation Committee working group recommended at its winter meeting in February 2002 that the AAVLD begin adopting international standards as outlined in the OIE *Standard for Management and Technical Requirements for Laboratories Conducting Tests for Infectious Animal Diseases* into its *Essential Requirements* document and accreditation process. The Accreditation Committee unanimously approved this recommendation.

The following steps were outlined as a means of implementing this recommendation.

1. Broadly announce and distribute the White Paper and recommendations to AAVLD-associated laboratories and personnel.

2. Maintain a 5-year interval between accreditation site visits, but require an annual report from all accredited laboratories outlining all substantive changes that could affect accreditation status.

3. Make available to all laboratories a model Quality Manual addressing all aspects of the OIE *Standard*.

4. Provide training to Accreditation Committee and Quality Managers Committee members on OIE and ISO 17025 standards.

5. Incorporate the OIE *Standard* on laboratory management and technical requirements into the AAVLD *Essential Requirements for an Accredited Veterinary Medical Diagnostic Laboratory*.

6. Modify the Standard Operating Procedure for an accreditation site visit as necessary to adhere to the OIE *Standard*.

Implementation of these steps either has begun (steps 1, 2, and 3) or is scheduled to begin (steps 4, 5, and 6) by mid-year, 2002. The final timeline for complete implementation of the recommendations will be decided at the summer meeting of the Accreditation Committee in July 2002.