U.S. Department of Agriculture

Animal and Plant Health Inspection Service

The National Veterinary Services Laboratories and the Center for Veterinary Biologics

Response to Recommendations in Battelle Memorial Institute Review

July 30th, 2009

The National Veterinary Services Laboratories (NVSL) and the Center for Veterinary Biologics (CVB) welcome outside reviews as opportunities to improve our processes, procedures, and overall Quality Management Systems. The recent laboratory process review conducted by the Battelle Memorial Institute found that both facilities are highly efficient, well-managed organizations that are appropriately protecting U.S. animal health. The review also provided several recommendations for improvement, which are addressed below.

APHIS greatly appreciates all of the work that the review team put into their evaluation. The final report is a thorough and objective evaluation of the NVSL and the CVB laboratory and program processes.

Laboratory Quality Management Systems (ISO Systems 17025 and 9001):

Recommendation: The CVB may wish to consider ISO 9001, instead of pursuing ISO 17025, as the quality standard for the laboratory.

Response: The CVB was certified according to ISO 9001 in September 2007 and intends to maintain that certification. This standard for quality management systems contains requirements to maintain procedures that cover all key processes in the business, monitor those processes for effectiveness, and facilitate continual improvement.

ISO 17025 is a quality management standard used by testing laboratories and is aimed at improving the ability to consistently produce valid results. The assessors commented that the majority of CVB testing is inherently more variable than the standardized testing performed by the NVSL, and accreditation to ISO 17025 may have limited value. The CVB, however, also performs codified Standard Requirement tests on many veterinary biologics. Although the CVB has placed the ISO 17025 strategic goal on hold for budgetary reason, we feel it is appropriate to follow ISO 17025 guidelines for this standardized testing and our laboratory proficiency program.

Select Agent Program:

Recommendation: We recommend upon moving to the new building the registrations be under the same authority (either Animal Plant Health Inspection Services (APHIS) or Centers for Disease Control) and the number of principal investigators (PI) for the NVSL be decreased.

Response: As required by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, the Select Agent (SA) program necessitates that individuals possessing, using, or transferring agents or toxins deemed a severe threat to public, animal or plant health, or to animal or plant products, be registered with the Secretary of either USDA or Health and Human Services. We have initiated the process of consolidating SA registration for the National Centers for Animal Health (NCAH[1]) under one regulatory authority. Due to different agency reporting structures, two separate registrations (APHIS and USDA-ARS) will be maintained under one oversight authority.

The NVSL's current model of multiple PIs appears to be the best fit for the diverse nature of the laboratories' work and reporting structure. However, the NVSL supports the goal of implementing the most efficient and cost-effective SA program possible.

Recommendation: We recommend that Select Agent (SA) Manuals be standardized across the NVSL/CVB organization to ensure accuracy, consistency, and ease of staff reference and familiarization.

Response: The NVSL and the CVB agree with this recommendation. As discussed above, we have begun the process to consolidate registration under one regulatory authority, which will allow us to standardize procedures and documentation across all SA activities.

Recommendation: The SA Program documents could also be improved through some physical consolidation…to improve document control and simplify the entire process of document retrieval.

Response: The NVSL and the CVB will implement this recommendation in late 2009 in conjunction with the move to the new consolidated laboratory facility.

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[1] The NCAH was created by the co-location of the NVSL, CVB (both USDA-APHIS), and the National Animal Disease Center (USDA-ARS). The three programs within the NCAH share combined service units for administration, buildings and grounds, safety and security, information management, laboratory support and materials handling, and animal care. Personnel will move to a new combined laboratory facility in 2009.

Laboratory Biosafety Practice:

Recommendation: Given the importance of biosafety in the implementation of the Select Agent Program, it is recommended that the general Biosafety/Biosecurity program of the NCAH be based primarily on the Biosafety in Microbiological and Biomedical Laboratories (BMBL) guidelines, Occupational Safety and Health Administration (OSHA) regulations, and National Institutes of Health guidelines for research involving recombinant DNA molecules. We strongly recommend that many of the safety aspects of the SA Program be extended to other biological materials in the laboratories.

Response: In recent years, the NCAH has increased the emphasis, funding, and staffing related to biosafety/biosecurity activities. The NCAH established a Safety and Security Unit in 2007 to expand upon existing safety and occupational health programs and to coordinate implementation campus-wide. Its work has led to the development of an updated NCAH Biosafety Manual based on the BMBL, which is currently being finalized. The manual will address all infectious or potentially hazardous biological materials handled in the laboratory, including select agents. We plan to continue our efforts using available resources to advance our biosafety and biosecurity programs.

Recommendation: We recommend that the NCAH task the Institutional Biosafety Committee or, preferably, a separate biosafety committee with the primary purpose of ensuring a robust biosafety program. Compliance with the Select Agent regulations should be a subtask of the committee.

Response: Since receiving review recommendations, the NCAH has increased the emphasis on biosafety in addition to maintenance of more general safety and occupational health programs. A biosafety manager position has been created and filled. An operational readiness review, focusing extensively on biosafety for the consolidated laboratory facility, has been completed. The creation of a separate biosafety committee, or a subcommittee of the current Safety and Health Committee, is currently being evaluated.

Training Systems and Documentation:

Recommendation: We recommend an overall review of the process of training, training documentation, and assign a responsible person as the training coordinator for all the laboratory activities, or one for NVSL and one for CVB.

Response: The NVSL and the CVB agree that accurate and well-documented training is a cornerstone of effective laboratory operations. We merged training activities into a single administrative/combined service unit following a review of the training program, with assistance from other departmental personnel. By the end of fiscal year 2009, the NVSL and the CVB will use USDA's web-based Learning Management System (AgLearn) as the main source for non-technical training records.

The NVSL will maintain technical training records using quality management software, which will be fully implemented by December 2009. This software will capture all data currently captured on hard copy records in the labs including training on specific equipment, proficiency test records, training on new standard operating procedures and quality management, and internal auditor training. In addition, the system will generate reminders for periodic refresher training.

Upcoming revisions to the CVB Quality Manual will include consolidation of APHIS-mandated and competency-based training into one location. The NVSL/CVB Training program will be further enhanced by the finalization of the combined service administrative unit within the NCAH and the move to the new facilities, both of which are expected to occur in 2009.

Recommendation: For CVB, it is recommended that the quality manual include one section on training and include a complete description of the training process all in one section, including grandfathering of staff previously hired, and locations of the different training files, so as to avoid contradictory statements.

Response: The CVB agrees with this recommendation and has included it in a revision of the Quality Manual, currently under review. The new version of the Manual will be finalized upon completion of the move to the new consolidated laboratory facility.

Recommendation: It is recommended that the CVB Quality Manager consider providing a brief ISO refresher training every 1 to 2 years, to include documentation requirements and any significant issues or finds and lessons learned.

Response: The CVB agrees with this recommendation and has included it in a revision of the Quality Manual, currently under review. The new version of the Manual will be finalized upon completion of the move to the new consolidated laboratory facility.

Pharmacovigilance program:

Recommendation: The Adverse Event Reporting overall would be improved if it were made mandatory, at least to the level of licensed veterinarians using the products.

Response: The CVB agrees that the amount of adverse event reporting is impacted by the voluntary nature of the program. While the regulations currently mandate manufacturers to report instances of licensed products that are not in compliance with the laws and regulations, we are working with the Food and Drug Administration on the technical aspects of a standardized reporting system that could be utilized by practitioners and the biologics and pharmaceutical industries.