PROJECT SUMMARY

Overview

The Texas Veterinary Medical Diagnostic Lab is committed to building a strong environmental health, safety, and biosecurity program to maintain the safety and security of Agency personnel. This program will help ensure resources are used efficiently and effectively and in compliance with applicable laws, System regulations, and Agency rules. Considerable measures have been taken since 2006 to build a strong control structure such as developing a comprehensive set of standard operating procedures which include safety requirements, creating a database to track safety issues, and hiring additional resources dedicated to this work.

The Agency's most recent accreditation report included laudatory comments regarding the improvements in quality and safety. However, further improvements are needed to better ensure that some current safety processes are functioning effectively. Formal internal and external lab inspections had not been performed in more than a year prior to the start of the audit including inspections of the Biosafety Level 3 laboratory facilities. In addition, certain safety issues identified in the most recent lab inspections from 2006 and early 2007 have not been fully addressed. Other areas of improvement include addressing fire and life safety issues within the current lab inspection process and installing biosafety cabinets in receiving areas.

Summary of Significant Results

Laboratory Inspection Process

Formal internal inspections of laboratories last occurred in 2006 shortly after the current Director of Quality and Safety was hired. In addition, Biosafety Level 3 (BSL3) lab

Biosafety level: A specific combination of work practices, safety equipment, and facilities which are designed to minimize the exposure of workers and the environment to infectious agents.

The biosafety levels are:

Level 1 – suitable for work involving well-characterized agents not known to cause disease in healthy adult humans, and of minimal potential hazard to laboratory personnel and the environment.

Level 2 – similar to Level 1 and is suitable for work involving agents of moderate potential hazard to personnel and the environment.

Level 3 – applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents which may cause serious or potentially lethal disease as a result of exposure by the inhalation route.

Level 4 – required for work with dangerous and exotic agents which pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease.
facilities, including both the permanent and mobile BSL3 labs, were last inspected by the Texas A&M University Environmental Health and Safety Office in July 2006 and April 2007, respectively.

Without timely inspections of laboratory facilities including the resolution of issues identified, there is a greater chance that safety issues exist within the labs that could cause potential harm to employees and others who may be in close proximity to the labs.

Summary of Management’s Response

Texas Veterinary Medical Diagnostic Laboratory management considers safety the foundation for achieving our mission. As such, each recommendation from the audit team has been carefully examined and will be implemented to its fullest extent. In addition to the recommendations of the audit team, the Agency management team is identifying additional areas that will help enhance our safety procedures and ensure our facilities are operating in a safe and secure manner.

Scope

The review of environmental health, safety and biosecurity processes focused on the areas of safety guidance, communication and training, laboratory inspections, and safety issue resolution. Documentation and activities were reviewed primarily for the period September 2007 through July 2008 although some activities outside of this time period were examined as necessary. Fieldwork was conducted from May through July 2008.
OBSERVATIONS, RECOMMENDATIONS, AND RESPONSES

1. Laboratory Inspection Process

Observation

Although a laboratory inspection process is in place the following conditions were noted:

- Formal inspections of laboratories by safety personnel last occurred in 2006 shortly after the current Assistant Agency Director for Quality Assurance and Safety Programs was hired. Due to the intensive efforts in building the Quality Assurance and Safety infrastructure during the past two years, fewer resources have been available to focus on some current safety controls such as formal lab inspections. Informal lab reviews have occurred to some extent during everyday operations; however, formal inspections are needed to ensure that all safety issues have been identified and properly addressed.

- The Biosafety Level 3 (BSL3) lab facilities, including both the permanent and mobile BSL3 labs, last received an external inspection by the Texas A&M University Environmental Health and Safety Office in July 2006 and April 2007, respectively. An intrasystem agreement currently exists with Texas A&M for these services to be performed annually. However, the inspections were not performed within the past year as stated in the agreement. This agreement does not provide sufficient detail regarding the roles and responsibilities of each party, including assurances that these services will be carried out in a timely manner.

- The Agency has not fully addressed recommendations from the Texas A&M Environmental Health and Safety Office’s inspection of the mobile BSL3 laboratory performed in April 2007. The following recommendations remain:
  
  ◦ Seals in several areas on the laboratory trailer need to be repaired. Ideally, the seals should be checked whenever the trailer is moved.

  ◦ The eyewash unit installed in the laboratory trailer does not have adequate clearance and needs to be moved forward.

Without timely inspections of laboratory facilities including the resolution of issues identified, there is a greater chance that safety issues exist within the
labs that could cause potential harm to employees and others who may be in close proximity to the labs.

A&M System Regulation 24.02.01 states the Chief Executive Officer is responsible for establishing a procedure for environmental health and safety inspections so that potential hazards and risks are detected and corrected or controlled in a timely manner.

Recommendation

To improve the lab inspection process the Agency should:

- Prepare a schedule of laboratory safety inspections and ensure that all areas of the laboratory facilities are formally inspected at least annually by safety personnel.

- Ensure that formal safety inspections for BSL3 lab facilities are also performed at least annually by a qualified external entity by executing a contract with this entity specifying each institution’s roles and responsibilities for performing the inspections including assurances regarding performance.

- Fully address in a timely manner all laboratory inspection issues identified including the remaining recommendations from the April 2007 external inspection of the mobile BSL3 laboratory.

Management's Response

- The Agency is working to establish a memorandum of understanding (MOU) with the Texas A&M Office of Biosafety. Under this agreement, the Texas A&M Biosafety Officer will provide regular (annual) inspections of the Agency laboratories (Biosafety Level-2 and 3). These inspections, the first of which is scheduled for later in 2008, will involve evaluation of laboratory safety procedures and certifications of biological safety level-3 facilities. The MOU will define responsibilities of each party and is expected to be implemented by December 31, 2008. The MOU will be forwarded to System Internal Audit when finalized.

- The existing Agency agreement with the Texas A&M Environmental Health and Safety Office provides for chemical, fire and life safety, hazardous material shipping, biological safety (general safety protocol review), radiological safety and occupational safety services. This agreement will be reviewed in concert with establishing the new agreement with the Texas A&M Office of Biosafety. Duplicate services will be eliminated from the Environmental Health and Safety Office agreement. A copy of the new agreement will be forwarded to System Internal Audit when finalized.
• The Agency recently created a Laboratory Safety Officer position. The successful candidate for this position will be responsible for enhancing and implementing safety procedures at all four Agency laboratories; development and implementation of comprehensive safety and security programs; performance of regular and frequent laboratory internal reviews; providing deficiency reports to the Director; overseeing the correction of these deficiencies; inspecting diagnostic laboratory facilities for compliance with regulations and guidelines pertaining to use, handling and disposal of potential biohazards; reviewing plans for laboratory building construction; renovation of existing facilities to assure adherence to current biosafety and biosecurity practices; and working closely with the Texas A&M University Office of Biosafety.

Interviews for this position have been conducted, a qualified applicant has been offered the position and he is expected to begin work prior to December 15, 2008.

• The issues identified from the April 2007 external inspection of the mobile BSL-3 laboratory are at the following stages of completion:

  ° An adjustable eyewash station has been added to the sink in the mobile laboratory unit as required by the fourth edition of the Center for Disease Control's: Biosafety in Microbiological and Biomedical Laboratories (BMBL).

  ° Cracked seals have been caulked.

  ° Carpet will be removed from the cabinets by November 30, 2008.

  ° The mobile BSL3 Unit will be inspected as part of the MOU with the Texas A&M University Office of Biosafety. As such, a test and air balance and fault testing will be performed. At this time, its suitability for use as a BSL3 mobile unit will be determined.

2. Environmental Health and Safety Control Structure

Observation

Various elements in the Agency's environmental health and safety control structure have not been fully developed or refined.

Elements are still being developed and refined within the Agency's Quality Assurance function for controlling and monitoring environmental health and safety as follows:

• The Agency revised its Standard Operating Procedure (SOP) format to include safety requirements and other pertinent information. All SOPs are required to be converted to the new format by September 30, 2008. Several SOPs are still in the process of being updated and issued, and as a result do not yet contain safety sections. In addition, some Amarillo
2. Environmental Health and Safety Control Structure (cont.)

SOPs have not yet been fully incorporated into agency-level SOPs where appropriate.

- Six of ten corrective action requests (CARs), which are used to track issues that need to be resolved, from previous laboratory inspections were not closed properly within the due date according to the CARs tracking database. These were all issued prior to September 2006. Four of these six had been completed, but the database had not been updated to reflect these actions. Two of the six have not been completed. Also, a review of the database showed that there were two CARs that had been closed with reference to another CAR. Specific action and verification dates for the closed CARs were not noted in the database. Without properly updating and maintaining the CARs database, safety deficiencies identified may not be resolved.

- Currently, it is not possible to identify trends from the CARs tracking database due to the lack of a standard identification phrase or categorization for each CAR. The ability to identify and analyze trends in the CARs database is needed to help identify safety problem areas that may require greater focus and attention by safety personnel.

Recommendation

Complete the development of the Agency control structure elements over environmental health and safety by:

- Adding a safety section in all remaining SOPs and procedures and ensuring that SOPs and procedures are updated every two years in accordance with Agency procedures.

- Incorporating Amarillo operating procedures regarding safety into the new Agency SOPs to ensure that all safety issues have been adequately included.

- Reviewing and updating the CARs tracking database monthly to ensure information is accurate and complete and all CARs have been addressed in a timely manner.

- Adding a standard field to the CARs tracking database indicating the type/category of safety issue (e.g. storage, electrical, vaccinations, biological safety cabinets, etc.) to provide the ability to sort and track safety trends as needed.

Management’s Response

- Ninety-seven percent of SOPs have been converted to the new format which includes safety requirements and other pertinent information. The
remaining SOPs will be converted to the new format by November 30, 2008. In order to ensure that all SOPs are updated every two years in accordance with Agency policy, a complete list of SOPs that are approaching the review timeline will be provided to the Quality Management Team during the Agency's quarterly quality management review. Quality management reviews are now occurring on a quarterly basis instead of annually. This provides the Director and Executive Management Team with more frequent opportunities to review the direction and needs of the Quality Team and Quality Assurance Program. Converted SOPs will be provided to the System Internal Audit office when 100% completed.

- Amarillo’s standard operating procedures have been converted to the new format to ensure that all safety issues are adequately addressed.

- The database for tracking CARs is now updated on a monthly basis. This database is subsequently provided to each individual present at the Quality and Safety Committee meetings which are held monthly. Individuals at this meeting represent each laboratory and/or section within the Agency.

- The Corrective Action database has been expanded to include the type of corrective action (with regards to safety) that is being addressed in the respective CAR.

3. Fire and Life Safety

Observation

Fire and life safety is not currently included in the Agency’s Environmental Health and Safety Procedures, nor was it observed in the lab inspections performed during the audit. Fire and life safety programs and practices are designed to help ensure safe working environments for employees. A&M System Regulation 24.01.04 states that each Component shall, as appropriate, adopt procedures to identify and address fire/life safety deficiencies through inspections of facilities and grounds.

Recommendation

Add fire and life safety inspection processes to the current Environmental Health and Safety Procedures and address this area in all laboratory inspections performed.

Management’s Response

A fire and life safety section has been added to the Agency’s Environmental Health and Safety Procedure (TVMDLS-EHS-P0001, Section 9.30). Fire
3. Fire and Life Safety (cont.)

and life safety will be addressed in all internal and external laboratory safety inspections.

4. Biosafety Cabinets

Observation

Biosafety cabinets are not currently installed in the receiving areas at the College Station and Amarillo labs as recommended by the American Association of Veterinary Laboratory Diagnosticians. Without biosafety cabinets in the receiving areas, the possibility exists that employees could be exposed to potentially infectious materials when opening leaking packages or packages containing infectious materials. Management has indicated that plans are currently in place to install biosafety cabinets in these areas and address their use in the Agency’s standard operating procedures. Currently, in the absence of biosafety cabinets in the receiving area, management indicated that packages which contain potentially infectious materials or those packages that are leaking are opened in the necropsy area. The traffic in this area is restricted to authorized personnel only and thus provides a more biosecure environment for this type of activity.

Recommendation

Continue with current plans to install biosafety cabinets in the receiving areas at both the College Station and Amarillo labs and address their use in the Agency’s standard operating procedures.

Management’s Response

Management is currently working to enhance the safety and functionality of the sample receiving facilities at both the College Station and Amarillo laboratories.

Renovations to the Amarillo laboratory, which will begin during 2009, include complete renovation of the sample receiving area. A biological safety hood will be added to this area to enhance biosafety practices. Expected completion date is November 2010.

The College Station sample receiving area will be relocated within the facility. The current sample receipt area will continue to function until the newly identified area can be renovated to accommodate this function. This newly renovated space will contain a biological safety hood capable of protecting the workers from potentially infectious diseases. Renovation is expected to be completed by June 2010.
BASIS OF REVIEW

Objective

The overall objective was to review and assess the adequacy of the Agency's processes for the environmental health, safety, and biosecurity program. Also to determine if resources are used efficiently and effectively and in compliance with laws, policies, regulations, and rules to ensure the safety and security of Agency personnel.

Criteria

Our audit was based upon standards as set forth in the System Policy and Regulation Manual of The Texas A&M University System; the Treadway Commission's Committee of Sponsoring Organization's Internal Control - Integrated Framework (COSO); Texas Veterinary Medical Diagnostic Laboratory’s Standard Operating Procedures; federal and state laws; and other sound administrative practices. This audit was performed in compliance with the Institute of Internal Auditors’ “International Standards for the Professional Practice of Internal Auditing.”

Additionally, we conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

As part of its overall mission to aid and educate the animal industries of Texas in identifying diseases and helping to protect the health of the state's citizens by identifying diseases transmissible from animals to people, the Agency provides veterinary diagnostic services primarily to veterinary practitioners in Texas. The lab is one of only 32 full-service diagnostic labs in the United States and Canada accredited by the American Association of Veterinary Laboratory Diagnosticians. The Agency has two full-service laboratories (College Station and Amarillo) and two poultry laboratories (Center and Gonzales). The College Station facility houses the state's only Biosafety Level 3 veterinary diagnostic labs which are equipped to deal with the deadliest animal diseases. Over the next two years the Agency also plans to modify the current Amarillo building structure to add a Biosafety Level 3 laboratory and complete a construction project to improve the
Specimen Receiving and Specimen Processing facilities at this laboratory facility.

Laboratory safety comprises the most significant element of the safety function at Texas Veterinary Medical Diagnostic Laboratory. This function currently comprises a staff of four including staff at both the College Station and Amarillo labs. The Agency is also in the process of hiring a full-time laboratory safety officer so that the duties of quality assurance and safety can be divided and each given appropriate emphasis. This position will report directly to the Agency Director.
AUDIT TEAM INFORMATION

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