Privacy Impact Assessment
LabWare LIMS

Cyber and Privacy Policy and Oversight

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Privacy Impact Assessment for the LabWare LIMS

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Revision	**Date**	**Author**	**Comments**
1.0	11/4/2010	Brenda Bunn	Initial Release
1.1	10/25/2011	James A. Vanderwielen	Addition of Section 10 – Third Party Website/Application. Change to Project Manager assignment.
1.2	4/3/2012	Tony Lascio	Updated Contact Information Updated system information/connections Added APHIS ISSPM, CIO, and PO signature lines
1.3	8/7/2013	Tony Lascio	Updated dates and signature page with CIO information (replaced Marilyn Holland with Gary Washington)
2.0	4/24/2014	Tony Lascio	Updated dates and signature page. Also updated section 5.2 to include SORN information.

Abstract

- This Privacy Impact Assessment (PIA) is for the USDA, APHIS, Veterinary Services (VS), National Veterinary Services Laboratories (NVSL), Laboratory Information Management System (LIMS).
- The LabWare LIMS is used to manage diagnostic testing and reagent/agent inventory efforts at USDA, APHIS, VS, NVSL. It holds information related to the submitters and owners of samples, sample specific information, testing data, agent/reagent inventories and usage history.
- This PIA was conducted because the system collects personally identifiable information.

Overview

- The LabWare LIMS is owned by USDA, APHIS, VS, NVSL.
- The LabWare LIMS is a laboratory information system that tracks and saves test results on diagnostic samples received at the USDA, APHIS, VS, NVSL. This includes submitter/owner information, sample information, and test results.
- The LabWare LIMS contains information about customers and diagnostic samples they are submitting, employee names and job-related information, reagent inventory samples, and test results information.
- Users, which are USDA employees, enter data from laboratory records or paperwork provided by sample submitter into a form in the LabWare LIMS application. When that form is saved the application sends the data to the database server. Requests for information are made in a similar manner. The request is compiled on the application server and transmitted to the database. The database renders the information back to the application which then displays the information to the authorized user. Automated reports are delivered via email or fax when authorized for release. Access to the LabWare LIMS is internal to USDA, APHIS staff.
- STRAND is owned by USDA, APHIS, VS, NVSL.
- STRAND is an APEX based application that allows USDA, APHIS personnel to view test results, reports, and submission forms which have been released by the NVSL from LabWare LIMS.
- STRAND contains all information released on reports from the NVSL including submitter, owner, animal, and test result information.
- This application has an Authority to Operate (ATO) letter dated 2/11/08 and is categorized as a "Moderate" system. The system is currently awaiting concurrency for Phase 2 of its Certification and Accreditation (C&A).

Section 1.0 - Characterization of the Information

The following questions are intended to define the scope of the information requested and/or collected as well as reasons for its collection as part of the program, system, rule, or technology being developed.

1.1 What information is collected, used, disseminated, or maintained in the system?

The application collects the following types of information:

Customer:
- Shipping Address
- Invoice Address
- Contact Name
- Contact Phone Number
- Contact e-mail
- Order/Billing Information

(National Finance Center Account Number or Credit Card – only last 4 digits)

Employee:
- Employee Name
- Employee Business Phone Number
- Employee business e-mail
- Employee Organizational Group within NVSL and Center for Veterinary Biologics (CVB)

This information is maintained to determine current contact information as well as access requirements. A history of this information is not maintained in the system.

Other:
- Diagnostic sample information
- Diagnostic testing information
- Tracking information on biological agents and toxins
- Tracking information on reagents.

Employee information contained in the database is only job-related (e.g. name, position, job email). This application is a database that stores information from APHIS staff input, and creates data that are sent to the USDA, APHIS, User Fees System (UFS) application.

1.2 What are the sources of the information in the system?

The sources of information in the system are from submission forms that accompany laboratory specimens sent into the laboratory for diagnostic testing. The NVSL receives approximately 50,000 submissions annually from State and private veterinary diagnostic laboratories as well as private veterinary practitioners, Federal meat inspectors, Federal field veterinarians, and others. In addition, the NVSL receives laboratory samples from other countries for import cases and for cases where diagnostic assistance is requested.

The system also contains an inventory of biological reference and reagent material developed at the NVSL.

1.3 Why is the information being collected, used, disseminated, or maintained?

The information is required in order to process samples through the testing and reporting workflow in the laboratories. The system also maintains test records as required by APHIS policy.

1.4 How is the information collected?

The information is collected using an official NVSL submission form which best fits the type of sample being submitted. An official NVSL submission form is used for every sample submitted:

VS 10-4 – General Specimen Submission
VS 10-3 – Request for Salmonella Serotyping
VS 5-38 – Parasite Submission Form
VS 6-35 – Report of Thoracic Granulomas in Regular Kill Animals
VS 4-54 – Brucellosis Test Record Market Cattle Testing Program
VS 5-14 – Dip Sample Data
VS 17-31 – Dourine and Glanders Import Test Report

In addition, an inventory of biological reference and reagent material is maintained by authorized NVSL employees.

1.5 How will the information be checked for accuracy?

The following steps are taken for data verification:

1. Submission form received and data entered by receiving technician.
2. Testing is performed and documented by lab technician.
3. Test results are entered into the system by a data entry clerk or lab technician.
4. Lab Manager checks for accuracy, by reviewing submission documents and test results document that were entered into the system by a clerk or technician.
5. Case Coordinator verifies completeness of data by reviewing documents.

Data are randomly audited by internal quality assurance personnel and occasionally by external auditors conducting peer reviews or accreditation audits to ensure the NVSL is adhering to strict ISO accreditation standards.

An x_data_integrity_check.sql statement is run weekly. The SQL currently checks for errors in a variety of areas (including but not limited to):

- Closed accessions where all appropriate accession level data appropriately shows the accession as closed. For example, project.closed = 'T' and project.template like 'CLSD%' and project.x_internal_status = 'CF' or = 'XX', project.x_date_closed is not null.

- Closed accessions with parent samples that have not either been authorized or cancelled.

- Outbreak accessions where project.x_outbreak = T but x_outbreak_name is null. Accessions where required fields in project table are null.

- Billable accessions where there are errors in billing data.

Whenever a developer notices a new problem with data, they are asked to develop a SQL statement that can be used to detect if that data problem comes up again in the future.

1.6 What specific legal authorities, arrangements, and/or agreements defined the collection of information?

The collection of information in the LabWare LIMS system is thru OMB-approved forms 10-4, 10-3, 5-38, 6-35 and 5-14. Additional information on these forms can be found at: http://www.aphis.usda.gov/animal_health/lab_info_services/forms_publications.shtml. Validity of these forms invokes OMB's approval number:

U.S Legal Code: Title 7, Chapter 9, #8308 is invoked to validate the collection of information.

U.S Legal Code: Title 7, Chapter 9 #8308: Detection, control and eradication of diseases and pests:

(A) In general
The Secretary may carry out operations and measures to detect, control or eradicate any pest or disease of livestock (including the drawing of blood and diagnostic testing of all animals), including animals at a slaughterhouse, stockyard or other point of concentration.

(B) Compensation

(1) In general
The Secretary may pay a claim arising out of the destruction of any animal, article, or means of conveyance consistent with the purposes of this chapter.

(2) Specific Cooperative programs
The Secretary shall compensate industry participants and state agencies that cooperate with the Secretary in carrying out operations and measure under subsection (A) for 100 percent of eligible costs relating to cooperative programs involving Federal, State and industry participants to control diseases of low pathogenicity in accordance with regulations issued by the secretary.

(3) Reviewability
The action of the Secretary in carrying out paragraph (1) shall not be subject to review by any officer or employee of the Federal government other than the secretary or the designee of the secretary.

1.7 Privacy Impact Analysis: Given the amount and type of data collected, discuss the privacy risks identified and how they were mitigated.

All access to LabWare LIMS is internal to USDA, APHIS, VS staff. Submitting veterinarians, Area Veterinarian in Charge, and State veterinarians receive test reports through an APEX application (STRAND) that is fed by LabWare LIMS but they have no direct access to LabWare LIMS.

User accounts control the permissions in the LabWare LIMS. The LabWare LIMS functions are assigned to roles. A user account is granted one or more roles. At login, the user must select a role they have been granted which enables the associated functions. Users only see roles they have been granted. Row level access to information is enforced by the application. There are approximately 200 users to the system. The users are NVSL and CVB employees that are located at the USDA offices in Ames, Iowa, or Plum Island, New York.

Section 2.0 - Uses of the Information

The following questions are intended to clearly delineate the use of information and the accuracy of the data being used.

2.1 Describe all the uses of information.

Records in the system document the results of individual animal disease testing performed by or under the auspices of the NVSL. Records include official test reports for animal import, export, movement, and program disease status certifications. Also included are official test results for suspected foreign animal disease investigations and for animal diseases targeted by the USDA for control or eradication.

Records in the system provide current and historical data used for detecting animal diseases, conducting emergency responses, conducting and evaluating animal disease control measures, performing epidemiological investigations, and forecasting possible animal disease occurrences and outbreaks.

2.2 What types of tools are used to analyze data and what type of data may be produced?

This application is a database which stores information and does not analyze or produce data.

LabWare LIMS uses Crystal Reports and a PDF converter, which are embedded into the LabWare LIMS Commercial-Off-The Shelf (COTS) software. LabWare LIMS does not use open source software.

2.3 If the system uses commercial or publicly available data please explain why and how it is used.

The system does not use commercial or publicly available data.

2.4 Privacy Impact Analysis: Describe any types of controls that may be in place to ensure that information is handled in accordance with the above described uses.

Privacy rights of the customer and employees will be protected by USDA, APHIS, VS, NVSL management. Target systems also have security controls to address access/security of information.

- All access to the data in the system is controlled by formal authorization. Each individual's supervisor must identify (authorize) what functional roles that individual needs in the LabWare LIMS system. Once the roles have been identified, the individual must pass a proficiency test approved by the Quality Assurance staff and perform tasks associated with that role. Once the completed forms for both have been received verifying both areas, the individual is given access to the production instance of LabWare LIMS.
- All access to the system is limited by username/password.

- Access to information in the system is controlled using role-based access which limits access to relevant information and prevents access to unauthorized information.
- Users are trained and are required to formally confirm that they understand value and sensitivity of data in the system.
- All users receive formal system training and are required to pass a proficiency test before being given access to the system.
- Warning banner must be acknowledged before logging in.

Section 3.0 - Retention

The following questions are intended to outline how long information will be retained after the initial collection.

3.1 How long is information retained?

Paper records are retained for a minimum of 3 years. Data is maintained in the system for 25 years. The data is archived at 5 years intervals.

3.2 Has the retention period been approved by the component records officer and the National Archives and Records Administration (NARA)?

Records will be retained permanently until APHIS has a records retention schedule for the system approved by the National Archives and Records Administration.

3.3 Privacy Impact Analysis: Please discuss the risks associated with the length of time data is retained and how those risks are mitigated.

Risks associated with data retention are minimal and include the possibility of the data being accessed by unauthorized personnel. However, test reports and submission forms contain data of limited use. Very little, if any, of the data stored are of a sensitive nature. Personally Identifiable Information (PII) would be limited to names, addresses, and phone numbers of submitters; data that are usually easily accessible by other means.

Section 4.0 - Internal Sharing and Disclosure

The following questions are intended to define the scope of sharing within the USDA.

4.1 With which internal organization(s) is the information shared, what information is shared and for what purpose?

For customers who pay via NFC, LabWare LIMS information for diagnostic testing and reagents will be transferred to the NFC via the APHIS, VS, UFS.

Information is also shared with USDA, APHIS employees through STRAND. This information includes report data released by the NVSL to the AVICs and other internal employees.

4.2 How is the information transmitted or disclosed?

APHIS staff enters the data into a form in the LabWare LIMS application. When that form is saved the application sends the data to database server located in the same LAN. Requests for information are made in a similar manner. The request is compiled in the application and transmitted to the database. The database renders the information back to the application which then displays the information to the authorized user. Automated reports are delivered via email or fax when authorized for release.

All access to LabWare LIMS is internal to USDA APHIS staff. Submitting veterinarians, Area Veterinarian in Charge, and State veterinarians receive test reports through an APEXbased system (STRAND) that is fed by LabWare LIMS but they have no direct access to LabWare LIMS.

User accounts control the permissions. LabWare LIMS functions are assigned to roles. A user account is granted one or more roles. At login, the user must select which role they will be acting in, which enables the associated functions. Row level access to information is enforced by the application. There are approximately 200 users of the system. The users are NVSL and CVB employees that are located at Ames, Iowa, or Plum Island, New York.

Data is retrieved by either an accession number which is a system generated ID or a sample number which was assigned by the submitter. Searches may also be performed using personally identifiable information such as submitter first name, last name, or company name in order to determine accession numbers associated with their submitter number.STRAND access is controlled by user accounts and the accounts permissions. Roles consist of a state based role or a role that has access to all states. For users with the state based role a state or list of states must also be assigned to the user account to designate to which states the user has access.

STRAND is updated nightly with information released by the NVSL to the AVICs on that day. The designated information is pulled from LabWare LIMS and is only accessible to STRAND users in a view only format.

4.3 Privacy Impact Analysis: Considering the extent of internal information sharing, discuss the privacy risks associated with the sharing and how they were mitigated.

- All access to the data in the system is controlled by formal authorization.
- All access to the system is limited by username/password.
- The application limits access to relevant information and prevents access to unauthorized information.
- Users are trained and required to formally confirm that they understand value and sensitivity of data in the system.
- All users receive formal system training and are required to pass a proficiency test before being given access to the system.
- Warning banner must be acknowledged before logging in.
- Shared information is restricted to what pre-defined views and procedures allow.
- All information sharing with internal systems is done over the internal APHIS network.
- Encryption of information in transit between systems is defined by the host systems (USDA, APHIS, VS, UFS and National Animal Health Laboratory Network Information System), not LabWare LIMS. LabWare LIMS will comply with mandated encryption settings when communicating with said systems.

Section 5.0 - External Sharing and Disclosure

The following questions are intended to define the content, scope, and authority for information sharing external to USDA which includes Federal, State and local government, and the private sector.

5.1 With which external organization(s) is the information shared, what information is shared, and for what purpose?

All data for a submission is shared with the submitter and, when designated, state animal health officials of the submitter state, owner state, and animal location state. They receive a test report with the data submitted and the results of the testing. The original submission form may also be included with the test report.

The purpose of sharing the data is to provide diagnosis of domestic and foreign animal diseases and support of disease control and eradication programs.

5.2 Is the sharing of personally identifiable information outside the Department compatible with the original collection? If so, is it covered by an appropriate routine use in a SORN? If so, please describe. If not, please describe under what legal mechanism the program or system is allowed to share the personally identifiable information outside of USDA.

NVSL plans to share data collected in the LabWare database with the submitting veterinarian and State veterinarians of the submitter state, owner state, and animal location state; Federal officials to manage animal disease events; VS staff for administration, oversight, and decision-making about animal disease program activities; USDA officials for investigating possible violations of USDA regulations and Federal laws; and other VS staff. This sharing of information is compatible with the purpose of diagnosing animal diseases and supporting VS disease control and eradication programs.

A SORN has been published and is named APHIS-19 Laboratory Information Management System. Information shared with the submitting veterinarian and State veterinarian will be identified as a "routine use" in the SORN.

The animal health protection act: Title 7, CFR Chapter 109 specifically parts 8301, 8308, and 8310

5.3 How is the information shared outside the Department and what security measures safeguard its transmission?

Submitting veterinarians and State veterinarians receive test reports by email and/or through STRAND, but they have no direct access to LabWare LIMS.

5.4 Privacy Impact Analysis: Given the external sharing, explain the privacy risks identified and describe how they were mitigated.

The risks identified are minimal as they will only include sharing names and addresses of animal owners that are likely to be easily available to the State Veterinarians through other avenues such as plat maps or property tax records. The risks are mitigated through only sharing the data with the submitting veterinarian and State veterinarians of the submitter state, owner state, and animal location state that need to be aware of diseases and tests results in their state.

Section 6.0 - Notice

The following questions are directed at notice to the individual of the scope of information collected, the right to consent to uses of said information, and the right to decline to provide information.

6.1 Was notice provided to the individual prior to collection of information?

The data are submitted voluntarily when cases are submitted to the laboratory. There is an expectation by the submitter that a record will be kept of the test and test result. The majority of submitters are repeat customers and they know that they have a number assigned to their entity that is in our database.

6.2 Do individuals have the opportunity and/or right to decline to provide information?

Individuals that submit samples to be tested at the laboratory must submit all data required to assign appropriate test and report results. Individuals are not compelled to submit samples to the laboratory, however if an individual does choose to submit samples, required information to include personal information must be included.

6.3 Do individuals have the right to consent to particular uses of the information? If so, how does the individual exercise the right?

No. The data are treated uniformly for all submitters. Only information that is cleared through the Freedom of Information Act is available for use.

6.4 Privacy Impact Analysis: Describe how notice is provided to individuals, and how the risks associated with individuals being unaware of the collection are mitigated.

No data are collected without the individual's knowledge as all data are voluntarily submitted to the laboratory along with test samples.

Section 7.0 - Access, Redress and Correction

The following questions are directed at an individual's ability to ensure the accuracy of the information collected about them.

7.1 What are the procedures that allow individuals to gain access to their information?

Test results are delivered to the submitters after tests are complete via email or fax.

7.2 What are the procedures for correcting inaccurate or erroneous information?

Inaccurate data are corrected by submitting requests to the Information Management group at the laboratory, and laboratory manager approval is required in order for corrections to be made, and detailed auditable records are produced when changes are made identifying who authorized and made the change, and when it was made.

7.3 How are individuals notified of the procedures for correcting their information?

If changes are made to laboratory testing results, a corrected or amended final report would be furnished to the submitter with an explanation of the changes included.

7.4 If no formal redress is provided, what alternatives are available to the individual?

The data are factual, and no redress is required for this type of data reporting. The data are test reports that are voluntarily sought out by customers of the laboratory who are submitting samples for testing.

7.5 Privacy Impact Analysis: Please discuss the privacy risks associated with the redress available to individuals and how those risks are mitigated.

Data in the system are of limited sensitivity. Any data used or furnished to others would need to be cleared through the Freedom of Information Act process. Any data obtained illegally by unauthorized personnel would be of limited use and could potentially be obtained easily by other means (e.g. names, addresses, and telephone numbers). Data are all submitted voluntarily by customers who seek out diagnostic services from the NVSL. Incorrect data are corrected only with high level authorization, and corrected data are furnished to individuals affected.

Section 8.0 - Technical Access and Security

The following questions are intended to describe technical safeguards and security measures.

8.1 What procedures are in place to determine which users may access the system and are they documented?

Access to LabWare LIMS is based on the need to do business and determined by USDA, APHIS, VS, NVSL management. Criteria, procedures, and controls are documented in the internal standard operating procedure IMSOP300.03 (System Access to the National Veterinary Services Laboratories' Laboratory Information Management System – Labware).

8.2 Will Department contractors have access to the system?

Access is based on need and limited to USDA, APHIS, VS, NVSL employees. Department contractors do not have access to the system.

8.3 Describe what privacy training is provided to users either generally or specifically relevant to the program or system?

Currently, all individuals provided access to the LabWare LIMS system are required to complete annual Information Technology (IT) Security Awareness Training and must sign APHIS Rules of Behavior form prior to receiving access to the information system.

Users are trained and are required to formally confirm that they understand the value and sensitivity of data in the system. All users receive formal system training and are required to pass a proficiency test before being given access to the system.

A information security warning banner must also be acknowledged and accepted before logging in to the system.

8.4 Has Certification and Accreditation been completed for the system or systems supporting the program?

This application has an ATO dated 2/11/08. The system is currently awaiting concurrency for Phase 2 of its Certification and Accreditation (C&A).

8.5 What auditing measures and technical safeguards are in place to prevent misuse of data?

- All access to the data in the system is controlled by formal authorization.

- All access to the system is limited by username/password.
- Application limits access to relevant information and prevents access to unauthorized information.
- Users are trained and are required to formally confirm that they understand value and sensitivity of data in the system.
- All users receive formal system training and are required to pass a proficiency test before being given access to the system.
- Warning banner must be acknowledged before logging in.
- Auditing is enabled both at the application and database level. Application-level auditing is defined by the vendor and enabled in the LabWare LIMS implementation. Database-level auditing is implemented and monitored according to internal SOP.

8.6 Privacy Impact Analysis: Given the sensitivity and scope of the information collected, as well as any information sharing conducted on the system, what privacy risks were identified and how do the security controls mitigate them?

Given the sensitivity and scope of the information collected, as well as any information sharing conducted on the system, no privacy risks were identified.

Section 9.0 - Technology

The following questions are directed at critically analyzing the selection process for any technologies utilized by the system, including system hardware and other technology.

9.1 What type of project is the program or system?

The LabWare LIMS is a laboratory information system that tracks and saves test results on diagnostic samples received at the USDA, APHIS, VS, NVSL.

9.2 Does the project employ technology which may raise privacy concerns? If so please discuss their implementation.

This application does not employ technology which may raise privacy concerns.

Section 10.0 Third Party Websites/Applications

The following questions are directed at critically analyzing the privacy impact of using third party websites and/or applications.

10.1 Has the System Owner (SO) and/or Information Systems Security Program Manager (ISSPM) reviewed Office of Management and Budget (OMB) memorandums M-10-22 "Guidance for Online Use of Web Measurement and Customization Technology" and M-10-23 "Guidance for Agency Use of Third-Party Websites and Applications"?

The ISSPM has reviewed the memorandums. The system owner has not reviewed the memorandums as the system is not web enabled, is not an externally facing application, and does not use third party websites or applications.

10.2 What is the specific purpose of the agency's use of 3rd party websites and/or applications?

Not Applicable.

10.3 What personally identifiable information (PII) will become available through the agency's use of 3rd party websites and/or applications.

Not Applicable.

10.4 How will the PII that becomes available through the agency's use of 3rd party websites and/or applications be used?

Not Applicable.

10.5 How will the PII that becomes available through the agency's use of 3rd party websites and/or applications be maintained and secured?

Not Applicable.

10.6 Is the PII that becomes available through the agency's use of 3rd party websites and/or applications purged periodically?

Not Applicable.

10.7 Who will have access to PII that becomes available through the agency's use of 3rd party websites and/or applications?

Not Applicable.

10.8 With whom will the PII that becomes available through the agency's use of 3rd party websites and/or applications be shared - either internally or externally?

Not Applicable.

10.9 Will the activities involving the PII that becomes available through the agency's use of 3rd party websites and/or applications require either the creation or modification of a system of records notice (SORN)?

Not Applicable.

10.10 Does the system use web measurement and customization technology?

Not Applicable.

10.11 Does the system allow users to either decline to opt-in or decide to opt-out of of all uses of web measurement and customization technology?

Not Applicable.

10.12 <u>Privacy Impact Analysis</u>: Given the amount and type of PII that becomes available through the agency's use of 3rd party websites and/or applications, discuss the privacy risks identified and how they were mitigated.

Not Applicable. The system is not web enabled, is not an externally facing application, and does not use third party websites or applications.

Responsible Officials

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Approval Signature

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