Georgia is in urgent need of LIMS implementation to support its mission for public health, animal health, and food safety. Georgia laboratory systems operations would be more efficient and effective with integration amongst LIMS and its national disease surveillance system and eHealth system to share common data elements. Implement a LIMS that is interoperable with these existing systems would strengthen national laboratory system and real-time disease surveillance in Georgia.

LIMS User's Functional Requirements

LIMS Implementation in Georgia

Ministry of Labor, Health and Social Affairs/
National Center for Disease Control and Public Health (NCDC)
Ministry of Agriculture/Laboratory of Ministry of Agriculture (LMA)

Table of Contents

Executive Summary

A LIMS (Laboratory Information Management System) is a software program with multiple modules that manages laboratory work flows and information including but not limited to samples and test orders and results. A National Laboratory System, prepared to ensure health security in Georgia, must be able to characterize new threat events safely and securely, as early as possible, and rapidly notify public health authority, using secure laboratory Information systems. LIMS implementation aims to strengthen integrated laboratory networks and systems (both public and private) in a sustainable manner to rapidly detect, accurately identify, promptly report, which will enable public health authorities to rapidly contain and prevent infectious disease threats of public health concern, consistent with the International Health Regulations (IHR 2005).

Georgia has committed to lead The Global Health Security Agenda (GHSA) Real-Time Surveillance Action Package and a contributing country for GHSA Zoonotic Disease Action Package and GHSA National Laboratory System Action Package. GHSA was launched on February 13, 2014 to advance a world safe and secure from infectious disease threats and to bring together nations from all over the world to make new, concrete commitments, and to elevate global health security as a national leaders-level priority. LIMS is a critical component and foundation of a national laboratory system. Implementing LIMS will strengthen Georgia's capacities for real-time surveillance and zoonotic disease surveillance.

Georgia is now faced with a significant strategic decision point. Given there is no LIMS to support laboratory information management, NCDC and LMA laboratories are seizing the opportunity to evaluate the benefits of LIMS and seeking advice and input on best practices for implementation, user acceptability, and sustainability. Georgia is in urgent need of LIMS implementation to support its mission for public health, animal health, and food safety. Implementing a LIMS could address a number of following aspects:

- Improve the ability to manage laboratory test results for more rapid reporting, easier recall, and safe and secure long term storage
- Improve lab data quality and security
- Reduce duplicative data entry into multiple electronic systems
- Strengthen laboratories reference testing services and rapid result turn-around-time
- Improve laboratory management practices by tracking laboratory productivity, including, human resource requirements and material resource consumption
- Strengthen surveillance and better support of epidemiology and laboratory science efforts
- Support development of an integrated laboratory network
- Improve capability for Georgia national laboratory system to prepare for, detect and respond to public events

Georgia laboratory systems operations would be more efficient and effective with integration amongst LIMS and its national disease surveillance system (EIDSS) and One Health system (HMIS) to share

common data elements. Implementing a LIMS that is interoperable with these existing systems would strengthen national laboratory system and real-time disease surveillance in Georgia.

The User's Functional Requirements document is a collaborative effort by technical working group of NCDC and LMA, with technical assistance from the U.S. CDC, to provide guidance for LIMS implementation in Georgia. The User's Functional Requirements act as business processes to guide the development of LIMS technical specifications and implementation strategy. Twelve functional requirements that will be implemented in phases are agreed upon by NCDC and LMA.

07/17/2015

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Acronyms

AMR – Antimicrobial resistance
BT – Bio-terrorism
CBRN – Chemical, biological, radiological and nuclear warfare
CDC – The U.S. Centers for Disease Control and Prevention
CBEP – Cooperative Biological Engagement Program
DoD – Department of Defense
DTRA – Defense Threat Reduction Agency
ebXML – Electronic Business Extensible Markup Language (XML)
EDI – Electronic Data Interchange
EDP – Especially Dangerous Pathogens
EIDSS – Electronic integrated Disease Surveillance System
EQA – External Quality Assessment
FR – Functional Requirement
FY – Fiscal Year
GHS – Global health security
GHSA – Global Health Security Agenda
GIS – Geographic Information System
GUI – Graphic user interface
HCI – Human-Computer Interaction
HIPAA – Health Insurance Portability and Accountability Act of 1996
HMIS – Health Management Information System (part of Georgia eHealth)
ICD 10 – 10th revision of the International Statistical Classification of Diseases and Related Health Problems
ID – Identification
IHR - International Health Regulations (2005)
IT – Information Technology
LMA – Laboratory of Ministry of Agriculture
LIMS – Laboratory Information Management System
LOINC – Logical Observation Identifiers Names and Codes
LSS – Laboratory Support Station
MOA – Ministry of Agriculture
MOLHSA – Ministry of Labor, Health and Social Affairs
NFA – National Food Agency
NCDC – National Center for Disease Control and Public Health
PACS – Pathogen Asset Control System
PHL – Public Health Laboratory
QC – Quality Control
QA – Quality Assurance
RFP – Request for Proposal
SME – Subject Matter Expert
SMS – Short Message Service
SONMED – Systematized Nomenclature of Medicine

USG – The U.S. government
SOP – Standard Operational Procedure
ZDL – Zonal Diagnostic Laboratory

1. Georgia LIMS Implementation

1.1 Overview

A **LIMS** (Laboratory Information Management System) is a software program with multiple modules that manages laboratory work flows and information including but not limited to samples and test orders and results. The implementation of a LIMS will simplify data sharing between laboratories inside or outside of the network, improve data quality and security, facilitate central receiving of specimens and samples, and serve as an interoperability platform for the electronic exchange of test orders and results with public health labs (PHLs) at National Center for Disease Control (NCDC) and veterinary laboratories as well as food safety and plant health at Laboratory of Ministry of Agriculture (LMA).

The LIMS will be able to provide users in the NCDC and LMA Lab Networks to manage:

- Public health laboratory tests
- Veterinary health laboratory tests
- Food safety related laboratory tests
- Plant health laboratory tests
- Commercial laboratory tests

The LIMS will provide a different interface to various users to meet a specific workflow needs and to manage lab information in public health labs, veterinary labs, food safety labs, and plant labs and share lab data within the lab networks. With implementing a data exchange mechanism, the LIMS will also facilitate an electronic data interchange with other systems outside the lab networks. A LIMS conceptual diagram (Figure 1) demonstrates the LIMS implementation structure in Georgia.

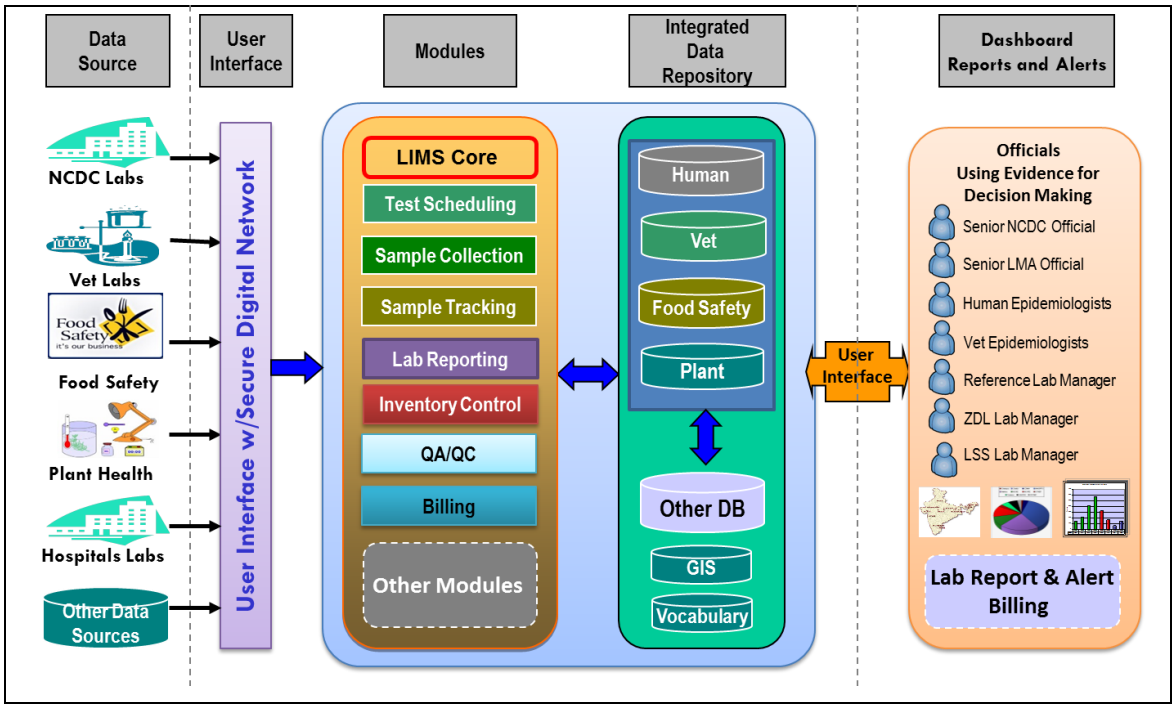


Figure 1: Georgia LIMS Conceptual Diagram

1.2 Goals and objectives

Goal of the LIMS Implementation in Georgia is

> To develop and deploy a Web-based LIMS that provides effective and efficient management of laboratory work flow and information in the NCDC and LMA laboratory networks.

Objectives:

- To implement a Web-based LIMS to manage various lab work flow and information for human health, animal health, food safety, and plant health
- To provide inventory management for NCDC and LMA laboratories at all levels
- To enable electronic data exchange (test results) amongst other electronic system, such as EIDSS, HMIS, and priority laboratory system
- To ensure QC and QA management in the NCDC and LMA laboratories
- To provide effective resource management including SOPs, equipment, grants, and certifications
- To enable electronic billing to laboratory services provided parties
- To ensure laboratory safety and assist with accident investigation
- To utilize a phased implementation approach to ensure core functionalities are ready for piloting in Fiscal Year (FY) 2016

1.3 Georgia National Laboratory System Overview

Laboratory networks provide their services to the citizens through the following two government agencies:

NCDC:

The National Center for Disease Control and Public Health (NCDC) is designated as a central Agency for public health in Republic of Georgia, under the Ministry of Labor, Health and Social Affairs (MOLHSA). As of December 2015, there are seven (7) Laboratory Support Stations (LSSs), two (2) Zonal Diagnostic Laboratories (ZDLs), and one (1) Reference Laboratory (the R. Lugar Center) comprising the NCDC tiered public health laboratory network (Figure 2).

Laboratory workflow and specimen/sample processes are further divided into Especially Dangerous Pathogens (EDP) and non-EDP areas. Non-EDP uses general public health laboratory procedures but EDP may have different procedures. The following is a summary of workflow for EDP.

- **Procedural chain of clinical sample registration:**
  - **Preanalytical stage:** Begins with receipt of notification about the case from the field work teams and ends with registration of the sample in the central register and giving it a status of sample tracking on-site
  - **Analytical stage:** Begins with submitting a sample to representative of laboratory and ends with evaluation of the results of testing and filling in the form with results of the analysis.
  - **Postanalytical stage:** Submitting the results of testing to the client.

Below are the activities by stages.

Preanalytical stage

1. Activities of the work team visiting the patient or source (reflected in FR #1.1 and FR #4)
    a) Receiving and registering notification of the case.
    b) Visiting the source by the field work team.
    c) Sample acquisition, filling in the accompanying documentation, tagging, packing, transporting.
    d) Presenting the sample and accompanying documentation at the central register.

2. Activities of the registrar at the central register (reflected in FR #1.2 and FR #4)
    a) Receiving and registration of unregistered sample, giving it a registration number.
    b) Receiving and registration of transit sample/specimen under the accompanying registration/identification number.
    c) Evaluation of condition of a sample/specimen (standard, substandard).
    d) Definition of purpose of a sample/specimen (tracking on-site, transit).
    e) Procedures for handling substandard sample/specimen.
    f) Procedures for sending standard sample/specimen and sample/specimen for transit.
    g) Submitting a standard sample and a sample tracking on-site to representative of laboratory.

Analytical stage

3. Activities before testing (reflecting in FR #1.3 and FR #4)
    a) Receiving of sample/specimen and accompanying documentation by a representative of the laboratory.
    b) Transporting of sample /specimen and accompanying documentation by a representative of the laboratory to laboratory's reception.
    c) Registration of sample /specimen in the laboratory registration journal under an accompanying number.
    d) Procedures of turning sample into specimen (preparation for sample processing, inscribing registration number on sample plate, preparation of derivatives, aliquot, storing, transferring, etc.).
4. Activities during testing (reflected in FR #1.4)
    a) Selecting laboratory algorithm according to required test (laboratory algorithm includes all the necessary tests for indication and identification of the given pathogen, put in a certain sequence).
    b) Staging of tests, registering and verifying results, entering results in special forms and journals.
5. Activities after testing (reflected in FR #1.5)
    a) Evaluating test results and making a final conclusion.
    b) Filling in the form of for results of laboratory study.

Post-analytical stage

6. Submitting the filled in answer forms to the central reception.
7. Submitting the filled in answer forms to the clients.

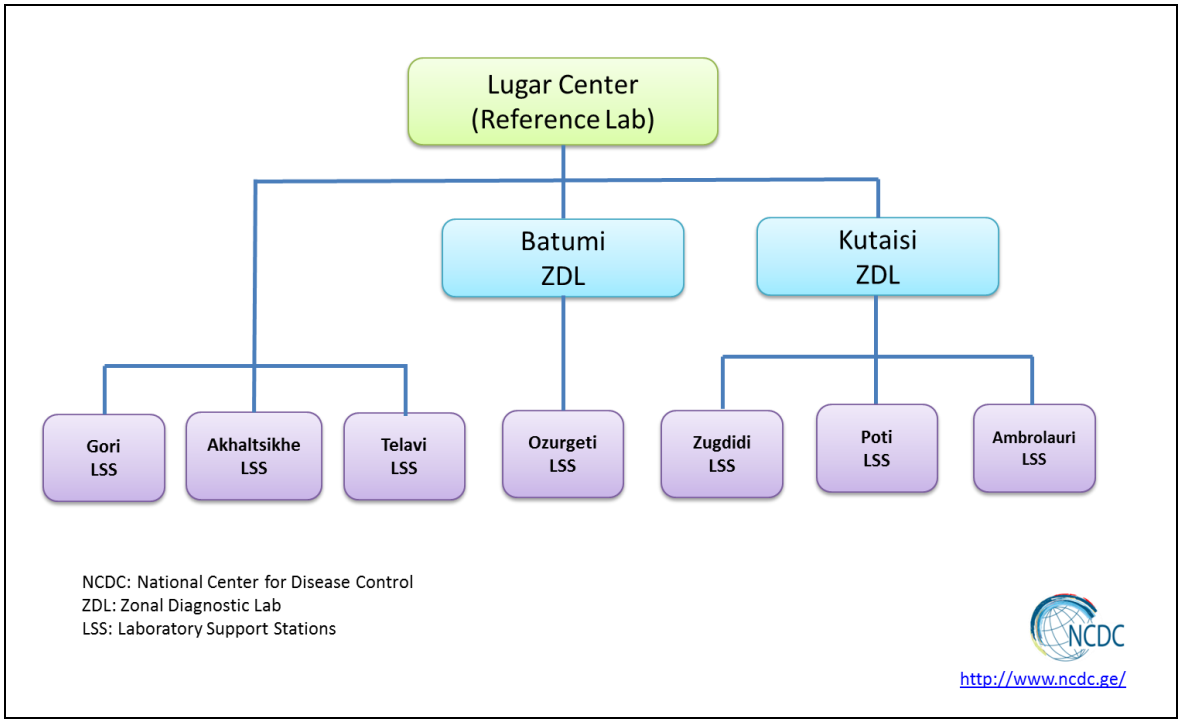


Figure 2: NCDC Tiered Lab Network

LMA

Ministry of Agriculture (MOA) has established a veterinary network that also consists of one (1) reference laboratory (Laboratory of Ministry of Agriculture – LMA), two (2) Zonal Diagnostic Laboratories (ZDLs), and eight (8) regional Laboratory Support Stations (LSSs) (Figure 3).

None of these laboratory networks has implemented or has utilized any electronic Laboratory Information Management System (LIMS). Laboratories utilize paper-based or Excel-based tools, often developed by the local laboratory staff, to manage laboratory data at the facility level. Both NCDC and MOA laboratory networks are supported by U.S. DoD Defense Threat Reduction Agency/ Cooperative Biological Engagement Program (DTRA/CBEP).

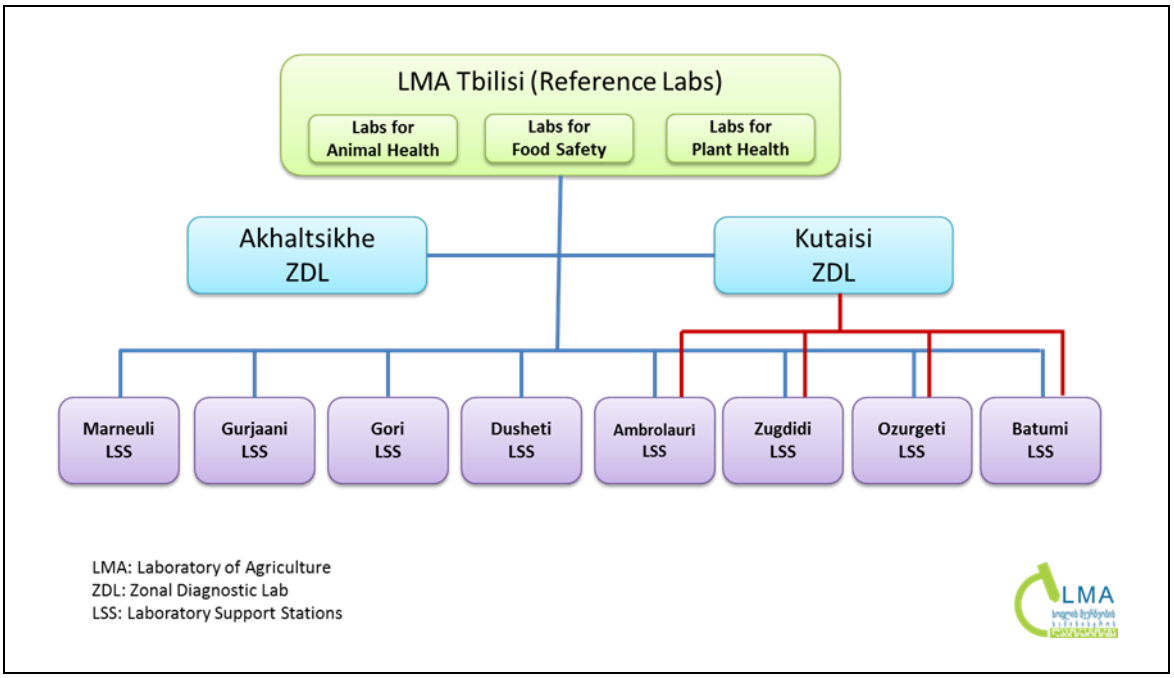


Figure 3: LMA Tiered Lab Network

1.4 Purpose and scope of this user's functional requirements

Defining system requirements is one of the most important steps in developing or acquiring any LIMS. If the requirements are not correctly defined, the system will not meet the needs of its users. With correct LIMS requirements, laboratories in the NCDC and LMA lab networks will be able to match their needs with commercial software products (with or without modifications) or a new development.

This document is designed to be both a roadmap and a tool. It is a roadmap for moving NCDC and LMA laboratories toward the vision in the fields of human health, animal health, food safety, and plant health. At the same time, it is a tool for structuring specific LIMS implementation and help in creating comprehensive vendor requests for proposals (RFPs).

In scope

This document addresses user's requirements for the LIMS implementation in Georgia NCDC and LMA:

- Define LIMS user's functional requirements to specify functionalities for the LIMS implementations
- Prioritize LIMS functionality that meet the user's needs
- Define LIMS user's interface specifications
- Define general system requirements
- Provide recommendations for defining the LIMS usability
- Provide recommend roadmap for LIMS implementation (Modular implementation and phased deployment approach)

Out of Scope

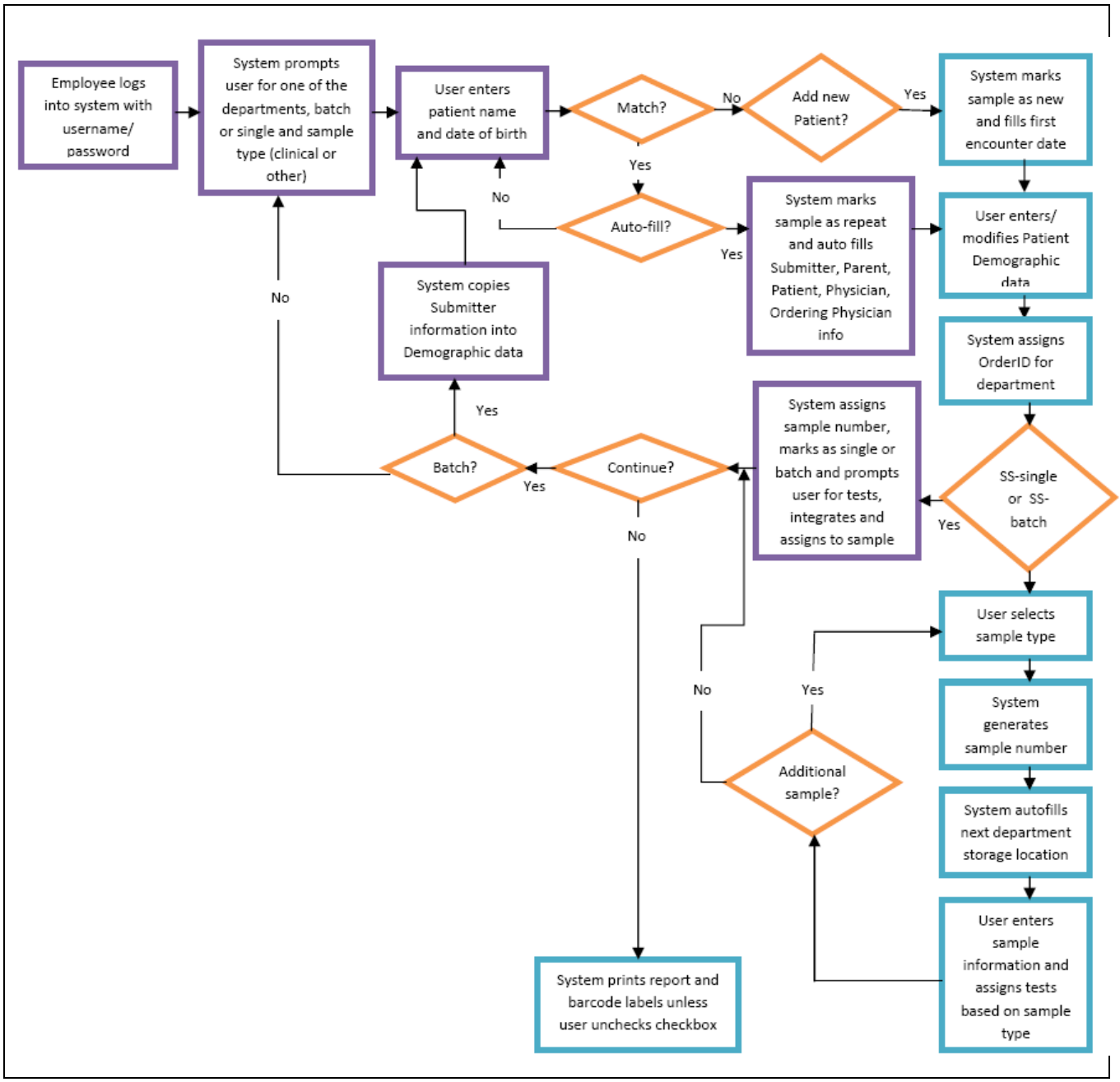
The following items in process LIMS deployment are out of scope:

- Define LIMS system specification including system usability and hardware specifications
- Develop a comprehensive vendor requests for proposals (RFPs)
- Select LIMS product
- Select LIMS developer
- Select LIMS implementer
- Define timeline for the LIMS implementation (Suggested timeline can be found in the section 9 but will be determined by NCDC, LMA, U.S. CDC and LIMS implementers)

2. General overview of functions

Successful LIMS implementations are those that have a high degree of acceptance of the system by all departments including the laboratory personnel. This requires full involvement of the laboratory in the implementation process and the support of management, QA, IT, and all levels of staff.
A laboratory information management system (LIMS) handles the receipt, processing and storage of information generated by laboratory processes. These systems may be required to interface with and transfer data to and from analytical instruments, and other information management systems, such as disease surveillance systems or health information management systems. LIMS can provide various data analysis modules and reporting capabilities, as well as various management modules. Additional functions can also include equipment and stock management, and support for Quality Management/Quality Control/Quality Assurance.

Figure 4 shows an example of detailed flowchart/algorithm for sample login workflow:



Sources： Information management and technology Guideline for Institutes of Public Health (Serbia) Laboratories. Version 1.0, Kevin Feltham and Dragan Toroman, European Union, 2009

3. Requirements

The following are drafted as functional requirements that the Georgia LIMS would have in term of implementation in laboratories at NCDC and LMA, so that the one LIMS could handle all tests that the laboratories offer to perform.

Priority Definitions

The following definitions are intended as a guideline to prioritize requirements.

Priority 1 – The requirement is a "must have" as core functionalities for system to function as desired

Priority 2 – The requirement is needed for improved processing, and the fulfillment of the requirement will create immediate benefits to improve information management

Priority 3 – The requirement is a "nice to have" which may include new functionality

3.1 Functional Requirements (FR)

Each of the functional requirements represents a business process but not necessarily a technical specification, which will be completed by the implementer based on the functional requirements.

FR #1: Core Functionality – Laboratory Test Processing

Objective: Securely deliver correct and complete test result reports to the submitting customer and other mandated recipients.

This functional requirement encompasses the core of a public health laboratory's (PHL) work in general that reflects core laboratory workflow of laboratories at NCDC and LMA: receiving, initial processing, analytical laboratory testing, and test result reporting for human, veterinary, food safety, plant, and environmental specimens and samples. Receiving includes verifying the completeness of the test request information, ensuring the adequacy/ appropriateness of the specimens/samples for testing, initial processing, and prioritizing the tests for the various internal laboratories. Test requests can be received by phone, FAX, hard copy, or electronic transmission from other electronic system, such as EIDSS, using an HL7 order message or XML. The testing task includes all analytical activities associated with the requested tests (and any further tests, if needed as a result of initial test results) and recording of results. Test result reporting includes verification and secure transmission of reports via hard copy, phone, FAX, electronic copy, XML, HL7 result message, etc., to the customer and other mandated recipients, as well as posting results where they can be retrieved by authorized parties.

FR #2: Test Scheduling

Objective: Optimize the use of laboratory personnel and instruments in order to maximize the use of resources available to the laboratory and be able to adapt to sudden surges in a specific test request volume and be able to set up (define) new tests.

In addition to the prioritization performed in receiving, each internal lab within NCDC and LMA schedules its workload by specific instrument or bench. Scheduling factors include "rush" test requests, the length of time a test takes, and holding/storage time requirements. In general, test requests are processed in the order in which they are received except during an event prioritization, such as outbreak investigations.

FR #3: Proactive Specimen/Sample Collection (Prescheduled Tests)

Objective: Receive prescheduled specimens/samples in an efficient and timely manner.

Tests can be prescheduled in some instances. This business process includes the identification and scheduling of either single (one-time) requests, or recurring tests over some period of time. In either case, the laboratory ideally should capture the test schedule in the computer system and track each requested test, starting with the distribution of the test kits and forms and ending with the receipt of the individual specimen/samples and completed forms. This process is a front end to the standard test processing described in Functional Requirement (FR) #1.

FR #4: Specimen and Sample Tracking/Chain of Custody

Objective: Create accurate and timely specimen and sample tracking and chain of custody documentation.

Specimens and samples must be tracked from the time of receipt until disposal. Unique identification of the sample and all of its aliquots is required so that results can be matched back to the originating sample. Besides the sequential processing from receiving through testing, specimens and samples may spend time in intermediate storage, as well as be stored for subsequent testing following the initial testing or stored as evidence. Long-term specimen and sample storage may also be required, including products/organisms grown from them. Additionally, samples may be sent to third parties for confirmatory testing or as overflow. In instances where chain of custody documentation is required, the lab must be able to document custody of the specimen or sample from receipt through disposal or return to the submitter or other agency. In many instances this requires a written signature or a digital signature from the custodian of the sample/specimen.

FR #5: Inventory Control Including Kits, reagent, lab supplies & Forms Management

Objective: Manage appropriately all items inventoried by a lab.

This business process covers all aspects of inventory control and management (ordering, tracking, and distribution) for all items inventoried by a lab. Examples include specimen and sample collection kits, testing kits, lab supplies, chemicals, equipment (not include IT equipment), and forms. Collection kit management includes order processing, component and kit assembly tracking, and assembled kit inventory tracking activities including lot number and expiration date tracking for QC purposes. Also, it provides orders for manufactured item replenishment and estimated quantity needed, manufactured item inventory status and usage rates, etc. Forms management encompasses version control, printing, and distributions are included as well.

FR #6: General Laboratory Reporting

Objective: Create timely and efficient general laboratory reports addressing all NCDC and LMA laboratories external obligations and internal management needs.

A lab may have a wide variety of external reporting requirements dictated by a wide variety of organizations (NCDC, LMA, NFA, Epidemiology Department, local health departments, test submitters, etc.), as well as internal reporting requirements that include both management reporting and records management. An example of an external reporting requirement would be reporting on laboratory capacity and critical personnel changes. This functional requirement includes all aspects of reporting

other than the direct test reporting to the customer and other mandated recipients as described in Functional Requirement #1.

FR #7: Quality Control (QC) and Quality Assurance (QA) Management

Objective: Provide appropriate QC and QA services to ensure all labs utilizing QC and QA management methodology.

Although many of these activities are woven into the performance of the laboratory testing process, the determination of the QC and QA activities to be performed, the performance tracking, and the subsequent reporting requirements are management responsibilities and, consequently, are defined as a separate business process under this heading. QA not only includes internal performance, but also relates to customer performance in meeting the requirements for proper test submittal and customer satisfaction with the lab's performance – this is important for commercial testing.

FR #8: Statistical Analysis and Surveillance

Objective: Create appropriate statistical analysis, surveillance outputs, and reports needed internally and supplied to external partners for statistical and surveillance purposes, such as for EIDSS and HMIS users.

Because of the unique laboratory role in notifiable diseases reporting (including human diseases and animal diseases) and laboratories' special relationship with epidemiology (for example, helping identify, understand and control disease outbreaks), laboratories must be able to perform statistical analysis and surveillance activities. This requirement covers serving the data needs of a variety of organizations, public health agencies, other laboratories, practitioners, etc., in order to identify trends and sentinel events indicating emerging health problems, as well as actively participating in mitigation of adverse health events once they have been identified.

FR #9: Billing for Laboratory Services

Objective: Collect and record billing revenue.

A laboratory, especially a reference laboratory may engage in a wide variety of billing activities associated with the provision of lab services. These include collecting fees prior to, as well as after, the performance of lab tests, withholding lab test results until fees have been paid in certain instances, provision of indirect billing services for the laboratory, billing customers under contract arrangements for testing and training services, and billing Medicaid and other health care plans for services rendered to their clients.

FR #10: Contract and Grant Management

Objective: Accurately manage contracts and grants per agreement requirements.

Contracts are normally used as a part of the definition of the business relationship between NCDC, or LMA and a regular customer, such as DTRA or other organization. A given customer may have multiple contracts with the laboratory at the same time or over a period of time. In addition, an NCDC or LMA laboratory may perform testing services under a grant mechanism in which there is an agreed amount of testing to be performed. Once the limit is reached, no further testing is done. This business process

is defined as the way in which the contracts and grants are managed within the NCDC and LMA. This requirement is to implement the management at NCDC and LMA administration level.

FR #11: Training, Education and Resource Management

Objective: Provide appropriate staff and customer training and education, and manage overall personnel resources.

This requirement includes staff and customer (if any) training and education activities, as well as the overall management of the NCDC and LMA laboratory personnel resources (including date of employment, education, certifications, etc.). Training and education includes course preparation, scheduling, attendance and follow up. Resource management includes tracking employee certifications and competency testing for each test they perform, as well as the instruments they use in testing. This requirement also includes the training, documentation, and reporting necessary to maintain a laboratory's certification and accreditation. This requirement may or may not include functionality of management of Standard Operational Procedures (SOP).

FR #12: Laboratory Safety and Accident Investigation

Objective: Help with creation of a safe and accident free laboratory environment.

The very nature of laboratory work mandates that safety is a key consideration. It involves elements of several of the other functional requirements discussed above but has been broken out separately to emphasize its importance. Safety involves training, follow up, monitoring and investigation of safety violations and safety related injuries and accidents. All tasks associated with these activities are included in this requirement.

As noted above, the 12 functional requirements are interdependent, linked to laboratory test processing (FR #1) and other requirements through tasks performed and outputs produced. For example, inventory is directly linked to test processing and supports this function. Without reagents and media, the laboratory could not perform testing. In this case, it would not be reasonable to implement the inventory business process without first implementing test processing. Integrating inventory control requirement supports into the LIMS produces efficiencies in laboratory operations that would not be possible if the inventory control function was supported by a separate information system or performed manually.

The description creates the framework for the LIMS functional requirements interfaces and impacts on the critical work activities to be supported within each of the dependent functionality. Each of these critical work activities is converted into requirements specifications in next section (developing later). Moreover, the dependency relationships define a logical phased implementation strategy for use where a given NCDC and LMA laboratory can only implement a subset of the functional requirement in each stage of the overall LIMS development. By the same token, it also suggests the logical sequence for **module implementation** if NCDC and LMA decide to support all or a large number of the functional requirements at the same time using a **phased implementation strategy**.

3.2 Implementation Prioritization

A LIMS system supports the laboratory's core functional process, testing. Prioritization begins with assumption that test processing is the lab's primary objective. Priorities for the remaining functional requirements are set according to their relative importance in test processing and agency's overall priorities.

This analysis is based on the degree to which the LIMS database required for support of test processing contains data sets relevant to one of the other business processes. For example, Quality Control (QC) and Quality Assurance (QA) (FR #7) are tightly linked to test processing, because the associated QC must be identified in any test, and the user must be able to reference the LIMS historically to determine whether QC sets for the instrument and other test items such as media were relevant at the time the test was performed. QC results also determine whether or not the test result was reliable and ready for verification and reporting.
This leads to the following prioritization groups (without internal prioritization):

First Priority Group:

- Test Scheduling (FR #2)
- Proactive Specimen/Sample Collection (FR #3)
- Sample Tracking/chain of custody (FR #4)
- General Laboratory Reporting (FR #6)
- QC and QA (FR #7)
- Billing for Laboratory Services (FR #9)

Second Priority Group:

- Inventory Control (FR #5)
- Statistical Analysis & Surveillance (FR #8)

Third Priority Group:

- Contract and Grant Management (FR #10)
- Training and Resource Management (FR #11)
- Lab Safety/Accident Investigation (FR #12)

The table 2 illustrates the priority groups over the implementation process.

FR #	FR Name	Priority 1	Priority 2	Priority 3
1	Laboratory Test Processing	Core FR		
2	Test Scheduling	X	X	X
3	Proactive Specimen/Sample Collection	X	X	X
4	Sample Tracking/chain of custody	X	X	X
5	Inventory Control		X	X
6	General Laboratory Reporting	X	X	X
7	QC and QA	X	X	X

8	Statistical Analysis & Surveillance		X	X
9	Billing for Laboratory Services	X	X	X
10	Contract and Grant Management			X
11	Training and Resource Management			X
12	Lab Safety/Accident Investigation			X

3.3 Functional Requirements (FR) Interdependency Descriptions

In general, the operational processes in a public health laboratory have been divided into three stages: the Pre-Analytic Stage, the Analytic Stage, and the Post Analytic Stage (see Figure 4)

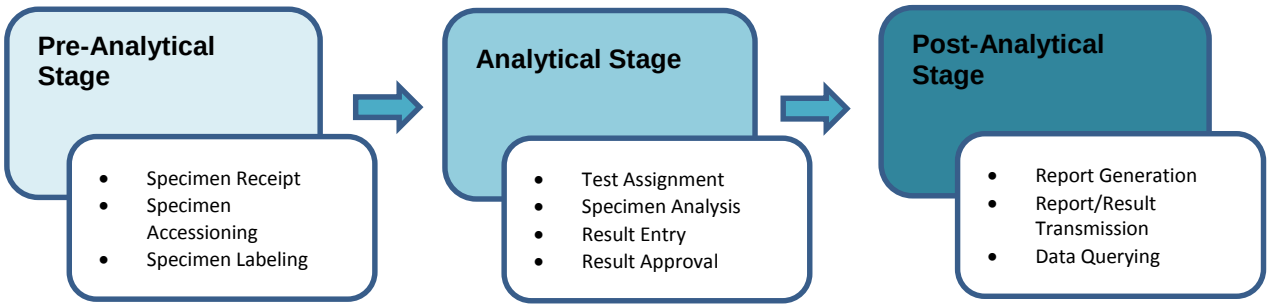


Figure 4 – Operational Processes

Functionalities for LIMS are defined in terms of functional requirements. Functional requirements are interdependent that represent exchanges of data sets between two or more functional requirements.

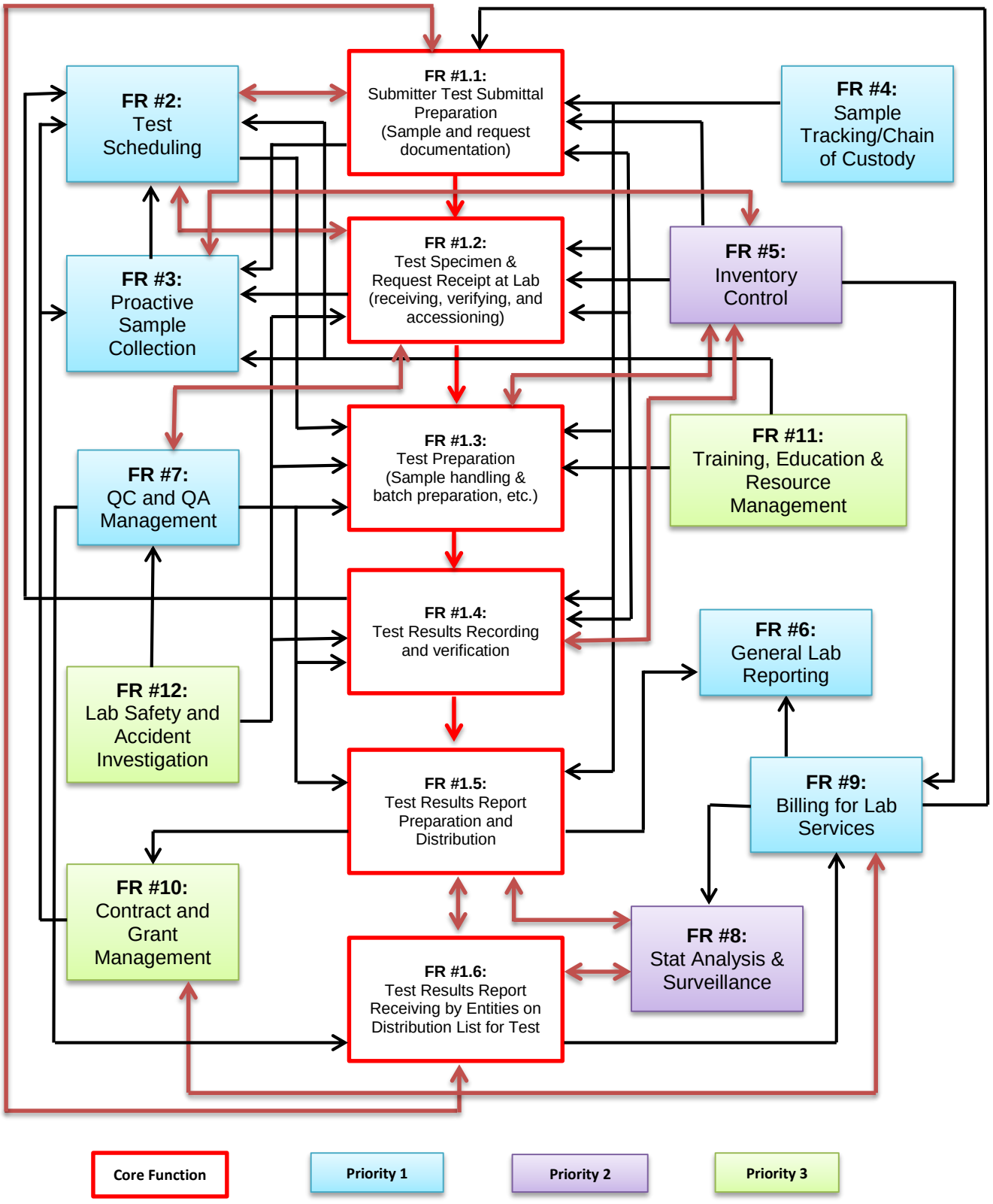


Figure 5: Lab Work Flow and Interface with Functional Requirements

Adapted from Requirements for Public Health Laboratory Information Management Systems: http://www.aphl.org/

Figure 5 describes the relationships between the various functional requirements. These functional requirements are considered as business processes.

The arrows (⟶) in Figure 2 represent the interdependencies with the head of the arrow pointing in the direction of the interaction. Two headed arrows (⟷) indicate that a two-way exchange of data occurs in the interface. Theoretically, one could show the input and output interdependencies associated with each business process, but that would simply duplicate each interdependency as an input to the receiving requirement and an output from the sending requirement.

In the following description, the interdependency has been stated on the *output side only, that is, in association with the originating functional requirement that performed the work task that created the output.* To state it again as an input would only repeat the statement of the same transaction. For example, in the first interdependency description below dealing with the submitter's relationship to the laboratory, the test submitter (FR #1.1) sends test specimens/samples and test requests to the Test Specimen/Sample & Request Receipt area of the laboratory (FR #1.2). These requests and specimens/samples originated as a result of work activities within the submitter organization that produced them as an output. By the same token, the submitter creates the "Request for accelerated testing/rush requests" sent to Test Scheduling (FR #2) based on some work activity within their organization (an output of FR# 1.2).

Interdependency Explanations:

FR #1.1: Submitter Test Submittal to:

- Test Specimen/Sample & Request Receipt (FR #1.2)
  - Test specimens/samples & Requests for processing
  - Additional epidemiology-related data as needed that is incorporated into the request form
- Test Scheduling (FR #2: two-way exchange of data)
  - Request for accelerated testing/ "rush requests"
  - Test Request advance notification

FR #1.2: Test Specimen/sample & Request Receipt to:

- Test Preparation (FR #1.3)
  - Request information in electronic form
  - Accession ID for use in processing test
  - Properly labeled specimens/samples
- Test Scheduling (FR #2: two-way exchange of data)
  - Information on test requests received
  - "Rush" request information
- Proactive Specimen/Sample Collection (FR #3)
  - Information on prescheduled test requests received
- QC/QA (FR #7: two-way exchange of data)
  - QA information on completeness of request form information received from each source

- QA information on adequacy/completeness/usability of specimens/samples received from each source

FR #1.3: Test Preparation to:

- Testing & Results Recording (FR #1.4)
  - Batched test requests
  - Specimens/samples or preprocessed specimens/samples (aliquots, etc.)
  - Batch worksheets
- Inventory Control (FR #5: two-way exchange of data)
  - Request for new media or reagent (reorder) for situations where preprocessing requirements dictate the need for these items

FR #1.4: Testing, Results Recording & Verification to:

- Test Result Report Preparation & Distribution (FR #1.5)
  - Test results and associated submitter test request information
  - Data sets on additional tests needed as a result of the initial testing
  - Associated information to determine if "preliminary" report should be issued
- Test Scheduling (FR #2)
  - Data sets on additional tests needed as a result of the initial testing
- Inventory Control (FR #5: two-way exchange of data)
  - Request for new Media or Reagent (reorder)

FR #1.5: Test Result Report Preparation and Distribution to:

- Test Report Receiving (FR #1.6: two-way exchange of data)
  - Preliminary and/or final test reports
  - Status reports on current outstanding tests
  - Responses to request for historical data on specific test submittals including chain of custody
- General Laboratory Reporting (FR #6)
  - Data sets on tests performed, results, and other associated information
- Statistical Analysis & Surveillance (FR #8: two-way exchange of data)
  - Data sets on tests performed and results
  - Epidemiological data sets associated with test submittals, such as cases reported on EIDSS and associated information on eHealth system (HMIS)
- Contract & Grant Management (FR #10)
  - Data on the number of tests performed under each contract and grant at periodic intervals
  - Projections of contract and grant fulfillment (time when the agreed upon testing will be completed based on testing rates)

FR #1.6: Test Result Receiving by Entities on Distribution List to:

- Test Result Report Preparation and Distribution (FR #1.5)
  - Inquiries on test report status and delivery
  - Inquiries on historical tests; chain of custody, etc.

- Laboratory Billing (FR #9)
  - Data sets on tests performed for each submitter where a charge is billed
- Statistical Analysis & Surveillance (FR #8: two-way exchange of data)
  - Inquiries for statistical analysis information
  - Data sets on tests performed and results
  - Epidemiological data sets associated with test submittals, such as cases reported on EIDSS and associated information on eHealth system (HMIS)

FR #2: Test Scheduling to:

- Submitters (FR #1.1: two-way exchange of data)
  - Updates of test schedule
  - Confirmation of test scheduling requests
- Lab Receiving (FR #1.2: two-way exchange of data)
  - Current Test Schedule Information (Rush orders, etc.)
- Test Preparation (FR #1.3)
  - Current test schedule information (rush orders, etc.)

FR #3: Proactive Specimen/Sample Collection to:

- Submitters (FR #1.1)
  - Current specimen/sample collection schedule
- Test Scheduling (FR #2)
  - Specimen/sample collection schedules
  - Specimen/sample collection schedule modifications/status
- Inventory Control (FR #5: two-way exchange of data)
  - Schedule for test kit, reagent, media, etc. order and distribution
  - Information on payment due for test kits, reagent, media, etc.
  - Schedule for lab supplies order and distribution
  - Information on payment due for lab supplies

FR #4: Specimen/Sample Tracking/Chain of Custody to:

- Submitters (FR #1.1)
  - Chain of custody requirements and form recommendations
- Lab Receiving (FR #1.2)
  - Specimen/sample tracking/chain of custody information
- Test Preparation (FR #1.3)
  - Specimen/sample tracking/chain of custody information
  - QC documentation
- Testing, Results Recording & Verification (FR #1.4)
  - Specimen/sample tracking/chain of custody information
  - QC documentation
- Test Result Report Preparation & Distribution (FR #1.5)
  - Specimen/sample tracking/chain of custody information

FR #5: Inventory Control to:

- Submitters (FR #1.1):
  - Shipment of specimen/sample collection kits to selected submitters at specified times for prescheduled specimen/sample collection schedules
  - Shipment of collection kits in response to submitter request
- Lab Receiving (FR #1.2)
  - Delivery of requested glassware and other inventory items needed for processing incoming specimens samples.
  - Order fulfillment documentation and associated QC (if any applicable)
- Test Preparation (FR #1.3)
  - Delivery of requested glassware, media, reagents, etc.
  - Order fulfillment documentation and associated QC (if any applicable)
- Proactive Specimen/Sample Collection (FR #3: two-way exchange of data)
  - Kit delivery capability/status
  - Kit shipping documentation (shipped to whom/where/when)
- Lab Billing (FR #9)
  - Billing information for items shipped to submitters and others (such as media used by other laboratories)

FR #6: General Laboratory Reporting to:

- No outputs to other specific business processes. However, report distribution to all management and external entities can be found in the specification of FR#7.

FR #7: Quality Control (QC) and Quality Assurance (QA) Management to

- Test Specimen/Sample and Request Receipt (FR #1.2: two-way exchange of data)
  - QC/QA concerns and recommendations relating to specimens/samples
- Test Preparation (FR #1.3)
  - QC/QA concerns and recommendations
- Testing, Test Recording & Verification (FR #1.4)
  - QC/QA concerns and recommendations
- Test Result Report Preparation and Distribution (FR #1.5)
  - QC/QA concerns and recommendations
- Test Result Report Recipients (FR #1.6)
  - QC documentation on specific tests when requested

FR #8: Statistical Analysis & Surveillance to:

- Test Result Report Preparation & Distribution (FR #1.5: two-way exchange of data)
  - Provision of test statistical information for test reporting (comparison data)
- Test Result Report Receiving (FR #1.6: two-way exchange of data)
  - Statistical analysis reports as requested
  - Standard statistical analysis, trends, observations on test loads, etc.

FR #9: Lab Services Billing to:

- Submitters (FR #1.1)
  - Invoices for kits and other materials

- General Laboratory Reporting (FR #6)
  - Billing reports
- Contract & Grant Management (FR #10: two-way exchange of data)
  - Grant & contract testing services provided
  - Cost information by grant/contract based on standard costs if needed
- Statistical Analysis & Surveillance (FR #8)
  - Data set of billings for testing services provided

FR #10: Contract and Grant Management to:

- Test Scheduling (FR #2)
  - Information on contract/grant testing schedule requirements
- Proactive Specimen/Sample Collection (FR #3)
  - Information on contract/grant test sampling schedules
- Lab Billing (FR #9: two-way exchange of data)
  - Contract/Grant billing information
  - Test volumes allowed under Contract/Grant

FR #11: Training, Education & Resource Management (including instruments) to:

- Submitters (FR #1.1)
  - Training schedule
  - Special education (as needed depending on QA related findings)
- Test Specimen/Sample and Request Receipt (FR #1.2)
  - Training schedule
  - Special education (as needed depending on QA problems)
- Test Preparation (FR #1.3)
  - Training schedule
  - Special education (as needed depending on QA problems)
- Testing (FR #1.4)
  - Training schedule
  - Special education (as needed depending on QA problems)
- Test Scheduling (FR #2)
  - Available qualified personnel counts by instrument
  - Instrument availability schedule
- Proactive Specimen/Sample Collection (FR #3)
  - Available qualified personnel counts by instrument
  - Instrument availability schedule

FR #12: Laboratory Safety/Accident Investigation to:

- Test Specimen/Sample and Request Receipt (FR #1.2)
  - Safety materials and status reports
  - Accident investigation reports
- Test Preparation (FR #1.3)
  - Safety materials and status reports
  - Accident investigation reports

- Testing, Test Recording & Verification (FR #1.4)
  - Safety materials and status reports
  - Accident investigation reports
- QC & QA (FR #7)
  - QA data on safety and accidents

3.4 Details of Functional Requirement Specifications

The requirements specifications reflect the unique requirements associated with NCDC and LMA laboratories' broader activities. Of primary importance is the population-based orientation of NCDC and LMA laboratories relative to the focus on individual testing common in commercial laboratories. This perspective has numerous impacts on NCDC and LMA LIMS requirements, reflected in requirements specifications relating to multiple users of test result information and the need for patient name and address along with expanded demographic and epidemiological data.

The requirements specifications are intended to be "forward looking" rather than mimicking current practice. There are tiered laboratory networks in Georgia. Each laboratory has its own priority and workflow, such as laboratory of plant health. A laboratory may not be able or need to implement certain segments of the requirements at this time. However, all of the requirements are feasible and practical in the next couple of years if the laboratory is doing or expecting to do all or most of the functions listed in the functional requirements.

The specifications for each functional requirement are developed for physical implementation strategy that covers the entire NCDC and LMA Laboratory Networks. However, decisions need to be made by each Laboratory Network at NCDC and LMA based on its own needs and the broader organizational structure in which it operates.

This section sets forth functional requirements specifications and contains information in the following categories for each of the **12 functional requirements**:

- **Overview:** A summary of the functional requirement
- **Workflow summary:** A brief description of the key workflow elements associated with the functional requirement
- **Specific functional requirements for each workflow area:** Presentation of the key requirements specifications associated with the workflow elements
- **Selected QC/QA specifications relevant to each functional requirement**
- **Selected system output requirements:** Examples of relevant outputs/reports not included in specific functional requirements above

This section begins with the core laboratory functionality, Functional Requirement #1: Laboratory Test Processing. This process has been broken into six internal segments as reflected in Figure 5, Lab Workflow and Interface with Functional Requirements of the previous section. Amongst 6 segments, the following 4 are needed to be specified:

FR #1.2 – Test Request and Samples Receiving
FR #1.3 – Test Preparation
FR #1.4 – Testing, Results Recording and Verification
FR #1.5 – Test Result Report Preparation and Distribution

The other 11 functional requirements are each treated as single segments.

Specifications for FR #1: Laboratory Test Processing (Human, animal, food, and plant samples)

FR #1.2: Test Request and Samples Receiving

Overview: This segment of test processing deals with test request and specimen/sample receipt and initial processing activities. Once this work is completed, the specimen/sample will have been routed to the specific laboratory and the test request entered in the LIMS. Any problems with test submittals will have been identified and the submitter will be notified. There should be a different interface for each of human, animal, food, and plant specimens/samples workflow. The human specimens/samples will come from EDP and non-EDP. The EDP may also contain environmental specimens/samples. Specimens/samples may also come in batch from research project or other programs, such as hepatitis C elimination or AMR (Antimicrobial resistance), etc.

Workflow summary: Receive and enter the test requests into the LIMS, check specimens/samples for completeness and acceptability, accession specimens/samples, and route to appropriate laboratories.

Laboratory specific requirements for each workflow area:

1. **Receive and log test requests received in electronic message structure utilizing agreed upon coding standards with other electronic systems (EIDSS, HMIS, and others)**
   - 1.1. Ability to create test request records in the LIMS directly from the electronic test request records, (this refers to the ability to parse a test request record), and including specimen package contents (e.g., group electronic test request submittals by physical specimen package where a package may contain multiple specimens for multiple subjects)
   - 1.2. Ability to audit electronic test request records and return acknowledgement (ACK) messages to submitter verifying receipt and processing of the transmission
   - 1.3. Ability to manually enter test request if received on paper form and perform independent verification on selected data fields by re-entry of the data in a second pass
   - 1.4. Ability to handle different test request information content for human versus animal versus other miscellaneous specimen/samples (food and plant) and identify each request record as to whether it is a outbreak, clinical, environmental or other test request in the LIMS
   - 1.5. Ability to accept and process additional epidemiology data associated with test requests from selected submitters (e.g., supplemental data segments)
   - 1.6. Ability for the user to define and create supplemental data segments and specify usage by selected submitters (e.g., a food sample testing contract may call for the collection of

additional specified data only relevant to the specific food safety study under the contract and agreement)

1.7. Ability to enter request forms with multiple test requests
1.8. Ability to enter multiple request forms from the same submitter as a batch; without repeating entry of common data
1.9. Ability to record whether or not hazard screening for bio-terrorism (BT) samples (e.g. CBRN – Chemical, biological, radiological and nuclear warfare) has been done before receipt by laboratory
1.10. Ability to link multiple specimens from same individual at same time for same test

2. Link specimens/samples to corresponding test requests and verify completeness

2.1 Ability to link specimens/samples to corresponding electronic test request records via a LIMS display of unprocessed test requests for a given submitter, submittal date, and package ID
2.2 Ability to record any specimen/sample problems that prevent testing to proceed (may happen at any point in the testing process)
2.3 Ability to send electronic error messages to a submitter from other electronic systems delineating which test request(s) have been rejected, and generate these messages automatically for all errors associated with a specific package once problems have been recorded in LIMS
2.4 Provide mechanism for name matching where LIMS "suggests" patient names in database that might be the same as that entered for current test request
2.5 Ability for user to establish link between current request name and database name (i.e. associate multiple separate test requests to same individual). For example, the linking of acute to convalescent specimens/samples when they are sent in separately.
2.6 Ability to monitor test requests that require subsequent submittals such as acute and convalescent specimens for the same patient
2.7 Ability to generate follow up letters and reports on outstanding subsequent test submittals (e.g., the notification of a submitter that a convalescent specimen/sample is required when the acute test was positive)

3. Accession specimens/samples

3.1. Ability to accession specimens/samples with NCDC and LMA wide unique numbers or individual laboratory specific unique numbers using a common accessioning protocol that allows real-time tracking of specimen progeny and siblings
3.2. Ability to create specimen/sample labels
3.3. Ability to create specimen/sample barcode labels using NCDC and LMA designated barcode format
3.4. Ability to create post script numbers for splits and aliquots of original specimen/samples
3.5. Ability to use accession number as a direct link to the corresponding LIMS test request record
3.6. Ability to create skeleton test request record (test ID, accessioning number, and other core data) when total data entry might preclude timely testing
3.7. Ability to flag skeleton record as incomplete and create queue of incomplete test request records needing remainder of data to be entered

4. Route specimens/samples to appropriate laboratories

4.1 Ability to update LIMS with routing information (laboratory to which a specimen sample is directed) and status code (the code will be defined by NCDC and LMA)

4.2 Ability to route specimens/samples associated with a test request submittal to multiple laboratories

4.3 Ability to route test requests to a centralized aggregation point, such as the reference laboratories, for special projects or when an event prioritization occurs.

4.4 Ability to create supporting documentation and packaging/shipping labels when routing specimens/samples to reference laboratories

4.5 Ability to utilize a directory or registry to hold message recipient contact and protocol information

4.6 Ability to modify or inactivate a test request

Selected QC/QA specifications

5. QC/QA specifications

5.1 Ability to capture specific data elements associated with QC/QA measures associated with this functional requirement (see Functional Requirement #7 for additional information)

Selected system output requirements

6. System output Report of specimen/sample rejections by rejection code and submitter for user specified time period

6.2. Report on tests requests forwarded to other reference laboratories (Lugar Center, LMA, or other)

6.3. Report on specimens/samples splits and aliquots

6.4. Reports on number of specimens accessioned by site (such as ZDLs and LSSs), program (such as non-EDP/EDP and AMR, etc.)

6.5. Report of overdue specimens, including the ability for an authorized user to define when a specimen is overdue

6.6. Reports on test requests by submitter and timeframe

FR #1.3: Test Preparation

Overview: Upon receipt in the laboratory, the specimen/sample will be prepared for testing. This work includes creating any desired aliquots, any preliminary processing completed, and batch runs created where appropriate.

Workflow summary: Test preparation preliminary processing and batch run creation

Laboratory specific requirements for each workflow area:

1. Test preparation and preliminary processing

1.1 Ability to create additional post scripted accessioning numbers for laboratory splits and aliquots

1.2 Ability to create and schedule a new test based on type of testing originally requested (a form of reflex testing)

1.3 Ability to update test request status and tracking record to track splits and aliquots
1.4 Ability to add additional tests to previously tested sample

2 Batch run creation (Also see Section VII on database interfaces)

2.1 Ability for user to define test instrument specific uniquely defined batches based on the specific needs of the analytical area. Further:
  2.1.1 Ability to determine position of each standard, control, and patient specimen in the batch and specify specimens/samples for duplicate testing.
  2.1.2 Ability to track specimen/sample dilutions
  2.1.3 Ability to specify whether test results are manually entered or will be "resulted" from an instrument. If test results are manually entered, the system should automatically call up all items on the list sequentially or the whole worksheet to be resulted at operator request.
  2.1.4 Ability to select all pending tests for worksheet generation, select a range of pending specimen/samples, if desired, (by date range, for example) and "tag" specific tests for worksheet generation.
  2.1.5 Ability to note specific safety concerns or hazards associated with the procedure's performance, reagents, on each worksheet
2.2 Ability to create and print batch worksheet and allow user to regenerate (modify) the worksheet and add tests up to the point when the batch run results are entered.
2.3 Ability to prioritize test requests from test queue for inclusion in a batch.
2.4 Ability to display and/or print batch map (specimen/sample location by well/position).
2.5 Ability to create additional numerical sequence numbers and labels for consecutive specimen/sample numbering within a batch.

Selected QC/QA specifications:

3. QC/QA specifications

3.1. Ability to capture specific data elements associated with QC/QA measures associated with this business process (see Functional Requirement #7 for additional information)

Selected system output requirements:

4. System output

4.1. Report of reflux and other subsequent testing organized by source test and reason
4.2. Report of patient name matches accepted and contents of combined lab records
4.3. Report of list of samples for retesting and reason

FR #1.4: Testing, Results Recording and Verification

Overview: This segment of the test processing encompasses the testing, QC checks for validity of the results, the recording of the test results, and the generation of additional test requests where additional testing, based on the initial test results, is needed. In addition, in the case of QC failure, retesting requests are generated.

Workflow summary: Test results reading and recording, QC verification, and creation of additional test requests

Laboratory specific requirements for each workflow area:

1. Test result recording

1.1. Ability to present uniquely identified batch worksheet result entry screen in same sequence as batch
1.2. Ability to allow manual entry of positive entries only and then default remainder of tests in batch to negative description
1.3. Ability to select result description from user defined table for valid entries for each given test and apply the selected description to multiple tests in batch
1.4. Ability to enter text field comments related to entire batch with the ability to code the comment as "internal lab use only" when appropriate so it doesn't show on reports sent outside the lab
1.5. Ability to remove "obvious outliers" when applicable
1.6. Ability to support complex calculations (concentration calculations, etc.)
1.7. Ability to change the specimen condition in resulting (lab accident, etc.)
1.8. Ability to enter text field comments related to specific test result
1.9. Ability to change mistakes in data / dates / results even in final submitted version
1.10. Ability to highlight positive tests so they stand out on batch presentation
1.11. Ability to capture ID of laboratory technician performing the test and creating the result entries along with date and time of analysis. Methods would include biometrics, etc.
1.12. Ability to allow easy recombination of individual determinations into multiple test suites (generally a tree type structure which may have multiple grouping levels)
1.13. Ability to average results on duplicate specimens/samples using the intra specimen sample variation as a QC parameter and store a recor1.d of all results
1.14. Ability to track specimen/sample dilution factors back to undiluted specimens/samples and select the most appropriate test result (based on per test preferred concentration ranges) and select a correction of the dilution and record a corrected result
1.15. Ability to monitor for and create alerts of "major" variations from normal

2. QC verification

2.1. Ability to define test (batch) specific control ranges
2.2. Ability to flag batch as suspect due to QC test values
2.3. Ability to reject the batch based on QC failure and create appropriate audit trail
2.4. Ability to tag each test in batch with QC failure reason
2.5. Ability to present peer (second reading entry or review) validation screen
2.6. Ability to enter peer validation edits and changes while keeping original recorded results with full audit trail for all changes/modifications
2.7. Ability to enter peer reviewer ID for each batch
2.8. Ability to create queue of batch test worksheets ready for peer or supervisory review
2.9. Ability to present supervisor review screen
2.10. Ability to enter supervisor validation edits and changes while keeping original and peer review recorded results
2.11. Ability to release test batch for result printing once all required reviews have been completed
2.12. Ability for a supervisor to over-ride a batch or individual test result tagged with a QC failure and to log a comment on why it was released despite the QC failure

3. Creation of additional test requests

3.1. Ability to trigger retest requirement and set up the tests in the test queue
3.2. Ability to arbitrarily repeat any individual test request in a batch
3.3. Ability to reuse same accessioning number for retest run
3.4. Ability to link rejected test run to subsequent rerun
3.5. Ability to create additional test requests associated with initial test results
3.6. Ability to link initial test information to subsequent/additional testing
3.7. Ability to reconcile current result with a previous result on same patient when result is different

Selected QC/QA specifications:

4. QC verification

4.1. Ability to capture specific data elements associated with QC/QA measures associated with this business process (see Functional Requirement #7 for additional information)
4.2. QC reports on what was changed, why, and by whom

Selected system output requirements:

5. System output

5.1. Workload statistics based on provider, test result, and time frame
5.2. Ability to create report on pertinent run data for a specific batch including QC data associated with each test request

FR #1.5: Test Report Preparation and Distribution

Overview: The recorded test results are used as the basis for the preparation and delivery of the test results report to the submitter and the creation and delivery of test results reports to other designated users

Workflow summary: Create and deliver hard copy or electronic test reports to submitter and other qualified users and prepare test result tabulations for other qualified users

Laboratory specific requirements for each workflow area:

1. Create and deliver test results to submitter

1.1 Ability to create electronic test report transactions and to transmit electronic test results either individually or by batch
1.2 Ability to control which results, detailed or summary, should be included in a report
1.3 Ability to transmit print image so that submitter can print out hard copy in the laboratory pre scribed form including letterhead image
1.4 Ability to send a test impression summary result that is an interpretation of multiple detailed test results
1.5 Ability to upload pictures of other file along with the results of sample inconsistency report, such as PCR gel picture, bacteriology results, and haemolysis
1.6 Ability to control which results, detailed or summary, should be included in a report

1.7 Ability to add comments to individual and batch test in a report for electronic and hard copy
1.8 Ability to transmit electronic test reports in secure format (such as ebXML format utilizing Public Key Infrastructure (PKI) encryption) conforming to HIPAA standards for privacy and security, if HIPAA (Health Insurance Portability and Accountability Act or similar) is implemented in Georgia
1.9 Ability to attach electronic signature to each electronic record when applicable
1.10 Ability to print hard copy test report for mailing containing an electronic signature (one way is to attach the printed signature field onto the test record as the report is prepared for printing rather than having it as a standard text field in the print format)
1.11 Ability to indicate that the report is "preliminary," "final," "corrected," or "amended and track multiple revisions to the same report
1.12 Ability to sort printed hard copy test results by submitter prior to printing, and print a cover sheet for each submitter grouping
1.13 Ability to create mailing labels for each submitter test report package
1.14 Ability to update test request record to indicate report has been created
1.15 Ability to create duplicate or amended test reports in either electronic or hard copy with indication that they are "duplicate" or "amended"
1.16 Ability to flag list of user-defined results requiring immediate submitter notification, including creation of call lists (submitter table will carry contact information)
1.17 Ability to record notification contact information including date and time, person notified, laboratory person making the contact, and the result(s) recorded

2. Prepare test result tabulations for other qualified users

2.1 Ability to qualify (i.e., grant permission to see) users by specific report
2.2 Ability to create and maintain authorized distribution list for each report (since some reports can contain HIPAA-defined personal health information for which the laboratory would have to have formal business associate agreements)
2.3 Ability to read a registry or directory to get contact and/or protocol information for report recipients
2.4 Ability to utilize a rules engine to determine the recipients for a message. The rules would dictate different recipients based on parameters ranging from: the type of test requested in the received test order; to the heightened urgency of the test as would be dictated during an event
2.5 Ability to tabulate test results by "positive" or total tests processed or a "rate positive" for a given geographic area by user over a specified time period through the use of a GIS tool when such a tool is available
2.6 Ability to release individual test results to a submitter prior to the completion of other related testing or recording of other test results in the same batch

HIPAA is the federal Health Insurance Portability and Accountability Act of 1996 in the U.S. The primary goal of the law is to make it easier for people to keep health insurance, protect the confidentiality and security of healthcare information and help the healthcare industry control administrative costs.

Selected QC/QA specifications

3. QC/QA specifications

3.1 Ability to capture specific data elements associated with QC/QA measures associated with this business process (see Functional Requirement #7 for additional information)

Selected system output requirements: (Many of these are embedded in the above requirements specifications)

4 System output

4.1 Data exports to other reporting programs such as EIDSS, HMIS, and Measurement of Uncertainty
4.2 Reports of number of tests per instrument per time period
4.3 Reports of number of tests performed by work unit by time period
4.4 Reports of number of tests by method by time period
4.5 Ability to create reports of tests (last three entries) for client specimen/sample tests only (i.e., exclude QC and proficiency tests)
4.6 Data extracts to NFA (food quality, food alterations, etc.)
4.7 Lab test kit performance reporting (reagent failure, performance problems, etc.)
4.8 Ability to create "overlays" of data from both clinical and environmental testing by geographic area
4.9 Reports on number of duplicate, amended, etc., reports issued

Specifications for FR# 2: Test Scheduling

Overview: This functional requirement deals with prioritizing and processing the test workload already received. Scheduling factors include request urgency, specimen/sample holding time, and other factors relating to the timely processing of the test requests. Long-term test workload projections are covered in the FR #3.

Workflow summary: Add requests received, prioritize requests, and remove requests that have been completed, and publish real-time test schedule.

Specific requirements for each workflow area:

1. Add requests received or additional tests generated in-house

1.1. Ability to add test requests and specimens/samples received and accepted by my lab to specific test schedule
1.2. Ability to add in-house generated tests to schedule

2. Prioritize requests

2.1. Ability to assign a submitter priority to a specific test
2.2. Ability to assign priority by type of test

2.3. Ability to generate internal priority based on holding times, number of days since receipt, and other factors associated with specimen/sample
2.4. Ability to adjust priorities
2.5. Ability to organize test "queue" by priority

3. Remove completed requests/transfers from active queue

3.1. Ability to automatically delete tests from the schedule once the result has been entered in the LIMS (and restore if needed)
3.2. Ability to manually delete a test request from the schedule/batch (and restore if needed) or delete an entire batch
3.3. Ability to select tests for diversion to mutual assistance laboratory and create file of diverted tests
3.4. Ability to create packing lists and other documentation for diverted tests
3.5. Ability to adjust holding times based on extractions and other reasons
3.6. Ability to divert specimens/samples to another area in-house based on a trigger from a completed test for subsequent testing (e.g., isolation of *E coli* 0157 through PFGE)

4. Publish real-time test schedule

4.1. Ability to calculate daily processing capacity for each test; adjusted by instrument avail ability and personnel availability
4.2. Ability to translate workload into N-day "rolling schedule" based on capacity limits where N is the number of days ahead of current date the user wants to include in the display
4.3. Ability to track test loads in the schedule at the specific instrument level
4.4. Ability to indicate which tests have been passed through to another laboratory (mutual assistance situation, etc.)
4.5. Ability to record test results for tests performed by another laboratory and indicate name of person who performed the test
4.6. Ability to create subsequent test requests from a given test request
4.7. Ability to flag overdue test requests based on schedule and notify submitter

5. Selected QA specifications:

5.1. Ability to capture specific data elements associated with QA measures associated with this functional requirement (see Functional Requirement #7 for additional information)

6. Selected system output requirements:

6.1. Reports of test processing time by priority
6.2. Test status reports

Specifications for FR #3: Proactive Specimen/Sample Collection (Prescheduled Tests) & Overall Workload Projections

Overview: Specimen/sample collection schedules may be received from submitters either as a part of a contract or grant agreement or independent of any formalized agreement. These specimen/sample collection schedules can involve kit distribution to multiple locations/ collectors over multiple time frames. The kit distribution process and timing constitutes a "leading indicator" for subsequent test

submissions. Overall workload projections are derived from adding "regular" submittal projections to the collection schedule derived projections.

Workflow summary: Record collection distribution schedules, monitor corresponding test request submittals, and update anticipated future workload

Specific requirements for each workflow area

1. **Record collection kit distribution schedules in schedule system**
   - 1.1. Ability to manually enter specimen/sample collection schedules by submitter and collector kit delivery point
   - 1.2. Ability to electronically receive and process submitter collection schedules
   - 1.3. Ability to translate collection schedule into anticipated test request receipt dates with the capability for a separate routine for each submitter
   - 1.4. Ability to create submitter collector specific kit delivery orders including volumes, shipping dates, and out dates

2. **Record test requests received against collection schedule**
   - 2.1. Ability to identify receipt of test requests generated from the collection schedule
   - 2.2. Ability to adjust workload projections by deducting the test requests received from the collection schedule
   - 2.3. Update anticipated future workload projections
   - 2.4. Ability to present adjusted workload projects as new collection schedules are added and tests received are deducted.
   - 2.5. Ability to have "real-time" current schedule available online for selected users
   - 2.6. Ability to create and add projections of "regular" workload by test for inclusion in the overall workload projections

Selected QA specifications:

3. **QA specifications**
   - 3.1. Ability to capture specific data elements associated with QA measures associated with this business process (see Functional Requirement #7 for additional information)

Selected system output requirements

4. **System output**
   - 4.1. Report of Current Specimen/Sample Collection Schedule by individual submitter or for all submitters
   - 4.2. Report of Current Test Workload by date and specific test
   - 4.3. Report of Current Kit Distribution orders by submitter, collector and time period

Specifications for FR #4: Specimen and Sample Tracking/Chain of Custody

Overview: In many instances, the chain of custody documentation originates outside the laboratory and will arrive with the test specimen/sample. Once started, the chain of custody needs to be maintained so most laboratories simply continue using the manual form. However, as back up to the formal chain of custody, the LIMS contains a great deal of information about the routing of the specimen/sample through the testing process. It could also contain entries to track the

specimen/sample into and out of primary storage and its ultimate disposition. Ideally, the LIMS would be able to identify the location of a specimen/sample at any step in the process, at least by storage location and device ID, if not also by the shelf and box location wherever it is stored. This would also facilitate the need to establish the link between specimen/samples and the QC documentation on storage temperature control (can be defined in the instrument management requirement), in that the temperature control sheets are date range-specific, and the date range for which the specimen/sample was in a given refrigerator would be captured as a part of the specimen/sample tracking transaction.

Workflow summary: Tracking specimens/samples, control materials and media movement into and out of storage.

Specific requirements for each workflow area:

1. **Record movement of specimens/samples**
   - 1.1 Ability to record storage refrigerator or container ID, date stored, date removed for a specific specimen/sample ID
   - 1.2 Ability to record dates and location when a specific specimen/sample was out of storage for testing process (could be linked to the test batch start and end times if recorded as a part of batch processing)
   - 1.3 Ability to record specimen/sample disposition date and disposition code (if any)
   - 1.4 Ability to move entire contents of a given storage location to another location (i.e., freezer mechanical failure)
   - 1.5 Ability to make a tracking stop mandatory (i.e., a specimen must end up in a specific freezer)
   - 1.6 Ability to identify and track individuals with specimen/sample custody
   - 1.7 Ability to support and modify "chain of custody routing rules" by type of specimen/sample and use the rules for alerts when the actual chain of custody deviates from the standard rule set (if such rule set exist)
   - 1.8 Ability to access threat assessment information for each specimen/sample
   - 1.9 Ability to flag a specimen/sample with a user defined code for "legal" or other desired code
   - 1.10 Ability to track specimen/sample to forwarded locations and to external lab
   - 1.11 Ability to track rejected specimen/sample

2. **Capture of temperature information (less important)**

   - 2.1 Ability to manually enter header record for specific temperature sheet for a specific refrigerator and sheet begin and end dates

Selected QA specifications

3. **QA specifications**
   - 3.1 Ability to capture specific data elements associated with QA measures associated with this business process (see Functional Requirement #7 for additional information)

Selected system output requirements

4. **System output**

4.1 Report on a given specimen/sample's location from receipt to disposition by location and date
4.2 Report on rejected specimen/sample sending to the submitter
4.3 Tracking reports of known specimens/samples (QC organisms, etc.)
4.4 Report on the contents of a given refrigerator/freezer on any given date

Specifications for FR #5: Inventory Control Including Kits, reagent, lab supplies & Forms Management

Overview: Based on manufacturer availability and the contractors for the Government of Georgia, inventories may contain manufacture test kits, media, reagents, stains, controls, or other items (i.e., laboratory supplies) used by the laboratories for test processing. Inventory items may be ordered from manufactories and are stored at center storage and then delivered to individual laboratories.

Workflow summary: Receive and process orders, and replenish inventory

1. Test kit management (a): Kit component ordering and receiving, kit assembly, submitter order receipt and processing, and shipping.
2. Inventory control (b): Monitor inventory quantities, create replenishment orders, receive inventory and add to balances, receive and fill orders from individual laboratories.
3. Forms management (c): The management of forms versions and distribution.

Specific requirements for each workflow area

1. Receive and process orders from internal laboratories and replenishment orders from inventory control. The replenishment order may be for more plates, which would potentially cause a need for more media to be produced which would have a ripple effect back to the inventory business process.

1.1 Ability to record orders
1.2 Ability to schedule manufacturing run based on inventory counts and orders
1.3 Ability to flag minimum quantity levels for triggering of reorders

2. Specific requirements for each kit management workflow area

2.1 Kit component ordering and receiving
  2.1.1 Ability to process proactive specimen/sample schedules and set delivery dates and inventory quantities
  2.1.2 Ability to track inventory status and create replenishment orders for kit components based on assembled kit shipping schedule
  2.1.3 Receive component orders and increment stock inventories
2.2 Process submitter orders
  2.2.1 Ability to create order packing slips for kit shipment to specific submitter locations based on proactive specimen/sample schedule delivery dates
  2.2.2 Ability to receive and process kit orders directly from submitters (lower level laboratories) either electronically or manually submitted
  2.2.3 Ability to block order preparation based on submitter budget status or records indicate they have sufficient quantity on hand based on number of test requests received by the laboratory

2.2.4 Ability to create submitter test kit invoice information for prepayment or payment subsequent to shipping for processing by billing function
2.2.5 Ability to decrease inventory counts for order items pulled for shipping

2.3 Ship submitter orders
2.3.1 Ability to create order package labels and change order status for each specific submitter ship to location
2.3.2 Ability to record shipping information for tracking purposes

3. Specific requirements for each inventory control workflow area

3.1 Monitor inventory levels and create replenishment orders
3.1.1 Ability to monitor inventory levels and anticipated usage
3.1.2 Ability to create replenishment orders

3.2 Receive orders and stock inventory
3.2.1 Ability to update stock on hand and decrease outstanding order quantities based on quantities received

3.3 Receive and fill internal and external laboratory and media kitchen orders
3.3.1 Receive and record orders (or receive them electronically from the individual laboratories or media kitchen)
3.3.2 Ability to decrease inventory counts for order items pulled for delivery to bench or shipped to other laboratories
3.3.3 Ability to create billing invoice for external sales
3.3.4 Ability to produce physical inventory worksheets and reconcile physical inventory counts with LIMS counts
3.3.5 Ability to create inventory labels to track date received, time put in use, etc.

4. Specific requirements for form management workflow

4.1 Ability to electronically create and distribute new versions of forms and other documents necessary for the operation of the laboratory
4.2 Ability to manage the acquisition and distribution of forms and documents obtained in hard copy from external sources (scanned form stored in LIMS database)
4.3 Ability for users to create and modify on-line requisition form for use by the laboratories in ordering items from inventory

5. Selected QC/QA specifications

5.1 Ability to capture specific data elements associated with QC/QA measures associated with this specific process (see Functional Requirements #7 for additional information)

6. Selected system output requirements

6.1 Inventory item usage by item and cost (also person/section who used)
6.2 Projections of inventory item usage by user defined time period and current proactive specimen/sample collection schedule, including estimated submitter inventory levels
6.3 Cost history by item, cost center, and other factors
6.4 Documentation of manufacturer QC for applicable items
6.5 Report on sales to external laboratories by laboratory and item for user specified time period

6.6 Reports of kit shipments to submitters by submitter location and/or collector
6.7 Reports of test cost profiles for all items supplied to laboratories
6.8 Reports on kit outdating (kits in inventory that have expiration dates)

Specifications for FR #6: General Laboratory Reporting

General Reporting: Many of these reports support general "business management" activities that are specified in each functional requirement. Standard reports embedded in LIMS are not necessarily specified in this section, but there are some examples that may be useful when looking for general reporting.

Examples include:

1. Ability to provide Workload Reports (periodic – weekly, monthly, yearly, etc. – workload reports that will indicate separate counts of specimen/samples received and tests performed for each analytical area)
2. Ability to provide reports that differentiate between client-ordered tests and tests done in house as part of a testing protocol or study
3. Ability to provide Work Time Unit reports (reports that calculate the amount of labor it took to run the tests). The system should also be flexible enough so the laboratories can add, delete, or change tests and work time units as needed.
4. Ability to provide Quality Assurance Reports which means that the system should produce reports based on any of data fields and the comment fields where additional QA information will be stored. Examples of QA reports include information about unsatisfactory specimens/samples, specimen/sample rejection, improperly labeled specimen/samples and/or request slips, etc.
5. Ability to provide Turn-around Time Reports (reports showing the turn-around times for specific tests or test groups, including the average turn-around times plus the number that meet, exceed, and are less than predetermined turn-around times)
6. Ability to provide Quality Control Reports (reports showing periodic summaries of QC results with detailed reports of exceptions including detailed listings of QC results for a particular date range, as well as tracking changes in QC measures and who made the changes)
7. Ability to provide Submitter Usage Reports (summarized reports providing lists of submitters and the tests they requested for a specified period of time)
8. Ability to provide EIDSS-entered Disease Report (reports listing all diseases entered in EIDSS based on the results of laboratory testing with flexibility to add, change, and/or delete tests as necessary)
9. Ability to provide Test Log Reports (reports on various test logs such as specimen/sample pending log, EIDSS-entered disease log, specimen/sample send-out log, etc., as well as a list for a specific test(s) or series of results for a given time period/submitter/etc.)

Specifications for FR #7: Quality Control (QC) and Quality Assurance (QA) Management

Overview: The key element for QC and QA is the ability to support an integrated view of QA/QC activities and quality measures.

1. For QC this involves the ability to determine the applicable QC elements that were operative at the time any test was performed and to be able to retrieve the documentation references through the use of the LIMS if the information is stored on hard copy. Ultimately, the goal would be to have electronic documentation complete with electronic signature capability.
2. For QA the goal is the ability to capture the data elements that define each QA measure and make it easier for the PHL to track and evaluate the QA measures. This functional requirement focuses on the overall management of the QC/QA function.

Workflow summary

1. Establish QC parameters for each test/method including manufactured or purchased ingredient used in conjunction with the test/method as well as specimen/ sample condition tracking, capture QC data for each test, and analyze trends in QC test results.
2. Establish and review each QA measure and determine data sources available for supporting each measure, capture QA measures, and analyze trends and institute corrective actions when necessary.

Specific requirements for each QC workflow area

1. Establish external quality assessment (EQA)

1.1. Ability to create and maintain a master record for test sent out for proficiency testing, rechecking retesting, and on-site evaluation with sample type, test methods, sample receiving laboratory information, time, payment information, etc. For example, NCDC and LMA reference lab sends tests to regional/private labs (customers), receives results, performs data analysis and generates final reports

1.2. Ability to create and maintain a master record for recording test results received from test sent out for proficiency testing, rechecking retesting, and on-site evaluation. For example, NCDC and LMA reference lab receives samples from abroad (international EQA providers) performs testing, sends results back to provider and receives final scores/report. If the results are not sufficient, after the management review center plans corrective actions, puts into the practice and assess their efficiency.

2. Set up each QC parameter and associated data elements

2.1. Ability to create and maintain a master record for each QC test by instrument/method.

2.2. Ability to create and maintain a master instrument/test/method records for associated input QC parameters (media, reagents, etc.).

2.3. Ability to create and maintain a master instrument/test/method record for specimen sample condition tracking elements (temperature control, holding time, etc.)

2.4. Ability to link the QC records for QC test, associated input, and specimen/sample condition if not created in same database table

2.5. Ability to capture SOP on each instrument/test/method along with effective dates for each version

3. Capture QC measures

3.1. Ability to electronically capture all QC measure values as appropriate as a part of the testing process
3.2. Ability to manually enter QC measure values in cases where the measures are not included in the testing process support (media manufacturing, etc.)
3.3. Ability for user to define the placement of QC and proficiency tests within a batch

4. Analyze QC measures

4.1. Ability to track QC measures and create analyses by time period or individual tests. For example, analysis capabilities might include:
4.1.1. Ability to perform a variety of data reduction capabilities including linear regression (straight line fit), Log (Logit), Four Parameter Logistic and Cubic Spline.
4.1.2. Ability to produce Levey-Jennings QC plots, as needed.
4.1.3. Ability to use institute specific or common QC rules (such as Westgard) to evaluate whether analysis is in or out of control. The rules must be able to be turned on or off as needed for each test performed as well as specifying which rules to use for each test. The rules must be able to be used on a real time basis for problem identification.
4.2. Ability to analyze information on unknown specimens/samples, spiked specimens/samples and duplicate specimens/samples
4.3. Ability to create alerts when QC measures trend toward limits
4.4. Ability to warn users that QC for one or more elements for an instrument/test/method has failed under either batch or individual test circumstances
4.5. Ability to automatically reschedule all tests invalidated by a QC failure with manual over-ride by supervisory personnel
4.6. Ability to create a report of all QC measures associated with a specific specimen/sample submission
4.7. Ability to include electronic signatures for QC entries

5. Perform Uncertainly Calculations (http://www.nordtest.info/) for LMA. The estimation of the measurement uncertainty is required in ISO 17025

5.1. Ability to export test results for uncertainty calculations using a third party analytic tool, such as MuKit – Measurement Uncertainty Kit (http://www.syke.fi/en-us/Services/Calibration_services_and_contract_laboratory/MUkit__Measurement_Uncertainty_Kit)
5.2. Ability to import and store the calculation results back to LIMS
5.3. Ability to create a link to the stored uncertainty calculation results

6. Specific requirements for each QA workflow area

6.1. Set up and maintain each QA measure
6.1.1. Ability to create and maintain master records for each QA measure
6.2. Capture each incidence of each QA measure
6.2.1. Ability to electronically transfer QA data associated with other business process support files
6.2.2. Ability to manually enter QA data not captured in the LIMS as a part of other process support

6.3. Analyze each QA measure and institute corrective action where necessary
  6.3.1. Ability to track QA measures and create analyses by time period
  6.3.2. Ability to create alerts when QA measures trend toward limits
  6.3.3. Ability to trigger special reports when QA measures have exceeded acceptable limits

7. Selected system output requirements

7.1. Reports of QC failures for specified timeframe by specific laboratory, instrument, test, and method
7.2. QC reports for support of audit activities
7.3. QC analysis reports on duplicate testing
7.4. Reports/screen displays of standard operating procedures for each method with "read only" security controls
7.5. QA reports for management by QA parameter

Specifications for FR #8: Statistical Analysis and Surveillance

Overview: Laboratories are in a position to greatly "enrich" the test data that is passed on to a variety of critical users and back to the submitters. Obviously, the key deliverable is accurate and timely test results. These results represent the major objective of a laboratory's activity and the reason for its existence. This functional requirement deals with several ways in which the laboratory can contribute to the broader public health objective of assessment, policy development, and assurance in terms of identifying and responding to adverse health events caused by disease or environmental factors in Georgia. These contributions can be broken out into two general categories: as a conduit for surveillance data and as a contributor to the understanding of the cause and impact of adverse test result patterns.

Workflow summary: Capture and pass along non-test specific information, perform additional testing for typing and understanding primary results, and perform statistical analysis activities intended to identify suspicious test request and result patterns

Specific requirements for each workflow area

1. Provide a conduit for non-test specific data associated with test request submittals

1.1. Ability to capture and store patient name, address and demographic data submitted in conjunction with test requests from specific submitters
1.2. Ability to capture and store risk factors, exposure information, and other patient characteristics associated with a test request from specific submitters
1.3. Ability to electronically transmit non-test data elements to specified users
1.4. Ability to electronically or manually capture and store the non-test specific data

2. Perform additional testing for typing and understanding of primary results

2.1 Ability to flag test results for which subsequent testing would be appropriate and automatically add follow up test requests to testing schedule
2.2 Ability to link the subsequent test results to the primary test report
2.3 Ability to build business rule tables for use in flagging described above (2.1)

3. **Analyze test result patterns**
   - 3.1 Ability to create positive test results as rates (positives related to total submittals)
   - 3.2 Ability to analyze positive test patterns by type of test
   - 3.3 Ability to present combinations of clinic and environmental tests by geographic location for clustering analysis
   - 3.4 Ability to create user defined extracts of test data for electronic transmittal to specified users utilizing a standard open file structure format such as comma delimited flat files

4. **Selected QA specifications:**
   - 4.1 Ability to capture specific data elements associated with QA measures associated with this business process (see Functional Requirement #7 for additional information)

5. **Selected system output requirements:**
   - 5.1 Ability to enable the laboratory to send certain specified test results to users (such as Epidemiology) other than the submitter before being sent to the submitter.

Specifications for FR #9: Billing for Laboratory Services

Overview: NCDC and LMA laboratories may engage in a wide variety of billing activities designed to help offset the testing costs. In general, the billing is associated with the following aspects of the laboratory's workflow: provision of collection kits and containers to submitters, testing and test reporting, provision of training services, and laboratory annual licensing fees and inspection services.

Workflow summary: The work involves obtaining the billing information from the submitter or other entities, tabulating the items to be billed, applying appropriate billing rates, and creating the invoices and supporting billing documentation. In some cases, the billing function is not performed by the laboratory. However, in this situation the laboratory still has to collect and prepare the billing information associated with each invoice

Specific requirements for each workflow area

1. **Obtaining submitter and other entity billing information**
   - 1.1. Ability to capture and maintain submitter billing address and responsible party information
   - 1.2. Ability to specify which services are included under a given contract agreement and tag each service with an active/inactive flag (or timestamp each unique set of services active under the agreement for any given service provision date)
   - 1.3. Ability to capture and maintain agreed upon charges for specific services if different than standard billing rates
   - 1.4. Ability to capture relevant patient billing information for a given service date from other third-party payment sources, such as hospital or other health system (HMIS).

2. **Identification of services performed and qualifying for billing**

2.1. Ability to match services provided against the submitter billing master for creation of billing ledger entries (i.e., selection of billable services from the LIMS records indicating the provision of the services)
2.2. Ability to allow for costing and fee development at either the instrument test level or test/method level.

3. Preparation of invoices and billing documentation

3.1. Ability for user to select specific billing ledger entries and create submitter specific billing invoices
3.2. Ability to create hard copy invoices grouped by submitter
3.3. Ability to create electronic billing invoices in lieu of paper
3.4. Ability to track billing and payment status
3.5. Ability to create billing invoices for services requiring prepayment that are linked to a submitter's purchase order or request for the services
3.6. Ability to block shipment of kits and other items if prepayment is required
3.7. Ability to collect payments (including cash payments), print receipts, and account for miscellaneous prepaid service requests (walk-in business for well water testing from the public, if applicable, for example)
3.8. Ability to create preliminary bill with initial test results

4. Selected QA specifications

4.1. Ability to capture specific data elements associated with QA measures associated with this business process (see Functional Requirement #7 for additional information)

5. Selected additional system output requirements

5.1. Ability to create billing reports by submitter, timeframe, service and other key parameters
5.2. Ability to track grant & contract services and associated fees
5.3. Ability to create reports for non-billable services indicating cash value by grant/contract based on standard costs
5.4. Ability to report on test billing – what tests have been billed and the amount billed by selected time period

FR #10: Contract and Grant Management

Overview: Contracts and grants between NCDC and LMA or with other institutes and users of the laboratory services may involving specific services requests (generally clinical from hospital or food safety testing) by type and quantity. Contract/grant limits may be stated in either number of tests to be performed or total dollars. The key aspect of contract and grant management in LIMS is the tracking and reporting of the services provided to the users to ensure that the laboratory has met the conditions of the agreement in terms of the services provided and the timeframe in which they were provided. Some agreements also contain schedules for the timing of test requests over the life of the agreement.

Workflow summary: The workflow includes creating the anticipated test request schedule, ensuring that all collection kits required are delivered in a timely manner to the submitter(s), tracking of tests

performed under the agreement (both dollars and numbers), and providing periodic updates of services performed under the agreement.

Specific requirements for each workflow area:

1. **Contract/grant set up**
   - 1.1 Ability to create tracking file containing grantor name and address information, time period, tests covered, and specimen/sample collection schedules
   - 1.2 Ability to create collection/collector name and address information associated with each contract/grant and link to collection schedule
   - 1.3 Ability to record and track contract/grant objectives and their achievement

2. **Service Scheduling & collection kit distribution**
   - 2.1. Ability to electronically create scheduling records in proactive specimen/sample collection schedule file [See Functional Requirement #3—Proactive Specimen/Sample Collection (Prescheduled Tests)]
   - 2.2. Ability to update proactive specimen/sample collection schedule based on contract grant modifications

3. **Tracking tests performed**
   - 3.1. Ability to track tests performed under each contract by collector within each grantee contract

4. **Periodic reporting on contract/grant status**
   - 4.1. Ability to alert test scheduling when contract/grant service limits have been or are close to being reached.
   - 4.2. Grant reporting tickler file (due dates and responsible party in NCDC or LMA)

5. **Selected QA specifications**
   - 5.1. Ability to capture specific data elements associated with QA measures associated with this business process (see Functional Requirement #7 for additional information)
6. **Selected system output requirements**
   - 6.1. Reports by contract/grant showing testing schedule, tests performed to date, and dollar value
   - 6.2. Summaries of contract/grant activity by grantee Billing summaries by test and unit cost for situations where the contract/grant is disbursed on the basis of work performed
   - 6.3. Billing summaries by test and unit cost for situation where the contract/grant is disbursed on the basis of work performed

FR #11: Training, Education and Resource Management

Overview: It is very important to note that it is not the intent to create a human resources management system within LIMS. In general, if a laboratory is using a human resources management system it is for a larger governmental unit. However, there are a number of critical data elements that pertain only to laboratory testing capabilities: primarily certification and proficiency on a given instrument and method. To capture instrument-specific information in a general human resources

system would not be feasible from the standpoint of the particularity of the data. By the same token, the information must be readily available for use with other related LIMS data. Thus, the only logical conclusion is that the data sets required for the support of the LIMS specific training, education, and resource management (data such as instrument preventive maintenance) must be incorporated in the LIMS to effectively support the laboratory's data needs in this regard.

Workflow summary for Training and Education: Create employee (primarily laboratory technicians) training record and populate it with relevant training and education experience, monitor records and testing trends to determine training needs, determine training opportunities and schedule training, and record training in employee record.

Workflow summary for SOP Management: Create records for each SOP and track changes and new versions SOPs have been developed. Provide version control capability with person and time include approvals.

Workflow summary for Resource (Instrument) Management: Create records for each instrument and instrument method if multiple methods are used on a given instrument, track instrument preventive and emergency maintenance, track next preventive maintenance date, and monitor instrument usage.

Specific requirements for each training workflow area:

1. **Create and maintain laboratory technician training records**
   - 1.1. Ability to create and maintain employee records pertaining to specialized training, such as date of employment, qualifications, list of certificates, list of assigned instruments/devices, list of specific analytical methods the technician is able to perform, etc.
   - 1.2. Ability to track employee immunization status (if needed)
   - 1.3. Ability to create and maintain code tables for training activities

2. **Monitor records for training needs**
   - 2.1. Ability to create and maintain business rules associated with each training activity including time intervals between "refresher" sessions
   - 2.2. Ability to flag employee training records when additional training is required and create reminders
   - 2.3. Ability to forecast training needs for specified time period (for example, projections for next 12 months by type of training)

3. **Determine training opportunities and schedule training**
   - 3.1. Create calendar for training offerings that can be accessed by employees and submitters (for example, instructions on specimen/sample packaging and shipping) for self-enrollment
   - 3.2. Ability to send reminder via email to the enrolled staff or flag in the LIMS at least two weeks prior to the scheduled training date

4. **Record training and proficiency information**
   - 4.1. Ability to record training received in laboratory supported training as well as external training attended
   - 4.2. Ability for employees to view their training records

5. **Track QC/QA issues and institute training for problem correction (both laboratory personnel and submitters)**
   5.1. Create and schedule training specifically addressed to correct QC or QA problems

Specific requirements for SOP management workflow area

1. **Create records for each SOP**
   1.1 Ability to create and maintain master records for each SOP with version information, such as person and time
   1.2 Ability to create and maintain history of changed SOPs
   1.3 Ability to create and maintain list of printed SOPs and their location

Selected system output requirements

1. **System output**
   1.1 Current SOP list and location including electronic and page SOPs
   1.2 List of SOPs with version and modification change history

Specific requirements for each resource (instrument/device) management workflow area

1. **Create records for each instrument/device and instrument/device method**
   1.1. Ability to create and maintain master records for each instrument and associated method and periodic verification of minimum detection limits (MDL)
   1.2. Ability to create and maintain master records for each instrument/device information including date of installation, date of validation/verification, standard samples for use
   1.3. Ability to create and maintain documentation list of instruments/devices including manufacture name, model, serial number, location, certificates, manual, acts, and printed manual location
   1.4. Ability to create list of technician assigned to the instruments/devices
   1.5. Ability to analyze test /method volumes and create capacity/day for each instrument/device method
   1.6. Ability to track preventive and emergency maintenance activity by instrument/device, including average "down time" for a preventive maintenance and average down time per month associated with emergency maintenance
   1.7. Ability to schedule instrument preventative maintenance and associated down time.

2. **Track instrument/device preventive and emergency maintenance**
   2.1. Ability to create date(s) of calibrations for each instrument/device
   2.2. Ability to create message on approach of term of calibration in one month prior to the termination of term and send to responsible staff by email and SMS
   2.3. Ability to create dates of instruments/devices maintenance
   2.4. Ability to create list of instruments/devices intermediate measurements
   2.5. Ability to record actual down time for preventive and emergency maintenance
   2.6. Ability to send email and SMS to responsible staff violations or deviations information when instruments/devices run on automatic mode

3. **Monitor instrument/device usage (tests by method)**
   3.1. Ability to report on test volumes and times by instrument/device and method

Selected QA specifications

1. **QA specifications**
   1.1. Ability to capture specific data elements associated with QA measures associated with this business process (see Business Process #14 for additional information)

Selected system output requirements

1. **System output**
   1.1. Current training schedule and associated information
   1.2. Schedule of special education (as needed depending on QA problems) and intended audience
   1.3. Reports of available qualified personnel counts by instrument
   1.4. Electronic instrument/device availability schedule and utilize it in scheduling activities
   1.5. Instrument/device maintenance schedules
   1.6. Reports of instruments/devices information mentioned above
   1.7. Email and SMS message to responsible staff mentioned above

FR #12: Laboratory Safety and Accident Investigation

Overview: The core activity of this functional requirement is support of investigation and reporting on all accident/safety violations and tracking laboratory items considered to be safety hazards.

Workflow summary: Create tracking record for each incidence, support the investigation process, and capture investigation findings.

Specific requirements for each workflow area

1. **Create incident tracking record and records for tracking chemical and biological waste handling and disposal (incidents would also involve personnel related safety violations and accidents)**
   1.1. Ability to create incident tracking records containing relevant data about the incident
   1.2. Ability to create and maintain records on chemical inventory and biological waste where appropriate
2. **Record pertinent investigation information**
   2.1. Ability to record predefined investigation data
3. **Record findings summary**
   3.1. Ability to create incident finding summaries using user-defined codes for cataloguing the findings
   3.2. Ability to record and follow up on recommendations for revisions to safety policies and procedures

4. **Selected QA specifications**
   4.1. Ability to capture specific data elements associated with QA measures associated with this business process (see Functional Requirement #7 for additional information)
   4.2. Ability to reference Material Safety Data Sheets (MSDS) management sheets on-line

5. **Selected system output requirements**
   5.1. Safety & materials status reports
   5.2. Accident investigation reports
   5.3. Special reports on QA data related to safety and accidents

4. User Interface Requirements

In addition to functions required, a graphic user interface (GUI) will be designed to provide various users from NCDC and LMA to easily log-in to corresponding module in Georgian and English. In general, the UGI should meet the following requirements.

- **Aesthetically pleasing**
  - Provide meaningful contrast between screen elements
  - Create groupings
  - Align screen elements and groups
  - Provide three dimensional representation
  - Use colors and graphics effectively and simply (Match NCDC and LMA color pattern if possible)
- **Clarity** The interface should be visually, conceptually and linguistically clear, including
  - Visual elements
  - Functions
  - Metaphors
  - Words and text
- **Compatibility** Provide compatibility with the following:
  - The user
  - The task and job
  - The product
  - Adopt the user's perspective
- **Comprehensibility** The LIMS should be easily understood and learned. A user should know the following
  - What to do
  - What to look at
  - When to do it
  - Where to do it
  - Why to do it
  - How to do it
  - The flow of actions, responses, visual preparations and information should be in a sensible order that is easy to recollect and place in context.
- **Configurability** Permit easy personalization, configuration and reconfiguration of settings.
  - Enhances a sense of control
  - Encourages an active role in understanding

- **Consistency** A system should look, act, and operate the same throughput. Similar components should:
  - Have a similar look
  - Have similar uses
  - Operate similarly
  - The same action should always yield the same result.
  - The function of the elements should not change
  - The position of standard elements should not change.
- **Control** The user must control the interaction.
  - Actions should result from explicit user requests
  - Actions should be performed quickly
  - Actions should be capable of interruption or termination
  - The user should never be interrupted for errors
  - The context maintained must be from the perspective of the user
  - The means to achieve goals should be flexible and compatible with the user's skills, experiences, habits and preferences
  - Avoid modes since they constrain the actions available to the user
  - Permit the user to customize aspects of the interface, while always providing a proper set of defaults
- **Directness** Provide direct ways to accomplish tasks
  - Available alternatives should be visible
  - The effect of actions on objects should be visible
- **Efficiency**
  - Minimize eye and hand movements, and other control actions
  - Transitions between various system controls should flow easily and freely
  - Navigation paths should be as short as possible
  - Eye movement through a screen should be obvious and sequential
  - Anticipate the user's wants and needs whenever possible
- **Familiarity** Employ familiar concepts and use a language that is familiar to the user
  - Keep the interface natural, mimicking the user's behavior patterns
  - Use real world metaphors
- **Flexibility** A system must be flexible to the different needs of its users, enabling a level and type of performance based upon
  - Each user's knowledge and skills
  - Each user's experience
  - Each user's personal preference
  - Each user's habits
  - The conditions at that moment
- **Forgiveness**
  - Tolerate and forgive common and unavoidable human errors
  - Prevent errors from occurring whenever possible
  - Protect against possible catastrophic errors
  - When an error does occur, provide constructive messages

- **Predictability** User should be able to anticipate the natural progression of the task
  - Provide distinct and recognizable screen elements
  - Provide cues to the result of an action to be performed
  - All expectations should be fulfilled uniformly and completely
- **Recovery** A system should permit
  - Commands or actions to be abolished or reversed
  - Immediate return to a certain point if difficulties arise
  - Ensure that users never lose their work as a result of an error on their part or communication problems
- **Responsiveness** The LIMS must rapidly respond to the user's requests to
  - Provide immediate acknowledgement for all user actions
  - Should be visual, textual, and auditory
- **Simplicity**
  - Provide as simple an interface as possible
  - Provide defaults
  - Minimize screen alignment points.
  - Make common actions simple at the expense of uncommon actions being made harder.
  - Provide uniformity and consistency
  - Ways to provide simplicity:
    - Present common and necessary functions first.
    - Prominently feature important functions,
    - Hide more sophisticated and less frequently used functions
- **Transparency**
  - Permit the user to focus on the task or job, without concern for the mechanics of the interface.
  - Workings and reminders of workings inside the computer should be invisible to the user.

5. General System Requirements

There are a number of general requirements that are neither functional requirements non business process specific, but are important from the perspective of overall system functioning. This section includes overall system capabilities to supplement the detailed functional requirements specifications in other sections.
This section concentrates on the LIMS application and operating environment.

LIMS Access and Navigation

5.1 Security: Control for system access by authorized users.

These specifications assume that NCDC and LMA have appropriate security in place to authenticate users to access the information system environment that is separate from authorization to LIMS functions and data.

5.1.1 Ability to create and maintain individual user specific security tables containing user ID and password information that is accessed only by administrator level security.

5.1.2 Ability to restrict user passwords to use combinations of characters of a standard minimum length

5.1.3 Ability to track user password revisions and force users to change their passwords at NCDC and LMA determined intervals

5.1.4 Ability to terminate log-on screen after NCDC and LMA determined number of unsuccessful tries by a user to log in

5.1.5 Ability to automatically log off idle workstations after a predetermined period of time

5.1.6 Ability to enable a user automatically logged off to log back in and have the system reset to the same screen the user was on when the automatic log off occurred

5.1.7 Ability to prevent a user from being logged on to multiple workstations at the same time

5.1.8 Ability to limit hours of access for individual users and lock them out of the system during non-authorized hours

5.1.9 Ability to create an audit trail of who, when, where, and what functions were accessed by a specific user

5.1.10 Ability to conform to any other NCDC and LMA specified security conditions as a part of its privacy and security documentation

5.2 User Rights and Privileges: This section generally covers what users are authorized to do once they are granted access to the LIMS.

5.2.1 Ability to create rights and privilege groups by type of user

5.2.2 Ability to create unique user rights based on functions and screen displays

5.2.3 Ability to control which users have the right to update specified data sets and track the data updated

5.2.4 Ability to lock certain records at some specified point after creation (test results for example)

5.2.5 Ability to include add/delete/edit/read only limits on user rights

5.3 Screen Access and Navigation: User rights notwithstanding, this segment relates to requirements specifications regarding system screen access and navigation.

5.3.1 Ability to access any allowed function from any workstation on the system

5.3.2 Ability to access various screens through the use of menus and appropriate icons on various screens

5.3.3 Ability to move easily from one screen to another utilizing screen appropriate icons or function keys

5.3.4 Ability for off-site customers to access limited read-only fields or portions of the Web LIMS for data entry and barcode generation

5.4 General Query Capabilities:

5.4.1 Ability to query specific records based on record key data fields

5.4.2 Ability to perform name searches utilizing soundex approaches if applicable

5.4.3 Ability to access query function screens from screens where it would be logical to do so rather than having to return to a system menu

5.4.4 Ability to query for any specific test request test status

Field Entry and Editing and System Table Maintenance

5.5 Field Value Entry and Editing: Any field containing a coded value rather than text should include the following:

5.5.1 Ability to enter the value desired directly or from a drop down table of valid values through standard mouse selection procedure

5.5.2 Ability to require mandatory fields to be filled before user can exit the screen, along with prompts or highlights that enable the user to quickly see which fields need to be completed

5.5.3 Ability to define data entry fields for dual entry with separate verification pass prior to accepting the data set

5.6 Other Field Editing: Editing of non-table fields

5.6.1 Ability to apply alpha/numeric edits

5.6.2 Ability to test for valid numeric value range

5.6.3 Ability to perform selected correlation edits between fields

5.6.4 Ability to edit for valid dates and reasonable date ranges

5.6.5 Ability to insert default values for any code or non-code field

5.6.6 Ability to default value for current date and time in all appropriate fields that are generated from the system clock, but allow user over-ride

5.7 System Maintenance: Maintenance of all LIMS tables for which the user has the responsibility for populating

5.7.1 Ability to control access to the system tables by authorized administrative personnel

5.7.2 Ability to update code tables directly from any screen where the field appears by authorized users only

5.7.3 Ability to maintain the value set for any table

5.7.4 Ability to time-stamp any table where changes are only valid starting on a specific date

Reporting and Data Transfer

5.8 General Reporting: Standard reports embedded in the LIMS. Many of these reports support general "business management" activities. Examples include:

5.8.1 Ability to provide Workload Reports (periodic – weekly, monthly, yearly, etc. – workload reports that will indicate separate counts of specimen/samples received and tests performed for each analytical area)

5.8.2 Ability to provide reports that differentiate between client-ordered tests and tests done in-house as part of a testing protocol or study

5.8.3 Ability to provide Work Time Unit reports (reports that calculate the amount of labor it took to run the tests). The system should also be flexible enough so the users can add, delete, or change tests and work time units as needed.

5.8.4 Ability to provide Quality Assurance Reports. The system should produce reports based on any of data fields and the comment fields where additional QA information will be stored. Examples of QA reports include information about unsatisfactory specimens/samples, specimen/sample rejection, improperly labeled specimen/samples and/or request slips, etc.

5.8.5 Ability to provide Turn-around Time Reports (reports showing the turn-around times for specific tests or test groups, including the average turn-around times plus the number that meet, exceed, and are less than predetermined turn-around times)

5.8.6 Ability to provide Quality Control Reports (reports showing periodic summaries of QC results with detailed reports of exceptions including detailed listings of QC results for a

particular date range, as well as tracking changes in QC measures and who made the changes)

5.8.7 Ability to provide Submitter Usage Reports (reports providing lists of submitters and the tests they requested for a specified period of time)

5.8.8 Ability to provide Reportable Disease Report (reports listing all reportable diseases based on the results of laboratory testing with flexibility to add, change, and/or delete tests as necessary)

5.8.9 Ability to provide Test Log Reports (reports on various test logs such as specimen/sample pending log, reportable disease log, specimen/sample send-out log, etc., as well as a list for a specific test(s) or series of results for a given time period/submitter/etc.)

5.9 Report Generation Strategy (Internal and Export): This general specification supplements the more specific specifications contained in other sections

5.9.1 Ability to provide a reports menu from which the user can select and run standard system reports

5.9.2 Ability to schedule the production of reports for non-peak system usage or nighttime

5.9.3 Ability to create user query reports utilizing a standard query tool compatible with the LIMS data base architecture

5.9.4 Ability to limit scope of query reports

5.9.5 Ability to select and export data sets for more intensive analysis on a workstation in a format compatible with appropriate desktop database products and statistical analysis packages

5.10 Web Front End: More general specification than contained in Section VII relating to database interfaces.

5.10.1 Ability to provide secure Internet site for the exchange of laboratory data sets

5.10.2 Ability to support user input screens for test request submission and specimen/sample collection

5.10.3 Ability for external users to pick up test reports and files as well as general purpose report data files

5.10.4 Ability to provide second-tier authentication for data access

Miscellaneous General Requirements Specifications

5.11 General Barcode Usage: Barcoding has been mentioned elsewhere in this document. This section pertains to the general use of barcodes in the LIMS environment.

5.11.1 Ability to support a variety of barcode labels for different uses that contain use-specific codes

5.11.2 Ability to print barcode labels on variety of printers

5.11.3 Ability to print user-defined number of copies

5.11.4 Ability to support multiple barcode standards

5.11.5 Ability to add additional standards and alert system as to which barcode standard is being scanned

5.12 Data Archiving: Although the cost of on-line storage has dropped dramatically there still may be a need to archive data sets from a system performance perspective or database size

5.12.1 Ability to construct logical parameters for selecting data sets to be archived

5.12.2 Ability to support multi-tiered archiving with a progression of movement from the system hard drive to other forms of data storage

5.12.3 Ability to find and retrieve specific archived data sets

5.12.4 Ability to delete archived data sets at end of specified holding periods

6. LIMS Interfaces

This section contains specification requirements for four major interface categories:

Category 1: Interfaces with submitter database systems (e.g., epidemiology, EIDSS, HMIS, Hospital and private laboratories)
Category 2: Interfaces with instruments
Category 3: Interfaces with submitter data sets and data users' databases (e.g., epidemiology, EIDSS, HMIS, and hospital systems)
Category 4: Interfaces via website with submitter and data users

These interfaces are critical from the standpoint of efficiency, data accuracy, timeliness (turnaround time), and surge capacity. The underlying intent of interfaces is to eliminate wherever possible the manual *re-entry* of data at any point during the continuum from submitter database to the LIMS, from the LIMS to test instruments, from the instruments to the LIMS, and from the LIMS to the test result users. It is apparent that where data re-entry is required, the data entry process is a potential

constraining factor impacting on the efficient, accurate, and timely processing of test requests. This point is illustrated in the following example.

If a test request must be entered manually together with the test receiving/accessioning process *without* delaying the start of testing, an initial "skeleton" record is often created to enable the LIMS to print batch worksheets and track the accessioning number and required name information. The remainder of the data is then added in a second data entry pass. The two-step data entry solution helps prevent the data entry process from holding up the test result processing. However, handling the request form twice increases the data entry workload. On the other hand, if the test request is received electronically, the processing time is shorter, not only for each individual test, but for creation of test batches as well.

For manual entry there is essentially a 1:1 relationship between the number of requests and the time it takes to enter them (i.e., there is no incremental gain or efficiency related to volume). Naturally time is involved in processing an electronic batch of test requests. However, processing the second batch should take significantly less time, and even if it doesn't, the total time for creating both batches is far less than for manual entry. Clearly from the perspective of data entry, electronic request submission greatly reduces the risk of data entry as the constraining factor in processing test requests. As will be seen below, the same logic can be applied to database interfaces (i.e., an electronic interface increases accuracy, helps ensure test processing in a timely fashion, and creates surge capacity, all of which increase overall laboratory efficiency).

Category 1: Interfaces with submitter database systems

1. Submitter Systems are from EIDSS, HMIS or hospital to the LIMS

In general, the EIDSS, HMIS or hospital systems initiate much or all of the test request data. Still, for a variety of reasons the test request submissions are made on paper (e.g., NCDC and LMA request forms are often multi-copy). Many times, the request form is wrapped around the specimen/sample and secured by a rubber band.
Specifications for submitter system to LIMS:

1.1. Creation of a HL7 (if HL7 is in use for transmission) message or standard file format containing standard terminology (if applicable) for test submittals that submitters can map to/from their system databases
1.2. Ability to securely transmit standard message or file
1.3. Ability to parse and load electronic test submittals directly into the LIMS
1.4. Ability to link electronically submitted test requests to corresponding specimen/samples when they are delivered to the NCDC or LMA laboratories
1.5. Ability to scan barcode labels on specimen/samples in order to establish link to associated electronic test submittal

Category 2: Interfaces with Instruments

2. Test data sets from the LIMS to the individual instruments (List of instruments can be found in Appendix)

In this interface, it is important to be able to electronically load test requests for a given test batch per the given instrument's electronic interface specifications. This often will require instrument-specific batch file creation as a part of the LIMS software.

Specifications for test data sets to instrument:

2.1. Ability to create instrument specific data sets for loading test batches into the instrument for processing
2.2. Ability to scan barcode labels for machine loading in cases where the instrument only utilizes a unique ID for processing the tests.
2.3. Ability to print out a hard copy of the test batch data loaded for each instrument run as documentation of the contents of the run

3. Instrument test results to the LIMS

Sometimes instrument output from test processing requires "interpretation" or subsequent calculations in order to arrive at a test result. Thus, this interface, in addition to performing the electronic test result loading to the LIMS, must have the ability to review and/or modify the data set extracted from the instrument prior to the transfer to the LIMS. As an option, the "interpretation" could be performed within the LIMS if all the required data was appropriate for inclusion in the LIMS database.

Specifications for instrument test results to LIMS:

3.1. Ability to create instrument specific test result data sets for processing into the LIMS
3.2. Ability to review and modify the test result data set prior to or following the release of the results to the LIMS
3.3. Ability to load the reviewed and/or modified test result data set into the LIMS
3.4. Ability to print out the extracted data set for hard copy record keeping
3.5. Ability to note modifications made to the original extract data set prior to loading into the LIMS
3.6. Ability to track who modified the result data set and the time the data set was modified
3.7. Ability to load raw instrument data directly to the LIMS and have the "interpretation" performed within the LIMS

Category 3: Interfaces with submitter data sets and data user's databases creating enriched data sets

4. Test results from the LIMS to the submitter data set and/or to authorized data users databases.

Test result reports sent from the laboratory to the submitter not only enriches submitter data sets but also submitters as well as others use the data user's databases, i.e., the data. The key to this interface is to create a laboratory test result report for authorized users that is an exact replica as generated by the LIMS for submitters.

Specifications for test results from LIMS to the submitter's data set and/or to authorized data user's databases:

4.1. Ability of LIMS to create standard message or file
4.2. Creation of a print file format for the test report for the purpose of allowing the submitter to print out a laboratory test report that would be identical to that which would be printed by the laboratory for manual test reporting
4.3. Creation of a standard test report file for use by the submitter to capture the test result information in their information system (submitter would map the test result files to their databases for processing)
4.4. Ability to create and attach an electronic signature to each test report. An example approach would be to attach the "signature" (authorized person's name) to the test report file only upon completion of the test results verification process
4.5. Ability to create standard summary test report files by date range, test IDs, results, result status, and other selected parameters of importance to authorized users
4.6. Ability to securely transmit message or file and route to submitter system
4.7. Ability to control which users have access to which reports

Category 4: Interfaces via the web for submitters and data users

5. Test request submittal via the Website

This interface creates the ability for the submitter to directly enter test requests in lieu of electronic or paper submittal. In the future, this interface may be extended (particularly in environmental health) to direct field entry at the time the specimen/sample is collected.

Submitter to Web Site Interface Specifications:

5.1. Ability for the submitter to enter test requests through the Web interface.
5.2. Ability to assign a processing number to each test request submission
5.3. Ability for the submitter to enter multiple test requests at the same time without repeating submitter data and other repetitive data
5.4. Ability to audit test request data set for completeness and present error messages to the submitter if request is incomplete or inaccurate

6. Transfer of test requests from the Website to the LIMS

This interface moves the test request data from the Web-entered test request to the LIMS

Web-Entered Test Requests to LIMS Interface Specifications:

6.1. Ability to move test requests entered into the Web LIMS to the core LIMS database
6.2. Ability to audit/track the movement of the test requests
6.3. Ability to link submitted test requests to corresponding specimens/samples when they are delivered to the NCDC or LMA laboratory
6.4. Ability to scan barcode labels on specimens/samples in order to establish link to associated test submittal

7. Suggested System Integration Requirements

Georgia laboratory systems operations would be more efficient and effective with integration amongst LIMS and its national disease surveillance system (EIDSS) and eHealth system (HMIS) for sharing common data elements. The system integration requirements are **out of scope of the user's functional requirements,** but the integration requirements are important for strengthening the Georgia disease surveillance capacities. It is strongly suggested that the system integration requirements need to be developed by electronic system integration specialists from contracted LIMS developer/implementers in collaboration with systems developers (e.g. EIDSS and HMIS).

EIDSS is Georgia's national electronic integrated disease surveillance system implemented across the country that is integrated with human health and veterinary health. HMIS is Georgia's eHealth system with various functionalities related to human health. LIMS implementation integration with both systems is one of "must have" functionalities, which will lay the foundation for establishing laboratory-based integrated disease surveillance in Georgia. Integration with other national system, for example, the National Tuberculosis Surveillance, for common data sharing, may also be taken into consideration. Figure 6 illustrates the concept of such integration of LIMS and EIDSS, HMIS, and other systems (if required). The following sections are critical for system integration.

7.1 Electronic Data Exchange

The electronic data exchange should be established to support data exchange between the laboratory and EIDSS and HMIS. Electronic Transmission of data refers to the laboratory's process of exchanging data with EIDSS and MHIS in a standardized manner. Communication is bi-directional and includes both receiving and sending information such as test orders and test results. To support interoperability amongst systems, data exchange refers to standard HL7 message receipt and message creation. However, at present neither EIDSS nor HMIS has not utilized HL7 messaging to transmit data. Regardless of the transport protocol, interoperability requires that systems are able to interpret the data they receive and this is accomplished by adhering to message formatting standards, such as HL7 and terminology standards, such as SNOMED and LOINC. Adherence to standards may be accomplished either by mapping local codes to standard codes, or by directly implementing the standard codes within the LIMS.

Electronic data exchange refers to the ability of the laboratory to interoperate with associated public health entities in a standardized manner. Several processes are required to support data exchange between the lab and external entities: the message must be transported using a secure transport protocol, the message payload must be constructed prior to transmission, a received message must be

parsed, and business rules will need to be maintained to control distribution lists and prioritization of testing.

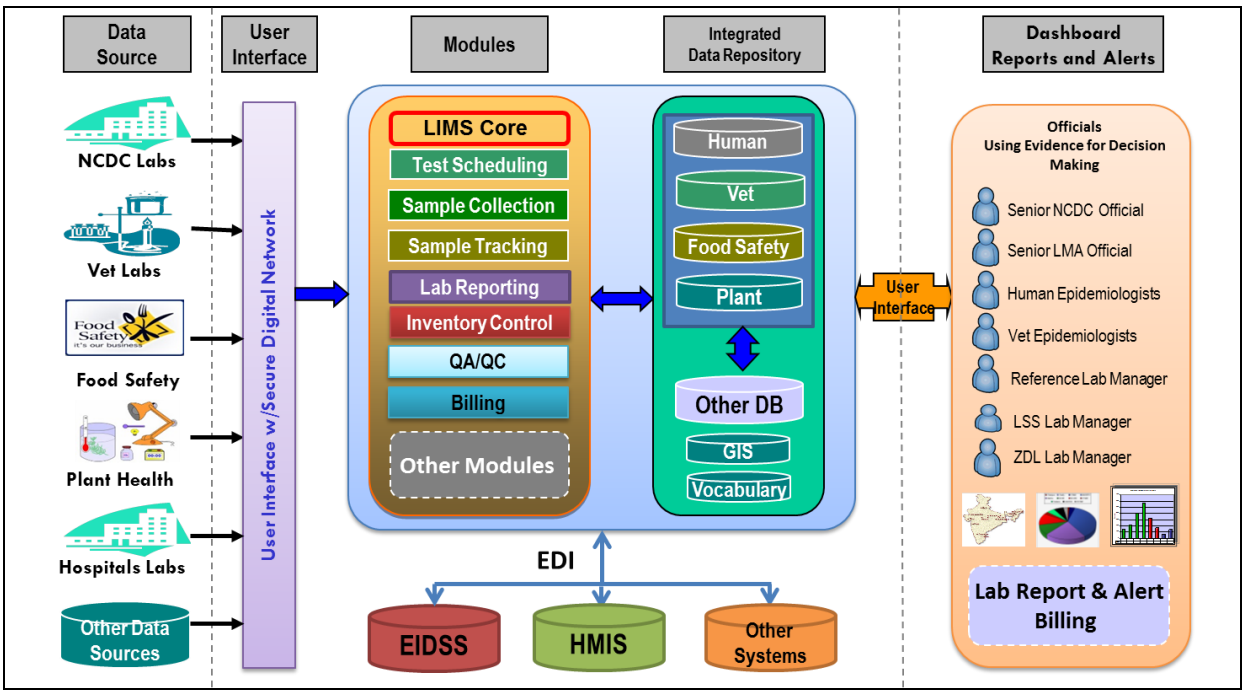


Figure 6: Georgia LIMS: A conceptual diagram for Laboratory-based Integrated Disease Surveillance

Secure Transport Protocol refers to the ability to transport a message or file in a mode that can only be interpreted by the intended party. Secure Transport protocol refers to HL7 messaging using ebXML and is typically handled by an application the LIMS invokes to manage the physical transmission of the message.

7.2 Standard Compliance

The International Classification of Diseases (ICD) is the standard diagnostic tool for epidemiology, health management and clinical purposes. Both EIDSS and HMIS have implemented the ICD 10 code system that includes the analysis of the general health situation of population groups. It has been used to monitor the incidence and prevalence of diseases and other health problems, proving a picture of the general health situation in Georgia.

It is recommended that LIMS developer and implementer should provide a mechanism so that LIMS can recognize and utilize the ICD 10 code system.

8. Suggested Usability Requirements (They will be defined by LIMS implementer and developer)

Usability specifies the effectiveness of users achieving tasks. NCDC and LMA technical working groups realize the importance of usability and recommend the application and consideration of

Schneiderman's 8 Golden Rules in defining the LIMS usability *(Shneiderman, B. and Plaisant, C., Designing the User Interface: Strategies for Effective Human-Computer Interaction: Fifth Edition, Addison-Wesley Publ. Co., Reading, MA, 2010)*.

8.1 Strive for consistency.

Consistent sequences of actions should be required in similar situations; identical terminology should be used in prompts, menus, and help screens; and consistent color, layout, capitalization, fonts, and so on should be employed throughout. Exceptions, such as required confirmation of the delete command or no echoing of passwords, should be comprehensible and limited in number.

8.2 Cater to universal usability.

Recognize the needs of diverse users and design for plasticity, facilitating transformation of content. Novice to expert differences, age ranges, disabilities, and technological diversity each enrich the spectrum of requirements that guides design. Adding features for novices, such as explanations, and features for experts, such as shortcuts and faster pacing, can enrich the interface design and improve perceived system quality.

8.3 Offer informative feedback.

For every user action, there should be system feedback. For frequent and minor actions, the response can be modest, whereas for infrequent and major actions, the response should be more substantial. Visual presentation of the objects of interest provides a convenient environment for showing changes explicitly.

8.4 Design dialogs to yield closure.

Sequences of actions should be organized into groups with a beginning, middle, and end. Informative feedback at the completion of a group of actions gives operators the satisfaction of accomplishment, a sense of relief, a signal to drop contingency plans from their minds, and an indicator to prepare for the next group of actions. For example, e-commerce web sites move users from selecting products to the checkout, ending with a clear confirmation page that completes the transaction.

8.5 Prevent errors.

As much as possible, design the system such that users cannot make serious errors; for example, gray out menu items that are not appropriate and do not allow alphabetic characters in numeric entry fields. If a user makes an error, the interface should detect the error and offer simple, constructive, and specific instructions for recovery. For example, users should not have to retype an entire name-address form if they enter an invalid zip code, but rather should be guided to repair only the faulty part. Erroneous actions should leave the system state unchanged, or the interface should give instructions about restoring the state.

8.6 Permit easy reversal of actions.

As much as possible, actions should be reversible. This feature relieves anxiety, since the user knows that errors can be undone, and encourages exploration of unfamiliar options. The units of

reversibility may be a single action, a data-entry task, or a complete group of actions, such as entry of a name-address block.

8.7 Support internal locus of control.

Experienced users strongly desire the sense that they are in charge of the interface and that the interface responds to their actions. They don't want surprises or changes in familiar behavior, and they are annoyed by tedious data-entry sequences, difficulty in obtaining necessary information, and inability to produce their desired result.

8.8 Reduce short-term memory load.

Humans' limited capacity for information processing in short-term memory (the rule of thumb is that we can remember "seven plus or minus two chunks" of information) requires that designers avoid interfaces in which users must remember information from one screen and then use that information on another screen. It means that cell phones should not require re-entry of phone numbers, web-site locations should remain visible, multiple-page displays should be consolidated, and sufficient training time should be allotted for complex sequences of actions.

The principles presented in the ensuing sections focus on increasing users' productivity by providing simplified data-entry procedures, comprehensible displays, and rapid informative feedback to increase feelings of competence, mastery, and control over the system.

9. Roadmap for LIMS implementation (modular implementation and phased deployment approach)

Georgia LIMS implementation should take modular implementation and phased deployment approach that is listed in **Section 3.2 Implementation Prioritization.** The ultimate goal for the pilot test in at least two sites should be conducted before the end of FY 2016, September 30th, 2016. The following 7 functional requirements (core functionalities) should be included as second phase development completion and be ready for piloting.

- Laboratory Test Processing (FR #1)
- Test Scheduling (FR #2)
- Proactive Specimen/Sample Collection (FR #3)
- Sample Tracking/chain of custody (FR #4)
- General Laboratory Reporting (FR #6)
- QC and QA (FR #7)
- Billing for Laboratory Services (FR #9)

Recommended roadmap provides the estimation of timeline to the phased LIMS development and implementation strategy. Stakeholders shall follow this recommendation so that the project objectives could be achieved.

Phase I: User's functional requirements completion (1 May – 30 September, 2015)
Tasks for phase I:

- Complete and finalize user's functional requirements
- Conduct 2-day LIMS workshop attended by selected LLS, ZDL, and reference laboratory professionals and leadership from NCDC and LMA, international LIMS companies, local IT companies, U.S. CDC and other stakeholders
- NCDC and LMA technical working group sign-off the user's functional requirements
- NCDC and LMA leadership acceptance of the signed-off the user's functional requirements
- Official user's functional requirements for Georgia LIMS is ready to release
- Select LIMS developer and implementer

Phase II: LIMS development and implementation (1 October, 2015 – 30 September, 2016)
Tasks for phase II:

- Development of LIMS technical specifications based on the user's functional requirements by selected LIMS developer and implementer
- Assessment of Georgia Laboratory Network (NCDC and LMA) computer hardware for the LIMS implementation
- Development Georgia LIMS based on the technical specifications
- Completion of LIMS core functionalities and selection laboratories for the piloting
- Completion of user's training for the pilot laboratory users
- Piloting the LIMS in selected piloting laboratories
- Completion of LIMS usability assessment at piloting laboratories
- Acceptance of LIMS with core functionalities

Phase III: LIMS roll out to the entire Georgia Laboratory Network (1 October, 2016 and beyond)
Tasks for phase III:

- Development of additional functional requirements (optional) as follows
    - Inventory Control (FR #5)
    - Statistical Analysis & Surveillance (FR #8)
    - Contract and Grant Management (FR #10)
    - Training and Resource Management (FR #11)
    - Lab Safety/Accident Investigation (FR #12)
- Completion of user's training for new development at pilot laboratories
- Piloting the full functional LIMS in selected piloting laboratories
- Completion of full functional LIMS usability assessment at piloting laboratories
- Acceptance of full functional LIMS
- Completion of user's training in all laboratories
- Roll out the LIMS to Georgia Laboratory Network with or without additional functionalities

10. Deleted or Deferred Requirements

Ref#	Functional Requirements	Status	Comments	Priority	Date reviewed	SME Reviewed /Approved

11. Requirements Confirmation/Stakeholder sign-off

Include documentation of the approvals or confirmations of the requirements in the table:

Meeting Date	Attendees' Name	Position	Comments

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Nature of Signoff	Person	Signature	Date	Role
Author	Wei Li		16 July, 2015	CDC SME and Consultant to NCDC/LMA
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Reviewer	Juliette Morgan	email	21 May, 2015	CDC SME
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Reviewer	Irakli Guledani		16 July, 2015	LMA Technical WG
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Reviewer	Lado Dolidze		16 July, 2015	LMA Technical WG
Reviewer	Vakhtang Tarielashvili		16 July, 2015	LMA Technical WG
Reviewer	Marina Donduashvili		16 July, 2015	LMA Technical WG

Reviewer	Ekaterine Adeishvili		16 July, 2015	NCDC Technical WG
Reviewer	Maiko Alkhazashvili		16 July, 2015	NCDC Technical WG
Reviewer	Gvantsa Chanturia		16 July, 2015	NCDC Technical WG
Reviewer	Tamar Ghaniashvili		16 July, 2015	NCDC Technical WG

DOCUMENT CHANGE RECORD

Date	Version	Author	Change Details
22 May, 2015	V02	Wei Li	Updates following CDC SME Internal review
9-10 July, 2015	V02	NCDC and LMA LIMS workshop attendees	NCDC and LMA WG review
15 July, 2015	V02	Wei Li	Updates following Lopota LIMS workshop
15 July, 2015	V03	Wei Li	Apply review comments and issue

12. References

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