President's Emergency Plan for AIDS Relief

Toolkit to Accompany the LIS High Level Requirements

Guidebook
High Level Requirements
Toolkit
Software Provider Report

APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES

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Section 1. About the LIS Documents

This Toolkit document is one of a set of documents provided by the Association of Public Health Laboratories (APHL) in support of the activities of the President's Emergency Plan for AIDS Relief (Emergency Plan) for the purpose of enhancing laboratory testing for the treatment and prevention of HIV infections and AIDS. The U.S. President's Emergency Plan for AIDS Relief through the Office of the Global AIDS Coordinator (OGAC) has provided funding for this project. This document is a cooperative effort of APHL, APHL associated contractors and the Centers for Disease Control and Prevention.

1.1. Acknowledgments

APHL would like to gratefully acknowledge the LIS team members that made this project possible:

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Comments, questions, and other correspondence regarding these documents may be sent to APHL in care of Patina Zarcone, Director, Strategic Initiatives and Research, at pzarcone@aphl.org. Information and assistance regarding the use of these documents by country HIV/AIDS programs or national laboratory programs may be sent to APHL in care of Ralph Timperi, Acting Director, Global Health Programs, at rtimperi@aphl.org.

1.2. About This Document

The Toolkit to Accompany the LIS High Level Requirements Document ("Toolkit") is one component of a nested set of resources developed by the Association of Public Health Laboratories (APHL) for the President's Emergency Plan for AIDS Relief (Emergency Plan) to support the development of Laboratory Information Systems (LIS) in resource-limited settings. Users of this document are encouraged to become familiar with the content of each of these references. We recommend that the users start with the Guidebook to familiarize themselves with the overall approach being described in this set of references. This toolkit is designed to assist your organization in selecting and implementing a Laboratory Information System. This toolkit should be used in conjunction with the High Level Requirements Document.

The toolkit contains:

- LIS selection process
- Suggestions on an LIS implementation process
- RFP template
- Functional requirements matrix
- A set of criteria to be used to evaluate the system provider responses
- A spreadsheet that can be used to weigh the scores of each system provider response
- A suggested set of minimal requirements for an LIS that would satisfy Emergency Plan needs.

1.3. Revision History

No changes are to be made to the requirements described within this document unless approved and documented as an amendment to this document.

Date	Revision	Description
07-2005	1.0	Initial draft release
10-24-2005	2.0	Initial public release - Updated look and feel - Updated content to fit with other documents in LIS Implementation set

Section 2. System Selection Process

Planning is critical to the success of an LIS. The following sections provide guidelines on planning.

2.1. Project Planning

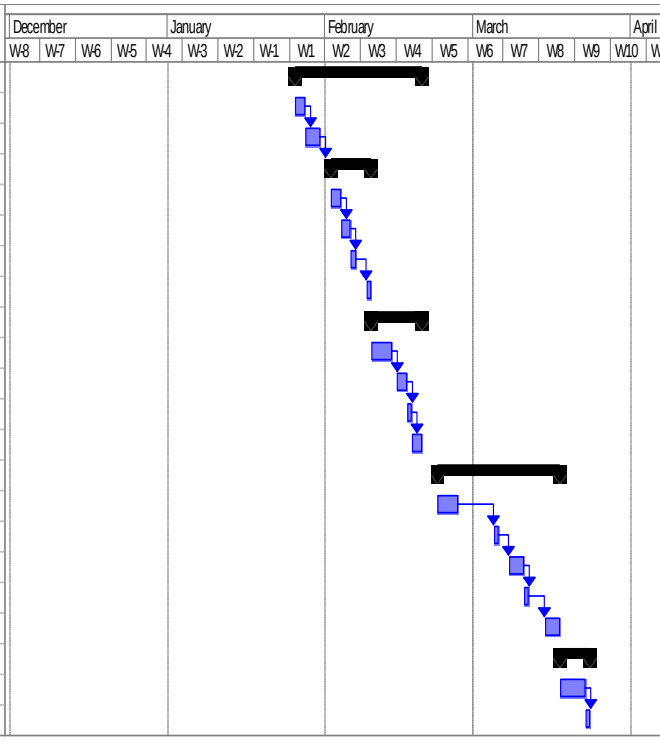
A good project plan is more than a list of tasks, completion dates, and assigned responsibilities. There are two simple but critical criteria for a good plan:

- Key individuals in all affected departments must understand the approach outlined in the plan and believe it is the best way to make the decision.
- They must agree to provide the resources required of their unit to conduct the project in the time frame indicated.

To develop a good plan one should start with example task lists obtained from a variety of sources. From these a set of tasks and milestones should be selected that make sense to the users, are in a logical order, and appear to cover all the bases.

Sample Project Plan:

ID	Task Name	Duration	Start	Finish
1	**PHASE I NEEDS ASSESSMENT / RFP DEVELOPMENT**	**20 days**	**Mon 1/26/04**	**Thu 2/19/04**
2	Project kickoff meeting	2 days	Mon 1/26/04	Tue 1/27/04
3	Needs assessment interviews	3 days	Wed 1/28/04	Fri 1/30/04
4	**Needs assessment report**	**6 days**	**Mon 2/2/04**	**Mon 2/9/04**
5	Development Draft Report	2 days	Mon 2/2/04	Tue 2/3/04
6	Draft Report Reviewed By NYC Selection Team	2 days	Wed 2/4/04	Thu 2/5/04
7	Meeting to Review Draft Report	1 day	Fri 2/6/04	Fri 2/6/04
8	Final Report	1 day	Mon 2/9/04	Mon 2/9/04
9	**RFP development**	**9 days**	**Tue 2/10/04**	**Thu 2/19/04**
10	Draft RFP	4 days	Tue 2/10/04	Fri 2/13/04
11	Draft RFP Reviewed By NYC Selection Team	2 days	Sun 2/15/04	Mon 2/16/04
12	Meeting to Review Draft RFP	1 day	Tue 2/17/04	Tue 2/17/04
13	Final RFP and Sent to Vendors	2 days	Wed 2/18/04	Thu 2/19/04
14	**PHASE II VENDOR EVALUATION PROCESS**	**18 days**	**Mon 2/23/04**	**Wed 3/17/04**
15	Vendor Presentations	4 days	Mon 2/23/04	Thu 2/26/04
16	Receive RFP Responses	1 day	Fri 3/5/04	Fri 3/5/04
17	Brief Review RFP Responses	3 days	Mon 3/8/04	Wed 3/10/04
18	Meeting to Select Two Finalists	1 day	Thu 3/11/04	Thu 3/11/04
19	Site Visits to Finalists Client Sites	3 days	Mon 3/15/04	Wed 3/17/04
20	**PHASE III VENDOR SELECTION**	**4 days**	**Thu 3/18/04**	**Tue 3/23/04**
21	Prepare Evaluation Material	3 days	Thu 3/18/04	Mon 3/22/04
22	Select Vendor	1 day	Tue 3/23/04	Tue 3/23/04



You must also understand and document your requirements for the LIS. Use the HLR document and modify it to fit your specific environment.

Sending out a Request for Proposal (RFP) at the beginning of a project may result in many detailed proposals to review. Screening system providers first based on major criteria and sending RFPs to a few finalists will drastically simplify the evaluation task and result in a better evaluation.

2.2. Team Selection

A small dedicated project selection team of four to eight people, where each member is assigned specific tasks should be adequate to conduct most evaluations. It is important to separate technical evaluation from management guidance and approval. The project team will conduct the technical evaluation of the systems and make recommendations to management at each major decision point.

2.3. System Provider Screening

An initial screening should be conducted from the LIS Software Provider Report to eliminate system providers that are not appropriate. Keep your list of system providers manageable (five or six at most).

2.4. Preparation

Team members should read any material provided by a system provider before the representative comes in for a presentation. This will make each meeting much more productive.

2.5. Sales Presentations

The MOH/user organization should schedule and manage system provider visits. The organization should prepare the presentation agenda so that each system can be compared using the same criteria.

A major part of an introductory presentation is to learn more about the company and their:

- System technology
- Installation and support
- Customer base

2.6. Preliminary Proposals

Even though a final configuration cannot be determined until later in the project, it is possible to obtain pricing information on a tentative configuration. Most system providers can produce a "budgetary proposal" with a small effort. It is very important to ask the same questions of all system providers including quantities of hardware so that all system providers will propose roughly comparable systems. In guessing at the initial configuration, it is better to err on the high side rather than to underconfigure.

The results of this budgetary proposal should be used to determine whether or not the preliminary justification was on track. If prices are much higher than suggested earlier, it would be legitimate to ask whether the original analysis was still valid.

No decisions should be made at this stage about whether or not a particular module will be used. All modules should be priced and included in the preliminary proposal.

2.7. Finalists Determined

Sending out Requests for Proposals (RFPs) and reading the responses is a time-consuming job. As a result, the number of system providers receiving an RFP should be strictly limited.

Finalists can be chosen through a simple matrix scoring scheme using high level functionality and criteria to judge the strength of the LIS provider (see next section). Only system providers that score highest at this level should be considered for detailed evaluation.

2.8. Evaluation Criteria

Evaluation criteria need to be prepared at the very start of the LIS project to ensure that the appropriate questions are addressed in the RFP. See section 6 for criteria to be used to evaluate system provider responses.

Note the following points.

- Pricing should be excluded from the evaluation until after a ranking based on system capability and corporate strength is complete.
- An assignment of weights and scores to various system features is needed to help with an unbiased selection process. These can then be totaled to come up with the final system provider ranking.

2.9. Request for Proposal

A Request for Proposal is used to ask system providers what their system does and how they will handle your requirements. The RFP is not a System Specification. See the sample RFP in this document.

Asking questions allows the system provider to offer suggestions and demonstrate methods of operation that you may not have thought of during earlier stages of the process. The evaluating team has only to compare answers to the RFP and judge which ones they like best.

System providers should not be asked to rush their responses unless there is good cause. One to two months is a reasonable amount of time to expect a detailed response.

2.10. On-Site Demonstrations

Live demonstrations of the LIS system allows users to find out more details about each system. Demonstrations offer the opportunity to expose a number of people, not just the project team, to the intricacies of each product. If certain aspects of a system are to be demonstrated at a particular time, individuals who have knowledge in these areas should be brought in to observe. The more exposure key individuals get before a system is installed, the less confusion there will be during the installation.

Demonstrations should be structured so all system providers address the same topics.

2.11. Site Visits

A site visit allows the user to see an instance of the application in use and understand the issues of installation and operation. It is valuable to learn how the system works in a comparable environment and talk to other users about their experiences.

2.12. System Evaluation

At this step the evaluation criteria that were developed before the RFPs were sent out can be used. Very little additional material should be needed because the RFP questions were developed to collect the information needed for comparing systems.

After this task, the team should have a tentative ranking of providers along with a list of reasons why each was ranked as it was. The ranking is a numeric score and the reasons justify each score.

2.13. Phone Surveys

For gathering further information on the system providers that scored high, the following are suggested:

- Talk to other users about specific details
- Conduct a structured survey of the five newest clients for each of the top ranked providers to discuss recent installation experience. Ask similar questions.
- Include open-ended questions that may not be provider-specific but will give insight into installation experience and challenges faced.

2.14. Follow-Up Site Visits

These visits are usually conducted on a selected finalist or the final two system providers remaining. Now that you are more aware about the details of each system, these visits allow for specific capabilities of the system to be observed if they were missed earlier.

2.15. Home Office Visit

Before a contract is signed, it maybe helpful if your managers and executives can meet managers in the provider organization to learn more about their organization. A major purchase cannot be made based solely on contact with a sales representative or marketing support analysts.

2.16. Cost/Benefit Analysis

If necessary, a detailed cost-benefit analysis can be performed at this time. For each system, consider these aspects:

- Exact system costs
- Complete descriptions of the systems capability
- The experience of other users - in terms of installation and operational costs

2.17. Ranking and Recommendation

With all of the homework completed, the team is in a position to recommend the top-ranked provider for negotiation. Document the reasons/justification for system selection. Aspects of justification that can be accomplished during each phase of evaluation are shown in the accompanying figure.

Summarize the work to-date so it can be presented to your business executives and board members.

2.18. Contract Negotiations

Contract negotiations almost always take longer than anticipated. The only way to make this task go quickly is to accept the standard contract with few changes. Significant changes must be reviewed and agreed to by executives and lawyers from both sides. This process takes time.

A good contract is the culmination of a sequence of well-planned evaluation and selection tasks. It is the formalization of the understanding between two parties and must describe, in user terms, exactly what the system provider is proposing to install.

Lower ranked system providers should not be ruled out until an agreement is signed.

2.19. Board/Senior Staff Presentation

The final presentation to the Board of Directors or senior staff includes a simple overview of the selection process and resulting recommendations.

2.20. Conclusion

Selecting an LIS is a complex process that needs careful planning. The list below can be used as a checklist for this process:

1. Project plan developed
2. System selection team assembled
3. Short list of system providers prepared
4. System providers invited for presentations
5. Preliminary proposals received
6. Final two or three systems selected
7. Detailed proposals invited from final system providers
8. System demos scheduled
9. System selected according to evaluation criteria
10. Contract negotiated.

Section 3. Steps for a Successful Installation

The definition of success for an LIS is different for each environment. Each shareholder also may have a different view of success, and their views may change over time. It is important to publish objectives and modify them as needed.

Steps for success:

- Manage a project; do not let it manage you
- Develop a risk / contingency plan for unexpected events
- Build teamwork, consensus, and ownership
- Manage change
- Educate, communicate, and motivate the team and the laboratory.

Reasons for marginal or failed implementation:

- Poor planning
- Lack of project management and oversight
- Ineffective management of personnel
- Limited focus on the change process
- Over-reliance on the system provider for support, skills, and resources.

3.1. Project Planning

The following are important aspects of planning for a successful installation:

- Realistic expectations
- Determining the needs and wants of the customers
- Realizing system provider capabilities
- Forming the correct project team
- Understanding the effect of outside parties on the project.

3.2. Project Team Skills and Availability

The project team is responsible for:

- Developing a detailed project plan, managing the project
- Assigning tasks to specific people with completion dates
- Coordinating efforts.

The person assigned to a task is responsible for completion of the task on schedule, reporting progress against the task, and if a problem occurs, informing the project leader so the problem can be addressed before it adversely affects the total project.

Items to consider regarding the makeup of the project team:

- The number of people needed on a project team depends on the size of the institution and the complexity of the implementation project.
- Realize that some individuals may need more training, mentoring, and assistance to complete their assignments.
- Involve individuals from every section with the LIS, including billing, medical records, Information Systems (IS), pathologists, and laboratory administrator(s), should either be on the team or be used as resources for expert advice.

- Regular team meetings are important tools to share information and develop a spirit of teamwork. The project leader should take notes at these meetings and publish accomplishments and assignments.

The project leader can be from information systems (IS) or the laboratory if he or she has the necessary skills and attitude. The project leader needs many qualities to achieve success. The leader should have:

- Expertise in the area the system is being installed
- Leadership skills
- Interpersonal skills
- Ability to relate to people at different organizational levels with diverse views of the project, such as administrators, pathologists, IS personnel, and phlebotomists
- Consideration and respect from other stakeholders
- The authority to encourage people to work together to complete mutually set goals.

3.3. Customer Needs and Wants

Customers include direct users of the LIS and those affected by implementation of the system. They include user within your organization and outside physicians, physicians' office staff, nurses, medical records, billing and finance departments, IS, administration, and others.

- Solicit input from customers when possible; all needs cannot be customized, but one or two choices can help them accept the system.
- Keep customers informed about the project, providing periodic updates on progress and changes.
- Provide formal training and follow-up to your customers, and inform people how you are working with your customers and how they are involved in the project.

3.4. Early, Small Successes

Arrange for early, small successes in your project plan. Celebrate successes as they occur and give credit to those who are responsible. Ensure that you have identified significant and visible milestones relatively early in the project to allow the project team to enjoy accomplishments.

3.5. The Project Plan

Installation is a technical process and implementation is a people process. System providers provide an installation plan, called such because system providers are installing a system. However, the laboratory is implementing a system, which is not just placing the hardware and software and physically installing the computer, but also making it work within the department and fitting and changing workflow to fit the system.

Start with the system provider's plan, but carefully examine it, modify it, and add to it so the plan includes laboratory needs and objectives.

Present the mutually acceptable plan to laboratory management; everyone needs to agree on a plan, process, and a timeline that is achievable within the ability of all parties to meet their commitments.

Identify and schedule resources to implement the plan. Typically you will need representation from the lab as well as from IT. The team members should include personnel who understand laboratory processes as well as those who understand any IT related constraints that exist within the organization. Additionally there should be some representation from management.

Involve the stakeholders in the team and inform stakeholders of progress and potential problems and give them opportunities to help or provide support. Confirm available and scheduled resources.

Confirm your resources. When tasks are assigned, make sure that available resources are adequate to the task. A good project plan will help, but be ready to adjust the plan by adding resources or shifting tasks to prevent delays.

Do not underestimate the time needed to make decisions. A decision might be clear to the project team, but adequate time must be allotted to go through all departments that may need to be involved.

3.6. Understanding Other Projects

Information technology projects can be highly interdependent. Even if the laboratory is managing the LIS implementation, IS will have significant influence and a direct role in the project. Make IS a part of the key project team and work closely with the project team to understand their priorities and plans.

3.7. Staying on Schedule

Although a quality outcome is the number one priority (and typically is stated as the number one measurement of success), success also may be defined in some cases as meeting a predefined schedule. If you are given an opportunity to develop a plan and set your own schedule, it will be much easier to meet that schedule. If you are given a schedule to meet that is not in your control, you will need to manage both the project and the expectations of the stakeholders to be successful.

Stakeholders must be kept informed of progress and potential problems. Be proactive in keeping everyone informed, especially of potential schedule delays, and give them the opportunity to help.

3.7.1. Causes of Schedule Delays

The reasons for delays in a schedule are as varied as the tasks necessary to make a project successful. Experience shows that delays usually are a combination of factors; however, inadequate management of the project is a factor in most. Sometimes external factors or other conditions totally outside the control of the project team contribute to delays. When planning the project, try to identify those factors and outline contingency plans for those possibilities.

3.8. Project Management

Project management is both a discipline and a tool to help plan and manage the work associated with the implementation. To manage a project, first have a detailed project plan outlining the tasks necessary for project objective achievement (in this case, implement an LIS). Tasks are laid out in the sequence in which they must be started or completed. It is this logically organized plan that will guide the team through the process of implementing the LIS.

Although specialized tools and terminology are available to help lay out and manage the plan, some simple steps are key to successful project management. These include:

- Describe tasks in terms of the expected outcome (what the task will accomplish) and deliverables (how to show that the task is complete).
- Assign tasks to a responsible person (task leader) to ensure task completion.
- Estimate and document time and effort required.
- Assign completion dates to tasks.
- Require the task leader to report regularly on the amount of effort expended toward task completion and the percentage completed.
- Expect the project manager to take corrective action if a task looks like it may not be completed on schedule (more time or effort expended than would be expected based on the percentage completed).

The project manager ultimately is responsible for working with the team and task leaders and providing the skills and knowledge to complete tasks. It also is up to the project manager to keep senior management and the stakeholders informed of tasks that may be delayed or might otherwise affect the schedule or the quality of the project outcome.

Project plans are dynamic. When a project is started, especially with a new product and new system provider, learning takes time. As you learn, the project plan may need to be altered; add a task, change a plan, modify a task, move a task, or reschedule it.

3.9. System Provider Relationships and Management

A number of issues must be considered when working with the system provider. Remember—the laboratory is forming a long-term partnership with the system provider.

- The project manager should manage the project and the system provider. Keep in mind that the system provider is part of the team, but you are responsible for overall management of the project, and, ultimately, delivery of the end product.
- Assign tasks to the system provider and require them to report back with their progress toward completing those tasks.
- Define in your project plan the tasks are the system provider's are to complete and the completion date. If possible, this detailed plan should be part of the contract so there will be no chance of misunderstandings about task assignments and completion dates.
- Monitor the provider's progress to determine whether the escalation protocol should be invoked.
- Avoid being confrontational with the provider.
- Include the provider in the decision process—keep them informed and involved.

3.10. Education and Training

Everybody needs training on the LIS at some level. The amount and type of training needed depends on the role the person will have in implementation and use in performing job tasks.

The following is a sample checklist of the type of individuals to be trained. Your checklist should be by individual.

Role	Training Needed	Date Completed
Project Team	Microsoft Project, Visio, Excel	
System Trainers	All system modules except System Admin functions	
System Administrators	All system functions	
Medical Staff	Result inquiry, report review	
Office Staff	Order entry, result inquiry, report printing	
Nursing	Result inquiry, report review	
Medical Records	Report review	
Billing	Billing reports and interfaces	
Information Services	Integration with other systems	
Administration	Result inquiry, report review	

Training plan suggestions:

- Timing of the training is critical.
- After the formal training, provide time for staff to practice on the LIS.
- Review laboratory policies and procedures during training and answer questions about how to perform that person's job with the system.
- Review downtime and recovery procedures and make them part of the training curriculum.
- Include ongoing LIS training after the system goes live. This includes training for:
    - New employees
    - People taking different jobs in the laboratory
    - Refresher training of the staff
    - New LIS modules and functions.

3.11. System Testing and Certification

When testing or setting up the test to certify the system, emphasize the areas of greatest risk. For example, areas that could cause publication of an incorrect result include misidentification of a patient specimen or result, loss of an order, and/or change in an order. Concentrate testing on unique areas or functions that differ from other systems, such as custom tables and interfaces.

- Test excessive delays when entering orders.
- Test this order entry from quality, timing, and performance perspectives.
- Test normal operations and department procedures and daily, weekly, monthly, and annual functions.
- Test failure situations, i.e., whether bringing up the backup automatically restores data, supplies correct information, and restores all information.
- Test troubleshooting procedures so users know what to look for, how to fix it, and how to tell when the interfaces are down.
- Test support procedures.
- When writing a test plan, attempt to create failures, not just validate operation.
- Use stress testing: type in data that should not work and see whether it comes back as an error, brings down the computer, or continues running.
- Perform some level of load testing before accepting the system and going live, it is one of the classic failures, and the system will not perform well and will be too slow.
- Freeze system changes during testing.
- Do not test while developing or building tables and training people.
- Re-test and re-validate after changes are made.
- Testing is not only for software, but for product quality, setup, and tailoring.

The bottom line is that you are validating that the system created and installed can be used in your environment without unacceptable risks to the patients. A plan for testing and validation should be practical and creative. Think of ways to test when doing other things. For example, as part of the training program, have different trainees enter hematology, chemistry, and microbiology data at the same time to test the system.

3.12. Data Conversion

Data file conversion is needed when:

- Going between platforms on the same system
- Bringing data from one system to another.

Data may be taken from manual files and entered into the system. Data can be converted by an automated or manual method.

To determine whether all data need to be entered into the LIS consider several factors, e.g., how the data will be used in your current system, as well as regulatory agency requirements.

Test the conversion when converting files between platforms on the same system or bringing data from one system to another. Do not convert 10,000 files at one time—do a test sample, validate the data, check that the patient name matches all data there and all data elements came across in the expected fields, then convert batches of the data.

3.13. Operational Readiness and Going Live

Evaluate whether the LIS is ready to go live by using the following guidelines:

- Installation and testing are complete.
- Hardware, networks, interface devices, operating system software, and application software have been installed and tested.
- The database is completely tested, files are converted and tested, and system testing is completed and documented.
- Load testing is completed; backup recovery is tested and documented.
- Procedures are validated and documented: normal user function, file and dictionary maintenance, system operations, report handling and distribution, support, maintenance, manual backup procedures, and recovery and validation.
- Training is complete for users, operational staff, support staff, and customers.
- Notify everyone of the intention to go live.
- Verify the timetable, exact sequence of events, and potential effects of these events on the user.
- Freeze the system; no more changes.
- Publish the timetable and get sign-offs from upper management and all involved departments.
- Develop and publish a detailed activation plan. This plan includes every step from the time you start to bring the system live, such as steps to turn off the old system, the point at which to change over, the time to stop entering results in the old system, and the time to start the system.
- Maintain the ability to go back to current operations. Manual procedures may need to be used during conversion when both systems are down for the switch.
- Set up a center for people to report problems. For a 24-hour operation, it should be staffed 24 hours a day. The use of "trouble tickets" will document the problem and the time it was fixed. Make sure the decision makers are available from start to system stable; in case of a crisis situation, they can make the decision to go manual.

Your planning is complete and the team is confident, rested, and ready to go. Months of hard work finally came to fruition; get the staff excited about the implementation.

3.14. Post Installation Issues

The system is running, but the job is not over. It is important not to have the entire project team, including the project manager and LIS manager, return to work on the bench the day after the system is working. The project plan should include post-installation responsibilities, e.g., installing subsystems that were on hold, functions and features not yet installed, and dealing with problems in particular features that were not fixed before going live. Otherwise, not all success factors may be met and the result may be a less than optimal system.

Managing the quality of implementation is forever; it never stops. LIS managers continue to:

- Perform file maintenance
- Bring up other functions
- Update hardware
- Audit the system regularly
- Perform customer satisfaction surveys
- Keep maintenance and problem logs
- Gain in-service education
- Participate in user groups.

3.15. Top 10 System Selection Mistakes

1. Not using a structured process
2. Not defining needs beforehand
3. Hiring a consultant with bias
4. Paying too much attention to bells and whistles
5. Not including key users in selection process
6. Buying more than you need
7. Allowing system providers to drive the process
8. Allowing those outside of the laboratory to choose the system
9. Confusing the salesperson with the product
10. Not using an RFP process.

Section 4. Sample Request for Proposal

4.1. Cover Page

Request for Proposal (ID #)
Procurement of a Laboratory Information System (LIS) for the
(Country or Lab/Hospital Name)

PROPOSAL DUE DATE: ***October xx, 200x***

4.1.1. Schedule

This schedule is subject to change at the discretion of the Ministry of Health.

Event	**Date**
Issue Request for Proposal	September xx, 200x
Questions and Letter of Intent due from System providers	October x, 200x
Question and answer period	September xx – October x, 200x
Issue addendum to RFP (if applicable)	As necessary
Proposals due (NOTE: must be received by 3 p.m.)	**October xx, 200x**
Evaluate proposals	October xx, 200x
Top two candidates for an onsite presentation & demonstration	November xx-xx, 200x
Announce "Apparent Successful Bidder"	December xx, 200x
Final negotiations with Apparently Successful Bidder	December xx - xx, 200x
Execute contract and begin contract work	January 200x

4.2. Introduction

This Request for Proposal sets forth the requirements of ***Laboratory Name*** regarding the search for a Laboratory Information System (LIS). The system providers receiving this RFP have been selected after careful evaluation based on their experience and success in installing systems similar in size and complexity to ***Laboratory Name***. It is the intention of ***Laboratory Name*** to select a system by ***Month & Year***.

Responses will be evaluated and those system providers selected as semi-finalists will be contacted by ***Project Manager Name*** to arrange for them to visit ***Laboratory Name*** to present and demonstrate their systems. We expect to conduct these meetings during ***Month & Year***. Once all system provider presentations are completed, ***Laboratory Name*** will select those providers to whom customer site visits will be made.

A Laboratory Information System Selection Committee has been established and these individuals will be reviewing all the material received in addition to making the necessary site visits.

Project Manager Name is the sole point of contact in MOH for this procurement. All communication between the System Provider and MOH upon receipt of this RFP shall be with the RFP Coordinator, as follows:

Mail, fax, phone and email:
Name and contact info
The delivery location for all bids and correspondence is
Address

Any other communication will be considered unofficial and non-binding on MOH. System Providers are to rely on written statements issued by the RFP Coordinator. If you communicate with any other employees of ***Government Entity*** concerning this RFP, unless such communication is otherwise required or allowed by law or written ***Government Entity*** policy, MOH may disqualify you from responding to this RFP.

4.2.1. Purpose and Background

The ***Country Name*** Ministry of Health (MOH) is soliciting proposals for the procurement, installation, training and ongoing maintenance (to include new machine interfaces) of a Laboratory Information System (LIS).

4.2.2. Objective

The following is sample verbiage that should be modified by each laboratory.

MOH is soliciting bids to provide a standardized client-server based Laboratory Information System (LIS) for the ***Country Name*** MOH. The requested LIS will be used (give brief description of sites and functions needed, 3-4 lines only).

Phase I of this project, the subject of this RFP, is to acquire the software necessary to achieve the goal above, implement the software in ***xxx*** areas within ***Initial Sites***, and provide ongoing maintenance and support of the software system.

The System Provider selected as a result of the Request for Proposal (RFP) will furnish an operational LIS software system, implement the system initially into ***xxx*** areas ***(xxx, xxxx, xxxx etc.)***, and provide ongoing support and maintenance of the system.

The bidder is asked to propose:

1. Project management and expertise information
2. Cost of the LIS system software (acquisition cost and any applicable licensing fees)
3. Cost and plan for implementing the system into the three laboratories noted above
4. Cost of ongoing maintenance of the system.

The new system will support the following goals and objectives:

- Replace all existing systems in the following offices: ***(list of sites)***
- Meet the functional and system requirements specified in Appendix C
- Achieve an improved level of performance attained by the current data management systems.

4.2.3. Funding (Optional)

Any contract awarded as a result of this procurement is contingent upon the availability of funding. The Ministry reserves the right to terminate any contract if state funds and/or approval are not granted or for any other reason at the discretion of MOH.

4.2.4. Period of Performance

The anticipated period of performance of any contract resulting from this RFP will be the date of execution (anticipated ***January 200x***) through ***August xx, 200x.***

Under no circumstances are contractors to perform any work until the contract and/or any subsequent work order has been fully executed. Any work performed on the contract before execution is at your risk. MOH is under no obligation to pay for any work performed prior to the start date of the contract and/or work order.

4.3. General Information for System Providers

4.3.1. Bidders' Questions and MOH Answers

Send questions concerning the RFP to:

Address and contact info

MOH will only answer questions received before the close of business on the date stated in the Schedule. In the interest of fairness, MOH will only answer questions received in writing (mail, e-mail, fax). Do not call the RFP Coordinator to ask questions. MOH will send a copy of all bidders' questions and MOH's official written answers to all Bidders who submit a Letter of Intent to Propose. In addition to being mailed or faxed, all communications regarding this RFP will be posted to the MOH website: ***www.xxx.xx.xx***

Address/send your Letter of Intent to:

Address

Your Letter of Intent must be received no later than 3:00 p.m. local time on the date stated in the Schedule.

4.3.2. Submission of Proposals

System providers are required to submit an original hardcopy of their proposal using the attached template (Exhibit D), plus an additional copy of the proposal must be submitted on CD (or allow e-mail). The original must have original signatures. The proposals will be divided into three sections: Management Proposal, Technical Proposal (System Architecture and Software, Business Requirements, and Implementation Plan), and Cost Proposal. The proposal, whether mailed or delivered, must arrive at the RFP Coordinator's location specified in the Schedule no later than the closing date and time for responses to this RFP as set forth herein. The envelope should be clearly marked to the attention of the RFP Coordinator.

System providers mailing proposals should allow normal mail delivery time to ensure timely receipt of their proposals by the RFP Coordinator. System providers assume the risk for the method of delivery chosen. MOH assumes no responsibility for delays caused by any delivery service. Proposals may not be transmitted using electronic media such as fax or email.

Late proposals will not be accepted and will be automatically disqualified from further consideration. All proposals and any accompanying documentation become the property of MOH and will not be returned.

Each system provider may submit only one proposal. Submission of multiple proposals is not allowed and will result in the rejection of all proposals submitted by the Provider. The RFP Coordinator is the sole point of contact in MOH for this procurement. All communication between the system provider and MOH upon receipt of this RFP shall be with the RFP Coordinator, as follows:

Mail, fax, phone and email:

Name and contact information

The delivery location for all bids and correspondence is:

Address

System providers may withdraw a proposal which has been submitted at any time up to the proposal closing date and time. A written request signed by an authorized representative of the system provider must be submitted to the RFP Coordinator. After withdrawing a previously submitted proposal, the system provider may submit another proposal at any time up to the proposal closing date and time.

4.3.3. Proprietary Information/Public Disclosure

Materials submitted in response to this competitive procurement shall become the property of MOH.

All proposals received shall remain confidential until the contract, if any, resulting from this RFP is signed by MOH and the apparent successful Contractor; thereafter, the proposals shall be deemed public records.

Any information in the proposal that the System Provider desires to claim as proprietary and exempt from disclosure must be clearly designated. The page must be identified and the particular exception from disclosure upon which the System Provider is making the claim. Each page claimed to be exempt from

disclosure must be clearly identified by the word “Confidential” printed on the lower right corner of the page.

4.3.4. Revisions to the RFP

In the event it becomes necessary to revise any part of this RFP, addenda will be provided to all who responded with a Letter of Intent to Propose. If a conflict exists or may exist between addenda, or between an addendum and the RFP, the document having the latest date shall take precedence.

MOH reserves the right to cancel or to reissue the RFP in whole or in part, prior to execution of a contract.

4.3.5. Acceptance Period

Proposals must provide 120 days for acceptance by MOH from the due date for receipt of proposals. Proposals that specify expiration in fewer than 120 days will be considered non-responsive and will be rejected.

4.3.6. Most Favorable Terms

MOH reserves the right to make an award without further discussion of the proposal submitted. Therefore, the proposal should be submitted initially on the most favorable terms which the System Provider can propose. There will be no best and final offer procedure. MOH does reserve the right to contact a System Provider for clarification of its proposal.

The System Provider should be prepared to accept this RFP for incorporation into a contract resulting from this RFP. Contract negotiations may incorporate some or the System Provider’s entire proposal. It is understood that the proposal will become a part of the official procurement file on this matter without obligation to MOH.

4.3.7. General Terms

1. MOH will not be liable for any costs incurred by the System Provider in preparation of a proposal submitted in response to this RFP, in conduct of a presentation, or any other activities related to responding to this RFP.
2. This RFP does not obligate the Government of ***Country Name*** or its MOH to contract for services specified herein.
3. MOH reserves the right at its sole discretion to reject any and all proposals received without penalty and not to issue a contract as a result of this RFP.
4. The Minister of Health or appointed designees are the only individuals who may legally commit MOH to the expenditure of funds for a contract resulting from this RFP. No cost chargeable to the proposed contract may be incurred before receipt of a fully executed contract.

4.3.8. Letter of Submittal (Not Scored) *(optional)*

The Letter of Submittal and the attached Certifications and Assurances form must be signed and dated by a person authorized to legally bind the system provider to a contractual relationship, e.g., the President or Executive Director if a corporation, the managing partner if a partnership, or the proprietor if a sole proprietorship. Along with introductory remarks, the Letter of Submittal must include by attachment the following information about the system provider (***NOTE: provide proposed subcontractors information where indicated)***:

a. Name, address, principal place of business, telephone number, and fax number/e-mail address of legal entity or individual with whom contract would be written (including any proposed subcontractors)
b. Name, address, and telephone number of each principal officer (President, Vice President, Treasurer, Chairperson of the Board of Directors, etc.) (including any proposed subcontractors)

c. Legal status of the system provider (sole proprietorship, partnership, corporation, etc.) and the year the entity was organized to do business as the entity now substantially exists (including any proposed subcontractors)
d. Location of the facility from which the System Provider would operate
e. Name and telephone number of the Lab Director where the System provider has installed the proposed LIS system at a Public Health Laboratory
f. Name and telephone number of a single managerial-level contact to coordinate all MOH requirements and to be the point of contact for any problems/questions which may arise.

4.3.9. RFP response (Mandatory – scored)

Bidders should use the Bidder's Template provided as Exhibit D, to respond to this RFP. The Bidder is required to respond in four separate areas, outlined in Exhibit D. These are;

- Management Proposal – outline the general qualifications of the system provider and relate project management skills as they relate to this project.
- Technical Proposal
    - System Architecture and Software Specifications – requirements for architecture and software compatibility are requested in this section.
    - Functional Requirements – the business needs are outlined in the Functional Requirement section. This is a listing of the functionality of the system that is being requested.
    - Implementation Plan – the bidder is asked to outline how the implementation will occur and what steps the bidder will take to ensure the project is done on time and within budget.
- Cost Proposal
- References

Information on the above requirements is included in Exhibit C. Exhibit C provides background information and specifications for MOH's requirements for an LIS.

4.4. Evaluation and Contract Award

4.4.1. Evaluation Procedure

Responsive proposals will be evaluated strictly in accordance with the requirements stated in this solicitation and any addenda issued. The evaluation of proposals shall be accomplished by an evaluation team, to be designated by MOH, which will determine the ranking of the proposals.

The evaluation process is designed to award this procurement not necessarily to the System provider of least cost, but rather to the System provider whose proposal best meets the requirements of this RFP.

MOH, at its sole discretion, will select the two top-scoring firms as finalists for an oral presentation and demonstration.

4.4.2. Evaluation Weighting and Scoring

Refer to the attached Evaluation Criteria Matrix for details on the scoring criteria.

The top two responsive bidders will be invited to demonstrate the proposed LIS to a group of evaluators at ***Lab*** in ***Location***. The demonstration will be scored and that score added to the above total to determine the apparently successful bidder.

4.4.3. Notification to System Providers

Firms whose proposals have not been selected for further negotiation or award will be notified via fax or e-mail.

4.5. Exhibit A - Technical and Operational Questions

These questions will help evaluate the capabilities of each vendor that relate to a system developer's capability to deploy and support a system as opposed to their ability to deliver the functionality needed.

4.5.1. CPU and Main Storage

1. List the manufacturer(s) and model number(s) of each CPU for which the system is currently designed. Indicate whether each model listed currently executes in a production environment among your clients. Please provide the relative on-line transaction processing performances among the models.
2. What type of response time can be expected for hardware support? Please list international support offices?
3. Do you permit the purchase of hardware from a Vendor other than yourself? Please explain.

4.5.2. I/O, Terminal, and Other Peripheral Devices

For the following questions below which ask for information regarding the devices that may be provided with your system, list the manufacturer(s) and model number(s), along with their other physical characteristics. Describe how many years each device model has been in use on your system and if you have any plans and/or knowledge that it will be discontinued or replaced.

1. What optional disk subsystems are available?
2. Does the system provide disk caching features? If so, what are they?
3. What types of tape media are available for the system? Please specify the number of tracks, density, data transfer rates.
4. What types of high speed line printers are utilized by the system? Please specify LPM or PPM ratings, the recommended/maximum throughput and service life time, the interfaces and drivers utilized for each.
    a. Please list support offices outside of North America
5. What types of bar code printers are utilized by the system? Please specify LPM or PPM ratings and the recommended/maximum throughput and service life time, the interfaces and drivers utilized for each. Also, please specify bar code format(s) printable, maximum number available for use and the functions supported by such equipment in each area of the Laboratory serviced by your system.
    a. Please list support offices outside of North America.
6. What types of bar code readers are utilized by the system? Also, please specify bar code format(s) readable, maximum number available for use and the functions supported by such equipment in each area of the Laboratory serviced by your system.
    a. Please list support offices outside of North America.
7. What type(s) of Terminals are utilized by your system? Please describe the screen size, rows and columns displayed, graphic capabilities, whether B/W and/or color is available and/or utilized by the system, standard and special keyboards available for specialized data entry functions and the nature of the functions they support.
    a. Please list support offices outside of North America
8. Are terminal servers utilized by the system? If so, please describe their characteristics. Also, please describe the devices which utilize each type of server and the maximum number of such devices.
    a. Please list support offices outside of North America.

4.5.3. Operating System Software

1. What operating system (s) does your system utilize?
2. Have you made any modifications to the standard version(s) of the Operating Systems you utilize? If so, please describe.
3. Does your system allow the user to have access to standard Operating System utilities for their own use? If so, explain any limitations and any procedures required.
4. Can security be set such that different levels of access can be defined?
5. Does the Operating System allow applications to be started and/or stopped according to predefined schedules without human intervention?
6. Does your system support Windows NT and follow the ODBC Model?

4.5.4. Data Management

1. Please describe the classes of data storage utilized by your system; i.e., files and/or databases.
2. If your system uses a database management system, please indicate the data model; i.e., hierarchical, networked, or relational.
3. Is your system ODBC compliant? JDBC compliant?
4. Is your system implemented with all data management functions; i.e. data, data processing logic and the database management system, residing on a single system or are data and the database management system distributed among multiple nodes?
5. What data and access security and integrity features, such as authorization, access control, on-line backup and recovery, are provided by your data management system? How are they implemented?
6. Are changes to major files translogged so that recovery can be automated or will manual re-entry be required in the event of loss of data?
7. Does your system allow users, including non-technical personnel to define, retrieve, manipulate and off-load data for conducting on-line ad-hoc inquiries and to generate reports? Is this facility provided with the system or available as a cost option? If so, please describe or attach documentation describing its use, capabilities, and limitations.

4.5.5. Application Software

1. What language(s) is the application software written in? If multiple languages are utilized, please describe the functions written in each.
2. Who is the supplier of the compiler(s) utilized by the system if other than the CPU manufacturer? Have you made any modifications to that compiler as supplied? If so, please describe.
3. Does your system utilize Object Oriented Programming?
4. Is source code and/or any software development aids such as on-line editors, screen formatters, debug facilities, development tools, etc., provided with the system? If so, please describe, including any associated costs.
5. What constraints do you place on a client's ability to modify or enhance the application software? What effect(s) do client modifications to the software have on system warranties, support services, or other contractual terms? If client is able to modify and/or enhance the application, does the system permit these developments in a test environment concurrent with production operation?
6. Describe how the system is protected from the destruction or inadvertent modification of the application software.

4.5.6. Presentation Management

Please describe your philosophy regarding this as well as the attributes you deem important for presentation management when implementing the LIS, and why the approach you utilize is the right choice.

4.5.7. Data Exchange

1. Does your system recognize and support all HL7 trigger events? At what version level?
2. Does your system recognize and support all HL7 message types? At what version level?
3. Does your system recognize and support all HL7 segments? At what version level?
4. Does your system recognize and support user-defined trigger events?
5. Does your system recognize and support user-defined message types?
6. Does your system recognize and support user-defined segments?

4.5.8. Data Communications

1. Please describe the attributes you deem important as network features when implementing the LIS, and why the network features you recommend are the right choice.
2. What types of communications adapters are available for the recommended platform? Please list all available.
3. What types of terminal servers/controllers are utilized?
4. What types of communications software are available for connecting this platform to other enterprise network?
5. What data communications protocol is utilized by terminal devices attached to the system?
6. Please specify the type of cable and any special cabling requirements necessary to install terminal devices on the system. Please indicate maximum distances permitted.

4.5.9. Instrument Interfaces

1. Please describe the manufacturer and model number(s) of each piece of automated Laboratory instrumentation that can be directly interfaced to your system. For each piece of instrumentation, describe the nature of the interface (one-way, bi-directional, host-query), any additional equipment, not previously described which is required for the interface, including the manufacturer, model number, and specifications of each, and the cost of the interface. Are there any quirks associated with the instrument identified by current users?
2. Can on-line instruments be connected directly to the system, or must they first be connected to a front end pre-processor like a PC or another CPU?
3. Please describe your customary approach to developing new instrument interfaces.

4.5.10. Environmental Considerations

1. Please provide specifications for the following to assist us in accessing space(s) suitable to house the CPU(s), disks, tape drive(s), line printer(s), and any other centralized hardware:
    a) Power requirements, including circuits, loads, line conditioning, UPS requirements, harmonic content, etc.
    b) Thermal loads, humidity and other environmental requirements, and other environmental factors
    c) Minimum and recommended square footage.

2. Please provide specifications for the following to assist us accessing space(s) suitable to house peripheral devices.
    a) Power requirements, including circuits, loads, line conditioning, UPS requirements, harmonic content, etc.
    b) Thermal loads, humidity and other environmental requirements, and other environmental factors
    c) Minimum and recommended square footage
    d) Any additional information consistent with the above.

4.5.11. Reliability and Backup/Restore

1. Please describe your position regarding backup and restores, as well as the attributes you deem important for backup/restore features when implementing the LIS, and why the backup/restore feature you recommended is an excellent choice.
2. How are backup/restore functions incorporated into your system?
3. Does translogging of major files occur so that restore is automatic and does not require manual recording or results?
4. Does backup require system downtime or make any system functions inoperative? For how long?
5. How are file rebuilds/maintenance handled? Require downtime?
6. How are backups tracked?
7. Explain any other end-of-day or week or month procedures that must be performed on your system.
8. Do any of the above procedures require system downtime or make any system functions inoperative? For how long?
9. Please provide Mean Time Between Failure (MTBF) and Mean Time To Repair (MTTR) data for each hardware component in your recommended configuration for which such data is available. Please indicate the source of this data.

4.5.12. Pre-Installation Planning

1. Please describe the number and type of staffing which you would assign during the implementation period, including job titles, responsibilities and reporting relationships.
2. What input does Client have in the selection of your installation team?
3. Please describe your standard approach to systems implementation, commencing with contract signing and ending with user acceptance and turnover of the last module implemented. Please describe your approach to testing and acceptance, including acceptance criteria at each major decision point.
4. Are there automated scripts written or that can be written to mimic testing; volume; specific?
5. Please describe in further detail the nature and approach to those tasks outlined in your response to item 3 above and any additional costs which relate specifically to replacement/conversion of an existing system.
6. Please describe your approach to project control and periodic progress reporting. Attach sample documents utilized in past implementations as illustrations.
7. Please describe the nature, extent, duration, timing and cost, if any, associated with training the Laboratory, Information Management Systems and Services and other personnel in the use and operation of the hardware and software. If all training-related activities are not provided on site, please indicate those which are not and where they are conducted. Please indicate any limitations on the number of attendees at each session and the cost for which the Laboratory will be responsible.

4.5.13. Post-Installation Software Maintenance and Support

1. Who provides standard software support services for the vendor's application software? For the operating system software? For any other third party software?
    a. Please list support offices outside of North America.
2. Please provide a description and the costs of all standard software support services. Also, please describe how such support services are provided.
    a. Please list support offices outside of North America.
3. Software support services should be available on a 24 hour, 7 day per week basis, including holidays. Does the standard charge for software maintenance include non-prime shift maintenance calls? If not, what additional costs are involved?
4. What is the maximum response time you will guarantee for non-emergency software maintenance calls? For emergency software maintenance calls?
5. Is a modem required to provide software support services? If so, please describe what services are provided, each party's responsibilities, and how services are supplied.
6. Do software support services include new releases, enhancements and/or upgrades to the application software? The Operating System software? Any third party software? Is training included? What costs, if any, are associated with such enhancements/upgrades?
7. How often are new releases of the software made available? Is there a schedule for upgrades? How far in advance is your client base notified and provided with documentation listing modifications and new features prior to the upgrade?
8. Please describe how often you have updated your system in the past three years and what these updates consisted of; i.e. program changes, new functionality, release levels, etc. Explain any costs associated with these updates, if any.
9. How many release levels/versions of the application software currently exist throughout your client base? How many of these are you supporting?
10. How far behind current release levels do you allow clients to be and still be eligible for software support services?
11. Please provide a list of all product announcements made by your firm for system enhancements and/or new features over the past 18 months. For each, please indicate the date it was expected to be available per the announcement and the actual date of availability.
12. Please describe the laboratory and Vendor responsibilities to implement new releases, enhancements, and/or upgrades to the system software.
13. Is a test region provided with the system to allow for testing and/or training associated with the installation of any or all new releases, enhancements, and/or upgrades to the system software, including any or all interfaces from the LIS to external systems? If so, please describe the implementation of the test region. Are there any additional costs associated with the implementation and/or maintenance of a testing environment on the system?
14. When new releases are available, is a release certification environment provided separate from testing environment?
15. If your company were to leave the laboratory system market, describe how your customers would support their software.

4.5.14. Post-Installation Hardware Maintenance and Support

1. Who provides standard hardware support services? If separate contractual arrangements are required for specific components of the system configuration, please indicate the components maintained by each party.

a. Please list support offices outside of North America.

2. Please provide a description and the costs of all standard hardware support services. Also, please describe how such support services are provided.

    a. Please list support offices outside of North America.

3. Does the laboratory have the right to contract with third parties for any or all hardware support services?

4.5.15. Documentation

1. Which of the following types of program and system documentation do you provide to client personnel?
    a. An overall technical summary of the system, oriented towards application and systems programmers
    b. Programmer guides for all application software
    c. Application source code listings
    d. Detailed system design documentation, including program flow for each function and file layouts and descriptions
    e. Programmer guides for operating system and utility software
    f. Technical descriptions of all instrument interfaces, both hardware and software
    g. Detailed user guides for all system functions.
    h. Is the documentation available on CD?

4.5.16. General

1. Is your company publicly or privately owned?
2. How long has your firm been in business? Please indicate the date your firm was incorporated in its present form.
3. Please describe the corporate organization of the firm and the number of professional employees in:
    a. Sales
    b. R & D
    c. Support
    d. Other
    e. Total

4. What is the number of laboratory systems you currently have installed?

    a. Provide a complete list of clients and highlight those outside the U.S. This list should include:
        i. Institution name and location
        ii. Contact and telephone number
        iii. Hardware and software installed
        iv. Date of installation.

5. How many of your clients that went operational with your system have contracted to replace your system?

6. Has your firm ever had legal proceedings initiated against it by a purchaser or lessee of one of your systems? If “yes,” please explain.

7. Please identify in one or two paragraphs what makes your company different from other vendors in the Laboratory computer market. Also identify what you consider to be your overall company strengths.

8. Do you have a user group? If yes, supply...
    a. Purpose of group
    b. When meetings are held
    c. Duration of meeting
    d. Last meeting date
    e. User group president.

4.6. Exhibit B - Functional Requirements Matrix

The laboratory environment in Emergency Plan–supported countries stretches across a continuum from the most basic screening facility to high complexity diagnostic laboratories. In terms of electronic laboratory information systems, this array of laboratories can be described by three main levels (as described by WHO) as the environment to be addressed by this project.

1. **Peripheral Level** – Perform simple tests such as microscopy, rapid tests, simple diagnostic methods using kits. Quality control records are usually kept in a paper format.
2. **Provincial/District Level** – Laboratories that perform some high complexity and definitive diagnostic testing, and receive specimens referred by Peripheral laboratories and/or from in-patients. These laboratories should have an LIS that manages specimens, patient data, test reporting and internal quality control and assurance.
3. **Central Referral Level** – Perform definitive diagnostic test methods as well as screening and other basic test methods and test specimens referred by the other level laboratories. In some scenarios these laboratories are National Reference Laboratories (NRL), which set quality control standards, and assure quality of laboratory testing. These laboratories need an LIS that manages specimens, test and patient data, and supports quality control/assurance. In addition, these laboratories have or should have the capability to receive and transmit laboratory data electronically via the Internet.

Level	Types of Testing	LIS	Connectivity	Full Time Laboratorian
Peripheral	Screening	No	No	Sometimes
Provincial/ District	Some diagnostic testing	Rarely	Mostly	Yes
Central Referral	Full diagnostic testing	Sometimes	Yes	Yes

The following matrix specifies the functional requirements at each level and specifies whether each individual requirement is required (R) or optional (O) at each level.

Feature Set		Peripheral	Provincial	Central
User Account Management		**R**	**R**	**R**
User Online Access	The LIS provides online access to various laboratory personnel.	R	R	R
	Online access to the LIS is granted only through dedicated user accounts	R	R	R
	The system maintains list of user accounts	O	R	R
	A user account shall consist of the following components: a. User Profile – contains user contact information b. User Credentials – contains user authentication information c. User Role – Defines user authorization and privileges	R	R	R

Feature Set		Peripheral	Provincial	Central
	The system allows authorized users to manage user accounts	R	R	R
User Profile	A user profile shall contain the following contact information a. Person's full name including last (family), first (given) and middle names b. Gender c. Title d. Organization or department the person works for e. One or more postal addresses such as work, mailing, etc. f. One or more telecommunication addresses such as telephone, fax, email, etc g. A specific site/laboratory identifier to which the user belongs to in the case of a centralized LIS that is used by several laboratories	R	R	R
	The system allows authorized users to manage user profiles	R	R	R
	The user may be allowed to manage his/her profile	R	R	R
User Credentials	User credentials consist of the following information: a. A unique username b. A password	R	R	R
	The system stores user credentials in encrypted format for security purposes	R	R	R
	The system requests the user to enter designated username and password, i.e. login using provided credentials, whenever the user tries to access the LIS	R	R	R
	The system authenticates user credentials, i.e. validates the provided username and password against the stored ones, upon user login attempt	R	R	R
	The system allows access to authenticated users	R	R	R
	The system allows authorized users to manage user credentials	R	R	R
	The user may be allowed to manage his/her own credentials	R	R	R

Feature Set		Peripheral	Provincial	Central
User Role	A user role defines user authorization and should reflect the person's title/job in the laboratory	R	R	R
	A user role represents a list of LIS features to which the user has been granted access, i.e. privileges	R	R	R
	Every user account is assigned a user role	O	R	R
	The system allows authorized users to manage user roles	R	R	R
	The system allows authorized users to manage user role privileges	R	R	R
Patient Management		**R**	**R**	**R**
	The system maintains list of patient profiles	R	R	R
	The patient profile shall consist of, but is not limited to, the following a. A unique patient identifier (internal LIS ID) b. Sending provider patient identification (patient ID as known to the provider) c. Full name including last (family), first (given) and middle names d. Mother's maiden name e. Also known as (AKA) f. Previously known as g. Gender h. Date of birth i. Government-assigned identification j. One or more postal addresses such as residence, work, mailing, etc. k. One or more telecommunication addresses (telephone, fax, email, etc.)	R	R	R
	The system allows authorized users to add additional profile fields such as birthplace, race, ethnicity, tribe, religion, etc.	R	R	R
	The system allows authorized users to manage patient profiles.	R	R	R
Provider Management		**O**	**R**	**R**
	The system maintains list of provider profiles. A provider is the healthcare organization that sends a laboratory order on behalf of a patient to a laboratory supported by the LIS.	O	R	R

Feature Set		Peripheral	Provincial	Central
	A provider may be a doctor office, a clinic, a hospital, another laboratory, etc.	R	R	R
	The provider profile shall consist of, but is not limited to, the following a. A unique provider identifier (internal LIS ID or code) b. Provider organization name c. Department d. One or more postal addresses such as physical, mailing, etc. e. One or more telecommunication addresses (telephone, fax, email, etc.)	R	R	R
	The system allows authorized users to manage provider profiles	R	R	R
Test Catalog Management		**R**	**R**	**R**
	The system maintains one or more catalogs of all the offered testing services, i.e. tests or procedures, at any specific laboratory supported by the LIS	R	R	R
	Tests may be grouped in one or more categories and sub-categories in a catalog	O	R	R
	A catalog test entry consists of, but is not limited to, the following: a. A unique test identifier/code, preferably adhering to a recognized coding standard such as: i. Logical Observations Identifiers Names and Codes (LOINC), or ii. Current Procedural Terminology (CPT) b. Test name c. List of other tests in the case of a test panel	R	R	R
	The system allows authorized users to assign one or more test catalogs to a laboratory	O	R	R
	The system allows authorized users to manage the test catalogs	O	R	R
	The system allows authorized users to import the test catalogs.	O	R	R
Request Management		**R**	**R**	**R**
	The system maintains a list of requests. The LIS request is a request by the receiving laboratory to perform testing services	R	R	R

Feature Set		Peripheral	Provincial	Central
	The system supports the capture of request data fields needed by all laboratories supported by the LIS	R	R	R
	The system allows additional data fields to be captured as needed by a laboratory and or test procedure	O	O	O
	A request consists of, but is not limited to, the following: a. A unique request identifier b. A unique accession number; in many case is the same as the request identifier c. Priority indicator d. Patient information e. Provider information f. List of tests to be performed g. Specimen information	R	R	R
	The system supports local (in the lab) and remote (at the provider location) accessioning, at both registration and order entry	O	R	R
	The system generates specimen accession numbers that are definable by laboratory, or test procedure category	O	R	R
	Search existing patient profiles during request creation to select/match the current patient request based on certain criteria such as a site assigned ID, government assigned ID, name, gender, date of birth, birthplace, etc.	R	R	R
	The system supports barcode label printing via: a. Online direct connection b. Modem connection c. Intranet or Internet using browser technology	O	R	R
	The system requires minimum demographic input during request creation and allows the remaining information to be input later	R	R	R
	System should be able to link to existing patient/client registry and capture relevant demographic information from that	R	R	R
	The required fields to be entered during request creation will be determined by test procedure type by laboratory	R	R	R

Feature Set		Peripheral	Provincial	Central
	Test procedures can be identified by users for selection and addition to a request during order entry via: a. Character search on partial entry of test procedure name b. Selection from a laboratory specific catalog	O	R	R
	The system presents to the user all specimen sources specific to the selected test procedures	R	R	R
	The system automatically calculates essential request parameters using existing patient data, e.g. enter date of birth and system calculates age	O	R	R
	The system checks for duplicate order entry based upon currently active orders, inactive or already performed orders	R	R	R
	The system validates all entered data to ensure accuracy	R	R	R
	Reflex testing, i.e. the ability to automatically order test procedures based on predefined criteria	O	O	O
	Register blinded QC samples, which are user definable and can be tracked and reported on statistical reports	O	O	R
	Request add-on tests to specimens that may be already registered and in storage	O	R	R
	The system allows authorized users to manage the requests.	R	R	R
Specimen Management		**R**	**R**	**R**
Specimen Registration	All specimens received at a laboratory must be registered using the LIS	R	R	R
	System allows specimens to be barcode labeled in the field or at registration	O	R	R
	The specimen shall be scanned into the LIS at registration if labeled in the field	O	R	R

Feature Set		Peripheral	Provincial	Central
	The specimen information captured at registration consists of the following: • Date/time of collection • Date/time of field registration • Date/time of shipment • Date/time of registration • Name of person entering data • Specimen type • Field identifier of specimen • Submitter identifier • Tests required • Container type • Condition of specimen • Approximate temperature of specimen • Volume of specimen, if applicable • Patient demographic data • If anything is missing, what and why (if known) • Accept/reject specimen based on predefined criteria • If specimens are associated with a specific outbreak, which one • If specimen is a quality control specimen	R	R	R
	g. Unique specimen identifier (accession number) to be assigned at specimen registration	R	R	R
	h. System allows the batch registration of specimens	O	R	R
	Create a request for a specimen that is being sent to an external laboratory. During this process the LIS should produce: a. An LIS assigned accession number b. A user-defined number of specimen labels that could include; accession number (human readable and barcode format), patient's name, submitter, and test ordered or organism suspected c. Referral laboratory request form with appropriate data entered during test request entry	O	R	R

Feature Set		Peripheral	Provincial	Central
Specimen Labeling	Create user-definable specimen barcode labels by laboratory, test procedure category and include the data elements to be printed on the label.	O	R	R
	At a minimum, all labels will contain the specimen identifier in barcode and numeric form	O	R	R
	Other data elements that could be included on the label (based on laboratory preference) are patient name, submitter code, date of birth, priority, sex, collection date and time, and the date and time a specimen was registered into the laboratory	O	R	R
	The number of labels that print per specimen will be definable by laboratory by test procedure category	O	R	R
	Once a specimen has been registered a label will be printed with the following information: • Specimen identifier • Unique laboratory identifier • Submitter identifier • Patient identifier	O	R	R
	Field applied labels includes: • Field location • Patient identifier • Date/Time			
	Labels contain a specimen type code to allow for the visual identification of specimens	O	R	R
	Specimens that are aliquoted or separated will have the same specimen identifier with a unique extension	O	R	R
	Reprint specimen labels as needed	O	R	R
	Print additional barcode labels as needed	O	R	R

Feature Set		Peripheral	Provincial	Central
	Additional assay barcode labels are user-definable by laboratory and test procedure category and should include the data elements to be printed on the label. At a minimum, all labels will contain the specimen identifier and suffix in barcode and numeric form. Other data elements that could be included on the label are patient name, submitter code, date of birth, priority, sex, etc.	O	O	O
	The number of labels that print per specimen will be definable by laboratory by test procedure category	O	O	O
	Additional specimen identifier and suffix is designed to fit on a single line on the label so that they can be scanned for identification in one motion.	O	O	O
Shipment forms	The system allow for the generation of shipment forms for shipment along with the specimen.	O	O	O
	The shipment form shall contain at least the following information: • Date of collection • Field number of specimen • Volume of each specimen, if applicable • Date/time of shipment • Submitter ID • Number of specimens shipped • Type of specimens • Any specific transport conditions, if applicable	R	R	R
Shipment Receipt	The system shall generate shipment receipt forms to be provided to the delivery person at the time a specimen is received at a laboratory.	O	O	O
	The shipment receipt shall include at least the following information: • Number of specimens received • Date/time of receipt • Person receiving the specimens.	O	R	R
Referral Laboratory Specimen	Track specimen sent to referral laboratories and produce reports that identify the referral laboratory by test group/category	R	R	R

Feature Set		Peripheral	Provincial	Central
	Track pending results (not yet received from the referral laboratory)	R	R	R
	Track test procedures that have gone beyond the normal testing time	R	R	R
	Enter a comment when a report is received from the referral laboratory	R	R	R
	Scan referral laboratory report into LIS when received from the referral laboratory and have it linked to the system specimen record	O	O	O
	Generate a duplicate referral laboratory result report upon request from the initial submitter	O	O	O
	Generate statistical data regarding information sent to referral laboratories via management reports ad hoc queries	O	R	R
	The system sends orders to and receives results from referral laboratory electronically	O	R	R
	Patient results that are not received electronically from a reference laboratory are entered manually into the LIS	R	R	R
	Enter reference ranges as part of the manual result entry process	O	O	O
Specimen Processing	Process specimens selected using one of the following criteria: • Specimens registered as batch from a submitter • Range of unique IDs selected by lab tech • Selected sequentially, one by one • Based on date collected or date received	O	R	R
	Assign a rejection reason if a specimen is rejected	R	R	R
	Track specimens assigned to permanent storage	O	R	R
Specimen Tracking Management		**O**	**R**	**R**
Specimen Storage	Define unique storage units and subunits such as facilities, rooms, racks, freezers, shelves and boxes	O	R	R
	Assign a specimen to a storage unit as a batch or individually	O	R	R
	Indicate the consumption of a specimen	O	R	R

Feature Set		Peripheral	Provincial	Central
	Indicate the return of a specimen	O	R	R
	Allow for specimen shipment	O	R	R
	Indicate the discarding of a specimen	O	R	R
	Checkout stored specimens as a batch or individually	O	R	R
	Check in of checked out specimens	O	R	R
	Search for a specific specimen	R	R	R
Specimen Retrieval	Whenever a specimen is retrieved from storage, the system accepts the following information: • Number of thaws • Initial volume of specimen • Initial temperature of freezer • Date time of retrieval • Final volume of specimen • Final temperature when specimen is placed in freezer • Date/time when specimen is placed in freezer	O	O	O
Specimen Long Term Storage	Capture the date/time and volume of specimen when it is assigned to long term storage	O	R	R
	Enter a discard date to be assigned to each specimen based on: • Submitter ID • Type of specimen	O	R	R
	Capture the storage location of each specimen. Each Specimen is assigned a room number or refrigerator number (if applicable), rack number, shelf number and box number for long term storage.	O	R	R
Specimen Short Term Storage	Each specimen is assigned a rack number, shelf number and box number for short term storage.	O	O	R
	The system periodically captures the temperature of the cold room	O	O	O
	The system captures the date/time a specimen is added to or removed from the cold room	O	R	R

Feature Set		Peripheral	Provincial	Central
Testing Management		**O**	**R**	**R**
	Support different types of resutls entry including: single test results, multiple test results, test comments, etc. Support entry of results as batch based on test category or entry at individal patient level	R	R	R
	Automatic capture of workload and test procedure statistics, which are available by: a. Test b. Patient identifier c. Laboratory	O	R	R
	Identify and track specimens that are sent to reference laboratories	R	R	R
	A specimen has a status field denoting whether a test is pending, in progress or completed	R	R	R
	Produce daily management workflow documents that can be printed or displayed by laboratory, test, workstation, date and date range, etc.	O	R	R
	Documents are user definable by laboratory, test procedure category. Examples: a. Work lists - produced automatically by the system, or manually set up by analyst, for batch processing, to be placed on a work list or instrument load list b. Pending procedure report c. Unverified result reports d. On demand or scheduled logs of completed tests e. On demand or scheduled logs of positive and reactive results	R	R	R
	Flag abnormal, critical and absurd values	R	R	R
	Capture all test data regardless of whether a test was successful or failed	R	R	R
	Flag by delta values that can be set by user definable criteria such as 50% change in a test value, in addition to critical alerts	O	R	R

Feature Set		Peripheral	Provincial	Central
	Age and/or sex adjusted reference ranges	O	R	R
	Access patient demographic, clinical data and orders during result entry	R	R	R
	Enter textual results by: a. Selecting predefined responses from a table b. Entering part of a data string and having a predefined response displayed.	R	R	R
	Define testing units and format to be used for each test procedure result entry.	R	R	R
	Send notification to user at result entry that a critical result(s) or control outlier is present, as such: a. Notification attempts must be documented b. Unsuccessful critical result notification attempts made during result entry must be captured c. Audit trail of all successful and unsuccessful notification attempts	O	R	R
	Capture the date/time, specimen type and ID and the user name/ID of the person performing the test	R	R	R
	Capture the volume of each aliquot	O	R	R
	Enter the following information when conducting a test: a. Worklist number b. Plate number c. Lot number/Kit number/Expiry date	O	R	R
	Keep a record of bench processes, for example the date/time when monoclonal antibodies or fixatives are added to a specimen	O	R	R
	Review previous results for a patient if that is required to perform a test	R	R	R
	Interface to major lab instruments instruments and produce ouput that can be reviewed by user and manipulated, if required, before upload to LIS	O	R	R
	Print outstanding specimen log by identifying the time interval in days	R	R	R

Feature Set		Peripheral	Provincial	Central
	Track which instrument performed any specific test	O	R	R
	Track whether a test result was entered manually, imported from a file, or read directly from an instrument	O	R	R
	Update the system with routing information (laboratory to which a *sample* is directed) and status code	O	R	R
	Route specimens/aliquots associated with a test request to multiple laboratories	O	R	R
	Allow reflex testing, i.e. the ability to automatically order test procedures based on predefined test results	O	R	R
	The result entry verification procedures are user definable by laboratory, test, or employee (analyst)	O	O	O
	The system tracks the identity of the analyst performing and/or completing the test procedure along with the date and time performed	R	R	R
	If a test fails, the system captures a reason for the failure and allows for retesting from the same specimen	R	R	R
	If the specimen is determined to be unusable for retesting for any reason the system captures the reason and request a redraw of the specimen from the patient	R	R	R
	Note ambiguous results of any test in the test result data	R	R	R
	Support manual inquiry or automatic review of other laboratory data before releasing results	R	R	R
	Maintain a complete audit trail of the result process	O	R	R
	The audit trail includes the following: a. Date and time of event change and initial result entry b. Record each step that occurred in the processing of a test procedure c. User who performed the step	R	R	R

Feature Set		Peripheral	Provincial	Central
Specific to HIV Specimens	For HIV specimens, workflow is based on the following recommendations by WHO/CDC/APHL: a. Serologic diagnosis of HIV infection is based on a multi-test algorithm for detecting antibodies to HIV b. Two simple/rapid diagnostic assays or one rapid assay and an enzyme immunosorbent assay (EIA) may be used for initial evaluation c. Confirmatory tests such as Western blot (WB) may be used to confirm infection in samples that are initially reactive on conventional EIAs	O	R	R
	System shall allow for user-definable and test procedure specific: a. Assay setups with instrument or manual defaults based on type of test, type of assay and source and specimen type. b. Serial testing or parallel testing setups with user-define defaults based on local testing practices, source and specimen type, assay type as needed. c. Test log summary information. d. Daily review information including: i. Test Request for initial assay (rapid assay A1) ii. Resulting of rapid assay iii. A screen dedicated to first line rapid assay A1 that summarize all test results as positive, negative and if relevant indeterminate or error. iv. Suggestion of confirmatory tests such as another rapid assay based on a different technology rapid assay A2, EIA or western blot (WB).	O	O	O
	Maintain anonymity of patients	R	R	R
	Identify which tests such as WB, PCR or Flow cytometry with CD4 counts or CD4:CD8 ratio need to be performed	O	R	R
	Support batch result reporting by test result	O	R	R

Feature Set		Peripheral	Provincial	Central
	Support the issuing of preliminary, final, supplemental and corrected and result reports	R	R	R
	Clearly identify and access specimens, sub-specimen, various assays and their daily readings from a common screen	O	R	R
	Worklog entry must be streamlined to allow for easy entry of data without the need to use the mouse to move around the workcard. Minimize use of mouse for data entry and use mostly keyboard	O	O	O
	Sort specimens based on the type of specimen, ordering facility, ordering physician or care provider	O	R	R
	Sort specimens based on patient name, sex, location, batch, reference lab, type of assay, type of result i.e. positive, negative indeterminate	R	R	R
	Sort by test category and type of result/critical results	O	R	R
	Submit test results for physician review	O	R	R
Scheduling Management				
	Add test requests and samples received and accepted by PHL to specific test schedule	O	R	R
	Add in-house generated tests to schedule	O	R	R
	Assign a submitter priority to a specific test	O	R	R
	Assign priority by type of test	O	R	R
	Generate internal priority based on holding times, number of days since receipt, and other factors associated with sample	O	R	R
	Adjust priorities	O	R	R
	Organize test queue by priority	O	R	R
	Automatically delete tests from the schedule once the result has been entered in the PHL-LIS (and restore if needed)	R	R	R
	Manually delete a test request from the schedule/batch (and restore if needed) or delete an entire batch	R	R	R
	Select tests for diversion to mutual assistance laboratory and create file of diverted tests	O	O	O

Feature Set		Peripheral	Provincial	Central
	Create packing lists and other documentation for diverted tests	O	O	O
	Adjust holding times based on extractions and other reasons	O	R	R
	Divert samples to another lab area/section based on a trigger from a completed test for subsequent testing	O	R	R
	Calculate daily processing capacity for each test; adjusted by instrument availability and personnel availability	O	R	R
	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	O	R	R
	Track test loads in the schedule at the specific instrument level	O	R	R
	Indicate which tests have been passed through to another laboratory (mutual assistance situation, etc.)	R	R	R
	Record, either electronically or manually, test results for tests performed by another (either a reference or a mutual assistance) laboratory and indicate name of person who performed the test utilizing standard formats as appropriate (i.e. HL7)	R	R	R
	Create subsequent test requests from a given test request	R	R	R
	Flag overdue test requests based on schedule and notify submitter	O	R	R
	Provide reports of test processing time by priority	O	R	R
	Provide test status reports	R	R	R
Results Management		**R**	**R**	**R**
	Access to results data shall be based on user roles and privileges	O	R	R
	Support searching and editing results data	R	R	R
	The automatic faxing or e-mailing of reports via laboratory-defined, submitter-specific schedules	O	O	O

Feature Set		Peripheral	Provincial	Central
	User-definable result reports by laboratory, test and submitter and be able to produce reports on either pre-printed forms or using free form laser printers and postscript printing. For mailing purposes, reports would be sorted by submitter and include the submitter's address. Alternatively, the system would print a submitter slip-sheet with the address for each batch of submitter reports. Result report production should be available in either an on-going, real-time process or printed on-demand in batches. The system will flag printed reports allowing for reprinting in the event of a problem.	O	R	R
	Highlight abnormal and critical results. Critical data and delta values should be highlighted differently from abnormal data.	R	R	R
	Print reference ranges, which are age, sex and specimen-type specific.	O	R	R
	Allow for the inquiry of results from users outside the laboratory with proper security clearance. The system maintains an audit trail of all data accessed.	O	O	R
	Support the storage and retrieval of all reports. Corrected reports should show highlighted changes	O	R	R
	The ability to print interim reports that contain preliminary result findings. a. Support the issuance of multiple interim reports on the same specimen and the same test b. Each interim report for the test contains each preliminary finding and the date it was reported. c. When a final report is produced, it contains all preliminary findings along with the date they were reported, as well as the final result	R	R	R
	Print multiple copies of a report for additional submitters.	R	R	R
	Generate a notification that an additional report is needed and to whom it should be sent, which would be initiated: a. At any time during the order entry process b. During the editing of a specimen record	O	R	R

Feature Set		Peripheral	Provincial	Central
	When multiple tests are ordered on the same specimen, the LIS support the option by laboratory, by test, or by submitter to do one of the following: a. Issue an interim report with available results and an indication that a test is pending and will follow b. Interim reports would be issued until all tests are complete for that specimen and each interim report will contain all completed test results to date, along with indication of any tests that are pending c. When all tests are completed, a final report will be issued which contains all completed disease/test results d. Hold all test results for a specimen until all work is complete and a final report issued	R	R	R
	When a final report has been issued and the submitter asks for additional testing on the same specimen , the LIS supports the option by laboratory, by test, or by submitter to do one of the following: a. Issue a report with the new test results only b. Issue a report containing new test results and previously reports disease/test results	R	R	R
	Correct result data and retain a clearly marked online record of the original and corrected reports with functionality to print a complete archived copy of the patient report including original reference ranges and interpretative comments	R	R	R
	Review all test data before they are released	R	R	R
Reports Management		**R**	**R**	**R**
	Management and statistical reports must be retrievable for: a. A single laboratory or test b. User-defined groups of tests or laboratories c. All laboratories	O	R	R
	Reports can be either displayed (viewed on a monitor) or printed	R	R	R

Feature Set		Peripheral	Provincial	Central
	Management and statistical report functions permit: a. The user development of specific ad hoc reports via the use of standard database tools. This should include all system data, i.e. all patient demographic and historical information b. Download user-selected information to other systems c. Access to information is based upon user role that would only allow access to data for specific laboratories, functions, and test procedures	O	R	R
Generated Reports	Order Entry Statistics Report – Summary **Description:** Provide summary data of how many Order Entry records were input into the system in a given date range for a particular submitter or all submitters. This report is used by Management to track number of orders.	R	R	R
	Order Entry Statistics Report – Detail **Description:** Retrieve Order Entry statistics details for Order Entry. The report provides a detail list of Order Entry records input into the system in a given date range for a particular submitter or all submitters. Management uses this report to track list of specimens being entered into the system.	R	R	R
	Specimen Registration Report **Description:** Retrieve information about any and all specimens registered. There are several kinds of registration reports: • Date/time and type of specimens received • If the specimens are being received on timely basis • If the specimens are complete and appropriately packed and shipped etc. • Specimen types received • Types of tests requested	R	R	R

Feature Set		Peripheral	Provincial	Central
	Pending Results Report **Description:** Retrieve incomplete test logs that show incomplete tests in the system. There are several kinds of incomplete: • If the results have not been verified and accepted • If the tests have been ordered but none have been performed • If a test procedure has gone beyond the normal turnaround time as defined for each test procedure in the system. This report lists all such incomplete results available in the system, to help track statistics for the same and lists incomplete tests chronologically with oldest test procedure first or by another user-definable sort.	R	R	R
	Positive Results Report **Description:** Retrieve statistics details for Positive Test results in the system for any given time period.	R	R	R
	Incomplete Order Entry Statistics Report **Description:** Report all records in the system that has incomplete Order Entry. This list is used to communicate with the submitters to get additional data for specific records to enable completion of Order Entry.	O	R	R
	Specimens Received Statistics Report **Description:** Retrieve a detail list of all specimens received for a given date range in the laboratory.	R	R	R
	Workload Statistics Report **Description:** List a summary of the following for the given time period in days, hours etc (to help organize workflow), submitter and test: • Patient Samples received in the lab • Results reported in the lab • Repeats performed in the lab • Rejected Test Results in the lab • QC samples tested in the lab • Incomplete Test Results in the lab	O	R	R

Feature Set		Peripheral	Provincial	Central
	Unsatisfactory Results Report **Description:** Generate a count of all Unsatisfactory Results in the system for a given time period, submitter and test.	R	R	R
	Amended Results Report **Description:** Retrieve list of Amended results in the system, i.e. results that have been modified since verification process was completed for the test result.	O	R	R
	Turnaround Times Report **Description:** Generate a list of average turnaround time between various points in the ordering and testing process.	O	R	R
	Incomplete Worksheets Report **Description:** Generate a list of incomplete worksheets in the system.	O	R	R
	Above reports should be able to be selected for: a. Date range b. Test procedure (selection by drop down, partial entry of test procedure name) c. A single submitter (selection by drop down, partial entry of submitter name, support for submitter levels) d. A user defined group of submitters e. All submitters.	R	R	R
	The system allows ongoing review of the database to uncover user-definable trends	O	O	O
	Data mining trends allowing either on demand or scheduled logs of the following important test data: • Cases that are positive and show results suggestive of liver and renal toxicity by user definable criteria • Cases that are positive and show signs of resistance to treatment either by increasing viral loads or decreasing CD 4 counts or total leucocyte count and total lymphocyte count as surrogates for CD 4 counts and CD4:CD8 ratio.	R	R	R

Feature Set		Peripheral	Provincial	Central
Quality Control Management		**O**	**R**	**R**
	Be able to define control samples (lot number, lot status, manufacturer / preparer, preparation/receipt data, expiry date, and test parameters by method and organism strain ID.	O	R	R
	Have the capability to define reagents (lot number, lot status, expiration date, concentration, manufacturer / preparer, preparation/receipt date, storage conditions, etc.).	O	R	R
	Be able to define instruments (model name and number, manufacturer, serial number, property number, location & installation date.	O	R	R
	Allow for user-defined criteria for evaluating QC results for each control, reagent, and instrument parameter.	O	R	R
	Handle statistics (mean, SD, CV) that can be manually defined, calculated on demand, or continually updated. Statistical outliers detection should be performed during calculation of statistics.	O	O	O
	Enable the user to define the layout and frequency for each/any standard or control as they are found in worksheets and load lists.	O	O	O
	Permit the entry of control results as desired by the user in addition to or instead of, using automatic prompts	O	R	R
	Allow QC results to be entered either manually or through an instrument interface.	O	O	O
	Allow personnel to edit manually entered QC results prior to final acceptance and provide an audit trail of edits.	O	R	R
	Notify the analyst of any QC results that fall outside user-defined criteria (i.e. outliers or trends as defined by user). Allow for the entry of a narrative comment, allowing analyst to enter a probable cause, and a response to the unacceptable results with the corrective action being documented.	O	R	R
	Provide the option of suspending patient results until supervisor intervention when QC results fail defined criteria.	R	R	R

Feature Set		Peripheral	Provincial	Central
	Be capable of displaying a visual warning of reagent expiration or pending expiration	O	R	R
	Allow QC results to be viewed on-line or printed in either graphic or trend format. Support the production of statistical plotting and graphing aids, i.e. Levey-Jennings chart, scatter graph etc.	O	R	R
	Allow for QC data review. For any individual piece of QC data, the system must be able to identify, allow for review, and track the following information: • The person who documented and accepted the QC result • The date/time the result was documented • The criteria used to evaluate the result • Any criteria that failed • The statistical range or endpoint in effect when result was documented • The assignable cause/corrective action comments • Supervisor intervention and any supervisor/director review comments documented against the result.	O	R	R
	Instrument identification and printed graphs w/ text	O	O	O
	Allow any/all QC data to be available for statistical evaluation. I.e. have statistics reporting that will list calculated mean, SD, & CV for user-selected time period and user-selected control test parameters, instrument function checks, etc.	O	R	R
	Must have the ability to set date parameters on a lab/test procedure basis for storing data and associated information. Must have the ability to link archival patient results and test procedure specific worksheets/work cards to appropriate QC results and lot numbers	O	R	R
	Allow reagent verification checks to be recorded and evaluated based on user-defined criteria.	O	R	R
Maintenance Management		**O**	**R**	**R**
	The system maintains list of equipment maintenance records	O	R	R

Feature Set		Peripheral	Provincial	Central
	The maintenance record consists of, but not limited, to the following: a. Equipment name b. Equipment manufacturer c. Equipment model d. Equipment serial number e. Equipment location f. Dates or interval of required maintenance g. Date maintenance was performed h. Problems identified during maintenance i. Corrective actions taken to resolve problems and when	R	R	R
	The system issues reminders for maintenance	O	O	O
	The system allows authorized users to manage the maintenance records	R	R	R
Billing Management		**O**	**O**	**O**
	Maintaining pricing of laboratory-offered tests	O	O	R
	Extending lines of credit (LOC) to customers	O	O	O
	Generating customer invoices	O	R	R
	Accounting for customer payments	O	R	R
	Generating financial reports	O	R	R
	Capture and maintain submitter billing address and responsible party information	O	O	O
	Specify which services are included under a given contract agreement and tag each service with a active/inactive flag (or timestamp each unique set of services active under the agreement for any given service provision date. The term “service” is used rather than “test” to include training fees, annual license fees, etc.)	O	O	O
	Capture and maintain agreed upon charges for specific services if different than standard billing rates	O	R	R
	Select specific billing ledger entries and create submitter specific billing invoices	O	R	R
	Create hard copy invoices grouped by submitter	R	R	R

Feature Set		Peripheral	Provincial	Central
	Create electronic billing invoices in lieu of paper	R	R	R
	Track billing and payment status	R	R	R
	Create billing reports by submitter, timeframe, service and other key parameters	O	R	R
	Track grants & contract services and associated fees	O	O	O
	Create reports for non-billable services indicating monetary value by grant/contract based on standard costs	O	O	O
	Report on test billing – what tests have been billed and the amount billed by selected time period	O	R	R
	Associate a fixed cost with a specific test and/or group of tests plus allow for new fixed costs to be added to the system when price increases are put into effect. Price increases should not distort the historical records for billing. In addition to fixed costs, there needs to be an allowance for each test if a surcharge for extra time spent during testing needs to be added	O	R	R
	Add in a surcharge to the fixed cost depending on the priority code assigned to the test request	O	O	O
	Accommodate billing/purchase order identification numbers plus client identification, test identification, date completed, plus several other identifiers	O	R	R
	Allow billing data to be produced by date range and client	O	R	R
	Produce costs by client either as tests completed or projected costs for tests requested but not yet completed	O	R	R
	Summarize costs in multiple ways: purchase order number, client, billing codes, etc.	O	R	R
	Void the cost of a test for valid reasons	O	R	R

Feature Set		Peripheral	Provincial	Central
Inventory Management		**O**	**R**	**R**
	Manage tangible items or a products used before, during and/or after the test process, and it covers consumable and durable goods, including: a. Test media b. Test kits c. Control reagents d. Paper forms such as request forms, shipment forms, etc. e. Containers for specimen f. Label rolls g. Masks h. Gauze pads i. Tapes j. Bandages	O	R	R
	Define unique storage units (and possible subunits) – hospitals, labs, clinics, facilities, bins, shelves, etc.	O	R	R
	Define item/product properties such as part number/SKU, name, description, manufacturer, date of manufacture, shelf life/expiration date, UOM, quantity, STD pack, Bundle, serialized, etc.	O	R	R
	Set inventory levels and quantities at a storage unit	O	R	R
	Define consumer/project/customer specific catalogs and bills of materials	O	R	R
	Assign supplies to a storage unit	O	R	R
	Move/transfer a supply between storage units	O	R	R
	Consume a supply	O	O	O
	Return a supply	O	R	R
	Supply shipment	O	R	R
	Receive/acknowledge supply shipment	O	R	R
	Discard a supply	O	O	O
	Checkout stored supply	O	O	O
	Check in checked-out supply	O	O	O
	Reconcile supply	O	R	R
	Manage product suppliers (distributors and manufacturers)	O	O	O

Feature Set		Peripheral	Provincial	Central
	Manage warehouses	O	O	O
	The warehouse consists of the following information: a. Name of the warehouse b. Unique identifier of the warehouse c. Description of the warehouse d. Contact information for the warehouse including name, address and telephone number e. Owning supplier	R	R	R
	Associate a warehouse to a product supplier	O	O	O
	Assign product fulfillment to a supplier's warehouse	O	O	O
	Create inventory replenishment requests for a site	O	R	R
	Generate alert/warning if inventory levels run below pre-defined limit	O	R	R
	An inventory replenishment request consists of the following: a. Requisition Number – System generated b. Requisition Creation Date – System generated. c. Contact information of entity that creates the request – System provided based on user login if manually created, otherwise from record if the request is system generated d. The site shipping address – System provided from preset site settings on record e. List of line items – Product part number and name from the site's predefined Bill of Materials f. Line item quantity – Manually entered or system generated	R	R	R
	Review inventory replenishment requests for a site	O	R	R
	Approve inventory replenishment requests for a site	O	O	O

Feature Set		Peripheral	Provincial	Central
	Schedule inventory replenishment requests for a site based on per product site inventory capacity (AKA Order Point) and minimum reorder level threshold	O	O	O
	Receive email notifications when site employees or the FMS issue new materials replenishment requests	O	O	O
	View inter-site inventory movement requests	O	R	R
	View inventory levels for all tracked materials at a site	O	R	R
	View the inventory levels of any secure materials removed and returned from and to the safe at participating sites	O	R	R
	View inventory levels of the materials on hand at a participating site	O	R	R
	View inventory levels of the materials actually used by a participating site	O	O	O
	View inventory levels of materials returned and scrapped by sites	O	O	O
	View inventory levels for all tracked materials for a warehouse	O	R	R
	View inventory levels of materials received from the manufacturers at a warehouse	O	O	O
	Run, view, and print a Serial Number Reconciliation report. The report shows any noted reasons for discrepancies	O	R	R
	Run, view and print an Inventory Capacity versus Actual Usage Per Site report	O	O	O
Localization Management		**R**	**R**	**R**
	This section captures the functional requirement that pertain to localization of the deployed LIS. Localization of the system is country specific and includes, but is not limited to, the setting of the following:	R	R	R
	1. Language(s)	R	R	R
	2. Calendar	R	R	R
	3. Date and time format	R	R	R
	4. Currency denomination and format	O	O	O
	5. Acceptable payment methods	O	O	O
	6. Available shipping carriers	O	O	O
	7. Additional user-define data fields.	O	O	O

Feature Set		Peripheral	Provincial	Central
Alert Management		**O**	**R**	**R**
	Generate alert based on critical values. A critical lab value is defined as one which represents a patho-physiological state at such variance to normal as to be potentially life-threatening or which requires immediate attention.	O	R	R

4.7. Exhibit C – Certifications and Assurances

Any legal or procedural certifications that the MOH needs.

Signature of Contractor Date

Name & Title

4.8. Exhibit D – Standard Terms and Conditions

Any standard contract and terms and conditions that the Ministry uses for procurement.

Section 5. Evaluation Criteria and Matrix

Systems that are being considered for deployment shall be evaluated according to the following criteria:

- Functional Design/Soundness: This area looks at the overall suitability of the proposed solution with respect to the functional requirements laid out in the RFP. Each system developer/system provider should be asked to rank the functionality provided by their system against the matrix. For each line in the matrix they should be asked to specify if their system provides the functionality, can be customized to provide it at additional cost or does not provide the functionality.
- Software Technology: This criteria evaluates the suitability of the proposed software packages in terms of meeting the technical requirements including the ability of the platform to meet future needs. The system should be compared against the System requirements for this category.
- Hardware: This area considers the hardware requirements of the specific system. The intent is to ensure that the system does not need any specific pieces of hardware that may be difficult to procure in the country.
- Support: After sales support is an important factor and the system provider needs to be able and willing to provide the requisite support both during deployment and once the systems are live. Each country should ensure that the system developer or system provider has a mechanism to provide long term support and that they have resources that are reasonably accessible.
- Security: The ability to control access to the system functionality and data is a critical capability. The system must be able to provide access to those authorized to receive particular access and to deny access to all others.
- Cost: The cost factor is evaluated based upon both the price quoted and our confidence in the respondent's ability to stay within the stated limits. We also consider the total cost of ownership including ongoing support costs both directly paid to the system provider and incurred internally.
- Time: How long does the system provider estimate it would take to deploy the solution and how soon after getting the go-ahead could they begin the work.
- Process: This area refers to the development methodology and deployment employed by the respondents.
- Company Focus: Here we examine the potential system provider's business from the point of view of determining how committed they are to the public health and lab environments and how viable they are as a system provider.
- Clients/Pedigree: This area looks at the suitability of the system provider from the point of view of the kinds of clients they have been serving, their ability to satisfy the needs of those clients and the similarities between those clients and the MOH countries.

Each system and system provider should be assigned a rank between 1 and 10 for each if these categories. When those ranks are entered in to the spread sheet below each system will be assigned an overall score that is calculated using the weights assigned to each category. Each country can change the weight assigned to the categories to suit its specific circumstances.

It is recommended that each country then do a detailed analysis of the two top-scoring systems. The final decision should be made after demonstrations and further evaluations of each system.

	Weight	System 1	System 4	System 5	System 11
Functional Design	25%	8	5	6	6
Software Tech.	20%	8	6	8	4
Hardware	5%	7	7	7	7
Security	5%	4	7	2	8
Support	13%	8	5	8	4
Time	5%	7	5	8	6
Cost	7%	7	5	7	6
Process	5%	7	7	5	7
Company Focus	10%	8	7	3	6
Clients/Pedigree	5%	8	6	3	7
Overall Score		7.58	5.75	6.18	5.59

Section 6. Minimal Requirements

While the full functional and system requirements are described below, we believe that successful deployment of an LIS in any country will require a phased approach. The first phase of any such project will likely be a pilot project deploying a minimum set of functionality. Based upon our discussions with laboratory experts from 17 GAP and Emergency Plan countries as well as from our observations in Ethiopia, Uganda, and Zimbabwe we believe that the system functionality described in this section is the minimum required to achieve the minimum Emergency Plan goals.

The minimal system has been defined specifically to meet the data collection and reporting requirements associated with the Emergency Plan–funded programs. While a country may choose to deploy different systems within different labs the same is not true for systems used to collect and report data from all the sites within the country. Each country will likely need to choose and deploy a single system for collecting patient, order and result data from the variety of sites where this data is generated. There is also a need to have the data format across the systems deployed by different countries be such that this data can be aggregated and compared at the regional or global level.

The objective of deploying these systems is to provide each country with the basic ability to quickly and easily collect and aggregate HIV incidence and prevalence data across the entire country and to be able to review and analyze this data in a timely manner.

6.1. Minimal System Requirements

Because these systems will be deployed at large numbers of locations that will, at best, have intermittent connectivity to any central server, as well as intermittent power they must meet the following system requirements:

1. Must be low cost to deploy and maintain
2. Must be capable of operating independent of any host/server connections
3. Must be able to connect to a central server and transfer data when connectivity is available
4. Must be compact enough to run on desktop PCs and notebook computers
5. Must be based on current architecture/technology, i.e. .Net or J2EE
6. Must be based on a database/operating system for which local expertise can be obtained (most likely combination would be Windows and MS Access)
7. Must support HL7
8. Must have the potential to support LOINC and SNOMED CT coding.

6.2. Minimal Functional Requirements

The most basic functions that such a system needs to perform are to accept patient data, create a test request, accept the test results and export this data via an electronic or physical medium. This means that the system must be able to perform the following functions:

1. User management
    a. Provide roles-based access
    b. Require a unique user ID and password for system access
    c. Allow authorized users to create user profiles
    d. Allow authorized users to search for user profiles
    e. Allow authorized users to modify user profiles
    f. Allow authorized users to delete user profiles.
2. Patient management
    a. Provide a unique patient ID
    b. Create a patient profile
    c. Modify a patient profile

   d. Delete a patient profile
   e. Search for a patient profile
   f. Check for duplicates.
3. Specimen management
   a. Register a specimen
   b. Enter specimen identifiers from labels
   c. Associate a specimen to a patient
   d. Modify a specimen
   e. Delete a specimen.
4. Order management
   a. Support tests related to HIV and opportunistic infections
   b. Create an order for a specific patient
   c. Associate a specimen to the order
   d. Modify an order
   e. Search for an order
   f. Delete an order
   g. Check for duplicate orders.
5. Link to patient registry, if it exists
6. Ad hoc query capability
7. Archiving of records
8. Linking/interfacing ability to other standard databases such as a hospital information system.