LIS ADOPTION AND POLICY ANALYSIS TOOL

Objectives

Use the data collected to understand:

- steps taken around ownership of the LIS project and if the laboratory is reducing dependency on donors
- policies that are lacking and therefore preventing the laboratory from fully utilizing the LIS and benefiting from all functionality
- LIS IT policy - Minimum IT infrastructure needed and associated policies to ensure the LIS is operating optimally

Laboratory Name	
Facility Name (if different)	
City	
Your name (assessment lead)	
Organization you are affiliated with	
Names of other members of assessment team with affiliation	
Date of assessment	

Laboratory Staff Involved in Completion of Questionnaire

Name	Job Title (related to LIS)	Telephone	Email address

Personnel & Security

Question	Response	Notes/ Comments
How many LIS users are there in the laboratory (total)?		
Are LIS users computer proficient?	Yes No	
Do laboratory personnel feel like there are enough knowledgeable LIS people to assist when they are unsure how to use a system function?	Yes No	
Is the LIS available during working hours and staff use it to support and aid their daily work?	Yes No	
Are LIS manuals, informational material & SOPs readily accessible?	Yes No	
Is training is available for newly hired staff ?	Yes No	
Is refresher training is available for all staff using the LIS?	Yes No	
Is documentation kept on both new and refresher trainings?	Yes No	
Is there a method in place to assess staff LIS competency level (after proper training)?	Yes No	
What are the different levels of users set up in the LIS? Circle those that the facility uses.	Administrator Users Super User Other	
Number of Administrators		
Number of Users		
Number of Super Users		
Number of "Other"		

Infrastructure and Hardware

Question	Response	Notes/ Comments
Is there a backup protocol in place to support laboratory and LIS functions when power outage occurs? If no, what usually happens if a power outage occurs?	Yes No	
Does the laboratory have an average of at least 8 hours of internet access each day?	Yes No	
Is there an adequate and continuous supply of electricity?	Yes No	
Are there an adequate number of electrical outlets to support all laboratory and LIS equipment? If no, please note how staff resolve the issue (use of extension cords, power strips etc.)	Yes No	
Is there a backup generator? If yes, is it working properly and is it tested regularly?	Yes No	
Where is the server located? Please observe: • Proximity to laboratory • Physical Access control (Can the area be locked) • Personnel access control (Are only certain people authorized to access the server) • Airflow • Temperature (for older servers) • Proximity to water (dripping A/Cs, open windows, leak in roof) • Back-up power/UPS/plug configuration		
Is there accessible fire fighting equipment and is still functional/valid?	Yes No	
Is there someone in the laboratory or hospital who is in charge of maintaining the computers? • Are they available on site? • Are they regularly available to deal with issues?	Yes No Yes No Yes No	
How long does it take to resolve a typical computer issue or problem?	≥1 hour ≥4 hours ≥8 hours ≤2 days ≤5 days	
Are LIS users familiar with the level of LIS support available? • Based on type of issue and the perceived level of support needed	Yes No	

Question	Response	Notes/ Comments
Is there a hardware* maintenance plan? • Introducing new hardware • Phasing out older hardware • Maintenance schedules • Responsible staff • Other *Hardware includes computers, printers, barcode readers, scanners, servers, analyzers	Yes No	
Does hardware appear to be in good shape?	Yes No	
Who do users contact in the event hardware is out of operation? Is the problem documented in a log?		
Is hardware (computers, printers, analyzers) connected to a UPS?	Yes No	
Is there a separate list or inventory of hardware provided for the deployment and use of the LIS?	Yes No	
Is there a separate maintenance and support contract for hardware provided for the LIS?	Yes No	
How many analyzers are present in the laboratory? • Are they all functional? (reagents available, trained personnel etc.) • How many analyzers have the ability to interface with the LIS? • Of these how many are currently interfaced with the LIS now? • Do users take advantage of the LIS interface?		
Are the analyzers rented or have they been purchased for long term use?	Rented Purchased	
Are barcode readers functional?	Yes No	

Data Security

Question	Response	Notes/Comments
Is there a data backup SOP?	Yes No	
Can the server log be accessed?	Yes No	
Are LIS data backed up? • How often? • On what type of media (paper or data storage media)? • Is the back-up stored on or off site? • Is it stored in a secure, access controlled location? • Who performs the back-up procedure?	Yes No	
How many months have LIS operations gone uninterrupted?	≥12 ≥6 ≥3 ≥1	
Does the facility have a Disaster Recovery Plan?	Yes No	
Is there anti virus software installed on computers? If yes: • Is it managed through individual PC's or through the server? • Is it up to date?	Yes No	
When was the last time the computers were infected with a virus, and how was the situation handled?		
Are there measures in place to assure physical data integrity?	Yes No	

Policies and Procedures

Question	Response	Notes/Comments
Does the laboratory have clearly defined processes for informatics policy making? • Policies may include signed, documented MOUs, data sharing agreements, SOPs and other policies that affect routine and special functions within the laboratory.	Yes No	
Please identify what SOPs have been developed and are available in the laboratory (examples: Basic specimen receipt, testing and result reporting, Specimen rejection, EQA/IQA)		
What reports does the laboratory run in the LIS to support ongoing quality assurance, and on what frequency (weekly, monthly, quarterly, yearly, other)?		
• Specimen rejection	Yes No	
• Test statistics	Yes No	
• Inventory reports	Yes No	
• QC data	Yes No	
• LJ charts	Yes No	
• Turnaround time	Yes No	
• IQC and EQC data	Yes No	
Indicate if the following actions are documented by the laboratory staff and how (either in LIS or otherwise):		
• Recording of nonconformities		
• Recording of corrective action		
• Recording of out-of-range QC data • Document the corrective action for out-of-range QC data		
• Analyzer calibration and maintenance		
• Specimen rejection/nonconformity		
• Record of maintenance/support work carried out by LIS support staff		

System Interoperability and Electronic Data Exchange

Question	Response	Notes/Comments
Is the LIS integrated with any systems?	Yes No	
If yes, what which systems: • Hospital information system • Electronic medical record • Pharmacy system • Stock/inventory system	Yes No Yes No Yes No Yes No	
Is the LIS used to refer samples to another laboratory?	Yes No	
Does the laboratory create an electronic message for test results using agreed upon standards?	Yes No	
Does the laboratory receive an acknowledgment of the delivery of electronic results?	Yes No	
Is the laboratory able to electronically submit results of all tests done on a patient or specimen?	Yes No	
Can the laboratory export sample-associated data out of the LIS?	Yes No	

Communications & Reporting

Question	Response	Notes/Comments
How does the laboratory communicate with lab management about LIS successes, challenges or concerns? Is this information documented?		
How often does the laboratory provide written reports to lab management on the operations and use of the LIS?	Daily Weekly Monthly Quarterly Annually Never	

OBSERVATION: Staff Use of the LIS

Question	Response	Notes/Comments
Do LIS users sign into the system with a unique unique username and password?	Yes No	
Do LIS users sign out of the system when they complete a task?	Yes No	
Do the computers have the screen saver function active? • If Yes, is it password protected?	Yes No	
Do users use the LIS at every step of the specimen life cycle? • Specimen registration • Test results • Reporting	Yes No	
Do users take advantage of the barcode readers? • At specimen registration • Entering demographics • Look-up specimen information • Other	Yes No	
Do laboratory staff use the LIS to generate test worksheets?	Yes No	
Do laboratory staff take advantage of the batch sample entry (when ordering tests)?	Yes No	
Do laboratory staff take advantage of batch testing (multiple specimens being tested using the same method?	Yes No	
Do laboratory staff and managers ensure that results are formally verified before being formally released to physician?	Yes No	
In your opinion, does the use of the system enhance or hinder the specimen workflow?	Enhance Hinder	
In your opinion, to what extent is the laboratory using the LIS (to support its workflow)?	≥95% ≥75% ≥50% ≥25%	
Please describe additional ways you observed laboratory staff interacting with the LIS:		

OBSERVATION: Review of Patient Reports

Question	Response	Notes/Comments
Do the reports generated by the laboratory all follow a standard?	Yes No	
Do the reports include:		
• Patient name	Yes No	
• Patient address	Yes No	
• Hospital/facility requesting	Yes No	
• Laboratory producing report	Yes No	
• Name of person requesting	Yes No	
• Type of sample	Yes No	
• Test requested	Yes No	
• Date/time of specimen collection	Yes No	
• Date/time of specimen receipt	Yes No	
• Date/time of release of report	Yes No	
• Normal reference ranges (if applicable)	Yes No	
• Interpretation of results (if applicable)	Yes No	
• Rejected specimen and reason (if applicable)	Yes No	
• Name of person authorizing release	Yes No	
• Critical results	Yes No	

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