# Laboratory Information Systems Management and Operations

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**KEYWORDS**

• LIS management • LIS operations • Change control • End-user training
• Quality control reports • Help desk

## OVERVIEW

The main mission of an LIS is to manage a laboratory's workflow (both specimens and patient data) and to deliver accurate results for clinical management, in a timely manner. A modern LIS should have built-in functionality for other required activities, such as regulations, billing, or quality assurance. Currently, in the United States, pathology laboratories are under continuous pressure to improve workflows by using lean initiatives. Technologies, such as tracking systems and automation, have been used successfully for decades in clinical laboratories; they are finally becoming the norm in pathology laboratories as well. Other useful LIS functions, particularly when used in an academic environment, are support for pathology education and research.

The successful selection and implementation of an anatomic pathology LIS is not complete unless it is complemented by long-term specialized information technology (IT) support. This should be provided by both in-house informatics and IT resources as well as by an LIS vendor. Nevertheless, optimal LIS operations depend on the availability of adequate, dedicated, and skilled informatics and IT personnel. For large health care systems, collaboration and communication between a laboratory's LIS staff and the hospital-wide IT personnel play a key role in the successful LIS maintenance.[1]

A LIS is required to remain continuously operational with minimal or no downtime. At the same time, an LIS team has to ensure that all operations are compliant with the mandated rules and regulations. As is the case for any health information system (HIS), close attention should also be shown to a system's development life cycle to further improve its functionality and usability. **Box 1** lists key operations that any LIS team needs to handle post–system implementation.

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**Box 1**
**Key operations that laboratory information system teams need to handle post–system implementation**

- Training
- Help desk support
- Change control
- System security
- System data backup
- Interface monitoring and maintenance
- Downtime management (unscheduled vs scheduled)
- Database maintenance
- Upgrades (software and hardware)
- Administrative and management reporting
- Budgeting and cost analysis
- System validation
- Documentation
- New product evaluation
- Quality assurance and quality improvement initiatives

## SYSTEM VALIDATION

Although a tedious and costly process, LIS validation must be performed to prove that an implemented system is fit for its intended use and that the system manages information well, with the expected accuracy, reliability, and file integrity, both initially and over time.[2] During the validation process, various LIS functions are performed while data are collected, maintained, and independently reviewed to demonstrate that the system performs consistently according to specifications. Pathology laboratories must establish protocols and standards for the validation process. All the validation steps and results must be well documented.

LIS vendors perform initial, internal system validations; however, any system must be revalidated whenever end users, vendors, or third parties add modifications or customizations. The Clinical and Laboratory Standards Institute published important factors that should be considered when developing validation protocols for LISs, including recommendations for preparation of validation protocols, to assess the accuracy and dependability of LISs in storing, retrieving, and transmitting data.[3]

## INTERFACE MAINTENANCE AND MONITORING

Electronic interfaces are critical components of any HIS, having a significant impact on the overall performance of information exchange and health care delivery. They allow transmission of data and information between LISs and other clinical information systems (eg, electronic medical records and billing systems) or between LISs and laboratory equipment (eg, automated immunohistochemistry slide stainers). Although electronic interfaces have been in use for years and attempts have been made to standardize their implementation, the whole process is still a time- and resource-consuming process. Interface customization depends significantly on the laboratory