CLINICAL AND LABORATORY STANDARDS INSTITUTE®

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AUTO08-A

Managing and Validating Laboratory Information Systems; Approved Guideline

This document provides guidance for developing a protocol for validation of the laboratory information system (LIS), as well as protocols for assessing the dependability of the LIS when storing, retrieving, and transmitting data.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.

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Abstract

Clinical and Laboratory Standards Institute (CLSI) document AUTO08-A—*Managing and Validating Laboratory Information Systems; Approved Guideline* identifies important factors that laboratory managers should consider when developing a protocol for the validation of the laboratory information systems (LIS). Also included are recommendations to help prepare validation protocols for assessing the accuracy and dependability of the LIS in storing, retrieving, and transmitting data.

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Contents

Contents (Continued)

Foreword

There are many automated systems that a laboratory must interface with, both internal and external to the laboratory. Clinical and Laboratory Standards Institute (CLSI) has a number of approved automation standards that address individual portions of an automated laboratory system. These approved standards cover the path of workflow in a laboratory (preexamination, examination, postexamination, and information management), yet there are no standards or guidelines that incorporate all these systems into a laboratory-wide validation process. This guideline contains recommendations for the preparation and execution of a laboratory information system (LIS) validation process. A laboratory information system (LIS) is also referred to as a clinical laboratory information management system (CLIMS) or laboratory information management system (LIMS) in some current publications. For consistency, this document will use the term LIS throughout when referring to these types of systems.

Key Words

Audit trail, interface, network, system, validation, verification

Managing and Validating Laboratory Information Systems; Approved Guideline

1 Scope

The laboratory industry is quickly moving into the era of electronic reports, transmission of information via the Internet, etc., and there is a need to develop guidelines that can provide consistency in the industry. The purpose of this guideline is to address the validation of LIS systems and any interface to an external system (e.g., electronic health record system [EHRS], formerly known as a hospital information system [HIS], point-of-care device [POCD], reference laboratory, data repository, instrumentation, laboratory automation system [LAS], or financial system) to ensure that information is accurate and reliable during sample accessioning, transmittal of test results, and throughout the system's intended use. This guideline addresses the validation process as it relates to:

- data entry;
- data analysis;
- data verification;
- data transmission;
- data storage; and
- data retrieval.

The primary focus of AUTO08-A is on the software within the clinical laboratory environment. Therefore, the recommendations presented in AUTO08-A are not directly applicable to over-the-counter devices or software on instruments. The document is intended for use by: laboratory compliance officers, laboratory LIS staff (e.g., LIS coordinator, system administrator), vendors of LIS and associated hardware, IT staff responsible for LIS, and network administrators.

2 Introduction

An LIS manages data related to test requisitions, patient demographics, and specimens. An LIS can either interface with the laboratory analytical and process instruments as the data management center or serve for data collection, reporting, transmission, and archiving. An LIS can also interface with other information systems (e.g., electronic health record system [EHRS]) for the transmission of test requisitions and final test results.

As stated previously, CLSI has a number of different approved standards that address individual portions of an automated laboratory system (path of workflow):

AUTO1: *Laboratory Automation: Specimen Container/Specimen Carrier* provides standards for the design and manufacture of specimen containers and carriers used for collecting and processing liquid samples for clinical testing in laboratory automation systems.

AUTO2: *Laboratory Automation: Bar Codes for Specimen Container Identification* provides specifications for use of linear bar codes on specimen container tubes in the clinical laboratory and for use on laboratory automation systems.

AUTO3: *Laboratory Automation: Communications with Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems* provides standards to facilitate accurate and timely electronic exchange of data and information among the automated laboratory elements.