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December 2006

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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Managing and Validating Laboratory Information Systems; Approved Guideline

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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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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.

AUTO4: *Laboratory Automation: Systems Operational Requirements, Characteristics, and Information Elements* defines system status information that supports laboratory-automated systems.

AUTO5: *Laboratory Automation: Electromechanical Interfaces* defines a standard, compatible connection between instruments and automation technology that will enable the user to create an automated laboratory environment.

AUTO10: *Autoverification of Clinical Laboratory Test Results* provides a general framework that will allow each laboratory to easily design, implement, validate, and customize rules for autoverification based on the needs of its own patient population.

GP19: *Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring* describes factors to be considered when developing new software-driven systems and selecting software user interfaces. Included are simple rules to help prepare validation protocols for assessing the functionality and dependability of software.

POCT1: *Point-of-Care Connectivity* provides a design framework for workstations and interfaces with an LIS.

Path of Workflow

Preexamination	Examination	Postexamination	Information Management
AUTO1		AUTO3	AUTO3
AUTO2		AUTO4	AUTO4
AUTO3			AUTO10
AUTO4			GP19
AUTO5			POCT1

AUTO08-A provides guidance for the development of a validation system for data management, which will incorporate all interfacing systems, both inside and outside the laboratory. It identifies those elements that should be included in a validation system and the critical areas that should be considered in the validation process.

In the modern clinical laboratory, it is necessary for a laboratory to use and interface with different automated systems. It is important that laboratory staff validate the integration/operation of all automated systems to ensure the accuracy of all test information.

AUTO08-A specifications are also intended to complement the interrelated CLSI/NCCLS standards developed by other automation subcommittees and to support overall operational goals for future development in laboratory instrumentation and automation.

3 Terminology

3.1 Definitions

accuracy (of measurement) – closeness of the agreement between the result of a measurement and a true value of the measurand (VIM93)[1]; closeness of agreement between a test result and the accepted reference value (ISO 3534-1)[2]; **NOTE 1:** A qualitative assessment of correctness or freedom from error; **NOTE 2:** A quantitative measure of the magnitude of error. Contrast with precision (IEEE 610.12-1990)[3]; **NOTE 3:** The measure of an instrument's capability to approach a true or absolute value. It is a function of precision and bias (FDA CDRH).[4]

The Quality System Approach

Clinical and Laboratory Standards Institute (CLSI) subscribes to a quality management system approach in the development of standards and guidelines, which facilitates project management; defines a document structure via a template; and provides a process to identify needed documents. The approach is based on the model presented in the most current edition of CLSI/NCCLS document HS1—*A Quality Management System Model for Health Care.* The quality management system approach applies a core set of "quality system essentials" (QSEs), basic to any organization, to all operations in any healthcare service's path of workflow (i.e., operational aspects that define how a particular product or service is provided). The QSEs provide the framework for delivery of any type of product or service, serving as a manager's guide. The quality system essentials (QSEs) are:

Documents & Records	Equipment	Information Management	Process Improvement
Organization	Purchasing & Inventory	Occurrence Management	Customer Service
Personnel	Process Control	Assessments—External and Internal	Facilities & Safety

AUTO08-A addresses the quality system essentials (QSEs) indicated by an "X." For a description of the other documents listed in the grid, please refer to the Related CLSI/NCCLS Publications section on the following page.

Documents & Records	Organization	Personnel	Equipment	Purchasing & Inventory	Process Control	Information Management	Occurrence Management	Assessments—External and Internal	Process Improvement	Customer Service	Facilities & Safety
GP19	GP19	GP19	AUTO1 AUTO2 GP19	GP19	X AUTO2 AUTO3 AUTO4 AUTO10 GP19 LIS4	AUTO3 AUTO4 AUTO5 GP19	GP19		GP19	GP19	GP19

Adapted from CLSI/NCCLS document HS1—*A Quality Management System Model for Health Care*.

Path of Workflow

A path of workflow is the description of the necessary steps to deliver the particular product or service that the organization or entity provides. For example, CLSI/NCCLS document GP26—*Application of a Quality Management System Model for Laboratory Services* defines a clinical laboratory path of workflow which consists of three sequential processes: preexamination, examination, and postexamination. All clinical laboratories follow these processes to deliver the laboratory's services, namely quality laboratory information.

AUTO08-A addresses the clinical laboratory path of workflow steps indicated by an "X." For a description of the other documents listed in the grid, please refer to the Related CLSI/NCCLS Publications section on the following page.

Preexamination				**Examination**			**Postexamination**	
Examination ordering	Sample collection	Sample transport	Sample receipt/processing	Examination	Results review and follow-up	Interpretation	Results reporting and archiving	Sample management
	X				AUTO10	AUTO10	X	

Adapted from CLSI/NCCLS document HS1—*A Quality Management System Model for Health Care*.

Related CLSI/NCCLS Publications*

AUTO1-A **Laboratory Automation: Specimen Container/Specimen Carrier; Approved Standard (2000).** This document provides standards for the design and manufacture of specimen containers and carriers used for collecting and processing liquid samples, such as blood and urine, for clinical testing in laboratory automation systems.

AUTO2-A2 **Laboratory Automation: Bar Codes for Specimen Container Identification; Approved Standard—Second Edition (2005).** This document provides specifications for use of linear bar codes on specimen container tubes in the clinical laboratory and for use on laboratory automation systems.

AUTO3-A **Laboratory Automation: Communications with Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems; Approved Standard (2000).** This document provides standards to facilitate accurate and timely electronic exchange of data and information between the automated laboratory elements.

AUTO4-A **Laboratory Automation: Systems Operational Requirements, Characteristics, and Information Elements; Approved Standard (2001).** This document describes operational requirements, characteristics, and required information elements of clinical laboratory automation systems. This information is used to determine the status of a clinical specimen within the clinical laboratory automation system, as well as the status of the actual components of the clinical laboratory automation system.

AUTO5-A **Laboratory Automation: Electromechanical Interfaces; Approved Standard (2001).** This document provides standards for the development of an electromechanical interface between instruments and specimen processing and handling devices used in automated laboratory testing procedures.

AUTO10-A **Autoverification of Clinical Laboratory Test Results; Approved Guideline (2006).** This document provides a general framework that will allow each laboratory to easily design, implement, validate, and customize rules for autoverification (automated verification) based on the needs of its own patient population.

GP19-A2 **Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring; Approved Guideline—Second Edition (2003).** This document identifies important factors that designers and laboratory managers should consider when developing new software-driven systems and selecting software user interfaces. Also included are simple rules to help prepare validation protocols for assessing the functionality and dependability of software.

LIS4-A **Standard Guide for Documentation of Clinical Laboratory Computer Systems (2003).** This guide covers documentation (defined as the information needed to install, use, maintain, or modify the system) for a computer system operating in a clinical laboratory.

POCT1-A2 **Point-of-Care Connectivity; Approved Standard—Second Edition (2006).** This document provides the framework for engineers to design devices, work stations, and interfaces that allow multiple types and brands of point-of-care devices to communicate bidirectionally with access points, data managers, and laboratory information systems from a variety of vendors.

* Proposed-level documents are being advanced through the Clinical and Laboratory Standards Institute consensus process; therefore, readers should refer to the most current editions.

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