Clinical and Laboratory Standards Institute®

March 2001

AUTO05-A

Laboratory Automation: Electromechanical Interfaces; Approved Standard

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.

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

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NOTE: This document is no longer being reviewed as part of the CLSI consensus process. However, because of its usefulness to segments of the health care community, it is available for its informational content.

AUTO05-A
Vol. 21 No. 5
ISBN 1-56238-432-5
Replaces AUTO5-P
ISSN 0273-3099
Vol. 19 No. 23

Laboratory Automation: Electromechanical Interfaces; Approved Standard

Volume 21 Number 5

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Abstract

CLSI document AUTO05-A—*Laboratory Automation: Electromechanical Interfaces; Approved Standard* defines a standard connection between instruments and specimen processing and handling devices (including automated centrifuges, automated aliquoters, specimen integrity devices, and automated storage and retrieval systems) and automation systems. The user of the technology can thus create an optimally functioning automated laboratory environment. The issues addressed include:

- optimal configuration of the transport system in relation to the instrument;
- relationship of the instruments and/or specimen processing and handling devices to different types of transportation referenced to a defined point of reference (POR) (e.g., automated guided vehicles or "AGVs," conveyors, and other mechanisms);
- responsibility for positioning of the specimen container in relation to the transport system and instrument;
- communication between the instruments and specimen processing and handling devices and the electromechanical interface transportation mechanism; and
- safety issues related to operation.

CLSI. *Laboratory Automation: Electromechanical Interfaces; Approved Standard*. CLSI document AUTO05-A (ISBN 1-56238-432-5). Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087, USA 2001.

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Suggested Citation

CLSI. *Laboratory Automation: Electromechanical Interfaces; Approved Standard.* CLSI document AUTO05-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2001.

Proposed Standard
October 1999

Approved Standard
March 2001

ISBN 1-56238-432-5
ISSN 0273-3099

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Contents

Matrix of NCCLS Laboratory Automation Standards

The laboratory automation standards documents, AUTO1, AUTO2, AUTO3, AUTO4, and AUTO05 are interdependent with respect to their implementation in automated laboratory systems. The matrix describes the engineering relationships between the standards elements in each of the five documents. This matrix is provided so that designers and engineers, as well as users and customers, understand the relationships between the different standards' components in an automated system. The matrix format allows the users of one document to easily identify other standard elements, which relate to the standard elements in the document or documents from which they may be working, to design a system correctly.

How to Read the Matrix (See matrix on the next page.)

The numbers listed on the horizontal (X) and vertical (Y) axes contain multiple-digit numbers (e.g., (1)5.4, (5)5.4.1.3).

The 'first digit' (in parentheses) represents one of the five automation documents (e.g., (1)5.4 is from AUTO1; (5)5.4.1.3 is from AUTO05).

The 'remaining digits' represent the specific section of that document.

The symbol XX represents the direct 'engineering relationship' between two sections.

The symbol ## represents the section's 'self'; when it has been lined up with itself on the other axis.

Matrix of NCCLS Laboratory Automation Standards

This matrix cross-links sections from NCCLS documents, AUTO1, AUTO2, AUTO3, AUTO4, and AUTO05.

	(1)5.4	(1)6.2	(1)6.6	(1)6.7	(1)6.8	(1)7.0	(1)7.2	(1)7.3	(1)7.6	(2)5.1	(2)5.2	(2)5.3	(2)5.4	(2)5.5	(2)5.6.1	(2)5.7.2	(3)5.2	(3)5.3.1	(3)5.3.3	(3)5.3.3.1.5	(3)5.3.3.10	(3)5.3.4	(3)5.3.4.2	(3)5.3.5	(3)5.3.5	(3)5.3.9	(4)5.1.1.2	(4)5.1.1.3	(4)5.2	(4)6.0	(4)7.1	(4)7.2	(4)7.3	(5)2.2.1	(5)2.2.2	(5)5.1.1	(5)5.1.2	(5)5.2.1.1.2	(5)5.2.1.1.3	(5)5.2.2.2	(5)5.3.1	(5)5.3.3	(5)5.3.3.1	(5)5.3.3.2	(5)5.3.3.3	(5)5.3.3.4	(5)5.3.3.5	(5)5.4.1.2	(5)5.4.1.3
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Preface to Laboratory Automation Standards

Background

In late 1996, NCCLS agreed to undertake the complex and challenging task of managing an effort to develop standards for clinical laboratory automation, based upon the urgent request of many leading individuals and institutions in the field. Standardization was needed to overcome difficulties and unnecessary costs incurred by laboratories and manufacturers in their efforts to integrate and simplify laboratory functions using technology.

As a result of discussions at an annual meeting of the International Conference on Automation, Robotics, and Artificial Intelligence Applied to Analytical Chemistry and Laboratory Medicine (ICAR) in 1994, an interested group of individuals had formed the Clinical Testing Automation Standards Steering Committee (CTASSC). The CTASSC approached NCCLS's leadership seeking collaboration, and believing that the desired standards could best be developed utilizing the unique voluntary consensus process, resources, and expertise of NCCLS and its member organizations. It was expected that cooperation would also be necessary with other complementary standards-developing bodies, such as ASTM, IEEE, and HL7.

The original shared vision was to take advantage of market forces within the industry and of the benefits of implementing prospective standards in the context of market forces and industry support so that customers (laboratories) and vendors could enjoy products that function together, and buyers and suppliers could agree on a format for laboratory automation systems.

NCCLS accepted the challenge and committed to the following:

- NCCLS's **voluntary consensus process** would be utilized to ensure balance, fairness, and broad review of documents by all institutions affected by the effort.
- The project would be **global** in scope and participation.
- Sources and mechanisms for **funding** would be identified to ensure that the projects would be given high priority to achieve timely completion.

NCCLS surveyed the interest of all institutions likely to be affected by the proposed standards effort, and confirmed high interest in providing both expertise and financial support. NCCLS presented the proposal at several meetings in the United States, Japan, and Europe to increase awareness of the activity and to invite broad, global participation. Based upon favorable response to the proposals, the NCCLS Board of Directors authorized the creation of a new Area Committee on Automation, chaired by Dr. Rodney S. Markin, with Mr. Paul S. Mountain serving as its vice-chairholder.

Mission Statement

The mission of the Area Committee on Automation is:

"…to identify the need for, set priorities for, and manage and coordinate the development of compatible standards and guidelines that address, in a prospective manner, the design and integration of automated clinical laboratory systems worldwide. In addition, the area committee will foster communication of the issues and developments worldwide."

Subcommittee Activities

Based upon the recommendations of the new area committee, the Board authorized establishment of five subcommittees to manage the development of the following documents:

- **AUTO1—*Specimen Container/Specimen Carrier*** contains standards for the design and manufacture of specimen containers and carriers used for collecting and processing samples, such as blood and urine, for testing on laboratory automation systems.

- **AUTO2—*Bar Codes for Specimen Container Identification*** provides specifications for linear bar codes on specimen containers for use on laboratory automation systems.

- **AUTO3—*Communications with Automated Systems*** facilitates accurate and timely electronic exchange of data and information among automated instruments, laboratory automation systems, and other information systems.

- **AUTO4—*Systems Operational Requirements, Characteristics, and Informational Elements*** provides standards of interest to operators for display of system status information such as specimen location, reagent supply, and warnings and alerts to support laboratory automation operations.

- **AUTO05—*Electromechanical Interfaces*** provides guidance for the standardization of electromechanical interfaces between instruments and/or specimen processing and handling devices and automation systems in the automated laboratory.

The five subcommittees began their efforts in the spring of 1997, with goals to develop proposed standards suitable for publication and review by the end of 1999 consistent with the formal NCCLS consensus process, and to advance them to the approved consensus stage in 2000.

Validation of Designs, Systems, and Software

The five laboratory automation standards are tools to help in the design, development, and implementation of Laboratory Automation Systems (LAS) for the clinical laboratory. Each standard may be used fully or in part, whether or not the intent is to design a completely automated or semiautomated system. These standards provide specifications that can be adhered to and verified during various phases of development for each LAS project. Adherence to standards alone does not ensure valid system design. Design validation confirms that the medical devices (LAS) meet user needs and intended use. Software validation is also a required component of the design validation of a medical device.[a] Also refer to NCCLS document GP19—*Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring.*

Attributes of Standards for Laboratory Automation Systems

It was agreed by the Area Committee on Automation that all of the laboratory automation system standards should share the following attributes:

- **Prescriptive** – Essential requirements should be prescriptive, and should define only those features essential for compatibility of instruments, devices, and laboratory automation systems.

[a] A good source of information on these and related subjects, plus other medical device regulations can be found on FDA/CDRH web pages: http://www.fda.gov/cdrh/.

- **Prospective** – Standards should describe the desired and necessary attributes which will enable and enhance the connectivity of laboratory automation system components in the future; the creation of a laboratory automation system from components should not be constrained by obsolete or inadequate technology which may be in current use.

- **Inclusive** – Current technology with widespread use should not be excluded unless it impedes connectivity; in some instances, a future date for discontinuation of a technology may be recommended to encourage upgrades, providing sufficient time for interested laboratories or suppliers to comply with new requirements.

- **Explanatory** – In cases where exclusions are recommended that are not obvious, or where consensus is not achieved, the documents should include a brief rationale and, possibly, a description of opposing viewpoints.

- **Differentiating** – In view of the complexity of the tasks, documents should differentiate between imperative prescriptions ("must" verbal forms) and discretionary recommendations ("should" verbal forms).

- **Enabling of Innovation** – The concept of "prescriptive, essential requirements" should be employed to ensure that performance requirements rather than design specifications are utilized to the extent possible.

- **Consistent** – Each document should be written to be "self-sufficient" with respect to the scope of its individual effort. The five documents are interrelated and interdependent, and presented in a consistent style using cross-references and a common glossary of terms (definitions) giving the appearance of a collection of documents.

The five interrelated automation standards are a system of related documents that are available separately or packaged in a manner similar to NCCLS “specialty collections.”

The clinical laboratory automation standards effort has attempted to engage the broadest possible worldwide representation in committee deliberations. Consequently, it was reasonable to expect that controversies existed and issues remained unresolved at the time of publication of the initial proposed-level documents. A mechanism for resolving such controversies through the subcommittees and the Area Committee on Automation was employed during the review and comment process.

The NCCLS voluntary consensus process is dependent upon broad distribution of documents for review and comment and upon the expertise of reviewers worldwide whose comments add value to the effort. At the end of the comment period, each subcommittee was obligated to review all comments and to respond in writing to all which are substantive. Where appropriate, modifications were made to the respective document, and all comments, along with the subcommittee's responses, are included in the Summary of Comments and Committee Responses at the end of each document.

Special Recognition of Global Participation

The NCCLS Board of Directors wishes to give special recognition and thanks to several organizations which have taken leadership roles in the development of these standards, including the Japanese Committee for Clinical Laboratory Standards (JCCLS), the Japanese Society for Clinical Chemistry (JSCC) and the International Federation of Clinical Chemistry (IFCC). These and other organizations have helped shape the global scope of these documents.

NCCLS can only succeed in fulfilling its responsibilities with the cooperation of other organizations and individuals. In view of the economic and quality benefits expected by laboratory practitioners and manufacturers upon implementation of standardization in automation, broad participation and cooperation was sought and obtained, and is gratefully acknowledged. NCCLS will continue to achieve a position of world leadership and influence in the development and harmonization of global standards for the healthcare community.

Recognition of the Efforts of Other Standards Organizations

NCCLS would like to acknowledge and thank the volunteers who are active participants in the related work of other standards organizations for their contributions to the laboratory automation program. Their effective leadership and outstanding volunteer service during the development and successful completion of the automation standards is greatly appreciated. This special recognition includes volunteers who are participants in the following standards organizations:

American National Standards Institute (ANSI) Health Informatics Standards Board (HISB)
ASTM Committee E31
Health Level 7 (HL7)
International Organization for Standardization Technical Committee 212 (ISO/TC 212)
Institute of Electrical and Electronics Engineers, Inc. (IEEE)
International Federation of Clinical Chemistry (IFCC)
Japanese Association of Healthcare Information Systems (JAHIS)
Japanese Committee for Clinical Laboratory Standards (JCCLS)
Japanese Society for Clinical Chemistry (JSCC)

Recognition of Laboratory Automation Fund Contributors

Many of the large instrument and automation system vendors and the users of the technology recognized the clear need to develop standards for clinical laboratory automation and information systems and actively supported NCCLS in meeting this need through the efforts of the Area Committee on Automation. To achieve standardization and ensure that automation projects do not compete with other NCCLS projects for resources, a Laboratory Automation Development Fund was created. We express our appreciation to all organizations that have supported this important program.

A list of Laboratory Automation Development Fund contributors is included on the inside front cover of this document.

Foreword

In 1996, NCCLS formed the Area Committee on Automation to develop global standards for automated laboratory systems that would result in automated system components that could be integrated into a laboratory, independent of manufacturer. Additionally, the area committee would foster communication of related issues and developments worldwide. These standards are developed to be flexible, such that they accommodate the needs of current systems as much as possible, but are targeted primarily toward future generations of laboratory automation equipment. Five interrelated standards were developed simultaneously to ensure that all aspects of automation were addressed as well as to ensure interconnectivity of the resulting designs.

AUTO05-A, *Laboratory Automation: Electromechanical Interfaces* was developed because the electromechanical interface between the instruments and specimen processing and handling devices and transportation systems is a critical part of the cost-effective manufacture, implementation, and operation of laboratory automation technology. The development of a standard**,** compatible connection between the instruments and specimen processing and handling devices and the automation systems should enable the user of the technology to create an automated laboratory environment that will function optimally for the user's individual laboratory.

In order to develop a standard that is truly global, input from all involved partiesXincluding instrument and specimen processing and handling device manufacturers, automation systems manufacturers and designers, government agencies, and laboratoriansXis necessary and has been sought. Representatives from all these arenas have participated in and contributed to the development and review of this standard. These individuals constitute the audience for this document, and we are grateful for their input. This has been an open process, and all viewpoints were considered valid and important.

These specifications are also intended to complement the interrelated NCCLS standards developed by other automation subcommittees and support overall operational goals for future development in laboratory instrumentation and automation:

AUTO1—*Laboratory Automation: Specimen Container/Specimen Carrier;*
AUTO2—*Laboratory Automation: Bar Codes for Specimen Container Identification;*
AUTO3—*Laboratory Automation: Communications with Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems;* and
AUTO4—*Laboratory Automation: Systems Operational Requirements, Characteristics, and Information Elements.*

Key Words

Clearance zones, instrument or specimen processing and handling device, laboratory automation system (LAS), point of reference (POR)

Laboratory Automation: Electromechanical Interfaces; Approved Standard

1 Introduction

Because the electromechanical interface between laboratory instruments and specimen processing and handling devices and transportation systems is a critical part of the cost-effective manufacture, implementation, and operation of laboratory automation technology, the NCCLS Area Committee on Automation and the Subcommittee on Electromechanical Interfaces developed this standard. The area committee and subcommittee believe that a standard**,** compatible connection between the instruments and specimen processing and handling devices and the automation systems will enable the user of the technology to create an optimally functioning automated laboratory environment.

2 Scope

Issues to be addressed in this standard include the optimal orientation of the transportation system in relation to the instrument and specimen processing and handling devices; relationship of the electromechanical interface to different types of transportation (e.g., automated guided vehicles, conveyors, and other transportation mechanisms) referenced to a defined point of reference; responsibility for positioning of the specimen container/specimen carrier in relation to the transportation system and instrument and specimen processing and handling devices; communication between the instruments and specimen processing and handling devices and the electromechanical interface/transportation mechanism; and safety and ergonomic issues related to operation.

Several issues were considered important to the proper functioning of the electromechanical interface, but were better addressed by one of the other interrelated standards. These issues include the placement of the bar-code label on the specimen container (AUTO2); specimen containers which would be supported (AUTO1); and communication between the laboratory automation system and the instrument and specimen processing and handling devices (AUTO3).

This standard fits into the series of interrelated NCCLS automation standards AUTO1—*Laboratory Automation: Specimen Container/Specimen Carrier*; AUTO2—*Laboratory Automation: Bar Codes for Specimen Container Identification*; AUTO3—*Laboratory Automation: Communications with Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems*; and AUTO4—*Laboratory Automation: Systems Operational Requirements, Characteristics, and Information Elements*.

3 Definitions[b]

Some of the computer-, automation-, or robotics–related terms used in the five interrelated NCCLS automation documents can be found in ANSI X3.172[1], ANSI X3.182-1990[2], ASTM D966[3], ASTM E1013[4], ASTM F149[5], ASTM F1156[6], IEEE 100,[7] IEEE 610,[8] IEEE 1007[9], and HL7 Version 2.4[10, 11]:

ACK, *n* – **1)** A data field name for a general acknowledgment message as specified in the HL7 protocol ***(HL7 V2.4*** **[10]*)***; **2)** A communication control character transmitted by a receiver as an affirmative response to a sender ***(ASTM).***

ADT, *n* – **1)** An abbreviation for admission, discharge, or transfer; **2)** A data field in a hospital information system denoting admission, discharge, or transfer.

[b] Some of these definitions are found in NCCLS document NRSCL8—*Terminology and Definitions for Use in NCCLS Documents.* For complete definitions and detailed source information, please refer to the most current edition of that document.