

# Development of Standards for Laboratory Automation

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In clinical laboratories, the installation of total laboratory automation systems and/or modular systems has grown dramatically in the 1990s, particularly in the US, Japan, and Europe. As the number of installations and level of interest grew, several individuals and corporations active in the automation field recognized that the development of prospective standards might enable customers of such systems or equipment to purchase analyzers, automation systems or devices, and software from different vendors and retain interconnectivity of such equipment. These individuals also believed that the total market for automation systems and equipment would be significantly greater with standards than without standards, especially if customers were not forced to purchase everything from one vendor, and that there might be competitive pricing and new technology fostered via the standards. This early interest in standards development led to the initiation of a program by NCCLS in 1996 to develop prospective standards for laboratory automation. Part of the NCCLS effort has involved interaction and cooperation with other standards organizations in the US and other countries. This report describes the current status of the development of prospective standards for laboratory automation by NCCLS and the relationship of those standards to those of other standards organizations.

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Since 1990, there has been a rapid increase in the installation of total laboratory automation systems and/or modular systems, particularly in the US, Japan, and Europe. Today, there are >170 laboratories in Japan (1), 35 in North America (B. Werner, Labotix Automation, Inc., Peterborough, Ontario, Canada, personal communication), and several in Europe with total automation

systems installed or in progress, and many more laboratories with various forms of modular automation or work cells. In the early 1990s, several individuals and corporations active in the automation field recognized that the existence of prospective standards might enable customers of such systems or equipment to purchase analyzers, devices, and software from different vendors and retain interconnectivity of such equipment. This concept is generally referred to as "plug and play" or "mix and match". Moreover, it was believed that the total market for automation systems and equipment would be significantly greater with standards than without standards, especially if customers were not forced to purchase everything from one vendor, and that there might be competitive pricing and new technology fostered via the standards. An ad hoc group, the Clinical Testing Automation Standards Steering Committee (CTASSC),<sup>3</sup> shown in Table 1, was formed and began to meet in conjunction with the annual meetings of the International Conference on Automation and Robotics and the AACC. The Chair of CTASSC was Dr. Rodney Markin, Department of Pathology, University of Nebraska.

In 1996, CTASSC approached NCCLS because of NCCLS's reputation and success in developing and publishing a wide range of consensus-based clinical laboratory standards. NCCLS hosted a meeting on March 13, 1996, to which executives of companies involved in laboratory automation as well as individuals in academic or laboratory environments with an interest in automation were invited. Subsequent to this meeting, which elicited a strong expression of support from the automation "industry", NCCLS agreed to undertake an aggressive program for the development of prospective standards. A special Laboratory Automation Development Fund was created to solicit financial commitments from instrument and

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<sup>3</sup> Nonstandard abbreviations: CTASSC, Clinical Testing Automation Standards Steering Committee; LIS, laboratory information system(s); HL7, Health Level Seven; ASTM, American Society for Testing and Materials; JSCC, Japanese Society for Clinical Chemistry; LAS, laboratory automation system(s); SIG, Special Interest Group (HL7); LECIS, Laboratory Equipment Control Interface Specification (ASTM); and POR, Point of Reference.

**Table 1. Members of CTASSC.**


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R. Markin, MD, PhD, University of Nebraska (Chairman)
K. Bennet, Mayo Foundation
G. Hoffmann, MD, Boehringer Mannheim Diagnostics
S. Howlett, Coulter Corporation
G. Kramer, PhD, National Institute of Science and Technology
P. Mountain, MDS AutoLab Systems
D. O'Bryan, PhD, SmithKline Beecham Clinical Labs
S. Savitz, Becton Dickinson Container Systems

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automation system vendors, large and small; laboratory information system (LIS) vendors; laboratories; professional organizations; and other users of the technology so that the standards development program could be "fast tracked" outside of the usual NCCLS budget process.

In 1996, NCCLS established an Area Committee on Automation, which consists of some CTASSC members and others. Since 1997, the Area Committee has formed and directed five separate subcommittees, which are actively developing standards that cover aspects of automation ranging from bar code labels, specimen containers (tubes), and carriers to the electromechanical and computer interfaces between devices, automation systems, and information systems and various operational considerations. The five interrelated prospective standards have all been approved for Proposed Level review with the goal to integrate them at the Approved Level during the revision process in 2000. More than 230 participants from 30 countries have been involved in this process, and cooperation and/or codevelopment has occurred with other standards organizations including Health Level Seven (HL7), the American Society for Testing and Materials (ASTM), the Japanese Committee for Clinical Laboratory Standards, the Japanese Society for Clinical Chemistry (JSCC), and the IFCC.

In addition to reviewing the need for standardization and what standards can do for consumers of automation systems or equipment, this presentation will overview the content of the five NCCLS standards, their current publication/approval status, the relationship with and involvement of other standards organizations, and NCCLS plans for future automation standardization activities.

### Need for Standards

At the NCCLS Executive Advisory Meeting (March 13, 1996, Arlington, VA), which led to the NCCLS initiative on clinical laboratory automation standards, Dr. Markin listed the following as reasons for developing automation standards: (a) reduction in total costs (including those costs for development of systems and equipment, costs paid by users or customers, manufacturing costs, and ultimately the costs paid by patients and third party payors); (b) improvement or maintenance of testing quality; (c) reduction in testing redundancy; (d) advancement

in laboratory automation technology; (e) reduction in installation and service costs; (f) availability of component-based systems (so-called plug and play); (g) recognition that no single vendor can do all; and (h) reduction in training and maintenance. Dr. Markin also noted that the time was right to initiate standards development, that there was a high level of interest in such a project among the stakeholders, that there was no current clinical laboratory automation group developing standards, and that a formal committee structure such as that used by NCCLS would ensure coordination between various worldwide standards groups.

E.J. Stephans (Enterprise Analysis Corporation, Stamford, CT), in his presentation at the same 1996 meeting, estimated that the annual worldwide market for clinical laboratory automation products would be four times greater (\$2 billion US vs \$0.5 billion) with the advent of prospective standards that could promote a mix-and-match or plug-and-play multivendor technology. He likened the prospects for the impact of automation standards to the development of standards for electronic mail, which has eliminated the incompatibilities that existed early in its development. Mr. Stephans noted his belief that automation is inevitable and will likely occur in stages, that instrument compatibility with robotics will be an important consideration, and that systems integration remains a feared nightmare. He listed several factors that would speed up the implementation of automation systems, one of which was the development of standards that promote multivendor, open architecture, mix-and-match installations.

### NCCLS Automation Standards Initiative

The Area Committee on Automation oversees five subcommittees: the Subcommittee on Specimen Container/Specimen Carrier (AUTO1); the Subcommittee on Specimen Identification (AUTO2); the Subcommittee on Communications with Automated Systems (AUTO3); the Subcommittee on System Status (AUTO4); and the Subcommittee on Electromechanical Interfaces (AUTO5). These subcommittees were formed and began meeting early in 1997. They have typically met in conjunction with the annual meetings of AACC and the Association for Laboratory Automation (ALA; these meetings are called LabAutomation '98, LabAutomation '99, and so forth) as well as at some other times. As of this report, all five subcommittees have completed standards that were approved at the Proposed Level using the NCCLS consensus process by the respective subcommittee, the Area Committee on Automation, and the NCCLS Board of Directors, and these Proposed Level Standards have been distributed for a 6-month period of review and comment. It is expected that all five standards will be approved in 2000 as Approved Level Standards and that the process of integrating them will be completed.

#### SUBCOMMITTEE ON SPECIMEN CONTAINER/SPECIMEN CARRIER (AUTO1)

The mission of this subcommittee was to establish standards for the specimen containers and carriers so that they will function optimally in laboratory automation systems (LAS) and to facilitate compatibility of the specimen carrier with specimen containers and the electromechanical interface (2). The principal accomplishments were the selection of four nominal collection container sizes as standard containers to be supported by laboratory automation systems— $13 \times 75$  mm,  $13 \times 100$  mm,  $16 \times 75$  mm, and  $16 \times 100$  mm—and the allowance of either single specimen container carriers or multiple specimen container carriers. Multiple specimen container carriers are required by the standard to have a minimum pitch (distance between the centers of adjacent tubes) of  $22.0 \pm 0.2$  mm to provide sufficient room for robotic grippers to lift the containers from the carriers (Fig. 1).

#### SUBCOMMITTEE ON SPECIMEN IDENTIFICATION (AUTO2)

The mission of this subcommittee was to assure that identification of specimen container bar codes will be effective in automated laboratory systems (3). The proposed standard defines the way bar-coded specimen identification labels are applied to clinical specimen containers. It documents the form, placement, and content of bar code labels on specimen container tubes that are used on clinical laboratory analyzers, and the specification also meets the requirement for laboratory automation systems, thus enabling the production of reliable bar coded symbols that are readable by any complying clinical laboratory analyzer and automation system. The standard uses Code 128 (4), a bar code symbology that accommodates many different languages, and recommends phasing out all other types of symbologies by the year 2003. In addition, the placement of the label was recommended to be 9 mm from the bottom and 10 mm from the top of the specimen container, with a total of no more than four

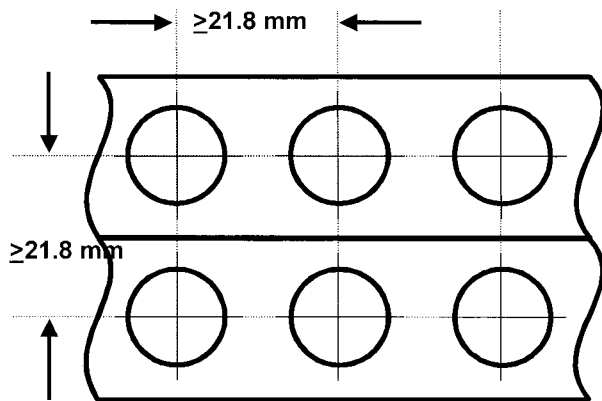


Fig. 1. Illustration of the x, y pitch orientation for a multiple specimen container carrier as defined in proposed standard AUTO1-P.

The minimum pitch allowed by the proposed standard is 21.8 mm (22 mm nominal). Equivalent x and y dimensions are maintained only if pitch and carrier width are the same. Reproduced with permission of NCCLS, Wayne, PA.

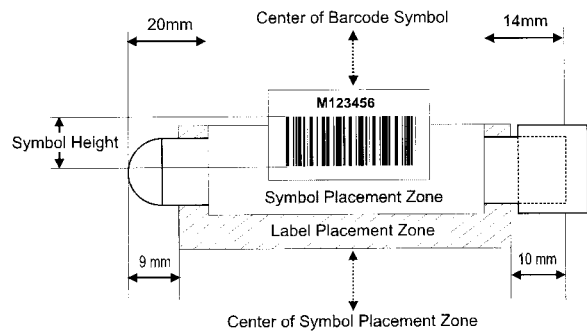


Fig. 2. Illustration of the bar code symbol read and placement zones on a tube of any length (lengths determined by standard AUTO1-P) as defined by the proposed standard AUTO2-P.

Minimum distances from the top and bottom of the tube for both the placement of the label and the position of the symbol (bar code) are defined in this standard. Reproduced with permission of NCCLS, Wayne, PA.

labels, including the manufacturer's label, applied to the tube (Fig. 2).

#### SUBCOMMITTEE ON COMMUNICATIONS WITH AUTOMATED SYSTEMS (AUTO3)

The mission of this subcommittee was to provide a protocol for communications between the LAS, LIS, automated instruments (analyzers), and pre- and postanalytical automated devices (5). The standard focuses on both the characteristics of the communications (low-level protocol) and the data to be transferred (high-level protocol). The low-level protocol was developed to meet the bandwidth and time characteristics required by automation. The high-level protocol defines specific messages and data to be transferred in automated communications. Furthermore, it was recognized that there are old protocols in use in clinical laboratories that are not supported by the standard. Because the overall intent of the standard is to be prospective in nature and to meet anticipated future needs for automation, of necessity it focuses on protocols that can meet the time and data characteristics for automation systems, and older (legacy) systems are not supported, although they are not necessarily excluded. Fig. 3 diagrams the architecture or communica-

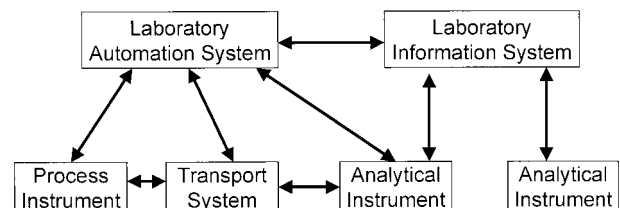


Fig. 3. Illustration of the communications flow between the different computers (or computers contained within various instruments) that may be involved in a laboratory automation environment as defined by the proposed standard AUTO3-P.

Not all elements are required, and some systems may combine the functions of a LAS and a LIS into the same computer. This model is called the Functional Control Model by the proposed standard. Reproduced with permission of NCCLS, Wayne, PA.

tions relationships between elements in a laboratory automation environment supported by this standard. Not all elements are required for implementation of the standard. As shown in the Fig. 3, separate, direct communication between the analyzer and a LIS is permitted without involving the LAS.

Early in the discussions of this subcommittee, it was concluded that one existing standard then in wide use by instrument manufacturers, ASTM 1394 (6), lacked sufficient scope and flexibility to meet the needs for total laboratory automation. Among other issues, this standard specified a low-level protocol that lacked the band width and time characteristics required by automation, and it did not specify the unique messages required for communications between the elements in an automation environment. At approximately the same time, JSCC provided to the subcommittee, through one of its members serving in both groups, a set of modifications to ASTM 1394 that JSCC believed would improve the ASTM standard. The NCCLS subcommittee passed these recommendations on to ASTM but felt that the ASTM 1394 standard, even if the JSCC modifications were adopted, still would not meet the perceived requirements for laboratory automation.

Moreover, the subcommittee recognized that the HL7 Standard (7) for electronic data exchange in all healthcare environments was not only widely used for communications within the healthcare community, but it was increasingly being adopted by LAS vendors to meet their communications needs. Thus, the subcommittee voted to use the HL7 format for a chapter that would comprise the high-level protocol of the standard. This chapter would specify new HL7 triggers, messages, and segments that the subcommittee believed were required for implementation of clinical laboratory automation communication interfaces.

To avoid violating HL7's copyrights, the Chair of the NCCLS Subcommittee on Communications with Automated Systems contacted HL7, which led to the formation of a Special Interest Group (SIG) on Laboratory Automation within the HL7 organization. This SIG has held several meetings within the HL7 meetings, leading to finalization of this proposed chapter of messages, triggers, and segments for laboratory automation. The Co-Chairs and principal participants on the HL7 SIG were also the key individuals on the NCCLS subcommittee, which brought consistency to this project. This proposed chapter would be a new HL7 chapter (Chapter 13) in the next HL7 version (Ver. 2.4) to be balloted to HL7 members in December 1999, with the approval process completed in early 2000 (8).

The control model in the NCCLS proposed standard is an extension of the model described in another standard, Laboratory Equipment Control Interface Specification (LECIS) (9). The difference between the two models is that the NCCLS model includes provisions for communication between modules, not just between controller and module. In the LECIS standard, the definition of "equipment"

includes the NCCLS definitions of both process instruments and analytical instruments. The LECIS standard describes a set of standard equipment behaviors that must be accessible under remote control to facilitate set up and operation of laboratory equipment in an automated laboratory. Details of the NCCLS standard's application of the LECIS standard are contained in the NCCLS document (5), and a table of the standard equipment behaviors from LECIS as adapted to the laboratory automation standards are contained in the NCCLS AUTO4 standard discussed below.

#### SUBCOMMITTEE ON SYSTEM STATUS (AUTO4)

The mission of this subcommittee was to delineate the operational requirements, characteristics, and information elements required to define the status of instruments and/or specimen processing/handling devices connected to and interacting with the LAS (10). The intent of the standard is to facilitate the compatibility between the instruments and/or specimen processing/handling devices and the LAS. The standardized system status information exchange should facilitate continuous, uninterrupted operation of the LAS with appropriate human intervention. Among many tables contained in this standard is a table of equipment states based on the LECIS standard (9) as discussed in the paragraph above. The standard also defines specimen quality measures, quality control, calibration, nomenclature, and inventory elements.

#### SUBCOMMITTEE ON ELECTROMECHANICAL INTERFACES (AUTO5)

The mission of this subcommittee was to define a standard-compatible connection between instruments and automated technology to create an automated laboratory environment that will function optimally for the individual laboratory (11). This standard establishes specifications for a "Point of Reference" (POR) that can be used by manufacturers of automated analyzers, process equipment and devices, and automation systems involving conveyors or tracks, robotic carts, or other transport devices to orient against so that one device can locate and access a specimen transported by another device. The standard specifies the height from the floor, the distance from the instrument, the location of the specimen container, and permits the use of false-bottom tubes and specimen cups. Fig. 4 is a graphic representation of the POR and the specimen container, showing the various dimensions and clearance zones relative to the floor and an analyzer as defined in the standard.

#### Path Forward for NCCLS Laboratory Automation Standards

Two of the five Proposed Level NCCLS standards (AUTO2 and AUTO3) completed 6-month comment periods at the end of June 1999. AUTO1 will complete that period at the end of January 2000, and AUTO4 and AUTO5 at the end of April 2000. After revisions to each standard to



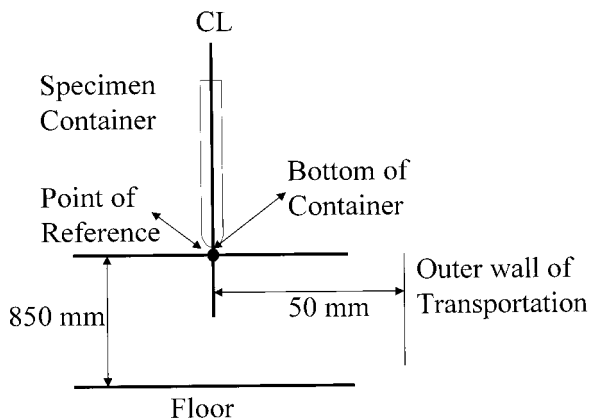


Fig. 4. Illustration of the POR for use by manufacturers of automated analyzers and automation systems to be able to mechanically interface their systems to each other.

In addition to the height from the floor, the proposed standard AUTO5-P also defines other essential clearances or distances to facilitate these interfaces. Reproduced with permission of NCCLS, Wayne, PA.

incorporate input received during the respective comment periods have been made, these five standards for laboratory automation will be integrated and published later in 2000 as Approved Level standards.

In the usual NCCLS process, subcommittees are "disbanded" after publication of their Approved Level standards, and each area committee assumes responsibility, ~5 years later, to review its standard for consideration of updating or revising information relevant to the needs of newer technologies being utilized. In the past, NCCLS standards applied to "mature" procedures or technologies that usually were not evolving rapidly. Because the automation standards are prospective in nature and do apply to a technology that is evolving rapidly, there are more issues that could be addressed in these standards that would make the standards more beneficial for both manufacturers and users. Therefore, updates are planned for cycles of 2-3 years instead of the typical NCCLS 5-year cycle. Among the possible extensions of the laboratory automation standards are standards for automation of pharmaceutical analytical laboratories.

The NCCLS project to develop prospective standards

for laboratory automation has been highly successful. Active participation in the drafting of the five Proposed Level standards was obtained from >230 participants in 30 countries, and cooperation was obtained from several other standards organizations. These prospective NCCLS standards will guide laboratorians seeking to automate their laboratories and manufacturers of automation equipment and automated analyzers, as well as facilitating continued progress in this field.

## References

1. Kawai T. The status of laboratory automation in Japan [Abstract]. First Cherry Blossom Symposium on Clinical Laboratory Automation and Robotics, March 29-April 1, 1998, Kochi, Japan:37.
2. NCCLS. Laboratory automation: specimen container/specimen carrier; proposed standard. NCCLS Document AUTO1-P [ISBN 1-56238-378-7]. Wayne, PA: NCCLS, 1999:1-20.
3. NCCLS. Laboratory automation: bar codes for specimen container identification; proposed standard. NCCLS Document AUTO2-P [ISBN 1-56238-360-4]. Wayne, PA: NCCLS, 1998:1-18.
4. ANSI/AIM. BC4-1995. Uniform symbology specification, code 128. Pittsburgh, PA: American National Standards Institute/Automatic Identification Manufacturers, 1995.
5. NCCLS. Laboratory automation: communications with automated clinical laboratory systems, instruments, devices, and information systems; proposed standard. NCCLS Document AUTO3-P [ISBN 1-56238-361-2]. Wayne, PA: NCCLS, 1998:1-58.
6. American Society for Testing and Materials. Standard specification for transferring information between clinical instruments and computer systems. ASTM 1394-91. Philadelphia, PA: American Society for Testing and Materials, 1991.
7. Health Level Seven. HL7 standard, Ver. 2.3.1. Ann Arbor, MI: Health Level Seven, Inc., 1999.
8. Hawker C, Knafel A, Boje JF, Keesom H, Kowalski B. Clinical laboratory automation. Proposed chapter 13 of HL7 standard, Ver. 2.4. Ann Arbor, MI: Health Level Seven, Inc., 2000.
9. American Society for Testing and Materials. Laboratory equipment control interface (LECI) specification. ASTM E49.52. Philadelphia, PA: American Society for Testing and Materials, 1998.
10. NCCLS. Laboratory automation: systems operational requirements, characteristics, and information elements; proposed standard. NCCLS Document AUTO4-P [ISBN 1-56238-389-2]. Wayne, PA: NCCLS, 1999:1-32.
11. NCCLS. Laboratory automation: electromechanical interfaces; proposed standard. NCCLS Document AUTO5-P [ISBN 1-56238-390-6]. Wayne, PA: NCCLS, 1999:1-28.