

Automation Alert**Standards in Lab Automation: Enabling Plug and Play**

Standards in Lab Automation: Enabling Plug and Play

By Charles Hawker, PhD

In late 1996 the NCCLS (now CLSI) established an Area Committee on Automation and initiated the development of prospective standards for laboratory automation to facilitate the more rapid growth of automation systems and components. One of the program's main goals was to enable laboratory users to select elements from more than one vendor or to connect analyzers from one vendor to the automation equipment of another vendor, a concept generally referred to as "plug and play." The initial NCCLS program resulted in five approved standards that were published in 2000-2001. These five standards, listed below, became important reference guides for all vendors of laboratory automation, for vendors of analyzers wishing to enable their systems to be connected to the automation systems of their prospective customers and for laboratories interested in purchasing automation systems.

AUTO1-A

AUTO1-A (Laboratory Automation: Specimen Container/Specimen Carrier) established four sizes of tubes (13 and 16 mm diameter and 75 and 100 mm lengths) that all automation systems were expected to accommodate. Further, specimen carriers—whether single carriers aggregated next to each other or carriers for multiple tubes—were expected to have a standard "pitch" of 22.0 0.2 mm. The pitch is defined as the distance from the center of one tube to the center of the adjacent tube in both the X and Y directions.

AUTO2-A

AUTO2-A (Laboratory Automation: Bar Codes for Specimen Container Identification) was revised and published in late 2005 as AUTO2-A2. This standard originally recommended that all automated systems employ the Code 128 symbology for bar codes by December 2003. Among several recommendations in the 2005 update, a principal change addressed the affixing of bar codes to non-cylindrical collection systems and devices.

AUTO3-A

AUTO3-A (Laboratory Automation: Communications with Automated Clinical Laboratory Systems, Instruments, Devices and Information Systems) was developed by CLSI in collaboration with another standards organization, Health Level 7 (HL7), because the CLSI subcommittee recognized that the HL7 standard possessed the basic framework to meet the communication needs in laboratory automation systems if the appropriate automation-specific information could be added to the existing standard; whereas other standards, such as those from ASTM, were judged to be too narrow in scope. Accordingly, members of the CLSI subcommittee began participating in HL7 as a Special Interest Group and wrote a new chapter of the HL7 standard (Chapter 13) as well as making modifications to other chapters of the standard. Both organizations were able to agree on joint publication rights, and the CLSI standard contains the relevant sections of the HL7 standard that pertains to laboratory automation and other important information for companies and laboratories developing automated systems.

AUTO4-A

AUTO4-A (Laboratory Automation: System Operational Requirements, Characteristics, and Information Elements) provides standards of interest to operators regarding system status information such as specimen location, reagent supplies, quality control and various warnings and alerts, and makes recommendations about the ability of an automated system to provide management information and performance metrics.

AUTO5-A

AUTO5-A (Laboratory Automation: Electromechanical Interfaces) provides the framework for the connections between automated specimen processing and handling equipment, transportation systems and analytical instruments. This standard established the concept of a "point of reference" (POR), which is where the specimen container on a transport system is to be positioned so that an analyzer probe can aspirate a sample and identify which system (e.g., the analyzer or automation system) should be responsible for each function or operation.

The Informatics Influence

In 2001, the scope of the Area Committee on Automation was expanded and its name changed to the Area Committee on Automation and Informatics. In part, this change was made since many of the newer projects being proposed as standards or guidelines were informatics related. Also in 2001, the American Society for Testing and Materials (ASTM) Committee on Health Informatics (E31) decided to no longer support its nine standards in the E31.13 series and, after discussions with CLSI, the latter agreed to take over the ownership of the standards. The ASTM E31.13 series of standards were renumbered by CLSI as LIS1-A through LIS9-A.

Additional Projects

The CLSI Area Committee for Automation and Informatics has undertaken numerous projects since the publication of the first five automation standards. Those of particular interest to laboratories developing or

implementing automated systems include: AUTO7-A, Laboratory Automation: Data Content for Specimen Identification and AUTO10-A, Automated Verification of Clinical Laboratory Test Results. The latter is particularly valuable to laboratories implementing automation since much of the productivity improvement related to automation is due to the interfacing of analyzers and the implementation of rules for autoverification. This guideline provides requirements and recommendations for the design, building, implementation, validation and compliance of algorithms for autoverification and establishes a means for design of an open framework that allows users to easily configure their systems to meet the needs of their laboratories based on their own medical philosophies and the needs of their physicians and patient populations.

Several of the other projects of the CLSI Area Committee are more informatics-related. They include: LIS2-A2, Specification for Transferring Information Between Clinical Laboratory Instruments and Information Systems (the original ASTM 1394-97 standard, but updated and reissued as a second edition by CLSI); GP19-A2, Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation; AUTO8-P, Protocols to Validate Laboratory Information Systems; AUTO9-A, Remote Access to Clinical Laboratory Diagnostic Devices via the Internet; and AUTO11-A, IT Security of IVD Instruments and Software Systems. These latter two standards provide security for protected patient information in situations where laboratory instruments are being accessed remotely via the Internet by the vendors for service-related issues or are interfaced to the laboratory's LIS.

The Hidden Standard

Finally, it is worth noting that there was an AUTO6-A. This standard, titled Point-of-Care Connectivity, was originally developed by a group of point-of-care vendors and users called the Connectivity Industry Consortium (CIC) with input from HL7 and the Institute of Electrical and Electronics Engineers Standards Association (IEEE-SA). The CIC needed a true standards organization to foster its publication and adoption and CLSI agreed to do that. CLSI later formed an Area Committee on Point-of-Care Testing, which took responsibility for this standard and subsequently renumbered it as POCT1-A.

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CLSI sponsors the ADVANCE bimonthly column, "POC Connectivity Concepts."

Suggested Reading

Hawker CD and Schlank MR. Development of standards for laboratory automation. *Clin Chem* 2000;46(5):746-750.

Approved Standards

- AUTO1-A: Laboratory Automation: Specimen Container/Specimen Carrier
- AUTO2-A: Laboratory Automation: Bar Codes for Specimen Container Identification
- AUTO3-A: Laboratory Automation: Communications with Automated Clinical Laboratory Systems, Instruments, Devices and Information Systems
- AUTO4-A: Laboratory Automation: System Operational Requirements, Characteristics and Information Elements
- AUTO5-A: Laboratory Automation: Electromechanical Interfaces

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