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Standard Guide for Laboratory Information Management Systems (LIMS)[1]

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1. Scope

1.1 This guide covers issues commonly encountered at all stages in the life cycle of Laboratory Information Management Systems from inception to retirement. The sub-sections that follow describe details of scope of this document in specific areas.

1.2 *High Level Purpose*—The purpose of this guide includes: *(1)* help educate new users of Laboratory Information Management Systems (LIMS), *(2)* provide standard terminology that can be used by LIMS vendors and end users, *(3)* establish minimum requirements for primary LIMS functions, *(4)* provide guidance for the specification, evaluation, cost justification, implementation, project management, training, and documentation, and *(5)* provide an example of a LIMS function checklist.

1.3 *LIMS Definition*—The term Laboratory Information Management Systems (LIMS) describes the class of computer systems designed to manage laboratory information.

1.4 *Laboratory Categories*—The spectrum of laboratories that employ LIMS is wide spread. The following break down provides an overview of the laboratory categories that use LIMS as well as examples of laboratories in each category.

1.4.1 *General Laboratories*:

1.4.1.1 Standards (ASTM, IEEE, ISO), and

1.4.1.2 Government (EPA, FDA, JPL, NASA, NRC, USDA, FERC).

1.4.2 *Environmental*:

1.4.2.1 Environmental Monitoring.

1.4.3 *Life Science Laboratories*:

1.4.3.1 Biotechnology,

1.4.3.2 Diagnostic,

1.4.3.3 Healthcare Medical,

1.4.3.4 Devices, and

1.4.3.5 Pharmaceuticals Vet/Animal.

1.4.4 *Heavy Industry Laboratories*:

1.4.4.1 Energy & Resources,

1.4.4.2 Manufacturing & Construction,

1.4.4.3 Materials & Chemicals, and

1.4.4.4 Transportation & Shipping.

1.4.5 *Food & Beverage Laboratories*:

1.4.5.1 Agriculture,

1.4.5.2 Beverages,

1.4.5.3 Food, and

1.4.5.4 Food Service & Hospitality.

1.4.6 *Public Sector Laboratories*:

1.4.6.1 Law Enforcement,

1.4.6.2 State & Local Government,

1.4.6.3 Education, and

1.4.6.4 Public Utilities (Water, Electric, Waste Treatment).

1.4.7 *Laboratory Size*:

1.4.7.1 This guide covers topics regarding LIMS for a range of laboratory sizes ranging from small with simple requirements to large multi-site/global laboratories with complex requirements. Although the guide addresses complex issues that impact primarily large LIMS implementations, laboratories of all sizes will find this guide useful. The implementation times and recommendations listed in this guide are directed at medium and large laboratories.

1.5 *Integration*—Integration between LIMS and other external systems (document management, chromatography data systems, laboratory instruments, spectroscopic data systems, Enterprise Resource Planning (ERP), Manufacturing Execution Systems (MES), Corrective Action and Preventative Action (CAPA), Electronic Laboratory Notebooks (ELNs) and data archive) provides significant business benefits to any laboratory. Integration between LIMS and other external systems is discussed at a high level in this guide including data interchange and XML standards.

1.6 *Lifecycle Phases*—The LIMS lifecycle described in this guide includes the following phases: *(1)* project initiation, *(2)* requirements analysis, *(3)* design, *(4)* build/configure, *(5)* test and commission, *(6)* operation and maintenance, and *(7)* retirement. This guide is intended to provide an understanding of the LIMS system life cycle and good practices for each of the activities. It will help first time LIMS implementers plan and manage their LIMS projects while seasoned LIMS users

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may use the LIMS system life cycle to maintain existing LIMS and prepare for the implementation of the next generation LIMS.

1.7 *Audience*—This guide has been created with the needs of the following stakeholders in mind: *(1)* end users of LIMS, *(2)* implementers of LIMS, *(3)* quality personnel, *(4)* information technology personnel, *(5)* LIMS vendors, *(6)* instrument vendors, *(7)* individuals who must approve LIMS funding, *(8)* LIMS application support specialists, and *(9)* software test/validation specialist. Information contained in this guide will benefit a broad audience of people who work or interact with a laboratory. New LIMS users can use this guide to understand the purpose and functions of LIMS. The guide can also help prospective LIMS users in understanding terminology, configurations, features, design, benefits and costs. Individuals who are purchasing a LIMS may use this guide to identify functions that are recommended for specific laboratory environments. Research and Development staff of commercial LIMS vendors may use the guide as a tool to evaluate, identify, and potentially improve the capabilities of their products. LIMS vendor sales staff may use the guide to represent functions of their LIMS product to prospective customers in more generic and product neutral terms.

1.8 *Out of Scope*—The full description and use of systems mentioned in this guide within the context of interfaces to LIMS are beyond the scope of this standard. Examples of these systems include Chromatography Data Systems (CDS), Electronic Laboratory Notebooks (ELN), Data Archive, Scientific Data Management Systems (SDMS), Enterprise Resource Planning (ERP), Manufacturing Execution Systems (MES) and Electronic Document Management Systems (EDMS).

2. Referenced Documents

2.1 *ASTM Standards:* [2]

E 1340 Guide for Rapid Prototyping of Information Systems

E 1947 Specification for Analytical Data Interchange Protocol for Chromatographic Data

E 1948 Guide for Analytical Data Interchange Protocol for Chromatographic Data

E 2066 Guide for Validation of Laboratory Information Management Systems

E 2077 Specification for Analytical Data Interchange Protocol for Mass Spectrometric Data

E 2078 Guide for Analytical Data Interchange Protocol for Mass Spectrometric Data

2.2 *ANSI Standards:*[3]

ANSI HL7 Arden Syntax for Medical Logic Systems

2.3 *EPA Data Standards:*[4]

40 CFR 160, Code of Regulations, 54 FR 34067, August 17, 1989

40 CFR 792, Code of Regulations, 54 FR 34043, August 17, 1989

EPA 2185 Good Automated Laboratory Practices Principles and Guidance to Regulations For Ensuring Data Integrity In Automated Laboratory Operations with Implementation Guidance, 1995 Edition

2.4 *FDA Regulations:*[5]

FDA 21CFR Part 11, Code of Regulations, 57 FR 32185, July 21, 1992

2.5 *GAMP:*[6]

GAMP 4 Good Automated Manufacturing Practice (GAMP) Guide for Validation of Automated Systems in Pharmaceutical Manufacture, ISPE, December 2001

GAMP Good Practice Guide, Validation of Laboratory Computerized Systems, April 2005 (this is a supplement to the GAMP 4 document)

GAMP GPG, IT Infrastructure Control and Compliance, ISPE, September 2005

2.6 *IEEE Standards:*[7]

IEEE 829 1998 IEEE Standard for Software Test Documentation

IEEE 830 1998 Recommended Practice for Software Requirements Specifications

IEEE 1008 1987 IEEE Standard for Software Unit Testing

IEEE 1012 2004 IEEE Standard for Software Verification and Validation

IEEE 1028 1997 IEEE Standard for Software Reviews

IEEE 1063 2001 IEEE Standard for Software User Documentation

2.7 *Instrument Interface Standards:*

AnIML (Analytical Information Markup Language), an emerging standard for laboratory instruments covering multiple analytical techniques. The E13.15 subcommittee is responsible for the development of this standard.[8]

NetCDF (Network Common Data Form), an interface for array-oriented data access and a library that provides an implementation of the interface. The netCDF library also defines a machine-independent format for representing scientific data. Together, the interface, library, and format support the creation, access, and sharing of scientific data. Unidata Program Center at the University Corporation for Atmospheric Research (UCAR).[9]

Staged Electronic Data Deliverable (SEDD), EPA—eXtensible Markup Language (XML)—joint standard developed by US EPA Office of Superfund Remediation and Technology Innovation (OSRTI) Analytical Services

[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

[4] Available from United States Environmental Protection Association (EPA), Ariel Rios Bldg., 1200 Pennsylvania Ave., NW, Washington, DC 20460.

[5] Available from Food and Drug Administration (FDA), 5600 Fishers Ln., Rockville, MD 20857.

[6] Available from the International Society for Pharmaceutical Engineering (ISPE) ,3109 W. Dr. Martin Luther King, Jr. Blvd., Suite 250, Tampa, FL 33607 USA.

[7] Available from Institute of Electrical and electronics Engineers, Inc., (IEEE), 445 Hoes Lan., P.O. Box 1331, Piscataway, NJ 08854-1331.

[8] Reference Schaefer, B. A., Poetz, D., and Kramer, G. W., "Documenting Laboratory Workflows Using the Analytical Information Markup Language," *Journal of the Association for Laboratory Automation*, 9 (6), 2004, pp. 375-381, and http://animl.sourceforge.net/

[9] Available from UCAR: http://www.unidata.ucar.edu/software/netcdf/guidec/guidec-16.ht

Branch (ASB)and US Army Corps of Engineers (US ACE)[10]

ISO/IES 12207 Subcommittee for Electronic Data Standards (SEDS), reference spectroscopic databases sponsored by the International Union of Pure and Applied Chemistry (IUPAC) and standards related to the Joint Committee on Atomic and Molecular Physical Data (JCAMP) and JCAMP-DX (XML in the chemistry area) ISO Standards ISO/IEC 12207 Information technology—Software life cycle processes, as amended by ISO/IEC 12207 AMD2[11]

2.8 *NRC Standards:*[12]

FDA CFR Pa rt 21 10 Code of Federal Regulations (CFR) Part 21.42 FR 28893, June 6, 1977

FDA CFR Part 50, Appendix B 10 Code of Federal Regulations (CFR) Part 50 Appendix B. 35 FR 10499, June 27, 1970, as amended at 36 FR 18301, Sept. 11, 1971; 40 FR 3210D, Jan. 20, 1975

FDA CFR Part 50, Appendix E 10 Code of Federal Regulations (CFR) Part 50 Appendix E. 45 FR 55410, Aug. 19, 1980, et sequentia as amended

FDA CFR Part 50, Appendix K 10 Code of Federal Regulations (CFR) Part 50 Appendix K. 21 FR 355, Jan. 19, 1956, unless otherwise noted

3. Terminology

3.1 This guide defines terminology used in the LIMS field. Section 3.2 defines LIMS terms specific to this guide. Users of this document should request a terminology list from each vendor with a cross reference to the terms used in this guide.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *CAPA*, *n*—acronym for corrective action, preventative action.

3.2.2 *Chromatography Data System (CDS)*, *n*—computer system used to acquire, analyze, store and report information from chromatography instruments.

3.2.3 *EDMS*, *n*—acronym for electronic document management system.

3.2.4 *ELN*, *n*—acronym for electronic laboratory notebook. computer system designed to replace paper laboratory notebooks.

3.2.4.1 *Discussion*—Lab notebooks in general are used by scientists and technicians to document research, experiments and procedures performed in a laboratory. A lab notebook is often maintained to be a legal document and may be used in a court of law as evidence. Similar to an inventor's notebook, the lab notebook is also often referred to in patent prosecution and intellectual property litigation. Electronic laboratory notebooks enable electronic access to information including searching, data capture from instruments and collaboration between laboratory personnel and personnel outside the laboratory.

3.2.4.2 *Discussion*—ELNs can be divided into two categories: specific ELNs contain features designed to work with specific applications, scientific instrumentation or data types. Refer to laboratory exectuion system (LES) as an example of a specific ELN. Cross-disciplinary ELNs or generic ELNs are designed to support access to all data and information that needs to be recorded in a lab notebook.

3.2.5 *ERP*, *n*—acronym for enterprise resource planning.

3.2.6 *GALP*, *n*—the GALPs are a union of federal regulations, policies, and guidance documents. Several of the GALP provisions are embodied in EPA's Good Laboratory Practice Standards (GLPs). The GLPs are regulations that govern the management and conduct of most nonclinical laboratory studies submitted to EPA's office of Toxic Substances and its Office of Pesticide Programs. Reference EPA 2185.

3.2.7 *GAMP*, *n*—acronym for good automated manufacturing practice.

3.2.8 *LES*, *n*—acronym for laboratory execution system. Computer system employed in the laboratory at the analyst work level to aid in step enforcement for laboratory test method execution.

3.2.8.1 *Discussion*—Laboratory execution systems (LES) are a sub class of electronic laboratory notebooks (ELNs) that focus on step execution of defined laboratory test methods. The LES are typically employed in Quality Control laboratories that have defined test methods. The functionality of LES and LIMS overlap in the areas of result entry, instrument integration and specification flagging. Deployment options include LES and LIMS systems deployed as an integrated solution, LIMS only or LES only (for limited functions).

3.2.9 *Laboratory Information Management System (LIMS)*, *n*—*(1)* acronym for laboratory information management System. Computer application(s) software and hardware that can acquire, analyze, report, and manage data and information in the laboratory; *(2)* computer software that is used in the laboratory for the management of samples, test results, laboratory users, instruments, standards and other laboratory functions such as invoicing, plate management, stability LIMS, work flow automation; and *(3)* a class of application software which handles storing and managing of information generated by laboratory processes. These systems are used to manage laboratory processes including defining master data, sample management and chain of custody, work assignment, instrument and equipment management, standard and reagent management, scheduled sample collection and testing, result entry, result review, reporting, trending and business rule enforcement. These systems interface with laboratory instruments (for example, chromatography data systems (CDS), spectrophotometers and balances) and other information systems such enterprise resource planning (ERP), manufacturing execution systems (MES), or health care based laboratory information systems). A LIMS is a highly flexible application, which can be configured or customized to facilitate a wide variety of laboratory workflow models.

3.2.10 *LIMS configuration*, *n*—refers to the process of preparing the LIMS for use in a particular laboratory. It typically involves using an interface provided by the vendor to enter information that describes the types of samples, analytical methods, specifications, etc. used in the laboratory.

[10] Available from US EPA http://www.epa.gov/superfund/programs/clp/sedd.htm

[11] Available from International Organization for Standardization (ISO).

[12] Available from U.S. Nuclear Regulatory Commission (NRC), PDR, 01F13, Washington, DC 20555.