# Chapter 1 — GALP Overview

## 1. PURPOSE

Most of the health and environmental data EPA uses in its regulatory programs are analyzed in and reported by laboratories. Increasingly, these laboratories employ laboratory information management systems (LIMS) to acquire, record, manipulate, store, and archive their data (see 2.c APPLICABLE SYSTEMS). Though many benchmarks are scattered across EPA's regulatory programs, EPA has no consistent set of standards for the use of LIMS that promote integrity of laboratory data.

The purpose of the Good Automated Laboratory Practices (GALPs) is to establish a uniform set of procedures to assure that all LIMS data used by EPA are reliable and credible.

## 2. SCOPE AND APPLICABILITY

### a. Organizations

The GALPs are applicable to all EPA organizations, personnel, or agents (contractors and grantees) of EPA who collect, analyze, process, or maintain laboratory data for EPA. These organizations include the Agency's Regional Laboratories, and laboratories submitting data through contracts or grants with EPA, including the Superfund Contract Laboratory Program (CLP). Other organizations who wish to improve assurance of the integrity of laboratory data where LIMS are used are encouraged to review and implement applicable GALP provisions (see also 6. RESPONSIBILITIES).

## b. Relation to Other Regulations and Requirements

Federal regulations, EPA directives, policies, and its contract requirements govern the activities performed by laboratories that submit data to the Agency. Various laboratories are involved in the collection and analysis of environmental data and not all laboratories are subject to the same set of regulations and requirements. EPA's Contract Laboratory Program sets requirements by explicit clauses and clauses incorporated by reference in their governing contracts. Similarly, laboratories that submit studies in support of the registration or re-registration of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) are subject to the Good Laboratory Practice (GLP) Standards [40 Code of Federal Regulations (CFR) Part 160. Federal Register Vol. 54, No. 158, August 17, 1989]. Laboratories that submit studies required by the test rules and negotiated testing agreements section of the Toxic Substances Control Act (TSCA) are subject to the GLP regulations at 40 CFR Part 792.

The GALPs include many of the GLP requirements for managing the conduct of studies. The GALPs supplement the GLPs with Federal and EPA policies that address automated hardware, software development and operation, electronic transfer, and systems security. These are collectively referred to by the term Information Resources Management (IRM) policies. Thus the GALPs integrate GLP practices and procedures with IRM practices and procedures, to ensure the integrity of data that are entered, stored, and manipulated by the LIMS (see Figure 1.1).

## c. Applicable Systems

The GALPs use the acronym LIMS, laboratory information management system, to describe the automated laboratory systems that collect and manage data discussed in this Directive. There is a limitless range of possible configurations of automated data collection and processing equipment, communication components, types of operating system software, database management systems, and application software that can constitute a LIMS. The GALPs are directed to *most* configurations that are involved with entering, recording, manipulating, modifying, and retrieving data.

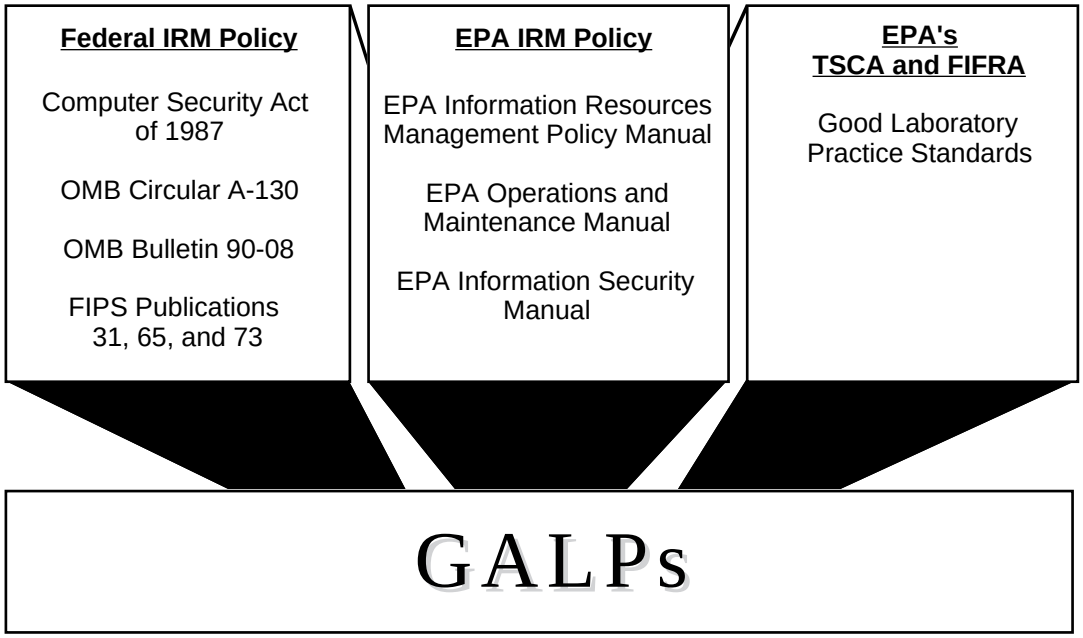


Figure 1.1. Principles and Regulations Used in Developing the GALPs
(See 10. ACRONYMS)

Not all automated laboratory systems are LIMS. Automated laboratory systems that record data but do not allow changes to the data are not LIMS (see Figure 1.2). For example, an instrument that measures weights and produces or maintains a readout of the weight is not a LIMS, if the true reading cannot be altered by a person prior to recording.

The ability to effect changes to original observations or measurements is the factor in determining whether the automated laboratory system is a LIMS (see Figure 1.3). If data entering automated laboratory systems can be manipulated or changed in any way by the action of a person prior to being recorded, then that automated laboratory system is a LIMS.

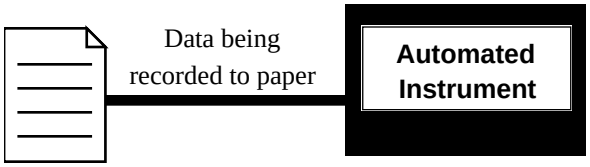


Figure 1.2. Automated Laboratory Systems NOT Subject to the GALPs

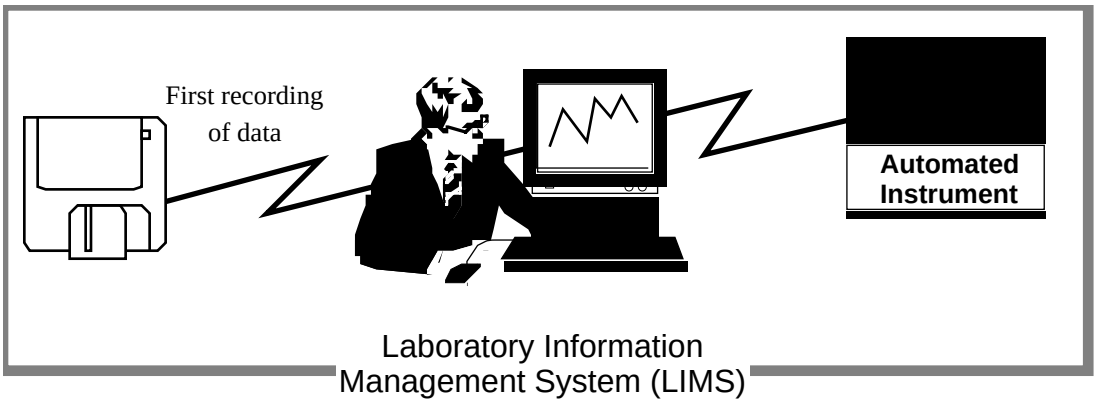


Figure 1.3. Automated Laboratory Systems Subject to the GALPs

## 3. DOCUMENT ORGANIZATION

This document is organized into two chapters. This first chapter, GALP OVERVIEW, describes basic facts about the GALPs, including the purpose they serve, the scope, applicability and organization of this directive, the policy the GALPs implement, authorities and references supporting the GALPs, responsibilities of organizations, background information, the GALP provisions, definitions of terms, list of acronyms, and sources for Federal information resources management publications referenced in the GALP.

Chapter 2, GALP IMPLEMENTATION ASSISTANCE, provides additional information about each GALP provision. It is intended to assist in the successful application of each GALP provision. See the introduction to Chapter 2 for additional discussion.

## 4. POLICY

It is EPA policy to implement and comply with all applicable information management laws mandated by Congress, all requirements issued by the Office of Management and Budget (OMB), all Federal Information Resource Management Regulations (FIRMR) issued by the General Services Administration (GSA), and all Information Processing Regulations issued by the National Institute of Science and Technology (NIST).

It is also EPA policy that data collected, analyzed, processed, or maintained to support health and environmental effects studies be of sufficient accuracy and integrity to support effective environmental management.

EPA recognizes that absolute data integrity is not possible and that reliability and defensibility are determined by adherence to principles and practices that contribute to improving integrity. The GALPs balance risk against cost, incorporating existing Federal and EPA policies.

## 5. AUTHORITIES AND REFERENCES

### a. Authorities

(1) Computer Security Act of 1987, Public Law 100-235

(2) EPA Information Resources Management Policy Manual, Chapter 17 and Chapter 18, September 1994

(3) EPA Information Security Manual, December 1989

(4) EPA Operations and Maintenance Manual, April 1990

(5) Federal Information Processing Standards (FIPS) Publication 31: Guidelines for Automatic Data Processing Physical Security and Risk Management, June 1974

(6) Federal Information Processing Standards (FIPS) Publication 65: Guidelines for Automatic Data Processing Risk Analysis, August 1979

(7) Federal Information Processing Standards (FIPS) Publication 73: Guidelines for Security of Computer Applications, June 1980

(8) Federal Insecticide, Fungicide and Rodenticide (FIFRA); Good Laboratory Practice Standards. 40 CFR Part 160. Federal Register Vol. 54, No. 158, August 17, 1989

(9) Office of Management and Budget (OMB) Circular A-130, Management of Federal Information Resources, as Amended, April 29, 1992 *(this Circular may be subject to revision*)

(10) Office of Management and Budget (OMB) Bulletin 90-08, Guidance for Preparation of Security Plans for Federal Computer Systems that Contain Sensitive Information, July 1990

(11) Toxic Substances Control Act (TSCA); Good Laboratory Practice Standards. 40 CFR Part 792. Federal Register Vol. 54, No. 158, August 17, 1989

### b. References

(1) Automated Laboratory Standards: Current Automated Laboratory Data Management Practices, EPA/OIRM (Final, June 1990)

(2) Automated Laboratory Standards: Evaluation of Good Laboratory Practices for EPA Programs, EPA/OIRM (Draft, June 1990)

(3) Automated Laboratory Standards: Survey of Current Automated Technology, EPA/OIRM (Final, June 1990)

(4) Automated Laboratory Standards: Evaluation of the Use of Automated Financial System Procedures, EPA/OIRM (Final, June 1990)

(5) Automated Laboratory Standards: Evaluation of the Standards and Procedures Used in Automated Clinical Laboratories, EPA/OIRM (Draft, May 1990)

(6) National Institute of Science and Technology (NIST) Special Publication 500-166, Computer Viruses and Related Threats: A Management Guide (August 1989)

(7) U.S. Department of Commerce National Bureau of Standards (NBS) Special Publication 500-101, Care and Handling of Computer Magnetic Storage Media (June 1983)

## 6. RESPONSIBILITIES

a. The Office of Information Resources Management (OIRM) shall:

(1) be responsible for developing, establishing, providing, and maintaining the GALPs.

(2) provide guidance and technical assistance, where feasible and appropriate, in implementing and improving the provisions of the GALPs.

b. Each "Primary Organization Head" (defined by EPA Order 1000.24 as the Deputy Administrator, Assistant Administrators, Regional Administrators, the Inspector General, and the General Counsel) is responsible for:

(1) complying with all applicable Federal and EPA rules and regulations affecting the collection, analysis, processing, storage, or maintenance of LIMS data. These are indicated in each GALP provision by the use of underlined lettering, such as *EPA Information Security Manual*.

(2) reviewing the GALPs and taking the necessary measures to implement appropriate provisions provided in the GALPs that will improve the integrity of LIMS data.

## 7. BACKGROUND

a. EPA relies heavily on laboratory data to accomplish its mission. The accuracy and integrity of these data are essential to EPA's ability to effectively formulate policy, make decisions, and take action on issues involving public health and the environment. Laboratory data are therefore critical Agency assets and must be managed and protected as such.

b. The computer is increasingly replacing and augmenting many manual operations in the laboratory. Much of the laboratory data now submitted to EPA have been created, collected, processed, managed, or in other ways manipulated by LIMS.

c. Laboratory data are exposed to potential loss and misuse from a variety of accidental and deliberate causes. Cases involving the corruption, loss, and inappropriate modification of computerized laboratory data provided to EPA have resulted in debarments, suspensions, fines, and criminal prosecution.

d. EPA's OIRM conducted several studies to assess the automated data management practices employed by laboratories to ensure data integrity. Principal findings and recommendations of these studies included:

(1) The integrity of computer-resident data is at risk in many laboratories providing scientific and technical data to EPA. Inadequate system security, data verification, standardized procedures, designation of responsibility, and documentation are to a large extent responsible for these risks.

(2) EPA has no Agencywide policy for laboratories that collect and manage LIMS data. The laboratories that provide data to EPA are subject to differing regulations, policies, and contract requirements for the conduct of studies and management and operation of the laboratory.

(3) In many cases, the requirements that a laboratory must follow in conducting a study are vague or ambiguous regarding the special concerns and issues related to LIMS. For example, FIFRA and TSCA GLPs refer to "recorded data from automated instruments"; however, standards or guidance for performing LIMS risk assessments and LIMS software development and modification are not directly addressed in the GLPs.

(4) EPA has no definitive guidelines to aid the Agency's inspectors and auditors when they inspect laboratories that use LIMS in the conduct of a study.

(5) The need for Agencywide standards and guidance is recognized and acknowledged by the laboratory community and LIMS vendors.

(6) Data management practices should be standardized for all laboratories supporting EPA programs and the Agency should assume the responsibility for establishing these standards. The guidance and training provided to the Agency's inspectors and auditors should also be augmented accordingly.

e. In response to the findings of these studies, OIRM initiated the development of the GALP. The first draft of the GALP was issued in December 1990. Since that time, over one thousand copies of the draft GALP document have been distributed to EPA regional and program offices, other Federal agencies, industry, associations, and private citizens and groups.

f. OIRM received over 600 individual comments on the first draft of the GALP document. OIRM additionally contracted for the review of the document by

subject-area experts in the fields of laboratory data systems, laboratory management, systems security, telecommunications, systems development, quality assurance, and information resources management. Document comments received from all sources were reviewed and evaluated by OIRM in the development of this final version of the GALP.

# 8. GOOD AUTOMATED LABORATORY PRACTICES

## 8.1 LABORATORY MANAGEMENT

When LIMS Raw Data (see **8.4.1**) are collected, analyzed, processed, or maintained, laboratory management shall:

8.1.1 ensure that personnel clearly understand the function(s) they are to perform on the LIMS.

8.1.2 ensure that a Quality Assurance Unit (QAU) monitors LIMS activities as described in **8.3**.

8.1.3 ensure that personnel, resources, and facilities are adequate and available as scheduled.

8.1.4 receive reports of QAU inspections of the LIMS (see **8.3.3**) and audits of LIMS Raw Data (see **8.3.5**) and ensure that corrective actions are promptly taken in response to any deficiencies.

8.1.5 approve the standard operating procedures (SOPs) setting forth the methods that assure LIMS Raw Data integrity, ensure that any deviations from SOPs and applicable GALP provisions are appropriately documented and that corrective actions are taken and documented, and approve subsequent changes to SOPs (see **8.11**).

8.1.6 assure that each applicable GALP provision is followed. With the exception of **8.1**, **8.2**, and **8.3**, laboratory management may delegate GALP implementation and compliance to one or more responsible persons.

## 8.2 PERSONNEL

When LIMS Raw Data are collected, analyzed, processed, or maintained, laboratory management shall ensure that all LIMS support staff and users:

8.2.1 have adequate education, training, and experience to perform assigned LIMS functions.

8.2.2 have a current summary of their training, experience, and job description, including their knowledge relevant to LIMS design and operation, maintained at the facility.

8.2.3 are of sufficient number for timely and proper operation of the LIMS.

## 8.3 QUALITY ASSURANCE UNIT

When LIMS Raw Data are collected, analyzed, processed, or maintained, laboratory management shall designate a Quality Assurance Unit (QAU) to monitor LIMS functions and procedures. The QAU shall:

8.3.1 be entirely separate from and independent of LIMS personnel, and shall report directly to laboratory management.

8.3.2 have immediate access to the LIMS data, SOPs, and other records pertaining to the operation and maintenance of the LIMS.

8.3.3 inspect the LIMS at intervals adequate to ensure the integrity of the LIMS Raw Data (see **8.3.5**); prepare inspection reports that include a description of the LIMS operation inspected, the dates of the inspection, the person performing the inspection, findings and problems observed, action recommended and taken to resolve existing problems, and any scheduled dates for reinspection; and report to laboratory management any problems that may affect data integrity.

8.3.4 determine that no deviations from approved SOPs were made without proper authorization (see **8.1.5**) and sufficient documentation.

8.3.5 periodically audit the LIMS Raw Data to ensure their integrity.

8.3.6 ensure that the responsibilities and procedures applicable to the QAU, the records maintained by the QAU, and the method of indexing such records are documented and are maintained.

## 8.4 LIMS RAW DATA

Laboratory management shall ensure that:

8.4.1 LIMS Raw Data (LRD) and LRD storage media on which they reside (see **9. DEFINITIONS** LIMS Raw Data and LIMS Raw Data storage media) are identified and documented. This documentation shall be included in the laboratory's SOPs.

8.4.2 the individual(s) responsible for entering and recording LIMS Raw Data is (are) uniquely identified when the data are recorded, and the time(s) and date(s) are documented.

8.4.3 the instrument transmitting LIMS Raw Data is uniquely identified when the data are recorded, and the time and date are documented.

8.4.4 procedures and practices to verify the accuracy of LIMS Raw Data are documented and included in the laboratory's SOPs, and managed as described in **8.11**.

8.4.5 procedures and practices for making changes to LIMS Raw Data are documented and provide evidence of change, preserve the original recorded documentation (see **8.4.2** and **8.4.3**), are dated, indicate the reason for the change, identify the person who made the change and, if different, the person who authorized the change. These procedures shall be included in the laboratory's SOPs, and managed as described in **8.11**.

## 8.5 SOFTWARE

When software is used to collect, analyze, process, or maintain LIMS Raw Data, laboratory management shall ensure that:

8.5.1 SOPs are established, approved, and managed as described in **8.11** for:

8.5.1.1 development methodologies that are based on the size and nature of software being developed. EPA and its agents shall comply with *EPA Information Resources Management Policy Manual, Chapter 17*.

8.5.1.2 testing and quality assurance methods to ensure that all LIMS software accurately performs its intended functions, including: acceptance criteria, tests to be used, personnel responsible for conducting the tests, documentation of test results, and test review and approval.

8.5.1.3 change control methods that include instructions for requesting, testing, approving, documenting, and implementing changes. When indicated, change control methods shall also include reporting and evaluating problems, as well as implementing corrective actions.

8.5.1.4 version control methods that document the LIMS software version currently used.

8.5.1.5 maintaining a historical file of software, software operating procedures (manuals), software changes, and software version numbers.

8.5.2 documentation is established and maintained to demonstrate the validity of software used in the LIMS:

8.5.2.1 for existing and commercially-available LIMS, minimum documentation shall include, but not be limited to: a description of the software and functional requirements; listing of all algorithms and formulas; and, as they occur, testing and quality assurance, installation and operation, maintenance/enhancement, and retirement.

8.5.2.2 for new LIMS development or modification of existing LIMS, documentation shall cover all phases of the generic software life cycle. EPA laboratories and those of its agents (contractors and grantees) shall comply with the documentation requirements specified in *EPA Information Resources Management Policy Manual*, *Chapter 17*.

8.5.3 all documentation specified in **8.5.2** is readily available in the facility where the software is used, and the SOPs specified in **8.5.1** are readily available in the laboratory areas where procedures are performed.

8.5.4 a historical file of software and the documentation specified in **8.5.2** are retained according to procedures outlined in **8.9**.

## 8.6 SECURITY

Laboratory management shall ensure that security practices to assure the integrity of LIMS data are adequate. EPA laboratories and those of its agents (contractors and grantees) shall comply with EPA's Information Security Policy.

## 8.7 HARDWARE

When LIMS Raw Data are collected, analyzed, processed, or maintained, laboratory management shall ensure that LIMS hardware and communications components are:

8.7.1 of adequate design and capacity, and a description is documented and maintained.

8.7.2 installed and operated in accordance with manufacturer's recommendations and, at installation, undergo acceptance testing that conforms to acceptance criteria. SOPs shall be established and maintained to define the acceptance criteria, testing, documentation, and approval required for changes to LIMS hardware and communications components.

8.7.3 adequately tested, inspected, and maintained. SOPs for and documentation of these routine operations shall be maintained. Documentation of non-routine maintenance shall also include a description of the problem, the corrective action, acceptance testing criteria, and the acceptance testing performed to ensure that the LIMS hardware and communications components have been adequately repaired.

## 8.8 COMPREHENSIVE TESTING

When LIMS Raw Data are collected, analyzed, processed, or maintained, laboratory management shall ensure that comprehensive testing of LIMS performance is conducted, at least once every 24 months or more frequently as a result of software (see **8.5.2**) or hardware (see **8.7.2**) changes or modifications. These tests shall be documented and the documentation shall be retained and available for inspection or audit.

## 8.9 RECORDS RETENTION

Laboratory management shall ensure that retention of LIMS Raw Data, documentation, and records pertaining to the LIMS comply with EPA contract, statute, or regulation; and SOPs for retention are documented, maintained, and managed as described in **8.11**.

## 8.10 FACILITIES

When LIMS Raw Data are collected, analyzed, processed, or maintained, laboratory management shall ensure that:

8.10.1 the environmental conditions of the facility housing the LIMS are regulated to protect against LIMS Raw Data loss.

8.10.2 environmentally adequate storage capability for retention of LIMS Raw Data, LIMS Raw Data storage media, documentation, and records pertaining to the LIMS are provided.

### 8.11 STANDARD OPERATING PROCEDURES

Laboratory management shall ensure that:

8.11.1 SOPs include, but are not limited to, those specified in **8.4.1, 8.4.4, 8.4.5, 8.5.1.1** through **8.5.1.5, 8.7.2**, **8.7.3**, and **8.9**. Each current SOP shall be readily available where the procedure is performed.

8.11.2 SOPs are periodically reviewed at a frequency adequate to ensure that they accurately describe the current procedures.

8.11.3 SOPs are authorized and changed in accordance with **8.1.5**.

8.11.4 a historical file of SOPs is maintained.

## 9. DEFINITIONS

The definitions below generally come from existing Federal and EPA information management publications. While broader or narrower definitions, published in other authoritative sources, could have been used, those below were selected because they are more focused on the environment of laboratory data management.

**Acceptance testing** Formal testing conducted to determine whether or not a system satisfies its acceptance criteria and to enable the customer to determine whether or not to accept the system. *FIPS Publication 101, June 1983.*

**Assurance** A measure of confidence that the security features and architecture of [a LIMS] accurately mediate and enforce the security policy. Modified from *EPA Risk Analysis Guideline (Draft) March 1992.*

**Audit** A qualitative and quantitative evaluation of the documentation and procedures associated with the LIMS to verify that resulting LIMS Raw Data are of acceptable quality. Modified from EPA Quality Assurance Management Staff, January 6, 1994.

**Change control** Management and implementation methodologies associated with increasing or correcting system capabilities, a partial system redesign, or determining software obsolescence. *EPA Operations and Maintenance Manual, April 1990.*

**Commercially-available software** Software that is available through lease or purchase in the commercial market. Software that is furnished as part of the [LIMS] system

but that is separately priced is included. *EPA Information Resources Management Policy Manual, Chapter 17, September 1994.*

**Data** A representation of facts, concepts, information, or instructions suitable for communication, interpretation, or processing by humans [or by a LIMS]. *EPA Risk Analysis Guideline (Draft) March 1992.*

**Design** (software life cycle) The stage that specifies the automated and manual functions and procedures, the computer programs, and data storage techniques that meet the requirements identified and the security and control techniques that assure the integrity of the system. *EPA Information Resources Management Policy Manual, Chapter 17, September 1994.*

**Documentation** The process of gathering written or electronic information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results. Modified from *ASME NQA-1, Quality Assurance Program Requirements for Nuclear Facilities, 1989 edition as cited in ANSI/ASQC E4-1994.*

**Facility** The premises and operational unit(s) that are necessary for operating a LIMS. Modified from *Organization for Economic Cooperation and Development Series on Principles of Good Laboratory Practice and Compliance Monitoring Number 1: The OECD Principles of Good Laboratory Practice. Environment Monograph No. 45 (1992).*

**Hardware** Physical equipment such as the computer and its related peripheral devices, tape drives, disk drives, printers, etc. *EPA Information Resources Management Policy Manual, Chapter 17, September 1994.*

**Information** Any communication or reception of knowledge such as facts, data or opinions, including numerical, graphic, or narrative forms, whether oral or maintained in any medium, including computerized databases (e.g., floppy disk and hard disk), papers, microform (microfiche or microfilm), or magnetic tape. *EPA Risk Analysis Guideline (Draft) March 1992.*

**Initiation** (software life cycle) A request for the development of a system to meet a need for information or to solve a problem for the individual making the request. *EPA Information Resources Management Policy Manual, Chapter 17, September 1994.*

**Inspect** To measure, examine, test or gauge one or more characteristics of an entity and compare the results with specified requirements in order to establish whether

conformance is achieved for each characteristic. Modified from *ANSI/ASQC 34-1994 Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs, January 3, 1995.*

**Installation and operation** (software life cycle) Incorporation and continuing use of the new system by the organization. *EPA Information Resources Management Policy Manual, Chapter 17, September 1994.*

**Integrity** Sound, unimpaired or perfect condition. That computer security characteristic that ensures that computer resources operate correctly and that the data in the databases are correct. This characteristic protects against deliberate or inadvertent unauthorized manipulation of the system and ensures and maintains the security of entities of a computer system under all conditions. Integrity is concerned with protecting information from corruption. *EPA Risk Analysis Guideline (Draft) March 1992.*

**Laboratory Information Management System (LIMS)** See **2.c APPLICABLE SYSTEMS.**

**Laboratory management** Those individuals directly responsible and accountable for planning, implementing, and assessing work, and for the overall operation of a facility. Modified from *ANSI/ASQC 34-1994 Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs, January 1995.*

**LIMS Raw Data (LRD)** Original observations recorded by the LIMS that are needed to verify, calculate, or derive data that are or may be reported.

**LIMS Raw Data (LRD) storage media** The media to which LIMS Raw Data are first recorded.

**Maintenance/enhancement** (software life cycle) Resolving problems not detected during testing, improving the performance of the product and modifying the system to meet changing requirements. (Full-scale enhancements require full life cycle analysis.). *EPA Information Resources Management Policy Manual, Chapter 17, September 1994.*

**Original observations** The first occurrence of human-readable information.

**Programming** (software life cycle) Coding of the program modules that implement the design. *EPA Information Resources Management Policy Manual, Chapter 17, September 1994.*

**Quality Assurance Unit** Any person or organizational element designated by laboratory management to monitor the LIMS functions and procedures. Modified from *EPA GLPs, August 17, 1989.*

**Records** All books, papers, maps, photographs, machine-readable materials, or other documentary materials, regardless of physical form or characteristics, made or received by an agency of the United States Government under Federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the government or because of the informational value of the data in them. Library and museum material made or acquired and preserved solely for reference or exhibition purposes, extra copies of documents preserved only for convenience of reference, and stocks of publications and of processed documents are not included. *44 U.S.C 3301.*

**Requirements analysis** (software life cycle) Determination of what is required to automate the function(s) identified by the organization. *EPA Information Resources Management Policy Manual, Chapter 17, September 1994.*

**Retirement** (software life cycle) The stage which ends use of the system. *EPA Information Resources Management Policy Manual, Chapter 17, September 1994.*

**Security** The set of laws, rules, and practices that regulate how an organization manages, protects, and distributes sensitive data. *EPA Risk Analysis Guideline (Draft) March 16, 1992.*

**Software** Computer programs, procedures, rules and associated documentation pertaining to the operation of a computer system. *EPA Information Resources Management Policy Manual, Chapter 17, September 1994.*

**Software life cycle** The period of time beginning when a software product is conceived and ending when the product no longer performs the function for which it was designed. The software life cycle is typically broken into phases such as initiation, requirements analysis, design, programming, testing and quality assurance, instal-

lation and operation, maintenance, and retirement. *EPA Information Resources Management Policy Manual, Chapter 17, September 1994.*

**Software version control** Management of changes or revisions to a specific baseline software module or application. Software version control provides a mechanism to control changes and to return to any previous revision of the application or module.

**Standard Operating Procedures (SOPs)** Documentation setting forth methods of operation that laboratory management is satisfied are adequate to insure the quality and integrity of LIMS Raw Data. Modified from *EPA GLPs, August 17, 1989.*

**Testing** The examination of the behavior of a program by executing the program on sample data sets. *EPA Information Resources Management Policy Manual, Chapter 17, September 1994.*

**Testing and quality assurance** (software life cycle) Ensuring that the system works as intended and that it meets applicable organization standards of performance, reliability, integrity and security. *EPA Information Resources Management Policy Manual, Chapter 17, September 1994.*

**Validity** A state or quality of software that provides confirmation that the particular requirements for a specific intended use are fulfilled. In design and development, validity concerns the process of examining a product or result to determine conformance to user needs. Modified from *ISO 8402:1994, Quality Management and Quality Assurance* as cited in *ANSI/ASQC E4-1994.*

**Verify** To review, inspect, test, check, audit, or otherwise establish and document whether or not LIMS Raw Data are accurate. Modified from *FIPS Publication101, June 1983.*

## 10. LIST OF ACRONYMS

| | |
|---|---|
| CFR | Code of Federal Regulations |
| CLP | Contract Laboratory Program |
| EPA | Environmental Protection Agency |
| FIFRA | Federal Insecticide, Fungicide, and Rodenticide Act |
| FIPS | Federal Information Processing Standard |
| FIRMR | Federal Information Resource Management Regulation |
| GALP | Good Automated Laboratory Practice |
| GLP | Good Laboratory Practice |
| GSA | General Services Administration |
| IRM | Information Resources Management |
| LIMS | Laboratory Information Management System |
| LRD | LIMS Raw Data |
| NIST | National Institute of Science and Technology |
| OIRM | Office of Information Resources Management |
| OMB | Office of Management and Budget |
| QAU | Quality Assurance Unit |
| SOP | Standard Operating Procedure |
| TSCA | Toxic Substances Control Act |

## 11. SOURCES

Copies of the Federal information resources management publications referenced in the GALP can be ordered via mail, telephone, or the Internet.

### Computer Security Act of 1987

This is a Federal regulation and should be available in local public libraries.

**The Internet World Wide Web address is**:

http://www.first.org/secplcy/csa_87.txt

### Office of Management and Budget (OMB) publications

Office of Management and Budget
Assistant Director of Administration
OMB Publications
725 17th Street, NW
Washington, D.C. 20503

telephone: (202) 395-7332 (then press 2)

**The Internet addresses for OMB publications are:**

World Wide Web: http://www2.infoseek.com/Titles?qt=OMB

Gopher: gopher://pula.financenet.gov:70/11/docs/central/omb

### EPA publications

U.S. Environmental Protection Agency
OARM/FMSD
Publication Distribution Section
Mailcode 3204
401 M St., SW
Washington, D.C. 20460

telephone: (202) 260-5797

For References 1 through 5 on page 1-6 (Automated Laboratory Standards), contact:


| | | |
|---|---|---|
| Rick Johnson | Voice: | (919) 541-1132 |
| EPA (MD-34) | Fax: | (919) 541-1383 |
| RTP, NC 27711 | Internet: | johnson.rick@epamail.epa.gov |


**The Internet addresses for EPA IRM documents are:**

| | |
|---|---|
| World Wide Web: | http://www.epa.gov/docs/IRMPolicy.html |
| Gopher: | gopher://gopher.epa.gov:70/11/Initiatives/IRM.Policy |

## National Institute of Standards and Technology (NIST) and National Bureau of Standards (NBS) publications

National Technical Information Service
U.S. Department of Commerce
5285 Port Royal Road
Springfield, VA 22161
(703) 487-4650

**The Internet World Wide Web address for NIST is**:

http://www.ncsl.nist.gov

**The Internet World Wide Web address for FIPS Publications is**:

http://www.ncsl.nist.gov/fips/