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LABORATORY INFORMATION MANAGEMENT SYSTEMS

A laboratory information management system (LIMS) is a computer or computer network used to automate the acquisition and management of raw analytical data. In its simplest form, it tracks samples and test results through analytical laboratories and provides summaries of the status of these samples and tests. In its most advanced form, the system is interfaced to the laboratory's instrumentation and communication network to allow automation of data gathering, compilation, and reporting.

The first LIMS appeared in the 1970s, and their use became more widespread as a result of U.S. Federal Government regulations (1, 2), particularly in the pharmaceutical industry. LIMS was seen as a method to meet the government agencies' requirement for laboratories to account for the results of analyses. In the mid-1980s, the U.S. Environmental Protection Agency (U.S. EPA) regulations for laboratories taking part in the Superfund program, to remediate designated sites, resulted in further expansion of the use of LIMS. In the early years, a LIMS was expensive and was customized for each installation using in-house personnel or a contract software vendor. More recently, the approximately 40 vendors selling LIMS have been able to design the systems with enough flexibility to meet the needs of most laboratories. Commercial systems can usually be delivered quickly and the laboratory benefits from a large user base, compatible accessories, and future enhancements.

The benefits of a LIMS depend largely on the needs of the laboratory and the type of system installed. In general, a LIMS improves the management of the laboratory by providing more accurate and timely information regarding work load and work-load distribution. The productivity is increased through the automation of many clerical and routine tasks associated with sample identification, tracking, and transcription of results. The quality of the data can be improved through automated data acquisition, reduction in transcription errors, and automatic enforcement of validation analysis and standardization procedures. Finally, the system can be used to meet regulatory agency compliance requirements.

1. LIMS Function

LIMS is a database management system designed to help laboratories, particularly analytical laboratories, manage the data generated in the laboratory. The LIMS database usually includes biographical information about the sample, such as its source, the customer, a project or charge number, and the final results of the analysis or analyses. An additional important function of a LIMS is to provide on-line information concerning a sample's status. This information can include the sample's location, the status of a particular analysis, and any completed results. LIMS is of most value when multiple or sequential analyses are required on one or a series of samples. A LIMS system can generate multiple requests and have samples split and sent to the appropriate laboratory. The system can then be used to compile results into a single report for the client. The various functions of a LIMS can be summarized as follows as analytical or managerial tasks (3) and Figure 1 outlines the typical flow of a sample coming into the laboratory (4). Suppliers of LIMS include Banyon Systems Inc., Beckman Instruments Inc., Challenger Group Inc., Chesapeake Software Inc., Cirrus Technology, Digital Equipment Corp., DSP Development Corp., Hewlett-Packard, IBM, Keithley Instruments, Laboratory Data

Systems Inc., Laboratory MicroSystems Inc., LabWare Ltd., Northwest Analytical Inc., Novell Inc., PE Nelson Div., Radian Corp., Statistical Graphics Corp., 3Com Corp., Varian Associates Inc., and VG Instruments (5).

Analytical level tasks

- Sample number generation
- Bar-code label generation
- Sample log-in
- Verification of data format entered into the computer
- Worksheet generation
- Construction and checking of calibrated curves
- Direct data acquisition from chromatographs
- Data collection for analytical instruments
- Entry of instrumental readings
- Manual results entry
- Interpretation of calibrated curves and quality control samples
- Interpretation and acceptance of sample data
- Routine automatic calculations
- Plotting routines for visualization of analytical data

Managerial level tasks

- Acknowledgement of sample receipt
- Backlog investigation
- Sample and status tracking
- Database searches
- Numbers of samples assayed
- Tests utilized
- Numbers of samples analyzed per instrument
- Cost per assay
- Customer charges
- Results collation and presentation
- Report generation
- Scheduling and rescheduling of work
- Archiving and retrieval of data
- Workload status and the justification of equipment
- Regulatory agency compliance
- Audit trail for all database transactions
- Security: class or hierarchy
- Instrument records and calibration where appropriate

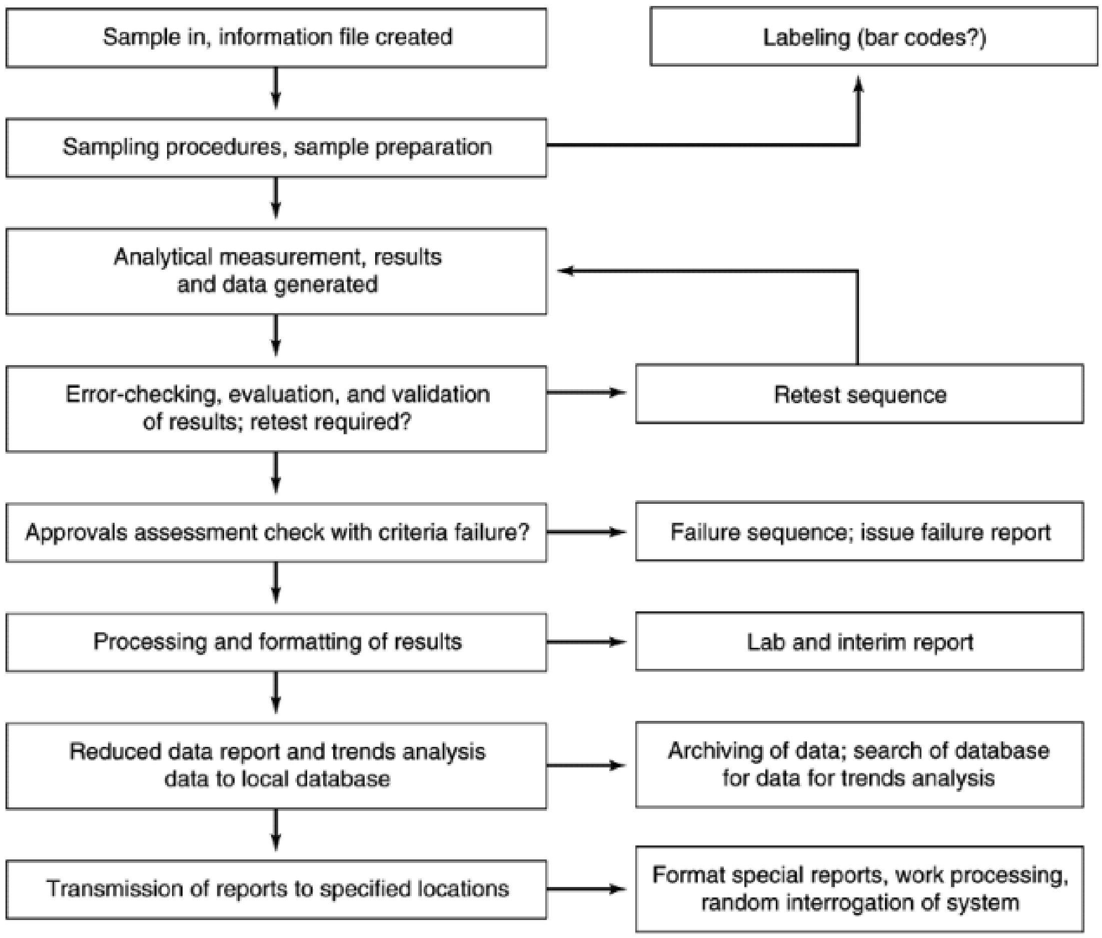

Fig. 1. LIMS procedure flow chart (sample handling and reporting) (4).(Courtesy of the Royal Society of Chemistry.)

2. Automation

The development and widespread use of computers and microprocessors in control laboratory instruments has made it possible to fully automate a laboratory, including interfacing instruments directly to a LIMS. In the fully automated laboratory, a sample is logged into a LIMS, then transferred to a laboratory where it is prepared for analysis by a robot, which then transfers it to an autosampler or analyzer. Once analyzed, the data is transferred through a communications link to a device which could convert the raw data into information that a customer needs. For example, in a simple case, a nmr spectrum could be compared to spectra on file to yield an identification of an unknown. In more complex instances, a data set could be compared to standards and by using pattern recognition techniques the LIMS would be able to determine the source of a particular raw material. Once the data is reduced and interpreted, the LIMS becomes the repository of the information. A schematic for such a fully automated laboratory is shown in Figure 2 (6).

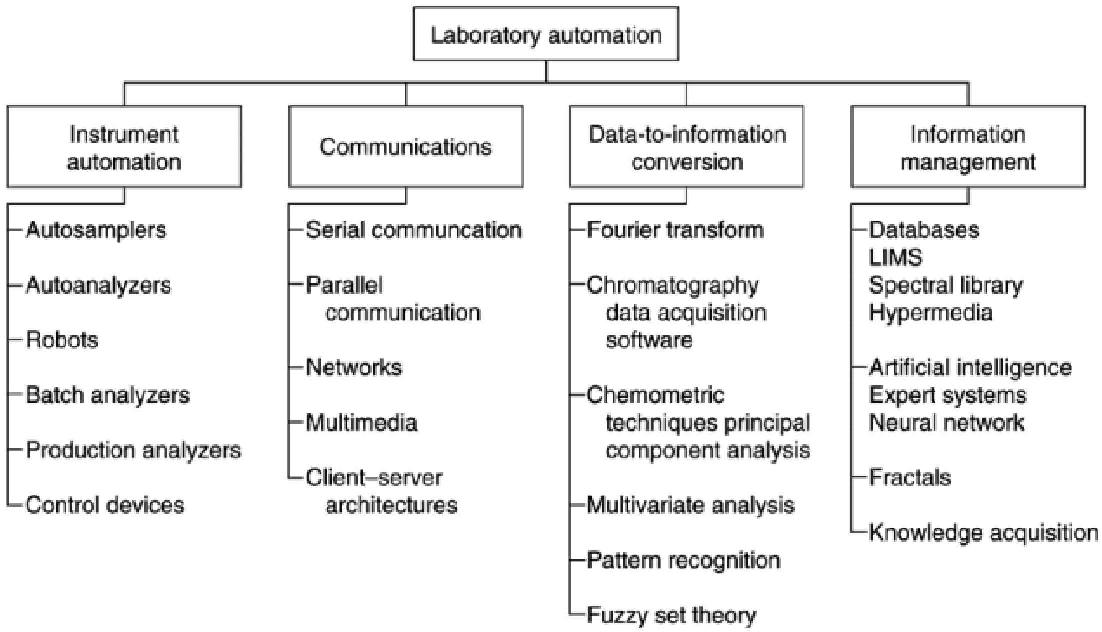

Fig. 2. Components of a fully automated laboratory (6).

3. Quality Management

The business activity of the organization dictates quality requirements for the LIMS. Security and regulatory requirements for LIMS data define the level of effort expended to validate a LIMS and the data being stored. In addition, the quality of the hardware and software used to implement the LIMS both play a role in determining overall system quality.

The level of quality required in a LIMS is related to the particular role played by the system in the organization's business. In an R&D environment, for example, the primary reason for a LIMS might be to compare and document new analytical methods.

Manufacturing organizations often implement LIMS systems in their Quality Assurance (QA) and Quality Control (QC) laboratories. These labs ensure that the product is of high quality (QA), and examine intermediates to keep the production process on target (QC). Statistical quality control (SQC) uses techniques such as Shewhart control charts, Pareto charts, and time-to-failure (Weibull) analysis (7). Production labs incorporate such features as alarms to notify of SQC limit violations and trend violations. LIMS can be used in conjunction with computer-integrated manufacturing systems (CIMS) to pinpoint problems during production. Some LIMS systems have built-in statistical tools, and others enable the user to export data to other software packages for analysis.

Clinical laboratories in the pharmaceutical and medical fields are subject to regulatory and confidentiality requirements. The U.S. Food and Drug Administration issues guidelines for good laboratory practices (GLP) and good manufacturing practices (GMP). Organizations manufacturing regulated products for use in humans (such as drugs and medical devices) must validate the integrity of their LIMS systems. The EPA has drafted good automated laboratory practice (GALP) guidelines to be used in their contract laboratories. This emerging standard promises to become a worldwide framework for the validation of automated data integrity (8).

The International Standards Organization 9000 (ISO 9000) standard, developed by the European Economic Community (EEC), also impacts manufacturers' implementation of LIMS systems. ISO 9000 is a set of standards which are required for manufacturers selling products to the EEC. The 9000 standards are credited with playing an important part in the impetus to greater computerization of laboratory information management (9).

A LIMS system must be validated to ensure data security and integrity and to ensure it complies with applicable government regulations. The validation process includes first developing a strategy and setting specific objectives for validation. Modular testing of the system should be employed, and a detailed test protocol should be developed for each LIMS module (10). Documentation is critical throughout the validation period. The test strategies and procedures, as well as flow charts for the LIMS source code, must be documented. Training documentation for LIMS users and administrators should be included in a complete validation package.

The hardware and software used to implement LIMS systems must be validated. Computers and networks need to be examined for potential impact of component failure on LIMS data. Security concerns regarding control of access to LIMS information must be addressed. Software, operating systems, and database management systems used in the implementation of LIMS systems must be validated to protect against data corruption and loss. Mechanisms for fault-tolerant operation and LIMS data backup and restoration should be documented and tested. One approach to validation of LIMS hardware and software is to choose vendors whose products are precertified; however, the ultimate responsibility for validation remains with the user. Validating the LIMS system's operation involves a substantial amount of work, and an adequate validation infrastructure is a prerequisite for the construction of a dependable and flexible LIMS system.

4. Costs and Benefits

The first step in acquiring a LIMS is justifying a need for it. The investment must provide increased value to laboratory customers, while also providing benefits to LIMS users and their management. The organizational framework has to be adaptable to the operational changes that acquisition of a LIMS will cause. If computer technology is not widely used in the organization, it may be difficult to automate laboratory functions. LIMS systems are specialized information systems tailored to an existing framework of functions. If an information strategy has been defined for the organization, a LIMS can be justified in terms of how it fits in with that strategy. If the organization has computing standards, the LIMS chosen should conform to those standards whenever possible.

An excellent tutorial on evaluating the costs and benefits of LIMS has been presented (11). The tutorial explains how to perform a cost–benefit analysis using a pragmatic approach to the economics involved. To assist in the analysis, a detailed list of specific LIMS costs and benefits from the tutorial is included here (see Tables 1–3) (12–14). The size of the system, based on the number of samples and analyses per year, can be used to approximate the cost. Table 4 summarizes the respective costs for small, medium, and large systems (15). Although the tutorial is a good starting point for accurately assessing the costs of a proposed system, the task of measuring the value of the benefits can be much more subjective in nature.

Benefits can be classified as tangible and intangible. Tangible benefits are benefits that are easily assigned a monetary value. These include items such as reductions in the costs of calculating and reporting data, improved capacity through better access to management of data in making assignments, and being able to identify and report sample status more quickly. Intangible benefits might include better overall service to customers and a general perception of better laboratory management through the use of state-of-the-art management techniques.

Another significant benefit of a LIMS is the improvement of the overall quality of the laboratory. In the case of a laboratory, quality is defined as satisfying customer needs in the areas of accuracy, reliability, clarity, and timeliness of analytical information. LIMS can enhance quality in a number of ways, eg, in checking conformance to requirements, in organizing and prioritizing work to ensure timeliness, in measuring laboratory

Table 1. Initial LIMS Costs[a]

Category	Cost factor
hardware	computer storage devices; device cabling and wiring; wiring, power conditioning; climate control; furniture; networking: interfaces, servers, cabling, wiring closets; user interaction: terminals, workstations; display devices: printers, plotters; sample ID: bar-code readers, printers, and label applicators; repair documentation, spares
software	operating system; system development tools, including communications and compilers; networking and connectivity software components; LIMS core and optional components; LIMS development tools; database systems and development tools; generic instrument interface software; special instrument interface software, eg, chromatography, process control; graphics and printing software; documentation: users, managers, development; furniture for storing documentation
installation and conversion	personnel to manage acquisition and installation; disruption due to installation; loss of replaced incompletely depreciated equipment; lost space for computers, terminals, printers; customization and configuration; development of computer usage procedures, LIMS usage procedures, and new laboratory procedures; determination off-line vs on-line data needs; development of archiving and backup procedures
training	computer training for users, managers, hardware engineers, support staff; LIMS training for users, managers, support personnel; instrument interface training for users, managers, hardware engineers, support staff; accessory software training for users, managers, support personnel; lost work during training; decrease in productivity during training, installation, and adaptation
configuration	time to identify database items; time to configure database to include these items; time to create necessary database forms; time to set up system security, desired audit trails, and enter valid users; time to design and create necessary reports, charts, and alarms; time to configure laboratory for tests, samples, instruments, projects, labs, etc; enter analysis procedures; set up accounting system, if used; develop interfaces to other corporate systems; hook up instruments, reconfigure automated instruments

[a]Ref. 12.

Table 2. Ongoing LIMS Costs[a]

Category	Cost factor
supplies	printer paper, forms, toner, drums; plotter paper, pens; bar-code labels, ribbons; fuses, keys cables, spare parts; media for backups and archives; cleaning supplies
maintenance fees	computer and networking hardware; operating system; LIMS core and option software; database software; other software packages;
personnel	administration of maintenance contracts; installation of updates; performing and supervising in-house preventative and nonpreventative maintenance; performing and supervising backups and archiving; archival costs; internal support personnel time; training of new personnel due to normal promotions and turnover
miscellaneous	power; computer lease and rental costs; communication rental (telephone, satellite, etc); depreciation costs

[a]Ref. 13.

performance in areas of technical quality and efficiency so as to provide continuous improvement, and in helping the laboratory to communicate clearly, completely, and consistently (16).

Table 3. LIMS Benefits[a]

Category	Benefit factor[b]
data management	data may be stored more systemically; more data conveniently stored per event; track a greater number and more complex relationships; change data more quickly; data may be more secure; security can be more highly tailored and may require less managerial oversight; audit trails can be automated; transactions are more traceable; managerial information on the amount and type of data are improved; data can be recalled more quickly and flexibly; improved reliability of data storage and retrieval; data may be handled more flexibly; reporting is faster; unit printing costs and cost of transferring data may be reduced; new relationships among data are more easily examined; data are available when needed by requiring its entry
laboratory throughput	entry of sample information and sample identification may be faster; reduced transcription (offset by possible increased data entry time); faster QA/QC or SPC; speed of analysis; automation of entire analysis; faster response to queries; faster and automated reporting; automatic validation of results; inspection only of discrepancies; assistance in remembering procedures, prompt for required data
quality of data	more accurate data because of automated acquisition and range checking; more accurate sample identification due to bar codes; reduced transcription errors; improved instrumentation reliability from QC and automated calibration procedures; more involved QC procedures; SPC on laboratory analyses; automatic enforcement of validation procedures, laboratory analysis procedures, and instrument standardization procedures; automatic prompt for missing data
laboratory management	improved accuracy of laboratory management information; increased quantity of laboratory management information; reduced labor to produce laboratory management information; more instruments, analysts, results handled per manager; reduction in lost opportunities due to inadequate knowledge and in unsolved backlog problems; improved validation procedures
quality of operations	SPC on manufactured products; SQC on laboratory operations; communicate with corporate CIM system; improved QA/QC on products; reduced testing costs; correlate laboratory analyses and process measurements; faster solutions to production problems tested in laboratory; faster notification of backlog problems; improved electronic data interchange capabilities; automated communication with inventory, ordering, and materials planning systems
regulatory compliance	automated regulatory report generation; regulation-compliant audit trail; enforce regulation-compliant laboratory procedures and result validation; improved response to changing regulations; fast compliance with regulatory audits

[a]Ref. 14.
[b]QA = quality assurance; QC = quality control; SQC = statistical quality control; SPC = statistical process control; CIM = computer-integrated manufacturing.

Table 4. LIMS Expenditures Based On Project Size[a]

Laboratory feature	Small	Medium	Large
project cost, $	60×10^3	300×10^3	$1,500 \times 10^3$
reports	20	70	300
people	5	50	500
laboratories	2	8	30
samples per year	6×10^3	40×10^3	300×10^3
analyses per year	30×10^3	250×10^3	$2,000 \times 10^3$
analysis time, wk	1	3	15
expenditure, $	3×10^3	9×10^3	45×10^3

[a]Ref. 15.

5. Selection

Before deciding on a LIMS product, a complete set of specifications for required functions of the LIMS should be written. The best time to do this is before any vendors have been contacted. Inviting vendors to participate in this process results in a specification which can be automatically fulfilled by their product. A thorough understanding of current data management processes is necessary to draw up a specification (17), and vendors do not have it.

When researching the requirements for a LIMS, answers to the following questions, courtesy of The Royal Society of Chemistry, should be sought (18). (*1*) Is the laboratory to be used for a single technique or multiple techniques, for a single product line or product type, or for all types of samples? Would a redesign of experimental procedures produce an increase in efficiency? (*2*) Are there management requirements, including secretarial assistance? (*3*) Are computing resources required, including a laboratory management data system, local data collection and storage of instrument results, data storage and filing requirements at laboratory level, use of personal workstations, introduction of local area networks (LANs), mainframe interfaces, and telecommunication facilities? (*4*) Are there reporting, archiving, and database requirements? (*5*) Are personnel records to be included in the computerized laboratory management scheme? (*6*) What overall response and speed of the system is necessary for the turnaround expected? (*7*) What is to be done about the education of users, a most important requirement that is easily overlooked in the planning stages?

The search for a vendor can begin once the specification is complete. The level to which a vendor's products conform to established requirements is the most important selection criterion for a LIMS. Financial stability of the vendor's organization is another consideration, because ongoing technical support from the vendor is vital to LIMS implementation and enhancements. The technology used in a vendor's products should be evaluated for robustness and longevity. For example, a vendor with software products written for nearly obsolete computing platforms would not be a strategic choice. Consulting services offered by a vendor can be valuable for implementing and maintaining a LIMS.

Once the need for a LIMS has been justified, specifications have been written, and available vendors surveyed, the LIMS selection process begins. Each vendor's product must be evaluated for conformance to the specification and flexibility for future modifications. If an adequate solution is not available commercially, consideration must be given to constructing a custom LIMS solution. This could be done in-house or by contractors. If the custom option is preferred, resources needed for future modifications and maintenance should be factored into the cost.

Selection of LIMS software should take into account both data compatibility and ease of use. Since a LIMS is one information system within an organization, it may need to share data with other systems. Therefore, the software should be capable of sharing data directly or exporting data into compatible formats.

6. Database Management

A database management system (DBMS) is used by most LIMS systems for storing data. Examples of commercially available DBMS are DB2, DBASE, Informix, INGRES, ORACLE, and RDB. All of these DBMS conform to the "relational" model developed by Codd (19). Figure 3 demonstrates the use of a relational DBMS for storing LIMS data. Here data is grouped by type so customer and analysis requests are stored separately from sets of sample information which are, in turn, stored separately from sets of analysis results. Individual records are linked or related by unique identification data.

Relational databases can store unlimited numbers of results for every sample and unlimited samples for every request. The advantage of a relational DBMS over a more traditional hierarchical system, in which data sets may contain other data sets, is that the design of the database only has to consider relationships between data elements, not the number of instances for any given variable.

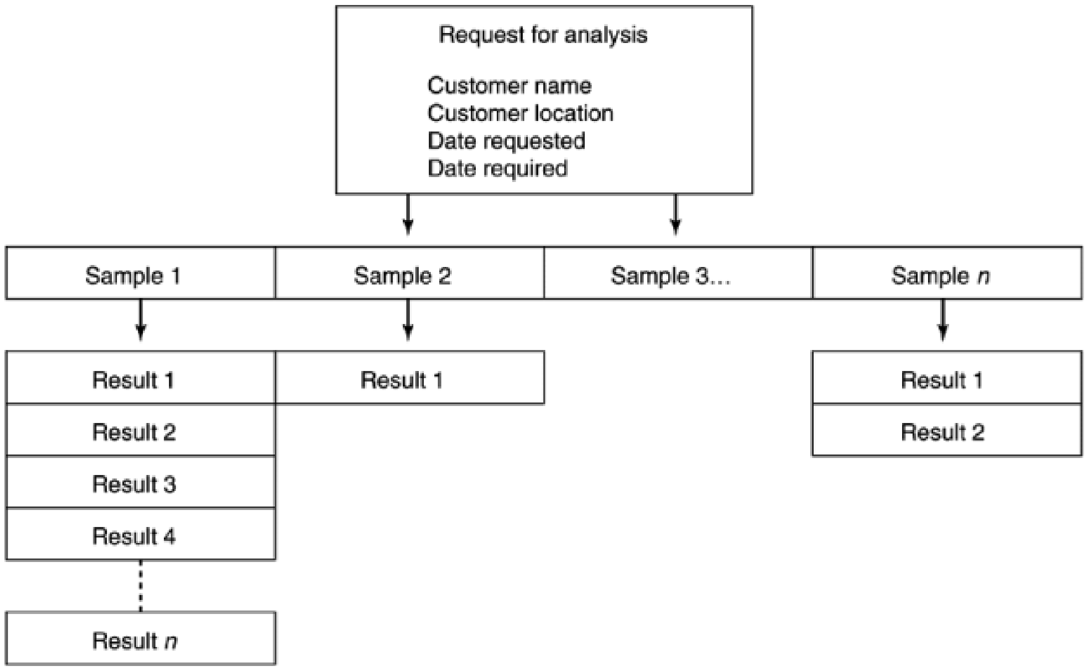

Fig. 3. Use of a relational database management system.

A DBMS performs what is called transaction management. This process allows multiple users to access and store data in the database without corruption. The ability to do this is particularly important when data are being written to the DBMS, because power interruptions or hardware failure can cause database transactions to be incompletely processed. Transaction managers use the "all or nothing" principle: all the data is written to the DBMS, ie, the transaction is completed, or none of it is written.

Another important feature of a LIMS DBMS is the ability to perform ad hoc database queries. It is impossible to predict all the forms in which LIMS users will want to display their data while the LIMS is being designed. As a result, it is desirable to select a LIMS which allows users to define their own reports. Most commercial DBMS have a standard query language (SQL) interface. SQL is a simple database query tool which is based on English-language commands. This sample SQL query says, "Give me all sample request data containing John Smith as the customer."

```
SELECT∗ FROM SAMPLE REQUEST
WHERE CUSTOMER NAME =John Smith
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7. Impacts of New Technology

Computer hardware costs have decreased dramatically. As a result, systems have become more affordable. Higher performance of new technology allows more functional capacity to be provided in a smaller, less costly machine.

Advances in network operating systems (NOS) provide database server and independent, simultaneous (distributed) data processing capabilities necessary to support LIMS functions throughout a network of computers. Previously this was possible only with a centralized processing model such as in traditional minicomputers and mainframes. The cooperative network model, also known as peer-to-peer processing, uses networks to distribute data and processing. This allows construction of systems that can be expanded as needed. The independence of each machine eliminates problems inherent in the centralized model, such as a single point of failure and high start-up and maintenance costs. Peer-to-peer networks were thought to be easier to maintain and operate. This is not actually true, because the distribution of data required for independence forces systems to store data temporarily and forward it to a central location to allow access by other network nodes. As a result, not all data is available in one place at one time, making efficient administration difficult for all but very small, highly tailored systems.

Another significant impact of new technology is the evolution of the client/server computing model into commercially viable systems. This model incorporates a more powerful computer for data storage and retrieval (the server), connected to client workstations via a network. Client computers perform processing for the user interface, and pass messages and data to the server. Clients are typically personal computers or other graphics-capable devices (such as X-Windows terminals). Under this model, processing can be distributed within a highly integrated, secure data storage environment. Client/server architectures achieve a system which provides the independence of the cooperative network (peer-to-peer) computing model, but is highly scalable, secure, robust, and easily administered. It has the added advantage of presenting a graphical user interface (GUI) to the LIMS user, in which computers, file systems, and programs are represented by simple icons, providing a familiar environment while hiding network and server complexities.

A significant concept of the client/server model is to extend the scope of the application to function in an enterprise-wide (possibly worldwide) network of interconnected LANs, which allow LIMS and other applications following the client/server model to be operable and administrable on a much larger scale than either LAN or central processing models.

The client/server model often allows easier integration with other network applications (eg, finance, project management, or human resources) which typically operate in the environment of the server component of the client/server system. Client/server can be gradually introduced in an existing minicomputer environment, often with little adverse incremental impact in terms of retraining and additional cost.

PC workstations have become powerful, are simpler to use, and are generally ubiquitous within both laboratory and office environments. Using Windows-based software now widely available on instrument data stations as a basis for the LIMS will reduce the training costs and capital requirements when implementing a LIMS.

Networks required for peer-to-peer LANs often already exist in some form as a result of other office integration efforts. The existence of these networks can often reduce LIMS implementation costs by taking advantage of the reusability of the systems and networks already present in the laboratory.

Databases are becoming more standardized, thereby allowing a greater number of supplemental functions to be added to a LIMS and foreign systems, eg, project accounting, to be more easily integrated.

For these reasons, the desktop and client/server models are expected to increase in percentage of LIMS software offerings and installed base in the future.

Instrumentation advances have increased the power and quality of the fundamental analytical techniques used in conjunction with LIMS. Unfortunately, these advances come at a price of increasing complexity and volume of information. Despite all of the architectural and technological advances of computer hardware and software, the demands of the information requirements still exceed the computing capabilities, so as to put continuing pressure on computer manufacturers to increase storage and processing capabilities even further.

Modern analytical instruments are tending toward results which cannot be reduced to the single-valued results easily entered into LIMS. Many of the newer instruments produce extremely complex results in the form of tables, spectra, images, or multidimensional relationships which are not easily represented in databases using the relational model employed by most current LIMS. Existing choices range from using a nonnumeric completion characteristic, which might reference a secondary computer file containing the complex results (this file may or may not exist on the same computer as the LIMS), to an alternative which treats the complex result as single objects and shifts to the use of object-oriented database tools to achieve the desired information within the LIMS itself. Shorter-term integration with existing file and document management systems may be used to simulate the object-oriented database (OODB) concept.

Data acquisition has evolved, but standards are still lacking (20). This makes data acquisition the most difficult and time-consuming aspect of the overall LIMS implementation. The time savings which result from automated data capture result in its generally being undertaken, to some degree, despite the difficulties. Other than chromatography laboratories and others which have a more uniform instrumentation environment, the data acquisition portion of the LIMS implementation tends to be a custom integration development project. This results in a relatively fixed system which can be adversely affected by changes (upgrades) to underlying analytical subsystems.

Work is being done to create uniform standards for exchange of information between analytical instrumentation and external (host) computers, but the diversity and the competitive nature of the instrumentation marketplace tend to impede these efforts, leading to an environment of constant change and a need for new and rewritten programs to communicate between LIMS and the automated instruments.

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