THE IMPACT OF THE LIS TO THE HOSPITAL'S ANALYTICAL LABORATORY QUALITY ACCREDITATION

A. Vagelatos
R.A. Computer Technology Institute
Eptachalkou 13, Thiseio
11581 Athens, Greece
Tel: +30 210 3416220
Fax: +30 210 3416250
E-mail: vagelat@cti.gr

J. Sarivougioukas
General Hospital of Athens
"G Gennimatas"
Mesogeiwn 154
15659 Athens, Greece
Tel/Fax: +30 210 7783040
E-mail: jcsari@hellasnet.gr

Abstract

Acceptable laboratory practices are available and described in the form of scientific methods. When laboratory practices are widely applied and well known they turn out to be standard methods. National and international organizations examine, evaluate and adopt the methods forming Standards. Notified bodies play the role of the laboratories' inspector to examine the fidelity of standards' application verifying the existing conformity to them. The generic character of the issued Standards provides the required availability to be interpreted embodying all application's peculiarities. Notified bodies' surveyors assure the Standards adoption either by inspection and consequent certification or by inspection and subsequent verification. In either case, the kept laboratory documentation works towards the proof of the followed practices. The developed bureaucracy finds remedy by the employment of Laboratory Information System (LIS) while, at the same time, it assures that the dictated procedures will be followed without exemption. Embedding Standards requirements into the LIS, assures and provides the promptly availability of the proving documentation while it rectifies the followed practice.

Introduction

The medical tests performed by the hospitals' analytical laboratories make use of well-known practical methods approved by the corresponding scientific societies. Part of the laboratories scientific practices receiving specimens, examining samples, and processing test results, present a repetitive character including routine procedures that have been left to be carried out by automated instruments. The procedural repetitions along with the employment of reliable analytical laboratory instruments fulfil all the requirements to introduce information technology solutions experiencing all the related benefits.

The laboratories' professional and scientific societies have determined the so-called Good Laboratory Practices (GLP) to define and assure the quality of the procedures' methods performing medical tests. The widely applied and accepted methods and practices turn in a certain period of time to form standards, approved by authorised organisations, which provide the means for a systematic proof of the quality management of the works carried in an analytical laboratory. The structured documentation demanded by the quality standards consist the objective proofs that may be verified by audits during the

accreditation processes. The carried inspections have the proving and verification character of the conformance of the laboratory under examination according to quality standards articles or rules. The academic knowledge and professional experience of the auditors is a necessary and sufficient condition that is provided by the Accreditation Body which verifies the laboratory's compliance to the quality standard. Documenting the laboratory procedures is a standards' requirement whose archiving is handled by the means of Information Systems. In this paper the impact of an LIS existence is discussed along with the medical laboratories' Quality Accreditation. It follows a reference to the available standards, the application of LIS in hospitals' laboratories, the benefits returned by the use of LIS and last, the drawn conclusions.

Accreditation in Hospital' Laboratories

The issue of quality management systems and accreditation is gaining increasing interest in Medical Laboratories. All over Europe laboratories have started to introduce quality management systems and harmonization of criteria for accreditation is of increasing importance. The standards to be used as basis for such systems are the subject of much discussion [Clinical Pathology Accreditation Ltd., 2003]. Existing international standards for general use, like the ISO 9000 series, and for general laboratories, like ISO guide 25 and the EN 45000 series, do not seem to fit the specific needs of medical laboratories. Recently, Essential Criteria for Quality Systems in the Medical Laboratory have been published by the European Communities Confederation of Clinical Chemistry (EC4) [Jensen et al., 2000]. This publication has stimulated the development by ISO of the Final Draft International Standard (FDIS) 15189 "Quality Management in the Medical Laboratory". This standard seems better suited for the needs of the laboratories. ISO has produced also the new IEC 17025 "General Requirements for the Competence of Testing and Calibrating Laboratories" for general laboratories, the successor of ISO guide 25 and EN 45000. Both ISO 15189 and 17025 cover the requirements of ISO 9000:2000, which make them easily acceptable for the public.

The quality standards are undergoing periodical revisions in order to satisfy the contemporary professional and scientific needs and expectations. The quality management is a necessary condition for all of the above standards. The selection and application of each of the quality standards depends entirely on the satisfaction of the objective purposes set by the laboratory administration. In spite of the choice of the particular quality standard, there exist a number of documents used to prove the acceptable performance of medical tests, which have to be archived and periodically processed. The developed volume of documents is proportional to the kind of the recognized quality standard and the number of medical tests performed.

Laboratory Information System

The analytical laboratory is usually one of the first areas in a hospital to become computerized mainly because of the large volume of data involved. Since the early 1970s the domain of laboratory medicine has

pioneered the exploitation of information technology. This has enabled a cost-efficient production environment through a combination of robot technology and information technology. The modern analytical laboratory is a complex, heterogeneous environment, typically with a mix of autonomous and partially inter-working applications running on a range of hardware platforms. A consequence is that bigger laboratories to-day are entirely dependent on their IT functionality, and that the laboratory IT solutions must be considered as 24-hour mission critical systems.
Today numerous information technology solutions exist for the hospital's laboratory, which operate either as stand-alone functionalities or with certain integration solutions [Vagelatos et al., 2003].

The LIS' impact to Quality Accreditation

The introduction and application of quality standards in Analytical Laboratories obliges the personnel to perform certain operations with the objective purpose to obtain the required by the applied standards quality assurance [Shen et al., 2001]. The additional operations dictated by the quality standards fall into three discrete general phases, operations before the exercise of examinations that assure acceptable laboratory conditions, the controls applied at critical laboratory applications, and the works that follow the laboratory's production concerning the necessary maintenance and the evaluation of the production. At each operational stage certain forms must be filled out in order to document the followed methodology. Such operations prolong the overall processing time giving an additional overhead to the laboratory's cost of operation, as it may be seen comparing the figures below (Figure 1 and Figure 2). In order to avoid undesired situations, the laboratory administration, usually employees excessive bureaucratic procedures not to jeopardize the laboratory's results.

Figure 1. A part of a sequence of laboratory operations
S={1,2,…,S+1,S+2,…S+k,…}

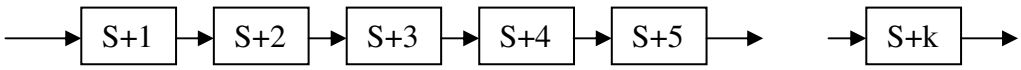
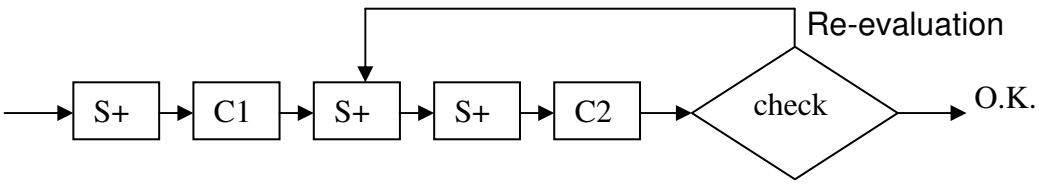


Figure 2. Quality standards' operations added to regular work flow



The laboratory's administration faces three tolerable factors to adjust, the minimization of the instruments' idling time, the minimization of the personnel's involvement into forms filling, and minimization of copying data by hand in order to reduce human bureaucratic in origins errors. Hence, the laboratory's administration is called to provide an optimal

solution on the following set of equations, taking under consideration the specific laboratory's peculiarities.

$$f_{\min}(instruments'idling, forms'filling, copying\_data) = 0$$

$$g(instruments'idling) = production\_planning$$

$$h(forms'filling, coppying\_data) = reliably\_entered\_demographic\_data$$

The bi-directional coupling of the available laboratory instruments to the LIS assures that the individual machines will be loaded whenever it is required. The sequence of operations and the associated instruments is determined by the LIS allowing the personnel to follow the predefined procedures for each test. The available time during the processing of the requested tests is left for the personnel to criticize the procedures and the results obtained avoiding, at the same time, any data transferring or copying. The structure of the laboratory's flows of work must be engineered in such a way that there are no conflicts at the points of controls. Points on the laboratory's workflow that experience bottlenecks must either be decomposed into different flows or the incoming demands of work be acceptably synchronized. Such actions may require the re-evaluation of the laboratory's operational structure, which has to be included in the initial steps of the quality standards application. The LIS must take under consideration factors such as the future expandability of the proposed system, its security, its transparency, its ability to avoid single points of failure, its interconnection requirements with other installed systems and instruments, its capability to get connected with instruments, and its embedded capability to automate procedures of the quality standards and the laboratory's too.

The lately issued quality standards for medical laboratories consider that all of the performed operations fall into the following nine categories:

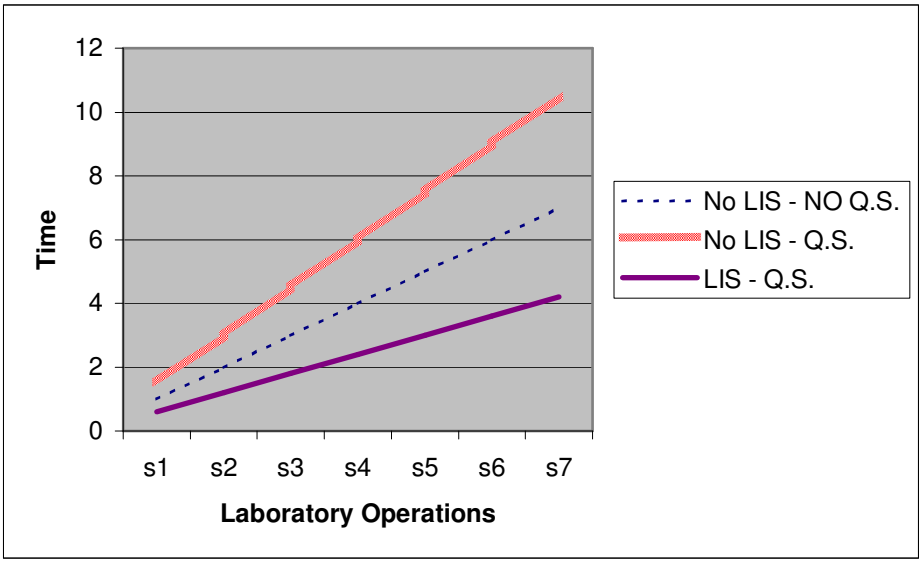
- the reception of patients' demographics,
- the collection and handling of specimens,
- the examination procedures,
- the application of additional procedures that ensure the quality of examination,
- the report of results,
- the transmission of the results,
- and the amendment of the reports,

which constitute the set of operations' classes that carried out in a laboratory.

For presentation purposes and without loosing from the general case, consider that all operations in each of the above categories lasts a single unit of time. Plotting the set of the classes of laboratory operations we end up with a straight line of the form *y=ax+b*. In the general case, the line will cross both lines of the axes in the formed graph. The slop of the line expresses the time interrelation among the various classes of laboratory operations. Applying quality assurance principles according to the existing international standards, the dictated

bureaucratic procedures will provide an additional load that will cause a increase in the slope of the hypothetical line given by $y=\varepsilon_1(ax+b)$, $\varepsilon_1 \in R \wedge \varepsilon 1>0$. Automating some of the operations, especially the bureaucratic ones, and assisting to shorten the time required to carry out some others is done through the adoption of an LIS. In this case, keeping the linear relationship among them, for the purposes of this presentation without missing anything from generality, the slope of the line is decreased by a factor $1/\varepsilon_2$, i.e. $y=(ax+b)/\varepsilon_2$, $\varepsilon_2 \in R \wedge 1>\varepsilon_1>0$. The consequences of the application and use of a LIS shrink the overall required time while the qualitative characteristics are expanded to maximum. The following figure pictures the three cases mentioned above.

Figure-3: The Lab's workload along with a quality system and/or an LIS



Discussion - Conclusions

The quality standards determine the minimum acceptable requirements about the laboratories productive operation, enforcing the application of a continuous re-examination cycle of the obtained quality, improving the offered services or performed work by quantifying the qualitative characteristics. The objective purpose for the quality is always set by the laboratory's administration to fulfill the customers' expectations. A constant level of the accredited laboratories' qualitative ratings is expected at all times by the clients. In order to obtain and to provide such standards, the LIS provide the means to constrain the freedom of choice of applied sequential operations and narrow down the personnel's actions within the predefined framework of laboratory's business and scientific activities.

Embedding the laboratory's scientific operations and the quality processes directed by the standards too into the LIS, the consequences focus on four facts. Firstly, the preparative actions for accreditation are carried out smoothly and within a short relatively time interval, depending upon the laboratories' peculiarities and its activities' spanning extend. The LIS stamps in terms of software the underlying

systematic organization. Secondly, most of the executed operations for reporting and documentation within the framework of the laboratory's operation are automated or require a minimum involvement and effort from the personnel shortening the necessary time and reducing the related errors too. The overall required time and the personnel's work for certain procedures are improved drastically. Thirdly, the accreditation introduces bureaucracy due to the required documentation by the applied quality standards to prove the way of operation. In other words, the quality standards require "to write whatever is performed within the laboratory" while they require to "perform within the laboratory whatever is written". The reduction of bureaucracy is achieved through the operation of an Information System that implements in terms of software both the laboratories' operational processes and the quality standards requirements. Lastly, the software implementation of both the scientific and quality processes, collecting and processing objective and quantitative data, permit the continuous self-evaluation of the laboratory's overall operation. The examination of the gathered data, by the LIS, provides objective evidences related to the laboratory's operation. Data processing proves either the laboratory's unacceptable incompetence that may be fixed efficiently through corrective actions or the laboratory's conformity that may grant the excuses to increase the qualitative characteristics improving the provided level of standards or the provided quality.

The structure of the LIS has to present two particular aspects. On the one hand, the LIS software must be designed to implement the specific scientific sequence of operations performed by the designated laboratory. On the other hand, the designed software must carry on all the characteristics ordered by the chosen for implementation quality standard. Both of the software aspects ought to co-exist not only without causing problems to their operations but in a complementary and transparent way.

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