# Design and Implementation of Laboratory Information System: A Case Study at the Medical Technology Clinic, Rangsit University

Jiraporn Gatedee[1], Somphon Phraephan[1], Kanjana Suriyaprom[1], Saranthum Phurijaruyangkun[1], Sunsiree Muangman[1], Preecha Pangsup[2] and Rachasak Somyanonthanankul[2*]

[1]Faculty of Medical Technology, Rangsit University, Thailand
[2]College of Information and Communication Technology, Rangsit University, Thailand
*Corresponding author, E-mail: ratchasak.s@rsu.ac.th

## Abstract

A laboratory information system (LIS) is widely used to operate the total testing process (TTP) in clinical laboratory. It consists of software, hardware, data, process, networking and also people such as programmer and laboratory staff. The international standard showing guidelines for the LIS design and implementation has been established. However, several clinical laboratories still have time consuming problems in the process of user customization to comply with the standard implementation designs of LIS. This study aims to describe the system and implementation process of LIS at the Medical Technology Clinic, Rangsit University. The designed LIS design system and implementation models were assessed following three main phases: pre-examination, examination, and post-examination phases. The clinic installation of such an integrated LIS was planned and scheduled in accordance with international standard, users, and experience of the company technicians. The implementation of LIS in The Medical Technology Clinic, Rangsit University was characterized as acceptably successful and the system has already been used in routine laboratory process. The described model would be practiced as valuable guidelines for the LIS implementation in the start-up clinical laboratory.

***Keywords*****:** *laboratory information system, medical technology, medical informatics*

**บทคัดย่อ**

ระบบสารสนเทศทางห้องปฏิบัติการนิยมใช้กันอย่างแพร่หลายสำหรับควบคุมการทำงานในทุกขั้นตอนของการทดสอบทั้งหมด ในห้องปฏิบัติการทางคลินิก ซึ่งประกอบด้วย ซอฟแวร์ ฮาร์ดแวร์ ข้อมูล กระบวนการ เครือข่าย และ บุคลากร เช่น โปรแกรมเมอร์และเจ้าหน้าที่ในห้องปฏิบัติการ โดยมีมาตรฐานสากลสำหรับแนวทางในการออกแบบระบบและกระบวนการทำงานอยู่แล้ว แต่อย่างไรก็ตามห้องปฏิบัติการทางคลินิกหลายแห่งต้องสูญเสียเวลานานในการปรับแต่งความต้องการของผู้ใช้งานให้เข้ากับกระบวนการดำเนินงานของระบบสารสนเทศทางห้องปฏิบัติการ ดังนั้นการศึกษาครั้งนี้จึงมี วัตถุประสงค์เพื่อนำเสนอโมเดลกระบวนการดำเนินงานของระบบสารสนเทศทางห้องปฏิบัติการในคลินิกเทคนิคการแพทย์ มหาวิทยาลัยรังสิต โดยกระบวนการทำงานของระบบสารสนเทศทางห้องปฏิบัติการนี้มีการดำเนินงานเป็นสามขั้นตอนหลักคือ ขั้นตอนก่อนการวิเคราะห์ ขั้นตอนวิเคราะห์ และขั้นตอนหลังการวิเคราะห์ โดยได้มีการวางแผนการดำเนินงาน และติดตั้งระบบสารสนเทศทางห้องปฏิบัติการให้เป็นตามมาตรฐานที่วางไว้ตามความต้องการของผู้ใช้ และตามประสบการณ์ของช่างเทคนิคจากบริษัท โดยระบบสารสนเทศทางห้องปฏิบัติการ ที่ดำเนินการติดตั้งที่ คลินิกเทคนิคการแพทย์ มหาวิทยาลัยรังสิต ได้ทำการติดตั้งเสร็จแล้ว และระบบได้ทดลองใช้พบว่าได้รับการยอมรับและสามารถใช้งานได้สำหรับการตรวจทางห้องปฏิบัติการในงานประจำวัน ดังนั้นการนำเสนอรูปแบบของการออกแบบระบบและกระบวนการทำงานระบบนี้ น่าจะมีประโยชน์สำหรับใช้เป็นแนวทางสำหรับการดำเนินงานที่เกี่ยวกับระบบข้อมูลทางห้องปฏิบัติการในห้องปฏิบัติการทางคลินิกที่จัดตั้งขึ้นใหม่

***คำสำคัญ:*** *ระบบสารสนเทศห้องปฏิบัติการ เทคนิคการแพทย์ สารสนเทศการแพทย์*

## 1. Introduction

In mid-June 2016, Rangsit University established the Medical Technology Clinic to support the academic practice, healthcare checkup, and medical research. In the future, this clinic will be facing the analysis of thousands of blood specimens as routine clinical work in medical practice throughout university members. Therefore, laboratory tests performed in clinical laboratories should be recorded in the computer-based laboratory information systems.

Laboratory information system (LIS) is critical for the operation of clinical laboratories. It is developed for executing tests on biological specimens collected from patients and providing information for its health status evaluation, diagnosis, prevention, and treatment of illnesses (Alanazi, 2015). It also tracks and stores clinical particulars of the patients during a laboratory visit. LIS is used to keep the laboratory information stored in the database for future reference. Nowadays, LIS performs as a source of diagnostic data for doctors in all clinics and hospital departments.

LIS has been implemented in many clinical laboratories to improve the quality of the services and reduce the errors. The LIS is a valuable tool for medical technologists to manage the total testing processes, ensure regulatory compliance, promote collaboration between departments of the same or different laboratories, deliver detailed reports, and develop the laboratory networking capabilities.

However, LIS implementation in laboratory may face some problems in the customization process including concerns about the data storage and also the use of proper hardware and software. The data stored in computer systems may be lost or changed by unauthorized personnel. Therefore, the specific measures should be followed carefully in order to protect the LIS, and solve the problems that may be encountered following the installation (Brerider, 1996).

Therefore, this study tends to describe the implementation process of LIS. The Medical Technology Clinic, Rangsit University was used as a model for the designed system of the implementation system. The designed system has three main phases including pre-examination, examination, and post-examination phases. Then, the clinic installation of such an integrated LIS was planned and scheduled according to the international standard, user's commands, and experience of the company technicians. The described model may be useful as guidelines for the LIS implementation system of the new established clinical laboratories.

## 2. Objectives

There were two main objectives in this study. The first objective was to describe the designed system and implementation process of LIS at the Medical Technology Clinic, Rangsit University. The second objective was to list the suggestions for designing and implementing LIS with the international standard of clinical laboratories.

## 3. Materials and methods

Before the LIS was installed at Rangsit University, the information system such as software, hardware, data, process, and networking in general laboratory testing was not complete and the manual system was used by the medical technologists to record and report all of patient's data. The main problems of the manual system have been found at all processes from pre-examination process wrong patient's information recorded and error in test selection ordering, examination process errors in recording results from automated machines, and post-examination process errors in reporting and interpreting results. (Fernald et al., 2015). Therefore, the faculty members decided to acquire the LIS from BJC Healthcare Company Limited.

### 3.1 Laboratory information system design

Analysis of the laboratory needed the practical LIS to keep the laboratory operating effective. The workflow analysis of the LIS of the Medical Technology Clinic, Rangsit University was performed by the steering committee. A detailed analysis was performed by the vendor on the need of the clinical laboratories which acted as a correcting feedback factor to the final design. The ultimate report of the LIS design was included among other aspects (Sinard & Castellani, 2015).

At the conceptual level, the system designs were shown several characteristics such as the ability to handle required the volume of data and user transactions, standardization of the interface, reasonable transaction and searching times. The primary function of the system was used to implement a given data model. Commercial software LIS has the scalability to handle an enormous data set, manage a large volume of transactions, and maintain transaction integrity. Moreover, a sophisticated tool of the administration was routinely availed for backups and performance tuning.

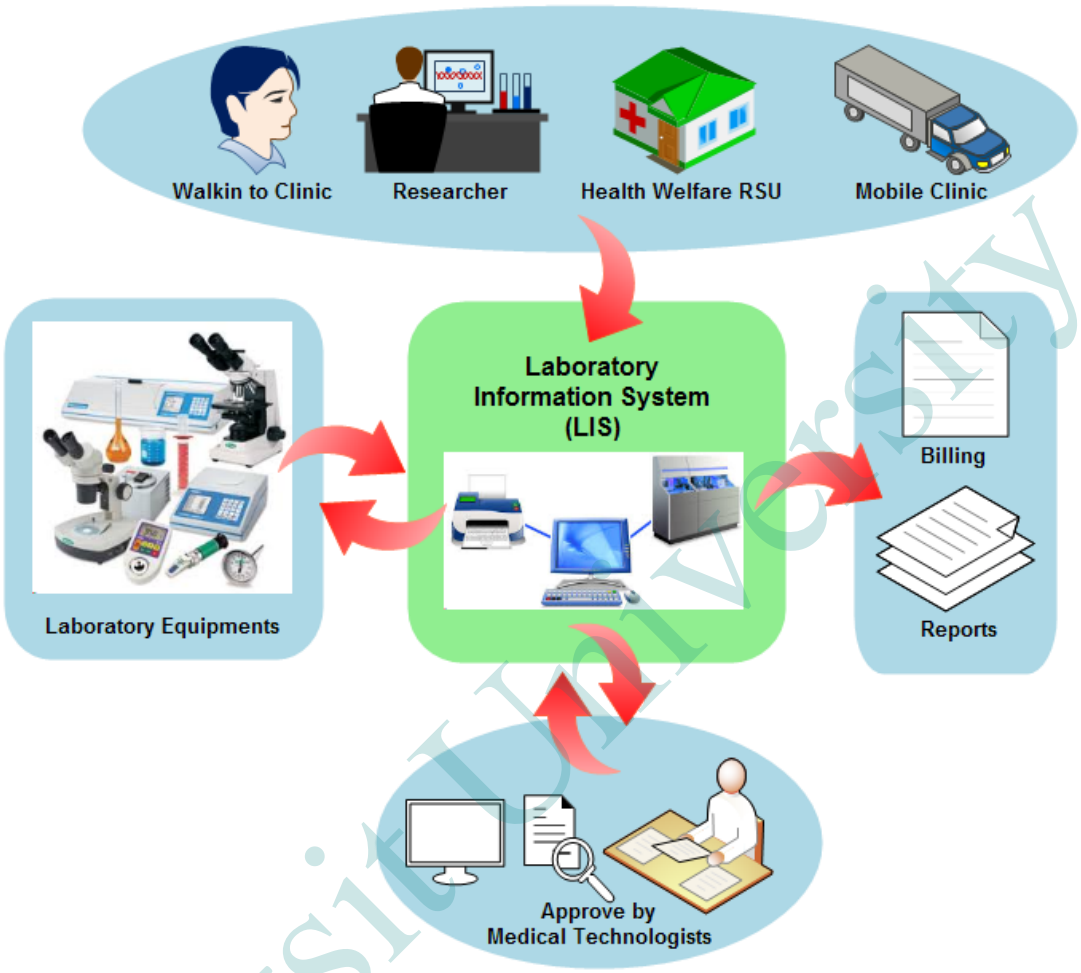


**Figure 1** Conceptual model of the Medical Technology Clinic, Rangsit University

The conceptual model of current workflow at the Medical Technology Clinic, Rangsit University was showed in Fig.1. A proposed software customization and design of the exact places in the laboratory where the computers and the peripherals positioned relatively to analytical devices and laboratory equipment were set to meet the requirement. A set of tasks was performed by various specialties of the laboratory staff regarding the LIS. The complete migration procedures for those of the labs were used to employ the computers and peripherals. The proposed security policy, compliance statement with the scientific methods, protocols, and standards were achieved by laboratory staff (Jin and Li, 2008).

The design was required to meet the complexity, flexibility, process control, and data integrity. The common laboratory scenario accommodating a new type of instrument and the basic direct model were compared to the one that used the meta-data. Since schema was changed very quickly the applications would always be lagged and could even be obsolete before the finish of the modifications. Additionally, meta-data can be strongly leveraged in this case. The new instrument type was a simple additional datum that could be appended to the LIS (Wendl and Smith, 2007). The phases of design can be classified as follows:

*Step1 Requirements gathering phase*: this phase is proved to be useful in getting a sense of the laboratory environment, basic needs to be fulfilled by the system analysis and the extent to which the existing paper-based methods are augmented by information technology.

*Step2 Review phase*: this phase comprises several iterations of user evaluation of selected review phase labs. User evaluations typically contain 4-6 tasks for the technicians to perform on the system. This

phase helps us to improve and simplify the user interface along with obtaining a list of further features to be added to LIS.

*Step3 Pilot phase*: this phase starts by identifying pilot laboratories and performing focused user evaluations and system refinement for them. While short listing laboratories for pilot phase, factors such as facility size, number of personnel, and site location were taken into an account to ensure that the LIS was tested on a wide variety of laboratory environments. This would help in gauging the degree of customizability and system stability in response to the variable workload and workflows.

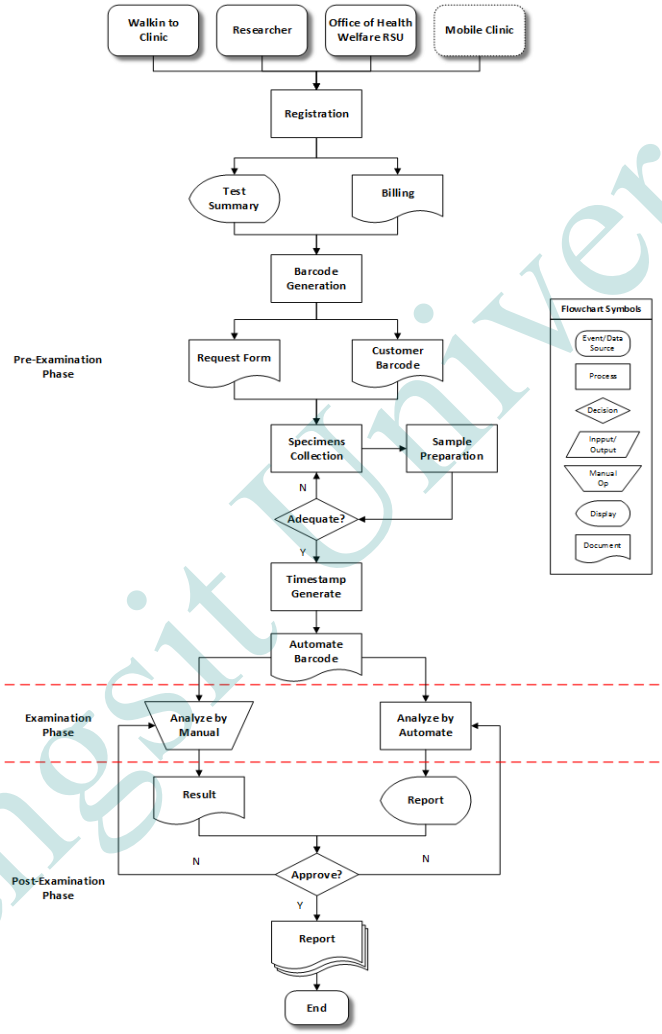


**Figure 2** Framework of total testing process in the Medical Technology Clinic, Rangsit University

These observations suggested that the use of a LIS laid out according to the design principles that provide a proper level of an abstraction. The best design could be used to resolve the data complexity, while assuring both data integrity and a high degree of flexibility to evolve as entities could be changed. We proposed a design methodology and LIS implementation in the next section that have been formulated with these principles in mind.

The LIS was designed to follow the ISO 15189:2012 in the content of management requirements and technical requirements. In management requirements, the LIS was configured for the authorities and responsibilities of all users to access, enter, change, and authorize the release of patient data and

information. The technical requirements included the pre-examination processes, examination processes, post-examination processes, and reporting and releasing the results.

3.2 Laboratory information system implementation

Total Testing Process (TTP) workflow was used in the testing process at the Medical Technology Clinic, Rangsit University. It consists of three phases of testing steps such as pre-examination, examination and post-examination phases (Fig 2). Pre-examination phase starts with the registration of patient's information through LIS. Then, the laboratory test orders, specimen collection, specimen identification, and duration of monitoring of the testing by time stamp record were performed by medical technologists.

The clinic installation was planned and separated into the discrete phases with the aim to deliver a fully functioned LIS. Each phase was overviewed by a steering committee consisting of the representative personnel of the Faculty of Medical Technology and College of Information and Communication Technology, Rangsit University. The project was scheduled according to the following phases, which included details and the agreement with the vendor of the system (Pantanowitz & Tuthill, 2012).

The first phase involved the installation of the computer software and hardware. The computer hardware, a main server, three workstations, printers, and peripherals were installed at laboratory facilities connected thought the local network of Rangsit University network. The computers were connected to the automation laboratory instruments. Devices and equipment deploying the proper communication interfaces taken under consideration factors such as ergonomic installation, human factors, safety, and scientific laboratory policies with respect to quality of measurements were achieved.

The second phase encompassed the installation, customization and configuration of the software. The designed software was installed and customized to cover the procedures followed by the laboratories including the employed methods, protocols, standards, and peculiarities demanded. The customization LIS user was interface demanded by the medical technologists corresponding to software technology and computer performance. The laboratory work instruction was carried on the installed system including the particular vocabulary used in the laboratory so that this could allow laboratory members to display the workflow as it was performed by the computer software. The system loaded with testing data and trial clinical orders were issued. Tests were carried out in such a way that the users accepted its correctness and completeness performing lab tasks, in compliance with the existing legislation.

The third phase was a user training. The laboratory staff were trained to become familiar with the use of the LIS while they were on their routine duties. An on-the-job training, a small portion of the total duration of the practical parts of the training had been covered in the laboratories during the time the laboratories provided results to users.

The last phase involved the system acceptance. The last period of the project was dedicated to system trials, performing minor changes, improvements, fixing problems as well as continuous on-the-job training. Satisfying the predefined operational characteristics of the system, the LIS was finally accepted and approved by the project committee.

**4. Result**

Laboratory information system design and implementation of topology at the Medical Technology Clinic, Rangsit University was showed in Fig.3. Hardware and software devices including computer server installed with software windows Server 2008 and TD Technidata webserver, CPU intel Xeon E5-2403 1.8 GHz, 10M cash, memory 32 GB RDIMM, RAID1, two hard disks drive 1 TB 7.2K RPM SATA, four computer clients installing software windows7, and TD Technidata clients were set at the Medical Technology Clinic, Rangsit University (Table 1, 2).

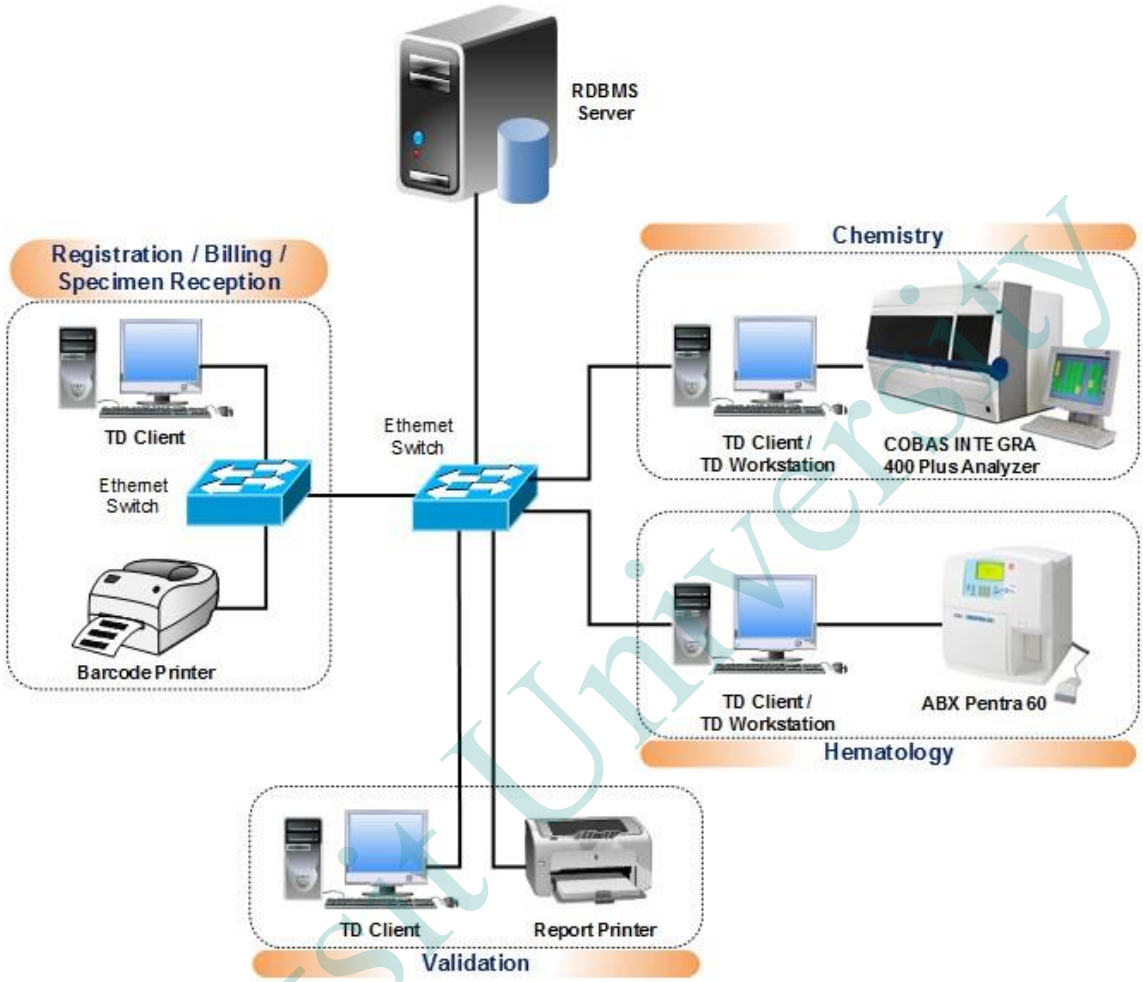


**Figure 3** Topology of the Medical Technology Clinic, Rangsit University

**Table 1** Hardware Device, type of hardware, and number of each item in LIS design and implementation

| Hardware | Type | Number | Specification |
|---|---|---|---|
| Automated Analyzer | Chemistry | 1 | COBAS Integra 400 Plus Analyzer |
| | Hematology (CBC) | 1 | ABX Pentra 60 |
| Computer | Server | 1 | Intel Xeon 1.8 GHz, Ram32 GB, HDD 1 TB |
| | Client | 4 | Intel Core i5 3.2 GHz, RAM 4 GB, HDD 500 GB |
| Printer | Barcode | 2 | Easy Coder PD41 (203 dpi) |
| | Report | 2 | HP Laser Jet P2015n, P1102 |
| Scanner | Register and Approve | 2 | Data Logic QW2100 |
| Network | Ethernet Switch | 2 | 10/1000 Mbps, 8 ports |

**Table 2** The list of LIS software, operating system, LIS application, and number of each items

| Computer | Operating System | Number | Application Software |
|---|---|---|---|
| Server | Windows Server 2008 | 1 | TD-General Laboratory (Core Program) |
| Client | Windows 7 | 2 | TD-Synergy Client Licenses |
| | | 2 | TD-Workstation |

After that, the LIS was interconnected with the existing two automation machines such as COBAS INTEGRA 400 Plus analyzer and ABX Pentra 60. Then, developed system had been complied with the personnel's appreciation and acceptance such as in clinical order sending, testing and calibration, and

receiving and validating results. The list of suggestions for designing and implementing was showed as follows.

*Phase1*: Analysis of the laboratory requirements regarding the ISO 15189:2012. The total testing process was performed by the faculty members. The LIS system was followed the list of suggestions from ISO 15189:2012.

*Phase2:* Installation of the computer hardware. The computer hardware, main servers, workstations, printers, and peripherals were installed at the faculty laboratories. The computers were coupled with the laboratory's instruments, devices and equipment deploying the proper communication interfaces taking under consideration factors such as ergonomic installation, human factors, safety and scientific laboratory policies considering with quality and measurements.

*Phase3:* Installation, customization and fine-tuning of the software. The designed software was installed and customized and the procedures were followed by the laboratories including the employed methods, protocols, standards and peculiarities demanded. The system loaded with data and trial clinical orders were issued and carried out in such a way that the users accepted its correctness and completeness performing directed lab tasks in compliance with the existing legislation.

*Phase4:* Training staff and user system acceptance. The laboratory's personnel were trained in the using the system while they were performing their usual duties. On-the-job training was a small portion of the total duration of the offered training since the practical parts of the training had to be covered in the laboratories and at the same time the laboratories had to provide results to clinical orders. The last month's project was dedicated to system trials, performing minor changes, improvements and fixing problems as well as continuous on-the-job training. Satisfied with the predefined operational characteristics of the system, the project's committee accepted and approved it.

Finally, the LIS was successfully designed and implemented at the Medical Technology Clinic, Rangsit University on time and followed the list of suggestions for designing and implementing LIS with ISO 15189:2012.

**5. Discussion**

The ultimate design and implementation of the LIS project is to be a productive use providing the valuable experience to distinguish certain influential parameters that adjust and control the user acceptance and the success of the entire project. In 2007, Vagelatos & Sarivougioukas suggested that the LIS project have to prepare the project staff who have enough skills and experiences for design and implementation (Vagelatos & Sarivougioukas, 2007). Therefore, this project recruited medical technologists and IT professional staff for design and implementation of the LIS together with outsourcing vender.

The professional work experiences gained in terms of parameters may bring the benefits to the development of analogous projects even without the detailed definition of their quantitative and qualitative aspects. The LIS parameters may be set up and adjusted to serve each application separately in a way that they may absorb the extreme fluctuating factors of the implementation operated by the laboratory. Optimal schedule management may not be considered as a major error in planning the LIS project. Generally, the LIS projects are not carefully planned and hardly completed on time, and anticipation of unplanned events is very essential.

In our study, the initial installation was designed to spend six months given the project due to get started in January, 2016. Due to various reasons (e.g. negotiations with the vendor and relocation of one laboratory), it was started in March, 2016 for the development of the project. On top of that as the first semester started in June, most of the faculty members need to be responsible for teaching and routine tasks. The LIS project of the Medical Technology Clinic, Rangsit University therefore had no progress during these months and had to be restarted in September, 2016.

Human resource management was also crucial for proper preparation of participating faculty members. This management involves the introduction of new installed LIS in the clinical laboratories. From time to time, the consequences including the installation of a new computer server, possibly a new operating system and database, five personal computers and various peripherals have to be monitored and maintained. Supportive maintenance program after the completion of the project was totally required to get

these programs and devices working properly, particularly, at the time the vendor's staff leaving the laboratory.

The application of the LIS in clinical laboratory was based on the existing work instructions adopting certain parts of them to be used in various technological levels and environments. The LIS was customized to meet the requirement of each laboratory regarding measurements, accuracy, employed methods to perform tests, and calibrations. The use of LIS led to the evolution of the performed procedures and processes to be solely carried out, controlled, and recorded by computers in a standard and uniform format.

In this study, the LIS project was accepted by the faculty committee of the Medical Technology members and laboratory technical staff as the automation tool to advance the quality of laboratory work, reduce the corresponding workload and keep the procedure infrastructure customized in such a way to be followed easily through the use of the installed system. Initially, it is acceptable to have satisfied users performing the laboratory tasks using the LIS. When the users are more comfortable with the LIS and start getting perception of the benefits from the use of the LIS, they are willing to use this in their routine work.

At some point, contract management could lead to a conflict between the vendor and the clinic. Our experiences have shown that at the management process, both parties have referred to the terms of the signed agreement. As a consequence, the contract details, holding terms and conditions, must not be let fulfilled by the lawyers in certain aspects of the implementation and operational procedures of the LIS and computer systems. The contract of the agreement by the vendor must be fulfilled with the assistance and co-operation of the LIS and laboratory staff as well as with advice of the procurement department.

The LIS has been widely accepted by its users. Generally, they have to be involved in the selection process and thus be responsible for the outcome. On the other hand, since the Information Technology Faculty members have to support the system afterwards, they must participate in all phases of the development. Both departments should co-operate throughout the deployment of the project by supervising and guiding the vendor. In this project, the head of clinical laboratories and IT members were formed by the project committee. The laboratory directors have taken part in weekly meetings along with the project committee to discuss the progression of the project as well as the problems occurring throughout the progression.

There are many standards and committees working towards the development of various nomenclatures and terminology regarding the LIS. The outcome of the LIS of the Medical Technology Clinic, Rangsit University has been proved successful in the clinical laboratories which started to work productively.

In terms of long-term management, the vendor of the LIS has to support the laboratories for a decade by offering the maintenance contract and upgrading new versions of the system including new laboratory methodologies. Tagger (2011) reported that a good partnership should be established in running the LIS at clinical laboratories. (Tagger, 2011) Hence, the vendor must be prepared and shown adequate arrangements for a long-term business plan regarding the support of the clinical laboratories. This is very important and may be a critical factor for the clinical laboratories to choose a vendor to install the LIS.

For technical management aspects, the client/server architecture was adopted due to the nature of workflow and the volume of data. The installed computers have been connected to the laboratory analyzers and other analytical instruments in order to control and to automate certain laboratory procedures. In the near future, there will be a proposed plan to install three more clinical laboratories into the integration of the LIS. The current main server (both data and application) is a standalone server. To operate at high speed of the terminals in running, application of its architectural design has to be considered. For personal devices, any computer specification above 200 MHz is considered to be adequate for performing some tasks using the LIS (Mutimer et. al., 2002)

Finally, the LIS was designed and implemented at the Medical Technology Clinic, Rangsit University on time and followed the list of suggestions for designing and implementing LIS with ISO 15189:2012.

## 6. Conclusion

The LIS may be designed and implemented independently and apart from the Clinical Information System. The interconnected interface of the LIS has to serve the purposes and principles of integrating control, information passing, user transparency, reliability, and scalability. Planning for the development of

the LIS with concern of discrete phases associated with specific objectives, time limits, necessary resources, and good organized contract was necessary.

In order to achieve both the on-time completion of the LIS project and the preservation of laboratory productivity, the procedures determined by the laboratory must be altered at a minimal level. Moreover, the well-trained staff must be involved in the project deployment. From our perspective, in most of the cases, sufficient information technology staff must be available for proper support for the LIS progression.

The contractor must provide all necessary terms, conditions, and the specific controlling terms that assist the laboratory personnel in the qualitative and quantitative acceptance of the developed LIS. The developing laboratory software must be flexible. Since the laboratory work is dynamically changed, the vendor will be frequently asked to make an alteration on the installed software, for instance, by changing existing modes, or adding new scientific or administrative methodologies.

Finally, there is uncertainty in prediction and predetermination of all hypothetical problems that might occur in the LIS processing. Provision of the appropriate corresponding solution by contractor is still needed to be opted to meet specific requirements by the laboratory. The contractor would provide the clear framework of the project by making the adjustable contract with terms and conditions seen through the prism of receiving services, not just a rigid one.

## 7. Acknowledgements

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