

# **Essentials of Clinical Laboratory Management in Developing Regions**

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## Chapter 1

### Why Essentials of Clinical Laboratory Management in Developing Regions?

Wim de Kieviet, Editor

#### 1.1 Introduction

The IFCC supports worldwide the work and activities of clinical laboratories. The needs of clinical laboratories in general and of specialists in clinical chemistry and laboratory medicine in particular differ not only from country to country, but also from laboratory to laboratory.

In general the main efforts of the IFCC have been focussed on raising the quality and functionality of already good-level clinical laboratories. These laboratories are present in the so called developed countries as well as, to a minor extend, in the so called developing countries. The terms developed and developing countries only reflects the financial possibilities and the availability of professional know-how on the field of clinical chemistry and laboratory medicine. It has no relation with the cultural and social status of the inhabitants of a country.

In countries with less financial possibilities the situation in the clinical laboratories differs strongly from location to location. In those countries well equipped and well organised laboratories exist next to laboratories with minimal diagnostic possibilities and a lack of good educated co-workers.

The essentials of clinical laboratory management (essential guidelines) of the Committee on Clinical Laboratory Management (C-CLM) of the IFCC has been written to support the development of low-level clinical laboratories in developing countries. The essential guidelines have the only intention to provide tools for those laboratories which they can use in their own development.

It is important that the development of clinical laboratories in developing countries is performed by their own staff and in a direction that is suitable for their local situation.

It is not the intention of the essential guidelines to bring all clinical laboratories of the world to the same level, because the required local level differs too much. The intention is supply tools to enforce the local laboratory diagnostics.

#### 1.2 Aims of the essential guidelines

The essential guidelines describe the minimal requirements of different topics. They are written in a compact way to give a quick insight in the problems to solve. The essential guidelines do not have the intention to provide a comprehensive overview of the themes. There are good handbooks and publications available of all the topics when the highest level is required. The Basic Guidelines will help with the decisions about 'what to do first and what to do later on'.

#### 1.3 Topics essential guidelines

The topics described in this monograph are:

##### 1. Managerial guidelines to set up a clinical laboratory under difficult circumstances

These guidelines inform about the managerial ins and outs in the case of the set up of a clinical laboratory under difficult circumstances. They describe the essential elements of the business plan, the threats and opportunities, and the cost analysis. Also already existing clinical laboratories can check their situation with these guidelines.

##### 2. Basic level of Laboratory Information Systems (LIS)

One of the essential parts of the clinical laboratory is the Laboratory Information System (LIS) to control the whole process in the laboratory. The guidelines describe the basic functionalities which are essential for laboratories with minimal resources e.g. the printing of laboratory reports.

### **3. Essential guidelines for Total Quality Management & Accreditation based on ISO 15189**

Even under difficult circumstances the quality of the work of the clinical laboratory is important. In developed countries accreditation systems according to ISO norms are used to secure and enhance the quality of the laboratory diagnostics. The guidelines describe the essential parts of the ISO norms 15189. Under difficult circumstances it is impossible to set up a quality system which fulfils all norms within a reasonable time, but with the help of the guidelines the start of the introduction of the quality system is within hands reach. The introduction of the quality system will eventually leads to a system of Total Quality Management.

### **4. Basic training in managerial skills**

Specialists in laboratory medicine are not only expected to be professional experts but are also expected to be excellent managers of their laboratories. With minimal financial possibilities it is difficult to train the managerial skills. In this monograph practical possibilities for low-cost managerial trainings are described.

### **5. Basic quality control at low cost**

Quality control is essential under all circumstances. This chapter describes the necessity and low cost possibilities the internal and external quality control for medical laboratories.

### **6. Environmental conditions**

In developing countries the environmental conditions are not always optimal. This chapter describes the effect of the different environmental conditions.

## **1.4 The Committee on Clinical Laboratory Medicine (C-CLM)**

The Committee on Clinical Laboratory Medicine (C-CLM) is part of the Education and Management Division (EMD) of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). The C-CLM produces guidelines for colleagues who have to work in difficult financial and supportive situations.

The C-CLM can also help by realizing twinning relations between clinical laboratories in developed and developing countries.

The C-CLM has the conviction that although assistance of colleagues working under difficult circumstances is important, the work itself has to be done by the local colleagues. Only by their work the level of laboratory diagnostics for the local patients will raise.

## Chapter 2

### Managerial guidelines to set up a clinical laboratory under difficult circumstances

Wim de Kieviet

#### 2.1 Aim

To provide guidelines for specialists in laboratory medicine to set up a clinical laboratory with minimal financial and material resources.

#### 2.2 Introduction

'The fundamental solutions to Africa's health problems lie with African people themselves. The main duty of the international community is to create the conditions that will allow Africa to develop and flourish.' as stated by Sanders, Todd and Chopra (1). The creation of circumstances in which the local workers can flourish is important for all developing countries. Focused on clinical laboratories in developing countries, the Education and Management Division (EMD) of the IFCC installed the Committee on Clinical Laboratory Management (C-CLM) to support the local workers in their attempts to serve the local population with laboratory care.

The setup of a clinical laboratory in developing regions, which fulfils minimal quality requirements, is difficult to achieve when the financial and material possibilities are insufficient. In most cases information and guidelines are used from societies of laboratory medicine from developed countries. It is then disappointing that not all items of the guidelines can be followed.

The C-CLM has recognized these problems and has started the series of monographs of guidelines which fulfil "minimal requirements".

This guideline will give information about the basic managerial needs for a clinical laboratory under difficult circumstances.

#### 2.3 Business plan

The first step in the set up of a clinical laboratory is the formulation of the intention in a plan, the so called business plan. This business plan gives information about the justification to set up the new founded clinical laboratory. It makes an inventory of the opportunities and threats of the organization. The business plan should minimally contain the following elements:

- The aim of the clinical laboratory organization based on the established needs of the region. Too ambitious and not realistic aims are not fruitful for the success of the new organization
- The outcome of the search about the needs of the region on the field of laboratory medicine. Other already existing regional clinical laboratories have to be described in the business plan. The search has to be based on real information from all kind of medical informants. Consulting the general practitioners (GP's) to get a good insight in the regional situation can be very helpful. The regional search can be facilitated by following the questionnaire of the branch-analysis of the region in table 1.

Table 1. Questionnaire branch-analysis of the region

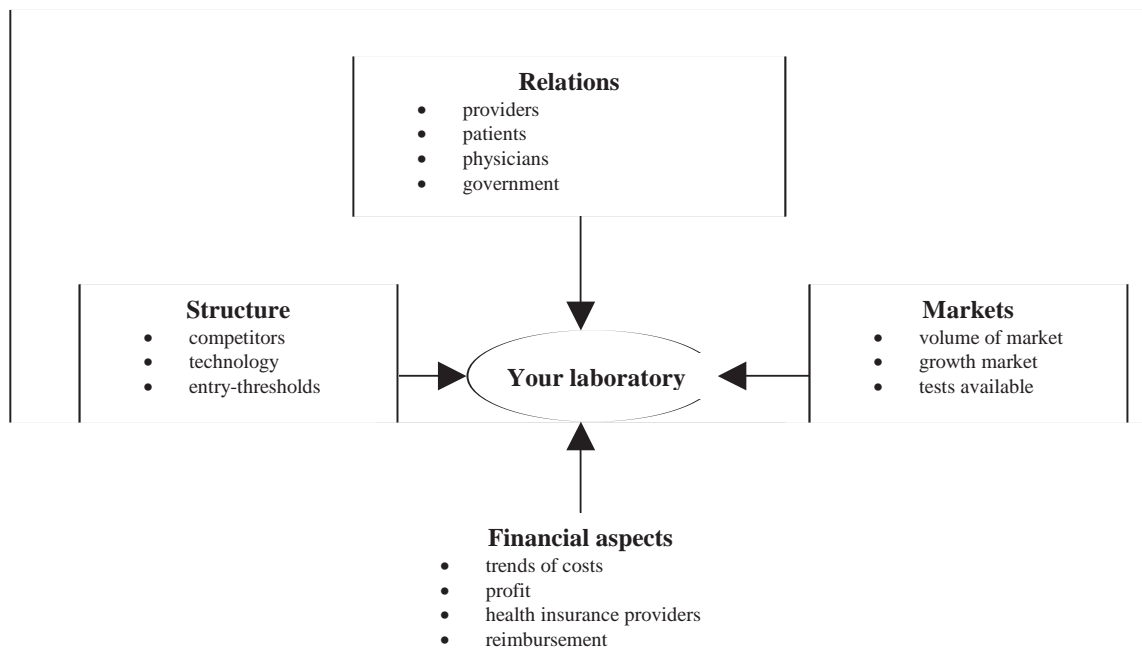
<p>Which clinical laboratories are present in the region?          Are there new clinical laboratories entering the market in the region?          What are the reasons that too few clinical laboratories have entered the regional market?          What is the percentage of the requested laboratory tests which has to be sent to outside the region?          What is the percentage of the regional population without access to a clinical laboratory?          What are the reasons that (a part of) the population has no access to a clinical laboratory?          What are the expectations of the growth in the requests of laboratory-tests in the region?          Are there local providers of laboratory equipment?          Can the local providers deliver reagents and consumables for the test?          Are there possibilities to appoint technicians and staff, or is it possible to educate local persons? Which tests are needed at the starting of the clinical laboratory?</p> <p>What are the costs of</p> <ul style="list-style-type: none"> <li>◆ the building (rent or investments)</li> <li>◆ the technicians and staff per year</li> <li>◆ the (post degree) education</li> <li>◆ the equipment (investment and writing-off for depreciation)</li> <li>◆ the expected spare parts per year</li> <li>◆ the expected reagents and consumables per year</li> <li>◆ the overhead (heating/cooling, water, etc) per year</li> <li>◆ the quality control system according to the minimal requirements</li> <li>◆ the license of the local authorities</li> <li>◆ the access to scientific information (internet, subscriptions, etc)</li> <li>◆ the blood collection system (decentralized or centralized)</li> <li>◆ the reports to the clinicians and GP's</li> <li>◆ the transport and testing of less frequent tests to other laboratories</li> <li>◆ the blood banking system</li> </ul>
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■ The justification of the panel of diagnostic tests for the laboratory.  
 The diagnostic panel has to be based on the regional search and not based on the expected possibilities of the future equipment.

■ A financial paragraph. The financial aspects have to be based on the regional search and not on expectations.

To answer the questions of the questionnaire a good insight in the elements of the regional branch is helpful. The regional branch analysis can be divided in 4 important elements: structure, relations, markets and financial aspects. These elements influence your laboratory (see figure 1).

Fig. 1 Elements of the regional branch analysis



*Structure.* Your laboratory will be dependent on the structure of the already existing laboratory facilities in the region (competitors). The possibilities of the competitors have to be investigated to avoid duplication of the laboratory services. Also the technological possibilities on the field of laboratory diagnostics influence your laboratory. Only the local available technology is interesting to use, because technology from other parts of the world will give problems with spare parts and service support from the suppliers.

Entry thresholds have to be known. These can differ from local agreements between the GP's and already existing laboratory facilities to demands from the government in the commercial code or other parts of the legislation.

*Relations.* The relations of local providers, patient groups or organisations, local physicians and GP's and representatives of the government with all the suppliers of laboratory diagnostics will influence the possibilities of your laboratory. A good insight in this part of the regional branch analysis will give you the right place in the field of force.

*Markets.* The volume and the movements of the laboratory medicine 'market' influence strongly the possibilities of your laboratory. Also when there are possibilities for you to enter the market you have to know the potential volume of the more important tests.

*Financial aspects.* Your laboratory can only perform test when somebody will pay for the costs. So insight in the expected costs is essential as well as in the possibilities of reimbursement. The local health insurance system have to give possibilities for your laboratory and health insurance companies must be willing to pay. Only with some profit the new laboratory can develop.

## 2.4 Opportunities and critical success factors

The opportunities of the clinical laboratory have to be described in the business plan. To establish a successful laboratory, information about the critical success factors (CSF's) has to be gathered and described. For the clinical laboratory the CSF's depends on the local situation of the following factors:

### *Technology*

The analytical and logistic technology has to be available on a level which fulfils the minimal requirements for quality and service to the physicians and patients. Be aware that it is not necessary that the newest technology has to be introduced, but that know and robust technology is more useful. Very essential is the delivering just in time of spare parts and consumables. The extent of the local distribution system of a company is more important than the costs of the investment of the equipment. The newest technology without the support of the local providers and without the easy access to reagents, disposables and spare part is a negative CSF!

For all the analytical devices good environmental conditions e.g. stable electricity, are needed.

### *Blood collection and logistic process*

Pre-analytical processes are as important as the analysis itself. An important CSF is a well organized blood-collecting department. The patients are the clients and must be "treated as a king". Even when the patient has no choice to go to a clinical laboratory elsewhere, it is essential for the future of your laboratory that the patient feels itself welcome in the blood-collection department.

After the blood and the other materials of the patient are collected the logistics of the process determine an important part of the costs. To minimize the costs streamlining is essential. Protocols have to be followed by performing the pre-analytical procedure. The protocols describe the route of the samples which will be handled in the pre-analytical run. Separate handlings of STAT samples are time consuming and have to be avoided. Make such agreements with the physicians that only in case of danger for the patient STAT procedure will be followed.

In the laboratory the number of handlings has to be as low as possible. Ensure that the samples follow a short and unequivocal route.

The system of reporting the test results to the physicians must be simple. Reporting results by telephone has to be reduced to STAT results and results which indicate that the patient is in danger. Telephonic reports will potentially cause errors and are time consuming.

### *Staff*

The staff is the "human capital" of the organization. Well educated and motivated staff members are essential as CSF. Only when the staff members are proud on their laboratory they are willing to work hard and will help to develop the tests and the organization.

The education of the staff members can be facilitated by the local education institutes or has to be set up by the specialist(s) of laboratory medicine. A yearly education scheme for all the staff members can regulate their scientific development. It is better to have less than under-educated staff members. It is important to pay reasonable wages.

To motivate the individual staff member it is important to give responsibility for (a part) of the work. Technicians, who are responsible for the analytical results and who are involved by the interpretation of the results, are more motivated to raise the laboratory diagnostics than technicians who are only allowed to run the analytical equipment.

Each staff member can be monitored by a periodical staff appraisal followed by a personal education plan. A staff-members documentation system is essential.

Team building activities are important for the loyalty to the laboratory organization.

The head (director) of the clinical laboratory has to realize that he/she has to organise optimal circumstances on the "working floor". Real service from the managerial staff to the workers in the laboratory is an important CSF.

### *Analytical service*

A CSF is the right panel of tests based on the real demands of the potential clients. Although it looks like hammer on an open door, it is mentioned because it is an easy way to take the panel with is possible with the existing equipment.

For each reported laboratory result the profit/cost ratio has to be calculated. In this calculation the following has to be taken into account:

- the costs of the reagents and consumables per test
- the costs of the quality assessment per test
- the costs of the pre-analytical phase per test (blood collection, pre-test handling, etc.)
- the costs of the scientific interpretation of the test-result
- the costs of the report to the physician calculated per test
- the costs of the overhead per test (building, temperature control, etc.)
- the costs of the staff calculated per test.
- the relation between the number of tests and the number of reported results

The profit per reported laboratory result depends on the local regulations and the reimbursement amounts of the health insurance companies. It is not necessary that each individual test will have positive profit. It is important that the sum of all profits (positive and negative) has a positive balance. When this is not the case, the tests with the most negative profits have to be send away to another clinical laboratory with the request to perform the tests. Centralization of less frequent tests is a good way to reduce the costs. Negotiations with the external laboratory about the price must deliver a lower price than the calculated price by the own laboratory.



### *Marketing*

Although marketing is not really usual in general health care, good information of the possibilities of the clinical laboratory towards the physicians and the patients is one of the CSF. The information has to contain the leading motto of the organization and insight in the performances of the laboratory and the level of quality assessment. For the patients it has to be clear that their laboratory investigations are in good hands in the concerning laboratory and that the laboratory staff is patient-oriented.

The contacts with the local physicians are an important CSF. A system of periodically consulting of the physicians to investigate their needs will give information for the growth and future of the laboratory.

### *Government and legislation*

Knowledge of the local legislation and contacts with representatives of the government will give insight in the possibilities of running a clinical laboratory. Especially the legislation of liability, working conditions and environmental policy are important for anticipation. In most countries the ministry of health or the ministry of home affairs gives information about the local regulations. Good contacts with the local chamber of commerce will provide insight in the local regulations and the necessary licenses.

Also knowledge of the local insurance and reimbursement system connected to the legislation of the government is profitable for your organisation. The set up of good contacts with the local health insurance companies is an important CSF.

### *IFCC membership*

Membership of the local society of clinical chemistry and laboratory medicine (IFCC member) is recommended. In countries, where the clinical laboratories are not yet organized in a society of clinical chemistry and laboratory medicine, effort are needed to set up a society. The IFCC stimulates the foundation of a society of clinical chemistry and laboratory medicine in each country.

## **2.5 Threats**

As every organization a clinical laboratory has to face its threats. To be aware of this will help in the completion of the business plan. The threats must have full attention in the business plan to avoid disappointments.

Well known threats are:

- too optimistic prognosis of the requests of laboratory diagnostics:  
exact knowledge, based on a real search about the needs, is essential.
- unexpected consequences of laws and regulations:  
every citizen has to know the law and the local regulations. Insufficient knowledge can be very costly. Uncertainty about new laws and regulations in developing countries can be decreased by the expected analogue to existing laws and regulations in other parts of the world. Especially new regulations for environmental conservation can cause unexpected expensive investigations.
- changing demands of laboratory tests:  
awareness of the possibilities of laboratory medicine can change the pattern of demands for laboratory diagnostics. Also a change of the local community caused by immigration of new groups of population can change the demands.
- other new clinical laboratories entering the local market:  
contacts with the local chamber of commerce can inform about the developments in the region.
- bankruptcy of the local suppliers or ending of their business activities:  
stay in good contact with the suppliers, ask periodically their plans and ideas for the future. Try to coordinate the choice of suppliers with the regional clinical laboratories.
- unexpected costs for the staff:  
the trade unions and the government can make new demands in the collective labour agreement. Make some reservation for these costs in the business plan.
- self complacency:  
it is a pitfall not to develop new plans when the clinical laboratory is running well. Be aware of the surrounding developments and continue in developing plans and innovation.

A good motto for treats is "make plans to convert treats to possibilities"

## 2.6 Segmentation of the clients

It is useful to make an analysis of the clients of the clinical laboratory and to group them together in segments with analogue demands. After segmentation it is possible to decide which segments can be focused on.

Segmentation of physicians who are sending patients to the clinical laboratory can be performed by the distance to your blood-collection department, the kind of patients they are specialized in, or the willingness to send patients to your laboratory.

After the segmentation it is possible to decide to focus on the special demands of the most relevant segments. In the case that the most relevant segments need the more expensive laboratory diagnostics and the reimbursement of the insurance companies is not sufficient, negotiations have to be started with the local authorities to face this problem. In some cases support from (inter)national bodies is possible to serve patients with epidemical diseases.

It is a pitfall to perform a detailed segmentation and then decide to focus on the segments which will give the most profit to the laboratory. Be aware that serving the most relevant segments will give a better continuation of your laboratory than choosing to maximize the short time profit.

## 2.7 Costs of laboratory diagnostics

To set up a laboratory under difficult circumstances it is essential to have insight in the costs per laboratory test. Most commonly a system of activity based costing is set up and is used as a managerial tool to regulate the costs.

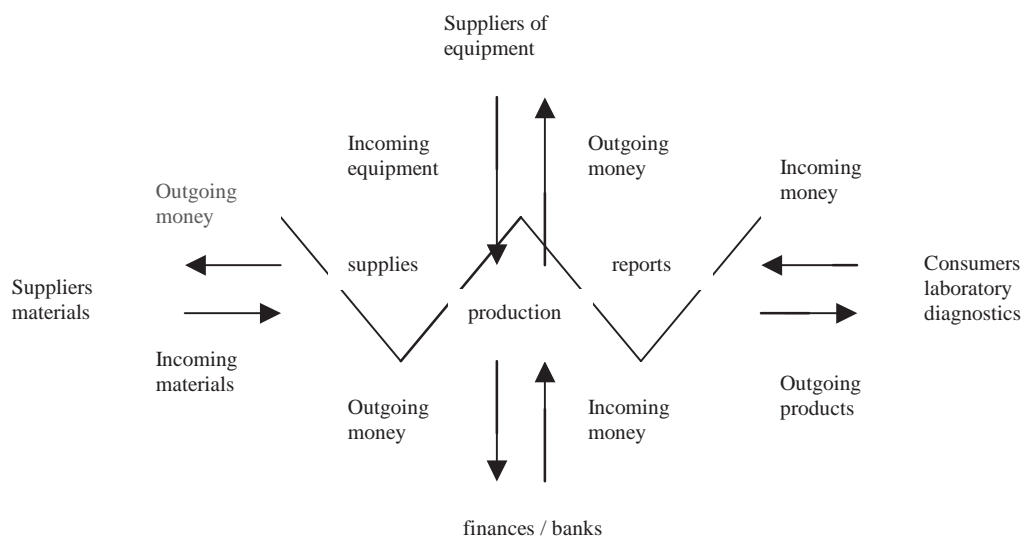
The basic idea of activity based costing is that the process (in this case the diagnostics of the clinical laboratory) can be described as a transformation process: the incoming request for laboratory diagnostics will be transformed in the laboratory process to laboratory results. The material pathway of the transformation process starts with the incoming materials and equipment from the suppliers to your laboratory to make the laboratory diagnostics possible. In your laboratory these materials are used in the production process to produce laboratory results. The laboratory results (outgoing products) are leaving your laboratory to the consumers.

Parallel to this process there exists another conversion process: money is converted to materials, materials to laboratory results and the results to money (reimbursement).

The transformation- together with the conversion process is called the operational process of the laboratory.

The operational process is schematically given in figure 2.

Fig. 2. The operational process of the clinical laboratory



The central rectangle is your laboratory. Materials from suppliers are 'converted' through the orders of laboratory diagnostics in the production process to reports of laboratory results for the consumers of laboratory diagnostics (horizontal process). For this transformation process your laboratory needs equipment and finances (vertical part of the figure). Parallel to this transformation process money is 'converted' to materials and back to money. The incoming money from the banks gives your laboratory the possibility to invest in equipment and materials. The incoming money from the consumers and their health insurance companies will give you the desired profit after paying all the costs.

This model can be used for the system of activity based costing.

In the system of activity based costing all costs are accounted to the laboratory products. The costs of the laboratory products (reported test results, including the interpretation of the test results, can be regarded as laboratory products) can be divided in direct costs and indirect costs.

Direct costs are costs which are accountable directly to a laboratory product. Examples are the costs per test of reagents, time of the technician, disposables, etc.

Indirect costs are overall costs and can be divided in indirect costs which relatively easily can be accounted to a laboratory product and indirect costs which can only arbitrary be accounted to a laboratory product.

Example of easily accountable indirect costs is the investment in analytical equipment. The investment normally has a depreciation of 10% per year. So 10% of the investment is the indirect costs for the laboratory results per year. This amount divided by the number of test results per year will give the indirect costs per test. Other examples of easily accountable indirect costs are the system of quality assessment, water and electricity, distribution costs of the results, rent of the accommodation, etc.

Examples of arbitrary accountable indirect costs are the costs of research, implementation of new tests, acquisition of new clients, advices to the physicians, temperature control of the laboratory, insurance contribution, telephone and internet costs, etc. These costs can only be accounted to the individual laboratory tests by a key of distribution or a surcharge to all the tests. As the key of distribution of these costs the working time of the technician per test can be taken, or the TAT (Turn around time) of the analytical part of the test. To make the system manageable only those indirect costs are accounted which are 5% or more of the indirect costs. The other indirect costs are grouped together.

Normally the 80 - 20 rule is applicable for the attribution of the costs of the tests: 80% of the costs are easily accounted to the individual tests; 20% of the costs can only arbitrary accounted to the individual tests.

Be aware that the overall costs must be equal to the sum of the costs accounted to the individual tests.

As stated above a test means a reported test result. In most cases more than one analytical test is needed to perform one reported result (e.g. analytical tests for quality control, retesting with diluted samples, etc.)

After this exercise the tariffs for the tests have to be fixed. Most easily is to take per test the tariff the same amount as the costs. Normally some differences between the costs and the tariffs exist because of marketing reasons. In some countries the government fixed the tariffs and it is not allowed to determine the own tariffs. Independent of the system of fixing the tariffs, the sum of the tariffs multiplied by the number of tests must minimally cover the total costs.

Of course it is difficult to do this exercise before the start of the laboratory. Nevertheless it is extreme important to get insight in the future financial situation as detailed as possible. It is dangerous to expect that a calculated deficit can be overcome by the (perhaps realistic) growth of the laboratory production. The expected production has to be based on the business plan.

A problem of the system of activity based costing is the a-synchronicity in time between the outgoing and incoming sums of money. This can be overcome by attributing all costs to the moment of performing the test.

After the start of the laboratory a system of controlling the costs is essential. Every three months the differences between the calculated and the real costs must be clear and have to be discussed by the management.

The annual report has to contain the financial outcome in relation to the expected financial prognosis.

An example of the method of activity based costing is recently given by Charuruks et.al.2. They calculated the costs of laboratory tests of the Central Laboratory of King Chulalongkorn Memorial Hospital in Bangkok, Thailand. The total direct costs were calculated from the labour costs, the material costs and the capital costs. The indirect costs were shared from the non-revenue producing cost centres (e.g. security, housekeeping, etc.), using appropriate criteria for allocation. The costs per test were calculated from the sum of direct and indirect costs.

The breakeven point (minimal number of tests to deliver profit) of each test-parameter was calculated by the equation:

$$\text{tariff per test} \times \text{number of tests} = \text{total indirect costs} + (\text{number of tests} \times \text{direct costs per test}).$$

This equation can be rearranged to calculate the breakeven point:

$$\text{breakeven point} = \frac{\text{total indirect costs}}{\text{tariff per test} - \text{direct costs per test}} .$$

The profitability ratio of each parameter was determined by

$$\frac{\text{total income}}{\text{total costs}}$$

Some examples are given in table 2.

Table 2. Data of number of tests, total indirect costs, direct costs, unit costs, price (tariff) per test and breakeven point of laboratory parameters of the Central Laboratory, King Chulalongkorn Memorial Hospital in the year 2002 (2).

Laboratory parameters	Routine Urinalysis	Glucose	Sodium	Routine Hematology CBC	ABO Blood group	Thin film Malaria
Tests number	136,682	143,501	107,832	180,396	57,578	4,254
Total indirect costs (USD)	6,640	9,434	8,386	13,314	377	303
Direct costs per test (USD)	0.304	0.132	0.164	1.485	0.042	0.040
Direct and indirect costs per test (USD)	0.345	0.198	0.242	1.542	0.048	0.111
Price (tariff) per test (USD)	1.50	1.20	1.50	2.40	0.90	0.90
Break even point	5,143	8,835	6,275	14,554	439	353
Difference unit costs – price per test (USD)	1.155	1.002	1.259	0.858	0.852	0.789
Total income (USD)	205,023	172,201	161,748	432,950	4,784	3,829
Total expenses (USD)	47,114	28,399	26,036	278,246	257	472
Profitability ratio	4.35	6.06	6.21	1.56	18.65	8.10

Direct costs will be dependent of the local situation. An example is given in table 3.

Table 3. Direct costs in the laboratories of the King Chulalongkorn Memorial Hospital, Bangkok, Thailand and the Sint Lucas Andreas Hospital, Amsterdam, The Netherlands.

Direct costs	King Chulalongkorn Memorial Hospital	Sint Lucas Andreas Hospital
Labour costs	13 %	49 %
Material costs	85 %	47 %
Capital costs	2 %	4 %

## 2.8 Position of the medical laboratory and education of the staff

The medical laboratory has to be an integrated part of the local health system network. In most cases a central hospital laboratory with specialist laboratory units is the trunk of the local network. The central hospital laboratory is usually staffed with laboratory specialists and technicians and has a leading position towards the local district laboratory services. Also in the district laboratories adequate trained laboratory staff is essential. The training programme with educational objectives to become a competent district laboratory officer has to be set up under the supervision of the central laboratory. The training has to be competency-based and task-oriented for the diagnostic tests offered to the patients.

Competency of the technicians is a major success factor in achieving a good quality of service. An example of a job-oriented, competency-based training programme for technicians is given by Cheesbrough (3).

The professional education is a continuing process. It includes on-going training in the own laboratory by skilled teachers. The health authorities have to be convinced about the importance of the on-going education and training of the staff for the quality of the local laboratory services and the medical health of the community. A surcharge tot the test price for education programmes can be reasonable.

A code of professional conduct can be helpful to express the professionalism. The code of the professional conduct describes the professional attitude of the laboratory staff by recognised standards. It expresses the responsibility of the staff to patients and their integrity. An example of the code of conduct has been published by the International Federation of Biomedical Laboratory Science (IFBLS) (4).

## 2.9 Laboratory Information System (LIS)

The Laboratory Information System (LIS) on a basic level is described in chapter 3. Although a LIS is not essential for the analytical results of the laboratory tests, it will enhance the quality of work substantially. The majority of the errors in the laboratory are caused by human acts. These errors can be reduced by the automation of the laboratory process by the introduction of a LIS. The LIS will also reduce the work load of the technicians. In the business plan the costs of the introduction of the LIS has to be discussed in relation to the required quality level.

## 2.10 Total quality management

The total quality management (TQM) on a basic level is described in chapter 4.

It is basic need for the good daily practice. The TQM is not only the analytical control of the diagnostic tests. It is a comprehensive system about all areas of the laboratory which influences the quality of the diagnostic services. The quality of the staff is one of the main issues in TQM. Also the correct use by the physicians of the diagnostic possibilities of the laboratory determines the overall quality gain of the local health care. The relevance of the laboratory tests and the interpretation of the tests results will determine the added value of the laboratory to the patient well-being. In the TQM system the demands of the patients (clients) are the heart of the system.

## 2.11 Summary basic managerial guidelines

- set up a realistic business plan based on a real information search
- determine opportunities and critical success factors
- be aware of the threats
- determine the level of analytical service
- develop an education and motivation system for the staff
- develop good contact with the governmental organizations
- keep good contacts with the physicians
- develop a system of activity based costing
- well educated staff and technicians are essential
- become member of the local IFCC related society

## 2.12 References

1. Sanders DM, Todd C, Chopra M, Confronting Africa's health crisis: more of the same will not be enough, *BMJ* 2005;331:755-8.
2. Charuruks N, Chamnanpai S, Seublinvog T, Cost analysis of laboratory tests: a study of the Central Laboratory of King Chulalongkorn Memorial Hospital, *J Med Assoc Thai* 2004; 87:955-63.
3. Cheesbrough M, *District laboratory practice in tropical countries, part 1*, Cambridge University Press 2005: 430-435
4. See <http://www.ifbls.org/why/IFBLS%20Code%20of%20Ethics.pdf>

## Chapter 3

### Basic Level of Laboratory Information Systems (LIS)

Herbert Stekel

#### 3.1 Aim

The aim of this chapter is to provide guidelines for specialists in laboratory medicine to choose a Laboratory Information System to cover minimal requirements. The guidelines could be useful for clinical laboratories in developing countries, which can be confronted with minimal financial resources.

#### 3.2 Introduction

Laboratory Information Systems (LIS) have rapidly developed over the past 25 years. Technological progress has been quite significant. This is evident in new hardware, new software development tools (programming languages) and improved communication within networks. Today LIS have developed into complex database systems. Nevertheless, the main purpose of these systems is printing reports. Printed reports are easier to read than those written by hand. This prevents the occurrence of writing errors, making information from the laboratory more reliable. As a result, current LIS facilitate more reliable decisions when treating patients. To overcome the absence of sufficient financial possibilities to buy a commercial LIS, some laboratories try to create their own system. This could be a very strenuous and expensive way. Most programmers have no laboratory experience. Typically, projects need much more development time than planned. Documentation is often poor. Together with some personnel turnover, this might be a very threatening situation for the laboratory. Finally yet importantly, the software debugging has to be done by the laboratory personnel. This can be extremely stressing for the end-users.

To overcome these problems, a suitable way to implement a laboratory information system is shown in Fig 1.

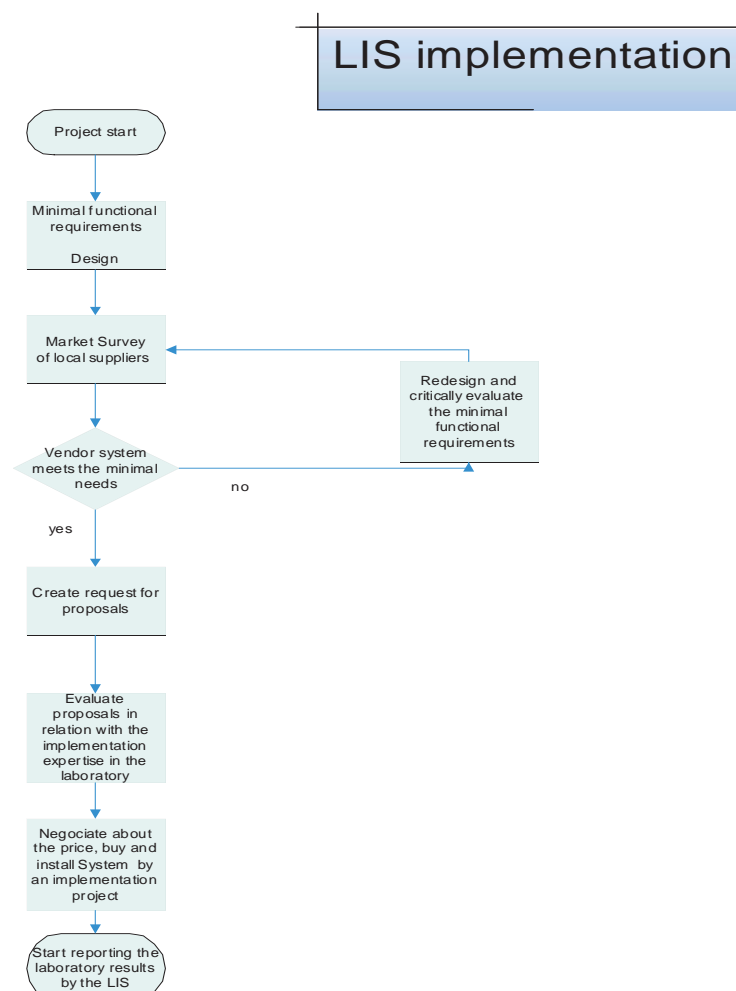


Fig. 1 A LIS must comply with country-specific regulatory requirements and electronic data security.

### 3.3 Functional features

There are certain basic functionalities, which all laboratory information systems must provide. As shown in the introduction the most important function is the printing of reports. To print reports in an accurate way, there are many items needed. First, information about the patient is needed. This encloses the patient's name, gender and date of birth. This can be a problem in certain developing countries with illiterate persons who are not able to write their name. Also the exact date of birth might be a problem. The use of a nickname may be helpful. Second, the destination of the report has to be printed. This could be the address of the patient, or the name and address of the requester or, in hospitals, the name of a functional unit, e.g. a ward or an intensive care unit. Next, the results of the laboratory tests have to be reported. Results are always printed together with the name of the parameter, the measuring unit, the biological reference values and the interpretations of the result where necessary. There must be space to print comments on the sample quality. Header data include the name and address of the laboratory, the date of report, and the identification and signature of the person checking or releasing the report.

The lay out of the reports has to be clear and well readable. All results with pathological findings should be easy to take in at a glance.

### 3.4 The way to the printed report - step by step

We need various steps to collect all the data to print a report. Each of these steps represents a step in laboratory workflow and a software module. An example of laboratory workflow is given in fig. 2.

The modules for basic functionality are:

- Patient data entry
- Requester data entry
- Sample request
- Worklist rebuild
- Input of results
- Validation
- Report printing
- Quality control
- Master data
- Statistics

For laboratories with a higher grade of automatisation and an increasing number of samples, the following modules may be helpful:

- Sample identification via barcode
- Distribution of samples
- Data exchange with analyzers

Laboratory information systems must support the workflow in the laboratory. Therefore, first, the workflow has to be exactly described. Fig.2 shows a very common example of laboratory workflow and the basic functions, where support by a LIS could be extremely helpful.



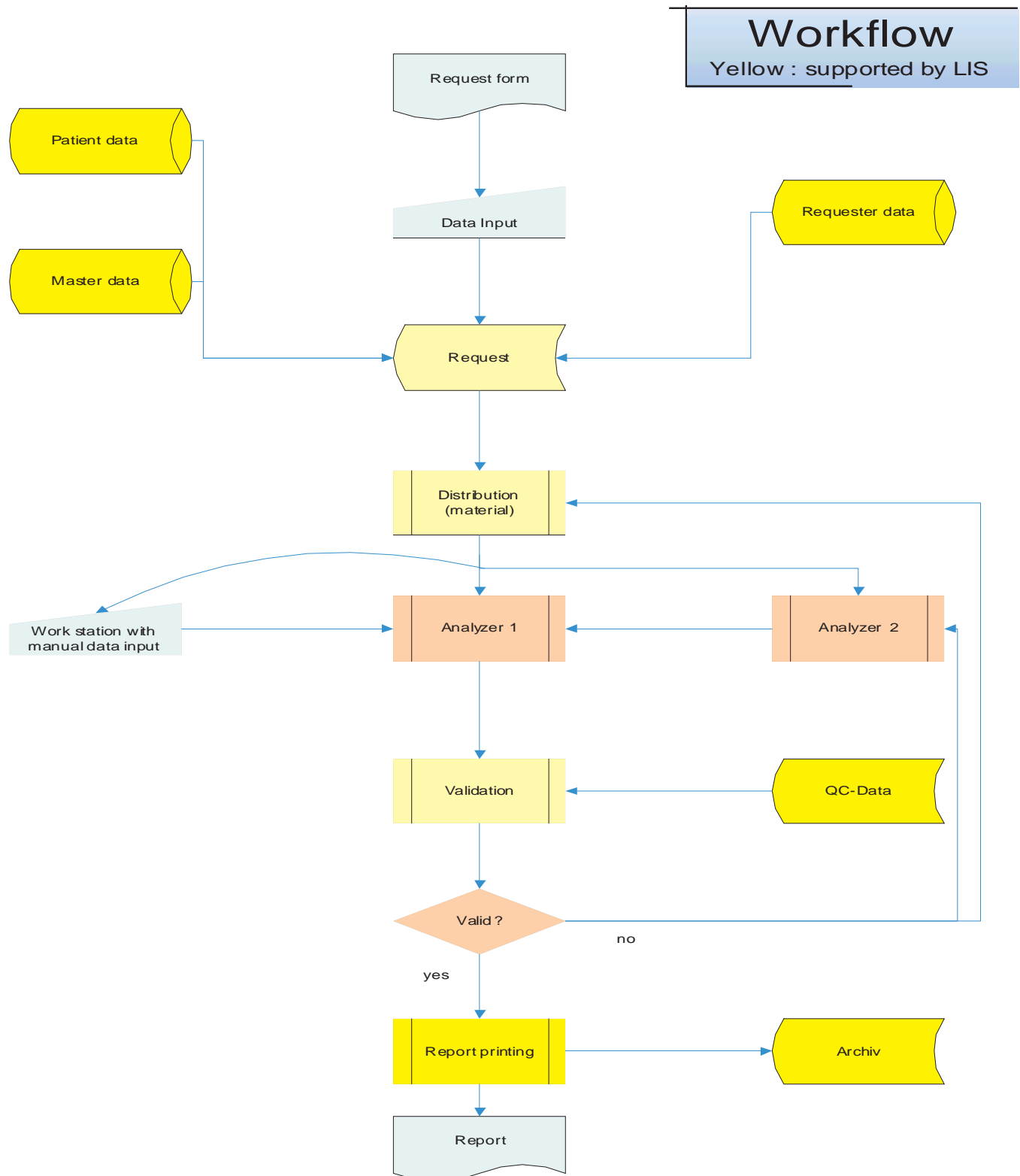


Fig. 2

### 3.5 Basic modules

Patient data entry has to be fast and easy, and it is most important for the dialogue to be user-friendly. Reliable patient identification must be possible. The minimum requirements are last name, first name, sex and date of birth (if possible). Other identifiers, such as nicknames can be used in specific cases if they help to avoid confusion. There are several different ways of inputting data into the system. In small laboratories, data can be entered via keyboard. It should be mentioned however, that in this case the error rate may be up to two per cent. Another option is data acquisition using barcodes. Some systems allow for the reading of 2D-codes, but printing these labels in the ward may be difficult or expensive. In most hospitals patient data already exist in the hospital information system and can be transferred to the LIS. This can be carried out every 5 or 10 minutes via the data network.

The input of requester data should also be quick and easy. Wherever possible, data should be collected in the master data module of the LIS. If possible, the database should cover more than 90% of the requester data needed. This is necessary to avoid variability from report to report. Requester data should consist of name and address, telephone number and e-mail address if case reports can be delivered by e-mail. It is also useful to hold all data required for invoicing, such as bank account or discount numbers.

The sample request dialog should run under the same conditions as mentioned above. All relevant information concerning the sample should be captured; date and time of collection, materials (e.g., blood, urine), and tests required. Additional information like "oral anticoagulant" should be captured easily. The function should take advantage of as many fields "pre-filled-in" as possible. Pull down lists are also a good tool.

All samples and requests shall be placed on the worklists. These Lists shall contain sample identification, date and time of sample collection, tests requested, identification of the patient, and information about the requester (e.g., telephone number).

Before generating a report, a LIS must have ways to enter test results. This can include manual entrance of results as well as automated down loading directly by an on-line coupling of analytical devices to the LIS. Absurd or impossible results should be detected by checking the entries against a predefined range of values.

Each result has to be systematically reviewed by authorised personal. Results shall be evaluated in conformity to the clinical information available.

The laboratory should approve and review the format and the content of the reports. This is to ensure that reports meet the needs of the medical staff. Reports have to content comments on sample quality (e.g., lipaemic) and comments on interpretation of results. Patient data should be compared with original input to ensure the integrity of data transfer. According to ISO 15189, 5.8.3., the report shall include identification of the examination, including, where appropriate, the measurement method; identification of the laboratory that issued the report; identification of patient; destination of the report; name of the requester, time stamp of sample collection, when available; time of sample receipt; date and time of release of report; results of the examination in SI units or units traceable to SI units; biological reference intervals; interpretation of results

The laboratory information system must allow appropriate quality control data to be entered. Data should be used to calculate precision and accuracy. The LIS shall include a possibility to generate QC-charts including standard deviation, trending and data validation through predefined criteria.

The input of master data should be made using graphic supported dialogues. There should be the possibility to define analysis including reference values and linearity limits. There must be also dialogues to define work lists, requesters, materials, QC-master data and the management to define the levels of access to the system.

Data management performed by a laboratory information system allows easy access to laboratory statistics. Minimal statistics include the counting of samples, requests and results. Each of these counts is associated with a defined time and with the requester.

### **3.6 Modules for laboratories with a higher grade of automatisation**

#### **Identification of samples**

The identification of samples is one of the most important aspects of laboratory work, and can be accomplished in various ways. The most frequently used method is to assign unique numbers (up to ten digits) or numbers in combination with the year. The link between sample and patient must be apparent throughout the process. Bar codes and hand scanners should be used as far as possible. Bar coding is about 20 times faster and 20,000 times more accurate than keyboard entry. (Paszko, C.; Turner, E. in "Laboratory Information Management Systems", Marcel Dekker Inc., Second Edition, p 28, New York 2001). Bar codes are also relatively easy to handle. In order to identify a sample, all you need is the bar code software and a label printer. Bar code labelling must be carried out prior to sample collection. If this is not possible (e.g. outside hospitals or laboratories), labelling must be carried out at the point of sample entry.

This picture (Fig 3) shows a barcode label from our laboratory. The unique sample number is printed as bar code and also on both sides of the label. You can also find information about the color of the cap of the blood collecting system, here red, used for ammonium. In our laboratory this material is also marked with the number 12. This number is also to find as an extension of the sample number printed in the barcode. The inverted font indicates, that this is an urgent sample. Further you can see the patients name and the case-number. On the bottom of the label you can find two more notes



for the users. Transport shall be "on ice" and the material must be centrifuged in the lab. The picture on the right hand (Fig.4) shows the proper positioning of a label. If a sample must be aliquotted or split, the LIS shall assign subsequent identification codes. These must be associated with the original sample.



**Paper forms vs. order entry**

If orders are handed using paper forms, the sample request dialogue should be conducted as described above. All relevant information relating to the sample should be captured: identification of patient, date and time of collection, materials (e.g., blood, urine) and tests required. Additional information such as "oral anticoagulant" should be easy to capture. The function should use "pre-filled fields" to the greatest extent possible. Drop-down lists are also a useful tool. Machine readable forms are a good way to reduce turnaround time.



Here (Fig. 5) you can see a part of a paper form. The form is machine readable, you can see the marks on the right border. There are different, material- specific labels. The colours are corresponding with the colours used for the caps of the blood collecting system. The labels are built similar to the one shown before. This form was used with printers, that printed the patients name on the labels and also the case number on the form. There is a possibility to mark urine collecting time and volume in a machine readable way. You can see this in the lower right corner.

**Lauris Administrator**  
Version 7.04.25

Formular bearbeiten

Datenbank: SWISSLAB  
Benutzer: hs

**Funktionen:**

- Cache Reset
- Kopie in die Zwischenablage
- Datensatzinfo
- Eintrag suchen

Wechseln zu:

- Hauptmenü

Anforderung	Bestimmung	Text	zu Profil	Behälter
<input type="checkbox"/> Notfall 24h-Labor				
<input type="checkbox"/> <b>Kontrollkette - Anforderer</b>	NAME			NAME
<input type="checkbox"/> Plan-Zeitpunkt				
<input type="checkbox"/> infektiös	FLAU	infekt		
<input type="checkbox"/> Chemo Therapie	FLAU	chemther		
<input type="checkbox"/> oral antikoagulant	FLAU	orako		
<input type="checkbox"/> Heparin	FLAU	hep		
<input type="checkbox"/> nicht nüchtern	FLAU	neu		
<input type="checkbox"/> Transfusion	FLAU	tran		
<input type="checkbox"/> LMW-Heparin	FLAU	lmwhep		
<input type="checkbox"/> Klinische Chemie				
<input type="checkbox"/> Virologie				
<input type="checkbox"/> Blutbild / Malaria				
<input checked="" type="checkbox"/> Blutbild	YBB			EDTA-8B
<input checked="" type="checkbox"/> Malaria (+ Serum!)				
<input checked="" type="checkbox"/> Gerinnung				
<input type="checkbox"/> Basisgerinnung	BASIS			CITRAT
<input type="checkbox"/> Großer Status	GRSTATUS			CITRAT
<input type="checkbox"/> PTZ und INR	PTZINR			CITRAT
<input type="checkbox"/> aPTT Actin FS	PTTA			CITRAT
<input type="checkbox"/> Fibrinogen	FIB			CITRAT
<input type="checkbox"/> AT III	AT3			CITRAT
<input type="checkbox"/> Thrombinzeit	TZ			CITRAT
<input type="checkbox"/> Reptilasezeit	REP			CITRAT
<input type="checkbox"/> D - Dimer	DDIM			CITRAT
<input type="checkbox"/> UFH Monitoring	UFH			CITRAT
<input type="checkbox"/> Faktor anti Xa Aktivität	FXA			CITRAT
<input type="checkbox"/> Notfall Gerinnung	notb			
<input checked="" type="checkbox"/> <b>Nur nach Anmeldung (1841)</b>				
<input type="checkbox"/> Medikamente / Toxikologie				
<input type="checkbox"/> Reproduktionsdiagnostik				

The most common - and also most secure - way is 'order entry' via data network. Orders are written by requesters in the wards using graphic user interfaces similar to Windows™.

Fig. 6 is a screenshot of a request form. On top, some information like anticoagulation are simply to mark.

Supporting the distribution of material e.g. whole blood, serum, is one of the key roles of LIS. If a sample is to be aliquoted or split, the LIS can assign subsequent identification codes that must be associated with the original sample.

All samples and requests are placed on work lists. These lists must contain sample identification, tests requested, patient identification and information about the requester (e.g., telephone number).

**Materialverteilung**

Funktion: Auswahl | Dokument: Info

Strategie: Notfall N | Mat.Nr.: 1 | Kitzmüller Hubert 23.06.1927 M | S: AX.20071825-45 | Wambacherstr. 44030 Linz 06.10.2007

Auftrag: 54250230 | 1 | Patient: | Archiv: | 09.10.2007 10:12 | 0168

Probe: 5425023001 | 3 | 4 | Patienteninformation/Diagnosen

Arbeitsplatz	Bezeichnung	Pos.	Anz.
8	PC-Notfall	6	24
1007	PPE-EMOD	5	1

Code	Einheit	Ergebnis	Bezeichnung
MCP			
hbc	g/l	5.42	
hct	l/l	3.99	
hb	g/dl	11.5	
hgt	l	34.2	
hba	g	87.2	
hba	g/dl	29.2	
hba	g/dl	33.5	
hba	g	13.2	
hba	g/l	201	
NA	mmol/l		
K	mmol/l		
CL	mmol/l		
CA	mmol/l		
MG	mmol/l		
PHOS	mmol/l		
HS	mg/dl		
BUN	mg/dl		
KREA	mg/dl		
TP	g/l		
AST	U/l		
ALT	U/l		
GTTP	U/l		
CH27	U/l		
AP27	U/l		
TBIL	mg/dl		
DBIL	mg/dl		
LD27	U/l		
DK27	U/l		
ME27	U/l		
CHOL	mg/dl		
TG	mg/dl		
CRP	mg/dl		
CTNT	mg/dl		
PTT	sec		

Verteilte Aufträge

Nr.	Auftrag	Name, Vorname	Mat.	Seqnr.
-----	---------	---------------	------	--------

Hilfe | Verteilinfo | Abbruch | Neu | CodeNeu | Kursul | Einnahm. | Speichern | Auftragsinfo | Quallo

Swisslab Administrator - Anzeige der zur Strategie gehörenden Arbeitslisten | DATA LAB | 10.23

The screenshot (Fig. 7) shows, how material distribution was supported in our LIS. On the right half you can see, that a serum specimen was presented to the bar code reader. Therefore all requested analysis, that are need serum, are printed in black. The requests shown in dark yellow need other materials or have results as the blood count on top. On the left side, to work places are listed. These are serum work areas, and they both need material, so we have to split our specimen.



This picture (Fig. 8) taken in our lab shows the work place where samples were distributed by hand. In the front, a decapping, splitting and distributing machine is assembled, it works now since March 2007



Fig. 9 shows the out sort part of the sorting machine. Racks in different colours are used, each one assigned to a work place. The yellow and grey racks on the right side are assigned to the specimen archives. All data needed are sent from the LIS. The reading of the sample barcode triggers the data transfer like in bidirectional connected analysers

Before generating reports, LIS must have ways of entering test results. This can include manual inputting of results as well as automated downloading directly by linking analytical devices to LIS online. Absurd or impossible results should be detected by checking the entries against a predefined range of values.

Each result must be systematically reviewed by authorised personnel, and all results evaluated against with the clinical information available.

Data exchange with analyzers should use the RS 232 port as a worldwide standard. The amount of equipment using net ports is slowly increasing. It is therefore possible that a new standard established will be within the next five years. Data exchange may be either unidirectional (results from analyzers transmitted to LIS), or bidirectional (work lists downloaded to analyzers; results transmitted). The best solution is a bidirectional dialogue based on samples identified by barcodes. After reading the barcode, the analyzer reviews the specific requests and sends the results after finishing the analysis.

### Items to print in a report

There are certain basic functions which all laboratory information systems must provide. As shown in the introduction, the most important function is printing reports. Many items are needed to print reports accurately. Firstly, information about the patient is needed, including the patient's name, sex and date of birth. This can be a problem in certain developing countries, where illiterate persons may be unable to write their names. The exact date of birth may also be a problem. Secondly, the destination of the report must be printed. This may be the address of the patient, or the name and address of the requester, or, in hospitals, the name of unit, e.g. a ward or an intensive care unit. Next, the results of the laboratory tests must be reported. Results are always printed together with the name of the parameter, units, biological reference values, and an interpretation of the result where appropriate. There must be space to print comments on the sample quality. Header data include the name and address of the laboratory, the date of report, and the identification and signature of the person checking or releasing the report.

The layout of reports must be clear and easily readable. All results with pathological findings should be easy to take in at a glance.

The laboratory should approve and review the format and content of reports to ensure that they meet the needs of medical staff. Reports must contain comments on sample quality (e.g., lipaemic) as well as comments on the interpretation of results. Patient data should be compared with original input to ensure the integrity of data transfer. According to ISO 15189, 5.8.3., reports should include identification of the examination, including, where appropriate, the method of measurement; identification of the laboratory issuing the report; patient identification; destination of report; name of requester, time stamp of sample collection, when available; time of sample receipt; date and time of report release; results of examination in SI units or units referable to SI units; biological reference intervals; interpretation of results.

The following pictures show some examples of reports with a wide variation of lay out.

BIOCHEMISTRY LABORATORY, REGIONAL GENERAL HOSPITAL, LIMERICK.				
TEL 061 201111 ext 2257				
DIRECT DIAL 061 482257 / 482266				
NAME:	AGE:		LOCATION:	
SEX: M	PID: BB365		DOCTOR:	
COMMENTS:			LAB NO: 365	
			IDEE: 0000365	
			COLLECTION DATE/TIME:	
			29/07/97 10:00	
			REPORT DATE/TIME	
			29/07/97 16:02:20	
SAMPLE TYPE: SERUM				
CHEMISTRY	RESULTS		UNITS	NORMAL RANGE
	NORMAL	ABNORMAL		
Sodium		135.0	MMOL/L	(136.0 - 149.0)
Potassium	4.48		MMOL/L	( 3.70 - 5.10)
Urea	5.0		MMOL/L	( 2.5 - 7.5)
Creatinine	87		UMOL/L	( 50 - 125)
Glucose	4.3		MMOL/L	( 3.6 - 5.0)
Total Calcium	2.32		MMOL/L	( 2.23 - 2.56)
Inorganic Phosphate	1.21		MMOL/L	( 0.88 - 1.45)
CREATINE KINASE	101		U/L	( 10 - 200)
Lactate Dehydrogenase		204	U/L	( 70 - 183)
Aspartate Amino Transferase	20		U/L	( 13 - 42)
Total Bilirubin	10		UMOL/L	( 5 - 17)
Alkaline Phosphatase	107		U/L	( 39 - 117)
Gamma GT		97	U/L	( 10 - 40)
Alanine Amino Transferase	17		U/L	( 10 - 35)
Total Protein	66		G/L	( 60 - 80)
Albumin	40		G/L	( 35 - 47)
Uric Acid	248		UMOL/L	( 120 - 420)
Magnesium	0.88		MMOL/L	( 0.88 - 1.00)
Cholesterol	5.9		MMOL/L	( 4.0 - 6.7)
Triglyceride		4.01	MMOL/L	( 0.80 - 2.00)
Amylase	42		U/L	( 22 - 100)
Acid Phosphatase (total)	5.1		U/L	( 2.0 - 11.0)
Acid Phosphatase (Tart. Res.)	2.2		U/L	( 2.0 - 7.0)
REVIEW BY: _____				

This (Fig.10) is an example of a very simple lay out. It can be printed on every type of printer, even a typewriter will do. But you can find all elements as described before:

- Information about the patient
- Destination of the report
- Results
- Name of parameter
- Units
- Reference Values
- Interpretation
- Name and address of the laboratory
- Date of report
- Sign

**Lauris Client** Version 7.04.25

**Befund-Ansicht**

Datenbank: SWISSLAB  
Benutzer: HS ADMIN  
Arbeitsplatz: PCM1464 DEBUG  
Abteilung: 895

**Funktionen:**  
Druckvorschau  
Direktausdruck  
Vademecum  
Verlaufsgrafik  
Kopie in die Zwischenablage  
Bestimmung suchen

**Wechseln zu:**  
Hauptmenü [F4]  
Patientenverwaltung [F3]  
Auftrags-Erfassung [F6]  
Auftrags-Ablage [F7]  
Befund-Ansicht [F8]  
Befund-Eingang [F9]

**Arbeit unterbrechen:**  
Programm sperren [F12]  
Programm beenden [Alt F4]

**Stornierte, Leistung, 12.11.1924, M 82**

Bestimmung: 05.07.2007 07:51 Wert Flag Status Vorwert von Einheit Referenz

Bestimmung	Wert	Flag	Status	Vorwert	von	Einheit	Referenz
<b>Rotes Blutbild</b>							
Erythrozyten	3.51	-	tech. val.			T/l	4.5 - 5.8
Hämoglobin	10.2	-	tech. val.			g/dl	14.0 - 17.0
Hämatokrit	30.1	--	tech. val.			%	42.0 - 50.0
MCV	85.9	-	tech. val.			fl	78.0 - 98.0
RDW	15.4	-	tech. val.			%	12.9 - 10.7
MCH	29.1	-	tech. val.			pg	27.0 - 33.0
MCHC	33.9	-	tech. val.			g/dl	32.0 - 36.0
<b>Weisses Blutbild</b>							
Leukozyten	14.62	+	tech. val.			G/l	4.0 - 10.0
Thrombozyten	97	-	tech. val.			G/l	150 - 400
<b>plasmatische Gerinnungsanalysen</b>							
Quick	s. Komm.	-	tech. val.	27.2	25.11.2005	%	70 - 140
Quick	Material fehlt	-	tech. val.	2.04	25.11.2005		2 - 4.5
INR	s. Komm.	-	tech. val.			sek.	23.0 - 31.9
aPTT Actin F5	s. Komm.	-	tech. val.				
<b>Ionenogramm</b>							
Natrium	130	-	tech. val.			mmol/l	136 - 150
Kalium	4.5	-	tech. val.			mmol/l	3.5 - 5.3
Chlor	110	-	tech. val.			mmol/l	95 - 115
Calcium	2.0	-	tech. val.			mmol/l	2.15 - 2.55
<b>Niere</b>							
BUN	15	-	tech. val.			mg/dl	6 - 20
Kreatinin	0.8	-	tech. val.			mg/dl	0.7 - 1.2
GFR nach aMDKD	98.4	-	tech. val.			ml/min/1.73m <sup>2</sup>	80 - 150
<b>Proteindiagnostik</b>							
Gesamteiweiß	60	-	tech. val.			g/l	66 - 87
<b>Streifenfest - Harn</b>							
spez. Gewicht	1.025	-	tech. val.	geloscht	24.03.2006		
pH-Wert	5.0	-	tech. val.	geloscht	24.03.2006		
Leukozyten	NEG	-	tech. val.	geloscht	24.03.2006	Jul	
Nitrit	NEG	-	tech. val.	geloscht	24.03.2006		
Eiweiß	NEG	-	tech. val.	geloscht	24.03.2006	mg/dl	

Fig. 11 shows a single report on a screen in the ward, showing also results and date of former analysis.

**Lauris Client** Version 7.04.25

**Befund-Ansicht**

Datenbank: SWISSLAB  
Benutzer: HS ADMIN  
Arbeitsplatz: PCM1464 DEBUG  
Abteilung: 895

**Funktionen:**  
Druckvorschau  
Direktausdruck  
Vademecum  
Verlaufsgrafik  
Kopie in die Zwischenablage  
Bestimmung suchen

**Wechseln zu:**  
Hauptmenü [F4]  
Patientenverwaltung [F3]  
Auftrags-Erfassung [F6]  
Auftrags-Ablage [F7]  
Befund-Ansicht [F8]  
Befund-Eingang [F9]

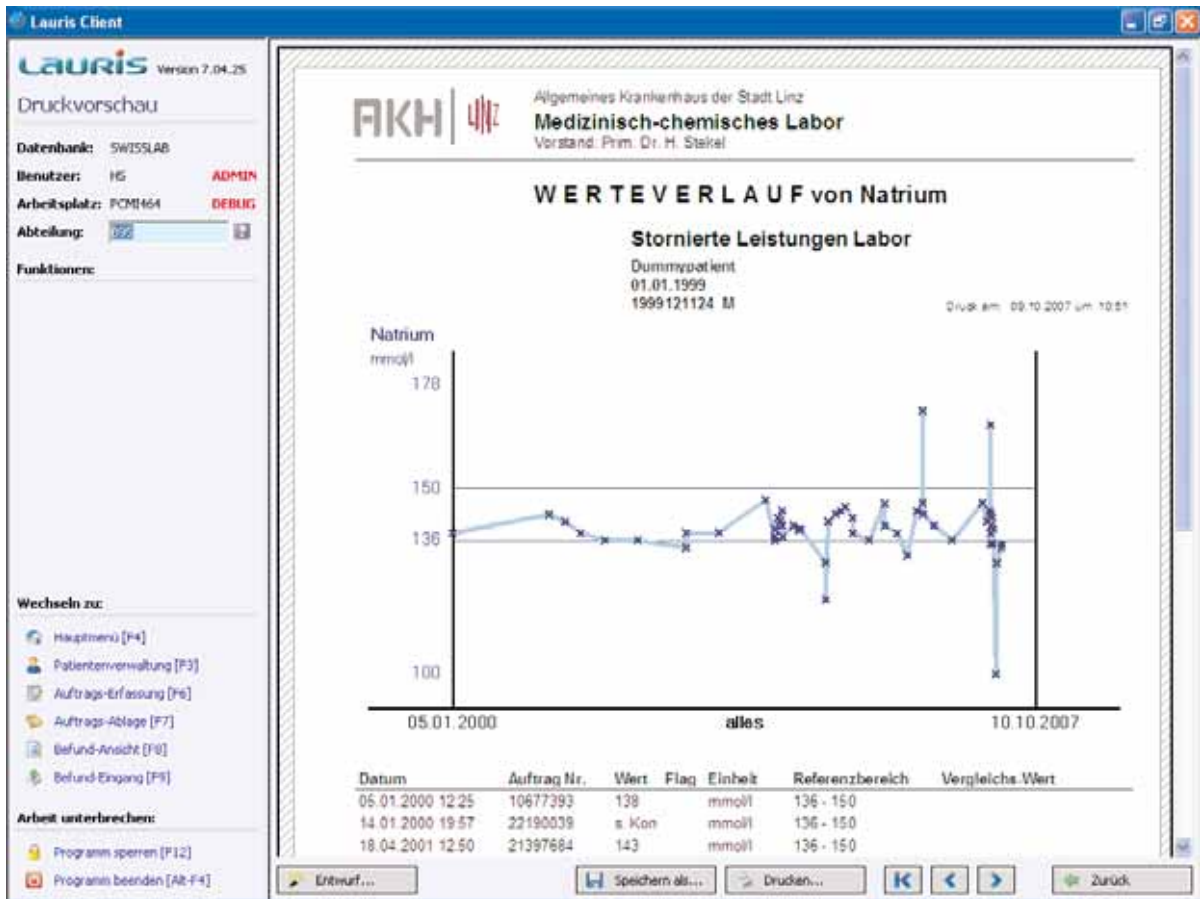
**Arbeit unterbrechen:**  
Programm sperren [F12]  
Programm beenden [Alt F4]

**Stornierte Leistungen Labor, Dummpatient, 01.01.1999, M B**

Bestimmung: 05.03.07 05.03.07 05.03.07 01.03.07 26.02.07 26.02.07 16.02.07 16.02.07 11-21 Einheit Referenz

Bestimmung	05.03.07	05.03.07	05.03.07	01.03.07	26.02.07	26.02.07	16.02.07	16.02.07	11-21	Einheit	Referenz
<b>Auftrag-Klassier</b>	17:18	17:18	10:41	16:51	14:07	14:05	11:21				
<b>Auftrag-Nummer</b>	64125648	53141022	64081018	52889727	51876674	63495445	90358312				
<b>Abnahme-Datum</b>											
<b>Abnahme-Uhrzeit</b>											
<b>Rotes Blutbild</b>											
Erythrozyten	3.73	4.21								T/l	3.9 - 5.1
Erythrozyten			3.27							T/l	4.2 - 5.1
Hämoglobin	12	11								g/dl	11.5 - 14.5
Hämoglobin			9.1							g/dl	12.3 - 15.3
Hämatokrit	38.1	35.3								%	35.0 - 45.0
Hämatokrit			28.5							%	38.0 - 45.0
MCV	102.1	83.9								fl	69.0 - 93.0
MCV			87.3							fl	70.0 - 96.0
RDW	12.7	14.6	17.6							%	12.9 - 18.7
MCH	32.2	26.2								pg	22.0 - 34.0
MCH			27.9							pg	27.0 - 33.0
MCHC	31.5	31.2	31.9							g/dl	32.0 - 36.0
<b>Weisses Blutbild</b>											
Leukozyten	17.99	11.56								G/l	4.5 - 13.5
Leukozyten			10.81							G/l	4.0 - 10.0
Neutrophile			84.6							%	40 - 74
Lymphozyten			9.2							%	19 - 48
Monozyten			3.3							%	3 - 9
Eosinophile			0.3							%	0 - 5
Basophile			0.2							%	0 - 2
Neutrophile abs.			9.145							G/l	1.8 - 7.7
Lymphozyten abs.			0.995							G/l	1.0 - 4.0
Monozyten abs.			0.357							G/l	0.2 - 0.8
Eosinophile abs.			0.032							G/l	0.0 - 0.4
Basophile abs.			0.022							G/l	0.0 - 0.2
div. lymph. Zellen			2.3							%	
div. lymph. Zellen abs.			0.249							G/l	
<b>Thrombozyten</b>											
Thrombozyten	250	267	334							G/l	150 - 400
<b>Blutviskosität</b>											

This screenshot (Fig. 12) shows a cumulative report, colours are used to mark values outside the reference range. Date, time and ID-Number of every report are shown.



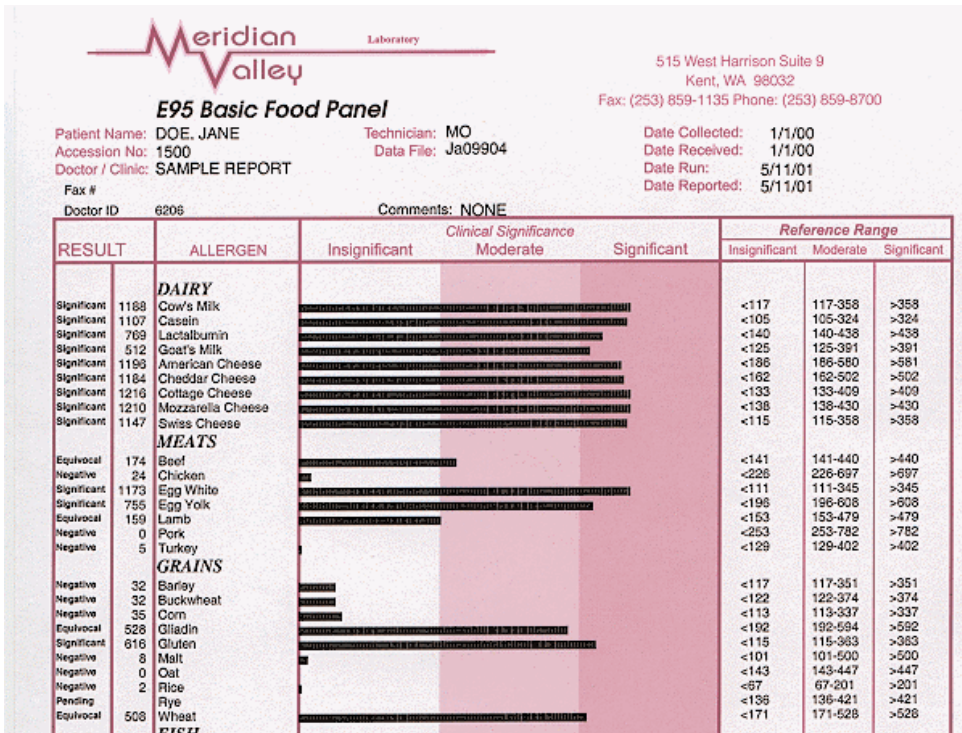
The graph (Fig. 13) shows results over a period of 7 years. The horizontal lines mark the reference range. This can be very informative when used to report results of parameters, which are measured over a long period as glycosylated haemoglobins or tumor markers. The picture shows results of a dummy-patient.

**Lab Results**  
 Patient: Sanchez, Maria  
 Specimen Info: Specimen: A0933566, Collected: , Received: , Reported: 09/11/2002 10:19 PM  
 Patient Info: DOB: 02-03-1966, Sex: F, SSN: , Phone: , Physician Info: Larry Smith Ph.D.

Test Name	In Range	Out of Range	Reference Range	Lab
CALCIUM		10.2	8.5-10.3 MG/DL	PML
BILIRUBIN, DIRECT		22.3	0.0-0.4 MG/DL	PML
ALT (SGPT)	PENDING		0-40 U/L	PML
PROSTATE SPECIFIC ANTIGEN		4.1	0.0-4.0 NG/mL	PML
ALKALINE PHOSPHATASE	31		30-125 U/L	PML
GAMMA GLUTAMYL TRANSFERASE	DNR		NONE ESTABLISHED	PML
LIVER ISOENZYMES	32		14.7-67.5 %	PML
BONE ISOENZYMES	44		12.5-65.3 %	PML
INTESTINAL ISOENZYMES		55	0.0-1.1 %	PML
PANCREATIC ISOENZYMES		66	0.0 %	PML
TRIGLYCERIDES	200		<200 MG/DL	RRL
CHOLESTEROL, TOTAL		201	<200 MG/DL	RRL
HDL-CHOLESTEROL		21	>30 MG/DL	RRL

(Fig. 14) Colours are used to mark results outside the reference range. Results, which are out of range, are printed in a separated column.

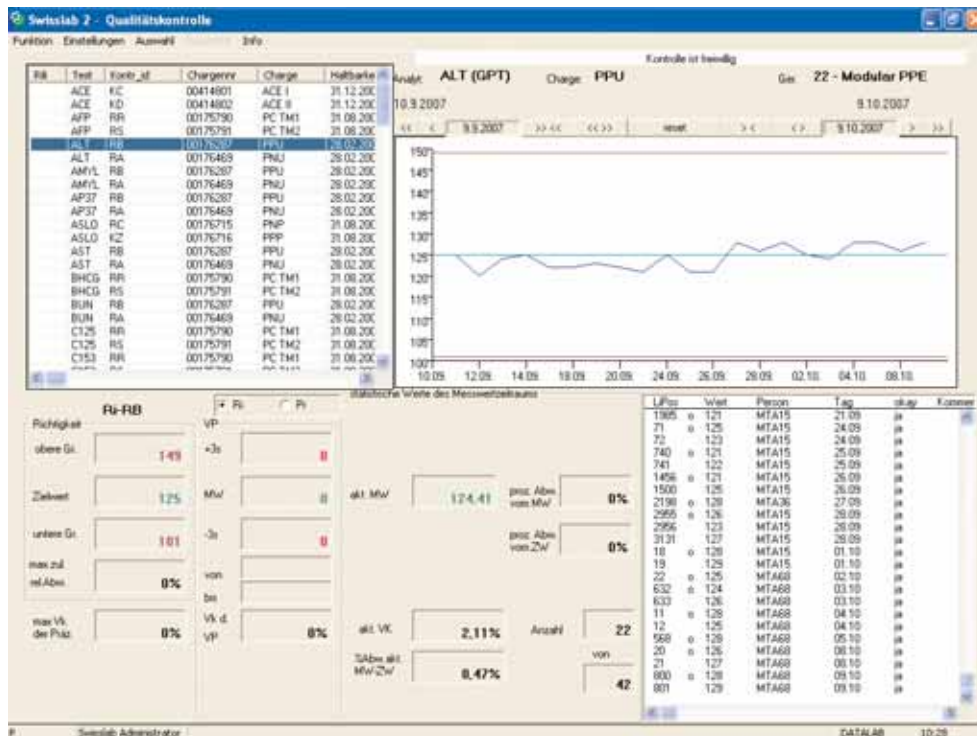




(Fig. 15) This example shows the use of colours and also graphic bars. It is an allergy report and the bars support the interpretation in a very clear way, making semi-quantitative comments like insignificant, moderate or significant on exactly measured results.

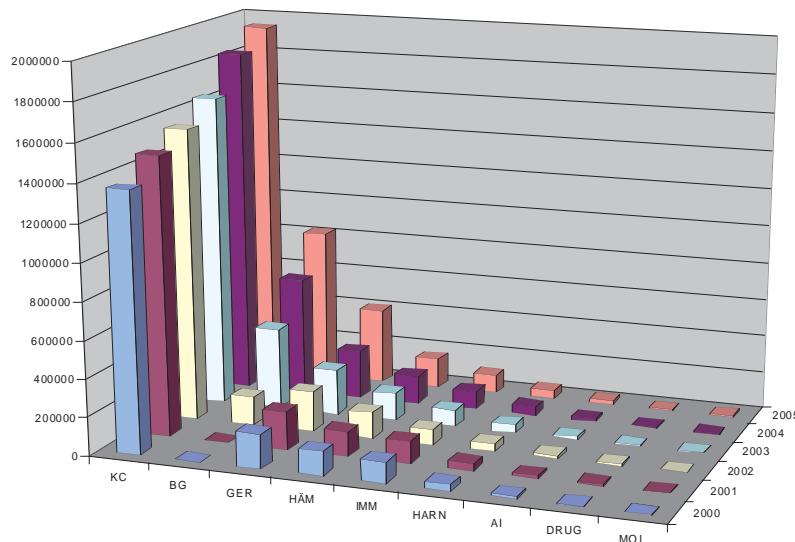
Laboratory information systems must allow appropriate quality control data to be entered. This data should be used to calculate precision and accuracy. LIS should also include a means of generating QC charts, including standard deviation, trending and data validation using predefined criteria. It is helpful to integrate quality control algorithms such as the Westgard rules ([www.westgard.com](http://www.westgard.com))

LIS can also support the validation of results. Using reference ranges and calculating differences between two requests (delta check) may be very helpful.



The screenshot (Fig. 16) shows a QC-Chart. You can see results, target values and range of allowed coefficient of variation.

Data management performed by laboratory information systems allows easy access to laboratory statistics. Minimal statistics include the counting of samples, requests and results. Each of these counts is associated with a defined time and the requester. LIS should store time stamps indicating when an order is accepted by the laboratory, when requests are written to the work list, when results are collected from analysers or by manual input, and the when the report is printed or the data sent to the requester. These time stamps make it is easy to calculate turnaround time or any delays in specific parts of the laboratory.



(Fig. 17) On this picture you can see a laboratory statistic from our own lab. The x-axis shows the different parts of the lab such as clinical chemistry, haematology, blood gas analysis or drug monitoring. The y-axis shows the count of analysis, the z-axis the year.

The billing of performed tests to the patients or their health insurance companies can be incorporated in the LIS to reduce the hands-on time of the financial department of the laboratory.

### 3.7 Environment

Only authorised persons should have access to any information facilities. Temperature, humidity, vibration protection have to comply with vendor specifications. All sensible parts of the laboratory information system, at least servers or mainframes should be connected to an uninterruptible power supply (UPS) to avoid loss of data in case of power failure.

Computer facilities and equipment should be in a clean, well-maintained condition. Fire-fighting equipment must be in good condition. Data storage media, especially back-up data should be stored strictly separated from data sources, mainframes or hosts. Actions, that are necessary to be taken in case of hardware or software failures or in case of fire or natural disasters must follow written procedures.

### 3.8 Hardware

A laboratory information system is more than a software program. It includes hardware such as servers, personal computers, printers and bar code readers. There are also network interface cards, hubs and routers. Most available systems need common PCs as Clients.

Equipment should be bought from local vendors to get best possible maintenance. Mean time to repair (MTTR) is to define, according to the goals of the laboratory. MTTR should not exceed one day. On the other hand, the mean time between failures (MTBF) should be as long as possible, more than six month would be a good range.

### 3.9 Software

All authorised users must have access to a complete computer manual. The manual must be written in the first language of the users.

Dialogues should be supported by a graphics user interface (GUI). Dialogues should use the end-users first language or the official language of the country.

All written procedures and manuals have to be reviewed periodically at defined intervals. Persons designated for this task must do the review.

All significant malfunctions of the laboratory information system have to be reported promptly to a responsible person.

Only authorized persons are allowed to enter, view and modify data. The LIS shall provide security features to ensure this. Access levels have to be defined.

### 3.10 Summary

Laboratory Information Systems may be very useful. The core competence is to print reports. To get all the information, which is needed to print a report, the collecting of data should follow a clear and structured way. The workflow in the laboratory defines the necessary modules of a LIS. At a higher degree of automatization, features as bar coding of samples or data exchange with analyzers via RS 232-port may be helpful. A number of useful items concerning hardware, software and environment can be found in the ISO 15189 (see also chapter 4).

### 3.11 References

All Figures by the author except:

Fig 10:

[http://www.ul.ie/~childsp/CinA/Issue52/issue52\\_files/main\\_files/cinact16.jpg](http://www.ul.ie/~childsp/CinA/Issue52/issue52_files/main_files/cinact16.jpg) (last visit 02/01/2008)

Fig. 14

<http://www.ngtvoice.com/images/synamed/labresult1.jpg> (last visit 02/01/2008)

Fig. 15

<http://www.meridianvalleylab.com/sample.html> (last visit 12/10/2007)

## Chapter 4

### Essential guidelines for Total Quality Management & Accreditation based on ISO 15189

Elizabeth Frank

#### 4.1 Background

Laboratory Medicine today is rapidly transforming into a highly automated business in developed countries. Point of care testing applications, miniaturized equipments, workstations on which many functions can be consolidated, advanced robotics and networking facilities have made Labs need minimal supervision and yet ensure better quality. The Scenario in the developing countries unfortunately is not the same. In many developing countries a fully automated state of the art laboratory may be still far away. Most developing countries have basic laboratories having minimum equipment or at best semi automation. Only Government funded academic institutions or large organizations have the luxury of fully automated laboratories.

Whatever the size of the laboratory, or its location, or its equipment the ultimate question one needs to ask is- what is the quality of the laboratory results that are generated, are they accurate, do they speak of competence, are the results reproducible, is there a quality system that is in place, is the system periodically reviewed and is it focused on continuous quality improvement.

To ensure quality at all levels a proper understanding of a quality system and it's positioning in the total management of the laboratory is necessary. Understanding of quality is sometimes limited to running Quality control (QC) sera daily in the laboratory. Although this is a good practice, and is being followed by many laboratories, it is done without proper understanding of the system and is done with a lack of proper analysis of the QC data. Including quality control sera in every run is not sufficient to ensure Total quality as it deals only with analytical quality.

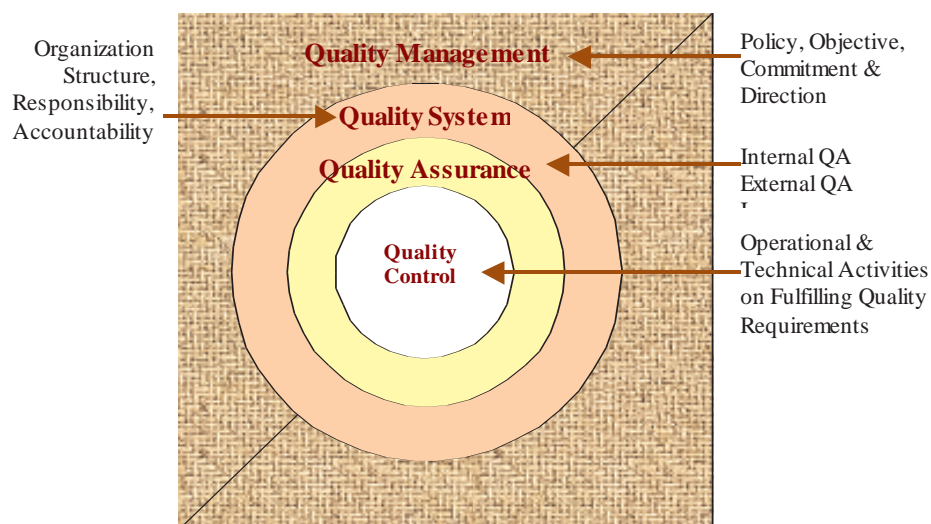


Fig. 1 Structure of quality approach

Accreditation helps to put systems in place and helps the laboratory generate accurate reports. The quality of reporting has direct bearing on patient health. In most developing countries there are no regulations or even minimum qualification required to start, or manage a clinical laboratory. Since accreditation is not yet mandatory, very often it is looked on as an unnecessary financial burden. The purpose of this document is to provide guidelines to help the lab set up a total quality management system and prepare for accreditation.

#### This aim of this chapter is

- To emphasize the need for setting Quality system leading to Total Quality Management for the Laboratory
- To explain basics of Quality system, quality Assurance and Total Quality management
- To give an understanding of, and interpretation of commonly used quality terminology
- To emphasize the need and Benefits of Accreditation
- To give an understanding of how to prepare the Lab for Accreditation
- To give an overview of ISO 15189 specific for the situation in developing countries.

## 4.2 Understanding Quality and Recognizing Quality needs

- **Define quality:** The Laboratory irrespective of its size, location and workload needs to define quality goals for itself. The laboratory Director, Quality manager as well as the technical manager first need to set quality goals for the Laboratory. This would involve a quality policy, which emphasizes the aim of the laboratory keeping in mind the expected level of competence, costing and service.
- **Continuous Quality Improvement and Systems approach:** Achieving quality is a continuous process. We need to constantly explore new ways by which we can define, improve and measure it. This can be done through planned concerted effort adopting proven QC, QA and TQM practices. The most important factors that contribute toward improvement are: to pay attention to the process, to ensure staff involvement and by responding to customer needs.
- **Benefits of Quality approach:** The lab will be able to demonstrate that it can deliver the best care to patients ensuring satisfaction and low cost. It will foster teamwork among laboratory staff and confidence in the quality of work both to the health care professional and the patient.

Quality is the heart of management in the laboratory. Understanding quality is in most cases limited to analytical quality. Analytical quality by itself cannot ensure the quality of results. The entire workflow starting from the receipt of requests to the dispatch of reports and to retrieval of information are involved. The pre analytical phase and the post analytical phase are as important as the analytical phase. The entire workflow needs to be designed and, monitored for the optimum result, taking customer needs into consideration. This would lead to a total quality management approach.

## 4.3 Total quality management (TQM)

Feigenbaum (1) first described TQM in 1957. Since 1980 this has become an important management theory in industry and business. TQM takes into consideration the customers' needs. The customers' needs are defined through communication with physicians and other health care providers and help the laboratory set up quality goals and criteria for an acceptable performance.

TQM philosophy is derived from earlier concepts of Quality control and quality assurance. Definition of TQM is not limited to standard setting and quality control, it encompasses with all aspects of organizational management with continuous effort towards improvement. It concentrates on processes as well as products. It is centered on quality and long-term success, client satisfaction being a priority.

TQM help the lab establish, manage and monitor a testing process to provide an appropriate Quality approach for its patient care services.

### The TQM framework involves

- Quality Laboratory Processes (QLP)
- Quality Control (QC).
- Quality Assessment (QA).
- Quality Improvement (QI)
- Quality Planning (QP)
- Quality Goals

**QLP:** This would describe the Policies, procedures, personnel, standards, Laboratory methods and System operating procedures for tests.

**QC:** Procedure for monitoring the process. A good QC system helps to prevent detect and correct problems. Statistically Quality control monitors analytical performance in relation to accuracy and precision.

**QA:** Monitors the overall performance. This includes both analytical as well as customer satisfaction. This should address the pre analytical, analytical and the post analytical phase. Turn around time, patient preparation, sample receiving, feed back from doctors and patients can serve as an indicator of QA of the pre and post analytical phase. External Quality Assurance and proficiency testing, monitor analytical quality.

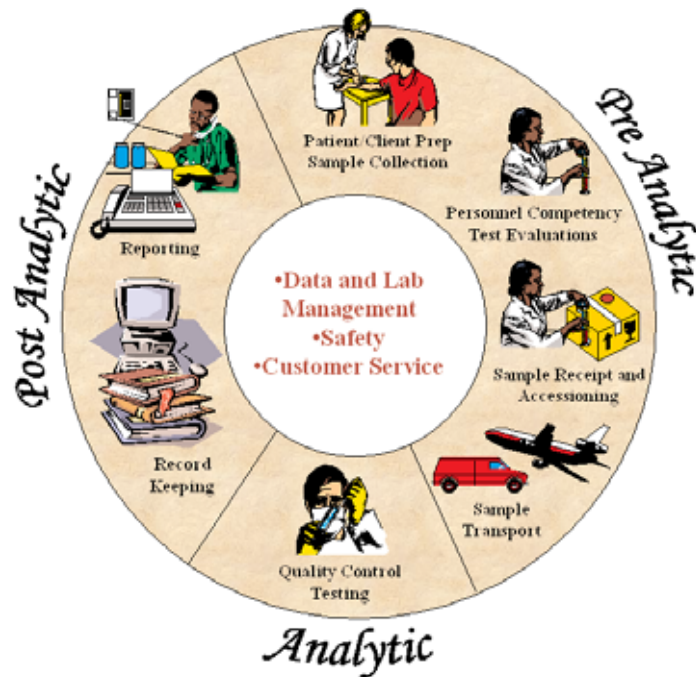


Fig. 2 The laboratory process circle, (reproduced from John Elliot PPTC, Wellington NZ).

**QI:** Quality improvement is the outcome of QC and QA. It helps to identify the source of the problem.

**QP:** Quality planning is a prerequisite to quality assurance. It establishes and validates process from both analytical quality as well as customer needs. It designs processes when one needs to adopt new methods or select new instrumentation. Quality planning also helps in designing appropriate QC programs.

**QC Goals:** Represents the requirement that must be achieved to satisfy customer needs. For analytical quality the requirement is to provide test results that are correct within the stated limits

#### To summarize

- QLP is the way to do things
- QC and QA are the ways to measure if QLP is being done the way it should be. They are indicators of the performance of the laboratory
- QI is the outcome of QA and QC. It helps to find the root cause of problems and eliminate it through Quality planning

#### TQM Benefits are

- Ensures quality of overall process
- Contains costs
- Encourages active and effective leadership and involvement by top management
- Involves and empowers staff
- Attempting to solve problems by "band-aid" fixes for individual mistakes as they occur is drastically reduced, resulting in cost saving
- Reduces errors by doing things right the first time: ensures consistency
- Staff will have greater confidence that the system will catch mistakes before they reach the patient report
- All operations are transparent to both staff and clients, staff will clearly understand their responsibilities
- Improves consistency within and between laboratories

#### 4.4 What is Accreditation?

The word accredit is related to the same root word as credible, or believable. An accredited organisation is one that can be believed by the customers.

Accreditation can be defined as a voluntary process by which the organization introduces a quality system according to specific requirements and is certified by an independent quality institute. It is a means of showing confidence in an organization's performance. Usually, certification is more focused on the technical aspects of the services provided, and accreditation is covering all the aspects of the organisation.

Accreditation is a peer-review process by which an authoritative body (quality institute) ensures that the laboratory meets explicit quality criteria, in order to give formal recognition that the laboratory is competent to carry out laboratory examinations. It is a procedure by which an authoritative body gives formal recognition that a body (laboratory) or person (signatory) is competent to carry out specific tasks (ISO/IEC Guide 2: 1996 (2). For clinical laboratories it is based on the guidelines of ISO 15189 (3). It contains particular requirements for quality and competence. Accreditation assures the client that the procedures are technically valid, recognizes the competence of laboratory staff and assures the client that the results are valid and endorses the quality management system.

So accreditation is a seal of competence, accuracy and quality.

#### Summary of accreditation benefits

- Demonstrates compliance with international standards.
- It improves patient care.
- Strengthens community confidence in test results.
- It provides continuous staff education, and attracts professional reference due to accuracy and competence.
- It meets the requirements of Insurance companies and third party requirement.
- In case of a discrepancy the Accreditation stands as a proof of competence of the laboratory, which can be verified.
- Improves liability insurance coverage and provides a competitive edge in the market.
- Provides professional advice

#### 4.5 Sources of standards

ISO 15189 (3) is the international standard for quality management in the medical laboratory. It is a replacement for ISO Guide 25/EN 45001:1989 (4) and ISO 17025:2000 General requirements for the competence of testing and calibration laboratories.

The ISO 9001:2000 guidelines focus on the quality management systems requirements. The continual improvement, also important for the ISO 15189 guidelines, is schematically given in fig. 3. The continue process of improvement of the quality is driven by the requirements and the satisfaction of the customers.



Fig. 3 Overview of ISO 9001:2000 (reproduced from GLP to TQM, S Cheng 2002)

#### Starting with a quality system according to ISO 15189

To prepare the Laboratory for accreditation based on ISO 15189 it is necessary to do a gap analysis. The gap analysis should point out lacunae's and should lead to preparing the quality manual. There should be clarity between a policy and procedure before writing of the quality manual is attempted.

## 4.6 Gap analysis

Before a laboratory attempts for accreditation, the lab must analyze its present policies, processes and procedure. A quality manager may take on this responsibility and evaluate the lab's existing status against the ISO 15189 requirements. This would help the lab to understand its lacunae and establish the needs in accordance with the specified ISO requirement.

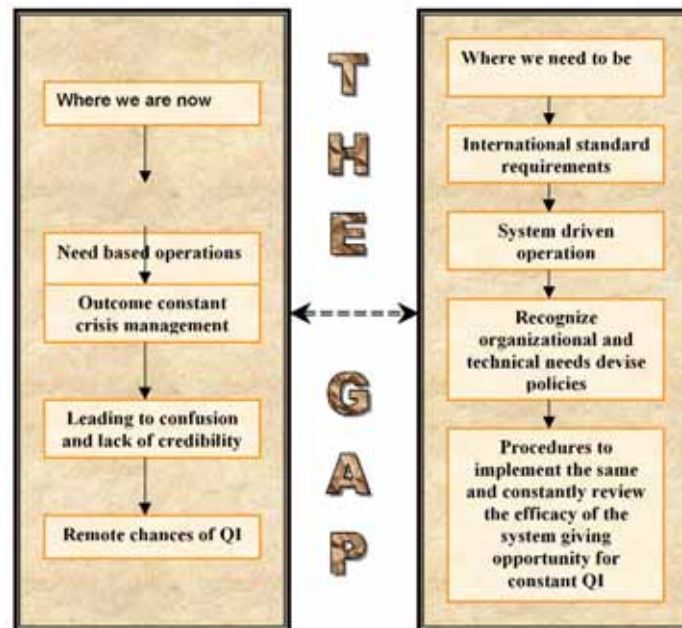


Fig.4 Gap between existing and required status of the quality system

## 4.7 General Terminology of ISO 15189

There are three types of documents used to describe protocols: Policies, Processes and Procedures.

### Policies

Generally policies are quite short. They are statements that describe what is done and why. They define goals and briefly state the intent and direction. The policies should give cross preference to processes and procedures

### Processes

Are a series of inter-related steps involved in an activity or examination that uses resources and is managed to transform inputs into outputs. They are displayed as flow charts and illustrate the workflow and the person responsible for that activity. They do not include step - by step instructions for individuals.

### Procedures

- A procedure is the written work instructions that specify a way to carry out an activity, examination or step in a process.
- It is a set of step-by-step instructions that each individual follows it form the typical procedure manual

Example: Procedure for performing glucose estimation

(The step-by-step instructions for a technologist to follow when performing the test)

### Quality Manager

The quality manager has the following tasks:

- Is responsible to maintain the integrity of the quality system
- Ensures that the Quality system is current and relevant
- Ensures staff commitment to the quality system

The ISO 15189 standard is divided in two major parts: Management requirements and Technical requirements.

### 1. Management requirements

Requirements related to quality management systems and the QMS must encompass all management activities and processes relating to quality assurance. For a summary see table 1.

### 2. Technical requirements

These consists of the following steps:

- Specific requirements related to activities carried out by clinical laboratories
- Once the Quality Management system is fully documented, do not expect it to stay static for long.
- The next phase is continuous improvement through the use of quality indicators, internal auditing, investigation of non-conformities, and management review. This is a primary objective of the QMS. For a summary see table 2.



Table 1: The Management Requirements of ISO 15189:2003 (3)

ISO 15189:2003	
4. Management requirements	
<b>4.1 Organization and Management</b>	Needs of users and Quality policy is to be addressed in this section. The Laboratory must have legal identity and free from political or financial conflict of interests. In this section we need to define requirements and responsibilities of the laboratory management like compliance to legal requirements. The laboratory must provide adequate financial education and human resources so as to meet the stated objectives. The responsibilities and personnel will be well defined, implementation of policies and organizational structure.
<b>4.2 Quality Management System</b>	Describes Quality objectives and plans, Quality manual, and the role of the quality manager. It indicates the need for the implementation of a Quality System that includes Quality Assurance, Quality Control, Proficiency Testing procedures, Calibration and Maintenance, described in a Quality Manual. Staff shall be educated about Quality Management System principles. This topic also presents a summary of issues to be addressed in a Quality Manual.
<b>4.3 Document Control</b>	Details Requirements for documentation control including elaboration, approval and review and updating of documents, control of documents in paper – or not. Document control includes control of process and control of Quality records
<b>4.4 Review of contracts</b>	The lab will first analyze the request of the client to ensure that it has the capability to meet the requirements of the customers and the need of communication of in case of change in request, methods, etc. Request need not always be formal documents, verbal agreement are also acceptable.
<b>4.5 Examination by referral laboratories</b>	Evaluation, selection and monitoring of referral laboratories, including the need for a clear definition of the interpretation of the examination results. The laboratory must maintain a register of all referral laboratories it uses and retain a copy of the results reported.
<b>4.6 External services and supply</b>	Selection and use of purchased external services, equipment and consumable supplies, including criteria for inspection, acceptance, rejection and storage of these materials according to pre-defined standards.
<b>4.7 Advisory services</b>	Advising & assistance on examinations. The laboratory should interact with clinical staff regarding services & clinical interpretation
<b>4.9 Identification and control of nonconformities</b>	All non-conformances or deviation from protocol must be documented and analyzed. Causes must be investigated and corrective actions taken. Sources of deviations include complaints, QC results, calibration procedures, audit results, etc.
<b>4.10 Corrective action</b>	The corrective action loop should be defined. Root cause analysis to be done corrective action identified. Establishment of corrective actions is very crucial to avoid recurrence of problems. Results must be evaluated in order to check if the actions taken were effective.
<b>4.11 Preventive action</b>	Identification of preventive actions to avoid occurrence of problems. Identify potential trouble area. And critical evaluate processes in this area and develop methodologies to minimize errors. Results must be evaluated in order to check if the actions taken were effective.
<b>4.12 Continual Improvement</b>	The lab management must review all operational procedures at a regular interval. Revision of procedures to improve their performance - by using indicators, for instance. The main idea is to identify opportunities for improvement and to update the laboratory.
<b>4.13 Quality and technical records</b>	Maintenance, safe disposal and retrieval of quality records. Records include quality control records, instrument print outs, patient test reports, patient test requisition, nonconformity reports, complaint records. Records must be kept for a specified period of time as defined by the Laboratory, Government bodies and Accreditation bodies.
<b>4.14 Internal audits</b>	Planning, organization and conduction of audits to check compliance of processes to the ISO 15189 standard and also to the internal procedures. The purpose of audit is to verify laboratory compliance with the quality system  ISO 15189 specifically requires annual internal audits. Audit findings are documented. The laboratory must develop a plan to correct or respond to audit finding
<b>4.15 Management review</b>	Evaluation of the effectiveness of the system implemented and the need for resources. Indicators, nonconformities and audits results are some issues to be addressed in a management review meeting.

The second part of ISO 15189 presents the technical requirements that are directly applicable for technical accreditation of the clinical laboratory competence. The laboratory will more easily recognize the terminology, as it is more specific to clinical laboratories. The main steps of the analytical procedures are called pre-examination, examination and post-examination procedures.

Table 2: The technical requirements of ISO 15189:2003 (3)

<b>ISO 15189:2003</b>	
<b>5. Technical Requirements</b>	
<b>5.1 Personnel</b>	Definition of responsibilities, evaluation of personnel competences * and training requirements. Records – job descriptions, personnel files, training records, competence evaluation results - shall be maintained. Personnel must be able to develop their functions. Responsibilities of the laboratory director and designees are listed in this topic.
<b>5.2 Accommodation and environmental conditions</b>	Facilities for staff and patients and storage are addressed health and safety issues are also addresses. Adequacy of space and work environment in order not to compromise the quality of the work performed and reduces the risks of injuries and occupational illness. Areas for dangerous materials storage and safe waste disposal must be provided. Environmental conditions must be controlled when they can affect the quality of the analytical process. Good housekeeping shall be ensured. Provisions must be made when the space is found not adequate.
<b>5.3 Laboratory Equipment</b>	Selection and monitoring of equipment, reference materials, consumables, reagents, instruments and analytical systems. This topic includes monitoring of the performance of equipment, calibration and maintenance procedures and also requirements for computer software and management of data, information and automated equipment.
<b>5.4 Pre-examination procedures</b>	Implementation of a process that includes definition of criteria for request forms, collection, identification, handling, transportation and receipt of primary samples. Criteria for accepting and rejecting samples must be defined. Samples collection procedures must be described in a manual. The Laboratory will maintain records of all samples received
<b>5.5 Examination procedures</b>	Control of the analytical process: validation, reference and critical intervals and documented procedures. This item addresses a set of information to be included, when applicable, in the documented procedures.
<b>5.6 Assuring quality of examination procedures</b>	Quality Control procedures: use of internal quality control systems and definition of the uncertainty of results, application of methods to calibrate measuring systems, participation in inter-laboratory comparison programs, External Quality assessment program or alternative mechanisms that can assure the quality of analytical procedures.
<b>5.7 Post-examination procedures</b>	Definition of criteria for storage and safe disposal of primary samples, review and release of results.
<b>5.8 Reporting of results</b>	Description of requirements for reports formatting, transmitting and alteration. The reports must clearly identify patient name, time and date of specimen collection, test performed, reference range, authorized signature of the person reviewing the reports. Definition of criteria for communication of delays and critical values, retention period of results, etc. This section will also address how to handle reporting by telephone, amended report when the need may arise and also clinical advice and interpretation. The laboratory must achieve compliance to national legal requirements, when applicable.

\*According to ISO, competence is the result of basic academic and continuing education, training and experience of work.

#### **4.8 Laboratory Information systems and Ethics in Laboratory Medicine**

The ISO 15189 standard also provides two important annexes: The Laboratory Information System (LIS) and ethics in laboratory medicine. Annex B has recommendations for the LIS security. Differently from ISO 9001:2000, the ISO 15189 clearly describes LIS recommendations about system security, data entry and reports, data retrieval, system maintenance, etc. The other annex (annex C) is related to ethics in Laboratory Medicine.

Table 3: The Laboratory Information System (3)

ANNEX B	
This section is dedicated to recommendations for protection of Laboratory Information System. (LIS)	
<b>B.1 General:</b>	This section deals with the policies and procedures that protect patient's data from harm caused by loss of change of data. this sections gives recommendations for maintaining the integrity of the data handled through the information system
<b>B.2 Environment:</b>	The computer facilities and equipment must be clean and should comply to vendor specifications, proper storage of files, cables protected from high traffic area, uninterrupted power supply and protection from unauthorized access
<b>B.3 Procedure manual:</b>	Detailed manual of the software should be available; the computer manuals should be periodically reviewed and approved byte laboratory director. Written down procedures necessary to protect data or the equipment in case of fire or hardware or software failure should addressed in this section
<b>B.4 System security</b>	This section emphasis authorization for use of computers. Polices will be defined as to who can access/alter patent data.
<b>B.5 Data entry and reports</b>	Addresses police to ensure of data transfer by detecting errors n transmission, storage and processing. Addresses issues of checking the correctness of patient data or results entered either automatically or manual before final acceptance and reporting by the computer. The reporting system should have provision for comments on sample quality that might compromise the accuracy of examination results. Audit mechanism to identify all who have entered patient data must be available
<b>B.6 Data retrieval and storage</b>	The stored patient data should be easily and readily retrievable, data should be stored properly labeled and should be protected from unauthorized use. An efferent back up should be in place to prevent loss of patient data
<b>B.7 Hardware and soft ware</b>	Procedure and all records of preventive maintenance of all computer should db available, the system should be checked after each back up to ensure that no alterations have occurred. Mistakes detected during. Any alterations to the software should be documented; Changes should be verified for proper performance. Adequate training should be provided to people using the software.
<b>B.8 System maintenance</b>	Should define downtime and procedures to handle system failure, breakdown. , Should provide details on regular maintenance and should maintain a log of all downtime period and other computer problems

Table 4: Ethics in laboratory medicine (3)

ANNEX C	
This section addresses issues of ethics in laboratory medicine	
<b>C.1 General</b>	Addresses ethics of the profession, and acceptable practice, which may vary from region to region. It shall ensure that the laboratory will not engage in practices restricted by law and will uphold the reputation of the profession
<b>C.2 General principles</b>	Patient's welfare is the most important consideration for the laboratory. No discrimination will be shown to patients
<b>C 3: Collection information</b>	The lab should collect only relevant data. The patient should be aware of the information collected and the purpose for which it was collected.
<b>C 4 Collection of primary samples</b>	Required consent from the patient will be obtained for all procedures carried out in the laboratory. Written consent will need to be given for invasive procedures. . The lab will endeavor to see that results with serious implications will be released only after adequate counseling. This section also ensures that the primary samples arrives to the laboratory in a suitable condition for the test requested
<b>C 5 Performance of examination</b>	All laboratory examination will be carried out in accordance to appropriate standards and will the level of skills and competence expected of the profession. Any fabrication of results is not accepted
<b>C.6 Reporting of Results</b>	These sections ensure that the results can be attributed to a specific patient. The laboratory is responsible for correct interpretation of results
<b>C.7 Storage and retention of medical records</b>	The lab will ensure that patient information will be safeguarded against loss, unauthorized access or tampering. Retention of records may be defined by various legislative requirements, which may differ indifferent countries. The lab will provide ready access of records when required
<b>C.8 Access to medical laboratory records</b>	Access to records will be available to patient and the referring physician. The lab should develop protocols for the same
<b>C.9 Use of samples for examination purposes other than those requested</b>	The samples will not be used for any other purpose than those requested without prior consent. They can be used if the samples are rendered anonymous or pooled this section refers to the laboratories policy for handling un requested information from identifiable samples
<b>C.10 Financial arrangements</b>	The lab will not enter into any financial arrangement with the referring physician. The lab should avoid situations that will give rise to conflict of interest

The overview of fig. 3 from ISO 9001:2000 can be converted to the requirements of ISO 15189. The result is given in fig.5, which shows the relationship between the different requirements of ISO 15189.

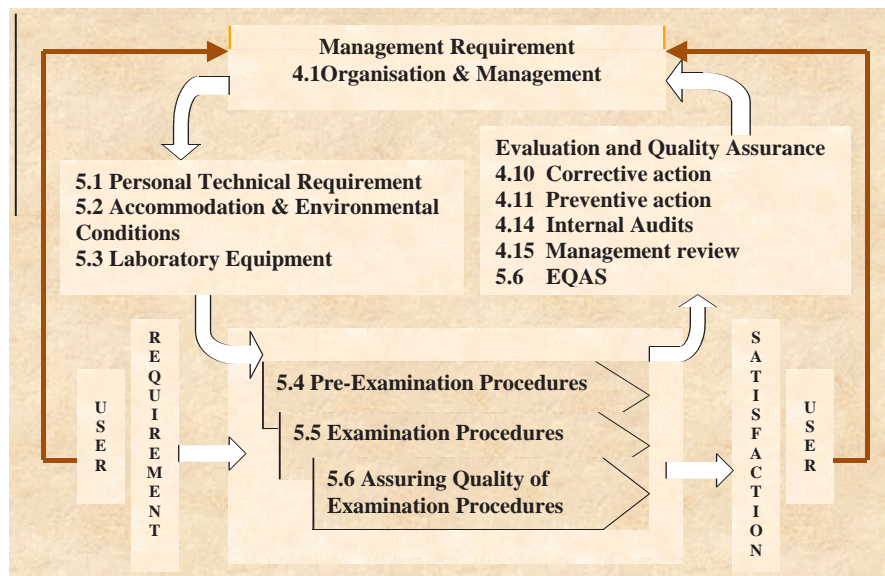


Fig. 5 Relationship between requirements of ISO 15189 [Modified from NPAAC guidelines for quality systems in medical laboratories].

### Quality improvement circle

The quality management system for a laboratory needs to be established, controlled, reviewed and improved for continual improvement. The quality improvement circle is given in fig. 6.

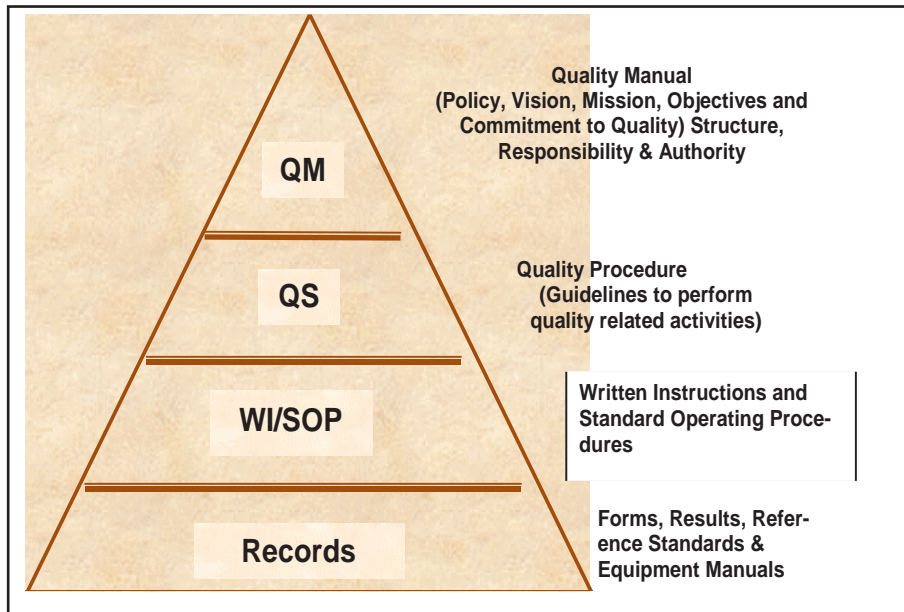


Fig. 6. The quality improvement circle. [Modified from NPAAC guidelines for quality systems in medical laboratories].

### 4.9 Structure of quality documents

The quality manual is an Apex document which includes the policy, vision, mission of the laboratory (see Fig.7). Its commitment to quality is emphasised in this main document. The Quality manual makes references to Quality procedures. Quality procedures are guidelines to perform quality related activities for e.g. Quality manual clause 4.10 would make cross-reference to Quality system procedures for "procedure for corrective actions".

The next level in the structure of the documents is the standard operating procedure (SOP) and written instructions (WI). These give detailed step-by-step description of all technical activities in the laboratory. At the base of the documentation triangle are the records. This includes both technical and managerial records. Procedures, products inserts material safety data sheets, research papers or journal articles that might support a testing protocol are all examples of records. The hierarchy is illustrated in Figure 7.



ISO 15189 requires that all the documents are controlled. The laboratory director must approve them. All documents should be periodically reviewed for its relevance and approved by the laboratory authority. Having a master list of documents currently in use their revision dates facilitates review of all laboratory documents. It also ensures that obsolete documents are properly archived ensuring inadvertent use.

#### 4.10 Scheme of the documentation system

The documentation system can be summarized as follows:

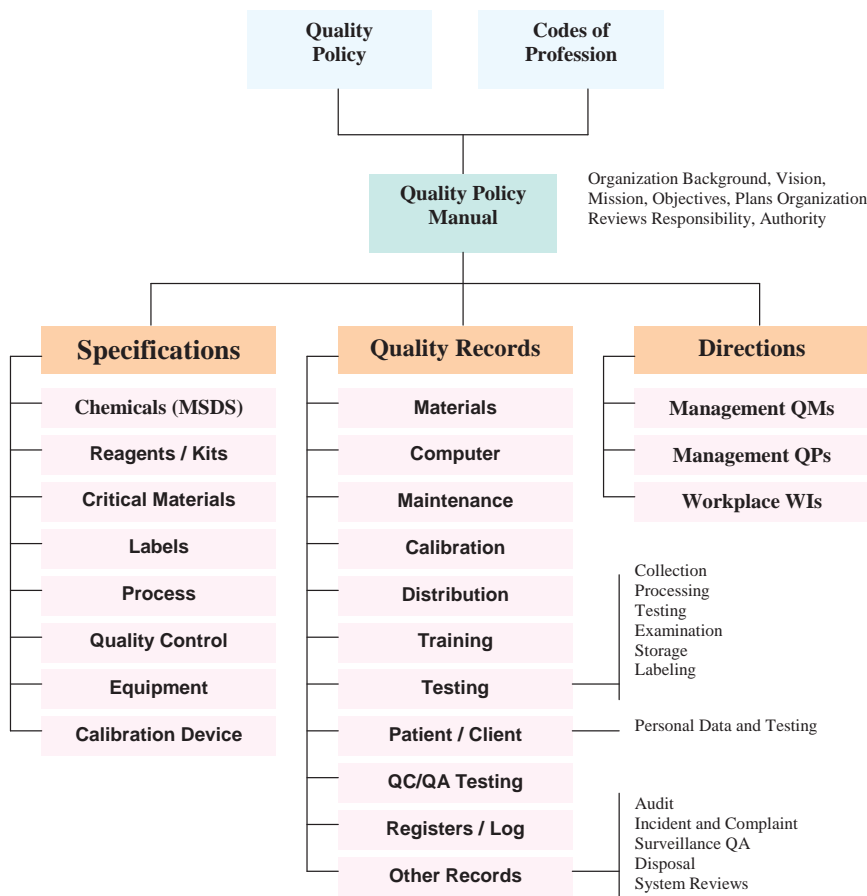


Fig. 8. Scheme of the documentation system.

Maintenance of Documents is mandatory and a core requirement for achieving accreditation based on ISO 15189.

#### 4.11 Evaluation of the ISO standards

ISO 15189 is the principal standard for clinical laboratories. Next to the ISO 15189 also the ISO 17025 standard exists. Table 5 shows difference between the two standards. The essential difference is that ISO 15189 has described a quality system that is aimed at continuous improvement and which is critical to patient care. This has not been addressed in ISO 17025.

ISO in general provides specific focus on tests, method validation, measurement traceability; these are addressed as sub-components in ISO 15189. ISO 15189 sets minimum standards for laboratory practice and structure under an ISO system. The beauty of the ISO quality system is that it is not static and is constantly evolving to meet the changing needs of the Laboratory and its clients.

Table 5: Comparison of ISO 17025 and ISO 15189 QSE's

<b>Difference in ISO standards</b>	
<b>ISO/IEC 17025:1999<sup>5</sup></b>	<b>ISO 15189:2002<sup>3</sup></b>
1.0 Scope	1.0 Scope
2.0 Normative references	2.0 Normative references
3.0 Terms and definitions	3.0 Terms and definitions
4.0 Management requirements	4.0 Management requirements
4.1 Organization	4.1 Organization and management
4.2 Quality System	4.2 Quality Management System
4.3 Document Control	4.3 Document Control
4.4 Review of requests, tenders and contracts	4.4 Review of contracts
4.5 Subcontracting of tests and calibrations	4.5 Examination by referral laboratories
4.6 Purchasing services and supplies	4.6 External services and supplies
4.7 Service to the client	4.7 Advisory services
4.8 Complaints	4.8 Resolution of Complaints
4.9 Control of nonconforming testing and /or calibration work	4.9 Identification and control of nonconformities
4.10 Corrective action	4.10 Corrective action
4.11 Preventive action	4.11 Preventive action
4.12 Control of records	4.12 Continual improvement
4.13 Internal audits	4.13 Internal audits
4.14 Management reviews	4.14 Management reviews
5.0 Technical requirements	5.0 Technical requirements
5.1 General	
5.2 Personnel	5.1 Personnel
5.3 Accommodation and environmental conditions	5.2 Accommodation and environmental conditions

#### 4.12 Where to begin and what has priority?

The first step of the laboratory and its management is placing 'quality thinking' central in all their decisions. This means that provisions are made to avoid errors and that 'thinking quality' and 'doing quality work' is the leading item. The mindset has to be accepted in the top management. The top management should be convinced that Quality is the corner stone to success and that it is an essential component of the improvement process. It should be implemented with two important guide-lines in mind:

- 1) 'Train the laboratory staff in Quality thinking will result in a positive change in quality'
- 2) 'Build a framework to sustain the change'.

Converting individuals to think quality for better patient care and then maintain successes into sustained performance by personnel is critical to the development of any change initiative. This requires creating a quality mindset - a far more challenging and time-consuming task than achieving the breakthrough improvement.

##### What is a quality mindset?

Using firefight as an example, the typical response to a fire is to fight it until it is extinguished. Then be ready to fight the next fire when it happens. Having a quality mindset also means responding to a fire by fighting it until it is extinguished. However, instead of waiting until the next fire, a quality mindset means finding the root cause of the first fire and working to prevent any other fires stemming from that cause.

Laboratories with a quality mindset recognize "If you do not improve, you deteriorate" and demand sustained, continuous improvement efforts by operating teams. In institutionalizing this approach, everyone involved has a role to play:

- Senior management - Regular critical-to-quality (CTQ) trend reviews with performance rewards/penalties and raising standards.
- Technical staffs - Regular plotting/review of control charts; killing new (or old) defects.
- Change agents - Institutionalization of the process or setting systems towards total quality management

Quality should be measured. This is where accreditation becomes meaningful. Accreditation not only provides a seal of quality but also makes provision for improvement for "what cannot be measured cannot be improved".

#### 4.13 Practical approach of the accreditation process

Accreditation sometimes may seem intimidating. Quality is the heart of management in the laboratory. Approach toward accreditations will vary from lab to lab. Possibilities differ with the size of the lab. In general small / medium / large sized labs going in for accreditation may use the following guide lines as a practical approach as the first step towards accreditation:

- 1) Put critical area which have direct impact on quality improvement if reporting in order first.
- 2) Define quality indicators: The lab should have an IQA, EQA and the data should be analyzed and the outcome should be used as indicators.
- 3) The quality data should be reviewed and document by qualified personnel.
- 4) All records should be document
- 5) A feasible policy towards patient care related to the size of the lab should be documented.

This can be seen as the first step to implement ISO 15189. Assuring the quality of results is interlinked to qualification of personal, training of relevant people, equipment maintenance, etc. The effect of quality on results is visible as raised patient satisfaction, etc.

Make sure that all policies are defined , procedure are written and all activities are documented and reviewed periodically. Once clause5 of ISO 15189 is taken care of it is relatively easy to deal with other management requirements.

##### Sustaining the Quality system

Sustain quality is as important as setting up a quality system.

Practical ways to do this is to

- 1) Selecting CTQ (Critical to Quality): This is a very important step in lab management; in every practice there are very regular areas sometimes seemingly unimportant that are critical to patient care. These area need to be selected, constantly monitored and reviewed. Define any problem that may arise. Problems maybe defined as Desired status minus current status.
- 2) Find root causes when problems occur.
- 3) Check Results.
- 4) Standardize controls.

In conclusion: We need to create quality awareness to develop a quality culture: Every quality project needs to have both tangible and intangible gains. The tangible gains are improved turn around time and faster customer service. The intangible gain is the quality mindset. The tangible gains may be much faster visible than the intangible gain. The intangible gain could be lost if not reinforced by senior management continuously.

**"The system approach begins when first you see the world through the eyes of another"**

*C.W. Churchman 1968*

#### **4.14 References**

- 1) When "good enough" Isn't Good enough, Core Ideas of Total Quality by Linda Tuner, Ron Tuner 1988
- 2) ISO/IEC guide 2: Standards and related activities - General vocabulary
- 3) ISO 15189:2003 Medical Laboratories - Practical requirement for Quality and Competence
- 4) ISO Guide 25 / EN 45001:1989
- 5) ISO/IEC Guide 25-1990 and European equivalent, EN 45001-1989, "General Requirements for the Competence of Testing and Calibration Laboratories"
- 6) ISO/IEC 17025:1999 General requirements for competence of testing and calibration laboratories



## Chapter 5

### Basic training in managerial skills

Wim de Kieviet

#### 5.1 Aim

The aim of this chapter is to provide basic managerial training tools for specialists in clinical chemistry and laboratory medicine who are confronted with limited possibilities to enlarge the managerial skills.

#### 5.2 Introduction

Specialists in clinical chemistry and laboratory medicine are expected to be up-to-date about the scientific possibilities and limitations of their laboratory tests.

Apart from this they are in most cases the head or the director of the laboratory, which requires managerial competences.

With minimal financial possibilities it is difficult to train the managerial skills in order to improve the competences of the manager.

Good leadership is essential for the wellbeing of the organisation. It inspires the technicians and other co-workers to bring the organisation to a higher level.

This chapter will provide information how to work out managerial trainings under financially difficult circumstances.

#### 5.3 Managerial training

The management of the laboratory organisation can be split up in a lot of managerial items. All the managerial items can be trained by the manager to be aware of his/her personal competences and position. The desired outcome of the training is to improve the organisation of the laboratory in order to raise the level of laboratory healthcare for the local patients.

#### 5.4 Training group

Before starting with the managerial training it is important to form a local group of colleagues to work out the training in one or more sessions. In remote areas it will be difficult to form such a group and to come together for the trainings. On the other hand it is good to realise that it is very difficult to learn 'management' by reading about it. Only training sessions with colleagues will give you insight in your 'way of leadership' and in the possibilities to improve them. In the training group it is possible to discuss about problems and difficulties and to create the possibilities to get feedback.

Therefore the first step is to form a training group and to plan a series of training sessions. It is advised to choose a quiet location apart from the laboratory site.

In the first session it can be decided that each session will be chaired by one of the participants. The chair can prepare the training parts of the session by reading about the training theme and to prepare examples from the daily practice.

The first session should start with statements of the participants about their motivation to participate and to discuss about the expected outcome of the training sessions.

General instructions for the training sessions:

- Organize the training sessions in a quiet place remote from the work area
- Plan several sessions in advance, each with one of the participants as chair
- The chair will prepare the training session by choosing the training theme
- The chair prints the roles of the participants for the role-game (take the description below with the addition of new details)
- At the start of a session the chair distributes the roles to the participants of the role-game. The others are observers.
- Take 5 minutes for reading the roles
- The chair starts the role-game
- Play the role-game for about 15 minutes
- After a short break the feed-back of the observers can start

## 5.5 Training themes

The basic training in managerial skills can be divided in two parts: The roles of the manager and the management of the organisation.

*The roles of the manager of the medical laboratory can be split up in:*

1. the directive role
2. the representative role
3. the controlling role
4. the stimulating and coaching role
5. the professional role

*The management of the organisation consists of:*

1. financial management and costs of laboratory products
2. the organisational structure
3. legislation and working conditions
4. flow of information
5. development and projects

## 5.6 The roles of the manager

In daily practice the roles of the manager n°1 and 5 are thought to be the most prominent roles in the work of the manager. Nevertheless it has to be stressed that all the roles are important for a well-balanced manager. All roles should be worked out in training sessions.

### The directive role of the manager

Skills to be trained: to take initiatives; to formulate the goals; to work out the plans and to give effective direction to the execution of the plans.

The directive role of the manager can be illustrated by the role of the general of the army in times of war: the general is the directive manager, who takes the decisions and leads to the victory of the organisation. The effectiveness of the directive role can be trained in small groups.

*Theory:*

Practising the directive role you must always use your personal strength and motivation. Your attitude must be energetically and positive. You must concentrate on your main goals. Be down-to-earth and tenacious. Create concrete and clear plans with reachable goals.

*Training:*

A specialist in laboratory medicine is the newly appointed manager of a new clinical laboratory. The opening was one week ago. The first week was scarred by confusion and numerous problems. With one exception the technicians appointed have no previous laboratory experiences. The problems during the last week were a combination of the staff not knowing the technical specifications of the laboratory equipment and staff acting with indifference toward the quality of the analyses performed.

The manager decide to meet the entire staff before the laboratory will open the next Monday to begin correcting the problems.

One of the training group is the manger. He/she conducts a meeting for 15 minutes to review the issues generated in the first week after the opening of the laboratory and to tell them about the decisions he/she will take.

3 participants of the training group are the staff members. The others are the observers.

Take 15 minutes for the role-play. After the role-play the players of the technician-roles and the observers will give feed-back to the manager about the effectiveness of the approach. What was effective and what was not as effective?

Leadership can be divided in 4 main leadership styles:

- High directive and high supportive; effective for unable and unwilling followers
- High directive and low supportive; effective for able but unwilling followers
- Low directive and high supportive; effective for unable but willing followers
- Low directive and low supportive; effective for able and willing followers

Which leadership style is effective for the staff of the newly opened laboratory?

Has the manager used this style of leadership?

### The representative role of the manager

*Skills to be trained:* the role of the manager by representing the medical laboratory towards the director of the institute/hospital, the clients (physicians, patients), the government and the clinical chemical firms.

In this role the manager has to negotiate or to bargain for the medical laboratory with the external persons/institutes to give the laboratory a good financial and marked position.

#### Theory:

The technique of bargaining is important in order to achieve good results. Bargaining can take place under zero-sum conditions when with no risk for both parties when the agreement will not be settled (distributive bargaining). An example of distributive bargaining is buying a second hands car; negotiate about wage for an eventually new job, etc.

Bargaining under non zero-sum conditions (when a positive agreement is essential for one of the parties) is calling integrative bargaining. An example of integrative bargaining is the purchase of an analyser which is unique and essential for the analytical work of the clinical laboratory.

The technique of bargaining consists of the following guidelines:

- Be aware of the other party's situation  
Acquire information about the interests and goals of the opponent.  
When you can anticipate on your opponent's position, you are better equipped to counter his arguments with facts that support your position.
- Have a concrete strategy.  
Think about your strategy before you start bargaining. Consider it as a chest game in which you also have to follow a strategy.
- Establish mutual interests  
Before starting the negotiations begin to establish mutual interests and create a positive climate e.g. by giving a small concession.
- Address problems, not personalities  
Concentrate yourself on the negotiation issues and not on the characteristics of your opponent.  
Separate the people from the problem and avoid personalizing the differences in opinions. Create an open and trusting climate. Skilled negotiators listen well, ask questions, are not defensive and avoid irritating the opponent.
- Pay little attention on initial offers  
Consider an initial offer as a point of departure, not as a realistic possibility. Generate other possibilities in line with your strategy.
- Use rational criteria for your proposals  
Make your decisions in the negotiation process based on rational results, not on emotions or pressure.  
Come with rational proposals by yourself.
- Emphasize win-win solutions  
Do not expect that the gain must come at the expense of the opponent. Look for an integrative solution (area AB in figure 5.1). Come with alternative possibilities, especially low costs concessions you can make that have high values for the opponent. Describe options in terms of your opponent's interests and look for solutions in which both parties can declare a victory.
- Accept third-party assistance  
Accept mediators when a stalemate is reached.

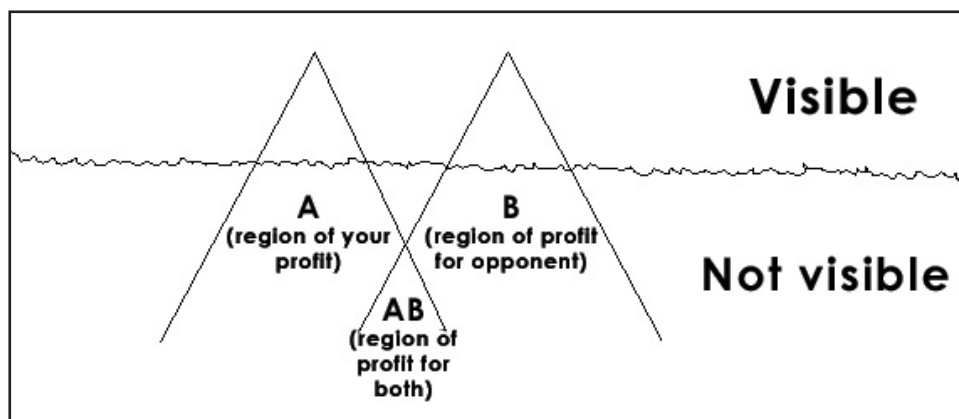


Fig 5.1 Positions of you and the opponent represented as icebergs. Under sea level and not visible at the start of the negotiations the region of the win-win situation AB.

*Training:*

Buying and selling a new laboratory office. One person of the training group act as buyer (manager medical laboratory) and one as seller (manager research laboratory) of a new building for the medical laboratory. The other participants are observers.

**Buyer:** You are working in a medical laboratory which is rather small. You have acquired the laboratory work of the local hospital and you have signed a contract with the hospital that you will start for them in 8 months. The only possibility to do the work is to buy a new laboratory. You have saved up USD 10,000.- and the bank will loan you USD 30,000.-. In the newspaper you find an announcement for a suitable building which will fulfil all your wishes. After consulting the local estate agent it is clear that this building is exactly the building you need.

**Seller:** You have a research laboratory. The work is booming, so you have bought a new building in the city for USD 45,000.-. With additional costs you need USD 50,000.-. You offered your present laboratory building for USD 55,000.- by placing an announcement in the local newspaper, although you know that in your street a comparable building, with no laboratory facilities, is offered for USD 45,000,-. You have to pay your new building within 3 months.

The chair asks the buyer and seller to negotiate about the new building after he/she has added additional circumstances which are only known by the buyer or by the seller. Negotiate 15 minutes in a role-game. After a short break the observers will give feed back to the actors.

**The controlling role of the manager**

*Skills to be trained:* create appraisal criteria from stated goals; apply the most effective method to measure performance; utilize performance appraisals as control devices to enhance the quality of work; provide feedback for further development.

*Theory:*

Control is the process of monitoring activities of the laboratory to ensure that they are accomplishing planned goals and of correcting any significant deviations.

The control process consists of three steps: measuring the actual performance; comparing the actual performance against a standard; taking action to correct deviations.

Measuring the actual performance: this needs the manager to acquire information about the process. It is important to determine how to measure and what to measure.

Comparing the actual performance against a standard: for certain parts of the laboratory process quality standards as ISO 15189 can be used. For other parts appraisal criteria have to be formulated. For example: individual task outcome for a technician is difficult to measure because he/she works in a team. Appraisal criteria for the performance of the technician can be: attitude to the diagnostic process, positive commitment in the team, progress of knowledge of the laboratory diagnostics, following of safety rules and regulations, etc. Taking action to correct deviations: Deviations from the standards of the appraisal criteria needs a corrective action. You first have to know why the performance has deviated. After this analysis your action is necessarily. This can be the remodelling of the logistic process, the modification of a protocol, to give a lecture about the theoretical background, etc. Actions towards the staff can be in the form of personal feedback interview. You can use positive and negative feedback. Positive feedback is more readily perceived than negative feedback. Negative feedback will give resistance, so try to formulate corrective feedback in a positive way. If negative feedback is unavoidable, it has to be supported by hard data or specific examples to avoid subjective impressions.

Rule of thumb for effective feedback are:

- It is descriptive rather than evaluative
- It is based on data rather than general thinking
- It is based on actual events rather than events from months ago
- It is most effective when the receiver is ready to accept it
- It is intended to help, not to punish

*Training:*

In this training session you have the opportunity to practice, observe, and receive feedback in a performance appraisal role-play.

Two participants of the training group will play the roles of

- the head of the laboratory (Joan)
- the staff-member responsible for haematological diagnostics (Steve)

The other participants will give feed back.

The 'head of the laboratory' and the 'staff-member' read their own role. They play their roles in front of the observers for a maximum of 15 minutes. After a small break the observers will give feed-back.

Role of the head of the laboratory (Joan): You are running a well equipped medical laboratory of a district hospital. You are well thought of in the laboratory and in the hospital and have excellent report from the director of the hospital. Steve is one of your staff and is responsible for the haematological part of the laboratory. You know that Steve is reasonable good at his job, but you also know that Steve believes himself to be 'outstanding', which is not true. You have arranged a meeting with him which is scheduled in 5 minutes. You will use this meeting to establish clearer communication as well as to convince Steve to adopt a less grandiose self-image. You believe that Steve is on the right track with his personal development. You think that it will take about 2 years to bring him to the level at which he can promote to a management position. As to Steve's performance you have received good reports as well as some letters of complaint. A few weeks ago you have said to him that his work was excellent, in order to keep him motivated. Maybe that was a mistake. You will discuss with him some targets for the next 2 years, after which you can give him promotion if it is deserved.

Role of the staff-member (Steve): You are technician in the haematological department of the medical laboratory in a district hospital. Joan is the head of the laboratory and your boss. You regard yourself as one of the best performers of the haematological department of the laboratory, and may even be the best. However you were not promoted last year. Joan has arranged a meeting with you. You know that she had called you 'excellent' although there are some letters of complaint against you. If Joan tries to delay your promotion, you plan to take the issue to her boss: the director of the hospital.

After playing the meeting between Steve and Joan in a role-game of about 15 minutes, the observers will give feed-back to Joan about the items:

- put the staff-member at ease and explained the purpose of the meeting
- use of specific objectives previously set as standards to measure progress against
- encouraged and supported while minimizing threats
- criticized performance, not the person, when giving negative feedback
- used specific examples to support ratings
- asked Steve to summarize the feedback to ensure understanding
- created a future plan of development with Steve

**The stimulating and coaching role**

*Skills to be trained:* to listen carefully to understand problems; to analyse and identify problems; to provide insight for improvement and to offer encouragement to help employees to improve their job performances.

*Theory:*

Coaching is a process of helping employees to improve their work performances. Effective coaching occurs without judgment and evaluation of the person. Effective coaching requires behavioural skills: establishing a supportive climate, listening active, being non-judgemental and understanding, solving problems jointly, and teaching the employee how to solve problems on their own.

A coach looks for opportunities to stimulate the employee to expand his/her performance capabilities. The coach observes the employees behaviour, asks questions about the way the employee is working and creates a supportive climate in which he/she empowers the employees to give the best for the laboratory and the organisation.

Coaching technicians in the process of learning new skills consist of the following steps:

- Explain the purpose and importance of that you are going to teach
- Explain the laboratory technique to be used
- Demonstrate the procedure of the analytical process
- Observe while the technician practices the process
- Provide immediate and specific feedback
- Express confidence in the technician's ability to be successful
- Agree on Follow-up actions

What motivates technicians to perform well?

Performance is the product of a person's ability multiplied by his/her motivation. Ability is the product of aptitude x training x resources. Motivation is the product of desire x commitment. All elements mentioned are necessary for high performance levels.

*Training:*

In this training session you have the opportunity to practice the coaching and stimulating role in a role-play. Two participants of the training group will play the roles of

- the head of the laboratory (Harold)
- the staff-member responsible for one of the local small medical laboratories (John)

The other participants will give feed back.

Role of the head of the laboratory (Harold): You are the head of the laboratory organisation. The organisation consists of a central medical laboratory in a district hospital and 5 small medical laboratories in remote areas. One of your staff-members, John, is responsible for one of the 5 local laboratories. John started one year ago in your organisation. In the first 6 months he was enthusiastic. He was a bit disorganised but willing to learn. After the first half-year John seems to be losing interest. He is impolite towards patients and physicians. The number of analyses decreased the last months and you decided to make an appointment with him in the remote laboratory to start a coaching project. The appointment was this morning at 9, but John was not present in the laboratory. You waited 15 minutes, then gave up. The local secretary tells you that John regularly comes in late for work in the morning and takes extra-long coffee breaks.

You don't want to fire John, because it is very difficult to find a replacement. You plan a new meeting with John which will start in 5 minutes.

Role of the staff-member of the local small medical laboratory (John):

You are now 1 year working as the staff-member responsible for one of the local small laboratories of the district laboratory organisation. The organisation consists of a central medical laboratory in the district hospital and 5 local laboratories. Harold is the head of the organisation and has appointed you in the local laboratory to bring it to a higher level. You were very enthusiastic for the job, although you knew that there is a lack in your knowledge because you had not finished the laboratory school. You also have problems with the computer system because you are not familiar with the new software.

To try to get more experience with the new software you have enrolled in an 8:00 A.M. extension course at the community college, which makes you about an hour late for work three days a week. The corresponding course on laboratory medicine you signed up for will have an good payoff for your work. You are working on it in the evening and during your breaks at work.

All this is a bit overwhelming and you have fallen a little behind in your work. The secretary of your laboratory just mentioned you that Harold has been at your office this morning at 9:00 hr. for the appointment with you. You were to your usual class and had completely forgotten it. You are informed that Harold will meet you this afternoon and will come in 5 minutes. You are wondering what the appointment is about.

15 minutes for the role-play. After a short break start with the feedback. Evaluate the coaching skills of Harold by the following items:

- Asked open questions to discover the problems of John
- Listened actively and showed genuine interest
- Educated instead of assisted
- Accepted mistakes and used then as learning opportunities
- Provided meaningful feedback for learning
- Recognized and rewarded small improvements
- Helped develop action plans for improvement

### **The professional role of the manager**

*Skills to be trained:* to help employees through education about the theory and practice of laboratory medicine; to mentor employees for long-term development; to stimulate employees about self education in the field of laboratory medicine.

*Theory:*

The professional knowledge of laboratory medicine is one of the basic requirements of the employees of the laboratory. The laboratory manager is responsible for maintaining the adequate level. The development of the theoretical knowledge of the technicians and the other employees can be achieved by teaching and by stimulating self-study.

Generally speaking the best ways to develop an employee is:

- to convince the employee that he/she is also responsible for his/her knowledge level (in relation to his/her abilities)
- to listen actively to the employee to clarify possible barriers to enhance the theoretical level
- to educate the employee or to stimulate self-education
- to give positive feedback in evaluations whenever possible
- to be flexible in your approach helping depending upon what causes the problem
- to approach mistakes as opportunities to learn

*Training:*

In this training session you can practice the professional role of the manager in a role-play. Essential skills to be trained are to stimulate and to mentor an employee.

Two participants of the training group will play the roles of

1. the head of the laboratory (William)
2. the technician working in a small annex laboratory in a remote village (Maria)

The other participants of the training group will give feed back.

Role of the head of the laboratory (William): You are the head of the laboratory organisation. The organisation consists of a central medical laboratory in a local hospital and 2 small medical laboratories in small villages in remote areas.

One of your technicians, Maria, is responsible for one of the 2 remote laboratories. It was difficult for you to find a technician for this remote place. You selected Maria a few months ago. She did not finish the laboratory school, but she was willing to live in the remote village.

From the local physicians of the remote area you have heard that Maria is unable to answer theoretical questions about the laboratory diagnostics and that it will take too much time before staff analyses are reported by Maria.

You called Maria and told her that you will drive to her to speak with her. The meeting with her will start in 5 minutes.

Role of the technician (Maria): You are now 4 months working as technician responsible for a small laboratory in a remote village. Far away in the district capital is the central medical laboratory of your organisation. William is the head of the organisation and has appointed you in the local laboratory to perform the analysis for the local physicians. You accepted the job in the remote village because you have been grown up in that area and you are very interested to work in the healthcare branch. It was difficult to get a job there, so you accepted the position as technician in the medical laboratory, although you knew that there is a lack in your theoretical knowledge. You have only followed a two-months course in medical laboratory science without examination. You are the only technician in the small laboratory so you can plan the work just as you like. You like to spend enough time for your hobbies. William just called you that he will come by car to you to discuss with you about your work. He will come in 5 minutes.

Take 15 minutes for the role-play. After a short break start with the feedback. Evaluate the managerial skills of William by the following items:

- ◆ Put Maria at ease
- ◆ Interviewed objectively
- ◆ Covered all important points
- ◆ Used open-ended questions
- ◆ Listened actively
- ◆ Came to an adequate solution
- ◆ Stimulated Maria to restart her study

## 5.7 Management of the organisation

### 5.7.1 Financial management and costs of laboratory products

The manager of the medical laboratory has to set up a cost-benefit calculation for each test. An example of a calculation system of the costs of laboratory diagnostics has been given in chapter 2.7.

*Training:* Calculate for 5 frequently requested tests approximately the costs for the last year in terms of direct costs, easy accountable direct costs and arbitrary accountable indirect costs. What will change in your calculation when you decide to invest in a new analyser for these tests? Discuss the outcome in the training group. Discuss also about the possibilities to improve the financial control system in order to get more insight in the costs-structure of the laboratory.

#### The organisational structure

Regarding the organisational structure of the medical laboratory several possibilities have been practised in the past. Based on older organisation theories like the 'scientific management' model and the 'bureaucratic management' model, the medical laboratories has been organised in such a way that the hierarchic structure was clear and that the logistic and diagnostic process determined the structure of the organisation. Newer organisation theories stressed the necessity to create an organisation structure in which the employees can grow and develop. This will give more benefit for the laboratory than a logistic/diagnostic orientated approach. Examples of the newer organisation theories are the 'human relations' model and the 'human resources' model. The 'human relations' model focuses on the creation of a good working climate for the employees in order to enhance the productivity and working pleasure. This can be achieved by organising good working circumstances and good leadership. Focussing on the 'human relations', will give insight in the 'informal social structure' of the employees of the laboratory. The 'informal social structure' exists apart from the formal organisation structure and will strongly influence the actual strength of the organisation.

The 'human resources' model fully focuses on the self-development of the employees to enlarge the strength of the organisation. The reason is that human-orientated organisations are more powerful than task-orientated organisations. In task-oriented medical laboratories the best methods to perform the analytical and logistic processes are realised. The employees are trained to practice the chosen methods. The management will control the work of the employees and will change the methods if necessary for the diagnostic process.

In human-orientated medical laboratories the employees are responsible for their own work and they have possibilities to influence the decision making of the management. The task of the management is more focussed on helping and stimulating the employees than controlling them. In this model the high level of education of the employees is essential.

In daily practice a combination of task and human oriented approaches can be used depending on the level of responsibility of the individual staff member. On the long term a human-orientated approach is more effective for the development of the laboratory than a task-orientated approach.

*Training:* Describe the structure of the organisation of your laboratory. Describe the formal structure as well as the informal structure. Formulate the mission of the laboratory which has inspired to come to the existing organisation structure. Describe the ideal organisation structure for your laboratory. Discuss about this in the training group.

#### Legislation and working conditions

To build up a strong and stable laboratory organisation knowledge of the local legislation and laws is essential as described in chapter 2.4 'Government and legislation'.

An important part of the legislation concerns the working conditions of the employees. These describe the minimal requirements of the laboratory in order to create a safe and clean environment for the staff as well as for the clients (patients, visitors, etc.). Good working conditions are expensive. Investigations in good working conditions will give profit on the long term and will stimulate the staff to improve the diagnostic processes. When employees are proud on their laboratory because of the good working circumstances, they are willing to be real ambassadors for the institute.

*Training:* Describe the positive and negative working conditions for your employees. A questionnaire for your employees can help you for a good survey. Formulate a plan to improve the situation. Discuss the situation and the plans in the training group.

#### Flow of information

Management of the flow of information is essential in a data-intensive branch as a laboratory. The Laboratory Information System (LIS) will streamline it as described in chapter 3.

*Training:* Describe the flow of information of your laboratory. Describe also the information which can not be handled by the LIS. Formulate 3 essential points which have to be improved. Discuss it in the training group.



## Development and projects

Development of the laboratory, professional on the field of laboratory medicine as well as organizational and logistic, is essential for the continuity and growth.

Sometimes major organization changes are needed. An unplanned change can be forced on the laboratory organization by external reasons. Also a planned change can be necessary to improve the laboratory operations. The best way to achieve it is planning the change in a project.

There are three phases of planned change: unfreezing the current state, changing and refreezing the new state. In the unfreezing phase the manager needs to help the employees accept that change is needed. Existing attitudes and behaviours need to be altered so that resistance to change is minimized. The changing phase is difficult because of the anxiety in letting go the familiar way of working. In the refreezing phase the new ways of working become stabilized.

The success of a planned change depends on the right diagnose of the situation and the clearly formulated goals of the plan.

It is important to recognize resistance to change. These can be expressed as slow downs, complains or more implicit as decreased motivation. Most problems can be overcome by clear and comprehensive information during each step of the changing process. Fear of the unknown has to be minimized by a good plan for the new situation. Participation and involvement of all employees will reduce the resistance to change.

Be aware that the normal human attitude phases in response to change are: denial of the need of change; resistance to change; attitude trough (anger and worry); exploration of the new situation; responsibility is accepted; commitment.

Awareness of the different phases can help the manager in the project of change.

*Training:* In this training session you have the opportunity to practice the process of managing an organization change in a role-play.

Participants of the training group will play the roles of

- the manager of the local medical laboratory (Sharon)
- a general practitioner, working next to the local medical laboratory (Geoffrey)
- 2 technicians of the local medical laboratory (Kenneth, Lynn)

The other participants will give feed back.

The 'manager of the local medical laboratory', the 'local practitioner' and the 2 technicians read their own role. They play their roles in front of the observers for a maximum of 15 minutes. After a small break the observers will give feed-back.

Role of the manager of the local medical laboratory (Sharon): You are running a local medical laboratory. Because of the bad financial situation of the laboratory you decided to close the laboratory next year. The analytical and administration work will be transmitted to the medical laboratory of the district hospital 25 miles away. Nearly all technicians can be appointed in the medical laboratory of the district hospital. You have formulated a plan which you will discuss with the representatives of the technicians (Kenneth and Lynn) and a representative of the local general practitioners (Geoffrey). The meeting with them will start in 5 minutes.

Role of the general practitioner (Geoffrey): Your busy practice is next to the local medical laboratory. You are happy with the service of the lab. You are asked to join a meeting with the manager (Sharon) and 2 technicians of the lab (Kenneth and Lynn) about the future. The meeting will start in 5 minutes.

Role of the technicians (Kenneth and Lynn): You are working as technician in a small local medical laboratory. You are happy with your work: the numbers of analysis per technician are easily low and you live only 0,5 miles from your lab. You (as one of the representative of the technicians) are asked to join a meeting with the manager of the lab (Sharon) about the future of the lab. One of the local general practitioners (Geoffrey) will also be present. The meeting will start in 5 minutes.

Take 15 minutes for the role-play. After a short break start with the feedback. Evaluate the managerial skills of Sharon by the following items:

- ◆ communicated widely about the changes
- ◆ performed an analysis of the situation
- ◆ developed vision and strategy for change
- ◆ formed a guiding coalition
- ◆ created a sense of urgency
- ◆ overcame resistance to change
- ◆ empowered the participants

## Chapter 6

### Basic Quality Control at low cost

Elizabeth Frank

#### 6.1 Introduction

Laboratory medicine is one of the corner stones on which scientific medicine stands. Clinical laboratory reports are therefore crucial in treatment. Analytical quality is the key to accurate reporting in a clinical laboratory. Clinical laboratories have achieved significant milestones in providing quality for diagnostic tests. Automation, traceable reagents, laboratory information systems have contributed to better quality of reports to the clinician. Advances in Laboratory medicine have occurred in concert with analytical accuracy that ensures that the analytes measured are specific and sensitive. Maintaining analytical accuracy is a daily practice and translates directly into quality of reporting. As a consequence, biochemists and pathologists are expected to meet and monitor stringent technical, management and quality-assurance standards.

It is unfortunate that the number and quality of clinical laboratories in developing countries however do not adhere to the required quality standards. Although a few top-of-the-line laboratories in these countries compare favourably with those in developed nations, their number is very small. The vast majority of patients do not have routine access to such laboratories. The first medical encounter with the patient is likely to be in a small, poorly run establishment without access to the necessary diagnostic tests, or in some cases access to tests whose quality is questionable. The reasons for this are multifaceted.

In many developing countries, a laboratory can be established without requiring permission from any government or any professional association. There is no paperwork since there are no regulations governing the management or quality of laboratory practice and no license is needed. The factors determining the performance of a clinical laboratory include good equipment, reliable reagents and trained, conscientious staff, but many laboratories compromise on such vital prerequisites- any lapse or mistake in the performance of tests can therefore lead to serious harm whether at the diagnostic stage or in the course of treatment.

In most developing countries, health care is primarily funded from general government revenue without charging the consumers. The expenditure on general health services is very low. Most funding is spent on high-profile projects in teaching institutions in large urban centres.

Small and medium sized laboratories, not attached to a teaching institute, also run on a low cost level as the patient pays for his tests rather than the government or insurance companies. Many times these labs use technicians who are unqualified or have inadequate training to cut down salary costs.. As result the quality of reports generated from these labs are highly questionable.

This document will provide some basic guidelines to labs in the developing countries to assure analytical quality diagnostic services to patients with minimal additional costs.

#### 6.2 Quality has a cost, it is not free

Is the cost spent on assuring quality justified? Does it raise the price of services delivered? Are huge savings possible by implementing continual improvement efforts? These answers may not be obvious as many times the effect of an efficient quality system is seen gradually. However quality is measurable, as are its costs. Philip Crosby, in *Quality is Free*, writes that the cost of quality is "the expense of non-conformance--the cost of doing things wrong." Some prefer the term "cost of poor quality" (COPQ) because that implies what happens when continual improvement efforts are derailed or postponed (1). What is often seen is the cost spent on assuring quality and not the cost of correcting errors that may happen due to lack of a consistent quality system.

So quality assurance is the essential organizational infrastructure that underlies all quality measurements. This would include all aspects of a laboratory like staff training and management, adequacy of lab equipment and environment, safety, storage, integrity and identity of samples, record keeping, maintenance and calibration of instruments, use of validated methods and standard reagents, which ultimately translates into quality of analytical measurements. Failure in any of these areas would reflect adversely in achieving the desired quality. However prevalence of these favourable circumstances will not ensure analytical quality unless Internal quality control (IQC) is conducted. In principle, quality control for analytical performance consists of two complementary activities: Internal Quality Control (IQC) and External Quality Assurance Scheme (EQAS). It is mandatory for any lab to at least have a predefined IQC and EQAS schedule.

The **Internal QC** involves the in-house procedures set up by each laboratory for continuous monitoring of operations and systematic day-to-day checking of the produced data to decide whether these are reliable enough to be released. The procedures primarily monitor the bias of data with the help of control samples and the precision by means of duplicate analyses of test samples and/or of control samples. These activities take place at batch level (second-line control)

The **external QC** involves reference help from other laboratories and participation in national and/or international inter laboratory sample and data exchange programs (proficiency testing; third-line control).

The internal QC needs has to be organized by the laboratory itself and is vital to achieve analytical quality. The External QC is just as indispensable as the internal QC.

### 6.3 How to ensure Internal Quality Control?

IQC is a set of procedures followed by the laboratory staff for the continuous monitoring of laboratory operation. The results of this monitoring decide whether or not these results are reliable enough to be released. So IQC is the back bone of quality assurance and ensures the production of reliable data with minimum errors.

Control materials are used for IQC and are treated as a sample is in a particular test run. Reference materials can be run as control. Ideal control materials are the certified ones. The control material should be run in an analytical sequence. The control sample whenever possible should be representative of the test materials with respect to matrix composition and the concentration range of the analyte.

IQC should be ideally run with each batch of samples tested. However a lab with a lower volume of work load could run at least two levels of control per day. The quality control data generated is then interpreted by using quality control charts.

The two frequently used charts are

- Control Chart of the Mean for the control of bias
- Control Chart of the Range of Duplicates for the control of precision.

### 6.4 Control Chart of the Mean (Mean Chart)

In each batch of test samples at least one control sample is analyzed and the result is plotted on the control chart. The basic construction of this Control Chart of the Mean is presented in Fig.1. (Other names are Mean Chart, x-Chart, Levey-Jennings, or Shewhart Control Chart). The interpretation and practical use of control charts is based on a number of rules derived from the probability statistics of the normal distribution. The basic assumption is that when a control result falls within a distance of  $2s$  from the mean, the system was under control and the results of the batch as a whole can be accepted. A control result beyond the distance of  $2s$  from the mean (the "Warning Limit") signals that something may be wrong or tends to go wrong, while a control result beyond  $3s$  (the "Control Limit" or "Action Limit") indicates that the system was statistically out of control and that the results need to be rejected: the batch has to be repeated after sorting out what went wrong and after correcting the system.

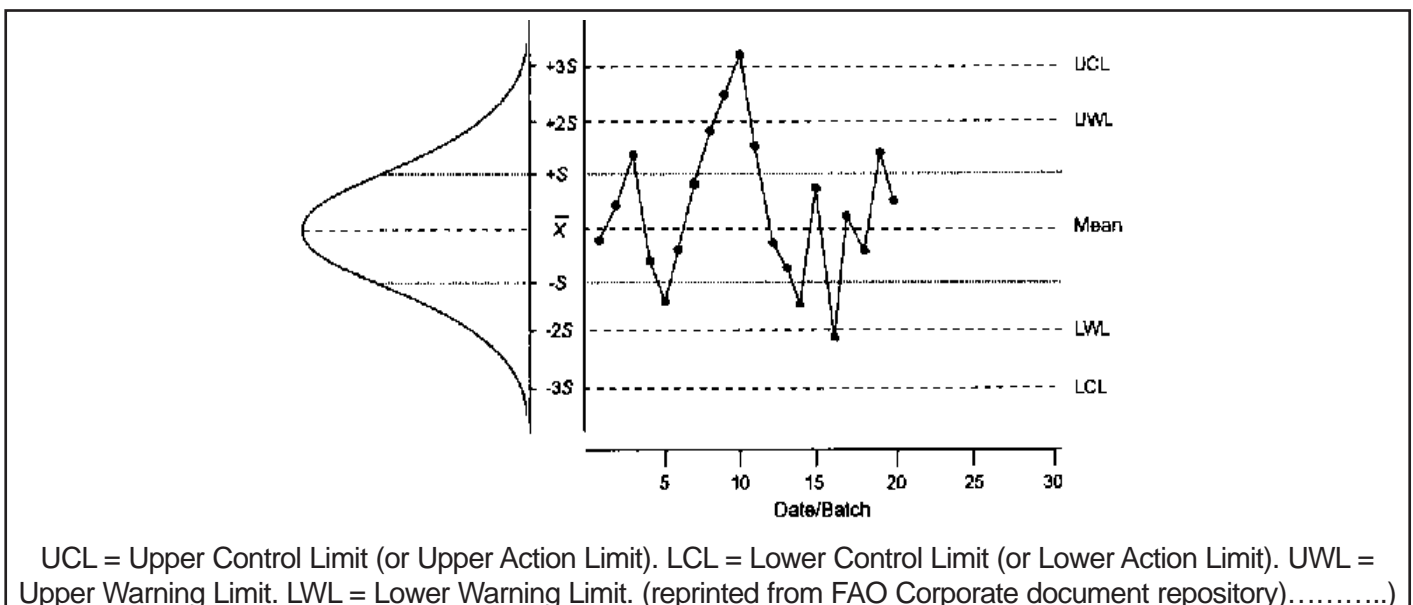


Fig. 1 Control Chart of the Mean

### Interpretation of Control Chart Mean

Quality control rules have been developed to detect excess bias and imprecision as well as shift and drift in the analysis. These rules are used to determine whether or not results of a batch are to be accepted. Ideally, the quality control rules chosen should provide a high rate of error detection with a low rate of false rejection. The rules for quality control are not uniform, they may vary from laboratory to laboratory, and even within laboratories from analysis to analysis. The rules for the interpretation of quality control charts are not uniform either. Very detailed rules are sometimes applied, particularly when more than one control sample per batch is used. However, it should be realized that stricter rules generally result in lower output of data and higher costs of analysis. The most convenient and commonly applied main rules are the following:

**Warning rule:** In this rule one Control result is beyond warning Limit. The data needs to be further evaluated before dispatch of reports in such cases.

**Rejection rules:** According to this rule the data are rejected if

- One control result beyond Action Limit.
- Two successive control results beyond same Warning Limit.
- Ten successive control results are on the same side of the Mean
- Whenever results seem unlikely (plausibility check).

### 6.5 Control Chart of the Range of Duplicates (Range Chart)

This chart helps to monitor between-batch precision. It can also be seen on the Control Chart of the Mean; a "noisy" graph with frequent and large fluctuations indicates a lower precision as compared to a smooth graph. Information about within batch precision (repeatability) is obtained by running duplicates in the same batch. The results obtained are plotted on a Control Chart of the Range of Duplicates (also called Range Chart or R-chart).

In each batch of test samples at least one sample is analyzed in duplicate and the difference between the results is plotted on the control chart concerned. The basic construction of such a Control Chart of the Range of Duplicates is given in Figure 2. It shows similarities with the Control Chart of the Mean in that now a mean of differences between the duplicates is calculated with corresponding standard deviation. Initiating a Control Chart of the Range of Duplicates is identical to initiating a Control Chart of the Mean Also the model of the chart is virtually identical with only  $\bar{x}$  replaced by  $\bar{R}$ . The parameters  $\bar{R}$  and  $s_R$  are determined for at least 10 initial pairs of duplicates In each batch of test samples at least one sample is analyzed in duplicate and the difference between the results is plotted on the control chart of the attribute concerned. A disadvantage is that precision is measured at one concentration level only (unless more than one control samples are used). The duplicates should be placed at random positions in the batch, not adjacent to each other. The necessary statistical parameters for the Range Chart,  $\bar{R}$  and  $s_R$ , can be determined as follows:

$$\bar{R} = \frac{\sum R_i}{m} \quad (8.5)$$

where

$\bar{R}$  = mean difference between duplicates

$\sum R_i$  = sum of (absolute) differences between duplicates

$m$  = number of pairs of duplicates

and

$$s_R = \sqrt{\frac{\sum R_i^2}{2m}} \quad (8.6)$$

where

$s_R$  = standard deviation of the range of all pairs of duplicates.

The warning line and control line are drawn at  $1s$  and  $3s$  distance from the mean of differences.

The graph is single-sided as the lowest observable value of the difference is Zero

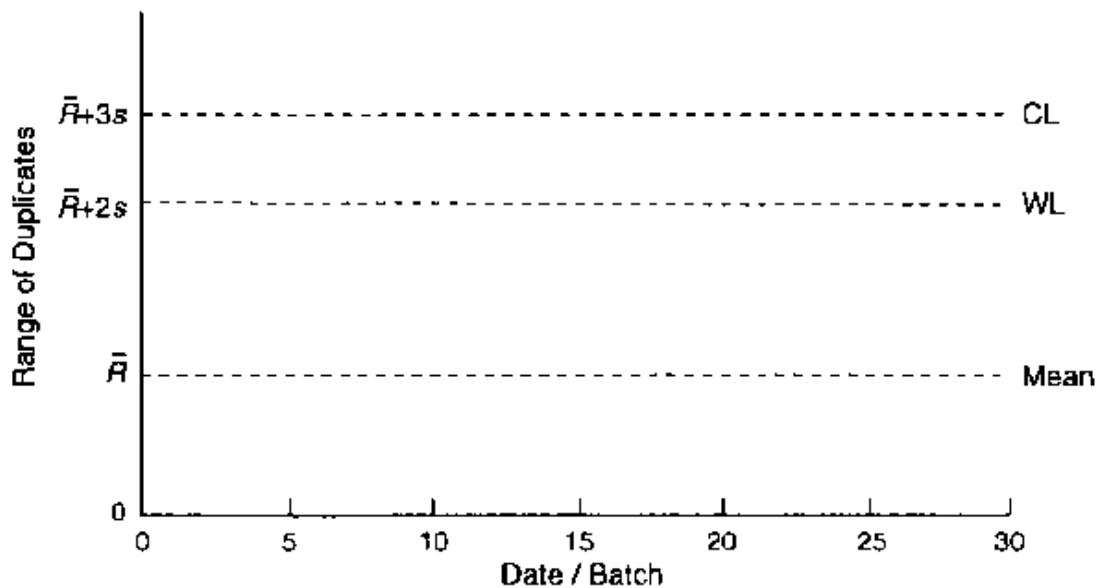


Fig. 2. Control Chart of the Range of Duplicates.  $\bar{R}$  = mean of the range of duplicates. WL = Warning Limit. CL = Control Limit (or Action Limit).

The interpretation rules of the Range Chart is very similar to those of the Mean Chart:

**Warning rule:**

- One control observation beyond Warning Limit

**Rejection rules:**

- One control observation beyond Control (or Action) Limit
- Two successive control observations beyond Warning Limit
- Ten successive control observations beyond  $\bar{R}$ .

The response to action taken for rejection rules is also similar. Investigate the problem and repeat the analysis

## 6.6 Practical and feasible interpretation of QC data

The laboratory should include for each kind of tests a minimum of one level QC at least once a day. However if the number of patients samples analyzed exceeds 25 per day then the laboratory should at least run 2 levels of Quality control. If the number of patients samples analyzed exceeds 75 per day, the laboratory should run two levels of QC at least twice a day. If the lab has a large work load then each run should carry a QC sample.

If a parameter for example thyroid hormone has a low load, running a daily QC may prove expensive for such rare analytes the lab can decide a frequency of QC run which is economically feasible. It is a good practice to calculate CV% based on the monthly QC data and monitor if there is any large shift in CV%.

### 2 SD control limit

Most laboratories use the mean plus and minus 2 SD control. This rule is known as 1 2s rule. This rule has a high rejection rate. This false rejection rate can cause 10 - 20 % waste of laboratory resources

### Multi rule QC

The most commonly used and meaningful interpretation of control charts in most laboratories is now done by Westgard's Multi rules. These rules detect both systemic (Trends or shifts) and random errors.

Interpretation based on multi rule when one level of QC is used

Reject QC if

- The value is outside 3 SD ( $1_3S$ )
- Two consecutive values are outside 2SD on the same side but within 3 2SD ( $2_2S$ )
- Ten consecutive values are above or below the mean but within 2 SD ( $10_x$ )

### Interpretation based on multi rule when two levels of QC are used

Reject QC if

- Either one of the QC values is outside 3SD ( $1_3S$ )
- Both QC values are outside 2 SD on the same side but within 3 SD ( $2_2S$ )
- Difference between both QC values is  $>4$  SD. When one level QC is  $> 2SD$  and the other level is  $< 2SD$  ( $R_4S$ ).
- Ten consecutive values of the same level QC are  $>/<$  than the mean but within 2 SD ( $10x$ )
- Five consecutive values of one level QC and five consecutive values of other level QC are  $>/<$  the mean but within 2 SD ( $10x$ )

### 6.7 When QC is out of control?

The First response in many laboratories to an out-of-control situation is just to repeat the controls, rather than to rectify the problem [2]. The immediate rationale is that the out - of -control situation may be a case of false rejection, therefore, let's check again. And often when the repeats are still out-of-control, the response is to prepare new controls for analysis. And, of course, if they're out, they will also be repeated. Sources of possible errors should be identified rather than blind repetition of controls.

It is recommended to have a step by step flow chart to manage an out-of-control situation. This flow chart should address the issues

- 1) Recent events that could have caused changes in QC values
- 2) Has there been a change in the environmental condition
- 3) QC sera stability
- 4) Problems, with instruments or calibrator
- 5) Operators error
- 6) Too many freeze thaw cycles of the QC materials.

### Interpretation of target values of Quality control materials

It is not advised to use the package insert of the quality control materials (bottle values) to calculate control limits. Values assigned on the bottles are reflecting overall performance of a group of laboratories. They have a large SDs and the control limits are wider than usually accepted. This can cause false negative error detection. Every lab needs to establish its own control limits. This ensures that the criteria for rejection becomes more stringent and that the efficiency in detecting errors will be enhanced. The mean and standard deviation of a control material should be established on the basis of repeated measurements on those materials by the methods in use in the laboratory. The use of cumulative control limits that are based on the means and SDs for several months of laboratory data are recommended.

### Reject out-of-control runs, identify the problem, and eliminate the cause

When QC procedures have been carefully selected to minimize false rejection and maximize detection of medically important errors, the proper response to an out-of-control signal is to reject the analytical run, trouble-shoot the method, identify the problem, eliminate the cause of the problem, and verify the test results for patient specimens.

### 6.8 Additional simple ways of ensuring analytical Quality

**Spiking:** Spiking is a way of creating a control material in which a value is assigned by a combination of formulation and analysis. This is possible when a test material is free of a particular analyte. After adequate analytical checks to ensure that the background level is low, the sample is spiked with a known amount of analyte. The reference materials prepared this way should have the same matrix as that of the sample. It is also possible to spike test material with the analyte present. The spiked amount have to be found after subtraction of the measured values after and before spiking.

**Blank determination:** Blank determination is an essential part of the analytical process. The simplest form of blank determination is reagent blank. The reagent blank checks for purity of reagents, detects contamination of the analytical system . A sample blank specially in an icteric or lipaemic serum is also very useful in ruling out interference and avoiding erroneous results

**Retained samples.** QC sera have a distinct expiration date . Mostly they can be used for only a short period. This will enhance the cost of the tests of a particular analyte. In such cases, one or more samples that are run together with one or two level QC are retained and are used as control in the next run. This saves the expenditure on control sera. For stable analytes using retained samples would save on the QC cost tremendously.

## 6.9 Trouble-shooting after detection of a quality problem

Whenever the quality control detects an error, corrective measures must be taken. Once an error is detected a systematic investigation must take place. This includes the checking of sample identification, standards, chemicals, pipettes, dispensers, glassware, calibration procedure, and equipment.

Clearly, every analytical procedure and instrument has its own characteristic weakness, which will become known by experience. It is useful to make a list of relevant check points for each procedure and adhere this to the corresponding SOP or maintenance logbook if it concerns an instrument. Update this list when a new flaw is discovered. Once the error or errors are detected it is rectified and the correction is applied to the system. The corrective action taken is then checked to see if the action taken is effective.

## 6.10 Complaints from Clients as a Quality Indicator

Errors that escaped detection by the laboratory may be detected or suspected by the client or the referring doctor. Although this particular type of quality control may not be popular, it should in no case be ignored and can sometimes even be useful. For the dealing with complaints a protocol must be made with an accompanying Registration Form with at least the following items:

- name client, and date the complaint was received
- work order number
- description of complaint
- name of person who received the complaint (usually the head of laboratory)
- person charged with investigation
- result of investigation
- name of person(s) who dealt with the complaint
- an evaluation and possible action
- date when report was sent to client

A record of complaints should be kept. The documents involved may be kept in the work order file. The trail of events (audit trail) may sometimes not be easy and particularly in such cases the proper registration of all laboratory procedures involved will be of great value.

## 6.11 External Quality Assessment Scheme (EQAS)

- EQAS is a system in which the analytical performance of the laboratory is assessed periodically and retrospectively by an independent agency. The results of the EQAS is crucial in that it indicates analytical short coming and it is a powerful indicator of a need in change or improvement of internal quality procedures. The lab must enrol itself in at least one EQAS program per analyte. All the analytes tested, test methods and all sections of the lab should be covered by this EQAS program. The EQAS samples must be treated as patient sample and no special attention should be given to the EQAS sample. Enrolling in an EQAS program is mandatory for being an accredited laboratory.

### EQAS Benefits

- Provides objective evidence of laboratory Quality to the client as well as the referring doctor
- Assures that the lab results are accurate and are comparable to national and international standards
- Identifies common errors, training needs and recommend corrective procedures
- Ensures that the SOPS are being followed and the integrity of reagents used are maintained
- It helps in evaluating the factors that effect Quality like interfering substances
- Motivates lab staff to perform better in each EAQS cycle and minimize errors.

### EQAS Methods

#### Proficiency Testing:

"A program in which multiple samples are periodically sent to members of a group of laboratories for analysis and/or identification; whereby each laboratory's results are compared with those of other laboratories in the group and/or with an assigned value, and reported to the participating laboratories and others." (NCCLS)

**Rechecking/Testing:** Sampling of specimens or slides for rechecking or retesting by a reference laboratory. Rechecking of slides is normally blinded. However retesting may not require blinding.

**On - Site evaluation:** Is normally a part of the accreditation process. The on site evaluatio assess laboratory practices, gives a realistic picture of the laboratory practices and helps to identify problem areas. The onsite evaluation is normally conducted by an accreditation organization using laboratory specialists or governmental co-workers. The frequency may be annual or biannual or as required by the accreditation regulations.

**Inter laboratory Comparison**

In many developing countries the problems in finding an EQAS provider is an issue, or the EQAS providers are very expensive. In such cases the laboratory can compare its results with the results of an accredited laboratory in the region.

Results of the EQAS should lead to effective corrective action and should be discussed in the yearly management review of the Laboratory and should be used as a quality indicator of Continuous Quality monitoring.

**Audits**

Internal and external audits can also be used as a tool to assess and to maintain Quality. Internal audits are a requirement of ISO 15189. An audit is a systematic independent examination of the entire quality management system. This in turn can verify analytical quality

Audits also help in recognising problems, taking corrective action and initiating preventive actions.

Quality Indicators: It is advised for each laboratory to set up a list of quality indicators which will determine and monitor as well as the analytical quality of the Lab as the overall Quality System performance.

**Reference**

1. Crosby, Philip (1996). Quality is still free: Making Quality Certain in Uncertain Times. McGraw-Hill. ISBN 0-07-014532-6
2. Gryna, F. M. (1988) "Quality Costs" in Juran, J.M. & Gryna, F. M. (1988, 4th Ed.), Juran's Quality Control Handbook, McGraw-Hill, page 4.2.
3. Westgard JO. Strategies for cost-effective quality control. Clin Lab News 1996;22:8-9. See also <http://www.aacc.org/clin/pdf/octfeat.pdf>



## Chapter 7

### Environmental Conditions

Herbert Stekel

#### 7.1 Introduction

The effects of environmental conditions on laboratory testing are manifold. In the worst case, such conditions could render it impossible to achieve correct results. Numerous factors of influence are known, such as temperature, humidity, dust, noise, light, magnetic fields or harmful substances. They can cause a wide range of faults and errors. Incorrect storage of reagents and mechanic faults due to vibration, for example, may generate high costs. In case of doubt it may be helpful to contact the manufacturer of reagents and analytic devices. Last but not least, the human factor should not be left out of consideration by the employer because the influence of environmental conditions on the employees caused by e.g. high temperatures, humidity, radiation or harmful substances can also be the cause of errors or - even worse - it could damage health.

Faults caused by problems relating to the power supply or to poor water quality are also subjects discussed in this chapter.

See also ISO 15189:2003, Chapter 5.2 "Accommodation and environmental conditions"

#### 7.2 Vibration

Heavy goods traffic, railway, subway and heavy machines such as printing presses or similar, situated in the same building as the laboratory, may cause disturbing vibration. Vibration could also be caused by construction sites or even by small but frequent earthquakes. This could lead to mechanic faults in analysers or hard disks and may even result in a head crash. In case of vibration, it can also be very difficult to use a microscope. A remedy could be to change the location of the laboratory. This is a perfect solution but in most cases difficult to achieve. If the building has some more stable areas, it can be helpful to locate sensitive equipment in these rooms. Another remedy could be to buy data processing equipment of shock-proof design. Laboratory equipment such as centrifuges or compressors may also be the cause of vibration. In this case it would be helpful to locate these machines at a distance from critical areas in the laboratory and/or place them on a vibration absorbing substructure.

#### 7.3 Temperature

High temperature is mostly caused by climatic conditions and solar radiation. High temperature inside the laboratory can cause a series of problems. Manufacturers of analytic devices and reagents describe an exact range of temperatures, within which devices and reagents are to be stored and used. Using the equipment outside this temperature range can result in wrong findings. Problems can arise when staining slides due to an increased rate of evaporation of solvents. Another important consideration is that high temperatures also increase the level of stress the employees have to cope with. In countries with a high mean temperature air conditioning equipment is very useful. There also has to be a satisfactory amount of refrigerators or a cold storage depot. The construction of the building is also of great influence; proper thermal insulation will help to keep overhead expenses low.

Another cause of high temperatures within the laboratory is waste heat. Therefore, the over all waste heat must be calculated for every single room. Large work cells have a heating power of up to 15 or 20 kW. This equals the power of 7 to 10 fan heaters. Refrigerators and incubators also emanate heat.

Low temperatures, on the other hand, may also be a source of problems. Proper storage conditions are described on the packages of the reagents, excessively low temperatures may cause crystallization.

#### 7.4 Humidity

In certain climatic conditions, humidity can reach up to 100%. Water bath is also a source of dampness. Humidity near 100% may cause leakage current. Instruments with high voltage power supplies such as photomultipliers or computer screens using picture tubes can be damaged. Condensation on cooled parts of the equipment can also cause trouble. As is the case with high temperatures, excessive humidity also puts a strain on the employees. If high humidity occurs along with high temperature, a dehumidifying air condition system is useful to keep both temperature and humidity within an acceptable range.

Low humidity, below 10%, may also cause some problems. High voltage operated equipment, as just described, requires environmental conditions to be kept within a defined range. The details are described by the manufacturer and they are to be strictly adhered to. A rapid loss of solvent, which has been observed in connection with high temperatures, may cause serious problems when staining slides. Employees, first of all those who are using a microscope, may encounter difficulties with dry eyes and they might need ophthalmic agents such as sterile eye drops. Humidifiers can also be helpful, but at the same time they can be a source of dramatic hygienic problems themselves. Humidifiers must be kept clean, parts like filter pads must be changed in prescribed intervals. Otherwise severe diseases like, for example, infections of the eye or pneumonia may occur.

### **7.5 Dust**

Dust consists of small, solid particles. These can be of natural origin like in the case of sand. Other sources could be industrial enterprises, the demolition of buildings, traffic etc. Exhaust particulate and smoke as a waste product of combustion also constitute dust. The effects of dust are as varied as their sources. Mineral dust can have grinding effects on mechanical parts such as bearings. Dust containing elements like calcium, iron, zinc or other trace elements can cause incorrect results if probes or instruments are contaminated. This problem mainly occurs in connection with atomic absorption techniques. Remedial action could consist of sealing windows and using an air condition system with dust filters. Work benches with filtered, circulating air are also a good way to avoid the described problems.

Dust containing pollen is a special case. High amounts of mineral substances can cause problems like the ones described above but, in addition, employees suffering from allergies can encounter massive health problems caused by dust containing pollen.

### **7.6 Light**

Sunlight and lamplight have an influence on substances like bilirubin. The higher the level of ultraviolet light, the higher the loss of bilirubin in vitro. To avoid this problem, specimen should not be exposed to sunlight or bright light of any origin. Another factor is reflected light on computer screens which can lead to errors due to bad legibility. Computer screens should be placed at spots where reflections from sunlight are impossible. Reflections of artificial light can be avoided using lamp shades or grids.

### **7.7 Magnetic fields**

The magnetic field of the earth is too weak to cause any problems in the laboratory. The influence on magnetic tapes and the possible resulting loss of data is the only known exception.

All other problems caused by magnetic fields are technical problems caused by the vicinity of the source of a magnetic field. Such powerful sources could be transformers, MRT equipment or electric cables. Transport systems with built in electric motors can also be sources of magnetic fields. Strong magnetic fields may cause malfunctions of electro-mechanical parts such as stepper motors used in analysers. In certain cases, computer screens using picture tubes might show no picture, as the electronic beam is deflected the wrong way.

The best way to avoid the influence of a magnetic field is distance, as the field intensity decreases with the cube of the distance. If the possible distance is insufficient, shielding with ferromagnetic materials may be helpful.

### **7.8 Electromagnetic fields / radio frequency**

Strong fields with high frequency may cause electronic equipment to malfunction. Therefore the use of mobile phones within the laboratory as well as the operation of transmitters should not be permitted. Transmitter equipment located close to the laboratory, for example a radio antenna, could be the source of electronic problems.

### **7.9 Radiation**

The main sources of radiation in the laboratory are reagents used for radio-immuno-assays (RIA). Proper handling according to local regulations should avoid harmful radiation altogether. Natural sources such as a few minerals (pitchblende, granite) are of less importance.

### **7.10 Noise**

Noise and its influence on health should not be underestimated. Injuries caused by excessive noise include defective hearing, poor concentration and many kinds of vegetative symptoms. Sources of noise outside the laboratory may be traffic, industrial areas, construction sites or similar. Building measures such as soundproofing of the windows are helpful.

Inside the laboratory, centrifuges, analysers, air condition and refrigerators are the most frequent sources of noise. The choice and proper location of quiet equipment together with absorbing substructures and sound-deadening wall covering could improve the situation.

### **7.11 Harmful substances**

Solvents used in the laboratory may cause health problems. There are many different types of dangerous substances therefore local regulations and guidelines for the user must be followed. Insecticides used in the laboratory are a special source of problems, as some of them are anticholinergics. If specimens become contaminated with insect spray, this has an effect on the employee's health and on top of this it may be difficult or impossible to analyse the cholinesterase (CHE).

### **7.12 Power supply**

Laboratory equipment requires power supply of a defined voltage and frequency. Information systems do not tolerate power failures that last longer than parts of a second. The same goes for built-in computing equipment. Consequences are loss of data, loss of time and reagents and a resulting increase in costs. Therefore the use of an uninterruptible power supply for computers, mainframes and analysers is highly recommended. If there is a possibility of frequent power failures lasting more than one hour, refrigerators and air conditioning equipment could also be affected. In this case, an emergency power generator should be used.

Instruments for cauterization such as the ones widely used in surgery are often a source of interference voltage in a high-frequency range. Inductive transients have their origin in operating equipment with inductive load like motors. Another source is lightnings. Interference voltage may cause incorrect operation of instruments. Interference suppression has to occur - whenever possible - near the source of interference voltage.

### **7.13 Gas supply**

Some laboratories have gas supply for operating a flame photometer or a Bunsen burner. Gas pressure must be kept at a constant level to avoid incorrect results. If the pressure varies greatly, it is better to use gas bottles.

### **7.14 Water supply**

A high number of operational steps require water of high quality. Water should be germfree, without contamination with organic or inorganic material. If tap water is of drinking water quality, purification by ion exchanger is appropriate. If germs, sand and other materials are contained in the water, additional steps of water treatment such as filtration and distillation are required. If tap water is not available at any time, it would be good to have an own well. It might also be helpful to use water tanks or a reservoir.

### **7.15 Cleanliness**

All rooms of a laboratory and the whole equipment have to be cleaned carefully and in short intervals. Traces of infectious material may be harmful for the employees. Dirty glassware or tubes can lead to wrong results. Even optical clean glass can cause problems, e.g. if glassware is not iron-free, results of iron testing will be false-high. If a new method is established in the laboratory, the influence of such disruptive factors should be taken into account.

Small rodents like mice may destroy laboratory equipment. Those animals gnaw at wires; this can lead to shortcuts or interruptions. If wires run underneath the floor or in a cable channel it can be very difficult and also expensive to locate the fault.

Other small animals like bugs or spiders are more a hygienic problem and may be the cause of soil in the laboratory. For the use of insecticides see also the comments given above ("Harmful substances").