

A laboratory work – the quality of virological tests in the context of the competence of the personnel

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Received: 2013.12.01 • Accepted: 2013.12.13 • Published: 2013.12.20

Summary:

The Quality Policy at any type of diagnostic facility involves ensuring that the research in the laboratory and its labs were carried out with due diligence and at the highest possible level in accordance with good laboratory practice. The superior objective should include meeting customer's requirements while meeting the requirements of PN-EN ISO/IEC 17025:2005 [1] specifying the general requirements for the competence of testing and calibration laboratories. In this paper, the actions leading to maintain the high quality of research and to ensure the reliability of the test results have been presented, which are reflected in the high competence of the medical staff

Key words: quality of microbiological research, quality policy, competency of staff, microbiological diagnostics.

Introduction

Every human action, including those implemented in a team, requires the organization and application of effective process and management tools [2]. Human Resources of an organization, regardless of the way of its functioning, are subject to a process of management as objects run by the entity to reach the adopted objectives and an assigned tasks. The main resources, on which the operation of any enterprise should be based, regardless of its size, specificity, as well as of the strategy, are:

- the staff of the first line of production or service (direct staff) and the staff of the

technical and administrative infrastructure (indirect staff);

- physical resources, especially the workplace and its equipment;
- financial resources;
- information – knowledge (related to the process and market) needed to function effectively in the marketplace[3].

Similarly, the accuracy and reliability of the research in microbiology laboratories are affected by many factors, of which the most important

are also: the staff, premises and environmental conditions in the laboratory, test methods and their validation, equipment, measurement traceability, and proper handling of specimens. The presented factors need to be analyzed in detail at the development of test procedures, training and qualifying personnel, and at the selection and calibration of measuring equipment, taking into account the impact that they have on the total measurement uncertainty in the microbiological examination.

Leadership in a team of people

Modern management means advising employees and coordinating their work. In management one should also take into account the needs and aspirations of employees. Therefore, it is the interaction of the manager and the employee in order to perform certain tasks facing the team. The manager who wants to succeed in his work, must know how to create an efficient and effective team. The person who manages the team becomes a leader, who should be able to:

- 1) determine the most urgent issues to implement and define the direction of the proper operation for the team,
- 2) chose for teamwork people with appropriate skills and potentials to cooperate with other team members, including the leader;
- 3) develop the flexibility of team members, which will allow individual employees to perform more than one task among those that the team implements;
- 4) together with the team set goals and tasks to be performed (e.g. joint scheduling of tasks) [4];

Therefore, a good manager should be able to:

- build a team and strengthen ties between people in it;
- motivate them with a wide range of stimuli;
- develop competencies of subordinates;
- introduce healthy competition in the team;

- avoid common mistakes of the managers (e.g. selection of inappropriate and ineffective tools to motivate team members, intuitive operation, not noticing or avoiding problems and conflicts, etc.);
- keep in a team the best employees[5].

The leader of the team and his superior (e.g. a director of the company) should agree on a common vision of team goals and reach agreement on the following issues:

- personnel decisions, especially in the case of interdisciplinary teams;
- expenditure exceeding the designated budget;
- outsourcing certain tasks to outside experts or consultants, as well as acquiring additional resources;
- changes in the scope of the objectives that the team has to achieve and changes in the work schedule[5].

The leader of the team should also make sure that all group members and members of senior management fully understand and accept the scope of team activities, in particular:

- the scope of discretion in a team,
- the range of decisions that will be taken outside of the team,
- the method and date of communication of the decisions to all persons and interested entities[5].

Effective team management requires consideration by the leader of the following issues:

- Has the goal of the team been clearly defined?
- Is the budget and work schedule realistic?
- Are the available resources sufficient to achieve the objective set?
- Does the team have enough freedom and support to pursue its objective?

Team management and effective leadership require the manager to adopt action-oriented attitude. An effective tool is the use of a simple

and practical operation model based on three co-operating elements, i.e. the task, the team, and an individual. This model determines the leader's basic operation that he must make in order to be effective in teamwork. Therefore, the task of a leader is:

- to perform the task,
- to construct and maintain the team,
- to develop the abilities of an individual[6].

The needs related to these three elements are the components of leadership, because people expect their leaders to help them accomplish the task, to achieve synergy in a team, and to meet their own needs. The task requires the creation of working groups or establishing an organization because one person is not able to perform it. The team needs constant promotion and maintenance of the group cohesion to ensure the execution of the task. An individual feels material needs (such as a salary) and psychological, such as the need for recognition, awareness of purpose and its implementation, the status and the need for relationships with other individuals.

The flow of information and biological material in a hypothetical diagnostic laboratory

In the laboratory computer system, owned by the medical establishment X, the recommendations for research are in a dual form: printed orders and electronic orders. Completed order forms for microbiological tests are delivered to from hospital wards or the collection facilities. Then they are scanned using the quick reader, by means of which the tests indicated on the order, along with a bar code, are automatically entered into the system. After the scan of the order is made, the person operating the reader checks the correctness of the registered tests with the order. Then, the patient's personal details should be filled in: name, surname, social security number (PESEL), address, etc. In addition to the automatic registration, the system allows manual registration, where a lab assistant records the tests from the list by selecting them by code or by name.

Swabs from the nose and throat, or other biological material at this time should be distributed, each sample is scanned with a barcode reader for inspection, material distribution. At this stage it allows for the possibility of finding the first of errors related to the registration of samples or correcting any deficiencies in material or the orders. Then, the sample is sent to the appropriate laboratory, for example a virological laboratory, where it is analysed. The device on which the sample is analysed, reads the information from the computer system about the type of analyses to be performed on the given material, as the orders scanned at the registration are then electronically sent via an internal network of the facility X to individual devices. The second kind of orders may be electronic orders, which are sent to be distributed in the laboratory from hospital wards through terminals installed there, or by way of the Internet in the case of outdoor units.

In the case of these orders, they are verified as those brought with the already completed forms, by scanning the material in the distribution lab. The program used in the laboratory should communicate with the parent hospital system using protocols recognized as international standards in the exchange of medical information. Competent specialists are responsible for synchronizing the circulation system of laboratory orders and samples, as well as the whole supervisory hospital system. By combining the two systems the commission of tests can be easily electronically ordered from the hospital system to the laboratory, and after their execution and approval by the laboratory diagnostician, they can be sent from the laboratory network to the hospital system. The access to the module of commissioning and the reception of the results in an electronic way are only for persons authorized by the Management of the given institution X. Monitoring of the laboratory work is made possible by tracking the order in the laboratory. This system shows, among others, where currently the indicated sample is (at what stage of the test) and where it should be sent later, to which laboratory. In addition, the program should provide information on the results obtained and the history of a particular order. Additionally, the registration of all entries and changes in the system should be made, recording the date, time, and the user.

The data backup should be made on the basis of the database server. All the data necessary for the operation of the laboratory are stored there. For safety purposes, a backup server is provided, to which with certain frequencies all data is transmitted. In addition, at the end of each day the backup is performed, which can then be stored on an independent electronic media. If necessary, the program of this type can optionally be provided with an application for restoration of backup, however, only the system administrator should be authorized to perform such an operation. Figure 1 shows the flow of information and material described above in detail.

An example of the way of receiving and registering the incoming orders and material to the laboratory, for virological laboratory of an undefined medical facility X.

quality in the performance of virological tests, such as the detection of genetic material of influenza viruses. The objective of the whole laboratory staff is to solve the problem of the patient in the most beneficial, fast, and comfortable way. Basic conditions and rules governing the implementation of the quality objectives posed by the management of a laboratory are described in the Book of Quality Management. This study provides information for the patient and for analysts on the actions taken by the Laboratory and various labs in order to ensure proper quality of all diagnostic services they provide. The head of a given laboratory and its staff are committed to comply with the processes described in the Book of Quality Management. The adopted quality policy should aim to establish and maintain an effective Quality Management System in accordance with the requirements of PN-EN ISO 9001 [7], PN-EN ISO 17025[1], as well as the rules of GLP Good Laboratory Practice.

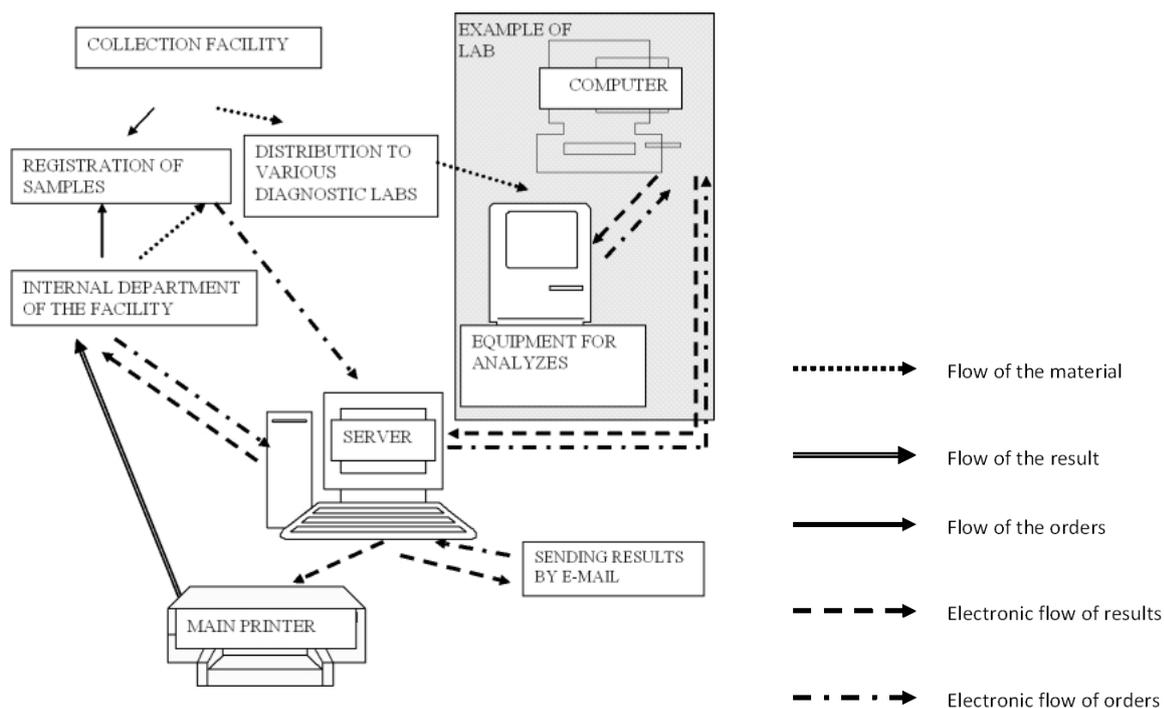


Figure 1: An example of the way of receiving and registering the incoming orders and material to the laboratory, for virological laboratory of an undefined medical facility X

Quality Policy

The development and implementation of Laboratory Quality Management System is to support and develop the quality in laboratory diagnosis, and in the case of virological laboratories, to develop the

Quality Control

The guarantee of the reliability of the tests performed in the virological laboratory are the results obtained in the interlaboratory and intralaboratory control. It is important that all parameters

identified in the laboratory were included in the quality control program. The control within the laboratory should be based on control materials from reputable companies, whose quality has been confirmed by certificates. The basic element in the construction of the control system within the laboratory is to determine the total allowable error. An additional tool to control the quality of research is the control between laboratories performed on the basis of the participation in national and international interlaboratory control programs, which for laboratories testing the flu virus can be: WHO External Quality Assessment Programme for the Detection of Influenza Virus Type A by PCR. The results obtained should be carefully analysed by the laboratory management and staff performing the tests.

Personnel

Virological laboratory staff should represent the vast majority of professional employees, technicians, diagnosticians, specialists in microbiology and analytics, and people with degrees, and sometimes doctors. Each employee must be trained in the field of his job and should have a documented training related to the subject concerning the procedures of the quality system. Moreover, laboratory personnel should be able to use external training.

The proper functioning of the laboratory is the responsibility of the laboratory manager – a specialist microbiologist[8]. In accordance with the Act of 23 June, 2006, amending the Act on laboratory diagnosis and the Act on professions of a doctor and dentist[9] the following persons are authorized to perform laboratory diagnostics:

- 1) laboratory diagnostician – is a person who has completed a degree in medical analytics and obtained a master's degree. Persons who have completed higher education in other fields (M.Sc. in biology, pharmacy, biotechnology, veterinary surgeon) must take post-graduate training at the Medical Analytics, confirmed by an examination, or obtain the title of a specialist in the field of microbiology.
- 2) doctor authorized to perform his profession, having a specialization in the field of laboratory diagnostics,

- 3) doctor authorized to perform his profession in the course of specialization, a technician or a Bachelor of medical analytics – these people work under the supervision of a laboratory diagnostician.

Summary

One of the most difficult choices that each employer of a medical facility has to take is the selection of personnel. People are the most valuable resource of any organization[10]. The aim of the article was to present the issue of employment of the diagnostic laboratory staff performing microbiological testing in the context of quality of the services provided. Medical laboratory staff includes medical and non-medical staff (administrative, economic). The most important issue of the staff in each type of creating a medical laboratory are lab diagnosticians, though they may be specialized medical doctors, but such cases are rare.

The functioning of any organization, including a laboratory, requires the possession, commissioning, and rational use of not only human resources, but also material, financial, and information resources. As practice shows, essentially only the use of modern methods of research under the quality system and the correct selection of the personnel will ensure the opportunity to succeed in the operation of a diagnostic laboratory.

To precisely define the different stages of development of the staff and its impact on the quality of the tests, the following questions should be answered: who are we looking for? why and what are we looking for?, where and how are we looking for?, how do we choose people?, whom do we choose? The recruitment and selection of personnel, especially medical, is a difficult task, which requires time, consisting of a series of interrelated activities, but having fundamental importance for each medical provider. A laboratory employs persons who have professional qualifications corresponding to the range of tasks at the workplace which in the end ensures the quality of the tests performed. A detailed list of qualifications necessary to perform professional tasks at individual jobs in the laboratory has its legal implications.

Acknowledgements

This paper constitutes a part of the thesis prepared by the author, entitled „Zarządzania czynnikiem ludzkim w ujęciu kształtowania

(restrukturyzacji) jakości badań mikrobiologicznych” [“Managing the human factor in terms of shaping (restructuring) the quality of microbiological tests”] Higher School of Public Administration, 2014, SZCZECIN.

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