

THE MANAGEMENT OF MEDICAL ANALYSIS LABORATORIES AND BIOLOGICAL RISK PREVENTION

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The increasing number of reports on biological terrorist threats identified at international level raised serious challenges not only for the scientists but also for people responsible of population health. This paper investigates the importance of standardizing and implementing regulations regarding the activity of biological hazards analysis. Medical analysis laboratories and public health units have responsibilities in this field and consequently the need and means to implement quality standards ISO 15189 and ISO 15190 is also examined.

Key words: biological threat, ISO 15189, ISO 15190, medical analysis laboratory.

1. INTRODUCTION

Biological threats and risks, although invisible, are extremely dangerous and often have a major impact on a country's population. Biological hazards are those hazards of biological origin which adversely impact both human health and the environment. The most common biological hazards are those derived from different infectious or toxic bacteria, fungi, protozoa, viruses, and certain cell cultures. Although animals and plants can accommodate one or more of these agents, it is often forgotten that human and animal fluids may contain such agents.

ISO standards are based on the principle of procedural approach and their implementation is very useful in preventing biological terrorist attacks. This involves identifying key processes and their description through the procedures. Thus, monitoring the efficiency and effectiveness of these processes becomes much easier.

According to Romanian legal framework, the medical analysis laboratory system consists of public or private owned units, which create a

network of medical service providers. Those services consist of [1]: a) The examination of human body components by using various methods and techniques of biochemistry, hematology, immuno-hematology, immunology, microbiology, genetics, cytology, pathology, toxicology, cellular and molecular biology, biophysics and so on, in order to provide information for the diagnosis treatment and prevention of disease or for assessing the health of the population; b) Advice on interpreting the results of investigations and any further investigation deemed necessary.

2. THE IMPORTANCE OF STANDARDIZING IN THE ACTIVITY OF BIOLOGICAL HAZARDS ANALYSIS

In accordance with the Order no. 1301 from 2007, article 22 (that approved the norms regarding the functioning of medical analysis laboratories) medical analysis laboratories should implement a Quality Management System congruent with ISO 15189 standard requirements [2]. This international standard is also

based on ISO/CEI 17025:2005 and ISO 9001:2008 standards.

The laboratory leadership should define and document policies and procedures for selection and use of external services and supplies, which could affect the quality of laboratory services.

Each country has its own rules and requirements regarding all medical staff responsibilities in this area. Before adopting the standard, the most common approach was to permit medical laboratories to develop their own quality management system and accreditation bodies to evaluate their own skills (confirmation and recognition of the medical laboratories competence).

The implementation of ISO 15189 is a strategic management decision because this international standard defines specific quality requirements of competence especially for medical analysis laboratories.

The standard was intended to be a valuable instrument for the analysis of trusted medical laboratories, especially because health care is essential form a national security point of view. Those institutions must be able to meet the needs of their patients and to provide a framework of standardized procedures for clinical staff in accordance with the generally accepted quality management systems. In terms of quality and competence, ISO 15189 recommends specific actions, measurements and validation procedures and establishes both management and technical requirements specific to medical analysis laboratories [3]. It contains requirements that must be achieved to allow a laboratory, that operates under a quality system (which is technically competent and is able to generate valid/consistent results), to be certified.

The quality of the medical staff responsible for patient care is essential for medical laboratory services. Such services could include: diagnosis, validation, interpretation,

reporting and patients' advice; preparation, identification, collection, transportation, storage, processing and analysis of human/ animal fluids; safety and ethical considerations regarding the activity in medical laboratories.

3. MANAGEMENT DUTIES AND THE PREVENTION OF BIOLOGICAL THREATS

To operate, medical analysis laboratories established and organized in accordance with law conditions must obtain sanitary authorization operating under the affidavit, in regard with ensuring compliance to hygiene and public health. Laboratory capability implies the existence of material resources, environmental and informational resources, skills and experience necessary to perform analyses. According to legal provisions, the position of chief medical analysis laboratory requires doctors specialized in laboratory medicine, clinical laboratory or microbiology or other higher education personnel authorized to work in the medical field (like biologists, biochemists, chemists and pharmacists who have an experience of at least five years in the specialty). The management responsibilities for the medical analysis laboratory include educational, administrative and organizational aspects, in relation with scientific or advisory work directly related to medical lab tests.

The head of a medical analysis laboratory must assign persons responsible for all key functions. In laboratories with a small number of staff, some people may have several functions. All personnel must be trained to know and follow the rules of bio-safety, universal precautions and post-exposure measures. The confidentiality of test results, data, information and documents of every kind is ensured through: staff training, inclusion of this requirement in the job description and by the declaration of

confidentiality signed by every medical analysis laboratory's staff.

In the prevention of biological threats activity, laboratory medical tests may be performed in relation with medical biochemistry, hematology, morphology, homeostasis, immuno-hematology, immunology, microbiology, bacteriology, virology, mycology, parasitology, molecular diagnostics, genetics, cyto-genetics, biochemical genetics, molecular genetics and toxicology corresponding to each compartment of the laboratory structure. The tests may also provide advice on the interpretation of any investigation's results and could determine further investigation.

Bacteriological diagnosis of tuberculosis and other mico-bacteriosis can be done only by personnel especially trained for this type of activity. The practical training activities in this area consist of microscopic examination, culture and anti-biogram which can be performed only in medical analysis laboratories within TB hospitals, hospitals with an air station structure for Phthisiology and tuberculosis (TB) sanatoriums.

4. MEDICAL ANALYSIS LABORATORIES

Medical analysis laboratories must be structured and equipped to prevent accidental contamination risk and to function smoothly. The subsequent sets of rules underlying this objective consist of: the medical analysis laboratory must be set as on a "one-way" flow of unidirectional laboratory activities. (otherwise, it must be ensured the separation of activities in time; the sectors working with patients must be completely separated from other units of the laboratory); sequential implementation procedures, taking appropriate precautions and protect the integrity of audit staff; to perform

blood sampling it is required the usage of materials and containers of single use, sterile and airtight; blood samples leaving the space for collection activity must complete a circuit different from that of the other products harvested or obey a special program to obtain separate transport times; transport blood samples must necessarily meet the appropriate transport boxes, marked with the icon "biohazard"; removal of waste from medical activities of medical analysis facilities must be done in sealed containers to prevent accidental contamination of samples, staff and the environment.

If the medical analysis laboratory has a specialized structure for diagnosis of tuberculosis and other mico-bacteriosis, its functional flows of activities (circuits) must be strictly separated from other circuits belonging to other parts of the medical institution. The microscopic examination, culture and anti-biogram involved will be made in separate workspaces, under the same provisions. Also, if sputum collection is mandatory there should be a dedicated collection room.

5. THE IMPLEMENTATION OF QUALITY MANAGEMENT IN BIOLOGICAL ANALYSIS INSTITUTIONS

As stated before in this article, quality management on medical analysis laboratories must be done in accordance with the general requirements and particular requirements for quality and competence specified in ISO 15189:2007. In addition, medical analysis laboratories that carry out bacteriological diagnosis of tuberculosis shall comply with the compulsory national quality control protocol, specified in national TB control program.

Medical analysis laboratory must participate regularly in external quality assessment programs.

Organizing internal quality control is the responsibility of the medical analysis laboratory head. To fulfill the quality control, the leading/ legal representative of the medical analysis laboratory is required to provide the necessary resources. Internal quality control is performed daily, at least every eight hours or whenever needed. The internal control results are analyzed by the specialist responsible for this activity, which decides acceptance or rejection of the outcome.

6. ADOPTING SECURITY POLICIES TO PREVENT BIOLOGICAL RISKS

From a biological safety point of view and for obtaining a safe activity/ environment of medical analysis laboratories, the standard ISO 15190 requires the existence of compliant national security and bio-safety guidelines [4]. To prevent biological risks, in medical analysis laboratory microbiology department, cultures and reference stock cultures are kept in secure and padlocked metal cases, which can be only accessed by authorized personnel.

It is mandatory for the leadership of the laboratories to commit on the management system's development and implementation under the terms and conditions stipulated in the "Policy Statement" document, by setting quality objectives and providing resources needed to achieve them. In addition, it is recommended that the laboratory management to continue to seek ways to improve the system's efficiency.

To adopt effective security policies and minimize the biological risks evolved, the leadership of such medical institutions should: conduct a management analysis; assess the compliance with customer requirements; conduct internal audits and request periodical external audits from inspections authorities; take in consideration positive and negative aspects found in laboratory's work by

the medical personnel; encourage the communication among employers and between them and the leading body, with a focus on explaining the need to improve all laboratory activities.

In this way, future development resulting from a better managerial and communication process will lead to an increasing trend of meeting customer requirements, legal requirements and other requirements applicable to the organization.

7. CONCLUSIONS

Accreditation of medical analysis laboratories is subject to documentation and implementation of a quality management system based on the application of international standard ISO 15189. However, medical analysis laboratory must also document and implement bio-security rules, universal precautions and post-exposure measures according to international standard ISO 15190:2005. In this respect, there are two requirements that should be accomplished. First, the quality manager must have direct access to top management. Second, the quality manager and the responsible for quality compliance analysis should be part of the permanent laboratory's staff. Only once these goals are met, we can say that the medical analysis laboratory has a quality oriented culture of the top management which permits the existence of a streamlined biological risk prevention activity.

REFERENCES

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