

ISO 15190:2003 MEDICAL LABORATORIES - REQUIREMENTS FOR SAFETY

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Summary

ISO 15190:2003 is a new standard developed by the International Organization for Standardization to address the safety aspects of medical laboratories. It is directly linked to the ISO 15189:2003, the standard for quality and competence. It provides a framework for a safety program based upon the principles of quality management, including designation of responsibilities and authorities, regular audits, and continuous improvement.

Introduction

Medical laboratories can be unsafe places. The medical laboratory is the place where human blood, tissues, urine, and other body substances, often with dangerous microorganisms, are sent for analysis. Often the equipment and the reagents used to perform the required tests have their own inherent dangers. Much of the work is exacting, leading to stress, accidents, and injury. In order to provide the essential information that only a medical laboratory can provide, all people entering the laboratory must be trained and knowledgeable of the potential risks and hazards, and be

competent to perform their task properly. Laboratorians can be assisted through this process by the creation, publication and application of standards that define how work can be done in a manner and an environment that will reduce the risk of error and accident. This is the role of the new international standard for medical laboratory safety. Laboratory safety is the active, assertive process based on evidence-based principles, to ensure safety from chemical, microbial, and physical hazards for workers, visitors, the public and the environment. Laboratory safety involves all aspects of the laboratory cycle, starting from before samples arrive in the facility, through the training of personnel, and the establishment and monitoring of safe working practices, through the proper use of reagents, materials, and equipment, through the safe storage and transport of agents, and ultimately to the safe disposal of samples.

Epidemiology of Laboratory-acquired Injuries

It is difficult to assess the real impact of injury and infection in the medical laboratory because of the lack of national registries of work related accidents and infections. In their absence one can only rely on surveys and literature. That being said, prior work has provided great insights. Accidents and injuries tend to occur in the same accident-prone people¹. Accidents occur usually when people know they are rushing, especially just before lunch and at the end of day. Accidents occur more frequently to people with poor regard for safety.

Of all laboratory-associated accidents and injuries, the most established and detailed records are related to laboratory-acquired infections²⁸. Throughout the decades, microorganisms including Hepatitis B virus, Mycobacterium tuberculosis, and HIV are consistently recognized as significant concerns. Transmission through aerosol production, hand-to-hand contamination, and environmental hazards are well described. That being said, in comparison to joint and back strains, repetitive stress injuries, lacerations, punctures, burns, and toxic chemical exposures, infections may be one of the least common injuries that occur in medical laboratories. It is therefore imperative that an international standard for medical safety be broadly encompassing, which well describes ISO 15190:2003⁹.

Safety as a part of quality management

ISO 15190:2003 is an independent standard, but is intimately tied to ISO 15189:2003 Medical laboratories -- Particular requirements for quality and competence, indeed 15189:2003 is a designated normative reference for the safety document. The connection is not superficial, indeed safety is integral to both quality and competency.

Safety is a planned program process, with a requirement for regular audit and review. Safety under ISO 15190:2003 is a process under continuous review and improvement. Safety is enhanced

when the laboratory provides a safety manual that provides policies, processes, and procedures.

Responsibility roles for laboratory safety

At the core of ISO is the essential duality of responsibility for safety. The standard indicates clearly and unambiguously that safety is at the same time everybody's responsibility and one person's responsibility.

W. Edwards Deming, over 60 years ago recognized that while quality experts were essential for quality management programs, successful programs required the direct and active involvement of management. Without the pressure from management for quality, nothing would happen¹⁰. The correlate to laboratory safety is clear. The laboratory director must be seen as being both supportive and responsible for safety within all areas of the laboratory. That being said, safety practices are unlikely to be regular and consistent unless they are the designated responsibility of an informed and knowledgeable individual given both the title safety officer and also the time and support to perform the tasks required. The safety officer receives authority and responsibility from, and reports to the laboratory director, management officers, and supervisors. The safety officer has the authority to provide expertise, advice and guidance, and importantly to stop activities that are deemed as unsafe.

At the same time, all personnel have important responsibilities for ensuring their own safety. Clear and specific requirements are made concerning personal practices including eating, drinking, clothing, immunization, and the use of personal protective equipment.

Safety through audit and inspection

The cornerstone of quality management is the process of continuous evaluation and improvement. A safety audit, based on 15190:2003 is provided as an annex with the standard. Audits can be internal, relying on the personnel of the laboratory, or external. While audits are clearly within the domain of the safety officer, audits provide an opportunity to engage everyone within the laboratory in both the quality management and safety aspects of the laboratory.

Laboratory audits are planned and documented events. Opportunities for improvement need to be recorded, and corrective actions implemented as required. Regular internal audits provide the opportunity to see risks and hazards before they manifest, and create the opportunity to plan preventive actions.

Audits need to be done on a regular schedule. The standard says that the whole facility should be inspected at least once per year. It is important to appreciate that this does not require that the audit be performed at a single time on a regular basis. An alternative approach is to section the audit by either function or location, and to perform a segment of the audit more frequently. Performing a different section audit every month provides a continuous process.

Safe practices by informed laboratory staff.

ISO 15190:2003 requires that laboratory workers are informed about safety. As aforementioned the laboratory is required to provide a safety manual that is maintained as current and up to date.

The manual must be readily available, and is deemed as required reading for staff.

In addition, it is required that worker safety training programmes are implemented for all new employees, and also repeated for the experienced staff. Training should be tailored to the individual and their specific requirements. All employees need to demonstrate that have understood the material, and their training experiences need to be recorded and maintained.

It is insufficient to create the training program once only. The training programme needs to be evaluated on a regular basis and continuous improvements implemented.

Safe practices in a safe environment

Safe practices will protect workers, but if the laboratory environment is not created and maintained as a safe workplace, then the risk of error, accident, and injury rises.

Part of creating a safe environment is to ensure that safety equipment is present, is known to be working properly, and personnel are trained in its proper use. While sophisticated laboratories will require specialized equipment including biological safety cabinets and chemical safety hoods (also referred to as fume hoods) and alarm systems, basic safe environments are provided with simple measures, and properly functioning basic equipment. Safety is enhanced by ensuring that personnel work within lighting that illuminates without glare, and by providing a comfortable work space that reduces the risk of stress and strain, and reasonable ventilation to control heat and humidity. Safety is enhanced by reducing distracting noise levels. Safety is enhanced by ensuring security by having lockable doors, and signs that clearly indicate to workers, and others, that laboratories may contain materials and products that may be hazardous if not handled properly. Laboratories need to provide stations to allow for effective handwashing, and for the very rare occasion when accidental exposures do occur available appropriate first aid materials.

Safe laboratories are routinely maintained as neat and clean.

In order to prevent accidents, workers must have access to personal protective equipment including goggles, respirator masks, protective gowns and masks, and must be trained in their use.

The creation of a safe workspace by the provision of these requirements is within reach of every laboratory. The standard is explicit that they are essential components of a safe laboratory.

Drawing on others

Documents providing guidance are described as either horizontal or vertical, with horizontal documents being broad, covering a large area of interest by principles of a general nature. Vertical documents are less broad, but address their specific issues in much depth. ISO 15190:2003 is a horizontal document, which is appropriate for a document that provides insight and guidance widely, and accommodates regulatory issues specific to individual countries.

ISO 15190:2003 is not the first document on medical laboratory safety. Indeed it draws upon many excellent documents from the United Kingdom, the United States, Canada, and other countries. In the process of creating this new international standard, Working

Group 1 has developed a consistent helpful document that harmonizes with established national documents.

For whom is ISO 15190:2003 intended?

ISO 15190:2003 will fit comfortably with any laboratory with more than a few employees, in any country. The requirements for quality management systems for safety do not require large or special resources including computers, and are not intended solely for laboratories in the developed countries. ISO 15190:2003 is not intended to replace existing national documents. It is clearly intended to complement existing documents, to provide a quality management framework upon which safety programs can be implemented.

Importantly, 15190:2003 is not intended to be a comprehensive requirement for specialized laboratories, especially those that work with exotic and dangerous microorganisms. It is recognized that for these organisms, a more rigorous and specific standard is required.

In summary

Providing a safe work place in medical laboratories does not just happen. It is an active process of planning, implementing, monitoring, and evaluation with a goal towards improvement. It is the active process of ensuring knowledge and competence. It is a topic for which an international, consistent standard plays an important role in structure and process development. ISO 15190:2003 is such a document.

References

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