

ORIGINAL ARTICLE

Exploration of a Training Model for Laboratory Personnel Based on ISO 15189

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SUMMARY

Background: This study aimed to explore the implementation of an effective training and competency assessment model for laboratory personnel in compliance with ISO 15189 standards, thereby enhancing laboratory testing capabilities and providing a reference for personnel training in other hospital laboratories.

Methods: A comprehensive training program was developed based on ISO 15189 requirements and the practical experience of our department. The program included determining training schedules and frequencies, defining training content, conducting training sessions, evaluating training outcomes, and performing assessments and competency evaluations.

Results: Through the implementation of the proposed training program, we successfully met ISO 15189 requirements for personnel training and competency assessment. The execution of the training plan significantly improved staff professional skills and professional ethics, further strengthening the laboratory's testing capabilities.

Conclusions: Implementing personnel training and competency assessment in laboratory departments in accordance with ISO 15189, combined with a scientifically designed training program, effectively enhances staff expertise and laboratory testing performance. This approach provides critical insights for laboratory quality management and international accreditation.

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KEYWORDS

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INTRODUCTION

Training and competency assessments for laboratory personnel are critical components in enhancing staff capabilities and professional qualities [1]. Among various standards and regulations, the CNAS-CL02 Application Requirements for Medical Laboratory Quality and Competence Accreditation (ISO 15189) provide explicit guidelines for personnel training and competency evaluation. These guidelines encompass the training content for new and existing staff, the methods for implementing competency and performance assessments, and the necessity of continuing education and professional development [2].

Our laboratory began preparations for ISO 15189 accreditation in early 2021, adhering to the standard's requirements for personnel training and competency assessment. After nearly two years of operation and continuous improvement, the laboratory successfully passed the initial on-site assessment for ISO 15189 accreditation organized by the China National Accreditation Service (CNAS) in November 2022. During the preparation period, significant efforts were devoted to personnel training, leading to the establishment of a structured training management model that provides clear standards and procedures for training activities.

This article draws on the practical experience of our laboratory to explore the implementation of training and competency assessment models for laboratory personnel in accordance with ISO 15189. The aim was to offer a reference for the practical application of personnel training and competency assessment in clinical laboratories.

DEVELOPMENT OF TRAINING PLANS

Scheduling and frequency of training

At the departmental level, training sessions are conducted weekly, fixed on Tuesday afternoons. Specialized group training occurs monthly, scheduled on the last Friday afternoon of each month.

Training content

Departmental training

According to section 5.1.5 of CNAS-CL02-A001:2021 Application Requirements for Medical Laboratory Quality and Competence Accreditation (ISO 15189), laboratories must provide training for all employees, covering: 1) the quality management system; 2) assigned work processes and procedures; 3) applicable laboratory information systems; 4) health and safety, including mitigating adverse events; 5) ethics; and 6) confidentiality of patient information [3]. Based on these guidelines and the specific conditions of our laboratory, the departmental training program focuses on the latest CNAS accreditation standards; training on the laboratory's quality manual, procedural documents, and related regulations; biosafety and fire safety training, including emergency response drills; training on laboratory information systems; education on new technologies and projects under development; training on ethical standards, national and regional laws, and patient confidentiality policies; and research skills, such as medical literature retrieval, statistical methods.

At the end of each year, training responsibilities are allocated to specific administrators (e.g., biosafety, information management, and academic management). These administrators organize monthly training topics, forming the training plan for the following year. According to the actual situation, new training content will be added, such as training on the diagnosis of monkey-pox- and cholera-related outbreaks in 2022.

The department also features unique training sessions focused on team building, emotional intelligence, and communication. For instance, the annual Psychological Nutrition Salon encourages self-recognition and professional growth, enhancing confidence. During challenging phases of ISO 15189 accreditation, the department head conducted Emotional Management Salons to alleviate stress. In cases of interpersonal conflicts, Interpersonal Communication and Emotional Intelligence Salons were organized to resolve issues and strengthen team cohesion. These initiatives demand high levels of competence and leadership from the department head.

Specialized group training

Specialized group training includes training on group-specific regulations and SOPs for equipment and projects, professional standards for each specialty, education on new technologies and projects within the group, operation training for advanced instruments, and specialized sessions tailored to specific groups, such as morphology training and staff comparison in the clinical laboratory group or HIV testing training in the immunology group.

Orientation for new employees

ISO 15189 specifies that laboratories must orient new employees to their assigned departments or areas, employment terms, facilities, health and safety requirements (including fire and emergency protocols), and occupational health services.

In addition to a week-long orientation organized by the hospital's Human Resources Department, our laboratory provides a three-day onboarding program for new hires. Led by the quality manager and other administrators, this program includes training on institutional regulations, health and safety, biosafety, occupational disease prevention, emergency response, and laboratory information systems. Upon passing the assessment, new employees proceed to specialized group training under the guidance of group leaders.

Continuing education

To keep pace with advancements in medical testing technologies and methods, the academic administrator formulates an annual continuing education plan. This includes department-hosted academic conferences, external meetings related to quality management and testing capabilities, annual medical testing conferences, topic-specific academic meetings, and training sessions tied to group qualifications, such as HIV testing certification, clinical gene amplification laboratory technician certification, and biosafety training [4].

TRAINING IMPLEMENTATION

Preparation of training materials

Instructors submit training materials, practice scripts, and corresponding assessment papers to the depart-

ment's public email two weeks before the session. The academic administrator reviews the content and provides feedback within five days for necessary revisions. Finalized materials are re-submitted for approval.

On-site training

On the training day, sessions are conducted using the finalized materials and scripts. The academic administrator oversees attendance, records key training points, and documents the event with photographs.

Evaluation of training outcomes

Post-training, the department head and participants provide feedback on the session content. These evaluations are documented and archived for future reference.

ASSESSMENT

Assessment is a critical component of laboratory personnel training, serving as a key method to evaluate training effectiveness, enhance engagement, and reinforce learned content. It directly influences the overall impact of training. However, its importance and methodologies are often overlooked in laboratory settings. To address this, our department emphasizes both the significance and diversity of assessment methods. Commonly employed approaches include written, practical, and oral assessments.

Written assessment

Written assessments involve testing participants using fill-in-the-blank, true/false, and short-answer questions. This method is frequently applied to training sessions on biosafety and ISO 15189 accreditation standards. Additionally, digital platforms for online training programs are increasingly utilized for extensive assessments.

Practical assessment

Practical assessments require participants to perform simulated tasks, such as cardiopulmonary resuscitation (CPR), monthly equipment maintenance, and hazardous chemical handling drills. For each type of practical assessment, detailed checklists highlighting key steps and scoring criteria are developed to ensure trainees effectively grasp the essential training points.

Oral assessment

Oral assessments involve on-the-spot questioning of trainees. For example, participants may be asked to verbally explain procedures for managing uncontrolled conditions during related training or to describe commonly used literature search platforms and their corresponding steps during research methodology sessions.

COMPETENCY EVALUATION

Specialized group level

Competency evaluation at the group level is primarily conducted during position rotations or onboarding assessments for new employees. Each role has specific competency requirements, such as an evaluation checklist for the ELISA immunology position. Trainees achieving a passing score ($\geq 80\%$) are granted authorization for the respective position.

Departmental level

At the departmental level, comprehensive employee evaluations are conducted annually, consisting of two components:

Professional group leader evaluation: Group leaders score each employee based on professional ethics (e.g., adherence to national laws, regulations, and quality system documents, impartiality in testing activities, and confidentiality practices) and technical proficiency (e.g., equipment maintenance, functional checks, and accurate record-keeping).

Annual performance review: At the end of each year, employees present their primary work achievements. The management team scores them based on various criteria, such as the absence of adverse events, completion of research tasks, training participation, and fulfillment of assigned responsibilities. The combined score from these two evaluations contributes to annual performance reviews and recognition for outstanding performance.

DISCUSSION

From the initial preparation to successfully passing the ISO 15189 accreditation's first on-site assessment, training has proven to be a pivotal measure for enhancing personnel capabilities and professional quality [5]. Training content should not be confined to professional knowledge but should be dynamically adjusted to include topics such as emotional intelligence, psychological development, and interpersonal communication, tailored to the team's status at different preparation stages. These efforts help alleviate team stress, foster cohesion, and enhance overall morale.

Furthermore, laboratory training programs should adhere to standardized policies and fixed models, placing greater emphasis on diverse assessment methods. This ensures that training transcends superficial implementation, fostering a positive learning atmosphere and a spirit of continuous improvement within the department.

Declaration of Interest:

The authors declare that they have no conflicts of interest.

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