Original Research Article

EVALUATION OF PERFORMANCE OF TRAINEE AT 4 DAYS MOODLE BASED INTERNAL AUDITOR TRAINING AS PER ISO 15189:2012 AND NABL-112

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Abstract

Background: For medical testing laboratories accreditation, laboratory has follow ISO: 15189:2012 and NABL-112. For this,quality manager of the laboratory must have to go under 4 days internal auditor training as per ISO 15189:2012 and NABL-112. Moodle is Learning Management System (LMS) which helps in systemic evaluation of trainee during internal auditor training.

Objectives: The study was done to measure performance of trainee after completion of internal auditor training by comparing for each sub-clause of ISO 15189:2012 as well as for various categories of trainee.

Materials and Methods: Online Moodle based - internal auditor training as per ISO 15189:2012 and NABL-112 was arranged in GMC, Surat, Gujarat for 4 days, with total 28 trainee. MCQ test was taken on-line with Moodle. Relationship of score with ISO 15189:2012 clauses and trainee category were analysed.

Results: Participant's average score in general, management and technical clause were 67% ,73.4% and 77.9% respectively. Teaching staff, Residents and Technicians scored 76.3 %, 77% and 70% respectively.

Conclusion: Training emphasis and effectiveness in ISO 15189:2012 management clause was comparable with technical clauses. Moreover, the study found that, Training was effective across all categories of trainee.

Keywords: ISO 15189:2012, NABL, Moodle

Introduction

National Accreditation Board for Testing & Calibration Laboratories (NABL) is an accreditation body for Laboratories in India working under the parent body of Quality Council of India (QCI) to provide accreditation of technical competence to testing laboratories, calibration laboraties, medical testing laboratories, Proficiency testing providers (PTP) & Reference Material Producers (RMP) with fullfillment of specified criteria as per specific ISO standard. For medical testing laboratories accreditation, laboratory has follow ISO: 15189:2012 and NABL-112. ISO: 15189:2012 is composite of 15 management clause (4.1 to 4.15) and 10 technical clause (5.1 to 5.10). Before applying for NABL accrediatation and apply quality standard in medical laboratory, key laboratory persons have to understand and implement all the clause 4.1 to 5.10 of the ISO 15189:2012 and specific requirement of NABL-112. For this purpose, quality manager of the laboratoy must have to go under 4 days internal auditor training as per ISO 15189:2012 and NABL-112.

Internal auditor training for this standard can be done with different teaching methods like lectures, small group discussion, problem based learning. Certain computer assisted learning software can be used for such training programs. Moodle is one such client-server software available.

Moodle (Modular Object-Oriented Dynamic Learning Environment) is learning Management System (LMS) [6], which assist the teachers and course developers in creating and managing the online courses.

Moodle is free learning platform that helps teachers create effective online teaching and learning experiences in a collaborative, private environment. [1]. Moodle is written in PHP and distributed under the GNU General Public License [2]. Moodle is used for distance education as well as for e-learning projects in schools in western countries [3]. Moodle is also used in corporate teaching programs[4]. Many Canadian Educational Psychology classes and constructivist

used Moodle as a technological tool to further enhance participation in a teacher education program.[7]

Moodle not only helps in training, but also helps in systemic evaluation of trainee during internal auditor training as per ISO:15189:2012 and NABL-112. Results of such systemic evaluation can help decide strategy to improve efficacy of such training, which in turn, enhance the understanding and implementation of standard in medical testing laboratories.

Aim and Objectives:

The study was done to measure performance of trainee after completion of internal auditor training as per ISO 15189:2012 and NABL-112. Performance was analyzed and compared for each sub-clause of ISO 15189:2012 as well as for various categories of trainee.

Materials and Methods:

Internal Auditor training as per ISO 15189:2012 and NABL-112 was arranged in Government Medical College, Surat, Gujarat from 23rd to 27th September 2019. All trainers of the training were certified external assessor of NABL from biochemistry section, pathology section and microbiology section of the NCHSLS (New Civil Hospital Surat Laboratory Services), Surat. Invitation for training was voluntary using Google form.

Course for this training was constructed in Moodle under guidance of technical team and trainers of the course. After drafting course on Moodle, proof reading were done by trainers as well as by previously trained laboratory persons for same training. Total 28 trainee participated for these 4 days training. All trainee were asked to bring laptop. On the day of the training, all trainee got access to Moodle based course through the server, on their personal laptop with individual user name and password. For whole four day, learning and skill development task as per ISO & NABL requirement were done through moodle.

At the end of four days training, evaluation of performance for training was done by 38 multiple choice questions. MCQ test was taken on-line with Moodle. All trainee attempted 38 MCQs on their laptop connected with wifi to the server. Relationship of score with ISO 15189:2012 clauses and trainee category were analysed.

Results

Chart-1 shows % Score obtained by 28 trainee in increasing order. The chart shows that individual score obtained were ranging from 47% to 92%. Average % Score obtained was 74.7.

Table 1 shows proportion of different clauses of ISO 15189:2012 in 38 questions asked. There were no MCQ from clause 4.2, 4.7,4.8, 4.10, 4.12,4.13, 5.7 and 5.10.

Chart-2 shows that average score in general clause, management clause and technical clause were 67%, 73.4% and 77.9% respectively. Sub-clause 4.5 (Examination by referral laboratories) and 4.9 (Identification and control of non-conformities) had poorest result, while 4.3 (Document control) and 5.9 (Release of report) had the highest results.

Average score obtained by all Trainee was 74.37%. Teaching staff, Residents and Technicians scored 76.3 %, 77% and 70% respectively.
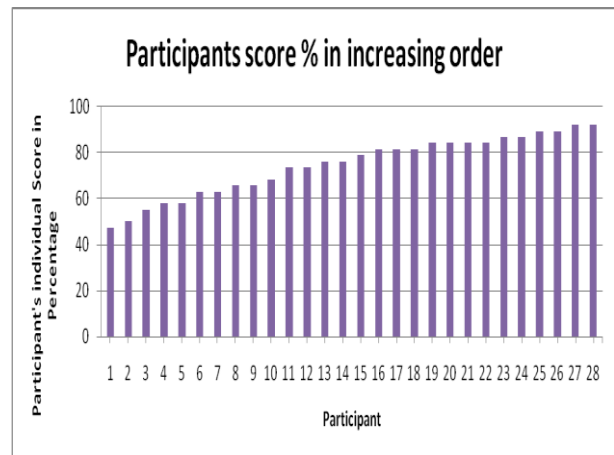

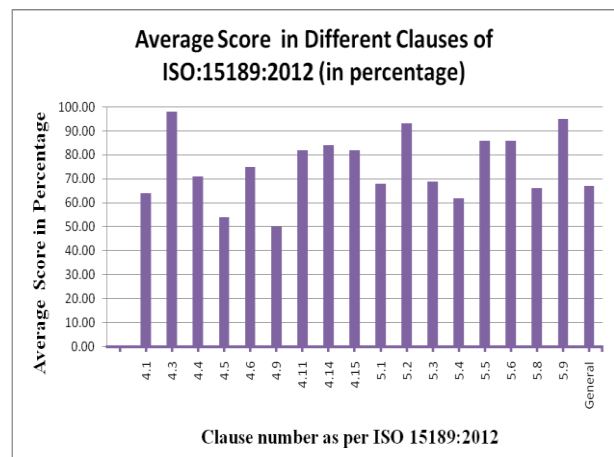**Chart 1:** Participants Score in %, N=28, arranged in ascending order

Chart 2: Average Percentage Score in Different Subclause of ISO 15189:2012 (results from 28 trainee)

Table 1: Weight age of the MCQ as per Clause and Sub-clause

	Clause	Sub-clause	No of Questions from Sub-clause	Percentage Question From Sub-clause	Percentage Question From Clause
General	1	1	3	7.89	7.89
Management Clause	4	4.1	2	5.26	31.58
		4.3	2	5.26	
		4.4	1	2.63	
		4.5	1	2.63	
		4.6	1	2.63	
		4.9	1	2.63	
		4.11	1	2.63	
		4.14	2	5.26	
		4.15	1	2.63	
Technical Clause	5	5.1	1	2.63	60.53
		5.2	3	7.89	
		5.3	4	10.53	
		5.4	4	10.53	
		5.5	3	7.89	
		5.6	1	2.63	
		5.8	5	13.16	
		5.9	2	5.26	
Total			38.00	100.00	100.00

Table 2: Category wise participants average score

Category of Participant	Number of Participant	Average Score out of 38	Average % Score
Teaching Staff	10.00	29.00	76.31
Resident Doctor	10.00	29.30	77.10
Technician	8.00	26.50	69.70
Average Score		28.27	74.37

Discussion:

ISO 15189:2012 Internal Auditor training covers both management and technical aspect of standard. Generally, pathologist, microbiologist, biochemist, laboratory technicians are well experienced in technical operation of laboratory, while management aspect of laboratory is entirely new concept for them. There is general apprehension among them about how to implement and audit management clauses of ISO 15189:2012. Any ISO 15189:2012 internal auditor training program must put adequate emphasis on management clauses of ISO 15189:2012, so that they are adequately implemented in the laboratory. Post-training evaluation is one way of assuring that, training is equally effective in management as well as technical clause. Scores obtained in this post-training evaluation in this study for management and technical clauses were excellent (>70%) and comparable, showing effectiveness of training across various clauses of ISO 15189:2012. Moreover, future training program should intensively train participants in clause 4.5 and 4.9.

The target group of ISO 15189:2012 Internal Auditor training is heterogeneous. One hand it may include experienced pathologist, microbiologist, biochemist. On the other hand it also includes new bee residents in medical colleges. It also includes laboratory technicians as well as administrative and management staff of big laboratories where they have separate staff for such functions. With such diverse of trainee, the teaching program needs to be equally effective. While medical doctors need more intensive training in management clauses, managerial staff needs to be taught more on technical requirements. This training program was equally effective with teaching staff, resident doctors and

technicians, all groups scoring nearly 70%. A little bit lower score of technicians may indicate lower English proficiency in the technicians attending the training. More discussion in mother tongue and possible separate training program for technician-only-group with English language difficulties may be required to improve training effectiveness in laboratory technicians.

Conclusion:

Training emphasis and effectiveness in management clause was comparable with technical clauses. Moreover, the study found that, Training was effective across all categories of trainee.

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