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Effectiveness of ISO 15189 2012: a requirement for medical laboratories with particular reference to Organization and Management Responsibility (clause 4.1) in medical laboratory quality assurance

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Abstract: *ISO 15189 is the global quality management standard published by International Organization for Standardization (ISO). The current version of the standard is ISO 15189 2012. The objective of the quality management standard is to deliver uniform quality output, overcome the trade barrier such as acceptability of the test report globally. ISO 15189 2012 standard has been adopted by all the MRA partner of ILAC Member countries Accreditation body for medical laboratory accreditation. The ISO 15189: 2012 standard covers total 25 clauses or Major Element for the development of quality management system in the laboratory. Clause 4.1 is the first clause of 25 clauses. Quality Management system of the organization depends on the First Clause 4.1 requirements on "Organization and Management responsibility" compliance in the organization. The study was carried out in 70 accredited laboratories where it was observed how much the requirement is hypothetical and facilitates quality assurance in the laboratory and relevant challenges. It is observed that the standard is not written customer need based practice, and it has not considered the practical aspect of implementation in competitive business environment.*

Keywords: *ISO 15189:2012 review, ISO 15189 clause 4.1, ISO 15189 effectiveness, Effective quality assurance, Effectiveness of quality management standard.*

I. Introduction

ISO 15189 2012 standard accreditation of the laboratory introduced to create confidence among the patient, institution based customer, clinician and other users. ISO 15189 is now commercialization of the quality based on the hypothetical requirement of the standard rather need of the user. When a laboratory is accredited, it is considered that it has implemented all the requirements of the quality management standard. But practically it becomes a packaging of its quality system for the branding purpose without taking care of its objectives. It is observed that user is not responsible for most of the aspect of the quality management standard unless a practical thought or idea or process is delivered to them. It is now the demand to review its impact in the laboratory with an alternate approach otherwise Quality will be misled. Organization and Management responsibility is the most important requirement of ISO 15189 2012. This article has enlightened the effectiveness of this clause requirements in the Accredited medical laboratories. This study is done in India and its subcontinent region only. However, these findings may be reviewed by the Accreditation Agency/ body and the global organization responsible for preparation of accreditation policy like International Laboratory Accreditation Cooperation (ILAC) and International Accreditation Forum (IAF).

The Article Contains Following:

1. Introduction.
2. Purpose.
3. Approach for Study and review.
4. Selected and Studied ISO 15189 2012 sub-clauses.
5. The extent of study.
6. Collected Evidence.
7. Categorization of the findings.
8. Data Tabulation based on categorization.
9. Statistical presentation of each subclause based on categorization.
10. Analysis Summary
11. ISO 15189 standard Review.
12. Major influencing factors.
13. Conclusion & Task for QA Effectiveness

II. Purpose

Organization and Management are the first and major element in all quality management standards. How we can define "organization" word for a medical laboratory in respect of Quality Assurance?

Organization is a base or platform is developed against defined social or business objectives and committed to fulfilling the user need.

Here Management is the group of people who are committed to managing technical and non-technical function to fulfill the social or business objectives and fulfilling the need of a user.

Management Responsibility: Responsible for all the function needed to execute to fulfill the objectives.

Organization and management responsibility is the first and foremost requirement to deliver a quality output in an organization. ISO 15189 is a global quality management standard followed by Medical laboratories across the world for their accreditation purpose. All Accreditation body as MRA partner of International Laboratory Accreditation Cooperation (ILAC) follow this standard for assessing laboratory competence through this standard. It is considered that uniform quality assurance can be developed through ISO 15189 quality assurance. So the effectiveness of quality assurance depends on the effective implementation of ISO 15189 quality management standard. The research project was undertaken primarily to understand the effectiveness of ISO 15189 quality management standard in medical laboratories. Organization and Management responsibility clause 4.1 is part of the entire research project.

III. Approach For Study And Review

A study in 70 medical laboratories was carried out to observe the effectiveness of ISO 15189 organization requirement in an accredited medical laboratory. The study was carried out from 2013 to 2015 period. Out of 70 laboratories, 20 laboratories were Hospital-based laboratories and 50 laboratories were Diagnostic Center based laboratories. The study was also carried out in few laboratories during the transition of ISO 15189 2007 to 2012, and some laboratories were implementing QMS directly in ISO 15189 2012 standard. The entire study was carried out during the implementation of ISO 15189 2012 for their laboratory accreditation purpose, and it was continued up to six months of post-accreditation assessment. The study was carried out with the help of their consultants who were assisting them for implementation of ISO 15189 2012 standard.

IV. Selected And Studied Iso 15189 2012 Sub-Clauses

Subclasses /parameter head implementation process observed is as below

Table: 01

Sl No	Subclause or Parameter	Title
1.	4.1.1.2	Legal entity
2.	4.1.1.3	Ethical conduct
3.	4.1.1.4	Laboratory Director
4.	4.1.2.1	Management commitment
5.	4.1.3	Quality Policy
6.	4.1.2.4	Quality objectives and planning
7.	4.1.2.5	Responsibility, authority, and interrelationships
8.	4.1.2.6	Communication
9.	4.1.2.7	General Requirements
10.	4.2.2.1	General
11.	4.2.2.2	Quality manual

V. Extent Of Study

The study period for each laboratory was the concept of implementation of standard to laboratory accreditation assessment. It was observed how the laboratory management is given importance on each subclasses parameter requirement and process of implementation in the laboratory. It was given importance to understand the following:

a) Requirement of each sub-clause of the standard and probable expected output of Quality assurance in the laboratory
b) How the laboratory wishes to implement it and method of implementation
c) Probable reason to implement in the particular mode
d) How the document was developed or objective evidence related to requirement
e) How the record was maintained for each requirement and objective evidence
f) How they have taken preparation for their QMS accreditation assessment

VI. Collected Evidences

The entire study was captured based on the following information and conclusion was tabulated in Table 02

a. Current QMS in comparison with the standard (ISO 15189: 2012)
b. Document evidence (related manual, procedure, WI, etc.)
c. Record evidence (requirement by the standard and generated internally
d. Time of document generation (when it was prepared)
e. Time of record generation (when it was prepared or recorded)
f. Management advice to follow the requirements (meeting/ notice/instruction)
g. Management effort on training/awareness on the requirement
h. Nature and Type of system compromised with the requirement
i. Management commitment on compliance (instruction, notice, supervision, etc.)
j. Requirement Importance to management (interview with the management)
k. System continuation (with record)

VII. Categorization Of The Findings

ISO 15189 Clause 4.1 implementation process observation was primarily done on 11nos subclasses or parameters. Study observation was categorized as per various requirement of the standard as below:

a) **Voluntarily implemented**: Understood the requirement and initiated system seriously and voluntarily
b) **Lacks genuine implementation**: System is not implemented, documentation and record maintained not actual, it is fabricated the fact to face Accreditation assessment, data are not generated from real scenario, not used at work bench level for implementation
c) **Partly implemented by lab**: Some part is understood and voluntarily implemented, part initiative taken by lab
d) **Silent:** Requirement has no effect on the quality system or nobody is aware of the standard requirement, or System is either partly existed before the introduction of the quality system or its effect on the system cannot be verified externally or no additional effort is given to fulfill the requirement of Quality system.

VIII. Data Tabulation Based On Categorization

A detailed analysis is done based on the fact and data observed, and findings are concluded, tabulated and characterized as below table 02:

Table: 02A

CLAUSE	HEADING	Category-Voluntary implemented			
Total no of Hospital Labs and Diagnostic Labs		Hospital Lab	Diagnostic labs	Total	Total %
4.1.1.2	Legal entity	20	50	70	100
4.1.1.3	Ethical conduct	*	*	0	0
4.1.1.4	Laboratory Director	*	*	0	0
4.1.2.1	Management commitment	*	*	0	0
4.1.3	Quality Policy	*	*	0	0
4.1.2.4	Quality objectives and planning	*	*	0	0
4.1.2.5	Responsibility, authority and interrelationships	*	*	0	0
4.1.2.6	Communication	3	1	4	6
4.1.2.7	General Requirements	*	*	0	0

Table: 02B

CLAUSE	HEADING	Category-Lacks genuine implementation			
Total no of Hospital Labs and Diagnostic Labs		Hospital Lab	Diagnostic labs	Total	Total %
4.1.1.2	Legal entity	*	*	0	0
4.1.1.3	Ethical conduct	*	*	0	0
4.1.1.4	Laboratory Director	*	*	0	0
4.1.2.1	Management commitment	*	*	0	0
4.1.3	Quality Policy	*	*	0	0
4.1.2.4	Quality objectives and planning	*	*	0	0
4.1.2.5	Responsibility, authority and interrelationships	*	*	0	0
4.1.2.6	Communication	5	26	31	44
4.1.2.7	General Requirements	20	50	70	100

Table: 02C

CLAUSE	HEADING	Category-Partly implemented by lab			
Total no of Hospital Labs and Diagnostic Labs		Hospital Lab	Diagnostic labs	Total	Total %
4.1.1.2	Legal entity	*	*	0	0
4.1.1.3	Ethical conduct	*	*	0	0
4.1.1.4	Laboratory Director	19	47	66	94
4.1.2.1	Management commitment	*	*	0	0
4.1.3	Quality Policy	*	*	0	0
4.1.2.4	Quality objectives and planning	*	*	0	0
4.1.2.5	Responsibility, authority and interrelationships	5	8	13	19
4.1.2.6	Communication	9	4	13	19
4.1.2.7	General Requirements	*	*	0	0

Table: 02D

CLAUSE	HEADING	Category-Silent			
Total no of Hospital Labs and Diagnostic Labs		Hospital Lab	Diagnostic labs	Total	Total %
4.1.1.2	Legal entity	*	*	0	0
4.1.1.3	Ethical conduct	20	50	70	100
4.1.1.4	Laboratory Director	1	3	4	6
4.1.2.1	Management commitment	20	50	70	100
4.1.3	Quality Policy	20	50	70	100
4.1.2.4	Quality objectives and planning	20	50	70	100
4.1.2.5	Responsibility, authority and interrelationships	15	42	57	81
4.1.2.6	Communication	3	19	22	31
4.1.2.7	General Requirements	*	*	0	0

IX. Statistical presentation of each subclause based on categorization

Each subclause requirement is analyzed statistically as below:

Table 03

Clause	Heading	Voluntary implemented	Lacks genuine implementation	Partly implemented by lab	Silent
4.1.1.2	Legal entity	100	0	0	0

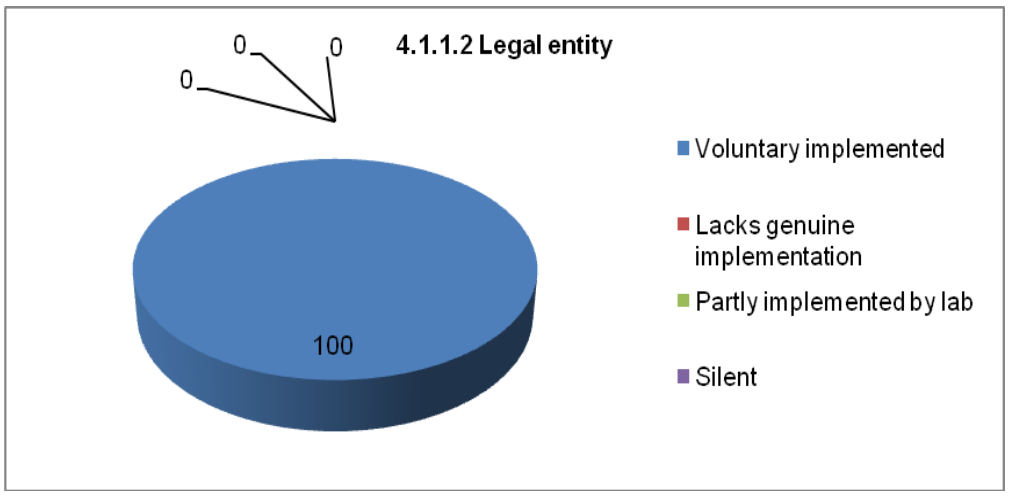


Table 04

Clause	Heading	Voluntary implemented	Lacks genuine implementation	Partly implemented by lab	Silent
4.1.2.1	Ethical conduct	0	0	0	100

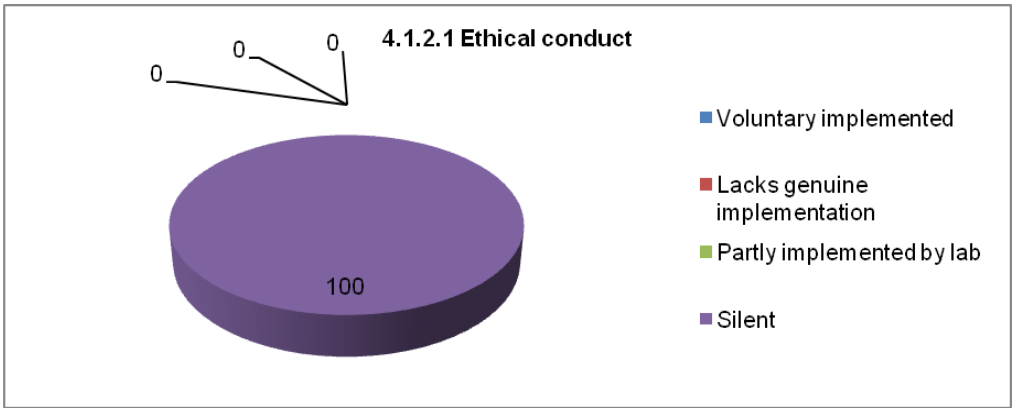


Table: 05

Clause	Heading	Voluntary implemented	Lacks genuine implementation	Partly implemented by lab	Silent
4.1.1.4	Laboratory Director	0	0	94	6

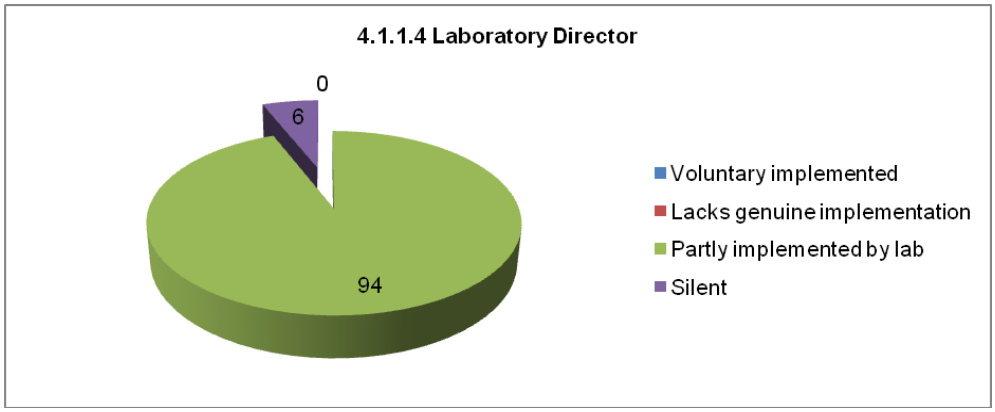


Table: 06

Clause	Heading	Voluntary implemented	Lacks genuine implementation	Partly implemented by lab	Silent
4.1.1.4	Management commitment	0	0	0	100

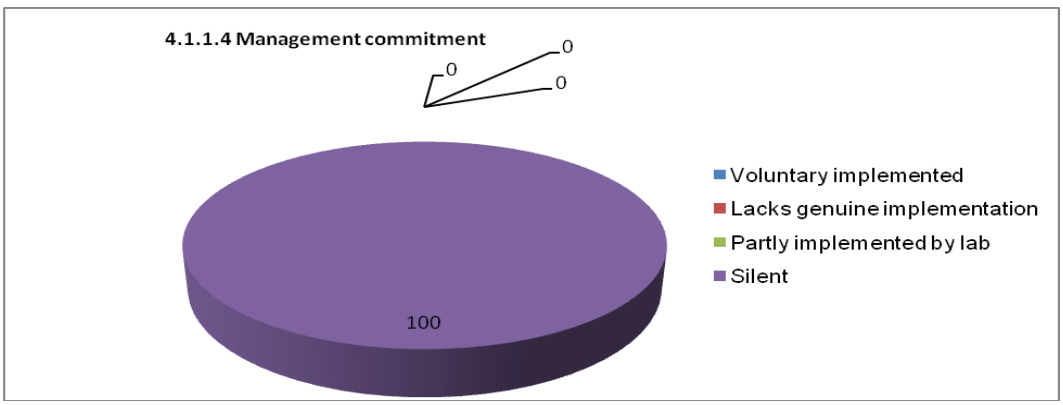


Table 07

Clause	Heading	Voluntary implemented	Lacks genuine implementation	Partly implemented by lab	Silent
4.1.2.3	Quality Policy	0	0	0	100

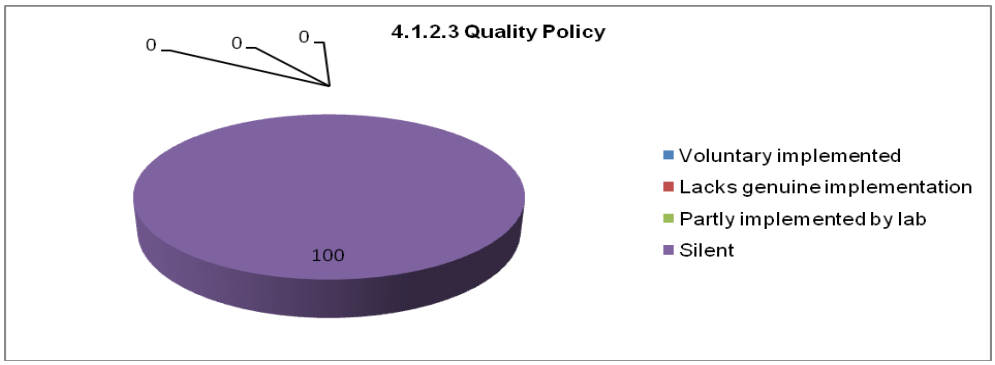


Table: 08

Clause	Heading	Voluntary implemented	Lacks genuine implementation	Partly implemented by lab	Silent
4.1.2.4	Quality objectives and planning	0	0	0	100

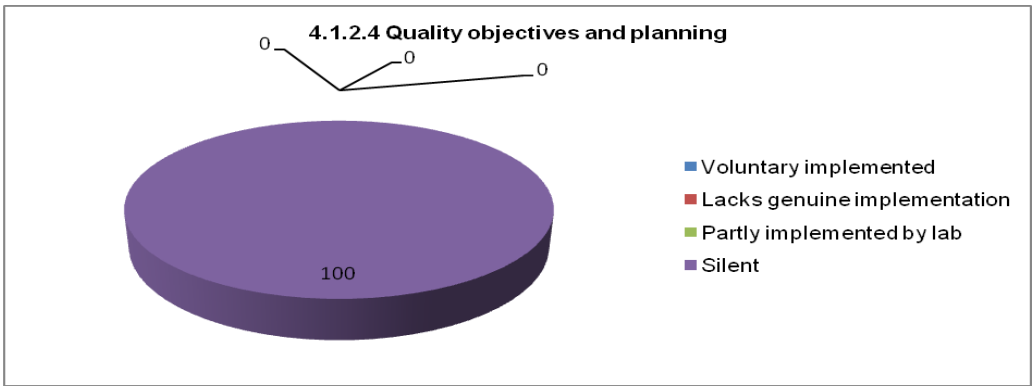


Table 09

Clause	Heading	Voluntary implemented	Lacks genuine implementation	Partly implemented by lab	Silent
4.1.2.5	Responsibility, authority and interrelationships	0	0	19	81

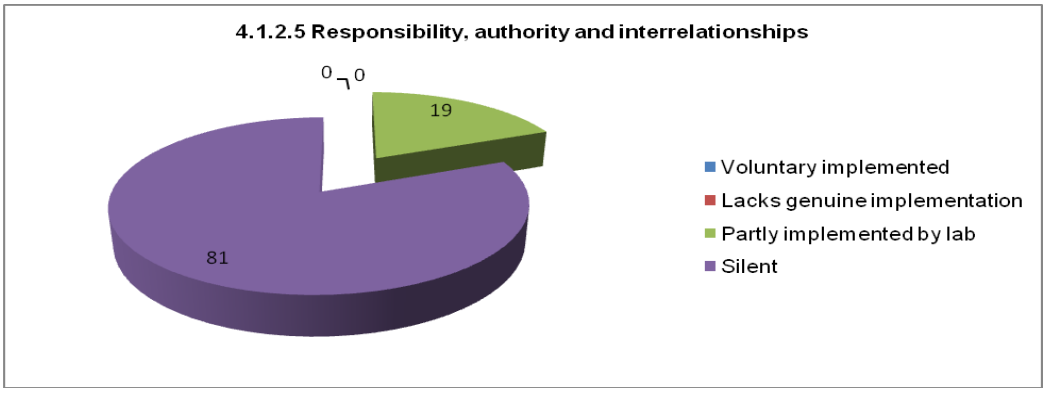


Table: 10

Clause	Heading	Voluntary implemented	Lacks genuine implementation	Partly implemented by lab	Silent
4.1.2.6	Communication	6	44	19	31

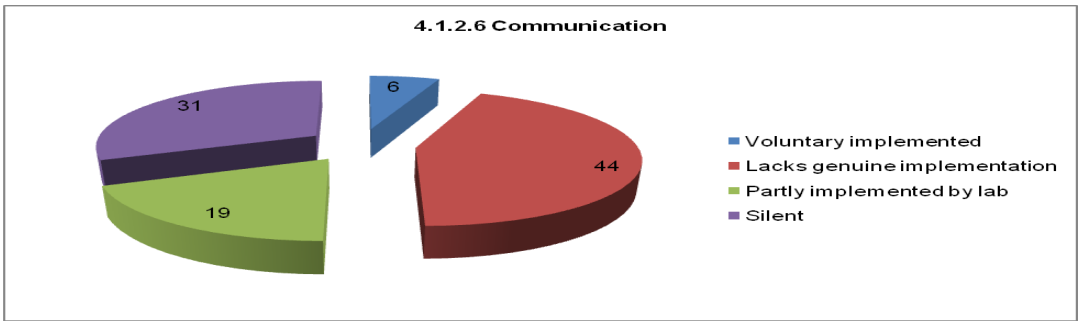
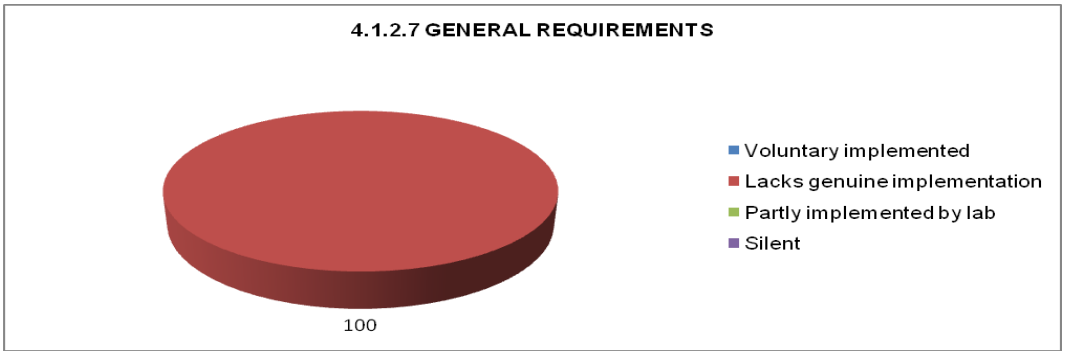


Table: 11

Clause	Heading	Voluntary implemented	Lacks genuine implementation	Partly implemented by lab	Silent
4.1.2.7	GENERAL REQUIREMENTS	0	100	0	0



X. Analysis Summary

It is observed Clause 4.1 requirement is practiced by the accredited laboratory in the following category.

Voluntarily implemented: 12%
Lacks genuine implementation: 16%
Partly implemented: 15%
Silent category: 57%

It is observed that sub-clause 4.1.1.2 is accepted by all laboratories for voluntary implementation. .1.1.2 should be categorized in silent but based on interview of lab management it is given in voluntary implementation category. Overall implementation trend on the standard requirement is observed within 27 % laboratory. 73% laboratory has shown that they are not interested on the requirement. Due to lack of measurable objectives and other condition 57 % lab is considered a silent category. But silent is also the category of doubt which also indicates that standard is not able to express the requirement to the labs and not earned confidence on it due to lack of transparency. It is also evident from the study that requirement of the clause 4.1 (organization and management responsibility) has less influence in the Quality system of the organization. Silent is also indicates that standard requirement trend is more hypothetical.

XI. Iso 15189 Standard Review

A review of the standard ISO 15189 2012 is also done, following comment and observations are made based on the above study and findings in the Table: 13.

Table: 13

Sub clause no	Content of the sub-clause	Observation and comment
4.1.1.1	The medical laboratory (hereinafter referred to as 'the laboratory') shall meet the requirements of this International Standard when carrying out work at its permanent facilities or in associated or mobile facilities.	Scope of Medical laboratory should be extended to all kind of test and application on human beings such as dope testing on human and all kind of drug monitoring on human
Sub clause no	**Content of the sub-clause**	**Observation and comment**
4.1.1.2	**Legal entity**	
	The laboratory or the organization of which the laboratory is a part shall be an entity that can be held legally responsible for its activities.	Being a regulatory requirement, it complies
4.1.1.3	**Ethical conduct**	
	Laboratory management shall have arrangements in place to ensure the following:	
	there is no involvement in any activities that would diminish confidence in the laboratory's competence, impartiality, judgment or operational integrity;	The measurable output is not clear; its compliance in the QA cannot be established. This requirement may be part of knowledge development
Cont. 4.1.1.3	management and personnel are free from any undue commercial, financial, or other pressures and influences that may adversely affect the quality of their work;	It should be informative and suggestive but doesn't play a role in quality assurance requirement because this is not measurable or verifiable, compliance of this cannot be evaluated in QA externally
	where potential conflicts in competing interests may exist, they shall be openly and appropriately declared;	DO
	there are appropriate procedures to ensure that staff treat human samples, tissues or remains according to relevant legal requirements;	As this is the part of regulation/law of the country, it should not be part of QA. It is expected in QA that lab will follow local regulations.
	Confidentiality of information is maintained.	It is ethical laboratory practice, should not be included in QA, this cannot be verified externally
4.1.1.4	**Laboratory Director**	
	The laboratory shall be directed by a person or persons with the competence and delegated responsibility for the services provided. The responsibilities of the laboratory director shall include professional, scientific, consultative or advisory, organizational, administrative and educational matters relevant to the services offered by the laboratory. The laboratory director may delegate selected duties and/or responsibilities to qualified personnel; however, the laboratory director shall maintain the ultimate responsibility for the overall operation and administration of the laboratory. The duties and responsibilities of the laboratory director shall be documented. The laboratory director (or the designates for delegated duties) shall have the necessary competence, authority and resources in order to fulfill the requirements of this International Standard. The laboratory director (or designate/s) shall :	Standard may prescribe requirement of for QA, may also define technical and managerial responsibilities needed to maintain QA. Organization will delegate the responsibility to the suitable designee. A Technical person may not agree to accept all the responsibility defined here, or management may not agree to delegate that. Very few Technical professional will agree to comply the prescribed standard requirement or laboratory top management will agree to delegate the responsibility as required by the standard
a)	provide effective leadership of the medical laboratory service, including budget planning and financial management, by the institutional assignment of such responsibilities;	This is the top management decision about the delegation of authority; management may delegate to Laboratory Director or may delegate it to some other designee. Standard should not recommend it and may not be requirement of quality assurance
b)	relate and function effectively with applicable accrediting and regulatory agencies, appropriate administrative officials, the healthcare community, and the patient population served, and providers of formal agreements, when required;	Do

Sub Clause No	Content of the Sub-Clause	Observation and Comment
c)	ensure that there are appropriate numbers of staff with the required education, training, and competence to provide medical laboratory services that meet the needs and requirements of the users;	Not related to quality system, it is management decision about the deployment manpower based on the productivity
d)	ensure the implementation of the quality policy;	Do
e)	implement a safe laboratory environment in compliance with good practice and applicable requirements;	
f)	serve as a contributing member of the medical staff for those facilities served, if applicable and appropriate;	
g)	ensure the provision of clinical advice with respect to the choice of examinations, use of the service and interpretation of examination results;	
h)	select and monitor laboratory suppliers;	
i)	select referral laboratories and monitor the quality of their service (see also 4.5);	
j)	provide professional development programs for laboratory staff and opportunities to participate in scientific and other activities of professional laboratory organizations;	
k)	define, implement and monitor standards of performance and quality improvement of the medical laboratory service or services;	QA requirement should be written, functional responsibility delegation is responsibility of top management not standard
l)	monitor all work performed in the laboratory to determine that clinically relevant information is being generated;	
m)	address any complaint, request or suggestion from staff and users of laboratory services (see also 4.8, 4.14.3 and 4.14.4);	
n)	design and implement a contingency plan to ensure that essential services are available during emergency situations or other conditions when laboratory services are limited or unavailable;	
o)	Plan and direct research and development, where appropriate.	This is not the requirement of QA, it should address separately if laboratory involves in research and this need a separate quality requirement
4..1.2	Management Responsibility	
4.1.2.1	Management commitment Laboratory management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improve its effectiveness by:	It may be the suggestive because it is a hypothetical concept. QA requirement must be transparent
a)	Communicating to laboratory personnel the importance of meeting the needs and requirements of users (see 4.1.2.2) as well as regulatory and accreditation requirements;	Nil
b)	establishing the quality policy (see 4.1.2.3);	It is hypothetical and decorative, but there is no role in improving Quality Assurance

Sub Clause No	Content of the Sub-Clause	Observation and Comment
c)	ensuring that quality objectives and planning are established (see 4.1.2.4);	DO
	defining responsibilities, authorities and interrelationships of all personnel (see 4.1.2.5);	Nil
	establishing communication processes (see 4.1.2.6);	Nil
	appointing a quality manager, however, named (see 4.1.2.7);	Nil
	conducting management reviews (see 4.15);	Nil
	ensuring that all personnel is competent to perform their assigned activities (see 5.1.6);	Nil
	ensuring availability of adequate resources (see 5.1, 5.2 and 5.3) to enable the proper conduct of pre-examination, examination and post-examination activities (see 5.4, 5.5, and 5.7)	Nil
4.1.2.2	**Needs of users**	
	Laboratory management shall ensure that laboratory services, including appropriate advisory and interpretative services, meet the needs of patients and those using the laboratory services. (See also 4.4 and 4.14.3).	Nil
4.1.2.3	**Quality Policy**	Work approach is Quality policy; no other statement is required
	Laboratory management shall define the intent of its quality management system in a quality policy. Laboratory management shall ensure that the quality policy:	It is hypothetical and decorative, but there is no role in improving Quality Assurance
	is appropriate to the purpose of the organization;	
	includes a commitment to good professional practice, examinations that are fit for intended use, compliance with the requirements of this International Standard, and continual improvement of the quality of laboratory services;	
	provides a framework for establishing and reviewing quality objectives;	
	is communicated and understood within the organization;	
	is reviewed for continuing suitability.	
4.1.2.4	**Quality objectives and planning**	
	Laboratory management shall establish quality objectives, including those needed to meet the needs and requirements of the users, at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy. Laboratory management shall ensure that planning of the quality management system is carried out to meet the requirements (see 4.2) and the quality objectives.	Not required and not in practice

Sub Clause No	Content of the Sub-Clause		Observation and Comment
4.1.2.4 contd	Laboratory management shall ensure that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.		
4.1.2.5	**Responsibility, authority, and interrelationships**		
	Laboratory management shall ensure that responsibilities, authorities and interrelationships are defined, documented and communicated within the laboratory organization. This shall include the appointment of person(s) responsible for each laboratory function and appointment of deputies for key managerial and technical personnel.		Quality assurance should not recommend for hiring deputy manpower. The user will decide it. Quality assurance commitment can be done without a deputy. For a small lab where productivity output doesn't allow to engage additional manpower should be considered by the standard
4.1.2.6	**Communication**		
	Laboratory management shall have an effective means for communicating with staff (see also 4.14.4). Records shall be kept of items discussed in communications and meetings. Laboratory management shall ensure that appropriate communication processes are established between the laboratory and its stakeholders and that communication takes place regarding the effectiveness of the laboratory's pre-examination, examination and post-examination processes and quality management system.		Records shall be kept of items discussed in communications and meetings" will create time-consuming unnecessary documentation in QA, should be left with user lab. Requirement of communication with stakeholders will also create complex system and documentation, need of communication will be identified by the lab and some other important communication under 4.8, 4.14, 4.15 can be done
4.1.2.7	**Quality Manager**		More clarity on responsibility of Quality Managers is required on entire standard requirement
	Laboratory management shall appoint a quality manager who shall have, irrespective of other responsibilities, delegated responsibility and authority that includes:		
	a	ensuring that processes needed for the quality management system are established, implemented, and maintained;	
	b	Reporting to Laboratory management, at the level at which decisions are made on laboratory policy, objectives, and resources, on the performance of the quality management system and any need for improvement;	
	c	Ensuring the promotion of awareness of users' needs and requirements throughout the laboratory organization.	

XII. Major Influencing Factors

Influencing factor on the implementation of ISO 15189 will vary from country to country based on geographical location, statutory, govt regulation, policy, education and training on QA, the attitude of the people toward Quality and mainly the economy of the place. However, this Study is primarily done in India, and its subcontinent location where all major influencing factors contributed in the implementation of ISO 15189 is identified. Those factors are given below:

a) Training and knowledge of Top and middle management
b) Management commitment to practice
c) Competitive work and business environment
d) Regulatory framework
e) Requirement of Accreditation /Certification body
f) Customer requirement
g) Availability of trained manpower and hiring capacity
h) Business profitability
i) Requirement and content of ISO 15189 quality standard

If we observe table no 02 A to 02D, we will find the following fact:

Voluntarily implemented: 12%
Lacks genuine implementation: 16%
Partly implemented: 15%
Silent category: 57%

It is also observed voluntary implementation in the Hospital-based laboratory is better than in diagnostic based laboratory.

During the Study following data was taken from the Organization and Management Profile as included below:

a) Organization Legal Identity
b) Total no of Top management person (Tier 01)
c) Qualification and Experience of Top Managements
d) Total no of Middle management persons (Tier 02)
e) Qualification and experience of Middle Management profession
f) No of Staff
g) No of the person assigned as Dy.
h) Total Patient Turnover
i) No of labs in 05 SQ KM
j) No of similar labs with 05 SQ KM
k) No of Training and workshop carried out in a month/quarterly/ yearly
l) No of meeting with employees
m) Communication process with employee
n) Daily supervision mode and report

Key Factors Influenced in Implementation Process of Organization and Management Responsibility of ISO 15189

a) **Training and Knowledge of Top and Middle Management**: Qualified Management professionals may understand easily the organization behavior and may support the organization management principles and practices. Very few labs are managed by highly qualified and corporate experienced management professionals. There is a fewer chance of implementation in non-corporate laboratory structure. Moreover, business growth is not that much of dependent on this factor and most of the labs are having similar kind of management professionals and expertise.
b) **Management Commitment to Practice**: Managements commitments are essential to follow the practice, Managements are not taken it seriously as its importance are not convincing to them. So voluntary implementation is not given that much of priority. As some of the features are common and standard practice, mostly those observation found in silent category. Unless Hypothesis transferred in measurable and achievable element, management would not give it priority
c) **Competitive Work and Business Environment**: the clinician primarily controls the Diagnostic market, Clinician interest is taken care, high-level practice on organization and management principles is not having significant role unless it is working in very large scale.

d) **Regulatory Framework**: Where regulatory framework is mandatory, there is a high chance of success, for example, legal Identity requirement. The legal framework always helps in effective implementation of the requirement. The regulatory framework is almost absent on organization and management responsibility requirement.
e) **The Requirement of Accreditation /Certification Body**: Standard followed by accreditation body is very subjective, the requirement is not specified, and mostly it is hypothetical, accreditation body has less influence on its implementation. Accreditation body involvement in education, training, monitoring is almost absent. Lack of trained and knowledgeable auditors system is also not evaluated appropriately, which convey the message to management as "no so important."
f) **Customer Requirement**: Customer of the medical laboratories are Clinicians, patients and some corporate. Customer requirements are always given importance, but here Customer has no specific requirement on organization aspect rather silent category practices are fulfilled the customer requirement, which is considered as a common practice, like confidentiality of the data. The customer can play a key role in fulfilling the requirement, but most of the requirement of the standard is not the requirement of the customer.
g) Availability of Trained Manpower and Hiring Capacity: Industry lacks qualified and trained manpower within their affordability; many practices are compromised knowingly due to lack of efficient manpower or organization is not capable of retaining the efficient manpower due to high retention cost.
h) **Business Profitability:** It is also observed that any major restructuring for the purpose of the standard requirement will attract high overhead and other expenses, and these changes will not increase the profitability of the organization.
i) **Requirement and Content of ISO 15189 Quality Standard:** It is observed, mostly this part of the standard is subjective, not a specified requirement basis, content is considered hypothetical, and many requirements prescribed in the standard are not accepted by the user.

XIII. Conclusion & Task For QA Effectiveness

Unless mathematics and science very tough to conclude it. There can be further suggestive work on it. Need honest feedback from the consultants, accreditation body and laboratories from the different part of the world to work on it. Quality Management standard can be used for knowledge and education purpose but Certification is may not be a right process to declare the organization complies with the requirement or quality assurance is established as per quality management standard.

However, the findings and comment based on the sample taken. Most of the data is collected based on the sequence of incident, subjective evidence and interview based actual results may change. But a variation of data will not change the trend and broad based conclusion.The sample is also not global representation; the key factors are already explained in the major influencing factors #12. This needs more work on it including voluntary participation from all ILAC MRA partners, ILAC, IAF and other international organization including stakeholders of ILAC

But it is understood from the study that user laboratory will be interested in implementing quality management requirement where user interest is protected. Quality Management standard need revision of the requirement and approach for quality accreditation policy need to be changed considering the main objective and purpose of the standard. Revision of the standard alone will not bring any solution need to change the system approach including handling of influencing factors considering geographical distribution and its role in the economy.

Effective Quality Assurance in the area of Organization and Management:

The following task is needed to work on effective Quality Assurance in Organization and Management

- User need-based standard
- Local Statutory and Regulatory body should incorporate in their licensing requirement
- Separate inclusion of Education and information section
- Standard requirement should be measurable and verifiable
- Requirement is not measurable or verifiable may include in education and information
- Standard requirement should be based on activities of the labs
- LIMS based quality management system

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References:

[1]. BS EN ISO 15189:2012 Quality Management standard clause 4.1, page no 05