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Document Control Effectiveness in ISO 15189 Accredited Laboratories

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Abstract: *ISO 15189 is the global quality management standard published by the International Organization for Standardization (ISO). Document control is one of the Key requirements of ISO 15189. It is considered Document control is the major quality element to establish a quality management system. The research study was carried out to understand the effectiveness of a document control system followed in accredited medical laboratories. It was the key objective to identify the importance of document control system hypothesis vs practical implementation and Challenges of Document control system implementation. It was really hard to categorize the implementation status of document control, but I have tried to analyze it.*

In the study volume of up to date control document usage in functional area is estimated. Various effects of document control are also analyzed before implementing the accreditation system and post accreditation system. A structured document control system is also observed and compared with pre and the post accreditation system. In the study all reported events are analyzed to find out out the reported event in related to document control system. Risk analysis of document used in the laboratory is also analyzed. Total risk scoring is done based on the document risk involvement. Major challenges observed in the manual document control system. A suggestive idea is prescribed in the improvement of a document control system.

Keywords: *Document control, Document control effectiveness, ISO 15189 Document control, ISO 9000 Document control, control of document, Pseudo document control system*

1.INTRODUCTORY THOUGHT

Quality Management System is developed based on Documented system. We cannot build up a quality management system without a document and a document is developed in the quality management system to maintain the QMS. If we cannot control a document, the quality management system will not be in our control. If Quality management system is not in our control, we cannot generate quality output. It is observed that almost in every Quality audit non-conformances are raised in the document control system. It is commonly believed that an organization is not certified or accredited as per quality management system standard; they may not have a standard document control system and also indicates that they may not have documented QMS.

Should it be legitimate to say that laboratory is not having documented Quality Management System is not generating quality output? Or another way, an accredited laboratory maintaining Quality Management System standard diligently? Or an accredited laboratory has a sound document control system? If the laboratory is not following a document control system, what will be the implementation effect in the quality management system? A study carried out to understand the risk of document used in the quality management system to understand the effect when this control is out of control in the quality management system. This research project was undertaken to understand the pertinent issues observed in the accreditation process or in post accreditation stage.

QUALITATIVE AND QUANTITATIVE LOSS:

Qualitative loss indicates a loss associated with quality of service, delivery and total relationship management with customer and Quantitative loss is where the loss can quantify by money or quantifiable product/object.
For example Laboratory staff is not aware about the updated quality management system and procedure, as a result, delivery of wrong service and loss of reputation in the business.

We cannot ignore the role and importance of the document control in Quality Management System, hypothetically we can establish a model that in the absence of appropriate document control, a quality management system will be collapsed totally and we can estimate the qualitative and quantitative loss.
ISO 15189 2012 standard accreditation of the laboratory is introduced to create confidence among the patient, institution based customer, clinician, and other users. When a laboratory is accredited, it is considered that it has

implemented all the requirements of the quality management standard. Document control is one of the prime requirements of the standard. But practically true implementation of a Document control system is really a challenge.
All Accreditation body as an 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 mplementation of ISO 15189 quality management system. 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 standards in medical laboratories, document control is the part of the entire research project.

This study is done in India and Gulf countries 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).

2. APPROACH FOR STUDY AND REVIEW

This study was carried out in 70 medical laboratories in India and Gulf countries to observe the effectiveness of ISO 15189:2012 Quality Management System implementation in the medical laboratories. The study was carried out from on 2012 to 2015 period. Out of 70 laboratories, 20 laboratories were Hospital-based laboratories and 50 laboratories were Diagnostic Center based laboratories. The study was carried out in a 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 implantation of ISO 15189 2012 in their accreditation process. The study was carried out with the help of their consultants who were assisting them in the implementation of ISO 15189 2012 standard. All the laboratories were under observation up to 6 month period of post-accreditation assessment. Average time spent in observation of each laboratory was 14 months. The study was also included three labs separately on the actual application of document control as required by the international standard.

3. SELECTED AND STUDIED ISO 15189 2012 SUB-CLAUSES:

Document control Clause 4.3 a to j

4. 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 gives importance on each subclasses parameter requirement and process of implementation in the laboratory. It was given importance to understand the following:

a) The study involved entire laboratory includes all functional departments as available such Front office/reception, billing/ cash, phlebotomy, purchase, store, maintenance, biomedical, HR. And administration, marketing
b) The Study is not covered financial management section
c) Requirement of each sub-clause of the standard and probably expected output of Quality assurance in the laboratory
d) Type of documents handled by each laboratory
e) Use of controlled and uncontrolled documents
f) How the laboratory wishes to implement it and method of implementation
g) How they reacted when the standard requirement demands a change
h) Probable reason to implement it in the particular mode
i) How the document was developed or objective evidence related to the requirement
j) How the record was maintained for each requirement and objective evidence
k) How they have taken preparation for their QMS accreditation assessment

5. SCOPE OF DOCUMENT CONTROL

Scope of document control study was on 4 level document control system

Level-1: Quality Manual
Level-2: Quality Management System Procedure
Level-03: Standard Operating procedure for test (SOP) / Work instruction
Level-04: Formats used to maintain documents and records

Observation & Data collection: An arrangement was made with the quality consultant of the laboratory that every need of document changes will be brought to the notice since the date of issue of Quality manual. The entire study was done from the date of quality manual issue to completion of the laboratory accreditation. During the study every incident was recorded as below:

a) Total document revision and issue process
b) Review of document
c) Document change request
d) Reason to change
e) Manpower deployed for document control

6. SYSTEM REVIEW

Document control system was reviewed to observe how the document control system is practiced in the laboratory and how the system is really affecting their day to day business operation. The sample I have taken mostly they follow the document control system manually. In the study it was compared with the standard system model with commonly practiced document control system features which included at least:

a) Commonly practiced document control procedure for ISO 15189 2012
b) Scope of document control was all internal 4 level documents- Quality manual, procedure, SOP or work instruction and all formats
c) Commonly practiced document issue, revision or version system and protocol, including document change notes, amendment sheet, withdrawal of obsolete document and the list of controlled documents

7. 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. Documented evidence (related manual, procedure, WI, etc.)
c. All internal and external documents used by lab and other functional area, this includes, leaflet, brochure, posters, drawings and other unconventional item in the form of documents
d. Record evidence (a requirement of the standard and generated internally)
e. Time of document generation (when it was prepared)
f. Time of record generation (when it was prepared or recorded)
g. Management advice following the requirements (meeting/ notice/instruction)
h. Management effort on training/awareness on the requirement
i. Nature and Type of system compromised with the requirement
j. Management commitment to compliance (instruction, notice, supervision, etc.)
k. Requirement Importance to management (interview with the management)
l. System continuation (with record)
m. Operation indicators data (quality, business and profitability data) before ISO 15189 implementation and post accreditation

8. CATEGORIZATION OF THE FINDINGS

It is very hard to categorize the finding. Each subclause has multiple requirements and every requirement has multiple dimensions of the implementation. However, Study observation was categorized based on the research findings against implementation of ISO 15189 2012 Clause 4.3 document control requirements as below:

a) **Voluntarily implemented**: Requirements are Understood by the lab and implemented voluntarily, Implementation of the system is done as per the standard requirement. No fabrication or manipulation of the system is done. System, Documents, and records are genuine.
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 the real scenario, this is not used at work bench level for implementation.

c) **Partly implemented by the lab**: Some part is understood and voluntarily implemented, part initiative taken from the lab

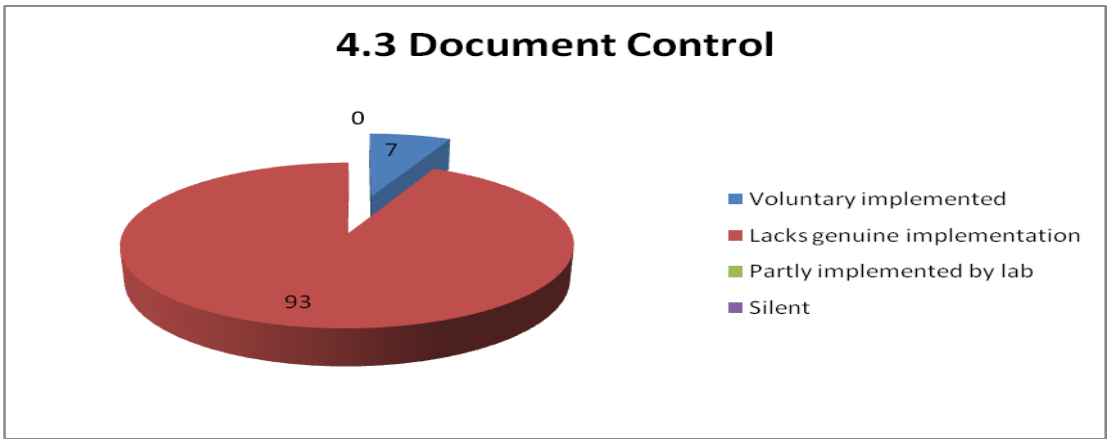
d) **Silent:** Requirement has no effect on the quality system or nobody is aware of the standard requirement, or System is either partly exist before the introduction of the quality system or its effect on the system cannot be verified externally or no additional effort is given to fulfill the requirement of Quality system.

e) Quantitative Analysis of Categorization：

The system of document generation and record keeping or its nature of implementation is not same in every laboratory. Sometimes classification of document and record as per categorization was not possible. Each sub clause has multiple requirements and every requirement has multiple dimension of implementation. I have observed conflict of categorization in many sub clause requirement due to multiple dimensions of implementation stage under one sub cause requirement. It was really tough to categorize the implementation. Each subclause has a different dimension of implementation effect. There is the influence of the data due to the dual meaning and interpretation of the standard. There is a probability of personal bias in the data who has shared it or his opinion on it. So declared laboratory participation expressed as % of compliance or categorization against the requirement should not be considered accurate, all categorization and laboratory participation % should consider as trend and bias towards category only.

Table-01: Quantitative Analysis of Categorization on ISO 15189 2012 Implementation Participation by Lab

Clause	Heading	Voluntary implemented (%)	Lacks genuine implementation (%)	Partly implemented by labs	Silent
4.3	Document Control	7	93	0	0



From the above study, it was observed 93% laboratory organizations had not implemented document control system as expected by the International quality management system standard. It was found 93% laboratory maintain a formal document control system in the day of ISO 15189 assessment. The study found that 7% laboratory which is total no of five laboratories have voluntary implemented the system. It was observed that out of 5 laboratories, one laboratory has controlled their document through the online system in soft copy version and another 4 labs operation was very small and incidentally other 4 have complied the system, The reason might be as follows:

a) They faced a minor document change requirement or
b) Change requirement is not reported or
c) And Quality manager was serious in maintaining the system. No major document control requirement event is also reported, during the study.

9. PSEUDO DOCUMENT CONTROL SYSTEM:

The study reveals in 70 organizations that Pseudo document control system exists in almost 93 % laboratory organization. The Pseudo document control system is the preservation of document in the Quality Management System museum. This is practiced in two categories, Category I is given the name as PSD- I and category II name is given PSD -II.

PSD-I: This is a document control system used to prepare and update QMS document before external assessment.

PSD-II: this is the document control system practiced mostly in corporate type organization where their document control preparation exercise starts before their internal assessment and continue up to external assessment.

PSD II is the better preservation of documents than PSD-I

We can also call all Pseudo documents as **"Preserved Fossil Document (PFD)".**

It is observed among the 70 sample organizations that 93% organizations were practicing PSD-I control and 7% are in PSD-II category. There was no other system found other than PSD me and PSD-II category. It is also to be mentioned that all the organizations were practicing manual document control system.

10.**EXTENDED STUDY ON THE EFFECT OF DOCUMENT CONTROL:**

I had selected some common event of a document control system to review how this brings effect in the absence of a document control system in the accredited laboratories. The three labs selected by me were an open reagent system of similar nature. The study is done over the period of 22 months. All three laboratories were PSD I category and the study carried out before the transition of ISO 15189 2007 to ISO 15189 2012.
The common incidence of Document control system taken as below:

Document control incidence	**Actual system followed**			
	LAB-01	**Lab-02**	**Lab-03**	**Remarks**
Change of test method in test report due to change of test reagent	Revision is made within 60 days, as LIMS had no provision and is completed before initial assessment	No revision is done, it is found during the external assessment almost after 4 months implementation of the system	No Revision, requirement not identified during the external assessment, identified in the PT failure analysis after post surveillance assessment	No direct effect to the user
Revision of test charges	No Revision in hard copy is done immediately but change is done in LIMS	No Revision in hard copy immediately but change is done in LIMS	No Revision in hard copy immediately but change is done in LIMS	Taken care in the patient billing, which is the primary need for survival
Revision of Calibration plan	The revision made before external assessment	The revision made before external assessment	The revision made before external assessment	Plan change in the document is not directly affecting the user of the plan
Revision of Quality control plan	Revision noticed within 7 days	The revision made before external assessment	Observed during external assessment	This is not considered as a priority need by the user. Plan is followed as per the instruction given by the consultant, plan documentation is only for accreditation purpose

Revision of Vendor list	Revision made before external assessment	No Revision	The revision made before external assessment	Purchase In charge is aware of the decision, documentation is not important for him

Analysis Summary:

Hypothetically the entire above event in the document control system is very important, a figure on quantitative and qualitative loss can be projected, but it actually doesn't reflect on the day to day operation. I have seen the document control is given priority when a user identifies the need for the same. But we cannot ignore its importance or associated risk. The challenges are the motivation; the challenge is time and recurring cost involvement. All the above event is very successful when it works in a controlled environment like controlled through LIMS or through their software based Management information system.

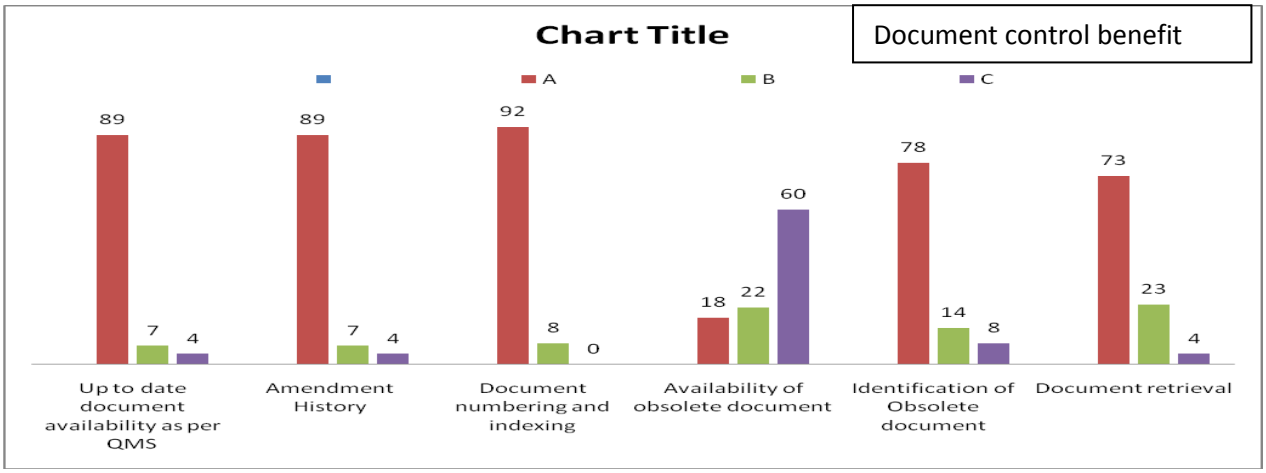
11. DOCUMENT CONTROL BENEFIT ESTABLISHED IN AN ACCREDITED LABORATORY: A study was carried out among 70 laboratories during the post accreditation assessment period to know the document control status of each laboratory. The observation was taken within 30 days from the date of external assessment. It was observed that the document control system ensures the availability of the document in the organization. Based on document availability in the organizations Findings are categorized as below,

a) Category A: When 70% or more of required documents (as per list of documents listed in QMS) is available of A >70%
b) Category B: When 50% or more but less than 70% required documents (as per list of documents listed in QMS) and information available: B >50% and B <70%
c) Category C: When required documents (as per list of documents of QMS) and information available is less than 50%: C <50%

List of documents includes their list of documents and documents needed by the ISO 15189 QMS.

Document control Benefit established in an accredited laboratory:

Sly no	**Name of control area**	**Number of Accredited Laboratory performance Category basis in (%)**			**Status before preparation of Accreditation**
		A	**B**	**C**	
1.	Up to date document availability as per QMS	89	07	4	Non ISO 9000 certified :Nil ISO 9000 Certified: 8 % partial
2.	Amendment History	89	07	4	Do
3.	Document numbering and indexing	92	08		Do
4.	Availability of obsolete document	18	22	60	Do
5.	Identification of Obsolete document	78	14	8	Do
6.	Document retrieval	73	23	04	Do

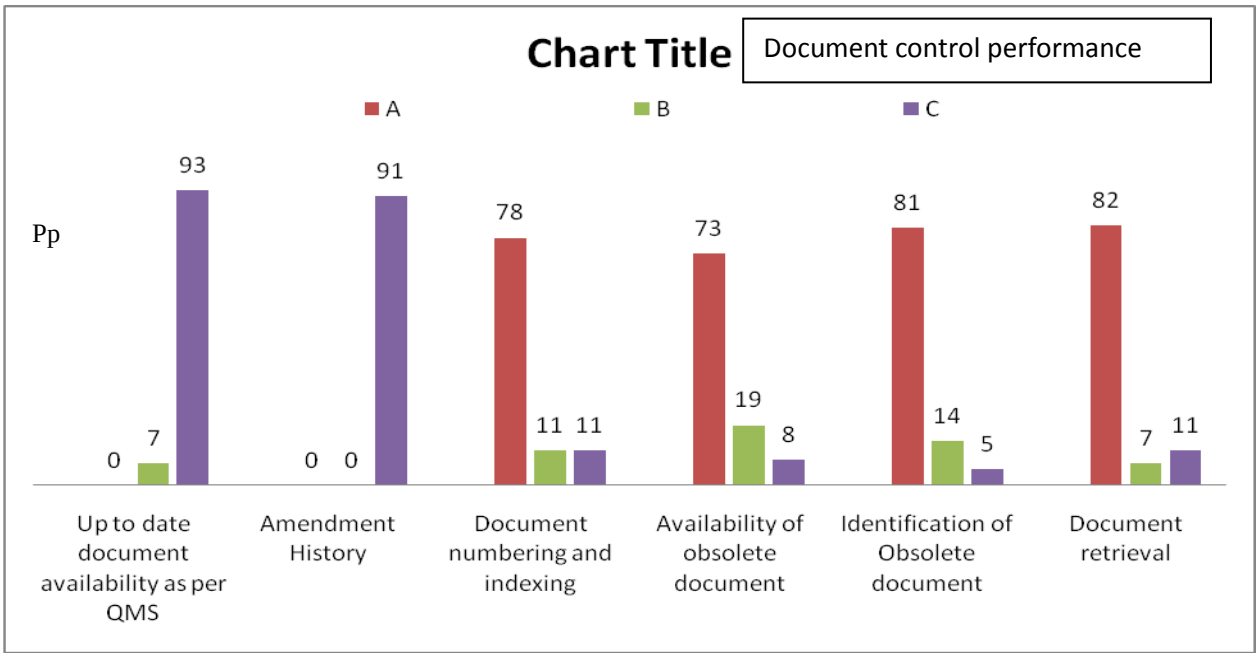


ANALYSIS SUMMARY: Study reflects a document control system almost was absent before ISO 15189 Accreditation except in some ISO 9000 certified organization.

This is observed that all the document control parameters are very good majorly performing category A, except the availability of obsolete document. It is observed document numbering and indexing parameter achieved the highest score of 92%. Document numbering and indexing system are most acceptable practice in document control. The average performance of document control parameter in the post accreditation assessment stage is very good. Availability of obsolete document performance is under category C.
This is observed during preparation for accreditation assessments, all documents were almost up to date. There are many changes happened before the assessment and immediate, post assessment, but copy of obsolete documents were not available as expected. Obsolete documents are not getting importance or its relevance in terms of the history of changes.

12. DOCUMENT CONTROL PERFORMANCE AFTER 9 MONTHS OF ACCREDITATION BEFORE THE SURVEILLANCE ASSESSMENT

Sly no	**Name of control area**	**Accredited Laboratory performance Category**				**REMARKS**
		A	**B**	**C**	**Not measurable**	
7.	Up to date document availability as per QMS	-	7	93	NM	There is hardly revision
8.	Amendment History	-	-	91	NM	Do
9.	Document numbering and indexing	78	11	11	-	Better performance than before
10.	Availability of obsolete document	73	19	8	-	Better performance than before
11.	Identification of Obsolete document	81	14	5	-	Better performance than before
12.	Document retrieval	82	07	11	-	Better performance than before



13. DOCUMENT CONTROL IMPLEMENTATION IN FUNCTIONAL AREA/ DEPARTMENT

Sly no	Functional area	Before Accreditation	Post Accreditation Average %	Major document and data not in control
1.	**Front office**	Nil	73	Laboratory information, booklet, diagnostic services, promotion booklet, posters
2.	**phlebotomy**	Nil	78	Posters, collection instruction kit related
3.	**Laboratory operation**	Nil	82	Kit literature, posters, technical journal-bulletin, Records formed as document, including report images of Haematology, Histopathology and, Cytopathology,
4.	**Purchase**	Nil	43	Technical specifications, operational formats
5.	**Facility planning**	0	0	Building plan (including architecture, plumbing, electrical) design, drawing, safety plans, signage's posters
6.	**Maintenance**	Nil	93	-
7.	**Store**	Nil	93	-
8.	**Marketing and Sales**	Nil	0	All documents
9.	**HR**	Nil	78	-
10.	**IT**	0	0	All Formats, including Web site information
11.	**Management and Administration**	0	0	External origin circular. Notices, legal compliance, etc

The Above figure is calculated: Number of document in control /No of document observed X 100

Average Document control implementation observed 43% in an organization

All data collected 30 days from the date of post-accreditation assessment.

14. DOCUMENT RISK ANALYSIS BASED ON PRACTICE AND TREND

Likelihood / Severity	Remote (1)		Occasional (2)	Frequent (3)
Minor (1)	Quality Manual		0	0
Moderate (2)	0		Procedure	-
Major (3)	0		SOP /work instruction	Kit literature, Format based checklist and recording format
Total Risk Score	01	02	06	09

Document Analysis based on Quality Management system Concept

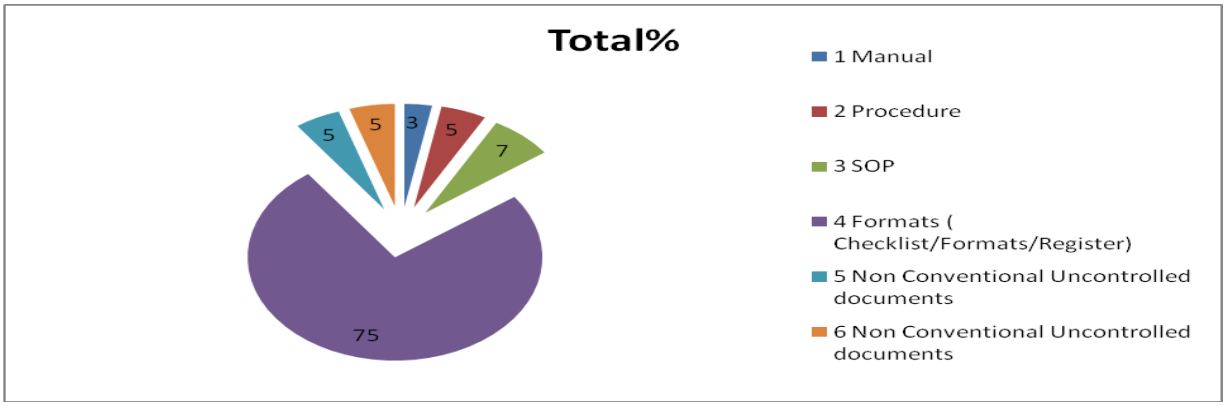
Likelihood / Severity	Remote (1)	Occasional (2)	Frequent (3)
Minor (1)	0	0	0
Moderate (2)	0	0	0
Major (3)	0	Quality Manual	Procedure SOP /Work Instruction and Format based checklist and recording format
Total Risk Score	0	06	09

Non-conventional uncontrolled document

Likelihood / Severity	Remote (1)	Occasional (2)		Frequent (3)
Minor (1)	0	0		0
Moderate (2)	0	Posters & Website, HR/Personnel information		Patient information booklet, product and kit literature
Major (3)	0		Legal document and circular, Facility Drawing	-
Total Risk Score	0	4	6	6

15. TYPE OF DOCUMENT USED IN LAB (OTHER THAN FINANCE)

Sl no	TYPE OF DOCUMENTS	TOTAL %
1.	MANUAL	3
2.	Procedure	5
3.	SOP	7
4.	Formats (checklist/ forms/Register)	75
5.	Non conventional uncontrolled documents	5
6.	Non conventional uncontrolled documents	5



16. 70 laboratories reported event analysis

Sly No	Subject	Observation
1.	Total No of laboratory information collected	70
2.	A total incident reported	540
3.	Incident not related to document control	533
4.	A total incident reported related to document control	07
5.	A total incident reported from a listed document under document control	0
6.	Average document type are is in controlled	185

REPORTED PROBLEMS IN DOCUMENT CONTROL

(70 LABORATORIES IN ONE YEAR PERIOD)

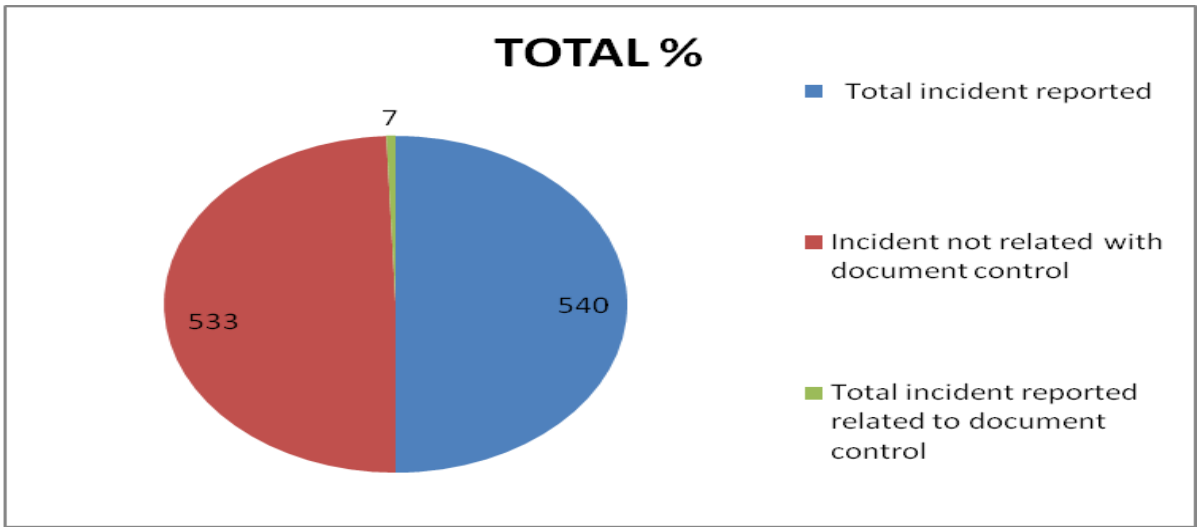
Sly no	Problems reported	Source /origin	Remarks
1.	Regulatory Body- Pollution control board circular	Non recorded event	Considered as major event lead to penalty and legal action against the laboratory
2.	Nonavailability of up to date Electrical drawings	Non recorded event	Considered as major event affected the quality of equipment and accommodation condition
3.	Website information	Legal complaint record	Moderate event affects reputation and goodwill
		Customer complaint	
4.	Wrong purchase order to wrong vendor	Recorded event from incident record	Affect the laboratory technical operation
5.	Patient preparation leaflet	Recorded event from sample rejection record	It can be considered moderate to major event

REPORTED EVENT VS REPORTED DOCUMENT CONTROL EVENT ANALYSIS

Total Number of laboratory data Analyzed: 70

Total number of events collected: 540

Period of data: one year



REASON FOR LESS NUMBER OF DOCUMENT CONTROL RELATED EVENT:

1. Reason for less Number document controls related event
2. Non-reported events
3. Reported but the document is not in controlled list
4. Reported but the document is not in controlled list
5. Non-reported incident related to document control, but not in the document control list

17. HOW THE MANUAL DOCUMENT CONTROLS BECOME A BURDEN IN THE QMS:

- Once Quality Manual, procedure, and work instruction are issued, this will attract few justified changes from the organization people time to time. The Change request will also be generated during an internal audit, management review meeting, internal and external desktop and on-site assessment.
- Once changes are accepted by the approving authority, there will be a chance to attract the further changes in linked QMSD like procedures, work instruction, etc.
- If procedure demands separate changes, it may attract separate changes in the quality manual and other documents.
- Once the procedure is changed it may reflect in standard operating procedure/ work instruction whatever name is called. There will be frequent changes in Standard operating procedure and work instructions.
- Once the format and checklist are issued, it also may demand some changes based on the user feedback.

It will be a very tedious process for multiple linked document changes and interesting fact is that no substantial improvement was observed and users were not convinced about the benefit of the Quality management System Document (QMS) and it gradually converted into PFD.

There was a further risk assessment program on document control and risk assessment results reveal following information:

a) All the high-risk informative document area, organization prefers to share the information immediately and not depending on the document change protocol. This is shared instantly through discussion, internal mail, circular etc.
b) All the medium risk document information is shared periodically.
c) Low-risk document information is mostly ignored, and organization is not giving importance on it.

18. REASON FOR PSEUDO DOCUMENT CONTROL SYSTEM IS USED:

a) Theory of document control is convincing, but practically its importance is not important to user
b) Cost of document control is very high considering the business risk of failure of a document control system
c) Document control system is very time-consuming
d) The manual document control system is not supporting the green environment concept
e) Established practicing document control system in not organization need-based system

19. MAJOR CHALLENGES IN DOCUMENT CONTROL SYSTEM: TASK AHEAD

a) **Change of Quality management system Normative Reference**: Normative reference such as ISO 15189 QMS should encourage for less document. Normative reference should not encourage for Quality manual, procedure, wok instructions. The user will decide its documentation requirement.
b) **Minimum Document to document**: Design the system such way that document should be as low as possible, the document only where quality will affect seriously. Fewer documents and then less effort for control of the document. Use only two documents, one Master, and one copy document only
c) **Flexible Document control system:** A rigorously disciplined document control system creates fear and made it PFD. This will design the organization based on the minimum feature related to change and this should be supported by the Quality Auditors:
    - Change of the content important not affected page no, section etc.
    - To be considered which is important to the user
    - Temporary document in any form should be used to understand the changes
    - Formal updating and revision will be as per user discretion
    - Understanding revised content is essential
d) **Use of Document Library**: Instead of an issue of the document at a workstation level, minimum document to be stored in the form of the library, so less issue and less control

e) **Document education**: the Restrict issue of a number of documents and stress on educating document. Instead of issuing hard copy documents, teach the user about the document, tech about changes, teach about the requirement so that use of hard copy will be restricted
f) **Training of Quality Auditors**: Not to encourage the use of a copy document at work bench level unless the work will be seriously affected. Discourage increase of procedure, process map, work instructions. Accreditation/Certification body should monitor strictly the Auditor that they should not propose or raise document in
g) **No Fight on Hypothesis**: Not to establish what will be happened if the document copy is available, promote if knowledge is not available instead of a document.
h) **Cloud Library**: Use cloud or drive based library for document reading, various open cloud and drive system available for document storage
i) **Use Document control Management solution**: use of document management software available in open-source or another type. So no hard copy document
j) **Document control Awareness:** Create awareness about the need of document control process established in the organization

20. FUTURE OF DOCUMENT CONTROL:

A) Use of Educative guideline: Less formal document, educative guideline will replace the formal documentation rather use of procedure and work instruction
B) Use of checklist compliance: System implementation and compliance based on the checklist
C) **Use of Centralized Management System (CMS) system in cloud:** All documents, checklist usage in cloud-based CMS
D) **Scanning, Issue, revision currency:** manual control will be replaced by the auto control document management system

21. ACKNOWLEDGEMENT:

- Tarak Mondal and other consultants of Institute of Applied Quality Management, Kolkata
- Maitreyi Chakraborty, COO-Institute of Applied Quality Management, Kolkata

22. REFERENCES:

BS EN ISO 15189:2012 Quality Management standard clause 4.3, page no 10

23. **Author Background**:

- A Quality Management consultant
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- Chairman- International Organization for laboratories (IOL)