IMPLEMENTATION OF A QUALITY MANAGEMENT SYSTEM IN ACCORDANCE WITH ISO15189 - EVALUATION OF ACCREDITED VERSUS NON-ACCREDITED RESOURCE LIMITED MEDICAL LABORATORIES IN SEVERAL INDIAN STATES

Mr. Manikchandra R Tiwari[1*], Dr. Anuja Pandey[2], Dr. Arti Rauthan[3], Dr. Preeti Chavan[4], Dr. Vivek Bhat[5]

Article History: Received: 28.02.2023 **Revised:** 12.04.2023 **Accepted:** 05.05.2023

Abstract

The reliability of test results is crucial in today's evidence-based medical care. Additionally, the ISO15189 quality management system (QMS) or acceptable guidelines should be used Because accreditation is optional in India, where the majority of the population is served by resource-limited medical labs (RLML) of which only a tiny number are accredited, results provided by unaccredited labs may be tainted. To understand the significance of accreditation, accredited and non-accredited RLMLs were assessed for meeting the ISO15189:2012 QMS requirements.

Fifty RLMLs, both accredited and unaccredited, from various Indian states, were evaluated for conformity with forty-one QMS criteria taken from ISO15189:2012. A chi-square test was employed to examine the RLMLs that satisfied each condition ($p<0.005$).

A few accredited RLMLs failed to keep adequate records of clinical advice, risk assessments, independent work authorization for recruits, temperature-humidity monitoring, reagent acceptance-rejection, and updated reports. Non-accredited RLMLs met legal-entity (100%), had a laboratory manager (58%) and minimal records (51%); their P-value was non-significant ($p>0.005$). For the remaining criteria, chi-square testing with a $p<0.005$ was significant.

Few accredited RLMLs' failures to comply may be attributed to routine procedural non-conformities discovered during their regular operations where the necessary documents were overlooked despite the lab's knowledge of the requirements. While the overwhelming majority of non-accredited RLMLs were found to have little to no knowledge of or awareness of many QMS requirements, demonstrating the need for standards. Accreditation enables the creation of acceptable, recognized laboratory practices.

Keywords: Resource-limited medical laboratories, Quality management system, ISO15189, Accreditation

[1*]M.Sc. Scientific Assistant "E", Research scholar (Ph. D. Healthcare management**)**: Department of clinical research and health care management, School of pharmaceutical sciences, Himgiri Zee University (HZU), P.O. Sherpur, Chakrata Rd, Dehradun, Uttarakhand 248197, India
ORCID ID: 0000-0002-0860-7494
[2]Ph. D. (Pharmacology) Associate Professor Department of clinical research and health care management, School of pharmaceutical sciences, Himgiri Zee University, P.O. Sherpur, Chakrata Rd, Dehradun, Uttarakhand 248197, India
[3]Ph. D. (Public health) Assistant Professor Department of clinical research and health care management, School of pharmaceutical sciences, Himgiri Zee University, P.O. Sherpur, Chakrata Rd, Dehradun, Uttarakhand 248197, India
[4]M.B.B.S., D.C.P Lab Manager and Officer in charge PS 124, Paymaster Shodhika, Advance Centre for Treatment Research and Education in Cancer (ACTREC), Tata Memorial Centre (TMC), Sector-22, Kharghar, Navi Mumbai, Raigad, Maharashtra 410210, India
[5]M.D. (Microbiology) Professor PS 124B, Paymaster Shodhika, Advance Centre for Treatment Research and Education in Cancer (ACTREC), Tata Memorial Centre (TMC), Sector-22, Kharghar, Navi Mumbai, Raigad, Maharashtra 410210, India

Email ID: [1*]manik.tmh@gmail.com, [2]pandey.anuja@gmail.com, [2]anuja.pandey@hzu.edu.in, [3]aartirrauthan@gmail.com, [4]drprreeti@yahoo.com, [4]pchavan@actrec.gov.in, [5]vbhat@actrec.gov.in

DOI: 10.31838/ecb/2023.12.s3.451

1. Introduction

Medical laboratory reports offer proof for disease diagnosis and aid the doctor in providing patients with appropriate, targeted care. Therefore, laboratories must ensure that the accuracy and dependability of their reports. This can only be guaranteed if the laboratory adheres to established standards for proficiency and excellence in order to meet the requirements for reliably delivering technically sound results. Such requirements can be methodically addressed by following accepted laboratory procedures or by obtaining laboratory accreditation (Schneider et al., 2017).

The medical laboratories - requirements for quality and competence ISO 15189 standard, often known as ISO 15189, was initially released in 2003 and amended in 2007, 2012, and again in 2022. The ISO 15189 standard is not a means of merely satisfying accreditation requirements or offering band-aid solutions for particular errors. As an alternative, laboratories using ISO 15189 work to make systems that are as fail-safe as feasible, that will detect faults before they become a problem, and that will reduce errors by doing things correctly the first time and always look for methods to improve through empowering and engaging their staff by involving them in the creation of solutions and the fixing of issues (Schneider et al., 2017).

Accreditation is an effective tool for recognising laboratories around the world and for proving the proficiency of laboratories. It is related to regular audits that encourage the upkeep and improvement of quality, which results in high standards of care for patients (Plebani & Sciacovelli, 2017; Zima, 2017). In India, "National Accreditation Board for Testing and Calibration Laboratories (NABL) provides voluntary accreditation to medical laboratories as per ISO 15189 (*NABL 100A General Information Brochure,* 2022, p. 6). Since accreditation for medical laboratories is not yet mandatory, implementing appropriate laboratory practises is challenging (Zima, 2017).

In this study, laboratory practise in both accredited and non-accredited resource-limited medical laboratories (RLML) in different states of India was evaluated using the quality management system (QMS) requirements of ISO15189:2012. This could provide information about the current state of laboratory practise in RLMLs in relation to the required standards. This compliance evaluation study may aid RLMLs in comprehending the significance of accreditation in creating high standards in medical laboratories and ultimately aiding in the production of accurate and trustworthy reports for diagnosis and improved patient health care management.

2. Methods

For this study, fifty RLMLs from various regions of India were randomly chosen. They included both accredited and unaccredited RLMLs, and their daily patient loads ranged from twenty-five to hundred. The western part of India (Thane, Palghar, Raigad, Boisar, Navi Mumbai, Mumbai), the north (Jaunpur, Varanasi, Lucknow), the east (Kolkata), the far east (Guwahati), and the south (Goa, Kerala) were the regions from which RLMLs were selected. One RLML was evaluated using forty-one criteria from ISO 15189:2012. If the RLML was considered to be in conformance, one point was given, and so on. A violation received a score of zero.

With the previous approval of the laboratory in-charge, data was collected via phone calls, virtual sessions, or in-person visits. The RLML was assured of anonymized circumstances and not associating the data collected and results with the name of the laboratory in any publication or paper.

The evaluation data that was so obtained was entered into an excel spreadsheet. Data was divided into two categories: RLMLs with NABL accreditation and RLMLs without accreditation (Table 1). For all categories, the percentage of RLMLs that met each criterion was evaluated, and for each criterion, a chi-square test with a significant p value of $p<0.005$ was performed.

3. Results

With a few exceptions, accredited RLMLs satisfied the majority of the QMS requirements. These exceptions included a lack of documentation of staff feedback, clinician suggestions, risk assessments, independent work authorization for new hires, temperature and humidity monitoring, reagent acceptance and rejection, and revised reports. In this case, 86% of RLMLs complied. (Table 1)

It was found that few compliances, such as having a clear legal entity (100%) and having access to laboratory managers (58%) and records (51%), were met by the majority of non-accredited RLMLs. With $p>0.005$, the P-value was non-significant.

Chi-square testing was determined to be significant with a $p<0.005$ for the remaining criteria.

Here, it was discovered that non-accredited RLMLs are in non-compliance with criteria, including the availability of qualified pathologists (40%), valid agreements (26%), an inventory management system (26%), the recording of clinician suggestions (26%), the management of biomedical waste (21%), and staff safety, including the use of personal protective equipment (26%) and vaccination against

HBsAg, tetanus, etc. (23%), procedure for equipment acceptance and rejections (30%), reagent and consumable storage environment (19%), completion of key information of test requisitions (23%), sample rejection criteria (12%), and use of commercial control materials (14%). The rest of the criteria listed (Table 1) were discovered to be poor among RLMLs.

Table 1: Compliance of accredited and non-accredited laboratories with ISO15189:2012's quality management system requirements

	Agreement to requirements of quality management system criteria as per ISO15189:2012 (Total QMS criteria is 41, Number of RLMLs is 50)	% Accredited RLMLs in compliance (Number of accredited RLMLs is 7)	% Non-accredited RLMLs in compliance (Number of non-accredited RLMLs is 43)	*p-value*	*P value* significant at *p<0.005*
1	Legal identity of RLML	7 (100%)	43 (100%)	0.010727	NS
2	Laboratory Director/Authorised signatory	7 (100%)	17 (40%)	0.002983	S
3	Managing Director/Quality Manager/Laboratory Manager	7 (100%)	25 (58%)	0.032376	NS
4	Documents (SOPs, manuals, etc) and retention	7 (100%)	3 (7%)	<0.005	S
5	Records and retention	7 (100%)	22 (51%)	0.015191	NS
6	Memorandum of understanding and their validity	7 (100%)	11 (26%)	0.000142	S
7	Review of referral laboratories	7 (100%)	2 (5%)	<0.005	S
8	Review of sample volume	7 (100%)	1 (2%)	<0.005	S
9	Vendor audit, selection and evaluation	7 (100%)	1 (2%)	<0.005	S
10	Inventory management system	7 (100%)	11 (26%)	0.000142	S
11	Clinician suggestion procedure and record	6 (86%)	11 (26%)	0.001842	S
12	Patient feedback procedure and record	7 (100%)	5 (12%)	<0.005	S
13	Staff feedback procedure and record	6 (86%)	3 (7%)	<0.005	S
14	Procedure for handling deviations and corrective action taken	7 (100%)	1 (2%)	<0.005	S
15	Planned internal audit and external assessment	7 (100%)	1 (2%)	<0.005	S
16	Risk assessment evaluation	6 (86%)	0 (0%)	<0.005	S
17	Plan for handling contingency	7 (100%)	2 (5%)	<0.005	S
18	Analysis of quality indicators	7 (100%)	4 (9%)	<0.005	S
19	Annual management review meeting	7 (100%)	0 (0%)	<0.005	S
20	Biomedical waste management as per latest BMW guidelines	7 (100%)	9 (21%)	<0.005	S
21	Staff records (basic and professional education, training, experience, periodic assessments)	7 (100%)	4 (9%)	<0.005	S
22	Staff safety (apron, gloves, masks, eye shower, drinking water, eating area)	7 (100%)	11 (26%)	0.000142	S
23	Induction of new staff and authorization to work independently	6 (86%)	1 (2%)	<0.005	S
24	Vaccination of staff (HBsAg, Tetanus, Covid-19)	7 (100%)	10 (23%)	<0.005	S
25	Temperature and humidity monitoring	6 (86%)	3 (7%)	<0.005	S
26	Equipment acceptance and rejection criteria	7 (100%)	13 (30%)	0.000476	S
27	Reagent acceptance and rejection criteria	6 (86%)	2 (5%)	<0.005	S
28	Storage space and appropriate storage temperature	7 (100%)	8 (19%)	<0.005	S
29	Directory of services	7 (100%)	2 (5%)	<0.005	S
30	Written laboratory documents (primary sample collection, laboratory safety and examination procedures)	7 (100%)	1 (2%)	<0.005	S
31	Adverse accident/incident (Post Exposure Prophylaxis procedures)	7 (100%)	1 (2%)	<0.005	S
32	Test request form details completion	7 (100%)	10 (23%)	<0.005	S
33	Consent form (HIV test) and patient counselling (pre-test and post-test)	7 (100%)	2 (5%)	<0.005	S
34	Sample acceptance and rejection criteria and sample accessioning	7 (100%)	5 (12%)	<0.005	S
35	Internal quality control (use of commercial materials and known patient's samples)	7 (100%)	6 (14%)	<0.005	S
36	Method validation and performance (% coefficient of variation, Levey-Jenning's chart, Westgard's rules)	7 (100%)	2 (5%)	<0.005	S
37	Participation in proficiency testing or interlaboratory comparison	7 (100%)	3 (7%)	<0.005	S
38	Sample storage temperature and retention period	7 (100%)	2 (5%)	<0.005	S
39	Informing critical or alert values to clinicians	7 (100%)	1 (2%)	<0.005	S
40	Revised report procedure	6 (86%)	1 (2%)	<0.005	S
41	Laboratory information system verification	7 (100%)	1 (2%)	<0.005	S

Legend: S - Significant, NS - Non-significant

4. Discussion

The laboratory must be recognised as a legal organisation in order to comply with the law and to be held accountable for its acts (*Laboratory Quality Stepwise Implementation Tool*, n.d.). Here, it can be observed that regardless of whether RLMLs are accredited or not, they all have a unique legal identity and the majority of them have a manager in charge. Additionally, it has been observed that many labs only preserve the bare minimum of records, which are crucial for the day-to-day operation of the laboratory, for extended periods of time.

An expert pathologist is dedicated to offering top-notch medical laboratory services (Friedberg & Rauch, 2007). The Supreme Court mandated in 2017 that only licenced pathologists could sign all diagnostic reports and lab work (Master, 2020). But, in response to India's severe pathologist shortage, the body that oversees medical education and practise, the Medical Council of India of Governors, in 2020, stated in a letter to the Union Health and Family Welfare Ministry that individuals with a master's degree in medical microbiology and medical biochemistry and a Ph. D. in pertinent fields can sign lab reports without providing any advice Master (2020). Here, we can see that many non-accredited RLMLs as well as all of the accredited ones have pathologists listed as authorised signatories, demonstrating the importance of accreditation.

To develop a quality management system, document control is regarded as the key component of quality (Chakraborty, 2016). Although there is strong evidence that accredited labs meet the criteria of documentation and document control better than non-accredited labs, this is still a work in progress. Multiple linked document modifications are a highly time-consuming operation, and it's interesting to note that no significant improvement was seen and users weren't persuaded of the value of the Quality Management System Document (Chakraborty, 2016).

Any lab that outsources patient samples needs to be aware of the referral lab's condition, making evaluation of the referral lab and its performance review crucial. For this, the lab must at least determine whether the contracted tests are covered by the accreditation scope of the referral laboratory (Tembuyser et al., 2016). The following should be checked at least once a year by laboratories (for example, during the management review): erroneous sample types, incompletely filled samples, inappropriate samples, contaminated samples, haemolyzed samples, or clotted samples (Vermeersch et al., 2021). Accredited RLMLs are considered to have met the requirements for sample suitability, kind, and volume, and such updated information is included in the directory of services.

Buying services and supplies: The laboratory must create standards for choosing its suppliers. Price, market reputation, cold chain preservation, and the capacity to deliver goods on schedule are possible factors. Using the aforementioned criteria, a list of suppliers should be created along with evaluation scores (Wadhwa et al., 2012). Accredited RLMLs adhere to these protocols.

Clinical staff, patient, and staff suggestions, as well as feedback or complaints, are all crucial components of the QMS. Maintaining a complaints policy will help to guarantee that all suggestions and grievances are addressed in a considerate, timely, private, and objective manner. All complaints, recommendations for enhancement, and other comments are noted, taken into account, and kept for process development and improvement purposes. The complainant will be informed of the complaint's conclusion by the labs (Refaat et al., 2021). Accreditation facilitates this process in labs.

A fast evaluation of the laboratory's current quality procedures is the major goal of an internal audit. It is a successful method for preparing for external audits and reveals any crucial non-conformity that could have negative effects at the time of external audits. An essential QMS tool that aids a laboratory in meeting regulatory, accrediting, and client criteria is internal auditing of work procedures (*Laboratory Internal Audit Program, CLSI*, 2022). Audits of laboratory procedures, records, and documentation offer unbiased proof of violations and dangers that may have an impact on the standard of laboratory services and patient safety (*Laboratory Internal Audit Program, CLSI*, 2022). ISO15189 will be a crucial template for evaluating and recognising a professional service's and its staff's effective quality management as well as the technical proficiency of medical laboratories (Kubono & Byori, 2004). In external assessment by NABL, the evaluation team confirms that the lab has implemented the information that has been documented and examines its adherence to ISO15189 and NABL standards. The evaluation report includes the assessment of competency (including personnel, facilities, and equipment), all pertinent material examined, tests/calibration observed, including those of retained samples, recommended accreditation scope (*NABL 100B Accreditation Process & Procedure*, 2022, p. 11). Such internal reviews and outside

evaluations are a regular feature of accredited lab operations; however, non-accredited labs lack this kind of documentation.

To guarantee that patient results are accurate and residual risks are kept to a clinically acceptable level after implementation, the laboratory's risk assessment approach should be regularly reviewed as new errors are discovered (Njoroge & Nichols, 2014). Here, the process identifies flaws in the preanalytical, analytical, and postanalytical testing phases and outlines precise measures to find, stop, and manage problems that could endanger patients (Wayne, 2011). This exercise is carried out accurately by the majority of accredited labs, as seen here.

An effective tool for laboratory service improvement is provided by quality indicators in the clinical laboratory. Improvements in the quality of laboratory services and patient care will undoubtedly be made by continuously working to improve the results of these indicators by implementing corrective measures over time (Chawla et al., 2010). Quality indicators may not be restricted to pre-analytical stage indicators such as sample collection, transport, or sample rejections analysis, analytical stage indicators such as % coefficient of variation or EQAS results, or post-analytical stage indicators such as turnaround time, critical value reporting, or issuing duplicate reports (Chawla et al., 2010; Sciacovelli et al., 2018) Accredited laboratories provide results of their evaluation on these.

The laboratory must have enough room to operate effectively, a welcoming atmosphere, and cross-contamination-free settings (*NABL 112 Specific Criteria for Accreditation of Medical Laboratories*, 2019/2019, p. 16). Due to inadequate rules, improper application of safety safeguards, or a lack of awareness of safety practises, several safety-related mishaps happen in laboratories (Abu-Siniyeh & Al-Shehri, 2020). Lab coats, shoes, gloves, and eye protection are the basic personal protective equipment items *Personnel Protective Equipment - Laboratory Biosafety Manual and Associated Monogram* (2020).

Vaccination among lab staff is a must as per many current guidelines. Also, post exposure prophylaxis (PEP), is a comprehensive medical approach to reduce the risk of infection among lab staff after a probable exposure to blood-borne viruses (HIV, HBV, and HCV). Counselling, risk assessment, pertinent laboratory testing based on the source's and the exposed person's informed consent, first aid, and, depending on the risk assessment, the administration of short-term (four-week) antiretroviral medications with follow-up and support are all included in this (*Post Exposure Prophylaxis (PEP) | National AIDS Control Organization | MoHFW | GoI*, n.d.). Accredited labs exhibit this awareness.

Biomedical wastes generated in health care facilities including medical laboratories are dangerous health and environmental concerns which need proper management based on international and national guidelines (Endris et al., 2021). Here, it is clear that non-accredited RLMLs are either unaware of the regulations or oblivious of the fact that they pose a significant risk to the health of their workers and the general public.

5. Conclusion

The laboratory must constantly strive for progress, which can be accomplished by leveraging the skills of every member of staff, regardless of level. Employees must understand exactly what to do, how to accomplish it, who is in charge of a particular process, and where to find all the information they require to complete their tasks. Such activities can be accomplished in a methodical manner by following accepted laboratory procedures or by obtaining laboratory accreditation. Although accredited RLMLs failed to meet a few QMS requirements, these failures can be attributed to routine procedural non-conformities that were discovered during their regular activity. The laboratories are aware of the standards' requirements, but they might not have kept the necessary records. While the majority of the RLMLs who are not accredited were found to have incomplete knowledge of or no awareness of numerous QMS requirements.

6. References

Abu-Siniyeh, A., & Al-Shehri, S. S. (2020). Safety in Medical Laboratories: Perception and Practice of University Students and Laboratory Workers. *Applied Biosafety*. https://doi.org/10.1089/apb.20.0050

Chakraborty, S. (2016). Document Control Effectiveness in ISO 15189 Accredited Laboratories. *International Journal of Business and Management Invention*, *5*(1), 12–23. www.ijbmi.org.

Chawla, R., Goswami, B., Singh, B., Chawla, A., Gupta, V. K., & Mallika, V. (2010). Evaluating Laboratory Performance With Quality Indicators. *Laboratory Medicine*, *41*(5), 297–300. https://doi.org/10.1309/lms2cbxba6y0owmg

Endris, S., Tamir, Z., & Sisay, A. (2021). *Medical laboratory waste generation rate, management practices and associated factors in Addis Ababa, Ethiopia*.

https://doi.org/10.1101/2021.08.17.21262112

Friedberg, R. C., & Rauch, C. A. (2007). The Role of the Medical Laboratory Director. *Clinics in Laboratory Medicine*, *27*(4), 719–731. https://doi.org/10.1016/j.cll.2007.08.001

Kubono, K., & Byori, R. (2004). Quality management system in the medical laboratory-ISO15189 and laboratory accreditation. *The Japanese Journal of Clinical Pathology*, *53*(2), 274–278. PMID: 15137330.

Laboratory Internal Audit Program, CLSI (2nd). (2022). Clinical and Laboratory Standards Institute.

Laboratory Quality Stepwise Implementation tool. (n.d.). Extranet.who.int. Retrieved May 25, 2023, from https://extranet.who.int/lqsi/content/ensure-laboratory-legally-identifiable-and-recognized-national-or-regional-if-applicable

Master, T. H. (2020, February 9). *Let non-doctors sign lab reports: MCI*. https://thehealthmaster.com/2020/02/09/let-non-doctors-sign-lab-reports-mci/

NABL 100A General Information Brochure (01, p. 6). (2022). National Accreditation Board for Testing and Calibration Laboratories.

NABL 100B Accreditation Process & Procedure (1st, p. 11). (2022). National Accreditation Board for Testing and Calibration Laboratories.

NABL 112 Specific Criteria for Accreditation of Medical Laboratories (4th, Vol. 1, p. 16). (2019). National Accreditation Board for Testing and Calibration Laboratories. (Original work published 2019)

Njoroge, S. W., & Nichols, J. H. (2014). Risk Management in the Clinical Laboratory. *Annals of Laboratory Medicine*, *34*(4), 274–278. https://doi.org/10.3343/alm.2014.34.4.274

Personnel protective equipment - Laboratory biosafety manual and associated monogram (ISBN 978-92-4-001141-0; 4th). (2020). World health organization.

Plebani, M., & Sciacovelli, L. (2017). ISO 15189 Accreditation: Navigation Between Quality Management and Patient Safety. *Journal of Medical Biochemistry*, *36*(3), 225–230. https://doi.org/10.1515/jomb-2017-0038

Post Exposure Prophylaxis (PEP) | National AIDS Control Organization | MoHFW | GoI. (n.d.). Naco.gov.in. Retrieved May 25, 2023, from https://naco.gov.in/post-exposure-prophylaxis-pep

Refaat, M., ElBagoury , M., & Hutchinson, A. (2021). Standard Operating Procedures for Feedback and Complaints in Healthcare Organizations. *Journal of Biotechnology and Immunology*, *3*(1).

Schneider, F., Maurer, C., & Friedberg, R. C. (2017). International Organization for Standardization (ISO) 15189. *Annals of Laboratory Medicine*, *37*(5), 365. https://doi.org/10.3343/alm.2017.37.5.365

Sciacovelli, L., Secchiero, S., Padoan, A., & Plebani, M. (2018). External quality assessment programs in the context of ISO 15189 accreditation. *Clinical Chemistry and Laboratory Medicine (CCLM)*, *56*(10), 1644–1654. https://doi.org/10.1515/cclm-2017-1179

Tembuyser, L., Van Campenhout, C., Blanckaert, N., & Dequeker, E. M. C. (2016). ISO 15189-accredited laboratories fulfill the JCI Hospital Accreditation Standard requirements for the use of referral laboratories: report of a consensus meeting. *Accreditation and Quality Assurance*, *21*(6), 425–431. https://doi.org/10.1007/s00769-016-1232-x

Vermeersch, P., Frans, G., von Meyer, A., Costelloe, S., Lippi, G., & Simundic, A.-M. (2021). How to meet ISO15189:2012 pre-analytical requirements in clinical laboratories? A consensus document by the EFLM WG-PRE. *Clinical Chemistry and Laboratory Medicine (CCLM)*, *0*(0). https://doi.org/10.1515/cclm-2020-1859

Wadhwa, V., Rai, S., Thukral, T., & Chopra, M. (2012). Laboratory quality management system: Road to accreditation and beyond. *Indian Journal of Medical Microbiology*, *30*(2), 131–140. https://doi.org/10.4103/0255-0857.96647

Wayne, P. (2011). *Laboratory quality control based on risk management, Approved guideline: Vols. EP23-A* (1st ed.). Clinical and Laboratory Standards Institute.

Zima, T. (2017). Accreditation of Medical Laboratories – System, Process, Benefits for Labs. *Journal of Medical Biochemistry*, *36*(3), 231–237. https://doi.org/10.1515/jomb-2017-0025

Declaration of conflicting interests
The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding
The author(s) received no financial support for the research, authorship, and/or publication of this article.

Ethical Approval
Not required

Contributor ship
Mr. Manikchandra R Tiwari: Concept, design, literature search, data acquisition, data analysis, statistical analysis, manuscript preparation, definition of intellectual content
Dr. Anuja Pandey: manuscript review, guarantor
Dr. Arti Rauthan: manuscript review, guarantor
Dr. Preeti Chavan: manuscript review, guarantor
Dr. Vivek Bhat: Writing – manuscript editing, manuscript review

Acknowledgments
None